Office of the Special Assistant to the Secretary of Defense for Gulf War Illnesses, Medical Readiness and Military Deployments

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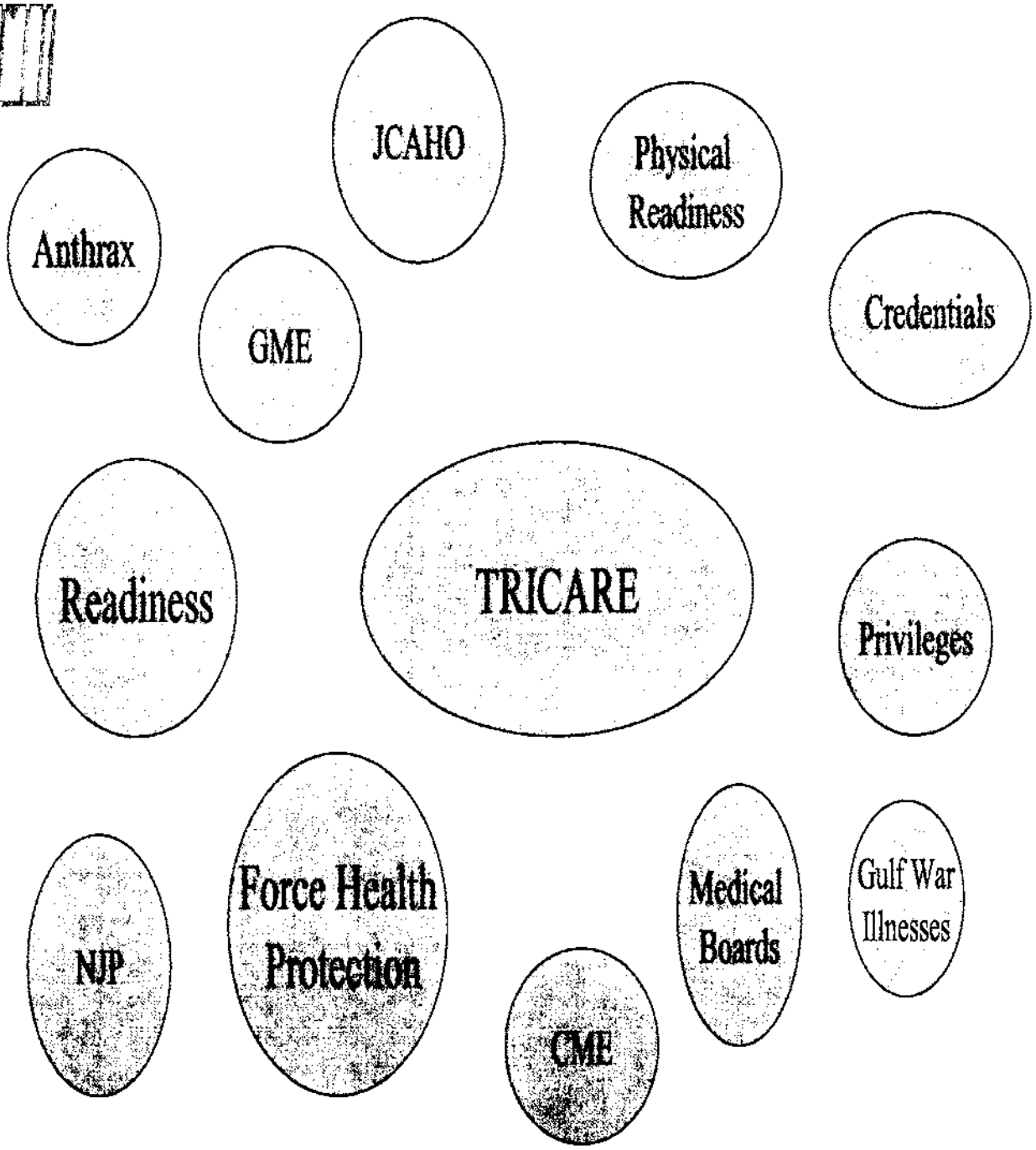

JCAHO
Physical Readiness
Anthrax
Credentials
GME
Readiness
TRICARE
Privileges
Force Health Protection
Medical Boards
Gulf War Illnesses
NJP
CME

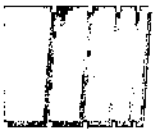
Special Assistant

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members

Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DoD adapts doctrine, policy and procedures to reduce risks for troops in the future.



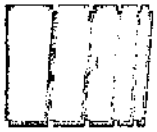
Who Served in the Gulf War

697,000 U.S. service members

ARMY	50%
NAVY	23%
MARINE	15%
AIR FORCE	12%

259,000 Coalition Forces

Source: Presidential Advisory Committee on Veterans Illnesses, Final Report



Who Served in the Gulf War

MALE	93%
FEMALE	7%
ACTIVE	83%
RESERVE/NATIONAL GUARD	17%
OFFICER	10%
ENLISTED	90%

< 26 years old - 55%; 26-35 years old - 32%; > 35 years old - 13%

Medical Support

Largest emergency health care system since WW II

- 41,000 medical personnel
- 18,000 beds
  - 2 hospital ships
  - 63 combat zone hospitals

source: CENTCOM Publications - Commander-in-chief US CENTCOM "Desert Shield/Desert Storm Facts, Figures, Quotes and Anecdotes 7 AUG 90-11 APR 91," prepared by CENTCOM PAO

Medical Support

- 27,000 hospitalizations in theater
- 8,000 medical evacuations
- ????? outpatient visits

U.S. Deaths

Non-Battle	224
Battle	148

Symptoms

Tiredness

Rashes

Headaches

Muscle aches

Joint pains

Abdominal pain

Diarrhea

Hair loss

Memory loss

Sleep disturbance

Depression

Concentration problems

Medical Evaluations

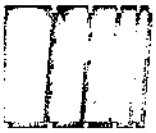
- Comprehensive Clinical Evaluation Program (CCEP)

Total Participants	55,883	
Decline examination	15,899	
Examined		39,984
♦ Veterans Affairs Registry -examined		79,710
Total Examined		**119,694**

Source: OASD (Health Affairs) 28 Jul 00 VA Registry 25 Jul 00

Diagnosis Distribution

Categories	CCEP (%)	VA Registry (%)
Healthy	10	12
Symptomatic	90	88
Medically explained	80	80
Medically unexplained	**20**	**20**



Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"
"It's all in your head!"
"You're faking these symptoms!"

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Epidemiology Studies

	Deployed (%)	Non-Deployed (%)
Medical separation (Aug 91 - Dec 93)	**2.20**	**2.56**
Hospitalizations (Aug 91 - Sep 93)	**21.6**	**21.6**
Hospitalizations unexplained illnesses (Aug 91 - Apr 96)	**1.21**	**1.27**
Birth Defects (Aug 91 - Sep 93)	**7.45**	**7.59**
Mortality (Aug 91 - Sep 93)	**.025**	**.023**

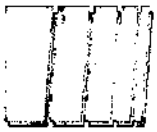
Possible Causes

CHEMICAL WARFARE	BIOLOGICAL WARFARE
PESTICIDES	OIL WELL FIRES
VACCINES	DEPLETED URANIUM
PYRIDOSTIMINE BROMIDE	INFECTIOUS DISEASES
STRESS	COCKTAIL EFFECT

Lessons Learned

CHEMICAL WARFARE

- 14,000 M8 units
- False Positives
- In and out of MOPP, no explanations
- Alarms turned off
- No need to know
- Brain Damage

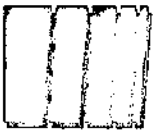


Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

- Navy Forward Laboratory
- No positive cultures



Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

- DEET, permethrin, organophosphates
- Unapproved items: flea collars, SNIP

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

- Soot, ash, black cloud
- No information
- EPA monitoring March 91
- Particulates, no toxic fumes

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

- Vaccines "secret"
- No records
- No explanations
- Squalene

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

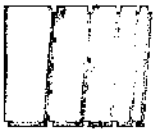
VACCINES

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

- Tank armor, penetrators
- No training
- Heavy metal, proximal tubule
- Surveillance of most exposed



Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

- Soman prophylaxis
- Not FDA approved use
- Recognized side effects
- Medical confusion
- No explanations, no records
- Varied protocols

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

INFECTIOUS DISEASES

- 12 malaria, 32 leishmaniasis
- Diarrhea, URI's
- *Mycoplasma fermentans incognitus*

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

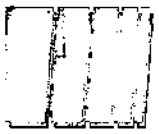
DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

INFECTIOUS DISEASES

STRESS

- NO DoD policy that "stress is the cause of symptoms"
- CNN, communications home
- Uncertainties
- Profiles are stress of chronic disease
- PTSD rate lower than Vietnam
- Stress can amplify already existing symptoms



Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

STRESS

BIOLOGICAL WARFARE

OIL WELL FIRES

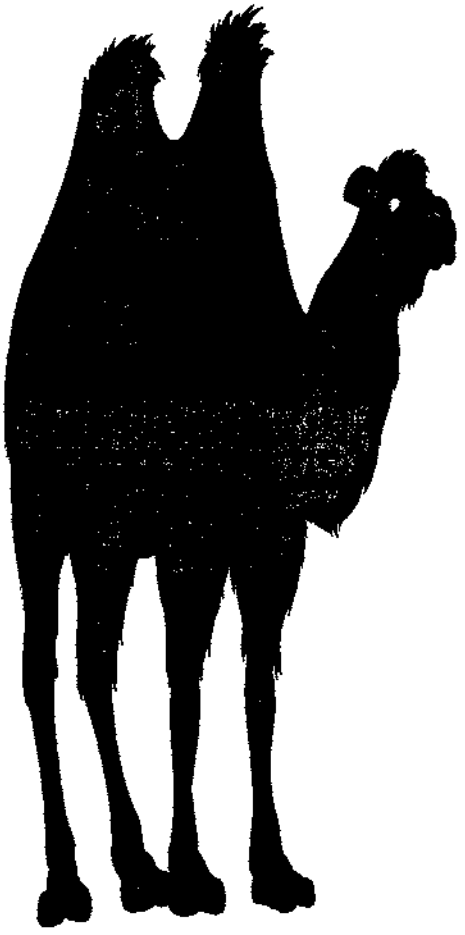
DEPLETED URANIUM

INFECTIOUS DISEASES

COCKTAIL EFFECT

- No scientific evidence yet

THE BLACK CAMEL



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Possible Causes

- Normal disease rate
- New disease paradigm - a Black Camel

Major Lesson Learned from the Gulf War

DoD Does Not Deal Well With Non-Traditional Issues

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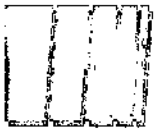
Deployments

- Unexpected and rapid personnel movement
- Personal and family hardships
- Stress in the field
  - Missile attacks
  - Chem-bio attacks
  - Witnessing death/atrocities
  - Harsh Living Conditions
  - Foreign cultures
  - Racial/ethnic hatred
- Inadequate communication
- No answers to questions after returning



Force Health Protection

Predeployment

Health Promotion
Immunizations Current
Health Assessment Surveys
Medical Threat Briefing
Environmental Threat

Deployment

Environmental & Medical Surveillance
Food and Water Inspections
Industrial/Occupational Surveillance
Forward Deployed Labs
Host Nation Medical Support
Combat Stress Teams

Post Deployment

Health Assessment Surveys
Medical Debriefings
Medical Surveillance
Risk Communication

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Risk Communication

1. Allow Ventilation
2. Determine Underlying Concern
3. Empathy
4. Conclusion Soundbite
5. Facts (2)
6. Next Steps

Art of Medicine

1. Ask open-ended questions
2. Chief complaint
3. Managed similar problems
4. Diagnosis
5. Lab, physical findings
6. Treatment, next appointment

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CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-497-6261
GulfLINK	*www.gulflink.osd.mil*

COL Francis L. O'Donnell MC, USA

phone 703-845-3374 fax 703-578-8501

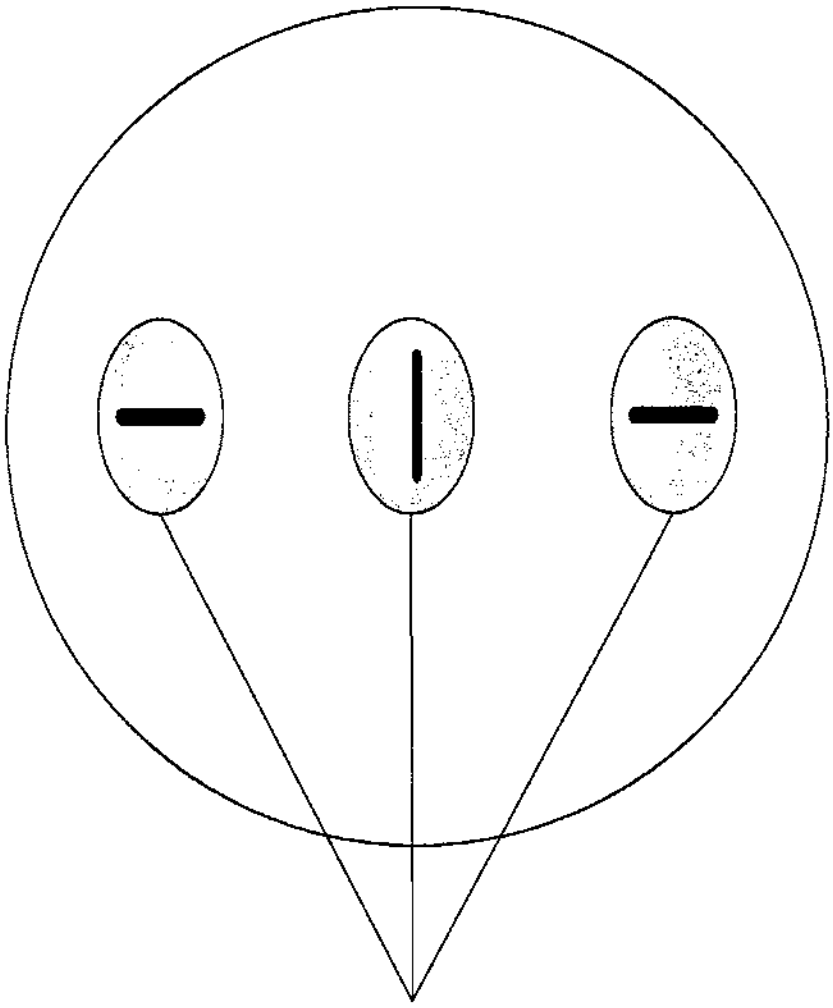
email: fodonnel@gwillness.osd.mil

Anthrax

- We have a safe and effective vaccine
- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods
  - At least seven potential adversaries suspected of researching, developing and/or weaponizing anthrax.

Vaccination against anthrax is critical for your protection

Anthrax Bacteria



Toxins

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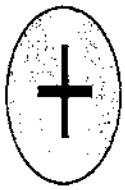
Anthrax Bacteria

Toxin Combination

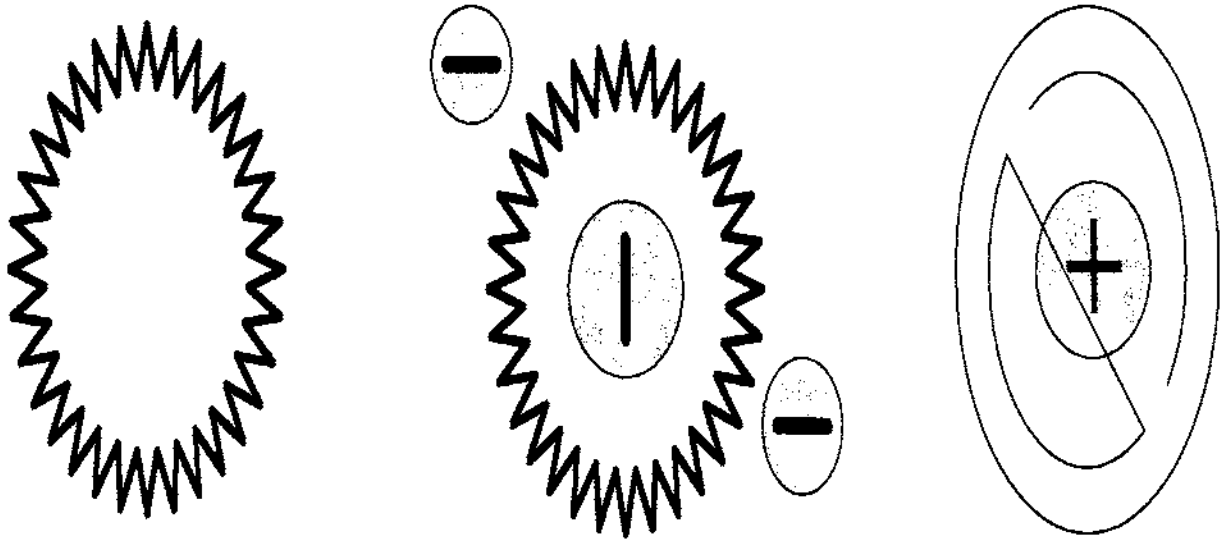
 = **Death**

Anthrax Vaccine

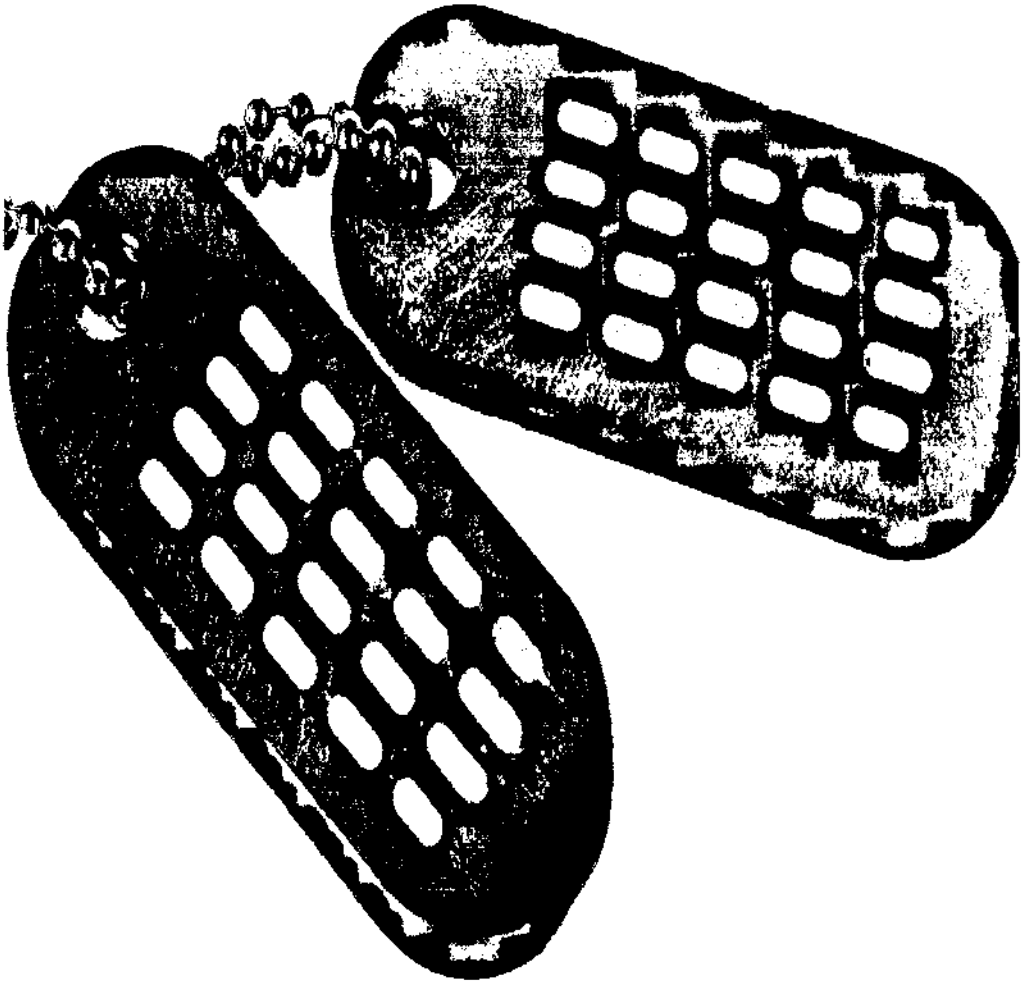
Produces

Attacks
Toxin

PROTECTS



Medical Personal Information Center (PIC)



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Where Do We Go From Here?

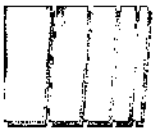
- Concept - Deployment Medicine Clinics
  - Connected to all deployment sites
  - Source for pre and post deployment information
  - Information for family members
- Concept - Education on Vaccines
  - Start updating electronic record entrance
  - Validate accuracy with leave/bonus requests
  - Internet linkage to CDC for recommendations
- Concept - ????

Understanding Today's Military Member

- 55% are married
- 46% have children
- 40% of the 1.3 million children are < 6 years old
- 6% are single parents
- 8% care for elder parents
- 14% are women

Concerns of the Deployed Member

- Importance of the mission
- Recognition by others of his/her role
- Ability to express fears/concerns/problems to leadership
- Recognition for performance



Successful Mission

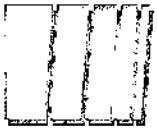
- Knew why I was there and agreed
- Knew what to do
- Knew how to do it
- Had what I needed to do it
- Did it well
- Was appreciated for my contribution
- Returned proud I had been there

Distribution of CCEP Diagnoses by Major ICD-9 Categories

	Primary (%)	All Dx (%)
• Musculoskeletal	19.6	20.8
• Symp., Signs, IDC	17.4	19.0
• Psychological	17.3	14.8
• V-Codes	10.1	6.0
• Respiratory Sys.	6.5	5.9
• Digestive	6.1	7.3
• Skin	5.9	6.5
• Nervous System	5.5	5.9

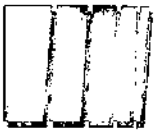
Distribution of CCEP Diagnoses by Major ICD-9 Categories (cont)

	Primary (%)	All Dx (%)
• Infections	2.6	3.0
• Circulatory Sys.	2.5	2.8
• Endocr.-Metab.	2.3	2.7
• Genitourinary	1.3	1.8
• Injury-Poisoning	0.9	1.1
• Neoplasms	0.9	0.9
• Blood	0.6	0.9



Musculoskeletal / Conn. Tissue

• Pain in Joint	5.5 %
• Osteoarthrosis	3.6 %
• Back Pain and other Back Disorders	2.8 %
• Disord. of Tendons, Muscle Attachments	1.6 %
• Other Disorders of Soft Tissue	1.4 %
• Disc Disorders	1.0 %
• Knee Derangements	0.4 %



Symptoms, Signs, Ill Defined Cond.

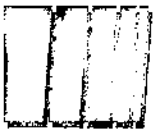
• Malaise, Fatigue	4.2 %
• Sleep Disturbances	3.3 %
• General Symptoms and Hyperhidrosis	1.9 %
• Symp. Of Respiratory Sys. And Chest	1.6 %
• Symptoms involving the Skin	1.1 %
• Alterations of Consciousness, Awareness	0.6 %
• Abdom. Pain, Various Locations	0.4 %
• Symptoms of Digestive System	0.4 %

Psychological

• Depressive Disorder	2.9 %
• Neuroses	2.8 %
• Prolonged PTSD	2.6 %
• Affective Disorders	1.8 %
• Adjustment Reactions	1.2 %
• Sleep Disorders	0.6 %
• Organic Brain Syndromes, Various	0.5 %

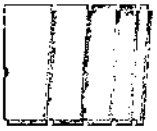
Respiratory Tract

- Asthma 2.2 %
- Allergic Rhinitis 1.5 %
- Chronic Upper Respir. Inflammation 1.5 %



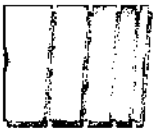
Healthy

- Feared complaint, no diagnosis 8.0 %
- Routine general medical examination 0.9 %



Gastrointestinal

- Irritable Colon 1.5 %
- Esophageal Reflux 1.3 %
- Enteritis and Colitis 0.6 %

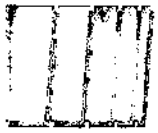


Integument

- Alopecia, hirsutism, other dis. of hair 1.3 %
- Fungus infections of skin 1.3 %
- Contact dermatitis, other eczema 1.2 %
- Urticaria, various types 0.5%

Headache

- Tension Headache 3.1 %
- Migraine 2.9 %
- Headache 2.5 %



Other

- Hypertension, essential 1.2 %
- Lipoid Metabolism Disorders 0.6 %
- Hearing Loss 0.4 %
- Hypothyroidism 0.4 %

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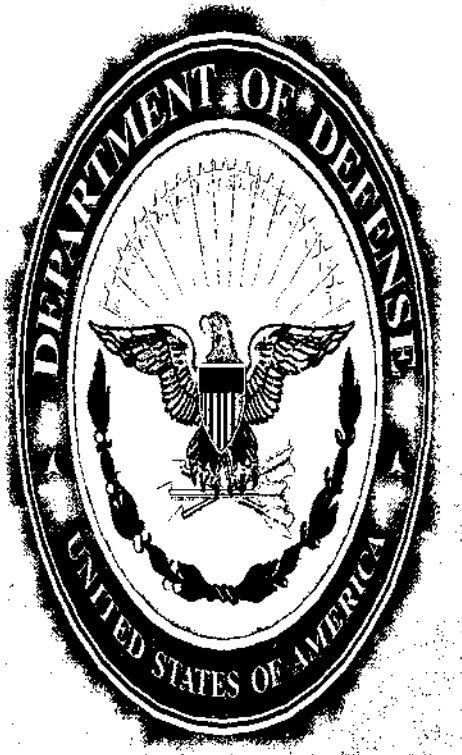


for Gulf War Illnesses, Medical Readiness and Military Deployments

DSN 761-1078 fax 703-578-8501

email: brostker@gwillness.osd.mil

Briefing Overview

- Mission Statement
- The Gulf War
- Post Gulf War Issues
- Searching for answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining help and information

Vision of Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

- The Department of Defense recognizes the right of those involved in deployments to receive information that enables them to make informed decisions about their health.
- We will develop and disseminate such information in a relevant and timely fashion.
- We will work with others in the Defense Department to incorporate lessons from previous deployments to foster the well-being of deployed forces.

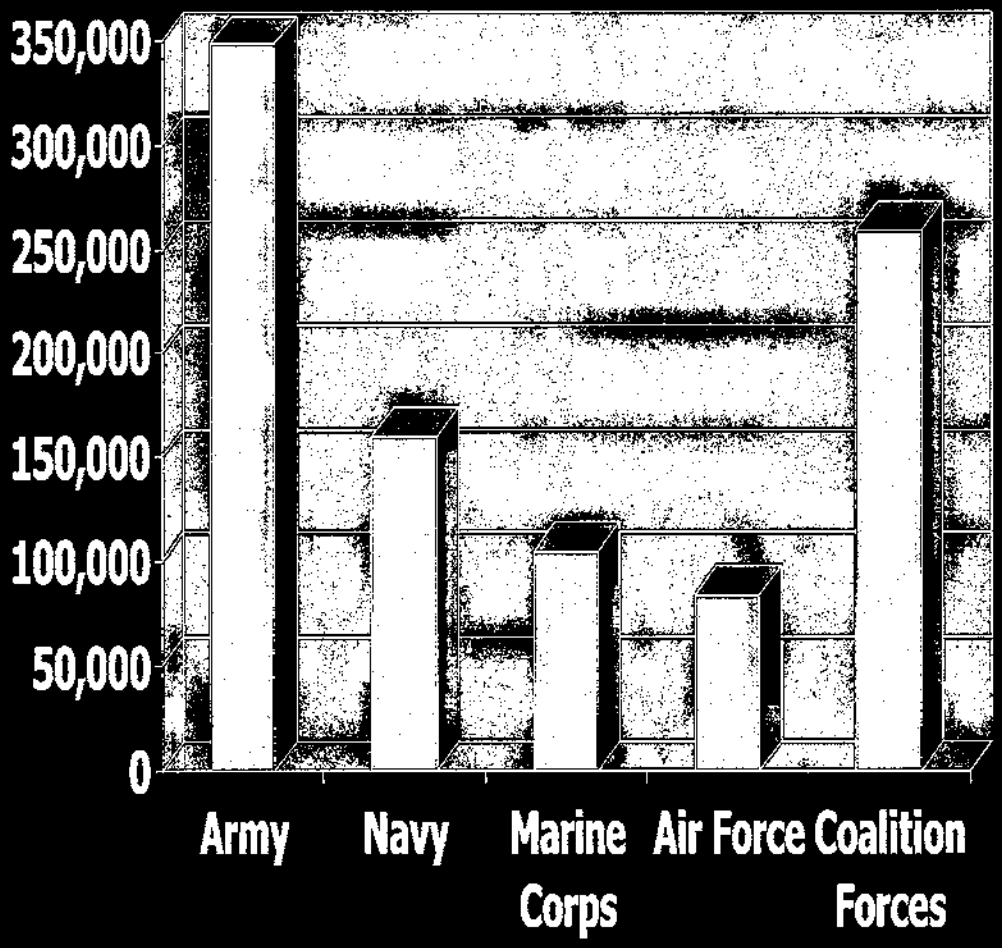
Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Why Should I Care

- Lessons from the Gulf War about dirty battlefields
- You must protect yourself against hazards
- You will be leading Gulf War vets
- You are responsible for force protection
  - What are the dangers of the dirty battlefield?
  - How good are our detectors and MOPP gear?
  - How do we determine if we are exposed?
  - Will our counter-fire put us at risk?
  - How do we identify captured CW/BW?
  - What if my fighting vehicle is hit with DU?

Gulf War Theater Forces



697,000 U.S. service members

1 in 7 Veterans Reported Symptoms Since The War

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Confounding Issues

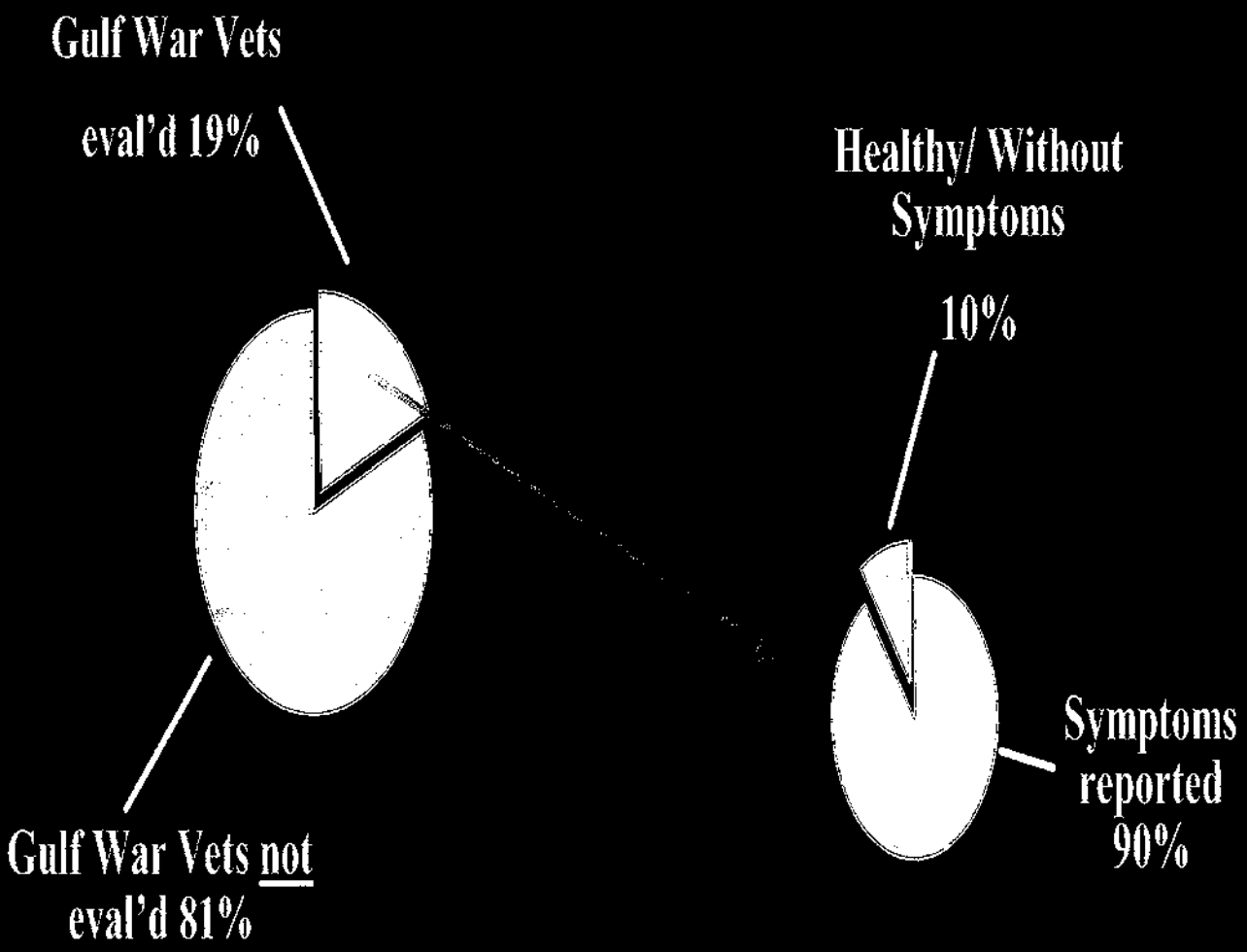
- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

Taking Care of Service Members

- DoD Comprehensive Clinical Evaluation Program
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
  - Civilian employees
- VA Persian Gulf Registry
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- Available to *all* service members deploying to South West Asia
  - Most people evaluated can be treated

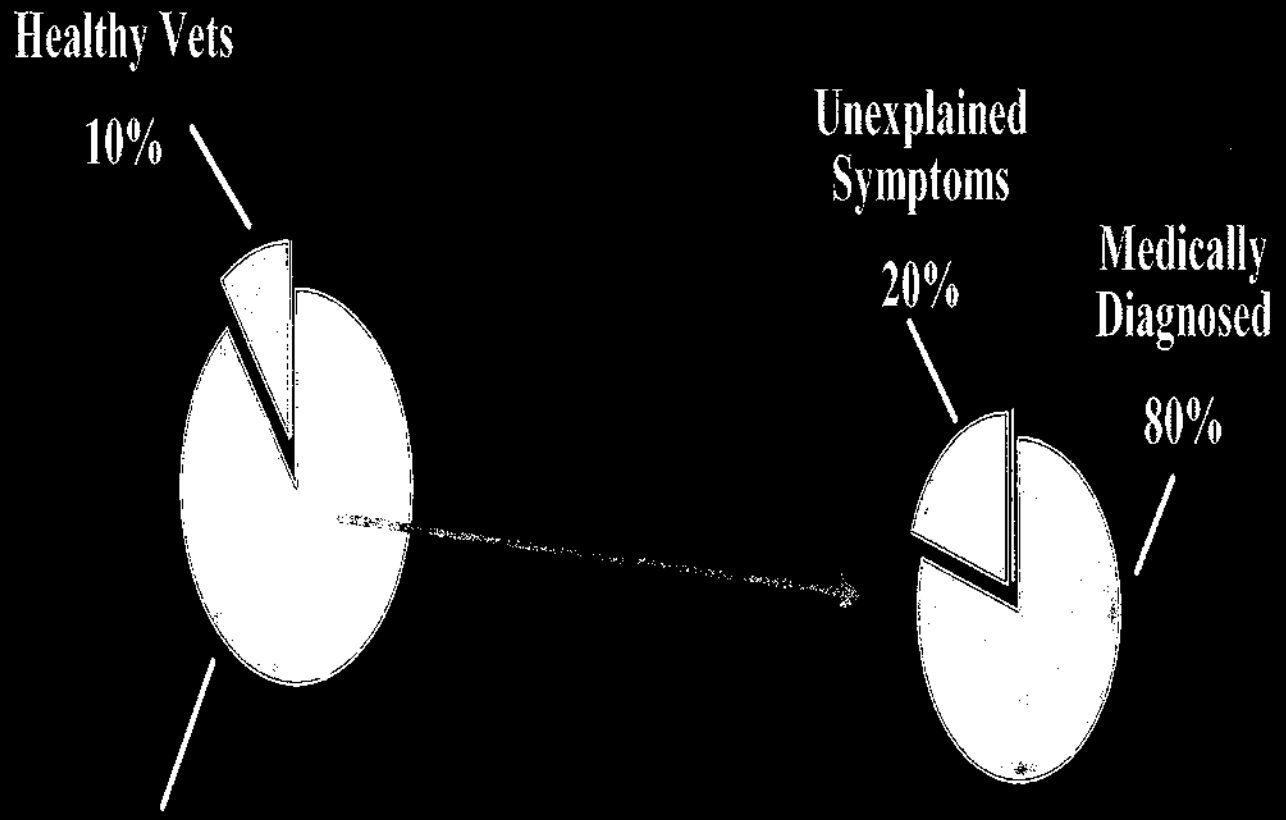
Don't Tough It Out!

Evaluation Distribution of 697,000 CCEP/VA



Diagnosis Distribution of Evaluated Veterans

CCEP/VA



Don't tough it out!

OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
    - Science doesn't support DU or Oil Well fires as causes
    - Still examining particulates and pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Persian Gulf War Veterans Coordinating Board-Scientific Research
  - 180+ studies sponsored by DoD, HHS & DVA
  - Science shows no exposure cause or effect relationship yet!

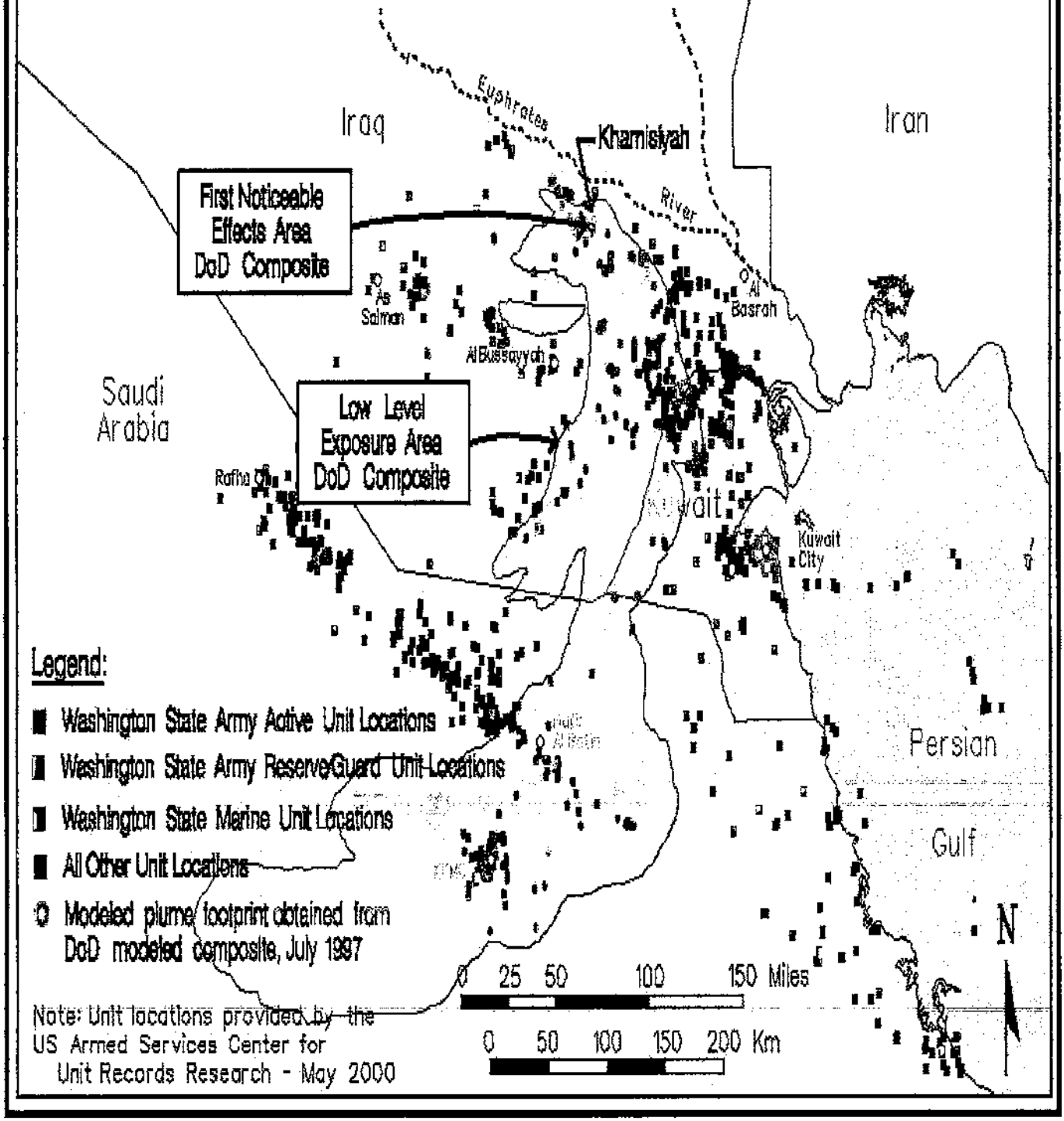
A New Reality –
The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, Man made environmental hazards (Oil Well Fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Pesticides, Stressors, Investigational New Drugs, PB

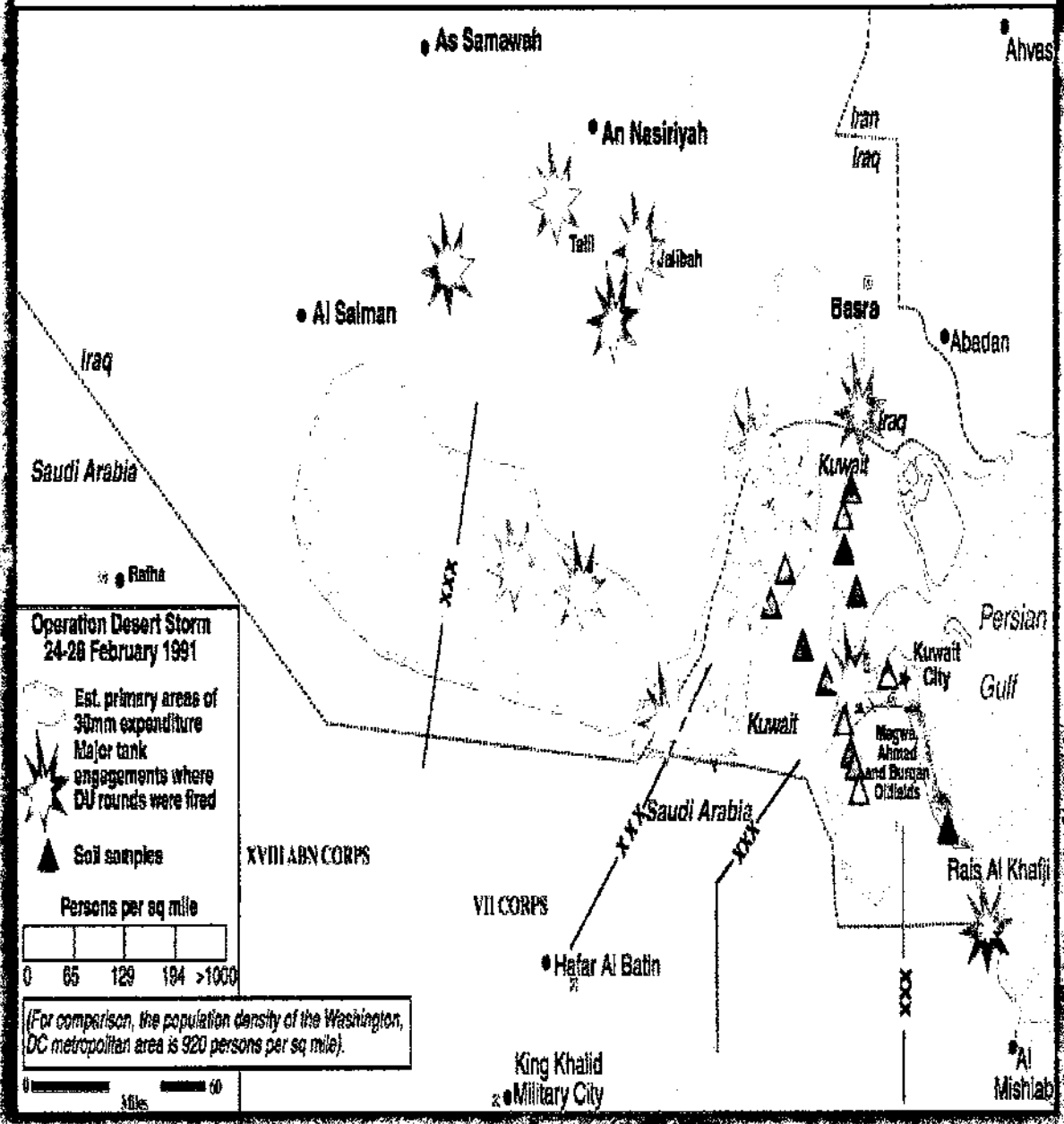
Current and future conflicts and humanitarian deployments have and will have these challenges

Day 2, 11 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Seattle Outreach Visit



Primary Areas of DU Expenditure



DU Exposure Issues

- Radiation
- Consequences of exposure
- Heavy metal toxicity
- Reproductive effect
- Contamination of theater

Gulf War Investigation Results

- Poor intelligence about Iraq's CW/BW weapons
- Not enough vaccines and no explanation given
- Limited environmental survey
- Information about nerve agent pre-treatment (PB) wasn't given to troops
- Inadequate training about DU or CW detectors
  - Training could have averted unnecessary exposure to DU and anxiety resulting from false alarms
- *Veterans re-deployed and left service without thorough medical exam or debrief*

Applying Lessons Learned

You

- Train self and others to recognize and avoid hazards
- Improve feedback and cross talk
- You are your own best health advocate

Your Unit

- CW/BW detection:earlier with fewer false positives
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU
- Debrief to explain what happened
- Monitor service members' health & environment

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

You are your own best health advocate!

Anthrax

- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods
  - At least seven potential adversaries suspected of researching, developing and/or weaponizing anthrax.
- We have a safe and effective vaccine

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
- Dosing schedule is six doses over 18 months
  - 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster
- Shortages in stockpiled doses require temporary slowdown of AVIP
  - No new vaccine available from renovated facility until FDA approves [new vaccine lots] safety and effectiveness
  - Vaccinations continue for service members assigned or deployed at least 30 days in highest threat areas
  - Next scheduled doses for those <u>not</u> in high threat areas will be deferred until sufficient doses are available

(877) GET-VACC DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman.
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Conclusions about PB

- We cannot rule out pyridostigmine bromide as a contributor to increased health symptoms in Gulf War veterans.
- Further research is needed to determine the effectiveness of the current dose of PB against Soman.
- Additional research about safety and effectiveness of PB for humans is needed.

Bottom Line

- You will deploy on missions to dirty areas
- Everyone is responsible for force protection
- Evaluating PB and pesticides as contributors to GW vets' symptoms
- Lessons learned from the Gulf War affect today's doctrine and deployments
- You are your own best health advocate
- Vets should not tough it out; get examined
- Vaccination against anthrax protects you

Obtaining Help and Information

- GWIMRMD Veterans' Helpline (800) 497-6261
- Comprehensive Clinical Evaluation Program (800) 796-9699
- MAMC CCEP (253) 968-3172
- Veterans Affairs Persian Gulf Registry program (800) 749-8387

http://www.gulflink.osd.mil

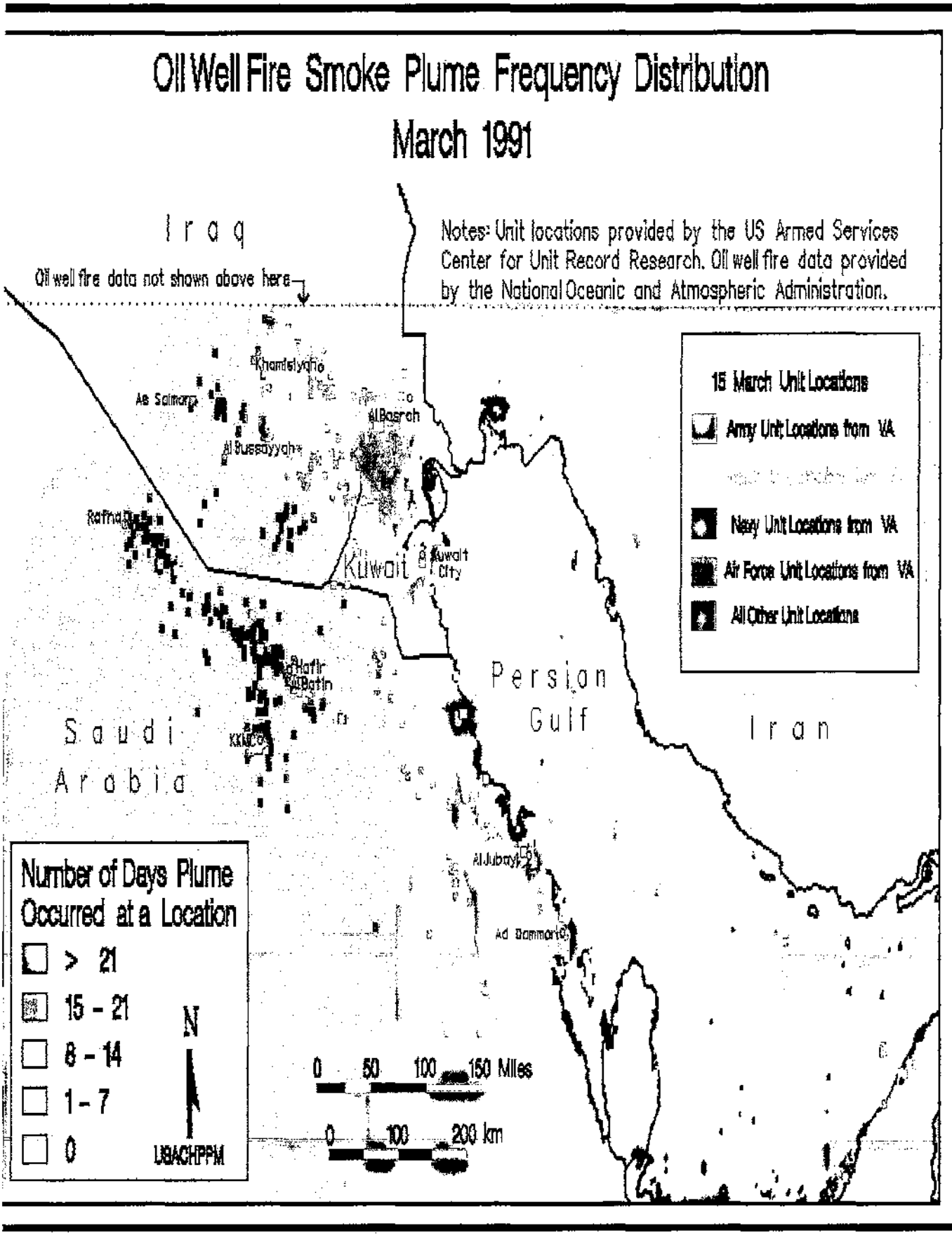
Back-up Slides

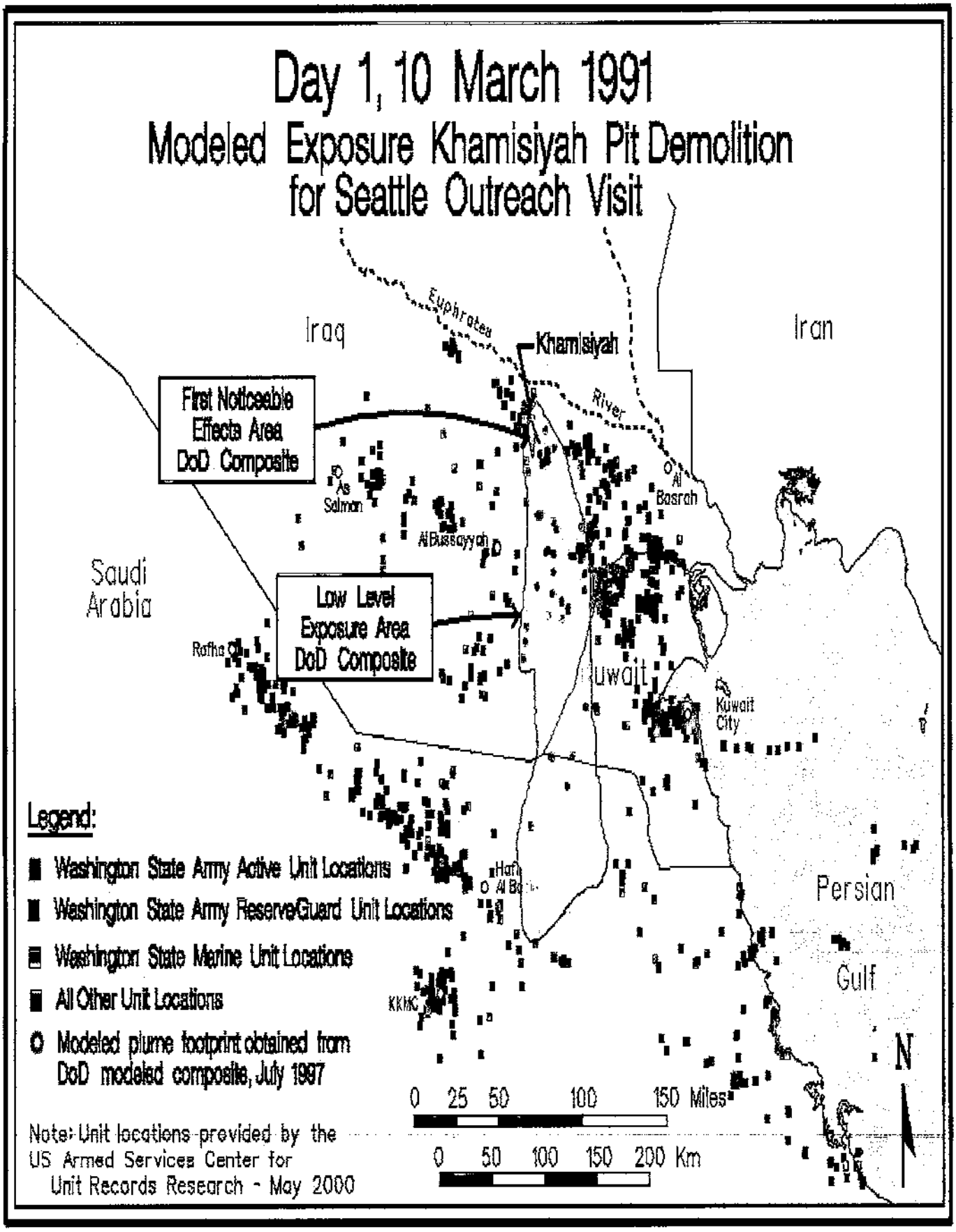
Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,584 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	Normal spectrum of illnesses known
CW or DU cause	Evaluating many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

A National Effort

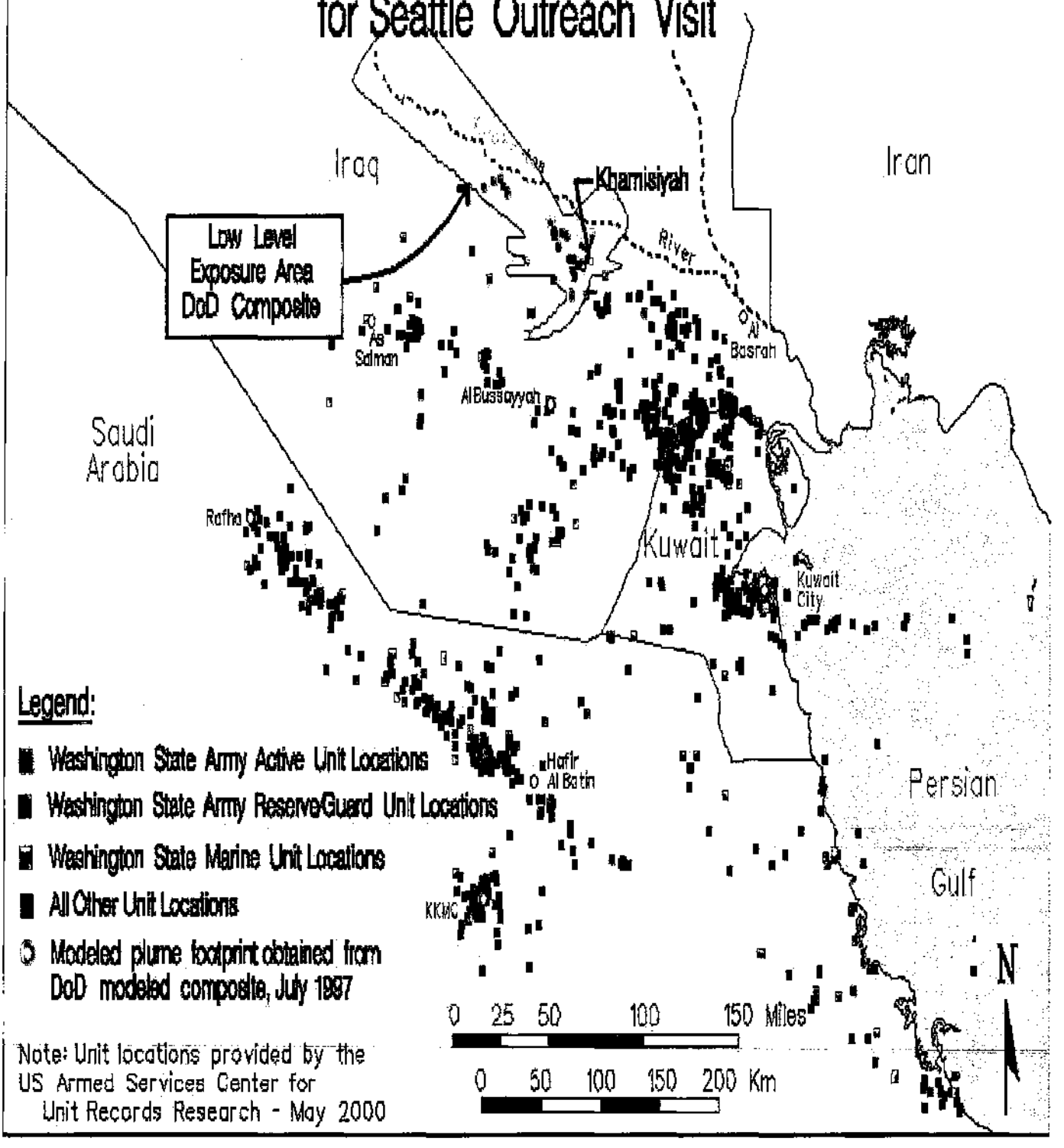
- **OVERSIGHT:** Presidential, 7 Congressional Committees, VSOs, Veterans, the Media
- **INVESTIGATIONS:** IGs, GAO, SIU
- **DoD:** ASDs, Special Assistants, DIA, the Surgeons General
- **OUTSIDE AGENCIES:** CIA, VA, HHS, GWVCB, CDC
- **DECLASSIFICATION:** CIA, DIA, and the Services
- **TECHNICAL PROJECTS:** Dugway, Edgewood, Picatinny, CHPPM, Think tanks, outside experts


Oil Well Fire Smoke Plume Frequency Distribution
March 1991
Iraq
Oil well fire data not shown above here
Notes: Unit locations provided by the US Armed Services Center for Unit Record Research. Oil well fire data provided by the National Oceanic and Atmospheric Administration.
15 March Unit Locations
Army Unit Locations from VA
Navy Unit Locations from VA
Air Force Unit Locations from VA
All Other Unit Locations
Khamisiyah
As Salman
Al Basrah
Al Bussayyah
Kuwait
Kuwait City
Persian Gulf
Iran
Saudi Arabia
Hafir al Batin
Khafji
Al Jubayl
Ad Dammam
Number of Days Plume Occurred at a Location
> 21
15 - 21
8 - 14
1 - 7
0
N
0 50 100 150 Miles
0 100 200 km
USACHPPM


Day 1, 10 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Seattle Outreach Visit
Iraq
Iran
Euphrates
Khamisiyah
River
First Noticeable Effects Area DoD Composite
As Salman
Al Busrah
Al Busayyah
Saudi Arabia
Low Level Exposure Area DoD Composite
Rafha
Kuwait City
Persian Gulf
KKMC
Legend:
Washington State Army Active Unit Locations
Washington State Army Reserve/Guard Unit Locations
Washington State Marine Unit Locations
All Other Unit Locations
Modeled plume footprint obtained from DoD modeled composite, July 1997
Note: Unit locations provided by the US Armed Services Center for Unit Records Research - May 2000
0 25 50 100 150 Miles
0 50 100 150 200 Km
N

Day 3, 12 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Seattle Outreach Visit



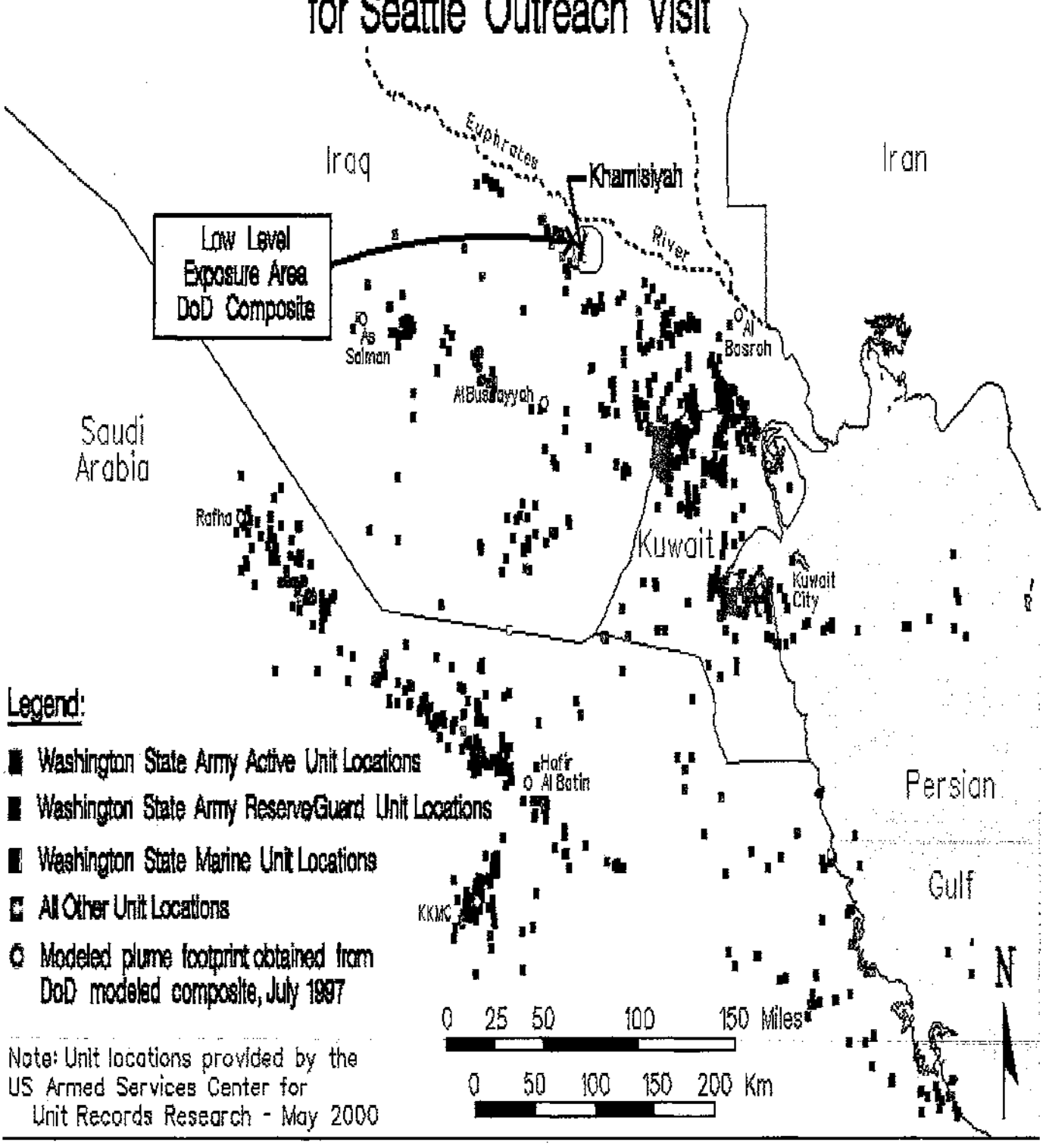
Legend:

- Washington State Army Active Unit Locations
- Washington State Army Reserve/Guard Unit Locations
- Washington State Marine Unit Locations
- All Other Unit Locations
- Modeled plume footprint obtained from DoD modeled composite, July 1997

Note: Unit locations provided by the US Armed Services Center for Unit Records Research - May 2000

Day 4, 13 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Seattle Outreach Visit



Legend:

- Washington State Army Active Unit Locations
- Washington State Army Reserve/Guard Unit Locations
- Washington State Marine Unit Locations
- All Other Unit Locations
- Modeled plume footprint obtained from DoD modeled composite, July 1997

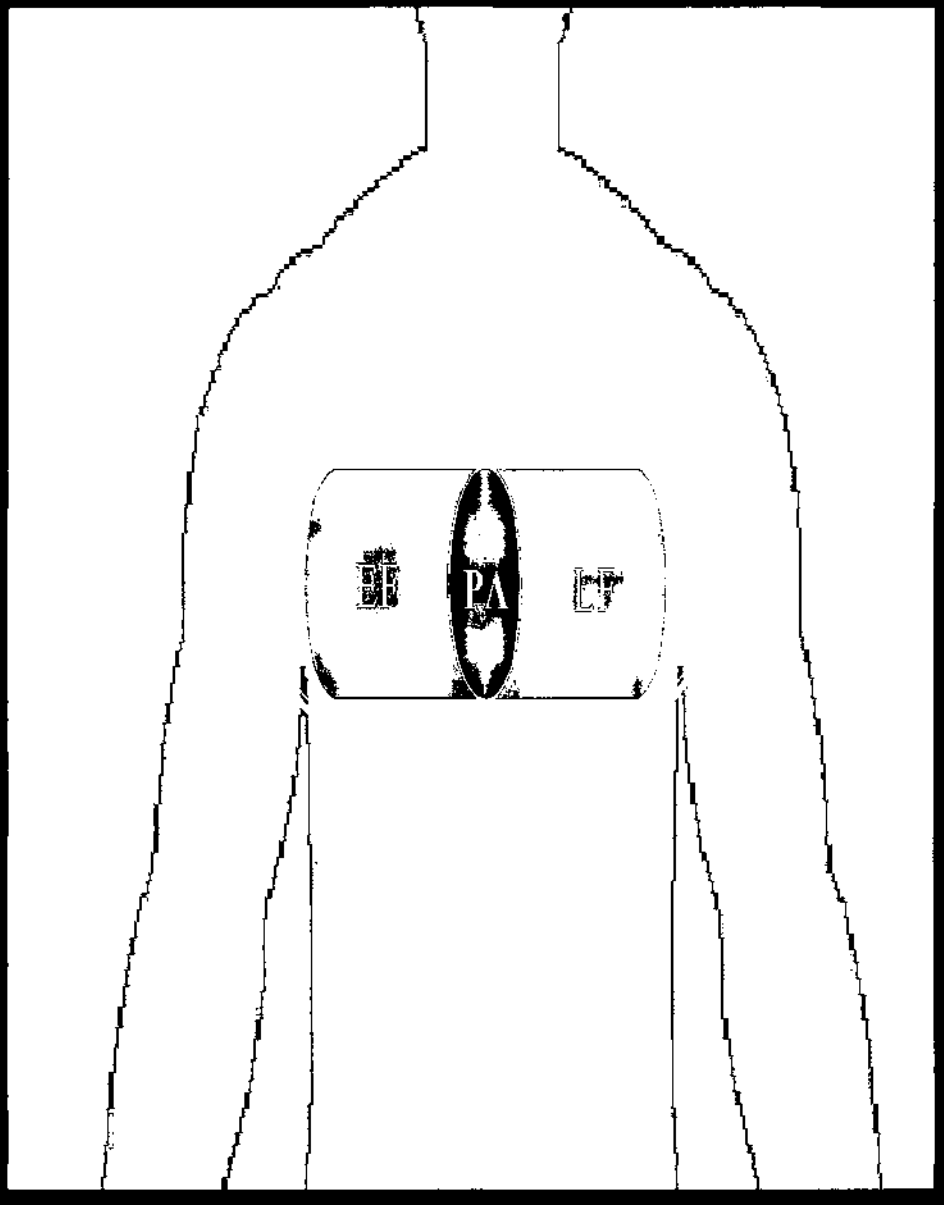
Note: Unit locations provided by the US Armed Services Center for Unit Records Research - May 2000

Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of methods
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4 prevents exposure
- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

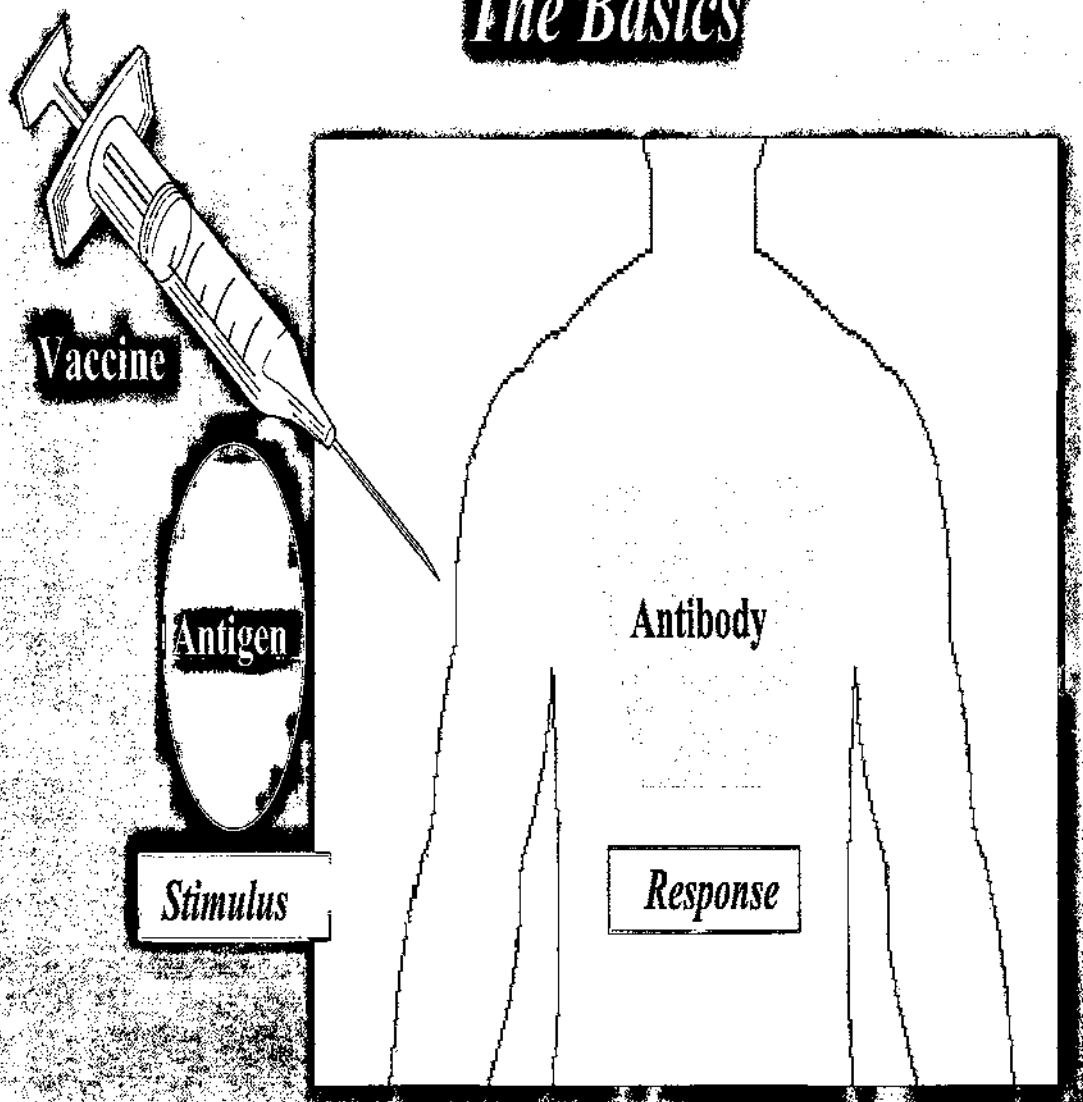
ANTHRAX BACTERIA ATTACK



= Death

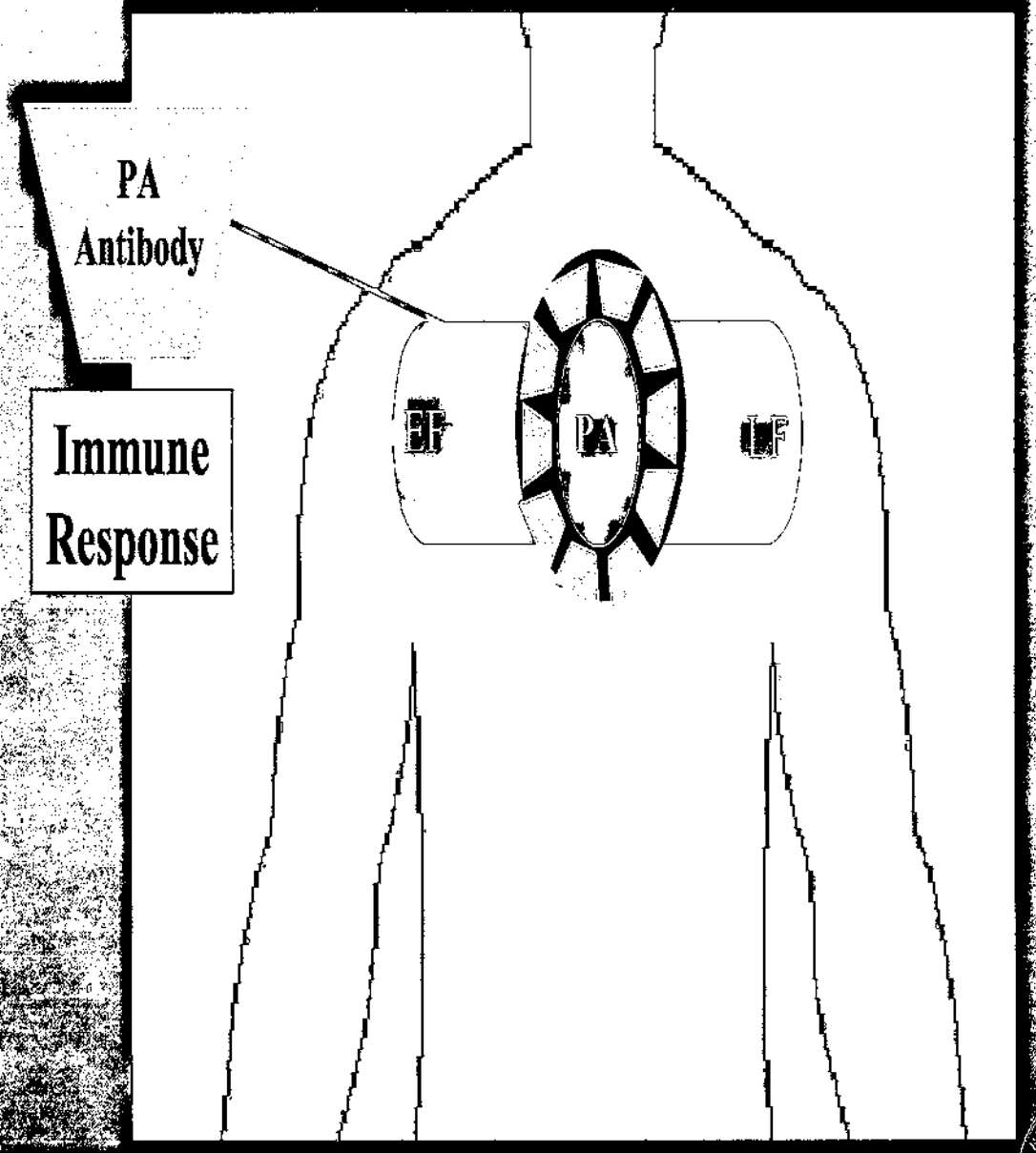
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



AFTER ANTHRAX VACCINE

Antibodies at Work



Office of the Special Assistant

Anthrax Vaccine Program

- Licensed by the FDA since 1970
  - Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers
- Shot schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster

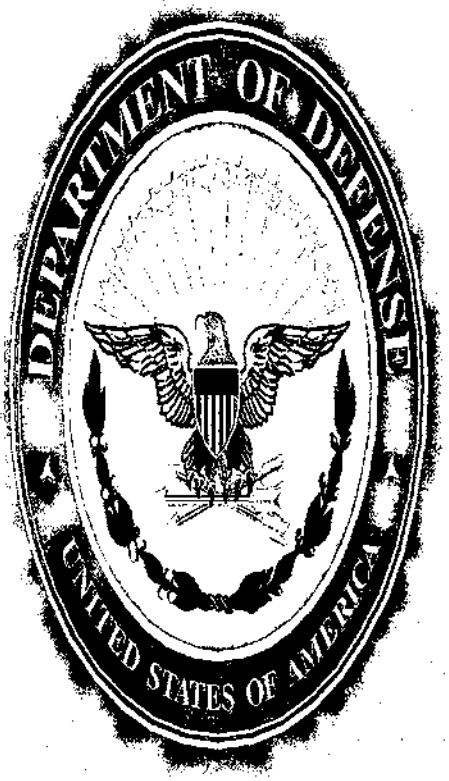
1-877-GET-VACC

DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Office of the Special Assistant to the Deputy Secretary of Defense



for Gulf War Illnesses

(800) 754-2132 fax 703-578-8501
email: brostker@gwillness.osd.mil

Briefing Overview

- Organization - Mission Statement
- Why should I care?
- Symptoms and Illnesses
- Looking for causes
- Gulf War Lessons Learned
- Force Health Protection
- Obtaining help and information

Special Assistant for Gulf War Illnesses

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members

Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops deploying now and in the future.

Why Should I Care?

- Lessons from the Gulf War about dirty battlefields.
- You must protect yourself against hazards.
- You will be working with or leading Gulf War vets.
- You will probably deploy overseas.
- You are responsible for force protection.

Who Served in the Gulf War

697,000 U.S. service members

Army	348,000	50%
Navy	160,000	23%
Marine	105,000	15%
Air Force	84,000	12%

259,000 Coalition Forces

Who Served in the Gulf War

MALE	93%
FEMALE	7%
ACTIVE	83%
RESERVE/NATIONAL GUARD	17%
OFFICER	10%
ENLISTED	90%

< 26 years old - 55%; 26-35 years old - 32%; > 35 years old - 13%

Medical Support

Largest emergency health care system since WW II

41,000 medical personnel

- 18,000 beds

- 2 hospital ships

- 63 combat zone hospitals

source: CENTCOM Publications - Commander-in-chief US CENTCOM "Desert Shield/Desert Storm Facts, Figures, Quotes and Anecdotes 7 AUG 90-11 APR 91," prepared by CENTCOM PAO

Medical Support

- Over 27,000 hospitalizations in theater
- 8,000 medical evacuations
- ????? outpatient visits

U.S. Deaths

Battle deaths	148
Non-battle deaths	224

Post War

Shortly after re-deployment, many individuals in units reported common symptoms

- Aching joints
- Headaches
- Rashes
- Sleep disorders
- Diarrhea
- Hair loss
- Memory loss
- Fatigue

Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"

"It's all in your head!"

"You're faking these symptoms!"

Confounding Issues

- No clustering
- No symptom consistency
- Variable onset
- No long term study
- As yet - no new disease or links between exposures and symptoms

Looking for Causes

The Dirty Battlefield

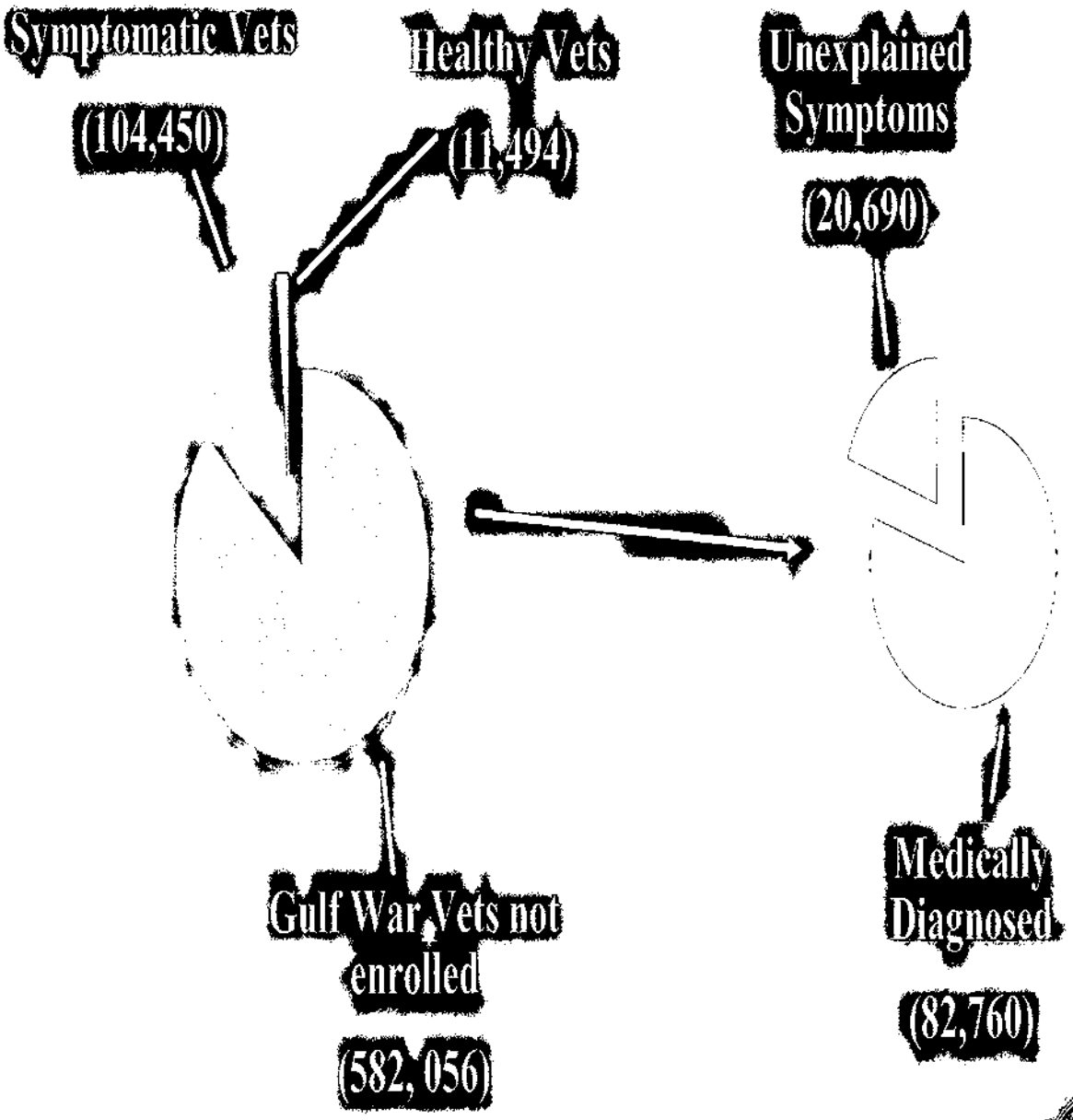
- What Iraq may have done to us.
  - Oil Well Fires, Chem/Bio threat
- What the environment may have done to us.
  - Sand, Insects, Infectious diseases
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide
- Challenges in future conflicts and humanitarian deployments.

OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
- Medical issues and lessons learned:
  - Vaccines, PB, records, policy
    - "Cocktail" effect

Diagnosis Distribution/697,000 Deployed

CCEP/VA Participants



Epidemiology Studies

	Deployed (%)	Non-Deployed (%)
Medical separation (Aug 91 - Dec 93)	2.20	2.56
Hospitalizations (Aug 91 - Sep 93)	21.6	21.6
Hospitalizations unexplained illnesses (Aug 91 - Apr 96)	1.21	1.27
Birth Defects (Aug 91 - Sep 93)	7.45	7.59
Mortality (Aug 91 - Sep 93)	.025	.023

Proactive Measures - You

- Recognize and contend with potential hazards:
  - Improve intel notification
  - Train all personnel
  - Reduce adverse effects of and stress from potential exposures
  - Understand the environment and culture before deploying
- Improve feedback and cross talk

Proactive Measures - Your Unit

- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Improve operational and medical records handling
- Adapt for the future
  - Retain individual unit locations and records
  - DU training
  - Improved medical surveillance
  - Force health protection

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Pre-deployment serum sample
- Verify HIV test in last 12 months
- Immunizations
- Verify current physical exam
- Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect serum sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

Future Equipment

- Personal Information Carrier (PIC)
- Biological Integrated Detection System (BIDS)
- Automatic Chemical Agent Alarm (ACADA)
- Medic Cam - Tele medicine

Anthrax Vaccine

- What is Anthrax?
  - Bacteria
  - Easily obtained, stored and weaponized
  - Deadly - (skin vs inhaled exposure)
- Vaccine is safe and necessary!
  - FDA Licensed in 1970
  - Used for many years to protect textile mill workers
  - Recommended by Centers for Disease Control (CDC):
    - Workers occupationally exposed to anthrax (labs, mills)
    - Treatment of anyone exposed to anthrax aerosols
    - Only known pretreatment and protection against exposure

Anthrax Vaccine

- DoD Policy - mandatory for total force
  - Phased implementation
- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea (8/99)
- Phase III - Total force (early 2000's)
- Vaccine series:
  - 0, 2, 4 weeks; then 6, 12, 18 months; annual booster
  - 1,147,349 doses, 211 adverse reactions=0.018% (01 Oct 99)
    - 155 systemic reactions, 56 local reactions

- DoD anthrax web site: www.anthrax.osd.mil

Obtaining help and information

- Comprehensive Clinical Evaluation Program (CCEP)
  - 1-800-796-9699
- Veterans Affair registry program
  - 1-800-749-8387
- Town Hall
  - Thursday, November 4, 1999/Infantry Hall (Bldg. 4), 1900hrs
- Displays
  - P.X., Infantry Hall (Bldg. 4), and Martin Army Community Hospital
- Contact managers

Bottom Line

- Gulf War Veterans key for our work
- You must protect yourself on the Dirty Battlefield
- Anyone deployed to South West Asia is eligible for CCEP *(family members included)*
- Don't tough it out - Get signed up and evaluated
- You are your best health advocate
- Apply these lessons learned

Office of the Special Assistant for Gulf War Illnesses

CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Direct Hotline for GWV	800-497-6261

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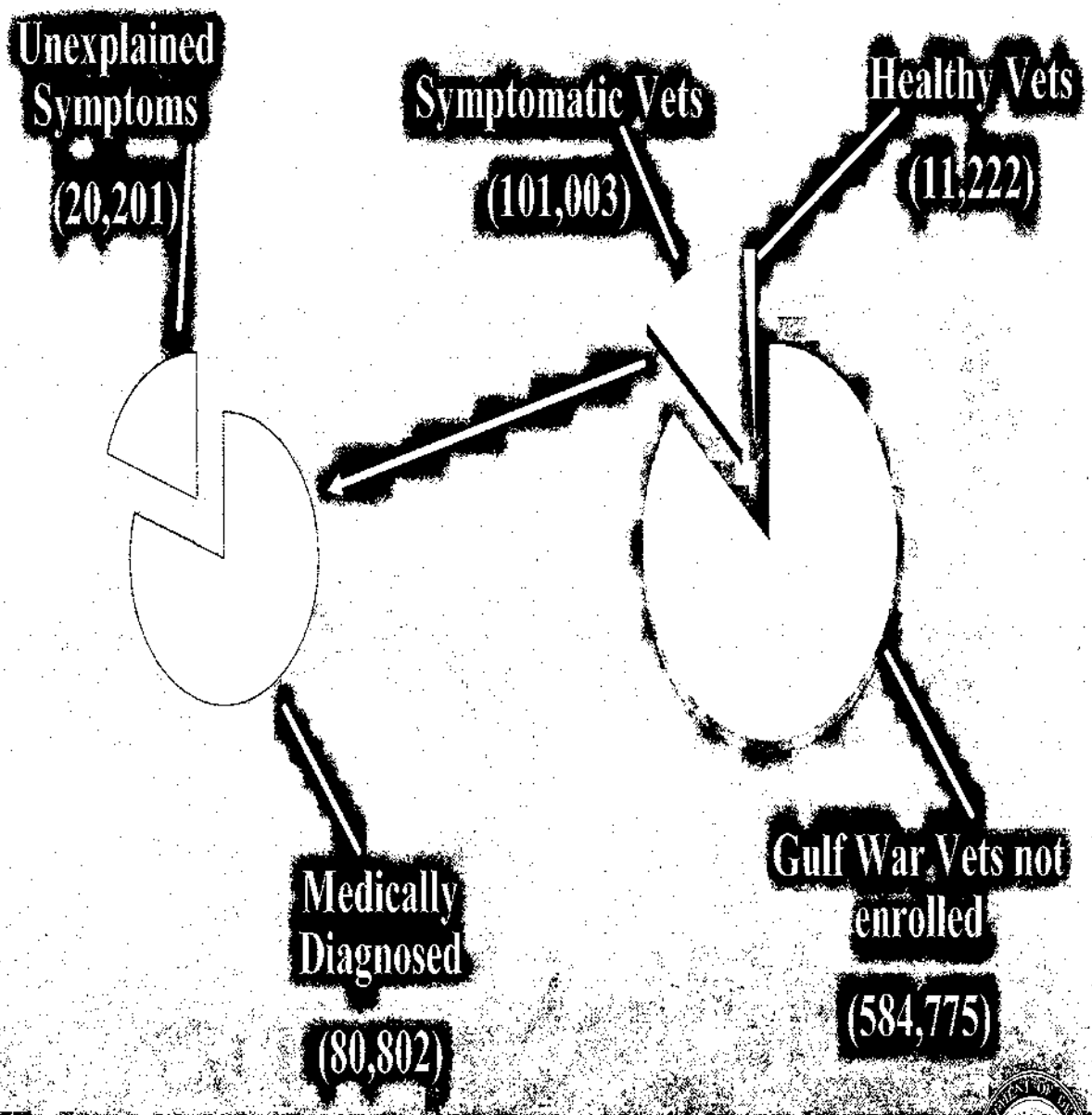

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  - 1-800-749-8387
- Town Hall
  - Thursday, Aug 26 at the Haszard Auditorium, 1900hrs
- Displays
  - P.X., Ireland Army Community Hospital
- Contact managers

Bottom Line

- Gulf War Veterans key for our work
- You must protect yourself on the Dirty Battlefield
- Anyone deployed to South West Asia is eligible for CCEP
- Don't tough it out - Get signed up and evaluated
- You are your best health advocate
- Apply these lessons learned

Office of the Special Assistant for Gulf War Illnesses

CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-472-6719

www.gulflink.osd.mil

Office of the Special Assistant to the Secretary of Defense

for Gulf War Illnesses, Medical Readiness, and Military Deployments

800-497-6261 fax (703) 578-8501

email: brostker@gwillness.osd.mil

Briefing Overview

- Mission Statement
- The Gulf War
- Searching for Answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining Help and Information

Vision of the Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

- The Department of Defense recognizes the right of those involved in deployments to receive information that enables them to make informed decisions about their health
- We will develop and disseminate such information in a relevant and timely fashion
- We will work with others in the Defense Department to incorporate lessons from previous deployments to foster the well-being of deployed forces

Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Gulf War Theater

- August 1990 to July 1991
- 697,000 US service members
- More than 27,000 hospitalizations
- 148 battle deaths
- 224 non-battle deaths

1 in 7 Veterans Reported Symptoms Since the War

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Confounding Issues

- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

Taking Care of Service Members

- **DoD Comprehensive Clinical Evaluation Program**
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
  - DoD civilians
- **VA Persian Gulf Registry**
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- **Available to *all* service members deploying to South West Asia**

Don't Tough It Out!

OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Scientific research under PGVCB
  - 180+ studies sponsored by DoD, DVA, & HHS
  - No cause and effect relationship shown so far

Investigation Results

- Gulf War
  - No offensive CW/BW use
  - Not enough vaccines and no explanation given
  - Limited environmental surveys
  - Information about nerve agent pre-treatment (PB) wasn't given to troops
  - Inadequate training
    - *Veterans returned home and left service without thorough medical exam or debrief*

The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, man-made environmental hazards (oil well fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Accidents, pesticides, investigational new drugs, PB

Current and future conflicts and humanitarian deployments have and will have these challenges

Applying Lessons Learned

- Train self and others to recognize and avoid hazards
- Monitor service member's health & environment
- Improve feedback and cross talk
- Know your equipment strengths and weaknesses
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU

Force Health Protection

- Pre-deployment
  - Medical screening/surveillance and briefings
- Deployment
  - Record keeping
  - Monitor environment and personnel
- Post Deployment
  - Medical screening and unit debriefing

Anthrax

- We have a safe and effective vaccine

- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
- Dosing schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster
- Shortages in stockpiled doses require temporary slowdown of AVIP

(877) GET-VACC DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Bottom Line

- Lessons learned from the Gulf War affect today's doctrine and deployments
- You will deploy on missions
- Everyone is responsible for force protection
- You are your own best health advocate
- Vets should not tough it out; get examined

Obtaining Help and Information

OSAGWI/MR/MD Veterans' Helpline
(800) 497-6261

Comprehensive Clinical Evaluation Program
(800) 796-9699

Veterans Affairs Persian Gulf Registry
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http://www.gulflink.osd.mil

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Back-up Slides

Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,584 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

A National Effort

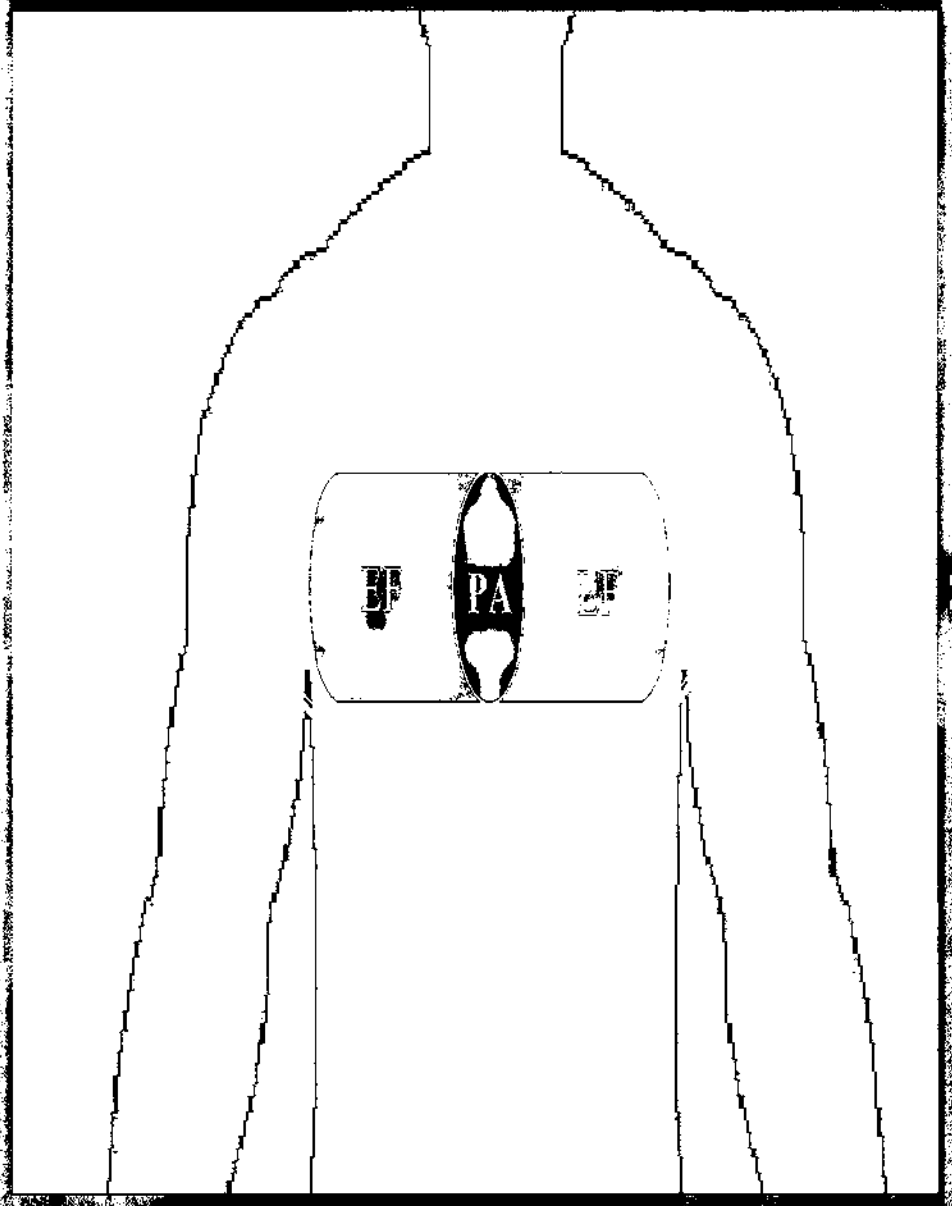
- **OVERSIGHT:** Presidential, 7 Congressional Committees, VSOs, Veterans, the Media
- **INVESTIGATIONS:** IGs, GAO, SIU
- **DoD:** ASDs, Special Assistants, DIA, the Surgeons General
- **OUTSIDE AGENCIES:** CIA, VA, HHS, GWVCB, CDC
- **DECLASSIFICATION:** CIA, DIA, and the Services
- **TECHNICAL PROJECTS:** Dugway, Edgewood, Picatinny, CHPPM, Think tanks, outside experts

Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of weapons
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4 prevents exposure
- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

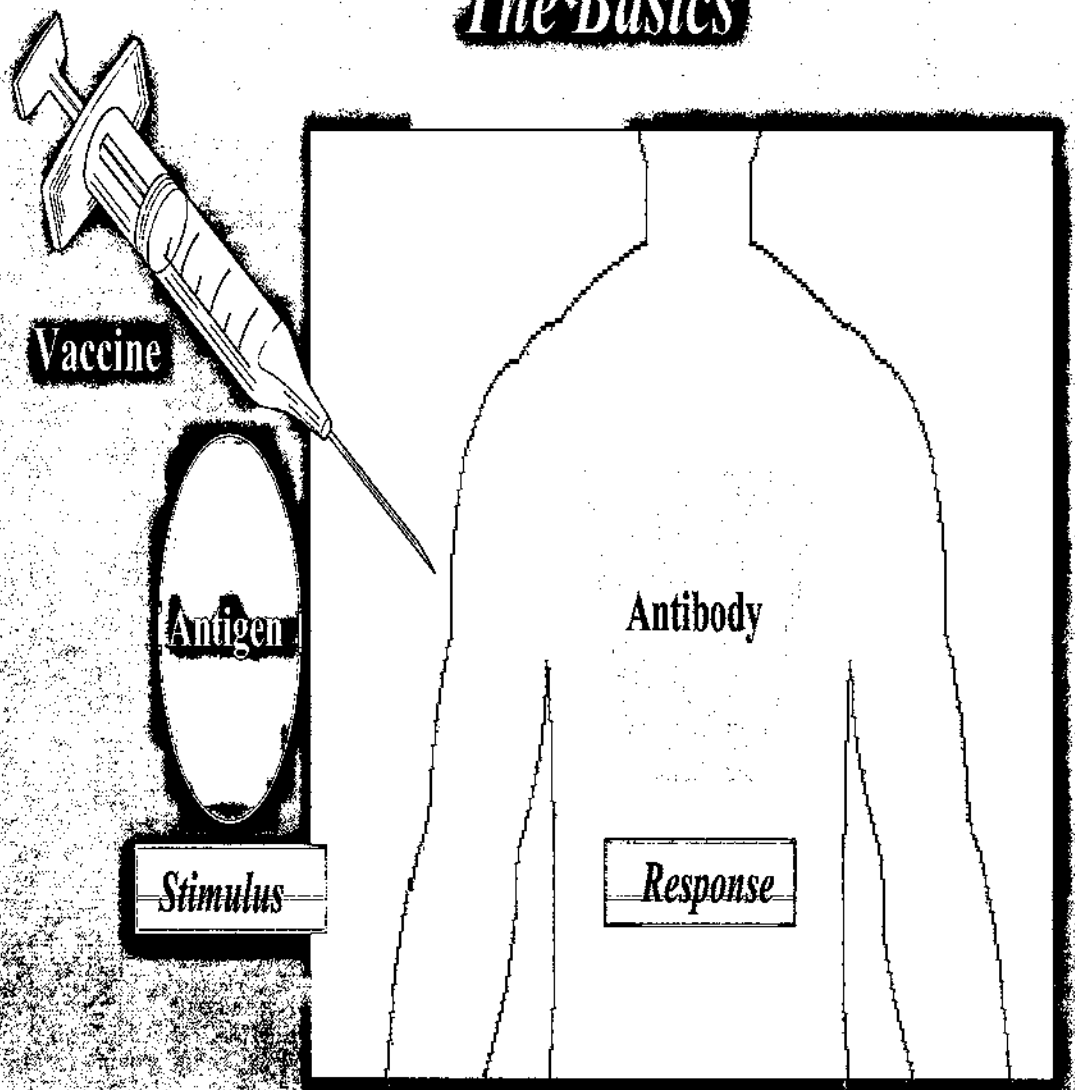
ANTHRAX BACTERIA ATTACK



= Death

IMMUNE SYSTEM ACTIVATION BY VACCINE

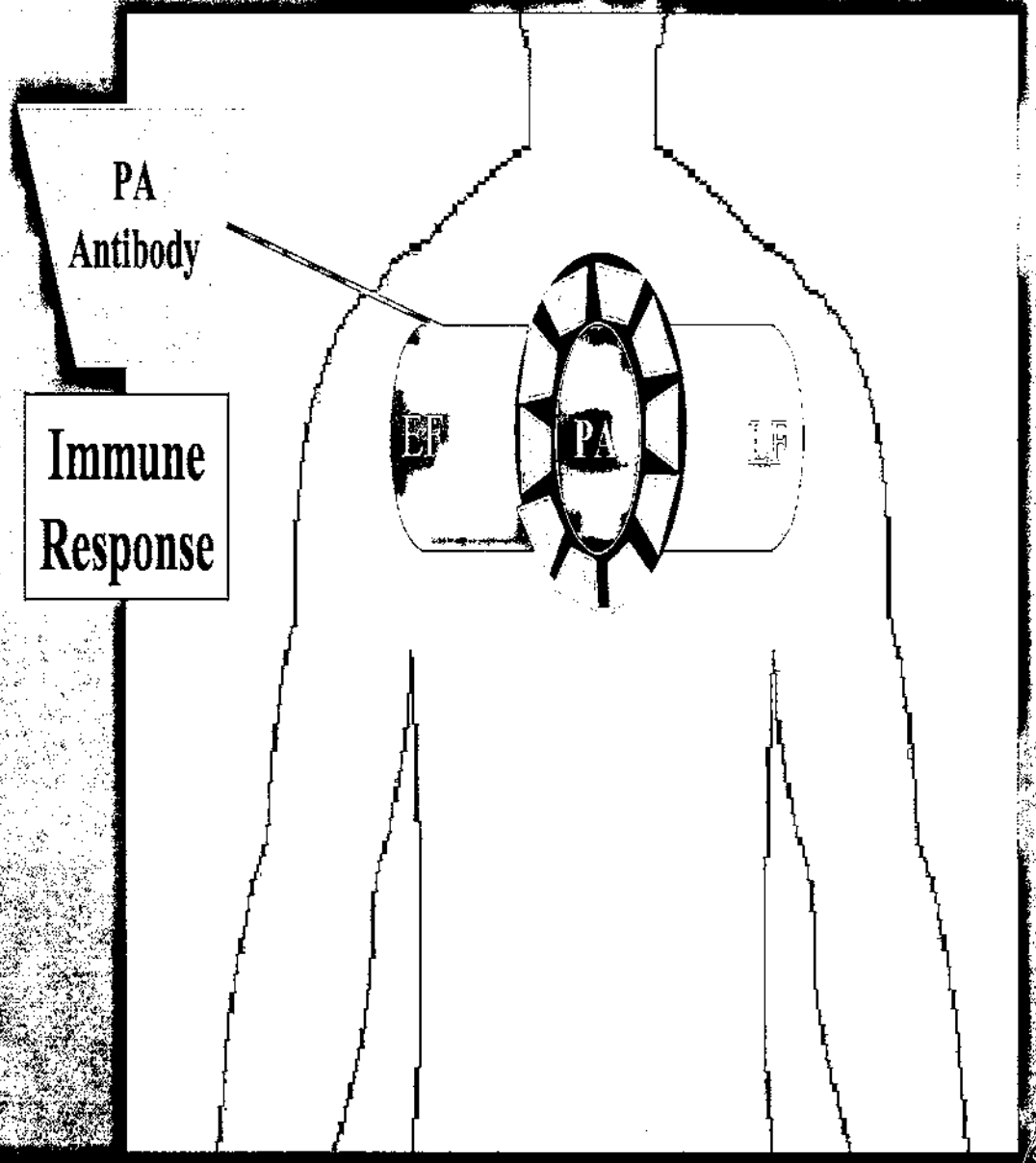
The Basics



Office of the Special Assistant

AFTER ANTHRAX VACCINE

Antibodies at Work



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for Gulf War Illnesses, Medical Readiness, and Military Deployments

800-497-6261 fax 703-578-8501

email: brostker@gwillness.osd.mil

207

Briefing Overview

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- Post Gulf War Issues
- Searching for answers
- Lessons Learned
- Force Health Protection
- Bottom Line
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Vision of Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

- The Department of Defense recognizes the right of those involved in deployments to receive information that enables them to make informed decisions about their health.
- We will develop and disseminate such information in a relevant and timely fashion.
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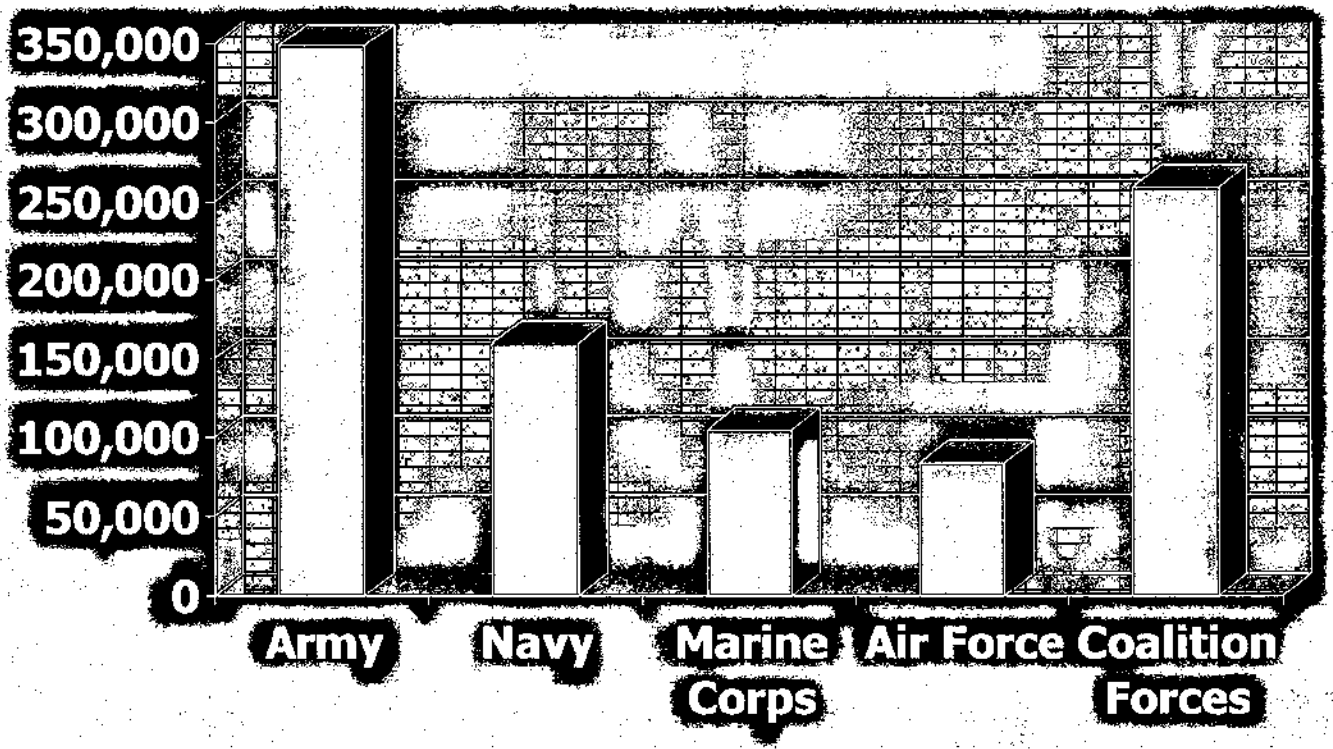
Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Why Should I Care

- Lessons from the Gulf War about dirty battlefields
- You must protect yourself against hazards
- You will be leading Gulf War vets
- You are responsible for force protection
  - What are the dangers of the dirty battlefield?
  - How good are our detectors and MOPP gear?
  - How do we determine if we are exposed?
  - Will our counter-fire put us at risk?
  - How do we identify captured CW/BW?
  - What if my fighting vehicle is hit with DU?

Gulf War Theater Forces



697,000 U.S. service members

Veterans' Health Concerns

Since re-deployment, one in seven veterans report common symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

and many other symptoms

Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Confounding Issues

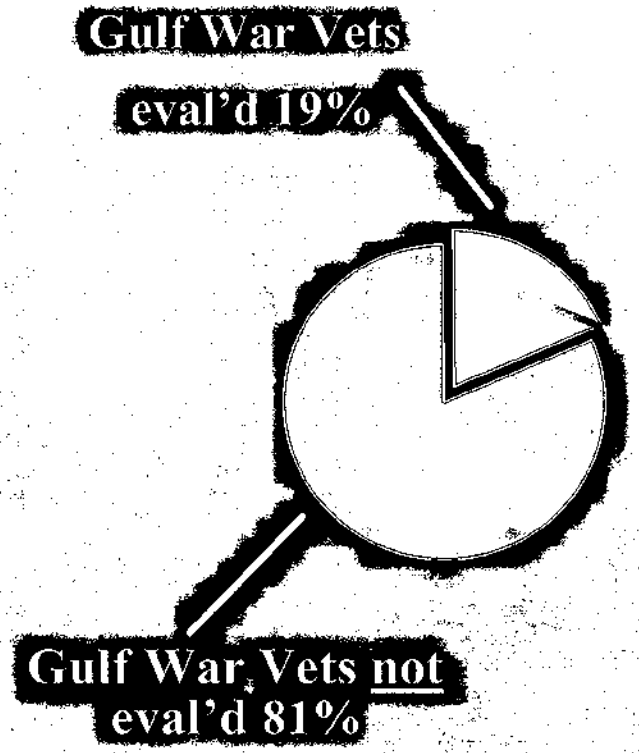
- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

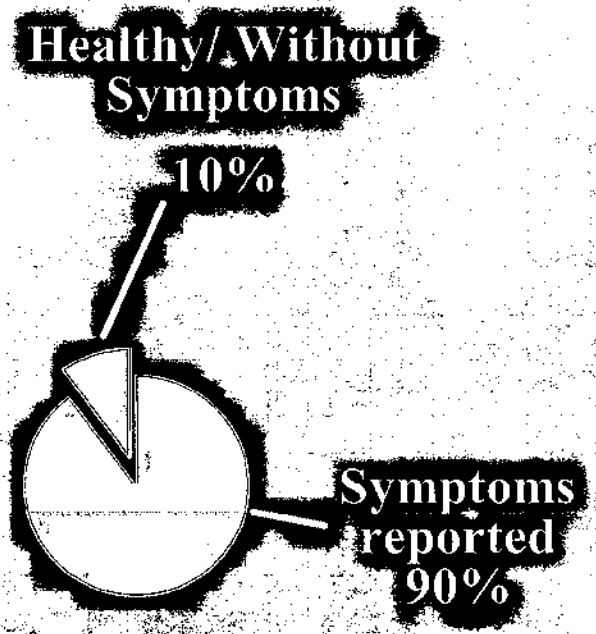
Taking Care of Service Members

- **DoD Comprehensive Clinical Evaluation Program**
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
  - Civilian employees
- **VA Persian Gulf Registry**
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- **Available to *all* service members deploying to South West Asia**
  - Most people evaluated can be treated

Don't Tough It Out!

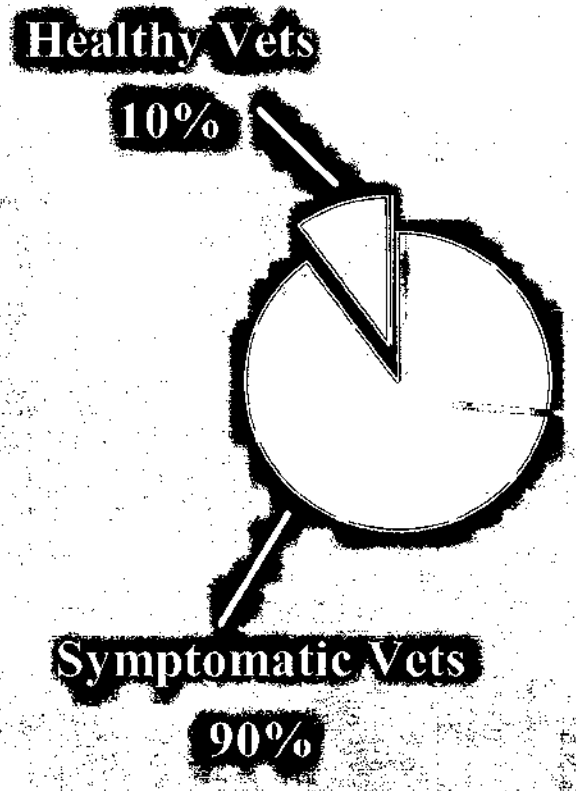
Evaluation Distribution of 697,000 CCEP/VA

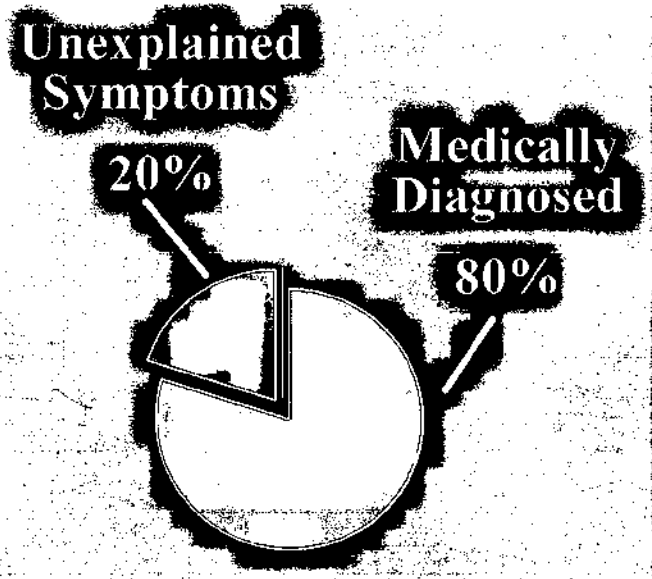




Diagnosis Distribution of Evaluated Veterans

CCEP/VA





Don't tough it out!

OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
    - Science doesn't support DU or Oil Well fires as causes
    - Still examining particulates and pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Persian Gulf War Veterans Coordinating Board-Scientific Research
  - 180+ studies sponsored by DoD, HHS & DVA
  - Science shows no exposure cause or effect relationship yet!

A New Reality =
The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, Man made environmental hazards (Oil Well Fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Pesticides, Stressors, Investigational New Drugs, PB
  - Current and future conflicts and humanitarian deployments have and will have these challenges

Gulf War Investigation Results

- Poor intelligence about Iraq's CW/BW weapons
- Not enough vaccines and no explanation given
- Limited environmental survey
- Information about nerve agent pre-treatment (PB) wasn't given to troops
- Inadequate training about DU or CW detectors
  - Training could have averted unnecessary exposure to DU and anxiety resulting from false alarms
- *Veterans re-deployed and left service without thorough medical exam or debrief*

Applying Lessons Learned

You

- Train self and others to recognize and avoid hazards
- Improve feedback and cross talk
- You are your own best health advocate

Your Unit

- CW/BW detection:earlier with fewer false positives
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU
- Debrief to explain what happened
- Monitor service members' health & environment

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

You are your own best health advocate!

Anthrax

- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods
  - At least seven potential adversaries suspected of researching, developing and/or weaponizing anthrax.
- We have a safe and effective vaccine

Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of methods
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  - Flu-like symptoms early, rapid deterioration, and death
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- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
- Dosing schedule is six doses over 18 months
  - 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster
- Shortages in stockpiled doses require temporary slowdown of AVIP
  - No new vaccine available from renovated facility until FDA approves [new vaccine lots] safety and effectiveness
  - Vaccinations continue for service members assigned or deployed at least 30 days in highest threat areas
  - Next scheduled doses for those <u>not</u> in high threat areas will be deferred until sufficient doses are available

(877) GET-VACC DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman.
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Conclusions about PB

- We cannot rule out pyridostigmine bromide as a contributor to increased health symptoms in Gulf War veterans.
- Further research is needed to determine the effectiveness of the current dose of PB against Soman.
- Additional research about safety and effectiveness of PB for humans is needed.

Bottom Line

- You will deploy on missions to dirty areas
- Everyone is responsible for force protection
- Evaluating PB and pesticides as contributors to GW vets' symptoms
- Lessons learned from the Gulf War affect today's doctrine and deployments
- You are your own best health advocate
- Vets should not tough it out; get examined
- Vaccination against anthrax protects you

Obtaining Help and Information

GWIMRMD Veterans' Helpline

(800) 497-6261

Comprehensive Clinical Evaluation Program

(800) 796-9699

Veterans Affairs Persian Gulf Registry Program

(800) 749-8387

http://www.gulflink.osd.mil

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Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,584 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	Normal spectrum of illnesses known
CW or DU cause	Evaluating many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

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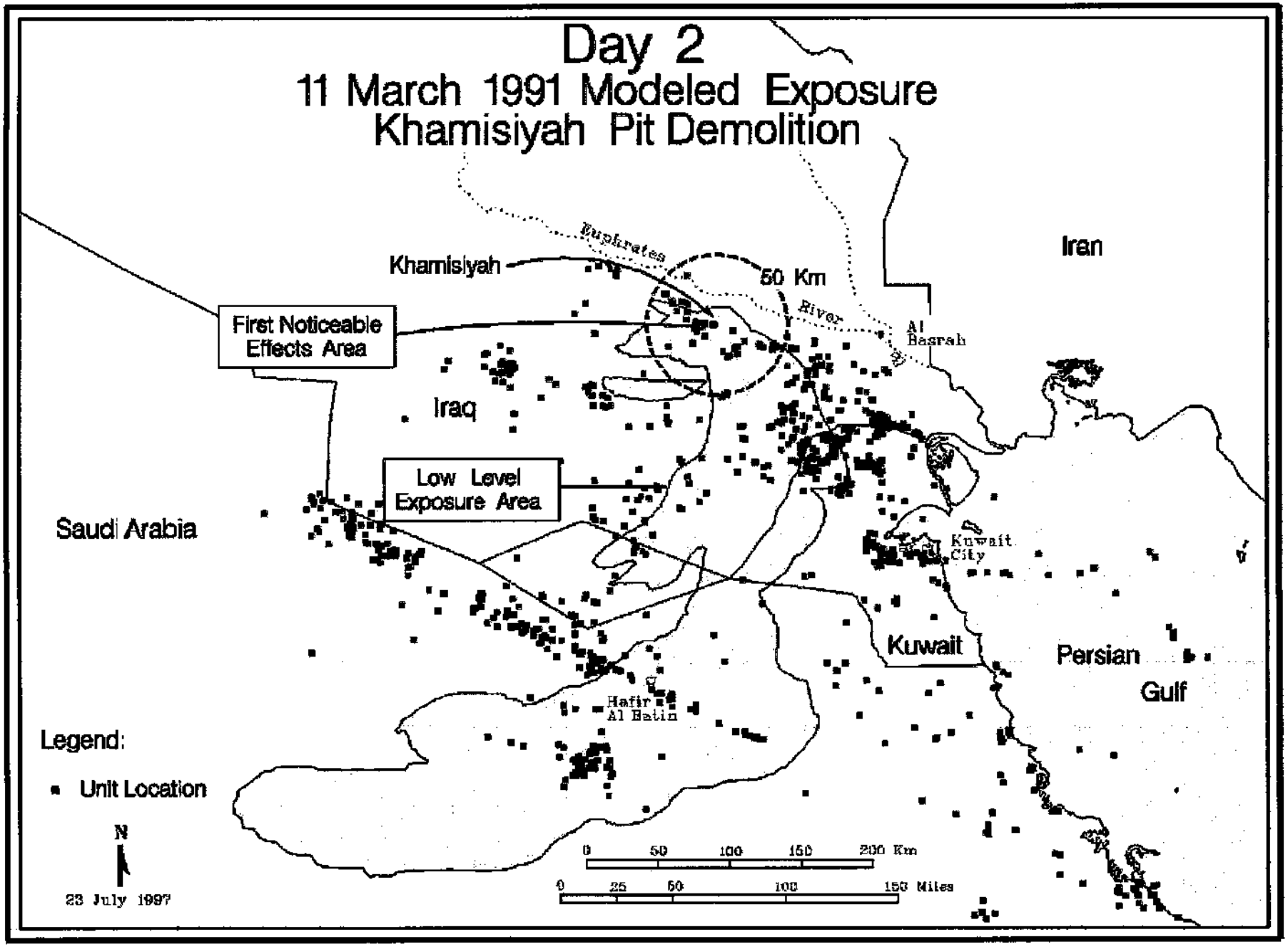
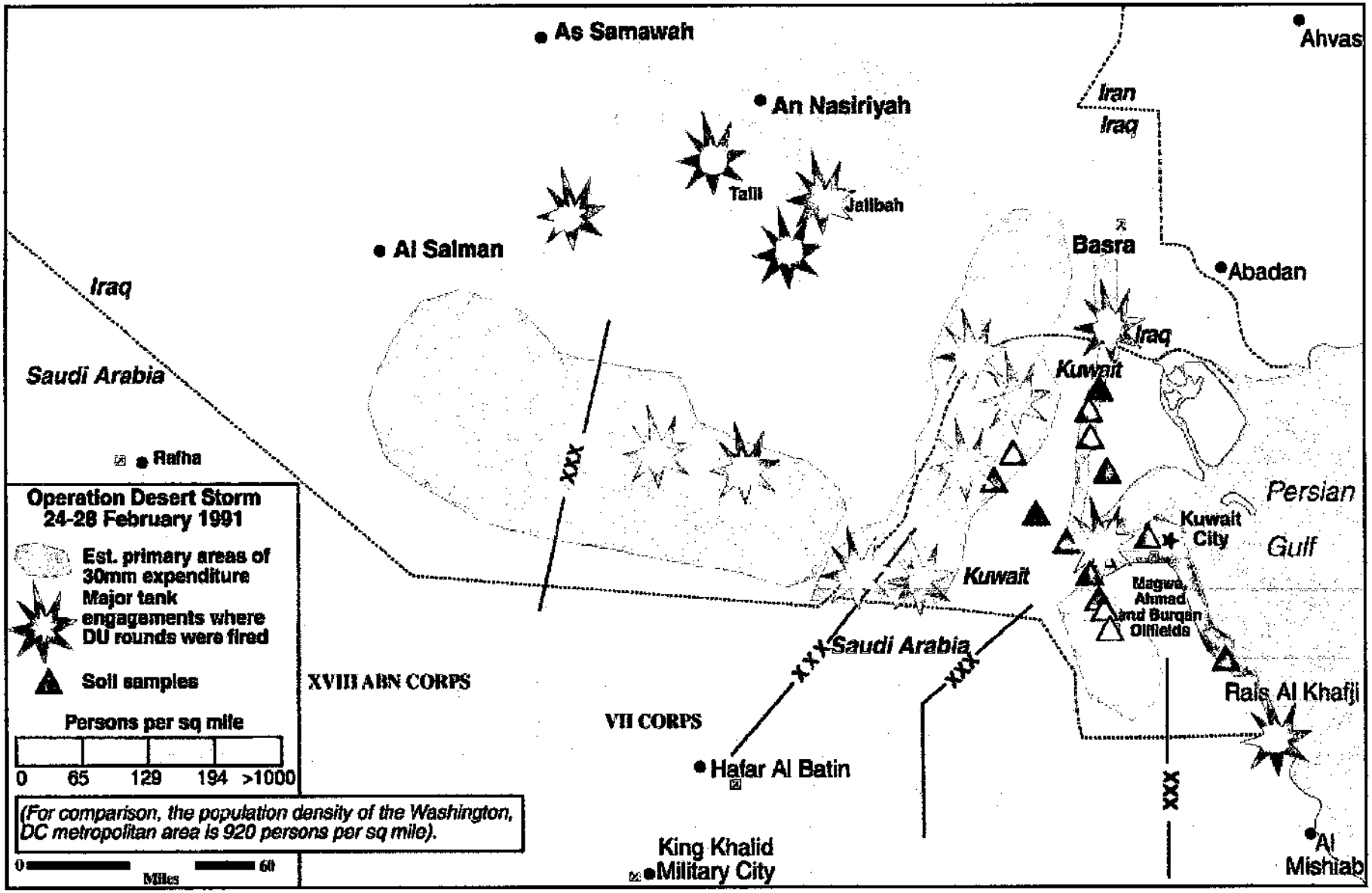
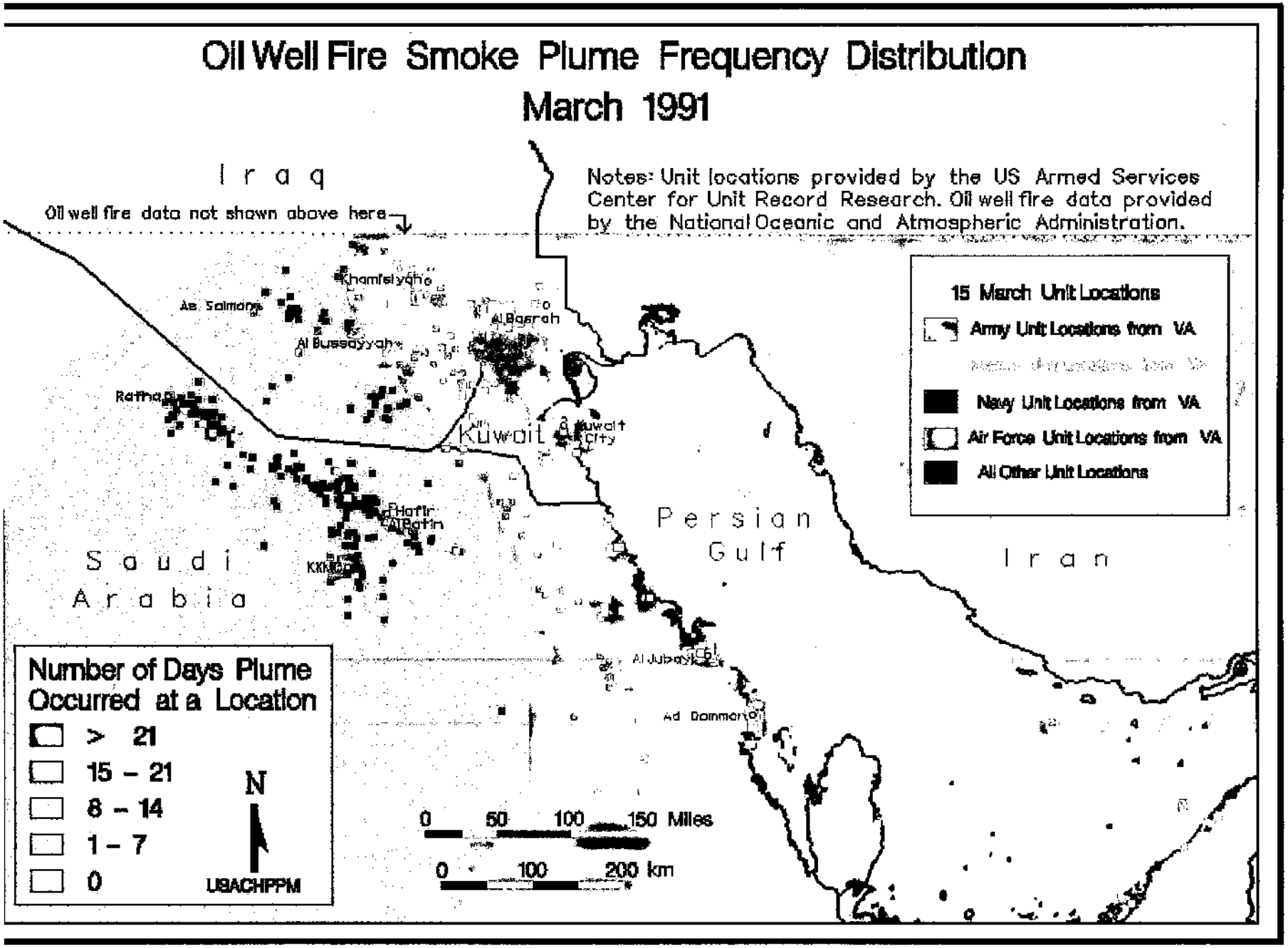

Day 2
11 March 1991 Modeled Exposure
Khamisiyah Pit Demolition
Euphrates River
Khamisiyah
50 Km
First Noticeable Effects Area
Low Level Exposure Area
Iraq
Iran
Saudi Arabia
Kuwait
Persian Gulf
Al Basrah
Kuwait City
Hafir Al Batin
Legend:
Unit Location
N
23 July 1997
0 50 100 150 200 Km
0 25 50 100 150 Miles

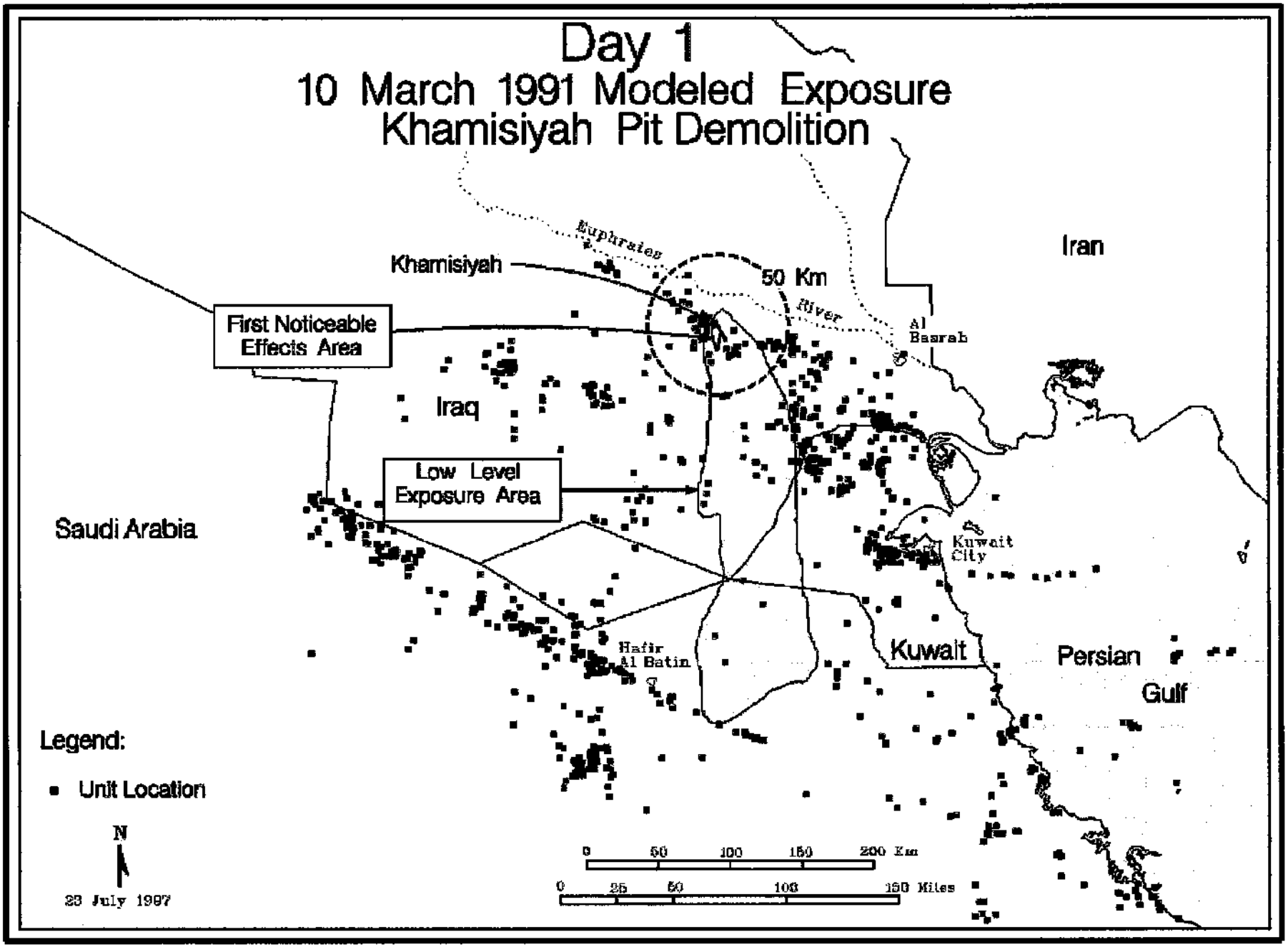
Primary Areas of DU Expenditure

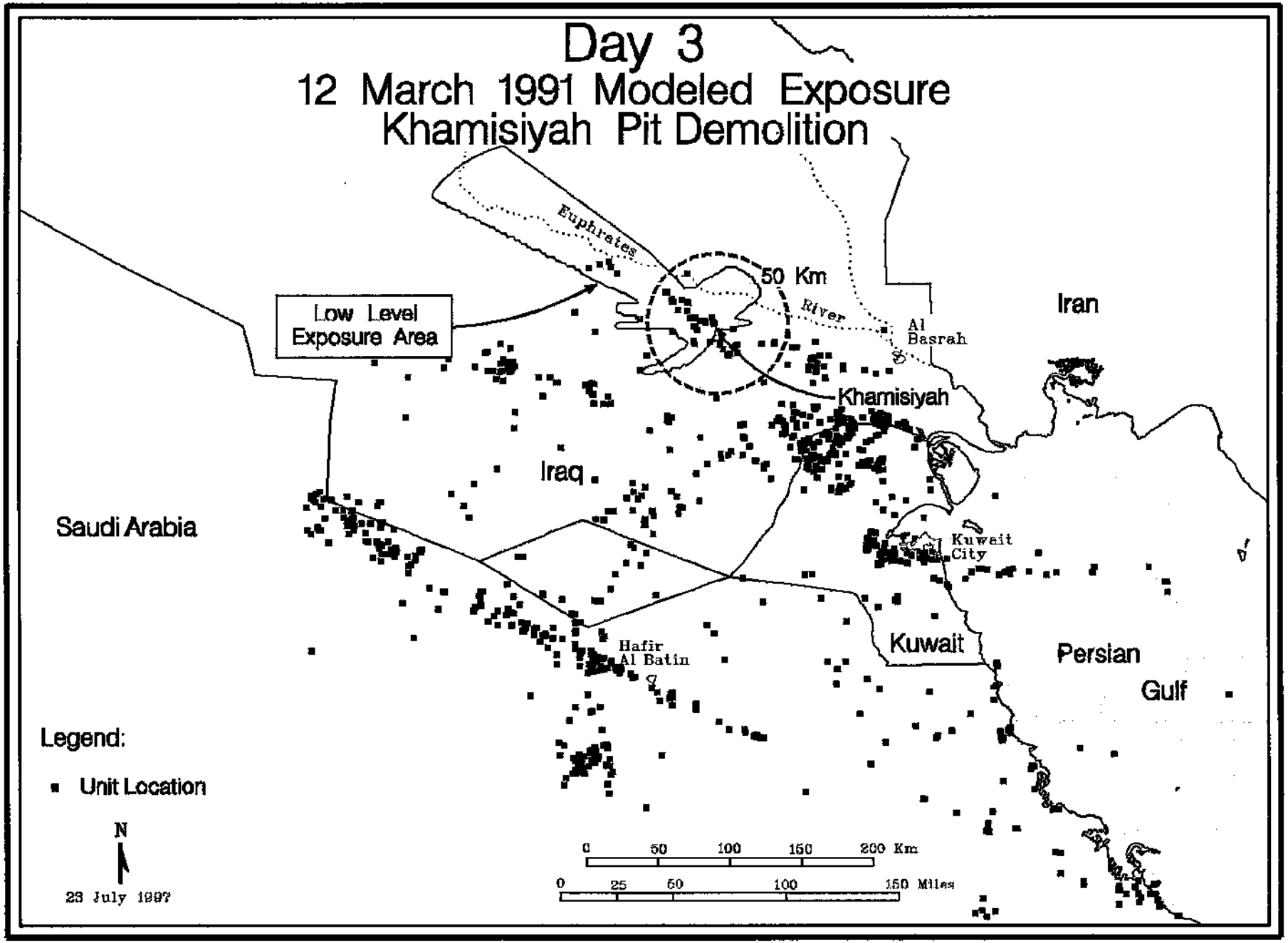


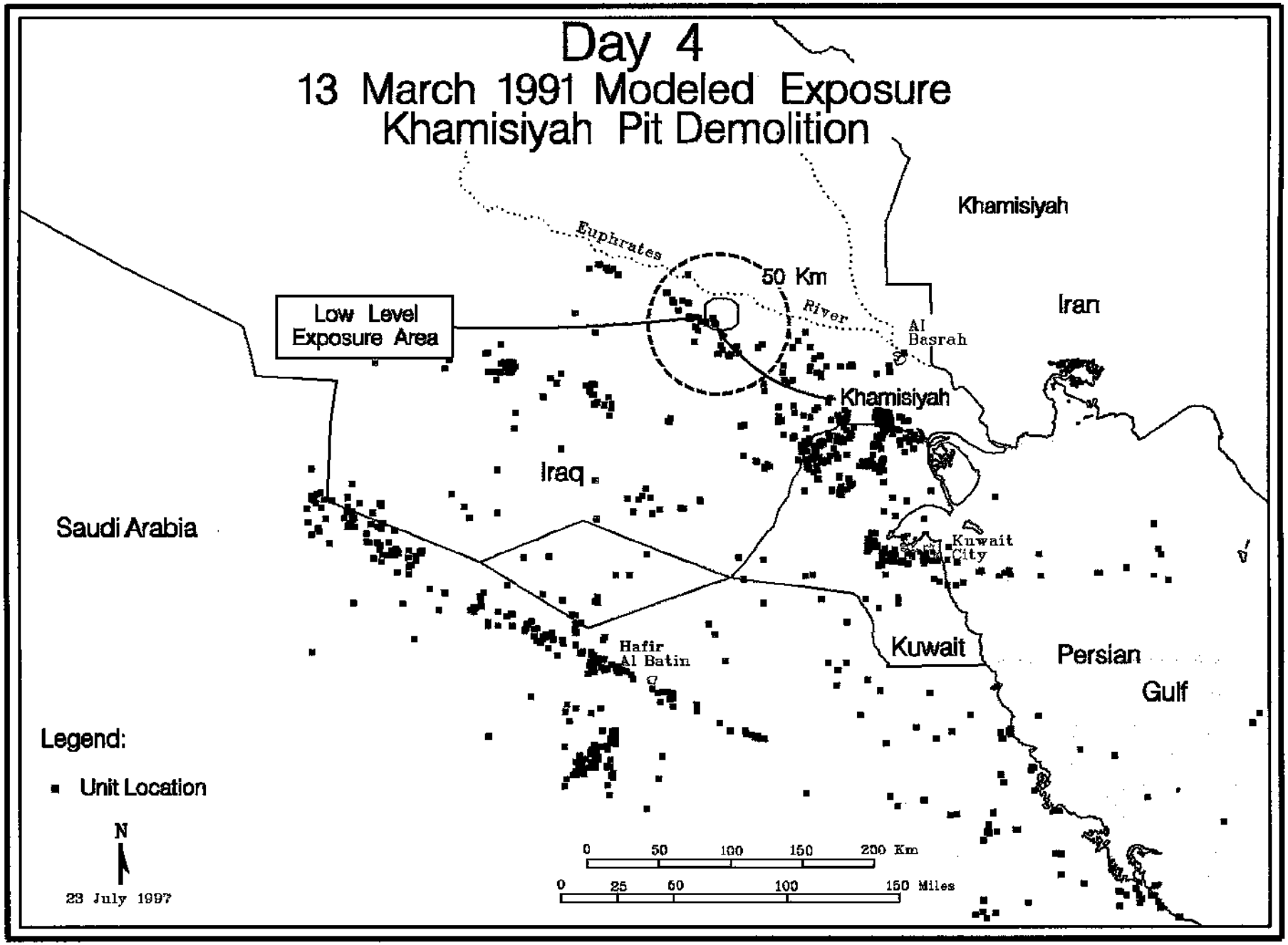
DU Exposure Issues

- Radiation
- Consequences of exposure
- Heavy metal toxicity
- Reproductive effect
- Contamination of theater

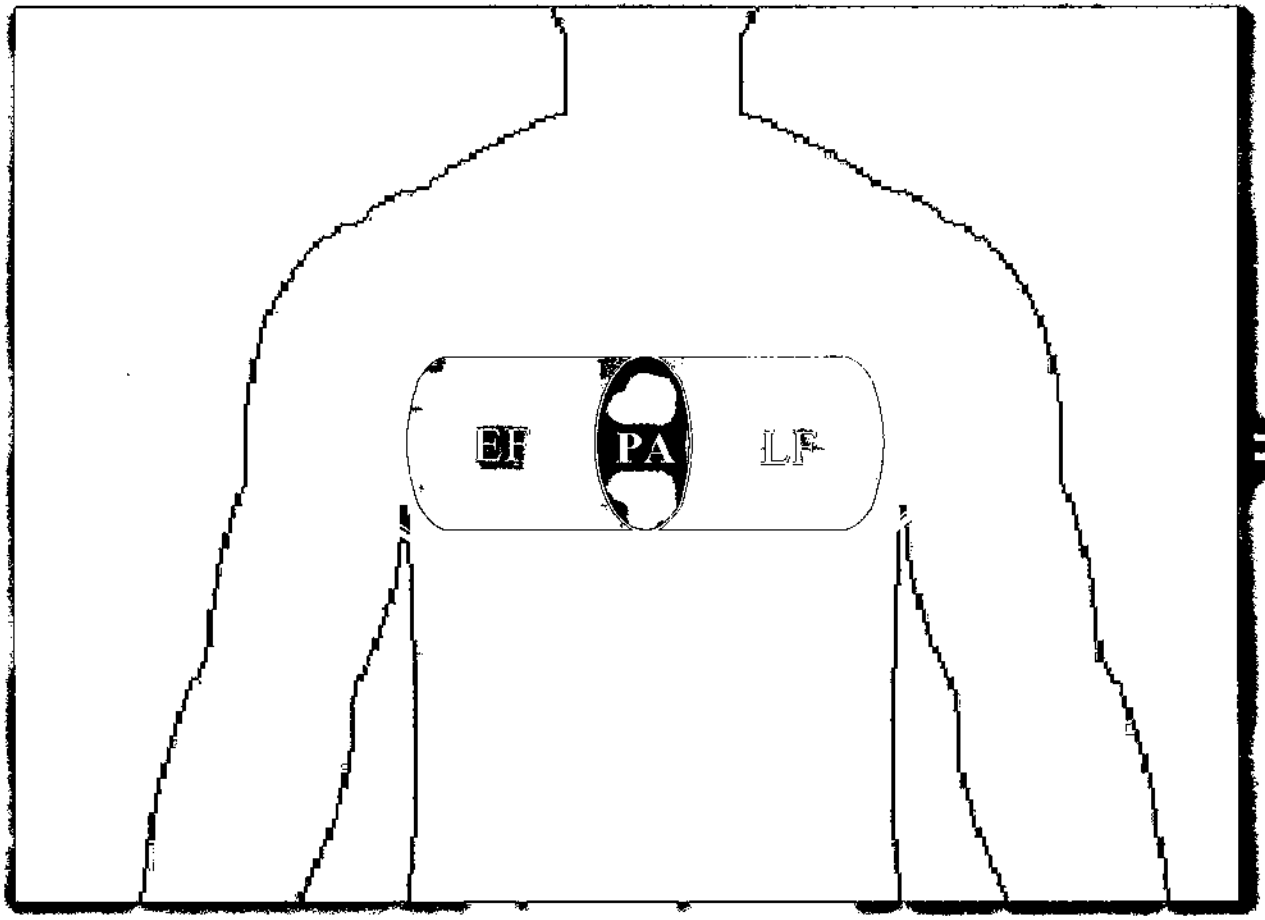

Oil Well Fire Smoke Plume Frequency Distribution
March 1991
Iraq
Oil well fire data not shown above here
Notes: Unit locations provided by the US Armed Services Center for Unit Record Research. Oil well fire data provided by the National Oceanic and Atmospheric Administration.
15 March Unit Locations
Army Unit Locations from VA
Navy Unit Locations from VA
Air Force Unit Locations from VA
All Other Unit Locations
Khamisiyah
As Salman
Al Basrah
Al Bussayyah
Rafha
Kuwait
Kuwait City
Hafir Al Batin
Persian Gulf
Iran
Saudi Arabia
Al Jubayl
Ad Dammam
Number of Days Plume Occurred at a Location
> 21
15 - 21
8 - 14
1 - 7
0
N
USACHPPM
0 50 100 150 Miles
0 100 200 km


Day 1
10 March 1991 Modeled Exposure
Khamisiyah Pit Demolition
Euphrates River
Khamisiyah
50 Km
First Noticeable Effects Area
Low Level Exposure Area
Iraq
Iran
Saudi Arabia
Kuwait
Al Basrah
Kuwait City
Hafir Al Batin
Persian Gulf
Legend:
Unit Location
N
23 July 1997
0 50 100 150 200 Km
0 25 50 100 150 Miles


Day 3
12 March 1991 Modeled Exposure
Khamisiyah Pit Demolition
Euphrates
50 Km
River
Low Level
Exposure Area
Iran
Al
Basrah
Khamisiyah
Iraq
Saudi Arabia
Kuwait
City
Hafir
Al Batin
Kuwait
Persian
Gulf
Legend:
Unit Location
N
28 July 1997
0 50 100 150 200 Km
0 25 50 100 150 Miles


Day 4
13 March 1991 Modeled Exposure
Khamisiyah Pit Demolition
Khamisiyah
Euphrates
50 Km
River
Low Level
Exposure Area
Iran
Al
Basrah
Khamisiyah
Iraq
Saudi Arabia
Kuwait
City
Hafir
Al Batin
Kuwait
Persian
Gulf
Legend:
Unit Location
N
23 July 1997
0 50 100 150 200 Km
0 25 50 100 150 Miles

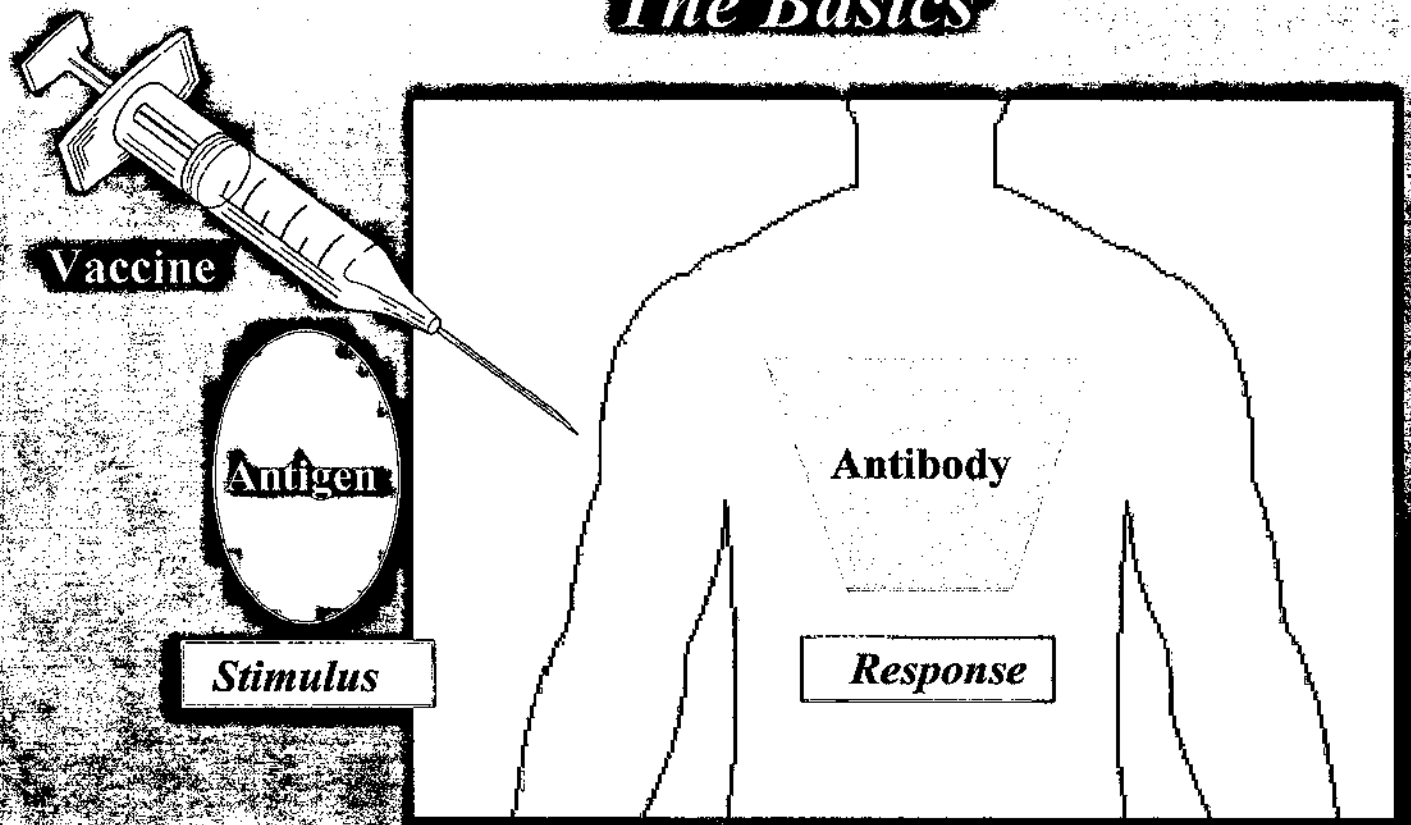
ANTHRAX BACTERIA ATTACK



= Death

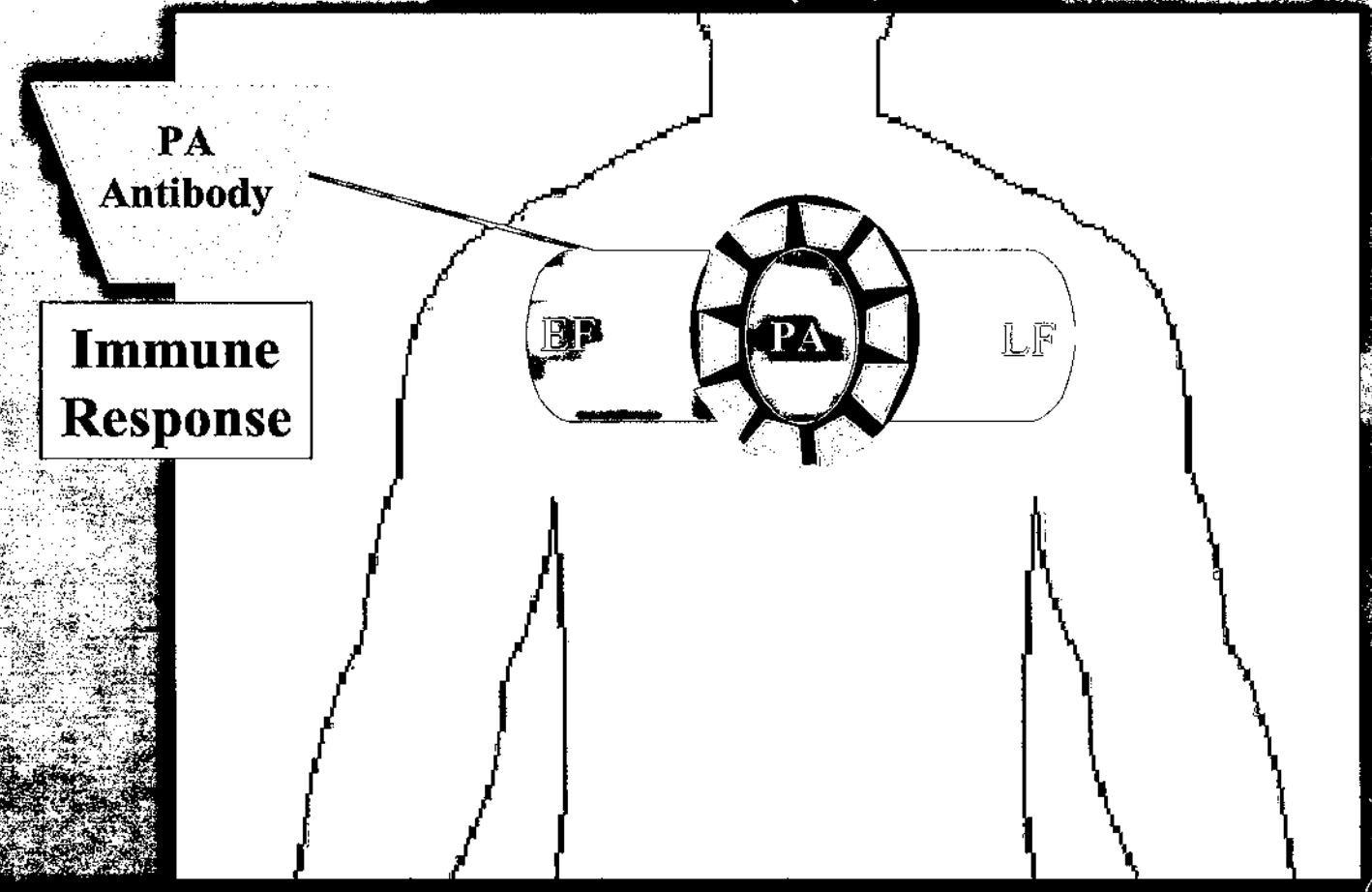
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



AFTER ANTHRAX VACCINE

Antibodies at Work



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1-877-GET-VACC
DSN: 761-5101
www.anthrax.osd.mil
www.aviationmedicine.com

(208)

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

NOV 2 0 2001

Mr. Kirt P. Love
The Desert Storm Battle Registry
P.O. Box 77381
Washington, D.C. 20013-7381

Dear Mr. Love:

This is in response to your November 3, 2001, e-mail note in which you provided comments on several topics and requested a public meeting with our organization on the anthrax vaccine program and the American military NBC mask.

We read your comments on our article and other topics with interest. We disagree with your statement that the Department of Defense is providing our servicemembers with substandard equipment. The new mask is being developed based on the biological and chemical threats we face today. Those closest to the program believe it will provide our soldiers the best chance of survival on the "dirty" battlefields of tomorrow.

Your claim that the Department of Defense does not recommend the anthrax vaccine for the general public is in error. Medical experts in the military and at the Centers for Disease Control and Prevention continue to support the anthrax vaccine as both safe and effective. It is the preferred method of defense against all anthrax exposures and provides the only safe and proven protection prior to exposure. It also provides, in combination with antibiotics, the most effective treatment for those who have already been exposed to anthrax spores. It is also a known fact that the current stock of vaccine, which is insufficient to support a wide-scale vaccination program for the general public, has been reserved for the military. The vaccine could not possibly be made available to the general public until full-scale production begins again.

We recommend you contact staff members at the Anthrax Vaccine Information Program about your concerns on the anthrax vaccine. They are the lead agency on this issue and can be reached at (800) 438-8222. However, I will be glad to meet with you at a time that is convenient to both of us to discuss your concerns and then will pass them on to the appropriate agency for consideration. Please call me to schedule the date and time.

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs

D R A F T

A Review of the Scientific Literature as It Pertains to Gulf War Illnesses, Volume III: Immunizations

Beatrice Alexandra Golomb

MR-1017/3-OSD

October 30, 2001

Prepared for the Office of the Secretary of Defense

National Defense Research Institute

Office of the Special Assistant to the Deputy Secretary of Defense

for Gulf War Illnesses

(800) 754-2132 fax 703-578-8501

email: brostker@gwillness.osd.mil

016

Pentagon Mobilizes: Special Assistant for Gulf War Illnesses

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members

Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Why Should I Care?

- Lessons from the Gulf War about dirty battlefields.
- You must protect yourself against hazards.
- You will be working with or leading Gulf War vets.
- You will probably deploy overseas.
- You are responsible for force protection.

Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,186 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

U.S. Deaths

Battle deaths	148
Non-battle deaths	224
Hospitalizations	Over 27,000

Post War

Shortly after re-deployment, many individuals in a few units reported common symptoms

- Aching joints
- Headaches
- Rashes
- Sleep disorders
- Diarrhea
- Hair loss
- Memory loss
- Fatigue

Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"

"It's all in your head!"

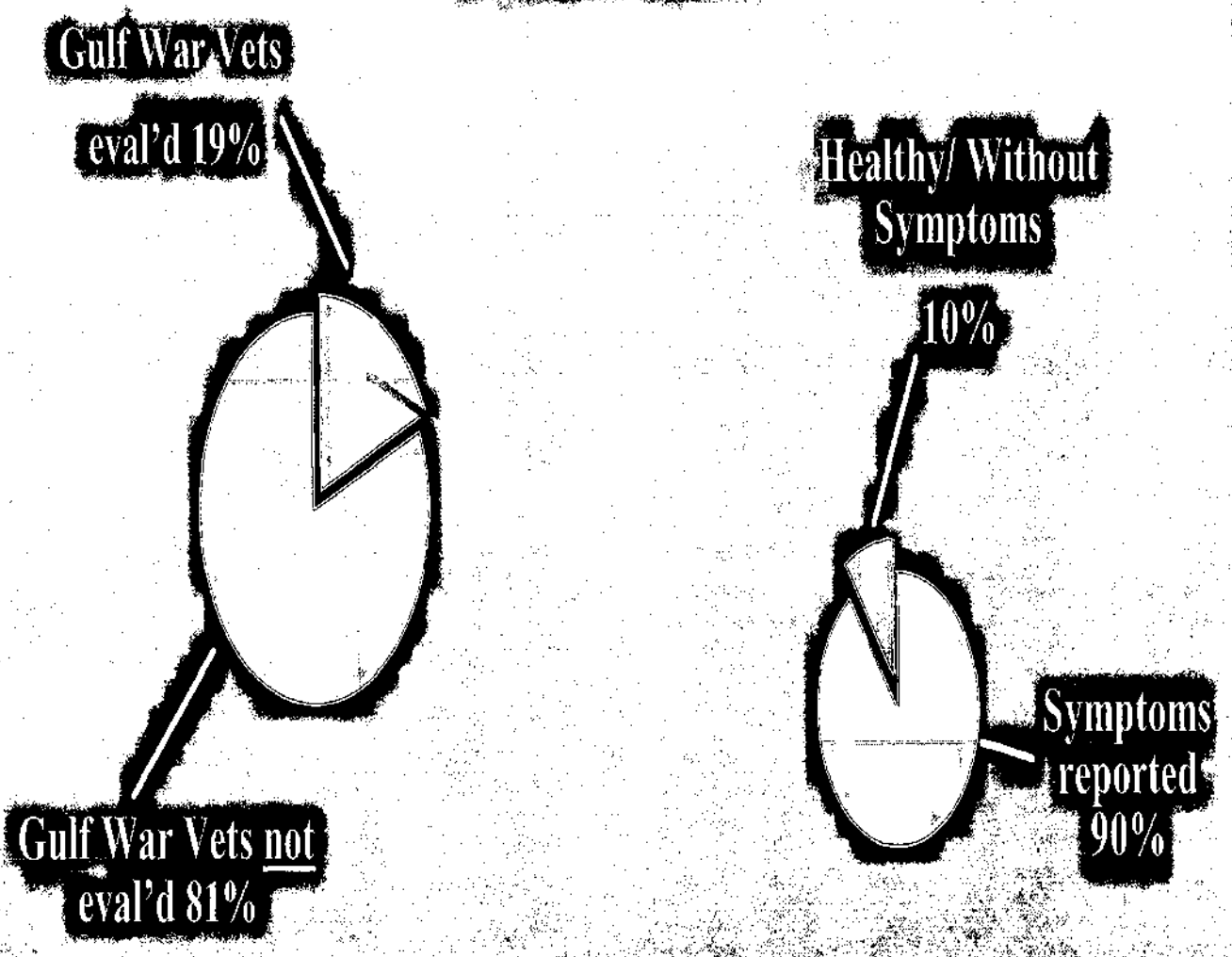
"You're faking these symptoms!"

Confounding Issues

- No clustering
- No symptom consistency
- Variable onset
- No longitudinal evaluation
- As yet - no new disease or links between exposures and symptoms

Evaluation Distribution of 697,000

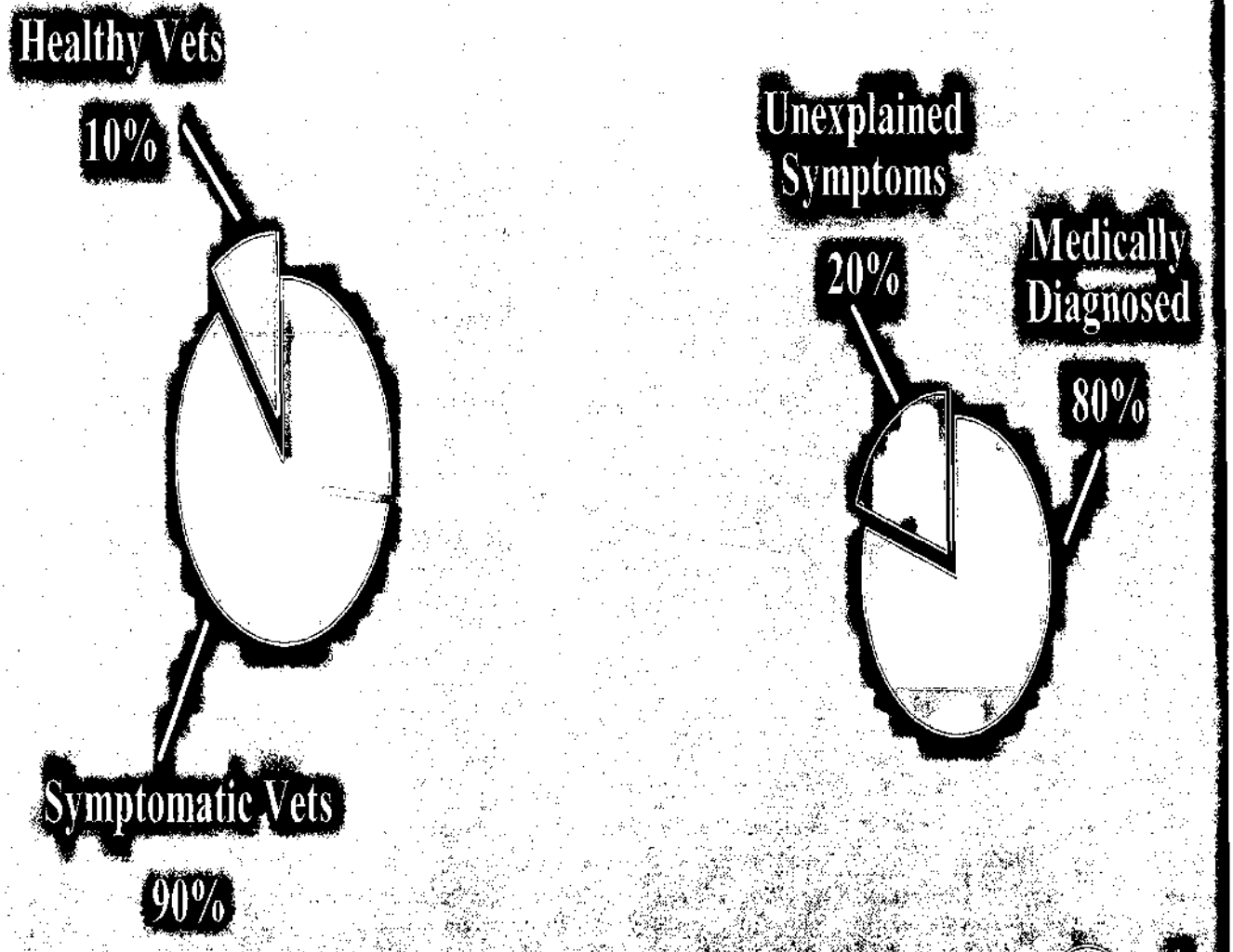
CCEP/VA



Office of the Special Assistant for Gulf War Illnesses

Diagnosis Distribution of Evaluated Veterans

CCEP/VA



Office of the Special Assistant for Gulf War Illnesses

Diagnosis Distribution

116,655 participants	CCEP/VA*
Healthy	10% - 11,665
Symptomatic (Sick)	90% - 104,990
Medically explained and treatable	80% - 93,324
Medically unexplained	20% - 23,331

As of Dec 99

*Comprehensive Clinical Evaluation Program (CCEP) and Dept. of Veteran's Affairs Registry, programs to provide health care to soldiers and veterans.

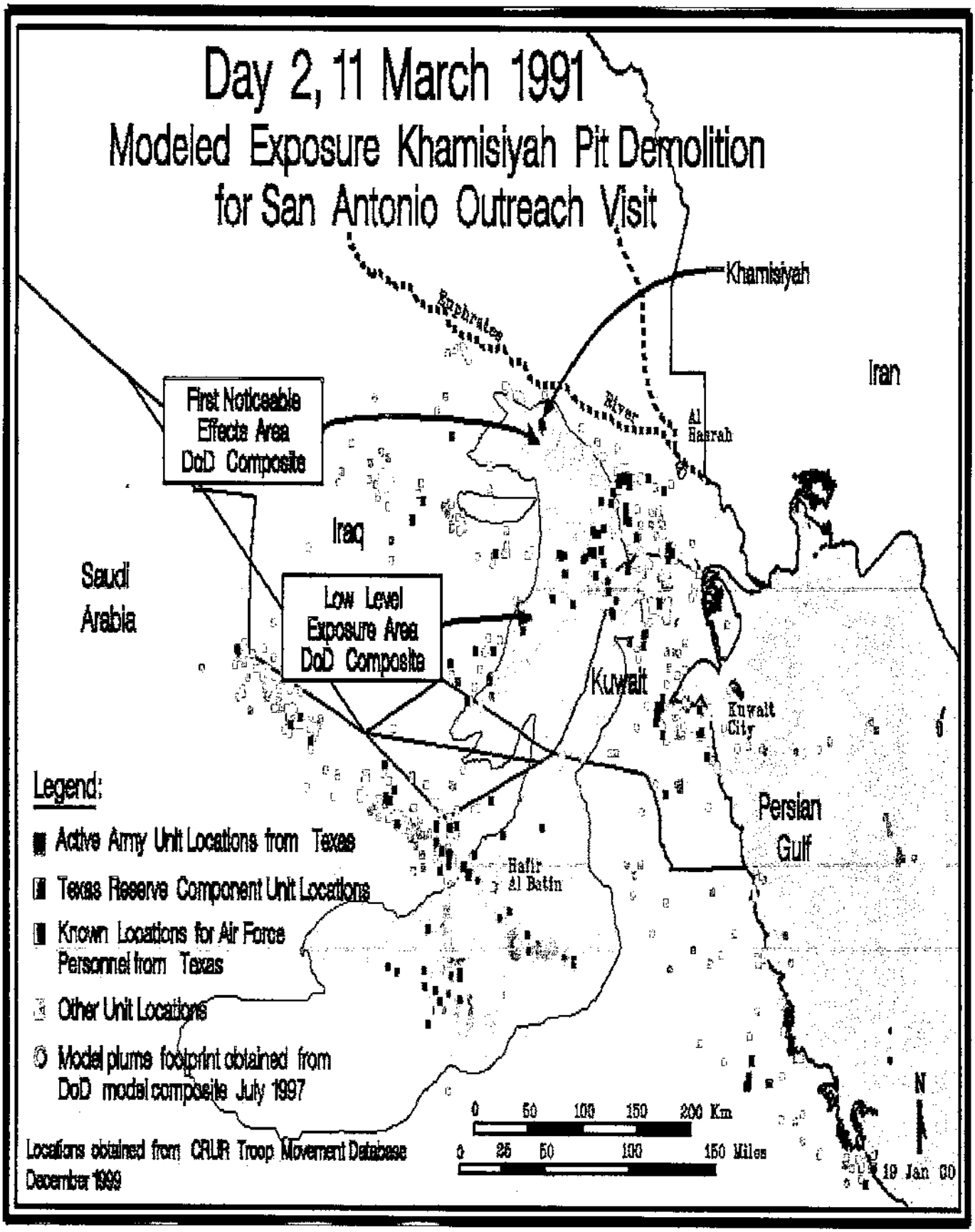
Looking for Causes

The Dirty Battlefield

- What Iraq may have done to us.
  - Oil Well Fires, Stress
- What the environment may have done to us.
  - Sand; Infectious diseases, bad food and water
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide, Low levels of CW agent, DU
- Challenges in the future range from low-tech pariah states to the revolution in military affairs.

OSAGWI Investigations

- Chemical/biological warfare:
  - Focus in 1997; 16 papers
  - Watershed is Khamisiyah
- Environmental:
  - Focus in 1998
  - Oil well fires, pesticides, depleted uranium (DU)


Day 2, 11 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for San Antonio Outreach Visit
Khamisiyah
Euphrates
River
Iran
Al
Hamrah
First Noticeable
Effects Area
DoD Composite
Iraq
Saudi
Arabia
Low Level
Exposure Area
DoD Composite
Kuwait
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N
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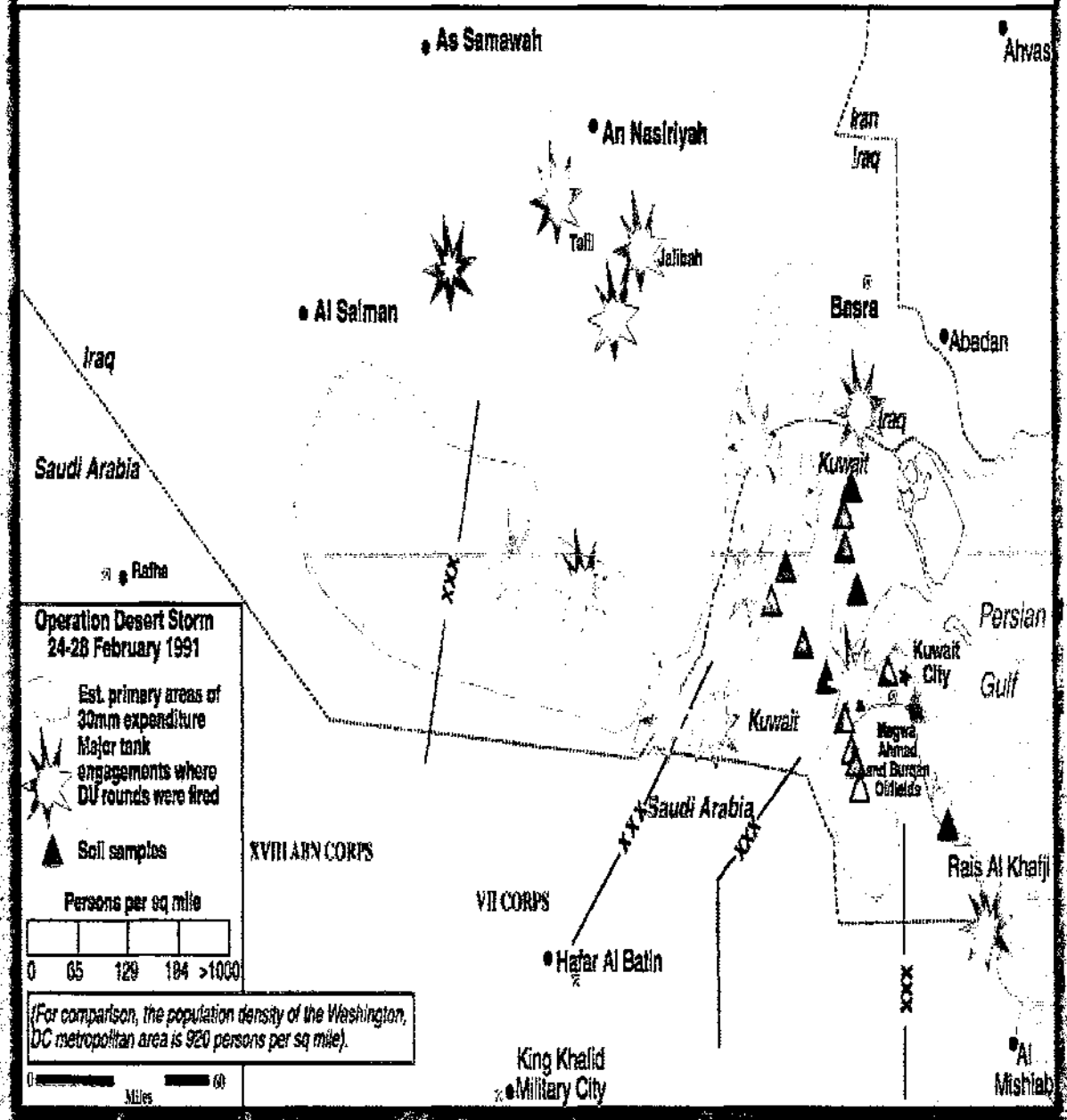
Primary Areas of DU Expenditure



Investigator's Message Sent

"The symptoms described were not consistent with symptoms associated with exposure to chemical warfare agents or depleted uranium."

Veteran's Messages Received

"You're wrong!"

"You can't possibly be sick because of this!"

DU Exposure Issues

- Radiation
- Heavy metal toxicity
- Consequences of exposure
- Reproductive effect
- Contamination of theater

DU Awareness Training

- Current CTT Task (031-503-1017)
- Better information is now available
  - Chemical toxicity vice radioactivity
  - Continue the mission
  - Respiratory protection for extended exposure
- Training support packages being updated
  - Includes updating the common task & GTA
  - Additional training for specialists
- Use existing training management system

OSAGWI Investigations

- Medical issues and lessons learned:
  - Focus in 1999
    - Vaccines, PB, records, policy
    - DU training
    - Managing hazards

Proactive Measures - You

- Recognize and contend with potential hazards:
  - Improve intel notification
  - Train all personnel
  - Reduce adverse effects of and stress from potential exposures
  - Understand the environment and culture before deploying
- Improve feedback and cross talk

Operational Lessons - Your Unit

- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Relate CW to operational and medical records
- Adapt for the future
  - Retain individual unit locations and records
  - DU training
  - Improved medical surveillance
  - Force health protection

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

Anthrax Vaccine

- What is Anthrax?
- Vaccine is safe and necessary
  - FDA Licensed in 1970
  - Used for many years to protect textile mill workers
  - Recommended by Centers for Disease Control (CDC):
    - Workers occupationally exposed to anthrax (labs, mills)
    - Treatment of anyone exposed to anthrax aerosols
    - Only known pretreatment and protection against exposure

Immunizations

- Anthrax Vaccination program
  - Vaccine is FDA licensed since 1970 and proven safe
  - Only known protection against exposure
  - Necessary because of real threat
    - Easily produced and weaponized
- Current program statistics
  - Vaccine series 0, 2, 4 weeks; then 6, 12, 18 months; annual booster
  - 1,370,914 doses provided to 387,067 people (22 Dec 99)
    - 65 reactions resulted in loss of duty for less than 24 hrs.
    - 6 reactions resulted in hospitalization
      - All six were allergic, inflammation reactions

Anthrax information -- www.anthrax.osd.mil

1-800-GET-VACC

Obtaining help and information

- Comprehensive Clinical Evaluation program (CCEP) 1-800-796-9699
- Veterans Affair Persian Gulf registry program 1-800-749-8387
- Hotline for OSAGWI 1-800-497-6261

http://www.gulflink.osd.mil

Outreach team

- Town Hall
  - 1900, Thursday, Feb. 4, Blesse Auditorium, Willis Hall, Fort Sam Houston
- Displays
  - Fort Sam Houston P.X., BAMC, Wilford Hall
- Contact managers

Bottom Line

- Gulf War Veterans key for our work
- You must protect yourself on the Dirty Battlefield
- Anyone deployed to South West Asia is eligible for CCEP
- Don't tough it out - Get signed up and evaluated
- You are your best health advocate
- Apply these lessons learned

Office of the Special Assistant for Gulf War Illnesses

CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Direct Hotline for GWV	800-497-6261

www.gulflink.osd.mil

Back-up Slides

Identifying Possible Causes

- Normal disease rate
- Linking hazards and illnesses
  - Research
  - New disease paradigm

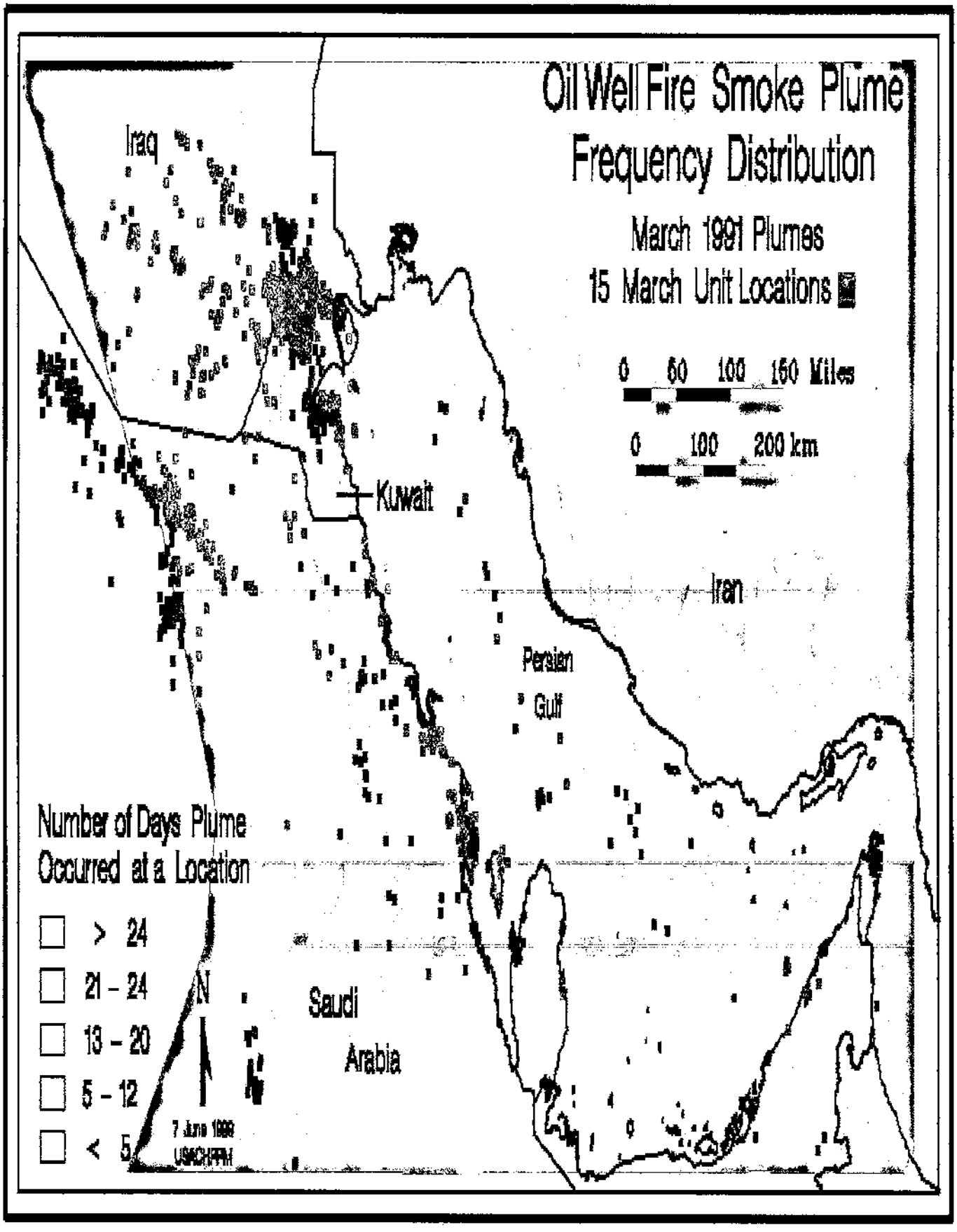
Symptoms

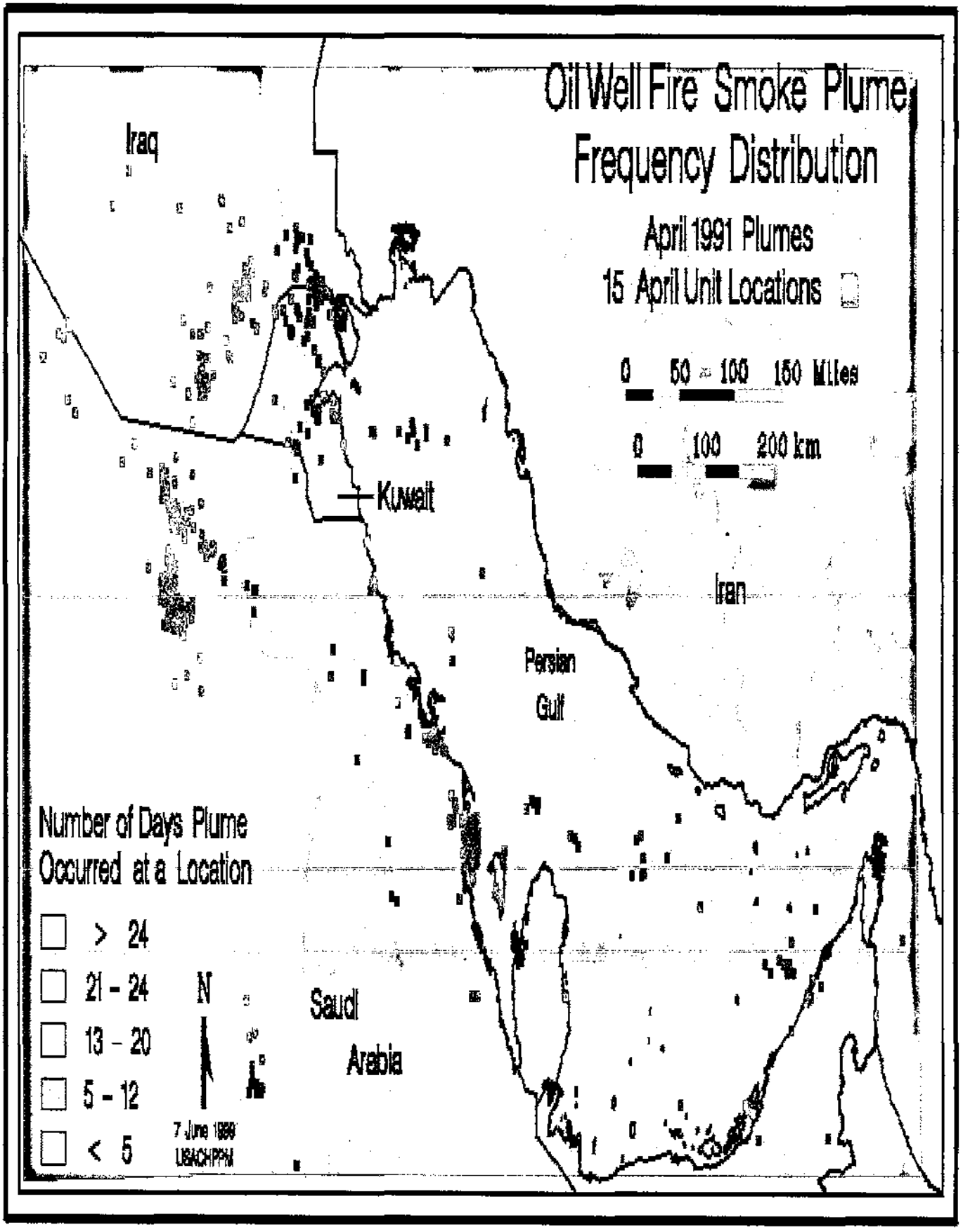
- Tiredness
- Rashes
- Headaches
- Muscle aches
- Joint pains
- Abdominal pain
- Diarrhea
- Hair loss
- Memory loss
- Sleep disturbance
- Depression
- Concentration problems

Hazards

- Chemical warfare agent
- Pesticides
- Vaccines
- Pyridostigmine bromide
- Stress
- Biological warfare agent
- Oil well fires
- Depleted uranium
- Infectious disease
- "Cocktail" effect

30+ offered as possible causes


Oil Well Fire Smoke Plume
Frequency Distribution
March 1991 Plumes
15 March Unit Locations
0 60 100 150 Miles
0 100 200 km
Iraq
Kuwait
Iran
Persian
Gulf
Saudi
Arabia
Number of Days Plume
Occurred at a Location
> 24
21 - 24
13 - 20
5 - 12
< 5
N
7 June 1999
USACHPPM


Oil Well Fire Smoke Plume
Frequency Distribution
April 1991 Plumes
15 April Unit Locations
0 50 100 150 Miles
0 100 200 km
Iraq
Kuwait
Iran
Persian
Gulf
Saudi
Arabia
Number of Days Plume
Occurred at a Location
> 24
21 - 24
13 - 20
5 - 12
< 5
N
7 June 1999
USACHPPM

Medical Training for Line Leaders

- Wellness Requirements = Mission Success
  - Routine examinations, vaccinations
  - Force Health Protection
  - Anthrax Vaccination
- Normal Disease Rates - Garrison or Deployment
  - Diarrhea
  - Sports injuries
  - Cancer, heart attacks, diabetes, etc.

Operational Lessons - You

- Recognize and contend with potential hazards:
  - Improve intel notification.
  - Train all personnel.
  - Reduce adverse effects of and stress from potential exposures.
  - Understand the environment and culture before deploying.
- Improve feedback and cross talk.

Who Served in the Gulf War

697,000 U.S. service members

Army	348,000	50%
Navy	160,000	23%
Marine	105,000	15%
Air Force	84,000	12%

259,000 Coalition Forces

Who Served in the Gulf War

Gender	
Men	93%
Women	7%
Component	
Active	83%
Reserve/National Guard	17%
Community	
Officer	10%
Enlisted	90%

<26 years old - 55%; 26-35 years old - 32%; > 35years old - 13%

Medical Support

Largest emergency health care system since WWII

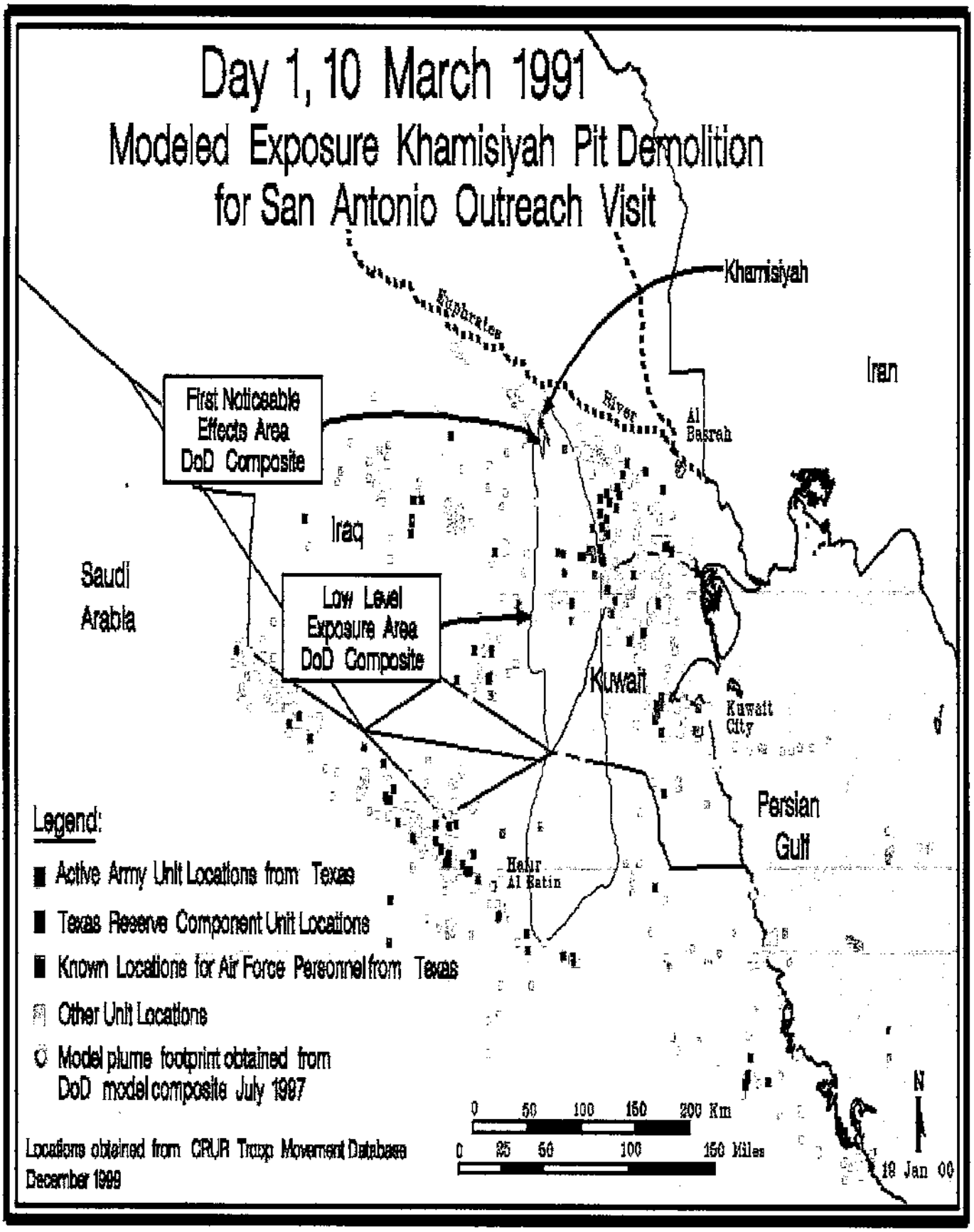
- 41,000 medical personnel
- 18,000 beds
- 2 hospital ships
- 63 combat zone hospitals

Possible Causes

- Normal disease rate
- New disease paradigm
- Research
- Black camel

Future Equipment

- Personal Information Carrier (PIC)
- Biological Integrated Detection System (BIDS)
- Automatic Chemical Agent Alarm (ACADA)
- Medic Cam - Tele medicine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for San Antonio Outreach Visit
Khamisiyah
Euphrates
River
Iran
Al
Basrah
First Noticeable
Effects Area
DoD Composite
Iraq
Saudi
Arabia
Low Level
Exposure Area
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Kuwait
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Legend:
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Texas Reserve Component Unit Locations
Known Locations for Air Force Personnel from Texas
Other Unit Locations
Model plume footprint obtained from
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Locations obtained from CRUR Troop Movement Database
December 1999
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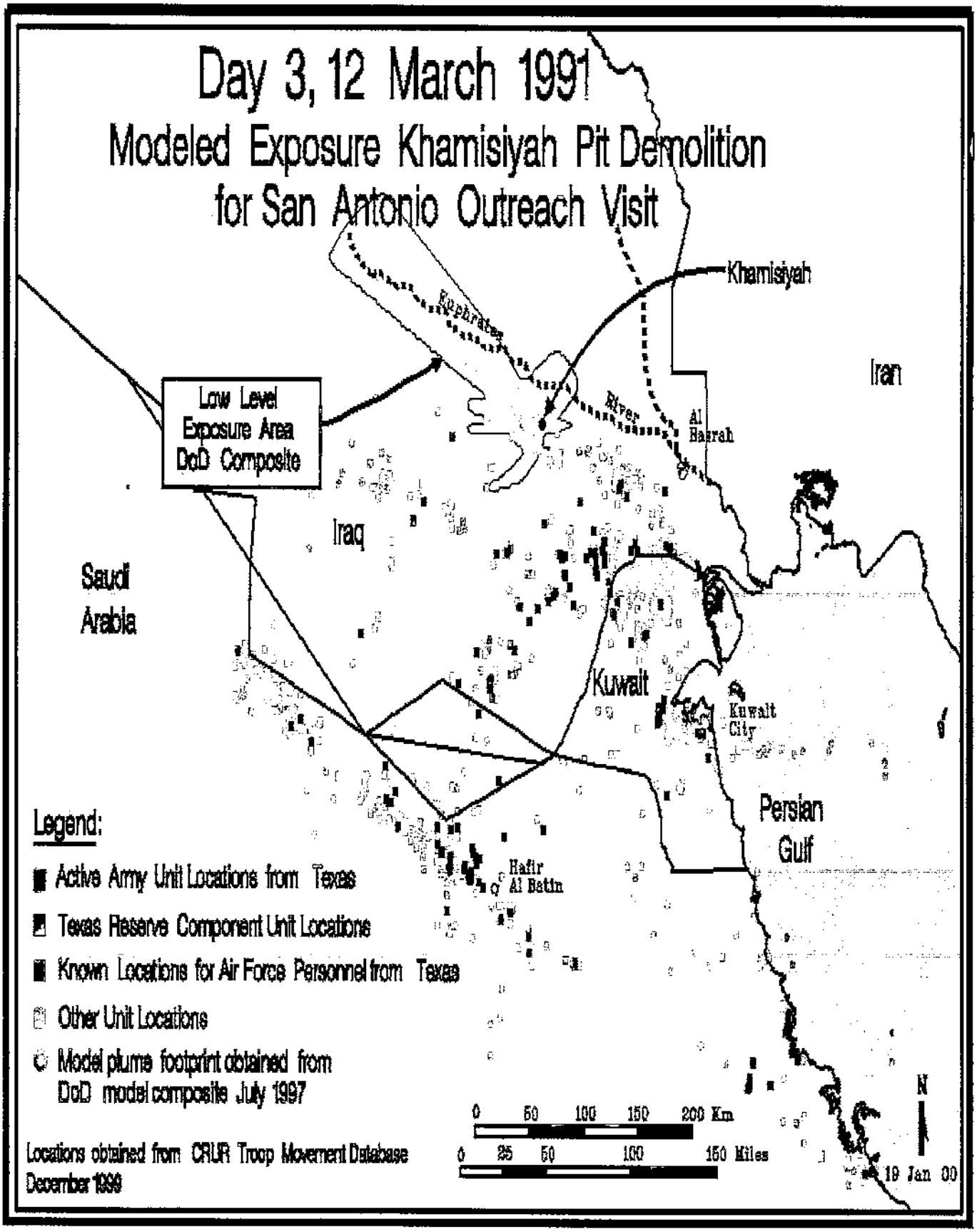
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for San Antonio Outreach Visit
Khamisiyah
Euphrates River
Low Level
Exposure Area
DoD Composite
Iran
Al
Basrah
Iraq
Saudi
Arabia
Kuwait
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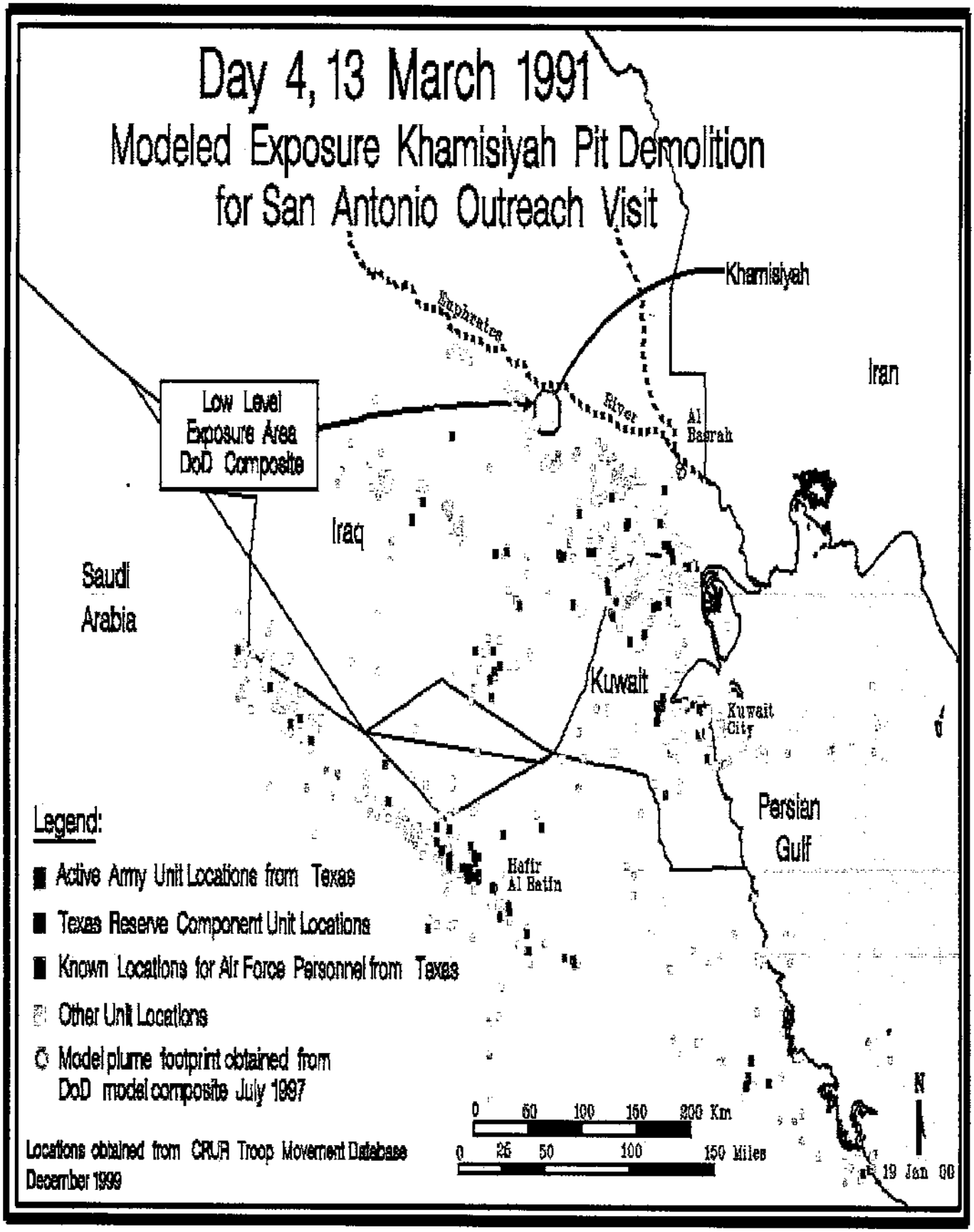
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Khamisiyah
Euphrates
River
Low Level
Exposure Area
DoD Composite
Iran
Al
Basrah
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Summary

- Work continues: "leave no stone unturned"
- We rely on Gulf War veterans:
  - To give us leads
  - To check our accuracy
- We rely on today's force – including you:
  - To ensure GW vets get proper testing and treatment
  - To apply lessons learned to the future

Office of the Special Assistant to the Deputy Secretary of Defense

for Gulf War Illnesses

(800) 754-2132 fax 703-578-8501
email: brostker@gwillness.osd.mil

Briefing Overview

- Organization - Mission Statement
- Why should I care?
- Symptoms and Illnesses
- Looking for causes
- Gulf War Lessons Learned
- Force Health Protection
- Help and information

Special Assistant for Gulf War Illnesses

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members

Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
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Post War

Shortly after re-deployment, many individuals in units reported common symptoms

- Aching joints
- Headaches
- Rashes
- Sleep disorders
- Diarrhea
- Hair loss
- Memory loss
- Fatigue

Physician Message Sent

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The Dirty Battlefield

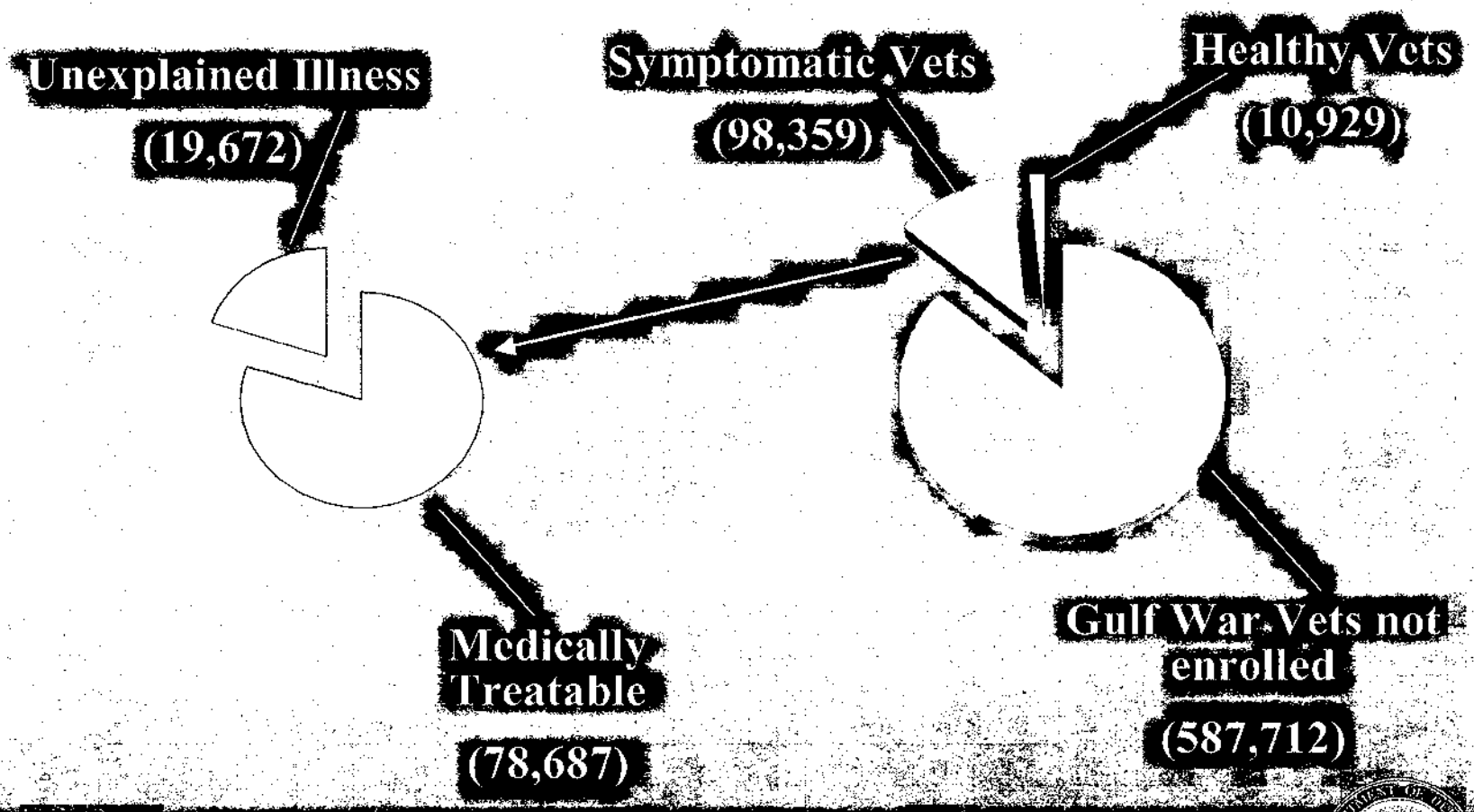
- What Iraq may have done to us.
  - Oil Well Fires
- What the environment may have done to us.
  - Sand, Infectious diseases
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide
- Challenges in the future from low-tech pariah states to the revolution in military affairs.

OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
- Medical issues and lessons learned:
  - Vaccines, PB, records, policy
    - "Cocktail" effect

Diagnosis Distribution/697,000 Deployed

CCEP/VA Participants



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- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Improve operational and medical records handling
- Adapt for the future
  - Retain individual unit locations and records
  - DU training
  - Improved medical surveillance
  - Force health protection

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Pre-deployment serum sample
- Verify HIV test in last 12 months
- Immunizations
- Verify current physical exam
- Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect serum sample
- Medical debriefs
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Future Equipment

- Personal Information Carrier (PIC)
- Biological Integrated Detection System (BIDS)
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Anthrax Vaccine

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  - Used for many years to protect textile mill workers
  - Recommended by Centers for Disease Control (CDC):
    - Workers occupationally exposed to anthrax (labs, mills)
    - Treatment of anyone exposed to anthrax aerosols
    - Only known pretreatment and protection against exposure

Anthrax Vaccine

- DoD Policy - mandatory for total force
  - Phased implementation
- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea (8/99)
- Phase III - Total force (early 2000's)
- Vaccine series:
  - 0, 2, 4 weeks; then 6, 12, 18 months; annual booster
  - 754,863 doses, 49 adverse reactions=0.006%
    - 23 systemic reactions, 26 local reactions

- DoD anthrax web site: www.defenselink.mil/specials/Anthrax

Obtaining help and information

- Comprehensive Clinical Evaluation Program (CCEP)
  - 1-800-796-9699
- Veterans Affair registry program
  - 1-800-749-8387
- Town Hall
  - Thursday, May 13th at the Woodruff Theater
- Displays
  - P.X. and Winn Army Community Hospital
- Contact managers

Bottom Line

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- You must protect yourself on the Dirty Battlefield
- Anyone deployed to South West Asia is eligible for CCEP
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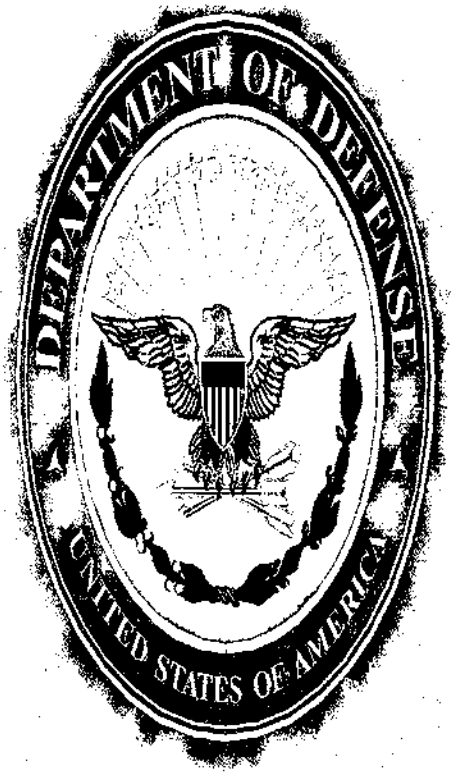
Office of the Special Assistant for Gulf War Illnesses

CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-472-6719

www.gulflink.osd.mil

Office of the Special Assistant to the Deputy Secretary of Defense



for Gulf War Illnesses

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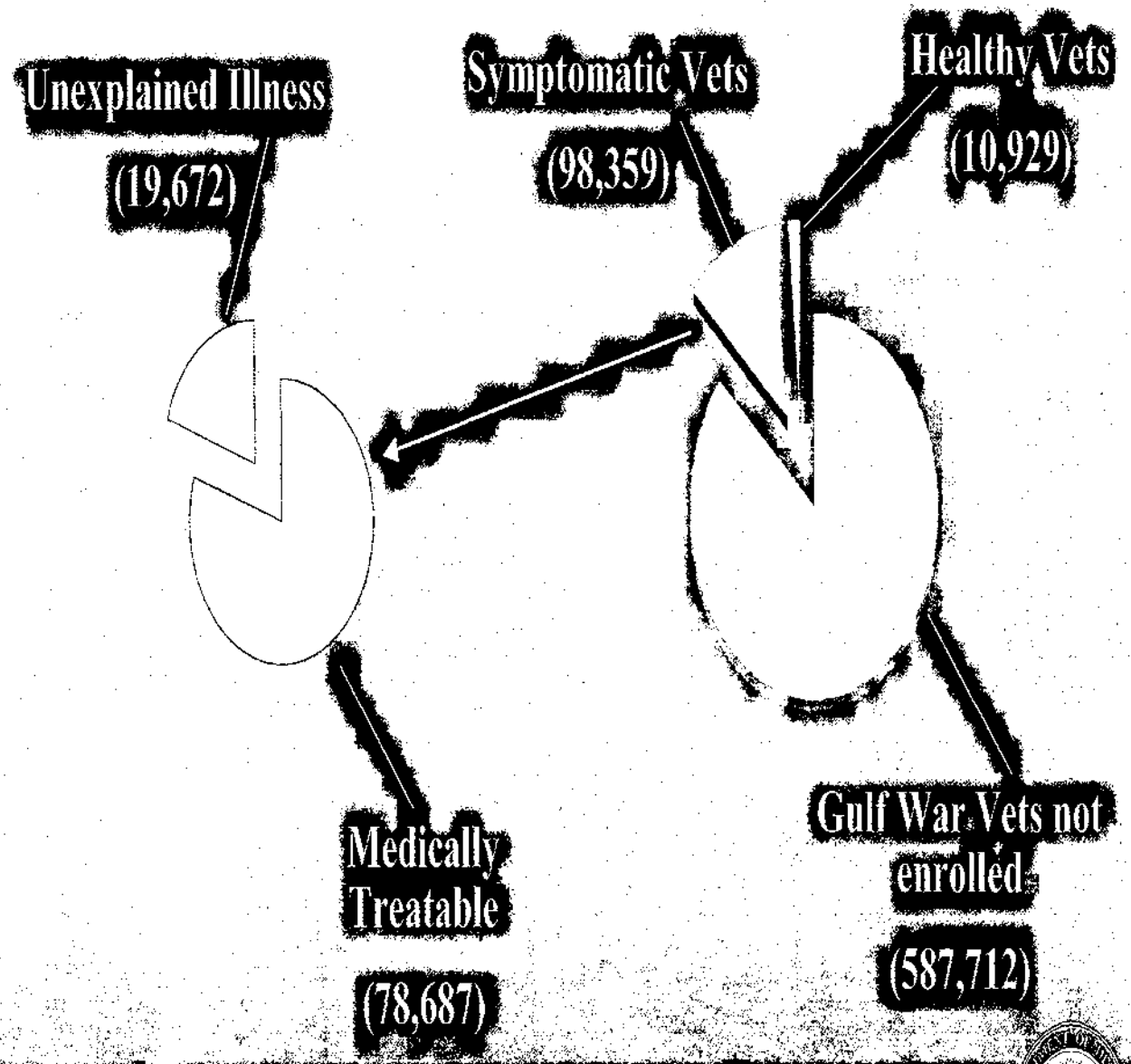

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Back Up Slides

Briefing

- Organization - Mission Statement
- Why should I care?
- Symptoms and Illnesses
- Looking for causes
- Gulf War Lessons Learned
- Force Health Protection
- Help and information

Special Assistant for Gulf War Illnesses

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
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- Lessons from the Gulf War about dirty battlefields.
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U.S. Deaths

Battle deaths	148
Non-battle deaths	224
Hospitalizations	27,000

Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"

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Symptoms

- Tiredness
- Rashes
- Headaches
- Muscle aches
- Joint pains
- Abdominal pain
- Diarrhea
- Hair loss
- Memory loss
- Sleep disturbance
- Depression
- Concentration problems

DU Exposure Issues

- Radiation
- Heavy metal toxicity
- Consequences of exposure
- Reproductive effect
- Contamination of theater

Proactive Measures - You

- Recognize and contend with potential hazards:
  - Improve intel notification.
  - Train all personnel.
  - Reduce adverse effects of and stress from potential exposures.
  - Understand the environment and culture before deploying.
- Improve feedback and cross talk.

Proactive Measures - Your Unit

- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Improve operational and medical records handling
- Adapt for the future
  - Retain individual unit locations and records
  - DU training
  - Improved medical surveillance
  - Force health protection

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Pre-deployment serum sample
- Verify HIV test in last 12 months
- Immunizations
- Verify current physical exam
- Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

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- Collect serum sample
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Future Equipment

- Personal Information Carrier (PIC)
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- Medic Cam - Tele medicine

Bottom Line

- Work continues: "leave no stone unturned"
- You must protect yourself on the Dirty Battlefield
- Anyone deployed to South West Asia is eligible for CCEP
- Don't tough it out - 80% are treated
- You are your best health advocate
- DU = "Silver Bullet" but handle it properly
- Anthrax shots - will protect you and they are safe

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Breting

- Organization Mission Statement
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- Looking for causes
- Gulf War Lessons Learned
- Force Health Protection
- Help and information

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- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
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697,000 U.S. service members

Army	348,000	50%
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Post War

Shortly after re-deployment, many individuals in units reported common symptoms

- Aching joints
- Headaches
- Rashes
- Sleep disorders
- Diarrhea
- Hair loss
- Memory loss
- Fatigue

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Confounding Issues

- No clustering
- No symptom consistency
- Variable onset
- No long term study
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Looking for Causes

The Dirty Battlefield

- What Iraq may have done to us.
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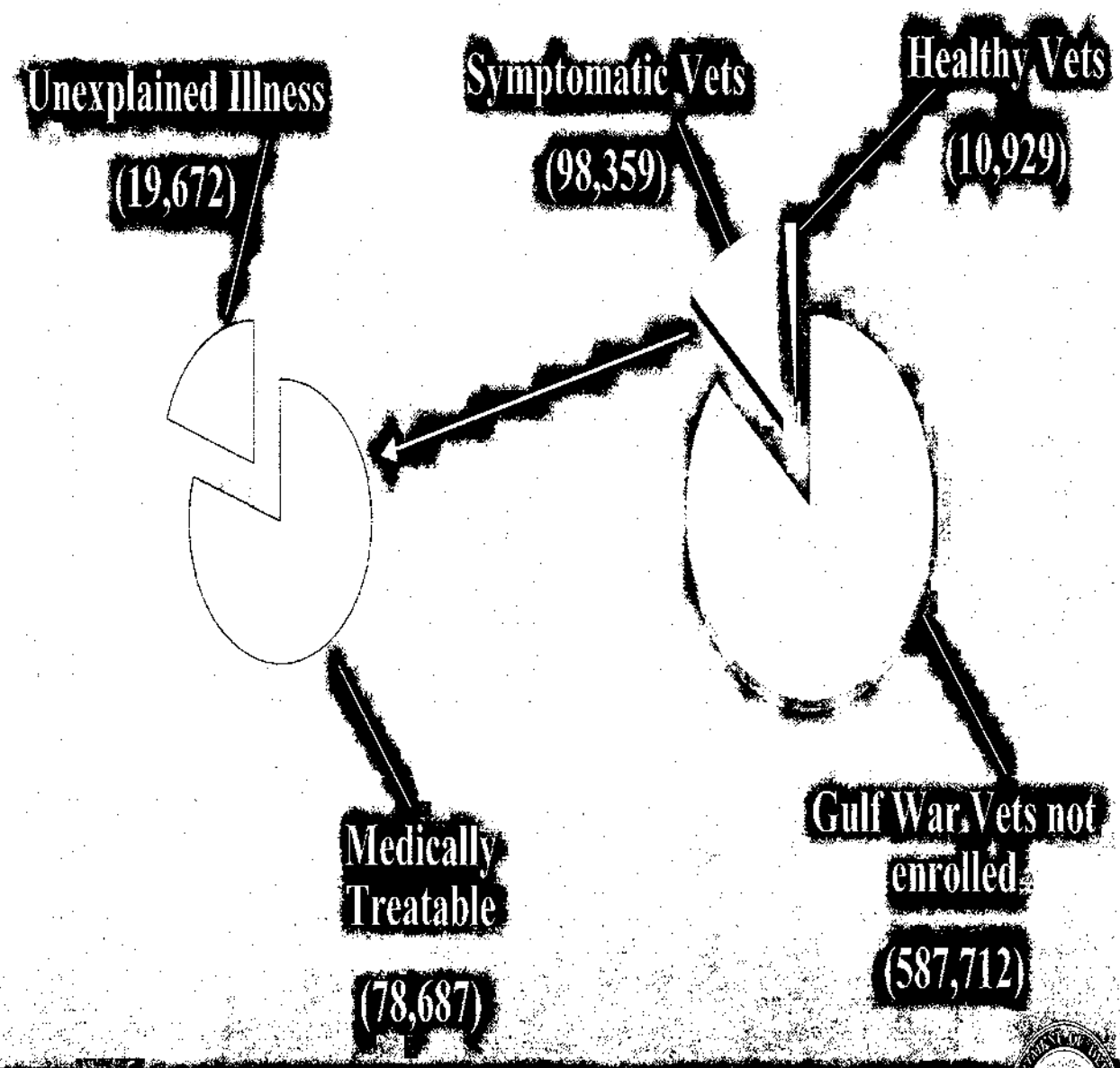
CCEP/VA Participants



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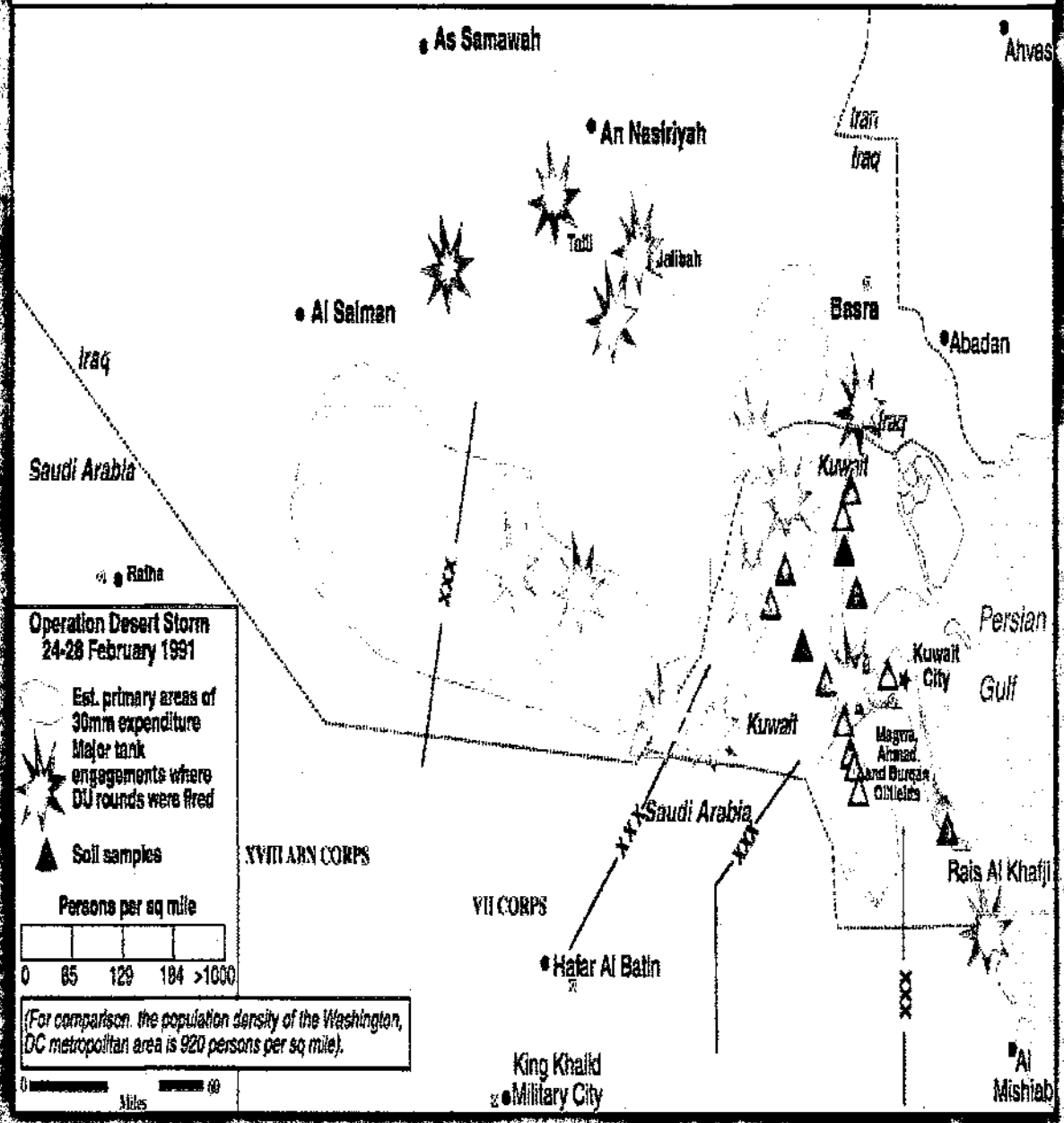

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Special Assistant for Gulf War Illnesses

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- What we may have done to ourselves.
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- Challenges in the future from low-tech pariah states to the revolution in military affairs.

Potential Causes

- Chemical warfare agent
- Biological warfare agent
- Pesticides
- Oil well fires
- Vaccines
- Depleted uranium
- Pyridostigmine bromide
- Infectious disease
- Stress
- "Cocktail" effect

30+ offered as possible causes

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- Chemical/biological warfare:
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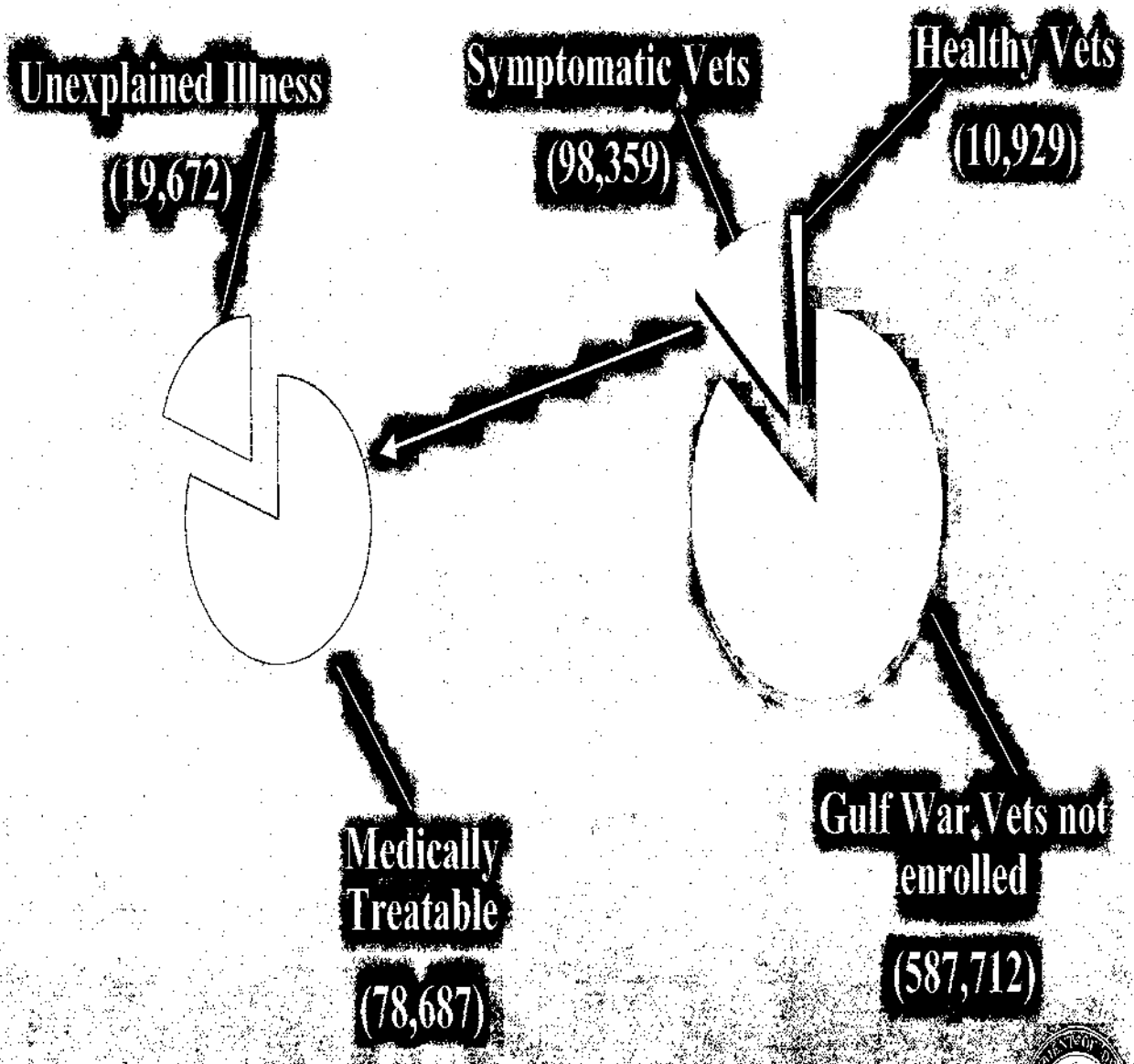

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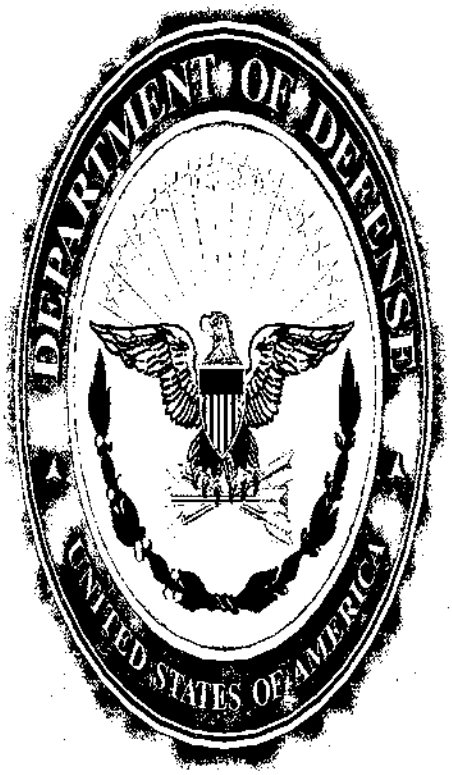

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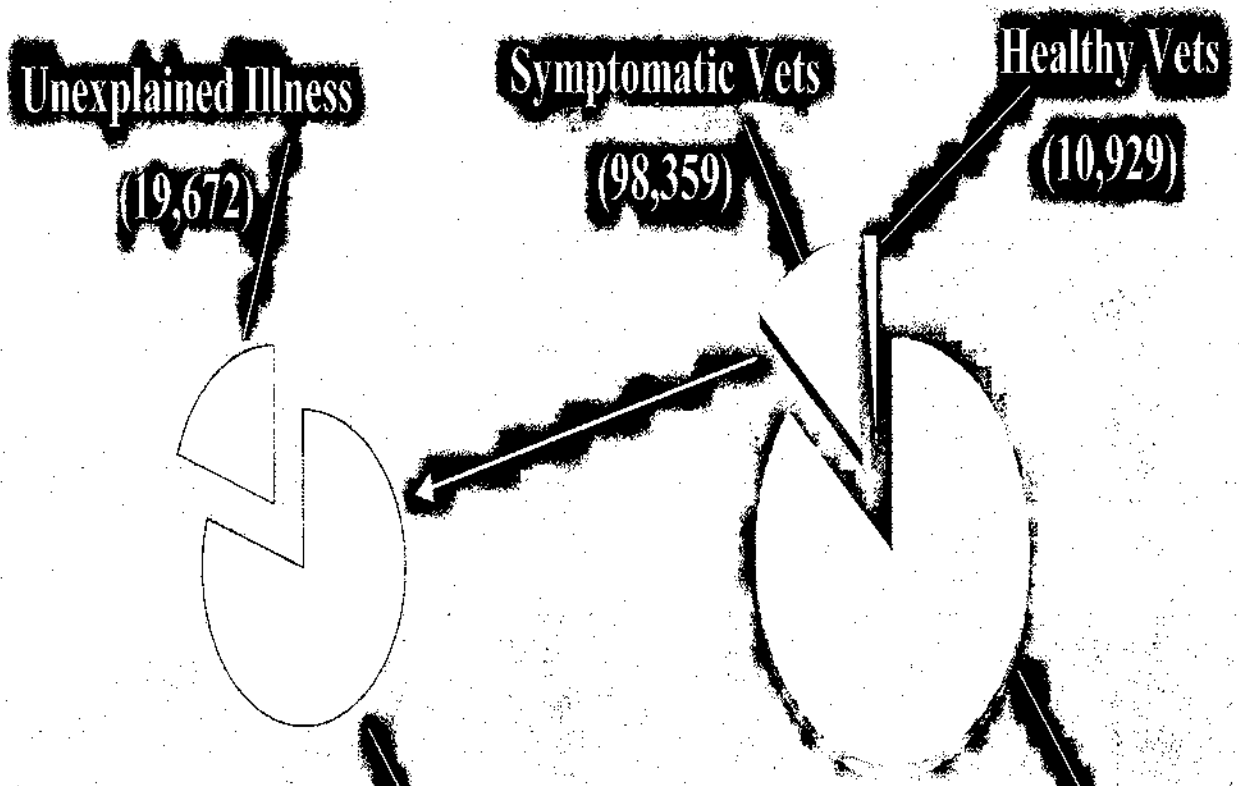

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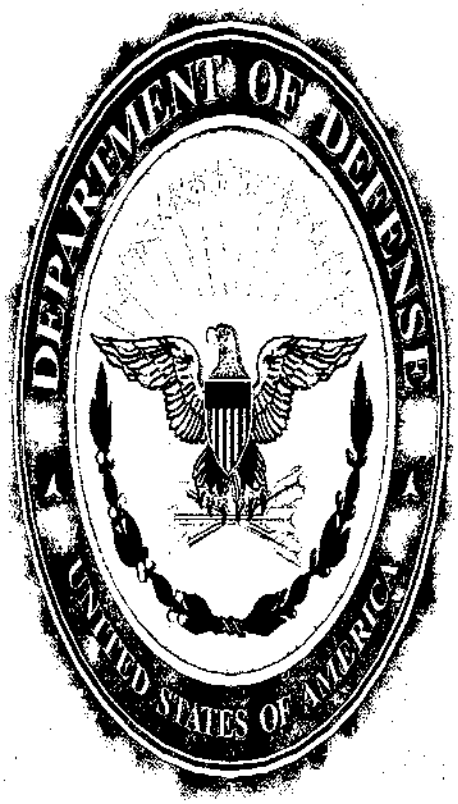

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Pentagon Mobilizes: Special Assistant for Gulf War Illnesses

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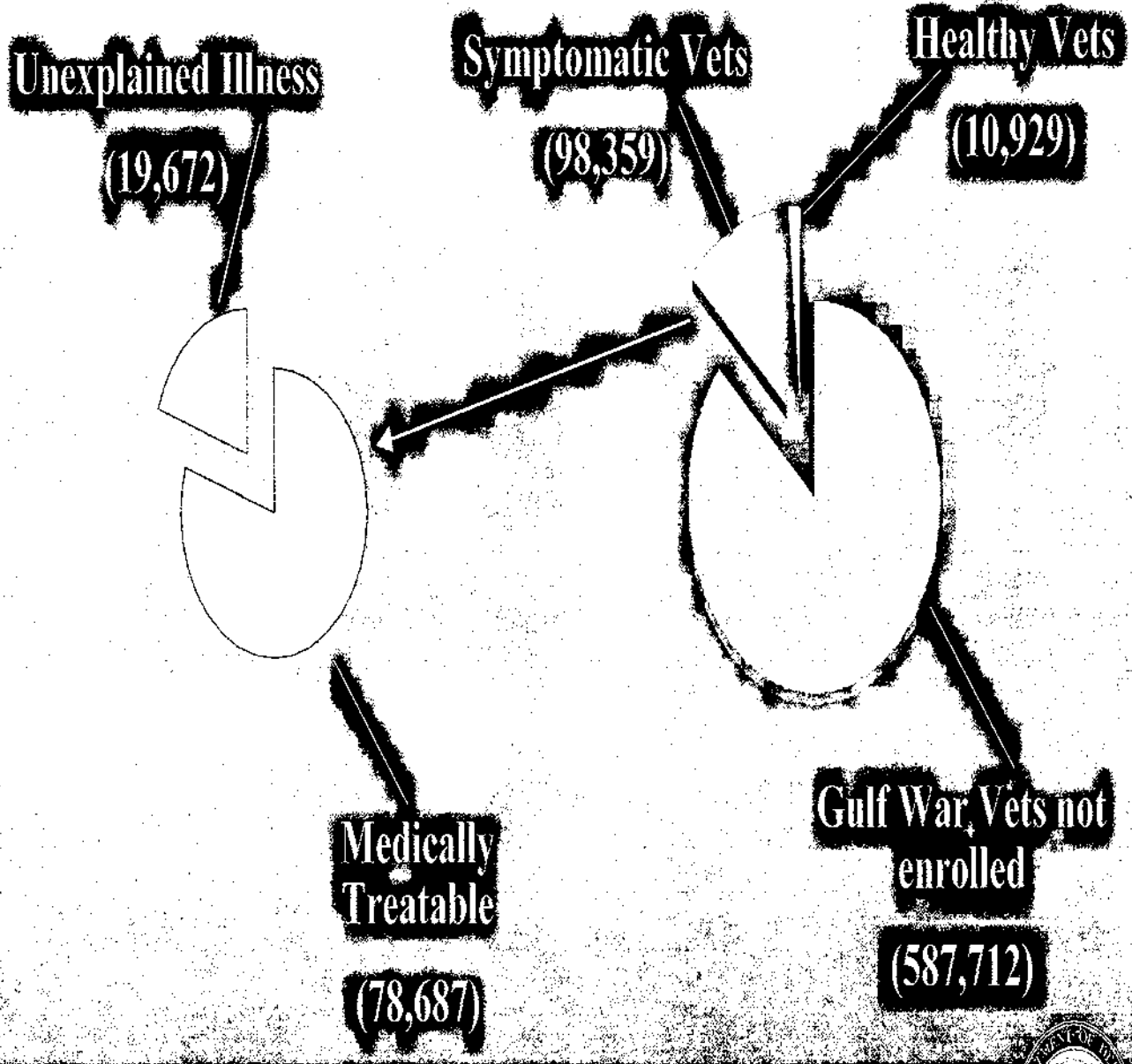

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The Dirty Battlefield

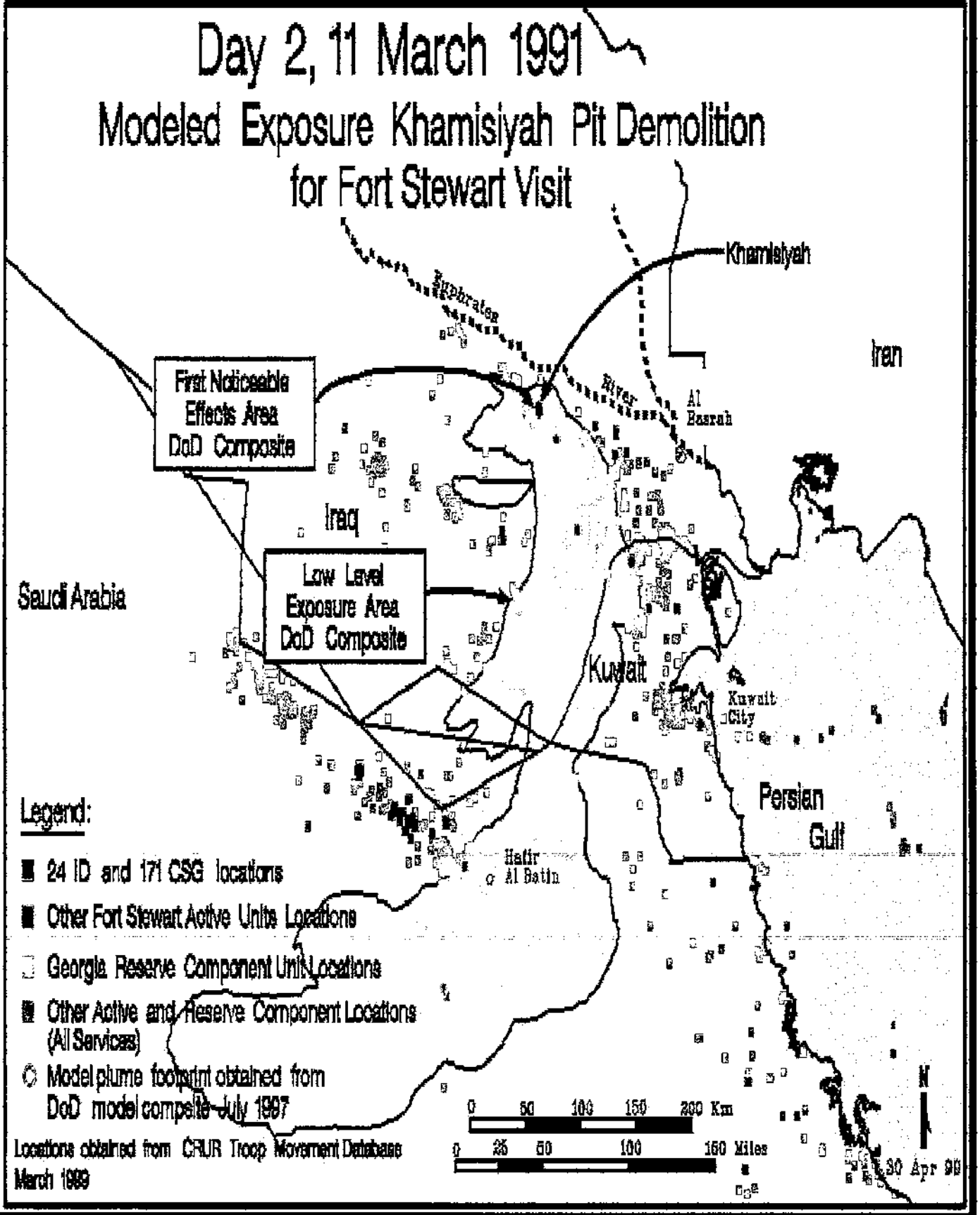
- What Iraq may have done to us.
  - Oil Well Fires, Stress
- What the environment may have done to us.
  - Sand, Infectious diseases, bad food and water
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide, Low levels of CW agent, DU
- Challenges in the future range from low-tech pariah states to the revolution in military affairs.

OSAGWI Investigations

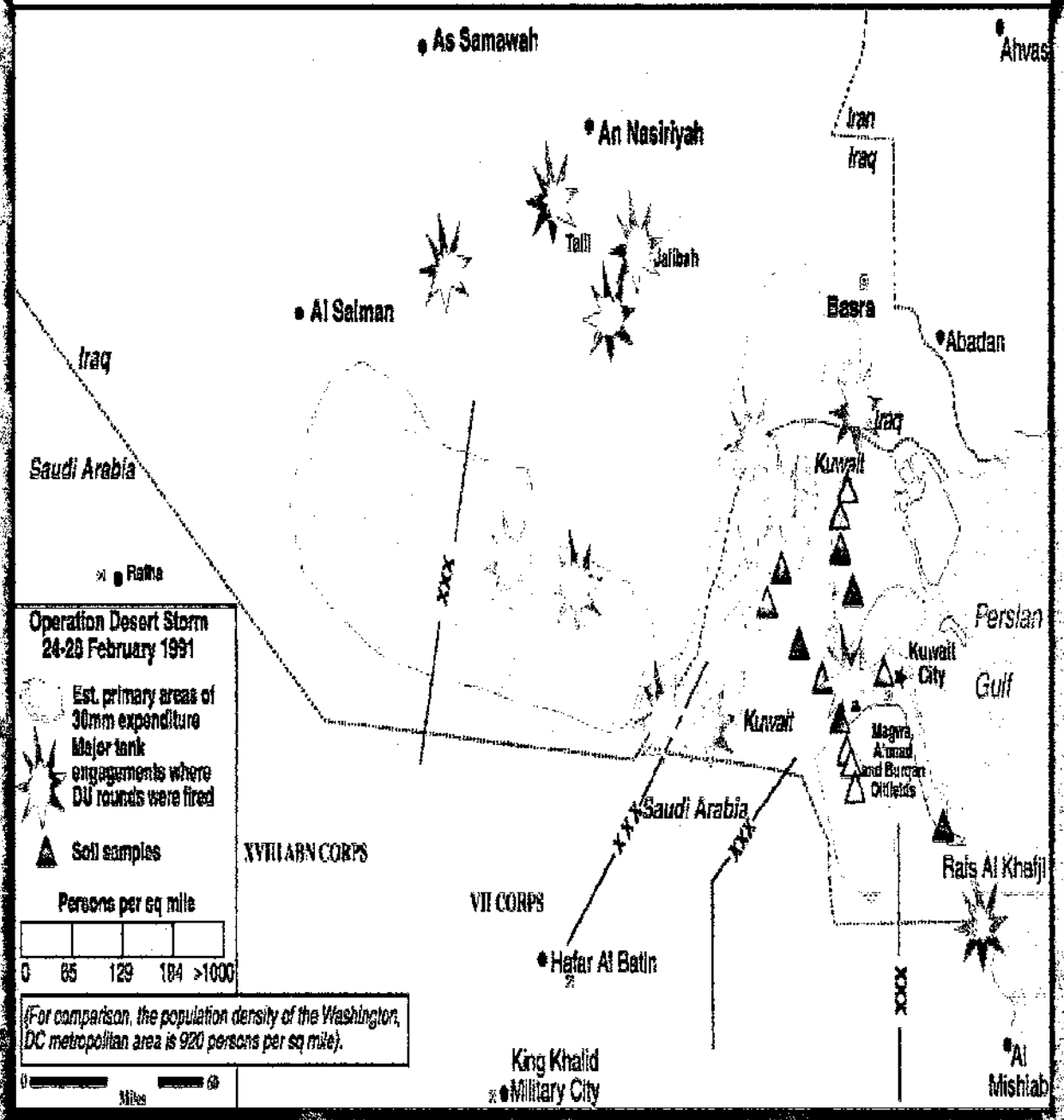
- **Chemical/biological warfare:**
  - Focus in 1997; 16 papers
  - Watershed is Khamisiyah
- **Environmental:**
  - Focus in 1998
  - Oil well fires, pesticides, depleted uranium (DU)

Day 2, 11 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Fort Stewart Visit



Primary Areas of DU Expenditure



Investigator's Message Sent

"The symptoms described were not consistent with symptoms associated with exposure to chemical warfare agents or depleted uranium."

Veteran's Messages Received

"You're wrong!"

"You can't possibly be sick because of this!"

DU Exposure Issues

- Radiation
- Heavy metal toxicity
- Consequences of exposure
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- Contamination of theater

DU Awareness Training

- Current CTT Task (031-503-1017)
- Better information is now available
  - Chemical toxicity vice radioactivity
  - Continue the mission
  - Respiratory protection for extended exposure
- Training support packages being updated
  - Includes updating the common task & GTA
  - Additional training for specialists
- Use existing training management system

OSAGWI Investigations

- Medical issues and lessons learned:
  - Focus in 1999
    - Vaccines, PB, records, policy
    - DU training
    - Managing hazards

Proactive Measures - You

- Recognize and contend with potential hazards:
  - Improve intel notification
  - Train all personnel
  - Reduce adverse effects of and stress from potential exposures
  - Understand the environment and culture before deploying
- Improve feedback and cross talk

Operational Lessons - Your Unit

- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Relate CW to operational and medical records
- Adapt for the future
  - Retain individual unit locations and records
  - DU training
  - Improved medical surveillance
  - Force health protection

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Pre-deployment serum sample
- Verify HIV test in last 12 months
- Immunizations
- Verify current physical exam
- Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect serum sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

Anthrax Vaccine

- What is Anthrax?
- Vaccine is safe and necessary
  - FDA Licensed in 1970
  - Used for many years to protect textile mill workers
  - Recommended by Centers for Disease Control (CDC):
    - Workers occupationally exposed to anthrax (labs, mills)
    - Treatment of anyone exposed to anthrax aerosols
    - Only known pretreatment and protection against exposure

Anthrax Vaccination Program

- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea (8/99)
- Phase III - Total force (early 2000's)
- 254,459 vaccinated - 754,863 doses (April 99)
- 49 adverse reactions = 0.006% (April 99)
  - 23 systemic reactions, 26 local reactions
- Complete supplemental testing on vaccine prior to release
- Plant renovation completed
- DoD anthrax web site: www.defenselink.mil/specials/Anthrax

Obtaining help and information

- Comprehensive Clinical Evaluation Program (CCEP)
  - 1-800-796-9699
- Veterans Affair registry program
  - 1-800-749-8387
- Town Hall
  - Thursday, May 13th at the Woodruff Theater
- Displays
  - P.X. and Winn Army Community Hospital
- Contact managers

Bottom Line

- Gulf War Veterans key for our work
- You must protect yourself on the Dirty Battlefield
- Anyone deployed to South West Asia is eligible for CCEP
- Don't tough it out - Get signed up and evaluated
- You are your best health advocate
- Apply these lessons learned

Office of the Special Assistant for Gulf War Illnesses

CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-472-6719

www.gulflink.osd.mil

Back-up Slides

Identifying Possible Causes

- Normal disease rate
- Linking hazards and illnesses
  - Research
  - New disease paradigm

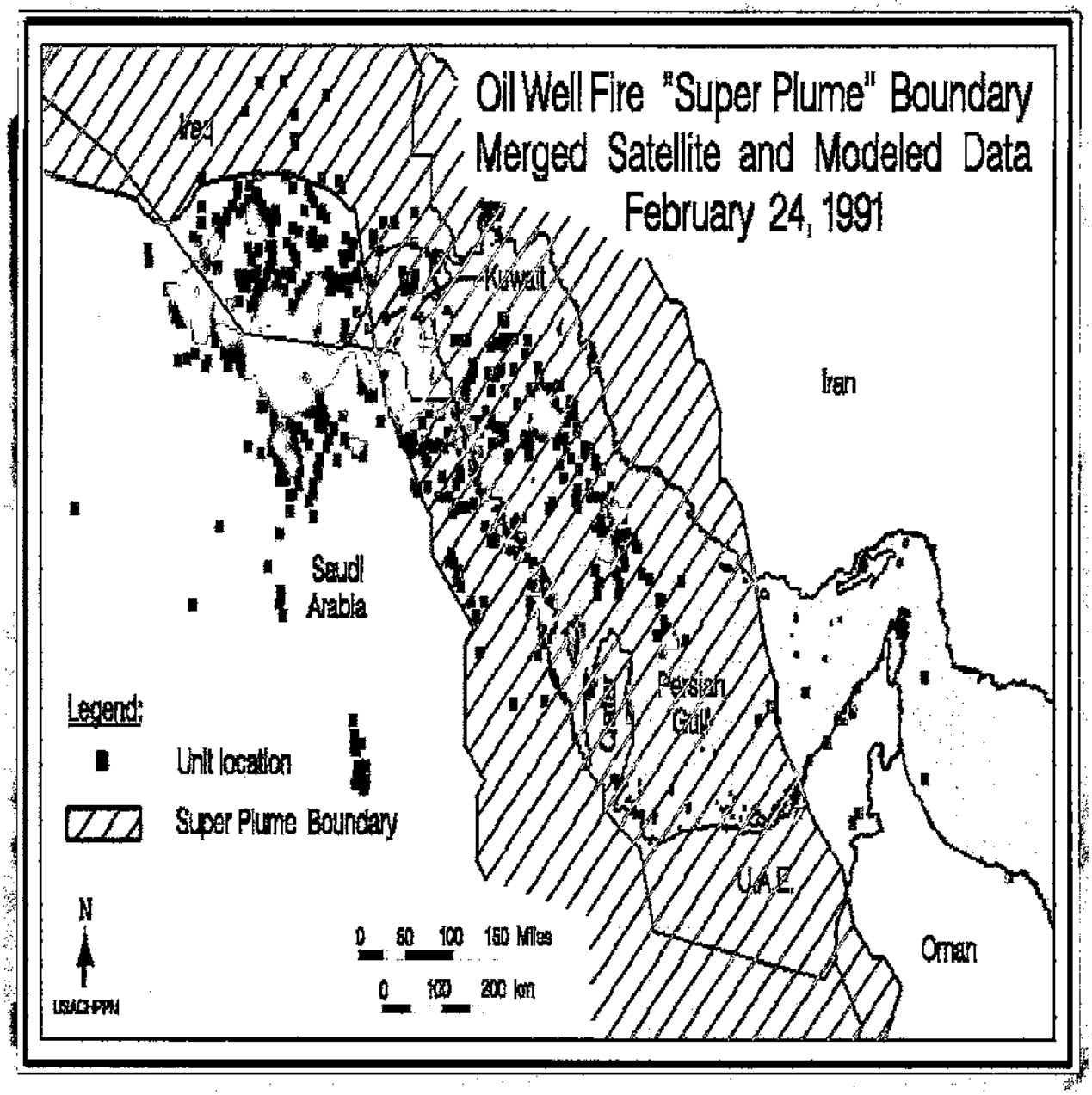
Symptoms

- Tiredness
- Rashes
- Headaches
- Muscle aches
- Joint pains
- Abdominal pain
- Diarrhea
- Hair loss
- Memory loss
- Sleep disturbance
- Depression
- Concentration problems

Hazards

- Chemical warfare agent
- Pesticides
- Vaccines
- Pyridostigmine bromide
- Stress
- Biological warfare agent
- Oil well fires
- Depleted uranium
- Infectious disease
- "Cocktail" effect

30+ offered as possible causes



Troop Unit Locations vs. Smoke Plume on February 24, 1991

Medical Training for Line Leaders

- Wellness Requirements = Mission Success
  - Routine examinations, vaccinations
  - Force Health Protection
  - Anthrax Vaccination
- Normal Disease Rates - Garrison or Deployment
  - Diarrhea
  - Sports injuries
  - Cancer, heart attacks, diabetes, etc.

Operational Lessons - You

- Recognize and contend with potential hazards:
  - Improve intel notification.
  - Train all personnel.
  - Reduce adverse effects of and stress from potential exposures.
  - Understand the environment and culture before deploying.
- Improve feedback and cross talk.

Who Served in the Gulf War

697,000 U.S. service members

Army	348,000	50%
Navy	160,000	23%
Marine	105,000	15%
Air Force	84,000	12%

259,000 Coalition Forces

Who Served in the Gulf War

Gender	
Men	93%
Women	7%
Component	
Active	83%
Reserve/National Guard	17%
Community	
Officer	10%
Enlisted	90%

<26 years old - 55%; 26-35 years old - 32%; > 35years old - 13%

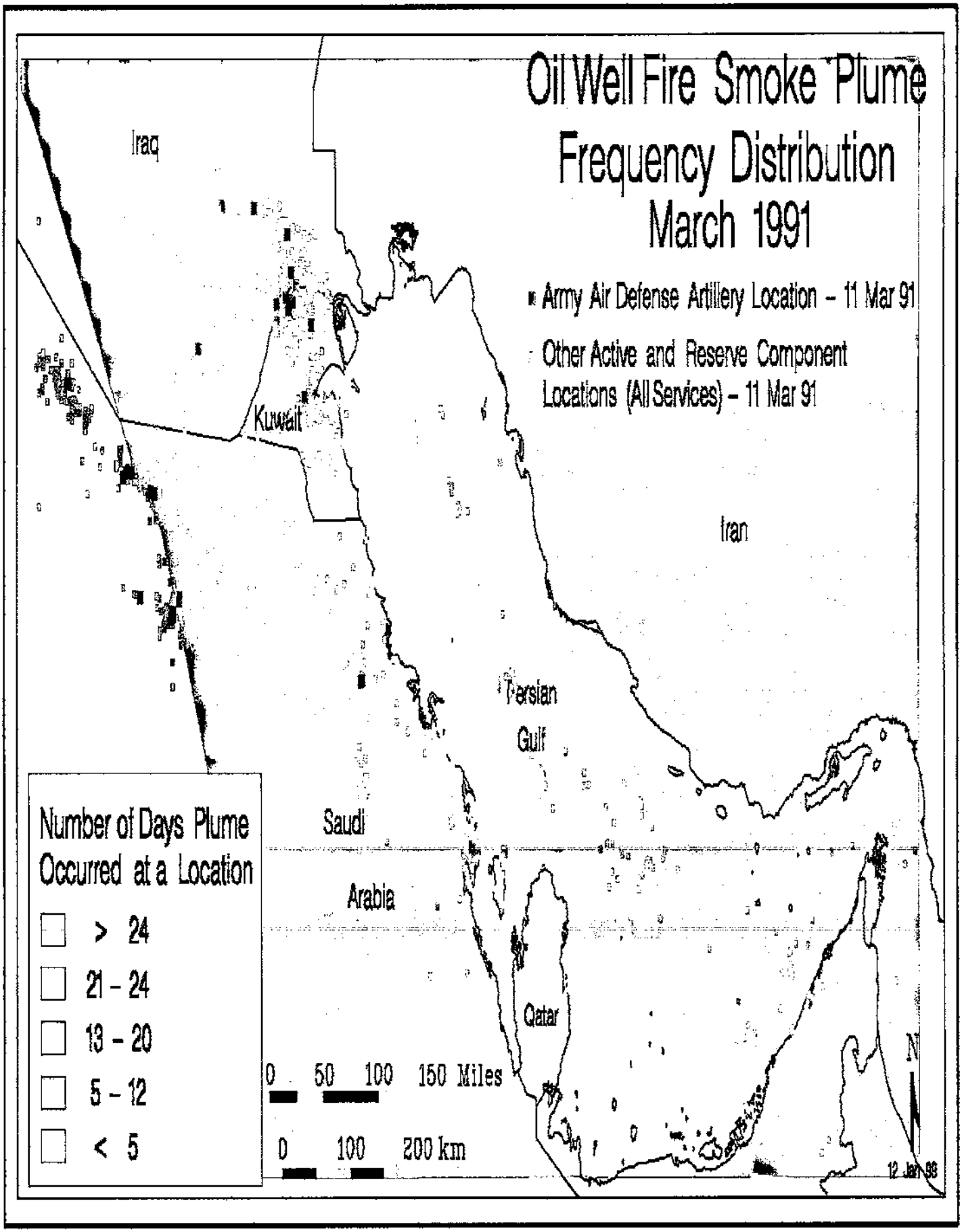
Medical Support

Largest emergency health care system since WWII

- 41,000 medical personnel
- 18,000 beds
- 2 hospital ships
- 63 combat zone hospitals

Possible Causes

- Normal disease rate
- New disease paradigm
- Research
- Black camel


Oil Well Fire Smoke Plume
Frequency Distribution
March 1991
Army Air Defense Artillery Location – 11 Mar 91
Other Active and Reserve Component Locations (All Services) – 11 Mar 91
Iraq
Kuwait
Iran
Persian Gulf
Saudi Arabia
Qatar
Number of Days Plume Occurred at a Location
> 24
21 – 24
13 – 20
5 – 12
< 5
0 50 100 150 Miles
0 100 200 km
N
12 Jan 98

Comprehensive Clinical Evaluation Program (CCEP)

DoD

Total Registered	51,138
Declined Physical	14,454
% Exams completed	96%

VA

Veterans Affairs Registry	72,122

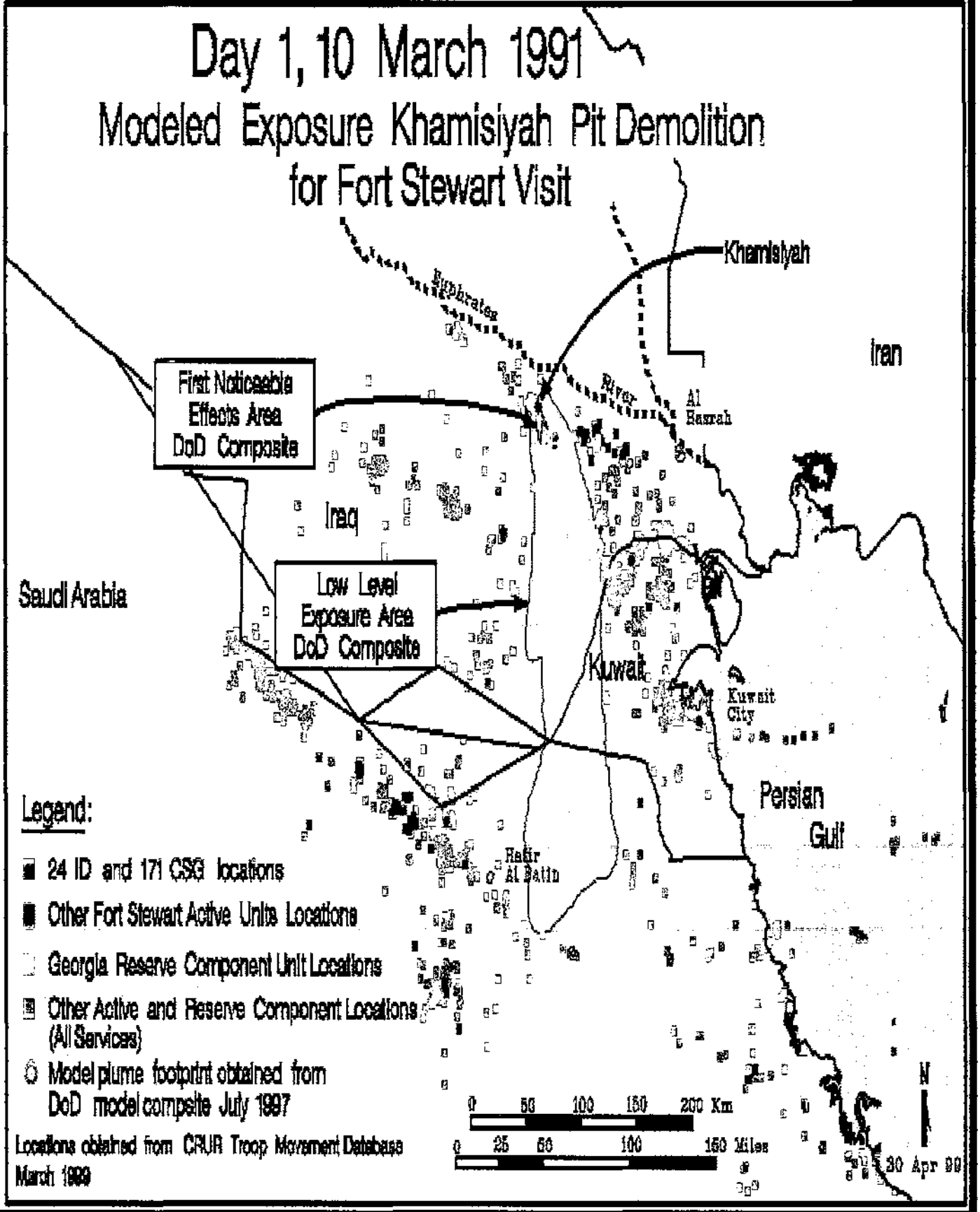
Source: CCEP 31 Dec 98

Future Equipment

- Personal Information Carrier (PIC)
- Biological Integrated Detection System (BIDS)
- Automatic Chemical Agent Alarm (ACADA)
- Medic Cam - Tele medicine

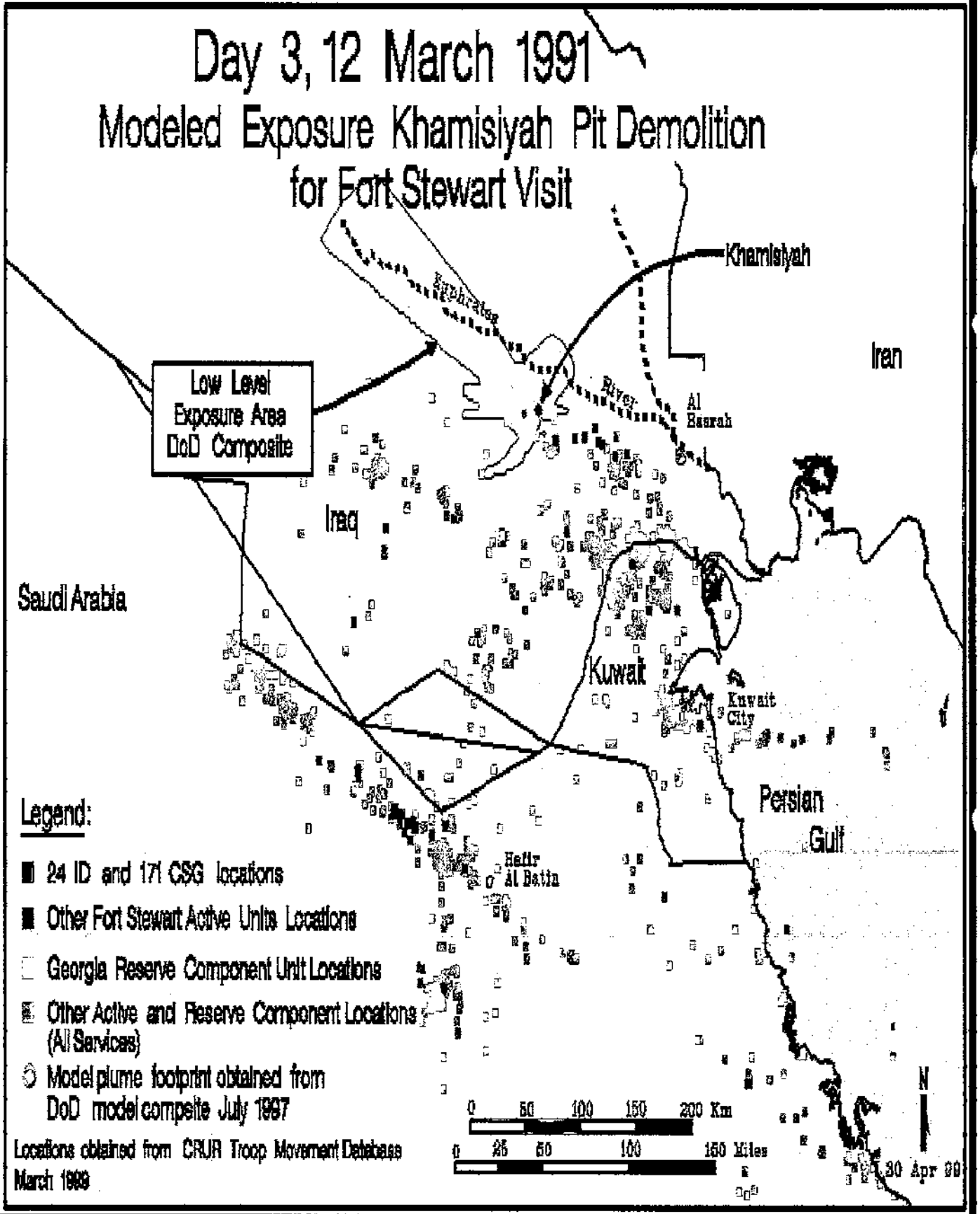
Day 1, 10 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Fort Stewart Visit



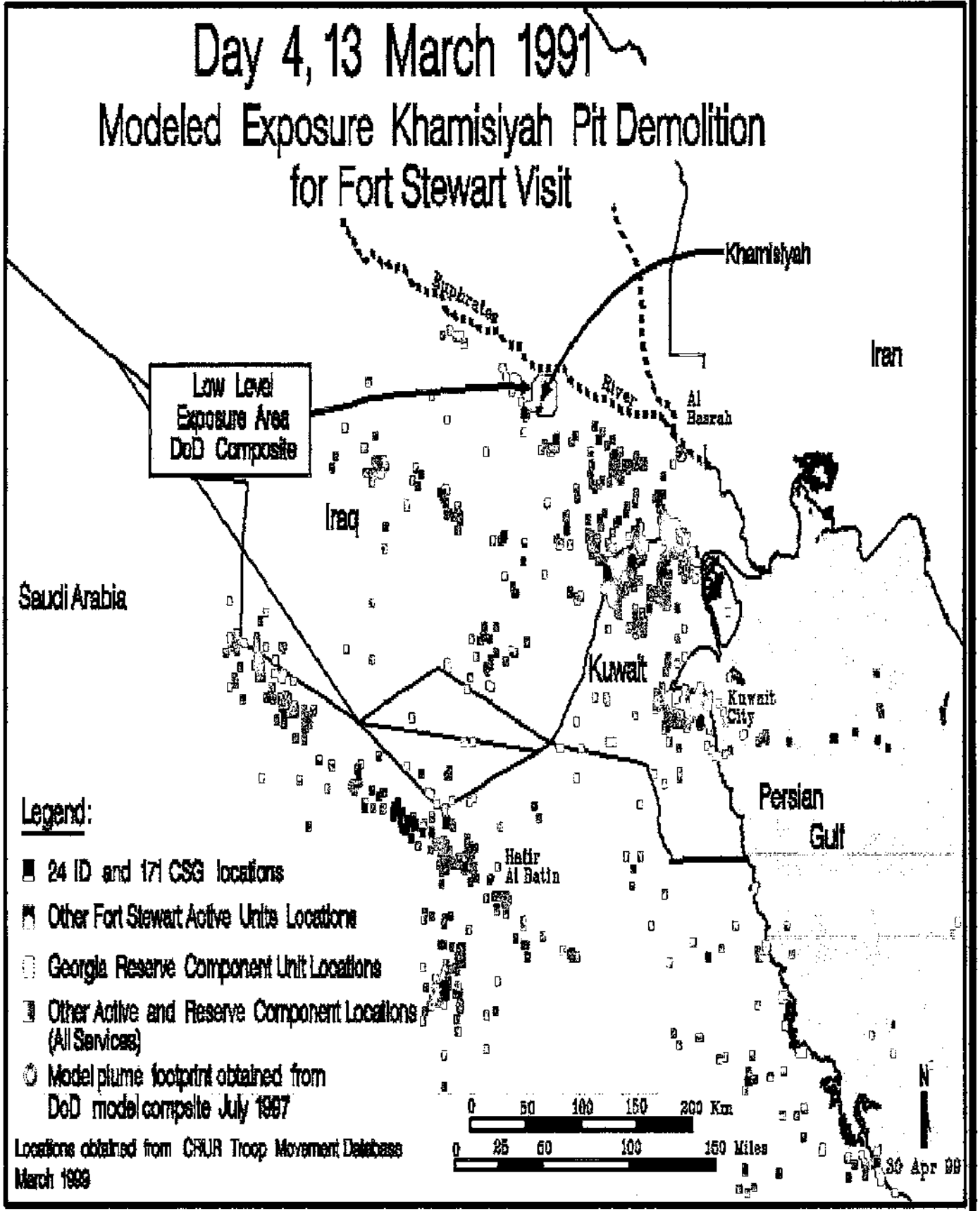
Day 3, 12 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Fort Stewart Visit



Day 4, 13 March 1991

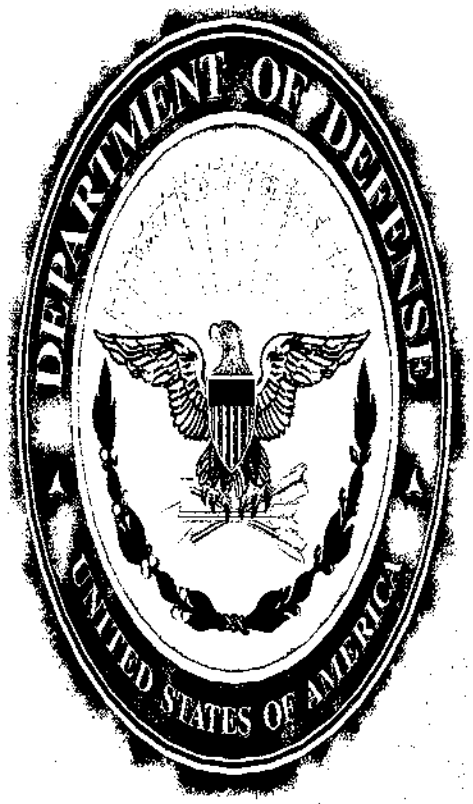
Modeled Exposure Khamisiyah Pit Demolition for Fort Stewart Visit



Summary

- Work continues: "leave no stone unturned"
- We rely on Gulf War veterans:
  - To give us leads
  - To check our accuracy
- We rely on today's force -- including you:
  - To ensure GW vets get proper testing and treatment
  - To apply lessons learned to the future

Office of the Special Assistant to the Deputy Secretary of Defense



for Gulf War Illnesses

(800)-754-2132 fax 703-578-8501

email: brostker@gwillness.osd.mil

Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Post War

Shortly after re-deployment, many individuals in a few units reported common symptoms

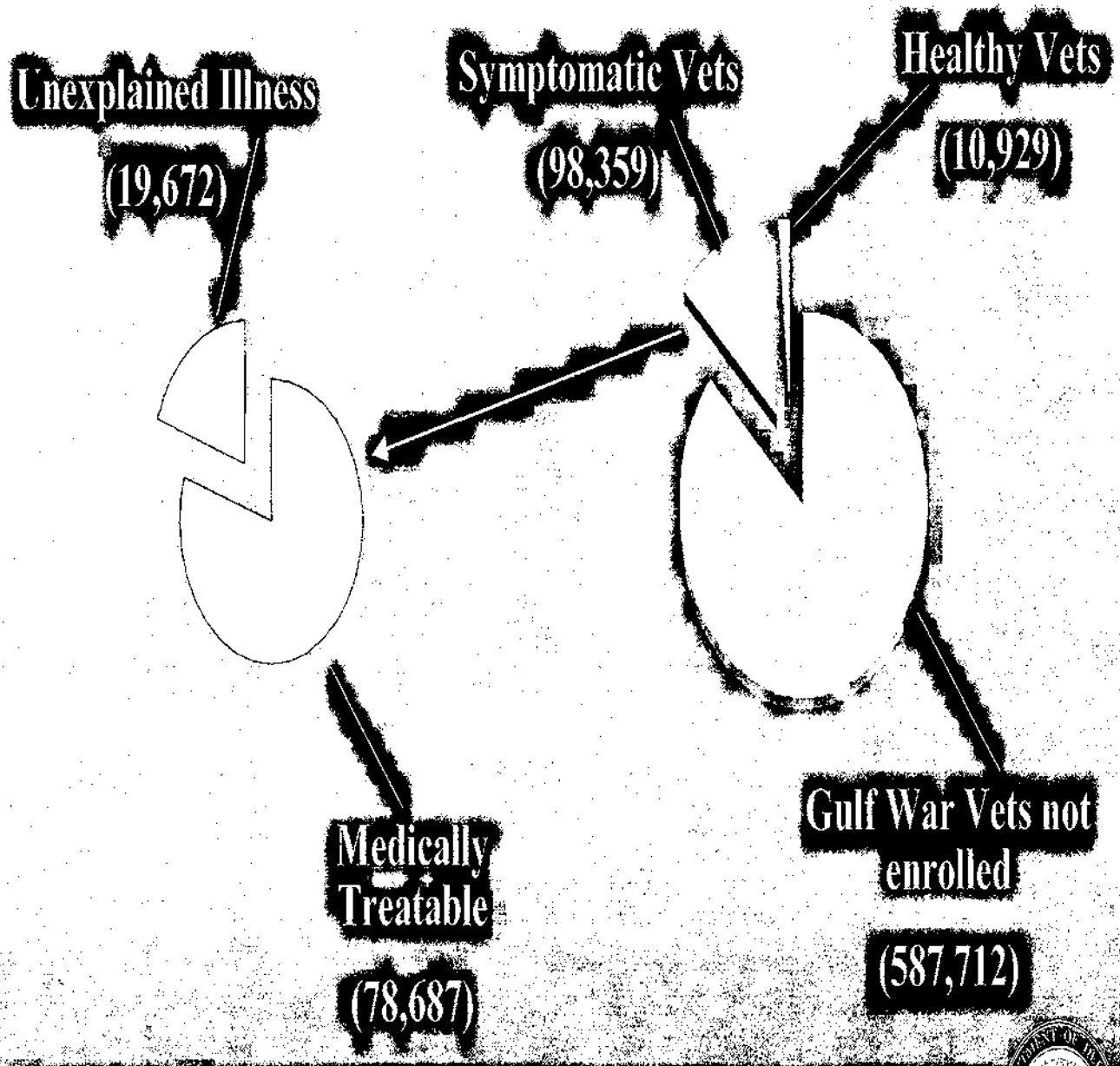
- Aching joints
- Headaches
- Rashes
- Sleep disorders
- Diarrhea
- Hair loss
- Memory loss
- Fatigue

Confounding Issues

- No clustering
- No symptom consistency
- Variable onset
- No longitudinal evaluation
- As yet - no new disease or links between exposures and symptoms

Diagnosis Distribution/697,000 Deployed

CCEP/VA Participants



Looking for Causes

The Dirty Battlefield

- What Iraq may have done to us.
  - Oil Well Fires, Stress
- What the environment may have done to us.
  - Sand, Infectious diseases, bad food and water
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide, Low levels of CW agent, DU
- Challenges in the future range from low-tech pariah states to the revolution in military affairs.

OSAGWI Investigations

- Chemical/biological warfare:
  - Focus in 1997; 16 papers
  - Watershed is Khamisiyah
- Environmental:
  - Focus in 1998
  - Oil well fires, pesticides, depleted uranium (DU)

DU Exposure Issues

- Radiation
- Heavy metal toxicity
- Consequences of exposure
- Reproductive effect
- Contamination of theater

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Pre-deployment serum sample
- Verify HIV test in last 12 months
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- Verify current physical exam
- Health questionnaire

Deployment

- Routine disease/injury reporting
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Anthrax Vaccination Program

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  - 23 systemic reactions, 26 local reactions
- Complete supplemental testing on vaccine prior to release
- Plant renovation completed.
- DoD anthrax web site: www.defenselink.mil/specials/Anthrax

Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	5,773 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

Summary

- Work continues: "leave no stone unturned"
- We rely on Gulf War veterans:
  - To give us leads
  - To check our accuracy
- We rely you:
  - To ensure GW vets get proper testing and treatment
  - To dispel myths and demand facts

Obtaining help and information

- Comprehensive Clinical Evaluation Program (CCEP)
  - 1-800-796-9699
- Veterans Affair registry program
  - 1-800-749-8387
- Town Hall
  - Thursday, May 13th at the Woodruff Theater
- Displays
  - P.X. and Winn Army Community Hospital
- Contact managers

Office of the Special Assistant for Gulf War Illnesses

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Department of Defense's Incident Reporting Line	800-472-6719

www.gulflink.osd.mil

Office of the Special Assistant to the Deputy Secretary of Defense

for Gulf War Illnesses

800-497-6261 fax 703-578-8501

email: brostker@gwillness.osd.mil

LIC

Briefing Overview

- Mission Statement
- The Gulf War
- Post Gulf War Issues
- Searching for answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining help and information

Our Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain illnesses in Gulf War veterans
- Ensure DOD adopts doctrine, policy and procedures to reduce health risks for troops deploying now and in the future

Gulf War Theater

- August 1990 to July 1991
- 697,000 US service members
- More then 27,000 hospitalizations
- 148 battle deaths
- 224 non-battle deaths

Veterans' concerns

Most frequently reported symptoms since re-deployment

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

and many others

Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Confounding Issues

- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

Taking Care of Service Members

- **DoD Comprehensive Clinical Evaluation Program**
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
- **VA Persian Gulf Registry**
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members

Available to *all* service members deploying to South West Asia

Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
    - Science doesn't support DU or Oil Well fires as causes.
    - Still examining particulates and pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Scientific research
  - 145 studies sponsored by DoD & DVA
  - Multiple exposures

A New Reality =
The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, Man made environmental hazards (Oil Well Fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Pesticides, Stressors, Investigational New Drug

Current and future conflicts and humanitarian deployments have and will have these challenges

Investigation Results

- Gulf War
  - Not enough vaccines and no explanation given
  - Limited environmental survey
  - Information about nerve agent pre-treatment (PB) wasn't given to troops
  - Inadequate training on limitations of FOX vehicle, M8A1 alarm and M256 kit
  - Veterans re-deployed and left service without thorough medical exam or debrief

Applying Lessons Learned

You

- Train self and others to recognize and avoid hazards
- Improve feedback and cross talk
- You are your own best health advocate

Your Unit

- Monitor service member's health
- Monitor the environment
- CW/BW detection: earlier with fewer false positives
- Create, relate and save operational, NBC, and medical records
- Adapt and train to reduce future risks

Force Health Protection - A Joint Concept

- Medical screening/surveillance
- Record keeping - Personal information carriers
- Integrate Force Health Protection into operational requirements
- Follow up to deployment

Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of weapons
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
  - Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers
- No dead or live anthrax bacteria
  - Cannot cause anthrax disease
  - Contains protective antigen (PA)
- Shot schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster

1-877-GET-VACC

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman.
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Bottom Line

- Lessons learned from the Gulf War affect today's doctrine and deployments
- You will deploy on missions
- Everyone is responsible for force protection
- You are your own best health advocate

Outreach team

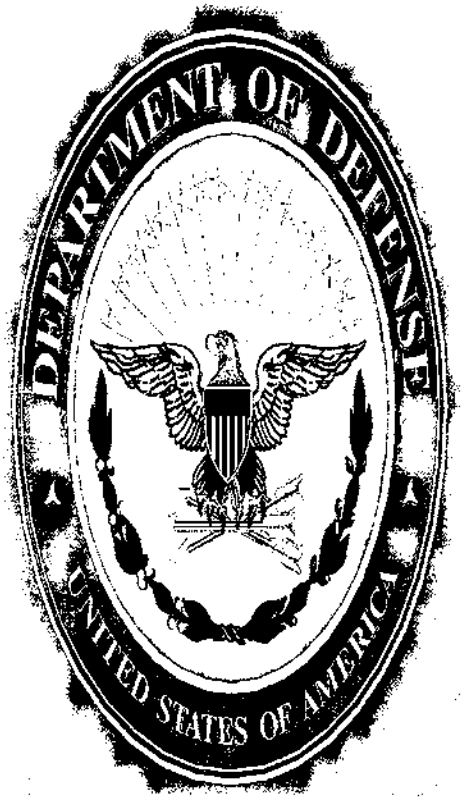
- Town Hall
  - 1900, Thursday, March 30 at the Naval Amphibious Base Little Creek, Base Theater, Building 3504, on 6th Street
- Displays
  - Navy Exchange at Naval Station Norfolk
  - Navy Exchange at NAS Oceana
  - Base Exchange at Langley Air Force Base
  - Portsmouth Naval Hospital
- Contact managers

Obtaining help and information

- Comprehensive Clinical Evaluation program (CCEP) 1-800-796-9699
- Veterans Affair Persian Gulf registry program 1-800-749-8387
- Hotline for OSAGWI 1-800-497-6261

http://www.gulflink.osd.mil

Office of the Special Assistant to the Deputy Secretary of Defense



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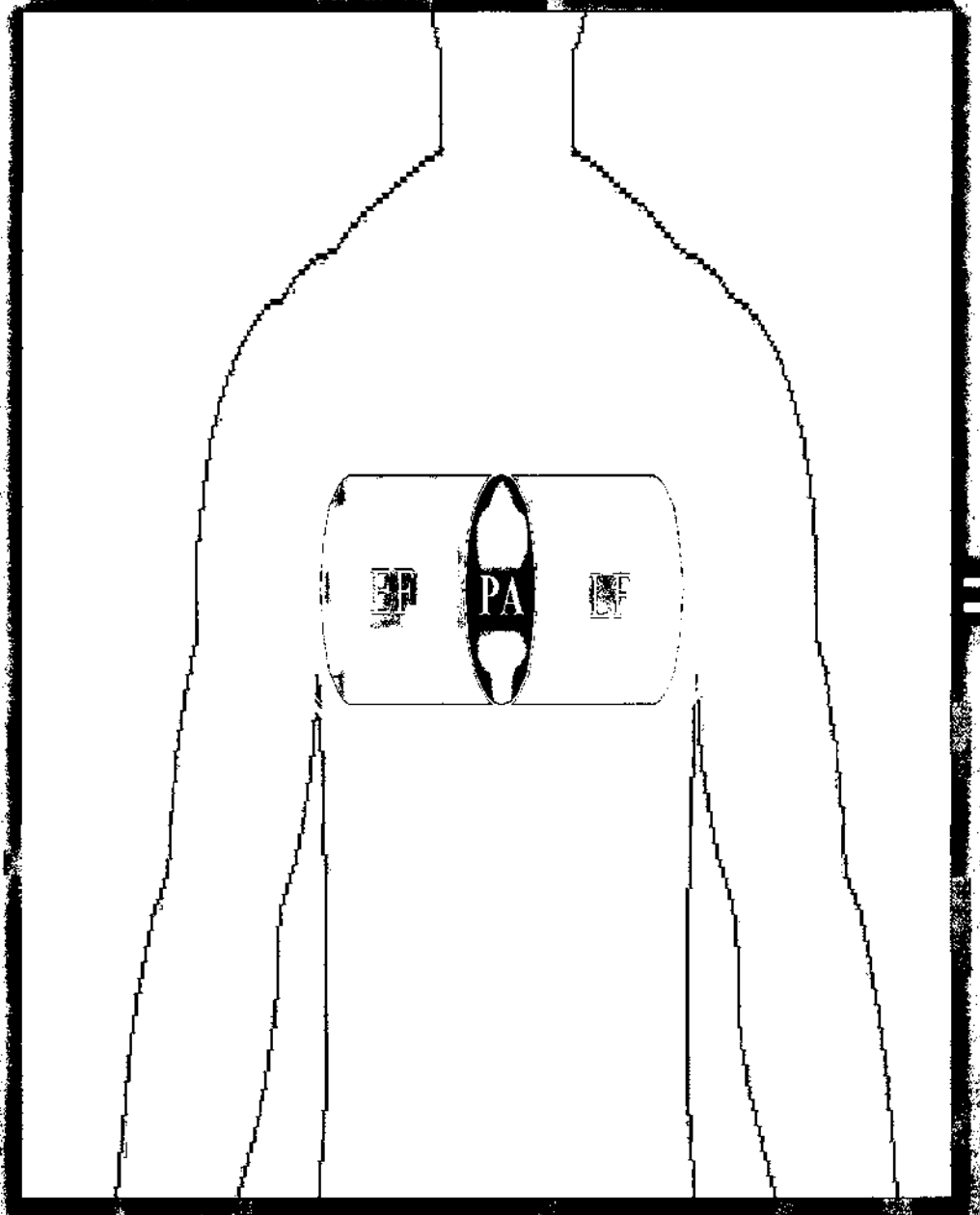
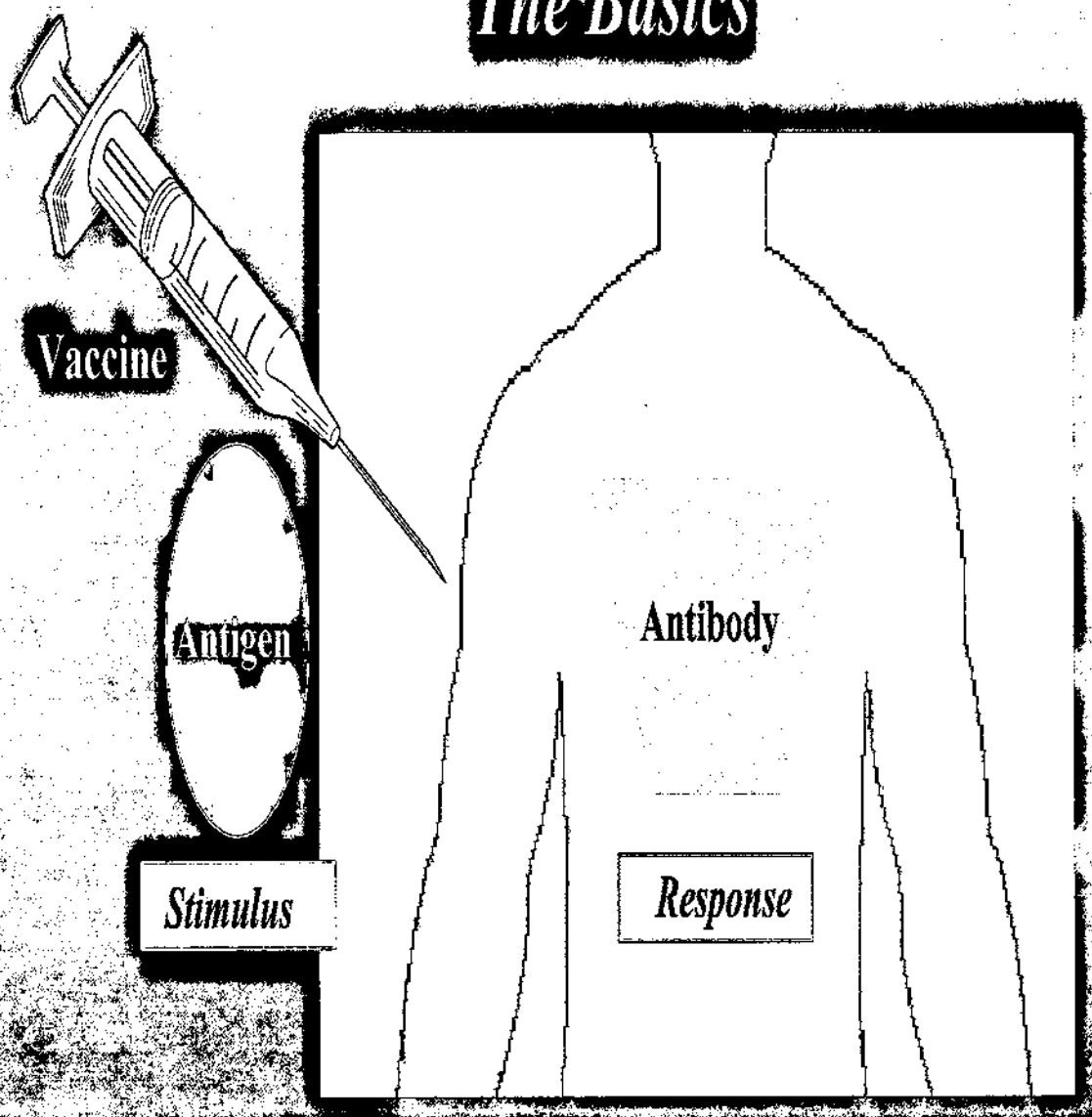
ANTHRAX BACTERIA ATTACK



= Death

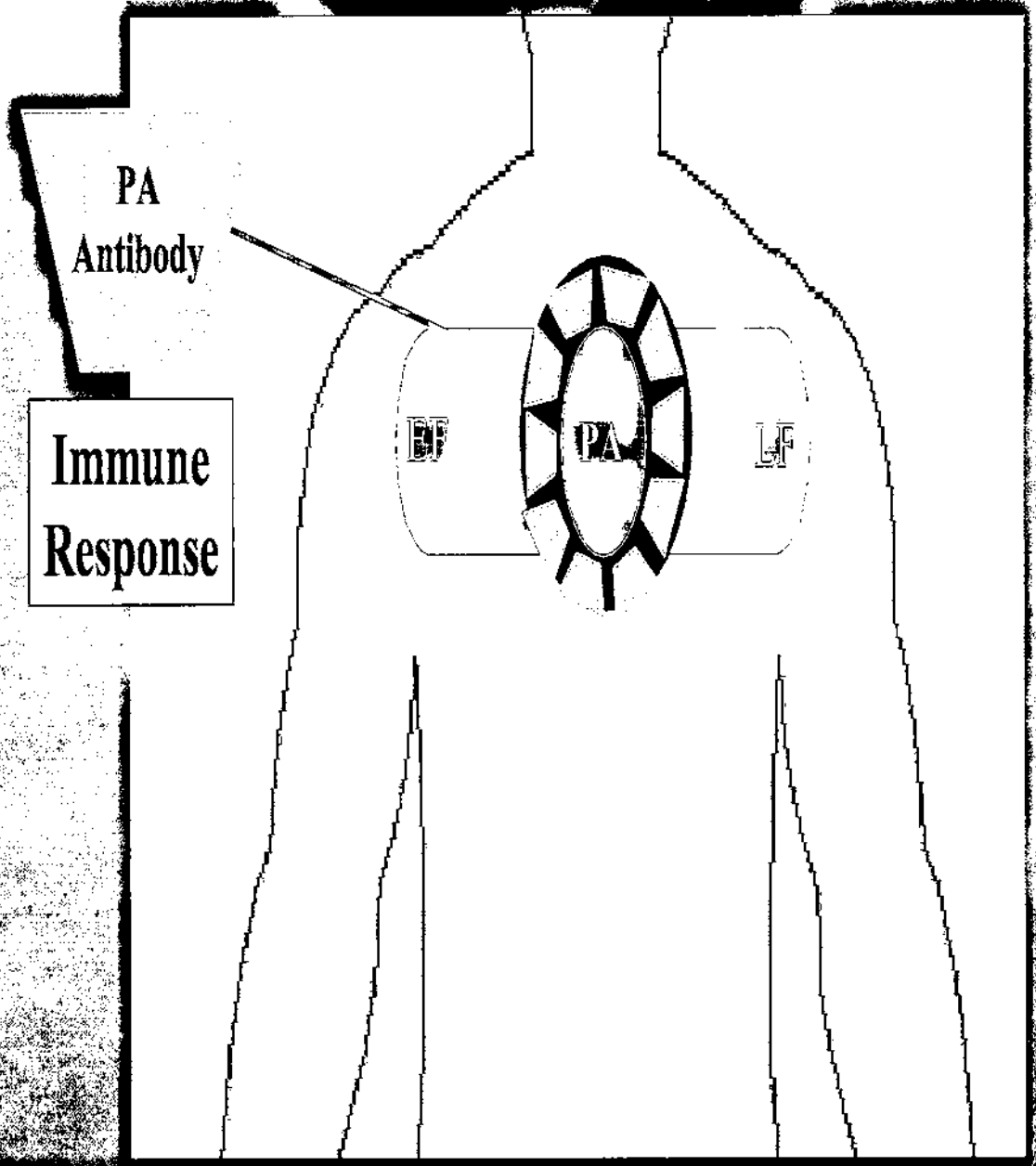
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics

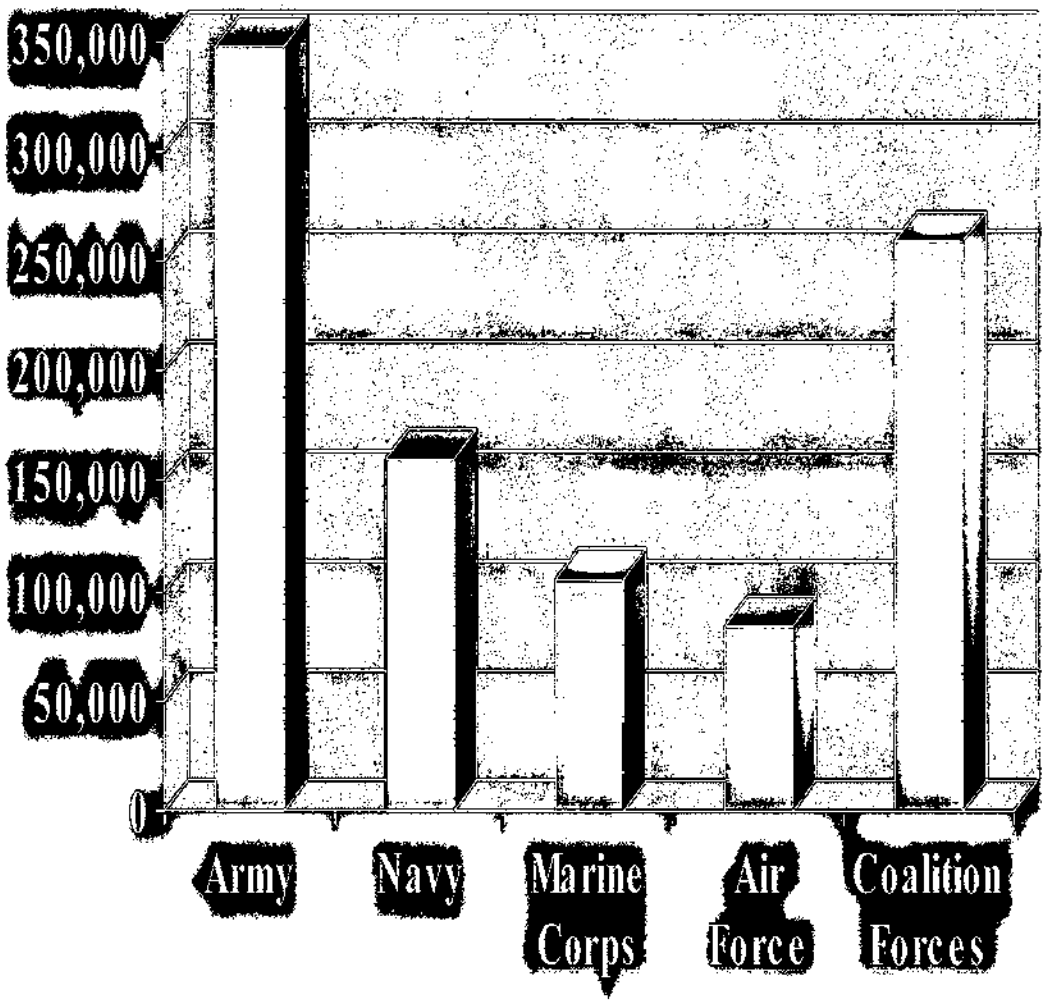


AFTER ANTHRAX VACCINE

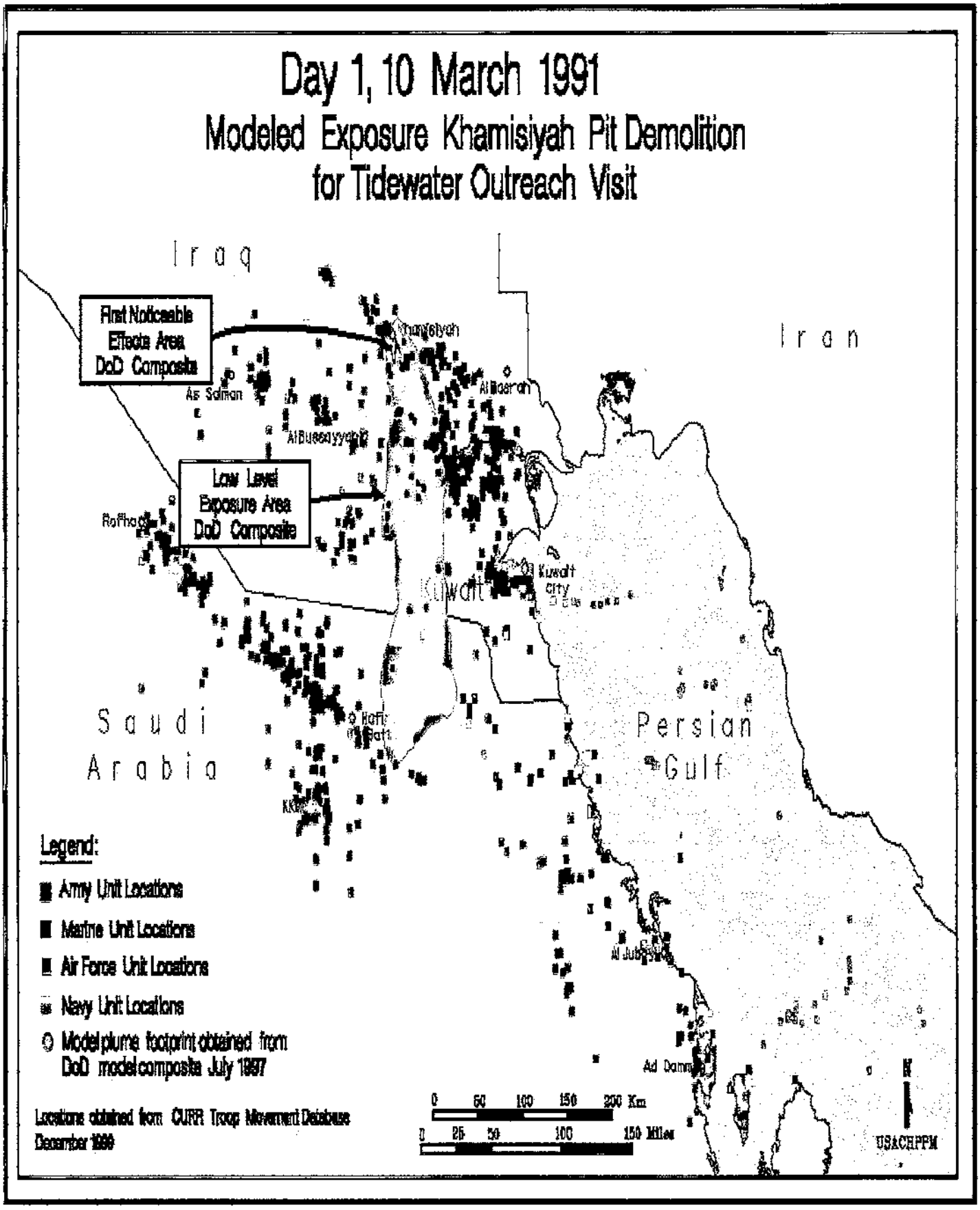
Antibodies at Work

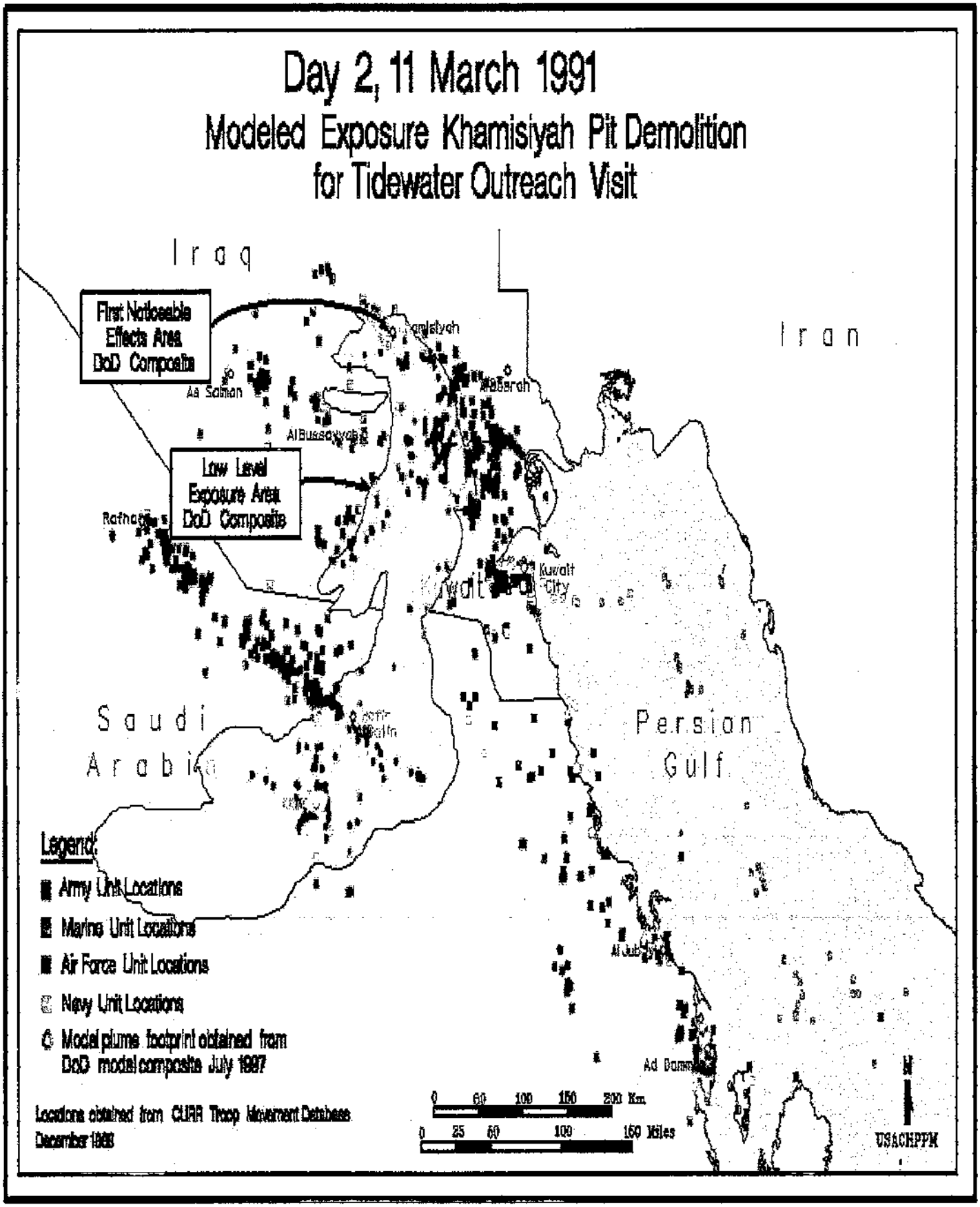


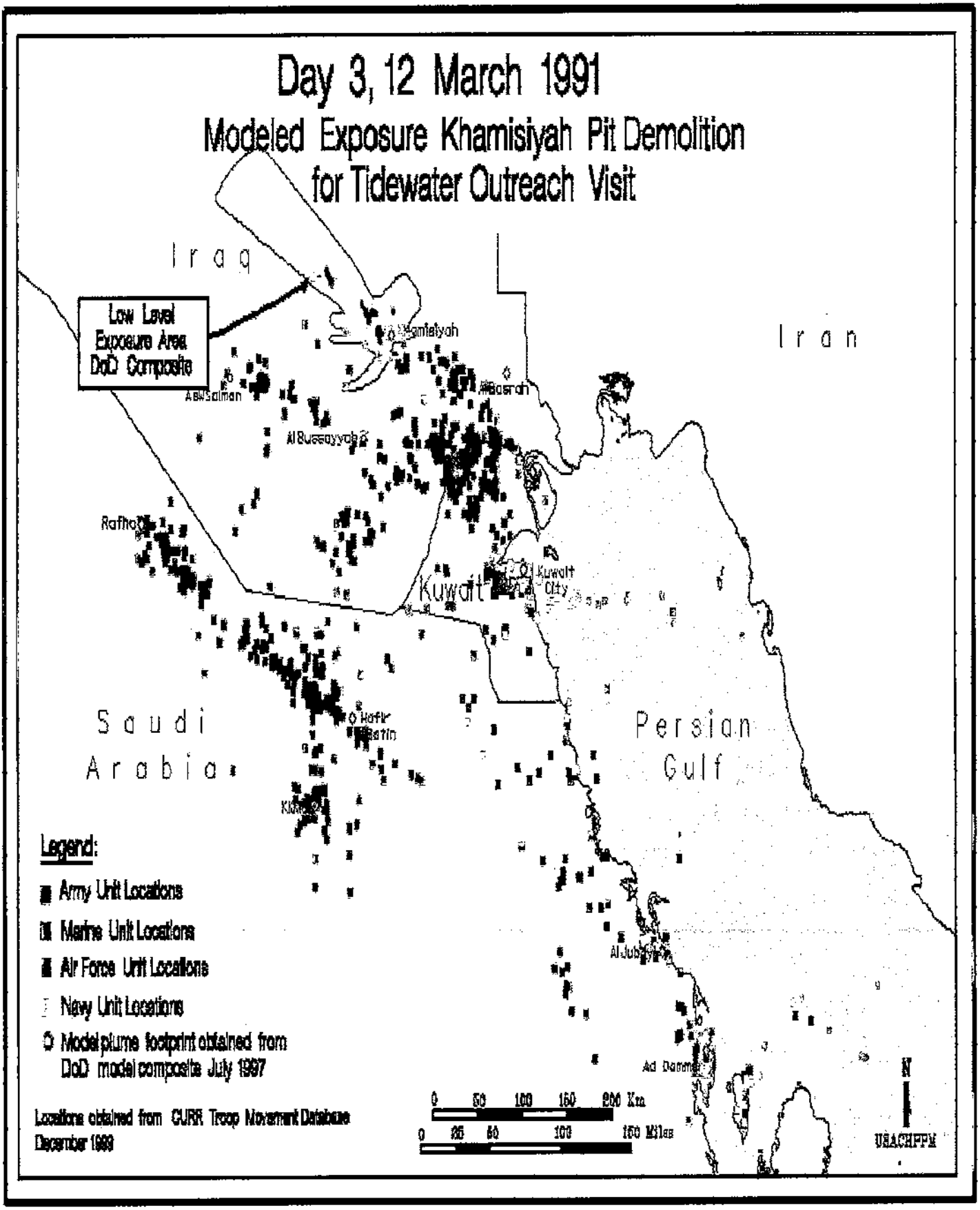
Gulf War Theater Forces



697,000 U.S. service members


Day 1, 10 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Tidewater Outreach Visit
Iraq
Iran
First Noticeable Effects Area DoD Composite
Low Level Exposure Area DoD Composite
As Salman
Khamisiyah
Al Basrah
Rafha
Kuwait
Kuwait city
Saudi Arabia
Persian Gulf
Legend:
Army Unit Locations
Marine Unit Locations
Air Force Unit Locations
Navy Unit Locations
Model plume footprint obtained from DoD model composite July 1997
Locations obtained from CURR Troop Movement Database December 1999
0 50 100 150 200 Km
0 25 50 100 150 Miles
N
USACHPPM


Day 2, 11 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Tidewater Outreach Visit
Iraq
Iran
First Noticeable Effects Area DoD Composite
Low Level Exposure Area DoD Composite
Kuwait City
Saudi Arabia
Persian Gulf
Legend:
Army Unit Locations
Marine Unit Locations
Air Force Unit Locations
Navy Unit Locations
Modal plume footprint obtained from DoD modal composite July 1997
Locations obtained from CURR Troop Movement Database December 1998
0 60 100 150 200 Km
0 25 60 100 150 Miles
N
USACHPPM


Day 3, 12 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Tidewater Outreach Visit
Iraq
Low Level
Exposure Area
DoD Composite
Khamisiyah
Iran
Basrah
Al Busayyah
Rafha
Kuwait
Kuwait City
Saudi
Arabia
Persian
Gulf
Hafir
Al Batin
Khafji
Al Jubayl
Ad Dammam
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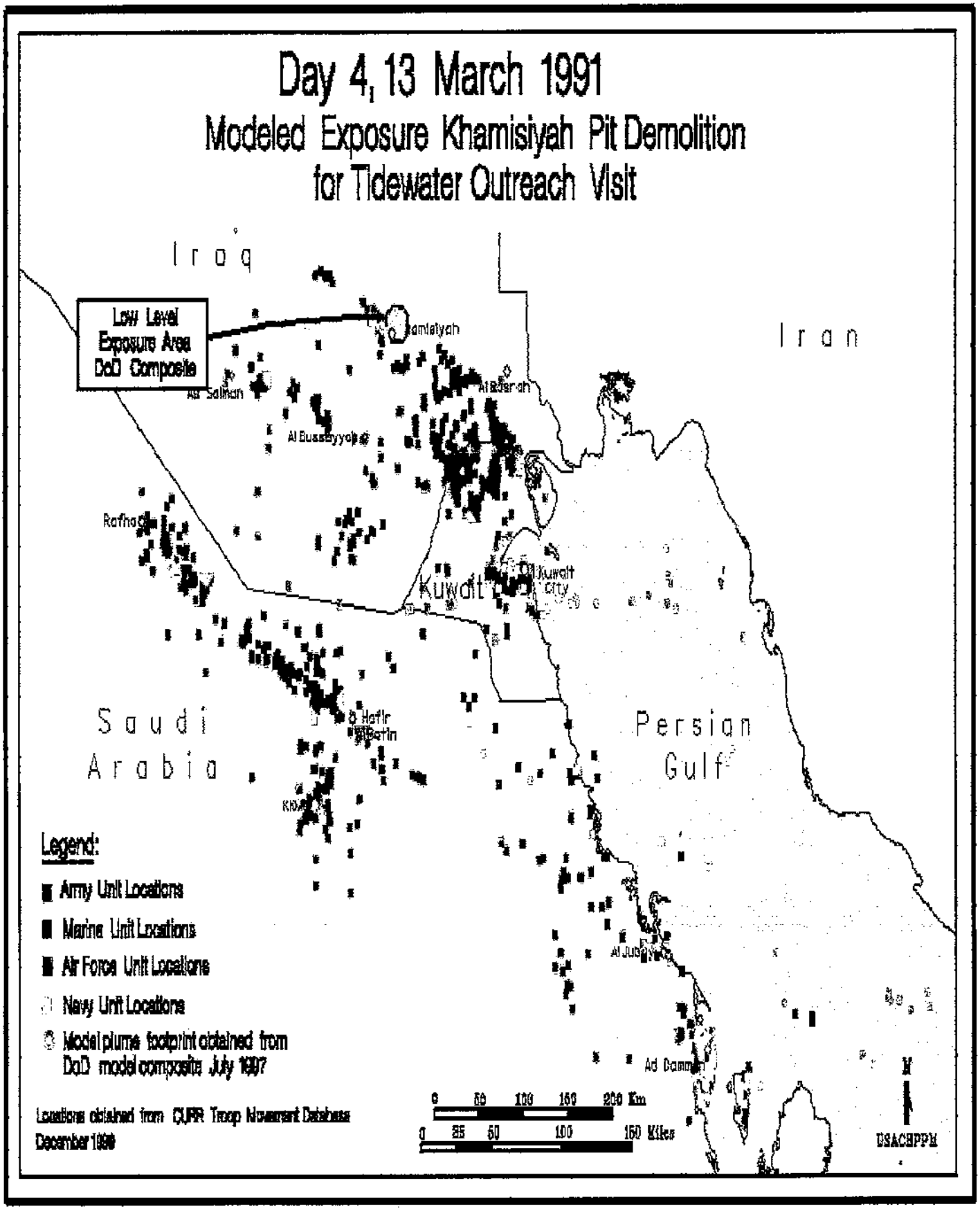
Day 4, 13 March 1991
Modeled Exposure Khamisiyah Pit Demolition
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Iraq
Iran
Low Level Exposure Area DoD Composite
Khamisiyah
As Salman
Al Busayyah
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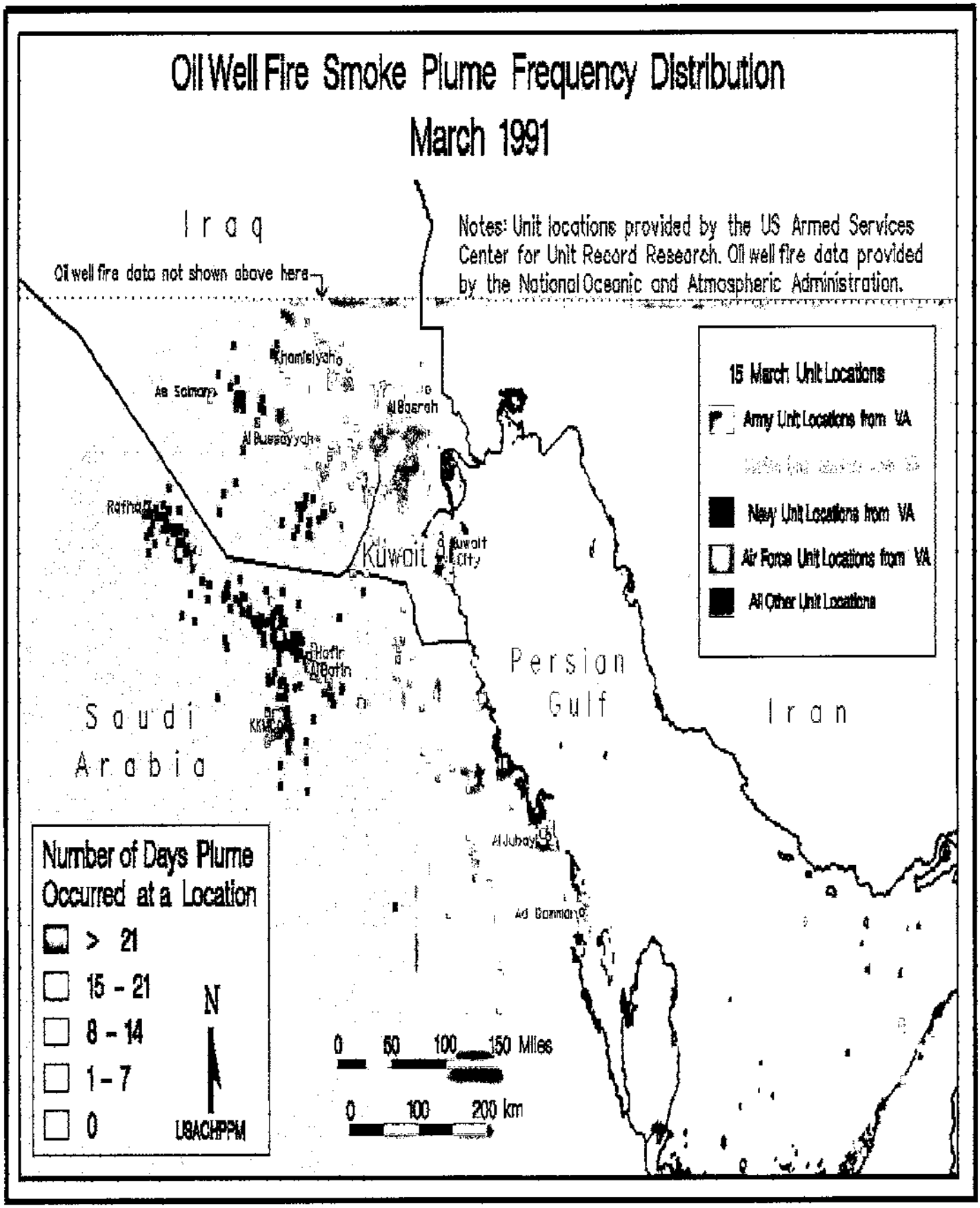
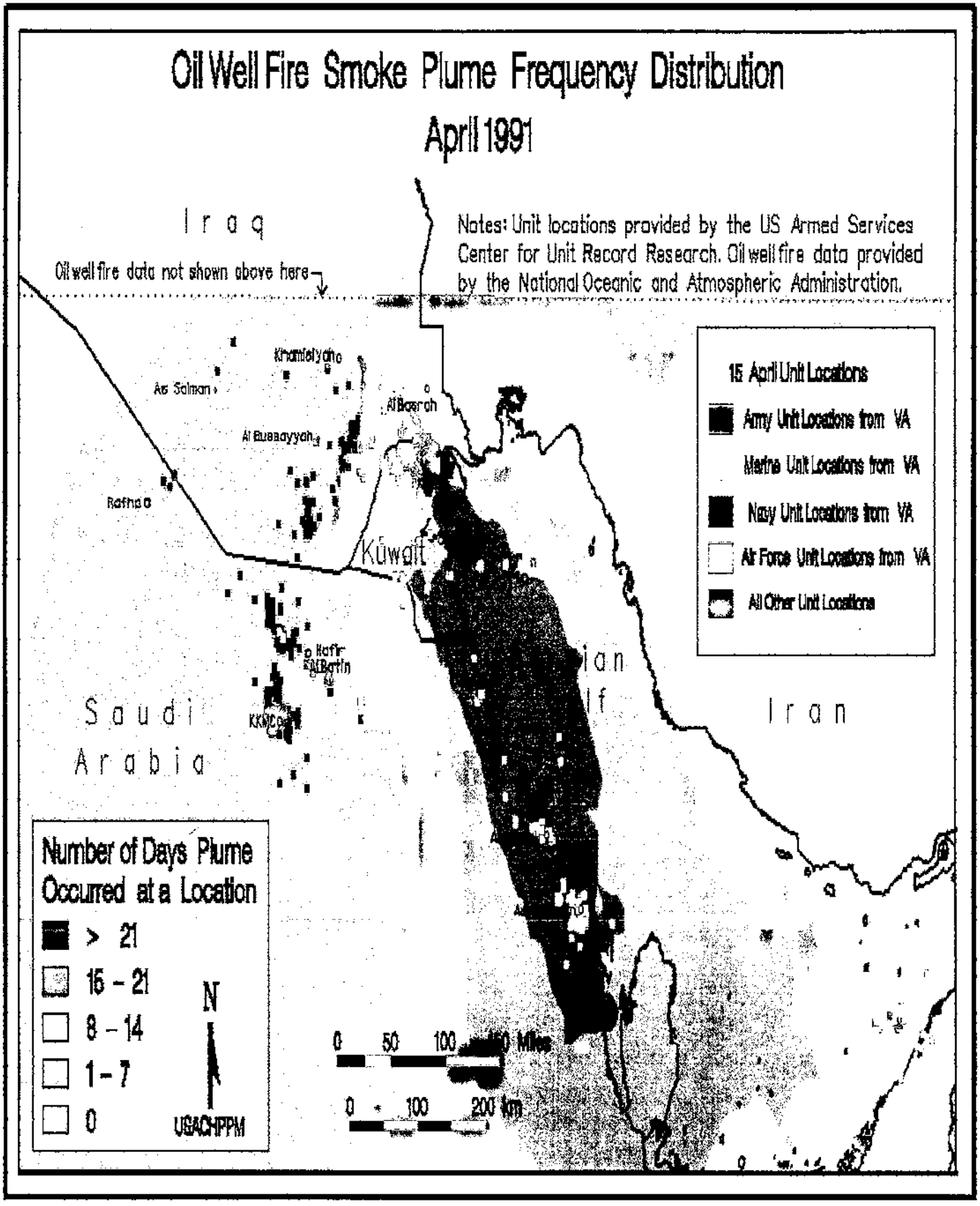

Oil Well Fire Smoke Plume Frequency Distribution
March 1991
Iraq
Oil well fire data not shown above here
Notes: Unit locations provided by the US Armed Services Center for Unit Record Research. Oil well fire data provided by the National Oceanic and Atmospheric Administration.
Khamisiyah
As Samawah
Al Basrah
Al Busayyah
Rafha
Kuwait
Kuwait City
Hafir Al Batin
Saudi Arabia
Persian Gulf
Iran
Al Jubayl
Ad Dammam
15 March Unit Locations
Army Unit Locations from VA
Navy Unit Locations from VA
Air Force Unit Locations from VA
All Other Unit Locations
Number of Days Plume Occurred at a Location
> 21
15 - 21
8 - 14
1 - 7
0
N
USACHPPM
0 50 100 150 Miles
0 100 200 km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April 1991
Iraq
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Al Busayyah
Al Basrah
Rafha
Kuwait
Kafr Al Batin
Saudi Arabia
Iran
15 April Unit Locations
Army Unit Locations from VA
Marine Unit Locations from VA
Navy Unit Locations from VA
Air Force Unit Locations from VA
All Other Unit Locations
Number of Days Plume Occurred at a Location
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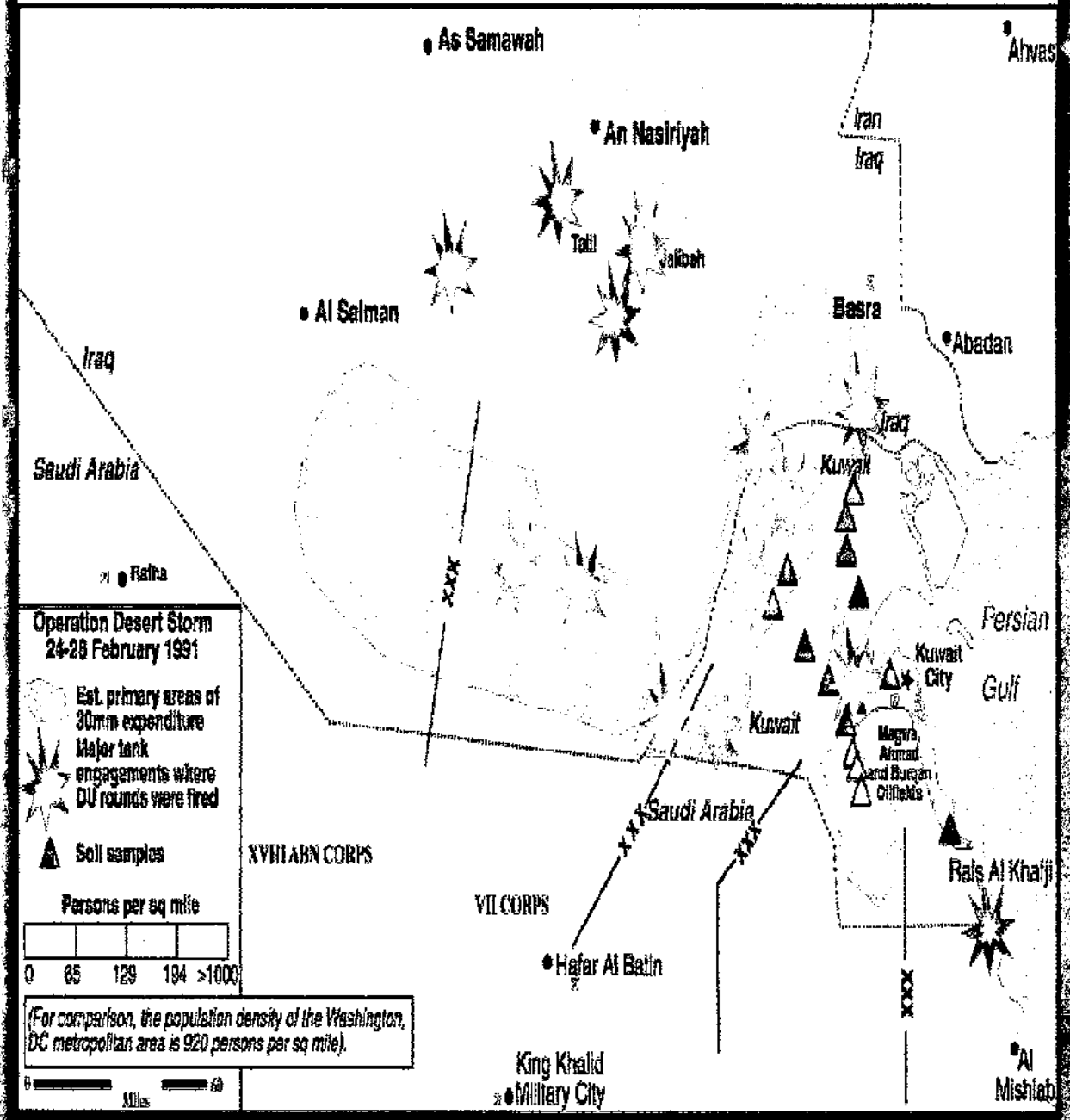
8 - 14
1 - 7
0
N
UGACHPPM
0 50 100 Miles
0 100 200 km

Primary Areas of DU Expenditure



RAND study on PB drew on Comprehensive Sources

- ~10,000 Titles
- ~6,000 Abstracts
- ~2,000 Documents Read
- ~1,000 Citations
- ~80 Interviews
- Documents declassified by British

Conclusions about PB

- We cannot rule out pyridostigmine bromide as a contributor to increased health symptoms in Gulf War veterans.
- Further research is needed to determine the effectiveness of the current dose of PB against Soman.
- Additional research about safety and effectiveness of PB for humans is urgently needed.

Office of the Special Assistant to the Deputy Secretary of Defense

for Gulf War Illnesses

800-497-6261 fax 703-578-8501

email: brostker@gwillness.osd.mil

Briefing Overview

- Mission Statement
- Why should you care?
- The Gulf War
- Post Gulf War
- Searching for answers
- Gulf War Lessons Learned
- Joint Concept - Force Health Protection
- Obtaining help and information

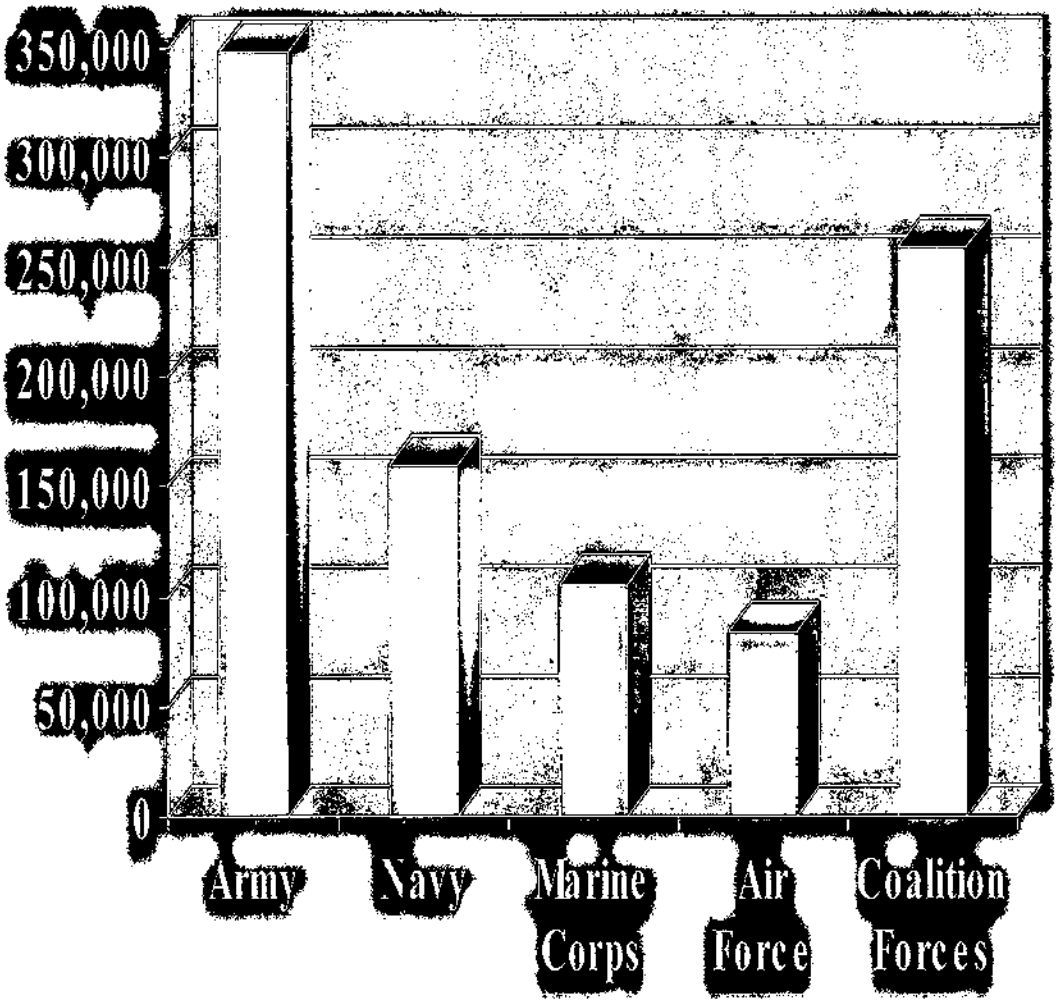
Our Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain illnesses in Gulf War veterans
- Ensure DOD adopts doctrine, policy and procedures to reduce health risks for troops deploying now and in the future

Why Should You Care?

- Lessons learned from the Gulf War affect today's doctrine and deployments.
- You will deploy overseas.
- You must protect yourself and others against CW/BW agents and other health hazards.
- Everyone is responsible for force protection.

Gulf War Theater Forces



697,000 U.S. service members

Gulf War Theater

- August 1990 to July 1991
- 697,000 US service members
- More then 27,000 hospitalizations
- 148 battle deaths
- 224 non-battle deaths

Veterans' concerns

Most frequently reported symptoms by one in seven veterans since re-deployment

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

and many others

Office of the Special Assistant for Gulf War Illnesses

Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Confounding Issues

- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

DoD recognizes problem

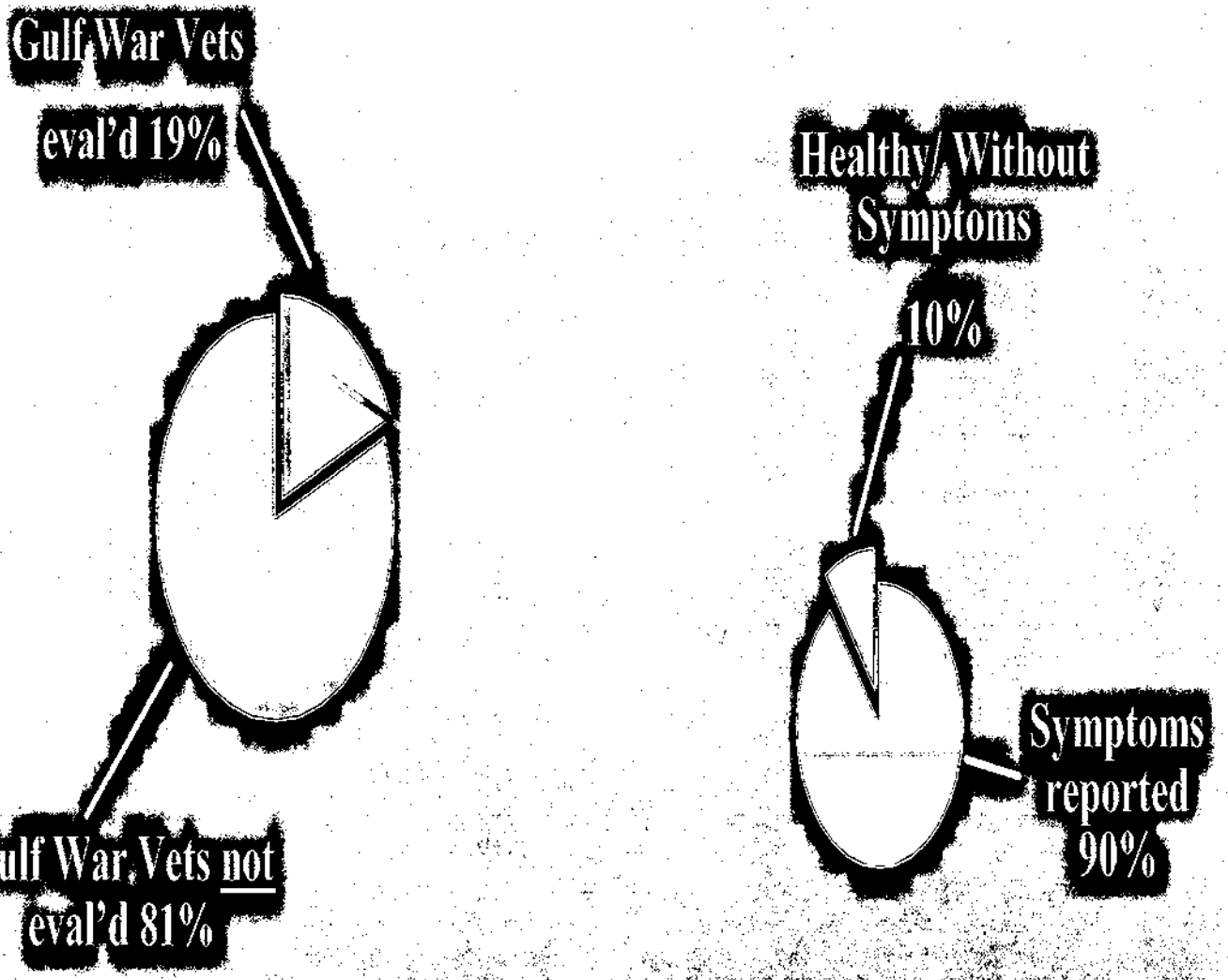
- CCEP established 1994
- OSAGWI created November 1996
  - Investigates all potential health hazards and possible causes.
- Extensive scientific research
  - DoD, VA, private
- Lessons learned identified and applied
- DoD develops Force Health Protection concept

Taking Care of Service Members

- DoD Comprehensive Clinical Evaluation Program
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
- VA Persian Gulf Registry
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members

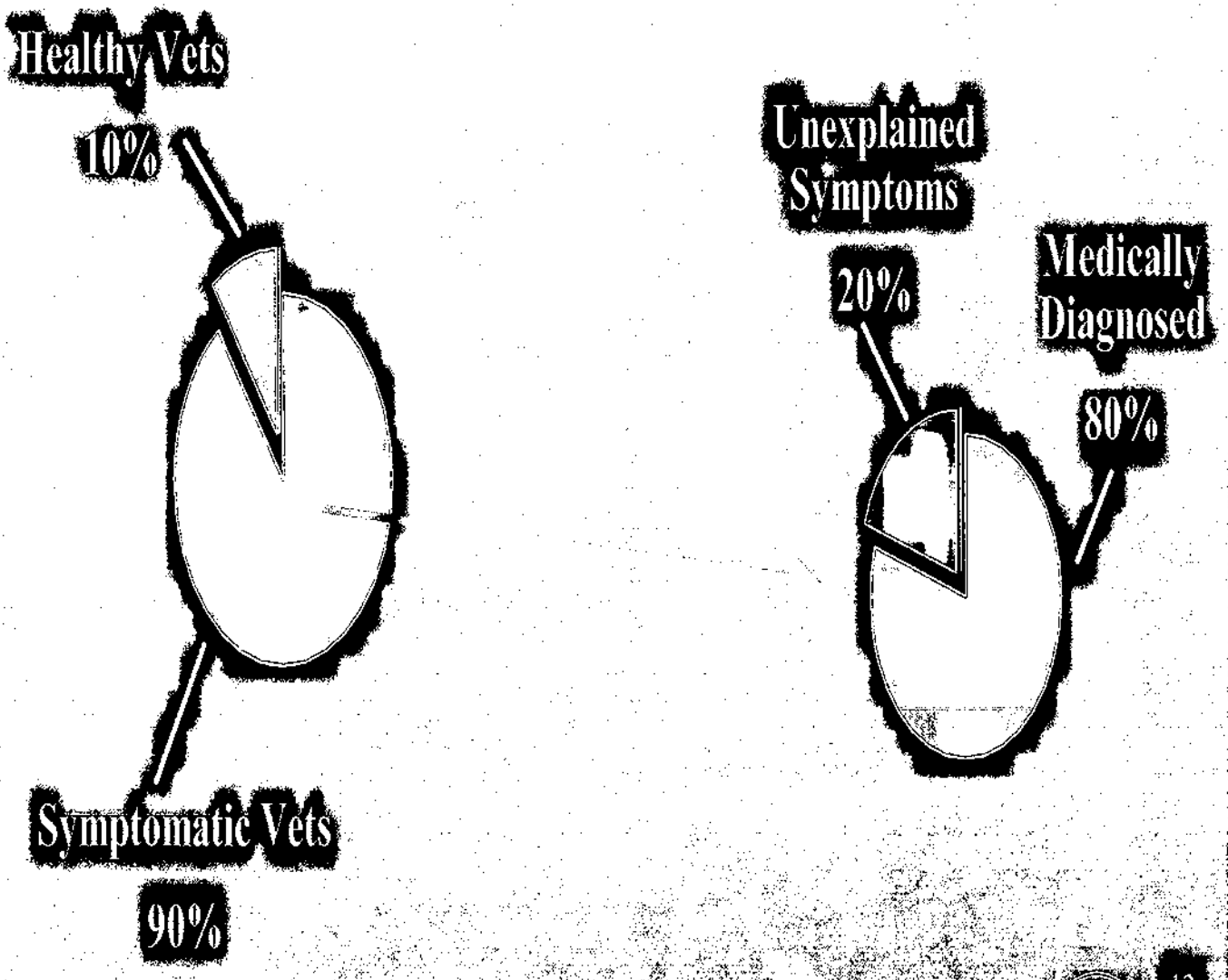
Available to *all* service members deploying to South West Asia

Evaluation Distribution of 697,000 CCEP/VA



Diagnosis Distribution of Evaluated Veterans

CCEP/VA



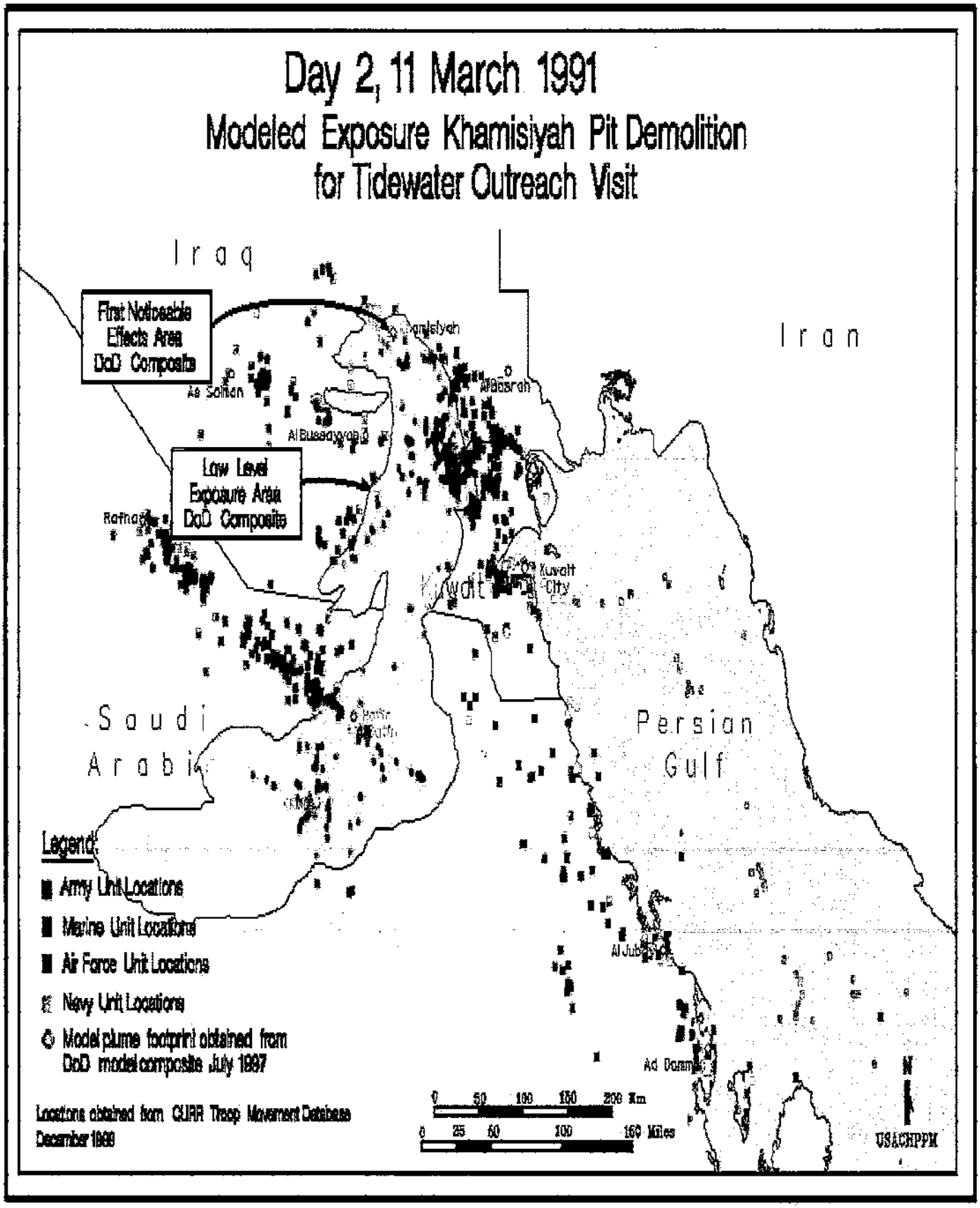
Investigations

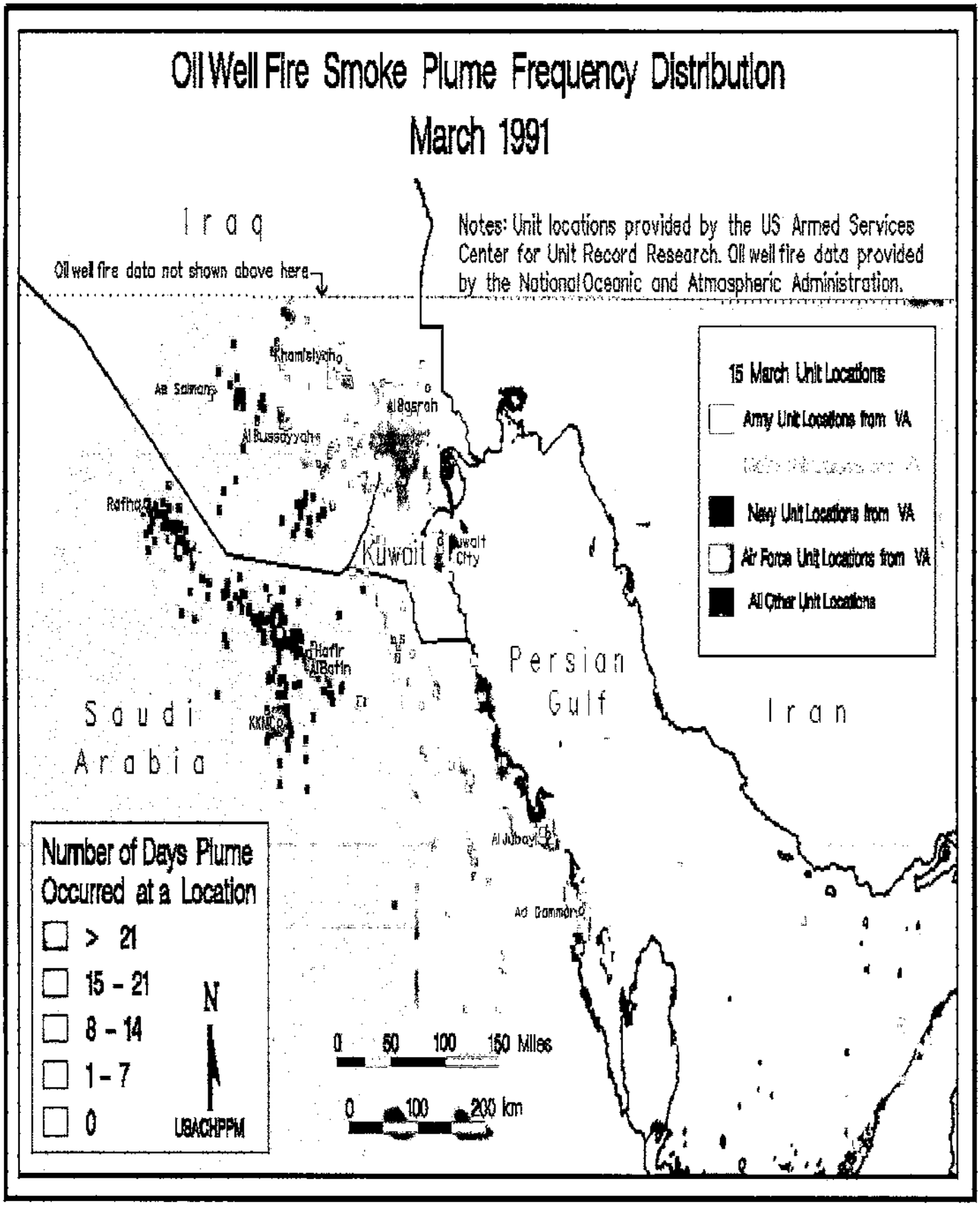
- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
    - Science doesn't support DU or Oil Well fires as causes.
    - Still examining particulates and pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Scientific research
  - 145 studies sponsored by DoD & DVA
  - Multiple exposures

A New Reality – The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, Man made environmental hazards (Oil Well Fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Pesticides, Stressors, Investigational New Drug

Current and future conflicts and humanitarian deployments have and will have these challenges


Day 2, 11 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Tidewater Outreach Visit
Iraq
Iran
First Noticeable Effects Area DoD Composite
Low Level Exposure Area DoD Composites
As Salman
Al Basrah
Kuwait City
Kuwait
Saudi Arabia
Persian Gulf
Legend:
Army Unit Locations
Marine Unit Locations
Air Force Unit Locations
Navy Unit Locations
Model plume footprint obtained from DoD model composite July 1997
Locations obtained from GWAR Troop Movement Database December 1999
0 50 100 150 200 Km
0 25 50 100 150 Miles
N
USACHPPM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March 1991
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Khamisiyah
Ar Salmany
Al Basrah
Al Busayyah
Rafha
Kuwait
Kuwait City
Hafr Al Batin
KKMC
Saudi Arabia
Persian Gulf
Iran
Al Jubayl
Ad Dammam
15 March Unit Locations
Army Unit Locations from VA
Navy Unit Locations from VA
Air Force Unit Locations from VA
All Other Unit Locations
Number of Days Plume Occurred at a Location
> 21
15 - 21
8 - 14
1 - 7
0
N
USACHPPM
0 50 100 150 Miles
0 100 200 km

Investigation Results

- Gulf War
  - Not enough vaccines and no explanation given
  - Limited environmental survey
  - Information about nerve agent pre-treatment (PB) wasn't given to troops
  - Inadequate training on limitations of FOX vehicle, M8A1 alarm and M256 kit
  - Veterans re-deployed and left service without thorough medical exam or debrief

Applying Lessons Learned

You

- Train self and others to recognize and avoid hazards
- Improve feedback and cross talk
- You are your own best health advocate

Your Unit

- Monitor service member's health
- Monitor the environment
- CW/BW detection: earlier with fewer false positives
- Create, relate and save operational, NBC, and medical records
- Adapt and train to reduce future risks

Force Health Protection - A Joint Concept

- Medical screening/surveillance
- Record keeping - Personal information carriers
- Integrate Force Health Protection into operational requirements
- Follow up to deployment

Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of weapons
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4 prevents exposure
- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
  - Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers
- No dead or live anthrax bacteria
  - Cannot cause anthrax disease
  - Contains protective antigen (PA)
- Shot schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster

1-877-GET-VACC

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman.
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Bottom Line

- Lessons learned from the Gulf War affect today's doctrine and deployments
- You will deploy on missions to dirty areas
- Everyone is responsible for force protection
- Don't tough it out - Get evaluated
- You are your own best health advocate

Outreach team

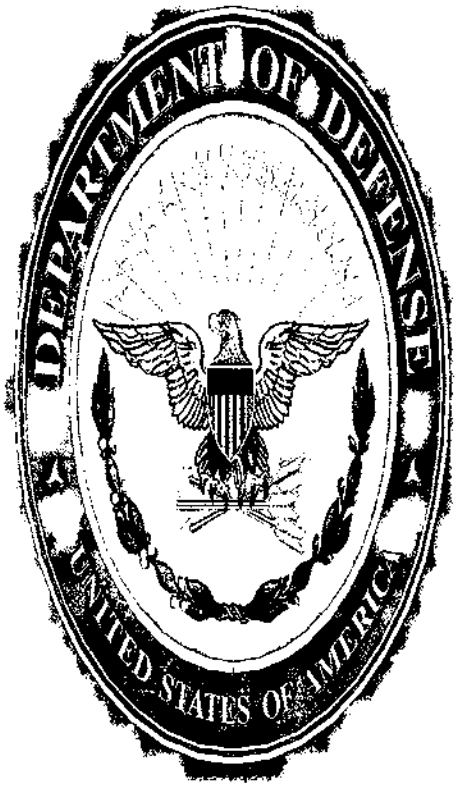
- Town Hall
  - 1900, Thursday, March 30 at the Naval Amphibious Base Little Creek, Base Theater, Building 3504, on 6th Street
- Displays
  - Navy Exchange at Naval Station Norfolk
  - Navy Exchange at NAS Oceana
  - Base Exchange at Langley Air Force Base
  - Portsmouth Naval Hospital
- Contact managers

Obtaining help and information

- Comprehensive Clinical Evaluation program (CCEP) 1-800-796-9699
- Veterans Affair Persian Gulf registry program 1-800-749-8387
- Hotline for OSAGWI 1-800-497-6261

http://www.gulflink.osd.mil

Office of the Special Assistant to the Deputy Secretary of Defense



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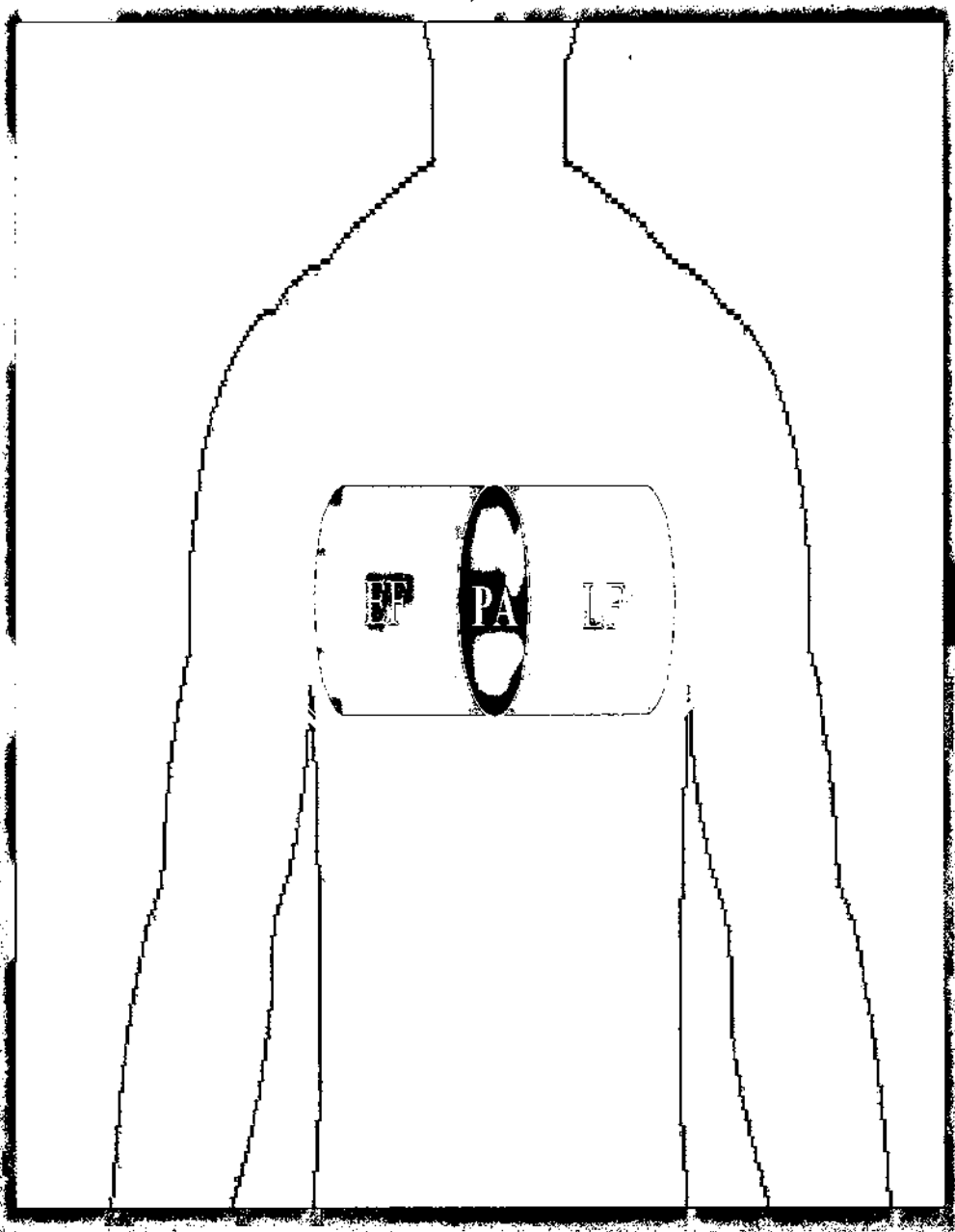
email: brostker@gwillness.osd.mil

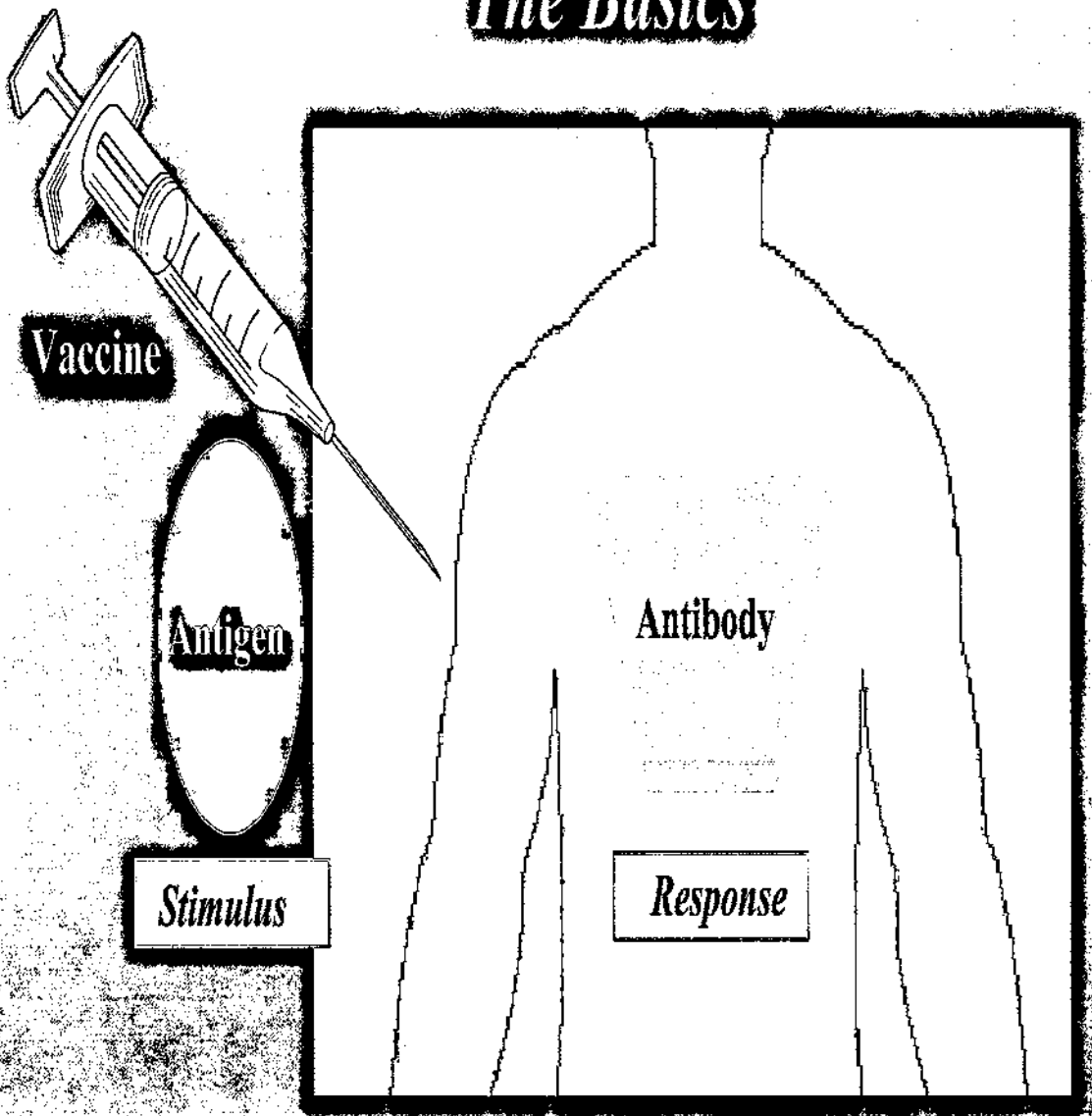
ANTHRAX BACTERIA ATTACK



= Death

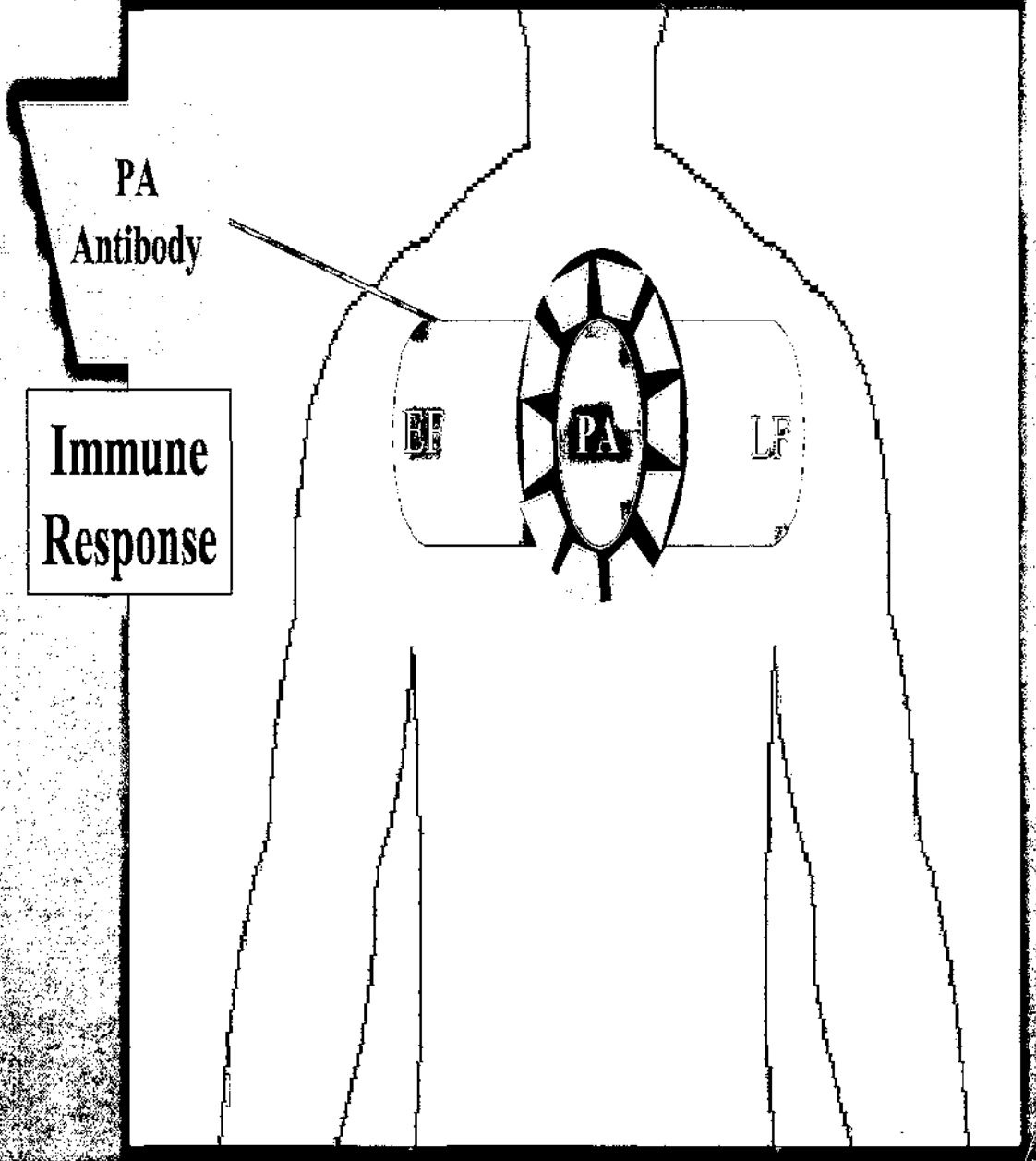
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



AFTER ANTHRAX VACCINE

Antibodies at Work



Immunizations

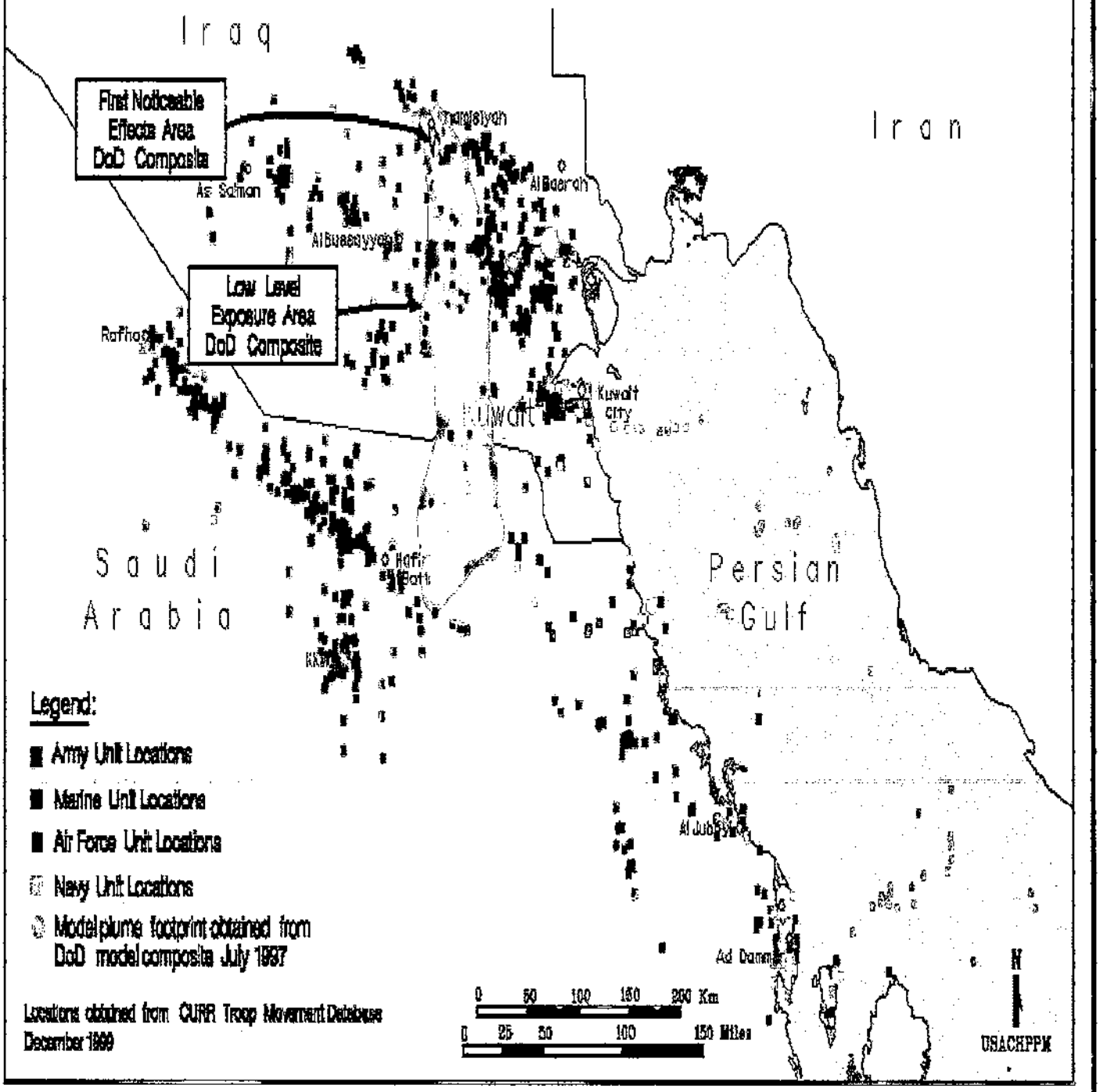
- Anthrax Vaccination program
  - Vaccine is FDA licensed since 1970 and proven safe
  - Only known protection against exposure
  - Necessary because of real threat
    - Easily produced and weaponized
- Current program statistics
  - Vaccine series 0, 2, 4 weeks; then 6, 12, 18 months; annual booster
  - 1,547,457 doses provided to 415,376 people (10 Mar 00)
    - 65 reactions resulted in loss of duty for less than 24 hrs.
    - 6 reactions resulted in hospitalization
      - All six were allergic, inflammation reactions

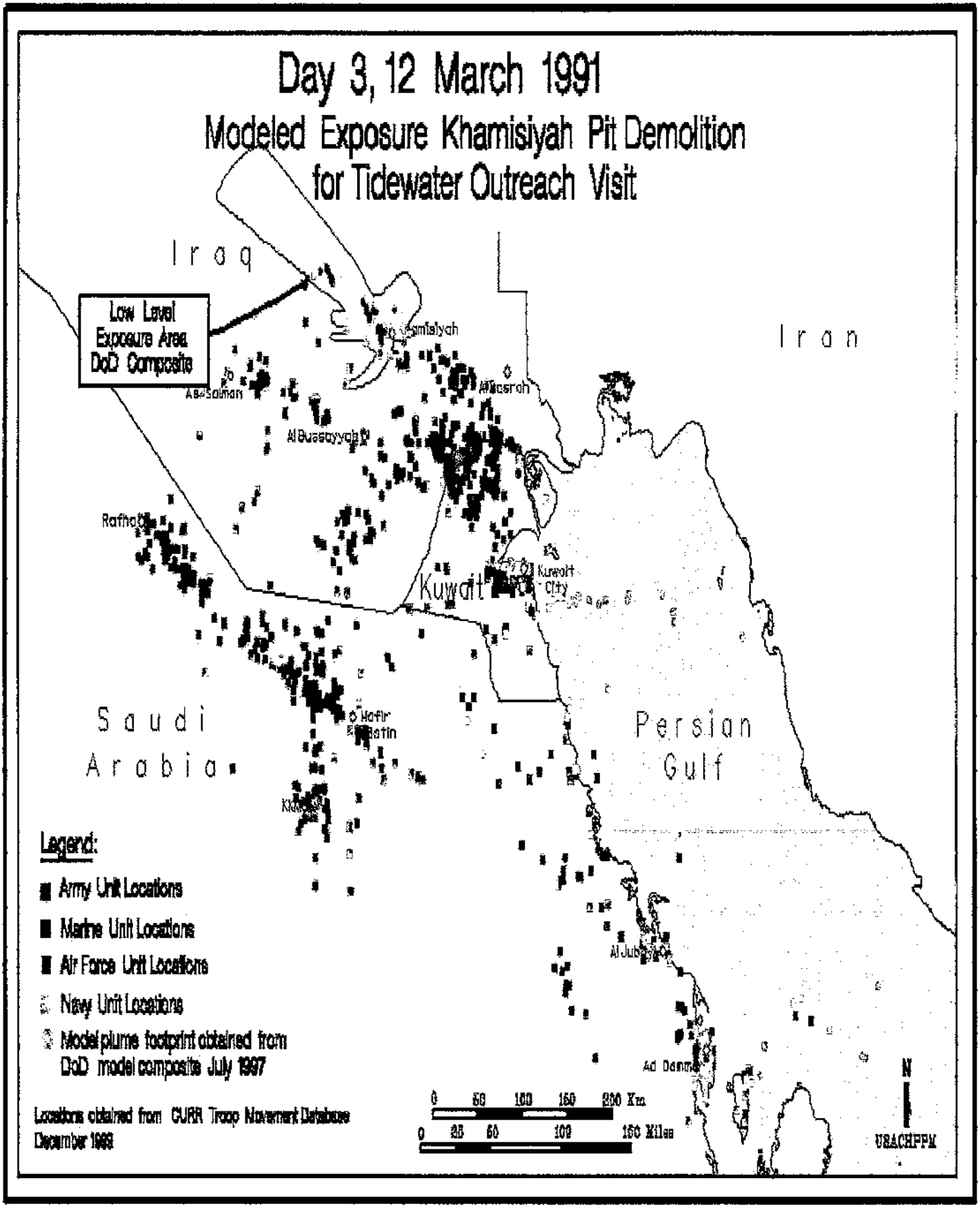
Anthrax information -- www.anthrax.osd.mil

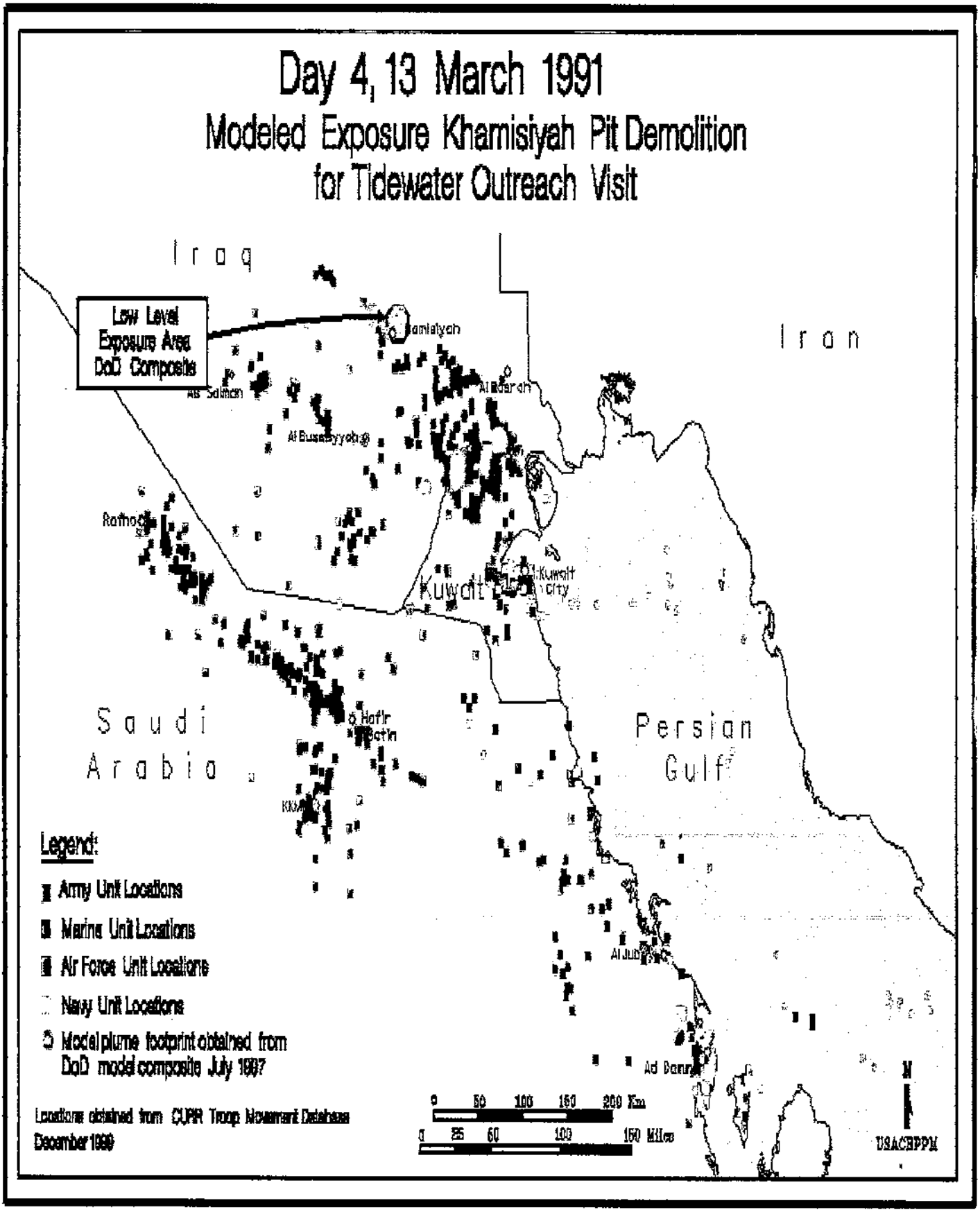
1-877-GET-VACC

Day 1, 10 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Tidewater Outreach Visit




Day 3, 12 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Tidewater Outreach Visit
Iraq
Low Level
Exposure Area
DoD Composite
Iran
Kuwait
Kuwait City
Saudi
Arabia
Persian
Gulf
Legend:
Army Unit Locations
Marine Unit Locations
Air Force Unit Locations
Navy Unit Locations
Model plume footprint obtained from
DoD model composite July 1997
Locations obtained from CURR Troop Movement Database
December 1998
0 50 100 150 200 Km
0 25 50 100 150 Miles
N
USACHPPM


Day 4, 13 March 1991
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Iraq
Iran
Low Level Exposure Area DoD Composite
Khamisiyah
As Salman
Al Basrah
Al Busayyah
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Kuwait
Kuwait City
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Locations obtained from CURR Troop Movement Database December 1999
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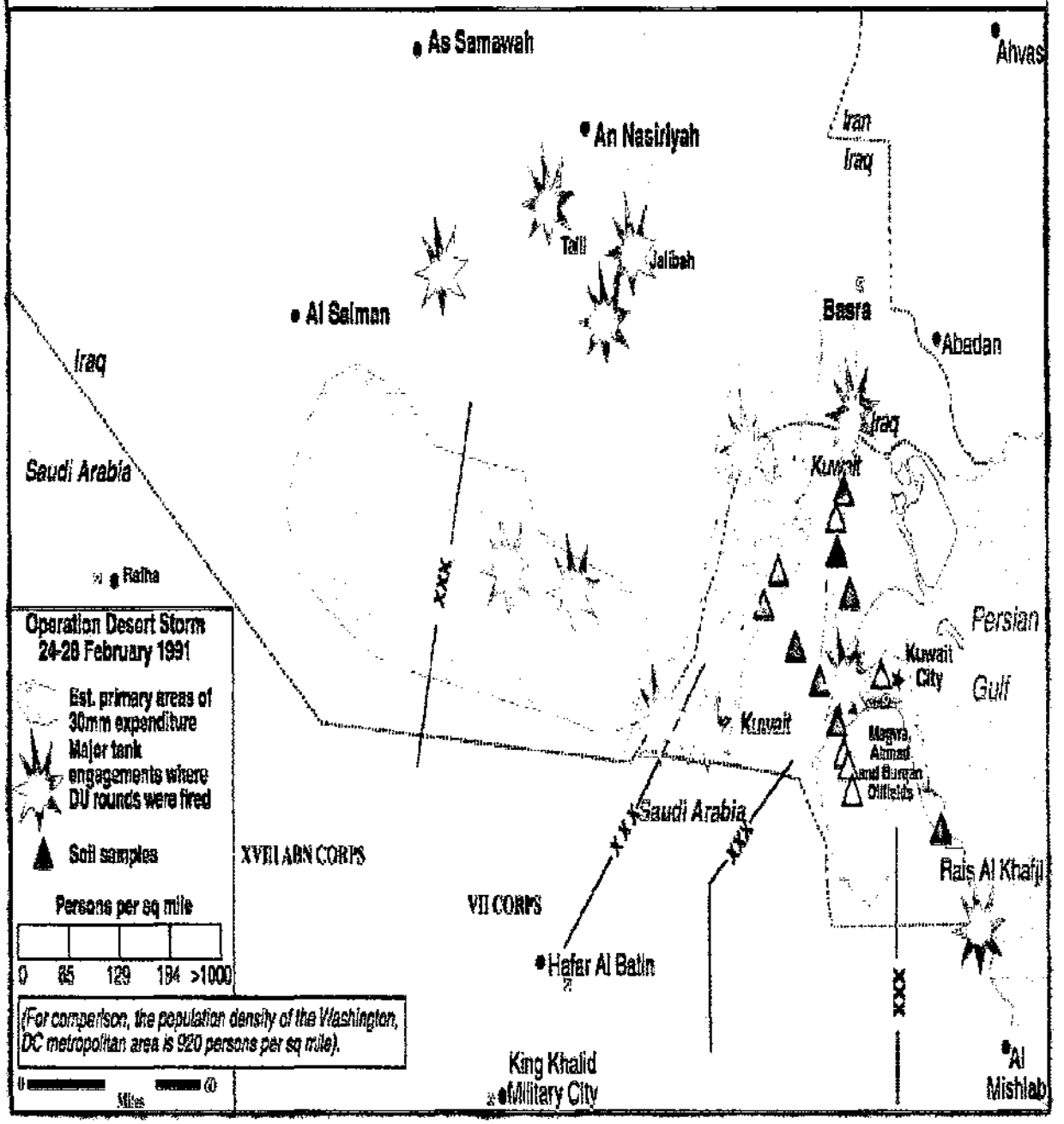
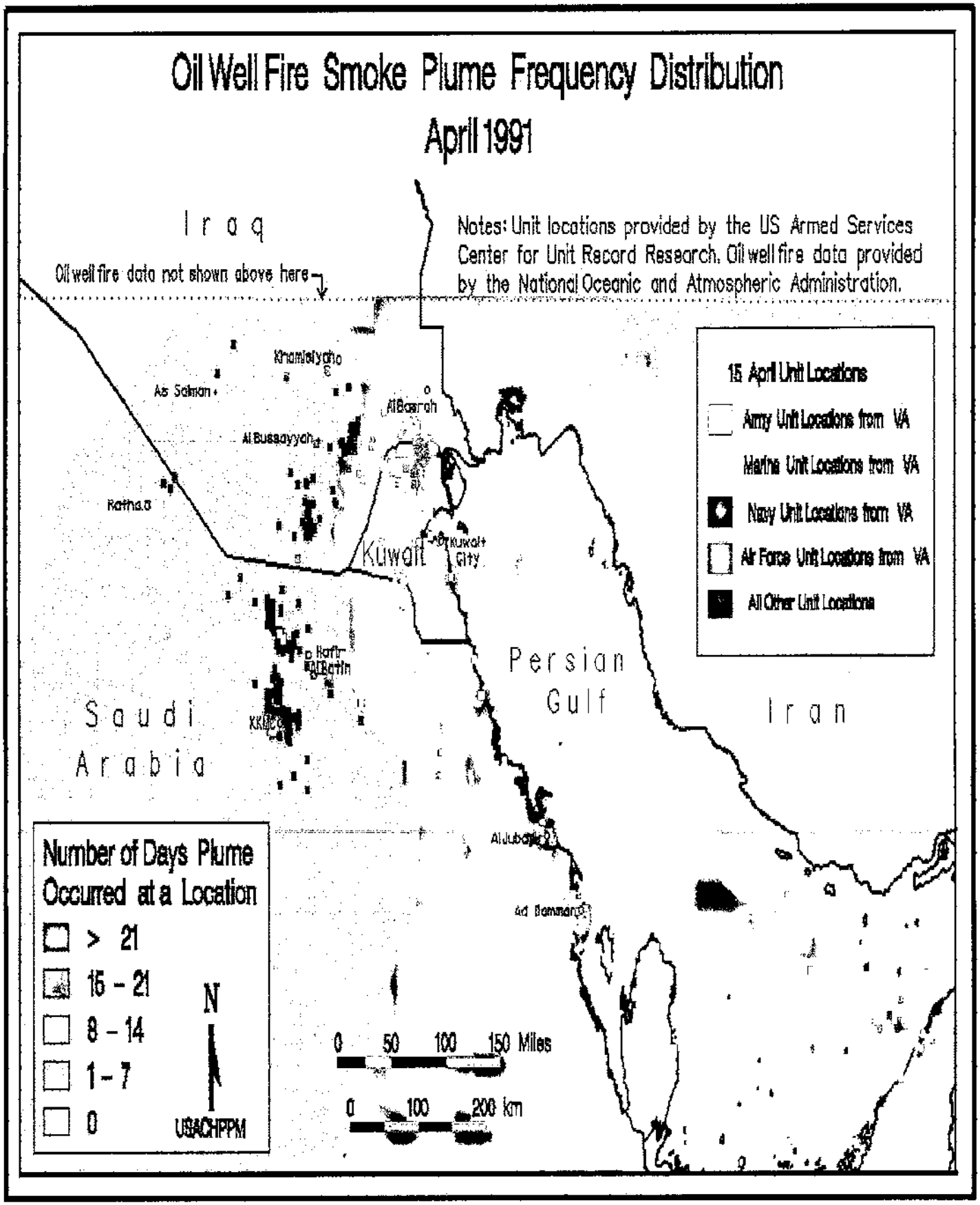
0 25 50 100 150 Miles
N
USACHPPM

Primary Areas of DU Expenditure



DU Exposure Issues

- Radiation
- Heavy metal toxicity
- Consequences of exposure
- Reproductive effect
- Contamination of theater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0 50 100 150 Miles
0 100 200 km

Force Health Protection-

A Joint Concept

Pre-deployment

- Verify DNA sample on file
- Pre-deployment blood sample
- Verify HIV test is current
- Verify immunizations are current
- Verify current physical exam
- Complete a health questionnaire

During deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

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- ~2,000 Documents Read
- ~1,000 Citations
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The American Society of
Tropical Medicine & Hygiene
Symposium 10

PROTECTING THE HEALTH OF DEPLOYED MILITARY PERSONNEL

Michael E. Kilpatrick, MD
Director, Deployment Health Support

CDR Michael McCarthy, MC, USN
Executive Officer, Naval Medical Research Center

Dr. Arthur Lee, Ph.D. P.E.
Senior Environmental Engineer, Deployment Environmental Surveillance Program
US Army Center for Health Promotion & Preventive Medicine

LTC Charles Engel, Jr., MD, MPH, MC, USA
Director, Deployment Health Clinical Center
Associate Professor of Psychiatry, Uniformed Services University

CDR Margaret Ryan, MC, USN
Director, DoD Center for Deployment Health Research

DEPLOYMENT HEALTH SUPPORT

TRICARE Management Activity
Office of the Assistant Secretary of Defense (Health Affairs)

Michael E. Kilpatrick, MD
Director

Phone: 703-578-8500 Fax: 703-578-8501
email: mkilpatr@gwillness.osd.mil

Deployment Health

- **Short Term Health Consequences**
  - Clinics, Hospitals
- **Long Term Health Consequences**
  - Locations, Exposures, Medical Records

The Gulf War

What Have We Learned ?

Lessons Learned from the Gulf War

- Information about health risks not always provided to Commanders
- Inconsistent dissemination of information on non-traditional issues

- Training on non-traditional threats and equipment capabilities varied
- Inconsistent health screening of troops before & after deployment
- Medical records a challenge

Summary of Research Results
Gulf War Veterans

- Medically undiagnosed physical symptoms more frequent (2-3 times) in Gulf War veterans (British, Canadians, Americans)
- No new syndrome or set of symptoms unique to Gulf War veterans
- No increase in rates of:
  - Diagnosed diseases
  - Hospitalizations
  - Deaths
  - Birth defects

Guiding Principles

To preserve the health of deployed forces, we believe:

- Lessons learned must be implemented at all levels to avoid mistakes in future deployments.
- Openness is essential in earning the trust of our personnel, their families and the American public.
- A fit and healthy force must have information that promotes an understanding of potential health threats and ensures preventive action.
- Feedback from those deployed is key to understanding health related incidents.

Force Health Protection

Pre-Deployment

- Health Promotion
- Immunizations Current
- Medical Threat Briefing
- Environmental Threat
- Health Assessment Surveys
- Risk Communication

Deployment

- Environmental & Medical Surveillance
- Food and Water Inspections
- Industrial/Occupational Surveillance
- Risk Communication

Post-Deployment

- Medical & Environmental Surveillance Debriefing
- Medical Debriefing
- Health Assessment Surveys
- Risk Communication

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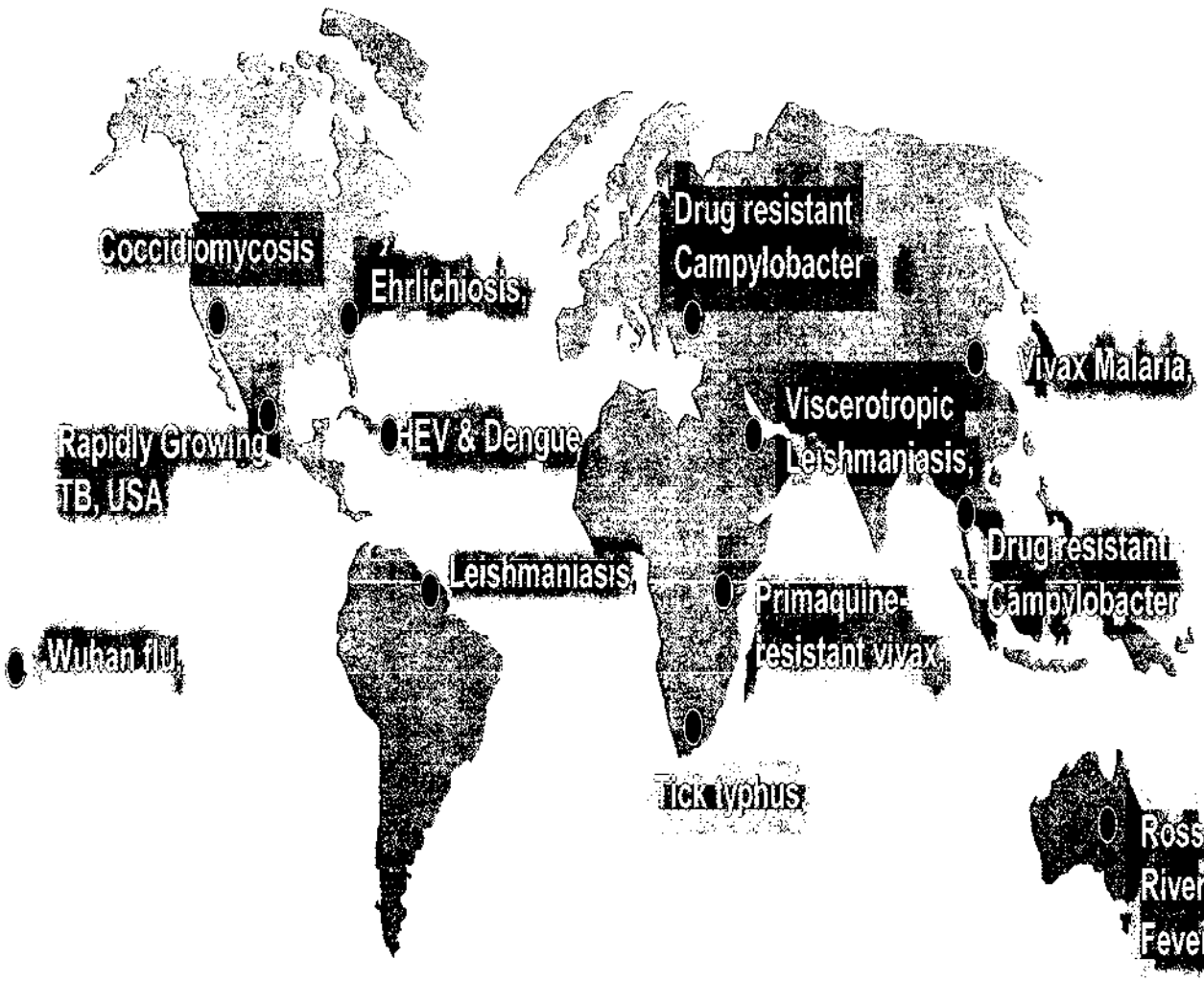
A coordinated, joint-service program to facilitate the early recognition and control of emerging and reemerging infectious disease threats

- THERE HAS BEEN A DETERIORATION IN THE LOCAL PUBLIC HEALTH INFRASTRUCTURES THAT MONITOR AND RESPOND TO DISEASE OUTBREAKS

- THE U.S. SHOULD LEAD THE EFFORT TO FORGE AN INTERNATIONAL PARTNERSHIP TO ADDRESS EMERGING INFECTIOUS DISEASES SINCE WE ARE AT THE FOREFRONT OF COMPUTER COMMUNICATIONS AND BIOMEDICAL RESEARCH

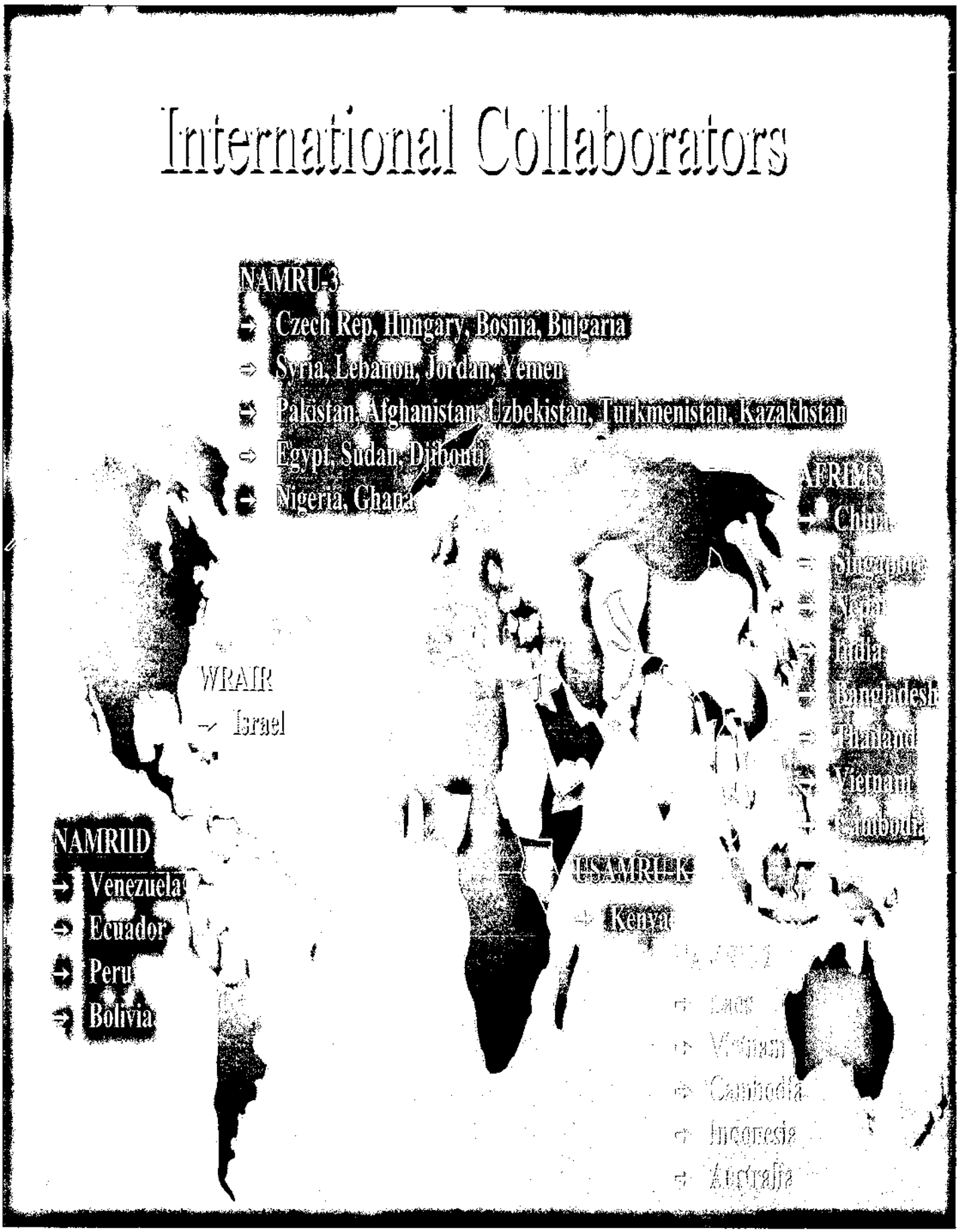
"The mission of DoD will be expanded to include support of global surveillance, training, research, and response to emerging infectious disease threats.

?


Coccidiomycosis
Ehrlichiosis
Drug resistant Campylobacter
Vivax Malaria
Rapidly Growing TB, USA
HEV & Dengue
Viscerotropic Leishmaniasis
Drug resistant Campylobacter
Leishmaniasis
Primaquine-resistant vivax
Wuhan flu
Tick typhus
Ross River Fever

- Extensive Infectious Disease Expertise
- World-Wide State-of-the-Art Communications
- Cutting Edge Field Diagnostic Reagents
- Special Drugs and Vaccines
- Globally Deployed Forces Under Medical Surveillance

International Collaborators



Regional Hubs for Sentinel Surveillance Networks

Response to outbreaks

Training of local nationals and US public health personnel

Building Global Capacity

- New and Emerging Infections
- Malaria
- Enteric Infections
- Dengue and Hemorrhagic Fever Viruses
- Rickettsia
- HIV-1
- Experimental Therapeutics

- Drug-resistant malaria
- Antibiotic-resistant enteric pathogens
- Influenza
- Hemorrhagic and other febrile infections

- Goal is to promote, facilitate, and coordinate the development of public health infrastructure

- Objective is the establishment of laboratory-based sentinel surveillance networks for emerging infectious diseases

- Ministries of Health
- US State Department
- CDC, NIH, USAID, NASA, FDA, USDA
- WHO, PAHO, UNAIDS
- Public and Private Universities

- Strengthens internal, DoD, host nation, and regional infrastructure
- Focuses on transfer of epidemiologic and microbiologic skills for locally supportable surveillance
- Facilitates replication of uniform surveillance procedures at other sites and subsequently enhanced data pooling
- Facilitates timely recognition and collaboration in outbreak control

- Improves medical threat assessments
- Enhances control of pandemic influenza and drug-resistant organisms
- Identifies relatively unusual infectious threats to troops
- Helps prevent epidemics during mobilization and training
- Helps prevent destabilizing effects on foreign governments
- Reduces post-deployment EID importations (esp. nosocomial spread)
- Reduces demand for costly humanitarian assistance
- Validates the effectiveness of preventive measures

The American Society of
Tropical Medicine & Hygiene
Symposium 10

PROTECTING THE HEALTH OF DEPLOYED MILITARY PERSONNEL

Michael E. Kilpatrick, MD
Director, Deployment Health Support

CDR Michael McCarthy, MC, USN
Executive Officer, Naval Medical Research Center

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Associate Professor of Psychiatry, Uniformed Services University

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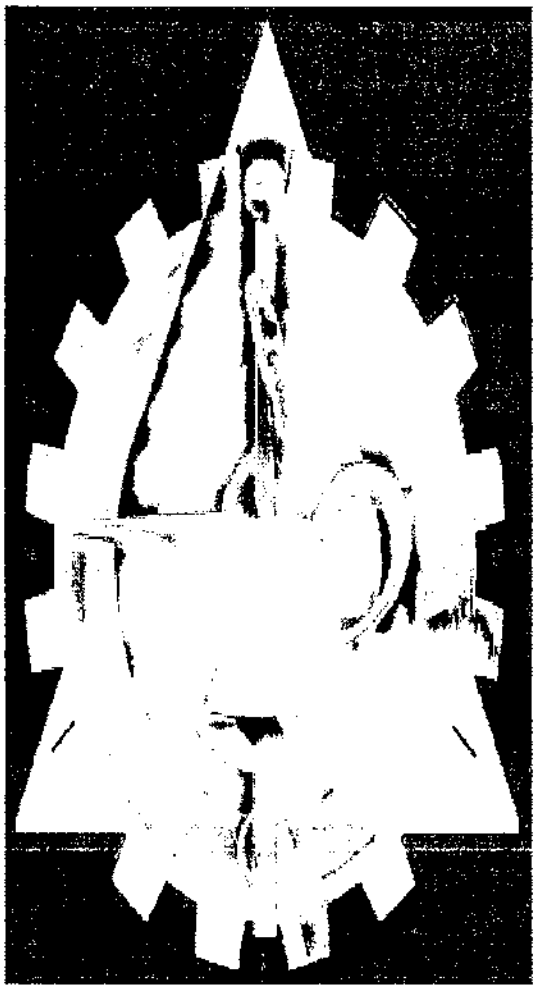
Director, DoD Center for Deployment Health Research

Deployment Occupational and Environmental Health Surveillance



Arthur Lee, Ph.D., P.E.

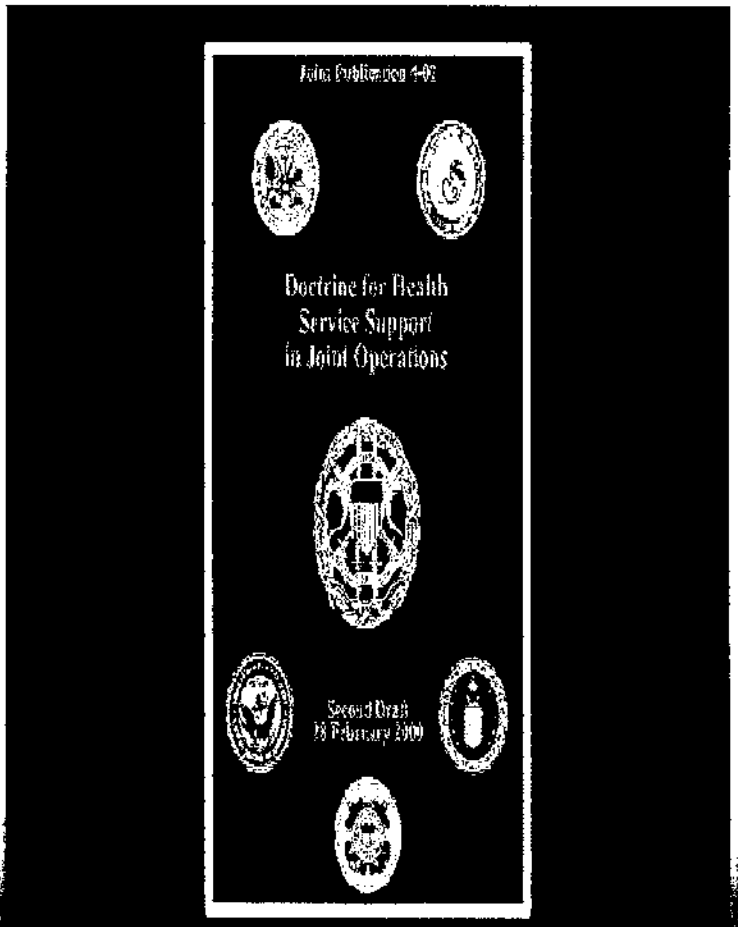
US Army Center for Health Promotion and Preventive Medicine

Deployment Occupational and Environmental Health Surveillance

- Policies & Doctrine
- Joint Environmental Surveillance Working Group
- Current Activities
- Challenges

USACHPPM
Readiness thru Health

DOD Policy/Doctrine



DOD Policy

- DOD-I 6490.3-Implementation and Application of Joint Medical Surveillance for Deployments, Aug 97
- DOD- 6055.1, Safety and Occupational Health Program, Aug 98
- JCS Memorandum MCM-251-98, 04 DEC 98, "Deployment Health Surveillance and Readiness," (Under Revision, 1 Oct 01)
- JCS Force Health Protection Capstone Document, Jan 00
- Presidential Review Directive #5, Force Health Protection, Aug 98

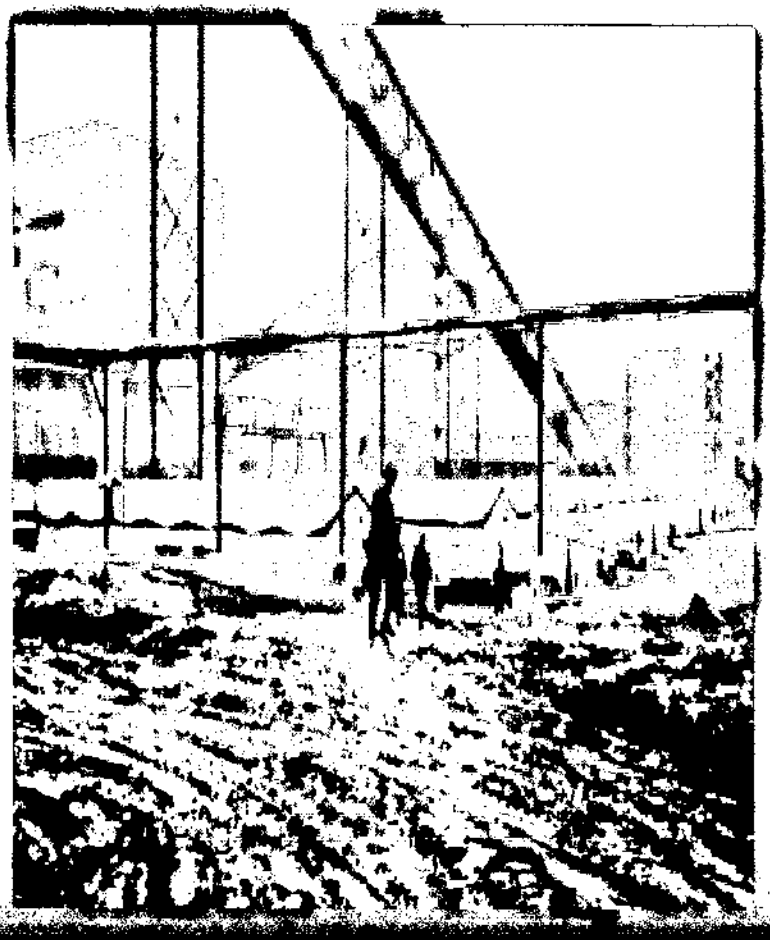
Joint Doctrine

- Joint Publication (JP) 4.04 - Joint Doctrine for Civil Engineering Support (under revision)
- JP 4.02 - Joint Doctrine for Health Service Support in Joint Operations (Aug 2001)
- JP 3.11 - Joint Doctrine for Operations in Nuclear, Biological, and Chemical (NBC) Environments, 11 Jul 00

- Common Theme: *"identify and assess potential hazards, and evaluate and document actual exposures....."*

USACHPPM
Readiness thru Health

Army Policy/Doctrine



Army Policy

- HQDA Policy –FHP Deployment OEH Threats, Jun 01
- Draft – Joint Service Instruction for Deployment Health Surveillance and Protection, Fall 99

Army Doctrine

- FM 3-0, OPERATIONS, Jun 01
- FM 100-14, Risk Management, Apr 98
- FM 8-10, Combat Health Support, Mar 91
- FM 4-02.17, Preventive Medicine Services, Aug 00
- FM 21-10/MCRP 4-11.1D, FIELD HYGIENE AND SANITATION, Jun 00
- FM 3-100.4, Environmental Considerations in Military Operations, Jun 00
- FM 3-11.4-1, Multi-service Procedures for NBC Defense Of Theater Fixed Sites, Ports, and Airfields, FCD Apr 00

*FM 3-0: "**Combat health support.** Maintain the force by preventing disease nonbattle injury casualties*

USACHPPM

DA Policy

Applicable to:

- The accidental or deliberate release of non-weaponized Toxic Industrial Materials (TIMs), hazardous physical agents, ionizing and non-ionizing radiological hazards
- Environmental contaminants to include vector- and arthropod-borne threats, and residues naturally occurring or from US forces activities, non-US military forces, local national governments, or local national activities.
- The TIMs or hazardous physical agents currently being generated as a by-product of the activities of US forces or other concerns

DA Policy Key Elements

Commanders are required:

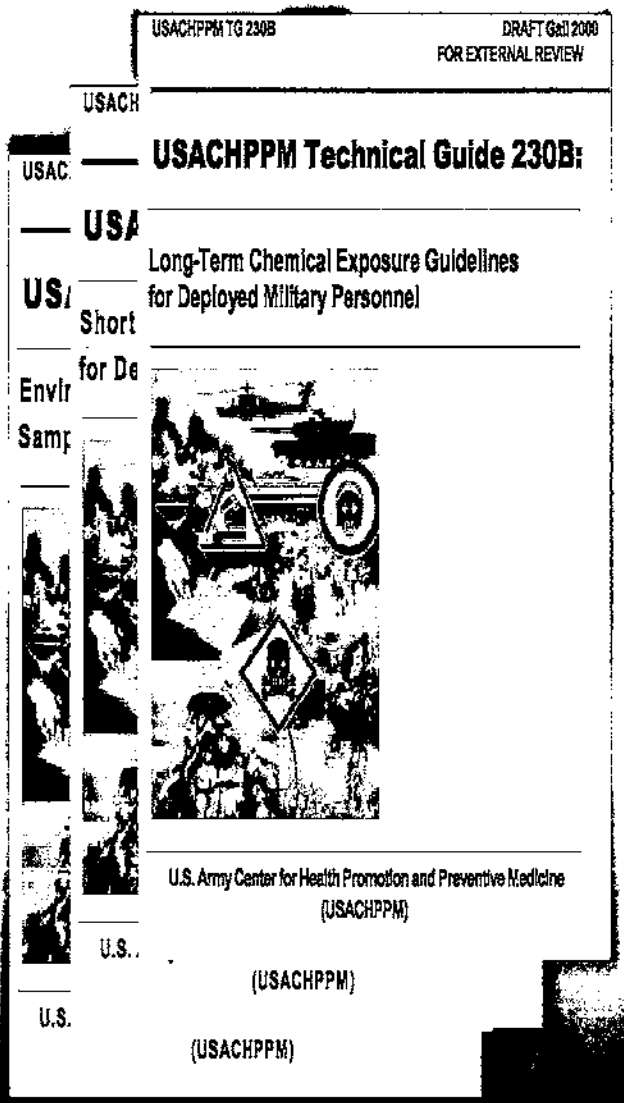
- To adhere, in non-deployed situations, to Federal, State, and host nation statutory and regulatory laws
- To adhere, in deployed situations, to garrison OEH standards, so far as the tactical situation permits.
- To use the ORM process to minimize the total risk to personnel
- To consider both short-term and long-term health risks to personnel
- To ensure that any decisions to override peacetime regulatory occupational and environmental health standards are documented, archived and reevaluated on a recurring basis.

Joint Environmental Surveillance Workgroup

- Formed at the direction of the Joint Preventive Medicine Policy Group to:
  - review, develop, and recommend functional aspects of environmental surveillance policy.
- Executive Membership:
  - U.S. Army Center for Health Promotion and Preventive Medicine
  - US Air Force Institute for Environment, Safety and Occupational Health Risk Analysis
  - U.S. Navy Environmental Health Center
  - Armed Forces Medical Intelligence Center
  - J-4 Medical Readiness Division

USACHPPM

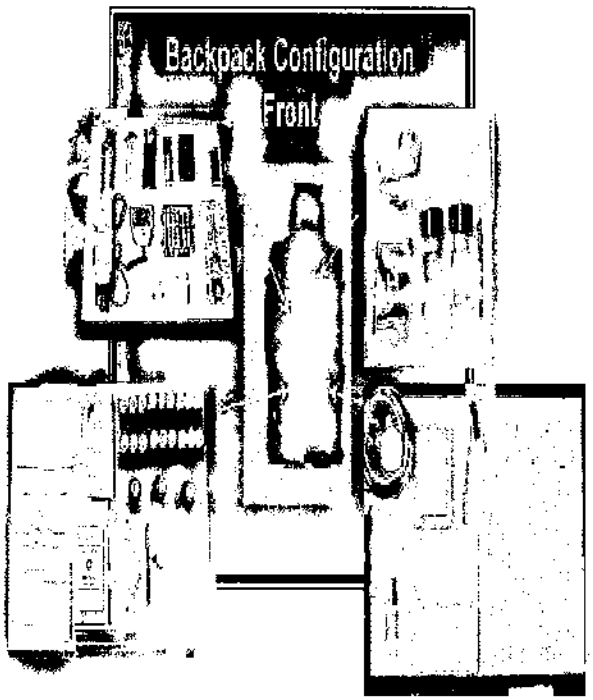
OEH Risk Assessment Guidance

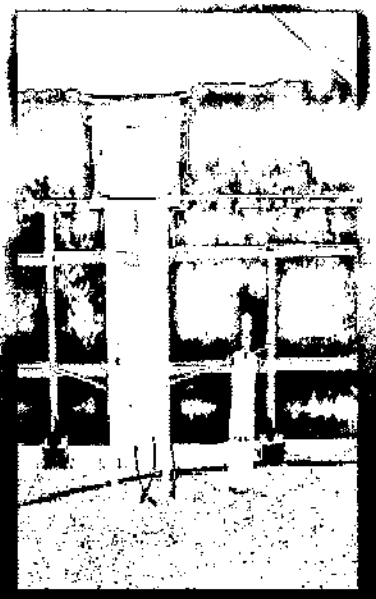


- TG 230 -Deployment Chemical Exposure Guidelines
  - 1 hour-2 weeks) – Final May 99
  - (1 year) – Draft Jun 00/Final Oct 01
- TG-238: Radiological Sources of Potential Exposure and/or Contamination, Final Jun 99
- TG-236A: Basic Radiological Dose Estimation- A Field Guide, Final Aug 01
- TG-239: Radiological Health Risk Assessment, Draft Jan 01/Final Sep 01.
- TG-236B (RD-236B): Advanced Radiological Dose Estimation (Draft 4QFY01/Final FY02)
- TG 251: Deployment Environmental Surveillance Sampling Guide, Draft Aug 01/Final Dec 01
- TG 248 – Guide for Deployed Military Personnel on Health Hazard Risk Management, Aug 01

USACHPPM
Readiness thru Health

Materiel/Training Initiatives

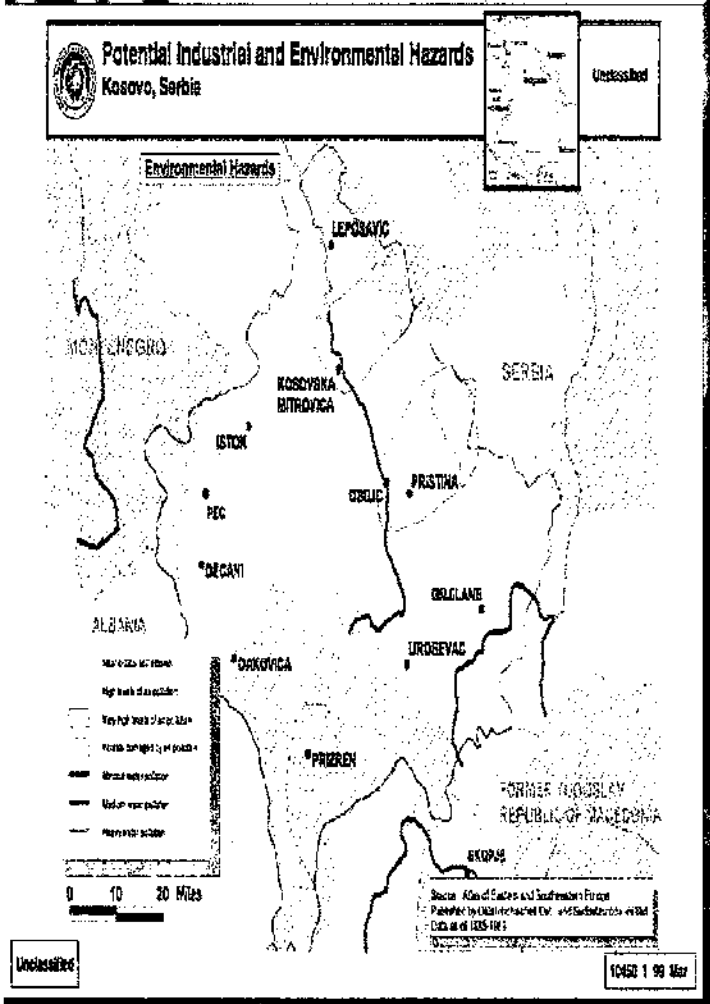




- Assessing COTS equipment for deployment use.
- Adapting laboratory analytical methods to minimize sample requirements.
- Providing "push packages" for deployable units.
- Training deploying personnel on equipment use.

USACHPPM
Readiness Ever Ready

Operation Joint Guardian
Environmental Intelligence

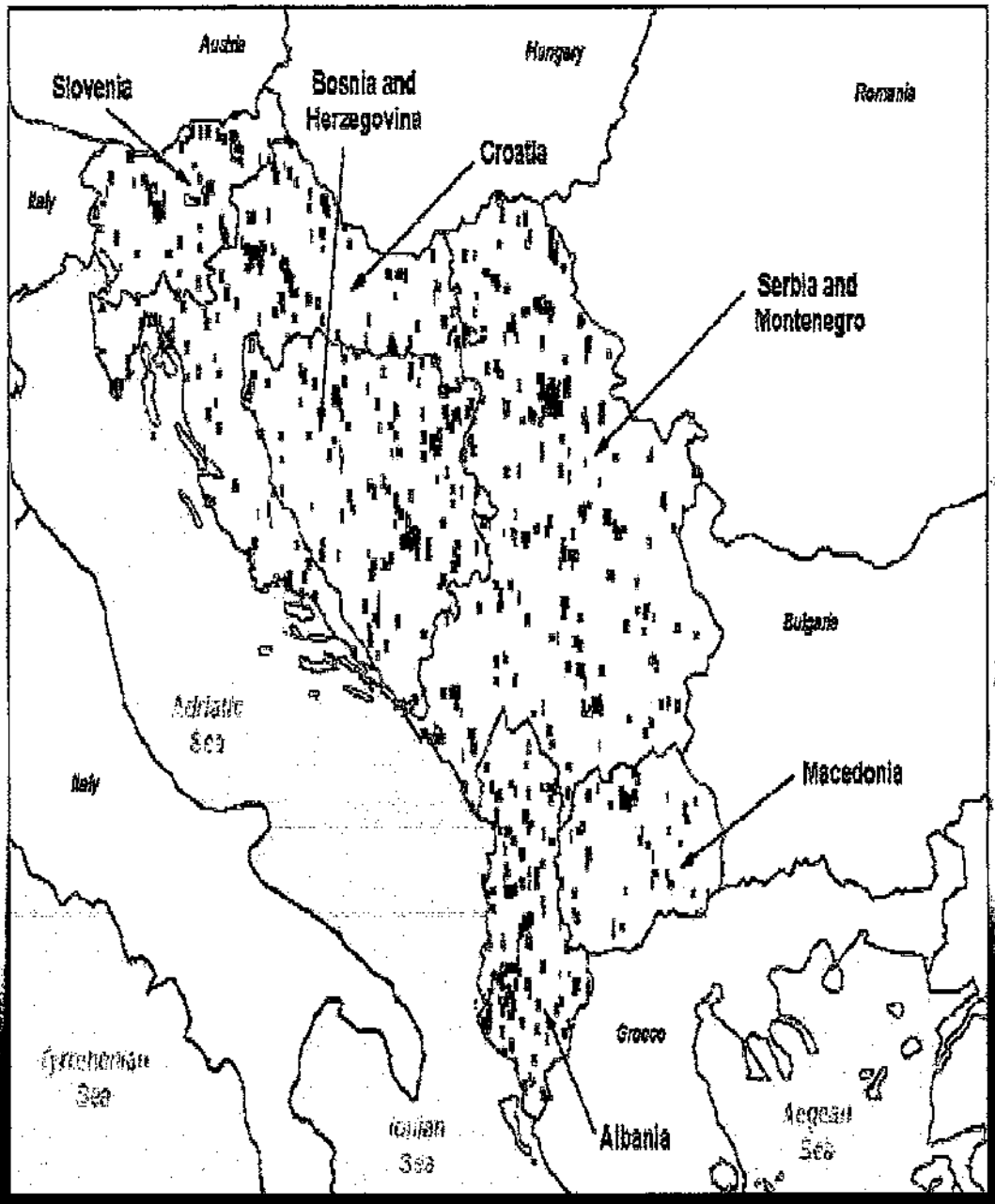


PRODUCTS:

- (U) Potential Industrial and Environmental Hazards of Operational Significance in Kosovo Province, Serbia (U), 24 Mar 99, AFMIC
- (U) Preliminary Industrial Hazard Assessment, Kosovo, Serbia, 30 Apr 99, USACHPPM.
- (U) Recommended Initial Entry Environmental Health Guidance, Operation Joint Guardian, 14 Jun 1999, USACHPPM

USACHPPM

Catastrophic Toxicological or Physical Hazard Industrial Sites Balkan States



Hazard Type

- Toxicological
- Physical
- Toxicological & Physical

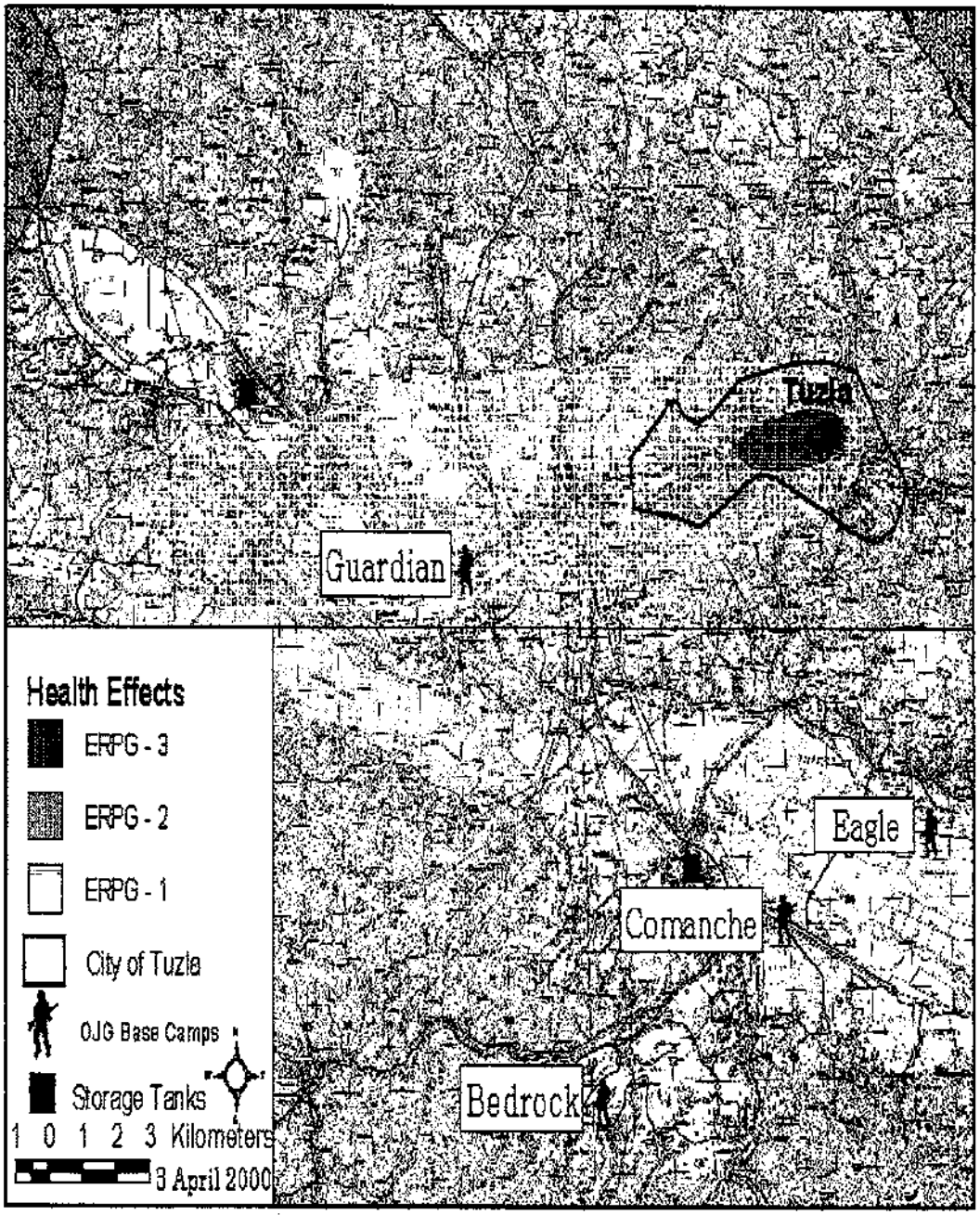
Source: DI-1816-8-99: Medical Intelligence Assessment of Deployment Environmental Risks, Jan 99

Overview of the NBC Threat from Toxic Industrial Materials

Operation Joint Guard (OJG)

Hypothetical Chlorine Gas Release in Tuzla

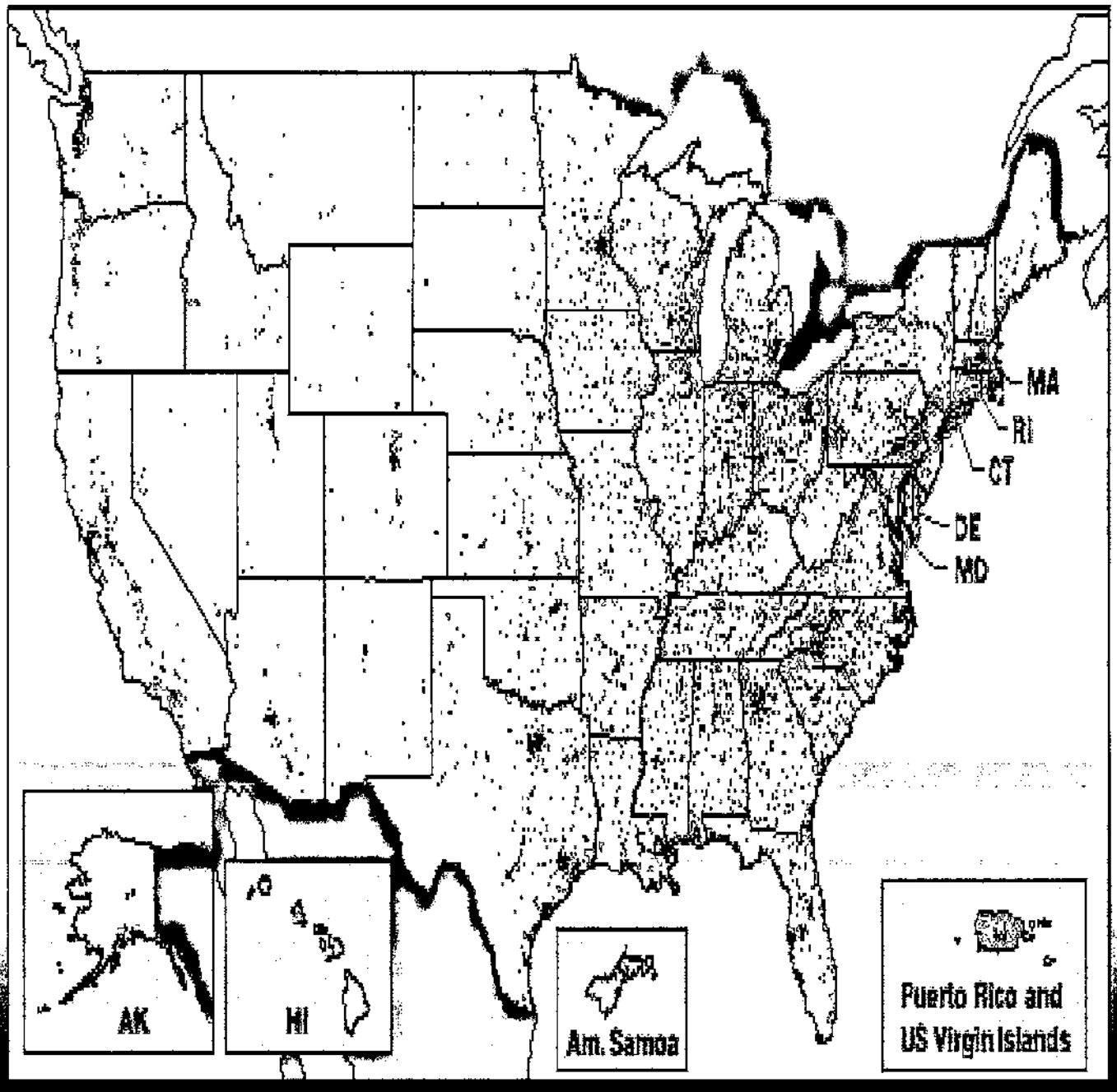
30 January 1998



NIMA ADRGs ARC7NL3443 and ARC7NL3450. OJG Base Camp Locations provided by USACHPPM.
Hypothetical Cholirne Gas Plume is chlorine concentration, date and weather condition specific.

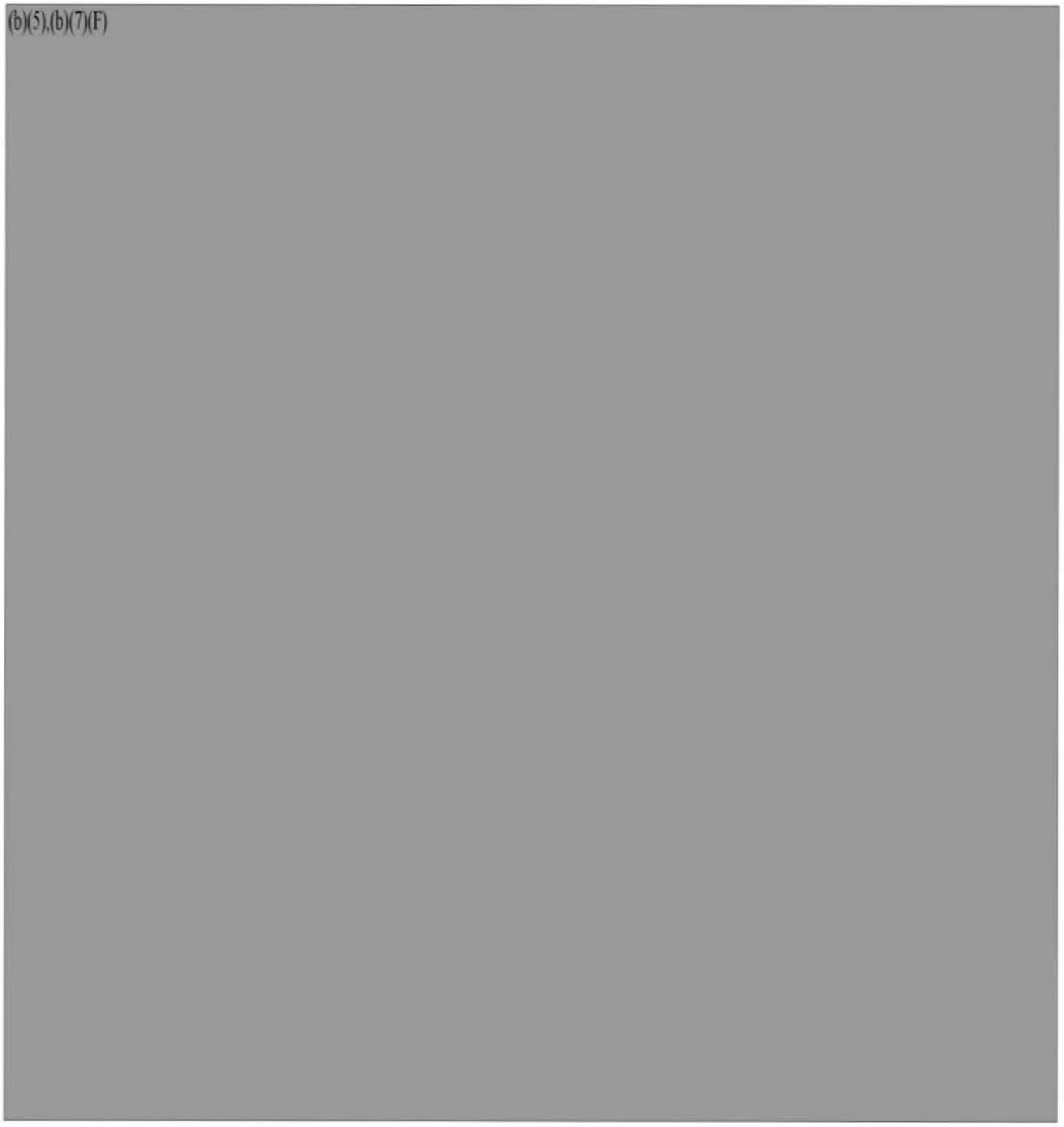
Overview of the NBC Threat from Toxic Industrial Materials

Toxic Chemical Releases from US Manufacturing Facilities

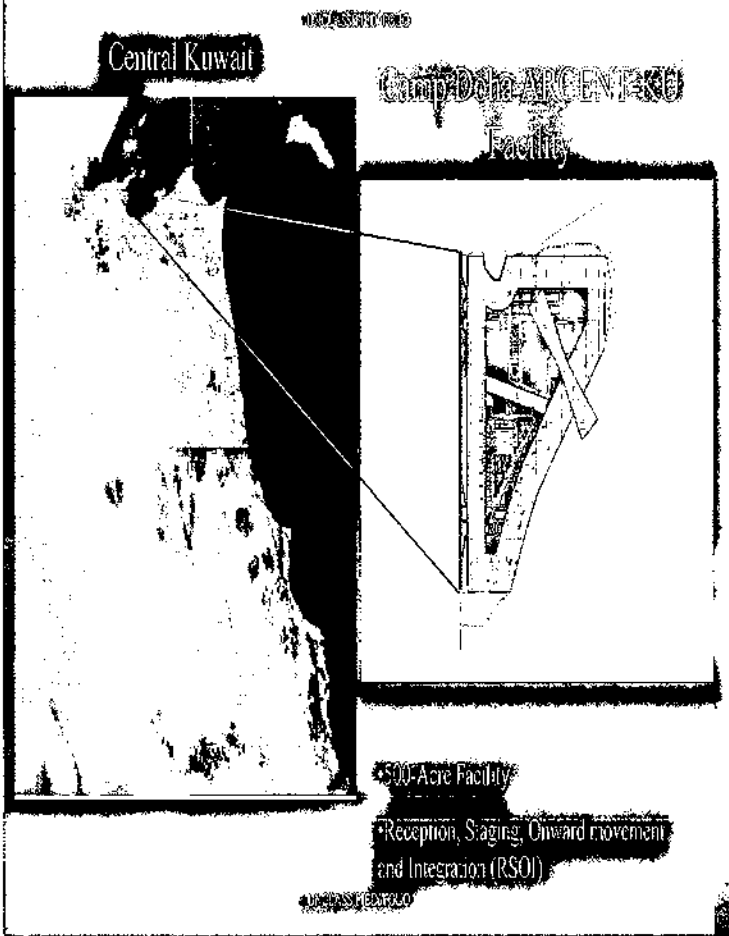


Source: Environmental Defense Scorecard, www.edf.org

Hypothetical Release
16,000 lbs of Chlorine from Cross Creek Water Reclamation Facility RMP
0800, 16 March 2000 ~~(For Official Use Only)~~



Operation Southern Watch
Camp Doha, Kuwait



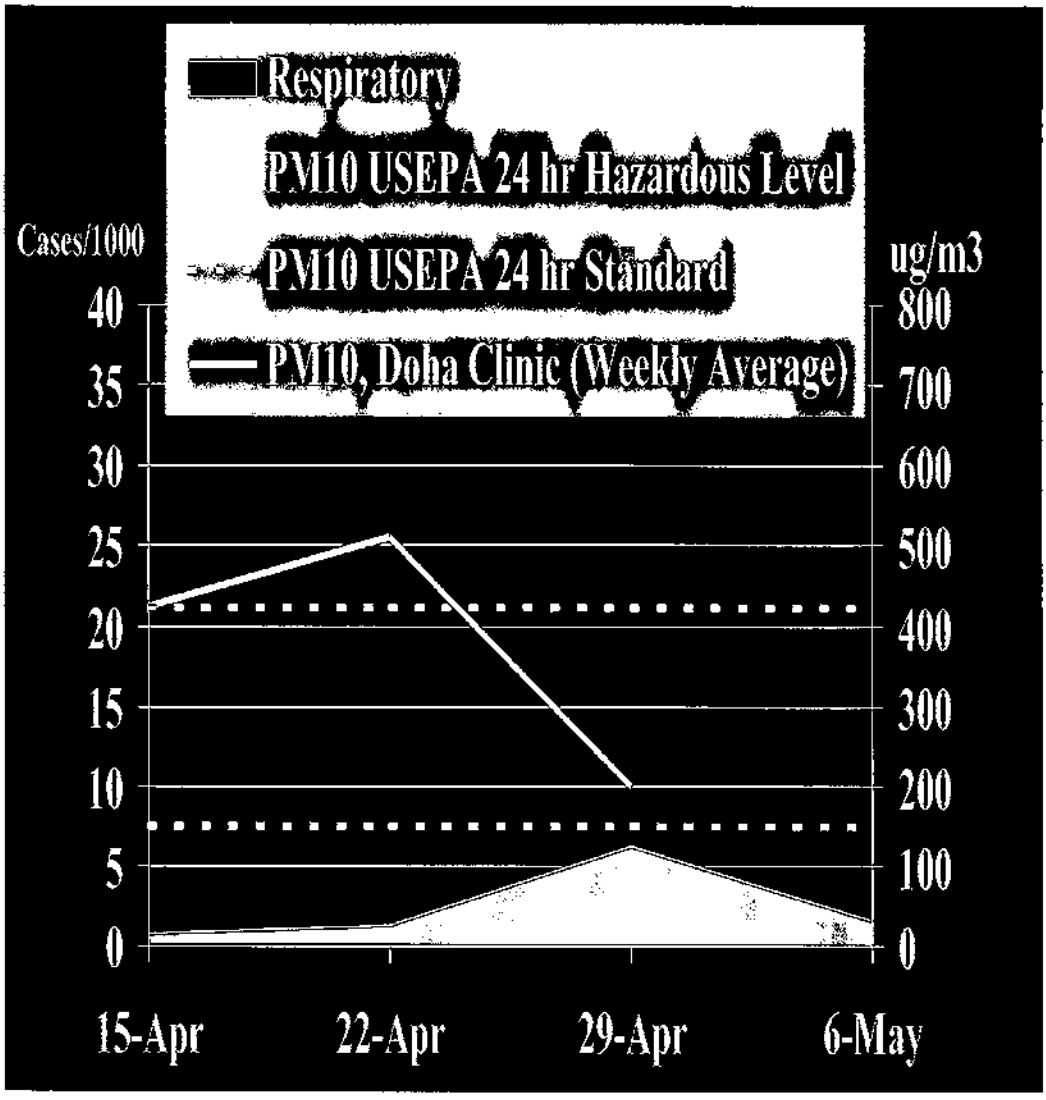
- All measured gaseous pollutant levels are below USEPA and DOD guideline levels
- Measured PM levels are above USEPA 24-Hour Standard (150 ug/m3)
- Two measured PM10 levels above 24-Hour USEPA hazardous level (425 ug/m3)
- Heavy Metals below Military Air Guidelines – Long Term
- AFIERA DNBI Comparison

USACHPPM
Readiness thru Health

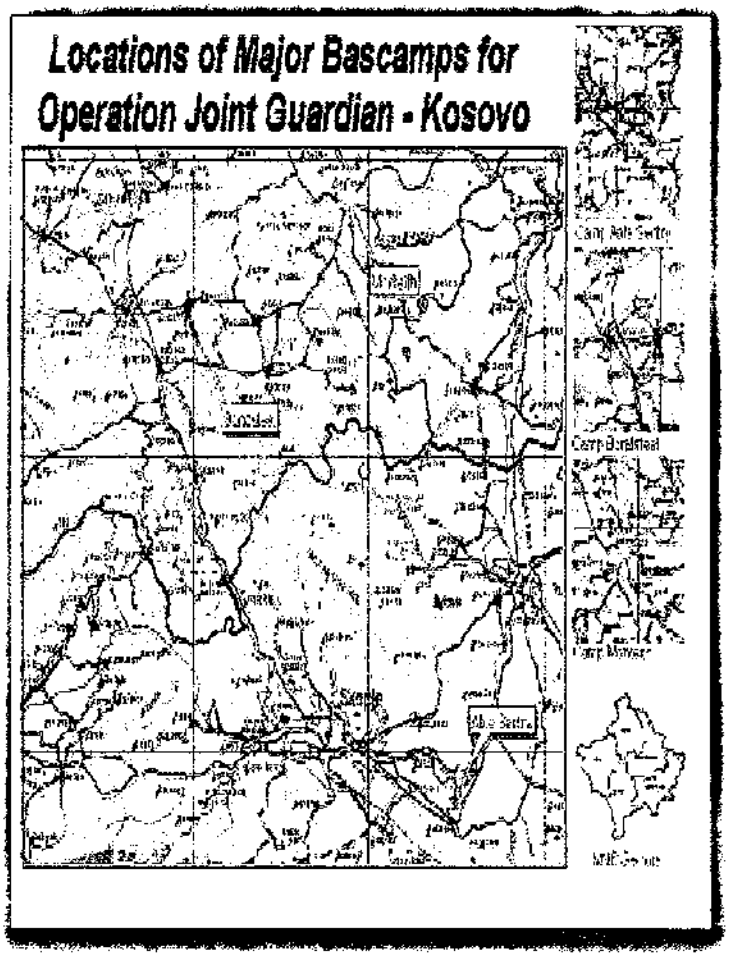
SWA

PM_{10} and Respiratory Illness

Doha Clinic



Operation Joint Guardian Interim Findings



- Deployment OEH Risks are Low (in US Sector)
- DOEH Surveillance at other USAFOR locations underway
- Unit location from Task Force Falcon SITREPS via SIPRNET.
- Recommend continuing OEH surveillance.

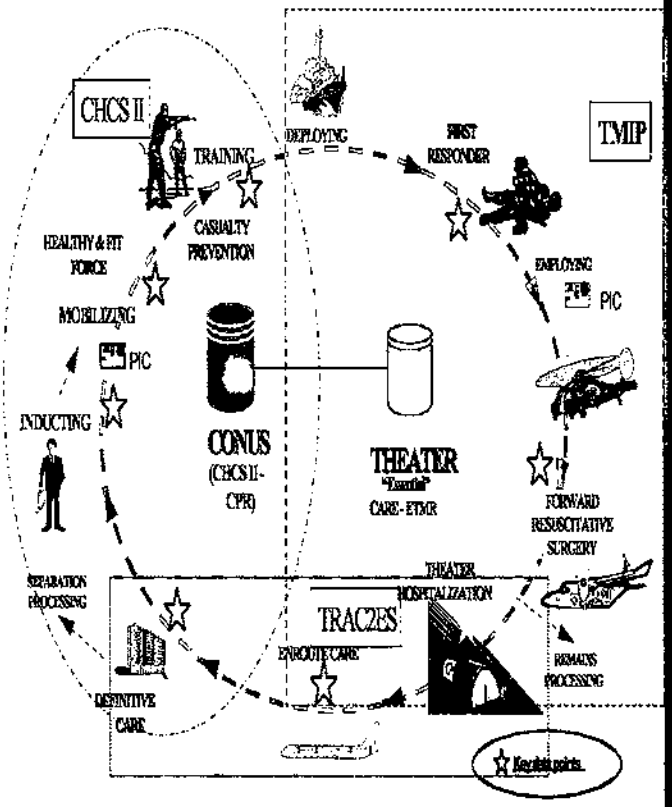
- On-going DOEH Surveillance at main US Locations by deployed PM units and CHPPM personnel.

USACHPPM
Readiness thru Health

IM/IT Strategy

- **Fundamental Strategy: Incorporate Deployment OEHS requirements into existing DOD Military Health Systems (DOEHRS/TMIP)**
- Accomplishments/Tasks:
  - Deployment OEHS Functional requirements Provided to DOEHRS/TMIP 4QFY98).
  - Use DOEHRS Data Warehouse (2QFY02)
  - MOU between TMIP/DOEHRS for ITDB archiving
  - Include Deployment OEHS in Block 2/3 TMIP
    - Build data bridge between Block 1 TMIP (REOHM) and DOEHRS Data Warehouse

Force Health Protection
Medical Operational Continuum



USACHPPM
Readiness thru Health

Challenges

- Providing operational support w/current OPTEMPO.
- Requires a comprehensive DTLOMS approach.
- Needs to be integrated with NBC Defense
- Requires robust, deployment IM/IT solution.
- Unit/Personnel Location Issue
- Linked w/Health Outcomes System (Environmental Epidemiology)
- Impact of PRD-5, Public Law 105-85 ("Low-level exposures)

USACHPPM
Readiness thru Health

Deployment Occupational and Environmental Health Surveillance

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- CAPT Richard Thomas, NEHC, 757.462.5567, thomasr@nehc.med.navy.mil
- LTC David Gibson, 210-536-1503, David.Gibson@brooks.af.mil
- MAJ Brian Balough, J-4, Medical Readiness Division, 703.693.5105, Brian.Balough@js.pentagon.mil
- Dr. Robert Garrett, AFMIC, 301.619.3832, rgarrett@afmic.deterick.army.mil

USACHPPM
Readiness thru Health

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PROTECTING THE HEALTH OF DEPLOYED MILITARY PERSONNEL

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Associate Professor of Psychiatry, Uniformed Services University

CDR Margaret Ryan, MC, USN
Director, DoD Center for Deployment Health Research

In Return For Their Sacrifice

Optimizing the Continuum of Post-Deployment Care

Charles C. Engel, Jr., M.D., M.P.H.

Lieutenant Colonel, Medical Corps, U.S. Army
Associate Professor of Psychiatry, Uniformed Services University
Director, Deployment Health Clinical Center, Walter Reed Medical Center

DoD Deployment Health Clinical Center

After the Gulf War
Health Problems Among Veterans

GW veterans, compared to era-veterans show:

- ❑ No significant increase in mortality due to disease up to '99.

  Writer et al, JAMA 1996; 275:118-121
  Kang & Bullman, NEJM 1996; 335:1498-1504
  Kang, 1999 Gulf War Investigators' Meeting, Pentagon City, VA

- ❑ No consistently increased incidence of DoD hospitalizations.

  Gray et al, NEJM 1996; 335:1505-13
  Knoke & gray, Emerg Infect Dis 1998; 4(2):211-19

- ❑ Significantly increased prevalence of physical symptoms and symptom syndromes

  MMWR 1995; 44(23):443-447
  Iowa Persian Gulf Study Group, JAMA 1997; 277:238-245
  Unwin et al, Lancet 1999; 353(9148):169-78

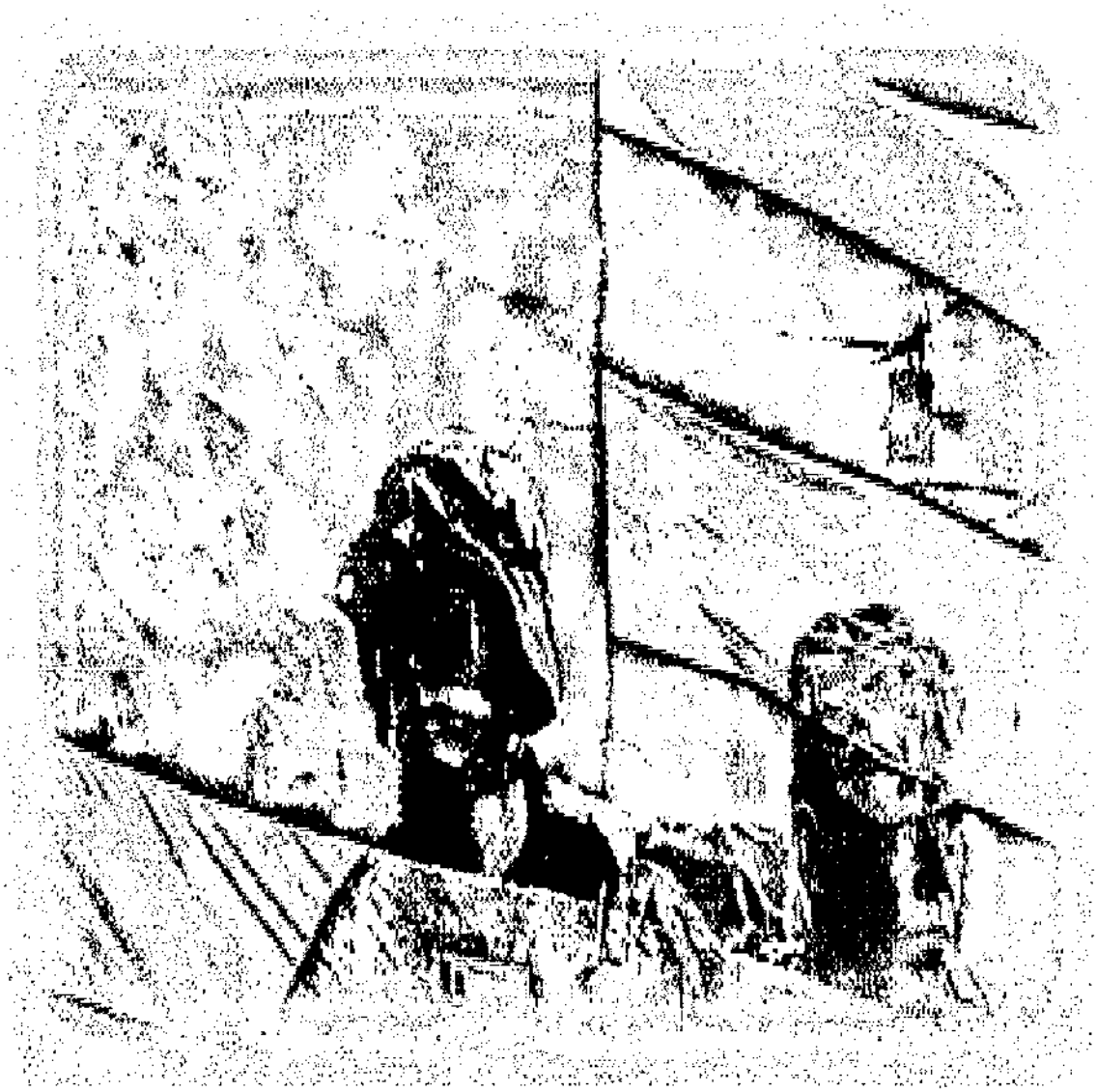
- ❑ Significantly decreased health-related quality of life

  Iowa Persian Gulf Study Group, JAMA 1997; 277:238-245
  Unwin et al, Lancet 1999; 353(9148):169-78

Gulf War Health Center

Caring for America's Finest

Walter Reed Army Medical Center



A Unique Phenomenon?
War Syndromes and Their Evaluation

- "Poorly understood war syndromes have been associated with armed conflicts since at least the US Civil War."

- "...war syndromes have involved fundamental, unanswered questions about the importance of chronic somatic symptoms..."

Hyams et al. *Ann Intern Med* 1996;125:398

Some Common Elements

- War, deployment or disaster
- Symptoms & concerns
- Suspicion & mistrust
- Debate regarding causes
- Inconclusive investigation

A Unique Phenomenon?

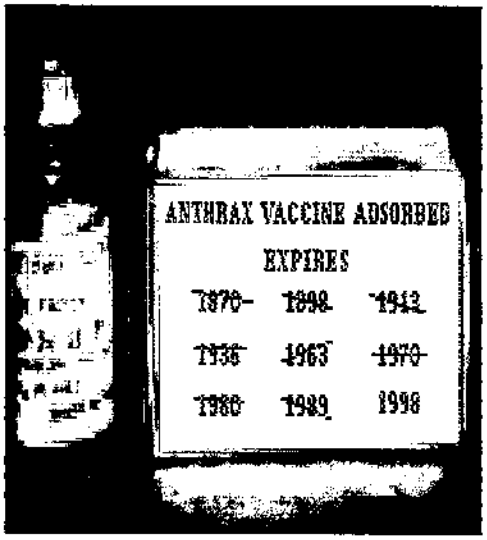
"Soldiers claim ill health after contact with contaminated soil in Croatia"

- Lancet, Aug, 1999

A Unique Phenomenon?

"Dover airmen report myriad ill effects from anthrax shots: one in four detail adverse reactions in pilot's informal survey"

– Air Force Times, April 17, 2000



A Unique Phenomenon?

THE SUNDAY TIMES

April 16 2000 BRITAIN

Ailing troops sue over Balkan war syndrome

SOLDIERS who served in the former Yugoslavia plan to sue the Ministry of Defence (MoD) after suffering chronic health problems they believe were caused by "Balkan war syndrome", *writes Lois Rogers*.

Doctors link their symptoms to exposure to depleted uranium in anti-tank missiles used during the Kosovo conflict. Research has shown that the heavy metal causes . . .

A Unique Phenomenon?

"Dutch Government Decides to Treat Battlefield as a Hazardous Workplace"

1980s	Peacekeepers in Lebanon
1992-3	"Jungle Disease" among 2900 peacekeepers in Cambodia
1995-6	Peacekeepers in Bosnia – 350 of 1300 individuals ill with respiratory, gastrointestinal, and dermatologic problems

Wall Street Journal
April 7, 2000

BOEING

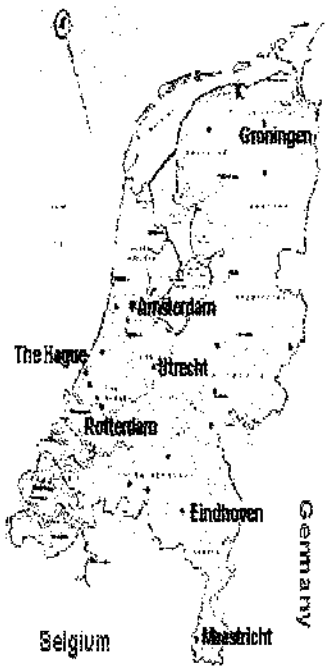
BOEING

HORIZONTAL TAIL STRUCTURE - (747)

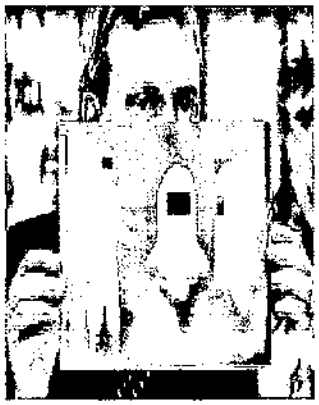
The mass balance weights on the outboard elevator of the 747 use depleted uranium.

The upper rudder of the 747 also uses depleted uranium for mass balance weight.

A Unique Phenomenon?



1992 El-Al Boeing crash in Amsterdam



DoD Deployment Health Clinical Center

Unexplained Physical Symptoms

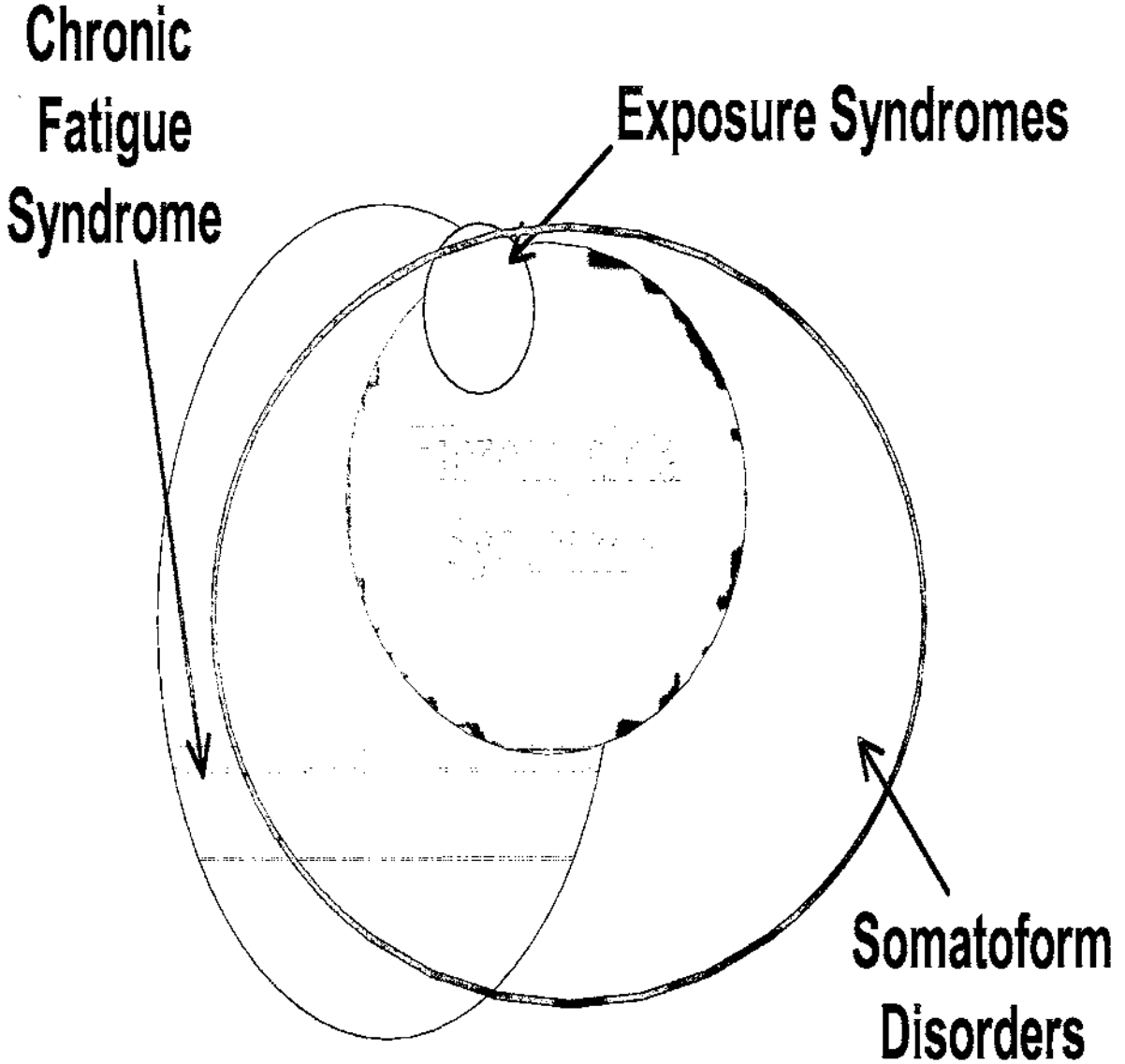
Medicine's "Dirty Little Secret"

Specialty	Clinical Syndrome
Orthopedics	Low Back Pain
	Patellofemoral Syndrome
Gynecology	Chronic Pelvic Pain
	Premenstrual Syndrome
ENT	Idiopathic Tinnitus
Neurology	Idiopathic Dizziness
	Chronic Headache
Urology	Chronic Prostatitis
	Interstitial Cystitis
	Urethral Syndrome
Anesthesiology	Chronic Pain Syndromes
Cardiology	Atypical Chest Pain
	Idiopathic Syncope
	Mitral Valve Prolapse
Pulmonary	Hyperventilation Syndrome
Endocrinology	Hypoglycemia

Specialty	Clinical Syndrome
Dentistry	Temporomandibular Disorder
Rheumatology	Fibromyalgia
	Myofascial Syndrome
	Siliconosis
Internal Medicine	Chronic Fatigue Syndrome
Infect Disease	Chronic Lyme
	Chronic Epstein-Barr Virus
	Chronic Brucellosis
	Chronic Candidiasis
Gastroenterology	Irritable Bowel Syndrome
	Gastroesophogeal Reflux
Physical Medicine	Mild Closed Head Injury
Occ Medicine	Multiple Chemical Sensitivity
	Sick Building Syndrome
Military Medicine	Gulf War Syndrome
Psychiatry	Somatoform Disorders

Symptom Based Disorders

One Syndrome or Many



DoD Deployment Health Clinical Center

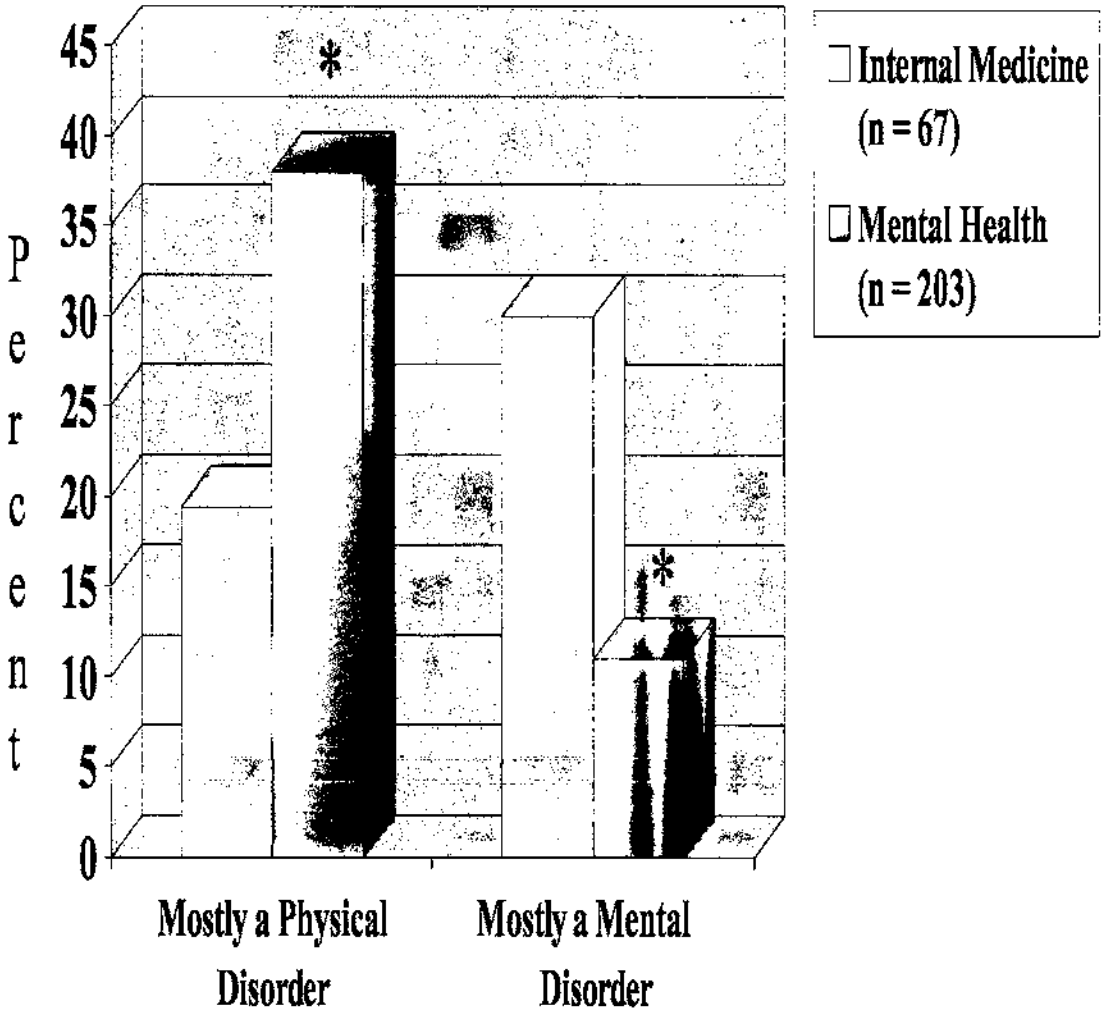
What is the Cause?
The Place for Interpretive Space

- No causes are proven
- Many putative causes are plausible
- Complicated "stress" dialogue
- Methodological problems plague research
  - the challenge of baseline data
  - the obscuring effect of time
  - the problem of "caseness"
  - "moving target" of exposure measurement
  - issues of privacy and confidentiality

Contested Illnesses & Exposures

Exposures with plausible health consequences or illnesses that are based on symptoms alone that become a matter of public debate, political controversy, or litigation.

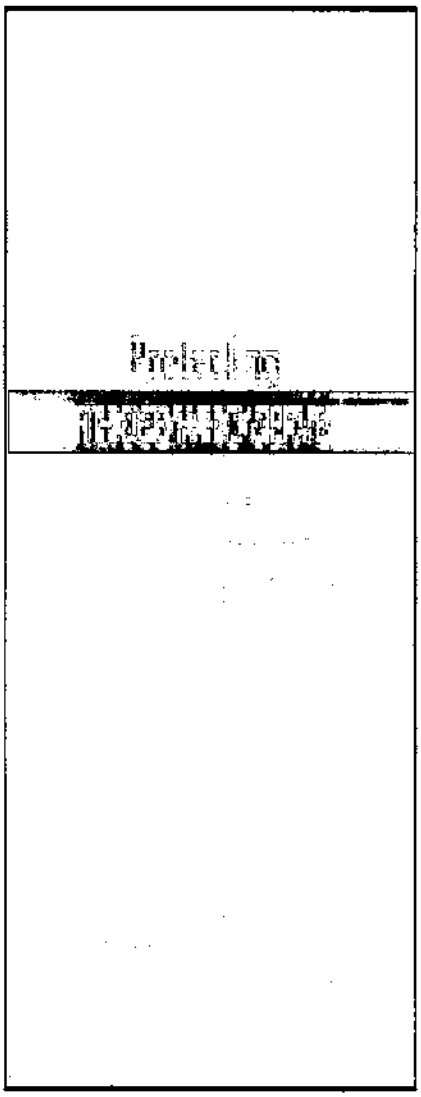
Rate the degree to which you believe "Persian Gulf Illness" is:



Richardson, Engel et al. Archives of Internal Medicine 2001; 161:1289-94

Institute of Medicine

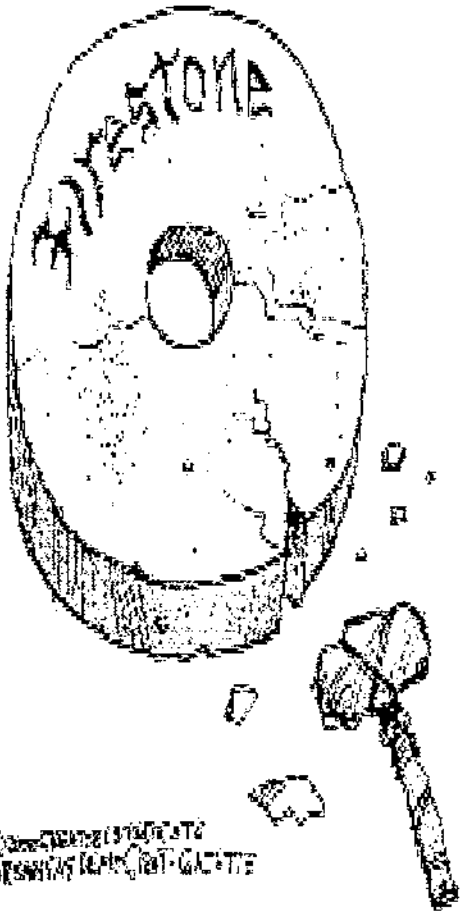
Strategy 5: "Implement strategies to address medically unexplained physical symptoms in populations that have been deployed."



WA, DC, National Academy Press; 2000

We've MAPPED THE HUMAN GENOME, MASTERED ARTIFICIAL INTELLIGENCE, AND UNLOCKED THE SECRETS OF THE UNIVERSE

THE WHEEL, THOUGH, STILL NEEDS SOME WORK



Good Technical Outcome, Poor Service Experience

A Verdict on Contemporary Medical Care?

Leon Eisenberg, MD

IN THE CLINICAL CROSSROADS IN THIS ISSUE OF THE JOURNAL, the deserving Dr Jennifer Daley rates the care the patient received as "good technical outcome, poor service experience."

No one will quarrel with the accuracy of the judgment rendered, but what a sad commentary—and understatement—about what happened to the patient. Most physicians and patients, and undoubtedly Ms G herself, would prefer that result to a rating of "good service experience, poor technical outcome" after such surgery, an outcome that was commonly the case with knee surgery 20 years ago, before orthopedic methods improved so remarkably. Being able to take a 3-week hiking trip after knee surgery is a tribute to modern orthopedics no less than to the skill of her surgeon.

But must there be an inverse relationship between technical outcome and service experience? Clearly not. Yet public dissatisfaction with care received has been increasing in recent years despite the greater and greater proficiency of medical and surgical specialists in reducing morbidity and mortality. Why might that be so? Some disinter-

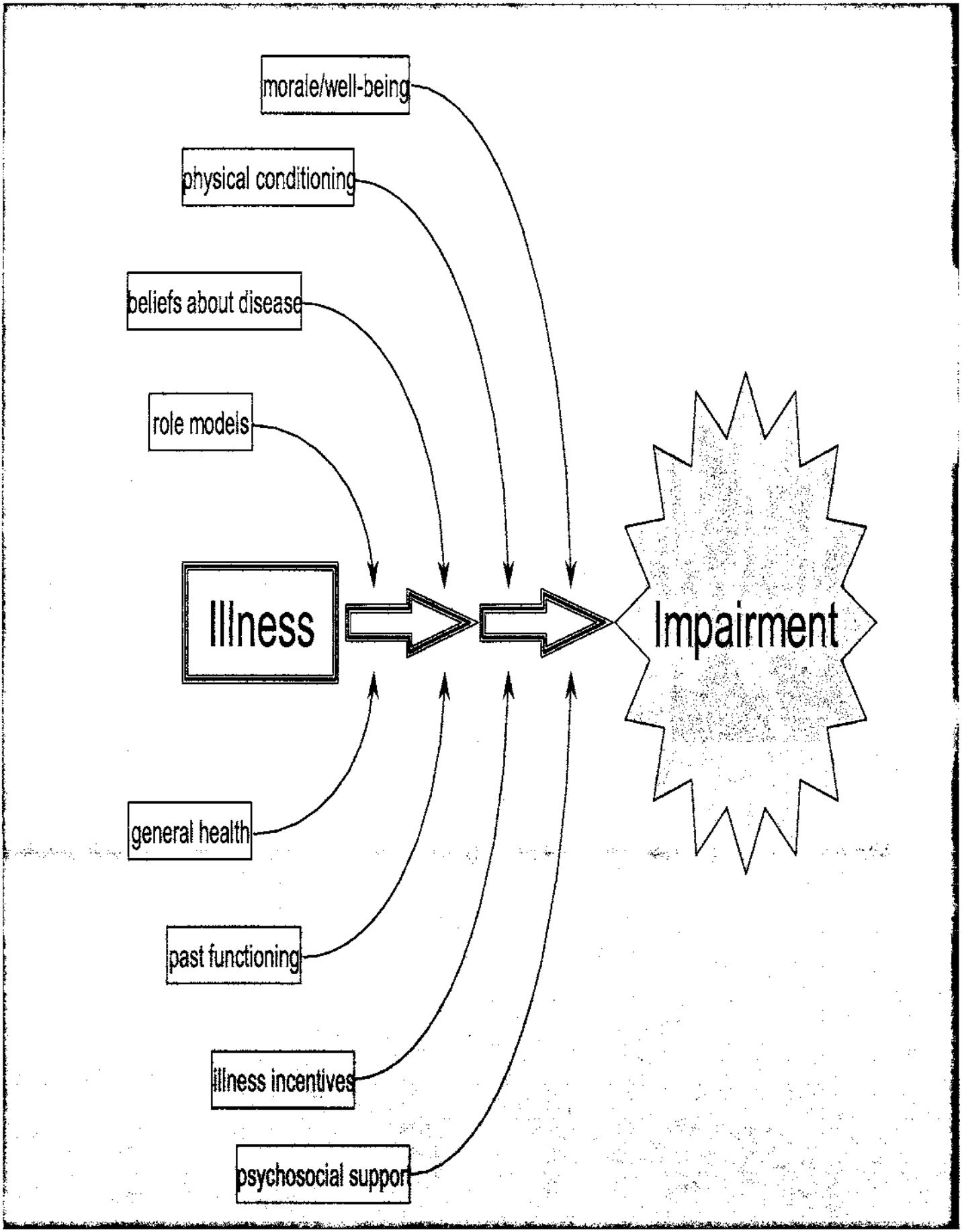
See also p 2679.

Author Affiliation: Department of Social Medicine, Harvard Medical School, Boston, Mass.

Corresponding Author and Reprints: Leon Eisenberg, MD, Department of Social Medicine, Harvard Medical School, 641 Huntington Ave, 2nd Floor, Boston, MA 02115.

The Goal: Collaborative Care

The primary goal is for patient & provider to *collaborate* in a joint effort to *activate* positive health-related behaviors. The two parties *negotiate* exact & explicit behavioral goals. They *monitor* progress using behavioral indices (e.g., symptom reports, quality of life estimates, or capacity to function and fulfill roles). Follow-up is *planned*, explicit, and valued over acute assessment.


morale/well-being
physical conditioning
beliefs about disease
role models
Illness
Impairment
general health
past functioning
illness incentives
psychosocial support

How Do We Get There From Here?

- Clinical experience
- Clinically relevant research
- Collation of clinical evidence
- Evidence-based practice guidelines
- Guideline implementation
- Pragmatic studies of implementation
- Recursive cycle

Deployment Health Clinical Center

DoD Center of Excellence for Post-deployment Care

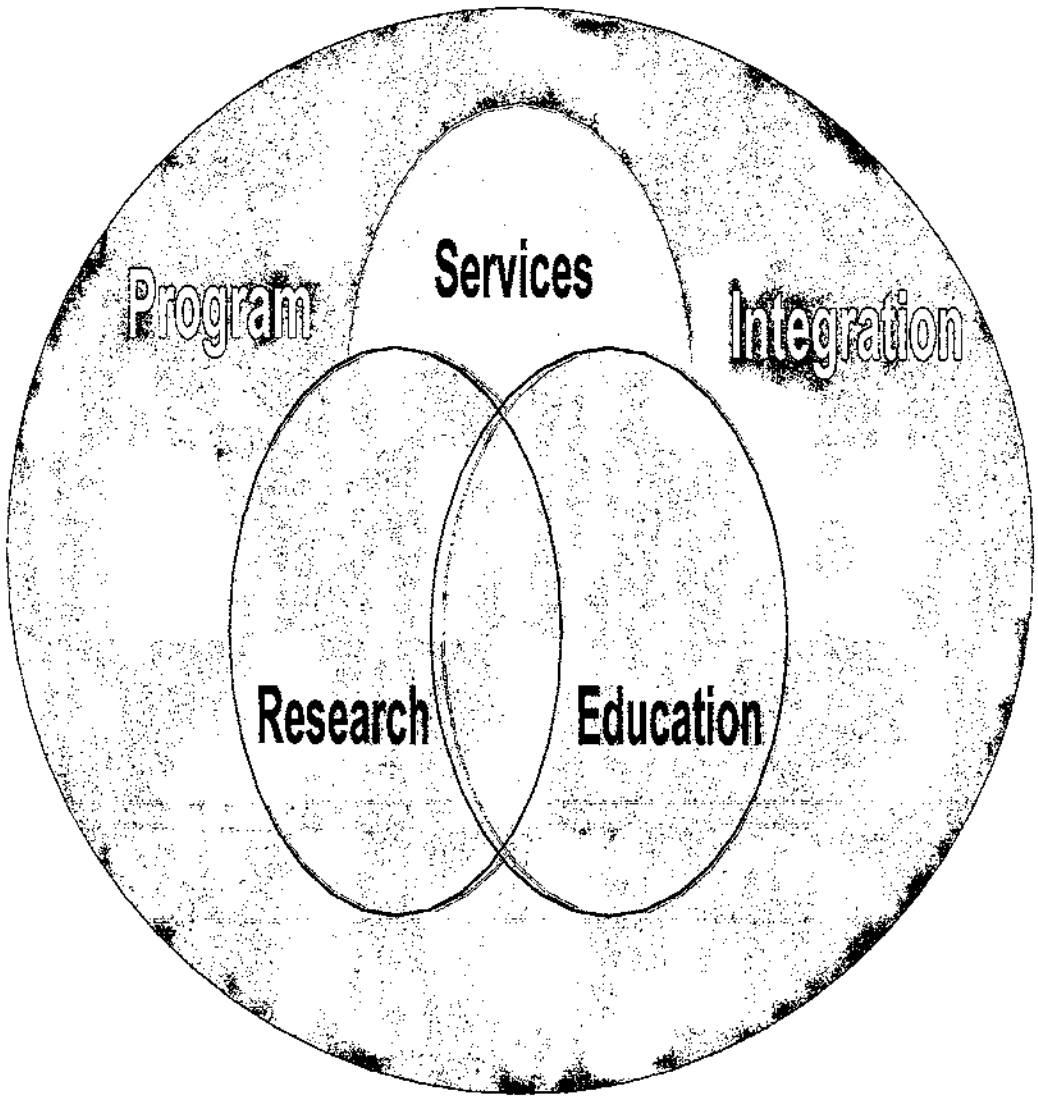
Program Integration

WWW Info Dissemination; Clinician Support; Planning & Program Development

Service Delivery	Research	Education
Referral Services	Services Research	Patient
Clinical Prevention	Multisite Trials	Provider
Risk Management	Clinician Communication	Public

Deployment Health Clinical Center

DoD Center of Excellence for Post-deployment Care



Three New DoD-VA Clinical Practice Guidelines

- Post-Deployment Health Evaluation & Management
- Unexplained Symptoms: Chronic Pain & Fatigue
- Post-Traumatic Stress Disorder

DoD & VA Practice Guideline Development...

- Is multiorganizational
- Is multidisciplinary
- Involves military personnel and veterans
- Systematically employs best evidence and independent policy recommendations
- Is recursive

Introduction To Guideline Features

- ❑ military-unique "fifth vital sign"
- ❑ stepped care approach
- ❑ clinically-based risk communication
- ❑ web-based clinician support
- ❑ longitudinal follow-up guidance
- ❑ outcomes monitoring
- ❑ supporting "Center of Excellence"

Military Unique Fifth Vital Sign

"Is your visit today related to war or deployment?" (yes–no–maybe)

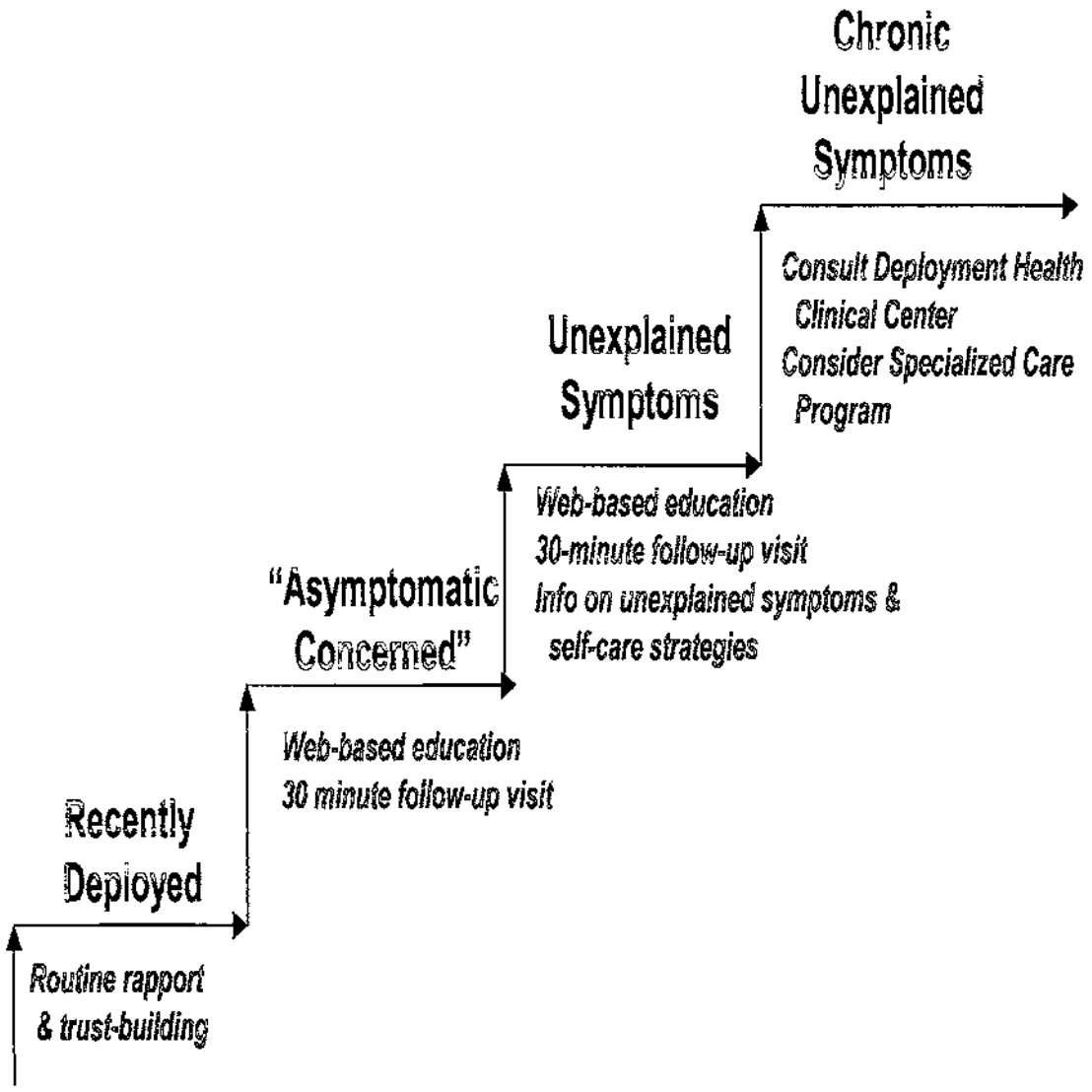
- vital sign for all visits except wellness care (e.g., periodic health examination, preventive care visits)
- patient-based rather than clinician-based
- 1% or less of patients say 'yes'

What is Stepped Care?

Explicit organizing of a care continuum.
Sequencing – intensity, cost versus benefit
Matching – based on identified need

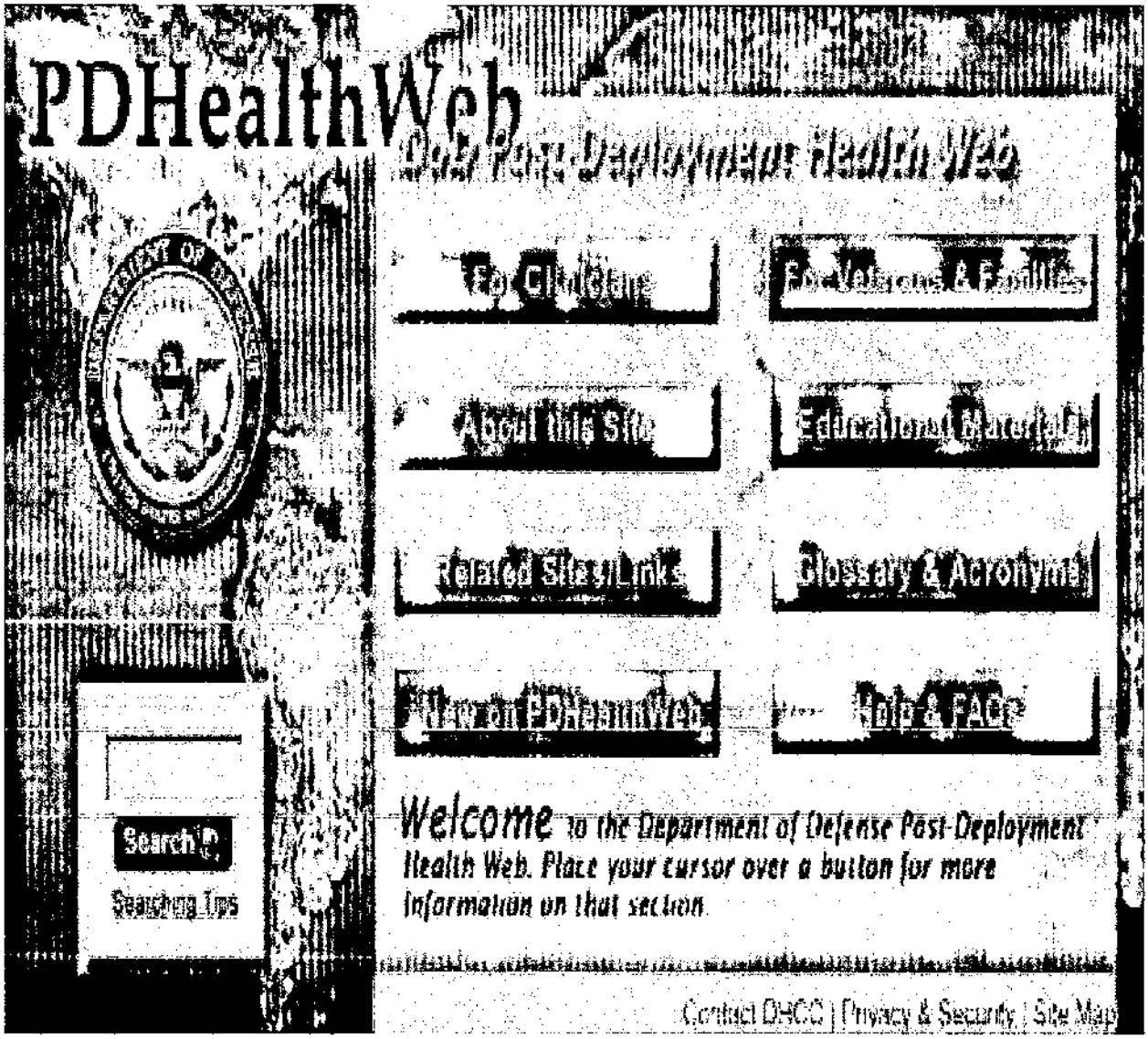
Matching patient to "step" (level of care
Previously used strategies
Problem trajectory.

Stepped Clinically-Based Risk Communication Strategy



http://www.PDHealth.mil

Web-Based Clinician Support



"Health-e VOICE"

An Online Clinical Risk Communication Continuing Education Tool

DoD Deployment Health Clinical Center

Current Guideline Projects

- Pilot Projects:
  - Fort Bragg, NC
  - Camp Lejeune, NC
  - McGuire Air Force Base, NJ
- Adapted Guideline Implementation:
  - Pentagon Primary Care Response Project
- Full DoD & VA Implementation in Feb 2002

Department of Defense Center of Excellence

Deployment Health Clinical Center & Specialized Care Program

Services Research

Multicenter Trials

Collaborating with VA Cooperative Studies Program to achieve clinical policy research capability

Center Director is Co-Chair of Three Trials...

- CSP 470: Exercise – Behavioral Therapy for CMI
  20 sites – ~1100 subjects – Completion: Jan 02
- CSP 475: Antibiotic Therapy for CMI
  30 sites – ~500 subjects – Completion: Jan 02
- CSP 494: Psychosocial Care for Women with PTSD
  12 sites – ~ 500 subjects – Completion: Jan 05

Other Research Directions

- Mechanistic studies on MUPS

  Coop agreement with Georgetown Center for Chronic Pain & Fatigue Research (DoD funding)

- Services research to testing the utility of

  Online clinician health risk communication training (CDC funding)

  Predicting mortality patterns of veterans (NIA)

"Unless...wars are fought solely by machines, the human cost of warfare will remain high. The troops must...be given a commitment for all necessary care for war-related illness."

Straus SE: Lancet 1999; 353:162-3

The American Society of

Tropical Medicine & Hygiene

Symposium 10

PROTECTING THE HEALTH

OF DEPLOYED MILITARY PERSONNEL

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CDR Margaret Ryan, MC, USN
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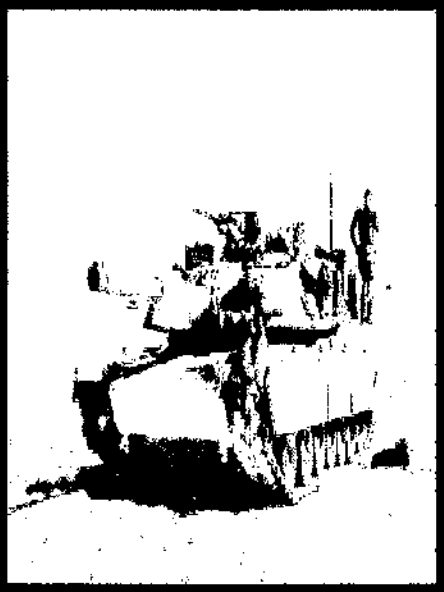
Ryan@nhrc.navy.mil
http://www.nhrc.navy.mil/

The Department of Defense Center for Deployment Health Research

Margaret Ryan, MD, MPH
CDR, MC, USN

American Society of Tropical Medicine and Hygiene
Annual Meeting, Atlanta, GA, 13 Nov 2001

DoD Center Research Program

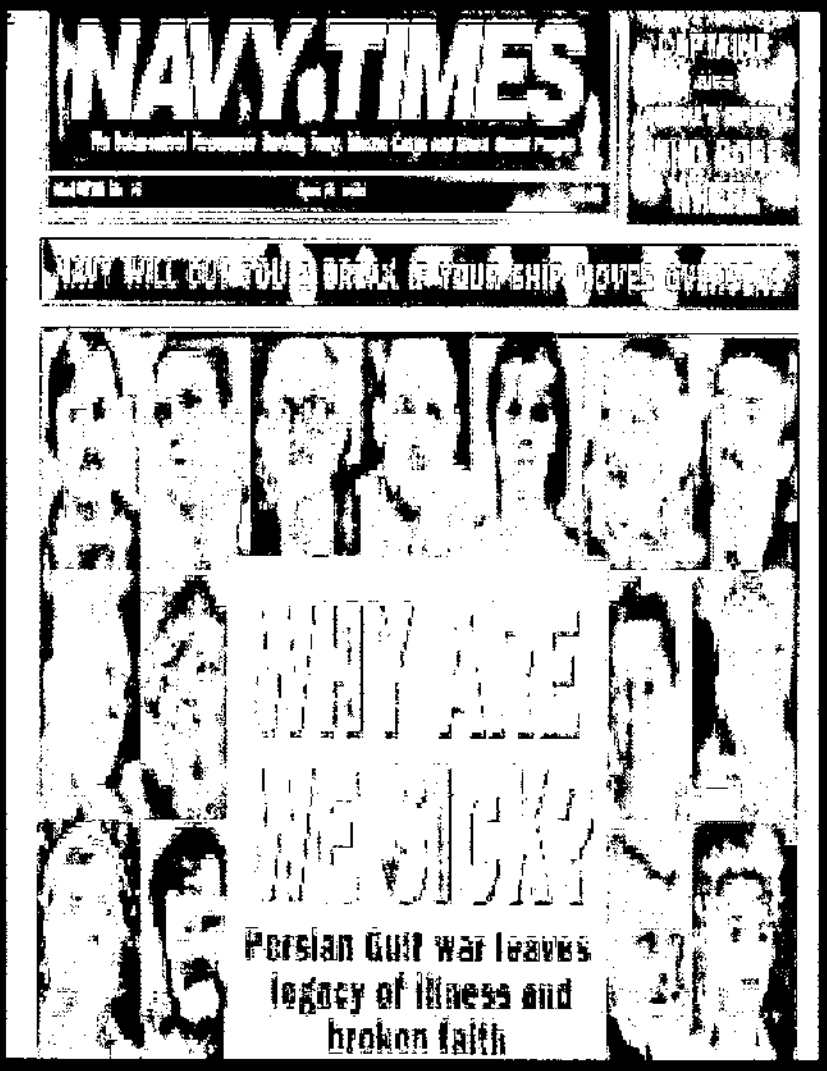


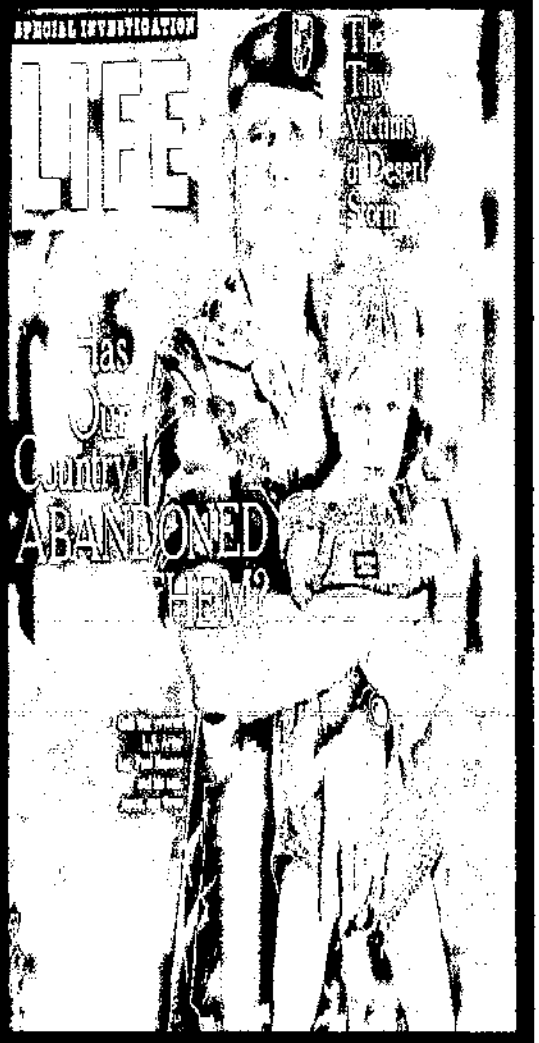
- Deployment Epidemiology

- Emerging Infectious Diseas Research

- 65 research staff

The Legacy of the Gulf War





Original Gulf War Studies

Symptoms	Hospitalizations	Reproductive Heal
Active Duty Seabee Survey (n=1500)	DoD Hospitalization Analyses (n=1.2 million persons)	DoD Birth Defect Analyses (n=1.2 million persons)
Seabee Health Study Survey (n=17,000)	Non-Federal Hospitalizatio Analyses (n=120,000 persons)	State Birth Defect Registry Study (n=80,000 births)
		Mail Survey of Reproductive Outcomes (n=16,000 couples)

Under leadership of CAPT Greg Gray, MC, USN (ret)

Gulf War Veteran Epidemiological Studi

Accomplishments

- Hospitalization study (N Eng J Med, 1996)
- Birth defects (N Eng J Med, 1997)
- Goldenhar syndrome (Teratology, 1997)
- Registry study (Amer J Epidemiol, 1998)
- Testicular cancer (Epidemiol, 1998)
- Emerging illnesses (Emerging Infect Dis, 1998)
- *M. fermentans* study (Am J Trop Med, 1999)
- Seabee study (Am J Trop Med, 1999)
- Khamisiyah study (Am J Epidemiol, 1999)
- Mental health hosp¢lin Epidemio,l1999)
- Nonfederal hospitalization study (Am J Epidemiol, 2000)
- Factor analysis study (Am J Epidemiol, 2000)
- PB and Gulf War veterans (Mil Med, 2000)
- SLE, ALS, and fibromyalgia (Amer J Epidemiol, 2000)
- GWV and birth defects, Hawaii (Teratology, 2000)

DoD Centers for Deployment Hea

Military and Veterans Health Coordinating Board

Research Center

Naval Health Research Center
San Diego, CA

Clinical Center

Walter Reed Army Medical Center
Washington, DC

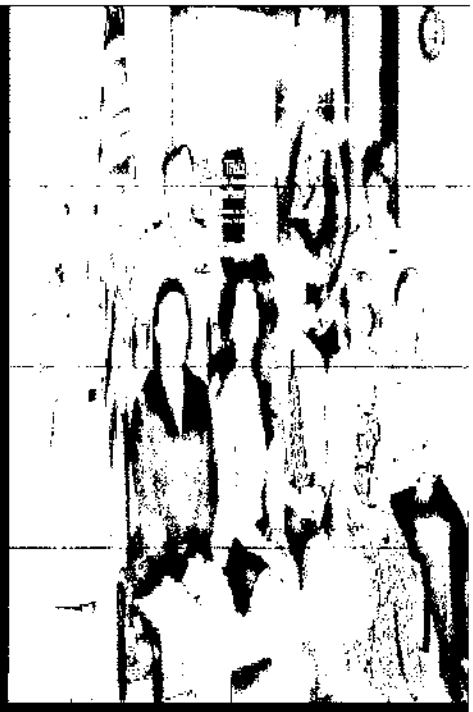
Medical Surveillance

US Army Center for Health Promotion and Preventive Medicine
Aberdeen Proving Ground, MD

DoD Deployment Health Research Center Projects FY01

- Anthrax vaccine and hospitalizations / birth defects
- Risk factors for dysfunctional families
- DoD and VA Health Registry studies
- Comparison of Southwest Asia, Gulf War, Bosnia
- Hospitalizations after oil well smoke fire exposure
- Survey study of alternative medicine use
- **The DoD Birth and Infant Health Registry**
- **The Recruit Assessment Program**
- **The Millennium Cohort Study**

Clinical Trials Center



- VA / DoD Cooperative Study 475 - Antibiotic Treatment of Gulf War Veteran Illnesses - double blind, placebo-controlled study.
- VA / DoD Cooperative Study 470 - Exercise, Cognitive Therapy Trial - controlled evaluation of multiple modalities to reduce symptoms.
- A controlled trial of the effects of combination therapy with DEET/PBPermethrinon symptoms andneurocognitivefunction.
- An assessment of relationship between obesity and past adenovirus infections.

The DoD Birth and Infant Health Registry

US Senate Committee on Veterans' Affairs recommended "establishing a birth defects registry for the military to gather data on possible reproductive health effects stemming from battle field exposures"

Report of the special investigation on Gulf War illnesses, 1998, Washington, DC.

Additional support for the Registry

- Committee to Review the Health Consequences of Services Durin the Persian Gulf War (1996)
- The Presidential Advisory Committee on Gulf War Veterans' Illnesses, *Special Report* (1997)
- OPNAVINST 5100.23D

Justification for Birth and Infant Health Registries

Birth defects are common

- ♦ may be present in >15% of all conceptions.
- ♦ major defects are found in 3-4% of live births.

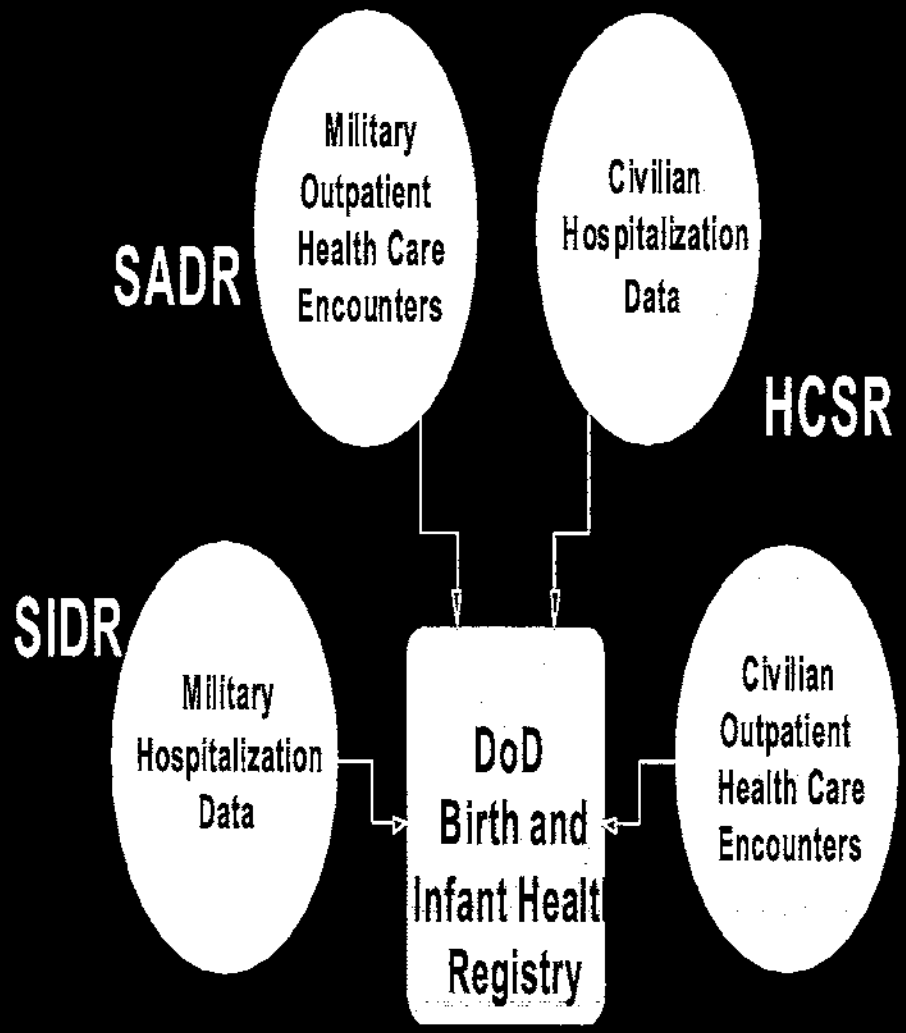
Birth defects are costly

- ♦ account for 25-30% of all pediatric hospitalizations.
- ♦ leading cause of infant mortality in the US.

Birth defects are concerning

- ♦ 38 states have birth defect registries.
- ♦ occupational and environmental exposures concern both parents and policymakers.

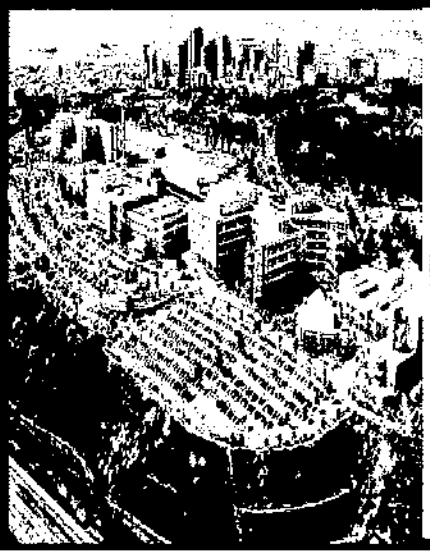
DoD Birth and Infant Health Registry Methodology



- Capture complete data on all births and health care encounters.
- Use standard definitions of outcomes, per CDC and state programs

Validation of DoD Birth and Infant Health Data

- Professional abstractors assigned to one of the largest DoD health care facilities, Naval Medical Center, San Diego.
- Data reviewed on over 3700 live births each year.
- Assess both over-reporting and under-reporting of birth defects in the electronic surveillance system.
- Find 93% complete data agreement. Most errors are miscoding of diagnoses; under-reporting of defects very rare.



DoD Birth and Infant Health Registry Results

- More than 90,000 births occur each year within the military.
- DoD births occur in all 50 states and >20 foreign countries.
- By simple linking to Defense Manpower Data Center data, the Registry can analyze birth defects by
  - geographic location of birth,
  - parents' past duty stations,
  - parents' occupational codes,
  - parents' deployments,
  - other exposures (e.g., anthrax vaccination)

DoD Birth and Infant Health Registry Results

- Overall prevalence of major defects among DoD-sponsored births has been found to be 3-4%.

- Most commonly diagnosed birth defects include:
  - patent ductus arteriosis
  - hypospadias & epispadias
  - atrial septal defect
  - ventricular septal defect

- Overall prevalence and types of defects are consistent with civilian birth defects surveillance data.

- DoD's ability to link data to parental environmental and occupational exposure data is a unique attribute -- *proving valuable in more detailed analyses.*

The Recruit Assessment Program

Collection of baseline health data on all military members is recognized as essential for:

- understanding health risks prior to entrance,
- understanding how service-related exposures (especially deployments) affect health,
- developing early intervention and prevention programs to protect health and readiness.

The Recruit Assessment Program

RAP survey content includes:

- demographic data
- clinical and medical history
- family history
- psychosocial history
- occupational history
- substance abuse and risk factor screens

Standard survey instruments used as much as possible.

- Linking demographic data to other systems, to speed recruit in-processing, makes RAP acceptable to training community.
- Project originally championed by CAPT C. Hajg Hyams, MC, USN(ret); now embraced by many throughout DoD.

The Recruit Assessment Program

Current Program Status

- Initiated at MCRD-San Diego June 20
- ~ 10,000 recruits entered.
- Survey honed to 11 pages (25 minutes)
- Initial test-retest results look sound.
- Prevalence of previously-studied factor appears consistent (e.g., 35% of recrui report being smokers)

- Fort Jackson (Army) now actively engaged (via CHPPM and WRAIR).
- Parris Island (Marines), Lackland (Air Force), and Great Lakes (Navy) all pursuing RAP implementation.
- For the future: other Army sites (Forts Leonard Wood, Benning, Knox, Sill) and all officer accession points.

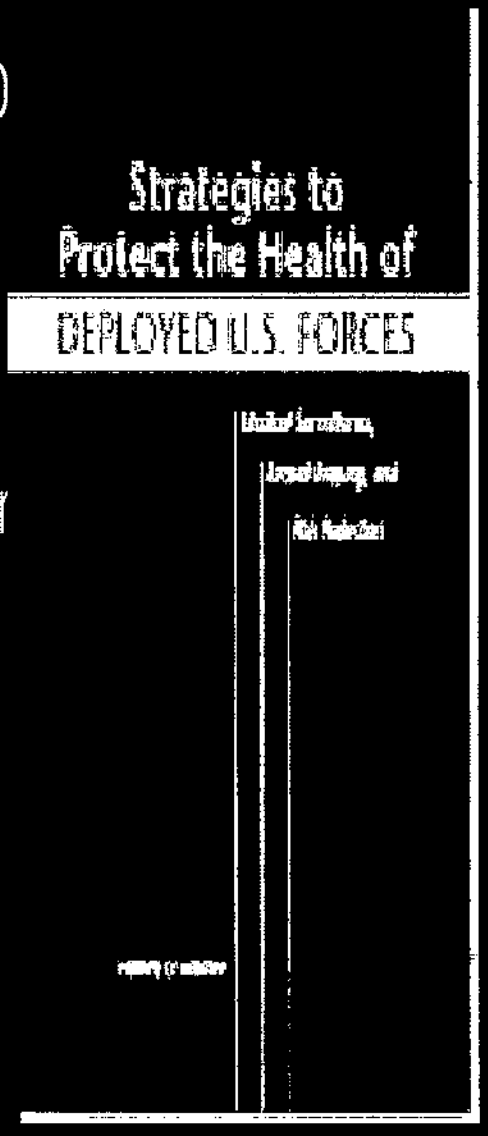
The Millennium Cohort Study

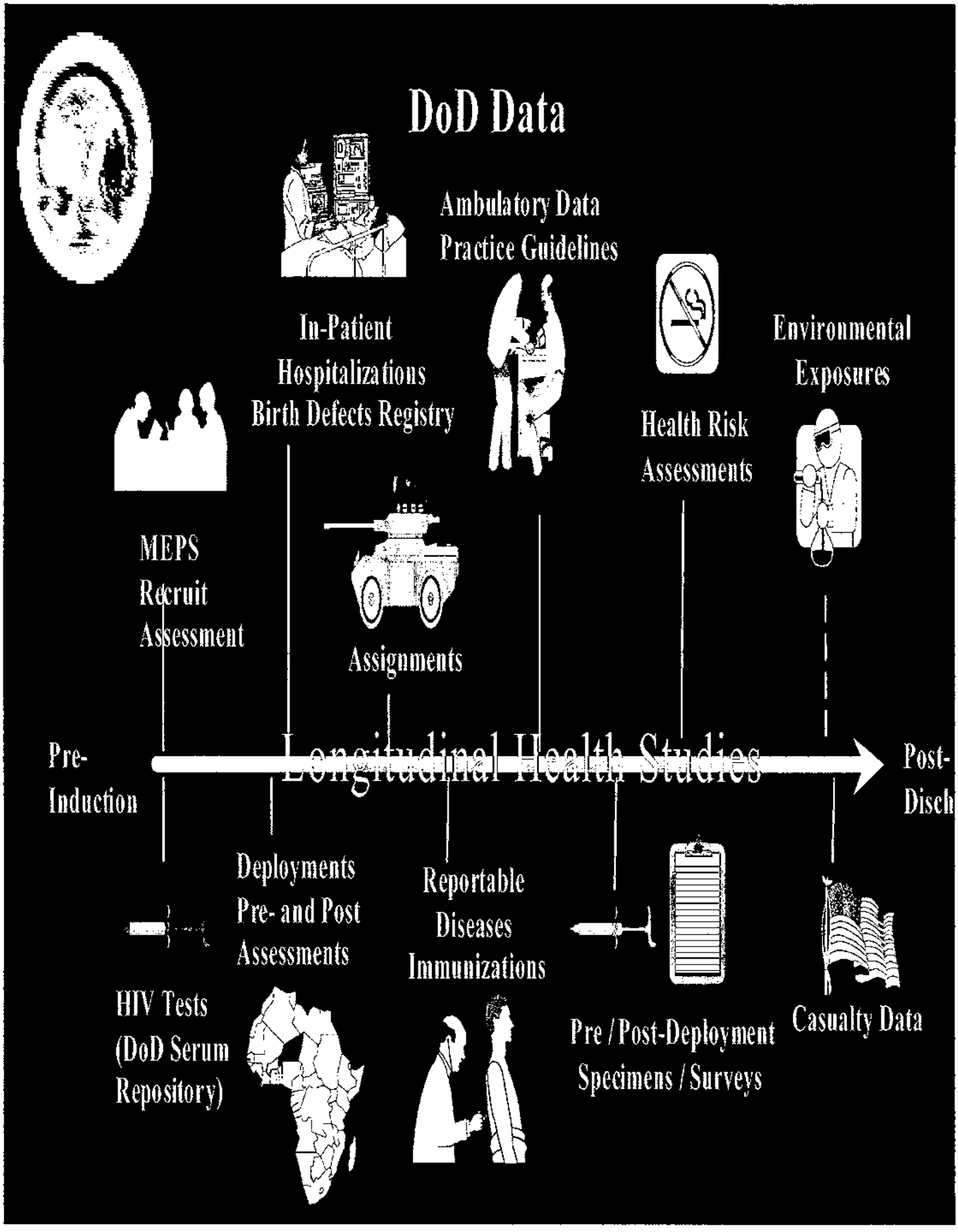
- Section 743 of the FY1999 Strom Thurmond Act authorized the Secretary of Defense to establish a... *longitudinal study to evaluate data on the health conditions of members of the Armed Forces upon their return from deployment.*

MILLENNIUM COHORT STUDY

The Millennium Cohort Study

- Capitalize on new and planned DoD surveillance and health care data policy changes
- Use data sources that were not available at the time of the Gulf War
- Add future deployment data as covariates
- For the first time, actually measure deployment impact prospectively



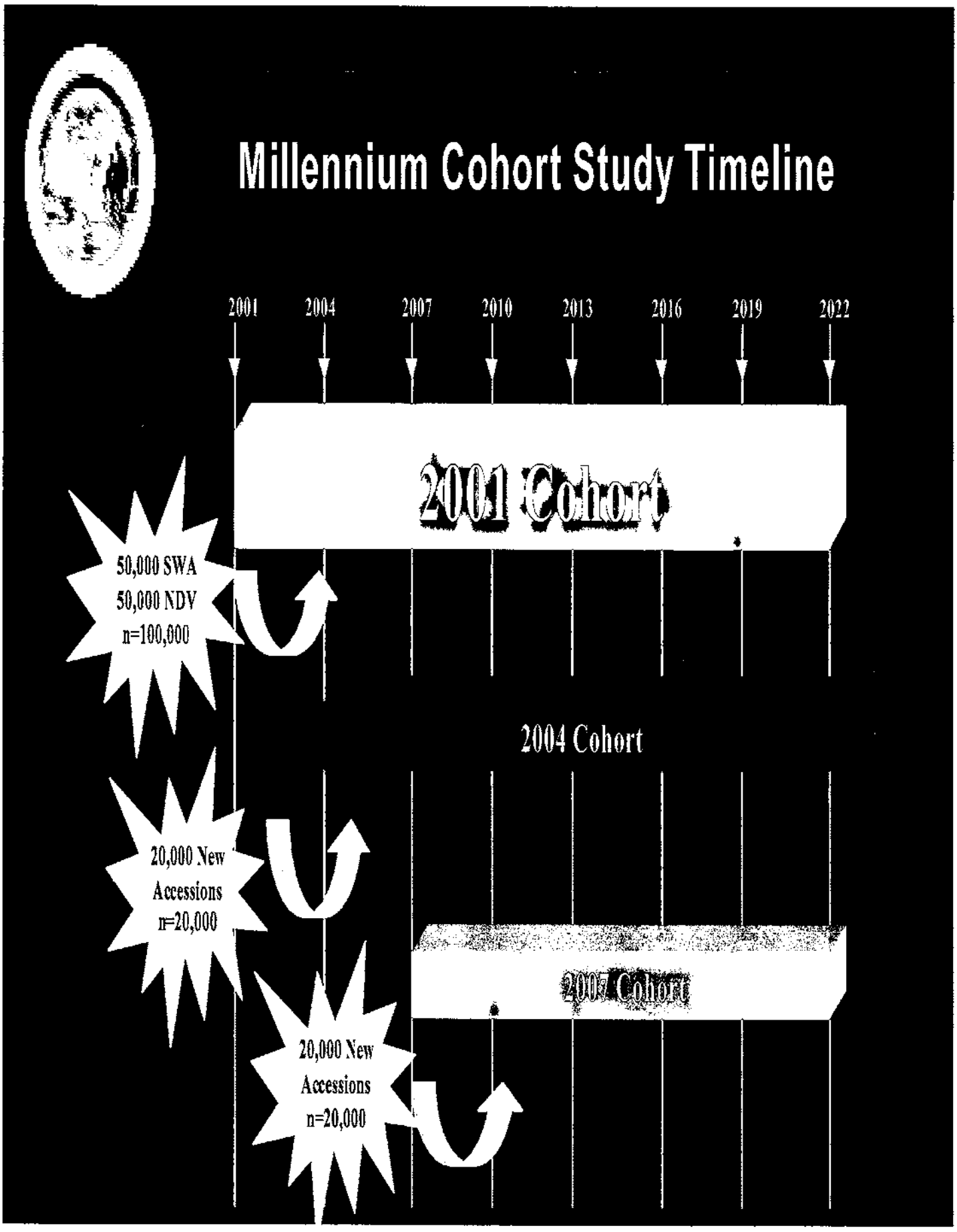

DoD Data
Ambulatory Data
Practice Guidelines
In-Patient
Hospitalizations
Birth Defects Registry
Environmental
Exposures
Health Risk
Assessments
MEPS
Recruit
Assessment
Assignments
Pre-
Induction
Longitudinal Health Studies
Post-
Disch
Deployments
Pre- and Post
Assessments
Reportable
Diseases
Immunizations
HIV Tests
(DoD Serum
Repository)
Pre / Post-Deployment
Specimens / Surveys
Casualty Data

The Millennium Cohort Study

Methods

- Probability-based cross-sectional survey of 100,000 (3.2%) of the 2.7M US service personnel who were on duty as of October 2000
- Re-survey population at 3-year intervals through 2022

  [Address-finding mail outs done annually]
- FY2004 and FY2007 - add new accession cohorts
- Assist in Force Health Protection modification such that initial survey data is adopted as DoD policy by 2011
- Other investigators may use these core data or augment serial samples with new data instruments


Millennium Cohort Study Timeline
2001
2004
2007
2010
2013
2016
2019
2022
2001 Cohort
50,000 SWA
50,000 NDV
n=100,000
2004 Cohort
20,000 New
Accessions
n=20,000
2007 Cohort
20,000 New
Accessions
n=20,000

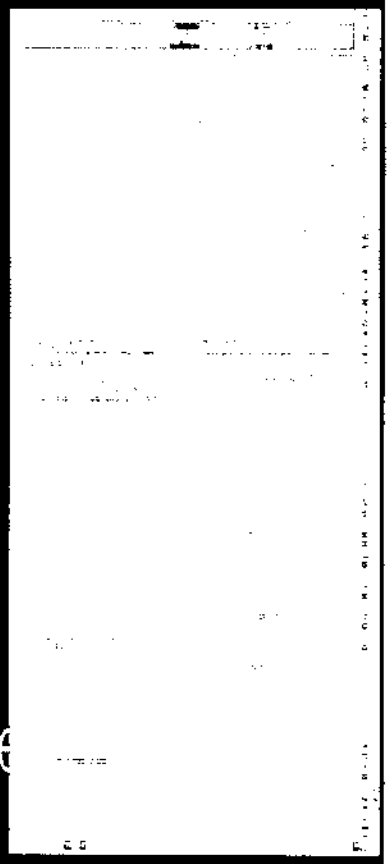
The Millennium Cohort Study

Some data sets to be linked to core survey data:

- Demographic and deployment data (DMDC)
- Immunizations
- Outpatient care
- Hospitalizations
- Birth Defects Registry data
- VA disability data
- Mortality data

The Millennium Cohort Study

Strategies to Maximize Participation



- Pretest survey in focus groups
- Simple, mark-sense questionnaire
- TraditionaDillmanmail methods:
  pre-survey introductory postcard,
  up to 3 survey mailings,
  telephone interview of non-responde
- Toll-free number for questions
- Annual address finding (DEERS, IRS, etc)
- Incentives (coaster, key chains, T-shirts)

Website wwwmillenniumcohordrg

Provides information anoption for survey completion.

The Millennium Cohort Study

Current status

- Pilot survey completed in spring 2001
- Full survey launched in Aug 2001
- Beginning 2nd mailing cycle. >29,000 respondents.
- Nearly 50% responded via website.

The Millennium Cohort Study

Oversight and Management

- DoD Research Program Office (DDRE) funding
- Protocols designed with expert external consultation
- AIBS external review
- Scientific Steering and Advisory Committee review
- Research Working Group of the MVHCB review

Co-investigators – all DoD services and VA represented

Paul Amoroso, LTC, MC, USA, USARIEM

Ed Boyko, MD, MPH, VA ERIC, Seattle

Gary Gackstetter, Col, BSC, USAF, USUHS

Greg Gray, MD, MPH, Univ Iowa

Tonie Hooper, MD, MPH, USUHS

Rick Riddle, LtCol, BSC, USAF, Armed Forces Epi Board

Megan Ryan, CDR, MC, USN, NHRC

The Millennium Cohort Study

Meeting of the Scientific Steering and Advisory Committee, May

Navy Hub for DoD Global Emerging Infection Surveillance (GEIS)

DoD-unique capabilities for diagnosis of militarily important respiratory pathogens:

- Influenza A & B
- Adenovirus
- *Mycoplasma pneumoniae*
- *Chlamydia pneumoniae*
- *Streptococcus pyogenes*
- *Streptococcus pneumoniae*
- *Bordetella pertussis*

Navy Hub for Dc
Global Emerging Infection Surveillance (GEIS)

DoD-unique capabilities for diagnosis of militarily important respiratory pathogens:

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- *Mycoplasma pneumoniae*
- *Chlamydia pneumoniae*
- *Streptococcus pyogenes*
- *Streptococcus pneumoniae*
- *Bordetella pertussis*


NHRC Respiratory Disease Surveillance Sites
Madigan Army MC
Great Lakes
Cape May
Ft Leonard Wood
Bethesda
Ft Knox
WRAIR
Ft Sill
Portsmouth
Ft Bragg
NMC San Diego
MCRD San Diego
BUDS
Ft Jackson
MCRD Parris Island
Ft Benning
Wilford Hall
Viral pathogens
S. pyogenes
S. pneumoniae
Pneumovaccine
Pertussis
RSV
Ensenada Mexico
HMS Raliegh United Kingdom

Pneumococcal Vaccine Trial

- Double-blind, placebo-controlled t
  of 23-valent pneumococcal vaccine in
  military recruits.

- Vaccine, FDA-approved, commonl
  given to elderly. 7-valent vaccine
  given to infants since 2000. Vacci
  value in healthy young adults uncl

- One of the largest vaccine trials in military history
  (nearly 200,000 people will be enrolled). Underway at 4 sites.

- Collaborators include Mayo Clinic and CDC. Results of great inte
  to military and civilian public health professionals.

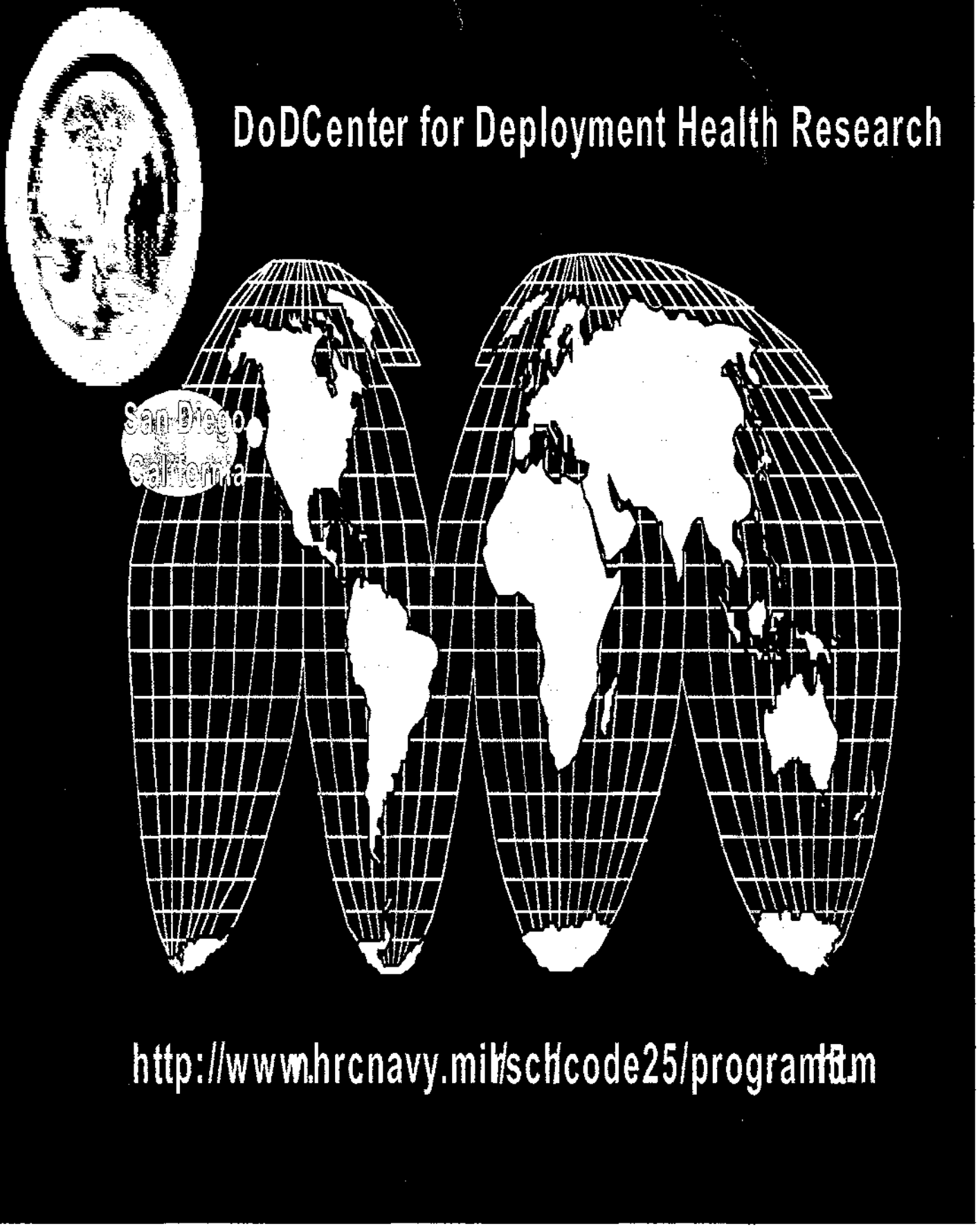
Global Emerging Infection Surveillance

Accomplishments of the Gregory C. Gray Laboratory

- Mycoplasma pneumoniae (Mil Med, 1997)
- Bordetella pertussis (Clin Infect Dis, 1997)
- Azithromycin trial (Clin Infect Dis, 1998)
- DoD respiratory threats (Emerg Infect Dis, 1999)
- Ft Jackson outbreak (Emerg Infect Dis, 1999)
- Ft Benning outbreak (MSMR, 1999)
- Navy Respiratory Disease Laboratory (Mil Med, 2000)
- Adenovirus orphaned vaccine (Clin Infect Dis 2001)
- USS Arkansas flu outbreak (Emerg Infect Dis 2001)
- Pertussis PCR (Mol Cell Probes 2001)
- Adenovirus DNA testing (J Med Micro 2001)
- USNA study (Mil Med 2001)
- BUDS study (Clin Infect Dis 2001)
- Pneumococcal vaccine study (Mil Med 2001)
- Pneumococcal surveillance (JID 2001)
- Adenovirus serotyping (J Clin Micro 2001)
- Adenovirus 7&3 outbreak (Clin Infect Dis 2001)
- Adenovirus deaths (MMWR 2001)

- CAP Certification (since 1999)
- WHO Collaborating Center - pe

DoD Center for Deployment Health Research at the Naval Health Research Center


DoDCenter for Deployment Health Research
San Diego
California
http://www.nhrcnavy.mil/schcode25/program.htm

Office of the Special Assistant to the Secretary of Defense for Gulf War Illnesses, Medical Readiness, & Military Deployments

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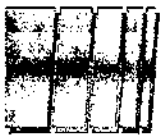
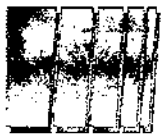


Outline

- Who served in the Gulf War
- Illnesses in Gulf War veterans
  - Types
  - Causes
- Lessons Learned
- Current and Future Deployments



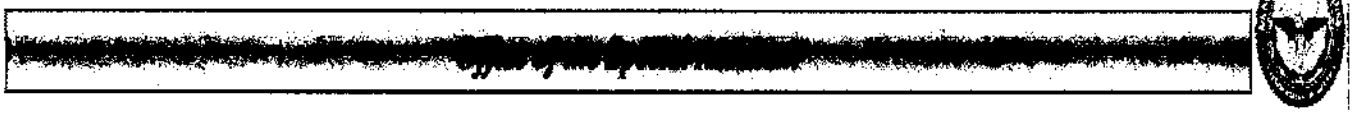
Who Served in the Gulf War

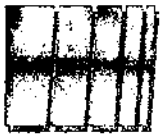
697,000 U.S. service members

ARMY	50%
NAVY	23%
MARINE	15%
AIR FORCE	12%

259,000 Coalition Forces

Source: Presidential Advisory Committee on Veterans Illnesses, Final Report





Who Served in the Gulf War

MALE	93%
FEMALE	7%
ACTIVE	83%
RESERVE/NATIONAL GUARD	17%
OFFICER	10%
ENLISTED	90%

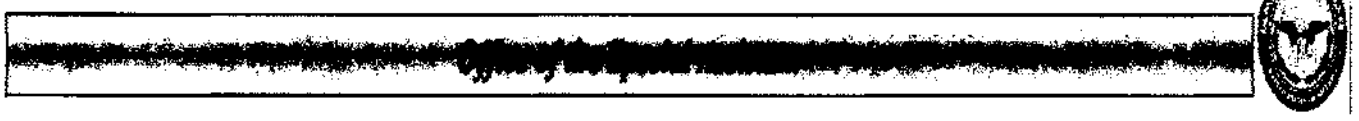
< 26 years old - 55%; 26-35 years old - 32%; > 35 years old - 13%

Medical Support

Largest emergency health care system since WW II

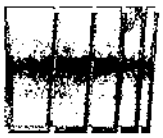
- 41,000 medical personnel
- 18,000 beds
  - 2 hospital ships
  - 63 combat zone hospitals

source: CENTCOM Publications - Commander-in-chief US CENTCOM "Desert Shield/Desert Storm Facts, Figures, Quotes and Anecdotes 7 AUG 90-11 APR 91," prepared by CENTCOM PAO



U.S. Deaths

Non-Battle	224
Battle	148



Symptoms

Tiredness

Rashes

Headaches

Muscle aches

Joint pains

Abdominal pain

Diarrhea

Hair loss

Memory loss

Sleep disturbance

Depression

Concentration problems

Medical Evaluations

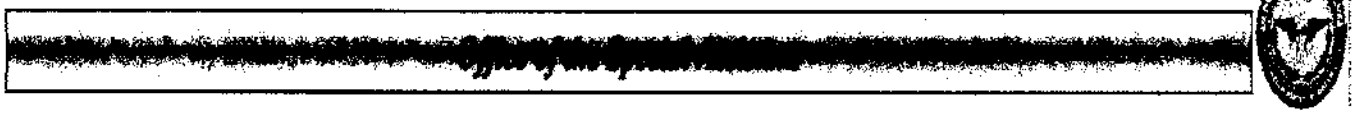
- Comprehensive Clinical Evaluation Program (CCEP)

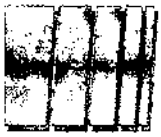
Total Participants	56,091	
Decline examination	15,948	
Examined		40,143
- Veterans Affairs Registry -examined		79,710
Total Examined		**119,853**

Source: OASD (Health Affairs) 31 Aug 00 VA Registry 25 Jul 00

Diagnosis Distribution

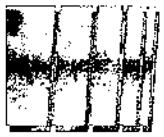
Categories	CCEP (%)	VA Registry (%)
Healthy	10	12
Symptomatic	90	88
Medically explained	80	80
Medically unexplained	**20**	**20**





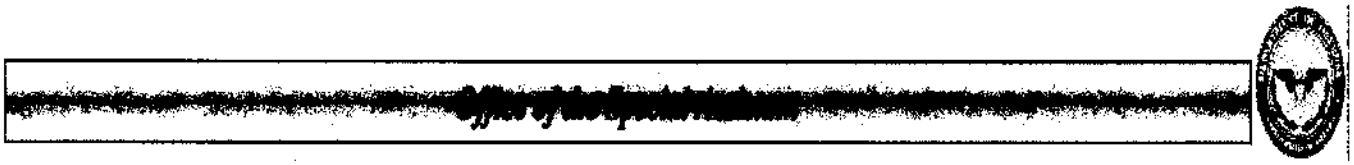
Epidemiology Studies

	Deployed (%)	Non-Deployed (%)
Medical separation (Aug 91 - Dec 93)	**2.20**	**2.56**
Hospitalizations (Aug 91 - Sep 93)	**21.6**	**21.6**
Hospitalizations unexplained illnesses (Aug 91 - Apr 96)	**1.21**	**1.27**
Birth Defects (Aug 91 - Sep 93)	**7.45**	**7.59**
Mortality (Aug 91 - Sep 93)	**.025**	**.023**



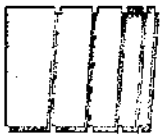
Possible Causes

CHEMICAL WARFARE	BIOLOGICAL WARFARE
PESTICIDES	OIL WELL FIRES
VACCINES	DEPLETED URANIUM
PYRIDOSTIMINE BROMIDE	INFECTIOUS DISEASES
STRESS	COCKTAIL EFFECT



Major Lesson Learned from the Gulf War

DoD Does Not Deal Well With Non-Traditional Issues



Understanding Today's Military Member

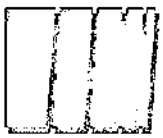
- 55% are married
- 46% have children
- 40% of the 1.3 million children are < 6 years old
- 6% are single parents
- 8% care for elder parents
- 14% are women

Deployments

- Unexpected and rapid personnel movement
- Personal and family hardships
- Stress in the field
  - Missile attacks
  - Chem-bio attacks
  - Witnessing death/atrocities
  - Harsh Living Conditions
  - Foreign cultures
  - Racial/ethnic hatred
- Inadequate communication
- No answers to questions after returning

Concerns of the Deployed Member

- Importance of the mission
- Recognition by others of his/her role
- Ability to express fears/concerns/problems to leadership
- Recognition for performance



Successful Mission

- Knew why I was there and agreed
- Knew what to do
- Knew how to do it
- Had what I needed to do it
- Did it well
- Was appreciated for my contribution
- Returned proud I had been there

Where Do We Go From Here?

- Concept - Deployment Medicine Clinics
  - Connected to all deployment sites
  - Source for pre and post deployment information
  - Information for family members
- Concept - Education on Vaccines
  - Start updating electronic record entrance
  - Validate accuracy with leave/bonus requests
  - Internet linkage to CDC for recommendations
- Concept - ????

Office of the Special Assistant

CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-497-6261
GulfLINK	*www.gulflink.osd.mil*

COL Francis L. O'Donnell MC, USA

phone 703-845-3374 fax 703-578-8501

email: fodonnel@gwillness.osd.mil

Force Health Protection

Predeployment

Health Promotion
Immunizations Current
Health Assessment Surveys
Medical Threat Briefing
Environmental Threat

Deployment

Environmental & Medical Surveillance
Food and Water Inspections
Industrial/Occupational Surveillance
Forward Deployed Labs
Host Nation Medical Support
Combat Stress Teams

Post Deployment

Health Assessment Surveys
Medical Debriefings
Medical Surveillance
Risk Communication

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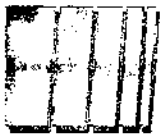
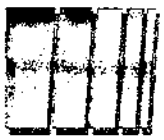


Distribution of CCEP Diagnoses by Major ICD-9 Categories

	Primary (%)	All Dx (%)
• Musculoskeletal	19.6	20.8
• Symp., Signs, IDC	17.4	19.0
• Psychological	17.3	14.8
• V-Codes	10.1	6.0
• Respiratory Sys.	6.5	5.9
• Digestive	6.1	7.3
• Skin	5.9	6.5
• Nervous System	5.5	5.9



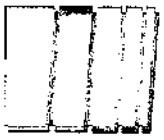
Distribution of CCEP Diagnoses by Major ICD-9 Categories (cont)

	Primary (%)	All Dx (%)
• Infections	2.6	3.0
• Circulatory Sys.	2.5	2.8
• Endocr.-Metab.	2.3	2.7
• Genitourinary	1.3	1.8
• Injury-Poisoning	0.9	1.1
• Neoplasms	0.9	0.9
• Blood	0.6	0.9

Lessons Learned

CHEMICAL WARFARE

- 14,000 M8 units
- False Positives
- In and out of MOPP, no explanations
- Alarms turned off
- No need to know
- Brain Damage

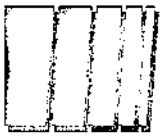


Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

- Navy Forward Laboratory
- No positive cultures



Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

- DEET, permethrin, organophosphates
- Unapproved items: flea collars, SNIP

Lessons Learned

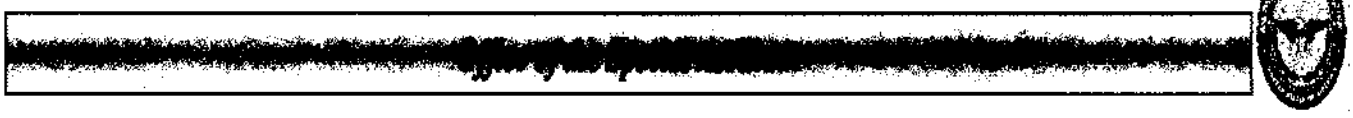
CHEMICAL WARFARE

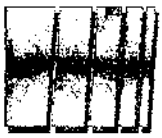
BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

- Soot, ash, black cloud
- No information
- EPA monitoring March 91
- Particulates, no toxic fumes





Lessons Learned

CHEMICAL WARFARE

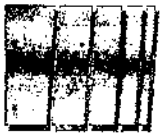
BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

- Vaccines "secret"
- No records
- No explanations
- Squalene



Lessons Learned

CHEMICAL WARFARE

PESTICIDES

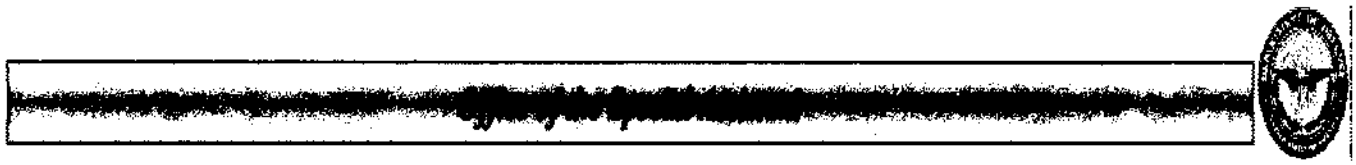
VACCINES

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

- Tank armor, penetrators
- No training
- Heavy metal, proximal tubule
- Surveillance of most exposed



Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

- Soman prophylaxis
- Not FDA approved use
- Recognized side effects
- Medical confusion
- No explanations, no records
- Varied protocols

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

INFECTIOUS DISEASES

- 12 malaria, 32 leishmaniasis
- Diarrhea, URI's
- *Mycoplasma fermentans incognitus*

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

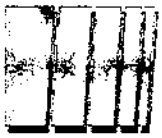
DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

INFECTIOUS DISEASES

STRESS

- NO DoD policy that "stress is the cause of symptoms"
- CNN, communications home
- Uncertainties
- Profiles are stress of chronic disease
- PTSD rate lower than Vietnam
- Stress can amplify already existing symptoms



Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

STRESS

BIOLOGICAL WARFARE

OIL WELL FIRES

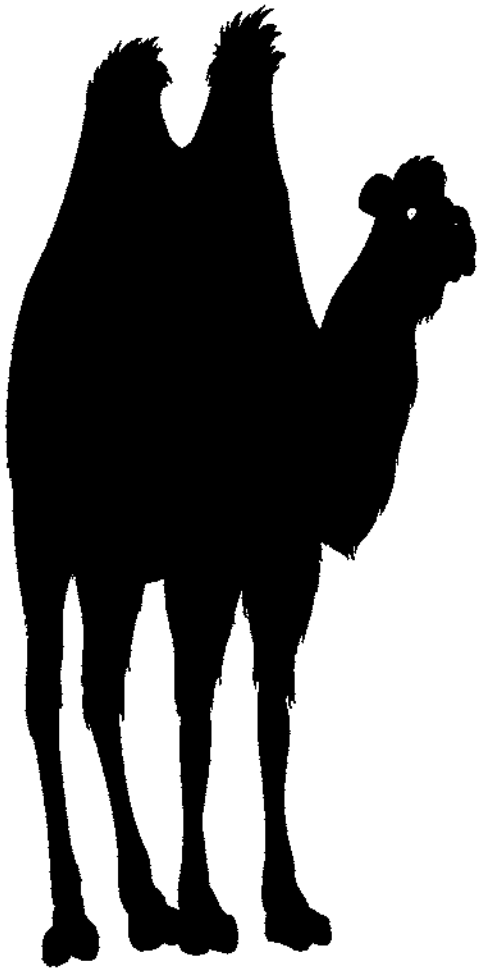
DEPLETED URANIUM

INFECTIOUS DISEASES

COCKTAIL EFFECT

- No scientific evidence yet

THE BLACK CAMEL



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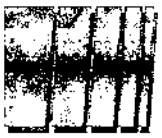
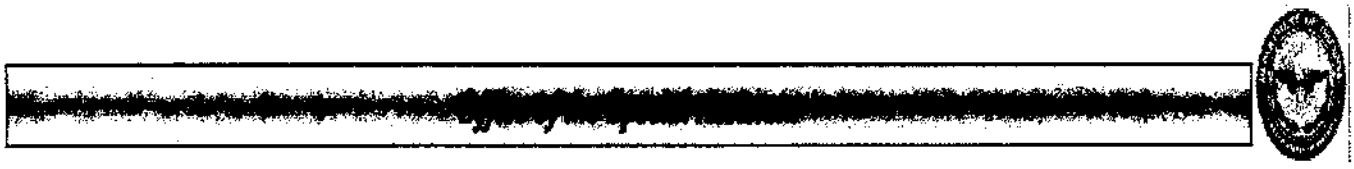
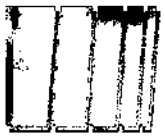


Possible Causes

- Normal disease rate
- New disease paradigm - a Black Camel



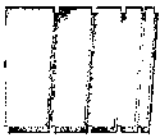


Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"
"It's all in your head!"
"You're faking these symptoms!"



Risk Communication

1. Allow Ventilation
2. Determine Underlying Concern
3. Empathy
4. Conclusion Soundbite
5. Facts (2)
6. Next Steps

Art of Medicine

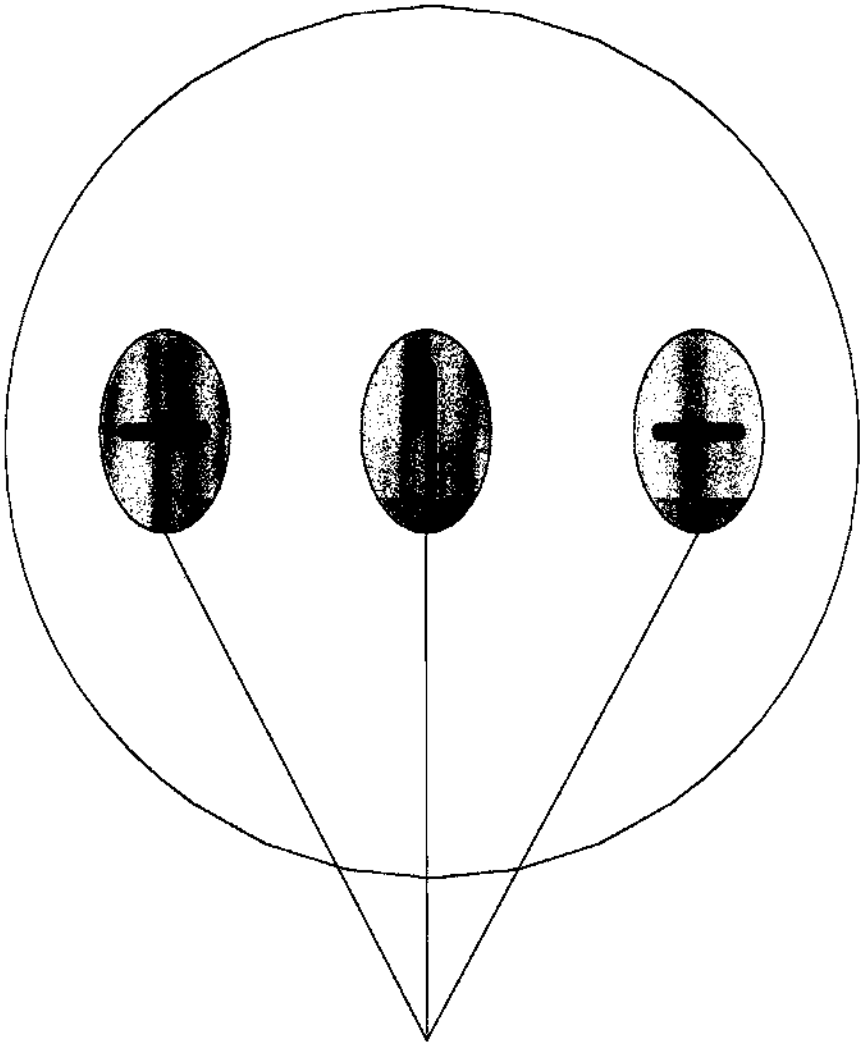
1. Ask open-ended questions
2. Chief complaint
3. Managed similar problems
4. Diagnosis
5. Lab, physical findings
6. Treatment, next appointment

Anthrax

- We have a safe and effective vaccine
- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods
  - At least seven potential adversaries suspected of researching, developing and/or weaponizing anthrax.

Vaccination against anthrax is critical for your protection

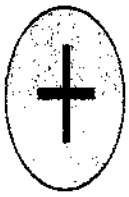
Anthrax Bacteria



Toxins

Anthrax Bacteria

Toxin Combination

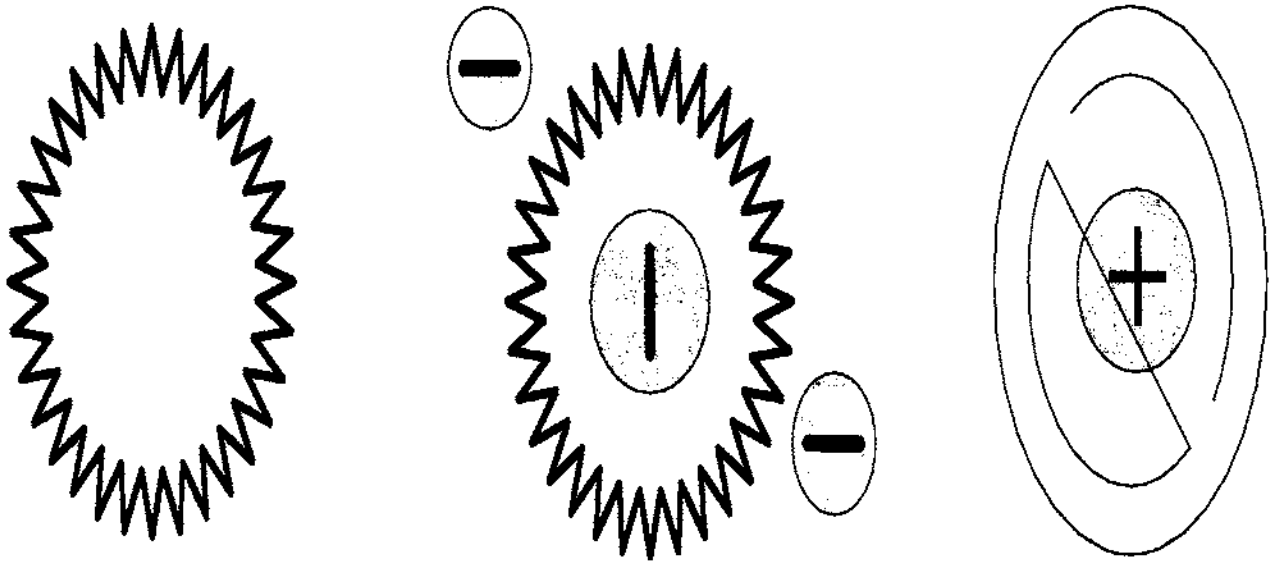
 = **Death**

Anthrax Vaccine

Produces

Attacks Toxin

PROTECTS



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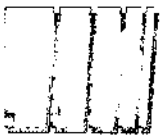
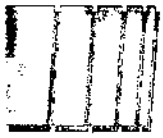
Medical Personal Information Center (PIC)

Office of the Special Assistant



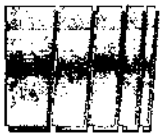
Musculoskeletal / Conn. Tissue

• Pain in Joint	5.5 %
• Osteoarthrosis	3.6 %
• Back Pain and other Back Disorders	2.8 %
• Disord. of Tendons, Muscle Attachments	1.6 %
• Other Disorders of Soft Tissue	1.4 %
• Disc Disorders	1.0 %
• Knee Derangements	0.4 %



Symptoms, Signs, Ill Defined Cond.

• Malaise, Fatigue	4.2 %
• Sleep Disturbances	3.3 %
• General Symptoms and Hyperhidrosis	1.9 %
• Symp. Of Respiratory Sys. And Chest	1.6 %
• Symptoms involving the Skin	1.1 %
• Alterations of Consciousness, Awareness	0.6 %
• Abdom. Pain, Various Locations	0.4 %
• Symptoms of Digestive System	0.4 %



Psychological

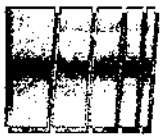
• Depressive Disorder	2.9 %
• Neuroses	2.8 %
• Prolonged PTSD	2.6 %
• Affective Disorders	1.8 %
• Adjustment Reactions	1.2 %
• Sleep Disorders	0.6 %
• Organic Brain Syndromes, Various	0.5 %

Respiratory Tract

- Asthma 2.2 %
- Allergic Rhinitis 1.5 %
- Chronic Upper Respir. Inflammation 1.5 %

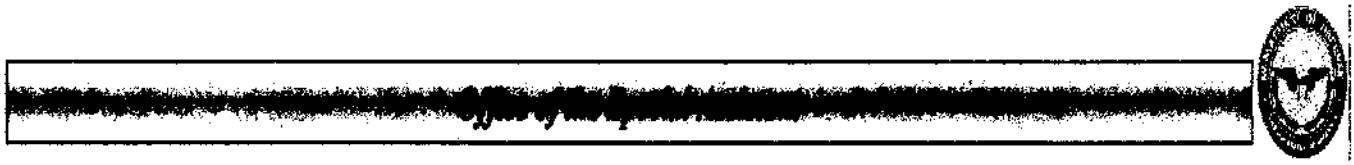
Healthy

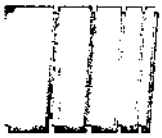
- Feared complaint, no diagnosis 8.0 %
- Routine general medical examination 0.9 %



Gastrointestinal

- Irritable Colon 1.5 %
- Esophageal Reflux 1.3 %
- Enteritis and Colitis 0.6 %



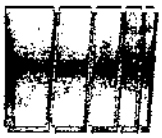


Integument

- Alopecia, hirsutism, other dis. of hair 1.3 %
- Fungus infections of skin 1.3 %
- Contact dermatitis, other eczema 1.2 %
- Urticaria, various types 0.5%

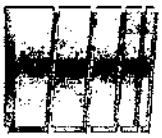
Headache

- Tension Headache 3.1 %
- Migraine 2.9 %
- Headache 2.5 %



Other

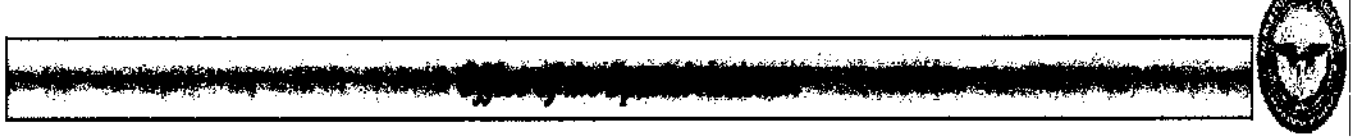
- Hypertension, essential 1.2 %
- Lipoid Metabolism Disorders 0.6 %
- Hearing Loss 0.4 %
- Hypothyroidism 0.4 %



Special Assistant

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members



Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DoD adapts doctrine, policy and procedures to reduce risks for troops in the future.

Medical Support

- 27,000 hospitalizations in theater
- 8,000 medical evacuations
- ????? outpatient visits

Office of the Special Assistant for Gulf War Illnesses

Michael E. Kilpatrick MD, FACP

Medical Outreach and Issues
Office of the Special Assistant for Gulf War Illnesses
703-578-8510 fax 703-578-8501
email: mkilpatr@gwillness.osd.mil

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Primer

on

Gulf War Illnesses

Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

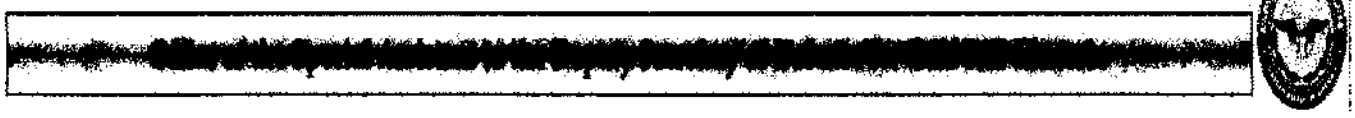
Who Served in the Gulf War

697,000 U.S. service members

ARMY	50%
NAVY	23%
MARINE	15%
AIR FORCE	12%

259,000 Coalition Forces

Source: Presidential Advisory Committee on Veterans Illnesses, Final Report



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FEMALE	7%
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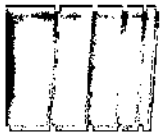
RESERVE/NATIONAL GUARD	17%
OFFICER	10%
ENLISTED	90%

< 26 years old - 55%; 26-35 years old - 32%; > 35 years old - 13%



Medical Support

Largest emergency health care system since WW II

- 41,000 medical personnel
- 18,000 beds
  - 2 hospital ships
  - 63 combat zone hospitals

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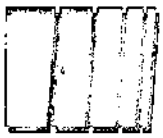

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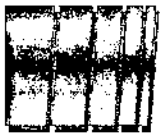


U.S. Deaths

Non-Battle	224
Battle	148

Symptoms

Tiredness

Rashes

Headaches

Muscle aches

Joint pains

Abdominal pain

Diarrhea

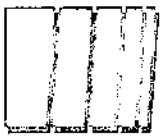
Hair loss

Memory loss

Sleep disturbance

Depression

Concentration problems



Medical Evaluations

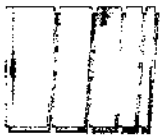
- Comprehensive Clinical Evaluation Program (CCEP)

Total Participants	55,564	
Decline examination	15,700	
Examined		39,864
♦ Veterans Affairs Registry -examined		78,869
Total Examined		**118,733**

Source: OASD (Health Affairs) 31 May 00 VA Registry 26 May 00

Diagnosis Distribution

Categories	CCEP (%)	VA Registry (%)
Healthy	10	12
Symptomatic	90	88
Medically explained	80	80
Medically unexplained	**20**	**20**

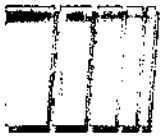


Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"
"It's all in your head!"
"You're faking these symptoms!"

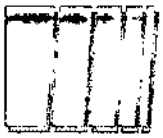


VA Disabilities
Gulf War Veterans

- 696,530 personnel served in the Gulf War
- 132,891 have some service connected medical condition
- 43,875 veterans' medical conditions have been rated at less then 10%
- 89,016 veterans' medical conditions have been rated at 10% or greater

Top Service Connection Conditions Among Gulf War Veterans

1. Impairment of the knee
2. Skeletal system disability
3. Lumbosacral strain
4. Arthritis due to trauma
5. Scars
6. Hearing loss
7. Tinnitus
8. Hypertension
9. Intervetebral disc syndrome



Epidemiology Studies

	Deployed (%)	Non-Deployed (%)
Medical separation (Aug 91 - Dec 93)	**2.20**	**2.56**
Hospitalizations (Aug 91 - Sep 93)	**21.6**	**21.6**
Hospitalizations unexplained illnesses (Aug 91 - Apr 96)	**1.21**	**1.27**
Birth Defects (Aug 91 - Sep 93)	**7.45**	**7.59**
Mortality (Aug 91 - Sep 93)	**.025**	**.023**

Possible Causes

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIMINE BROMIDE

INFECTIOUS DISEASES

STRESS

COCKTAIL EFFECT

Lessons Learned

CHEMICAL WARFARE

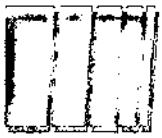
- 14,000 M8 units
- False Positives
- In and out of MOPP, no explanations
- Alarms turned off
- No need to know
- Brain damage

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

- Navy Forward Laboratory
- No positive cultures



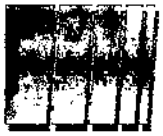
Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

- DEET, permethrin, organophosphates
- Unapproved items: flea collars, SNIP



Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

- Soot, ash, black cloud
- No information
- EPA monitoring March 91
- Particulates, no toxic fumes

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

- Vaccines "secret"
- No records
- No explanations
- Squalene

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

- Tank armor, penetrators
- No training
- Heavy metal, proximal tubule
- Surveillance of most exposed

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

- Soman prophylaxis
- Not FDA approved use
- Recognized side effects
- Medical confusion
- No explanations, no records
- Varied protocols

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

INFECTIOUS DISEASES

- 12 malaria, 32 leishmaniasis
- Diarrhea, URI's
- *Mycoplasma fermentans incognitus*

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

INFECTIOUS DISEASES

STRESS

- NO DoD policy that "stress is the cause of symptoms"
- CNN, communications home
- Uncertainties
- Profiles are stress of chronic disease
- PTSD rate lower than Vietnam
- Stress can amplify already existing symptoms

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

STRESS

BIOLOGICAL WARFARE

OIL WELL FIRES

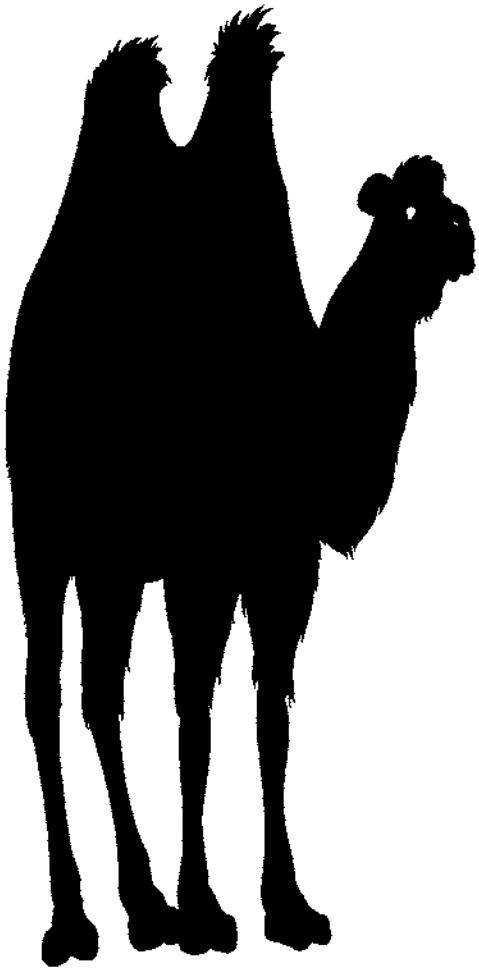
DEPLETED URANIUM

INFECTIOUS DISEASES

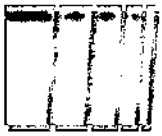
COCKTAIL EFFECT

- No scientific evidence yet

THE BLACK CAMEL



Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

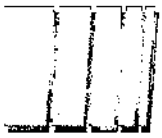


Possible Causes

- Normal disease rate
- New disease paradigm - a Black Camel

The Art of Medicine

- Today's Patient
  - Better informed
  - More demanding
  - Concerned symptoms are masking sinister disease
- What's Missing
  - Trust from both sides
- Patient's desire
  - More time
  - Advanced technology



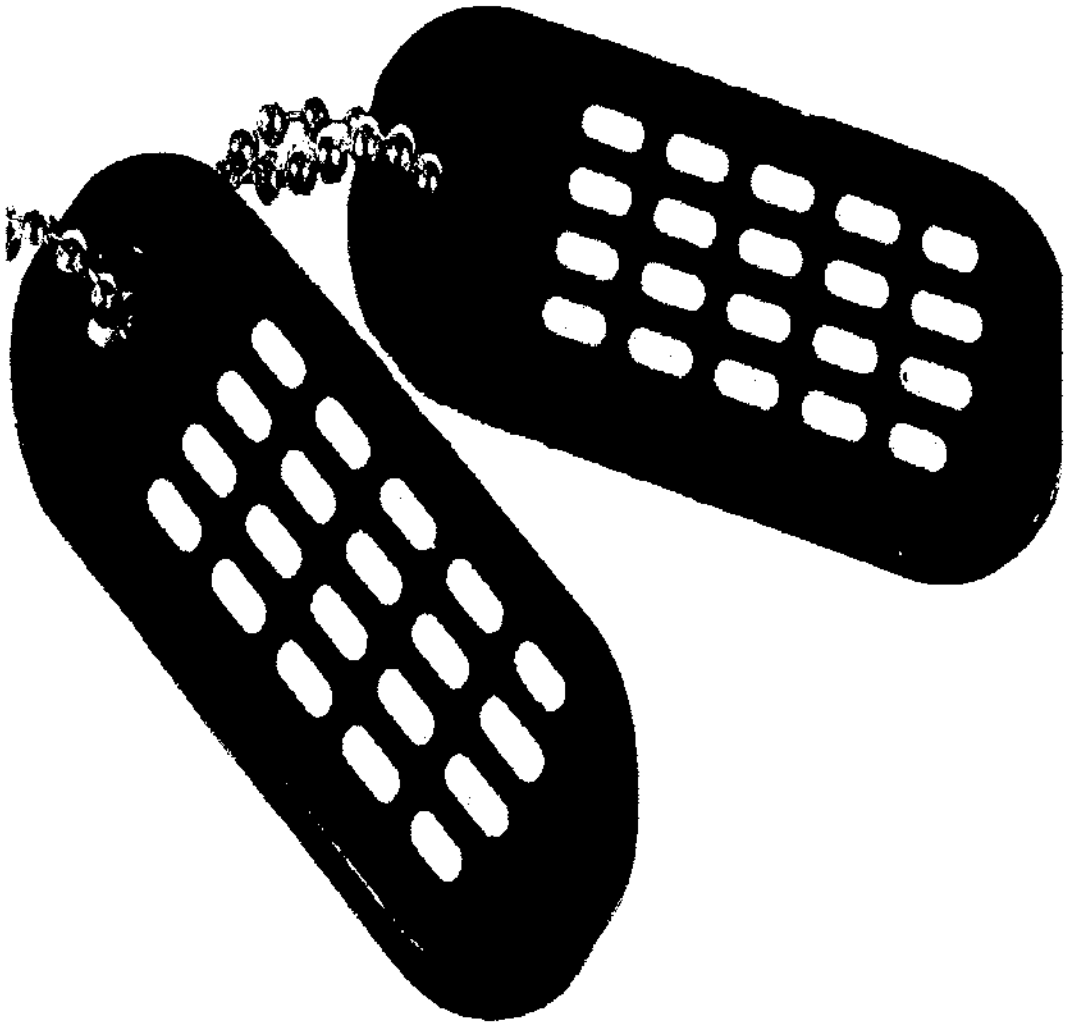
Risk Communication

1. Allow Ventilation
2. Determine Underlying Concern
3. Empathy
4. Conclusion Soundbite
5. Facts (2)
6. Next Steps

Art of Medicine

1. Ask open-ended questions
2. Chief complaint
3. Managed similar problems
4. Diagnosis
5. Lab, physical findings
6. Treatment, next appointment

Medical Personal Information Center (PIC)



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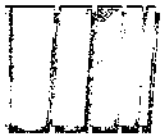


Force Health Protection

Predeployment

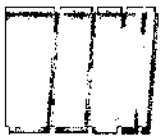
- Medical threat briefing
- Distribute medical information
- Verify HIV test in last 12 months
- Verify current physical examination
- Verify DNA sample on file
- Predeployment serum sample
- Immunizations
- Predeployment health questionnaire

Deployment

- Daily and weekly disease/injury reporting
- Environmental monitoring
- Forward medical laboratory
- Immunization tracking
- Medical threat updates

Post Deployment

- Post deployment serum sample
- Post deployment health questionnaire
- Analysis of "lessons learned"
- Medical debriefs
- Screening exams as needed



Office of the Special Assistant for Gulf War Illnesses

CONTACT NUMBERS

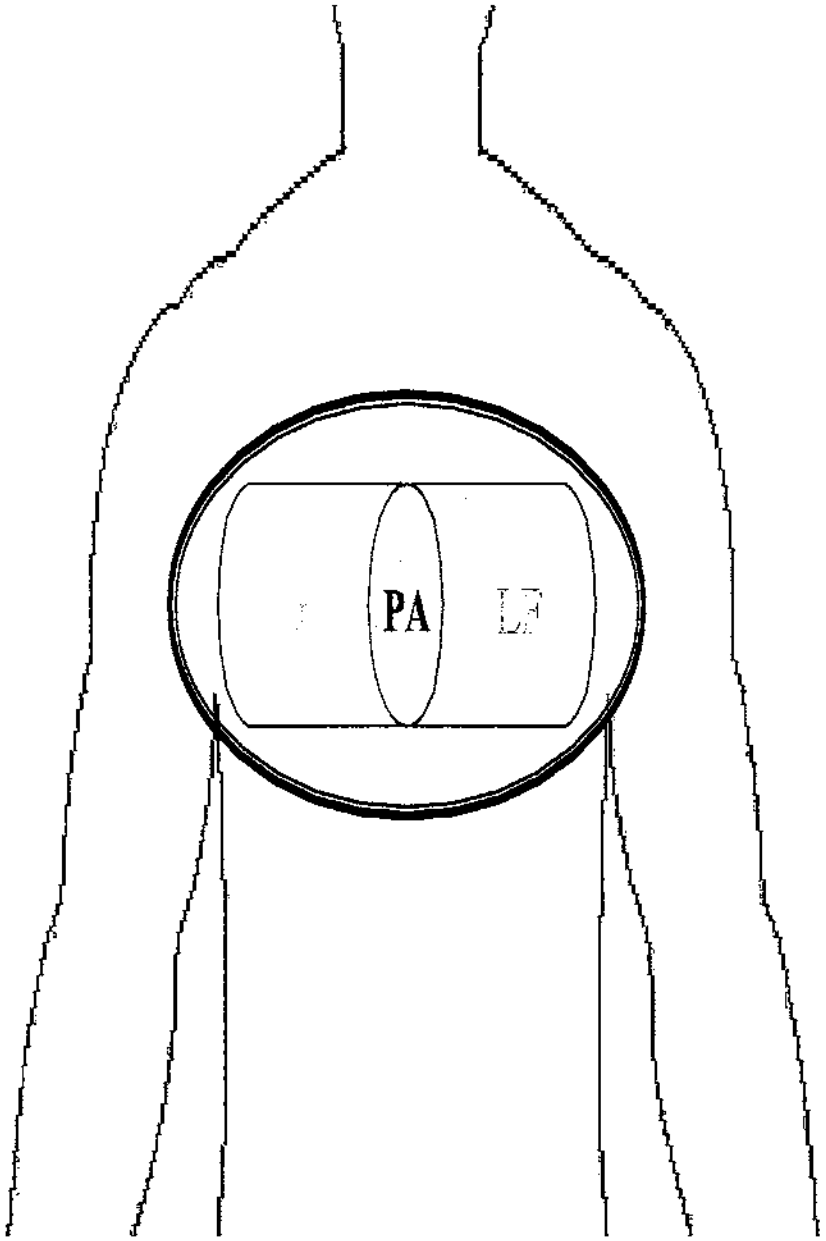
Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-472-6719
GulfLINK	*www.gulflink.osd.mil*

Michael E. Kilpatrick MD, FACP

phone 703-578-8510 fax 703-578-8501

email: mkilpatr@gwillness.osd.mil

ANTHRAX BACTERIA ATTACK

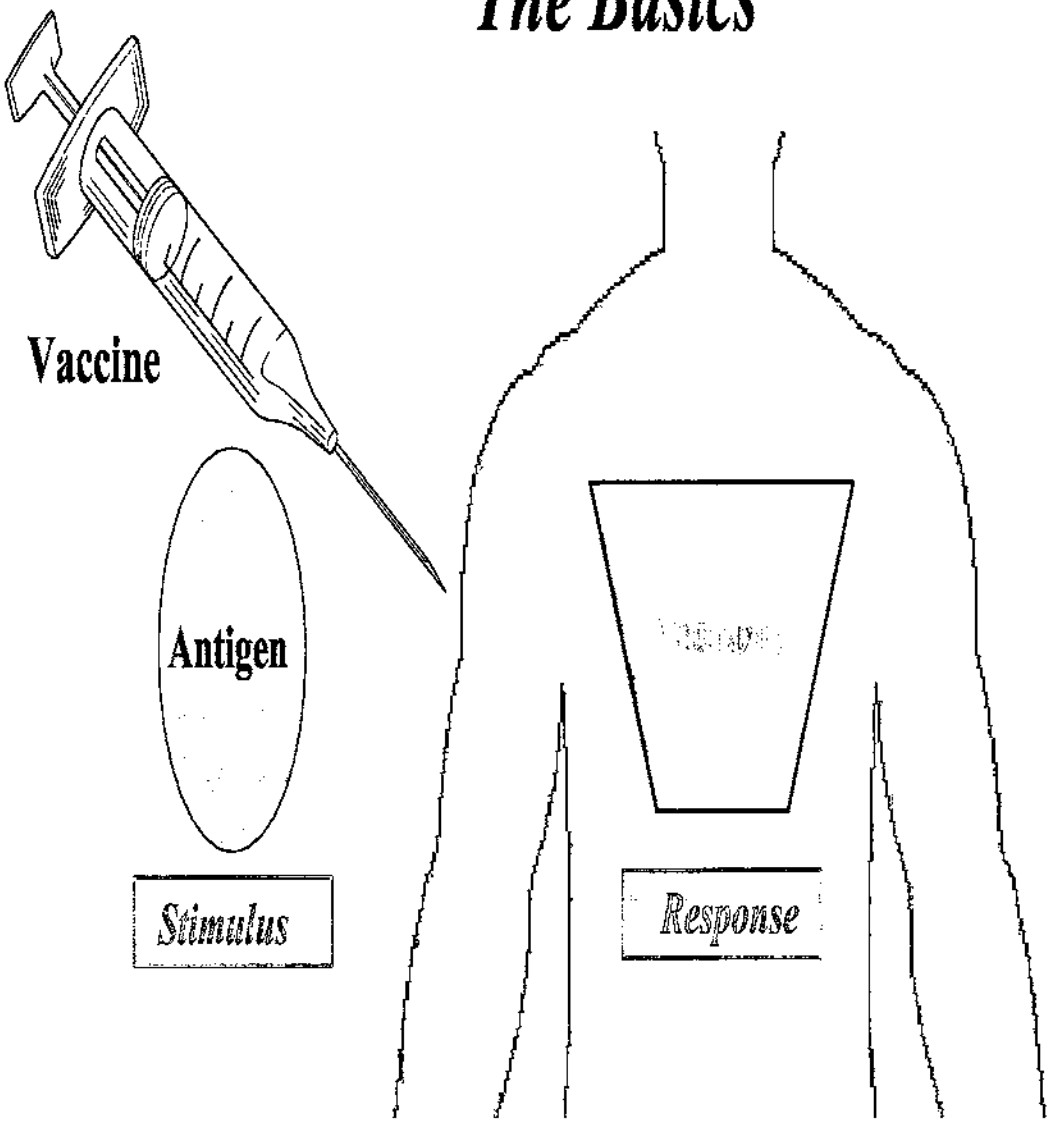


= Death

Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



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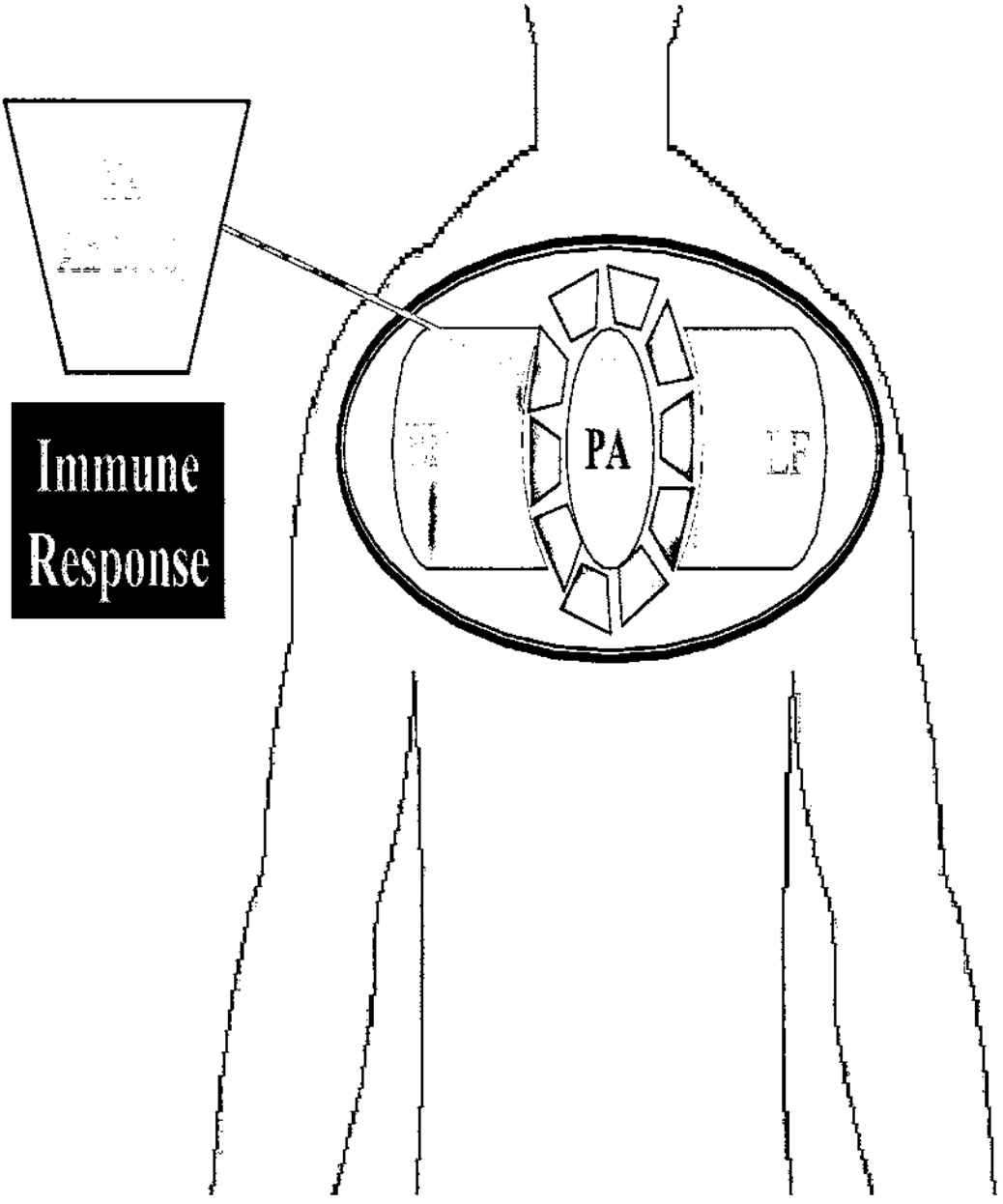
AFTER ANTHRAX VACCINE

Antibodies at Work



Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

Anthrax Vaccine Program

- Licensed by the FDA since 1970
  - Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers
- Shot schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster

1-877-GET-VACC
DSN: 761-5101
www.anthrax.osd.mil
www.aviationmedicine.com

Anthrax Vaccination Program

- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea
- Phase III - Total force
- 445,452 vaccinated - 1,738,860 doses (10 May 00)
- Complete supplemental testing on vaccine prior to release
- Plant renovation completed
- DoD anthrax web site: ***www.anthrax.osd.mil***

Office of the Special Assistant for Gulf War Illnesses

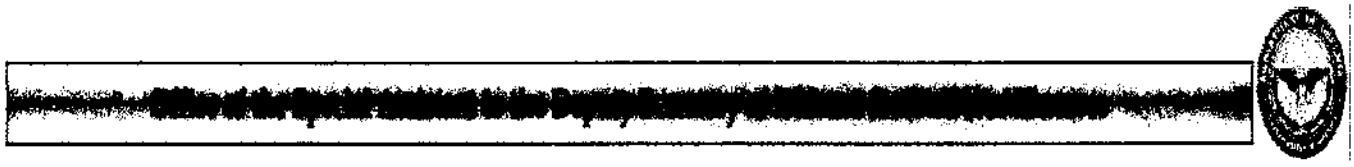
Francis L. O'Donnell
Colonel, Medical Corps, United States Army

Director, Medical Outreach and Issues
Office of the Special Assistant for Gulf War Illnesses
703-845-3374 fax 703-578-8501
email: fodonnel@gwillness.osd.mil

Primer

on

Gulf War Illnesses



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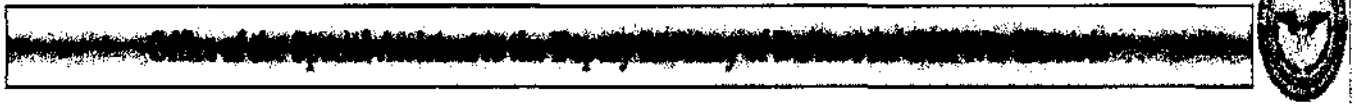

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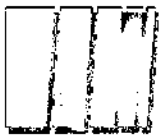

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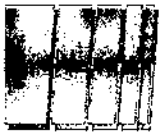

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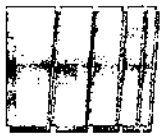

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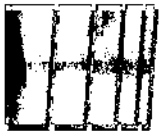

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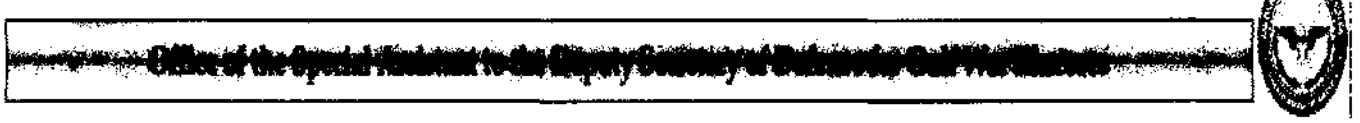
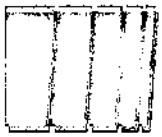
Medically unexplained	**20**	**20**





Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"
"It's all in your head!"
"You're faking these symptoms!"

Epidemiology Studies

	Deployed (%)	Non-Deployed (%)
Medical separation (Aug 91 - Dec 93)	**2.20**	**2.56**
Hospitalizations (Aug 91 - Sep 93)	**21.6**	**21.6**
Hospitalizations unexplained illnesses (Aug 91 - Apr 96)	**1.21**	**1.27**
Birth Defects (Aug 91 - Sep 93)	**7.45**	**7.59**
Mortality (Aug 91 - Sep 93)	**.025**	**.023**

Possible Causes

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIMINE BROMIDE

INFECTIOUS DISEASES

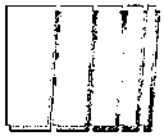
STRESS

COCKTAIL EFFECT

Special Assistant for Gulf War Illnesses

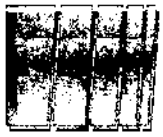
Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members



Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DoD adapts doctrine, policy and procedures to reduce risks for troops in the future.



Lessons Learned

CHEMICAL WARFARE

- 14,000 M8 units
- False Positives
- In and out of MOPP, no explanations
- Alarms turned off
- No need to know

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

- Navy Forward Laboratory
- No positive cultures

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

- DEET, permethrin, organophosphates
- Unapproved items: flea collars, SNIP

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

- Soot, ash, black cloud
- No information
- EPA monitoring March 91
- Particulates, no toxic fumes

Lessons Learned

CHEMICAL WARFARE

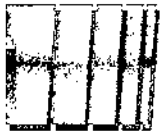
BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

- Vaccines "secret"
- No records
- No explanations
- Squalene



Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

- Tank armor, penetrators
- No training
- Heavy metal, proximal tubule
- Surveillance of most exposed

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

- Soman prophylaxis
- Not FDA approved use
- Recognized side effects
- Medical confusion
- No explanations, no records
- Varied protocols

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

INFECTIOUS DISEASES

- 12 malaria, 32 leishmaniasis
- Diarrhea, URI's
- *Mycoplasma fermentans incognitus*

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

INFECTIOUS DISEASES

STRESS

- NO DoD policy that "stress is the cause of symptoms"
- CNN, communications home
- Uncertainties
- Profiles are stress of chronic disease
- PTSD rate lower than Vietnam
- Stress can amplify already existing symptoms

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

STRESS

BIOLOGICAL WARFARE

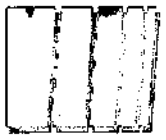
OIL WELL FIRES

DEPLETED URANIUM

INFECTIOUS DISEASES

COCKTAIL EFFECT

- No scientific evidence yet



Force Health Protection

Predeployment

Medical threat briefing
Distribute medical information
Verify HIV test in last 12 months
Verify current physical examination
Verify DNA sample on file
Predeployment serum sample
Immunizations
Predeployment health questionnaire

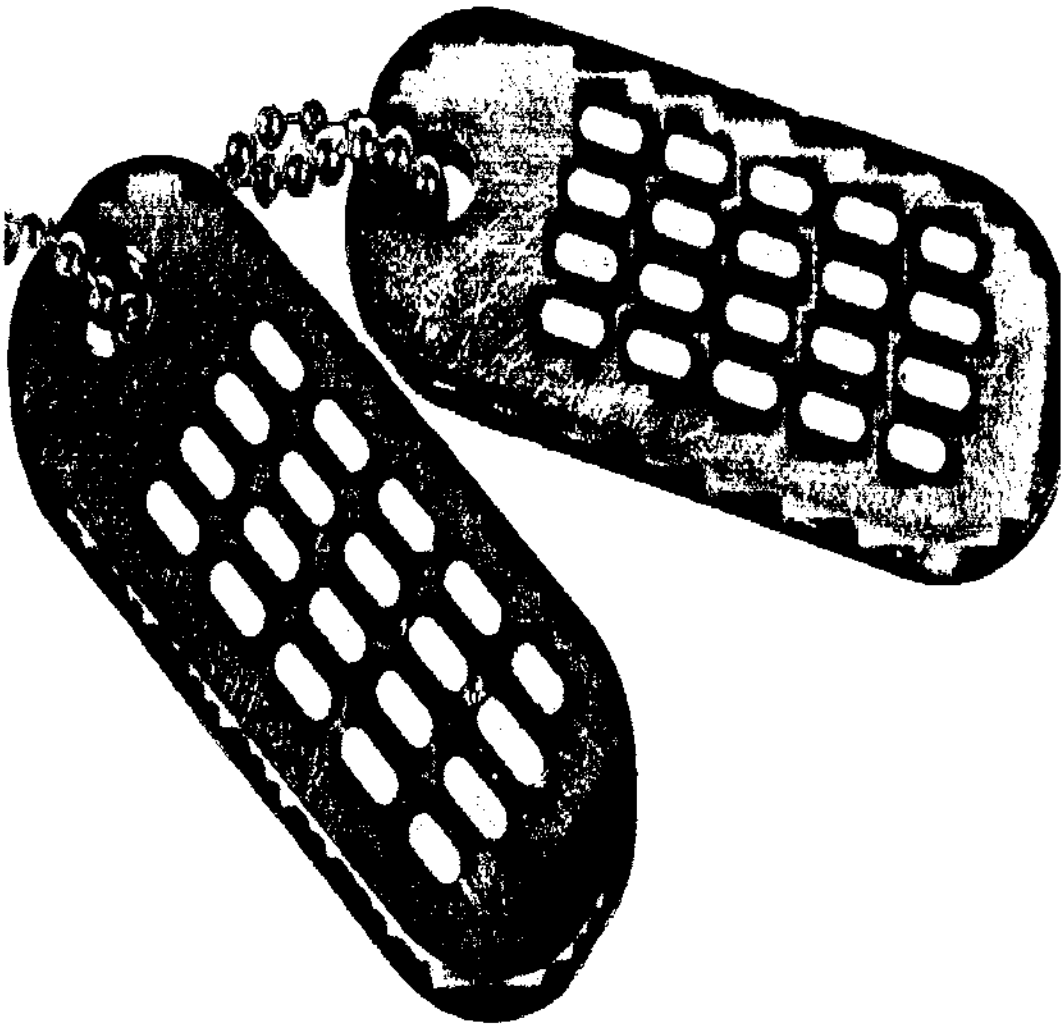
Deployment

Daily and weekly disease/injury reporting
Environmental monitoring
Forward medical laboratory
Immunization tracking
Medical threat updates

Post Deployment

Post deployment serum sample
Post deployment health questionnaire
Analysis of "lessons learned"
Medical debriefs
Screening exams as needed

Medical Personal Information Center (PIC)



Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

Anthrax

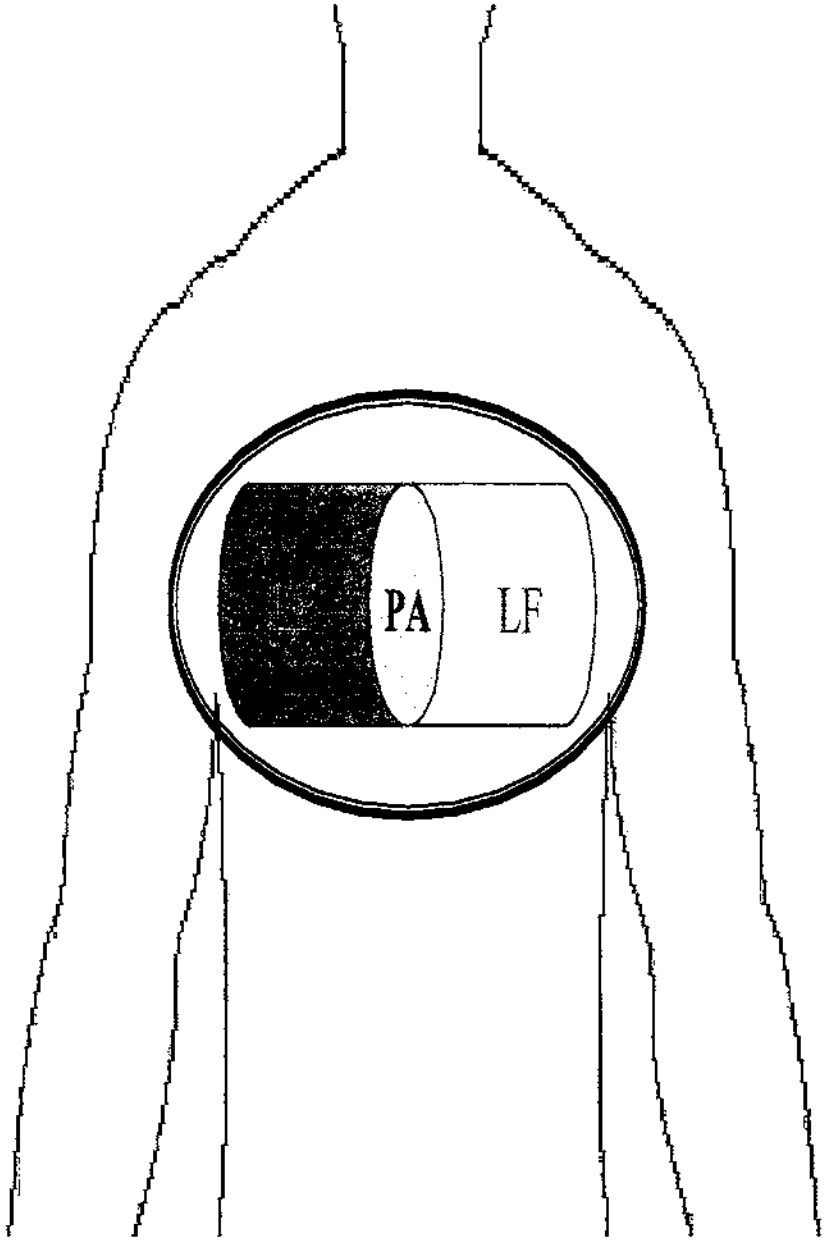
- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of weapons
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4 prevents exposure
- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

Anthrax Vaccination Program

- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea
- Phase III - Total force
- 432,918 vaccinated - 1,637,853 doses (19 Apr 00)

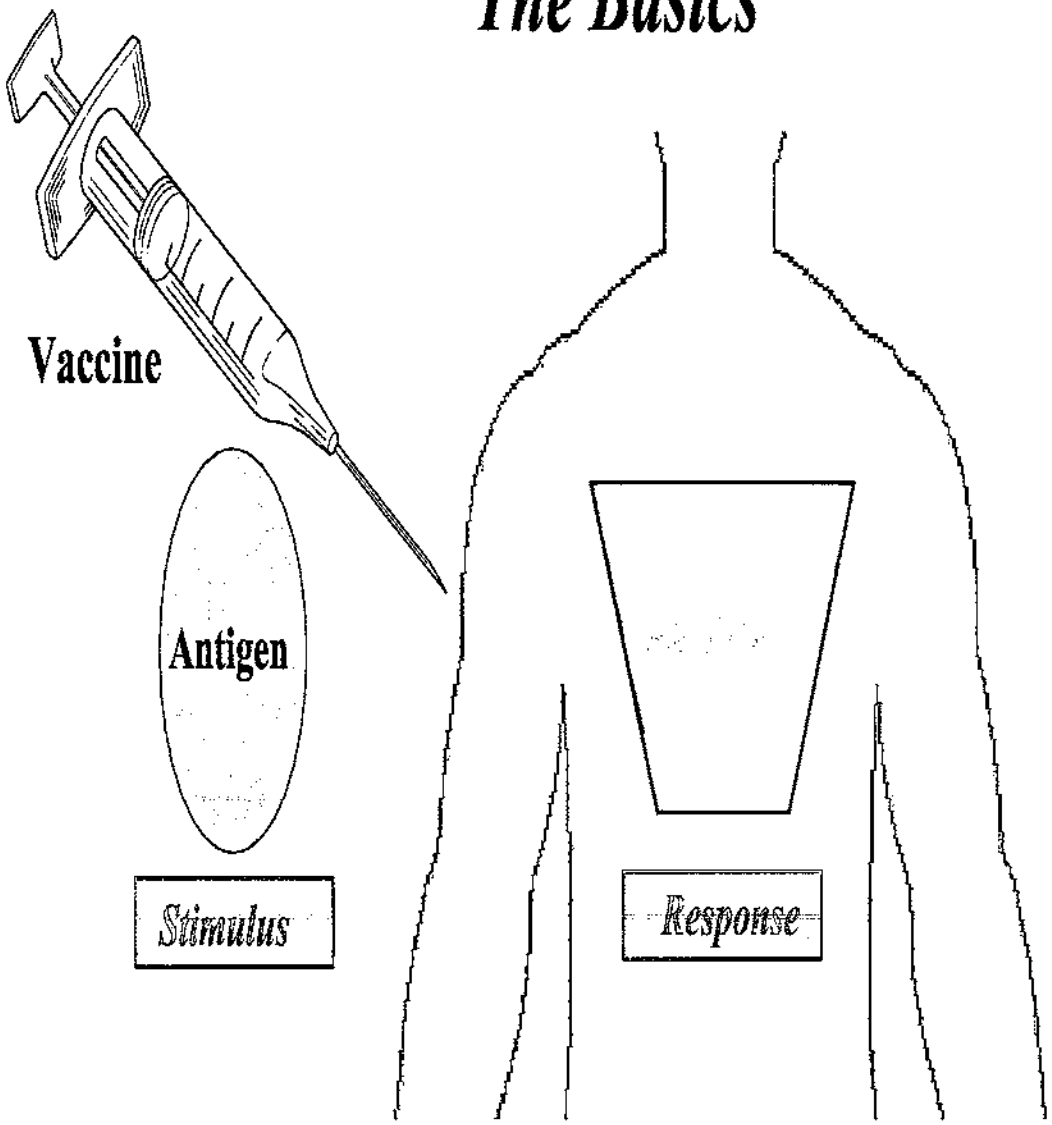
ANTHRAX BACTERIA ATTACK



= Death

IMMUNE SYSTEM ACTIVATION BY VACCINE

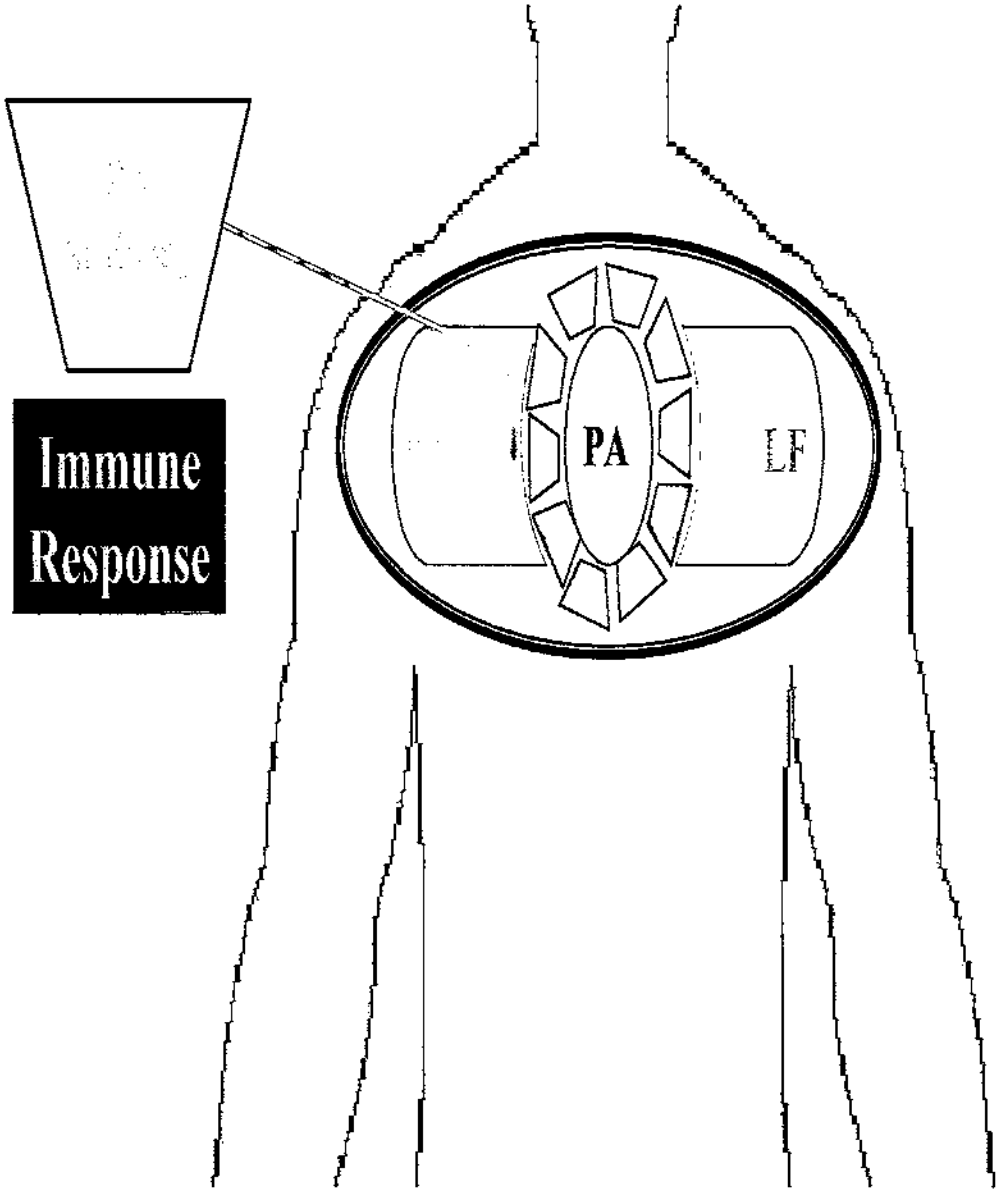
The Basics



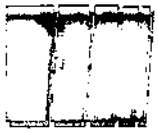
Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

AFTER ANTHRAX VACCINE

Antibodies at Work



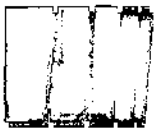
Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses



Anthrax Vaccine Program

- Licensed by the FDA since 1970
  - Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers
- Shot schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster

1-877-GET-VACC
DSN: 761-5101
www.anthrax.osd.mil
www.aviationmedicine.com



Office of the Special Assistant for Gulf War Illnesses

CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-497-6261
GulfLINK	*www.gulflink.osd.mil*

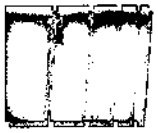
Colonel Francis L. O'Donnell MC, USA

phone 703-845-3374 fax 703-578-8501

email: fodonnel@gwillness.osd.mil

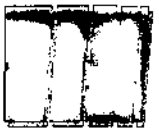
Distribution of CCEP Diagnoses by Major ICD-9 Categories

	Primary (%)	All Dx (%)
• Musculoskeletal	19.6	20.8
• Symp., Signs, IDC	17.4	19.0
• Psychological	17.3	14.8
• V-Codes	10.1	6.0
• Respiratory Sys.	6.5	5.9
• Digestive	6.1	7.3
• Skin	5.9	6.5
• Nervous System	5.5	5.9



Distribution of CCEP Diagnoses by Major ICD-9 Categories (cont)

	Primary (%)	All Dx (%)
• Infections	2.6	3.0
• Circulatory Sys.	2.5	2.8
• Endocr.-Metab.	2.3	2.7
• Genitourinary	1.3	1.8
• Injury-Poisoning	0.9	1.1
• Neoplasms	0.9	0.9
• Blood	0.6	0.9



Musculoskeletal / Conn. Tissue

• Pain in Joint	5.5 %
• Osteoarthrosis	3.6 %
• Back Pain and other Back Disorders	2.8 %
• Disord. of Tendons, Muscle Attachments	1.6 %
• Other Disorders of Soft Tissue	1.4 %
• Disc Disorders	1.0 %
• Knee Derangements	0.4 %

Symptoms, Signs, Ill Defined Cond.

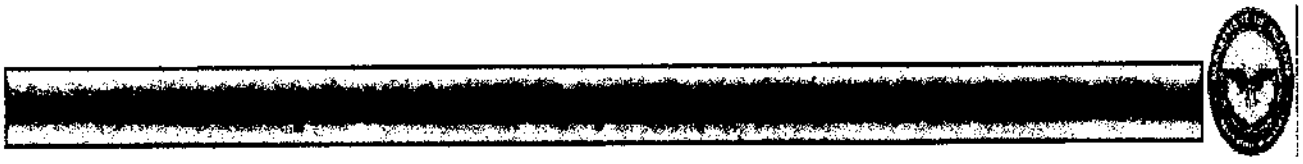
• Malaise, Fatigue	4.2 %
• Sleep Disturbances	3.3 %
• General Symptoms and Hyperhidrosis	1.9 %
• Symp. Of Respiratory Sys. And Chest	1.6 %
• Symptoms involving the Skin	1.1 %
• Alterations of Consciousness, Awareness	0.6 %
• Abdom. Pain, Various Locations	0.4 %
• Symptoms of Digestive System	0.4 %

Psychological

• Depressive Disorder	2.9 %
• Neuroses	2.8 %
• Prolonged PTSD	2.6 %
• Affective Disorders	1.8 %
• Adjustment Reactions	1.2 %
• Sleep Disorders	0.6 %
• Organic Brain Syndromes, Various	0.5 %

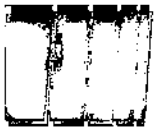
Respiratory Tract

- Asthma 2.2 %
- Allergic Rhinitis 1.5 %
- Chronic Upper Respir. Inflammation 1.5 %



Healthy

- Feared complaint, no diagnosis 8.0 %
- Routine general medical examination 0.9 %



Gastrointestinal

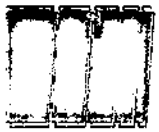
- Irritable Colon 1.5 %
- Esophageal Reflux 1.3 %
- Enteritis and Colitis 0.6 %

Integument

- Alopecia, hirsutism, other dis. of hair 1.3 %
- Fungus infections of skin 1.3 %
- Contact dermatitis, other eczema 1.2 %
- Urticaria, various types 0.5%

Headache

- Tension Headache 3.1 %
- Migraine 2.9 %
- Headache 2.5 %



Other

• Hypertension, essential	1.2 %
• Lipoid Metabolism Disorders	0.6 %
• Hearing Loss	0.4 %
• Hypothyroidism	0.4 %

Evaluation of Future Deployments

Michael E. Kilpatrick MD, FACP

Medical Outreach and Issues
Office of the Special Assistant for Gulf War Illnesses
703-578-8510 fax 703-578-8501
email: mkilpatr@gwillness.osd.mil

Major Lesson Learned from the Gulf War

DoD Does Not Deal Well With Non-Traditional Issues

Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

Deployments

- Unexpected and rapid personnel movement
- Personal and family hardships
- Stress in the field
  - Missile attacks
  - Chem-bio attacks
  - Witnessing death/atrocities
  - Harsh Living Conditions
  - Foreign cultures
  - Racial/ethnic hatred
- Inadequate communication
- No answers to questions after returning

Force Health Protection

Predeployment

- Medical threat briefing
- Distribute medical information
- Verify HIV test in last 12 months
- Verify current physical examination
- Verify DNA sample on file
- Predeployment serum sample
- Immunizations
- Predeployment health questionnaire

Deployment

- Daily and weekly disease/injury reporting
- Environmental monitoring
- Forward medical laboratory
- Immunization tracking
- Medical threat updates

Post Deployment

- Post deployment serum sample
- Post deployment health questionnaire
- Analysis of "lessons learned"
- Medical debriefs
- Screening exams as needed

Who's Involved?

Predeployment

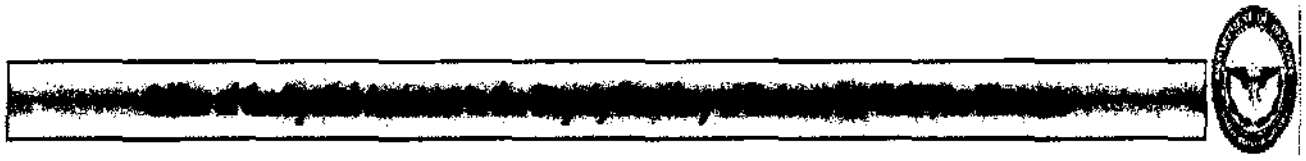
Unit medical personnel
AFMIC
CHPPM
Risk Communicators

Deployment

Unit medical personnel
Environmental team
CHCS
Rapid diagnostic team
AFMIC
Risk Communicators

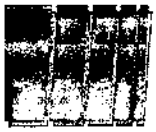
Post Deployment

Unit medical personnel
Unit operational personnel
Risk Communicators
DoD/VA healthcare systems



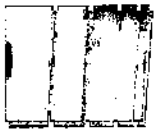
Understanding Today's Military Member

- 55% are married
- 46% have children
- 40% of the 1.3 million children are < 6 years old
- 6% are single parents
- 8% care for elder parents
- 14% are women



Today's Military Member

- Better informed
- More demanding
- Concerned
- Concerned about military medicine
- Wants high technology answers



Today's Deployments

- Increased by 60%
- Personnel and Budget Decreased by 34%
- Trained to be Warfighters
- High Technology Weapons, Communications
- Assignments
  - Peacekeepers
  - Drug Interdiction
  - Humanitarian Relief
  - CB Terrorism Response
- Targets for Random Acts of Violence

Concerns on the Deployed Member

- Importance of the mission
- Recognition by others of his/her role
- Ability to express fears/concerns/problems to leadership
- Recognition for performance

Successful Mission

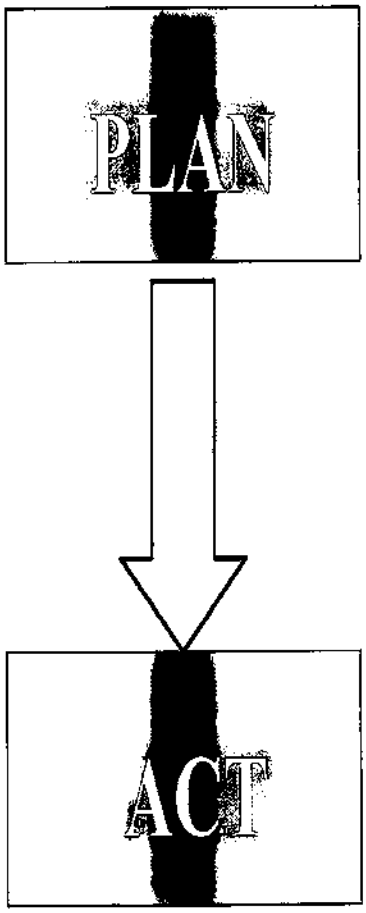
- Knew why I was there and agreed
- Knew what to do
- Knew how to do it
- Had what I needed to do it
- Did it well
- Was appreciated for my contribution
- Returned proud I had been there

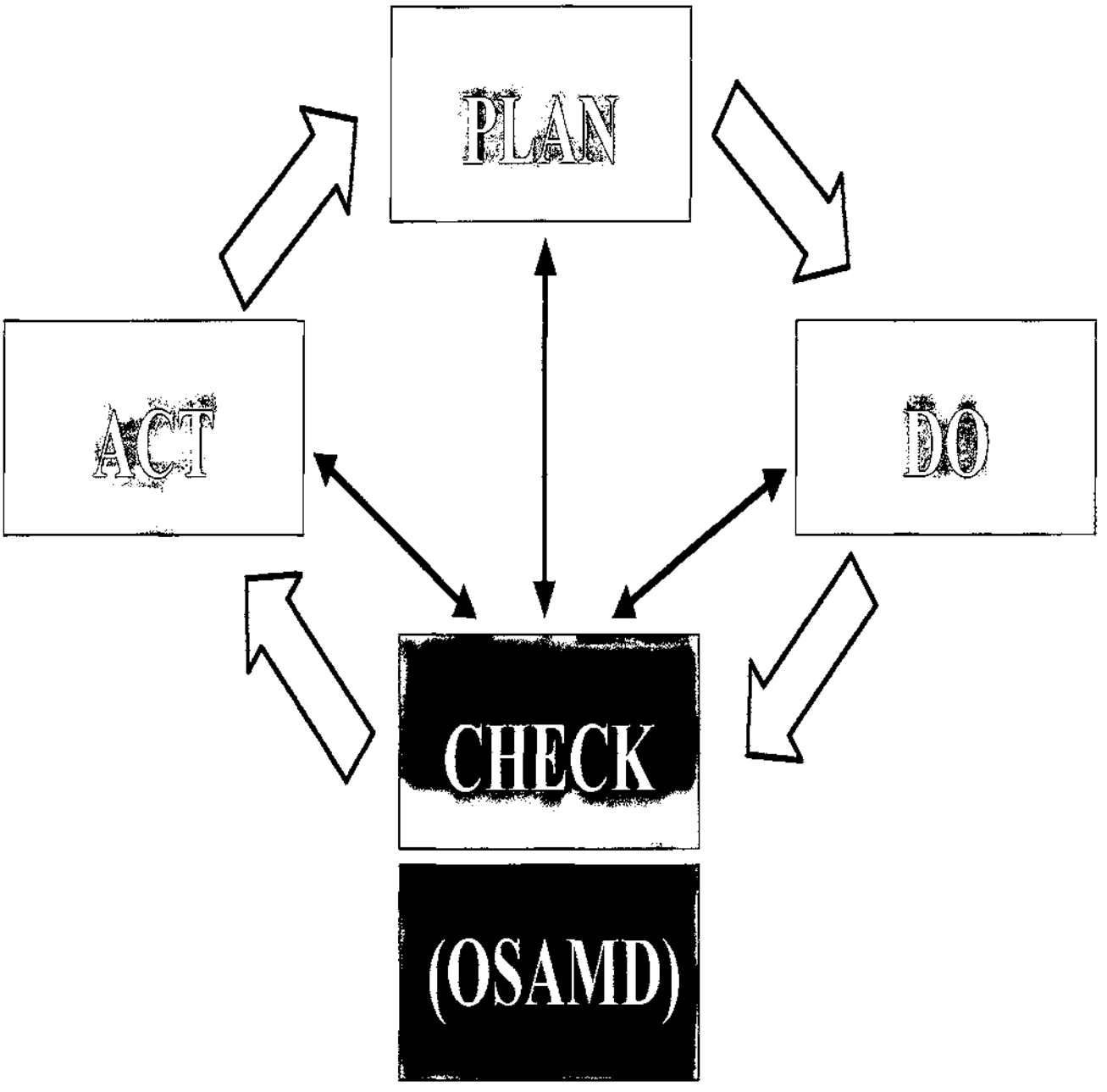
Recent Developments

- Military Veterans Health Coordinating Board
  - DoD, VA, HHS
- VA National Center for Military Deployment Health Research
- DoD Center for Deployment Medicine
  - Naval Health Research Center
  - Walter Reed Center for Deployment Medicine
  - Center for Health Promotion & Preventive Medicine

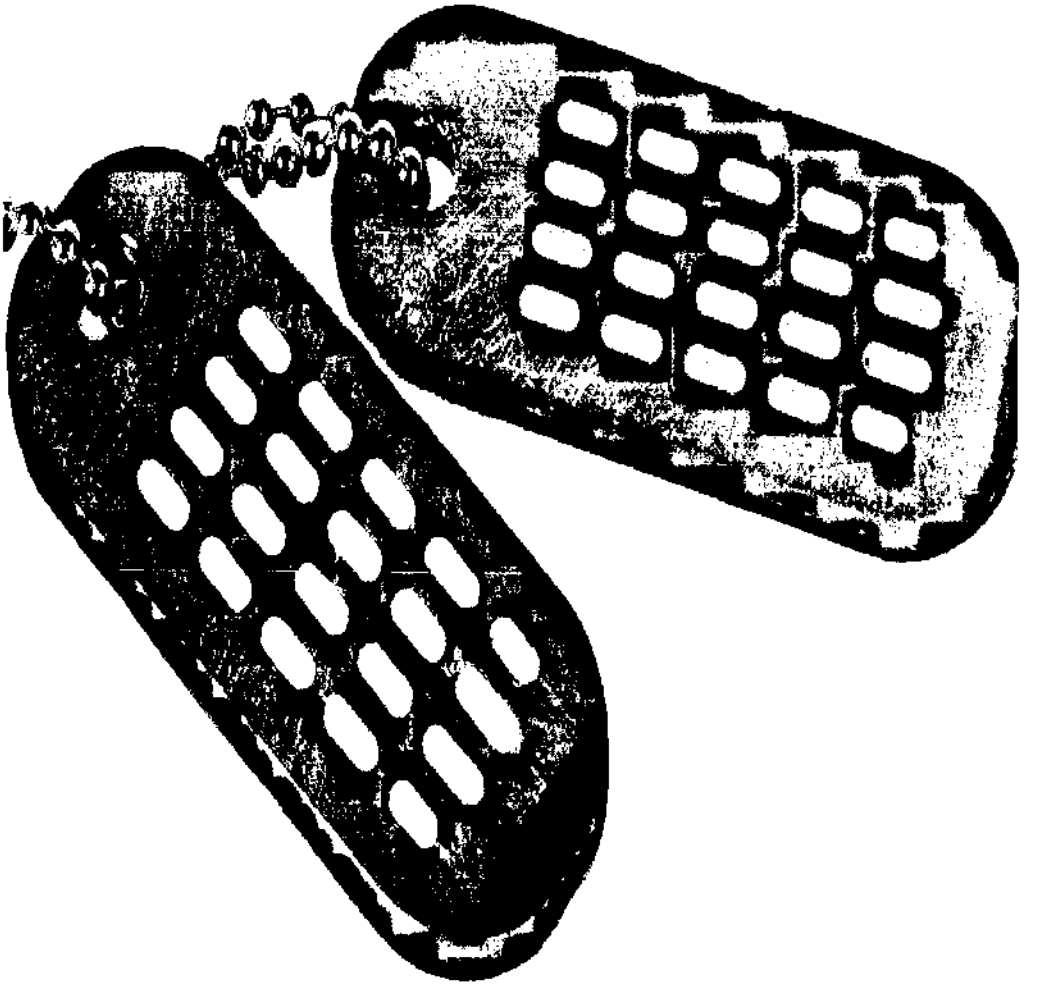
Office of the Special Assistant for Military Deployments

- Respond to veterans' deployment health related questions
- Facilitate assimilation of health related lessons learned
- Assure effectiveness of DoD programs protecting health during deployment


PLAN
ACT

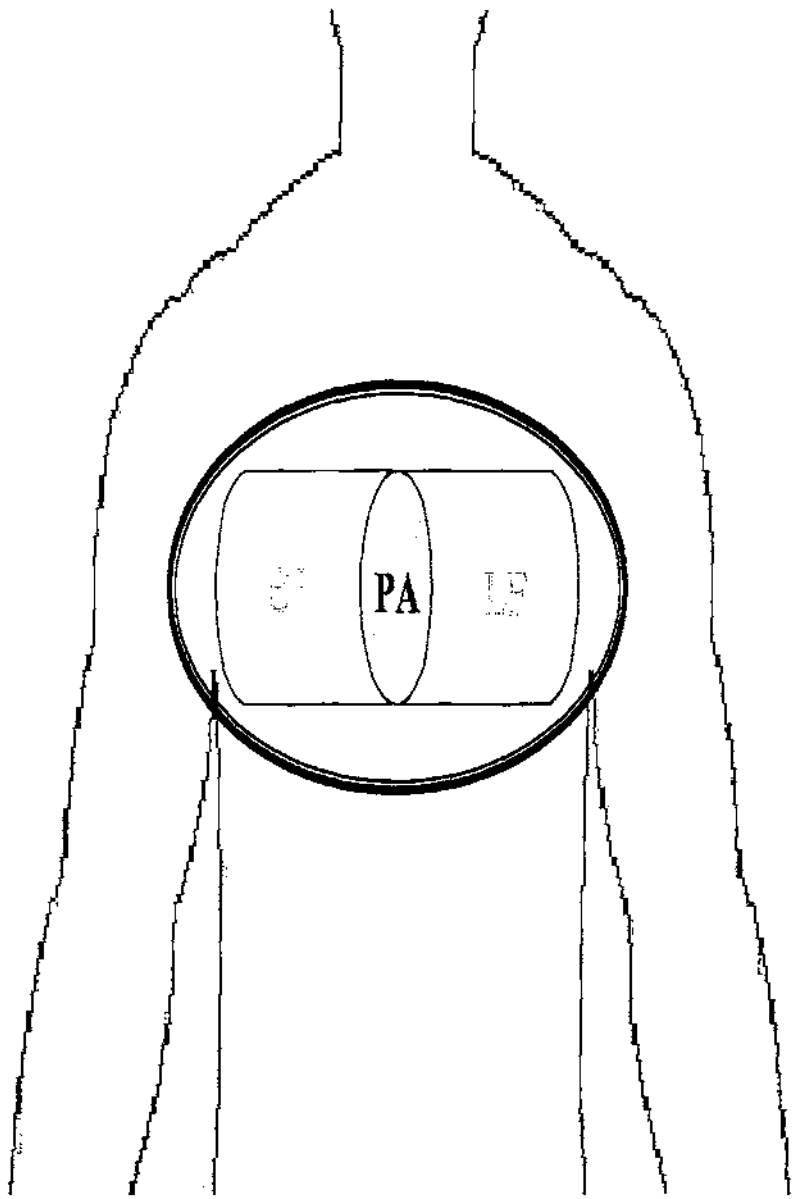

PLAN
ACT
DO
CHECK
(OSAMD)

Medical Personal Information Center (PIC)



Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

ANTHRAX BACTERIA ATTACK

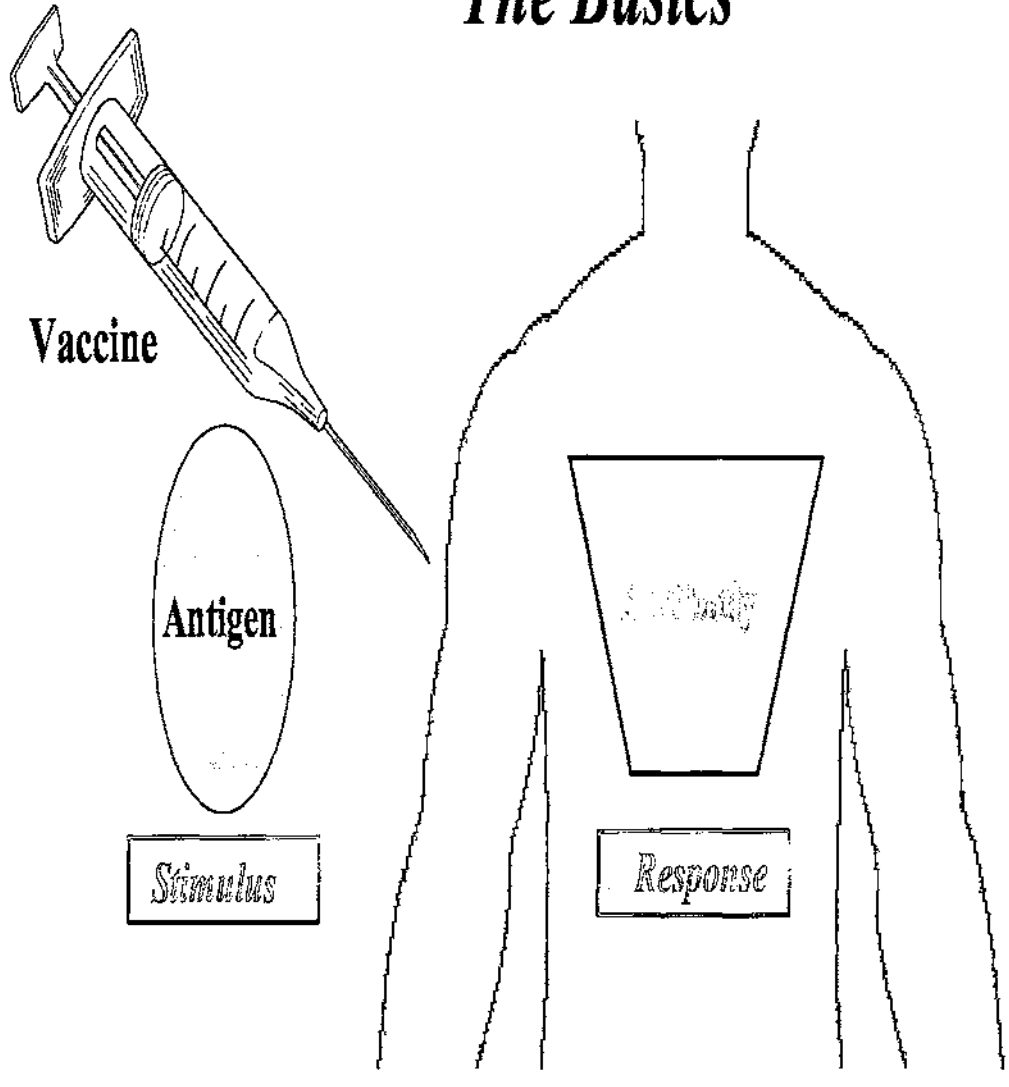


= Death

Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

IMMUNE SYSTEM ACTIVATION BY VACCINE

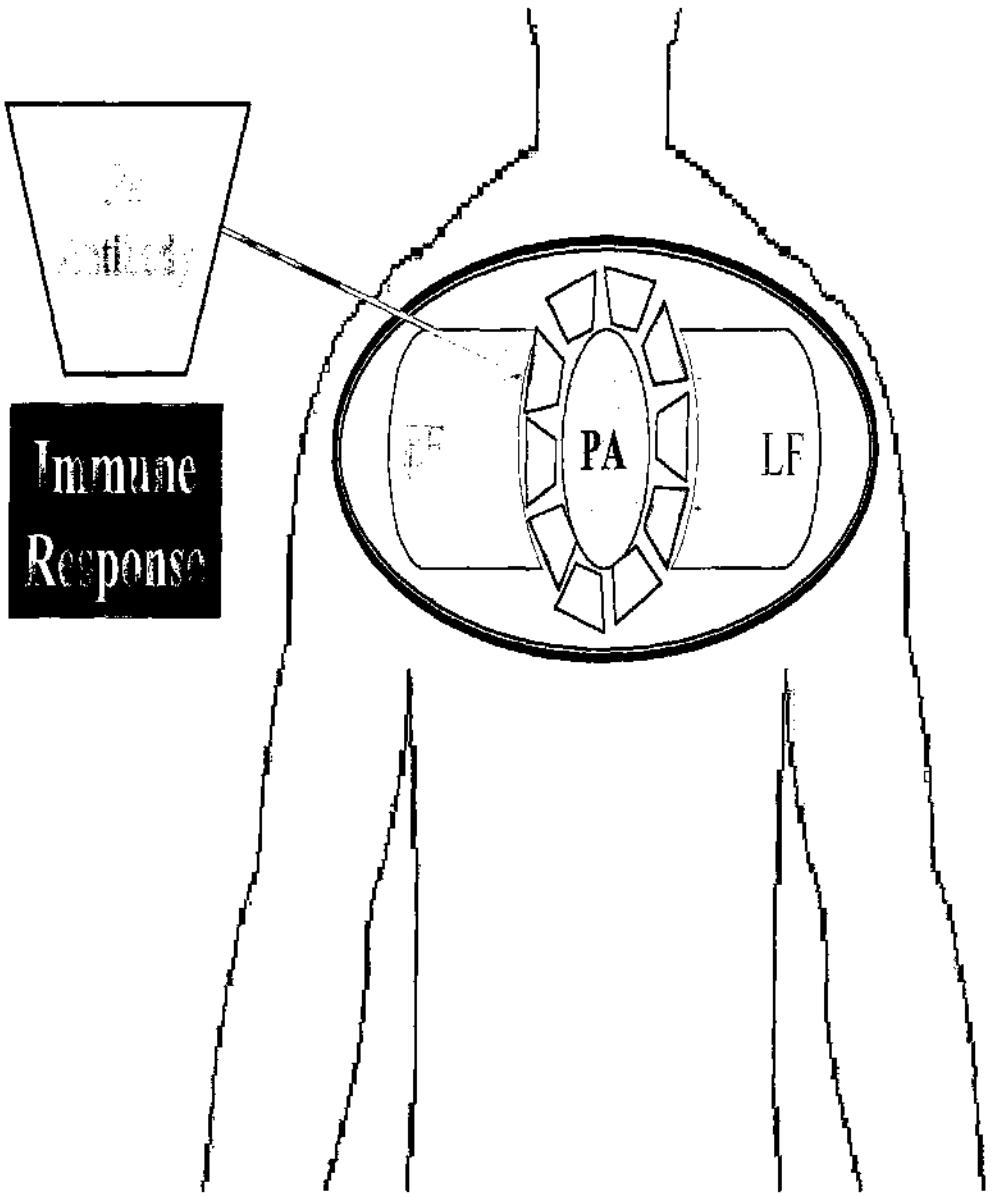
The Basics



Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

AFTER ANTHRAX VACCINE

Antibodies at Work



Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

Anthrax Vaccine Program

- Licensed by the FDA since 1970
  - Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers
- Shot schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster

1-877-GET-VACC
DSN: 761-5101
www.anthrax.osd.mil
www.aviationmedicine.com

Anthrax Vaccination Program

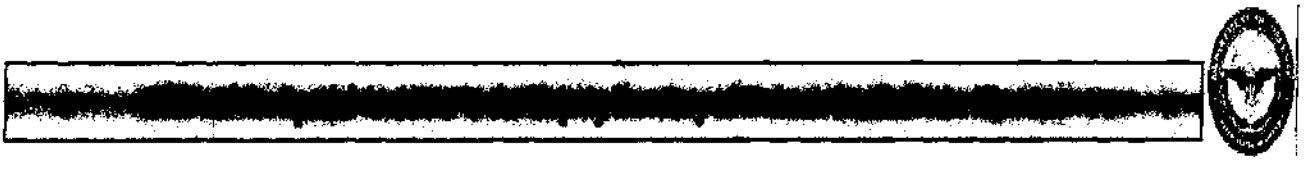
- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea
- Phase III - Total force
- 453,435 vaccinated - 1,797,597 doses (14 June 00)
- Complete supplemental testing on vaccine prior to release
- Plant renovation completed
- DoD anthrax web site: ***www.anthrax.osd.mil***

Risk Communication

1. Allow Ventilation
2. Determine Underlying Concern
3. Empathy
4. Conclusion Soundbite
5. Facts (2)
6. Next Steps

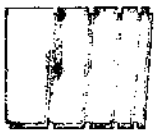
Art of Medicine

1. Ask open-ended questions
2. Chief complaint
3. Managed similar problems
4. Diagnosis
5. Lab, physical findings
6. Treatment, next appointment



Where Do We Go From Here?

- Concept - Deployment Medicine Clinics
  - Connected to all deployment sites
  - Source for pre and post deployment information
  - Information for family members
- Concept - Education on Vaccines
  - Start updating electronic record entrance
  - Validate accuracy with leave/bonus requests
  - Internet linkage to CDC for recommendations
- Concept - ????



Office of the Special Assistant for Gulf War Illnesses

Michael E. Kilpatrick MD, FACP

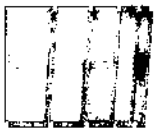
Medical Outreach and Issues
Office of the Special Assistant for Gulf War Illnesses
703-578-8510 fax 703-578-8501
email: mkilpatr@gwillness.osd.mil

JCAHO
Physical Readiness
Anthrax
Credentials
GME
Readiness
TRICARE
Privileges
Force Health Protection
Medical Boards
Gulf War Illnesses
NJP
CME

Primer

on

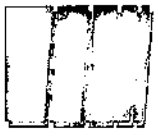
Gulf War Illnesses



Special Assistant for Gulf War Illnesses

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members



Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DoD adapts doctrine, policy and procedures to reduce risks for troops in the future.

Who Served in the Gulf War

697,000 U.S. service members

ARMY	50%
NAVY	23%
MARINE	15%
AIR FORCE	12%

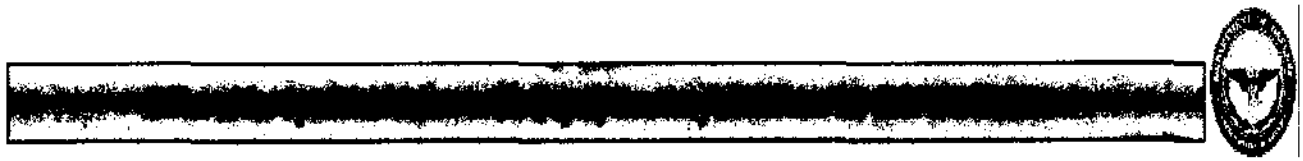
259,000 Coalition Forces

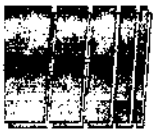
Source: Presidential Advisory Committee on Veterans Illnesses, Final Report

Who Served in the Gulf War

MALE	93%
FEMALE	7%
ACTIVE	83%
RESERVE/NATIONAL GUARD	17%
OFFICER	10%
ENLISTED	90%

< 26 years old - 55%; 26-35 years old - 32%; > 35 years old - 13%



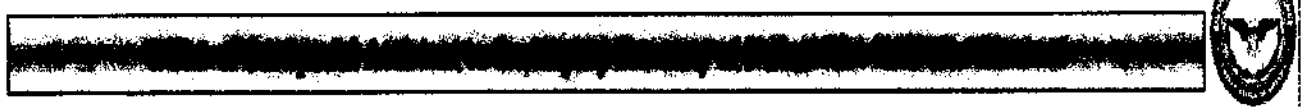


Medical Support

Largest emergency health care system since WW II

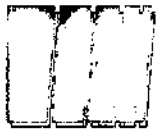
- 41,000 medical personnel
- 18,000 beds
  - 2 hospital ships
  - 63 combat zone hospitals

source: CENTCOM Publications - Commander-in-chief US CENTCOM "Desert Shield/Desert Storm Facts, Figures, Quotes and Anecdotes 7 AUG 90-11 APR 91," prepared by CENTCOM PAO



Medical Support

- 27,000 hospitalizations in theater
- 8,000 medical evacuations
- ????? outpatient visits



U.S. Deaths

Non-Battle	224
Battle	148

Symptoms

Tiredness

Rashes

Headaches

Muscle aches

Joint pains

Abdominal pain

Diarrhea

Hair loss

Memory loss

Sleep disturbance

Depression

Concentration problems

Medical Evaluations

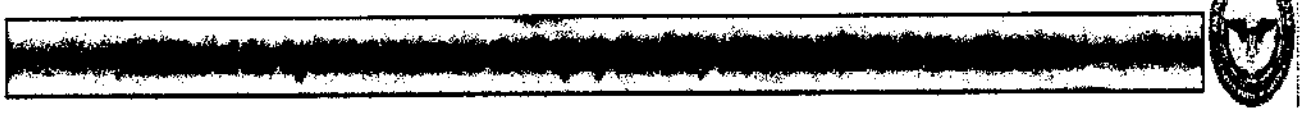
- Comprehensive Clinical Evaluation Program (CCEP)

Total Participants	55,564
Decline examination	15,700
Examined	39,864
♦ Veterans Affairs Registry -examined	78,869
Total Examined	**118,733**

Source: OASD (Health Affairs) 31May 00 VA Registry 26 May 00

Diagnosis Distribution

Categories	CCEP (%)	VA Registry (%)
Healthy	10	12
Symptomatic	90	88
Medically explained	80	80
Medically unexplained	**20**	**20**

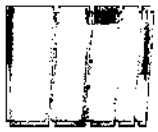


Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"
"It's all in your head!"
"You're faking these symptoms!"



VA Disabilities
Gulf War Veterans

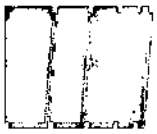
- 696,530 personnel served in the Gulf War
- 132,891 have some service connected medical condition - 19%
- 43,875 veterans' medical conditions have been rated at less then 10%
- 89,016 veterans' medical conditions have been rated at 10% or greater

Top Service Connection Conditions Among Gulf War Veterans

1. Impairment of the knee
2. Skeletal system disability
3. Lumbosacral strain
4. Arthritis due to trauma
5. Scars
6. Hearing loss
7. Tinnitus
8. Hypertension
9. Intervetebral disc syndrome

Epidemiology Studies

	Deployed (%)	Non-Deployed (%)
Medical separation (Aug 91 - Dec 93)	2.20	2.56
Hospitalizations (Aug 91 - Sep 93)	21.6	21.6
Hospitalizations unexplained illnesses (Aug 91 - Apr 96)	1.21	1.27
Birth Defects (Aug 91 - Sep 93)	7.45	7.59
Mortality (Aug 91 - Sep 93)	.025	.023



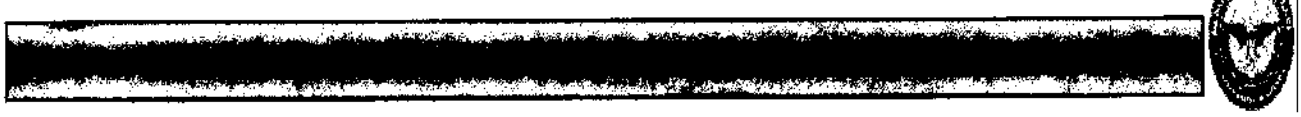
Possible Causes

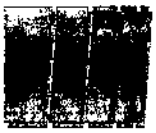
CHEMICAL WARFARE	BIOLOGICAL WARFARE
PESTICIDES	OIL WELL FIRES
VACCINES	DEPLETED URANIUM
PYRIDOSTIMINE BROMIDE	INFECTIOUS DISEASES
STRESS	COCKTAIL EFFECT

Lessons Learned

CHEMICAL WARFARE

- 14,000 M8 units
- False Positives
- In and out of MOPP, no explanations
- Alarms turned off
- No need to know
- Brain Damage



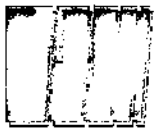


Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

- Navy Forward Laboratory
- No positive cultures



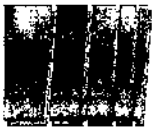
Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

- DEET, permethrin, organophosphates
- Unapproved items: flea collars, SNIP



Lessons Learned

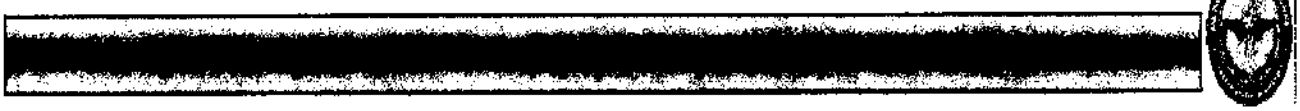
CHEMICAL WARFARE

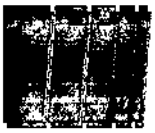
PESTICIDES

BIOLOGICAL WARFARE

OIL WELL FIRES

- Soot, ash, black cloud
- No information
- EPA monitoring March 91
- Particulates, no toxic fumes





Lessons Learned

CHEMICAL WARFARE

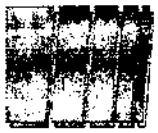
BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

- Vaccines "secret"
- No records
- No explanations
- Squalene



Lessons Learned

CHEMICAL WARFARE

PESTICIDES

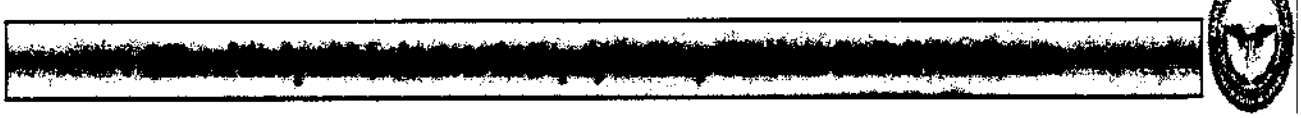
VACCINES

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

- Tank armor, penetrators
- No training
- Heavy metal, proximal tubule
- Surveillance of most exposed



Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

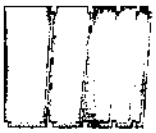
OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

- Soman prophylaxis
- Not FDA approved use
- Recognized side effects
- Medical confusion
- No explanations, no records
- Varied protocols



Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

INFECTIOUS DISEASES

- 12 malaria, 32 leishmaniasis
- Diarrhea, URI's
- *Mycoplasma fermentans incognitus*

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

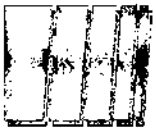
DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

INFECTIOUS DISEASES

STRESS

- NO DoD policy that "stress is the cause of symptoms"
- CNN, communications home
- Uncertainties
- Profiles are stress of chronic disease
- PTSD rate lower than Vietnam
- Stress can amplify already existing symptoms



Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

STRESS

BIOLOGICAL WARFARE

OIL WELL FIRES

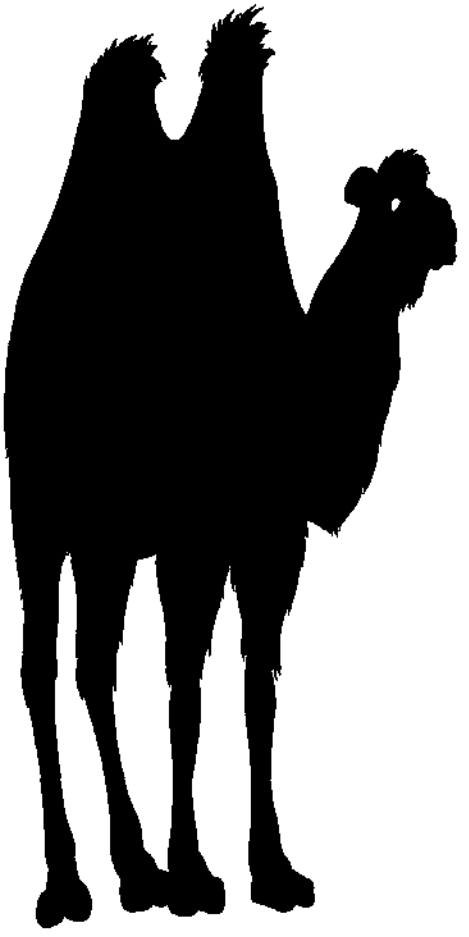
DEPLETED URANIUM

INFECTIOUS DISEASES

COCKTAIL EFFECT

- No scientific evidence yet

THE BLACK CAMEL



Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

Possible Causes

- Normal disease rate
- New disease paradigm - a Black Camel

Force Health Protection

Predeployment

- Medical threat briefing
- Distribute medical information
- Verify HIV test in last 12 months
- Verify current physical examination
- Verify DNA sample on file
- Predeployment serum sample
- Immunizations
- Predeployment health questionnaire

Deployment

- Daily and weekly disease/injury reporting
- Environmental monitoring
- Forward medical laboratory
- Immunization tracking
- Medical threat updates

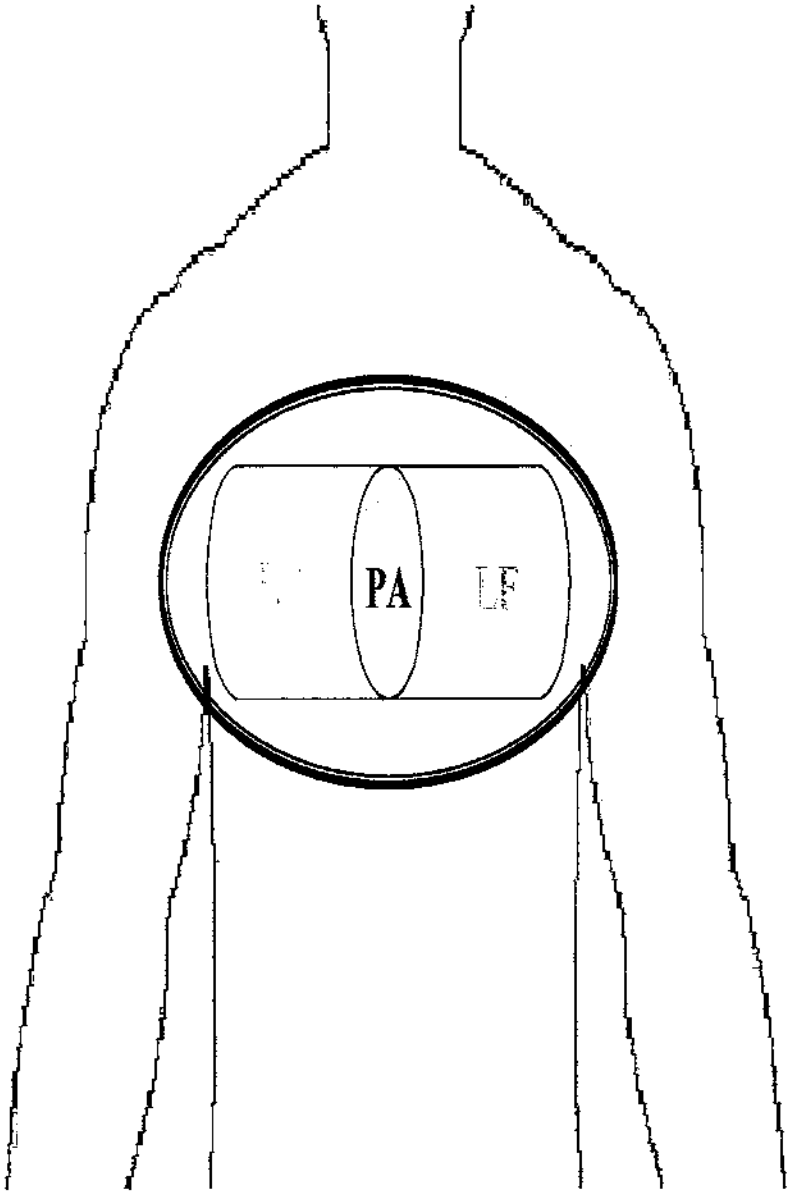
Post Deployment

- Post deployment serum sample
- Post deployment health questionnaire
- Analysis of "lessons learned"
- Medical debriefs
- Screening exams as needed

Medical Personal Information Center (PIC)

Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

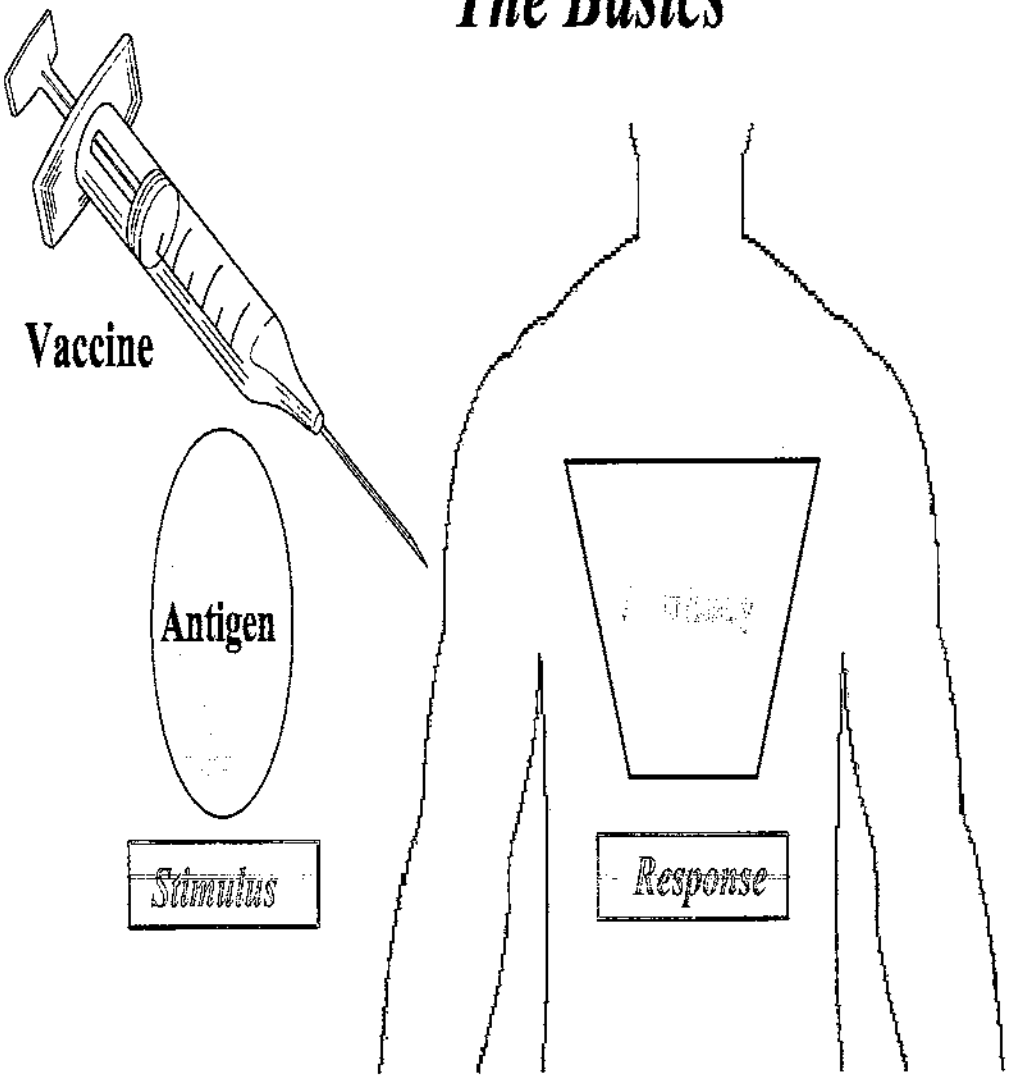
ANTHRAX BACTERIA ATTACK



= Death

IMMUNE SYSTEM ACTIVATION BY VACCINE

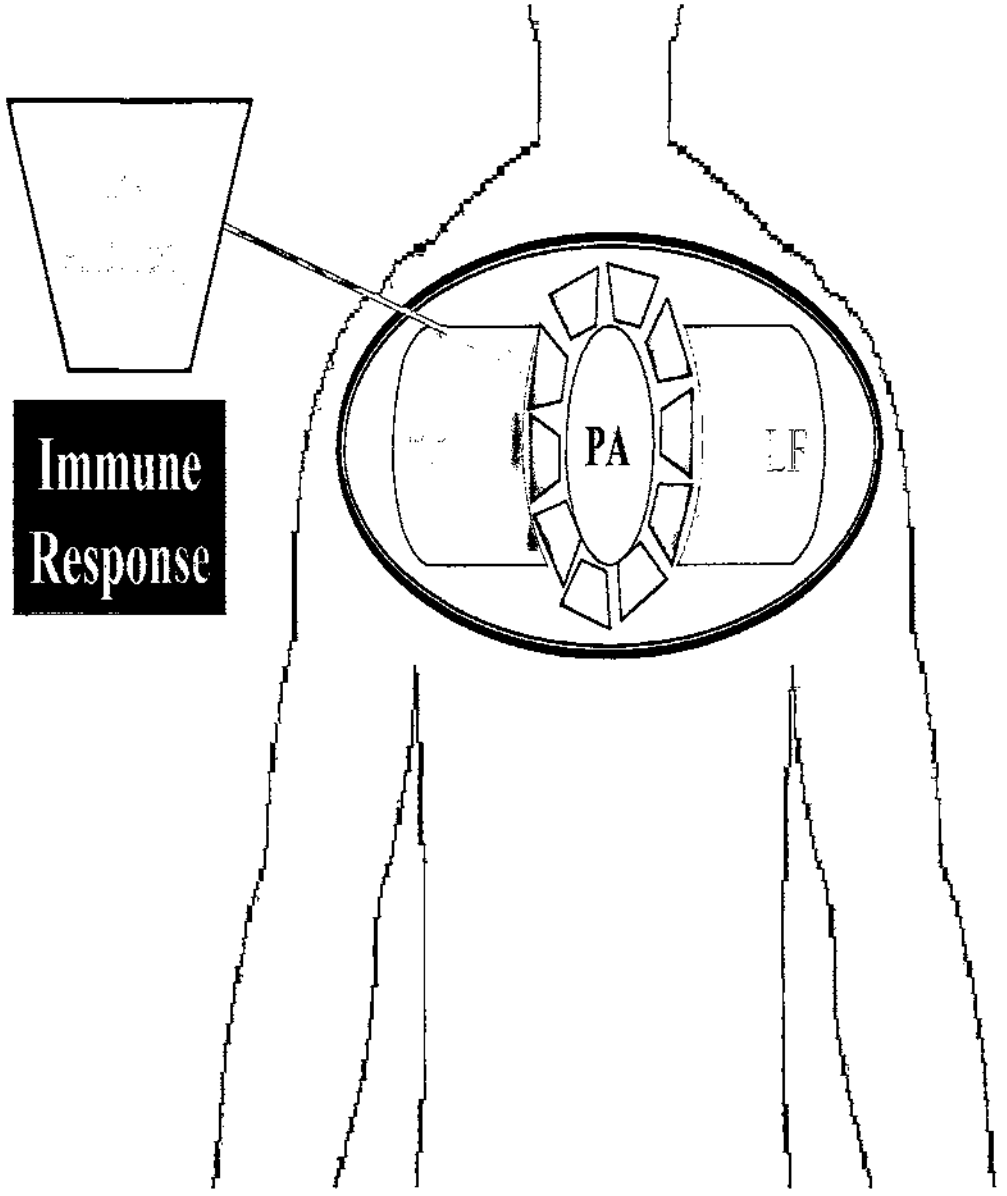
The Basics



Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

AFTER ANTHRAX VACCINE

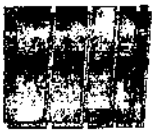
Antibodies at Work



Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses

The Art of Medicine

- Today's Patient
  - Better informed
  - More demanding
  - Concerned symptoms are masking sinister disease
- What's Missing
  - Trust from both sides
- Patient's desire
  - More time
  - Advanced technology



Risk Communication

1. Allow Ventilation
2. Determine Underlying Concern
3. Empathy
4. Conclusion Soundbite
5. Facts (2)
6. Next Steps

Art of Medicine

1. Ask open-ended questions
2. Chief complaint
3. Managed similar problems
4. Diagnosis
5. Lab, physical findings
6. Treatment, next appointment

Office of the Special Assistant for Gulf War Illnesses

CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-497-6261
GulfLINK	*www.gulflink.osd.mil*

Michael E. Kilpatrick MD, FACP

phone 703-578-8510 fax 703-578-8501

email: mkilpatr@gwillness.osd.mil

Anthrax Vaccine Program

- Licensed by the FDA since 1970
  - Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers
- Shot schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster

1-877-GET-VACC
DSN: 761-5101
www.anthrax.osd.mil
www.aviationmedicine.com

Anthrax Vaccination Program

- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea
- Phase III - Total force
- 453,435 vaccinated - 1,797,597 doses (14 June 00)
- Complete supplemental testing on vaccine prior to release
- Plant renovation completed
- DoD anthrax web site: ***www.anthrax.osd.mil***

225

CMAT Control #
2001334-0000005

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

UNCLASSIFIED

INFO MEMO

November 29, 2001 2:45 PM

FOR: SPECIAL ASSISTANT FOR GULF WAR ILLNESSES, MEDICAL READINESS, AND MILITARY DEPLOYMENTS

FROM: Michael E. Kilpatrick, M.D., Director, Deployment Health Support

SUBJECT: GulfLINK

- A recent *New York Times* news article (Tab A) reports that two Pakistani scientists were detained and a number of anthrax-related documents found in their office. Among those identified in the article were documents attributed to a "... Web site devoted to better informing Persian Gulf war veterans...."
- Without seeing the documents, we are unable to determine if, in fact, the referenced site is GulfLINK. However, we reviewed the content of our web site, and found that it is possible that the cited documents are posted there.
- From the description in the news story, we believe the reference is to information on anthrax provided in our An Nasiriyah Southwest Ammunition Storage Point case narrative final report, published January 13, 2000, footnote 121 (Tabs B1-B3). The same information is in the amended An Nasiriyah Southwest Ammunition Storage Point case narrative final report, published September 28, 2000, footnote 119 (Tabs C1-C3).
- In both cases, the primary reference was from the U.S. Army Medical Research Institute of Infectious Diseases handbook, published in July 1998 (Tabs B2 and C2), supported by the October 1999 web site of the DoD Anthrax Vaccine Immunization Program (Tabs B3 and C3).
- We anticipate no further media interest.

COORDINATION: NONE

Attachments:
As stated

Prepared by: (b)(6)

UNCLASSIFIED

New York Times
November 28, 2001

2 Pakistanis Linked To Papers On Anthrax Weapons

By Douglas Frantz with David Rohde

ISLAMABAD, Pakistan, Nov. 27 — Pakistan said today that it had detained two retired nuclear scientists after the recent discovery in offices they had used in Afghanistan of documents describing ways to use anthrax as a weapon and other suspicious material.

The scientists, Sultan Bashiruddin Mahmood and Chaudry Abdul Majeed, were first questioned in October after American intelligence officers expressed concern about trips the two had made to the Afghan capital, Kabul. They were interrogated about their ties to the Taliban.

After he retired from Pakistan's Atomic Energy Agency in 1998, Mr. Mahmood founded a private relief organization, Ummah Tameer-e-Nau, that operated in Afghanistan.

Documents from the organization's Kabul offices examined by The New York Times have been found over the past several days describing the history of anthrax and a Pentagon program to immunize all members of the United States military against anthrax attacks.

Also found were a box of gas masks, a diagram showing a plane shooting down a weather balloon and promotional material from militant Islamic groups. These findings were first reported last week in the British daily The Evening Standard.

Plans for building a balloon and what appeared to be a rocket were found on a piece of paper along with empty steel tubes and parts of a rocket-propelled grenade. A container of helium sat on a work bench.

The diagrams of the balloons seem to show a possible method for slowly dispersing some type of biological or chemical agent from the air. Words scribbled in the diagram appear to say "cyanide."

One diagram found in the Kabul offices show four balloons flying together in tandem with a box around them. The box appears to show how the agent would be dispersed across a wide area.

The house, like others in the Afghan capital apparently used by Osama bin Laden's terrorist network, Al Qaeda, seems to have been hastily abandoned when the Taliban fled Kabul two weeks ago. It is not clear who may have been in the house since then.

Referring to the scientists, Maj. Gen. Rashid Qureshi, the top Pakistani military spokesman, said today in Islamabad: "Both of them are under detention." He declined to elaborate, but officials said the new detentions related to the discoveries in Kabul.

The first arrest of the scientists last month was linked to American suspicions that Pakistan's nuclear weapons technology could have found its way into the hands of Osama bin Laden, Al Qaeda or the Taliban.

An American intelligence official said today that the first interrogation of the two Pakistani scientists has resulted in an assessment that Mr. Mahmood and Mr. Majeed did not know enough to help build a nuclear weapon. "These two guys were nuclear scientists who didn't know how to build one themselves," the American official said. "If you had to have guys go bad these are the guys you'd want — they didn't know much."

Neither of the Pakistani scientists has been charged with any wrongdoing. Their families have said they are innocent and that their interest in Afghanistan was humanitarian. The families have written to government officials protesting their interrogation and earlier detention.

They had been released after the initial questioning in October, but remained under loose house arrest. The new detentions indicate that concern about their activities in Afghanistan have intensified.

Mr. Mahmood and Mr. Majeed worked for the relief organization, whose official purpose was to upgrade roads, build flour mills and carry out other projects to assist Afghanistan. Both spent a considerable amount of time in Afghanistan.

Maj. Gen. Qureshi, the military spokesman, said of their new detention: "When we have completed the investigation, I'm sure the details will be coming out."

The diagrams in the Kabul offices of the relief organization were detailed. One had an arrow pointing to a balloon and the word "wireless" written next to it, suggesting that some type of communications device might be used as a trigger. Other diagrams had the word "SAM-7" and "Stinger" written near the balloon, suggesting that the two types of anti- aircraft missiles could be fired at the balloon to get it to release it contents.

Nearly all of the information found about anthrax in the house came from the United States military. The copies of the military paper describing the anthrax immunization program and expansion of anthrax vaccine production in Michigan were all from original documents, not documents downloaded from the Internet.

Someone had written a half dozen stars across the top of the Michigan study, suggesting that they found it valuable.

Whoever was conducting the research also effectively mined United States military Web sites for information. Copies of a printout of the first page of a military Web site devoted to better informing Persian Gulf war veterans with related illnesses were found in the house.

The site offers highly detailed descriptions of how Anthrax can be used as a weapon and spread through artillery shells, airplanes and trucks. It lists what size of anthrax dose kills people who have been immunized, and refers readers to more detailed academic studies on anthrax.

The house used by Mr. Mahmood's organization, one of three adjacent structures occupied by Pakistani scientists in the Wasi Akbar Khan section of Kabul, the city's wealthy diplomatic corner, it is an unremarkable two-story cinderblock home.

Books and toys suggest that children recently lived in the house. A young girl's second-grade English literature workbook lay on the living room floor surrounded by mounds of abandoned clothing. There was no hint of the effort underway in the workroom upstairs Mr. Mahmood was a director-general of nuclear power plants for the Atomic Energy Agency and Mr. Majeed was once director of uranium-enrichment laboratories.

Pakistani officials said earlier that neither man was affiliated with its nuclear weapons program. President Pervez Musharraf of Pakistan repeated the denial in a television interview on Monday.

But Pakistani newspapers have reported that Mr. Mahmood was involved in developing the atomic bombs Pakistan tested in its western desert in May 1998. Western intelligence agencies estimate that Pakistan has a stockpile of about 20 nuclear weapons.

Shortly after the Sept. 11 attacks on the United States, a team of American law enforcement and intelligence officials raised the safety of Pakistan's nuclear weapons in discussions in Islamabad with Pakistani officials.

The papers and blackboard drawings found in a Kabul house appear to describe the Taliban's notions for dispersing biological and possibly chemical agents by balloons and other methods. Those concepts are backed up by rudimentary calculations and information from Department of Defense Web sites and at

least one report prepared for the United States military on anthrax vaccines.

The report, prepared by Science Applications International Corporation, a private research firm with contracts with the Pentagon, was not classified, said Zuraidah Hashim, a spokeswoman for the firm, in Frederick, Md. It was titled "Renovation of Facilities and Increased Anthrax Vaccine Production at the Michigan Biologic Products Institute."

"This report was not a how-to manual of any kind," Ms. Hashim said. "It was not a report that gave instruction of how to produce anthrax or anthrax vaccine." Instead, Ms. Hashim called it "an evaluation report" on the institute's vaccine program.

The papers also contained copies of Web pages with information on anthrax. An internet search on phrases on the pages quickly led to Department of Defense and other sites with relatively detailed information on anthrax and biological weaponry.

One page correctly explains the difference between cutaneous, gastrointestinal and inhalation anthrax and shows a photograph of former Defense Secretary William S. Cohen at a press conference holding a five-pound bag of sugar, which the caption indicates is the amount of anthrax needed to destroy half the population of Washington, D.C.

The drawings on a wallboard are more difficult to interpret, but they appear, in part, to illustrate the dispersal of an agent by balloons. Why the Taliban considered that concept is unknown, but terror experts said it was far from an ideal method.

For one thing, said Dr. Ashok Gadgil, a biological terror expert and senior staff scientist at Lawrence Berkeley National Laboratory, agents released outdoors would be so widely dispersed as to be useless in many circumstances. Pinpoint release of the agents over, say, a city, would be difficult with a balloon.

"It's a very poor way to release something that you hope to release at a particular urban site," Dr. Gadgil said. "It doesn't sound like a very good game plan."

TAB A - Acronyms, Abbreviations, and Glossary

This tab provides a listing of acronyms and abbreviations found in this report. Additionally, the glossary section provides definitions for selected technical terms that are not found in common usage.

Acronyms and Abbreviations

AAR	after action report
ACR	armored cavalry regiment
ASP	ammunition storage point
BDA	bomb damage assessment
Bn	battalion
Bde	brigade
BW	biological warfare
CBW	chemical or biological warfare
CIA	Central Intelligence Agency
CONUS	Continental United States
CP	command post
CW	chemical warfare
DoD	Department of Defense
Engr	engineer
EOD	explo[illegible]

Glossary

Anthrax

Anthrax is a disease normally associated with plant-eating animals (sheep, goats, cattle, and to a lesser degree swine). It is caused by the bacteria *Bacillus anthracis*. Transmission is made through scratches or abrasions of the skin, wounds, inhalation of spores, eating insufficiently-cooked infected meat, or by flies. Recovery from a mild exposure to the disease may be followed by immunity. However, when anthrax is used as a biological weapon, breathing anthrax spores infects people with inhalation anthrax disease.

Symptoms of inhalation anthrax can begin as early as 24 hours after breathing the spores. Initial symptoms include fever, cough, and weakness and usually progress to breathing problems, shock, and death. The spores are very stable and may remain viable for many years in soil and water, and they can resist sunlight for varying periods of time.[121]

ANTHRAX

SUMMARY

Signs and Symptoms: Incubation period is 1-6 days. Fever, malaise, fatigue, cough and mild chest discomfort is followed by severe respiratory distress with dyspnea, diaphoresis, stridor, and cyanosis. Shock and death occurs within 24-36 hours after onset of severe symptoms.

Diagnosis: Physical findings are non-specific. A widened mediastinum may be seen on CXR. Detectable by Gram stain of the blood and by blood culture late in the course of illness.

Treatment: Although effectiveness may be limited after symptoms are present, high dose antibiotic treatment with penicillin, ciprofloxacin, or doxycycline should be undertaken. Supportive therapy may be necessary.

Prophylaxis: An FDA licensed vaccine is available. Vaccine schedule is 0.5 ml SC at 0, 2, 4 weeks, then 6, 12, and 18 months for the primary series, followed by annual boosters. Oral ciprofloxacin or doxycycline for known or imminent exposure.

Isolation and Decontamination: Standard precautions for healthcare workers. After an invasive procedure or autopsy is performed, the instruments and area used should be thoroughly disinfected with a sporicidal agent (chlorine).

OVERVIEW

Bacillus anthracis, the causative agent of Anthrax, is a rod-shaped, gram-positive, sporulating organism with the spores constituting the usual infective form. Anthrax is primarily a zoonotic disease of herbivores, with cattle, sheep and horses being the usual domesticated animal hosts, but other animals may be infected. Human disease may be contracted by handling contaminated hair, wool, hides, flesh, blood and excreta of infected animals and from manufactured products such as bone meal, as well as by purposeful dissemination of spores. Infection is introduced through scratches or abrasions of the skin, wounds, inhalation of spores, eating insufficiently cooked infected meat, or by flies. All human populations are susceptible. Recovery from an attack of the disease may be followed by immunity. The spores are very stable and may remain viable for many years in soil and water. They will resist sunlight for varying periods.

HISTORY AND SIGNIFICANCE

Anthrax spores were weaponized by the United States in the 1950's and 1960's before the old U.S. offensive program was terminated. Other countries have weaponized this agent or are suspected of doing so. The anthrax bacterium is easy to cultivate and spore production is readily induced. Spores are highly resistant to sunlight, heat and disinfectants - properties which could be advantageous when choosing a bacterial weapon. Iraq admitted to a United Nations inspection team in August of 1991 that it had performed research on the offensive use of *B. anthracis* prior to the Persian Gulf War of 1991, and in 1995 Iraq admitted to weaponizing anthrax. This agent could be produced in either a wet or dried form, stabilized for weaponization by an adversary and delivered as an aerosol cloud either from a line source such as an aircraft flying upwind of friendly positions, or as a point source from a spray device. Coverage of a large ground area could also be theoretically facilitated by multiple spray bomblets disseminated from a missile warhead at a predetermined height above the ground.

CLINICAL FEATURES

Anthrax presents as three distinct clinical syndromes in man: cutaneous, inhalational, and gastrointestinal disease. The cutaneous form (also referred to as malignant pustule) occurs most frequently on the hands and forearms of persons working with infected livestock. It begins with a papule followed by formation of a blister-like fluid-filled vesicle. The vesicle typically dries and forms a coal-black scab, hence the term anthrax (Greek for coal). Sometimes this local infection will develop into a systemic infection which is often fatal. Endemic inhalational anthrax, known as Woolsorters’ disease, is a rare infection contracted by inhalation of the spores. It occurs mainly among workers handling infected hides, wool, and furs. The intestinal form, which is also very rare in man, is contracted by the ingestion of insufficiently cooked meat from infected animals. In man, the mortality of untreated cutaneous anthrax ranges up to 25 per cent; in inhalational and intestinal cases, the case fatality rate is almost 100 percent.

DIAGNOSIS

After an incubation period of 1-6 days, presumably dependent upon the dose and strain of inhaled organisms, the onset of inhalation anthrax is gradual and nonspecific. Fever, malaise, and fatigue may be present, sometimes in association with a nonproductive cough and mild chest discomfort. These initial symptoms are often followed by a short period of improvement (hours to 2-3 days), followed by the abrupt development of severe respiratory distress with dyspnea, diaphoresis, stridor, and cyanosis. Shock and death usually follow within 24-36 hours after the onset of respiratory distress. Physical findings are typically non-specific. The chest X-ray may reveal a widened mediastinum ± pleural effusions late in the disease in about 55% of the cases, but typically is without infiltrates. *Bacillus anthracis* will be detectable by Gram stain of the blood and by

blood culture with routine media, but often not until late in the course of the illness. Only vegetative encapsulated bacilli are present during infection. Spores are not found within the body unless it is open to ambient air. Studies of inhalation anthrax in non-human primates (rhesus monkey) showed that bacilli and toxin appear in the blood late on day 2 or early on day 3 post-exposure. Toxin production parallels the appearance of bacilli in the blood and tests are available to rapidly detect the toxin. Concurrently with the appearance of anthrax, the WBC count becomes elevated and remains so until death.

MEDICAL MANAGEMENT

Almost all inhalational anthrax cases in which treatment was begun after patients were significantly symptomatic have been fatal, regardless of treatment. Penicillin has been regarded as the treatment of choice, with 2 million units given intravenously every 2 hours. Tetracyclines and erythromycin have been recommended in penicillin allergic patients. The vast majority of naturally-occurring anthrax strains are sensitive *in vitro* to penicillin. However, penicillin-resistant strains exist naturally, and one has been recovered from a fatal human case. Moreover, it might not be difficult for an adversary to induce resistance to penicillin, tetracyclines, erythromycin, and many other antibiotics through laboratory manipulation of organisms. All naturally occurring strains tested to date have been sensitive to erythromycin, chloramphenicol, gentamicin, and ciprofloxacin. In the absence of information concerning antibiotic sensitivity, treatment should be instituted at the earliest signs of disease with intravenous ciprofloxacin (400 mg q 8-12 hrs) or intravenous doxycycline (200 mg initially, followed by 100 mg q 12 hrs). Supportive therapy for shock, fluid volume deficit, and adequacy of airway may all be needed.

Standard Precautions should be practiced. After an invasive procedure or autopsy, the instruments and area used should be thoroughly disinfected with a sporicidal agent. Iodine can be used, but must be used at disinfectant strengths, as antiseptic-strength iodophors are not usually sporicidal. Chlorine, in the form of sodium or calcium hypochlorite, can also be used, but with the caution that the activity of hypochlorites is greatly reduced in the presence of organic material.

PROPHYLAXIS

Vaccine: A licensed vaccine is derived from sterile culture fluid supernatant taken from an attenuated strain. The vaccination series consists of six 0.5 ml doses SC at 0, 2, and 4 weeks, then 6, 12 and 18 months, followed by yearly boosters. Limited human data suggest that the vaccine protects against cutaneous anthrax. There is insufficient data to know its efficacy against inhalational anthrax in humans, although studies in rhesus monkeys indicate that good protection can be afforded after only two doses (15 days apart) for up to 2 years. However, it should be emphasized that the vaccine series should be completed according to the routine 6 dose primary series. As with all vaccines, the degree of protection depends upon the magnitude of the challenge dose; vaccine-induced protection could presumably be overwhelmed by extremely high spore challenge.

Contraindications for use of this vaccine include hypersensitivity reaction to a previous dose of vaccine and age < 18 or > 65. Reasons for temporary deferment of the vaccine include pregnancy; active infection with fever; or a course of immune suppressing drugs such as steroids. Reactogenicity is mild to moderate. Up to 6 percent of recipients will experience mild discomfort at the inoculation site for up to 72 hours (e.g., tenderness, erythema, edema, pruritus), while less than 1 percent will experience more severe local reactions, potentially limiting use of the arm for 1-2 days. Modest systemic reactions (e.g., myalgia, malaise, low-grade fever) are uncommon, and severe systemic reactions such as anaphylaxis, which precludes additional vaccination, are rare. The vaccine should be stored between 2-6 °C (refrigerator temperature, not frozen).

Antibiotics: The choice of antibiotics for prophylaxis is difficult to make; for example, it seems relatively easy to induce penicillin and tetracycline resistance in the laboratory. Therefore, prophylaxis with ciprofloxacin (500 mg po bid) or doxycycline (100 mg po bid) is recommended. If personnel are unvaccinated, a single 0.5 ml dose of vaccine should also be given subcutaneously. Should the attack be confirmed as anthrax, antibiotics should be continued for at least 4 weeks in all those exposed, and until all those exposed have received three doses of the vaccine. Two additional 0.5 ml doses of vaccine should be given 2 weeks apart in the unvaccinated; those previously vaccinated with fewer than three doses should receive a single 0.5 ml booster, while vaccination probably is not necessary for those who have received the initial three-doses of the primary series, within the previous six months. Upon discontinuation of antibiotics, patients should be closely observed; if clinical signs of anthrax occur, patients should be treated as indicated above. If vaccine is not available, antibiotics should be continued beyond 4 weeks and withdrawn under medical observation. Optimally, patients should have medical care available upon discontinuation of antibiotics, from a fixed medical care facility with intensive care capabilities and infectious disease consultants.

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THE BACTERIA

WHAT YOU NEED TO KNOW

Anthrax is an infectious bacterial disease spread by contact with infected animals, handling infected products, eating infected meat, or breathing weapon-dispersed anthrax spores.

METHOD OF DELIVERY

Projectiles Missiles, Artillery shells

Sprayers Aircraft, Trucks

Hand-held aerosols

Defense Secretary William Cohen holds a 5-pound bag of sugar to show the amount of the biological weapon anthrax that could destroy half the

Why is it a threat?

Anthrax spores are the top choice in biological weapons for "germ warfare."

Anthrax is effective as a biological weapon because:

- Anthrax is almost always DEADLY if not treated early.
- Spores can be produced in large quantities using basic knowledge of biology.
- Spores can be stored for decades without losing viability.
- Spores can be easily spread in the air by missiles, rockets, artillery, aerial bombs & sprayers.

We KNOW there are potential adversaries developing it as a weapon.

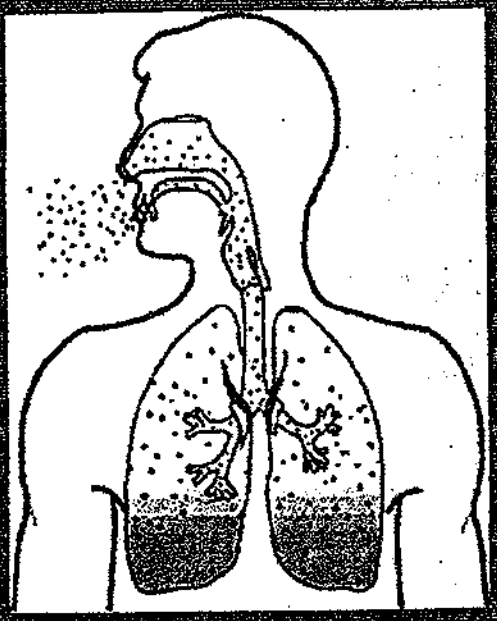
- At least 7 of our potential adversaries have worked to develop an offensive biological warfare capability using anthrax.
- Iraq has admitted to producing and weaponizing anthrax.

There is no indication of exposure.

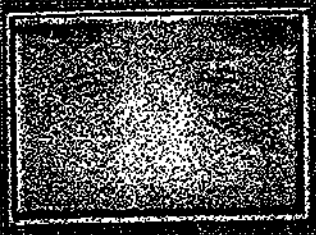
- There is no cloud or color.
- There is no smell.
- There is no taste.
- There is no indication of an attack when dispersed by aerosol spray.

There is no effective treatment for unvaccinated victims of

- Shock and death occur within 24-36 hours



How it works: The airborne anthrax spores are inhaled and lodge in the lungs. There, they move to local lymph nodes, multiply and produce toxins that spread through the body via the bloodstream.



Data Sources

- Benenson AS, ed. Control of Diseases Manual. 16th ed. Washington, DC: American Public Health Association; 1995.
- Brachman PS, Friedlander AM. Anthrax. In: Plotkin SA, Orenstein WA, ed. Vaccines. 3rd ed. Philadelphia, W. B. Saunders; 1999.
- Inglesby TV, Henderson DA, Bartlett JG, Ascher MS, Eitzen E, Friedlander AM, Hauer J, McDade J, Osterholm MT, O'Toole T, Parker G, Perl TM, PK, Tonat K, Working Group on Civilian Biodefense. Anthrax as a biological weapon: Medical and public health management. Journal of the American Medical Association 1999;281:1735-45. www.ama-assn.org/sci-pubs/journals/archive/jama/vol_281/no_18/jst80027.htm

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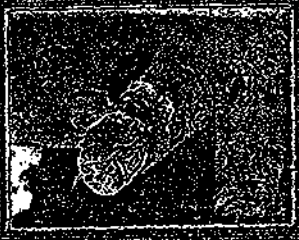
agent to manufacture.



Cutaneous Anthrax

How it works: The airborne anthrax spores are inhaled and lodge in the lungs. There, they move to local lymph nodes, multiply and produce toxins that spread through the

Symptoms of inhalation anthrax include:

- Flu-like aches & pains
- Fever, malaise, fatigue, cough and mild chest discomfort followed by severe difficulty breathing

Diagnosed by:

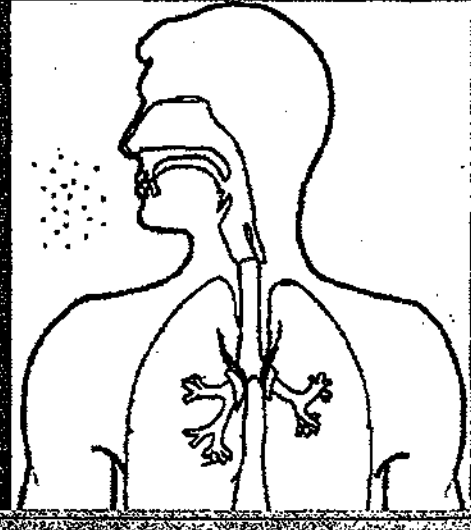
- Isolating the bacteria from blood, other body fluids or skin lesions
- Blood culture, measuring specific antibodies late in the course of the disease

Treatment:

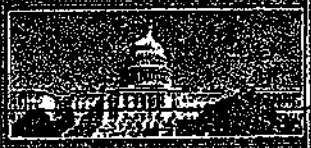
- Treatment is usually not effective after symptoms are present
- High dose antibiotic treatment can lower the death rate slightly

What it does:

- The disease occurs when spores enter lungs, migrate to the lymph nodes, change to the bacterial forms, multiply, and produce toxins
- These toxins cause bleeding and destruction of structures in the middle of the chest (medical term: hemorrahgic necrotizing mediastinitis)
- Shock and death occur within 24-36 hours



destroy half the population of Washington, D.C.



There is no effective treatment for unvaccinated victims of inhalational anthrax.

- Antibiotics will suppress infection only if administered early after exposure -- usually within the first 24 - 48 hours.
- By the time symptoms develop, it is highly likely death will occur despite the best efforts of modern medical science.
- 99% lethal to unprotected individuals.

What it is:

Bacillus Anthracis

- Anthrax is produced by the bacteria *Bacillus anthracis*. A tough protective coat allows the bacteria to survive for decades as spores.
- Anthrax is dangerous because, it is:
- Highly lethal
- One of the easiest biological agents to manufacture
- Relatively easy to develop as a weapon
- Easily spread in the air over a large area
- Easily stored and dangerous for a long period

- Three types of Anthrax diseases:
  - **Cutaneous Anthrax** - caused by contact with infected animals or contaminated animal products
  - **Gastrointestinal Anthrax** - caused by ingestion of contaminated meat
  - **Inhalation Anthrax** - caused by inhalation of anthrax spores (*MOST DEADLY - BIGGEST THREAT*)

Incubation period - 1 to 6 days

Anthrax is the easiest biological agent to manufacture.

Symptoms of inhalation anthrax include:

- Flu-like aches & pains
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This tab provides a listing of acronyms and abbreviations found in this report. Additionally, the glossary section provides definitions for selected technical terms that are not found in common usage.

Acronyms and Abbreviations

ACR	armored cavalry regiment
ASP	ammunition storage point
BW	biological warfare
CBW	chemical or biological warfare
CIA	Central Intelligence Agency
CONUS	Continental United States
CW	chemical warfare
DoD	Department of Defense
EOD	explosive ordnance disposal
FMIB	Foreign Material Intelligence Battalion
HE	high explosive
JCMEC	Joint Captured Material Exploitation Center
KTO	Kuwait theater of operations
Mk-82/83/84	A family of US general purpose bombs
MOPP	mission oriented protective p

Glossary

Anthrax

Anthrax is a disease normally associated with plant-eating animals (s cattle, and to a lesser degree swine). It is caused by the bacteria *Bacillu* Transmission is made through scratches or abrasions of the skin, wound of spores, eating insufficiently-cooked infected meat, or by flies. Reco mild exposure to the disease may be followed by immunity. However, used as a biological weapon, breathing anthrax spores would develop leading to inhalation anthrax disease.

Symptoms of inhalation anthrax can begin as early as 24 hours after b spores. Initial symptoms include fever, cough, and weakness and usually breathing problems, shock, and death. The spores are very stable and viable for many years in soil and water, and they can resist sunlight periods of time.[119]

MEDICAL MANAGEMENT OF BIOLOGICAL CASUALTIES

HANDBOOK

Third Edition

U.S. ARMY MEDICAL RESEARCH

INSTITUTE OF INFECTIOUS DISEASES

FORT DETRICK FREDERICK, MARYLAND

July 1998

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DISCLAIMER

The purpose of this Handbook is to provide concise supplemental reading material to assist in education of biological casualty management. Every effort has been made to make the information in this handbook consistent with official policy and doctrine. The information contained in this handbook is not official Department of the Army policy or doctrine, and it should not be construed as such.

ACKNOWLEDGMENTS

This handbook would not be possible without the generous assistance and support of COL David Franz, COL Gerald Parker, LTC Gerald Jennings, SGM Raymond Alston, COL James Arthur, COL W. Russell Byrne, LTC Les Caudle, Dr. John Ezzell, COL Arthur Friedlander, Mr. Darren Gerlach, SGT Kevin Gianunzio, Dr. Robert Hawley, LTC Erik Henchal, COL(ret) Ted Hussey, Dr. Peter Jahrling, LTC Ross LeClaire, Dr. George Ludwig, Mr. William Patrick, Dr. Mark Poli, Mr. Paul Porreca, Dr. Fred Sidell, Dr. Jonathon Smith, Mr. Richard Stevens, COL Stanley Wiener, Mr. Benjamin Wilson and others too numerous to mention. The exclusion of anyone on this page is purely accidental and in no way lessens the gratitude we feel for contributions received.

ANTHRAX

SUMMARY

Signs and Symptoms: Incubation period is 1-6 days. Fever, malaise, fatigue, cough and mild chest discomfort is followed by severe respiratory distress with dyspnea, diaphoresis, stridor, and cyanosis. Shock and death occurs within 24-36 hours after onset of severe symptoms.

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MEDICAL MANAGEMENT

Almost all inhalational anthrax cases in which treatment was begun after patients were significantly symptomatic have been fatal, regardless of treatment. Penicillin has been regarded as the treatment of choice, with 2 million units given intravenously every 2 hours. Tetracyclines and erythromycin have been recommended in penicillin allergic patients. The vast majority of naturally-occurring anthrax strains are sensitive *in vitro* to penicillin. However, penicillin-resistant strains exist naturally, and one has been recovered from a fatal human case. Moreover, it might not be difficult for an adversary to induce resistance to penicillin, tetracyclines, erythromycin, and many other antibiotics through laboratory manipulation of organisms. All naturally occurring strains tested to date have been sensitive to erythromycin, chloramphenicol, gentamicin, and ciprofloxacin. In the absence of information concerning antibiotic sensitivity, treatment should be instituted at the earliest signs of disease with intravenous ciprofloxacin (400 mg q 8-12 hrs) or intravenous doxycycline (200 mg initially, followed by 100 mg q 12 hrs). Supportive therapy for shock, fluid volume deficit, and adequacy of airway may all be needed.

Standard Precautions should be practiced. After an invasive procedure or autopsy, the instruments and area used should be thoroughly disinfected with a sporicidal agent. Iodine can be used, but must be used at disinfectant strengths, as antiseptic-strength iodophors are not usually sporicidal. Chlorine, in the form of sodium or calcium hypochlorite, can also be used, but with the caution that the activity of hypochlorites is greatly reduced in the presence of organic material.

PROPHYLAXIS

Vaccine: A licensed vaccine is derived from sterile culture fluid supernatant taken from an attenuated strain. The vaccination series consists of six 0.5 ml doses SC at 0, 2, and 4 weeks, then 6, 12 and 18 months, followed by yearly boosters. Limited human data suggest that the vaccine protects against cutaneous anthrax. There is insufficient data to know its efficacy against inhalational anthrax in humans, although studies in rhesus monkeys indicate that good protection can be afforded after only two doses (15 days apart) for up to 2 years. However, it should be emphasized that the vaccine series should be completed according to the routine 6 dose primary series. As with all vaccines, the degree of protection depends upon the magnitude of the challenge dose; vaccine-induced protection could presumably be overwhelmed by extremely high spore challenge.

Contraindications for use of this vaccine include hypersensitivity reaction to a previous dose of vaccine and age < 18 or > 65. Reasons for temporary deferment of the vaccine include pregnancy; active infection with fever; or a course of immune suppressing drugs such as steroids. Reactogenicity is mild to moderate. Up to 6 percent of recipients will experience mild discomfort at the inoculation site for up to 72 hours (e.g., tenderness, erythema, edema, pruritus), while less than 1 percent will experience more severe local reactions, potentially limiting use of the arm for 1-2 days. Modest systemic reactions (e.g., myalgia, malaise, low-grade fever) are uncommon, and severe systemic reactions such as anaphylaxis, which precludes additional vaccination, are rare. The vaccine should be stored between 2-6 °C (refrigerator temperature, not frozen).

Antibiotics: The choice of antibiotics for prophylaxis is difficult to make; for example, it seems relatively easy to induce penicillin and tetracycline resistance in the laboratory. Therefore, prophylaxis with ciprofloxacin (500 mg po bid) or doxycycline (100 mg po bid) is recommended. If personnel are unvaccinated, a single 0.5 ml dose of vaccine should also be given subcutaneously. Should the attack be confirmed as anthrax, antibiotics should be continued for at least 4 weeks in all those exposed, and until all those exposed have received three doses of the vaccine. Two additional 0.5 ml doses of vaccine should be given 2 weeks apart in the unvaccinated; those previously vaccinated with fewer than three doses should receive a single 0.5 ml booster, while vaccination probably is not necessary for those who have received the initial three-doses of the primary series, within the previous six months. Upon discontinuation of antibiotics, patients should be closely observed; if clinical signs of anthrax occur, patients should be treated as indicated above. If vaccine is not available, antibiotics should be continued beyond 4 weeks and withdrawn under medical observation. Optimally, patients should have medical care available upon discontinuation of antibiotics, from a fixed medical care facility with intensive care capabilities and infectious disease consultants.

THE BACTERIA
WHAT YOU NEED TO KNOW

Anthrax is an infectious bacterial disease spread by contact with infected animals, handling infected products, eating infected meat, or breathing weapon-dispersed anthrax spores.

METHOD OF DELIVERY

Projectiles Missiles, Artillery shells

Sprayers Aircraft, Trucks,

Hand-held aerosols

Defense Secretary William Cohen holds a 5-pound bag of sugar to show the amount of the biological weapon anthrax that could destroy half the

Why is it a threat?

Anthrax spores are the top choice in biological weapons for "germ warfare."

Anthrax is effective as a biological weapon because:

- Anthrax is almost always DEADLY if not treated early.
- Spores can be produced in large quantities using basic knowledge of biology.
- Spores can be stored for decades without losing viability.
- Spores can be easily spread in the air by missiles, rockets, artillery, aerial bombs & sprayers.

We KNOW there are potential adversaries developing it as a weapon.

- At least 7 of our potential adversaries have worked to develop an offensive biological warfare capability using anthrax.
- Iraq has admitted to producing and weaponizing anthrax.

There is no indication of exposure.

- There is no cloud or color.
- There is no smell.
- There is no taste.
- There is no indication of an attack when dispersed by aerosol spray.

There is no effective treatment for unvaccinated victims of

destroy half the population of Washington, D.C.

There is no effective treatment for unvaccinated victims of inhalational anthrax.

- Antibiotics will suppress infection only if administered early after exposure -- usually within the first 24 - 48 hours.
- By the time symptoms develop, it is highly likely death will occur despite the best efforts of modern medical science.
- 99% lethal to unprotected individuals.

What it is:

Bacillus Anthracis

- Anthrax is produced by the bacteria *Bacillus anthracis*. A tough protective coat allows the bacteria to survive for decades as spores.
- Anthrax is dangerous because, it is:
- Highly lethal
- One of the easiest biological agents to manufacture
- Relatively easy to develop as a weapon
- Easily spread in the air over a large area
- Easily stored and dangerous for a long period

- Three types of Anthrax diseases:
  - Cutaneous Anthrax - caused by contact with infected animals or contaminated animal products
  - Gastrointestinal Anthrax - caused by ingestion of contaminated meat
  - Inhalation Anthrax - caused by inhalation of anthrax spores "MOST DEADLY - BIGGEST THREAT"

Anthrax is the easiest biological agent to manufacture.

Incubation period - 1 to 6 days

Symptoms of inhalation anthrax include:

- Flu-like aches & pains
- Fever, malaise, fatigue, cough and mild chest discomfort followed by severe difficulty breathing

Cutaneous Anthrax

Diagnosed by:

- Isolating the bacteria from blood, other body fluids or skin lesions
- Blood culture, measuring specific antibodies late in the course of the disease

agent to manufacture.

Cutaneous Anthrax

How it works: The airborne anthrax spores are inhaled and lodge in the lungs. There, they move to local lymph nodes, multiply and produce toxins that spread through the

Symptoms of inhalation anthrax include:

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- Fever, malaise, fatigue, cough and mild chest discomfort followed by severe difficulty breathing

Diagnosed by:

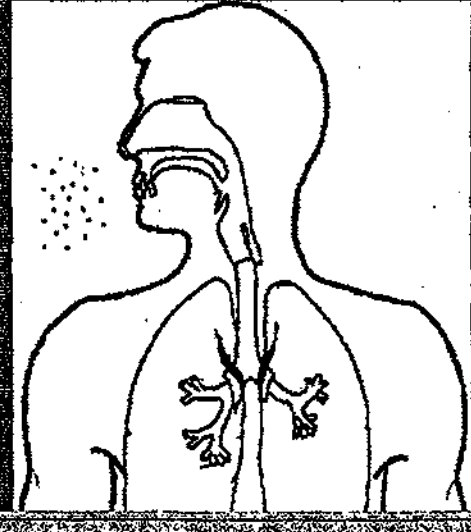
- Isolating the bacteria from blood, other body fluids or skin lesions
- Blood culture, measuring specific antibodies late in the course of the disease

Treatment:

- Treatment is usually not effective after symptoms are present
- High dose antibiotic treatment can lower the death rate slightly

What it does:

- The disease occurs when spores enter lungs, migrate to the lymph nodes, change to the bacterial forms, multiply, and produce toxins
- These toxins cause bleeding and destruction of structures in the middle of the chest (medical term: hemorrhagic necrotizing mediastinitis)
- Shock and death occur within 24-36 hours



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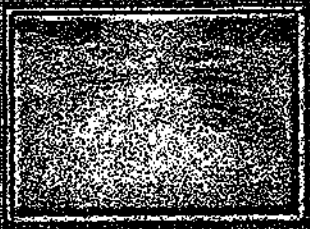

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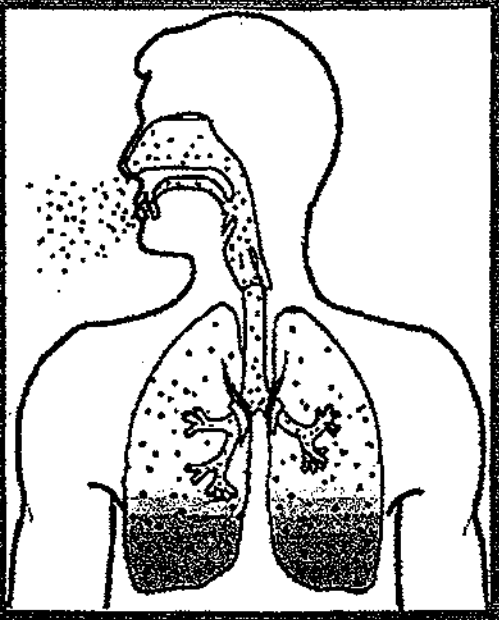

Data Sources

- Benenson AS, ed. Control of Diseases Manual. 16th ed. Washington, DC: American Public Health Association; 1995.
- Brachman PS, Friedlander AM. Anthrax. In: Plotkin SA, Orenstein WA, ed. Vaccines. 3rd ed. Philadelphia: W. B. Saunders; 1999.
- Inglesby TV, Henderson DA, Bartlett JG, Ascher MS, Eitzen E, Friedlander AM, Hauer J, McDade J, Osterholm MT, O'Toole T, Parker G, Perl TM, PK, Tonat K, Working Group on Civilian Biodefense. Anthrax as a biological weapon. Medical and public health management. Journal of the American Medical Association 1999;281:1735-45. www.ama-assn.org/sci-pubs/journals/archive/jama/vol_281/no_18/jsr20027.htm

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SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

UNCLASSIFIED

INFO MEMO

November 29, 2001 2:45 PM

FOR: SPECIAL ASSISTANT FOR GULF WAR ILLNESSES, MEDICAL READINESS, AND MILITARY DEPLOYMENTS

FROM: Michael E. Kilpatrick, M.D., Director, Deployment Health Support

SUBJECT: GulfLINK

- A recent *New York Times* news article (Tab A) reports that two Pakistani scientists were detained and a number of anthrax-related documents found in their office. Among those identified in the article were documents attributed to a "... Web site devoted to better informing Persian Gulf war veterans...."
- Without seeing the documents, we are unable to determine if, in fact, the referenced site is GulfLINK. However, we reviewed the content of our web site, and found that it is possible that the cited documents are posted there.
- From the description in the news story, we believe the reference is to information on anthrax provided in our An Nasiriyah Southwest Ammunition Storage Point case narrative final report, published January 13, 2000, footnote 121 (Tabs B1-B3). The same information is in the amended An Nasiriyah Southwest Ammunition Storage Point case narrative final report, published September 28, 2000, footnote 119 (Tabs C1-C3).
- In both cases, the primary reference was from the U.S. Army Medical Research Institute of Infectious Diseases handbook, published in July 1998 (Tabs B2 and C2), supported by the October 1999 web site of the DoD Anthrax Vaccine Immunization Program (Tabs B3 and C3).
- We anticipate no further media interest.

COORDINATION: NONE

Attachments:
As stated

Prepared by: (b)(6)

UNCLASSIFIED

New York Times
November 28, 2001

2 Pakistanis Linked To Papers On Anthrax Weapons

By Douglas Frantz with David Rohde

ISLAMABAD, Pakistan, Nov. 27 — Pakistan said today that it had detained two retired nuclear scientists after the recent discovery in offices they had used in Afghanistan of documents describing ways to use anthrax as a weapon and other suspicious material.

The scientists, Sultan Bashiruddin Mahmood and Chaudry Abdul Majeed, were first questioned in October after American intelligence officers expressed concern about trips the two had made to the Afghan capital, Kabul. They were interrogated about their ties to the Taliban.

After he retired from Pakistan's Atomic Energy Agency in 1998, Mr. Mahmood founded a private relief organization, Ummah Tameer-e-Nau, that operated in Afghanistan.

Documents from the organization's Kabul offices examined by The New York Times have been found over the past several days describing the history of anthrax and a Pentagon program to immunize all members of the United States military against anthrax attacks.

Also found were a box of gas masks, a diagram showing a plane shooting down a weather balloon and promotional material from militant Islamic groups. These findings were first reported last week in the British daily The Evening Standard.

Plans for building a balloon and what appeared to be a rocket were found on a piece of paper along with empty steel tubes and parts of a rocket-propelled grenade. A container of helium sat on a work bench.

The diagrams of the balloons seem to show a possible method for slowly dispersing some type of biological or chemical agent from the air. Words scribbled in the diagram appear to say "cyanide."

One diagram found in the Kabul offices show four balloons flying together in tandem with a box around them. The box appears to show how the agent would be dispersed across a wide area.

The house, like others in the Afghan capital apparently used by Osama bin Laden's terrorist network, Al Qaeda, seems to have been hastily abandoned when the Taliban fled Kabul two weeks ago. It is not clear who may have been in the house since then.

Referring to the scientists, Maj. Gen. Rashid Qureshi, the top Pakistani military spokesman, said today in Islamabad: "Both of them are under detention." He declined to elaborate, but officials said the new detentions related to the discoveries in Kabul.

The first arrest of the scientists last month was linked to American suspicions that Pakistan's nuclear weapons technology could have found its way into the hands of Osama bin Laden, Al Qaeda or the Taliban.

An American intelligence official said today that the first interrogation of the two Pakistani scientists has resulted in an assessment that Mr. Mahmood and Mr. Majeed did not know enough to help build a nuclear weapon. "These two guys were nuclear scientists who didn't know how to build one themselves," the American official said. "If you had to have guys go bad these are the guys you'd want — they didn't know much."

Neither of the Pakistani scientists has been charged with any wrongdoing. Their families have said they are innocent and that their interest in Afghanistan was humanitarian. The families have written to government officials protesting their interrogation and earlier detention.

They had been released after the initial questioning in October, but remained under loose house arrest. The new detentions indicate that concern about their activities in Afghanistan have intensified.

Mr. Mahmood and Mr. Majeed worked for the relief organization, whose official purpose was to upgrade roads, build flour mills and carry out other projects to assist Afghanistan. Both spent a considerable amount of time in Afghanistan.

Maj. Gen. Qureshi, the military spokesman, said of their new detention: "When we have completed the investigation, I'm sure the details will be coming out."

The diagrams in the Kabul offices of the relief organization were detailed. One had an arrow pointing to a balloon and the word "wireless" written next to it, suggesting that some type of communications device might be used as a trigger. Other diagrams had the word "SAM-7" and "Stinger" written near the balloon, suggesting that the two types of anti- aircraft missiles could be fired at the balloon to get it to release it contents.

Nearly all of the information found about anthrax in the house came from the United States military. The copies of the military paper describing the anthrax immunization program and expansion of anthrax vaccine production in Michigan were all from original documents, not documents downloaded from the Internet.

Someone had written a half dozen stars across the top of the Michigan study, suggesting that they found it valuable.

Whoever was conducting the research also effectively mined United States military Web sites for information. Copies of a printout of the first page of a military Web site devoted to better informing Persian Gulf war veterans with related illnesses were found in the house.

The site offers highly detailed descriptions of how Anthrax can be used as a weapon and spread through artillery shells, airplanes and trucks. It lists what size of anthrax dose kills people who have been immunized, and refers readers to more detailed academic studies on anthrax.

The house used by Mr. Mahmood's organization, one of three adjacent structures occupied by Pakistani scientists in the Wasi Akbar Khan section of Kabul, the city's wealthy diplomatic corner, it is an unremarkable two-story cinderblock home.

Books and toys suggest that children recently lived in the house. A young girl's second-grade English literature workbook lay on the living room floor surrounded by mounds of abandoned clothing. There was no hint of the effort underway in the workroom upstairs Mr. Mahmood was a director-general of nuclear power plants for the Atomic Energy Agency and Mr. Majeed was once director of uranium-enrichment laboratories.

Pakistani officials said earlier that neither man was affiliated with its nuclear weapons program. President Pervez Musharraf of Pakistan repeated the denial in a television interview on Monday.

But Pakistani newspapers have reported that Mr. Mahmood was involved in developing the atomic bombs Pakistan tested in its western desert in May 1998. Western intelligence agencies estimate that Pakistan has a stockpile of about 20 nuclear weapons.

Shortly after the Sept. 11 attacks on the United States, a team of American law enforcement and intelligence officials raised the safety of Pakistan's nuclear weapons in discussions in Islamabad with Pakistani officials.

The papers and blackboard drawings found in a Kabul house appear to describe the Taliban's notions for dispersing biological and possibly chemical agents by balloons and other methods. Those concepts are backed up by rudimentary calculations and information from Department of Defense Web sites and at

least one report prepared for the United States military on anthrax vaccines.

The report, prepared by Science Applications International Corporation, a private research firm with contracts with the Pentagon, was not classified, said Zuraidah Hashim, a spokeswoman for the firm, in Frederick, Md. It was titled "Renovation of Facilities and Increased Anthrax Vaccine Production at the Michigan Biologic Products Institute."

"This report was not a how-to manual of any kind," Ms. Hashim said. "It was not a report that gave instruction of how to produce anthrax or anthrax vaccine." Instead, Ms. Hashim called it "an evaluation report" on the institute's vaccine program.

The papers also contained copies of Web pages with information on anthrax. An internet search on phrases on the pages quickly led to Department of Defense and other sites with relatively detailed information on anthrax and biological weaponry.

One page correctly explains the difference between cutaneous, gastrointestinal and inhalation anthrax and shows a photograph of former Defense Secretary William S. Cohen at a press conference holding a five-pound bag of sugar, which the caption indicates is the amount of anthrax needed to destroy half the population of Washington, D.C.

The drawings on a wallboard are more difficult to interpret, but they appear, in part, to illustrate the dispersal of an agent by balloons. Why the Taliban considered that concept is unknown, but terror experts said it was far from an ideal method.

For one thing, said Dr. Ashok Gadgil, a biological terror expert and senior staff scientist at Lawrence Berkeley National Laboratory, agents released outdoors would be so widely dispersed as to be useless in many circumstances. Pinpoint release of the agents over, say, a city, would be difficult with a balloon.

"It's a very poor way to release something that you hope to release at a particular urban site," Dr. Gadgil said. "It doesn't sound like a very good game plan."

TAB A - Acronyms, Abbreviations, and Glossary

This tab provides a listing of acronyms and abbreviations found in this report. Additionally, the glossary section provides definitions for selected technical terms that are not found in common usage.

Acronyms and Abbreviations

AAR	after action report
ACR	armored cavalry regiment
ASP	ammunition storage point
BDA	bomb damage assessment
Bn	battalion
Bde	brigade
BW	biological warfare
CBW	chemical or biological warfare
CIA	Central Intelligence Agency
CONUS	Continental United States
CP	command post
CW	chemical warfare
DoD	Department of Defense
Engr	engineer
EOD	explo-

Glossary

Anthrax

Anthrax is a disease normally associated with plant-eating animals (sheep, goats, cattle, and to a lesser degree swine). It is caused by the bacteria *Bacillus anthracis*. Transmission is made through scratches or abrasions of the skin, wounds, inhalation of spores, eating insufficiently-cooked infected meat, or by flies. Recovery from a mild exposure to the disease may be followed by immunity. However, when anthrax is used as a biological weapon, breathing anthrax spores infects people with inhalation anthrax disease.

Symptoms of inhalation anthrax can begin as early as 24 hours after breathing the spores. Initial symptoms include fever, cough, and weakness and usually progress to breathing problems, shock, and death. The spores are very stable and may remain viable for many years in soil and water, and they can resist sunlight for varying periods of time.[121]

ANTHRAX

SUMMARY

Signs and Symptoms: Incubation period is 1-6 days. Fever, malaise, fatigue, cough and mild chest discomfort is followed by severe respiratory distress with dyspnea, diaphoresis, stridor, and cyanosis. Shock and death occurs within 24-36 hours after onset of severe symptoms.

Diagnosis: Physical findings are non-specific. A widened mediastinum may be seen on CXR. Detectable by Gram stain of the blood and by blood culture late in the course of illness.

Treatment: Although effectiveness may be limited after symptoms are present, high dose antibiotic treatment with penicillin, ciprofloxacin, or doxycycline should be undertaken. Supportive therapy may be necessary.

Prophylaxis: An FDA licensed vaccine is available. Vaccine schedule is 0.5 ml SC at 0, 2, 4 weeks, then 6, 12, and 18 months for the primary series, followed by annual boosters. Oral ciprofloxacin or doxycycline for known or imminent exposure.

Isolation and Decontamination: Standard precautions for healthcare workers. After an invasive procedure or autopsy is performed, the instruments and area used should be thoroughly disinfected with a sporicidal agent (chlorine).

OVERVIEW

Bacillus anthracis, the causative agent of Anthrax, is a rod-shaped, gram-positive, sporulating organism with the spores constituting the usual infective form. Anthrax is primarily a zoonotic disease of herbivores, with cattle, sheep and horses being the usual domesticated animal hosts, but other animals may be infected. Human disease may be contracted by handling contaminated hair, wool, hides, flesh, blood and excreta of infected animals and from manufactured products such as bone meal, as well as by purposeful dissemination of spores. Infection is introduced through scratches or abrasions of the skin, wounds, inhalation of spores, eating insufficiently cooked infected meat, or by flies. All human populations are susceptible. Recovery from an attack of the disease may be followed by immunity. The spores are very stable and may remain viable for many years in soil and water. They will resist sunlight for varying periods.

HISTORY AND SIGNIFICANCE

Anthrax spores were weaponized by the United States in the 1950's and 1960's before the old U.S. offensive program was terminated. Other countries have weaponized this agent or are suspected of doing so. The anthrax bacterium is easy to cultivate and spore production is readily induced. Spores are highly resistant to sunlight, heat and disinfectants - properties which could be advantageous when choosing a bacterial weapon. Iraq admitted to a United Nations inspection team in August of 1991 that it had performed research on the offensive use of *B. anthracis* prior to the Persian Gulf War of 1991, and in 1995 Iraq admitted to weaponizing anthrax. This agent could be produced in either a wet or dried form, stabilized for weaponization by an adversary and delivered as an aerosol cloud either from a line source such as an aircraft flying upwind of friendly positions, or as a point source from a spray device. Coverage of a large ground area could also be theoretically facilitated by multiple spray bomblets disseminated from a missile warhead at a predetermined height above the ground.

CLINICAL FEATURES

Anthrax presents as three distinct clinical syndromes in man: cutaneous, inhalational, and gastrointestinal disease. The cutaneous form (also referred to as malignant pustule) occurs most frequently on the hands and forearms of persons working with infected livestock. It begins with a papule followed by formation of a blister-like fluid-filled vesicle. The vesicle typically dries and forms a coal-black scab, hence the term anthrax (Greek for coal). Sometimes this local infection will develop into a systemic infection which is often fatal. Endemic inhalational anthrax, known as Woolsorters’ disease, is a rare infection contracted by inhalation of the spores. It occurs mainly among workers handling infected hides, wool, and furs. The intestinal form, which is also very rare in man, is contracted by the ingestion of insufficiently cooked meat from infected animals. In man, the mortality of untreated cutaneous anthrax ranges up to 25 per cent; in inhalational and intestinal cases, the case fatality rate is almost 100 percent.

DIAGNOSIS

After an incubation period of 1-6 days, presumably dependent upon the dose and strain of inhaled organisms, the onset of inhalation anthrax is gradual and nonspecific. Fever, malaise, and fatigue may be present, sometimes in association with a nonproductive cough and mild chest discomfort. These initial symptoms are often followed by a short period of improvement (hours to 2-3 days), followed by the abrupt development of severe respiratory distress with dyspnea, diaphoresis, stridor, and cyanosis. Shock and death usually follow within 24-36 hours after the onset of respiratory distress. Physical findings are typically non-specific. The chest X-ray may reveal a widened mediastinum ± pleural effusions late in the disease in about 55% of the cases, but typically is without infiltrates. *Bacillus anthracis* will be detectable by Gram stain of the blood and by

blood culture with routine media, but often not until late in the course of the illness. Only vegetative encapsulated bacilli are present during infection. Spores are not found within the body unless it is open to ambient air. Studies of inhalation anthrax in non-human primates (rhesus monkey) showed that bacilli and toxin appear in the blood late on day 2 or early on day 3 post-exposure. Toxin production parallels the appearance of bacilli in the blood and tests are available to rapidly detect the toxin. Concurrently with the appearance of anthrax, the WBC count becomes elevated and remains so until death.

MEDICAL MANAGEMENT

Almost all inhalational anthrax cases in which treatment was begun after patients were significantly symptomatic have been fatal, regardless of treatment. Penicillin has been regarded as the treatment of choice, with 2 million units given intravenously every 2 hours. Tetracyclines and erythromycin have been recommended in penicillin allergic patients. The vast majority of naturally-occurring anthrax strains are sensitive *in vitro* to penicillin. However, penicillin-resistant strains exist naturally, and one has been recovered from a fatal human case. Moreover, it might not be difficult for an adversary to induce resistance to penicillin, tetracyclines, erythromycin, and many other antibiotics through laboratory manipulation of organisms. All naturally occurring strains tested to date have been sensitive to erythromycin, chloramphenicol, gentamicin, and ciprofloxacin. In the absence of information concerning antibiotic sensitivity, treatment should be instituted at the earliest signs of disease with intravenous ciprofloxacin (400 mg q 8-12 hrs) or intravenous doxycycline (200 mg initially, followed by 100 mg q 12 hrs). Supportive therapy for shock, fluid volume deficit, and adequacy of airway may all be needed.

Standard Precautions should be practiced. After an invasive procedure or autopsy, the instruments and area used should be thoroughly disinfected with a sporicidal agent. Iodine can be used, but must be used at disinfectant strengths, as antiseptic-strength iodophors are not usually sporicidal. Chlorine, in the form of sodium or calcium hypochlorite, can also be used, but with the caution that the activity of hypochlorites is greatly reduced in the presence of organic material.

PROPHYLAXIS

Vaccine: A licensed vaccine is derived from sterile culture fluid supernatant taken from an attenuated strain. The vaccination series consists of six 0.5 ml doses SC at 0, 2, and 4 weeks, then 6, 12 and 18 months, followed by yearly boosters. Limited human data suggest that the vaccine protects against cutaneous anthrax. There is insufficient data to know its efficacy against inhalational anthrax in humans, although studies in rhesus monkeys indicate that good protection can be afforded after only two doses (15 days apart) for up to 2 years. However, it should be emphasized that the vaccine series should be completed according to the routine 6 dose primary series. As with all vaccines, the degree of protection depends upon the magnitude of the challenge dose; vaccine-induced protection could presumably be overwhelmed by extremely high spore challenge.

Contraindications for use of this vaccine include hypersensitivity reaction to a previous dose of vaccine and age < 18 or > 65. Reasons for temporary deferment of the vaccine include pregnancy; active infection with fever; or a course of immune suppressing drugs such as steroids. Reactogenicity is mild to moderate. Up to 6 percent of recipients will experience mild discomfort at the inoculation site for up to 72 hours (e.g., tenderness, erythema, edema, pruritus), while less than 1 percent will experience more severe local reactions, potentially limiting use of the arm for 1-2 days. Modest systemic reactions (e.g., myalgia, malaise, low-grade fever) are uncommon, and severe systemic reactions such as anaphylaxis, which precludes additional vaccination, are rare. The vaccine should be stored between 2-6 °C (refrigerator temperature, not frozen).

Antibiotics: The choice of antibiotics for prophylaxis is difficult to make; for example, it seems relatively easy to induce penicillin and tetracycline resistance in the laboratory. Therefore, prophylaxis with ciprofloxacin (500 mg po bid) or doxycycline (100 mg po bid) is recommended. If personnel are unvaccinated, a single 0.5 ml dose of vaccine should also be given subcutaneously. Should the attack be confirmed as anthrax, antibiotics should be continued for at least 4 weeks in all those exposed, and until all those exposed have received three doses of the vaccine. Two additional 0.5 ml doses of vaccine should be given 2 weeks apart in the unvaccinated; those previously vaccinated with fewer than three doses should receive a single 0.5 ml booster, while vaccination probably is not necessary for those who have received the initial three-doses of the primary series, within the previous six months. Upon discontinuation of antibiotics, patients should be closely observed; if clinical signs of anthrax occur, patients should be treated as indicated above. If vaccine is not available, antibiotics should be continued beyond 4 weeks and withdrawn under medical observation. Optimally, patients should have medical care available upon discontinuation of antibiotics, from a fixed medical care facility with intensive care capabilities and infectious disease consultants.

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THE BACTERIA

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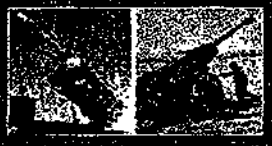

Projectiles Missiles, Artilery shells

Sprayers Aircraft, Trucks,

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Anthrax spores are the top choice in biological weapons for "germ warfare."

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- Spores can be stored for decades without losing viability.
- Spores can be easily spread in the air by missiles, rockets, artillery, aerial bombs & sprayers.

We KNOW there are potential adversaries developing it as a weapon.

- At least 7 of our potential adversaries have worked to develop an offensive biological warfare capability using anthrax.
- Iraq has admitted to producing and weaponizing anthrax.

There is no indication of exposure.

- There is no cloud or color.
- There is no smell.
- There is no taste.
- There is no indication of an attack when dispersed by aerosol spray.

There is no effective treatment for unvaccinated victims of

destroy half the population of Washington, D.C.

There is no effective treatment for unvaccinated victims of inhalational anthrax.

- Antibiotics will suppress infection only if administered early after exposure -- usually within the first 24 - 48 hours.
- By the time symptoms develop, it is highly likely death will occur despite the best efforts of modern medical science.
- 99% lethal to unprotected individuals.

What it is:

- Anthrax is produced by the bacteria *Bacillus anthracis*. A tough protective coat allows the bacteria to survive for decades as spores.
- Anthrax is dangerous because it is:
- Highly lethal
- One of the easiest biological agents to manufacture
- Relatively easy to develop as a weapon
- Easily spread in the air over a large area
- Easily stored and dangerous for a long period

Bacillus Anthracis

- Three types of Anthrax diseases:
  - Cutaneous Anthrax - caused by contact with infected animals or contaminated animal products.
  - Gastrointestinal Anthrax - caused by ingest on of contaminated meat.
  - Inhalation Anthrax - caused by inhalation o' anthrax spores.**MOST DEADLY - BIGGEST THREAT**

Anthrax is the easiest biological agent to manufacture.

Incubation period - 1 to 6 days

Symptoms of inhalation anthrax include:

- Flu-like aches & pains
- Fever, malaise, fatigue, cough and mild chest discomfort - followed by severe difficulty breathing

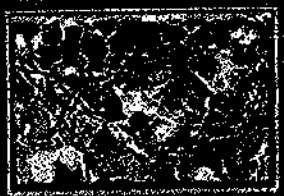
Cutaneous Anthrax

Diagnosed by:

- Isolating the bacteria from blood, other body fluids or skin lesions
- Blood culture, measuring specific antibodies late in the course of the disease

agent to manufacture.

Cutaneous Anthrax



How it works: The airborne anthrax spores are inhaled and lodge in the lungs. There, they move to local lymph nodes, multiply and produce toxins that spread through the

Symptoms of inhalation anthrax include:

- Flu-like aches & pains
- Fever, malaise, fatigue, cough and mild chest discomfort followed by severe difficulty breathing

Diagnosed by:

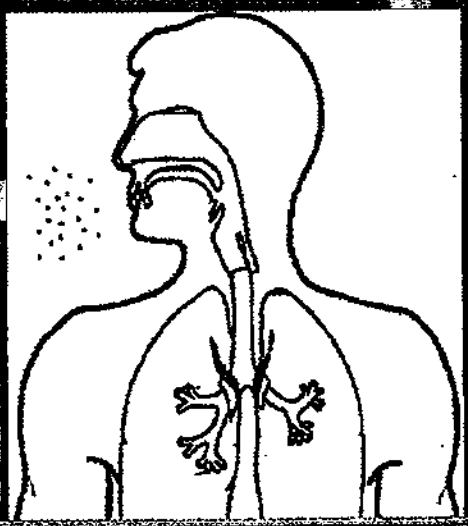
- Isolating the bacteria from blood, other body fluids or skin lesions
- Blood culture; measuring specific antibodies late in the course of the disease

Treatment:

- Treatment is usually not effective after symptoms are present
- High dose antibiotic treatment--can lower the death rate slightly

What it does:

- The disease occurs when spores enter lungs, migrate to the lymph nodes, change to the bacterial forms, multiply, and produce toxins
- These toxins cause bleeding and destruction of structures in the middle of the chest (medical term: hemorrahgic necrotizing mediastinitis).
- Shock and death occur within 24-36 hours



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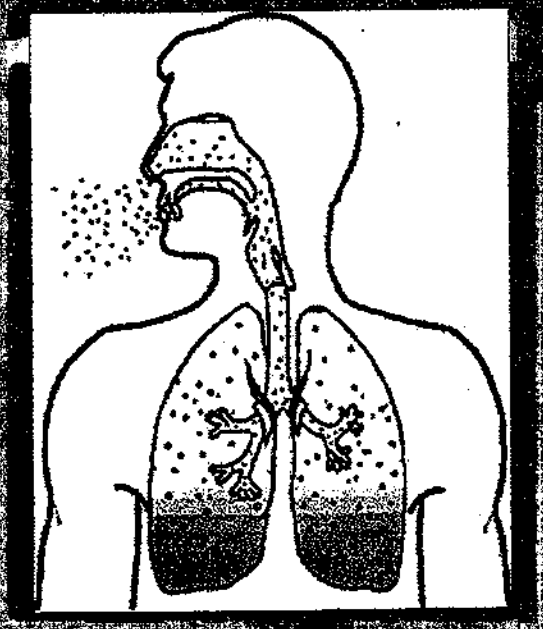

How it works: The airborne anthrax spores are inhaled and lodge in the lungs. There, they move to local lymph nodes, multiply and produce toxins that spread through the bloodstream.

Data Sources:

- Benenson AS, ed. Control of Diseases Manual, 16th ed. Washington, DC: American Public Health Association; 1995.
- Brachman PS, Friedlander AM. Anthrax. In: Plotkin SA, Orenstein WA, ed. Vaccines, 3rd ed. Philadelphia: W. B. Saunders; 1999.
- Inglesby TV, Henderson DA, Bartlett JG, Ascher MS, Eitzen E, Friedlander AM, Hauer J, McDade J, Osterholm MT, O'Toole T, Parker G, Perl TM, PK, Tonat K, Working Group on Civilian Biodefense. Anthrax as a biological weapon: Medical and public health management. Journal of the American Medical Association 1999;281:1735-45.
- www.ama-assn.org/sci-pubs/journals/archive/jama/vol_281/no_18/jst80027.htm

| First Page | Prev Page | Next Page | Back to Text |

TAB A – Acronyms, Abbreviations, and Glossary

This tab provides a listing of acronyms and abbreviations found in this report. Additionally, the glossary section provides definitions for selected technical terms that are not found in common usage.

Acronyms and Abbreviations

ACR	armored cavalry regiment
ASP	ammunition storage point
BW	biological warfare
CBW	chemical or biological warfare
CIA	Central Intelligence Agency
CONUS	Continental United States
CW	chemical warfare
DoD	Department of Defense
EOD	explosive ordnance disposal
FMIB	Foreign Material Intelligence Battalion
HE	high explosive
JCMEC	Joint Captured Material Exploitation Center
KTO	Kuwait theater of operations
Mk-82/83/84	A family of US general purpose bombs
MOPP	mission oriented protective p

Glossary

Anthrax

Anthrax is a disease normally associated with plant-eating animals (s cattle, and to a lesser degree swine). It is caused by the bacteria *Bacillu* Transmission is made through scratches or abrasions of the skin, wound of spores, eating insufficiently-cooked infected meat, or by flies. Reco mild exposure to the disease may be followed by immunity. However, used as a biological weapon, breathing anthrax spores would develop leading to inhalation anthrax disease.

Symptoms of inhalation anthrax can begin as early as 24 hours after b spores. Initial symptoms include fever, cough, and weakness and usually breathing problems, shock, and death. The spores are very stable and viable for many years in soil and water, and they can resist sunlight periods of time.[119]

MEDICAL MANAGEMENT OF BIOLOGICAL CASUALTIES

HANDBOOK

Third Edition

U.S. ARMY MEDICAL RESEARCH

INSTITUTE OF INFECTIOUS DISEASES

FORT DETRICK FREDERICK, MARYLAND

July 1998

Editors:

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LTC George Christopher

CDR Randall Culpepper

Comments and suggestions are solicited and should be addressed to:

Operational Medicine Division

Attn: Mr. Paul Porreca

U.S. Army Medical Research

Institute of Infectious Diseases

Fort Detrick, Maryland 21702-5011

DISCLAIMER

The purpose of this Handbook is to provide concise supplemental reading material to assist in education of biological casualty management. Every effort has been made to make the information in this handbook consistent with official policy and doctrine. The information contained in this handbook is not official Department of the Army policy or doctrine, and it should not be construed as such.

ACKNOWLEDGMENTS

This handbook would not be possible without the generous assistance and support of COL David Franz, COL Gerald Parker, LTC Gerald Jennings, SGM Raymond Alston, COL James Arthur, COL W. Russell Byrne, LTC Les Caudle, Dr. John Ezzell, COL Arthur Friedlander, Mr. Darren Gerlach, SGT Kevin Gianunzio, Dr. Robert Hawley, LTC Erik Henchal, COL(ret) Ted Hussey, Dr. Peter Jahrling, LTC Ross LeClaire, Dr. George Ludwig, Mr. William Patrick, Dr. Mark Poli, Mr. Paul Porreca, Dr. Fred Sidell, Dr. Jonathon Smith, Mr. Richard Stevens, COL Stanley Wiener, Mr. Benjamin Wilson and others too numerous to mention. The exclusion of anyone on this page is purely accidental and in no way lessens the gratitude we feel for contributions received.

Special Assistant to the Under Secretary of Defense (Personnel & Readiness) for Gulf War Illnesses, Medical Readiness, and Military Deployments

CMAT #:

Date:

Action Tasking // Internal Routing Sheet

		Action	Info	Comments
	Special Assistant (SA)			
4	Chief of Staff (CoS)			
1	☐ Director, Investigation & Analysis ___(IAD) ☐ OAT__ ☐ ENV __ ☐ INTEL ___		15 11/29	
	Dir Lessons Learned Implementation (LLI)			
2	Dir Public Affairs & Outreach (PAO) ☐ VDM __		11-29	
	Dir Medical Readiness (MR)			
	Legal Advisor (LGL)			
	Info Technology & Security (ITS) ☐ MED RES __ WD&P ___			
3	PM Support (PM)			
	☐ CMAT __ ☐ OPCEN __ ☐ DMT __			
	Editorial Review (ER)			
	Legislative Affairs OASD(LA)			
	☐ COMEBACK COPY TO: _____ AMB ☐ GET CMAT # WHEN SIGNED ☐ READING FILE ☐ CHRON FILE			

SUSPENSE:

Prepare reply for signature of: ☐ SA
☐ Chief of Staff
☐ Director, IAD / PA / MR / LLID / IT&SEC

☐ Congress	☐ Oversight	☐ FOIA	☐ OSD	☐ WBM	☐ VSO/MSO	☐ Outgoing
☐ Ltr to SA/COS	☐ IR	☐ E-Mail	☐ OGA	☐ Other		☐ Veteran

KEYWORDS:

Office of the Special Assistant to the Secretary of Defense

for Gulf War Illnesses, Medical Readiness and Military Deployments

DSN: 761-1078 fax 703-578-8501

email: brostker@gwillness.osd.mil

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Briefing Overview

- Mission Statement
- The Gulf War
- Searching for Answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining Help and Information

Vision of the Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

- The Department of Defense recognizes the right of those involved in deployments to receive information that enables them to make informed decisions about their health
- We will develop and disseminate such information in a relevant and timely fashion
- We will work with others in the Defense Department to incorporate lessons from previous deployments to foster the well-being of deployed forces

Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Gulf War Theater

- August 1990 to July 1991
- 697,000 US service members
- More than 27,000 hospitalizations
- 148 battle deaths
- 224 non-battle deaths

1 in 7 Veterans Reported Symptoms Since the War

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Confounding Issues

- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

Taking Care of Service Members

- DoD Comprehensive Clinical Evaluation Program
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
  - DoD civilians
- VA Persian Gulf Registry
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- Available to *all* service members deploying to South West Asia

Don't Tough It Out!

OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Scientific research under PGVCB
  - 190+ studies sponsored by DoD, DVA, & HHS
  - No cause and effect relationship shown so far

Investigation Results

- Gulf War
  - No offensive CW/BW use
  - Not enough vaccines and no explanation given
  - Limited environmental surveys
  - Information about nerve agent pre-treatment (PB) wasn't given to troops
  - Inadequate training
    - *Veterans returned home and left service without thorough medical exam or debrief*

The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, man-made environmental hazards (oil well fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Accidents, pesticides, investigational new drugs, PB

Current and future conflicts and humanitarian deployments have and will have these challenges

Applying Lessons Learned

- Train self and others to recognize and avoid hazards
- Monitor service member's health & environment
- Improve feedback and cross talk
- Know your equipment strengths and weaknesses
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU

Force Health Protection

- Pre-deployment
  - Medical screening/surveillance and briefings
- Deployment
  - Record keeping
  - Monitor environment and personnel
- Post Deployment
  - Medical screening and unit debriefing

Anthrax

- We have a safe and effective vaccine

- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
- Dosing schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster
- Shortages in stockpiled doses require temporary slowdown of AVIP

(877) GET-VACC DSN: 761-5101
www.anthrax.osd.mil
www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Bottom Line

- Lessons learned from the Gulf War affect today's doctrine and deployments
- You will deploy on missions
- Everyone is responsible for force protection
- You are your own best health advocate
- Vets should not tough it out; get examined

Obtaining help and information

- Comprehensive Clinical Evaluation program

  Comm: 06371-86-8340

  DSN: 486-8340

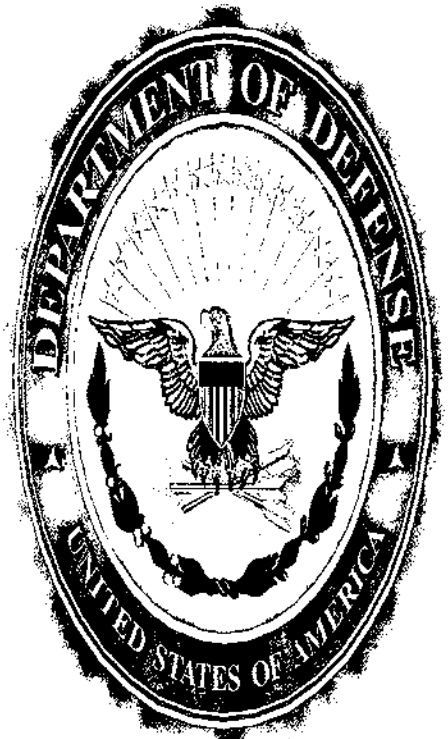
- Veterans Affair Persian Gulf registry program

  Local U.S. consular office or 1-800-749-8387

- Hotline for OSAGWI DSN: 761-1078

http://www.gulflink.osd.mil

Office of the Special Assistant to the Secretary of Defense



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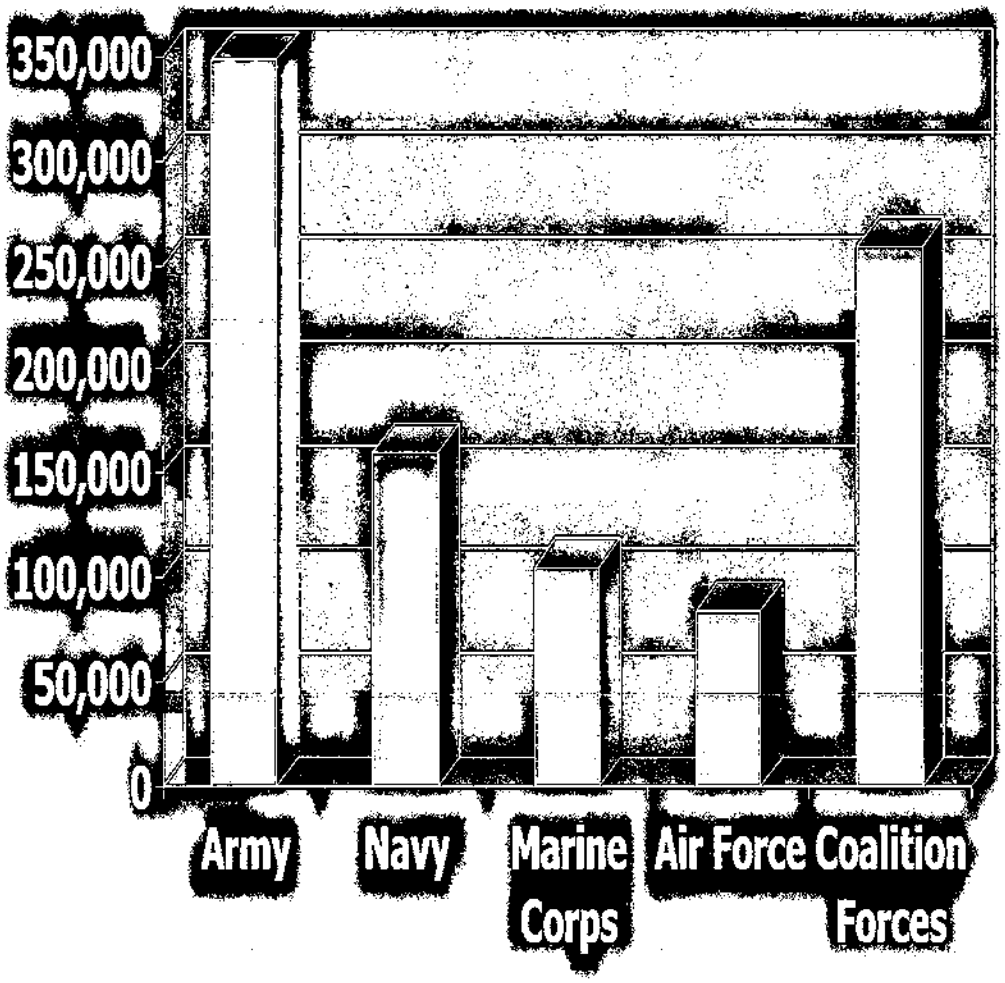
- Investigate and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Why Should I Care

- Lessons from the Gulf War about dirty battlefields
- You must protect yourself against hazards
- You will be leading Gulf War vets
- You are responsible for force protection
  - What are the dangers of the dirty battlefield?
  - How good are our detectors and MOPP gear?
  - How do we determine if we are exposed?
  - Will attacking enemy CW/BW stockpiles put us at risk?

Gulf War Theater Forces



697,000 U.S. service members

1 in 7 Veterans Reported Symptoms Since The War

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

Office of the Special Assistant

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- Healthcare professionals unable to provide answers
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- No new disease or links between exposures and symptoms
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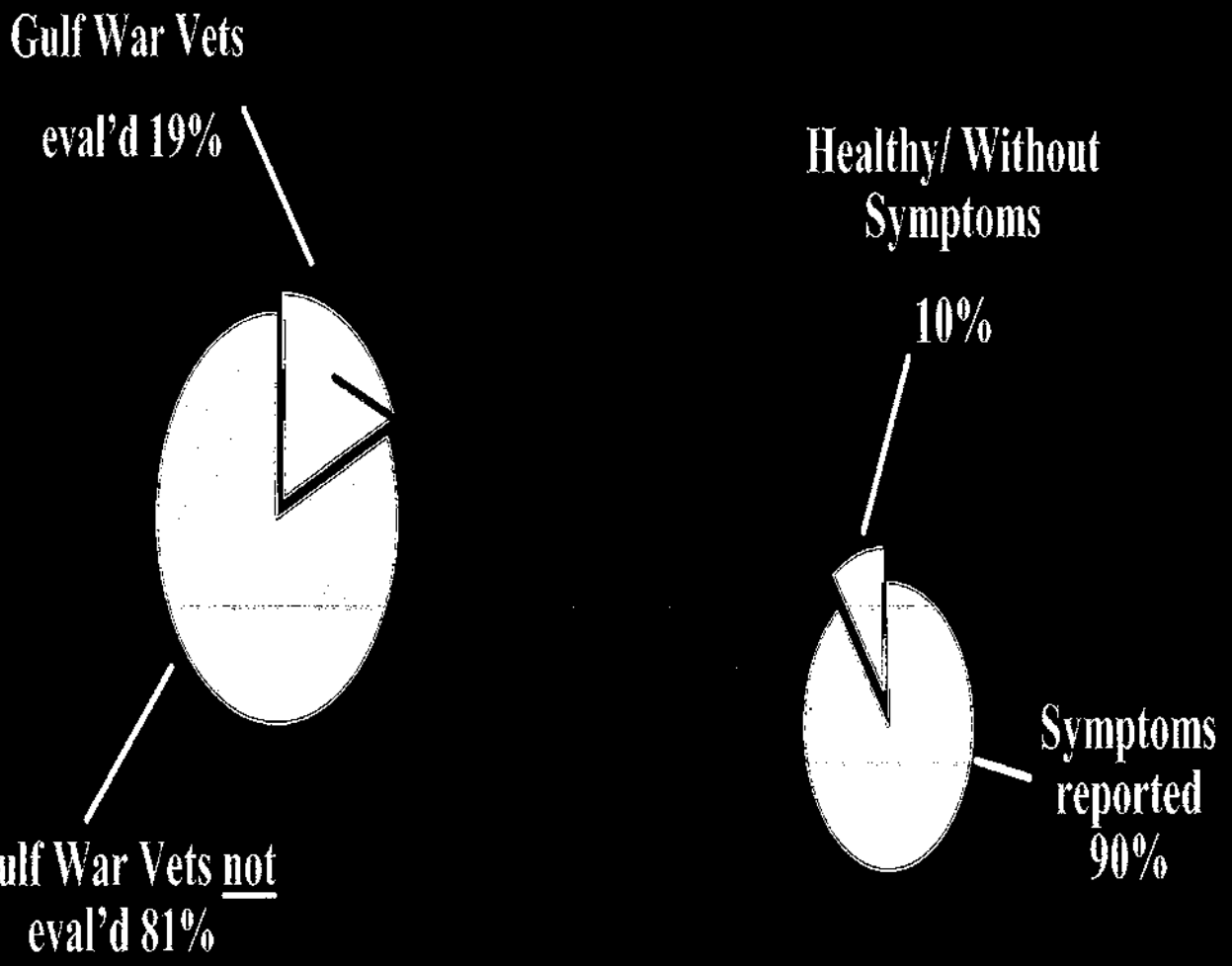
  - Active service member deployed to SWA since war ended
  - Family members
  - Civilian employees
- VA Persian Gulf Registry
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- Available to *all* service members deploying to South West Asia
  - Most people evaluated can be treated

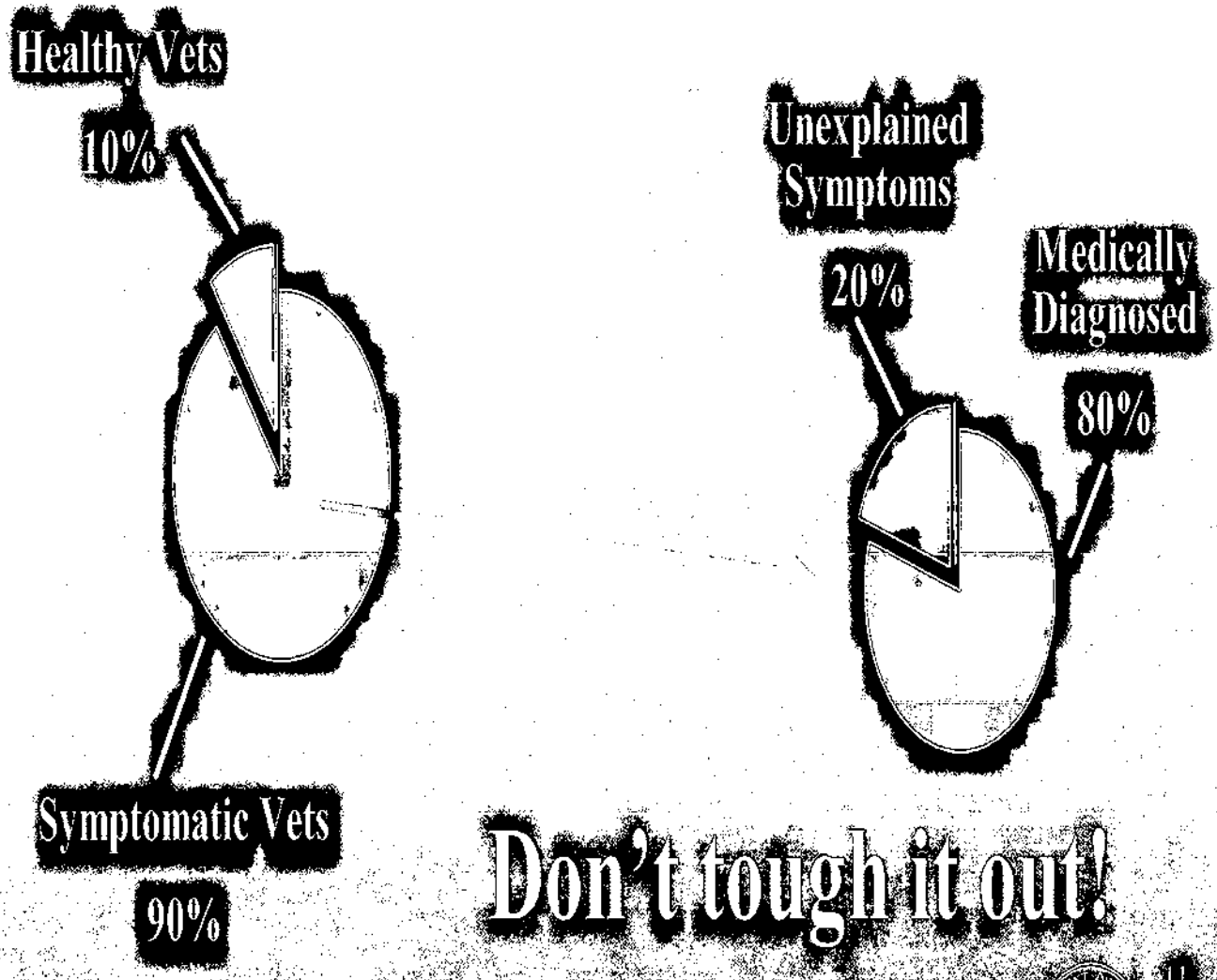
Don't Tough It Out!

Evaluation Distribution of 697,000 CCEP/VA



Diagnosis Distribution of Evaluated Veterans

CCEP/VA



Don't tough it out!

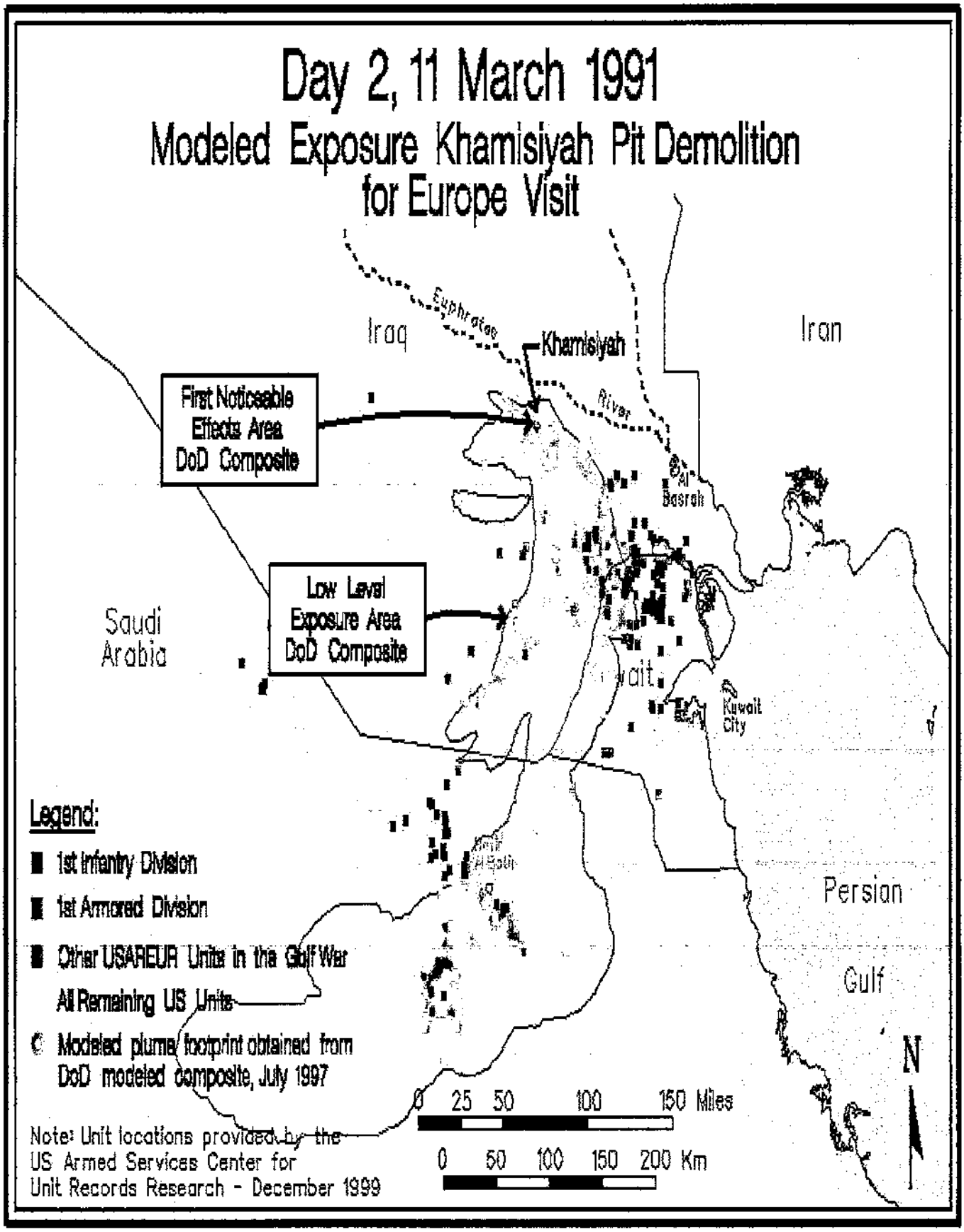
OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
    - Science doesn't support DU or Oil Well fires as causes
    - Still examining particulates and pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Persian Gulf War Veterans Coordinating Board-Scientific Research
  - 190+ studies sponsored by DoD, HHS & DVA
  - Science shows no exposure cause or effect relationship yet!

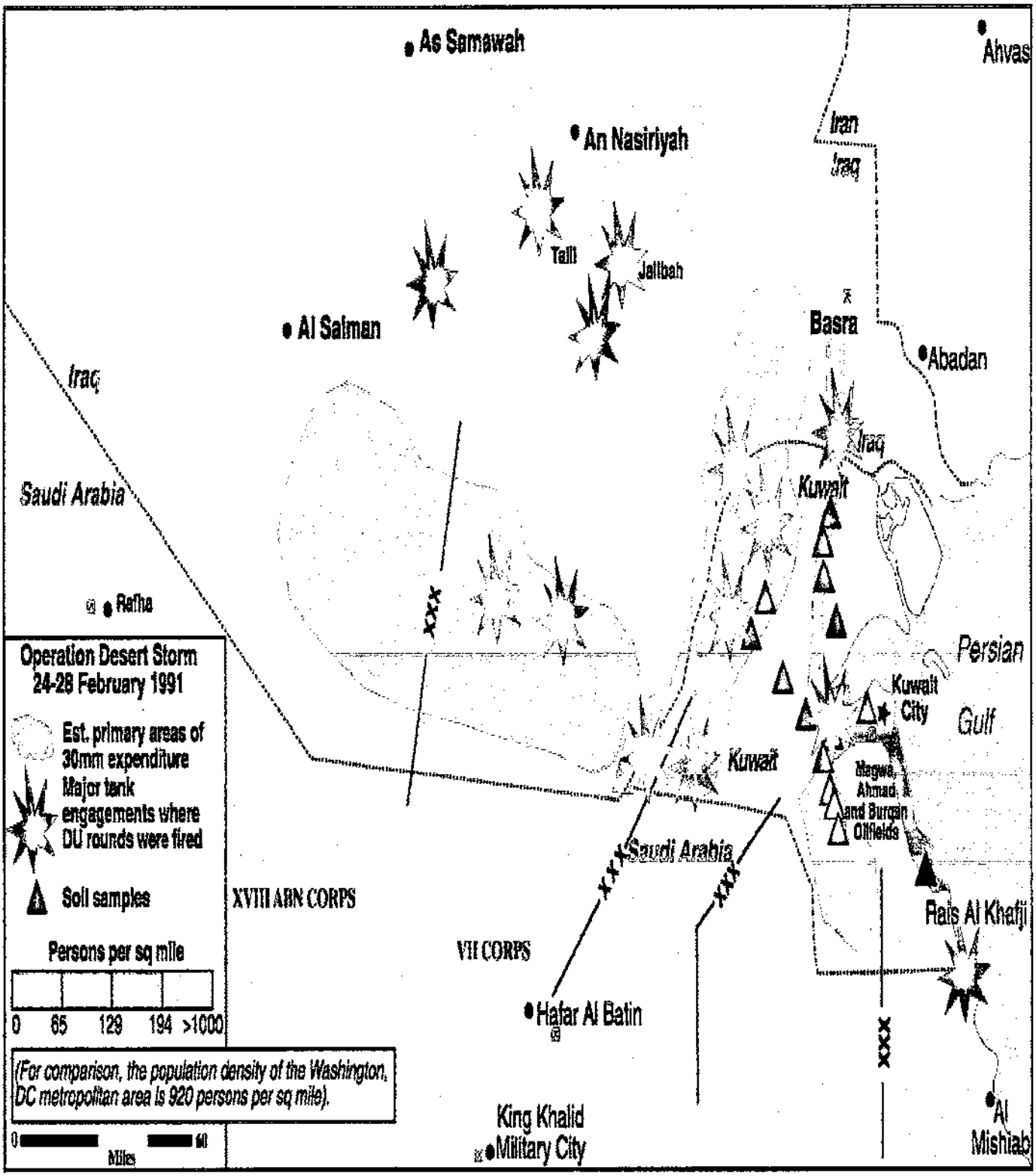
A New Reality --
The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, Man made environmental hazards (Oil Well Fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Pesticides, Stressors, Investigational New Drugs, PB

Current and future conflicts and humanitarian deployments have and will have these challenges


Day 2, 11 March 1991
Modeled Exposure Khamisiyah Pit Demolition for Europe Visit
Iraq
Euphrates River
Khamisiyah
Iran
First Noticeable Effects Area DoD Composite
Low Level Exposure Area DoD Composite
Saudi Arabia
Al Basrah
Kuwait City
Persian Gulf
Legend:
1st Infantry Division
1st Armored Division
Other USAREUR Units in the Gulf War
All Remaining US Units
Modeled plume footprint obtained from DoD modeled composite, July 1997
0 25 50 100 150 Miles
0 50 100 150 200 Km
N
Note: Unit locations provided by the US Armed Services Center for Unit Records Research - December 1999

Primary Areas of DU Expenditure



DU Exposure Issues

- Radiation
- Consequences of exposure
- Heavy metal toxicity
- Reproductive effect
- Contamination of theater

WHAT THE GULF WAR EXPERIENCE TAUGHT US

- Commanders need to have *greater sensitivity* to non-traditional risks on the modern battlefield
- The demands of Force Health Protection require a *proactive approach*
- The key to maintaining trust and credibility with servicemembers and their families is *responsive communication*
- Commanders should be *risk managers*, rather than consequence managers

Enhanced Unity of Effort

LEADERSHIP

- Unit Leaders rarely understood their central role in risk management (especially risk communication)
- If unaddressed, perceptions and fears can produce unanticipated consequences
- Staff response to exposure risks and events lacked coordination and cohesion
- Unity of effort problematic among Medical, Safety, and Line staffs

LEADERS MUST MANAGE RISK TO PROTECT HEALTH

Applying Lessons Learned

You

- Train self and others to recognize and avoid hazards
- Improve feedback and cross talk
- You are your own best health advocate

Your Unit

- CW/BW detection:earlier with fewer false positives
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU
- Debrief to explain what happened
- Monitor service members' health & environment

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

You are your own best health advocate!

Anthrax

- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods
  - At least seven potential adversaries suspected of researching, developing and/or weaponizing anthrax.
- We have a safe and effective vaccine

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
- Dosing schedule is six doses over 18 months
  - 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster
- Shortages in stockpiled doses require temporary slowdown of AVIP
  - No new vaccine available from renovated facility until FDA approves [new vaccine lots] safety and effectiveness
  - Vaccinations continue for service members assigned or deployed at least 30 days in highest threat areas
  - Next scheduled doses for those <u>not</u> in high threat areas will be deferred until sufficient doses are available

(877) GET-VACC DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman.
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Conclusions about PB

- We cannot rule out pyridostigmine bromide as a contributor to increased health symptoms in Gulf War veterans.
- Further research is needed to determine the effectiveness of the current dose of PB against Soman.
- Additional research about safety and effectiveness of PB for humans is needed.

Bottom Line

- Lessons learned from the Gulf War affect today's doctrine and deployments
- Leaders must manage risk to protect health
- Everyone is responsible for force protection
- You are your own best health advocate
- Vets should not tough it out; get examined
- Vaccination against anthrax protects you

Obtaining help and information

- Comprehensive Clinical Evaluation program

  Comm: 06371-86-8340

  DSN: 486-8340

- Veterans Affair Persian Gulf registry program

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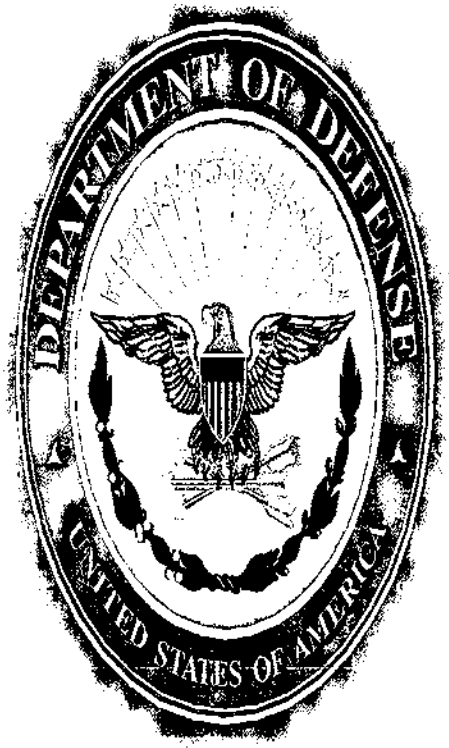

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Back-up Slides

Myths versus Reality

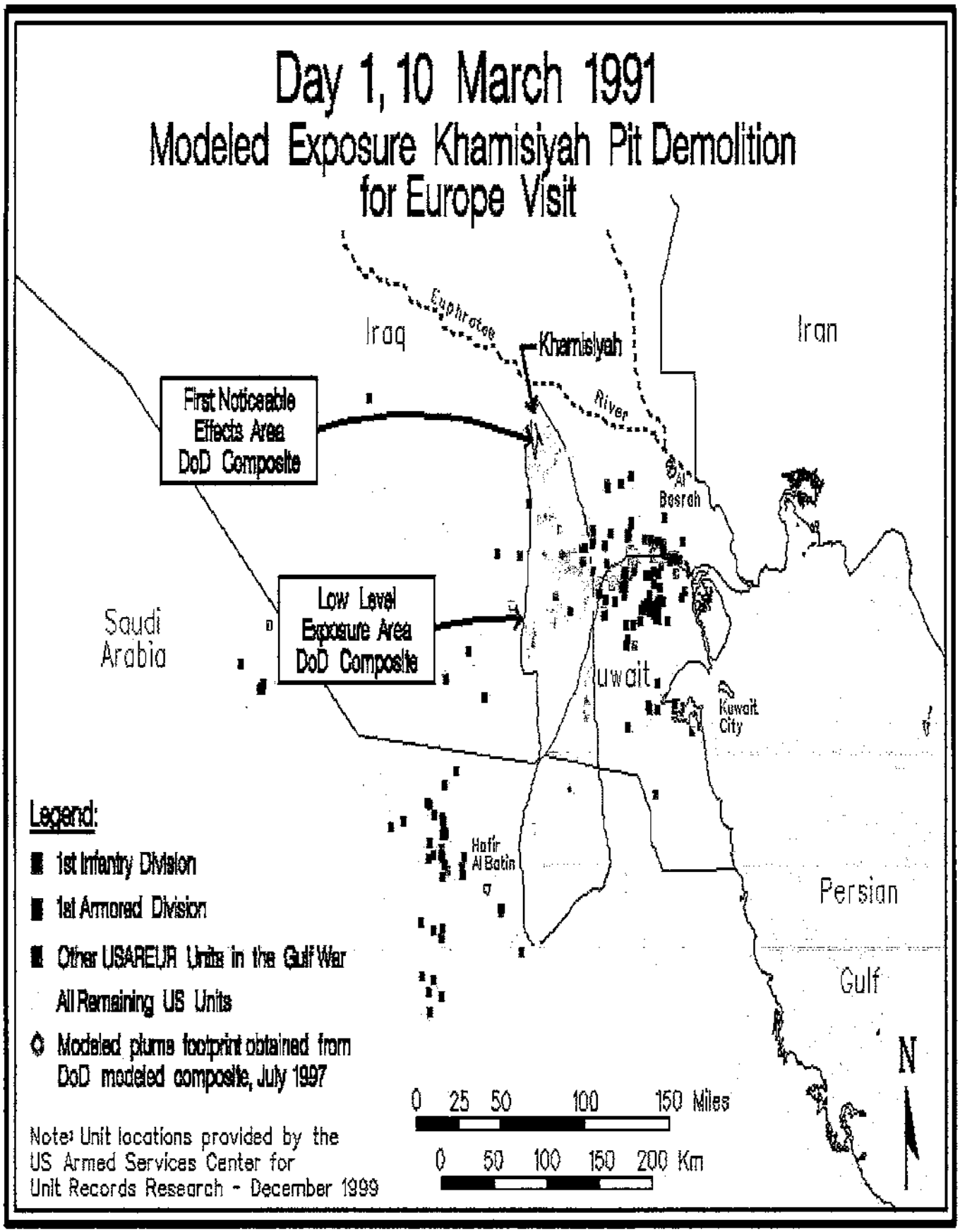
Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,686 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	Normal spectrum of illnesses known
CW or DU cause	Evaluating many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

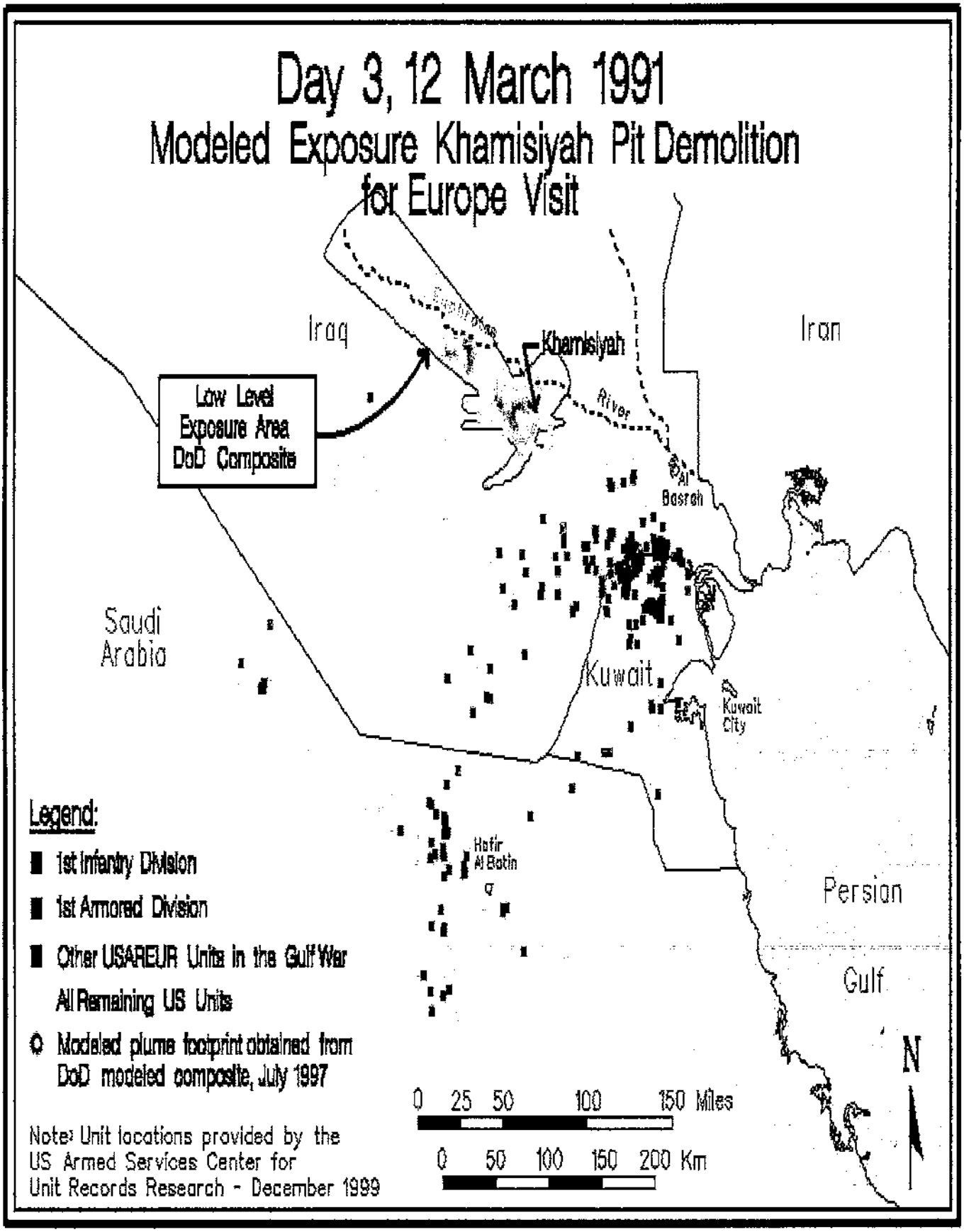
A National Effort

- **OVERSIGHT:** Presidential, 7 Congressional Committees, VSOs, Veterans, the Media
- **INVESTIGATIONS:** IGs, GAO, SIU
- **DoD:** ASDs, Special Assistants, DIA, the Surgeons General
- **OUTSIDE AGENCIES:** CIA, VA, HHS, GWVCB, CDC
- **DECLASSIFICATION:** CIA, DIA, and the Services
- **TECHNICAL PROJECTS:** Dugway, Edgewood, Picatinny, CHPPM, Think tanks, outside experts

Gulf War Investigation Results

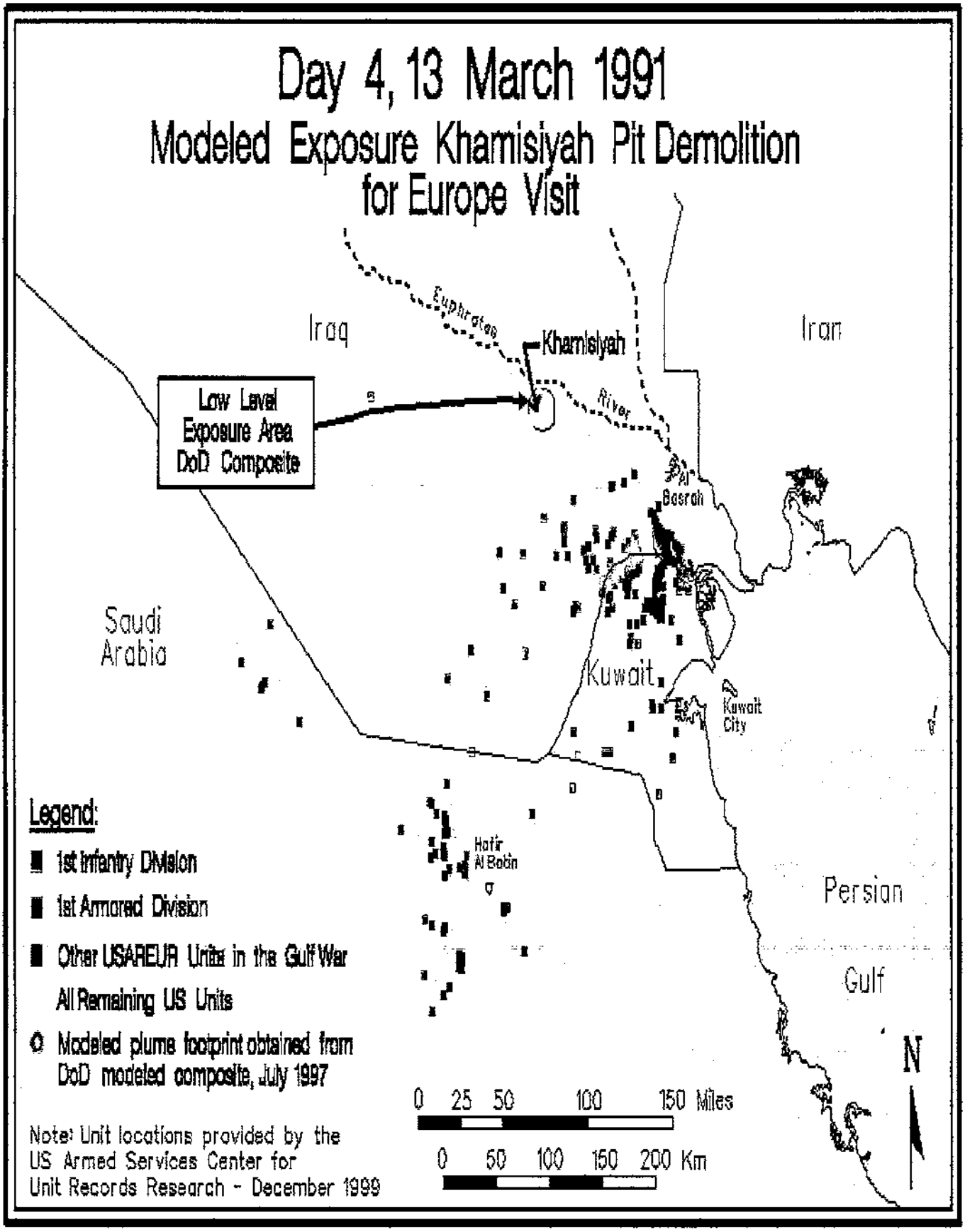
- Poor intelligence about Iraq's CW/BW weapons
- Not enough vaccines and no explanation given
- Limited environmental survey
- Information about nerve agent pre-treatment (PB) wasn't given to troops
- Inadequate training about DU or CW detectors
  - Training could have averted unnecessary exposure to DU and anxiety resulting from false alarms
- *Veterans re-deployed and left service without thorough medical exam or debrief*

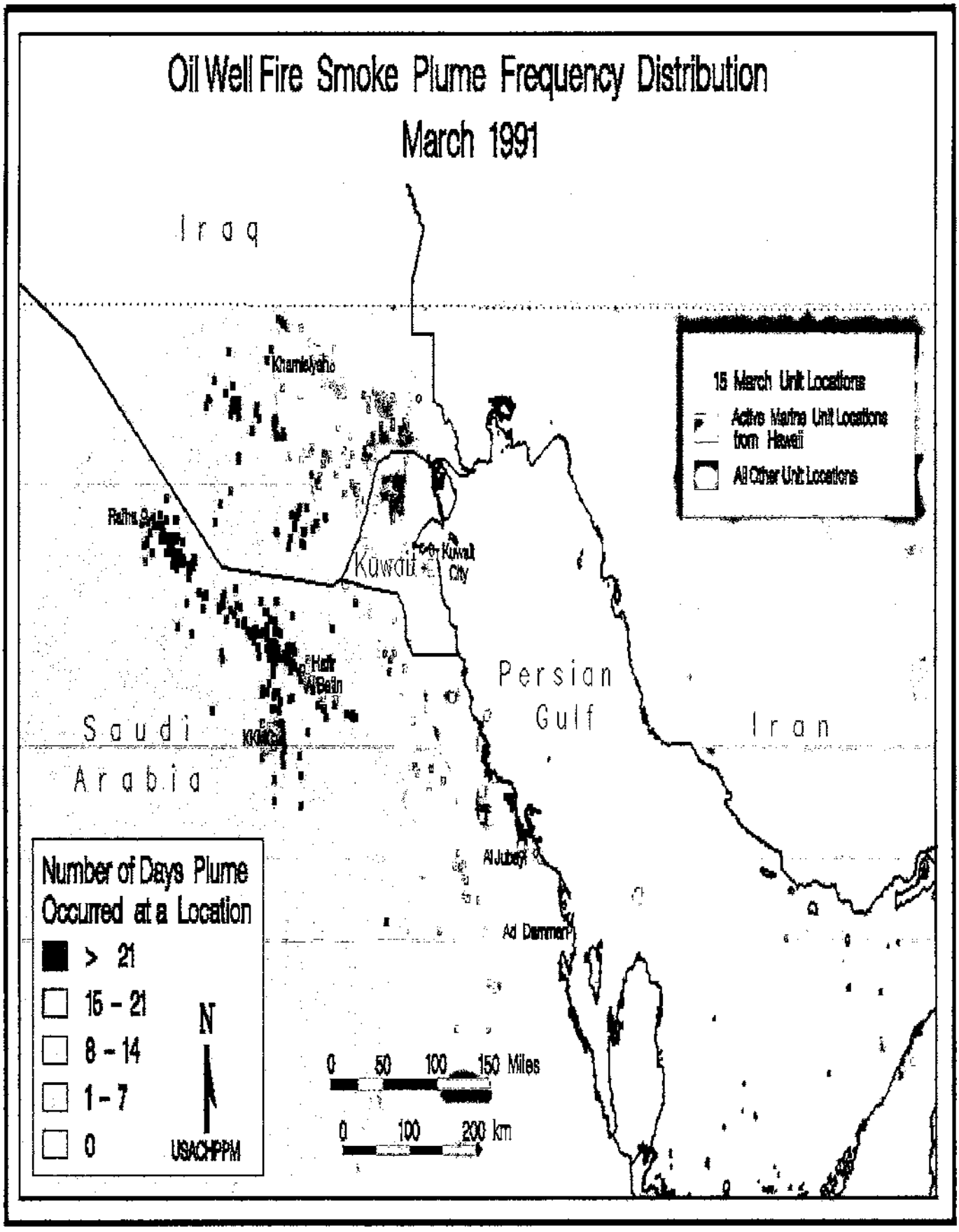

Day 1, 10 March 1991
Modeled Exposure Khamisiyah Pit Demolition for Europe Visit
Iraq
Euphrates River
Khamisiyah
Iran
First Noticeable Effects Area DoD Composite
Low Level Exposure Area DoD Composite
Saudi Arabia
Kuwait
Al Basrah
Kuwait City
Hafir Al Batin
Persian Gulf
Legend:
1st Infantry Division
1st Armored Division
Other USAREUR Units in the Gulf War
All Remaining US Units
Modeled plume footprint obtained from DoD modeled composite, July 1997
Note: Unit locations provided by the US Armed Services Center for Unit Records Research - December 1999
0 25 50 100 150 Miles
0 50 100 150 200 Km
N


Day 3, 12 March 1991
Modeled Exposure Khamisiyah Pit Demolition for Europe Visit
Iraq
Iran
Khamisiyah
Euphrates River
Low Level Exposure Area DoD Composite
Al Basrah
Saudi Arabia
Kuwait
Kuwait City
Hafir Al Batin
Persian Gulf
N
Legend:
1st Infantry Division
1st Armored Division
Other USAREUR Units in the Gulf War
All Remaining US Units
Modeled plume footprint obtained from DoD modeled composite, July 1997
Note: Unit locations provided by the US Armed Services Center for Unit Records Research - December 1999
0 25 50 100 150 Miles
0 50 100 150 200 Km

Day 4, 13 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Europe Visit



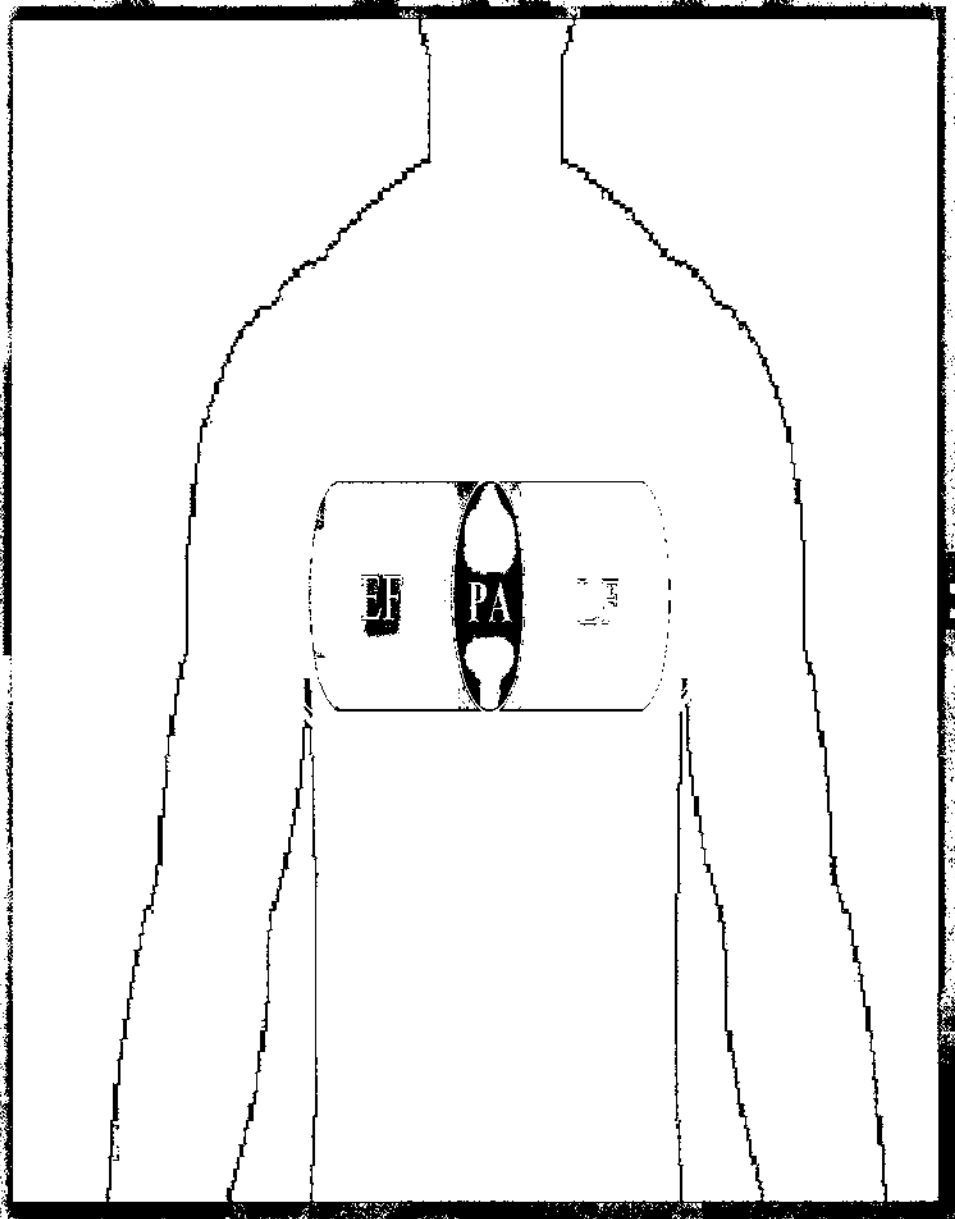

Oil Well Fire Smoke Plume Frequency Distribution
March 1991
Iraq
Khamisiyah
Rafha
Kuwait
Kuwait City
Hafr Al Batin
Saudi Arabia
Persian Gulf
Iran
Al Jubail
Ad Dammam
15 March Unit Locations
Active Marine Unit Locations from Hawaii
All Other Unit Locations
Number of Days Plume Occurred at a Location
> 21
15 - 21
8 - 14
1 - 7
0
N
USACHPPM
0 50 100 150 Miles
0 100 200 km

Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of methods
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4 prevents exposure
- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

ANTHRAX BACTERIA ATTACK

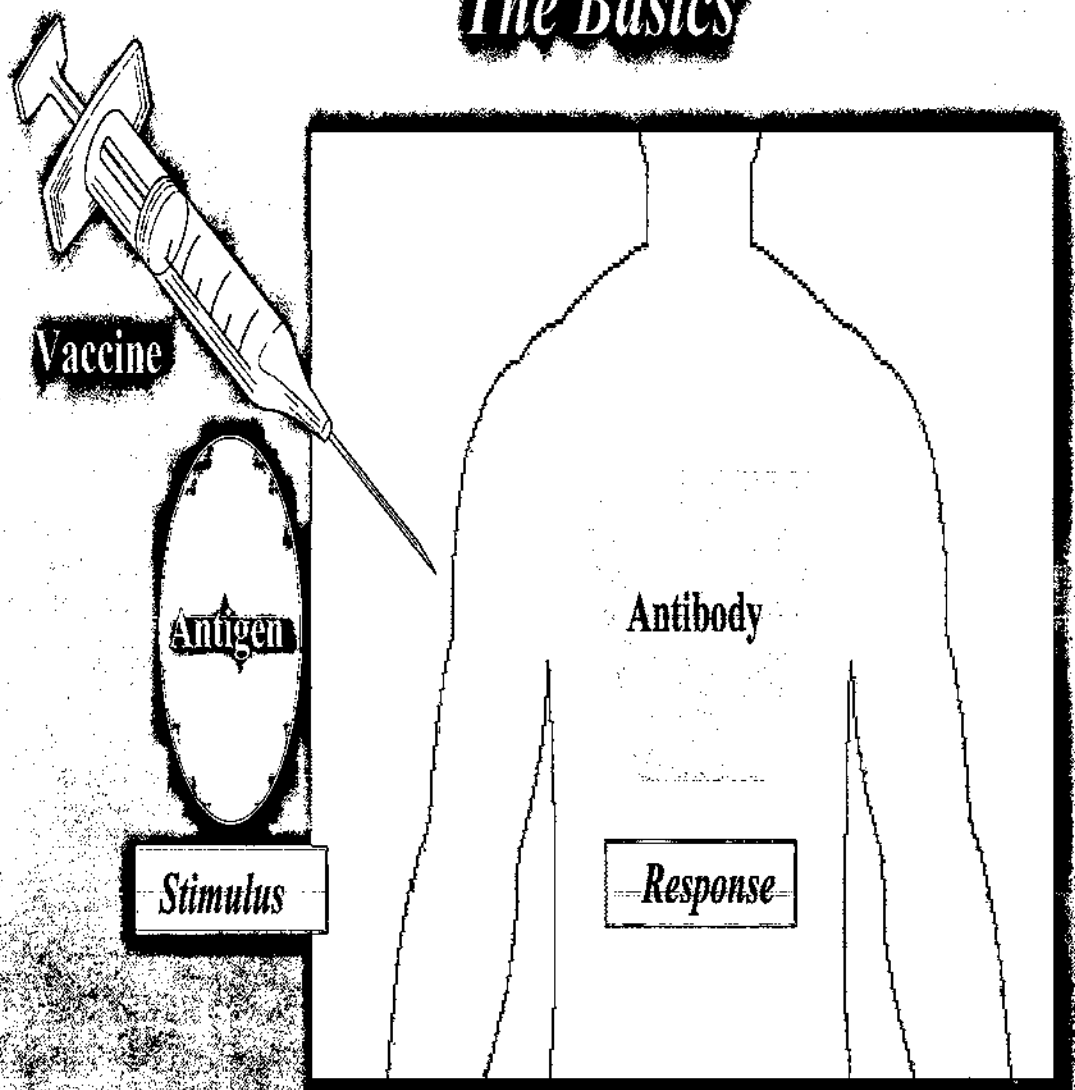


= Death

Office of the Special Assistant

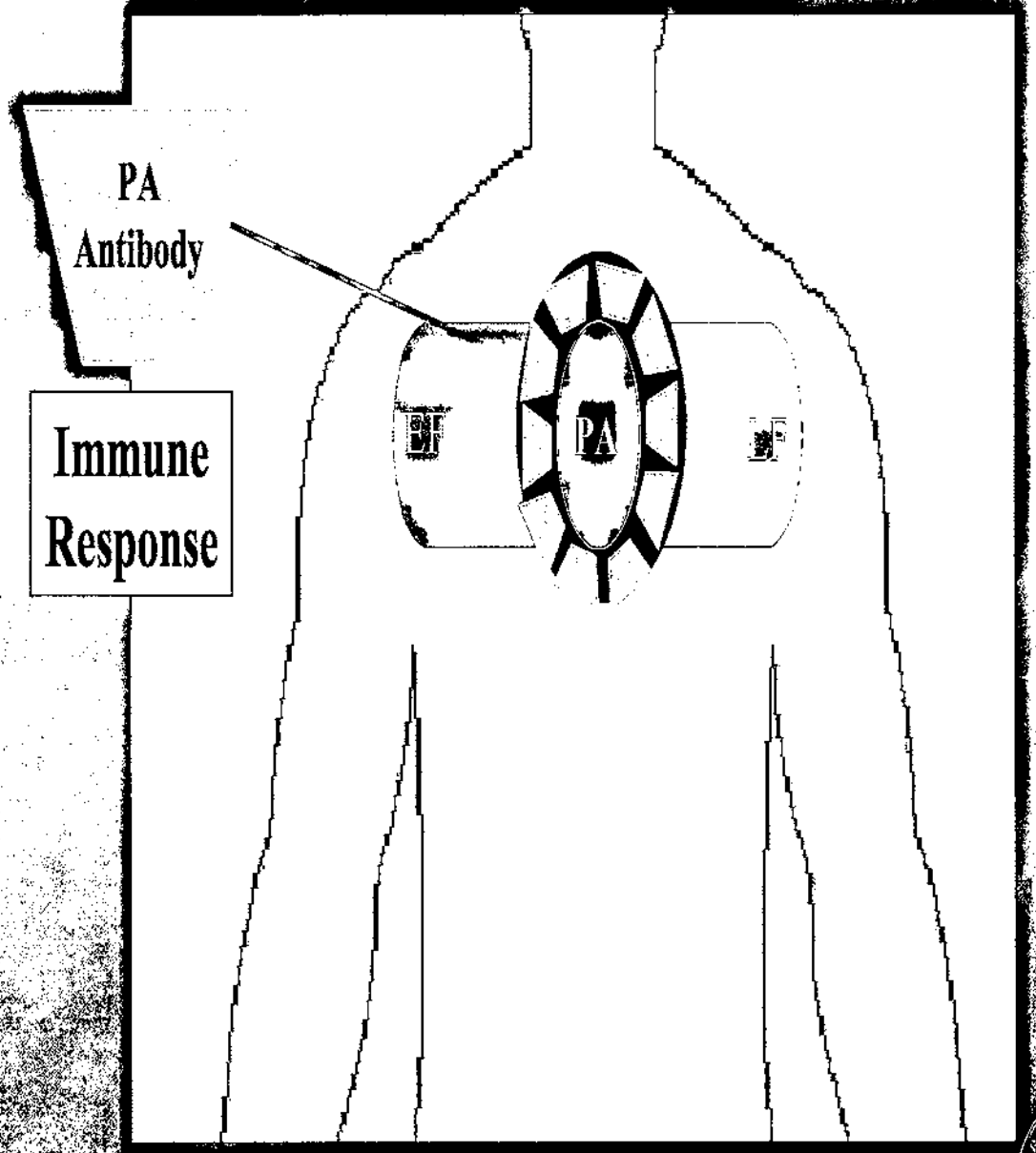
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



AFTER ANTHRAX VACCINE

Antibodies at Work

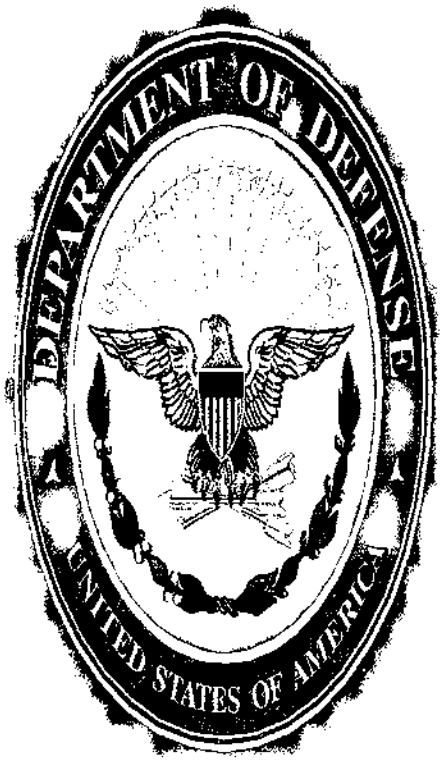


Anthrax Vaccine Program

- Licensed by the FDA since 1970
  - Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers
- Shot schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster

1-877-GET-VACC
DSN: 761-5101
www.anthrax.osd.mil
www.aviationmedicine.com

Office of the Special Assistant to the Deputy Secretary of Defense



for Gulf War Illnesses

(800) 754-2132 fax 703-578-8501
email: brostker@gwillness.osd.mil

Briefing

- Organization - Mission Statement
- Why should I care?
- Symptoms and Illnesses
- Looking for causes
- Gulf War Lessons Learned
- Force Health Protection
- Help and information

Special Assistant for Gulf War Illnesses

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members

Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Myths versus Reality

Cover up	Open process
Not listening	Solicit eyewitness reports
Destroy records	Significant oversight
20,000 veterans dead	5,773 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

Why Should I Care?

- Lessons from the Gulf War about dirty battlefields.
- You must protect yourself against hazards.
- You will be working with or leading Gulf War vets.
- You will probably deploy overseas.
- You are responsible for force protection.

Who Served in the Gulf War

697,000 U.S. service members

Army	348,000	50%
Navy	160,000	23%
Marine	105,000	15%
Air Force	84,000	12%

259,000 Coalition Forces

U.S. Deaths

Battle deaths	148
Non-battle deaths	224
Hospitalizations	27,000

Post War

Shortly after re-deployment, many individuals in units reported common symptoms

- Aching joints
- Headaches
- Rashes
- Sleep disorders
- Diarrhea
- Hair loss
- Memory loss
- Fatigue

Confounding Issues

- No clustering
- No symptom consistency
- Variable onset
- No long term study
- As yet - no new disease or links between exposures and symptoms

Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"

"It's all in your head!"

"You're faking these symptoms!"

Looking for Causes

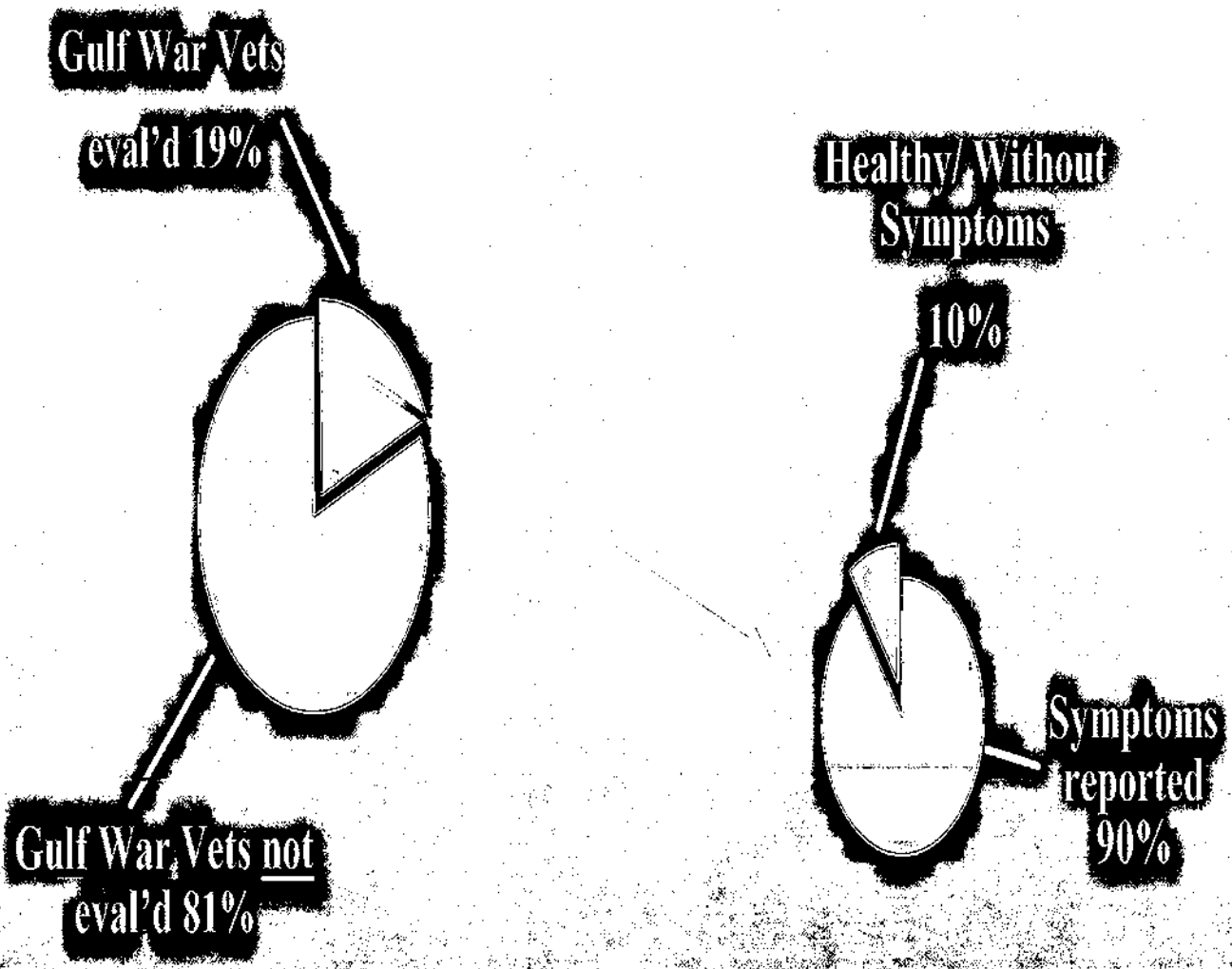
The Dirty Battlefield

- What Iraq may have done to us.
  - Oil Well Fires
- What the environment may have done to us.
  - Sand, Infectious diseases
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide
- Challenges in the future.

OSAGWI Investigations

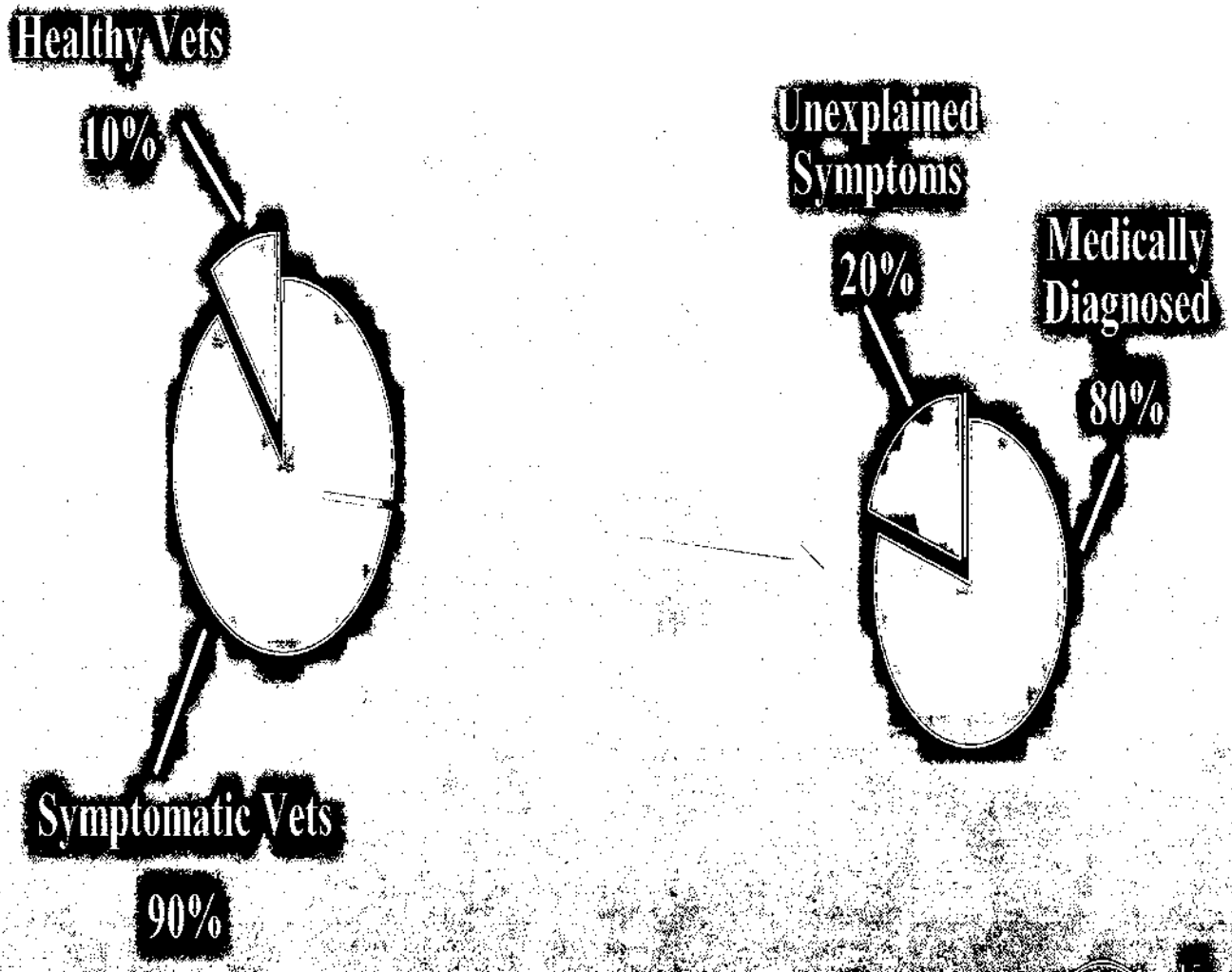
- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
- Environmental:
  - Depleted uranium (DU)
- Medical issues and lessons learned:
  - Vaccines, PB, records, policy
    - "Cocktail" effect

Evaluation Distribution of 69,000 CCEP/VA



Diagnosis Distribution of Evaluated Veterans

CCEP/VA



Proactive Measures - You

- Recognize and contend with potential hazards:
  - Improve intel notification.
  - Train all personnel.
  - Reduce adverse effects of and stress from potential exposures.
  - Understand the environment and culture before deploying.
- Improve feedback and cross talk.

Proactive Measures - Your Unit

- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Improve operational and medical records handling
- Adapt for the future
  - Retain individual unit locations and records
  - DU training
  - Improved medical surveillance
  - Force health protection

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Pre-deployment serum sample
- Verify HIV test in last 12 months
- Immunizations
- Verify current physical exam
- Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect serum sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

Future Equipment

- Personal Information Carrier (PIC)
- Biological Integrated Detection System (BIDS)
- Automatic Chemical Agent Alarm (ACADA)
- Medic Cam - Tele medicine

Anthrax Vaccine

- What is Anthrax?
- Vaccine is safe and necessary!
  - FDA Licensed in 1970
  - Used for many years to protect textile mill workers
  - Recommended by Centers for Disease Control (CDC):
    - Workers occupationally exposed to anthrax (labs, mills)
    - Treatment of anyone exposed to anthrax aerosols
    - Only known pretreatment and protection against exposure

Anthrax Vaccine

- DoD Policy - mandatory for total force
  - Phased implementation
- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea (now)
- Phase III - Total force (early 2000's)
- Vaccine series:
  - 0, 2, 4 weeks; then 6, 12, 18 months; annual booster
- Reported reactions (18 Aug 99 per DoD/Health Affairs):
  - 1,060,278 doses, 157 adverse reactions=0.015%
- DoD anthrax web site: www.anthrax.osd.mil

Obtaining Help and Information

- Comprehensive Clinical Evaluation Program (CCEP)
  - 1-800-796-9699
- Veterans Affair registry program
  - 1-800-749-8387
- Contact managers

Bottom Line

- Gulf War Veterans key for our work
- Apply lessons learned
- You must protect yourself on the Dirty Battlefield
- Anyone deployed to South West Asia is eligible for CCEP *(family members included)*
- Don't tough it out - Get signed up and evaluated
- You are your best health advocate

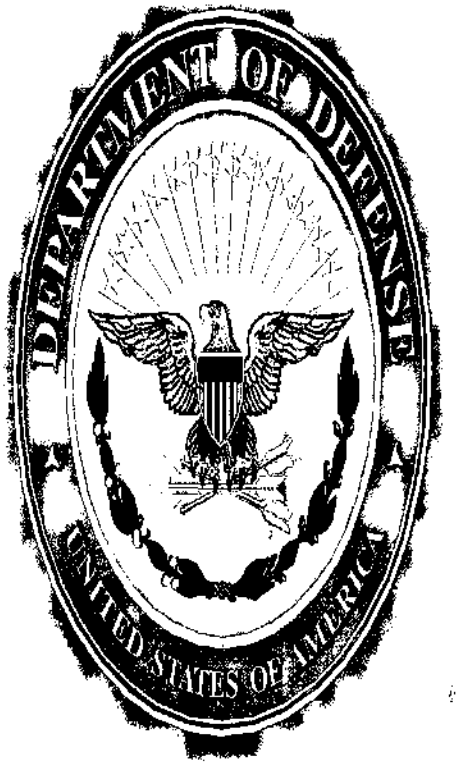
Office of the Special Assistant for Gulf War Illnesses

CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-472-6719
OSAGWI Contact Managers	800-497-6261

www.gulflink.osd.mil

Office of the Special Assistant to the Deputy Secretary of Defense



for Gulf War Illnesses

IMAGE ONLY FILE. USE/VIEW IMAGE FOR COMPLETE DOCUMENT INFORMATION.

KEYWORDS:
CMAT # 1999060-0000006
MEDICAL HISTORICAL - DEPARTMENT OF DEFENSE ANTHRAX VACCINE IMMUNIZATION PROGRAM UPDATE BRIEF

CMAT Control #
1998060-0000006

Department of Defense Anthrax Vaccine Immunization Program

UPDATE BRIEF

Deputy Secretary of Defense

9 February 1999

[redacted]

ANTHRAX VACCINE IMMUNIZATION PROGRAM

Agenda

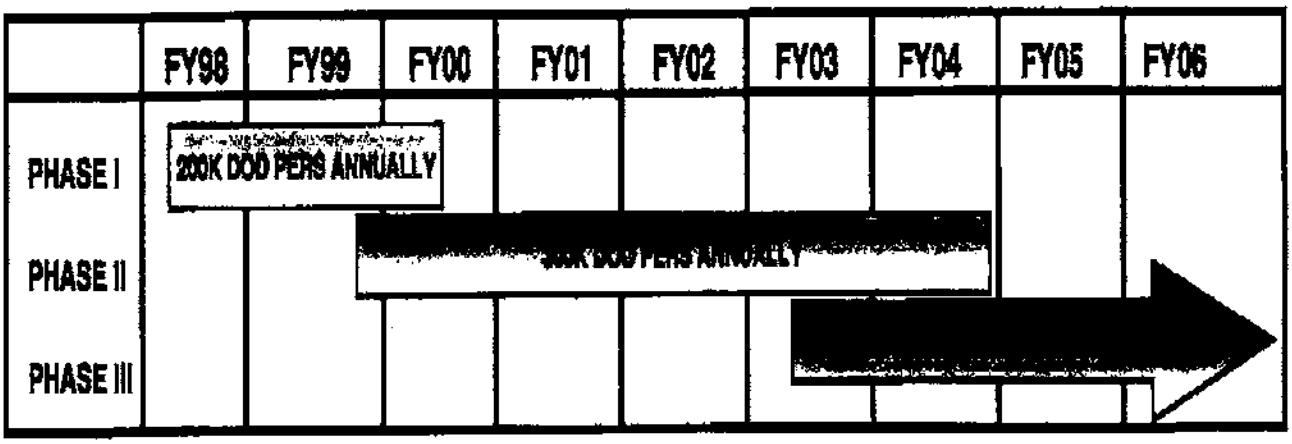
- AVIP Implementation Progress
- AVIP Policy Updates
- Vaccine Acquisition, Stockpiling and Distribution
- Adverse Reactions and Clinical Outcomes
- Working The Internet
- Resources
- Service Specific Discussions

ANTHRAX VACCINE
IMMUNIZATION PROGRAM AVIP

AVIP Execution Timeline

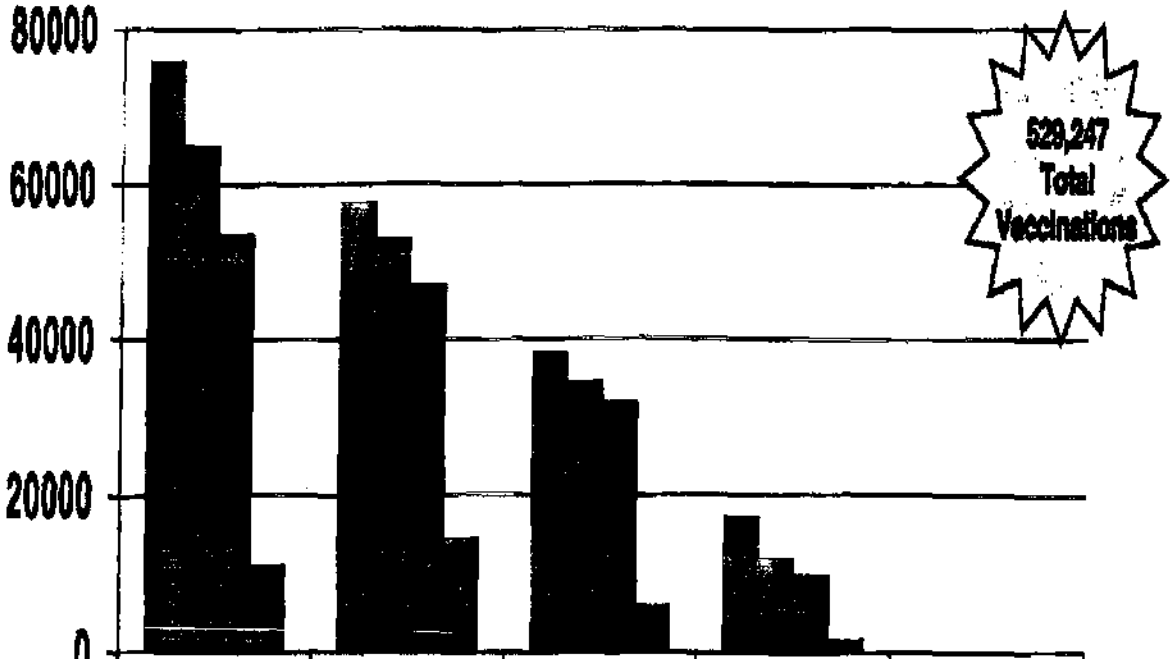
Phased execution across the Total Force

- Phase I. Forces assigned or rotating to High Threat Areas of SWA and Korea
- Phase II. Early deploying forces (C to C+35) into High Threat Areas of SWA and Korea
- Phase III. Remainder of total force, accessions, and program sustainment



ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Current Force Immunization Status



	Army	Air Force	Navy	Marines	Total
Shot # 1	76018	57724	38173	17304	189,219
Shot # 2	64931	52845	34686	11874	164,336
Shot # 3	53441	46983	31741	9828	141,993
Shot # 4	11247	14416	6254	1782	33,699

* All Data From DEERS 022400 Feb 99

ANTHRAX VACCINE
IMMUNIZATION PROGRAM AVIP

Compliance Rates

[redacted]

[redacted]			
ARMY	[redacted]	76,018	90%
NAVY/MARINES	[redacted]	55,477	83%
AIR FORCE	[redacted]	57,724	92%

189,219

[redacted]

- Within DoD Standard
- Not Within DoD Standard/Minor Problem
- Not Within DoD Standard/Major Problem

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

AVIP Policy Updates

- **Zero-Day Policy (ZDP):**
  - Services and CINCs concur, staffing for USD(P&R) signature

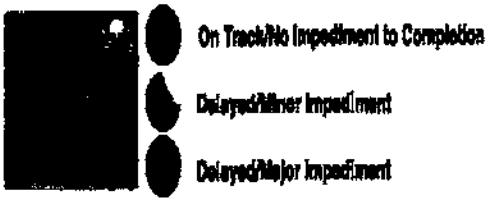
- **Immunization Refusal Policy:** *Consensus for NO DoD Policy*
  - Status: Each Service crafting their own policy

- **Adverse Reaction Reporting Procedures:** synchronizes guidance for reporting adverse reactions
  - Status: Staff through Service SGs, signature by ASD(HA)

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Vaccine Acquisition and Stockpile

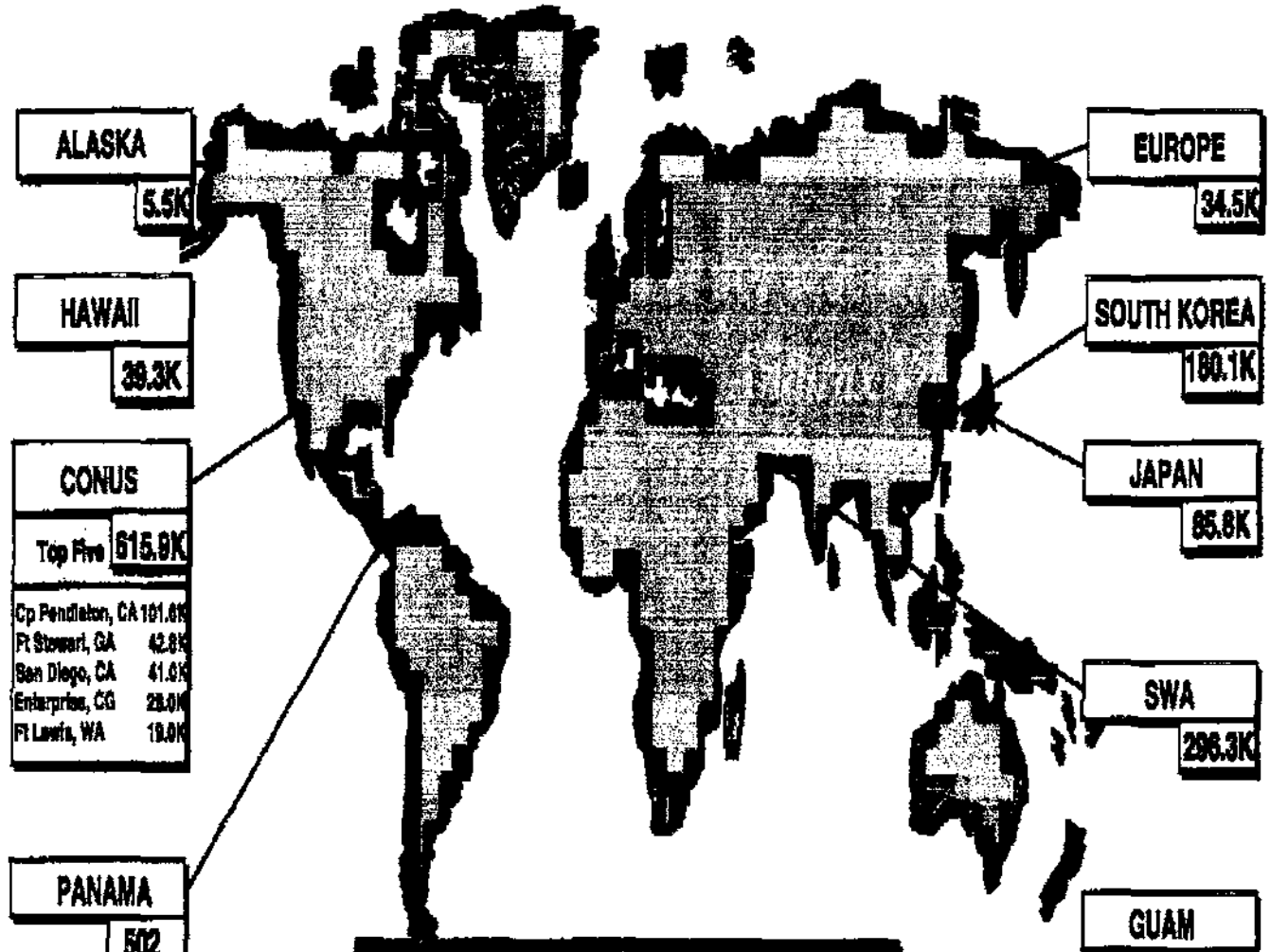
Stockpile Supplemental Testing		**Testing Ongoing;** ➤ 6 lots/ 1.26M doses supplementally tested, packaged and labeled ➤ 2 lots, 369K recently released ➤ All lots complete supplemental testing May 99
Plant Renovation		**Renovation and FDA Certification** ➤ Began Mar 98; renovation completed Jan 99 ➤ New vaccine available after FDA Certification of facilities and new lots, 4QFY99



ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Anthrax Vaccine Distribution

1,270,000 Doses Shipped to 368 Locations Worldwide



USA	USAF	USN	USMC	FMS
311,360	247,610	310,640	313,660	8,209

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Anthrax Vaccine Adverse Reactions

Anthrax Vaccine Adverse Event Reporting System (VAERS)
Week Ending 1 Feb 99

Service	VAERS	Classification			
		Local Reaction			Syst Reac
		Mil	Moderate	Sev	
USA		0	0		0
USN		0	0		0
USAF		0	0		0
USMC		0	0		0

Cumulative Data

Service	VAERS	Classification			
		Local Reaction			Syst Reac
		Mil	Moderate	Sev	
USA		7	6		1
USN		0	0		3
USAF		2	2		0
USMC		0	0		0

9 8 7 14

38 adverse reactions of 529,247 vaccinations given = .007%

- Duration 24 - 48 hours
- Local redness and hardness 1 to 2 centimeters

Moderate

- Local redness and hardness 5 centimeters
- Subcutaneous nodule at injection site

- Swelling at injection site and entire forearm

- Malaise
- Chills and fever
- Anaphylaxis

VAERS

- Loss of duty > 24 hours
- Hospitalization

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Anthrax Vaccine Clinical Outcomes

- **Armed Forces Epidemiological Board review of VAERS–3 Aug 98**
  - Recommended no change in current DoD AVIP
- **TAMC Survey - Korea PROFIS**
  - Sample size–603 soldiers
  - 3 VAERS reports–none hospitalized, 1 missed 24 hours duty
    - < 5% sought any medical attention for any symptom/side effects
- **Vaccine External Review Panel of Adverse Events**
  - Oversight--Vaccine Injury Compensation Program, Health Resource Services Administration, DHHS
  - Report due mid-Feb 99

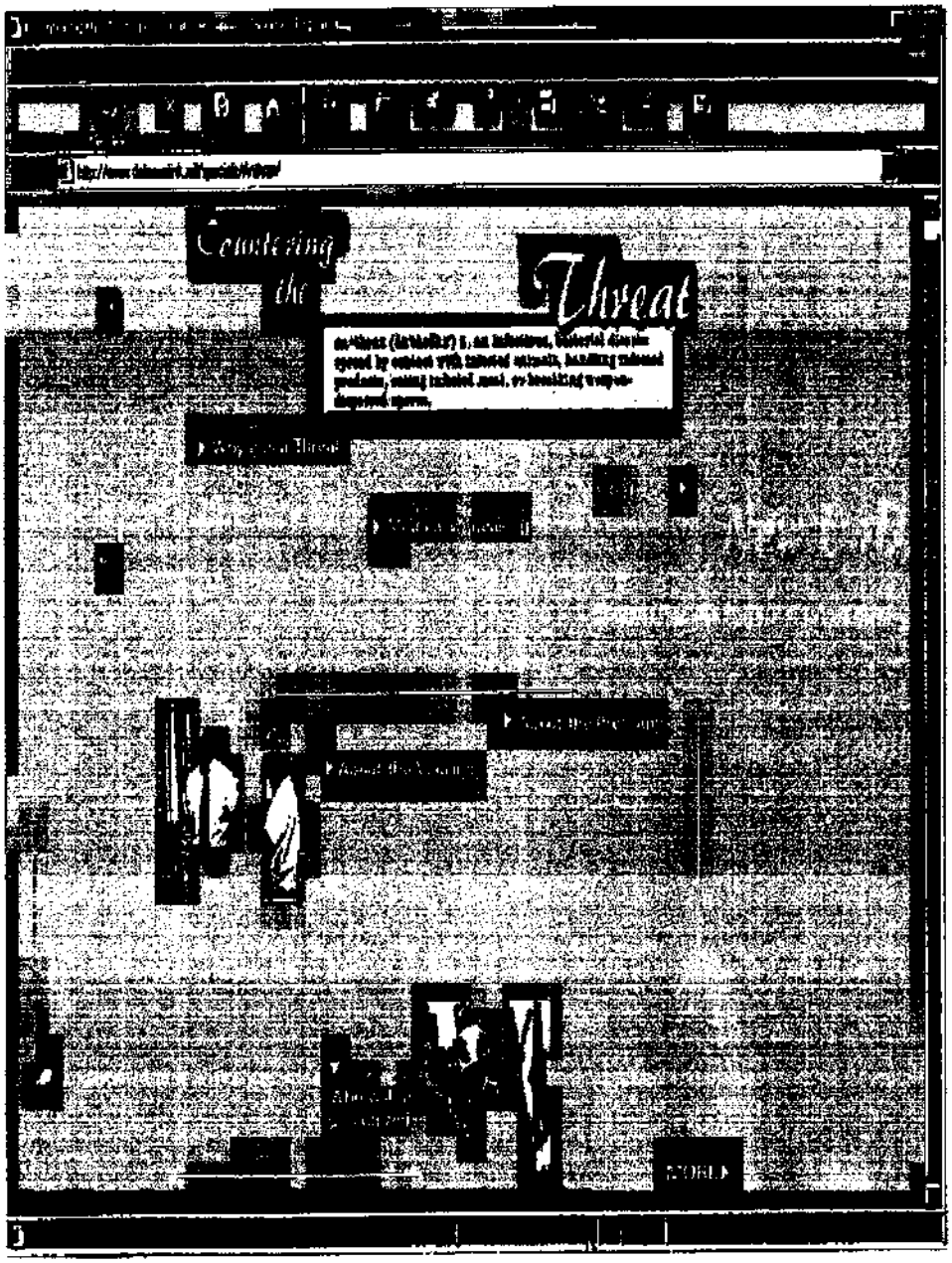
ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Working The Internet

- **Anthrax vaccine disinformation**
  - 3 main anti-AVIP web sites; major source of disinformation
  - Television--focused on refusals
  - Press--focused on refusals
- **DoD initiatives to counter disinformation**
  - New DoD anthrax web site: www.defenselink.mil/specials/anthrax
    - Highest number of "hits" (13%) in the Defenselink "specials" category
    - Accessed 700 times/day (25-50% more than anti-AVIP sites)
  - Enhanced anthrax website (cost implications)
    - Enhanced web architecture; position within commercial search engines
    - Focused on AD, spouses, parents, scientific community, press, media
    - Feedback mechanisms
      - & Live chat rooms, bulletin boards
      - & Organized "frequently asked questions"
      - & Dedicated 1-800 number

ANTHRAX VACCINE IMMUNIZATION PROGRAM

New DoD Web Site



ANTHRAX VACCINE
IMMUNIZATION PROGRAM AVIP

Resources

- **DoD AVIP implementation/monitoring efforts currently unfunded**

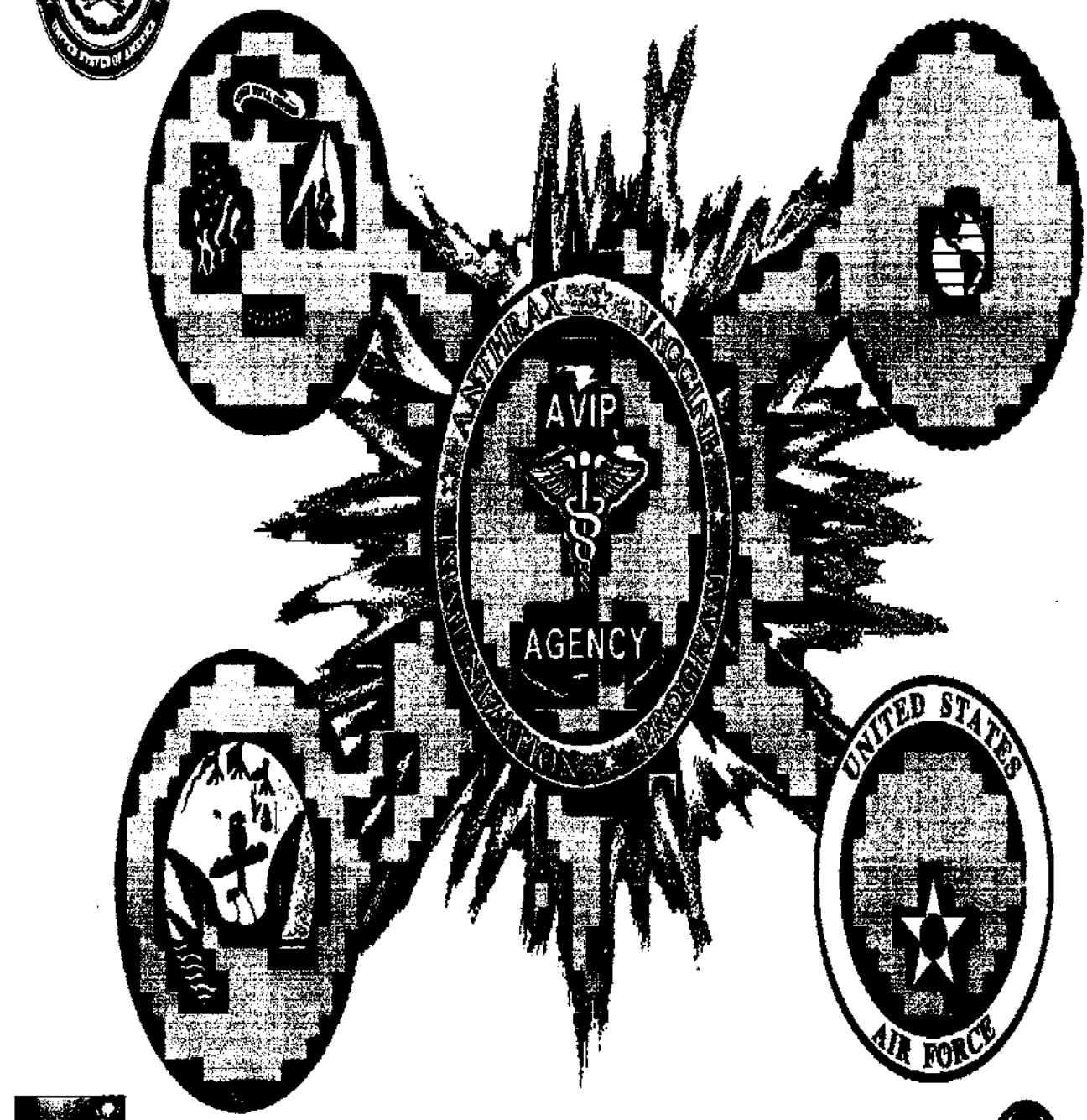
	Current	Needed
USA	$ 2.1M DHP	$4.46M to do entire program
USAF	(Data coming)	
USN/USMC	(Data coming)	

- **DoD enhanced anthrax education/communications initiative**
  - Start and sustain FY00–$810K

- **VA/DHHS/DoD Force Health Protection Initiative**
  - RC access to anthrax vaccinations (FY 00 - 05)–$(Data coming)M

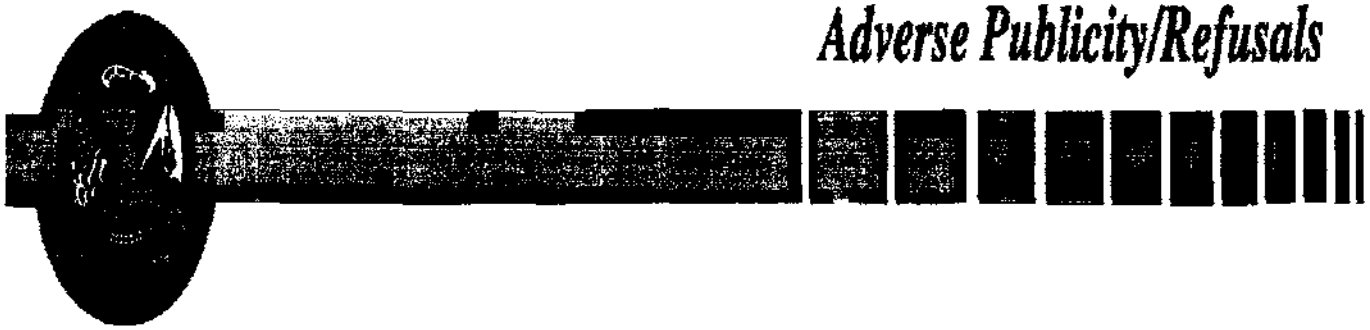
ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Service Presentations



ANTHRAX VACCINE
IMMUNIZATION PROGRAM AVIP

Adverse Publicity/Refusals



- 9 Army refusals after extensive education/re-education/counseling
  - 8 refusals in Korea
  - 1 refusal at Ft Stewart, GA

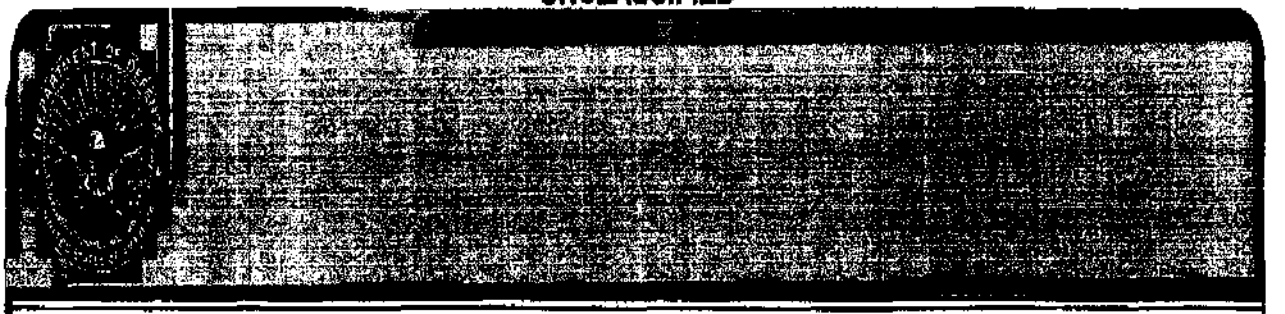
- Revision of AR 600-20, Army Command Policy
  - Under normal circumstances, will not forcibly vaccinate
  - Clear guidance to commanders on management of soldier refusals
  - Use minimum force necessary to vaccinate soldiers only under conditions of imminent threat
    - Imminent threat determined by GCMCA
    - May be delegated by GCMCA to O-5 commanders and above
  - Status--Pending approval by CSA and SECARMY, estimate action complete and ALARACT message in Feb 99.

IMAGE ONLY FILE. USE/VIEW IMAGE FOR COMPLETE DOCUMENT INFORMATION.

KEYWORDS:
CMAT # 1999060-0000014
MEDICAL HISTORICAL - JPO-BIODEFENSE BRIEFING ON ANTHRAX VACCINE

11/7/96

- Anthrax Vaccine (Licensed and Produced by MBPI)
  - 6,000 Doses Available at Outset
  - 400,000 Doses Delivered During ODSS
  - Production Capacity - One 100 Liter Fermentor
- Botulinum Pentavalent Toxoid (A-E) Vaccine (IND and Produced by MBPI)
  - 30,000 Doses Available at Outset
  - 190,000 Doses Delivered During ODSS
  - No Operational Production Capacity in U.S.



Surg Gen Office Vaccine Prod'n Facility

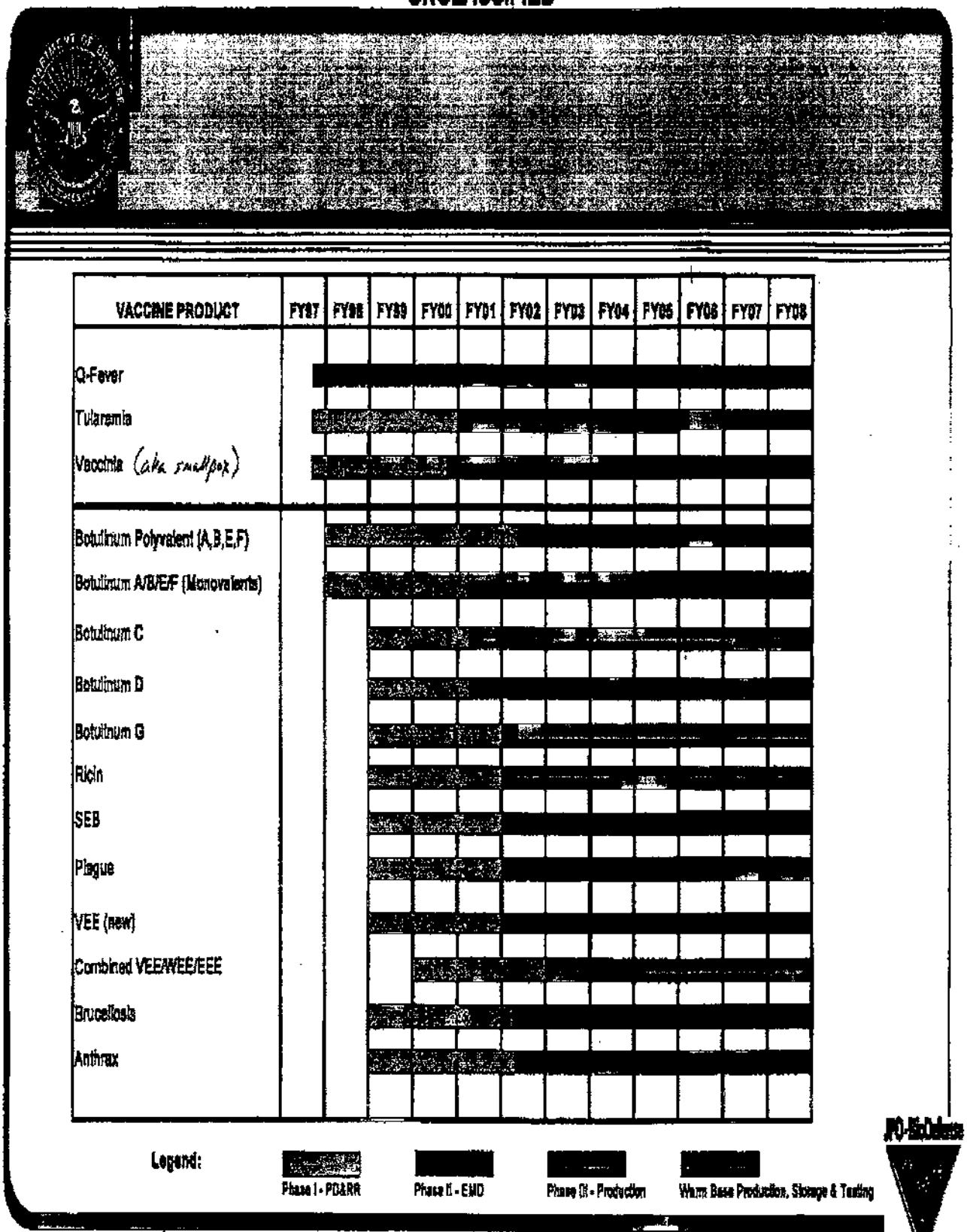
- May 1991 - Army SGO Initiative to Build a VPF
- September 1992 - PDM for FY94 Funds to Construct VPF
- June 1993 - ADM Directs Establishment of JPO-BD
- January 1994 - Independent Government Analysis Favors COCO Facility
- April 1994 - DoD/Industry Conference to Determine Level of Industry Interest in Producing BD Vaccines
- May 1994 - ADM Directs Assessment of Best Approach for BD Vaccine Production
- January 1995 - Prime System Contractor Approach Developed. DEPSECDEF Supports Concept
- April 1995 - SSC Agrees with Prime System Approach. Army Defines Stockpile of BD Vaccines
- May 1995 - ADM Directs Prime System Approach for Contracting
- January 1996 - PBD 724 Directs Prime System Approach IAW ADM
- August 1996 - RFP Released for JVAP Prime System Contractor

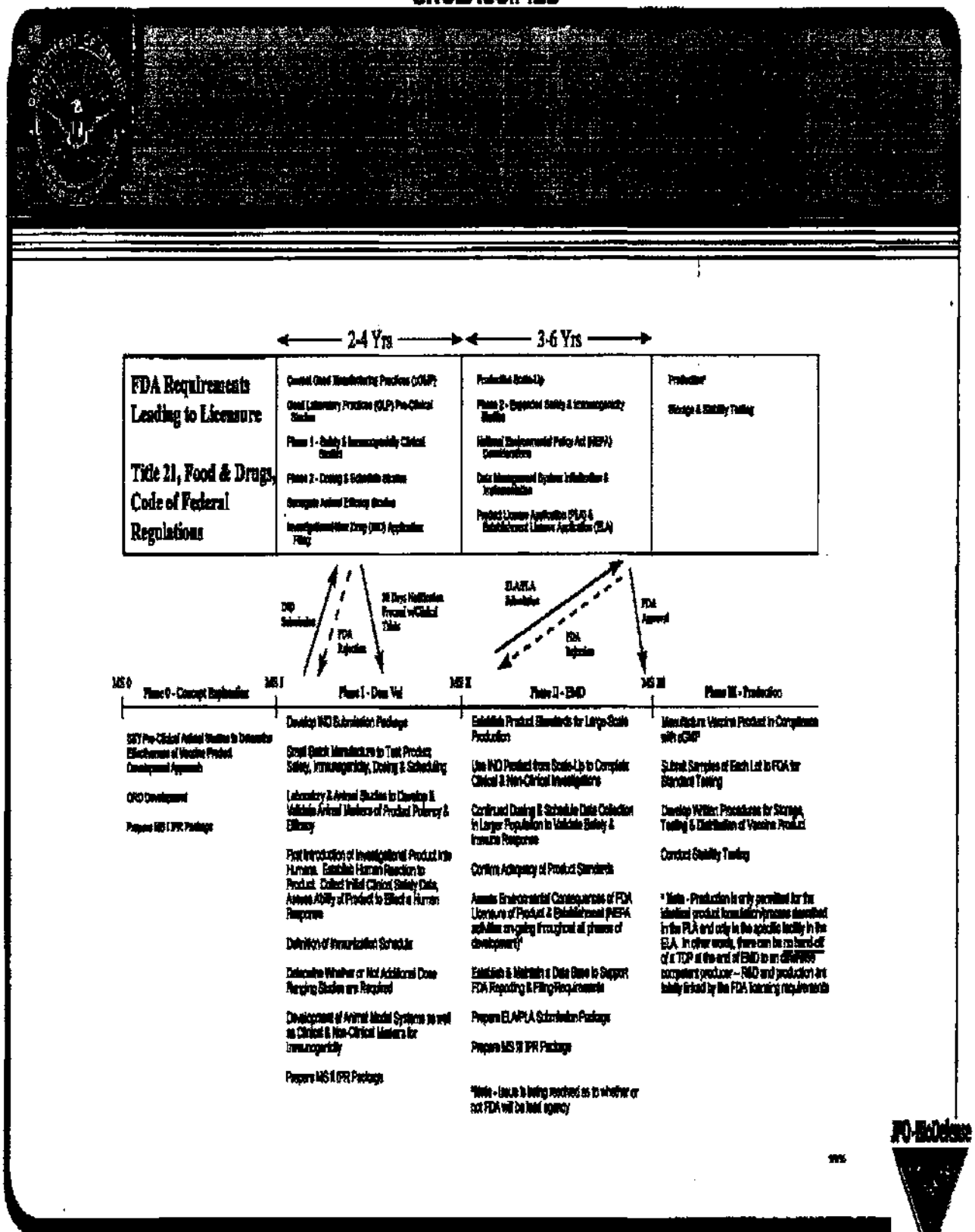
Acquisition Decision Memo

JPO-BioDefense

- Stockpile
  - 1.2M Troop Equivalent Doses for 2 High Threat Biological Warfare Agents (BWA) (Will have this by March 97) Have to work hard for But.
  - 0.3M Troop Equivalent Doses for all Other BWA
- Likely Additional Requirements
  - Annual Immunization
  - Commander's Reserve (add 50% to Stockpile)

- Prime Systems Contract
  - Single Integrator Responsible for:
    - > Advanced Development
    - > FDA Licensure
    - > Production
    - > Testing
    - > Post Marketing Surveillance
  - Single Information Management Database
  - Individual Vaccines May Be Subcontracted
- Project Office at Ft Detrick


VACCINE PRODUCT
FY97
FY98
FY99
FY00
FY01
FY02
FY03
FY04
FY05
FY06
FY07
FY08
Q-Fever
Tularemia
Vaccinia (aka smallpox)
Botulinum Polyvalent (A,B,E,F)
Botulinum A/B/E/F (Monovalents)
Botulinum C
Botulinum D
Botulinum G
Ricin
SEB
Plague
VEE (new)
Combined VEE/WEE/EEE
Brucellosis
Anthrax
Legend:
Phase I - PD&RR
Phase II - EMD
Phase III - Production
Warm Base Production, Storage & Testing


2-4 Yrs
3-6 Yrs
FDA Requirements Leading to Licensure
Title 21, Food & Drugs, Code of Federal Regulations
Control Good Manufacturing Practices (CGMP)
Good Laboratory Practices (GLP) Pre-Clinical Studies
Phase 1 - Safety & Immunogenicity Clinical Studies
Phase 2 - Dosing & Schedule Studies
Surrogate Animal Efficacy Studies
Investigational New Drug (IND) Application Filing
Production Scale-Up
Phase 3 - Expanded Safety & Immunogenicity Studies
National Environmental Policy Act (NEPA) Considerations
Data Management System Initialization & Implementation
Product License Application (PLA) & Establishment License Application (ELA)
Production*
Storage & Stability Testing
IND Submission
FDA Rejection
90 Days Notification Prior to Clinical Trials
ELA/PLA Submission
FDA Rejection
FDA Approval
MS 0
Phase 0 - Concept Exploration
MS I
Phase I - Dose Val
MS II
Phase II - EMD
MS III
Phase III - Production
SBIR Pre-Clinical Animal Studies to Determine Effectiveness of Vaccine Product Development Approach
CRO Development
Prepare MS I IPR Package
Develop IND Submission Package
Small Batch Manufacture to Test Product Safety, Immunogenicity, Dosing & Scheduling
Laboratory & Animal Studies to Develop & Validate Animal Models of Product Potency & Efficacy
First Introduction of Investigational Product into Humans. Establish Human Reaction to Product. Collect Initial Clinical Safety Data, Assess Ability of Product to Effect a Human Response
Definition of Immunization Schedule
Determine Whether or Not Additional Dose Ranging Studies are Required
Development of Animal Model Systems as well as Clinical & Non-Clinical Markers for Immunogenicity
Prepare MS II IPR Package
Establish Product Standards for Large-Scale Production
Use IND Product from Scale-Up to Complete Clinical & Non-Clinical Investigations
Continued Dosing & Schedule Data Collection in Larger Population to Validate Safety & Immune Response
Confirm Adequacy of Product Standards
Assess Environmental Consequences of FDA Licensure of Product & Establishment (NEPA activities on-going throughout all phases of development)*
Establish & Maintain a Data Base to Support FDA Reporting & Filing Requirements
Prepare ELA/PLA Submission Package
Prepare MS III IPR Package
*Note - Issue is being resolved as to whether or not FDA will be lead agency
Manufacture Vaccine Product in Compliance with cGMP
Submit Samples of Each Lot to FDA for Standard Testing
Develop Written Procedures for Storage, Testing & Distribution of Vaccine Product
Conduct Stability Testing
* Note - Production is only permitted for the identical product manufacturing process described in the PLA and only in the specific facility in the ELA. In other words, there can be no hand-off of a TDP at the end of EMD to an alternate competent producer -- R&D and production are totally linked by the FDA licensing requirements
WRS

- Production of the Licensed Anthrax Vaccine
- Reduction from 6 to 2 Immunization Regime for Anthrax Vaccine
- Licensing of the Existing Bot Tox Pentavalent Vaccine
- Studies on Long Term Effects of Multiple Immunizations with BD Vaccines

GOCO Option

Ft. Vaccine

- ***Why Started?*** **Lessons From ODSS**
  - No Surge Capacity for BD Vaccines
  - Limited Industry Interest
- ***Why Stopped?*** **DOD and Congressional Directives**
  - Need for Dedicated DOD Facility?
  - Most Economical Approach?

ADM Directed Cost/Benefit Analysis

COCO Option

- ***Why Started?*** **Cheaper**
- ***Why Modified?*** **Affordability**
  - $450M Unfunded Requirement FY96-01
  - Industry Survey

Prime (Systems) Contract

- ***Why Started?*** **Optimum Resource Utilization**
  - Reduces Requirement for New Facilitization
  - Most BD Vaccines Already Produced by Industry
  - Enhances Competition

(232)

IMAGE ONLY FILE. USE/VIEW IMAGE FOR COMPLETE DOCUMENT INFORMATION.

KEYWORDS:
CMAT # 1999169-0000017

ANTHRAX VACCINE ADVERSE EVENTS BRIEFING

CMAT Control #
1999169-0000017

Anthrax Vaccine Adverse Events

Vaccine Adverse Event Reporting System (VAERS) Military
Week Ending 11 June 99

Service	VAERS R	Classification			
		Local Reaction			Syste
		Mild	Moderate	Se	Reac
USA	3	0	0		3
USN	5	1	0		4
USAF	11	1	1		11
USMC	5	0	0		5

Cumulative Data

Service	VAERS R	Classification			
		Local Reaction			Syste
		Mild	Moderate	Se	Reac
USA	41	8	7		24
USN	14	1	2		8
USAF	35	4	5		24
USMC	9	0	0		8

FDA Reported 123

Total Local = 38

Total Systemic = 64

Mild

- Duration 24 - 48 Hours
- Local Redness and Hardness 1 to 2 Centimeters

Moderate

- Local Redness and Hardness 5 Centimeters
- Subcutaneous Nodule at Injection Site

- Swelling At Injection Site and Entire Forearm

- Malaise
- Chills and Fever
- Anaphylaxis

VAERS

- Loss of Duty > 24 Hours
- Hospitalization

Only 14 reports met strict reporting requirements

ANTHRAX KILLS

102 Adverse Reactions of 935,632 Vaccinations Given = .011%

IMMUNIZATION PROGRAM

(233)

CMAT Control #
1999132-0000011

Anthrax Vaccine Adverse Events

Vaccine Adverse Event Reporting System (VAERS) Military
Week Ending 18 June 99

Service	VAERS	Classification			
		Local Reaction			Syst Reac
		Mild	Moderate	Se	
USA		0	0		
USN		0	0		
USAF		0	0		
USMC		0	0		

Cumulative Data

Service	VAERS	Classification			
		Local Reaction			Syst Reac
		Mild	Moderate	Se	
USA		8	7		2
USN		1	2		
USAF		4	5		2
USMC		0	0		

FDA Reported 175

Total Local = 38

Total Systemic = 65

[redacted]

103 Adverse Reactions of 961,720 Vaccinations Given = .011%

Mild

- Duration 24 - 48 Hours
- Local Redness and Hardness 1 to 2 Centimeters

Moderate

- Local Redness and Hardness 5 Centimeters
- Subcutaneous Nodule at Injection Site

- Swelling At Injection Site and Entire Forearm

- Malaise
- Chills and Fever
- Anaphylaxis

VAERS

- Loss of Duty > 24 Hours
- Hospitalization

Only 14 reports met strict reporting requirements

ANTHRAX VACCINE ADVERSE EVENTS
DoD-General VAERS-1 Reports

As of 23 June 99

SYSTEMIC REACTIONS

1) USAF DMSS 3 VAERS 113512	FEVER, MALAISE	**QTRS 24 HRS/RESOLVED**
2) USN DMSS 4 VAERS 111835	GUILLIAN-BARRE SYNDROME	**HOSP/RECOVERED**
3) USAF DMSS 5 VAERS 113514	POTENTIAL ALLERGIC RXTN, RASH ON TRUNK	RESOLVED
4) USAF DMSS 6 VAERS 112155	FDA GENERATED AS SECOND REPORT for VAERS # 112156	RESOLVED
5) USAF DMSS 7 VAERS 112156	DIZZINESS, NAUSEA, DIARRHEA DOUBLE VISION	RESOLVED
6) USA DMSS 9 VAERS 114365	URTICARIA ON BACK, CHEST ARM	RESOLVED
7) USA DMSS 12 VAERS 113595	COMPLAINED OF DIZZINESS AND EMESIS 7 DAYS FOLLOWING VAQCCINATION	NO TREATMENT/RTD
8) USAF DMSS 13 VAERS 113746	SYNCOPE AND CHEST PAIN	NO TX/RESOLVED
9) USAF DMSS 14 VAERS 113740	NUMBNESS AND TINGLING TO RT SIDE OF FACE, BACK, SHOULDER, AND ARM	NO TX/RESOLVED
10) USA DMSS 17 VAERS 115375	CHEST PAIN, SOB, ARTHRALGIA, ACHES, CHILLLS, FEVER 3-4 DAYS	**QUARTERS/RESOLVED**
11) USA DMSS 19 VAERS 115374	MYALAGIA, KINETIC TREMORS, LF FLEXOR DIGITORUM, PROFUNDUS WEAKNESS	TREATED/RESOLVING
12) USN DMSS 25 VAERS 115540	EMESIS, SOB, SYNCOPE (7 MIN POST VAC) FLAGGED	**QUARTERS/RESOLVED**

13) USN DMSS 37 VAERS 117106	ANGIOEDEMA LF JAW	**HOSP/RESOLVING**
14) USA DMSS 38 VAERS	WORSENING OF UNDERLYING AUTOIMMUNE DIEASE (ANKYLOSING SPONDYLITIS)	TREATED/RESOLVING
15) USAF DMSS 39 VAERS	ANGIOEDEMA FROM NECK DOWN	TREATED/RESOLVED
16) USA DMSS 40 VAERS	NUMBNESS IN 4TH & 5TH LEFT DIGIT WITH SMALL AMOUNT OF WEAKNESS	NO TREATMENT
17) USA DMSS 41 VAERS 120109	SLE	**HOSP/SOME RESIDUAL**
18) USMC DMSS 42 VAERS	URTICARIA, HOT FLASHES, LIGHT HEADED	TREATED/RESOLVING
19) USAF DMSS 43 VAERS 119382	NAUSEA, VOMITING, CHILLS LASTING 4-5 HOURS	TREATED/RESOLVED
20) USAF DMSS 44 VAERS 120453	PT HAD MASAL AND EYE DRAINAGE, EDEMA OF TONGUE AND THROAT NO SOB	TREATED/RESOLVED
21) USAF DMSS 45 VAERS 119383	URTICARIA 12 HOURS POST VACCINATION	TREATED/RESOLVING
22) USA DMSS 48 VAERS 118777	URTICARIA x 24HRS	TREATED/RESOLVED
23) USA DMSS 49 VAERS 117197	SEVERE HA, NECK PAIN	**HOSP/RESOLVED**
24) USN DMSS 51 VAERS 115895	FACIAL BURNING SENSATION, ITCHING REDNESS, DRY AND PEELING	TREATED/RESOLVED
25) USMC DMSS 53 VAERS 118818	UPPER BODY ITCHING AND RASH	TREATED/RESOLVED
26) USA DMSS 54 VAERS 122087	INTERMITTENT FASCICULATIONS, LID TWITCHING, NUMBNESS, TINGLING OF ARMS	RESOLVED
27) USA DMSS 55 VAERS 122086	LEFT TO RIGHT ARM PAIN AND DISTAL WEAKNESS THAT PERSISTS	TREATED/RESOLVING

28) USMC DMSS 56 VAERS 121164	URTICARA AND DYSPNEA 24 HOURS AFTER SHOT, BRONCHIOLITIS	**QTRS 14 DAYS/RESOLVING**
29) USN DMSS 57 VAERS 117881	HA FOR 4-5 DAYS, FEVER AND NAUSEA 8-10 HOURS AFTER 1ST AND 2ND SHOT	RESOLVED
30) USA DMSS 59 VAERS 121457	CHILL, SWEATING AND MALAISE x 2 DAYS	RESOLVED
31) USA DMSS 60 VAERS	ARTHRALGIA IN LEFT HIP B 1ST MCP, MTP	RESOLVED
32) USAF DMSS 61 VAERS 121874	HA, DIARREHEA, FATIGUE, SHORTNESS OF BREATH	RESOLVED
33) USAF DMSS 62 VAERS 121872	DIARREHEA, HA, WEAKNESS, SLEEPLESSNESS FATIGUE, SKIN BLISTERS	RESOLVED
34) USAF DMSS 63 VAERS 121876	ABDOMINAL CRAMPS, MIGRAINES, NAUSEA FATIGUE, INSOMNIA, DIZZINESS, MEMORY LOSS SHORTNESS OF BREATH, CONFUSION	RESOLVED
35) USAF DMSS 64 VAERS 121873	HA, DIARRHEA, SKIN BLISTERS, SHORTNESS OF BREATH	RESOLVED
36) USAF DMSS 66 VAERS 121012	ABDOMINAL CRAMPS, MIGRAINES, NAUSEA, FATIGUE, INSOMNIA, DIZZINESS, MEMORY LOSS STATE OF CONFUSION, SOB	RESOLVED
37) USMC DMSS 68 VAERS 120947	DIFFUSE RASH 72 HR POST VACCINATION TYPE-4 DELAYED REACTION	RESOLVED
38) USA DMSS 69 VAERS 120760	PAPULAR RASH AT INJECTION SITE WITH EACH VACCINATION, GENERALIZED RASH WITH PURITIS & DERMATITIS AFTE 3RD VACCINATION	RESOLVED
39) USA DMSS 70 VAERS 122048	NAUSEA, VOMITTING, HA, TENDERNESS AT INJECTION SITE X3 DAYS	RESOLVED
40) USA (C) DMSS 71 VAERS 122047	13X10 AREA OF EDEMA, PAIN, DECREASE RANGE OF MOTION, FLU-LIKE SYMPTOMS, TEMP > 100 DEGREE,	RESOLVED
41) USA DMSS 73 VAERS 122045	PRURITIS AND ERUPTION OF PAPULAR, ERYTHEMATOUS BEGAN ON LEGS AND SPREAD CIPHALAD	RESOLVED
42) USA DMSS 74	HERPES ZOSTER AFTER VACCINATION	RESOLVED

VAERS 122044		
43) USA DMSS 75 VAERS 122043	GENERALIZED PRURITIS, ERYTHEMATOUS HIVES OVER TRUNK, ARMS, LEGS 1 HR AFTER VACCINATION	RESOLVED
44) USA DMSS 78 VAERS 120761	15MM SWELLING AT INJECTION SITE, HA, NAUSEA, VOMITING 6 HRS AFTER VACCINATION	RESOLVED
45) USA (C) DMSS 79 VAERS 120758	NAUSEA, CHILLS, FEVER WITHIN AN HOUR OF VACCINATION, LOW GRADE FEVER X24 HOURS, TACHYCARDIA, RESOLVED WITHIN 24 HRS	RESOLVED
46) USA (C) DMSS 81 VAERS 120157	LOSS OF COORDINATION OF UPPER AND LOWER EXTREMITIES, VERTIGO, NAUSEA, LOSS OF VISION IN R EYE, DIZZINESS	**HOSP/RESOLVING**
47) USA DMSS 82 VAERS 120589	ERYTHEMA MULTIFORME	RESOLVED
48) USN DMSS 83 VAERS 122269	UNSPECIFIED SPONDYLARTHROPATHY	UNKNOWN
49) USMC DMSS 86 VAERS 120563	HIVES, SOB, COUGH ONE DAY POST VACCINATION ANTHRAX VACCINE SKIN TEST NEGATIVE	UNKNOWN
50) USN DMSS 87 VAERS 122237	POST SECOND VACCINATION, ACHING JOINTS, HA X5 DAYS, CHILLS, FEVER 101-103 DEGREE	RESOLVED
51) USMC DMSS 88 VAERS	DEVELOPED ITCHING, URTICARIAL RASH ON FACE ARMS, BACK, BUTTOCKS, LEGS, 15 MIN POST 2ND VACCINATION	RESOLVED
52) USMC DMSS 89 VAERS	RASH DEVELOPED I DAY AFTER 3RD VACCINATION ON ARMS, FACE, NECK, RED ITHCY BLISTERS SCABS POSSIBLE CONTACT DERMATITIS	RESOLVED
53) USN DMSS 90 VAERS	HIVES ALL OVER 5 WEEKS AFTER 3RD VACCINATION LARGE HIVE AT INJECTION SITE	RESOLVED
54) USAF DMSS 91 VAERS 121290	HA X9 DAYS POST 1ST VACCINATION, HIVES, BILATERAL UPPER EXTREMITY, CHEST AND BACK. MILD PURITIS SEVERE HA X4 DAYS POST 2ND VACCINATION	RESOLVED
55) USAF DMSS 93 VAERS 121014	BODY ACHES, JOINT PAIN, HA, CHEST PAIN, DIARRHEA STOMACH CRAMPS, FLU-LIKE SYMPTOMS, BLISTERS IN MOUTH, SWEATING OR CHILLS, TREMOR, COUGH	SELF GENERATED/ SAUGHT TX AT CIVILIAN PHYSICIAN
56)USAF DMSS 94 VAERS 121320	24HR POST VACCINATION, HIVES AND SOB BEGAN, FATIGUE 4HRS POST VACCINATION	RESOLVED
57) USAF DMSS 95 VAERS 120280	HIVES, TICHING, REDNESS AT FACE	RESOLVED

58) USAF DMSS 96 VAERS 120463	ITCHING AND THICKENING OF THE TONGUE, INJECTION SITE HOT AND ERYTHEMIC APPROX. 1-3/4" WITH SPASM REFERRAL TO ALLERGY	RESOLVED
59) USAF DMSS 97 VAERS 119698	>10X10CM LOCAL RXTN, IRRITABILITY, NAUSEA RESTLESS, PURITIS RASH ON LEGS AND BACK	RESOLVED
60) USAF DMSS 98 VAERS 121152	NAUSEA, VOMITING, DIARRHEA, BODY ACHES, FEVER CHILLS 10 DAYS POST VACCINATION	RESOLVED
61) USAF DMSS 99 VAERS 120911	JOINT & MUSCLE ACHES, CHILLS, DIZZINESS, NAUSEA WEAKNESS, SHAKES, DIFFICULTY BREATHING, EAR, N NOSE AND THROAT SORENESS, HA, DIARRHEA, BACKACHE	UNKNOWN/SELF GENERATED
62) USAF DMSS 100 VAERS 121198	BLOOD GLUCOSE 700+ POST 5TH VACCINATION NVICP PANEL-UNRELATED TO VACCINE	**HOSP/UNKNOWN**
63) USA DMSS 101 VAERS 121197	EXHAUSTIVE FATIGUE, MALAISE WITHIN 24 HR, SOB WEAK, HA	**QRTRS/RESOLVED**
64) USMC DMSS 102 VAERS 120562	HIVES 24 POST 1ST VACCINATION	RESOLVED
65) USA DMSS 103 VAERS	FAINT SANDPAPER-LIKE RASH ON LEFT FLANK AXILLA POST VACCINATION 5-7 DAYS LATER. SIMILAR RASH POST 2ND VACCINATION ON RIGHT FLANK	RESOLVED

LOCAL REACTIONS

1) USAF DMSS 1 VAERS 107470	LOCAL MODERATE/REDNESS, PAIN, SWELLING AT INJECTION SITE	**HOSP/RESOLVED**
2) USAF DMSS 2 VAERS 113513	LOCAL SEVERE/NODULE TO LEFT DELTOID AT INJECTION SITE NO DRAINAGE, REDNESS, OR TENDERNESS	RESOLVED
3) USN DMSS 8 VAERS 110504	LOCAL SEVERE/RED, PAINFUL ARM AT INJECTION SITE	RESOLVED
4) USA DMSS 10 VAERS 114514	ERYTHEMA, INDURATION, MYALIGIA, HA TIMES 3 DAYS	NO TX/RTD
5) USA DMSS 11 VAERS 114513	ERYTHEMA AND PURITIS	RESOLVED
6) USAF DMSS 15 VAERS 113745	ERYTHEMA AT INJECTION SITE LOCAL MILD	RESOLVED
7) USAF DMSS 16 VAERS 113742	ERYTHEMA, REDNESS, TENDERNESS AT INJECTION SITE	RESOLVED
8) USA DMSS 18 VAERS 115376	PURITIS AND PAIN, SWELLING TO FOREARM AND ENCIRCLING ¾ OF THE ARM, LASTED 10-11 DAYS	RESOLVED
9) USAF DMSS 20 VAERS 116135	ERYTHEMA, NODULE, PURITIS AT INJECTION SITE, LOCAL MODERATE	NO TREATMENT
10) USA DMSS 21 VAERS 115560	MILD LOCAL FLU LIKE SYMPTOMS	NO TX/RTD
11) USA DMSS 22 VAERS 115561	MILD LOCAL FLU LIKE SYMPTOMS	SELF GENERATED/NO TREATMENT SAUGHT
12) USA DMSS 23 VAERS 115537	URTICARIA, SORE SWOLLEN ARM	SELF GENERATED/ TREATED/RTD
13) USA DMSS 24 VAERS 115541	MILD LOCAL FLU LIKE SYMPTOMS	TREATED/RTD
14) USA DMSS 26 VAERS 116086	RUE ERYTHEMA, SWELLING, PRURITIC ARM AND CHEST	TREATED/RESOLVED
15) USA	LUE ERYTHEMA 22X30 CM, LIMITED	TREATED/RESOLVED

DMSS 27 VAERS 116085	ARM MOTION	
16) USA DMSS 28 VAERS 116082	ERYTHEMA 14X14 CM AT INJECTION SITE PROGRESSING TO ENTIRE ARM	TREATED/RESOLVED
17) USA DMSS 29 VAERS 116078	URTICARIA ON ARMS, NECK AND TORSO TIMES 2 WEEKS	TREATED/RESOLVING
18) DOD-CIV DMSS 30 VAERS 116058	ERYTHEMA 30 CM EXTENSION TO HAND LIMITATION OF MOTION	**HOSP/RESOLVED**
19) USA DMSS 31 VAERS 116081	LOCAL REACTION AT INJECTION SITE	TREATED/RESOLVED
20) USA DMSS 32 VAERS 116116	LOCAL SWELLING 18 X 14 CM	NOT TX/RESOLVED
21) USA DMSS 33 VAERS 116084	ERYTHEMA/SWELLING AT INJECTION SITE TO FOREARM	NO TX/RESOLVING
22) USA DMSS 34 VAERS 116083	SWELLING 7 PAIN AT INJECTION SITE	NO TX/RESOLVED
23) USA DMSS 35 VAERS 116118	ERYTHEMA/INDURATION 22X26 CM AT INJECTION SITE	NO TX/RESOLVED
24) USN DMSS 36 VAERS 117143	SEVERE LOCAL – ERYTHEMA VESTICULAR ERUPTION	TREATED/RESOLVING
25) USA DMSS 46 VAERS 118758	SWELLING AND PAIN AT INJECTION SITE	NO TREATMENT
26) USAF DMSS 47 VAERS 118527	130MM X 90MM ERYTHEMA, LOCAL MODERATE	NO TREATMENT
27) USA DMSS 50 VAERS 121383	SWELLING, WARMTH, SORENESS AT INJECTION SITE	NO TREATMENT
28) USN DMSS 52 VAERS 118714	2 DAYS AFTER SHOT RIGHT ARM SWOLLEN, ITCHY AND SORE. EDEMA, HYSN PAIN AT INJECTION SITE, PRURITUS	RESOLVED
29) USAF DMSS 58 VAERS	LEFT ARM SWELLING TO ENTIRE ARM AND FOREARM WITHIN 48 HOURS OF VACCINATION SEVERE LOCAL	**HOSP/RESOLVING**
30) USAF DMSS 85	SEVERE LOCAL REACTION - R+ RADIAL NERVE RADICULOPATHY	RESOLVED

VAERS 121893

31) USA DMSS 67 VAERS 120776	PRURITIS, ERYTHEMA ON RIGHT ARM SWELLED AFTER THIRD VACCINATION SEVERE LOCAL REACTION	RESOLVED
32) USAF DMSS 72 VAERS 122046	INCREASE PAIN AND REDNESS AT INJECTION SITE, MILD LOCAL REACTION	RESOLVED
33) USN DMSS 76 VAERS 122042	EDEMA, ERYTHEMA AT INJECTION SITE	RESOLVED
34) USAF DMSS 77 VAERS 120759	½ DOLLAR SIZE AREA OF ITCHING AFTER 15 MINUTES POST VACCINATION, ERYTHEMA EXTENDED FROM SHOULDER TO ELBOW, MODERATE REACTION	RESOLVED
35) USAF DMSS 80 VAERS	PURITIS, SWELLING AT SITE, LEFT 37 CM AND RIGHT 32 CM IN UNAFFECTED ARM, ERYTHEMA 2 DAYS AFTER 2ND VACCINATION	RESOLVED
36) USN DMSS 84 VAERS 120468	PURITIS AND ERYTHEMA AT THE INJECTION SITE, TENDER, 4X4CM FOLLOWED BY A 5X5CM AREA ERYTHEMA	RESOLVING
37)USMC DMSS 85 VAERS 120487	LEFT ARM EDEMA, ERYTHEMA, PURITIS POST 2ND VACCINATION AFTER 2-3 DAYS. LASTING 5 DAYS, SWELLING OF ENTIRE ARM	RESOLVED
38) USAF DMSS 92 VAERS	LOCALIZED EDEMA, ERYTHEMA AND PRURITIS	RESOLVED

OPERATION DESERT STORM
(AMSA UNVAILIDATED)

ODS	JOINT PAIN, FATIGUE, RASH DYSPNEA	HOSP/RESOLVED
ODS	RASH, FATIGUE, DYSPNEA	RESOLVED
ODS	ABD PAIN, FATIGUE, JOINT PAIN	HOSP/RESOLVED
ODS	RASH, JOINT PAINS, FATIGUE, LYMPH NODE SWELLING	RESOLVED

IMAGE ONLY FILE. USE/VIEW DOCUMENT
FOR COMPLETE INFORMATION.

KEYWORDS:

CMAT #:1999203-0000008

ANTHRAX VACCINE ADVERSE EVENTS REPORTING SYSTEM UPDATE –WEEK ENDING 16 JULY 1999

CMAT Control #
1999203-0000008

Anthrax Vaccine Adverse Events

Vaccine Adverse Event Reporting System (VAERS) - DoD
Week Ending 16 July 99

Service	Form VAERS-1 Reported	Classification			
		Local Reaction			Systemic Reaction
		Mild	Moderate	Severe	
USA	2	0	1	0	1
USN	1	0	0	0	1
USAF	0	0	0	0	0
USMC	1	0	0	0	1

Cumulative Data

Service	DoD Form VAERS-1 Reported	Classification			
		Local Reaction = 42			Systemic Reaction = 71
		Mild	Moderate	Severe	
USA	47	8	8	5	26
USN	15	1	2	2	10
USAF	36	4	5	3	24
USMC	15	0	2	2	11

113 Form VAERS-1 Submitted of 1,013,662
Vaccinations Given = .011% VAERS-1 Report Rate

FDA Reported 215
AVEC Reviewed 174

Mild

- Duration 24 - 48 Hours
- Local Redness and Hardness 1 to 2 Centimeters

Moderate

- Local Redness and Hardness 5 Centimeters
- Subcutaneous Nodule at Injection Site

Severe

- Swelling At Injection Site and Entire Forearm

Systemic

- Malaise
- Chills and Fever
- Anaphylaxis

VAERS

- Loss of Duty > 24 Hours
- Hospitalization

Only 15 reports met strict reporting requirements

IMAGE ONLY FILE. USE/VIEW DOCUMENT
FOR COMPLETE INFORMATION.

KEYWORDS:

CMAT #: 1999230-0000012

ANTHRAX VACCINE ADVERSE EVENTS CHARTS

Anthrax Vaccine Adverse Events

Vaccine Adverse Event Reporting System (VAERS) - DoD
Week Ending 06 August 99

Service	Form VAERS-1 Reported	Classification			
		Local Events			Systemic Events
		Mild	Moderate	Severe	
USA	7	0	0	1	6
USN	0	0	0	0	0
USAF	15	0	1	0	14
USMC	0	0	0	0	0
USCG	0	0	0	0	0

Cumulative Data

Service	DoD Form VAERS-1 Reported	Classification			
		Local Events = 47			Systemic Events = 101
		Mild	Moderate	Severe	
USA	54	8	8	6	32
USN	15	1	2	2	10
USAF	63	6	6	3	48
USMC	15	0	2	2	11
USCG	1	0	1	0	0

148 Form VAERS-1 Submitted of 1,047,553 Vaccinations Given = .014% VAERS-1 Report Rate

As of 30 Aug 99
FDA Reported 243
AVEC Reviewed 243

Mild

- Duration 24 - 48 Hours
- Local Redness and Hardness 1 to 2 Centimeters

Moderate

- Local Redness and Hardness 5 Centimeters
- Subcutaneous Nodule at Injection Site

Severe

- Swelling At Injection Site and Entire Forearm

Systemic

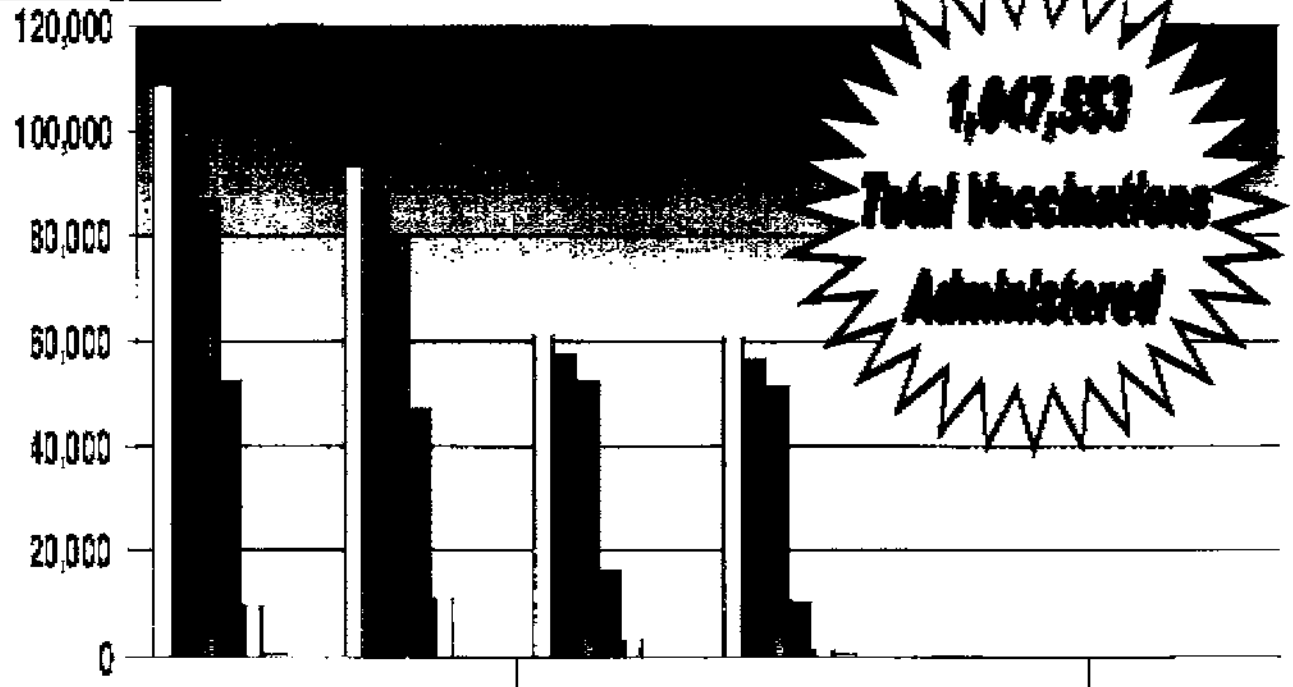
- Malaise
- Chills and Fever
- Anaphylaxis

VAERS

- Loss of Duty > 24 Hours
- Hospitalization

Only 24 reports met strict reporting requirements

Anthrax Immunization Status



	Army	Air Force	Navy	Marines	Coast Guard	Total
Shot #1	108,135	92,705	61,488	60,877	291	323,496
Shot #2	98,263	86,661	57,562	56,876	276	299,638
Shot #3	86,547	79,801	52,345	51,596	262	270,551
Shot #4	52,358	47,504	16,216	10,740	112	126,930
Shot #5	9,945	11,425	3,265	1,444	8	26,087
Shot #6	426	102	41	282	0	851
Total	355,674	318,198	190,917	181,815	949	1,047,553

All Data From DEERS 11 Aug 99

(236)

CMAT Control #
1998357-0000006

Anthrax Vaccine Immunization Program

Executive Overview Brief to the National Academy Of Sciences Institute Of Medicine

2 October 1998

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

AGENDA

- **Background**
  - ➤ SECDEF Direction
  - ➤ Concept of Execution
  - ➤ Total Force AVIP
  - ➤ Immunization Tracking Systems
  - ➤ Roles and Responsibilities
- **Vaccine Acquisition, Stockpiling and Distribution**
- **Clinical Outcomes**
- **Service Member Refusals**
- **Current Topics**
- **Force Immunization Status**

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

BACKGROUND

- **Anthrax - A Significant Battlefield Threat**
  - ➤ Routes of Infection - Ingest, Skin, Inhale (99% Lethal)
- **Anthrax Countermeasures**
  - ➤ Vaccine - Safe, Effective, 28 yr Record, Fully FDA Licensed
  - ➤ Protocol - 6 Doses Over 18 Mos; Annual Booster
- **Key Directives**
  - ➤ Nov 93 DOD 6205.3, Immunization Programs for Biological Warfare Defense
  - ➤ Dec 97 SECDEF Press Announcement
  - ➤ Mar 98 SECDEF Approved SWA Accelerated Program
  - ➤ May 98 SECDEF Approved Total Force Program

ANTHRAX KILLS VACCINATION PROTECTS

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

BACKGROUND: SECDEF DIRECTION/STATUS

- **Vaccinate the Total Force With Anthrax Vaccine Beginning With Forces Assigned or Rotating to High Threat Areas. Four Preconditions:**

	STATUS	RESP	EC DATE	STATUS
1. Supplemental Testing		JPO-BD	1QFY99	Dr. Gilbreath, JPO-BD Supply Testing Ongoing;
2. Tracking System	Co[redacted]te	J4(MRD)	15 Jul 98	RADM Cowan, J4(MRD) Services' ITSs in Place
3. Op/Comms Plans	Co[redacted]te	J5	29 Apr 98	LTC Brown, J5 Service Approved Plans in Place
4. Independent Review	Co[redacted]te	Dr. Burrow	2 Mar 98	CAPT Mateczun, OASD(HA) Complete

ANTHRAX KILLS VACCINATION PROTECTS

On Track/No Impediment to Completion

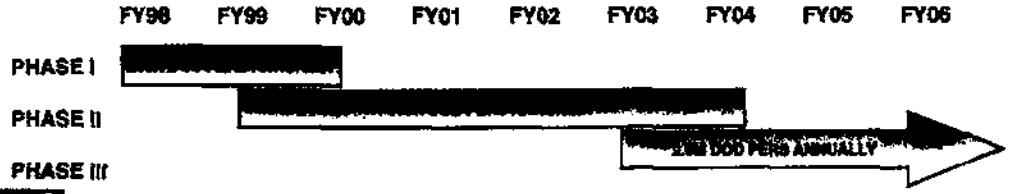
Delayed/Minor Impediment

Delayed/Major Impediment

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

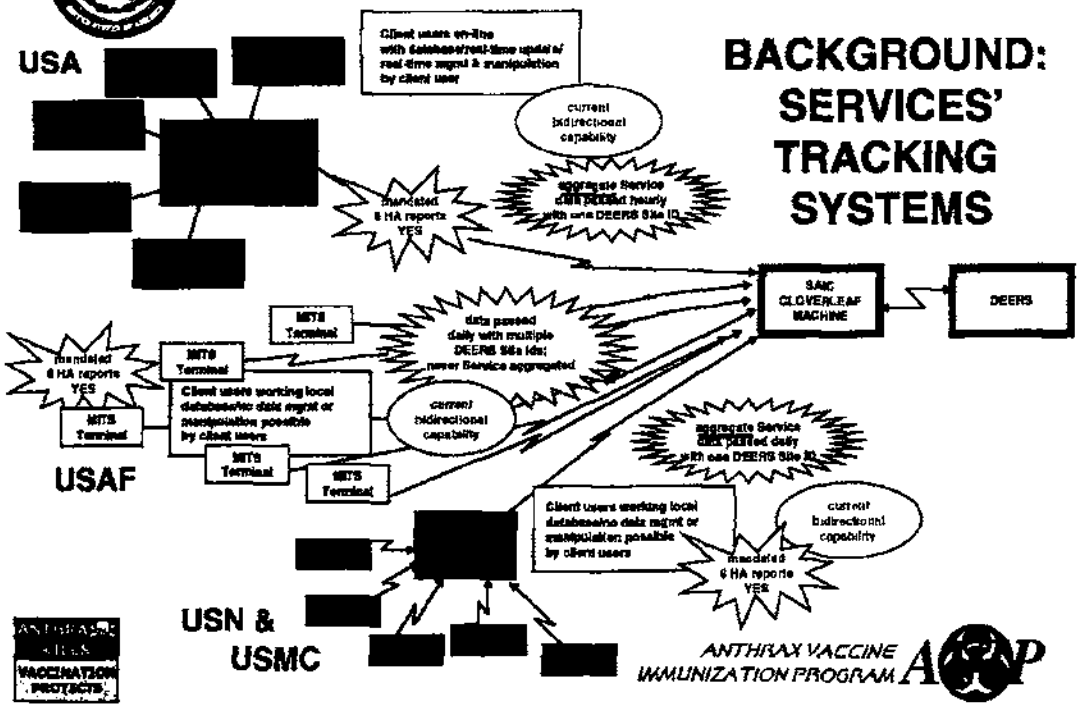
BACKGROUND: CONCEPT OF EXECUTION

- Phased Execution Across the Total Force
  - Phase I. Forces Assigned or Rotating to High Threat Areas of SWA and Korea
  - Phase II. Early Deploying Forces (C to C+35) Into High Threat Areas of SWA and Korea; RC Demo Project
  - Phase III. Remainder of Total Force, Accessions, and Program Sustainment



ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

BACKGROUND: SERVICES' TRACKING SYSTEMS



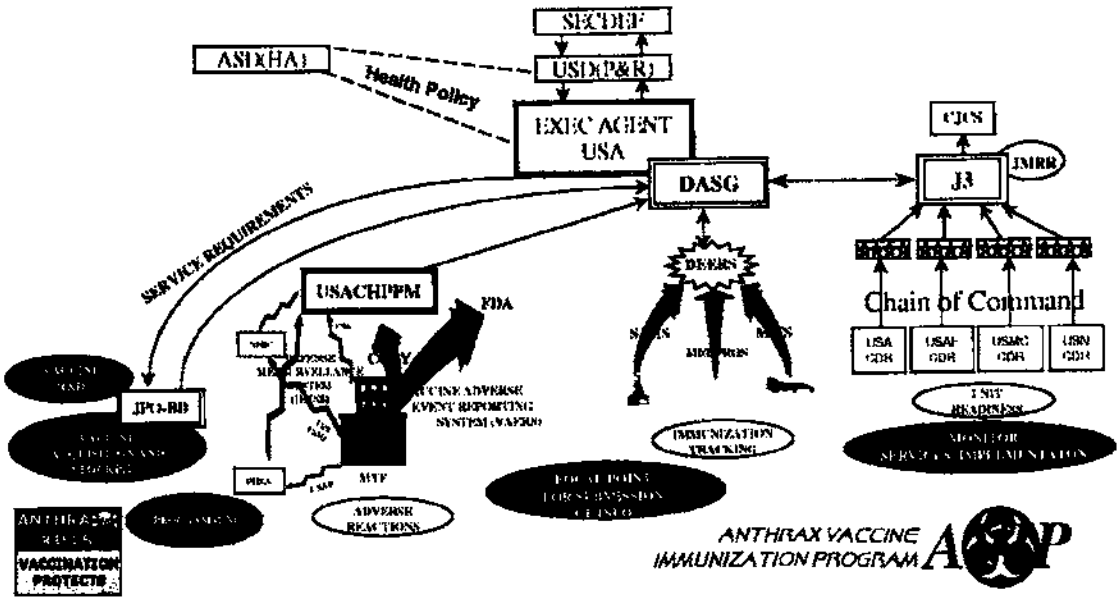
ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

BACKGROUND: ROLES AND RESPONSIBILITIES

- USD (P&R) - Monitors Implementation
- SECARMY - DOD Executive Agent
  - ➤ Vaccine Acquisition/Stockpiling/Programming
  - ➤ Vaccine Research/Development
  - ➤ Focal Point for Information Submission
  - ➤ Monitor Services' Implementation
  - ➤ Qtrly Report to USD (P&R)
- Service Secretaries
  - ➤ Implement, Monitor, Evaluate, Document Their Own AVIP
  - ➤ Coordination/Report Information to Executive Agent
- Unit Commanders - Ensure Personnel Receive/Report Req'd Vaccinations
- Med Treatment Facilities/Command Surgeons
  - ➤ Train/Equip Medics to Vaccinate
  - ➤ Policies/Procedures for Immunization Records

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

BACKGROUND: EXECUTIVE AGENCY RESPONSIBILITIES AND INFORMATION FLOW



ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

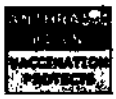
Phase I Implementation

- Began 16 Aug 98
- Continues SWA-Focused AVIP
- Begins Korea-Focused AVIP
- PCS Orders to SWA/Korea Will Reflect Anthrax Vaccination Requirement
- Continue Worldwide Centrally-Managed AVA Distribution
  - ➤ Setting New World-Class Shipping Standards
  - ➤ Presenting New Challenges (Shipment to Japan)
  - ➤ Meeting All Service Requirements

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Implementation In Korea

- CINC's Execution Began With Flawless "Wet Run" 24-25 Aug 98
- Main Force Vaccinations Began 9 Sep 98
- Vaccine In Place To Support All Service Requirements For First Three Doses
- Immunization Tracking...
  - ➤ USAF: MITS, Already In Place
  - ➤ USA: MEDPROS, Trained and Tested
  - ➤ USMC/USN: SAMS and MEDPROS, Location Dependent



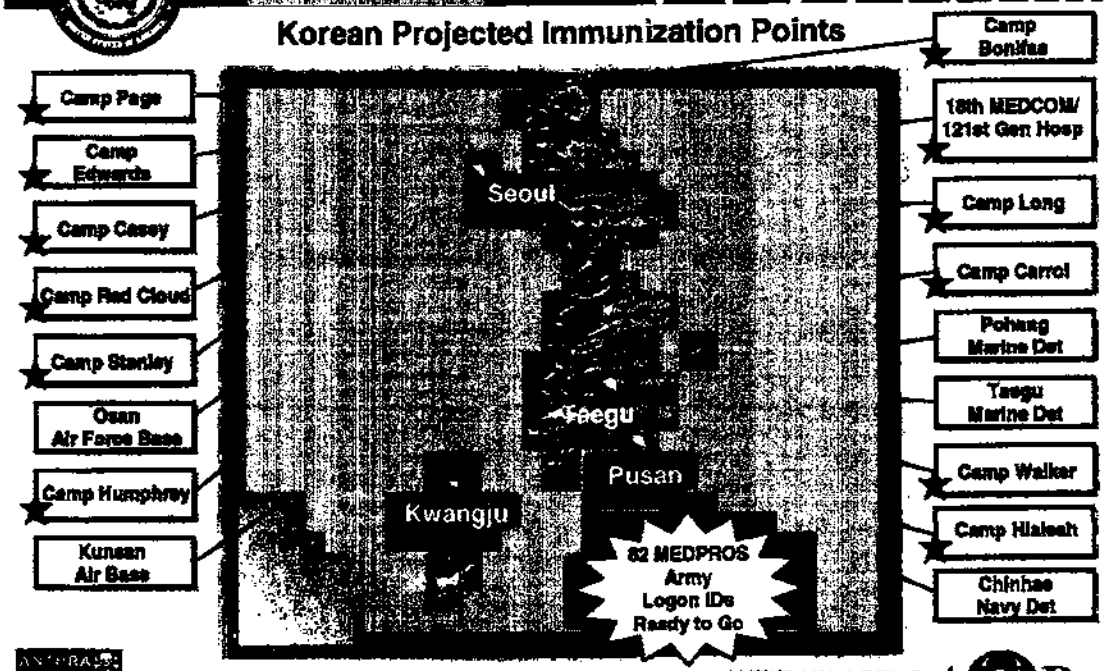
ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Implementation in Korea
(continued)

- **USFK CINC's Communication Plan**
  - Solid, Aggressive Plan
  - Conscious Decision To Begin 24 Aug After Ulchi Focus Lens
  - Characterized By Active PAO and Command Support
  - Trifolds Given To Each Service Member
  - Commanders' Briefings To All Service Members BEFORE 9 Sep Start
  - Multiple Newspaper Articles
  - 6 TV Spots Aired Total Of 400 Times

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Korean Projected Immunization Points



★ MEDPROS - Aug 98 Formal Training

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Function: Vaccine Acquisition and Stockpiling

INDICATOR	STATUS/METRIC
Stockpile Supplemental Testing	**Testing Ongoing;** ➢ 8 Lots/ 800K Doses Supplementally Tested, Packaged and Labeled ➢ All Doses Completed By 1QFY99 - On Schedule
Plant Renovation	**Renovation and FDA Certification** ➢ Began Mar 98; Renovation To Be Completed Jan 99 ➢ New Vaccine Available After FDA Certification Process, 4QFY99
Plant Privatization	**Michigan State Administration Board** ➢ Transfer of Deed Complete ➢ Became BioPort Corporation effective 6 Sep 98
New Production/Expansion Contract	**Currently Negotiating Contract;** ➢ Target Completion Of Negotiated Contract 4QFY98 ➢ Expansion Completed FY04 Will Double Production Cap. to 32 Lots/Year ≅ 6.4M Doses/Year

On Track/No Impediment to Completion
Delayed/Minor Impediment
Delayed/Major Impediment

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Anthrax Vaccine Doses Shipped

As of 31 Aug 98

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Function: Clinical Outcomes

Overdue Vaccinations

DOD Goal	90%

INDICATOR	STATUS	# Overdue	
Army		466 as of 30 Sep 98	99%
Navy/Marines		1661 as of 28 Sep 98 Predominantly Commo Issue-Not Truly Vaccinations Overdue	92%
Air Force		270 as of 28 Sep 98	99%

On Track/No Impediment to Completion
Delayed/Minor Impediment
Delayed/Major Impediment

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Function: Clinical Outcomes

Anthrax Adverse Reaction Reports
Week Ending 25 Sep 98

Service	VAERS Rep	Classification			
		Local Reaction			Syste Reac
		Mild	Moderate	Seve	
USA	3	0	2	0	1
USN	0	0	0	0	0
USAF	0	0	0	0	0
USMC	0	0	0	0	0

Cumulative Data

Service	VAERS Rep	Classification			
		Local Reaction			Syste Reac
		Mild	Moderate	Seve	
USA	3	0	2	0	1
USN	2	0	0	1	1
USAF	5	0	1	1	3
USMC	0	0	0	0	0

Mild
- Duration 24 - 48 Hours
- Local Redness and Hardness 1 to 2 Centimeters

Moderate
- Local Redness and Hardness 5 Centimeters
- Subcutaneous Nodule at Injection Site

- Swelling At Injection Site and Entire Forearm

- Malaise
- Chills and Fever
- Anaphylaxis

VAERS
- Loss of Duty > 24 Hours
- Hospitalization

ANTHRAX KILLS VACCINATION PROTECTS

10 Adverse Reactions of 201,059 Vaccinations Given = .005%

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Service Member Refusals

Service	Number	Disposition
USAF	15	15, Nonjudicial Punishment 2, Pending Admin Discharge Board
USA	8 12	from Korean vaccination program
USMC	0	
USN	12 / 14	12, Nonjudicial Punishment, 7, Admin Discharge; Remaining 5 Pending Admin Discharge

[redacted]

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Current Topics

- GAO Anthrax Vaccine Safety and Efficacy Review (713030)
  - *Entrance Brief 30 Jun 98; Interim Report By 31 Aug 98*
  - Vaccine/FDA/MBPI Focus
  - Request Of Chairman Christopher Shays, Subcommittee On Human Resources, Committee On Government Reform and Oversight

[redacted] Dr Shearer GAO

- GAO AVIP Processes Review (703254)
  - Entrance Brief Scheduled 30 Jul 98; Interim Report 2QFY99
  - Storage, Transportation, Tracking, Database Management Focus
  - Request Of Senate Committee On Veterans' Affairs

[redacted] Mr Hegg Bio + GAO

- Future Anthrax Vaccine Management
  - DLA Projected to Assume Management NLT 1 Oct 99

[redacted]

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

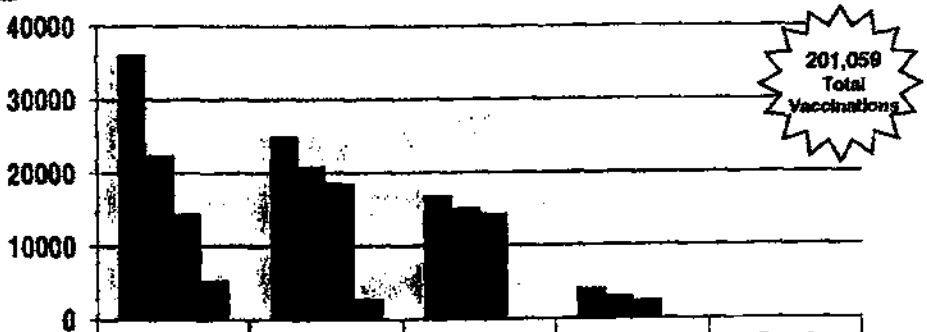
Current Topics
(Continued)

- **New DOD Website Targets Young Service Members**
  - ASD(PA) Initiative/ Funded
  - AVIP Selected As First Topic
  - On-Line Mid-Oct 98
- **DOD Trifold Updated**
- **In-Theater Time Requirement Policy Change Being Staffed**
- **Armed Forces Epidemiological Board Review of Adverse Reactions 3 Aug 98**
  - Recommends No Change In Current DOD AVIP
  - Recommends Review of VAERS Form At Service Level For Completion
  - Suggests Prospective "Small Records Review Study" To Record All Reactions (650 Persons/Tripler Army Medical Center)

ANTHRAX KILLS VACCINATION PROTECTS

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Force Immunization Status



	Army	Air Force	Navy	Marines	Total
Shot # 1	36083	24950	16801	4063	81897
Shot # 2	22442	20925	15122	3047	61536
Shot # 3	14475	18495	14168	2532	49670
Shot # 4	5240	2684	7	25	7956

ANTHRAX KILLS VACCINATION PROTECTS

* All Data From DEERS 29 Aug-30 Sep 98

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Program Points of Contact

- **DOD/USA**
  - ➢ Ms. Cathy Call — 703.681.3292; DSN 761.XXXX
  - ➢ MAJ Guy Strawder — 703.681.6530
  - ➢ LTC Randy Randolph — 703.681.8204
- **USAF**
  - ➢ CPT Hayley Hughes — 202.767.4270; DSN 297.XXXX
- **USMC**
  - ➢ LCDR Ann Fallon — 703.614.4478; DSN 224.XXXX
- **USN**
  - ➢ CDR Tina Dimarco — 703.601.1701; DSN 224.XXXX

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

(237)

CMAT Control #
2001092-0000001

2001092-0000001

Grunard is Jean

Executive Overview Brief

Department of Defense Anthrax Vaccine Immunization Program

18 March 1999

- How do you handle Gov't calls?
- PA request?
- Contractor's?

you will soon become
communications is the key
initial report calls from PA department -

How the game works -
How the vaccine works

ANTHRAX KILLS

Program Points of Contact

DOD/USA

MAJ Guy Strawder	703.681.6530; DSN 761 .XXXX
Ms. Cathy Call	703.681.3292

USAF

COL Harvey Crowder	202.767.4280; DSN 297.XXXX
LTC Jack Davis	202.767.4216

USMC

LCDR Ann Fallon (Med)	703.614.4478; DSN 224.XXXX
LTC Ken Firoved (Opns)	703.614.4222 X5367

USN

LCDR Tena DiMarco	703.601 .1701; DSN 224.XXXX
LCDR Celia Quivers	703.601 .1700

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Frequently Asked Questions

Los Alamos Claims of Resistant Russian Strain of Anthrax

- There is no experimental data to suggest that mixtures of anthrax strains, such as those alleged by Russian scientists, is resistant to the FDA-licensed vaccine used by the US military
- Under OSD Cooperative Threat Reduction Program, we are involved with State Center for Applied Microbiology at Obolensk, Russia

Severe Disciplinary Action Against Service Members

- FHP issue--like wearing body armor or protective mask
- Failure to follow lawful orders is a commanders issue

"Off Label Use" is You Don't Complete the Series

- No off label use if a person doesn't elect to complete series or is no longer eligible

Why Not a Voluntary Program

- The threat is real--half or one quarter of a vaccinated force attacked with a BW agent still results in a failed mission
- Long history of compulsory vaccination--tetanus, typhoid, and yellow fever was required of soldiers in WWII resulting in 0 cases of yellow fever, 12 cases of tetanus (despite 2.7M hospital admissions for wounds and injuries) and 0.05 cases per thousand of typhoid (compared to 0.42 per thousand-in WWI)

ANTHRAX VACCINE
IMMUNIZATION PROGRAM AVIP

Other parameters such as fibrin degradation products, fibrinogen, activated partial thromboplastin time, prothrombin time, and platelets were not affected.

Discussion

A human anthrax vaccine must protect against all forms of anthrax, including inhalation anthrax, which, although rare, is usually fatal. The data in this study demonstrate that the MDPH vaccine is highly efficacious against inhalation anthrax in rhesus monkeys. The rhesus monkey is a useful model for inhalation anthrax in humans, although there is currently no known surrogate marker or in vitro correlate of immunity that allows direct comparison of immunity in humans to that in monkeys. Although the current vaccine regimen in humans calls for doses at 0, 2, and 4 weeks, 6 months, 12 months, 18 months, and then yearly thereafter, in this study only two doses of vaccine, at 0 and 2 weeks, were required to provide substantial protection for almost 2 years. Based on this study's data, the MDPH human anthrax vaccine confers substantial protection against inhalation anthrax, and the recommended immunization regimen may be able to be reduced with respect to the number of doses.

PA is a major component of MDPH, and previous efficacy studies[13] demonstrated that PA must be present in a non-living anthrax vaccine or produced in a live vaccine. Other components such as edema factor, lethal factor, and cell-surface antigens may be present in some lots of MDPH and might affect the vaccine's efficacy. MDPH contains as an adjuvant aluminum hydroxide (Alhydrogel), which is a good stimulator of humoral immunity, but not cell-mediated immunity[1]. The high level of efficacy of MDPH in rhesus monkeys suggests that humoral immunity is important in the specific resistance of rhesus monkeys to anthrax. In guinea pigs, however, intramuscular immunization with MDPH only partially protects against a challenge with anthrax spores[6-10].

These findings suggest that the importance of various specific immune mechanisms against inhalation anthrax may vary in different animal species, or that the ability of the licensed human anthrax vaccine to stimulate cell-mediated immunity may be greater in some species than others.

Table 1. Protection of rhesus monkeys by MDPH from aerosol challenge by B. anthracis Ames spores

Time after first immunization	LD_{50}	Survived/total (%)		Time to death in days (range)
8 weeks[a]				
MDPH	255-760[b]	10/10	(100)	----
PBS	189-419[c]	0/5	(0)	3-5
38 weeks				
MDPH	161-247[d]	3/3	(100)	-----
100 weeks				
MDPH	290-557[e]	7/10	(70)	4
PBS	211-439[f]	0/2	(0)	4

[a]Monkeys were immunized intramuscularly at 0 and 2 wk with 0.5 ml of MDPH human anthrax vaccine. [b]Mean LD_{50} = 407. [c]All surviving monkeys had negative bacterial cultures through 10 days after challenge. [d]Mean LD_{50} = 320. [e]Mean LD_{50} = 393. Mean LD_{50} = 350. [f]One of the seven surviving monkeys had a positive bacterial culture (days 2-6) after challenge. [g]Mean LD_{50} = 523.

Table 2. Anti-PA ELISA titers of immunized monkeys

Time after first immunization	Geometric mean titers
0 weeks[a]	ND[b]
2 weeks[a] (before second immunization)	14
8 weeks[a] (before 8-wk challenge)	919
10 weeks[a] (2 weeks after challenge)	7,879
99 weeks[c] (1 week before 100-wk challenge)	200
102 weeks[d] (2 weeks after 100-wk challenge)	25,265

[a] ELISA performed by using indirect method
[b] ND = Not detectable.
[c] Not previously challenged at 8 weeks or 38 weeks.
[d] ELISA performed by using direct method. Titers obtained by the direct method gave values which were approximately 1.71-fold greater than those obtained by the indirect method

References

1. Allison AC, Byars NE. Immunological adjuvants and their mode of action. *Biotechnology* 1992;20:431-449.
2. Brachman PS, Gold H, Plotkin SA, Fekety FR, Werrin M, Ingraham NR. Field evaluation of a human anthrax vaccine. *Am J Pub Health* 1962;52:632-645.
3. Cown WB, Kethley TW, Fincher EL. The critical orifice liquid impinger as a sampler for bacterial aerosols. *Appl Microbiol* 1957;5:119-124.
4. Friedlander AM, Welkos SL, Pitt MLM, Ezzell JW, Worsham PL, Rose KJ, Ivins BE, Lowe JR, Howe GB, Mikesell P, Lawrence WB. Postexposure prophylaxis against experimental inhalation anthrax. *J Infect Dis* 1993;167:1239-1242.
5. Iacono-Connors LC, Welkos SL, Ivins BE, Dalrymple JM. Protection against anthrax with recombinant virus-expressed protective antigen in experimental animals. *Infect Immun* 1991;59:1961-1965.
6. Ivins BE, Ezzell JW, Jemski J, Hedlund K, Ristroph JD, Leppla SH. Immunization studies with attenuated strains of *Bacillus anthracis*. *Infect Immun* 1986;52:454-458.
7. Ivins BE, Fellows PF, Nelson GO. Efficacy of a standard human anthrax vaccine against *Bacillus anthracis* spore challenge in guinea pigs. *Vaccine* 1994;12:872-874.
8. Ivins BE, Welkos SL. Recent advances in the development of an improved human anthrax vaccine. *Eur J Epidemiol* 1988;4:12-19.
9. Ivins BE, Welkos SL, Knudson GB, Little SF. Immunization against anthrax with aromatic compound-dependent (Aro-) mutants of *Bacillus anthracis* and with recombinant strains of *Bacillus subtilis* that produce anthrax protective antigen. *Infect Immun* 1990;58:303-308.
10. Ivins BE, Welkos SL, Little SF, Crumrine MH, Nelson GO. Immunization against anthrax with *Bacillus anthracis* protective antigen combined with adjuvants. *Infect Immun* 1992;60:662-668.
11. May KR. The Collison nebulizer, description, performance and applications. *J Aerosol Sci* 1973;4:235-243.
12. Puziss M, Manning LC, Lynch JW, Barclay E, Abelow I, Wright GG. Large-scale production of protective antigen of *Bacillus anthracis* in anaerobic cultures. *Appl Microbiol* 1963;11:330-334.
13. Turnbull PCB, Broster MG, Carman JA, Manchee RJ, Melling J. Development of antibodies to protective antigen and lethal factor components of anthrax toxin in humans and guinea pigs and their relevance to protective immunity. *Infect Immun* 1986;52:356-363.

Antibioti

M.N. JONES

Anthrax Sect
CBDE, Porto

Summary

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Frequently Asked Questions

Bio Weapons Arms Race

- Threat is real and consequences grave
- 810 adversaries suspected of weaponizing--twice the number since 1972 BWC
- Admissions of BW capability by USSR post cold war
- Discovery of Iraq's capability
- Aum Shinrikyo's use in the Tokyo sub-

Allegations of Expired and Contaminated Vaccine

- All lots are approved and released by the FDA
- All lots completed supplemental testing for potency, purity, sterility, and general safety with oversight from an independent agency

Plant Concerns--Who Inspects and Poor Inspection Results

- DoD conducts audits of those they are contracted with, but that in no way obviates the FDA from conducting their periodic required inspections
- FDA cited problems, but never closed the facility--plant has completed modernization of production suites and increased capacity as of Jan
- FDA will soon conduct followup inspection

ANTHRAX *VACCINE*
IMMUNIZATION PROGRAM AVIP

Frequently Asked Questions

Long Term Cancer and Fertility Studies

- Extracted from product insert--virtually no vaccine has been studied longitudinally for cancer or reproductive health
- Prevailing scientific knowledge is that vaccines do not contribute to these problems
- Polio, yellow fever, Hep A, Hep B, Tetanus, Diphtheria, Typhoid, MMR have similar product insert statements

GWI Link

- The IOM, PAC, VA, and NIH have investigated the cause of GWI and concluded that the anthrax vaccine does not explain the long term chronic effects

Efficacy Studies Against Inhalation Mode of Transportation

- Field studies conducted in late 1950's demonstrated efficacy in humans--unethical to continue
- Animal modes studies are extremely compelling--Rhesus monkeys with only two doses have survived lethal challenges (90-400 times the LD 50) up to 2 years later

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Background: "A Grave and Emerging Threat"

● Anthrax as an Offensive BW Agent

- Highly lethal - aerosolized BW agent anthrax is estimated at 99 percent
- Easy to produce in large quantities
- Relatively easy to develop as a weapon
- Easily spread in the air over a large area
- Easily stored and dangerous for a long period
- "The Poor Nation's Atom Bomb"
- ***At least 10 countries suspected of weaponizing anthrax***

● Three Modes of Transmission

B. anthracis is not dermally lethal.

- **Cutaneous** - skin contact with infected animals or contaminated animal products.
- **Intestinal** - ingestion of spores.
- **Inhalation** - caused by inhalation of anthrax spores

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Feb. 17, 1999 >> 10:47 am ES
Rich Henriques'

on:target

Americans Becoming Aware of Bioterrorism Threat

Reuters
16-FEB-99

WASHINGTON, Feb 16 (Reuters) - Americans are waking up to the threat of bioterrorism, but growing public awareness of the issue may also be giving ideas to extremists, experts told a conference on Tuesday.

"It may not happen immediately, but somewhere, sometime in the future, terrorists may well threaten to use, or attempt to use, a biological weapon against the United States," Health and Human Services Secretary Donna Shalala said in opening the conference on bioterrorism.

The growing interest in bioterrorism was clear as people overflowed from the packed conference, organised by Johns Hopkins University and the Health and Human Services Department (HHS). Delegates ranged from intelligence experts to local emergency services officials.

"Over the last couple of years there has been a lot of interest developing," Col. Edward Eitzen, chief of operational medicine at the U.S. Army Medical Research Institute of Infectious Diseases, said in an interview.

But it was not just the government taking note, he said.

"Over the last several years we're seeing terrorist interest in this sort of thing," Eitzen added.

Experts told the conference that growing public awareness of bioterrorism inevitably generated ideas by countries like Iraq and groups like the Aum Shinri Kyo cult, which released poison gas on the Tokyo subway in 1995.

Consultant Kyle Olson of Research Planning Inc. told the group that Aum leader Shoko Asahara got his idea for a sarin gas attack partly from watching television reports about the care U.S. troops were taking in preparing for Iraq's biological and chemical weapons ahead of the 1990-91 Gulf War.

"He saw the greatest military force in the world taking extreme precautions about a third-rate country's biological weapons capability," Olson said.

The Aum group's subway attack killed 12 people and injured betweer

3,800 and 6,000 others.

"It's clear that terrorists are interested in weapons of mass destruction," said Jessica Stern, a former member of the National Security Council, who is now with the Council on Foreign Relations.

But she said she thought a low-tech assault -- similar to the salmonella poisoning of Oregon salad bars in 1984 by members of the Rajneesh group -- was more likely than someone setting off an anthrax bomb over New York City.

Religious and millennium cults were the most likely to try to take that route, Stern said.

"Some want to mimic God. Some want to mimic Hitler," she said. "Others want to mimic other terrorists and we see that in hoaxes."

Stern detailed more than 40 incidents in which people were threatened with anthrax. Usually a brown powder was sent in an envelope with a note saying the recipient had just been exposed to anthrax. Although some people were treated with antibiotics, no one became ill.

There were 37 such incidents in 1998, compared to one in 1997. Stern said more such incidents were likely as the threat of bioterrorism got more attention.

Experts also said countries like Iraq and the nations of the former Soviet Union maintained their capability to attack the United States. If they could not challenge the United States with conventional weapons, the experts said, they might turn to chemical and biological weapons of mass destruction.

"Currently the United States is unprepared to deal with a bioterrorist attack," said David Siegrist, an expert in biological terrorism at the Potomac Institute for Policy Studies, a nonprofit organisation.

He said U.N. inspectors and the US. government believed Iraq maintained a biological weapons capability despite repeated military strikes targeting its weapons industry.

Thousands of pounds (kilograms) of the medium used to grow biological warfare agents remained unaccounted for by Iraq, he said.

Aum Shinrikyo-according to NYTimes

- **BW was first weapon of choice. Produced by its Ministry of Health and Welfare. Full record not knowable--murder of key figure and destruction of records.**
- **Acquired botulinum from Japanese wilderness in March 1990 and a month later sent 3 spray trucks to crisscross Tokyo to attack 4 targets, including US naval base and Narita airport.**
- **Then acquired anthrax stock from a local university. In June and July 1993 slurry pumped from roof. Then again tried truck delivery.**
- **Returned to bot in March 1995 for a subway attack. Failure led to use of sarin 5 days later.**
- **2 buildings for bio production, with a 3rd under construction. At least one l-ton fermenter. 160 barrels of peptone. Traveled to Zaire for Ebola. Evidence of production of Q Fever. [No use of 1500 microbe banks.] Downloaded Brookhaven databank for molecular design of toxins. Bought associated software & hardware. Russian connection?**

Previous slide Back to first slide View graphic version

ANTHRAX

SUMMARY

Signs and Symptoms: Incubation period is 1-6 days. Fever, malaise, fatigue, cough and mild chest discomfort is followed by severe respiratory distress with dyspnea, diaphoresis, stridor, and cyanosis. Shock and death occurs within 24-36 hours after onset of severe symptoms.

Diagnosis: Physical findings are non-specific. A widened mediastinum may be seen on CXR. Detectable by Gram stain of the blood and by blood culture late in the course of illness

Treatment: Although effectiveness may be limited after symptoms are present, high dose antibiotic treatment with penicillin, ciprofloxacin. or doxycycline should be undertaken. Supportive therapy may be necessary.

Prophylaxis: An FDA licensed vaccine is available. Vaccine schedule is 0.5 ml SC at 0, 2, 4 weeks, then 6, 12, and 16 months for the primary series, followed by annual boosters. Oral ciprofloxacin or doxycycline for known or imminent exposure.

Isolation and Decontamination: Standard precautions for healthcare workers. After an invasive procedure or autopsy is performed, the instruments and area used should be thoroughly disinfected with a sporicidal agent (chlorine).

OVERVIEW

Bacillus anthracis, the causative agent of Anthrax, is a rod-shaped, gram-positive, sporulating organism with the spores constituting the usual infective form. Anthrax is primarily a zoonotic disease of herbivores, with cattle, sheep and horses being the usual domesticated animal hosts, but other animals may be infected. Human disease may be contracted by handling contaminated hair, wool, hides, flesh, blood and excreta of infected animals and from manufactured products such as bone meal, as well as by purposeful dissemination of spores. Infection is introduced through scratches or abrasions of the skin, wounds, inhalation of spores, eating insufficiently cooked infected meat, or by flies. All human populations are susceptible. Recovery from an attack of the disease may be followed by immunity. The spores are very stable and may remain viable for many years in soil and water. They will resist sunlight for varying periods.

HISTORY AND SIGNIFICANCE

Anthrax spores were weaponized by the United States in the 1950's and 1960's before the old US. offensive program was terminated. Other countries have weaponized this agent or are suspected of doing so. The anthrax bacterium is easy to cultivate and spore production is readily induced. Spores are highly resistant to sunlight. heat and disinfectants - properties which could be advantageous when choosing a bacterial weapon, Iraq admitted to a United Nations inspection team in August of 1991 that it had performed research on the offensive use of *B. anthracis* prior to the Persian Gulf War of 1991, and in 1995 Iraq admitted to weaponizing anthrax. This agent could be produced in either a wet or dried form, stabilized for weaponization by an adversary and delivered as an aerosol cloud either from a line source such as an aircraft flying upwind of friendly positions, or as a point source from a spray device. Coverage of a large ground area could also be theoretically facilitated by multiple spray bomblets disseminated from a missile warhead at a predetermined height above the ground.

CLINICAL FEATURES

Anthrax presents as three distinct clinical syndromes in man: cutaneous, inhalational, and gastrointestinal disease. The cutaneous form (also referred to as malignant pustule) occurs most frequently on the hands and forearms of persons working with infected livestock. It begins with a papule followed by formation of a blister-like fluid-filled vesicle. The vesicle typically dries and forms a coal-black scab, hence the term anthrax (Greek for coal). Sometimes this local infection will develop into a systemic infection which is often fatal. Endemic inhalational anthrax, known as 'woolsorters' disease, is a rare infection contracted by inhalation of the spores. It occurs mainly among workers handling infected hides, wool, and furs. The intestinal form, which is also very rare in man, is contracted by the ingestion of insufficiently cooked meat from infected animals. In man, the mortality of untreated cutaneous anthrax ranges up to 25 per cent; in inhalational and intestinal cases, the case fatality rate is almost 100 percent.

DIAGNOSIS

After an incubation period of 1-6 days, presumably dependent upon the dose and strain of inhaled organisms, the onset of inhalation anthrax is gradual and nonspecific. Fever, malaise, and fatigue may be present, sometimes in association with a nonproductive cough and mild chest discomfort. These initial symptoms are often followed by a short period of improvement (hours to 2-3 days), followed by the abrupt development of severe respiratory distress with dyspnea, diaphoresis, stridor, and cyanosis. Shock and death usually follow within 24-36 hours after the onset of respiratory distress. Physical findings are

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Anthrax Vaccine Research Program

Part B: Non-hunk Primate Study

Institute of Medicine
January 7, 2002

Jairam Lingappa
David Ashford
Meningitis and Special Pathogens Branch, NCID, CDC

Overview of this Presentation

- Review original NHP study design
- Comments from FDA, IOM and Expert Committees
- Modified NHP study/application to Human Clinical Study
- Integration with ongoing VDRS
- Issues to be discussed

AVRP Principal Objective

Use non-inferiority to the licensed regimen to compare alternative AVA regimens in humans

- Use animal challenge to support conclusions
  - Relate challenge outcomes at specific times to regimens and time points in the human study
  - Use challenge data to assess need for booster doses
- Evaluate immunological correlates of protection

FDA Issues for AVRP Animal Studies

- Does human AVA dose overstimulate macaques?
  - Demonstrate human dose not inappropriate for macaques

Original NHP Study Objectives

- Vaccine Dose Ranging Study (VDRS)
  - Compare immunogenicity of AVA doses
- Immunogenicity & Challenge Study (ICS)
  - Evaluate protection at different times conferred by regimens w/ or w/o booster doses
  - Identify immunologic correlates of protection

Original NHP VDRS

- Select the vaccine dose to be used for macaques

Group	Route	Dosage	N*	Schedule
1	IM	1	10	0-4 wks, 6 mns
2	IM	1:5	10	0-4 wks, 6 mns
3	IM	1:10	10	0-4 wks, 6 mns
4	IM	1:20	10	0-4 wks, 6 mns
5	IM	1:40	10	0-4 wks, 6 mns

* 2 controls per group

Original NHP ICS

- Use selected dose from VDRS to assess regimens

Group	Route	Number/ group*	Schedule**	Aerosol Challenge***
1	IM	10	0-4wks, 6 mns	12 mns
2	IM	10	0-4wks, 6 mns	18 mns
3	IM	10	0-4wks, 6-18 mns	42 mns
4	IM	10	0-4wks, 6 mns	42 mns

* 2 controls for each group
** Blood samples collected at various points
*** Ames Strain, 200 to 300 LD-50s

VDRS/ICS Study Design Concerns

- Evaluation of "appropriateness" of dose?
- How to bridge results to humans?
- Underpowered study due to likely low number of "vaccine failures"?
- Interim IOM report recommended input from expert panels

NHP and Statistics Expert Committees

- Statistics Committee (October 1-2,2001)
  - Donald Rubin, PhD, Harvard University
  - Stephen Self, PhD, Fred Hutchinson Cancer Institute
  - Greg Ridgeway PhD, Rand Corporation
- NHP Committee (October 4-5, 2001)
  - C. Scott Giebink, PhD, University of Minnesota
  - Porter Anderson, PhD, University of Rochester (retired)

Statistics Expert Committee Comments

- Selection of an "appropriate" AVA dose for NHPs is irrelevant to the study objectives
- Study is underpowered to assess specific comparisons between study arms
  - Total number of animals is low
  - Number of vaccine failures will be low

Statistics Expert Committee Recommendations

Do not focus NHP study on specific regimens

Do not use vaccine dose dilutions to select macaque dose

Do use animals to relate immune response elicited by AVA to survival

- Use vaccine dose dilutions (or other methods) to result in a varied NHP immune response
- Relate immune response to outcome from challenge

Apply relationship to human study

NHP Expert Committee Recommendations

- Concurred with recommendations of Statistics Expert Committee

Modified NHP Study-Design

Use vaccine dose dilutions to vary NHP immune response

Relate level of immunologic factors to NHP survival
- Challenge **NHPs** at **selected times after vaccination**
- **Regression analysis of immunologic factors vs. NHP survival**

Apply this relationship to the human clinical study to predict protection of **vaccinees**

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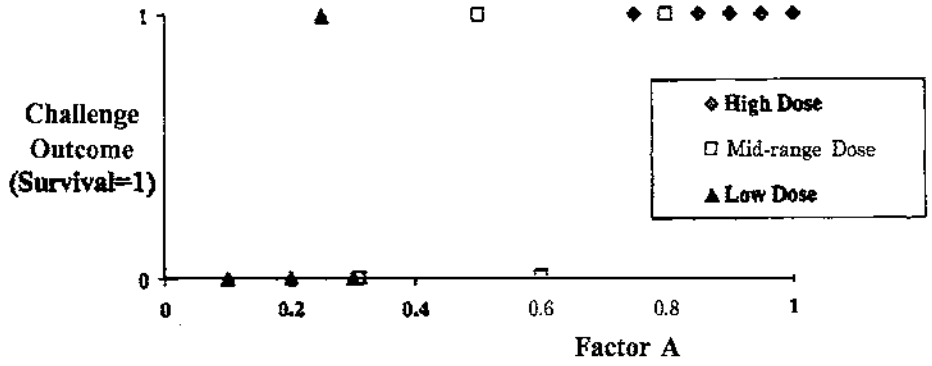
Survival Proportions vs. Factor A

Survival After Challenge at 12 Months:
Hypothetical Association with Vaccine Dose



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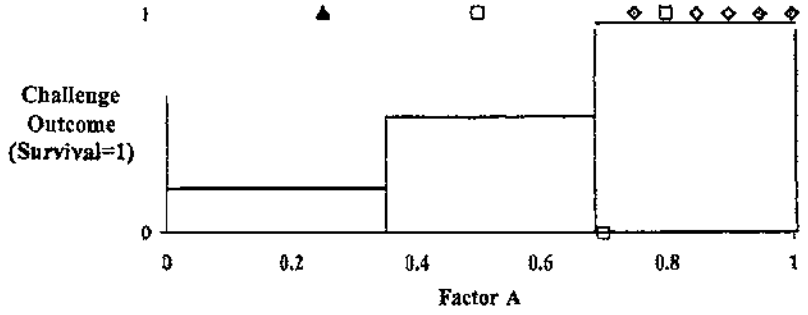
Survival Proportions vs. Factor A

Survival After Challenge at 12 Months:
Hypothetical Association with Vaccine Dose



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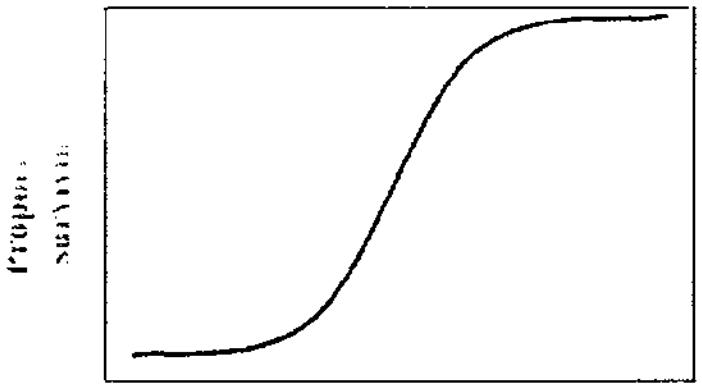
Survival versus Factor A



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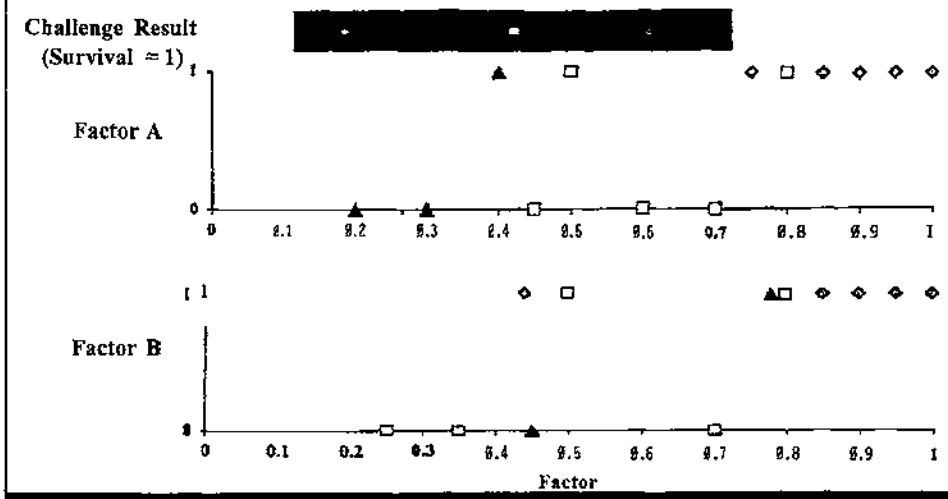
Survival Proportions: Factors A+B



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Immunogenicity Score (IS)

- Regression analysis with model building to combine impact of multiple immunologic factors on survival:
  - $IS_{t0} = f(A_{t0}, B_{t0}, C_{t0}, \ldots..)$
  - $IS_{t1} = f(A_{t1}, B_{t1}, C_{t1}, \ldots..)$
  - $IS_{t2} = f(A_{t2}, B_{t2}, C_{t2}, \ldots..)$
- Final model includes immunologic factors that best predict outcome

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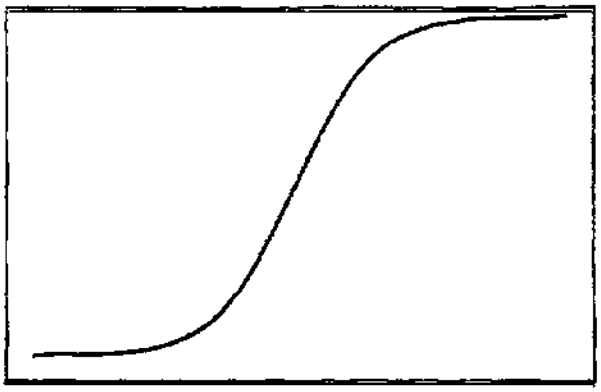
Survival versus Immunogenicity Score



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Assumptions to Bridge to Human Study

Changes in immune response from varying vaccine dose are relevant to protection

The NHP immunogenicity-survival curve can be used to predict protection in humans

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Human Clinical Study

- Primary endpoints are still:
  - Geometric mean concentration of anti-PA antibody
  - 4-fold rise of anti-PA antibody titers
  - Comparison of regimens by non-inferiority to licensed regimen
- Modified NHP study applies correlates of protection data to support human study

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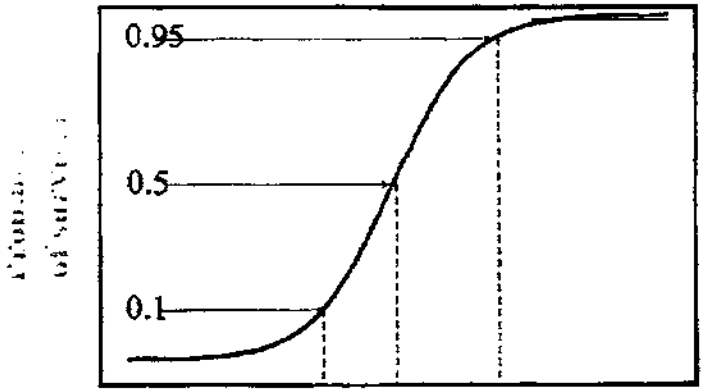
Human Clincal Study: Predicting Individual Survival Probability



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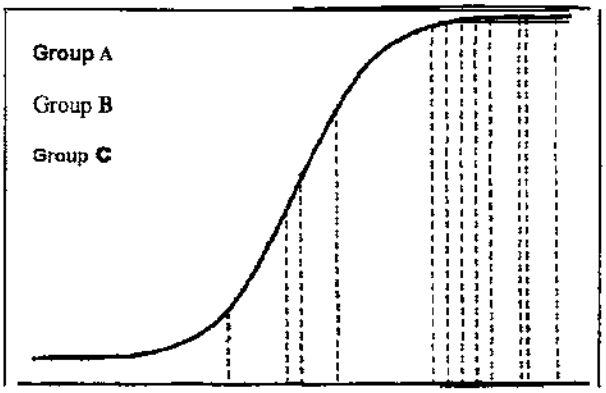
Hypothetical Relationship of Human Study Groups to Predicted Survival



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Modified NHP Study-Design

- Use vaccine dose dilutions to vary NHP immune response
- Relate level of immunologic factors to NHP survival
  - Challenge NHPs at selected times after vaccination
  - Regression analysis of immunologic factors vs. NHP survival
- Apply this relationship to human clinical study to predict protection of vaccinees

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Modified NHP Study Details

- Challenge times
- Allocation of animals to vaccination dilution groups

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Issues Affecting Selection of Challenge Times

- At 12 months - macaques protected* with high antibody titers
  At 24 months - continued protection* with no antibody present
  No data for challenge several years after vaccination
  1:12 dilution dose yields* deaths at 12 month challenge

  Early VDRS data will be helpful at further defining challenge times

* 2-dose regimen

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Modified NHP Study

Dose*	Total #	Challenge Times**		
		Early	Middle	Late
Full dose	13	0	5	9
1:5	21	7	6	8
1:10	20	7	6	7
1:20	22	8	7	7
1:40	16	9	7	0
Control	15	5	5	5
Total (N=108)	108	36	36	36

*** All groups with 0-4wk-6mo schedule**

****Measured from start of vaccination**

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Integration of Current VDRS: Maximize Efficiency

- 60 existing VDRS **NHPs now** 9 months from start of vaccination
  - Allocate to challenge at middle and late challenges
- 48 animals vaccinated during 2002
  - Allocate to challenge at early and middle challenges
  - Adjust vaccination times so challenges can be grouped (several additional animals)

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Summary

- Concerns expressed about VDRS/ICS study design
- Modified NHP study recommended by statistics experts
  - Use vaccine dose dilution to vary immune response
  - Relate immune response to survival
  - Apply relationship to human study to predict survival probability
- Modified study can be integrated with current VDRS
  - Allocate existing VDRS animals to later challenge
  - Time vaccination of new animals to allow challenges to be grouped

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DSD-SA

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DEPARTMENT OF DEFENSE
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MAY 27 1999

MEMORANDUM FOR SECRETARY OF THE ARMY

SUBJECT: Notice of GAO Final Testimony without Recommendations

Reference: GAO Testimony, GAO/T-NSIAD-99-148, "MEDICAL READINESS: Safety and Efficacy of the Anthrax Vaccine," April 29, 1999 (GAO Code 713030/OSD Case 1828)

The GAO recently forwarded copies of the referenced testimony to the DoD. A copy is enclosed for your information and review. The DoD was not afforded an opportunity to comment on the draft testimony.

The GAO has advised that the testimony is only an interim product for the referenced review. A full report is planned at the completion of the audit. Accordingly, underlying GAO code 713030 should remain open.

Since the testimony is essentially informational and contains no recommendations, DoD comments are not required and no further action is necessary. However, if you determine that a DoD response to the testimony is needed, please advise us by June 4 and we will jointly establish a schedule for developing and coordinating the proposed response. Otherwise, we will close the case without further action.

If you have questions, please contact my action officer for this case, Mr. (b)(6), (b)(6), e-mail (b)(6) @dodig.osd.mil>. If he is not available, contact Mr. (b)(6), (b)(6). Our fax number is (b)(6).

(b)(6)

Deputy Director for
GAO Affairs

Enclosure

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United States General Accounting Office

GAO

Testimony

Before the Subcommittee on National Security, Veterans' Affairs, and International Relations, Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at
10:00 a.m., EST
Thursday,
April 29, 1999

MEDICAL READINESS

Safety and Efficacy of the Anthrax Vaccine

Statement of Kwai-Cheung Chan, Director, Special Studies and Evaluations, National Security and International Affairs Division

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the results of our ongoing examination of the safety and efficacy[1] of the anthrax vaccine, which is being done at your request. My testimony presents preliminary findings on (1) the short- and long-term safety of the vaccine, (2) the efficacy of the vaccine, and (3) problems the Food and Drug Administration (FDA) found in the vaccine production facility in Michigan that could compromise the safety, efficacy, and quality of the vaccine. We plan to issue the final report on our review this fall.

As you know, concerns have been raised about the Department of Defense's (DOD) anthrax immunization program since the Department began vaccinating the first of 2.4 million active duty and reserve members. For example, some Gulf War veterans are suffering from unexplained illnesses that they believe might have been caused by anthrax vaccines that they received during the war. Also, some active duty military personnel expressed concerns regarding the safety and efficacy of the anthrax vaccine after the FDA found problems during the inspection of the facility that was manufacturing the anthrax vaccine. With this background, I will discuss our results.

Results in Brief

The anthrax vaccine being given to U.S. military personnel was licensed in 1970. Before the vaccine was licensed, the vaccine and the manufacturing process were changed, creating a similar vaccine, produced by the Michigan Department of Public Health (MDPH), which was the one eventually licensed.[2] The safety study conducted before licensing used both the original vaccine and MDPH vaccine. Knowledge to date about the safety of the vaccine includes the results of the original study and a 1998 DOD study of 500 vaccine recipients. While these studies identified varying

[1]Safety means relative freedom from harmful effects to persons affected directly or indirectly by a product that has been prudently administered, taking into considerations the character of the product in relation to the condition of the recipient at the time. Efficacy is not an absolute term. It is a measure of a product's ability to produce a given response. An effective vaccine will provide a certain degree of protection for a certain period of time.

[2]The original license for the production of anthrax vaccine was issued to MDPH. In 1995, the facility changed its name to the Michigan Biologic Products Institute. In 1998, the facility was sold, and its name was change to BioPort. The term MDPH will be used to refer to the licensed facility throughout this testimony.

rates of adverse reactions, they did not question the safety of the vaccine. The long-term safety of the vaccine has not yet been studied.

Prior to the time of licensing, no human efficacy testing of the MDPH vaccine was performed. However, a study was done on the efficacy of the original vaccine. This study concluded that the vaccine provided protection to humans against anthrax penetrating the skin. In the 1980s, DOD began testing the efficacy of the licensed vaccine on animals, focusing on its protection against inhalation anthrax. DOD recognizes that correlating the results of animal studies to humans is necessary and told us that it is planning research in this area.

Careful control of the manufacturing process is essential to ensure the quality of the product. The FDA inspections of the facility where the licensed vaccine was manufactured uncovered numerous problems. The facility received warning letters from FDA, including one in March 1997 stating its intent to revoke the facility's license. The facility closed its plant in 1998 and is now being renovated. FDA requires the manufacturer to meet specifications for sterility, stability, purity, and potency. In addition to the lot release testing required by FDA, DOD is conducting supplemental testing of each lot from this plant before distributing the vaccine.

Background

The nature and magnitude of the military threat of biological warfare (BW) has not changed since 1990, both in terms of the number of countries suspected of developing BW capability, the types of BW agents they possess, and their ability to weaponize and deliver those BW agents. Inhalation anthrax is considered by DOD to be the primary BW threat because of its lethality, ease of production, and weaponization.

The original anthrax vaccine was developed by George Wright in the 1950s and first produced on a large scale by Merck. After a 1962 study on the vaccine's effects in mill workers, its manufacturing process was changed, and MDPH took over as the vaccine's producer. This changed vaccine was licensed in 1970 by the Division of Biologics, National Institute of Health, to be manufactured by MDPH.

Vaccines have three distinguishing features that contrast with those of chemical drugs. First, either they have no clearly chemically defined composition, or simple chemical analysis is insufficient for effective characterization. Second, proper evaluation of them (qualitatively or quantitatively) is usually done by measuring their effects *in vivo* (in the

living organism). Finally, quality cannot be guaranteed from final tests on random samples but only from a combination of in-process tests, end-product tests, and strict controls of the entire manufacturing process.

Vaccine Safety

Studies have been performed to examine the safety of both the original vaccine and the licensed vaccine. These two vaccines were made using different processes and have different data to support their safety. While these studies identified varying rates of adverse reactions, they did not question the safety of the vaccine. The long-term safety of the vaccine has not yet been studied.

Data on Safety of the Original Vaccine

A study on the original vaccine's safety was done by Philip Brachman and published in 1962.[3] Brachman reported on 379 subjects that received this vaccine. About 35 percent had local reactions, a figure that varied during the inoculation series. Some recipients developed more severe edema that extended to the mid-forearm or wrist. Two individuals had systemic reactions in addition to the edema. The researchers actively collected data on adverse reactions to the vaccine, and the study concluded that individual reactions to the vaccine were relatively minor.

Data on Safety of the Licensed Vaccine

After the original vaccine was developed, MDPH was granted a license for a similar vaccine that differed from the original vaccine in three ways. First, the manufacturing process changed when MDPH took over. Second, the strain of anthrax that Merck used to grow the original vaccine was changed, and another strain was used to grow the MDPH vaccine. Finally, to increase the yield of the protective antigen (which is believed to be an important part of the vaccine's protective effects), the ingredients used to make vaccine were changed from the original vaccine.

Four safety studies have been done that include the licensed vaccine. The results of those studies are presented in table 1. The Center for Disease Control collected data on the Investigational New Drug (IND) study, DOD collected data for both the Pittman study and the Tripler Army Medical Center (TAMC) Anthrax Survey, and DOD is currently collecting reports on

[3]P.S. Brachman et al., Field evaluation of a human anthrax vaccine, American Journal of Public Health, vol. 52 (1962), pp. 632-645.

adverse events. The number of adverse reactions appears to depends, in part, upon whether the mechanism for monitoring reactions is active or passive. (Active monitoring means that the vaccine recipients are contacted to ascertain any adverse reactions after vaccine administration; passive monitoring means that the onus is on the vaccine recipients to report any adverse reactions after vaccine administration.) None of the studies questioned the vaccine's safety.

Table 1: Reactions to Licensed Anthrax Vaccine Reported in Various Studies

			Local reactions (percent)		Systemic reactions (percent)	
Study	Type of reporting	Number vaccinated (or doses)	Mild	Moderate/ severe	Mild	Moderate/ severe
IND	Active/passive	3,984[a]	6 – 20[b]	1 – 10[b]	None[b]	.05[b]
Pittman (1997)	Active	508	16	5	29[c]	14
TAMC (1998)	Active	536	Not addressed	Not addressed	43[d]	5
DOD (Current monitoring)	Passive	223,000[e]	e	e	e	e

[a]This number represents the number of study participants who received the first dose of the licensed vaccine.

[b]These figures represent the percentage of people who experienced this type of reaction during the study, even if they had previously been inoculated with the Merck vaccine.

[c]This figure also includes persons who had reactions of "unknown" severity.

[d]This figure represents the frequency of the most common side effect, myalgia.

[e]DOD testified that as of March 16, 1999, more than 223,000 servicemember have been immunized. There had been 42 reports on adverse effects submitted to the FDA and CDC. Only seven servicemembers required hospitalization or experienced loss of duty for more than 24 hours.

Vaccine Efficacy

Studies on the efficacy of the original and the licensed vaccines have been limited to a study of the efficacy of the original vaccine for humans, and studies of the efficacy of the licensed vaccine for animals. The study on the original vaccine concluded that the vaccine offered protection against anthrax penetrating human skin. The studies on the licensed vaccine focused on the efficacy of the vaccine in protecting animals against inhalation of anthrax. These studies, while showing some positive results, may not be extrapolated to humans. DOD is planning to conduct such correlating studies.

Human Efficacy Study

The only study of the efficacy of the vaccine for humans was performed by Brachman, using the original vaccine. The Brachman study claimed that the vaccine gave 93 percent (and a lower confidence limit of 65 percent) protection against anthrax penetrating the skin. It found that the number of individuals who contracted anthrax by inhalation was too low to assess the efficacy of the vaccine against this form.

Because the vaccine used in the Brachman study was different from the licensed vaccine, additional data were submitted to the Division of Biologics, Department of Health, Education, and Welfare (HEW), to support the license application for the MDPH vaccine. In a February 1969 memorandum, an HEW committee concluded that based on the data, the assumption of efficacy appeared speculative. Similarly, a 1991 Army document noted that "it would be scientifically incorrect to assume that this (*licensed*) vaccine would be totally efficacious under different circumstances, that is, beyond the parameters of the study design." Thus, assuming that the epidemiological evidence from the original vaccine is applicable to the licensed vaccine, we can conclude that the licensed vaccine is efficacious against cutaneous exposure but that testing still needs to be conducted on inhalation anthrax. In the absence of a specific study, efficacy of the licensed vaccine for humans has been inferred from other data, including a reduction in the incidence of anthrax following immunization of at-risk individuals and from animal experiments.

Animal Efficacy Studies of Licensed Vaccines

Beginning in the late 1980s, DOD began studying the efficacy of vaccines on animals, using guinea pigs, rabbits, and monkeys. All of these studies support the view that in these animals, the licensed vaccine can protect against exposure to some strains of anthrax either by inoculation or inhalation. It is clear, however, that animal species differ in their susceptibility. Studies of guinea pigs show that some anthrax strains are more or less resistant to vaccines for humans (both the U.S. and U.K. versions) but are protected by the live spore veterinary vaccine.[4]

[4]P.C.B Turnbull, et al., Development of antibodies to protective antigen and lethal factor components in humans and guinea pigs and their relevance to protective immunity, Infectious Immunology, vol. 52 (1988) pp. 356-363.

Research using monkeys showed for the first time that monkeys could be protected against aerosol exposure.[5] However, in both the guinea pig and monkey studies, protection did not correlate with levels of antibodies to a protective antigen. Several studies have shown no direct comparison of immunity in humans to that in monkeys. Study findings suggest that "the importance of various specific immune mechanisms against inhalation anthrax may vary in different animal species or . . . the ability of the licensed human vaccine to stimulate cell-mediated immunity may be greater in some species than others." A 1998 study comes to the same conclusion and emphasizes the need for further studies. In animals, the lack of correlation of protection with antibodies to protective antigen has some important consequences.

DOD recognizes the importance of establishing a correlate of immunity in humans. Recently, it has sought to develop a serologic correlate of immunity in an animal model to use for humans.

Vaccine Manufacturing Process

The quality of a vaccine is closely linked to its manufacturing process, which must be rigorously controlled to ensure that batches of vaccines produced on different occasions are of reproducible and consistent quality. In general, quality is achieved by applying the current good manufacturing practice. This process is not static but involves manufacturers and regulators in a continuing process of assessment and upgrades as scientific progress, technical development, and experience help to identify deficiencies and make improvements possible. Such principles also apply to the facilities and equipment in which products are manufactured.

Accordingly, vaccine production is very highly regulated to ensure that the products are of consistent quality and safe and effective for the purpose(s) for which regulatory approval was granted. Until 1993, FDA inspectors did not inspect the MDPH facility where the anthrax vaccine was made. According to FDA, access was not granted because its inspectors had not been vaccinated against anthrax.

FDA's inspections of the MDPH facility found a number of deficiencies. The deficiencies that FDA identified in its February 1998 inspection fall

[5]B.E. Ivins, et al., Efficacy of a standard human anthrax vaccine against Bacillus anthracis aerosol challenge in rhesus monkeys, in "Proceedings of the International Workshop on Anthrax, Salisbury Medical Bulletin, Special Supplement no. 87 (1996) pp. 125-126.

broadly into two categories: those that, although serious, might affect only one or a limited number of batches that were produced when the deficiency was extent and those of a generic nature that could compromise the safety and efficacy of any or all batches. DOD had also identified deficiencies during a March 1992 inspection, including the absence of stability studies. In 1998, MDPH closed its plant, which is now being renovated. DOD has directed that supplemental testing be done on the lots of vaccine in the current inventory.

Mr. Chairman, this concludes my statement. I will be happy to answer any questions you or members of the Subcommittee may have.

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The first copy of each GAO report and testimony is free. Additional copies are $2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary, VISA and MasterCard credit cards are accepted, also.

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CONGRESSIONAL or SPECIAL CORRESPONDENCE

CMAT: 9152
~~9EE1~~ - 057
Date: 6-1-99

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action	Info	Comments
	Special Assistant	(SA)			
	Deputy Special Assistant	(DSA)			
	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____				
	Dir Lessons Learned Implementation	(LLI)			
	Dir Public Affairs & Outreach	(PA)			
	Dir Legislative Outreach	(LA)			
	Dir Quick Reaction Team	(QR)			
	Dir Medical Outreach & Issues	(MOI)	X		no comments FOO 6/2/99
	Legal Advisor	(LGL)			
	PM, Gulf War Illnesses Support	(PM)			
	Editorial Review ☐ AMB _____ ☐ Editors _____	(ER)			
	CMAT	(CMAT)			
	Action Management Call 845-8369 ☐ COMEBACK COPY TO: _____ ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☐ CHRON FILE ☐ ADD TO GulfNEWS				(b)(6) close out and send to MOI

SUSPENSE: 6-4-99

Prepare reply for signature of:

☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI NFA

(b)(6)

-determine if comments are required-

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO

☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

KEYWORDS:

CMAT Control #
1999246-0000004

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-2884

SEP 1 1999

MEMORANDUM FOR SECRETARY OF THE ARMY

SUBJECT: General Accounting Office Letter, "Various Issues Involving the Anthrax Vaccine," (GAO Code 713048): NOTIFICATION OF GAO REVIEW

The Department of Defense (DoD) recently received the enclosed General Accounting Office (GAO) notification letter announcing a new review. At the request of Chairman Dan Burton, House Committee on Government Reform, the GAO plans to assess several issues concerning the anthrax vaccine as discussed in the GAO letter.

The DoD Directive 7650.2 designates this office as the central DoD liaison for tasking, controlling, and monitoring GAO survey, review, and report activities. The enclosed Information Sheet describes the specific DoD procedures for tasking GAO surveys/reviews and the DoD Primary Action Office (PAO) responsibilities.

Your office is the PAO for the review. We have been advised that (b)(6), located in the Office of the Army Surgeon General, is your action officer for this case. An identification of the collateral action offices (CAOs) follows this memorandum. The CAOs are requested to provide Col Gerber and this office, if they have not already done so, with the name, phone number, fax number, and mailing address of their action officers as soon as possible.

An entrance conference for this review was held on August 30 in conjunction with the entrance conference for the related GAO review of adverse reactions to the anthrax vaccine, GAO Code 713047. Staying informed on GAO survey/review activity depends on the PAO, the other involved DoD components, and this office working closely together. Your full support is requested in these efforts to prevent surprises related to the GAO review and to ensure that the DoD obtains the maximum benefits from the GAO work.

If you have questions, please contact my action officer for this case, Mr. (b)(6), (b)(6), e-mail (b)(6) @dodig.osd.mil>.

If he is not available, please call Mr. (b)(6), (b)(6) (b)(6). Our fax number is (b)(6).

Donald L. Myers
for Carlos J. Chapa
Deputy Director for
GAO Affairs

Enclosures: GAO notification letter
Information sheet

CAO Copies: SEC NAVY
SEC AIR FORCE
CMDT, USMC
ASD(HA)
ASD(RA)
DIR, JS

Info Copies: USD(A&T)
USD(P&R)
ASD(LA)
ASD(PA)
DSD/SA-Gulf War Illnesses
DGC(F)
AIG-AUD-CM (Mr. Granetto)

GAO
United States
General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

August 30, 1999

The Honorable William S. Cohen
The Secretary of Defense

Attention: DOD Office of the Inspector General
Deputy Director for GAO Affairs

Dear Mr. Secretary:

This is to advise you that the U.S. General Accounting Office is beginning a study examining various aspects of anthrax vaccine. The assignment code is 713048. This study is in response to a request from Chairman Dan Burton, House Government Reform Committee.

The objectives of the study include addressing the following issues:

1) What scientific information is required by the Food and Drug Administration for administration of a vaccine to children and pregnant or lactating women? Were these studies conducted for the anthrax vaccine?

2) What is the ongoing Biological Warfare vaccine research? How has the Department of Defense addressed these issues?

3) What proportion of pilots at select bases have resigned or become sick as a result of the administration of the anthrax vaccine? What characteristics are important to consider for a diverse and representative sample of pilots impacted by the anthrax immunization program?

4) What ongoing studies are being conducted by the Department of Defense to follow the health of members who have experienced adverse events?

5) Is the Department of Veterans Affairs treating patients with health conditions resulting from the anthrax vaccine, or other vaccines? Are there any long-term follow-up studies?

6) How accurate and scientifically valid is the information the Department of Defense is disseminating to the public and its members on the safety and efficacy of the anthrax vaccine? This should include a review of the web sites, brochures, and the video that has been tested in Hawaii?

If you have any questions regarding this work, please contact me at (b)(6), or (b)(6), Assistant Director, at (b)(6)

Sincerely yours,

(b)(6)

Director, Special Studies and Evaluations

INFORMATION SHEET
(Revised 11/96)

DoD PROCEDURES FOR PROCESSING, MONITORING, AND MANAGING GENERAL ACCOUNTING OFFICE (GAO) SURVEYS AND REVIEWS
(References: DoD Directives 7650.1, 7650.2)

1. GAO Notification Letters of Surveys and Reviews

Before contacting DoD officials to initiate new survey/review work, the GAO has agreed to issue a notification letter to the Secretary of Defense, Attention: OIG, DoD, Deputy Director for GAO Affairs. The notification letter includes the objectives of the planned work and a six digit GAO assignment code. When the GAO staffs contact DoD personnel, they should be asked if they have properly announced their work with a notification letter through the OIG, DoD. The GAO staffs should be prepared to provide a copy of the notification letter on request. The DoD personnel should verify that the GAO work has been announced within the Department. They can contact the appropriate component audit liaison, collateral action office, or this office. If the GAO work has been announced, this office can telefax a copy of the GAO notification letter along with the DoD official announcement. Meetings should not be scheduled nor information released until the GAO work is properly announced. All questions or special arrangements on GAO surveys and reviews should be coordinated with GAO Affairs-- the address, phone number and telefax number is as follows:

Office of the Inspector General, DoD
Deputy Director for GAO Affairs
400 Army Navy Drive, Room 539A
Arlington, VA 22202-2884

Commercial: (b)(6) DSN: (b)(6)
Telefax: DSN:
Telefax: DSN:

2. GAO Notices of Visit and Security Clearances

Besides the GAO notification letter, the GAO should notify appropriate agency officials about 10 days before any proposed visit using the "Notice of GAO Visit" form. The GAO should provide a copy of that form to GAO Affairs. In cases of unusual urgency, the GAO should make arrangements with the agency officials by phone. The responsibility for assuring that a GAO representative has the proper clearance to review/receive classified information rests with the DoD individual providing the information.

If a GAO representative does not provide the notice of visit or if the DoD contact needs additional information, the assigned GAO Affairs action officer should be contacted for assistance.

3. **Tasking of GAO Surveys and Reviews**

On receipt of a GAO notification letter, GAO Affairs identifies the primary action office (PAO) and a PAO point of contact through discussions with DoD component audit liaison offices and DoD officials. For most surveys/reviews, the PAO is at the Office of the Secretary of Defense (OSD) staff level. The OIG issues a tasking memorandum assigning responsibility for the GAO effort to the PAO with copies to identified collateral action offices (CAO).

The DoD component audit liaisons receive action or information copies of the GAO Affairs tasking memorandum for further distribution to the appropriate offices. The memorandum is given wide distribution to help identify action offices and inform them of the GAO review. This is important so that the correct DoD components attend the GAO entrance, interim status, and exit meetings.

4. **GAO Entrance, Interim Status, and Exit Meetings**

The GAO Affairs action officer will work with the PAO and the CAO to arrange a joint, headquarters level entrance meeting. The purpose of the entrance meeting is to provide the PAO, CAOs and other DoD components with details about the GAO review. It is an opportunity to ask questions and provide the GAO the names of DoD points of contact.

The PAO, CAO, and GAO Affairs should work together to help ensure that (1) interim status and exit meetings are held, when appropriate, (2) the PAO, CAO, and OIG action officers attend such meetings, and (3) the meetings include all key DoD officials. The PAO and CAO action officers, through their ongoing contacts with the GAO, should be alert to the need for interim status and exit meetings, and should advise GAO Affairs in advance so that appropriate actions can be taken to facilitate the meeting.

Before any interim status or exit meeting at the headquarters level, the GAO usually holds separate meetings at the field activity level. Action officers at the field level should advise the PAO of such meetings through the component CAO or the component audit liaison.

The purpose of interim status and exit meetings with the GAO is to provide the DoD an opportunity to discuss the accuracy and completeness of the GAO work results and to avoid surprises to the DoD. The GAO Affairs action officer will normally ask for an exit meeting before the GAO issues a draft or final report.

The interim status and exit meetings are particularly important because these meetings may be the only DoD opportunity to comment on GAO work that could result in budget reductions or program direction decisions by the Congress. The GAO Affairs action officer will ask the GAO to provide work products (fact sheets, draft reports, advance testimony, or other written documents not officially issued) before the meetings to better prepare DoD officials in providing accurate and complete comments.

The DoD officials' comments provided at interim status and exit meetings are unofficial. The only official DoD comments (whether oral or written) are those that are properly coordinated with all the appropriate DoD offices through the OIG, DoD.

5. Access to Records

Under 31 U.S.C. 716(a), the GAO has broad access rights. The DoD Directives 7650.1 and 7650.2 provide the DoD policy and procedures regarding GAO access to records. Both oral and written requests from GAO representatives should be handled informally. Efforts should be made to accommodate the GAO needs at the lowest organization level possible.

If it is unclear what information the GAO is requesting orally, it may be appropriate to ask the GAO to put its request in writing, listing the specific documents requested and explaining the need in connection with the survey or review. While oral requests should be acceptable, written requests can help clarify the information desired.

The DoD components and action officers should not deny the GAO access without further checking through the appropriate channels. Depending on the document(s) requested, that could include: officials in the chain of command, the component legal office, the audit liaison office, the PAO, and the appropriate OSD general counsel's office. The GAO Affairs action officer will provide assistance as necessary, working with DoD component liaison officials in processing action requests and arranging meetings between DoD and GAO representatives.

If informal attempts fail and the GAO decides to pursue its request, the Comptroller General, by law, may issue a formal demand letter to the Secretary of Defense. By law, the DoD has 20 days to respond to the GAO. If after 20 days full access has not been granted, the Comptroller General may file a written report with the President of the United States, the Director of the Office of Management and Budget, and the Attorney General. Following that, the Comptroller General may seek a court order to compel the release of Federal records or subpoena nonfederal records.

6. GAO Questionnaires and other Data Collection Instruments

All questionnaires and other data collection instruments should be coordinated with the Deputy Director for GAO Affairs before distribution within the DoD. Any DoD component or official receiving GAO questionnaires or other data collection instruments should ask the GAO staff if they have properly coordinated the instrument through the OIG. Responses should not be provided nor information released until the GAO has properly coordinated its work.

7. Termination of Surveys/Reviews

The GAO should notify the DoD through the Deputy Director for GAO Affairs when it decides to terminate a survey or review without issuing an external report. The GAO sometimes overlooks issuing a termination letter to the DoD. If the PAO or CAO action officers learn that GAO work is terminated, they should alert GAO Affairs.

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE, ROOM 539A
ARLINGTON, VA 22202

date: _____
no. of pages: _____

OAIG-AUD-AFU

From: (b)(6) Phone (b)(6) Fax: (b)(6) E-mail: (b)(6) @dodig.osd.mil>

SUBJECT:

GAO Code 713048 OSD Case

PAO CAO INFO		Component and Office Symbol	PAO & CAO POINTS OF CONTACT / FAX TRANSMITTAL
INFO		DSD-SA GCI	name (b)(6) office address
CAO		USD(A&T) DDR&E	name office address
INFO		AIG-AUD-CM	name office address
			name e-mail office phone address fax
			name e-mail office phone address fax
			name e-mail office phone address fax
			name e-mail office phone address fax
			name e-mail office phone address fax

(10/97)

PAGE 2 OF ___

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE, ROOM 539A
ARLINGTON, VA 22202

date: 8-2-99
no. of pages: 10

OAIG-AUD-AFU

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SUBJECT:

GAO Code 713048 OSD Case

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CAO		USMC HQMC/HS	
CAO		ASD (RA)	
CAO		JS J-4-MRO	
CAO		ASD (HA)	
INFO		ARMY DASG-IRO	

(10/97)

PAGE 1 OF

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Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

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	Deputy Special Assistant	(DSA)			
	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____				
	Dir Lessons Learned Implementation	(LLI)			
	Dir Public Affairs & Outreach	(PA)			
	Dir Legislative Outreach	(LA)			
	Dir Medical Outreach & Issues	(MOI)			
	Legal Advisor	(LGL)			
	PM, Gulf War Illnesses Support	(PM)			
	Editorial Review ☐ AMB _____ ☐ Editors _____	(ER)			
	CMAT	(CMAT)			
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☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO

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KEYWORDS:

06/17/99 Issuance

CMAT Control #
1999237-0000002

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-2884

AUG 24 1999

MEMORANDUM FOR SECRETARY OF THE ARMY

SUBJECT: General Accounting Office Letter, "DoD Efforts to Address Adverse Reactions to the Anthrax Vaccine," (GAO Code 713047): NOTIFICATION OF GAO REVIEW

On August 19, 1999, the Department of Defense (DoD) received the enclosed General Accounting Office (GAO) notification letter announcing a new review. At the request of Representative Jan Schakowsky, the GAO plans to evaluate how the DoD has addressed adverse reactions to the anthrax vaccine, with a particular emphasis on different rates of reactions between men and women.

The DoD Directive 7650.2 designates this office as the central DoD liaison for tasking, controlling, and monitoring GAO survey, review, and report activities. The enclosed Information Sheet describes the specific DoD procedures for tasking GAO surveys/reviews and the DoD Primary Action Office (PAO) responsibilities.

Your office is the PAO for the review. We have been advised that (b)(6) located in the Office of the Army Surgeon General, is your action officer for this case. An identification of the collateral action offices (CAOs) follows this memorandum. The CAOs are requested to provide Col Gerber and this office, if they have not already done so, with the name, phone number, fax number, and mailing address of their action officers as soon as possible.

This office has contacted the GAO to arrange a joint, headquarters level entrance meeting so that the GAO can identify and discuss its detailed work plans and begin work. The entrance conference is scheduled for Monday, August 30 at 10:00 in room 691, Skyline 6. Each action office should send a representative to the entrance conference, as appropriate.

Staying informed on GAO survey/review activity depends on the PAO, the other involved DoD components, and this office working closely together. Your full support is requested in these efforts to prevent surprises related to the GAO review and to ensure that the DoD obtains the maximum benefits from the GAO work.

AUG 24 1999

If you have questions, please contact my action officer for this case, Mr. (b)(6), (b)(6), e-mail (b)(6)@dodig.osd.mil>. If he is not available, please call Mr. (b)(6), (b)(6). Our fax number is (b)(6)

(b)(6)

Deputy Director for
GAO Affairs

Enclosures: GAO notification letter
Information sheet

CAO Copies: SEC NAVY
SEC AIR FORCE
CMDT, USMC
ASD(HA)
ASD(RA)
DIR, JS

Info Copies: USD(A&T)
ASD(LA)
ASD(PA)
DSD/SA-Gulf War Illnesses
DGC(F)

GAO

United States
General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

August 18, 1999

The Honorable William S. Cohen
The Secretary of Defense

Attention: DOD Office of the Inspector General
Deputy Director for GAO Affairs

Dear Mr. Secretary:

This is to advise you that the U.S. General Accounting Office is beginning a study examining how DOD has addressed adverse reactions to the anthrax vaccine, with a particular emphasis on different rates of such reactions between men and women. The assignment code is 713047. This study is in response to a request from Representative Jan Schakowsky, a member of the Government Reform Committee.

The objectives of the study include addressing the following three major issues:

1) to what extent do gender differences exist with regard to anthrax vaccine, what scientific research has been done with regard to this issue, and how have those military personnel who developed adverse reactions to anthrax vaccine been treated by DOD medical personnel;

2) To what extent does DOD incorporate women in military medical research (past and ongoing); and

3) What strategies has DOD developed for management of adverse reactions for vaccines.

If you have any questions regarding this work, please contact me at (b)(6) or (b)(6), Assistant Director, at (b)(6).

Sincerely yours,

(b)(6)

Director, Special Studies and Evaluations

INFORMATION SHEET
(Revised 11/96)

DoD PROCEDURES FOR PROCESSING, MONITORING, AND MANAGING GENERAL ACCOUNTING OFFICE (GAO) SURVEYS AND REVIEWS
(References: DoD Directives 7650.1, 7650.2)

1. GAO Notification Letters of Surveys and Reviews

Before contacting DoD officials to initiate new survey/review work, the GAO has agreed to issue a notification letter to the Secretary of Defense, Attention: OIG, DoD, Deputy Director for GAO Affairs. The notification letter includes the objectives of the planned work and a six digit GAO assignment code. When the GAO staffs contact DoD personnel, they should be asked if they have properly announced their work with a notification letter through the OIG, DoD. The GAO staffs should be prepared to provide a copy of the notification letter on request. The DoD personnel should verify that the GAO work has been announced within the Department. They can contact the appropriate component audit liaison, collateral action office, or this office. If the GAO work has been announced, this office can telefax a copy of the GAO notification letter along with the DoD official announcement. Meetings should not be scheduled nor information released until the GAO work is properly announced. All questions or special arrangements on GAO surveys and reviews should be coordinated with GAO Affairs-- the address, phone number and telefax number is as follows:

Office of the Inspector General, DoD
Deputy Director for GAO Affairs
400 Army Navy Drive, Room 539A
Arlington, VA 22202-2884

Commercial: (b)(6)
Telefax:
Telefax:

DSN: (b)(6)
DSN:
DSN:

2. GAO Notices of Visit and Security Clearances

Besides the GAO notification letter, the GAO should notify appropriate agency officials about 10 days before any proposed visit using the "Notice of GAO Visit" form. The GAO should provide a copy of that form to GAO Affairs. In cases of unusual urgency, the GAO should make arrangements with the agency officials by phone. The responsibility for assuring that a GAO representative has the proper clearance to review/receive classified information rests with the DoD individual providing the information.

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On receipt of a GAO notification letter, GAO Affairs identifies the primary action office (PAO) and a PAO point of contact through discussions with DoD component audit liaison offices and DoD officials. For most surveys/reviews, the PAO is at the Office of the Secretary of Defense (OSD) staff level. The OIG issues a tasking memorandum assigning responsibility for the GAO effort to the PAO with copies to identified collateral action offices (CAO).

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4. GAO Entrance, Interim Status, and Exit Meetings

The GAO Affairs action officer will work with the PAO and the CAO to arrange a joint, headquarters level entrance meeting. The purpose of the entrance meeting is to provide the PAO, CAOs and other DoD components with details about the GAO review. It is an opportunity to ask questions and provide the GAO the names of DoD points of contact.

The PAO, CAO, and GAO Affairs should work together to help ensure that (1) interim status and exit meetings are held, when appropriate, (2) the PAO, CAO, and OIG action officers attend such meetings, and (3) the meetings include all key DoD officials. The PAO and CAO action officers, through their ongoing contacts with the GAO, should be alert to the need for interim status and exit meetings, and should advise GAO Affairs in advance so that appropriate actions can be taken to facilitate the meeting.

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The DoD officials' comments provided at interim status and exit meetings are unofficial. The only official DoD comments (whether oral or written) are those that are properly coordinated with all the appropriate DoD offices through the OIG, DoD.

5. Access to Records

Under 31 U.S.C. 716(a), the GAO has broad access rights. The DoD Directives 7650.1 and 7650.2 provide the DoD policy and procedures regarding GAO access to records. Both oral and written requests from GAO representatives should be handled informally. Efforts should be made to accommodate the GAO needs at the lowest organization level possible.

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The DoD components and action officers should not deny the GAO access without further checking through the appropriate channels. Depending on the document(s) requested, that could include: officials in the chain of command, the component legal office, the audit liaison office, the PAO, and the appropriate OSD general counsel's office. The GAO Affairs action officer will provide assistance as necessary, working with DoD component liaison officials in processing action requests and arranging meetings between DoD and GAO representatives.

If informal attempts fail and the GAO decides to pursue its request, the Comptroller General, by law, may issue a formal demand letter to the Secretary of Defense. By law, the DoD has 20 days to respond to the GAO. If after 20 days full access has not been granted, the Comptroller General may file a written report with the President of the United States, the Director of the Office of Management and Budget, and the Attorney General. Following that, the Comptroller General may seek a court order to compel the release of Federal records or subpoena nonfederal records.

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All questionnaires and other data collection instruments should be coordinated with the Deputy Director for GAO Affairs before distribution within the DoD. Any DoD component or official receiving GAO questionnaires or other data collection instruments should ask the GAO staff if they have properly coordinated the instrument through the OIG. Responses should not be provided nor information released until the GAO has properly coordinated its work.

7. Termination of Surveys/Reviews

The GAO should notify the DoD through the Deputy Director for GAO Affairs when it decides to terminate a survey or review without issuing an external report. The GAO sometimes overlooks issuing a termination letter to the DoD. If the PAO or CAO action officers learn that GAO work is terminated, they should alert GAO Affairs.

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AUG 9 1999

Memorandum For: Offices Listed Below

Subject: General Accounting Office Testimony "MEDICAL READINESS: Issues Concerning the Anthrax Vaccine" dated July 21, 1999

Enclosed for your information is a copy of the subject testimony the GAO recently presented before the Subcommittee on National Security, Veterans' Affairs, and International Relations, House Committee on Government Reform. The information in the testimony relates to work the GAO has been performing under Code 713030. The GAO assigned Code 713043 to the subject testimony for processing purposes only. The testimony is being provided for your information only—no action is necessary.

The GAO has not yet determined whether any further audit work or reporting will be performed in connection with Code 713030. In the meantime that code should remain open. Call me if you have any questions.

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Testimony

Before the Subcommittee on National Security, Veterans' Affairs, and International Relations, Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at
10:00, a.m., EDT
Wednesday,
July 21, 1999

MEDICAL READINESS

Issues Concerning the Anthrax Vaccine

Statement of Kwai-Cheung Chan, Director Special Studies and Evaluations, National Security and International Affairs Division

GAO/T-NSIAD-99-226

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to share the results of our work on the anthrax vaccine. As you know, questions have been raised about the Department of Defense's (DOD) anthrax immunization program because of concerns related to (1) the safety and efficacy of the vaccine and (2) problems found over the past few years by the Food and Drug Administration (FDA) during its inspection of the facility that was manufacturing the vaccine. We reported our findings on these issues to you in previous testimonies.[1]

In December 1997, the Secretary of Defense announced that all U.S. forces would be inoculated against the potential use of anthrax on the battlefield. Although a version of the anthrax vaccine was shown to be effective against cutaneous exposure, the vaccine has not been tested against inhalation anthrax in humans. DOD has recognized that some of the concerns about using the current vaccine might be mitigated in the future through actions such as testing and research and adjustments to the program based on new data.

As requested, we will discuss (1) the extent to which data support the need for six initial shots and an annual booster of the anthrax vaccine, (2) the relative merits and weaknesses of a passive surveillance system in determining adverse events,[2] (3) the available data on differences in adverse reaction rates between men and women receiving the anthrax vaccine, and (4) the disadvantages of the current vaccine and the status of federal efforts to develop an improved anthrax vaccine.

Results in Brief

No studies have been done to determine the optimum number of doses of the anthrax vaccine. A study done during the early 1950s showed that animals could be protected against cutaneous anthrax using a three-dose schedule. However, the number of doses was increased to six when three people who had received three doses of the vaccine were infected after exposure to anthrax. In a study of the vaccine's human efficacy published

[1] Medical Readiness: Safety and Efficacy of the Anthrax Vaccine (GAO/T-NSIAD-99-148, Apr. 29, 1999) and Contract Management: Observations on DOD's Financial Relationship With the Anthrax Vaccine Manufacturer (GAO/T-NSIAD-99-214, June 30, 1999).

[2] Clinical events reported to a passive surveillance system are usually termed adverse events rather than adverse reactions because causally-related events to the vaccine is not usually possible.

in 1962, a six-dose schedule was used, and the researchers concluded that the vaccine provided protection against cutaneous exposure to anthrax.[3] In 1998, the current manufacturer of the vaccine submitted an FDA application (Investigational New Drug) to determine whether the number of shots in the initial schedule could be reduced from six to five. Although annual boosters are given, the need for this frequency and the amount of the booster dose has also not been evaluated.

DOD submits data on adverse events associated with the anthrax vaccine to the Vaccine Adverse Events Reporting System (VAERS).[4] This system has several advantages. It alerts FDA/CDC to previously unreported or unexpected increases in reported adverse events. It is also a relatively affordable way to supplement the data collected on vaccines before they are licensed. However, it is a passive surveillance system, which means that FDA/CDC must rely on vaccine recipients or their health care providers to report any adverse events after receiving the vaccine; studies show that adverse events are reported significantly less than they would be in an active surveillance system. In an active system, which is generally more costly to administer, vaccine recipients are monitored to find out if they had any adverse events after being inoculated.

In addition to reporting data to VAERS, DOD has conducted three efforts to actively collect data on adverse reactions after servicemembers received the anthrax vaccine. Data from these efforts show that women reported twice the rate of adverse reactions than men for both local (e.g., swelling) and systemic (e.g., malaise and chills) reactions. In addition, a higher proportion of women than men reported making an outpatient medical visit after a vaccination, and more than twice the percentage of women reported that they missed one or more duty shifts after their vaccinations than did men.

The anthrax vaccine has several disadvantages. The amount of protective antigen in the vaccine cannot be precisely measured, and it varies from lot to lot. Also, the requirement for a six-dose schedule and annual booster shots, rather than a smaller number of doses, complicates the logistics of inoculating all of DOD's troops and increases the cost of the vaccine program. Knowledge of anthrax infection and studies of experimental

[3]P.S. Brachman et al., "Field evaluation of a human anthrax vaccine," American Journal of Public Health, vol. 52 (1962), pp. 632-645.

[4]The system is an FDA/Centers for Disease Control and Prevention (CDC) system.

anthrax vaccines indicate that a second-generation vaccine with a more precise amount of protective antigen could be developed and that fewer doses of the vaccine would be required. However, a second-generation vaccine has not been fully tested, and the testing required for licensing alone would take about 3 years. FDA approval of the manufacturing of the vaccine would take longer. In 1995, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)[5] developed a second-generation recombinant vaccine (that is, a vaccine produced through DNA extraction) against anthrax. The vaccine was tested on animals, but clinical trials were not conducted in humans. DOD currently considers such a vaccine an unfunded requirement. The Department of Health and Human Services recently funded several active research grants to develop a second-generation recombinant vaccine because of a perceived growing bioterrorism concern. In developing a new vaccine, researchers also believe they should consider the impact of new and engineered strains of anthrax.

Background

DOD currently plans to vaccinate all 2.4 million servicemembers against anthrax using the vaccine licensed in 1970 by the Division of Biologics Standards, National Institutes of Health (NIH). As of July 14, 1999, more than 300,000 servicemembers had received at least one dose of the vaccine. Initial immunization consists of three shots given at 0, 2, and 4 weeks followed by three additional shots given at 6, 12, and 18 months.

Some studies have been done on the short-term effects of the licensed vaccine. We previously testified that the number of adverse reactions reported in these studies partly depended on whether an active or passive surveillance system was used to monitor adverse reactions.[6] Also, we reported that the long-term safety of the vaccine has not been investigated but that DOD is considering a study to examine long-term effects of the vaccine.

[5]USAMRIID, an organization of the U.S. Army Medical Research and Materiel Command, conducts research to develop strategies, products, information, procedures, and training programs for medical defense against biological warfare threats and naturally occurring infectious diseases that require special containment. It is located at Fort Detrick, Maryland.

[6]Medical Readiness (GAO/T-NSIAD-99-148, Apr. 29, 1999).

Data on the Need for Six Shots Are Not Available

The original inoculation schedule of three doses was based on a regimen developed using animals in the early 1950s. However, three people (two in Fort Detrick and one in a private wool mill) who received three doses of the vaccine became infected after exposure to anthrax. The number of doses was then increased to six for the human efficacy study published in 1962. The study did not provide enough information to determine whether the vaccine was effective against inhalation anthrax. There were no studies done to determine the optimum number of doses of the vaccine. Also, according to DOD researchers, the choice of six doses was arbitrary. The license for the vaccine, which was granted to the Michigan Department of Public Health (MDPH),[7] calls for the six-dose schedule and annual boosters used in the human efficacy study, and DOD has followed this regimen. In September 1998, BioPort submitted to FDA an application (Investigational New Drug) to determine whether the number of shots in the initial schedule could be reduced from six to five.

In November 1971, the Division of Biologics Standards, NIH, noted an apparent increase in reports of adverse reactions after individuals received booster shots. The Division considered it advisable to reevaluate the need for annual boosters and possibly the amount of the booster dose. Although the record is unclear as to whether or not NIH requested a reevaluation, to date, no such reevaluation has been done.

The Relative Merits and Weaknesses of Passive Surveillance Systems in Determining Adverse Events

DOD submits data on adverse events associated with the anthrax vaccine to VAERS. VAERS is a passive surveillance system to alert FDA and CDC of adverse events that may be associated with licensed vaccines. Information is voluntarily reported to VAERS by health care providers, patients, or families, who are encouraged to report any adverse events after a person receives a vaccine.

VAERS has several advantages. It is a relatively affordable way to supplement data on short-term adverse events that are collected using active means during the clinical trials before a vaccine is licensed. Most important, however, VAERS serves as a signal for the detection of previously unreported adverse events and/or unexpected increases in

[7]MDPH was granted the original license to produce the anthrax vaccine. In 1995, the facility changed its name to the Michigan Biologic Products Institute. In 1998, the facility was sold, and its name was changed to BioPort.

reported events. Prelicensing clinical trials are limited in detecting the range of adverse reactions because of the small samples, short durations, and the homogeneous population used as subjects. In addition, both the general public and doctors can report adverse events to the system, and the data is open to public scrutiny.

VAERS also has several disadvantages. Studies show that adverse events are often underreported in a passive surveillance system.[5] A former FDA commissioner acknowledged the underreporting of adverse events in passive surveillance systems and cited one study showing that "only about 1 percent of serious events" attributable to drug reactions are reported to FDA.[6] Reporting of adverse events appears to depend on several factors, such as the clinical seriousness of the event, the length of time between the shots and the event, and health care workers' awareness of and obligation to report particular adverse events. Also, outcomes with delayed onset after vaccination or outcomes not generally recognized to be associated with vaccination are often underreported. According to the National Vaccine Information Center, there is no mechanism within VAERS for a 1-, 3-, or 10-year follow-up to evaluate vaccine reactions that have a long latency period. According to CDC, the limitations of VAERS data suggest it is not a valid source for assessing the rate of adverse events.

In an active surveillance system, health care workers monitor people that have been vaccinated to find out if they have had adverse reactions. Such systems are generally used during clinical trials and are more costly to administer than passive systems because of the additional infrastructure and personnel required. However, such systems are sometimes used to obtain information when questions arise about the safety of a vaccine after licensing.

[5]S. Rosenthal and R. Chen, "The Reporting Sensitivities of Two Passive Surveillance Systems for Vaccine Adverse Events," American Journal of Public Health, vol. 85 (1995), pp. 1706-1709; R.T. Chen et al., "The Vaccine Adverse Event Reporting System (VAERS)," Vaccine, vol. 12 (1994), pp. 542-550; and R.T. Chen, "Special Methodological Issues in Pharmacoepidemiology Studies of Vaccine Safety," Ed. B.L. Strom, Pharmacoepidemiology (Chicester: John Wiley and Sons, 1994).

[6]D.A. Kessler, "Introducing MEDWatch: A New Approach to Reporting Medication and Devise Adverse Effects and Product Problems," Journal of the American Medical Association, vol. 269 (1993), pp. 2765-2768, and H.D. Scott, et al., "Rhode Island Physicians' Recognition and Reporting of Adverse Drug Reactions," Rhode Island Medical Journal, vol. 70 (1987), pp. 311-316.

Women Report More Adverse Reactions Than Men

In addition to DOD's reporting of adverse events to VAERS, DOD has conducted three efforts to actively collect data that can be used to examine gender differences in adverse reactions after servicemembers have received the anthrax vaccine. The first effort, conducted by USAMRIID, included data on shots given at Fort Detrick during 1977-96. The second effort, conducted in 1999 by a DOD physician stationed in Korea, was a survey given to servicemembers when they reported for their initial six-dose schedule of shots; it asked questions about their reactions to the previous shot. Results from this effort reflect the researcher's preliminary analysis of the data. The third effort, conducted in 1998-99 at Tripler Army Medical Center, Hawaii, included a survey on adverse reactions to the first three shots when individuals reported for their fourth shot and later included a follow-up survey on adverse reactions to the fourth shot. None of the efforts used a control group. Also, all three relied on self-reported data and were not adjusted for factors such as occupation, physical activity level, and age. Because of differences in the way data were collected, reaction rates are not strictly comparable among the different efforts.

According to the data gathered in all three efforts, a higher proportion of females reported reactions to the anthrax vaccine than did their male counterparts. Tables 1 and 2 summarize the rates of reported reactions to the vaccine during the two efforts at Fort Detrick and in Korea. The researchers at Fort Detrick determined that the statistical difference was significant[10] in the reported reaction rates of males and females after their second and subsequent shots. The researchers for the other two efforts did not report whether the difference in reported reaction rates was statistically significant.

[10]Tests of significance deal with the question of whether a difference is real or just a chance variation. It does not deal with the question of how important the difference is or what caused the difference. The test does not check the design of the study. If a test is significant at the 99-percent level, the results could be due to chance 1 percent of the time.

Table 1: Gender Differences in the Reported Rate of Reactions to the Anthrax Vaccine, From Fort Detrick Data (1977-98)

Dose number	Males percent (number of doses)	Females percent (number of doses)
First	3.75 (1,013)	3.86 (259)
Second	3.06[a] (979)	7.29[a] (247)
Third	1.71[a] (938)	5.06[a] (237)
Fourth and subsequent	3.40[b] (5062)	7.06[b] (737)

Note: As a result of GAO's recalculation, the percentages reflect minor differences from those reported by the researcher.

[a]The gender difference in reported reaction rates is statistically significant at the 99-percent confidence level.

[b]The gender difference in reported reaction rates is statistically significant at the 99.99-percent confidence level.

Source: DOD.

Table 2: Preliminary Data on Gender Differences in the Reported Rate of Reactions to the Anthrax Vaccine, From Korea Survey (1999)

Dose number	Males percent (number of doses)	Females percent (number of doses)
First	42.1 (2036)	71.8 (495)
Second	44.4 (1953)	74.0 (474)

Note: This represents a preliminary analysis of the data by the researcher, and at the time of our review, data on reactions to the third shot were not available.

Source: DOD.

The data gathered in Korea shows that after the first two shots, more than twice the proportion of women reported the systemic reactions of fever, malaise, or chills than men (see table 3).

Table 3: Preliminary Data on Gender Differences in Systemic Reactions, From Korea Survey (1999)

Numbers in percent

	Fever		Malaise		Chills	
Dose number	Male	Female	Male	Female	Male	Female
First	0.9	2.8	6.0	15.6	1.5	5.5
Second	1.7	4.8	7.1	15.4	1.9	4.0

Note: This represents a preliminary analysis of the data by the researcher, and at the time of our review, data on reactions to the third dose were not available.

Source: DOD.

The Tripler effort also demonstrates gender differences in reported reactions (see table 4). These data show that a higher proportion of women reported making an outpatient visit after a vaccination than their male counterparts. In addition, more than twice the proportion of women reported that they missed one or more duty shifts after their vaccinations than did males.

Table 4: Gender Differences in Reported Local Reactions, Outpatient Medical Visits, and Missed Duty, From Tripler Army Medical Center Survey (1998-99)

Numbers in percent

Reaction	Dose 1	Dose 2	Dose 3	Dose 4
Moderate to severe redness				
Male	17.5	20.4	17.2	31.6
Female	49.1	46.9	51.4	39.8
Swelling of lower arm				
Male	9.7	9.5	9.2	7.1
Female	13.4	13.5	13.0	8.4
Pain limiting motion of elbow				
Male	9.7	8.7	7.6	7.9
Female	17.1	13.5	11.7	8.6
Localized itching				
Male	25.2	25.7	24.5	27.7
Female	62.6	60.4	57.9	39.2
Lump or knot				
Male	63.9	64.4	60.5	65.5
Female	89.9	87.8	83.6	73.2
Muscle soreness				
Male	66.6	64.7	61.8	60.4
Female	79.7	76.4	70.8	61.6
Outpatient medical visit				
Male	5.3	2.0	2.7	
Female	10.0	13.8	3.9	[a]
Missed one or more shifts of duty				
Male	2.2	2.0	0.9	
Female	5.0	5.1	3.9	[a]

Note: Between 421 and 471 men and between 74 and 83 women responded to each question on the survey.

[a]Data were not available.

Source: DOD.

Status of Federal Efforts to Develop a Second-Generation Anthrax Vaccine

According to researchers and the Institute of Medicine of the National Academy of Sciences, the current anthrax vaccine has several disadvantages.[11] The amount of protective antigen in the vaccine is variable from lot to lot because the manufacturing process cannot precisely quantify the antigen.[12] Also, there is some evidence that the current anthrax vaccine may have diminished efficacy against certain virulent strains of anthrax (*Bacillus anthracis*). And the required six-dose schedule and annual boosters complicate the logistics of inoculating all of DOD's troops and increase the cost of the vaccine program.

According to DOD research, a second-generation recombinant vaccine created with a process that is fully defined, quantified, and controlled in terms of protective antigen, can be developed and that fewer doses could be required.[13] DOD research also shows that a recombinant vaccine could be created using modern techniques to produce highly purified protective antigen. This process not only would remove unwanted bacterial proteins but also would enable precise amounts of the purified protective antigen to be incorporated into the vaccine. A further potential benefit is that, compared to the current vaccine, the protective antigen could be produced in a nonspore-forming organism. As a result, according to DOD officials, manufacturers could use their buildings and equipment to produce the anthrax vaccine as well as other vaccines.

In 1995, USAMRIID developed a new recombinant protective antigen vaccine against anthrax. This vaccine was successfully tested in experiments using animals but has not been tested on humans. USAMRIID officials stated that this testing would take about 3 years, and FDA approval of the manufacturing of the vaccine could take years longer. DOD considers further development of this vaccine candidate an unfunded requirement. In response to the perceived threat of bioterrorism, the

[11]P.S. Brachman and A. Friedlander, "Anthrax," Vaccines, ed. S.A. Plotkin and E.A. Mortimer, Jr., (Philadelphia: W.B. Saunders Company, 1994), p. 737, and Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response, Institute of Medicine (Washington, D.C.: National Academy Press, 1999), p. 135.

[12]Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response, Institute of Medicine (Washington, D.C.: National Academy Press, 1999), p. 135.

[13]B. Ivins et al., "Immunization Studies with attenuated strains of *Bacillus anthracis*," Journal of Infection and Immunity, vol. 52 (1986), pp. 454-458; B.E. Ivins, "The Search for a New-Generation Human Anthrax Vaccine," Clinical Immunology Newsletter, vol. 9 (1988), pp. 30-32; and Y. Singh et al., "Study of Immunization Against Anthrax with the Purified Recombinant Protective Antigen of *Bacillus anthracis*," Journal of Infection and Immunity, vol. 66 (1998), pp. 3447-3448.

Department of Health and Human Services' National Institute of Allergy and Infectious Diseases formed a working group to develop and test a second-generation anthrax vaccine. The Institute recently funded several active research grants in this regard.

In developing a second-generation recombinant anthrax vaccine, researchers believe they will need to address the additional problem of whether strains of deliberately engineered or naturally occurring anthrax can overcome the protective immunity of such a vaccine. A variation in virulence among anthrax strains and a variation in relative resistance to vaccine-induced immunity has been observed in experiments on animals. However, the reasons for the variation have not been scientifically proven.

Mr. Chairman, this concludes my formal statement. If you or other members of the Subcommittee have any questions, we will be pleased to answer them.

Contacts and Acknowledgments

For future contacts regarding this testimony, please contact Kwai-Cheung Chan at 512-3652. Individuals making key contributions to this testimony included Sushil Sharma, Howard Deshong, and Nancy Ragsdale.

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MEMORANDUM FOR SECRETARY OF THE ARMY

SUBJECT: Notice of GAO Final Letter Report without Recommendations

Reference: GAO Final Report, GAO/NSIAD-00-54R, "Safety and Efficacy of the Anthrax Vaccine," November 4, 1999 (GAO Code 713057/OSD Case 1916-A)

The GAO recently forwarded copies of the referenced letter report to the DoD. A copy is enclosed for your information and review. The DoD was not provided an opportunity to comment on a draft of the report.

The GAO did not perform additional review work in the DoD to prepare the letter. Rather, the GAO drew from information developed under prior GAO reviews. It also reflects information that was included in the referenced GAO testimonies presented earlier this year.

As the final report contains no recommendations, DoD comments are not required. However, if you determine that an official DoD response to the letter report is needed, please advise us by December 17 and we will jointly establish a schedule for developing and coordinating the proposed response. Otherwise, we will close the case without further action.

We are also providing copies of the final report and this memorandum to the collateral action officers (CAOs) and to your action officer, (b)(6). If you have questions, please contact my action officer, Mr. (b)(6) at (b)(6), e-mail (b)(6)@dodig.osd.mil. If he is unavailable, contact Mr. (b)(6) at (b)(6). Our fax number is (b)(6).

(b)(6)
Technical Director for
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National Security and
International Affairs Division

B-284044

November 4, 1999

The Honorable Steve Buyer
Chairman, Subcommittee on Military Personnel
Committee on Armed Services
House of Representatives

Subject: Summary of GAO's Findings on the Safety and Efficacy of the Anthrax Vaccine

Dear Mr. Chairman:

Concerns have been raised about the Department of Defense's (DOD) anthrax immunization program since DOD began vaccinating its 2.4 million active duty and reserve members in 1998. At your request, we are providing you with information we have previously reported concerning (1) the need for a six-shot regimen and annual booster shots, (2) the long- and short-term safety of the vaccine, (3) the efficacy of the vaccine and (4) the extent to which problems the Food and Drug Administration (FDA) found in the vaccine production facility in Michigan could compromise the safety, efficacy, and quality of the vaccine.[1] We are also providing for you the three testimonies that are the source of the information we are providing you today.

BACKGROUND

The original anthrax vaccine was developed in the 1950s and was first produced on a large scale by the Merck Pharmaceutical Corporation. In 1962, a study was published on the safety and efficacy of the Merck vaccine against cutaneous anthrax in wool mill workers. Later, the Michigan Department of Public Health took over as the vaccine's producer but the manufacturing process, the strain, and the ingredients differed from the Merck vaccine. This changed vaccine, which is the vaccine currently being given to U.S. military personnel, was licensed in 1970 by the Division of Biologics Standards, National Institutes of Health. FDA is currently responsible for licensing new vaccines and ensuring vaccine safety.

[1] *Medical Readiness: Safety and Efficacy of the Anthrax Vaccine* (GAO/T-NSIAD-99-148, Apr. 29, 1999); *Medical Readiness: Issues Concerning Anthrax Vaccine* (GAO/T-NSIAD-99-226, July 21, 1999); and *Anthrax Vaccine: Safety and Efficacy Issues* (GAO/T-NSIAD-00-48, Oct. 12, 1999).

As of July 1999, more than 315,000 service members had received at least one dose of the vaccine. Initial immunization consists of three shots given at 0, 2, and 4 weeks followed by three additional shots given at 6, 12, and 18 months.

SUMMARY OF OUR KEY FINDINGS

Our work has identified that data on the current immunization schedule and the vaccine's safety and efficacy is limited in some areas. Moreover, FDA has identified some deficiencies concerning the manufacturer's controls over the vaccine's quality. DOD and the company that purchased the vaccine production facility in 1998 have several efforts planned or underway to address these issues.

Data on the Need For Six Shots and Annual Boosters Are Unavailable

No studies have been done to determine the optimum number of doses of the anthrax vaccine. A three-dose regimen was used initially for the original vaccine based on a regimen developed using animals in the early 1950s. However, the number of doses was increased to six after three people who received three doses of the vaccine became infected. The licensed vaccine adopted this schedule and DOD has followed this regimen. Although annual boosters are required, the need for annual booster shots has not been evaluated.

Long-term and Short-term Safety of the Vaccine

The long-term safety of the licensed vaccine has not been studied. However, DOD is designing studies to examine the vaccine's long-term effects.

With regard to short-term safety, according to FDA officials, data from two studies conducted prior to licensing of the current anthrax vaccine are difficult to interpret since one study used the original vaccine, and part of the study population in the other study had already received the original vaccine.

Post-licensing data on safety are limited because only a limited number of doses—about 68,000—were distributed by the manufacturer from 1974 through 1989. Also FDA did not establish its Vaccine Adverse Event Reporting System (VAERS) until 1990. This system, which DOD uses, alerts FDA and the Centers for Disease Control to increases in adverse events.[2] However, it is a passive surveillance system, which means that FDA and the Centers for Disease Control must rely on vaccine recipients or their health care providers to report any adverse events after receiving the vaccine. Studies show that adverse events are reported significantly less frequently with passive surveillance systems than they would be in an active system where vaccine recipients are monitored to find out if they had any adverse effects.

[2]Clinical events reported to a passive surveillance system such as FDA's are usually termed adverse events rather than adverse reactions because there is usually insufficient evidence that the vaccine, rather than other health conditions, caused the reported events.

DOD has recently conducted two studies using active monitoring where DOD personnel contacted the vaccine recipients directly to find out if they had any adverse reactions. Data from these studies, conducted in 1998 and 1999, showed that a higher proportion of women reported both local and systemic reactions to the vaccine than their male counterparts. In addition, data from one of the studies showed that more than twice the proportion of women reported that they missed one or more duty shifts after their vaccinations than did males.

Vaccine Efficacy

A study on the efficacy of the original vaccine concluded that it provided protection to humans against anthrax penetrating the skin but did not provide sufficient data to determine its effectiveness against anthrax that was inhaled. Beginning in the late 1980's, DOD began studying the efficacy of the licensed anthrax vaccine on animals, using guinea pigs, rabbits, and monkeys. All of these studies support the view that in these animals, the licensed vaccine can protect against exposure to some but not all strains of anthrax either by inoculation or inhalation. It is clear, however, that animal species differ in their susceptibility. Studies of guinea pigs show that some anthrax strains are more or less resistant to vaccines for humans but are protected by the live spore veterinary vaccine.

Research using monkeys showed for the first time that monkeys could be protected against aerosol exposure. However, several studies have shown no direct comparison of immunity in humans to that in monkeys. DOD officials recognize that correlating the results of animal studies to humans is necessary and told us that DOD is planning research in this area. DOD also plans to develop a second generation anthrax vaccine, and as part of this effort, it will need to address whether strains of deliberately engineered or naturally occurring anthrax can overcome the protective immunity of such a vaccine.

Problems with the Vaccine Manufacturing Process

With regard to the manufacturing process, it is important to note that the quality of a vaccine is closely linked to its manufacturing process, which must be rigorously controlled to ensure that batches of vaccines produced on different occasions are of consistent quality. Accordingly, vaccine production is highly regulated to ensure that the products are of consistent quality and safe and effective for the purpose(s) for which regulatory approval was granted. Until 1993, FDA inspectors did not inspect the Michigan Department of Public Health facility where the anthrax vaccine was made. According to FDA, access was not granted because its inspectors had not been vaccinated against anthrax. DOD conducted inspections, however, and identified deficiencies during a March 1992 inspection.

FDA's inspections of the vaccine production facility in 1996 and 1998 found a number of deficiencies. The deficiencies that FDA identified in its February 1998 inspection fall broadly into two categories: those that might affect only one or a limited number of batches that were produced and those that could compromise the

safety and efficacy of any or all batches. In 1998, the manufacturer shut down the facility for renovation. A new company, which purchased the facility in mid-1998, is addressing the issues identified by FDA.

If you need additional information on these issues, please call me on (b)(6) or (b)(6) Assistant Director, on (b)(6)

Sincerely yours,

(b)(6)

Director, Special Studies and Evaluations

(713057)

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INSPECTOR GENERAL
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FEB 8 2000

MEMORANDUM FOR SECRETARY OF THE ARMY

SUBJECT: Notification of GAO Review

Reference: GAO Letter, "DoD's Anthrax Vaccine Immunization Program," January 14, 2000 (GAO Code 713059)

On January 27, 2000, the GAO announced plans to begin the referenced review, which is the latest in a series of reviews dealing with various aspects of the anthrax vaccine issue. The referenced review was mandated in the FY 2000 Defense Appropriations Conference Report and will address (1) the program's effects on military morale, retention, and recruiting, (2) civilian costs and burdens associated with adverse reactions of Reserve members, (3) the adequacy of long and short term health monitoring, and (4) an assessment of the anthrax threat. A copy of the GAO letter is enclosed.

In accordance with DoD Directive 7650.2, we have identified your office as DoD's primary action office (PAO) for the review. Enclosed is an information sheet that explains PAO and collateral action office (CAO) responsibilities and provides guidance for working with GAO.

We will be coordinating with your action officer to arrange an entrance conference so that the GAO can discuss its objectives and its audit plan for the review. Each CAO will be notified when the meeting arrangements are made and should plan to send a representative to the entrance conference, as appropriate. In addition, each CAO should provide us and the PAO listed below with the name, e-mail address, phone and fax numbers, and mailing address of their action officer, if they have not already done so.

Your action officer for this case is COL Fred Gerber, (b)(6), Office of the Army Surgeon General. If you have questions, please contact my action officer, Mr. (b)(6) at (b)(6), e-mail (b)(6) @dodig.osd.mil>. If he is not available, please call Mr. (b)(6) at (b)(6). Our fax number is (b)(6).

(b)(6)
Technical Director for
Audit Followup & GAO Affairs

Enclosures: GAO notification letter
Information sheet

Distribution: See next page

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United States General Accounting Office
Washington, DC 20548

National Security and
International Affairs Division

January 14, 2000

The Honorable William Cohen
The Secretary of Defense

Attention: DOD Office of the Inspector General
Deputy Director for GAO Affairs

Dear Mr. Secretary:

As mandated in the Fiscal Year 2000 Defense Appropriations Conference Report (106-371), the General Accounting Office is initiating a review of DOD's Anthrax Vaccine Immunization Program (AVIP). Specifically, we have been asked to report on (1) the program's effects on military morale, retention, and recruiting, (2) the civilian costs and burdens associated with adverse reactions of reserve component members, (3) the adequacy of long/short term health monitoring, and (4) the assessment of the anthrax threat. The work will be conducted under assignment code 713059.

If you should have any questions regarding this work, please contact me on (b)(6) (b)(or my Assistant Director, (b)(6), on (b)(6).

Sincerely yours,

(b)(6)

Director, Special Studies
and Evaluations

INFORMATION SHEET
(Revised 11/96)

DoD PROCEDURES FOR PROCESSING, MONITORING, AND MANAGING GENERAL ACCOUNTING OFFICE (GAO) SURVEYS AND REVIEWS
(References: DoD Directives 7650.1, 7650.2)

1. GAO Notification Letters of Surveys and Reviews

Before contacting DoD officials to initiate new survey/review work, the GAO has agreed to issue a notification letter to the Secretary of Defense, Attention: DIG, DoD, Deputy Director for GAO Affairs. The notification letter includes the objectives of the planned work and a six digit GAO assignment code. When the GAO staffs contact DoD personnel, they should be asked if they have properly announced their work with a notification letter through the OIG, DoD. The GAO staffs should be prepared to provide a copy of the notification letter on request. The DoD personnel should verify that the GAO work has been announced within the Department. They can contact the appropriate component audit liaison, collateral action office, or this office. If the GAO work has been announced, this office can telefax a copy of the GAO notification letter along with the DoD official announcement. Meetings should not be scheduled nor information released until the GAO work is properly announced. All questions or special arrangements on GAO surveys and reviews should be coordinated with GAO Affairs-- the address, phone number and telefax number is as follows:

Office of the Inspector General, DoD
Deputy Director for GAO Affairs
400 Army Navy Drive, Room 539A
Arlington, VA 22202-2884

Commercial:	(b)(6)	DSN:	(b)(6)
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2. GAO Notices of Visit and Security Clearances

Besides the GAO notification letter, the GAO should notify appropriate agency officials about 10 days before any proposed visit using the "Notice of GAO Visit" form. The GAO should provide a copy of that form to GAO Affairs. In cases of unusual urgency, the GAO should make arrangements with the agency officials by phone. The responsibility for assuring that a GAO representative has the proper clearance to review/receive classified information rests with the DoD individual providing the information.

If a GAO representative does not provide the notice of visit or if the DoD contact needs additional information, the assigned GAO Affairs action officer should be contacted for assistance.

3. Tasking of GAO Surveys and Reviews

On receipt of a GAO notification letter, GAO Affairs identifies the primary action office (PAO) and a PAO point of contact through discussions with DoD component audit liaison offices and DoD officials. For most surveys/reviews, the PAO is at the Office of the Secretary of Defense (OSD) staff level. The OIG issues a tasking memorandum assigning responsibility for the GAO effort to the PAO with copies to identified collateral action offices (CAO).

The DoD component audit liaisons receive action or information copies of the GAO Affairs tasking memorandum for further distribution to the appropriate offices. The memorandum is given wide distribution to help identify action offices and inform them of the GAO review. This is important so that the correct DoD components attend the GAO entrance, interim status, and exit meetings.

4. GAO Entrance, Interim Status, and Exit Meetings

The GAO Affairs action officer will work with the PAO and the CAO to arrange a joint, headquarters level entrance meeting. The purpose of the entrance meeting is to provide the PAO, CAOs and other DoD components with details about the GAO review. It is an opportunity to ask questions and provide the GAO the names of DoD points of contact.

The PAO, CAO, and GAO Affairs should work together to help ensure that (1) interim status and exit meetings are held, when appropriate, (2) the PAO, CAO, and OIG action officers attend such meetings, and (3) the meetings include all key DoD officials. The PAO and CAO action officers, through their ongoing contacts with the GAO, should be alert to the need for interim status and exit meetings, and should advise GAO Affairs in advance so that appropriate actions can be taken to facilitate the meeting.

Before any interim status or exit meeting at the headquarters level, the GAO usually holds separate meetings at the field activity level. Action officers at the field level should advise the PAO of such meetings through the component CAO or the component audit liaison.

The purpose of interim status and exit meetings with the GAO is to provide the DoD an opportunity to discuss the accuracy and completeness of the GAO work results and to avoid surprises to the DoD. The GAO Affairs action officer will normally ask for an exit meeting before the GAO issues a draft or final report.

The interim status and exit meetings are particularly important because these meetings may be the only DoD opportunity to comment on GAO work that could result in budget reductions or program direction decisions by the Congress. The GAO Affairs action officer will ask the GAO to provide work products (fact sheets, draft reports, advance testimony, or other written documents not officially issued) before the meetings to better prepare DoD officials in providing accurate and complete comments.

The DoD officials' comments provided at interim status and exit meetings are unofficial. The only official DoD comments (whether oral or written) are those that are properly coordinated with all the appropriate DoD offices through the OIG, DoD.

5. **Access to Records**

Under 31 U.S.C. 716(a), the GAO has broad access rights. The DoD Directives 7650.1 and 7650.2 provide the DoD policy and procedures regarding GAO access to records. Both oral and written requests from GAO representatives should be handled informally. Efforts should be made to accommodate the GAO needs at the lowest organization level possible.

If it is unclear what information the GAO is requesting orally, it may be appropriate to ask the GAO to put its request in writing, listing the specific documents requested and explaining the need in connection with the survey or review. While oral requests should be acceptable, written requests can help clarify the information desired.

The DoD components and action officers should not deny the GAO access without further checking through the appropriate channels. Depending on the document(s) requested, that could include: officials in the chain of command, the component legal office, the audit liaison office, the PAO, and the appropriate OSD general counsel's office. The GAO Affairs action officer will provide assistance as necessary, working with DoD component liaison officials in processing action requests and arranging meetings between DoD and GAO representatives.

If informal attempts fail and the GAO decides to pursue its request, the Comptroller General, by law, may issue a formal demand letter to the Secretary of Defense. By law, the DoD has 20 days to respond to the GAO. If after 20 days full access has not been granted, the Comptroller General may file a written report with the President of the United States, the Director of the Office of Management and Budget, and the Attorney General. Following that, the Comptroller General may seek a court order to compel the release of Federal records or subpoena nonfederal records.

6. GAO Questionnaires and other Data Collection Instruments

All questionnaires and other data collection instruments should be coordinated with the Deputy Director for GAO Affairs before distribution within the DoD. Any DoD component or official receiving GAO questionnaires or other data collection instruments should ask the GAO staff if they have properly coordinated the instrument through the OIG. Responses should not be provided nor information released until the GAO has properly coordinated its work.

7. Termination of Surveys/Reviews

The GAO should notify the DoD through the Deputy Director for GAO Affairs when it decides to terminate a survey or review without issuing an external report. The GAO sometimes overlooks issuing a termination letter to the DoD. If the PAO or CAO action officers learn that GAO work is terminated, they should alert GAO Affairs.

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FEB 9 2000

NOTICE OF GAO ENTRANCE CONFERENCE

To addressees, per fax sheet:

REFERENCE: GAO audit "DoD's Anthrax Vaccine Immunization Program," (GAO Code 713059)

- The entrance conference with the GAO for the referenced new review has now been set. The meeting will be Tuesday, February 15, at 14:00 in room 640, Skyline 6. The DoDIG and Army request you send a representative to this important meeting.

- This entrance conference is our opportunity to better understand GAO's objectives in this latest anthrax review and to influence the direction the GAO work may take. Please be prepared for an open discussion of how the GAO can best achieve their objectives.

- The DoD primary action officer is (b)(6), Army Surgeon General's office, (b)(6). His fax is (b)(6).

Please call myself or COL Gerber if you have any questions.

(b)(6)
PHONE: (b)(6)
FAX:
E-mail Address: (b)(6)@dodig.osd.mil>

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INSPECTOR GENERAL
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October 17, 2000

MEMORANDUM FOR SECRETARY OF THE ARMY

SUBJECT: General Accounting Office Testimony, GAO-01-92T, "ANTHRAX VACCINE: Preliminary Results of GAO's Survey of Guard/Reserve pilots and Aircrew Members," dated October 11, 2000 (GAO Code 713048/GAO Code 2098)

On October 11, 2000, the General Accounting Office (GAO) presented the subject testimony before the House Committee on Government Reform. A copy is enclosed, The testimony was presented by Mr. Kwai-Cheung Chan, Director, Applied Research and Methods. The GAO issued the testimony under Code 713048 whichrewmains open. Additional products are expected from this GAO effort. The testimony is being provided for information only. No action is required.

If you have any questions, please call my action officer, Ms. (b)(6) on (b)(6) If she is not available, call Mr (b)(6) (b)(6) Our fax number is (b)(6)

(b)(6)

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United States General Accounting Office

GAO

Testimony

Before the Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at 10:00 a.m.
Wednesday,
October 11, 2000

ANTHRAX VACCINE

Preliminary Results of GAO's Survey of Guard/Reserve Pilots and Aircrew Members

Statement of Kwai-Cheung Chan, Director
Applied Research and Methods

GAO-01 -92T

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the preliminary results of the ongoing work we are doing at your request on the Department of Defense's (DOD) Anthrax Vaccine Immunization Program. As you know, numerous concerns have been raised about the program since DOD began vaccinating its 2.4 million active duty and reserve members in 1998.[1] Of particular concern was the program's potential impact on the Air National Guard and Air Force Reserve's retention of trained and experienced personnel.

In response to your request, we are examining the impact of the vaccination program on retention, the basic views of Guard and Reserve pilots and other aircrew members regarding the program, and the extent of adverse reactions experienced by anthrax vaccine recipients. These components provide essential support to critical defense operations on a worldwide basis. They provide strategic and tactical airlift, aerial refueling, aeromedical evacuation, and augment DOD's overall fighter force.

To conduct our work, we developed, pretested, and validated a questionnaire that was sent to 1,253 randomly selected Guard and Reserve pilots and other aircrew members. These included pilots, flight engineers, loadmasters, navigators, crew chiefs, and others. Collectively, they represent about 13,000 servicemembers of the total fiscal year 1999 end strength of approximately 176,000, which includes about 29,000 officers and 147,000. enlisted personnel. We shared the draft questionnaire with DOD program officials and their medical experts and incorporated appropriate comments and suggestions. We administered the survey on an anonymous basis between May and September 2000. The overall response rate was 66 percent. Our methodology is described in detail in appendix 1. The information we are presenting today has been weighted to represent the population of Guard and Reserve pilots and other aircrew members who are currently active and assigned to a unit.

Summary

While many factors can influence an individual's decision to leave the military, surveyed Guard and Reserve pilots and aircrew members cited the anthrax immunization as a key reason for leaving or otherwise changing their military status. Since September 1998, an estimated

[1] We have previously reported on a *number of* concerns regarding the safety and efficacy of the anthrax vaccine and other *related* matters. (See appendix III).

25 percent of the pilots and aircrew members of the Guard and Reserve in this population transferred to another unit (primarily in a non-flying position), left the military, or moved to inactive status. While several reasons influenced their decision when asked to rank the one most important factor, the anthrax immunization was the highest, followed by other employment opportunities, and family reasons. Further, about one in five (18 percent) left before qualifying for military retirement benefits. Additionally, 18 percent of those still participating in or assigned to a unit reported their intentions to leave within the next 6 months. These individuals also ranked the anthrax immunization as the most important factor for their decision to leave, followed by unit workload and family reasons. Each of these groups-those who have left and those who plan to do so-had accumulated an average of more than 3,000 flight hours, which symbolizes a seasoned and experienced workforce.

On our survey, most Guard and Reserve pilots and aircrew members expressed a positive view toward general immunizations. Almost three out of four believe that immunizations are effective (74 percent), and more than half believe immunizations to be safe (60 percent). However, their views on the anthrax immunization program and potential biological warfare immunizations in the future are very different. For example, two out of three reported little or no support for the anthrax program (65 percent). Despite DOD's high-visibility campaign to educate servicemembers, about the anthrax immunization program, only about one in four believes that the information provided on DOD's anthrax Web site is timely (25 percent), 19 percent believe it to be complete, and 17 percent believe it to be accurate. Just 1 in 10 (11 percent) believe the information to be unbiased. Further, three out of four indicated they would not or probably would not take the shots if the anthrax immunization program were voluntary (76 percent). Eighty-seven percent, or almost 9 out of 10, indicated they would or probably would have safety concerns if additional vaccines for other biological warfare agents were added to the military immunization program.

Forty-two percent of the respondents reported that they had received one or more anthrax shots. Of those taking the shots, 86 percent reported experiencing some type of local or systemic reactions, for example, a knot in the arm or joint pain. For some reactions, the reported duration was more than 7 days (for example, limited arm/body motion and joint pain). Some of these reactions could have implications for work performance. About one-third (36 percent) reported that they had been provided information concerning what action to take in the event of side effects or reactions. But 71 percent reported being unaware of the Food and Drug Administration's Adverse Events Reporting System which is a passive

surveillance system to alert the Food and Drug Administration and the Center for Disease Control and Prevention of adverse events that may be associated with licensed vaccines. Further, about 60 percent of those experiencing reactions had not discussed them with military health care personnel or their supervisors-some citing fear of the loss of flight status, possible adverse effects on their military or civilian careers, and ridicule as reasons for nondisclosure (49 percent).

Background

In December 1997, the Secretary of Defense announced that all U.S. forces would be inoculated against the potential use of anthrax on the battlefield. In August 1998, DOD began immunizing its 2.4 million U.S. military personnel-including active and reserve component personnel-with a licensed anthrax vaccine. This program is mandatory. Some members of the armed forces have expressed concerns regarding the safety and efficacy of the anthrax vaccine. Those refusing the vaccine have been disciplined under service-specific policies for disobeying a lawful order. Anecdotal information suggests that an unknown number of Reservists and National Guard members have resigned or transferred to units or non-flying positions that do not require anthrax vaccinations at this time. DOD does not collect uniform records on such changes in status.

Congress and the Department of Defense have become increasingly concerned about the readiness of U.S. armed forces. Key reasons for this concern are the increasing pace (tempo) of operations due to deployments, parts shortages and maintenance backlogs, and past problems in recruiting and retaining quality people. The reserve components are experiencing difficulties in filling their ranks with new recruits at a time when DOD is relying on them more heavily to support operations around the world. Specifically, the retention of pilots and other aircrew members has been and continues to be a problem that could impact readiness. The impact of an exodus of Guard and Reserve pilots and aircrew members would be significant. Without adequate numbers of pilots and aircrew, the Guard and Reserve could not support the active force in its worldwide operations. In addition, it costs the military an average of almost $6 million to train and develop a fully qualified experienced aviator, which the Air Force suggests takes about 9 years.

Anthrax Is a Key Factor Affecting Individual Decisions to Change Military Status

Twenty-five percent of the pilots and aircrew members of the Guard and Reserve we surveyed have transferred to another unit, left the military, or moved to inactive status. Of these, 25 percent ranked anthrax immunization as the most important factor influencing their decision to leave or transfer followed by other employment opportunities at 16 percent and family reasons at 16 percent. The general military immunization program was cited as the least important reason for a change in their military duty status. Further, about one in five (18 percent) left before they had qualified for a military retirement. Forty-three percent of those who separated or are no longer in military flying status because of the anthrax program indicated that they would or probably would consider returning to a unit or to military flying status if the anthrax vaccination program were not mandatory.

Of those who are still in Guard and Reserve units, 18 percent reported that they planned to leave the military within the next 6 months. Again, when asked to rank the most important factor for their decision to leave, the anthrax immunization was the most frequently reported reason (61 percent), followed by heavy unit workload and family reasons. Each of these groups (that is, those who left and those who intend to leave) had in excess of 3,000 flight hours, which symbolizes a seasoned and experienced workforce.

Anthrax Vaccine Immunization Program Is Not Widely Supported

Most Guard and Reserve pilots and aircrew members support immunization programs in general; however, relatively few appear to support the anthrax program or future immunization programs for other biological warfare agents. Almost three out of four (74 percent) of the pilots and aircrew members of the Guard and Reserve believe that immunizations in general are moderately to very effective, and 60 percent believe that immunizations are moderately to very safe. On the other hand, 65 percent, or two out of three servicemembers, reported little or no support for the anthrax immunization.

DOD has employed a high-visibility campaign to educate servicemembers about the program and has taken steps to address the controversy surrounding the program. In addition, it expanded its communications efforts by updating the program's Internet site, opening a toll-free anthrax information line and forming a speakers' bureau of anthrax experts. DOD also updated briefings for installation leaders and medical personnel to provide more detailed information on the anthrax threat. We had previously reported in October 1999 that servicemembers were not

satisfied with the information provided to them.[2] In our current survey, relatively few respondents reported being moderately to very satisfied with the information provided at the DOD Web site. For example, only 19 percent were satisfied with the completeness of the information 17 percent were satisfied with the information's accuracy, and 25 percent were satisfied with its timeliness. Just 11 percent were satisfied that the information was unbiased.

In terms of all information provided by DOD to servicemembers on the anthrax program through the Web site and other sources, 39 percent indicated that they were moderately to very satisfied with the information provided on the military anthrax threat. On the other hand, only 12 percent were moderately to very satisfied with the information received about the vaccine's long-term safety.

Seventy-six percent of survey respondents indicated that they would not or probably would not take the shots if the anthrax immunization program were voluntary. Just 11 percent reported they would or probably would take the shot on a voluntary basis. About 13 percent were uncertain. Further, 87 percent reported that they would or probably would have concerns about safety if additional vaccines for other biological warfare agents were added to military immunization requirements.

Most Adverse Events to Anthrax Immunizations Are Not Reported

Adverse events are adverse outcomes for which a cause and effect relationship with an exposure (to a vaccine or a medication) has not yet been determined. DOD has used data from the Vaccine Adverse Event Reporting System to monitor adverse events (or reactions) to anthrax vaccinations. It is a 'passive" surveillance system, which relies on vaccine recipients or their health care providers to report any adverse events after receiving the vaccine. Studies show that significantly fewer adverse events are reported under a passive system when compared to an active surveillance system in which vaccine recipients are actively monitored to identify and track any adverse reactions to a vaccine.

Forty-two percent of the respondents reported that they had received one or more anthrax shots. Of these, 86 percent reported experiencing side effects or adverse reactions. About 60 percent indicated that they had not discussed any side effect to the anthrax vaccine with military health care personnel or their supervisors-some (49 percent) citing as their reasons

[2]Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program (GAO/NSIAD-00-36, October 1999).

fear of losing their flight status, adverse effects on their military or civilian careers, and ridicule. Seventy-one percent reported that they were unaware of the Food and Drug Administration's Vaccine Adverse Events Reporting System. Slightly less than 6 percent of those who had a reaction reported to this system.

Our survey showed that for some local and systemic reactions (for example, a knot or lump in the vaccinated arm and joint pain), the reported duration was more than 7 days. (See table 1 in app. II for a list of reported reactions). The prevalence and duration of the reported symptoms varied widely. A number of reported symptoms are expected reactions to the anthrax vaccine; however, their frequency and duration was more than DOD reported (0.007 percent). For example, two out of three reported burning in the vaccinated arm (79 percent) and a knot or a lump in the vaccinated arm (82 percent). Also, 10 percent reported swelling in the arm lasting for more than 7 days, and 6 percent reported arm pain and limited motion for more than 7 days. Six percent reported extreme fatigue, and 7 percent reported joint pain lasting for more than 7 days.

These reported reactions are significant because they could potentially impact individual ability to carry out military duties. However, 60 percent of those who experiencing reactions had not discussed them with military health care personnel or their supervisors. Forty-nine percent did not report because the reactions were not severe enough; however, another 49 percent did not report because of the fear of losing flight status, possible adverse effects on their military and civilian careers, and a fear of ridicule. Since many **individuals** are not reporting their reactions to military medical personnel or to the Vaccine Adverse Events Reporting System, the actual duration, the extent or impact on units and individuals, and the ultimate resolution of these reactions are unknown.

Because we had limited time to analyze all of the data we obtained, we will provide additional detailed analyses of the data to the **Committee** in a later report. Other issues such as impact of anthrax vaccine program on morale and quality of life will also be addressed in that report.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions you have at this time.

Contacts and Acknowledgments

For future questions regarding this testimony, please contact Kwai-cheung Chan at (202) 512-3652. Other individuals making key contributions to this testimony includes **Sushil** K. Shanna, Ph.D., **DrPH.** Foy D. Wicker and Stanley J. **Kostyla.**

Scope and Methodology

The best way to reliably assess the pulse and views of military members is by surveying a representative sample of personnel. This year, we developed and administered such a survey that was designed to obtain the views of selected Air National Guard and Air Force Reserve personnel regarding issues associated with the DOD's Anthrax Vaccine Immunization Program (AVIP). The survey was mailed in May 2000 to a random sample of 1,258 personnel. As of September 7, 2000,829 individuals had completed and returned the survey. Our work was conducted in accordance with generally accepted government auditing standards.

Questionnaire Development

The survey was developed with the assistance of discussion groups made up of pilots and other aircrew members of the Air National Guard and Air Force Reserve. It was pretested at **Andrews** Air Force Base, Maryland, and further pretested and refined at Guard and Reserve units located in Hartford, Connecticut; **Newburg**, New York; Madison, Wisconsin: Battle Creek Michigan; Memphis, Tennessee; Travis Air Force Base, California; March Air Force Reserve Base, California; Fort Wayne, Indiana; and, Dover, Delaware

Sample Construction

The sample consisted of 1,253 Air National Guard and Air Force Reserve aircrew personnel who were in the service at any time between September 1998 and February 2000. Our sample was drawn from pilot and aircrew member populations provided by the Air National Guard and Air Force Reserve in early 2000. In addition the Anthrax Vaccine Immunization Program **Office** provided information as to vaccination status. For the sample design, personnel in our universe were categorized by two factors: military status (left versus on board) and vaccine status (shot versus no shot). The sample was adjusted for groups with differing expected rates of survey completion and adjusted to provide a level of precision of ± 7 percentage points.

Survey Administration

As of September 7, 2000, we had received 828 responses from eligible respondents, an overall response rate of 66 percent. We used a contractor to create a database based on reported responses. We validated the data provided to us by the contractor to ensure accuracy.

Weighting Responses and Potential Nonresponse Bias

The survey responses were weighted to reflect the Air National Guard and Air Force Reserve population for the survey. This weighting procedure adjusts for the different proportions of individuals sampled from each cell and the actual response rate for that cell in the sample design. The survey results assume that nonrespondents would have answered like respondents. This assumption involves some unknown risk of nonresponse bias. Weighting can be used to statistically adjust for differing sampling rates and response rates; however, weighting cannot adjust for possible differences between those who do and those who do not respond to a survey.

Prevalence of Local and Systemic Adverse Reactions by Duration

Type of reaction	<1 Day	1-3 Days	4-7 Days	> 7 Days	Total
Local	Percent	Percent	Percent	Percent	Percent
Redness 2.5 inches or less	21	20	7	5	53
Redness >2.5 inches	5	12	10	6	33
Swelling in arm	16	16	11	10	55
Burning in arm	60	14	3	3	79
Arm Pain limited motion	20	22	11	6	59
Itching in arm	18	10	7	5	40
Knot/lump in arm	17	14	21	30	82
Systemic					
Chills	5	4	3	1	13
Fever	7	6	2	1	16
Extreme fatigue	6	7	3	6	22
Dizziness	1	2	1	1	5
Headaches	6	6	2	1	15
Blurred vision	1	1	0	1	3
Numbness in extremities	3	1	1	2	7
Joint pain	6	5	5	7	23
Memory loss	1	1	1	2	5
Blackouts	0	0	0	0	0
Ringing in ears	2	1	1	2	6
Insomnia	1	1	2	1	5
Nausea	3	2	2	0	7
Other	1	1	2	3	7

Source: GAO Survey, 2000.

Gulf War Illnesses: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved (GAO/NSIAD-99-5, Mar. 29, 1999).

Medical Readiness: Safety and Efficacy of the Anthrax (GAO/T-NSIAD-99-148, Apr. 29, 1999).

Contract Management: Observations on DOD's Financial Relationship with the Anthrax Vaccine Manufacturer (GAO/T-NSIAD-99-214, June 30, 1999).

Medical Readiness: Issues Concerning the Anthrax Vaccine (GAO/T-NSIAD-99-226, July 21, 1999).

Anthrax Vaccine: Safety and Efficacy Issues (GAO/T-NSIAD-00-48, Oct. 12, 1999).

Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program (GAO/-NSIAD-00-36, Oct. 1999).

Medical Readiness: DOD continues to Face Challenges in Implementing Its Anthrax Vaccine Immunization Program (GAO/T-NSIAD-00-157, Apr. 2000).

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NOV 2 1999

MEMORANDUM FOR SECRETARY OF THE ARMY

SUBJECT: Notice of GAO Final Testimony without Recommendations

Reference: GAO Testimony, GAO/T-NSIAD-00-48, "ANTHRAX VACCINE: Safety and Efficacy Issues," October 12, 1999 (GAO Code 713049/OSD Case 1916)

The Department of Defense (DoD) recently received copies of the referenced testimony from the General Accounting Office (GAO). A copy is enclosed for your information.

The GAO presented the testimony before the House Committee on Government Reform. Earlier in 1999, the GAO presented two related testimonies concerning the anthrax vaccine, designated GAO/T-NSIAD-99-148 and GAO/T-NSIAD-99-226. The GAO advised that the subject testimony completes its work for underlying code 713030 and no further reporting is planned.

Since the GAO testimony contains no recommendations, DoD comments are not required. It is, therefore, being provided for information only; no DoD action is required.

We are also providing copies of the testimony and this memorandum to the collateral action officers and to your action officer (b)(6), (b)(6). If you have questions, please contact my action officer for this case, Mr. (b)(6), (b)(6), e-mail (b)(6) @dodig.osd.mil>. If he is not available, contact Mr. (b)(6), (b)(6). Our fax number is (b)(6).

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1999307-0000040

United States General Accounting Office

GAO

Testimony

Before the Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at 1:00 p.m., EDT
Tuesday,
October 12, 1999

ANTHRAX VACCINE

Safety and Efficacy Issues

Statement of Kwai-Cheung Chan, Director, Special Studies and Evaluations, National Security and International Affairs Division

OSD CASE # 1911

G A O

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GAO/T-NSIAD-00-48

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the results of our ongoing examination of the safety and efficacy[1] of the anthrax vaccine. My testimony is based on previous studies[2] we have conducted to determine (1) the need for a six-shot regimen and annual booster shots, (2) the long- and short-term safety of the vaccine, (3) the efficacy of the vaccine and (4) the extent to which problems the Food and Drug Administration (FDA) found in the vaccine production facility in Michigan could compromise the safety, efficacy, and quality of the vaccine. Finally, I would like to discuss the effects of the anthrax vaccine on children, pregnant women or lactating women.

As you know, concerns have been raised about the Department of Defense's (DOD) anthrax immunization program since DOD began vaccinating its 2.4 million active duty and reserve members in 1998. For example, some active and reserve military personnel expressed concerns regarding the safety and efficacy of the anthrax vaccine after the FDA found problems during the inspection of the vaccine production facility. In addition, some Gulf War veterans are suffering from unexplained illnesses that they believe might have been caused by anthrax vaccinations received during the war.

The original anthrax vaccine was developed in the 1950s and was first produced on a large scale by the Merck Pharmaceutical Corporation. After a 1962 study on the vaccine's effect on mill workers, its manufacturing process was changed and the Michigan Department of Public Health took over as the vaccine's producer. This changed vaccine, which is the vaccine being given to U.S. military personnel, was licensed in 1970 by the Division of Biologics Standards, National Institutes of Health. FDA is currently responsible for licensing new vaccines and ensuring vaccine safety.

[1]Safety means relative freedom from harmful effects to persons affected directly or indirectly by a product that has been prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time. Efficacy is a measure of a product's ability to produce a given response. An effective vaccine will provide a certain degree of protection for a certain period of time.

[2]See *Medical Readiness: Issues Concerning the Anthrax Vaccine* (GAO/T-NSIAD-99-226, July 21, 1999) and *Medical Readiness: Safety and Efficacy of the Anthrax Vaccine* (GAO/T-NSIAD-99-148, April 29, 1999).

Summary

No studies have been done to determine the optimum number of doses of the anthrax vaccine. Although annual boosters are given, the need for a six-shot regimen and annual booster shots have not been evaluated.

The long-term safety of the licensed vaccine has not been studied. However, DOD is designing studies to examine the vaccine's long-term effects. Data on the prevalence and duration of short-term reactions to the vaccine are limited but suggest that women experience a higher rate of adverse reactions than do men. FDA's system for collecting data on adverse events associated with the vaccine, which DOD uses, relies on vaccine recipients or their health care providers to report adverse events.[3] Body Text?[4] Brachman reported on 379 subjects that received this vaccine. The study concluded that individual reactions to the vaccine were relatively minor. About 35 percent had local reactions, a figure that varied during the inoculation series. Some recipients developed more severe edema, or swelling, that extended to the mid-forearm or wrist. Two individuals had systemic reactions in addition to the edema. In addition to this study, some data was collected to support licensing of the vaccine but is of limited use because some participants had already received the earlier vaccine and it is not possible to identify who received which vaccine.

Post-licensing data are limited because only a limited number of doses—about 68,000—were distributed by the manufacturer from 1974 through 1989. Also, FDA did not establish its Vaccine Adverse Event Reporting System until 1990. This system, which DOD uses, alerts FDA and the Centers for Disease Control to increases in adverse events. However, it is a passive surveillance system, which means that FDA and the Centers for Disease Control must rely on vaccine recipients or their health care providers to report any adverse events after receiving the vaccine. Studies show that adverse events are reported significantly less frequently with passive surveillance systems than they would be in an active system where vaccine recipients are monitored to find out if they had any adverse effects.

[3]Clinical events reported to a passive surveillance system such as FDA's are usually termed adverse events rather than adverse reactions because there is usually insufficient evidence that the vaccine, rather than other health conditions, caused the reported events.

[4]P.S. Brachman et al., "Field Evaluation of a Human Anthrax Vaccine," American Journal of Public Health, vol. 52 (1962), pp. 632-645.

Since DOD's mandatory inoculation program began in 1998, DOD has conducted two efforts to actively collect data on the short-term safety of the vaccine. These data also allow one to examine gender differences in adverse reactions after servicemembers have received the anthrax vaccine. The first effort, conducted in 1999 by a DOD physician stationed in Korea, was a survey given to service members when they reported for their initial six-dose schedule of shots; it asked questions about their reactions to the previous shot. Results from this effort reflect the researcher's preliminary analysis of the data. The second effort, conducted in 1998-99 at Tripler Army Medical Center, Hawaii, included a survey on adverse reactions to the first three shots when individuals reported for their fourth shot and later included a follow-up survey on adverse reactions to the fourth shot.

According to the data gathered in both efforts, a higher proportion of females reported reactions to the anthrax vaccine than did their male counterparts. Table 1 summarizes the rates of all reported reactions to the vaccine in Korea. The data show that a higher proportion of females reported reactions than males.

Table 1: Preliminary Data on Gender Differences in the Reported Rate of Adverse Reactions to the Anthrax Vaccine, From Korea Survey (1999)

Dose	Males Percent (number of doses)	Females Percent (number of doses)
First	42.1 (2036)	71.6 (495)
Second	44.4 (1953)	74.0 (474)

Note: This represents a preliminary analysis of the data by the researcher, and at the time of our review, data on reactions to the third shot were not available.

Source: DOD 1999.

The data gathered in Korea also show that after the first two shots, more than twice the proportion of women than men reported systemic reactions of fever, malaise, or chills than did men (see table 2).

Table 2: Preliminary Data on Gender Differences in Systemic Reactions, From Korea Survey (1999)

	Fever		Malaise		Chills	
Dose number	Male (percent)	Female (percent)	Male (percent)	Female (percent)	Male (percent)	Female (percent)
First	0.9	2.8	6.0	15.6	1.5	5.5
Second	1.7	4.8	7.1	15.4	1.9	4.0

Note: This represents a preliminary analysis of the data by the researcher, and at the time of our review, data on reactions to the third dose were not available.

Source: DOD.

The Tripler survey also demonstrates gender differences in reported reactions (see table 3). These data show that a higher proportion of women reported making an outpatient visit after a vaccination than their male counterparts. In addition, more than twice the proportion of women reported that they missed one or more duty shifts after their vaccinations than did males. In light of the fact no gender specific data were available from the pre-licensure studies, these findings underscore the need for monitoring to better understand the specific effects of this vaccine in different groups.

Table 3: Gender Differences in Reported Local Reactions, Outpatient Medical Visits, and Missed Duty, From Tripler Army Medical Center Survey (1998-99)

Reaction		Dose 1 (percent)	Dose 2 (percent)	Dose 3 (percent)	Dose 4 (percent)
Moderate to severe redness	(m)	17.5	20.4	17.2	31.6
	(f)	49.1	46.9	51.4	39.8
Swelling of lower arm	(m)	9.7	9.5	9.2	7.1
	(f)	13.4	13.5	13.0	8.4
Pain limiting motion of elbow	(m)	9.7	8.7	7.6	7.9
	(f)	17.1	13.5	11.7	8.6
Localized itching	(m)	25.2	25.7	24.5	27.7
	(f)	62.6	60.4	57.9	39.2
Lump or knot	(m)	63.9	64.4	60.5	65.5
	(f)	89.9	87.8	83.6	73.2
Muscle soreness	(m)	86.6	84.7	61.8	60.4
	(f)	79.7	76.4	70.8	61.6
Outpatient medical visit	(m)	5.3	2.0	2.7	[a]
	(f)	10.0	13.8	3.9	
Missed one or more shifts of duty	(m)	2.2	2.0	0.9	[a]
	(f)	5.0	5.1	3.9	

Note: Between 421 and 471 men and between 74 and 83 women responded to each question on the survey.

[a]Data were not available

Source: DOD.

Vaccine Efficacy

Studies on the efficacy of anthrax vaccine have been limited to a study of the efficacy of the earlier vaccine for humans, and studies of the efficacy of the licensed vaccine for animals. The only study of the efficacy of the vaccine for humans was performed by Brachman, using the original vaccine. The Brachman study claimed that the vaccine gave 93 percent (and a lower confidence limit of 65 percent) protection against anthrax penetrating the skin. It found that the number of individuals who contracted anthrax by inhalation was too low to assess the efficacy of the vaccine against this form. There has been no specific study of the efficacy of the licensed vaccine in humans. Rather, its efficacy in humans has been inferred from other data, including a reduction in the incidence of anthrax following immunization of at-risk individuals and from animal experiments.

Beginning in the late 1980s, DOD began studying the efficacy of the licensed anthrax vaccine on animals, using guinea pigs, rabbits, and monkeys. All of these studies support the view that in these animals, the licensed vaccine can protect against exposure to some strains of anthrax either by inoculation or inhalation. It is clear, however, that animal species differ in their susceptibility. Studies of guinea pigs show that some anthrax strains are more or less resistant to vaccines for humans but are protected by the live spore veterinary vaccine.[5]

Research using monkeys showed for the first time that monkeys could be protected against aerosol exposure.[6] However, several studies have shown no direct comparison of immunity in humans to that in monkeys. DOD officials recognize that correlating the results of animal studies to humans is necessary and told us that DOD is planning research in this area. DOD also plans to develop a second generation anthrax vaccine, and as part of this effort, it will need to address whether strains of deliberately engineered or naturally occurring anthrax can overcome the protective immunity of such a vaccine. A variation in virulence among anthrax strains and a variation in relative resistance to vaccine-induced immunity have been observed in experiments on animals. However, the reasons for the variation have not been scientifically proven.

Vaccine Manufacturing Process

The quality of a vaccine is closely linked to its manufacturing process, which must be rigorously controlled to ensure that batches of vaccines produced on different occasions are of consistent quality. Accordingly, vaccine production is very highly regulated to ensure that the products are of consistent quality and safe and effective for the purpose(s) for which regulatory approval was granted. Until 1993, FDA inspectors did not inspect the MDPH facility where the anthrax vaccine was made. According to FDA, access was not granted because its inspectors had not been vaccinated against anthrax. DOD conducted inspections, however, and identified deficiencies during a March 1992 inspection, including the absence of stability studies.

[5]P.C.B Turnbull, et al., "Development of antibodies to protective antigen and lethal factor components in humans and guinea pigs and their relevance to protective immunity," Infectious Immunology, vol. 52 (1988) pp.356-363.

[6]B.E. Ivins, et al., "Efficacy of a standard human anthrax vaccine against Bacillus anthracis aerosol challenge in rhesus monkeys," Proceedings of the International Workshop on Anthrax, Salisbury Medical Bulletin, Special Supplement no. 87 (1996) pp.125-126.

FDA's subsequent inspections of the production facility in 1997 and 1998 found a number of deficiencies. The deficiencies that FDA identified in its February 1998 inspection fall broadly into two categories: those that might affect only one or a limited number of batches and those of a generic nature that could compromise the safety and efficacy of any or all batches. The facility received warning letters from FDA, including one in March 1997 stating its intent to revoke the facility's license. In 1998, the manufacturer closed its plant, which is now being renovated. DOD has directed that supplemental testing for purity, potency, sterility and safety be done on the lots approved by FDA before the current vaccination program began.

Effects of the Vaccine on Children and Pregnant and Lactating Women

The anthrax vaccine is not intended to be administered to children, pregnant or lactating women, and consequently no studies have been conducted to determine the specific effects of administering the anthrax vaccine to these groups. Before approving vaccines or drugs for marketing, FDA currently requires the submission of clinical data broken down by (among other things) gender and age. FDA then evaluates these data to determine efficacy and safety for specific subgroups of the general population. In addition, depending on FDA's assessment of clinical data, specific labeling requirements pertaining to potential effects on pregnant women, nursing mothers and pediatric use may also be required. However, the Division of Biologics, National Institutes of Health, which licensed the vaccine in 1970, did not require the submission of data broken down this way.

Mr. Chairman, this concludes my statement. I will be happy to answer any questions you may have.

Contacts and Acknowledgments

For future contacts regarding this testimony, please contact Kwai-Cheung Chan at (202) 512-3652. Individuals making key contributions to this testimony included Sushil K. Sharma, Jonathan R. Tumin, and Howard Deshong.

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MEMORANDUM FOR SECRETARY OF THE ARMY

SUBJECT: Receipt of Corrected GAO Final Testimony without Recommendations

Reference: GAO Testimony, GAO/T-NSIAD-00-48, "ANTHRAX VACCINE: Safety and Efficacy Issues," October 12, 1999 (GAO Code 713049/OSD Case 1916)

On November 2, we forwarded to you for your information a copy of the subject testimony we received from the General Accounting Office (GAO). The GAO presented the testimony before the House Committee on Government Reform on October 12.

On November 17 we received additional copies of the testimony with a letter from GAO explaining that the earlier copies had some information omitted. A copy of the GAO letter explaining their error and the corrected testimony is enclosed for your information; no DoD action is required.

We are also providing copies of the testimony and this memorandum to the collateral action officers and to your action officer, (b)(6), (b)(6). If you have questions, please contact my action officer for this case, Mr. (b)(6), (b)(6). e-mail (b)(6)@dodig.osd.mil>. If he is not available, contact Mr. (b)(6), (b)(6). Our fax number is (b)(6).

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National Security and
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November 5, 1999

Please disregard the copy of the testimony, *Anthrax Vaccine: Safety and Efficacy Issues* (T-NSIAD-00-48) that was mailed to you. The version you received had some information omitted. I apologize for any inconvenience.

Sincerely yours,

(b)(6)

Assistant Director
Special Studies and Evaluations

United States General Accounting Office

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Testimony

Before the Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at 1:00 p.m., EDT
Tuesday,
October 12, 1999

ANTHRAX VACCINE

Safety and Efficacy Issues

Statement of Kwai-Cheung Chan, Director, Special Studies and Evaluations, National Security and International Affairs Division

GAO/T-NSIAD-00-48

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the results of our ongoing examination of the safety and efficacy[1] of the anthrax vaccine. My testimony is based on previous studies[2] we have conducted to determine (1) the need for a six-shot regimen and annual booster shots, (2) the long- and short-term safety of the vaccine, (3) the efficacy of the vaccine and (4) the extent to which problems the Food and Drug Administration (FDA) found in the vaccine production facility in Michigan could compromise the safety, efficacy, and quality of the vaccine. Finally, I would like to discuss the effects of the anthrax vaccine on children, pregnant women or lactating women.

As you know, concerns have been raised about the Department of Defense's (DOD) anthrax immunization program since DOD began vaccinating its 2.4 million active duty and reserve members in 1998. For example, some active and reserve military personnel expressed concerns regarding the safety and efficacy of the anthrax vaccine after the FDA found problems during the inspection of the vaccine production facility. In addition, some Gulf War veterans are suffering from unexplained illnesses that they believe might have been caused by anthrax vaccinations received during the war.

The original anthrax vaccine was developed in the 1950s and was first produced on a large scale by the Merck Pharmaceutical Corporation. After a 1962 study on the vaccine's effect on mill workers, its manufacturing process was changed and the Michigan Department of Public Health took over as the vaccine's producer. This changed vaccine, which is the vaccine being given to U.S. military personnel, was licensed in 1970 by the Division of Biologics Standards, National Institutes of Health. FDA is currently responsible for licensing new vaccines and ensuring vaccine safety.

[1]Safety means relative freedom from harmful effects to persons affected directly or indirectly by a product that has been prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time. Efficacy is a measure of a product's ability to produce a given response. An effective vaccine will provide a certain degree of protection for a certain period of time.

[2]See *Medical Readiness: Issues Concerning the Anthrax Vaccine* (GAO/T-NSIAD-99-226, July 21, 1999) and *Medical Readiness: Safety and Efficacy of the Anthrax Vaccine* (GAO/T-NSIAD-99-148, April 29, 1999).

Summary

No studies have been done to determine the optimum number of doses of the anthrax vaccine. Although annual boosters are given, the need for a six-shot regimen and annual booster shots have not been evaluated.

The long-term safety of the licensed vaccine has not been studied. However, DOD is designing studies to examine the vaccine's long-term effects. Data on the prevalence and duration of short-term reactions to the vaccine are limited but suggest that women experience a higher rate of adverse reactions than do men. FDA's system for collecting data on adverse events associated with the vaccine, which DOD uses, relies on vaccine recipients or their health care providers to report adverse events.[3] Studies have shown that such systems may not accurately reflect the incidence of events due to underreporting. However, data from two recent DOD efforts to identify the prevalence of adverse events associated with anthrax vaccine show that a higher proportion of women reported both local and systemic reactions to the vaccine than their male counterparts. In addition, more than twice the proportion of women reported that they missed one or more duty shifts after their vaccinations than did males.

A study on the efficacy of the earlier vaccine concluded that it provided protection to humans against anthrax penetrating the skin but did not provide information to determine its effectiveness against inhalation anthrax. In the 1980's, DOD began testing the efficacy of the licensed vaccine in animals, focusing on its protection against inhalation anthrax. The studies showed that the vaccine protected some animals against inhalation anthrax. However, the level of protection varied for different species and the results cannot be extrapolated to humans. DOD recognizes that correlating the results of animal studies to humans is necessary and told us that it is planning research in this area. DOD also plans to develop a second generation anthrax vaccine and, as part of this effort, will need to address whether strains of deliberately engineered or naturally occurring anthrax can overcome the protective immunity of such a vaccine.

FDA's inspections of the vaccine production facility in 1997 and 1998 found a number of deficiencies. The deficiencies that FDA identified in its February 1998 inspection fall broadly into two categories: those that might

[3]Clinical events reported to a passive surveillance system such as FDA's are usually termed adverse events rather than adverse reactions because there is usually insufficient evidence that the vaccine, rather than other health conditions, caused the reported events.

affect only one or a limited number of batches that were produced and those that could compromise the safety and efficacy of any or all batches. The facility was shut down in early 1998. A new company, which purchased the facility in mid-1998, is addressing these issues.

Finally, you expressed concerns about the effects of the anthrax vaccine on children, pregnant women, or lactating women. The anthrax vaccine is not intended to be administered to children, pregnant women, or lactating women. No studies have been conducted on the vaccine's effects on these groups.

Background

In December 1997, the Secretary of Defense announced that all U.S. forces would be inoculated against the potential use of anthrax on the battlefield. Initial immunization consists of three shots given at 0, 2, and 4 weeks followed by three additional shots given at 6, 12, and 18 months. DOD has recognized that some of the concerns about using the current vaccine might be mitigated in the future through actions such as testing and research and adjustments to the program based on new data.

The inspection process for ensuring vaccine safety is more stringent and complex than for chemical drug because vaccines have three distinguishing features. First, either they have no clearly chemically defined composition, or chemical analysis is extremely difficult. Second, proper evaluation of vaccines generally requires measuring their effects in animals. Finally, quality cannot be guaranteed from final tests on random samples but only from a combination of in-process tests, end-product tests, and strict controls of the entire manufacturing process.

From the 1970s until 1998, DOD had been procuring the anthrax vaccine from a facility owned by the State of Michigan, the only facility in the country licensed to produce the vaccine. In 1997 and 1998, FDA identified numerous manufacturing problems at the facility. In response to concerns about the potential loss of anthrax vaccine production, DOD began funding renovation of the facility. Production facilities were shut down in early 1998. In the summer of 1998, the State of Michigan sold the facility to the BioPort Corporation for $25 million. DOD contracts were then transferred to BioPort. BioPort is addressing manufacturing problems.

Data on the Need for Six Shots and Annual Boosters Are Not Available

No studies have been done to determine the optimum number of doses of the anthrax vaccine. The immunization schedule of three doses used for the earlier vaccine was based on a regimen developed using animals in the early 1950s. However, the number of doses was arbitrarily increased to six when three people (two at Fort Detrick and one in a private wool mill) who received three doses of the vaccine became infected after exposure to anthrax. In a study of the vaccine's human efficacy published in 1962, a six-dose schedule was used, and the researchers concluded that the vaccine provided protection against anthrax penetrating the skin. The study did not provide enough information to determine whether the vaccine was effective against inhalation anthrax. The license for the vaccine, which was granted in 1970, calls for the six-dose schedule and annual boosters used in the human efficacy study, and DOD has followed this regimen. In September 1998, the manufacturer submitted an Investigational New Drug application to FDA to determine whether the number of shots in the initial schedule could be reduced from six to five.

In November 1971, the Division of Biologics Standards, National Institutes of Health, noted an apparent increase in reports of adverse reactions after individuals received booster shots. The Division considered it advisable to reevaluate the need for annual boosters and possibly the amount of the booster dose. Although the record is unclear as to whether or not the Division requested the manufacturer to conduct a reevaluation, no such reevaluation has been done to date.

Vaccine Safety

The long-term safety of the licensed vaccine has not been studied. However, DOD is designing studies to examine the vaccine's long-term effects.

With regard to short-term safety, data on the prevalence and duration of short-term reactions to the vaccine are limited but suggest that women experience a higher rate of adverse reactions than men. A study on the earlier vaccine's safety was done by Philip Brachman and published in 1962.[4] Brachman reported on 379 subjects that received this vaccine. The study concluded that individual reactions to the vaccine were relatively minor. About 35 percent had local reactions, a figure that varied during the

[4]P.S. Brachman et al., "Field Evaluation of a Human Anthrax Vaccine," *American Journal of Public Health*, vol. 52 (1962), pp. 632-645.

inoculation series. Some recipients developed more severe edema, or swelling, that extended to the mid-forearm or wrist. Two individuals had systemic reactions in addition to the edema. In addition to this study, some data was collected to support licensing of the vaccine but is of limited use because some participants had already received the earlier vaccine and it is not possible to identify who received which vaccine.

Post-licensing data are limited because only a limited number of doses—about 68,000—were distributed by the manufacturer from 1974 through 1989. Also, FDA did not establish its Vaccine Adverse Event Reporting System until 1990. This system, which DOD uses, alerts FDA and the Centers for Disease Control to increases in adverse events. However, it is a passive surveillance system, which means that FDA and the Centers for Disease Control must rely on vaccine recipients or their health care providers to report any adverse events after receiving the vaccine. Studies show that adverse events are reported significantly less frequently with passive surveillance systems than they would be in an active system where vaccine recipients are monitored to find out if they had any adverse effects.

Since DOD's mandatory inoculation program began in 1998, DOD has conducted two efforts to actively collect data on the short-term safety of the vaccine. These data also allow one to examine gender differences in adverse reactions after servicemembers have received the anthrax vaccine. The first effort, conducted in 1999 by a DOD physician stationed in Korea, was a survey given to service members when they reported for their initial six-dose schedule of shots; it asked questions about their reactions to the previous shot. Results from this effort reflect the researcher's preliminary analysis of the data. The second effort, conducted in 1998-99 at Tripler Army Medical Center, Hawaii, included a survey on adverse reactions to the first three shots when individuals reported for their fourth shot and later included a follow-up survey on adverse reactions to the fourth shot.

According to the data gathered in both efforts, a higher proportion of females reported reactions to the anthrax vaccine than did their male counterparts. Table 1 summarizes the rates of all reported reactions to the vaccine in Korea. The data show that a higher proportion of females reported reactions than males.

Table 1: Preliminary Data on Gender Differences in the Reported Rate of Adverse Reactions to the Anthrax Vaccine, From Korea Survey (1999)

Dose	Males Percent (number of doses)	Females Percent (number of doses)
First	42.1 (2036)	71.6 (495)
Second	44.4 (1953)	74.0 (474)

Note: This represents a preliminary analysis of the data by the researcher, and at the time of our review, data on reactions to the third shot were not available.

Source: DOD 1999.

The data gathered in Korea also show that after the first two shots, more than twice the proportion of women than men reported systemic reactions of fever, malaise, or chills than did men (see table 2).

Table 2: Preliminary Data on Gender Differences in Systemic Reactions, From Korea Survey (1999)

	Fever		Malaise		Chills	
Dose number	Male (percent)	Female (percent)	Male (percent)	Female (percent)	Male (percent)	Female (percent)
First	0.9	2.8	6.0	15.6	1.5	5.5
Second	1.7	4.8	7.1	15.4	1.9	4.0

Note: This represents a preliminary analysis of the data by the researcher, and at the time of our review, data on reactions to the third dose were not available.

Source: DOD.

The Tripler survey also demonstrates gender differences in reported reactions (see table 3). These data show that a higher proportion of women reported making an outpatient visit after a vaccination than their male counterparts. In addition, more than twice the proportion of women reported that they missed one or more duty shifts after their vaccinations than did males. In light of the fact no gender specific data were available from the pre-licensure studies, these findings underscore the need for monitoring to better understand the specific effects of this vaccine in different groups.

Table 3: Gender Differences in Reported Local Reactions, Outpatient Medical Visits, and Missed Duty, From Tripler Army Medical Center Survey (1998-99)

Reaction		Dose 1 (percent)	Dose 2 (percent)	Dose 3 (percent)	Dose 4 (percent)
Moderate to severe redness	(m)	17.5	20.4	17.2	31.6
	(f)	49.1	46.9	51.4	39.8
Swelling of lower arm	(m)	9.7	9.5	9.2	7.1
	(f)	19.4	13.5	13.0	8.4
Pain limiting motion of elbow	(m)	9.7	8.7	7.6	7.9
	(f)	17.1	13.5	11.7	8.6
Localized itching	(m)	25.2	25.7	24.5	27.7
	(f)	62.6	60.4	57.9	39.2
Lump or knot	(m)	63.9	64.4	60.5	65.5
	(f)	89.9	87.8	83.6	73.2
Muscle soreness	(m)	66.6	64.7	61.8	60.4
	(f)	79.7	76.4	70.8	61.6
Outpatient medical visit	(m)	5.3	2.0	2.7	[a]
	(f)	10.0	13.8	3.9	
Missed one or more shifts of duty	(m)	2.2	2.0	0.9	[a]
	(f)	5.0	5.1	3.9	

Note: Between 421 and 471 men and between 74 and 83 women responded to each question on the survey.

[a]Data were not available

Source: DOD.

Vaccine Efficacy

Studies on the efficacy of anthrax vaccine have been limited to a study of the efficacy of the earlier vaccine for humans, and studies of the efficacy of the licensed vaccine for animals. The only study of the efficacy of the vaccine for humans was performed by Brachman, using the original vaccine. The Brachman study claimed that the vaccine gave 93 percent (and a lower confidence limit of 65 percent) protection against anthrax penetrating the skin. It found that the number of individuals who contracted anthrax by inhalation was too low to assess the efficacy of the vaccine against this form. There has been no specific study of the efficacy of the licensed vaccine in humans. Rather, its efficacy in humans has been inferred from other data, including a reduction in the incidence of anthrax following immunization of at-risk individuals and from animal experiments.

Beginning in the late 1980s, DOD began studying the efficacy of the licensed anthrax vaccine on animals, using guinea pigs, rabbits, and monkeys. All of these studies support the view that in these animals, the licensed vaccine can protect against exposure to some strains of anthrax either by inoculation or inhalation. It is clear, however, that animal species differ in their susceptibility. Studies of guinea pigs show that some anthrax strains are more or less resistant to vaccines for humans but are protected by the live spore veterinary vaccine.[5]

Research using monkeys showed for the first time that monkeys could be protected against aerosol exposure.[6] However, several studies have shown no direct comparison of immunity in humans to that in monkeys. DOD officials recognize that correlating the results of animal studies to humans is necessary and told us that DOD is planning research in this area. DOD also plans to develop a second generation anthrax vaccine, and as part of this effort, it will need to address whether strains of deliberately engineered or naturally occurring anthrax can overcome the protective immunity of such a vaccine. A variation in virulence among anthrax strains and a variation in relative resistance to vaccine-induced immunity have been observed in experiments on animals. However, the reasons for the variation have not been scientifically proven.

Vaccine Manufacturing Process

The quality of a vaccine is closely linked to its manufacturing process, which must be rigorously controlled to ensure that batches of vaccines produced on different occasions are of consistent quality. Accordingly, vaccine production is very highly regulated to ensure that the products are of consistent quality and safe and effective for the purpose(s) for which regulatory approval was granted. Until 1993, FDA inspectors did not inspect the MDPH facility where the anthrax vaccine was made. According to FDA, access was not granted because its inspectors had not been vaccinated against anthrax. DOD conducted inspections, however, and identified deficiencies during a March 1992 inspection, including the absence of stability studies.

[5]P.C.B Turnbull, et al., "Development of antibodies to protective antigen and lethal factor components in humans and guinea pigs and their relevance to protective immunity," *Infectious Immunology*, vol. 52 (1988) pp.356-363.

[6]B.E. Ivins, et al., "Efficacy of a standard human anthrax vaccine against Bacillus anthracis aerosol challenge in rhesus monkeys," *Proceedings of the International Workshop on Anthrax, Salisbury Medical Bulletin*, Special Supplement no. 87 (1996) pp.125-126.

FDA's subsequent inspections of the production facility in 1997 and 1998 found a number of deficiencies. The deficiencies that FDA identified in its February 1998 inspection fall broadly into two categories: those that might affect only one or a limited number of batches and those of a generic nature that could compromise the safety and efficacy of any or all batches. The facility received warning letters from FDA, including one in March 1997 stating its intent to revoke the facility's license. In 1998, the manufacturer closed its plant, which is now being renovated. DOD has directed that supplemental testing for purity, potency, sterility and safety be done on the lots approved by FDA before the current vaccination program began.

Effects of the Vaccine on Children and Pregnant and Lactating Women

The anthrax vaccine is not intended to be administered to children, pregnant or lactating women, and consequently no studies have been conducted to determine the specific effects of administering the anthrax vaccine to these groups. Before approving vaccines or drugs for marketing, FDA currently requires the submission of clinical data broken down by (among other things) gender and age. FDA then evaluates these data to determine efficacy and safety for specific subgroups of the general population. In addition, depending on FDA's assessment of clinical data, specific labeling requirements pertaining to potential effects on pregnant women, nursing mothers and pediatric use may also be required. However, the Division of Biologics, National Institutes of Health, which licensed the vaccine in 1970, did not require the submission of data broken down this way.

Mr. Chairman, this concludes my statement. I will be happy to answer any questions you may have.

Contacts and Acknowledgments

For future contacts regarding this testimony, please contact Kwai-Cheung Chan at (202) 512-3652. Individuals making key contributions to this testimony included Sushil K. Sharma, Jonathan R. Tumin, and Howard Deshong.

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Survey of Issues Associated with the Anthrax Vaccine Immunization Program

Introduction

The United States General Accounting Office (GAO) is the independent investigative arm of the Congress. It is not affiliated with the Department of Defense or the Military Services. The Chairman of the House Committee on Government Reform has asked the GAO to gather information on the views of current and former members of the Guard and Reserve concerning the military's Anthrax Vaccine Immunization Program (AVIP). We are also collecting general background information, specific information from those who have received the immunizations, and information on other issues related to the administration of the program.

Following the instructions provided, please complete the questionnaire in its entirety. At the end of the questionnaire you may provide any additional written comments you may have.

Thank you in advance for your cooperation.

Privacy Protection

GAO will take steps to protect the privacy of the information you provide. For that reason, we have purposely not asked you to provide information that can readily or easily identify you. Your responses **will be aggregated in our report, and you will not be personally identified.**

Return to:

GAO
Room 4015
441 G Street NW
Washington, D.C.
20548

ATTN: Anthrax

Directions for Completing This Survey

The survey should take about 20 to 30 minutes to complete. We encourage you to answer each question as honestly and as completely as possible. Providing information is voluntary; however, your views on these issues are very important to the Congress.

Before choosing a" answer, please read each question and all possible response choices carefully. You may use a pen or pencil to mark your answers.

Some response choices are followed by a skip instruction. This instruction, to skip to another question following a response choice, is there to save you time and to prevent you from answering questions that don't apply to you. If you select a response that is followed by "→*Skip to Question _*," please skip to the question indicated and do&answer any questions between your current answer and the specified question.

You will be asked to supply two types of answers.

- Most often, you should check only one answer, but a few questions may ask you to *"Check all that apply."* For this type of question, you should place a check mark in the circle(s) next to the one or more answers that best describes your situation or your opinion. Where we ask for your opinion, there are no right or wrong answers. Your honest opinions are what we seek.
- A second type of question asks you to write a short answer or a more detailed statement. If you need additional space for your answer, it is provided on the last page of the survey. Be sure to indicate the question number when you write any additional comments on the last page.

Points of Contact

If you have any questions about the survey, you may contact either (1) (b)(6) by e-mail (b)(6) @gao.gov) or telephone (b)(6) or (2) (b)(6) at (b)(6) @gao.gov) and (b)(6) (b)(6)

Background and Current Status

1. Of what service are you currently **a** member? If you **are** no longer in the service, of what service were you last a member? *(check one)*
   0 Air National Guard
   0 Air Force Reserve
   0 **Army** Guard
   0 Army Reserve
   0 Naval Reserve
   0 Marine Forces Reserve

2. Are you now, **or** were you last assigned as an AGR or Technician? *(check one)*
   0 Yes
   0 No

3. What is your current military status? *(check one)*
   0 Assigned to unit (Guard or Reserve)
   0 Inactive (IRR or IMA)
   0 Separated
   0 Retired
   0 Other @lease specify): _____

4. What is your current **paygrade** or, if you have separated from the military, what was your **paygrade** at the time of your separation? *(check one)*

   Military
   0 E1-E3
   0 **E4 – E6**
   0 **E7 – E9**
   0 01-03
   0 04 and above
   General Schedule
   0 **GS1 – GS5**
   0 **GS6 – GS8**
   0 **GS9 – GS12**
   0 **GS13** and above
   Wage Grade
   0 **WG1 – WG5**
   0 **WG6 – WG8**
   0 **WG9 – WG12**
   0 **WG13 – WG15**

5. Are you currently employed in a flying position with the commercial, corporate, or general aviation sector? *(check one)*
   0 Yes
   O *No*

Change in Military Status

6. Have you changed your military status (e.g., transferred to another unit, left the military, or moved to inactive status) since March **1, 1998?** *(check one)*
   0 Yes
   *0 No →**Skip** to Question 20*

7. *0"* what approximate date did you last change your military status? (enter *the month and year, e.g., "06/98")*

   ____/____
   M M / Y Y

8. What **was** your last change in military status? *(check one)*
   0 Transferred to another unit
   0 Moved to inactive **status**
   0 Left the military
   0 Other (please *specify*): _____

9. When you last changed status, approximately how long had you served in the military? (enter *the number of years and months)*

   ____ **years** _ *months*

10. When you last changed status, were you in a military flying position? *(check one)*
    0 Yes
    *0 No →**Skip** to Question 14*

11. When you last changed status, approximately how many military flying hours bad you accumulated?

    _____ hours

12. What was your duty position when you last changed status? *(check one)*
    0 Pilot
    0 Flight Engineer
    0 Loadmaster
    0 Navigator
    0 Crew chief
    0 Flight attendant
    0 other *(**please** specify):* _____

13. If you were a pilot, what crew position did you hold when you last changed status? *(check one)*
    0 Not applicable, not a pilot
    0 Flight examiner
    0 Flight instructor
    0 Aircraft commander
    0 First pilot
    0 Co-pilot
    0 Other (*please* specify): _____

Reasons for Change in Military Status

14. What official reason(s) did you provide in your paperwork **and/or** exit interview regarding your last change in status? ***(check all that apply)***
    - 0 None
    - 0 Eligible for retirement
    - 0 Family reasons
    - 0 Other employment opportunity
    - 0 Heavy unit workload (general OPTEMPO)
    - 0 Unit morale
    - 0 Individual morale
    - 0 Military immunization program in general
    - 0 Anthrax immunization
    - 0 Other @lease ***specify):*** _____

15. Did the real reason(s) for your lost change in status match the official reason(s) provided to the military in **your** paperwork and/or exit interview? ***(check one)***
    0 Yes
    0 No *(please **explain):*** _____

16. To what extent did each of the following factors influence your decision to change your status or leave the military? ***(check one circle for each item)***

To little or no extent	*To some extent*	*To a moderate extent*	*To a great extent*	*To a very great extent*	
0	0	0	0	0	a. Eligible for retirement
0	0	0	0	0	b. Family reasons
0	0	0	0	0	c. Other employment opportunity
0	0	0	0	0	d. Heavy "nit workload (general OPTEMPO)
0	0	0	0	0	e. Unit morale
0	0	0	0	0	f. Individual morale
0	0	0	0	0	Militaryimmunizationprogramin general
0	0	0	0	0	h. Anthrax immunization
0	0	0	0	0	i. Other *(please specify)*. _____

17. Which of the factors listed in Question 16 is the **one** most important reason for your decision to change your status or leave the military? ***(check one)***
    0 Eligible for retirement
    0 Family reasons
    0 Other employment opportunity
    0 Heavy unit workload (general OPTEMPO)
    0 Unit morale
    0 Individual morale
    0 Military immunization program in general
    0 Anthrax immunization
    0 Other @lease ***specify***): _____

18. If you are either separated or are no longer in military flying status because of the anthrax vaccine immunization program, would you consider returning to a unit or to military flying status if the anthrax vaccination were not mandatory? ***(check one)***
    0 Not applicable
    0 No
    0 Probably no
    0 Uncertain
    0 Probably yes
    0 Yes

19. Did **your** change in status result in the forfeiture of **your** military retirement benefit? ***(check one)***
    0 Yes
    0 No
    0 Don'tknow

Flying Status

20. Do you plan on changing your military status (e.g., transferring to another unit, leaving the military, or moving to inactive status) within the next 6 months? ***(check one)***
    0 Yes
    0 No→Skip to Question 22
    0 Not applicable, left the military or moved to inactive status) ***→Skip to Question 27***

21. To what extent have each of the following factors influenced your decision to change your status or leave the military within the next 6 months?
(check one circle for each item)

--To little or no extent
| --To some extent
| | --To a moderate extent
| | | --To a great extent
| | | | --To a very great extent
| | | | |

O O O O O **a.** Eligible for retirement
O O O O O h . Family reasons
0 0 0 0 0 c . Other employment opportunity
0 0 0 0 0 d . Heavy unit workload (general OPTEMPO)
0 0 0 0 0 e . Unit morale
0 0 0 0 0 f . Individual morale
0 0 0 0 0 g . Military immunization program in **general**
0 0 0 0 0 h . Anthrax immunization
0 0 0 0 0 i . **Other** *(please specify).* _____

_____

22. Are **you** currently in a military flying status? *(check one)*
0 Yes
0 No→Skip to Question 27

23. What is your current military flying status? *(check one)*
0 Flying
0 Non-flying (DNIF)
0 other @/ease *specify*): _____

24. Approximately how many military flying hours have **you** accumulated?

_____ hours

25. What is your current duty position? *(check one)*
0 Pilot
0 Flight Engineer
0 Loadmaster
0 Navigator
0 Crew chief
0 Flight attendant
0 Other *(please specify)*: _____

26. If you are a pilot, what is your highest crew qualification? *(check one)*
0 Not applicable, not a pilot
0 Flight examiner
0 Flight instructor
0 Aircraft commander
0 First pilot
0 Co-pilot
0 Other @lease specify): _____

Anthrax Vaccine Immunization Program

27. Did the military provide you with information about whom to contact within the military if you had any questions about the anthrax vaccine immunization program? *(check one)*
0 Yes
0 No
0 Don't know/can't remember

28. Did the military inform you of DOD's anthrax vaccine immunization program **website** on the Internet?
(check one)
0 Yes
0 No
0 Don't know/can't remember

29. Have you visited the **website?** *(check one)*
0 Yes
0 No→Skip to Question 31

30. How satisfied are you that the information provided **at** the DOD **website is...***(check one circle for each item)*

--Very satisfied
| --Moderately satisfied
| | --Neither satisfied nor dissatisfied
| | | --Moderately dissatisfied
| | | | --Very dissatisfied
| | | | |

0 0 0 0 0 a. Complete?
0 0 0 0 0 b. Accurate?
0 0 0 0 0 **c.** Timely?
0 0 0 0 0 d. Unbiased?
Comments: _____

_____

_____

31. Did the military provide you with oral or written information about each of the following? *(check one circle/or each item)*

--Yes
| --No
| | --Don't know/can't remember
| | |

0 0 0 a. The military threat from anthrax
0 0 0 b. The vaccine's effectiveness in **battlefield exposures**
0 0 0 **c.** The history and past "sage of the vaccine
0 0 0 d. The short-term safety of the vaccine
0 0 0 e. The long-term safety of the vaccine
0 0 0 **f.** The possible side effects from and reactions to the vaccine
Comments: _____

_____

32. How satisfied are you that the military has provided you with complete and accurate information about each of the following? *(check one circle for each item)*

-- Very satisfied
| --Moderately satisfied
| | --Neither satisfied nor dissatisfied
| | | --Moderately dissatisfied
| | | | --Very dissatisfied
| | | | |

0 0 0 0 0 a. The military threat from anthrax
0 0 0 0 0 b. The vaccine's effectiveness in battlefield exposures
0 0 0 0 0 c. The history and past "sage of the vaccine
0 0 0 0 0 d. The short-term safety of the vaccine
0 0 0 0 0 **e.** The long-term safety of the vaccine
0 0 0 0 0 f. The possible side effects from and reactions to the vaccine

Comments: _____

_____

_____

33. To what extent are you concerned about the anthrax vaccine and the following issues? *(check one circle/or each item)*

--To little or no extent
| -- To some extent
| | --To a moderate extent
| | | --To a great extent
| | | | --To a very great extent
I | I I

0 0 0 0 0 a. Male fertility
0 0 0 0 0 b. Female fertility
0 0 0 0 0 c. Possible health effects on offspring
0 0 0 0 0 d. Increased risk for auto-immune disease
0 0 0 0 0 e. Other (*please specify*):_____

_____

34. How **safe** do **you** believe immunizations in general to be? *(check one)*

0 Very safe
0 Moderately safe
0 Neither safe "or unsafe
0 Moderately unsafe
0 Very unsafe
0 Don't know

35. **How effective do you** believe immunizations in general to be? *(check one)*

0 Very effective
0 Moderately effective
0 Neither effective "or ineffective
0 Moderately ineffective
0 Very ineffective
0 Don't know

36. Would you have any concerns about safety if additional vaccines for other biological warfare agents were added to the military immunization requirement? *(check one)*

0 Yes
0 Probably yes
0 Uncertain
0 Probably no
0 No

37. Did the military provide you with information concerning what action you should take in the event you experienced side effects from or reactions to the anthrax vaccination? *(check one)*

0 Yes
0 No
0 Don't know/can't remember

38. Were you exempted from taking any of the anthrax vaccine **shots?** *(check* one)

0 Yes
0 No ***→Skip to Question** 40*

39. Why were you exempted from taking the anthrax vaccine shots? *(check&that apply)*

0 Chronic illness not associated with the vaccine
0 Chronic illness associated with the vaccine
0 Local reaction to the vaccine
0 Pregnancy
0 Other @lease explain):_____

_____

40. If the anthrax vaccine immunization program were voluntary, would **you** volunteer to take the shots? *(check one)*

0 Yes
0 Probably yes
0 Uncertain
0 Probably no
0 No

41. Have you received any of the anthrax vaccine shots? *(check one)*

0 Yes
*0 No →Skip to **Question** 57*

42. How many anthrax vaccine shots have you received? (enter the *number of shots including the **annual** booster)*

_____ shots

43. When did you receive your **first** shot? (enter *the month and year, e.g., "08/99")*

__/__
M M/ Y Y

44. **Did you experience <u>any</u> side effects from or reactions to any of the shots (such as redness, swelling, fever, headaches, or any of the side effects or reactions listed on the chart in Question 45 below)?** *(check one)*
0 Yes
*0 No →**Skip** to Question 57*

45. **For each shot, indicate <u>all</u> of the side effects or reactions that you experienced. If you had no side effects or reactions to any given shot, check "None" in the box for that shot.** *Under each shot number, indicate the duration of the side effects or reactions you experienced by coding with the appropriate letter code shown on the right.*

<u>S</u> – for Short duration reactions lasting less than 24 hours.
M-for <u>M</u>edium duration reactions lasting from 1 to 3 days,
L-for <u>L</u>ong duration reactions lasting 4 to 7 days, and
<u>E</u> -for Extended duration reactions lasting <u>over</u> 7 days

Side Effect(s) or Reaction(s)	Shot number						
	1	2	3	4	5	6	Booster
a. None *(check if there were no side effects/reactions)*							
Local Reactions:							
b. Redness (2.5" or less in diameter)							
c. Redness (greater than 2.5" in diameter)							
d. Swelling in arm							
e. Burning sensation in arm							
f. Arm pain/limited motion							
g. Itching in arm							
h. Knot/lump in arm							
Systemic and other reactions:							
i. Chills							
j. Fever							
k. Extreme fatigue							
l. Dizziness							
m. Headaches							
n. Blurred vision							
o. Numbness in extremities							
p. Joint pain							
q. Memory loss							
r. Blackouts							
s. Ringing in ears							
t. Insomnia							
u. Nausea							
v. Other *(please describe in the space below)*							

46. For each shot indicated of the consequences of the side effects and reactions you experienced. *If there were no consequences as a result of the side effects or reactions to a particular shot, check the box labeled "None" for that shot.*

Consequences of Side Effect(s) or Reaction(s)	Shot number						
	1	2	3	4	5	6	Booster
a. *None (check if there were no consequences of the side effects/reactions)*							
b Restricted activity (enter # *of days for the applicable shot)*							
c. Limited duty *(enter # of days for the applicable shot)*							
d. Missed military work *(enter # of days for the applicable shot)*							
e. Missed civilian work *(enter # of days for the applicable shot)*							
f. Required prescribed medication(s) *(enter # of days for the applicable shot)*							
g. Went to military clinic or doctor *(enter # of times for the applicable shot)*							
h. **Went to private clinic or doctor** *(enter # of times*							
i. Hospitalized *(enter # of days for the applicable shot)*							
j. Sent for specialized consult/treatment *(enter # of times for applicable shot)*							
k. Other *(please describe in the space below)*							

47. Were you given any other vaccine shot(s) at the same time that you received the anthrax vaccine shot? ***(check one)***

0 Yes

If Yes, please specify which vaccine(s):

_____

0 No
0 Don'tknow

48. Have you had any prior history of adverse reactions to any prescription drugs or vaccines other than the anthrax vaccine? ***(check one)***

0 Yes (please describe). _____

_____

_____

_____

0 No
0 Don'tknow

49. Did you discuss your side effects from or reactions to the anthrax vaccine with military health care personnel or your superiors? ***(check one)***

0 Yes
0 No→Skip to Question 51

50. How did they respond? ***(indicate to whom you talked, military health care personnel or your superiors, and how they responded)***

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

51. From whom did you receive treatment for your side effects or reactions to the anthrax vaccine? ***(check one)***

0 Both military and civilian health care personnel
0 Military health care personnel only
0 Civilian health care personnel only
0 No one

52. If you have **not** received treatment for your side effects or reactions to the anthrax vaccine, what were your reasons for not seeking treatment? ***(check&that apply)***

0 Not applicable, I did receive treatment
0 Didn't have time, too busy
0 Treated myself for the side effect(s)/reaction(s)
0 Side effect(s)/reaction(s) were not severe enough
0 Fear of ridicule
0 Possible loss of flight status
0 Possible adverse effect on my career
0 Other *(please **explain).*** _____

_____

_____

53. If you received any treatment from military health care personnel for your side effects or reactions to the anthrax vaccine, how satisfied are you with the treatment you received? ***(check one)***

0 I did not seek or receive treatment from the military for my side effects or reactions to the vaccine
0 Very satisfied
0 Moderately satisfied
0 Neither satisfied nor dissatisfied
0 Moderately dissatisfied
0 Very dissatisfied

54. Are you aware of the Food and Drug Administration's Vaccine Adverse Events Reporting System (VAERS) which the military is using to report adverse reactions to the anthrax vaccine? ***(check one)***

0 Yes
0 No→Skip to Question 57

55. Did you report your side effects or reactions to the Vaccine Adverse Events Reporting System (VAERS)? ***(check one)***

0 Yes
0 No (please explain): _____

56. To your knowledge, did the military report your side effects or reactions to the vaccine to the Vaccine Adverse Events Reporting System (VAERS)? ***(check one)***

0 ***Yes***

If yes, please specify the approximate date if known *(e.g., "03/99")*

_____
M M/ Y Y

0 No
0 Don'tknow

57. *Are you? (check one)*
0 Male →***Skip to*** *Question 62*
0 *Female*

Anthrax Vaccination-Women's Issues

58. **Did the military provide you with information (in briefings, brochures, etc.) about the anthrax vaccine and the following women's issues?** *(check one)*

--Yes	*--No*	*--Don't know/can't remember*	
0	0	0	**a. Pregnancy immediately after the shot**
0	0	0	**h. Breast feeding after the shot**
0	0	0	**c. Future pregnancy risk**
0	0	0	**d. Other (please *specify):* _____**

59. **At the time you received the anthrax vaccination shot(s), did medical personnel advise you not to take the vaccination if you were pregnant or possibly pregnant?** *(check one)*
0 *Not* **applicable,** I have not received an anthrax vaccination
0 Yes, always
0 Yes, sometimes
0 No
0 Don't know/can't remember

60. **Have you expressed any concerns to military medical personnel or your unit superiors about any female-specific issue as it relates to the anthrax vaccine?** *(check one)*
0 *Yes*
0 *No* →***Skip to*** *Question 62*

61. **How satisfied are you with the military's response to your female-specific concerns about the anthrax** vaccine? *(check one)*
0 **Very satisfied**
0 Moderately satisfied
0 Neither satisfied nor dissatisfied
0 Moderately dissatisfied
0 Very dissatisfied

Quality of Service Issues

62. **In general, how satisfied are you now, or if you are separated from the service, how satisfied were you prior to your separation with . . .** *(check one circle for each item)*

--Very satisfied	*--Moderately satisfied*	*--Neither satisfied nor dissatisfied*	*--Moderately dissatisfied*	*--Very dissatisfied*	
O	O	O	O	O	**a. Military values?**
0	0	0	0	0	**h. Military lifestyle?**
0	0	0	0	0	**c. Morale in your unit?**
0	0	0	0	0	**d. Availability of equipment/spare parts in your unit?**
0	0	0	0	0	**e. Amount of off-duty free time?**
0	0	0	0	0	**f. Your overall experience in the Guard/Reserve?**

63. **In general, how satisfied are you now, or if you are separated from the service, how satisfied were you prior to your separation with the leadership of...** *(check one circlefor each item)*

--Very satisfied	*--Moderately satisfied*	*--Neither satisfied nor dissatisfied*	*--Moderately dissatisfied*	*--Very dissatisfied*	
0	0	0	0	0	**a. Your immediatemilitary supervisor?**
0	0	0	0	0	**b. Senior military leaders above your unit level?**
0	0	0	0	0	**c. DOD and Service civilian leaders?**

64. **Overall, to what extent, do you support the military's anthrax vaccine immunization program?** *(check one)*
0 To a very great extent
0 To a great extent
0 To a moderate extent
0 To some extent
0 To little or no extent

65. **In your opinion, to what extent, do the following groups or individuals agree or disagree with your views on the military's anthrax vaccine immunization program?** *(check one circle for each item)*

--Strongly agree with my views	*--Generally agree with my views*	*--Neither agree nor disagree with my views*	*--Generally disagree with my views*	*--Strongly disagree with my views*	*--Don't know*	
0	0	0	0	0	0	**a. Your immediate family**
0	0	0	0	0	0	**b. Your co-workers**
0	0	0	0	0	0	**c. Superiors at your unit**

Additional Comments

66. Do you have any other comments that you would like to supply about anything discussed in this survey?

Thank you ***for*** your *participation.*

- ***Please return this survey in thepre-addressed business reply envelope that was enclosed with the survey.***
- ***At the same time, please mail back the enclosedpostcard <u>separately.</u> This will guarantee that we cannot associate your name with your survey and, at the same time, let as know that you have returned the survey.***

Presidential Advisory Committee on Gulf War Veterans' Illnesses
Final Report

Chapter Four

GULF WAR RISK FACTORS

U.S. service members potentially were exposed to a broad range of risk factors during the Gulf War. The Committee evaluated the potential health effects of several suspected risk factors, which were selected based on our charter, previous reports on Gulf War veterans' illnesses, and expert and stakeholder testimony at meetings held nationwide. We also have attempted to analyze the extent and likelihood of exposure to these risk factors during the Gulf War. In most instances, however, exposure data have been difficult to obtain or nonexistent. This chapter reports the Committee's findings on the following risk factors:

- pesticides,
- chemical warfare agents,
- biological warfare agents,
- vaccines,
- pyridostigmine bromide,
- infectious diseases,
- depleted uranium,
- oil-well fire smoke,
- petroleum products, and
- psychological and physiological stress.

The chapter first reports what is known currently about possible U.S. troop exposure to each risk factor. Following this analysis, we discuss health effects known to date, and we present our findings and recommendations in the final section of this chapter.

EXPOSURE TO RISK FACTORS IN THE GULF

As described in the Committee's *Interim Report*, few exposure data exist on many key Gulf War risk factors. In fact, for most of the risk factors we analyzed, the only exposure information available today is anecdotal recollections of Gulf War veterans. As a consequence, it will be difficult to link, in a scientifically valid manner, any adverse health outcomes detected by ongoing research to specific exposures or risk factors. As noted in chapter 2, the Committee has concluded that DOD's Persian Gulf Registry of Unit Locations will be of little use for investigating questions about Gulf War veterans' health issues and is certainly an inadequate substitute for missing exposure data.

Exposure to Pesticides

Precise records exist for pesticides DOD shipped to the Gulf region (table 4-1). All pesticides shipped were approved by EPA or FDA for general use in the United States at the time of the Gulf War. U.S. consumers can purchase these at grocery, gardening, and other stores in products such as: OFF® and Cutters® (DEET), Raid® Ant and Roach Killer Spray and Raid® Yard Guard (permethrin), Black Flag® Insect Spray (Baygon), permethrin spray for treating clothes, and a variety of Ortho® brand and other name brands of gardening products containing carbaryl, diazinon, malathion, chlorpyrifos, and permethrin.

While DOD can document what pesticides were shipped-and how much-there are virtually no records available today on how these pesticides were used in the Gulf region. DOD made no provisions for collecting or keeping distribution or use records of U.S.-shipped and approved products. Reports from a few veterans about the use of other, locally obtained, unapproved pesticides are impossible for the Committee to followup.

Assuming DOD adhered to its policies on pesticide use, its programs closely parallel those established by EPA and FDA regulations for domestic pesticide use. According to DOD policy, the majority of U.S. service members had access to two pesticides: permethrin in a spray can (for treating uniforms) and DEET liquid or stick as a personal mosquito and fly repellent. DOD reports about 2.2 spray-cans of permethrin and 2.0 tubes of DEET (33 percent formulation) were shipped to the Gulf for each U.S. service member. According to DOD, U.S. troops were not provided with permethrin pretreated uniforms. All other pesticides shipped to the Gulf region were to be used only by specifically trained individuals or for special applications. For example, lindane apparently was used nearly exclusively on Iraqi prisoners of war as a delousing agent.

Exposure to Chemical Warfare Agents

DOD has fully acknowledged one case of CW agent exposure. U.S. Army Sergeant Fisher was exposed to a small amount of mustard agent while patrolling an Iraqi bunker during the war. Diagnosis was made on the basis of small chemical burns on his arms consistent with mustard exposure.[52] DOD also has confirmed nerve agent detections by Czech units, but has identified neither sources nor potentially exposed U.S. troops.[13,119] DOD has confirmed release of nerve agent at Khamisiyah in March 1991, and the Committee has concluded that troops near the demolition activity should be presumed to have been exposed to some level of nerve agent (see chapter 2). The Committee does not presume, however, that this implies long-term health effects in those exposed. DOD continues to investigate other reported CW agent detections.

Except for the Fisher incident, DOD reports in-theater medical surveillance observed no immediate or characteristic poisoning symptoms from any exposure to CW agents. According to representatives from the U.S. Army Medical Corps, which was responsible for training medical personnel to be alert during the war for signs and symptoms of CW agent exposures, characteristic poisoning from nerve agents such as sarin and soman were not seen by medical personnel during the Gulf War.[52] At least one other DOD medical repre

sentative, however, posits that a presumption of low-level exposure to OP nerve agents should be made when evaluating unexplained medical problems reported by some Gulf War veterans.[13]

Exposure to Biological Warfare Agents

Based on classified and public information currently available, the Committee has concluded there is no persuasive evidence that U.S. troops were exposed to BW agents during the Gulf War.[35,51,52,119,148,274] We note our determination is based on imperfect information. For instance, the United Nations cannot verify the quantities and weaponization status of Iraqi BW products because Iraq claims it unilaterally destroyed all its biological weapons. Additionally, the United States did not deploy a real-time BW agent detection system during the war.

Two salient factors, however, led to the Committee's conclusion. First, there were no verified detections of anthrax or botulinum toxin during the war. Second, stateside examination of soil samples and enzyme assays did not reveal the presence of BW agents. The Committee's review of U.S. Army hospital admissions records identified one admission for anthrax (a disease indigenous to the Gulf region) and none for botulinum poisoning.[342,343] DOD has investigated reports of dead animals that might have succumbed to biological agents, and we concur with the finding that the evidence does not implicate BW agents. Finally, UNSCOM reported to the Committee that Iraqi officials have denied any use of biological weapons during the war and that its own assessment supports this claim.

Exposure to Vaccines

DOD estimates approximately 150,000 U.S. military personnel received at least one anthrax vaccination, and about 8,000 service members received at least one dose of BT vaccine during the Gulf War. As noted in the Interim Report, however, medical recordkeeping on these and other matters was woefully inadequate.

Exposure to Pyridostigmine Bromide

All U.S. troops received blister packs containing PB pills during the Gulf War. The pills were intended to be self-administered upon a unit commander's order. DOD estimates approximately 250,000personnel took at least some PB during the Gulf War.[118] As noted in the Interim Report, accurate assessment of PB exposure of U.S. troops is not possible today because no records were kept of self-administered medications.

Exposure to Infectious Diseases

Infectious diseases endemic to the Gulf region include shigellosis, malaria, sandfly fever, and cutaneous leishmaniasis.[6,65,90,187] Along with

these infectious diseases, DOD medical personnel also monitored troops for dengue, Sindbis, West Nile fever, Rift Valley fever, and Congo-Crimean hemorrhagic fever.[90,293]

According to DOD, no cases of sandfly fever were reported during Operations Desert Shield/Desert Storm. Medical personnel saw seven individuals with malaria, one with West Nile fever, and none with rickettsial or other arthropod-borne viral illnesses; arthropod-borne viral diseases endemic to the Gulf are not known to cause chronic infection or disease. The documented low rates of infection among U.S. troops suggest exposures were minimal and/or preventive measures were effective.

Exposure to Depleted Uranium

According to the Office of the Army Surgeon General, 36 U.S. service members are known to have been exposed to DU when wounded in "friendly fire" incidents involving DU munitions.[112,267] VA reports it believes about two dozen of these individuals retain embedded DU shrapnel in their bodies.

In addition to exposure through "friendly fire" incidents, a review by the U.S. General Accounting Office concluded that several dozen service members were exposed to DU while retrieving or servicing vehicles damaged by DU munitions.[267,306] This number comprises about two dozen Army National Guard soldiers from the 144th Service and Supply Company who have reported they were unknowingly exposed to DU-contaminated debris while working with combat vehicles hit by DU munitions. Another two dozen soldiers from the 24th Infantry Division have reported they were unknowingly exposed to such debris in the course of vehicle recovery and maintenance operations.[96,97,267,306]

Although DOD had appropriate procedures for protecting personnel who worked with DU contaminated vehicles during the Gulf War, apparently few U.S. service personnel were adequately trained in these procedures. U.S. service personnel also could have been exposed to DU if they inhaled DU dust particles during incidental contact with vehicles destroyed by DU munitions, or if they lived or worked in areas contaminated with DU dust from accidental munitions fires. Thus, unnecessary exposure of many individuals could have occurred.[15,18,20,27,42 44,57,141,142,161,186,191,203,226,260,267,306]

With the exception of individuals who retain embedded DU munitions fragments, it is not possible to use *in vivo* monitoring today to develop accurate assessments of DU exposure in the Gulf. Whole-body counting to detect photons of x-ray or gamma radiation cannot be used to test for DU: The equipment is not designed to detect the low energy photons associated with DU decay.87 Moreover, the time that has elapsed since the Gulf War is long compared to the body's retention rate of uranium-i.e., it would be difficult to detect DU even with more sophisticated equipment performing specialized tests such as lung counts.[87,259]

Exposure to Oil-well Fire Smoke

In contrast to other risk factors, exposure to oil-well fire smoke is better characterized. Many U.S. service members who remained in the Gulf after the oil well fires started could have been exposed to oil-well fire smoke. The burning wells were located in eastern Kuwait, with the majority to the south of Kuwait City. Smoke plumes rose and combined in a "superplume" that could be seen for hundreds of kilometers and sometimes even partially blocked out the sun. Occasionally, smoke plumes touched down to the ground, sometimes enveloping nearby troops. Exact exposure levels for individual soldiers are not certain, but local and regional exposure information is available for oil well fires.

Multiple U.S. and international agencies performed extensive air monitoring during the fires and did not find pollutant levels likely to cause long-term health effects:

- A U.S. Interagency Air Assessment team-comprised of scientists from EPA, the National Oceanographic and Atmospheric Administration, and DHHS-arrived in Kuwait in March 1991 to assess the potential health effects of the oil well fires.[311]
- Scientists from 12 countries, including Kuwait and neighboring countries, were involved in a data collection effort overseen by the World Meteorological Organization.[339]
- The U.S. Army's Environmental Hygiene Agency carried out the largest effort, collecting nearly 4,000 ambient air and soil samples from May to December 1991.[265]

The data indicate that, despite the dramatic appearance of the oil plumes, pollutant levels were surprisingly low. All groups found that levels of nitrogen oxides, carbon monoxide, sulfur dioxide, hydrogen sulfide, other pollutant gases, and polycyclic aromatic hydrocarbons (PAHs) were lower than anticipated and did not exceed those seen in urban air in a typical U.S. industrial city.[89,289,302,339]

High levels of airborne particulate matter (sand and soot), however, were observed frequently at several monitoring sites. Analysis of samples suggested particles were mostly sand-based materials; high levels of airborne sand particulates are typical for this region of the world. Within the samples of particulate matter, levels of PAHs and toxic metals were low.[84,265]

Samples were collected during at least one instance when the smoke plume had touched down, providing "worst case" exposure data. Although airborne contaminants were detectable, they were surprisingly low compared to current U.S. occupational standards for these contaminants-even within the plume touchdown.[84,265,266]

Various biological samples also were collected from troops or other personnel working in Kuwait while the fires burned. One CDC study found blood levels of volatile organic compounds (VOCs) in firefighters were significantly higher than those in a U.S. reference population,[55] but individuals in Kuwait City, about 20 km from oil fires, had VOC levels approximately that of the reference group. These data are limited by small sample size and the short half-life of VOCs in service members' blood, but they suggest oil-well fire smoke did not significantly increase VOC exposures in troops in the Kuwait City area when most of the fires were active.

Blood and urine samples collected from a group of U.S. service members before, during, and after their 1991 deployment to Kuwait were analyzed for VOCs, PAH-DNA adducts, metals, and sister chromatid exchange (SCE) frequency in lymphocytes.265 Pulmonary function tests and questionnaires also were administered. Levels of metals, VOCs, and PAH-DNA adducts showed no changes or showed decreases in troops living in Kuwait compared to troops living in Germany, with few exceptions. Lead levels in blood were not statistically significantly altered during deployment to the Gulf region.*

Exposure to Petroleum Products

Few specific data exist about possible exposures of U.S. service members to petroleum fuels or their combustion products. Operating the vehicles and machinery used in the Gulf War involved exposure to petroleum-based material. Petroleum fuels also were used for burning wastes and trash, dust suppression, and fueling stoves and tent heaters; none of these uses is unique to the Gulf War. Such uses, however, probably led to increased petroleum vapor and combustion product exposures. Thus, some U.S. service members were exposed to petroleum materials, including benzene, toluene, xylene, ethyl benzene, and combustion products including carbon monoxide, sulfur dioxide, nitrogen dioxide, particulates, lead, and other pollutants.

The U.S. Army's air monitoring (and blood monitoring done by CDC in a small study) found no evidence of elevated exposure to VOCs (including petroleum materials).[55,265] Still, some service members clearly experienced short-term, elevated exposures to petroleum fuels. For example, diesel was sprayed on the ground to suppress dust from the fine sand found in the Gulf region. A U.S. Central Command document lists crude oil/waste oil as the least desirable option for dust suppression, but does not mention diesel fuel.[280] One U.S. Army sanitary engineer testified to the NIH Technology Assessment Panel in 1994 that units used water or diesel fuel for dust suppression during the war.[100] He described one brigade dumping 30,000 gallons of diesel fuel on the roads daily, and said U.S. service members living in tents near the roads-and particularly truck drivers carrying out the spraying-complained of nausea from breathing the resulting fumes. As a result, the preventive medicine person to whom they complained obtained respirators for the drivers' use.[101] Another occupational group that could have experienced some risk of elevated exposures to petroleum products during the Gulf War were those who worked at military "Petroleum, Oils, and Lubricants" points where these materials were distributed.

The fuel used most widely during the war for both vehicles and equipment was Jet A-1, an internationally used kerosene-based aviation fuel provided at no cost by the Saudi Arabian government. Of the 1.8 billion gallons of fuel used during Operations Desert Shield/Desert Storm, roughly 75 percent was jet fuel (mostly Jet A-1), 24 percent was diesel fuel, and 1 percent was gasoline.[248] The gasoline used during Operations Desert Shield/Desert Storm was commercial leaded gasoline refined to Saudi Arabia's national standard.[135]

Combustion products from heaters used in poorly ventilated areas also are a general exposure concern for Gulf War participants. Burning leaded fuels indoors without proper ventilation-e.g., heaters in tents-could have caused increased lead exposure. Kerosene heaters, widely used in the United States, also could have been significant sources of exposure to nitric oxides, sulfur dioxide, inorganic combustion gases, carbon monoxide, and particles when used with inadequate ventilation.[165] During the war, four hospitalizations in U.S. Army field hospitals occurred because of asphyxiation from carbon monoxide.[342,343]

Exposure to Psychological and Physiological Stress

U.S. service members encountered many stressors during the Gulf War, including short deployment notice, uncertainty about length of deployment, isolation and separation from family, a polluted environment, poor living conditions with little privacy or social outlets, prolonged work hours, decreased income and worry about job retention, fear of SCUD missile and chemical and biological weapon attacks, anticipation of high casualty rates and torture, frequent CW agent alarms

that often required a defensive posture and full chemical gear, and dealing with casualties and dead bodies.

Even when the war was over, many veterans experienced postdeployment stress on their return from the Gulf. These included financial and employment difficulties, unresolved military pay issues, the revelation of cases of leishmaniasis and the consequent temporary ban on blood donations, increasing numbers of health complaints and "unexplained illnesses," and media accounts of apparent increased numbers of birth defects and cancer.

HEALTH EFFECTS OF GULF WAR RISK FACTORS

The Committee undertook a comprehensive analysis of the health effects of the ten Gulf War risk factors for which we examined possible exposures. Our analysis of possible health effects was performed independently of whether exposures were undocumented, imprecise, or known. That is, we considered the possible health consequences of a range of scenarios from high-level to low-level exposure and from single to multiple event and chronic or continuing exposure. The Committee also considered short-term and long-term health effects, including symptoms that might have appeared while service members were still in the KTO and symptoms that might not have appeared until sometime after the service members left the Gulf. The Committee's search for possible health effects extended to all organ systems and to cancer and noncancer outcomes.

Our examination of health effects drew on three types of sources: scientific literature; briefings and workshops with recognized experts; and information presented at Committee meetings. The Committee reviewed human exposure (mostly occupational) data and laboratory animal data. We found extensive scientific literature describing the human health effects for all the risk factors investigated, including CW agents, for which we initially had anticipated would have significant data gaps. The breadth and depth of information generally were sufficient** to make conclusions about the short- and long-term health effects that would be anticipated for U.S. service members exposed to a particular risk factor during the Gulf War.The information available in these sources, however, represents the boundaries of the Committee's investigation. We conducted no primary research and elected not to base our findings on research not yet subjected to peer review.

Finally, the Committee drew conclusions about the role of each risk factor in Gulf War veterans' illnesses based on comparison of the known health effects of the risk factor to the symptoms reported by Gulf War veterans. Symptoms reported by Gulf War veterans used in these comparisons were based on DOD's CCEP and VA's Persian Gulf Health Registry (see table 3-2).

Pesticides

As noted earlier in this chapter, pesticides DOD shipped for use during the Gulf War fell into five major categories: OP pesticides, methyl carbamate pesticides, organochlorine pesticides (lindane), pyrethroid pesticides (chiefly permethrin), and DEET.

Organophosphorus pesticides. Several OP pesticides were used during the Gulf War, including chlorpyrifos, diazinon, dichlorvos, and malathion. When administered in high doses, OP pesticides cause irreversible inhibition of acetylcholinesterase, an enzyme crucial to normal nerve and nerve/muscle function. Inhibiting acetylcholinesterase leads to unique and highly characteristic poisoning symptoms. Immediate symptoms of OP poisoning in humans usually develop within four hours of exposure and include narrowing of the pupil of the eye (miosis), headache, nausea, dizziness, anxiety, and restlessness. Severe and rapid onset poisoning symptoms include muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps, diarrhea, sweating, salivation, tearing, runny nose, and production of phlegm. Life-threatening symptoms include unconsciousness, incontinence, convulsions, and depression of breathing function. According to DOD, its medical monitoring and surveillance efforts reported no cases of immediate and severe OP poisoning symptoms in U.S. military personnel during the Gulf War.

Some individuals who recover from immediate and severe OP poisoning show long-term (lasting more than a year), subtle, neuropsychological abnormalities that can be detected using a battery of standardized neuropsychological tests. In an epidemiologic study of such long-term effects, severely poisoned individuals showed clear but subtle differences in intellectual functioning, academic skills, abstraction and flexibility of thinking, and simple motor skills. For example, about a five point difference in IQ was measured in severely poisoned versus control subjects.

Neurophysiologic effects were less apparent; abnormalities were found only in measurements of memory, abstraction, and mood and on one test of motor reflexes.221 These effects could not be detected, however, in a subset of the same worker population that had been exposed to doses of OP pesticides that were too low to cause the symptoms of immediate and severe poisoning.241 Other studies of low-level occupational exposures reinforce the finding that these types of long-term effects present solely in the aftermath of severe and immediate OP agent poisoning.[4,241]

Some OP pesticides that are no longer sold in the United States have been associated with human cases of a second type of delayed toxic effect called organophosphate-induced delayed neurotoxicity (OPIDN, sometimes referred to as delayed neuropathy). Initial symptoms are muscular incoordination progressing to numbness, tingling, fatigue or a cramp-like pain in the calf muscles, and even moderate to severe muscular weakness and paralysis.[7,117] Typically, effects occur 7 to 14 days following recovery from immediate and severe poisoning by the OP pesticide and involve neuropathologic lesions and degeneration of the nerve axon and myelin nerve sheath in both the central and peripheral nervous systems;[117] these effects are easy to measure in a clinical setting. In general, OPIDN caused by OP pesticide poisoning is associated with immediate poisoning symptoms.

All OP pesticides sold in the United States today are routinely screened for OPIDN toxicity with a standardized hen assay used by EPA; the hen is a laboratory animal especially sensitive to OPIDN effects. For some OP agents, these effects only can be observed by giving the hen extremely high doses that would rapidly lead to death, but then keeping the hen alive through the use of protective drugs such as atropine. Many investigators conclude any OP agent theoretically could cause this effect at sufficiently high doses, but that, in fact, immediate toxic effects cause death before delayed effects can be seen.[117] None of the pesticides DOD shipped to the Gulf War test positive for OPIDN in standard EPA screens.

Methyl carbamate pesticides. Methyl carbamate insecticides shipped for use during the Gulf War included propxur (Baygon®), carbaryl (Sevin®), and methomyl (Lannate®). These insecticides reversibly inhibit acetylcholinesterase, which leads to poisoning effects similar to OP poisoning. Poisoning with methyl carbamates tends to be of much shorter duration-with a greater margin of safety between symptom-producing and lethal doses-compared to OP pesticides, which bind permanently with acetylcholinesterase.

Pyrethroid pesticides. DOD shipped the pyrethroid insecticide permethrin to the Gulf for use as an insect repellent. Permethrin is used widely in the United States as the active ingredient in personal care products, such as shampoos and lotions, and for treating clothes to make them insect repellent. There are few reported poisonings of humans by permethrin, most likely because such a large dose is required to cause poisoning. Humans rapidly detoxify and excrete permethrin. Clinical signs of immediate permethrin poisoning following large oral doses become evident within two hours and include incoordination, ataxia, hyperactivity, and convulsions, followed by prostration, paralysis, and death.[171] Unlike OP pesticides, the Committee found no reports of long-term effects from permethrin poisoning in humans.

A National Research Council (NRC) subcommittee that reviewed possible health problems for military personnel wearing permethrin-treated military clothing concluded it is unlikely that soldiers using such uniforms would experience adverse health effects at the suggested exposure levels. The subcommittee concluded, "the weight of evidence shows that permethrin is unlikely to be a skin irritant or skin sensitizer for military personnel who are exposed to it dermally from wearing permethrin impregnated [uniforms]." The estimated "no observable adverse effect level" for immediate neurotoxic effects in humans from daily exposure is 200 milligram (mg)/kilogram, which is approximately three million times greater than estimated dermal exposure from permethrin treated uniforms.[171] NRC's worst-case estimate of lifetime carcinogenicity risk for humans wearing permethrin treated uniforms was less than 2 in 1,000,000.

In laboratory animal studies, dermal absorption of permethrin is low, although scientists observe neurotoxic effects if the substance is injected.[171,301] Most, but not all, studies have reported permethrin does not cause damage to genetic material in a wide variety of standard measurement systems. Permethrin is neurotoxic to laboratory animals at high oral doses. Rats fed permethrin at 6,000 mg/kg for 14 days showed fragmented and swollen sciatic nerve axons and myelin degeneration. However, nerve conduction studies in 23 permethrin workers showed no evidence of nerve impairment associated with permethrin exposure.[171] Rodent bioassays of chronic exposure to permethrin showed carcinogenic effects, such as liver and lung adenomas and lung carcinomas in mice, but data on human carcinogenicity of permethrin are lacking.

Organochlorine pesticides. DOD shipped one organochlorine pesticide, lindane, to the Gulf region. Lindane, once widely used as an agricultural insecticide in the United States, is still available as a lotion to treat head and body lice and scabies.[283,301] Lindane is dermally absorbed, stored in body fat, and only slowly leaves the body. Reports document that a few people who have used large amounts of lindane on their skin have had blood disorders and even seizures. Under conditions of extremely high exposure, lindane can cause liver and kidney disease.

Some pregnant laboratory animals orally treated with the maximum tolerated dose (the dose just below that causing immediate and severe toxicity) showed a statistical increase in the number of fetuses with extra limbs, indicating that lindane is a teratogen for this laboratory animal strain. Lindane has not been shown to be a human carcinogen, although long-term oral exposure of lindane to certain species and strains of laboratory rodents has been reported to cause liver cancer.[283] Hence, DHHS has determined that lindane should be viewed as a human carcinogen.

DEET. DEET, first introduced in 1955, continues to be a widely used liquid insect repellent in the United States, and DOD shipped approximately two 2-oz tubes per U.S. service member during the Gulf War. According to EPA, 50 to 100 million Americans use DEET-containing insect repellents annually. Relative to most pesticides, DEET has notably low immediate toxicity.[190,301] Although generally well tolerated when used as an insect repellent applied to human skin, about five to nine percent is absorbed through skin, and reports exist of tingling, mild irritation, and occasional skin peeling following repeated application.[301] Topically applied DEET is rapidly eliminated, mostly in the urine. In the past 35 years a few reports in the medical literature suggest rare neurotoxic effects.[190] In adult humans, ingestion of enormous doses of DEET has been associated with immediate toxic effects, including tremors, generalized seizures, and coma, although no long-term effects of poisoning have been reported.[320] (For possible synergistic effects, see section on PB later in this chapter.)

Rats continuously fed DEET up to the maximum tolerated dose over three generations showed a slight increase in the high-dose animals in a single neurological abnormality-a slight increase in exploratory locomotor activity-and no histopathologic central nervous and peripheral nervous system changes of significance.[190] Other reports indicate that rats fed the maximum tolerated dose of DEET can show severe and often fatal prostration accompanied by a brain myelinopathy.[320]

What do we conclude about the risks of pesticides to Gulf War veterans? According to DOD, after-action reports from in-theater medical personnel did not reveal any U.S. troops reporting symptoms that would indicate pesticide poisoning. Evidence from studies of humans poisoned by OP pesticides suggests that low-level exposures that do not cause signs and symptoms of immediate and severe poisoning will not result in long-term health effects. Thus, the Committee concludes it is unlikely that health effects and symptoms reported today by Gulf War veterans are the result of exposure to pesticides during the Gulf War. Lindane is an animal liver carcinogen, but it is too early to see an elevated liver cancer rate in Gulf War veterans.

Chemical Warfare Agents

At the time of the Gulf War, the U.S. military believed Iraq had weapons that could deliver OP nerve agents, including sarin, soman, and VX, and mustard (blister) agents. Hence, U.S. forces were supplied with protective gear, detectors, and prophylactic drugs to protect against the known consequences of exposure.

Immediate signs and symptoms of nerve agent poisoning. OP nerve agents are designed to incapacitate and kill humans. Inhalation exposure to these agents leads to immediate effects, including miosis, runny nose, and increased salivation. Immediate effects following skin exposure include local sweating and muscle twitching. Eye exposure rapidly produces miosis, which often is associated with eye pain, headache, and blurred vision.[264] In fact, miosis is the most sensitive and specific immediate response to acute poisoning in humans, and this reaction has served as the basis for establishing allowable occupational concentrations for CW nerve agents. Higher doses of these agents cause more severe effects, including convulsions, neuromuscular blockage, profuse airway obstruction and apnea-developing within one to two minutes of exposure.[77] Death occurs due to respiratory paralysis. The effects of nerve agent poisoning (figure 4-1) are virtually identical to those of severe OP-pesticide poisoning.

Data on human effects of CW nerve agent poisoning derive largely from human experiments carried out by the U.S. Army from the 1940s to the 1960s. Table 4-2 illustrates the type of information on immediate poisoning effects from low-level exposures to the OP nerve agent sarin.

Immediate signs and symptoms of mustard agent poisoning. With mustard agents, poisoning symptoms are severe irritation and tissue damage to eyes, skin,

and respiratory and gastrointestinal (GI) tracts. Usually the onset of symptoms is delayed for some hours after exposure.

One report of Iraqi use of mustard agent against Iranian troops in 1984 documented health effects in more than 5,000 Iranian casualties. Affected individuals had first to third degree burns over 20 to 70 percent of the total skin surface. Eye exposure caused tearing, severe conjunctivitis, and temporary loss of vision. Corneal abrasion was nearly always present, and photophobia and blurred vision developed in some cases. Upper airway involvement due to chemical burning of the throat led to pharyngitis and tracheobronchitis. These effects were quite severe, and this group suffered approximately 15 percent mortality. Those who survived the initial symptoms later experienced various GI complaints, including nausea, vomiting, and diarrhea. After five to seven days, hematologic problems were the greatest health threat to survivors.[105]

Long-term health effects of exposure to CW nerve agents. Two NRC reports addressed possible long-term morbidity and mortality in about 1,400 servicemen intentionally exposed to CW nerve agents in experiments conducted over a 20-year period ending in 1975. The possibilities of excess cancer risk and adverse mental, neurologic, hepatic, and reproductive effects were reviewed. Both NRC analyses concluded that no evidence exists that CW nerve agents cause long-term, adverse human health effects at the doses tested. The doses were nonlethal, but were high enough to cause clinical effects (such as miosis). NRC reported that both analyses had the power to detect any major health effects had they been present. A statistically significant increase in admissions to VA hospitals for malignant neoplasms was detected, with the caveat that admission numbers were small, showed no dose relationship, and no clustering of specific chemicals in relation to tumor site.[174,175]

Numerous studies in humans and animals report that survival from severe, immediate poisoning by OP nerve agents (including OP pesticides) can be associated with measurable, long-term neurological effects. One study of 77 industrial workers exposed to levels of sarin that caused immediate toxicity showed slight alterations in electroencephalograms (EEGs) one year after exposure. The study also reported, however, that trained experts could not distinguish an individual EEG from an exposed individual from an EEG of a person who had not been exposed, and that no clear relationship existed between alterations in EEG frequency spectrum and alterations in brain function.[22] A 1975 review by Lohs of the effects of CW agents in humans similarly reported long-lasting effects following severe, immediate OP pesticide and CW agent poisoning.[140]

CW nerve agents do not show OPIDN toxicity as measured in EPA's standardized hen bioassay for evaluating OP pesticides, except with extremely high doses (10 to 100 times the lethal dose) where immediate and severe toxic effects, including death, are seen.[117] Because OP CW nerve agents are chemically similar to OP pesticides and affect the same enzyme system in the body, similar long-term health effects would likely occur in the aftermath of immediate, severe poisoning with sarin, soman, or VX-i.e., the subtle, but measurable, neurophysiological and neuropsychological effects described earlier in this chapter. Again, these health effects did not occur in populations that had been exposed to subclinical amounts of OP pesticides. Current scientific evidence suggests that subclinical exposure to OP CW nerve agents does not result in long-term neurophysiological and neuropsychological health effects. Ongoing research at the Boston and Portland Environmental Hazards Research Centers is investigating the possibility of such effects in Gulf War veterans.

Long-term health effects of exposure to mustard agents. Based on epidemiologic research, humans exposed to mustard agent are at increased risk for lung cancer.[98,287] Several other reviews of human exposure to mustard agent during World War I (WWI) and other wars also indicate veterans exposed to mustard agents during the Gulf War could experience other respiratory problems as well.[98,287]

During World War II (WWII), more than 60,000 U.S. service members were used as human test subjects and exposed to mustard agents, including at least 4,000 individuals exposed to high concentrations of these agents.[98] An Institute of Medicine (IOM) review concluded that several specific chronic diseases are causally associated with mustard agent exposure. These include various respiratory cancers, skin cancer, chronic skin ulceration and scar formation, chronic respiratory disease including asthma, chronic bronchitis, emphysema, chronic eye diseases, and various psychological disorders including PTSD. IOM also found suggestive evidence (weaker than the associations for the conditions just mentioned) that exposure to mustard agent was associated with leukemia. Finally, IOM also analyzed two studies that examined the link between mustard and reproductive dysfunction, but determined that the database could not be used to make conclusions about human reproductive health effects.[98]

What do we conclude about the risks of CW agents to Gulf War veterans? Current scientific literature indicates that when exposure to OP CW agents results in immediate and severe poisoning, long-term, subtle neuropsychological and neurophysiological effects could occur. Available scientific evidence does not indicate that such long-term effects occur in humans following low-level exposures, but the amount of data from either human or animal research on low-level exposures is minimal. Long-term effects in humans exposed to mustard agents include an elevated risk of lung cancer beginning decades after exposure. Based on available data, it is unlikely the health effects reported by Gulf War veterans today are the result of exposure to OP or mustard CW agents during the Gulf War. Ongoing or planned federally-funded studies focused specifically on low-level exposures and delayed neurotoxicity of CW agents should elucidate gaps in knowledge and eliminate uncertainty and/or identify new directions for research.

Biological Warfare Agents

The U.S. military prepared for the possibility that Iraq might use two BW agents-anthrax and botulinum toxin-against U.S. service members during the Gulf War. After the war, new data revealed Iraq had also weaponized aflatoxin. The Committee evaluated the potential health effects of these three BW agents on the long-term health of Gulf War veterans.

Anthrax. Anthrax is a bacterial disease most often found in cattle and sheep. Human infection can occur by contact with infected animals or by inhalation of spores from infected animal products (e.g., as hides or wool). Left untreated the disease usually is fatal. After exposure, the anthrax bacteria travel to the intestines and other areas where they cause severe tissue damage. Initial symptoms include nonspecific malaise, low grade fever, and nonproductive cough. Initially, anthrax can be difficult to diagnose because symptoms, although severe, are not specific.[103] As the disease progresses, symptoms include high fever, labored breathing, choking cough, and vomiting; death usually occurs within four days.[276] Terminal symptoms include abrupt onset of shortness of breath, harsh breathing, skin turning blue, excessively rapid heartbeat, and rapid progression to shock and death. Cases of pulmonary anthrax caused by inhalation of aerosolized spores (which would be the case in a military use) are almost invariably fatal if not treated immediately with antibiotics. Exposure to small numbers of infecting spores can increase the incubation time of the disease from a few days to several weeks, but if infection occurs, the disease progresses toward death in the same manner as for high-level exposure.[103,276] No long-term effects have been reported in persons successfully treated for anthrax.

Botulinum toxin. Botulinum toxin is a group of related, highly poisonous protein agents isolated from fermentation of the bacterium *Clostridium botulinum,* which naturally occurs in soil and can grow in many meats and vegetables. Botulinum toxin is fast-acting, usually producing symptoms within 18 to 36 hours after ingestion. Death occurs in 80 percent of an exposed population after one to three days.[276] Botulinum toxin blocks neuromuscular conduction by binding to receptor sites on motor nerve terminals and by inhibiting the release of acetylcholine. Symptoms at high exposure levels can include respiratory distress and respiratory paralysis, which may persist for six to eight months.[117] Disability progresses from difficulty in walking and swallowing and impaired vision and speech to convulsions. Ultimately, symptoms include paralysis of the respiratory muscles, suffocation, and death-all within a few hours or days, depending on the amount of toxin ingested.[276] In cases of accidental exposure in the general population, the fatality rate is 35 to 65 percent and is fatal in three to ten days.[117] Botulism antitoxin can be effective if administered within days of exposure.[276] The Committee found no scientific literature suggesting adverse long-term health effects from low-level exposure to botulinum toxin.

In fact, botulinum toxin has conventional medical therapeutic uses. Botox® is an FDA-approved, purified, type A botulinum toxin, and injecting it into the muscle of patients causes a localized, temporary denervation and muscle paralysis. Such an effect is therapeutically useful for treating a number of conditions, including blepharospasm (an involuntary recurrent spasm of both eyelids) and for use in certain types of eye surgery. Studies on thousands of adults treated with Botox® have shown only mild side effects-e.g., a diffuse skin rash lasting several days-as a result of the localized muscle paralysis effects of the toxin. The only long-term effect reported is a slight reduction in the effectiveness of Botox® due to a person's natural immune responses.

Aflatoxin. Aflatoxin is a naturally occurring toxic metabolite from certain fungi that sometimes occur on grains, peanuts, and other foods stored under certain conditions.[117] Aflatoxin ingestion can result in immediate, toxic effects in many different species, and death results from acute liver toxicity.[29,117] Aflatoxicosis in humans has been reported following ingestion of aflatoxin contaminated food, and symptoms include vomiting, abdominal pain, pulmonary edema, gastrointestinal hemorrhage, convulsions, coma, and death.[29] Several epidemiologic studies suggest aflatoxin causes liver cancer in humans. The only documented health effect that could be expected from low-level exposure to aflatoxin would be an increased prevalence of liver cancer years to decades after exposure.

What do we conclude about the risks of BW agents to Gulf War veterans? In cases where an individual survives exposure to anthrax or botulinum toxin, no known, long-term health consequences exist. The Committee concludes it is unlikely the health effects reported today by Gulf War veterans are the result of exposures to BW agents. Aflatoxin, however, is a liver carcinogen, and increased rates of liver cancer could result decades following low-level exposure, although available evidence reviewed by the Committee does not indicate such exposures occurred during the Gulf War (see chapter 2).

Anthrax and Botulinum Toxoid Vaccines

Before U.S. troops deployed to the Gulf region, they received a standard series of inoculations against infectious diseases-e.g., cholera, typhoid, tetanus, diphtheria, polio, and measles-that might be given to any U.S. citizen traveling to these regions. After arriving in the Gulf War region, some U.S. service members received two additional vaccines for protection against the BW agents anthrax and botulinum toxin.

Anthrax vaccine. In 1970, FDA licensed anthrax vaccine to protect civilian workers against possible infection by anthrax bacteria. Since 1967 and before the Gulf War, more than 20,000 inoculations had been routinely administered to at-risk populations, including laboratory personnel who work with the bacteria that causes anthrax, persons in industries that work with animal hides and wool (which can be a source of anthrax infection), and veterinarians who come in contact with anthrax-infected animals.

Although active long-term safety surveillance is not generally part of the FDA vaccine licensing process, the FDA encourages U.S. health care providers and the law requires manufacturers to report serious adverse reactions for all licensed vaccines.[305] FDA has not received data that raise concerns about the safety of the anthrax vaccine.

Historical data for short-term health effects of the anthrax vaccine indicate up to six percent of recipients experience mild discomfort, including tenderness, redness, swelling or itching at the inoculation site for up to 72 hours. Fewer than one percent experience a more severe local reaction that potentially limits the use of the arm for one to two days. Systemic reactions, e.g., fever, malaise, are uncommon (about 0.1 percent).[102,103]

According to DOD, medical monitoring and surveillance conducted during the Gulf War found the expected short-term side effects of anthrax vaccines occurring at approximately the historical rates.[53] A single hospitalization for a vaccination site infection was reported. DOD points out that precise information about all possible short-term side effects is unknown, however, because of difficulties in collecting such data during and after the Gulf War.

Botulinum toxoid vaccine. Botulinum toxoid (BT) vaccine has been used for more than 25 years to protect industry and laboratory workers from occupational exposure to the extremely poisonous botulinum toxins. All civilian vaccinations have been administered under an investigational new drug (IND) application sponsored by CDC. For both civilian and military use, BT vaccine remains in "investigational" status-i.e., not yet licensed by FDA.

Since 1970, as part of the IND evaluation, FDA has reviewed information from CDC about the cumulative safety record for BT vaccine. Records of more than 10,000 administered vaccine doses (including approximately 2,200 in the five years before the Gulf War) indicate that treated individuals experience only local side effects often associated with many types of vaccinations. These effects, primarily at the injection site, include local pain, tenderness, swelling, redness, and itching. Systemic reactions such as temporary fever, tiredness, headache, or muscle pain also can occur. Rarely, reactions include soreness of the arm sufficient to leave individuals unable to perform duties for a day or two or development of a lump at the injection site that generally resolves within several weeks. Such adverse reactions also are observed with other licensed toxoid vaccines, such as diphtheria and tetanus toxoids.[53,102]

The U.S. Army examined the frequency of side effects of BT vaccinations seen in some U.S. service members. In one report of 237 Gulf War veterans who had received BT vaccine, 2.5 percent had systemic reactions. This rate parallels that recorded by the U.S. Army and CDC prior to the Gulf War.[127]

Precautions against contaminants. The Committee examined the hypothesis that Gulf War veterans' illnesses could be the result of contamination of anthrax

vaccine lots by *Mycoplasma incognitus*.[182] Discussions with staff of FDA, Walter Reed Army Medical Center, U.S. Army Medical Research and Materiel Command, academic experts, and the manufacturer of the vaccines indicate that *Mycoplasma* could not survive in the anthrax and BT vaccines.[136,138,168,303] *Mycoplasma* is difficult to grow, and the culture media used to produce Anthrax and BT vaccines do not contain serum, an essential ingredient for *Mycoplasma* growth. In addition, the vaccines are preserved and/or processed with other products that create a hostile environment for *Mycoplasma*, including:

- formaldehyde (anthrax and BT vaccines),
- benzethonium chloride (anthrax vaccine only),
- isotonic saline solution (BT vaccine only), and
- Thimerosal (BT vaccine only).

The Committee concludes it is unlikely that *Mycoplasma* organisms contaminated anthrax vaccine or BT vaccine.

Health effects of multiple vaccines. The human immune system has evolved the capability to deal with thousands of foreign substances, to sort them out, and to regulate immune response. Humans live among a vast population of hostile microorganisms, and vaccinations-even multiple, contemporaneous vaccinations-are a small part of total immune stimulation. Individual vaccines can cause adverse effects, but several studies of the effects of giving multiple vaccinations at one time have found no adverse effects associated with the practice. Research on this issue continues, but based on available evidence, the Committee believes it is unlikely that multiple vaccines are responsible for illnesses reported today by Gulf War veterans.[202,219,268]

What do we conclude about the risks of vaccines to Gulf War veterans? The Committee concludes it is unlikely that health effects reported by Gulf War veterans today are the result of exposures to the BT or anthrax vaccines, used alone or in combination.

Pyridostigmine Bromide

PB is a pretreatment drug used to protect against the CW nerve agent soman. By itself PB is not protective against CW nerve agent poisoning. Used as a pretreatment, however, PB might enhance the antidote effects of the standard atropine and 2-PAM treatments used by the U.S. military for nerve agent poisoning.[269]

Since 1955, FDA has approved PB for use by persons suffering from myasthenia gravis. No long-term health problems thought to be associated with PB have been reported for persons with myasthenia gravis who regularly take PB over many years or decades.[196,220] DOD filed a New Drug Application in May 1996, but PB currently has the status of an IND for nerve gas pretreatment use.

According to FDA, its conclusion that PB was safe for use by U.S. service members during the Gulf War was based largely on the extensive cumulative experience with this drug in patients with myasthenia gravis. Typically these patients are treated with PB doses of up to 1,500 mg per day for many years, compared to the prescribed dose of 90 mg per day for a maximum of seven days use during the Gulf War. Reported side effects of PB include increased salivation, increased tearing, urinary urgency and frequency, nausea, vomiting, muscle weakness, abdominal cramps and diarrhea.[167] These effects disappear when individuals stop taking PB.

Data from one DOD retrospective study on 30 medical support officers of the 18th Airborne Corps reveal a similar range of short-term health effects from PB. The 18th Airborne Corps instructed 1,650 soldiers (6.5 percent women) to take PB tablets at the onset of Operation Desert Storm in January 1991. Half those surveyed reported gastrointestinal symptoms, 5 to 30 percent reported increased urinary urgency and frequency, and fewer than 5 percent reported headaches and tingling of extremities. The need for a medical visit was reported by less than 1 percent, and the decision to discontinue use based on medical advice was reported by less than 0.1 percent. As with myasthenia patients, DOD reported that side effects ceased when PB use was discontinued.[110] Other retrospective studies found similar results.[32,270]

A survey of 213 Israeli soldiers asked about possible symptoms of PB and their severity. The most frequent health complaints reported were generally mild and nonspecific, including dry mouth, general malaise, fatigue, and weakness, which appeared about 1.6 hours after taking the medication and recurred after each intake. For this group the typical side effects associated with PB, such as nausea, abdominal pain, frequent urination and runny nose, were infrequent.[228]

DOD recently completed a study begun in November 1994 that looked at differential tolerances to PB between women and men.[128,296] Ninety subjects, equally divided by gender and in three weight classes, took 30 mg of PB every 8 hours for 21 days (plus one dose). PB was found to be safe and well-tolerated. All side effects were mild and resolved with no intervention. Headaches, dizziness, nausea, rash, and hair loss were reported in both drug and placebo groups. Diarrhea and abdominal pain were reported in the PB group only (four study participants). Overall, the occurrence of adverse effects did not differ between active and placebo subjects, nor were differences observed among gender or weight groups. Results from a 1-year followup, indicated no long-term effects except possibly a skin rash that resolved with treatment.[128]

DOD continues to seek FDA approval to use PB for the protection of U.S. troops against CW agents. To support this approval process, DOD has sponsored various research efforts since 1984 to gather information on the effects of PB pretreatment on healthy individuals. To date, DOD reports no serious or long-term reactions from this research.

Genetic predisposition to PB sensitivity. Some scientists suggest that persons who are genetically unable to produce the plasma enzyme butyryl cholinesterase (BuChE) could be more sensitive to PB's known side effects, and at least one apparent case has been reported.[139] The estimated frequency in the general population of persons unable to produce BuChE is about 0.03 percent. Exposure to PB (or similar compounds) could causeimmediate and marked health effects in these individuals. Based on studies of PB-related compounds in BuChE deficient individuals, however, symptoms vanish when exposure to PB is removed. Limited population genetic data indicate that about four percent of all people have slightly reduced ability to produce functional BuChE. It is unclear whether these individuals could be more susceptible to temporary PB side effects.[1,67,68,71,139,192,193,224,269]

Synergistic effects. Concern has been raised about the possibility of increased health problems from PB when it is combined with other risk factors. Some

researchers have hypothesized that PB in combination with stress may create central nervous system effects.[59,170,228] The insect repellent DEET and the insecticide permethrin are most often mentioned as cofactors with PB for Gulf War illnesses.

After the Gulf War, one U.S. Department of Agriculture researcher conducted a study on synergistic effects of various chemicals, including DEET and PB, on cockroaches. DEET showed a four-fold increase on the lethality of PB-i.e., it took one fourth as much PB to kill cockroaches in the presence of a sublethal dose of DEET.[314] In 1996, another researcher reported that PB given at near lethal levels to chickens could increase the toxicity of DEET and permethrin.[1] Under these conditions, nervous system damage to the chickens was reported. A 1995 DOD study with rats reported that PB caused a slight increase in lethality of DEET and permethrin when compared to expected additive values.[263]

These three studies report enhanced toxic effects from PB, DEET, and permethrin in combination. However, doses used in the laboratory experiments were far greater than exposures U.S. service members could have experienced during the Gulf War. Moreover, for DEET and permethrin, the routes of administration were not comparable to that used by U.S. service members in the Gulf War. For example, in the chicken model, DEET and permethrin were injected underneath the skin and, in the rat study, they were administered orally. During the war, DEET should have been applied to the skin, and permethrin should have been applied to the uniform.

These studies did not address the effect PB, DEET, and permethrin-individually or in combination-would have on morbidity in humans and what illnesses might be induced by such use. Neither did the studies answer whether there would have been detectable harmful effects in humans in-theater under the likely operational use by U.S. troops.

Some researchers suggest the immediate toxicity of the OP pesticides available to Gulf War veterans could have been increased from coexposure to PB,[1,150,151] leading to the well-characterized, long-term signs and symptoms of immediate and severe poisoning described earlier in this chapter. As previously mentioned, however, DOD reports that on-site medical personnel did not observe any immediate and severe effects of OP poisoning among U.S. service members, and the current scientific knowledge base indicates that long-term health effects do not occur in the absence of immediate poisoning.

In setting priorities for new research projects on Gulf War veterans' health issues, a subcommittee of the RWG of the Coordinating Board gave priority to toxicology studies on subtoxic exposures to PB and pesticides, either alone or in combination. Several federally funded studies now underway are assessing combined exposure to PB and other chemical risk factors.

What do we conclude about the risks of PB to Gulf War veterans? Given the extensive cumulative experience with the use of PB in patients with myasthenia gravis and data collected from military personnel, the Committee concludes it is unlikely that health effects reported today by Gulf War veterans are the result of exposure simply to PB. Ongoing federally funded studies should help the scientific community draw conclusions about the synergistic effects of PB and other risk factors.

Endemic Infectious Diseases

During WWII, British military units were stationed in the Gulf region and based on this experience documented the nature of endemic infectious diseases. Thus, the U.S. command was concerned about diseases, including shigellosis, malaria, sandfly fever, and cutaneous leishmaniasis.[6,65,90,187] For example, cutaneous leishmaniasis, known locally as the Baghdad boil, is endemic to that area; 80 to 90 percent of people in some parts of Southwest Asia have scars from previous attacks.[187] During WWII, rates of sandfly fever were 3 to 10 percent of all troops in the Middle East, and in some units it exceeded 50 percent.[187] Infectious diseases during the Gulf War, however, were not a major cause of sickness or lost work time.[90] During the Gulf War, only one death due to infectious disease (meningococcal meningitis) was reported.[342,343]

Experts attribute the lack of a problem with infectious diseases during the Gulf War to a comprehensive infrastructure of medical care and preventive medicine efforts.[90,185,271,273,293] DOD took measures to minimize infectious disease risk, including strict monitoring of drinking water purity, inspecting food sources and supplies, maintaining field camp sanitation, and instituting an insect vector control program. U.S. service members received booster doses of routine vaccinations, including typhoid, meningococcus and, during the fall, influenza. Immune gamma globulin was used to prevent Hepatitis A, and the small number of troops who entered Iraq near the Euphrates River valley received drug prophylaxis for malaria.

Most of the combat troops were isolated in barren desert locations, distant from rivers, oases, and urban areas. Additionally, maximum troop deployment occurred during the cooler winter months, which provided the least favorable conditions for the transmission of insect-borne diseases.[90,185] Indeed, the majority of the 12 individuals who developed viscerotropic leishmaniasis had been deployed to urban areas.[145]

Diagnosis of infectious diseases in-theater. Short-term diarrhea was a common symptom among troops in-theater. Most cases were mild, traveler's-type diarrhea that resolved spontaneously without antibiotics after a few days.[64,90] Gastroenteritis among outpatients decreased from four percent per week early in the deployment to less than 0.5 percent per week after U.S. medical command tightened control of food sources-especially imposing a ban on locally-grown fresh fruits and vegetables. The most common organisms identified in service members with diarrhea severe enough to warrant cultures were *Shigella sonnei* and *Escherichia coli*. DOD reports no confirmed cases in-theater of food-borne, diarrheal diseases, such as cholera, typhoid fever, or giardiasis.[90]

DOD medical personnel evaluated U.S. service members for several diseases transmitted by insects, including leishmaniasis, sandfly fever, malaria, dengue, Sindbis, West Nile fever, Rift Valley fever, and Congo-Crimean hemorrhagic fever.[90,293] As noted, sandfly fever had been a major concern, but no cases were seen during the Gulf War. DOD reports detecting seven cases of malaria and one case of West Nile fever, a mosquito-borne viral illness. No rickettsial illnesses and no cases of other arthropod-borne viral illnesses were identified.

Viscerotropic leishmaniasis (VL) and cutaneous leishmaniasis (CL) are the only endemic infectious diseases demonstrated to cause chronic morbidity among a number of Gulf War service members. These diseases are transmitted through the bites of sand flies; person-to-person infection does not occur. Thirty-two cases of leishmaniasis were diagnosed among U.S. troops, consisting of 12 cases of VL and 20 cases of CL.[145,277] CL causes a characteristic ulcerative or nodular skin rash that can persist for more than a year without treatment. And, while VL can be difficult to confirm, it is not considered to be a cause of widespread illness in

Gulf War veterans. All veterans diagnosed with VL, except one, have experienced the signs characteristic of the disease.[90,146,293]

It is unlikely that veterans in the Registry or CCEP who have unexplained illnesses are suffering from VL. The incidence of VL during the Gulf War and the five years since has been low (12 of 697,000), and other sandfly-borne infectious diseases in the troops have been absent.[90,278] Additionally, individuals with unexplained illnesses also lack signs and symptoms characteristic of VL. VL can sometimes occur following a prolonged incubation period (more than 18 to 24 months); there is also a risk of activation of latent infections in immunosuppressed persons.[65,90,146] To date, DOD and VA report that delayed onset of VL has not occurred.

From August 1990 through July 1991, the U.S. Army deployed approximately 347,000 individuals to the Gulf region. Based on information from U.S. Army field hospitals, the only infectious diseases that caused 30 or more each of approximately 14,000 admissions were pneumonia, intestinal infections, inflammation of the testes and/or epididymus, chicken pox, and kidney infections.[342,343]

What do we conclude about the risks of infectious diseases to Gulf War veterans? Based on a review of the rates and types of the diseases diagnosed during and after the Gulf War, the Committee concludes it is unlikely that infectious diseases endemic to the Gulf region are responsible for long term health effects in Gulf War veterans, except in a small, known number of individuals.

Depleted Uranium

Uranium is a naturally occurring, chemically toxic, and radioactive element composed of three isotopes. Relative to other radionuclides, natural uranium is only slightly radioactive because of its low specific activity.[288] When the uranium isotope used for nuclear reactors and weapons is extracted from natural uranium, DU is the byproduct.

DU is nearly twice as dense as lead-a property used to improve the performance of both armor and armor penetrating munitions. During the Gulf War, some U.S. tanks and U.S. aircraft fired DU munitions, which produced shrapnel and an aerosolized dust on impact with armor or on ignition in accidental munitions fires. DU retains natural uranium's toxicological properties and approximately half its radiological activity.[267] Most of DU's radiation cannot penetrate skin, and DU poses little threat to human health while it is external to the body.[288]

Because it is slightly radioactive, natural uranium is considered to be a potential carcinogen-albeit with a small cancer risk relative to other radionuclides.[288] Taken together, human and animal studies do not indicate conclusively that natural uranium causes cancer in humans. Epidemiologic studies of uranium miners experiencing extremely high, lifetime, occupational exposures to uranium show an increase in mortality due to lung cancer, but such cancers are thought to be caused by miners' concurrent exposures to radioactive radon gas and its decay products, tobacco smoke, silica and other dusts, or exhaust fumes from diesel engines.[172,321] Animal studies conclude that exposure to uranium for long periods of time does not result in increased incidence of cancer, except in the case of one study. This study found prolonged (more than five years) inhalation of high levels of uranium dioxide led to lung neoplasms in dogs.[130,131]

The chemical toxicity of uranium as a heavy metal is well characterized. In fact, the kidney is the most sensitive organ affected by exposure to uranium and is the critical target organ for risk assessment.[133,218,322,341] For this reason, uranium exposure is regulated based on its chemicaltoxicity and not its radiological properties.[129,156] Even so, more than 50 years of occupational health data from uranium miners reveal little epidemiologic evidence of excess kidney disease among workers exposed for years or decades.[322]

The health risks of internalized uranium or DU particles depend on dose, exposure pathway, and solubility of the ingested particle. Ingestion of insoluble uranium compounds poses little health hazard because they pass rapidly through the body and are eliminated in the feces. However, animal studies have shown that ingestion of large doses of relatively soluble uranium compounds are associated with kidney toxicity.[129,288] Inhaled uranium particles that are nonrespirable are cleared from the respiratory tract and either expelled from the body (cough) or swallowed and passed to the GI tract. Respirable and relatively soluble particles are cleared to blood and can affect kidney toxicity.[14,129] Less soluble particles can remain in the lung longer and in theory could pose a radiological hazard. The U.S. Army has conducted tests to characterize aerosols associated with DU munitions impacts with armor and with accidental DU munitions fires; it concluded a service member's risk exceeds civilian safety standards only when he or she is inside a vehicle when it is penetrated by DU munitions.[39,96,97] The adequacy of the research supporting this conclusion has been questioned by some reviewers.[229,267]

No studies of long-term human health effects of uranium metal implanted in tissue exist. Nevertheless, toxic effects are likely to be similar to the kidney toxicity observed from inhaled or ingested uranium. To date, VA has reported no kidney toxicity among soldiers wounded by DU fragments in friendly fire episodes.[112] VA currently monitors the health of approximately 30 veterans suspected of retaining embedded DU fragments, and the U.S. Army Medical Research and Materiel Command is funding animals studies to investigate the health hazards associated with short- and long-term exposure to DU metal fragments.[296]

What do we conclude about the risks of DU to Gulf War veterans? The Committee concludes it is unlikely that health effects reported by Gulf War veterans today are the result of exposure to DU during the Gulf War. Since uranium is a potential carcinogen, it is possible that exposure to DU during the Gulf War could lead to a slight increase in the risk for lung cancer after decades following the end of the war.

Oil-well Fire Smoke

At the end of the Gulf War, more than 600 Kuwaiti oil wells and several pools of spilled oil were left burning after being ignited by retreating Iraqi troops. Huge, dramatic plumes of billowing smoke from these fires rose high into the atmosphere. Occasionally the smoke remained low to the ground, in some cases enveloping U.S. military personnel.

Some chemicals contained in oil-well fire smoke, such as benzene and PAHs, are human carcinogens. As described earlier in this chapter, the amounts of these pollutants in the air were low. Hence, their contribution to excess cancer risk would be expected to be small and increased rates of cancers likely would not result.

The U.S. Army used EPA's standardized methodology to estimate cancer and noncancer risks from the oil-well fire smoke.[265] It concluded "the potential for significant long-term adverse health effects for the exposed DOD troop or civilian employee populations is minimal." Risks from cancers were estimated not to exceed two excess cancers per one million people exposed, a value well within EPA's acceptable range.

Noncancer risks from smoke exposure were calculated as Hazard Indices (HI). When the HI exceeds 1.0, there can be concern about potential noncarcinogenic health effects. In Saudi Arabia, the HI ranged from 0.6 to 2.0, while in Kuwait it ranged from 2.0 to 5.0. Most of this noncancer risk was contributed by inhalation of VOCs, particularly benzene. The U.S. Army concluded that risk of noncarcinogenic health effects among the U.S. service members was low since HIs are based on EPA toxicity values that are set far below levels thought to cause health effects and that also account for sensitive subpopulations such as children and the elderly. A congressional Office of Technology Assessment analysis of the U.S. Army's risk assessment methods and findings concluded "the risks to health from exposure to the smoke and the background air contaminants in the Persian Gulf are likely to be extremely small."[275]

Oil-well fire smoke appears not to have caused observable changes in lung tissue. Researchers at the Armed Forces Institute of Pathology found no significant differences when they compared lung tissue from autopsies of 33 U.S. service members who died after the start of the oil well fires to lung tissue from autopsies of soldiers who died before the fires.[164]

Information has been gathered from 110 firefighters working for private companies in the Kuwaiti oil fields in 1991. Individuals were deployed for 28-day periods, working daily at the well heads without breathing-protection equipment. Most were over 30 years old and had 10 or more years experience fighting similar well fires, many of them in Kuwait and elsewhere in Southwest Asia. No cases of illnesses resembling those reported by Gulf War veterans were reported, nor have such complaints been observed among thousands of oil-well firefighters who have spent years experiencing similar exposures.[60,61]

Known immediate health effects from inhaling large amounts of smoke and particulates are primarily respiratory, including coughing, wheezing, increased airway resistance, and respiratory infections. Toxic gases that can be found in oil-well fire smoke-such as hydrogen sulfide and sulfur dioxide-can cause eye and nose irritation, decreased pulmonary function, and increased airway reactivity.[312,315] Nevertheless, these toxic gases were not detected at high levels during the fires.[89,289,302,339] High levels of airborne particulates, which sometimes occurred in the Gulf region, are associated with increased rates of asthma and can exacerbate other chronic respiratory conditions. With chronic (months or years) exposure to particulates, there is increased risk of some loss in lung function or chronic bronchitis, especially in cigarette smokers.

What do we conclude about the risks of oil-well fires to Gulf War veterans? Based on research on human and animal health effects of exposure to air pollutants and on currently available exposure data, the Committee concludes it is unlikely exposure to oil-well fire smoke is responsible for symptoms reported today by Gulf War veterans. Although smoke from the oil-well fires did not include levels of carcinogens that would be expected to increase cancer rates among Gulf War participants, VA mortality studies will include cancer surveillance.

Petroleum Products

Diesel, kerosene, gasoline, jet fuel, and other petroleum-based fuels were widely used during the Gulf War for dust suppression, waste incineration, and for fueling vehicles, stoves, heaters and generators. U.S. service members in certain jobs were occupationally exposed to petroleum fuel vapors and combustion products, such as toluene, xylene, benzene, ethyl benzene, carbon monoxide, sulfur dioxide, nitrogen dioxide, particulates, lead, and other pollutants. Additionally, in some areas near the Kuwaiti oil-well fires, unburned crude oil drizzled down, covering the ground and troops below.[242]

Petroleum fuels are a complex mixture of aliphatic hydrocarbons and aromatic hydrocarbons such as benzene and PAHs. These fuels also commonly contain various additives, like lead. When burned, petroleum fuels produce a variety of potentially hazardous combustion products. High-level, short-term exposures to fuel solvents can cause immediate effects. In most cases, however, complete recovery occurs when the exposure ceases.[5,286]

U.S. service members could have been exposed to petroleum fuels by inhalation, ingesting contaminated water or dust, and skin contact. Inhalation exposure could depress the central nervous system (CNS). Symptoms include short-term effects ranging from fatigue, headache, nausea, blurred vision, and dizziness, to convulsions, paralysis, and loss of consciousness depending on the dose.[282,312] Again, exposure to high, nonlethal levels usually is followed by complete recovery, although rare cases of permanent brain damage after massive exposure have been reported.[117,205,282]

Prolonged breathing of diesel fuel vapors can damage kidneys or lower blood clotting ability.[284] Studies of workers occupationally exposed to certain hydrocarbon solvents in petroleum fuels suggest that long-term high-dose exposure over 12 to 14 years can lead to neurotoxic effects.[117,285] For example, psychomotor disturbances, visual memory and perception, and visuomotor learning ability were significantly affected in exposed gasoline-pump workers compared to matched controls, particularly workers exposed for more than a year.[125] Some studies suggest there are neurotoxic effects from long-term exposure, including decrements in memory, cognitive functioning, and sometimes neuromotor functions.[117] Other researchers, however, have challenged the existence of what is sometimes referred to as "chronic toxic encephalopathy," and uncertainty exists about CNS effects from long-term, low-level exposures to solvents.[69]

Benzene makes up about one percent of U.S. gasoline and up to five percent of European formulations. It is a known human carcinogen that is associated with certain types of leukemia. Nevertheless, more than 55 published epidemiologic studies of workers exposed occupationally to hydrocarbons such as gasoline generally do not replicate the carcinogenic effects reported for experimental animals.[157,282] Recent studies of refinery workers also do not reveal a clear association between gasoline production and leukemia.[88,282] Still, based on the limited evidence from animal studies and the presence of benzene in gasoline, the International Agency for Research on Cancer (IARC) concluded that gasoline is possibly carcinogenic to humans. It is not known if other petroleum products cause cancer in humans. IARC believes there are insufficient data to assess whether light fuel oils or light diesel fuels cause cancer in humans. However, IARC has determined that occupational exposure to fuel oils during petroleum refining is probably carcinogenic to humans.[284]

Although ingesting small amounts of fuel oils is unlikely to cause significant symptoms, ingesting fuel oils in larger quantities can cause vomiting, diarrhea, swelling of the stomach, stomach cramps, coughing, drowsiness, restlessness, irritability, and unconsciousness.[284] Ingestion of fuel oils can be accompanied (during vomiting) by aspiration of some of the material into the lungs, which can produce a chemical pneumonitis.

Skin exposure to large amounts of oil can physically clog pores and hair follicles, compromising body heat loss. Long-term exposure can cause acne and other skin problems. With high concentration or extended exposure, lighter components of crude oil or other fuel oils can defat the skin, leading to redness and itching or dermatitis.[284,312]

Exposure to the normal combustion products of petroleum fuels is also a health concern. Limited epidemiologic evidence indicates daily use of kerosene stoves for cooking or heating does not cause breathing problems for most people.[284] If insufficiently vented, however, carbon monoxide generated from fuel oil combustion can build up, causing drowsiness, nausea, and even asphyxiation. Individuals exposed to unvented combustion of fuels containing lead could experience health effects ranging from subtle biochemical changes in blood to severe CNS effects at high doses. Occupational exposure to inorganic lead is associated with subjective signs of neurotoxicity such as forgetfulness, lethargy, and weakness. These neurological signs and symptoms occur at about the same blood lead levels as other overt signs of lead intoxication, such as gastrointestinal complaints like abdominal pain, nausea, and vomiting.[286]

What do we conclude about the risks of petroleum products to Gulf War veterans? While certain subsets of Gulf War service members could have experienced occupational exposures to petroleum products that would entail increased risks of health effects, it is unlikely that health effects reported today by Gulf War veterans are due to exposure to petroleum products during the war.

Psychological and Physiological Stress

Virtually all Gulf War participants were exposed to a wide range of stressors associated with the war. Throughout human history, observers have noted a correlation between the horrors of war and "mysterious" illnesses in soldiers and veterans.[91] Only recently, however, have the broad range of symptoms for such illnesses been recognized as serious, physiological effects of stress.

Unexplained illnesses in soldiers were widely interpreted as a form of malingering until the 1940s. When WWII veterans experienced many of the same symptoms seen in WWI, Charles Samuel Dyers coined the term "shell shock." He began to study and write about what actually happened to the minds and bodies of soldiers on and off the battlefield. Physicians began to describe psychosomatic symptoms-physical disorders caused or influenced by a psychological state-as the normal and expected consequences of experiencing fear and fright, and recognized the relationship between intense emotion and bodily changes.

During this period, a telling example came to light that illustrated how traumatic experience can lead to a decline in physical health. A group of merchant marines in Norway during WWII were preselected for their excellent physical and mental health. Yet after exposure to extraordinary stress, they showed a sharp decline in their health. Many had symptoms of chronic fatigue, chronic pain, impotence, and irritability.

Today, scientists are beginning to unravel the physiological connection between the brain and various other parts of the human body. Recent animal and human studies reveal numerous pathways connecting the brain to the rest of the body, through which psychological stress can be physically expressed.[31] Animal studies demonstrate that stress can have measurable effects on the brain, immune system, cardiovascular system, and various hormonal responses. Although the human body can adapt to normal stresses, if the stress lasts longer it can be expressed in a variety of physical illness symptoms.[155] Some researchers suspect that the inadequate production of stress hormones and stress response occurs in some (not all) humans with CFS and PTSD.[31]

Based on this understanding and supported by decades of clinical observations, physicians recognize that many physical, as well as psychological, diagnoses are the consequences of stress. This connection is not limited to soldiers only. Experts now know that conventional stressors, such as bereavement, family problems, financial and job problems, domestic or other violence, can cause significant and long-term physical health effects.[76,184]

Physicians and scientists also note substantial variability in the human response to stress. One individual's reaction to trauma could be hypertension; in another individual, the reaction to similar trauma might be severe anxiety. A number of medical diagnoses are linked with stress, including somatoform disorders, CFS and FM. These conditions share many overlapping features, and each diagnosis depends on meeting specific case definitions. Significant evidence supports the likelihood of a physiological, stress-related origin for many of these ailments.

What do we conclude about the risks of stress to Gulf War veterans? The Committee concludes that stress does not cause a unique illness or set of symptoms. Stress can contribute to a broad range of physiological and psychological illnesses. Stress is likely to be an important contributing factor to the broad range of illnesses currently being reported by Gulf War veterans.

SUMMARY

The Committee has examined exposure and, independently, expected health effects for ten Gulf War risk factors: pesticides, CW agents, BW agents, vaccines, PB, infectious disease, DU, oil-well fire smoke, petroleum products, and psychological and physiological stress. In our evaluation, we used the substantial amount of relevant scientific information available in published peer reviewed literature, interviews with experts, invited testimony, public comment, and discussions with scientific experts in academic and government agencies. For most of the risk factors evaluated, the Committee has determined-even in the absence of exposure data-they are unlikely to be associated with the health problems currently reported by Gulf War veterans. Based on its review, the Committee makes the following findings and recommendations.

FINDINGS

- Although some veterans clearly have service-connected illnesses, current scientific evidence does not support a causal link between the symptoms and illnesses reported today by Gulf War veterans and exposures while in the Gulf region to the following environmental risk factors assessed by the Committee: pesticides, chemical warfare agents, biological warfare agents, vaccines, pyridostigmine bromide, infectious diseases, depleted uranium, oil-well fires and smoke, and petroleum products. Some of these risk factors explain specific, diagnosed illness in a few Gulf War veterans, for example, leishmaniasis has been diagnosed in 32 individuals. Prudence requires further investigation of some areas of uncertainty, such as the long-term effects of low-level exposure to chemical warfare agents and the synergistic effects of exposure to pyridostigmine bromide and other risk factors.
- A number of Gulf War risk factors-e.g., mustard agent, aflatoxin, and certain petroleum products-are potential human carcinogens that could cause

increased rates of cancer beginning decades after exposure.
- Stress is known to affect the brain, immune system, cardiovascular system, and various hormonal responses. Stress manifests in diverse ways, and is likely to be an important contributing factor to the broad range of physiological and psychological illnesses currently being reported by Gulf War veterans.

RECOMMENDATIONS

- DOD and VA should perform long-term mortality studies of Gulf War veterans appropriate for investigating cancer rates in the Gulf War veteran population in the coming decades.
- The entire federal research portfolio should place greater emphasis on basic and applied research on the physiologic effects of stress and stress-related disorders.

*As noted, individuals in this group also were assessed for SCEs, which were found to increase with deployment to Kuwait and remain elevated even after the return to Germany.[154] SCEs are a sensitive measure of DNA damage and repair and occur at a background rate in normal cells, but increase with exposures to DNA damaging agents. It is not clear what exposures in Kuwait could have led to the observed increases, since elevated SCEs are a nonspecific measure that can reflect exposure to infections and vaccinations, or to dietary, occupational, or environmental mutagens.

**In chapter 2, we identify those areas for which we believe new research data could fill in current gaps in knowledge.

United States General Accounting Office

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Testimony

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MEDICAL READINESS

DOD Continues to Face Challenges in Implementing Its Anthrax Vaccine Immunization Program

Statement of Carol R. Schuster, Associate Director
National Security Preparedness Issues
National Security and International Affairs Division

GAO/T-NSIAD-00-157

Mr. Chairman and Members of the Committee:

We are pleased to be here today to discuss our past work on the Department of Defense's (DOD) anthrax vaccine immunization program. As you know, DOD regards the biological agent anthrax, an infectious disease that is 99-percent lethal if inhaled by unprotected humans, as the single greatest biological weapon threat to U.S. military forces. DOD considers vaccination one of the measures critical to protecting U.S. forces against such weapons. In December 1997, the Secretary of Defense announced a plan to immunize all active and reserve military personnel with a licensed anthrax vaccine. In August 1998, DOD began immunizing all 2.4 million U.S. military personnel—including all active and reserve personnel—against anthrax.

Today we would like to provide a brief update on three key findings of our October 1999 report. The findings relate to vaccine supply, medical records, and efforts to educate servicemembers about the program.[1] We have also reviewed other aspects of the anthrax vaccine immunization program, including the safety and efficacy of the vaccine and the contracts with the manufacturer. Our related reports are listed in an attachment to this statement.

Summary

In October 1999, we reported on challenges to implementing DOD's anthrax immunization program. First, we noted that supply problems caused by the manufacturer's inability to obtain Food and Drug Administration (FDA) approval to distribute vaccine manufactured at its renovated facility and problems testing previously stockpiled vaccine jeopardized DOD's schedule for vaccinating all 2.4 million servicemembers. Today, this fundamental requirement of the program—maintaining an adequate supply of vaccine—has not yet been met. The manufacturer has not yet obtained FDA approval to distribute vaccine produced at its renovated facility, and this approval is not expected until late 2000. Program officials expect the current supply to last until July 2000. Although program officials expect FDA to approve the release of previously stockpiled vaccine before the available supply is depleted, this expectation may be optimistic given past testing problems. DOD is vaccinating only personnel who are being deployed to high-threat areas and has delayed vaccinations of personnel in units scheduled for early deployment. If the manufacturer does not obtain FDA approvals as

[1] *Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program* (GAO/NSIAD-00-36, Oct. 22, 1999).

expected, DOD may be forced to halt vaccinations, at least temporarily. Moreover, DOD still lacks a contingency plan in the event supply problems are not resolved in time.

Second, we reported that DOD's recording and tracking system of servicemembers who receive vaccinations is an improvement over the system used during the Gulf War and in Bosnia but that DOD was not meeting its requirement to record vaccination data consistently both in paper records and in its central database. DOD reported that it planned to take further steps to improve its central database. Also, we recommended that DOD collect data on the number of servicemembers refusing the vaccine so that it can better understand servicemembers' concerns. To date, the Army has drafted a policy to collect data every 3 months. The other services are not planning to require periodic reporting but will provide data on vaccine refusals when requested.

Finally, we reported on the results of our survey, which showed that servicemembers wanted more information on long-term side effects and procedures for reporting possible side effects from the vaccine. DOD has taken initiatives to carry out a high-visibility education campaign to inform servicemembers about the vaccine program. For example, it has implemented a speakers' bureau, has updated its Internet site, and is sponsoring studies of health effects related to the vaccine.

Supply Problems Jeopardize Vaccination Program

As of March 2000, DOD had administered at least 1.6 million anthrax vaccinations to about 419,000 servicemembers, but supply problems jeopardize its schedule for vaccinating all 2.4 million servicemembers.[2] As of April 10, 2000, DOD had approximately 273,000 doses of vaccine tested and available for use. Assuming the program continues to administer vaccines at its current rate of about 75,000 doses per month, DOD officials estimate that the supply will be depleted by July 2000 unless more lots[3] of vaccine are made available. The supply can only be increased if FDA grants permission for the sole manufacturer to release vaccine produced

[2] The vaccination program is scheduled to be implemented in three phases. Phase 1—begun in 1998—includes vaccinations of servicemembers assigned or rotating to high-threat areas. Phase 2—originally scheduled to begin in January 2000 but not yet begun—includes vaccinations for early deploying units. Phase 3 includes vaccinations for the remainder of the force. The regimen for the vaccine is an initial series of three vaccinations at 2-week intervals, followed by a series of three vaccinations at 6-month intervals, with annual boosters thereafter.

[3] A lot contains approximately 200,000 doses, but at the start of the program some lots contained fewer doses because of previous commercial sales and military use.

at its renovated facility or the vaccines stockpiled before the renovation are successfully tested and released by FDA. There are problems in both areas.

First, the manufacturer, BioPort Corporation,[4] Lansing, Michigan, has yet to receive FDA approval of its manufacturing processes following a 17-month shutdown of the facility for renovation. Until BioPort obtains this approval and additional approvals for the release of each lot, it cannot release lots produced after the renovation.[5] According to a DOD contractor's assessment of a November 1999 FDA inspection report, the FDA identified 30 deficiencies, largely dealing with BioPort not fully complying with FDA Good Manufacturing Practice regulations. The assessment noted that there may be at least two significant issues BioPort must address, namely implementing a program to validate vaccine manufacturing and testing processes and systems to ensure product quality. DOD has taken several initiatives to support and oversee BioPort's efforts to obtain FDA approval. According to a contracting official, DOD intends to order BioPort to stop production of the vaccine and focus efforts on measures to validate the manufacturing process. DOD also plans to assist BioPort by funding consultants to help BioPort obtain FDA approval and to keep the facility operating at a low level. DOD officials estimate BioPort will not obtain FDA approval of its manufacturing processes until late 2000. BioPort's inability to obtain FDA approval of its anthrax production processes has led to serious cash flow problems. Further delays will only exacerbate these problems.

Second, unless the currently available 273,000 doses are augmented with additional approved vaccine from the stockpile, the program will be without vaccine from July through late 2000 (or whenever BioPort obtains FDA approval) if it continues administering vaccinations at its current rate. When the manufacturer suspended production in January 1998 to undertake renovations, it still had 40 lots of anthrax vaccine stockpiled at its plant. Of these, 31 had passed all the tests and had received FDA approval for release. To ensure that no changes had taken place in the approved vaccine since FDA granted approval, DOD decided to subject the 31 approved lots to a series of supplemental tests for purity, potency, sterility, and safety. Since supplemental testing began in January 1998, 11

[4] In 1998, the facility was sold and the manufacturer's name was changed from Michigan Biologic Products Institute to BioPort Corporation. Plans for renovation began under the former name.

[5] According to a program official, the lots tested to obtain FDA approval of the new facility's manufacturing processes will also be tested for release and should therefore be immediately available. FDA will have to approve future lots produced after the renovation individually.

of the 31 lots have been made available for use; but 20 lots are still unavailable due to test failures or problems with the tests themselves. For example, some vaccine lots did not contain sufficient levels of a required preservative (test failure), while testing of other lots may have been invalidated because underweight guinea pigs were used as test subjects (test problems). For the remaining nine lots produced just before the renovation shutdown, BioPort needed only to obtain the normal FDA approval for release. As of April 10, 2000, five of these nine lots had been approved for release. In sum, only 16 of the 40 vaccine lots in the stockpile have been released, and according to program officials, almost all have already been used by the program.

Program officials plan to conduct tests on and obtain FDA approval for release of a limited number of stockpiled lots, thus augmenting the currently available doses before they are depleted. They estimate that this will provide sufficient vaccine to continue the program until FDA grants permission to release lots produced after BioPort's renovation, possibly by late 2000. Our analysis shows that DOD's time frames for testing and gaining FDA approval of these stockpiled lots may be optimistic. For example, it assumes that FDA will expedite approval of a revised testing protocol and final test results and that BioPort will not encounter testing problems as it has in the past.

Because of the limited vaccine supply, DOD is vaccinating only personnel who have deployed to high-threat areas and has delayed vaccinations of personnel in units scheduled for early deployment. The original date to begin vaccinating this latter population was January 2000. In response to our recommendation, DOD drafted a contingency plan to ensure the continued, measured implementation of the program, but the Office of the Secretary of Defense has not yet approved this plan.

Recording and Tracking of Vaccinations Have Improved, but Further Improvements Are Possible

In October 1999, we reported that DOD's recording and tracking system for the anthrax vaccination program is an improvement over the system used during the Gulf War and in Bosnia. However, DOD was not meeting its requirement to record vaccination data consistently both in paper records maintained at its installations and in electronic records in its central database. We compared servicemembers' vaccination records from DOD's central database with paper records at four military installations.[6] At three sites, we found that between 85 and 97 percent of paper and electronic records agreed on the number of anthrax vaccinations that had been administered. At two sites, however, matches were lower (between 17 and 69 percent) for the date of the vaccination and the vaccine's lot number. Matches in all categories were much lower at the fourth installation, with match rates of 22 percent for the number of vaccinations, 17 percent for the vaccination date, and 8 percent for the lot number.

These problems were caused in part by delays in updating data on information in the central database. For example, delays in updating data on individuals' duty stations impeded DOD's ability to use its central database to manage vaccination schedules and assess unit readiness. Commanders need updated duty station information to ensure that their personnel receive vaccinations on time and are ready for deployment. An accurate centralized database is also important for tracking which vaccine lots are administered, should health concerns about a specific lot emerge. In its response to our report, DOD said it would take aggressive steps to ensure the timely and accurate updating of personnel data in the database.

In addition, at the time of our review, DOD had not collected data on personnel who refused vaccination or left the service to avoid vaccination. DOD thus did not have an important tool to gauge the extent of resistance to the program and target training resources to give servicemembers needed and wanted information. In its response to our report, DOD said that it was reviewing a draft policy memorandum on reporting servicemembers' refusals to be vaccinated. In April 2000, a program official told us that this policy will apply only to the Army and will require major commands to provide quarterly reports on soldiers who refuse the vaccine. The other services are not planning to require periodic reporting but will

[6] We visited one location per service where a large number (more than 1,000) of vaccinations had been given: Fort Stewart, Hinesville, Georgia, for the Army; the *USS Eisenhower*, Norfolk Navy Shipyard, Portsmouth, Virginia, for the Navy; Langley Air Force Base, Hampton, Virginia, for the Air Force; and Camp Lejuene, Jacksonville, North Carolina, for the Marine Corps.

provide data on vaccine refusals when requested. According to the program official, a servicemember is considered to have refused the vaccine only after he or she initially declines the vaccine, receives education and counseling (either verbally or in writing), and then disobeys a direct order to take the vaccine.

DOD Has an Extensive Education Campaign and Has Begun to Monitor Its Effectiveness

DOD and the services have used a variety of measures to educate servicemembers about the program and have taken steps to address controversy surrounding the program. However, our survey of 249 servicemembers at the four military installations between December 1998 and March 1999 indicated that many of them wanted more information on the program. More than two-thirds of survey respondents reported that the information they received on the reasons for the program, vaccination requirements and schedules, and consequences of refusing the vaccination was at least moderately helpful. However, over half said they either received no information on possible long-term side effects and procedures for reporting side effects or found the information less than moderately helpful. Although many respondents wanted more information on long-term side effects, data on this topic is limited because no long-term studies have been carried out.

At the time of our survey, DOD had not monitored the effectiveness of its educational campaign. But after our survey, DOD initiated several steps to improve its educational campaign. It established a communications division to focus on servicemembers' information needs. The division updated the program's Internet site and set up a toll-free information line and a traveling speakers' bureau of experts on anthrax and the vaccine. DOD has also begun monitoring its educational efforts. Specifically, the program now surveys servicemembers who have begun or are scheduled to begin the series of anthrax vaccinations. The survey collects information on the availability, timeliness, and effectiveness of the program's educational materials.

In its comments to our October report, DOD stated that it had taken several actions to improve guidance and training on reporting adverse events associated with the vaccine.[7] These actions included updating or developing briefings and fact sheets required to be given to

[7] Adverse events are outcomes for which a cause-and-effect relationship with an exposure (to a vaccine or a medication) has not yet objectively been determined. An adverse event becomes an adverse reaction once objective evidence is available to establish a cause-and-effect link between an exposure and an adverse outcome.

servicemembers and clinicians and providing links to adverse event reporting forms through DOD's anthrax vaccine Internet site. We have not assessed these actions or evaluated their impact on the reporting of adverse health events.

To address questions regarding the safety of the anthrax vaccine, DOD established a Longitudinal Studies Concept Committee to define research needs and identify subsequent research designs. The Committee, which includes members from DOD, FDA, the Centers for Disease Control and Prevention, and the Armed Forces Epidemiological Board, met in August and September 1999 and recommended some research designs. One of the studies being planned is a prospective study of servicemembers that will follow the health effects over multiple years of vaccine and non-vaccine recipients. This study is scheduled to begin in 2001.

Mr. Chairman and Members of the Committee, this concludes our formal statement. We would be happy to answer any questions you may have.

Contact and Acknowledgments

For future contacts regarding this testimony, please contact Carol Schuster at (202) 512-5140. Individuals making key contributions to this testimony included Christine Fossett, Margaret Best, and Howard Deshong.

Related GAO Products

Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program (GAO/NSIAD-00-36, Oct. 22, 1999).

Anthrax Vaccine: Safety and Efficacy Issues (GAO/T-NSIAD-00-48, Oct. 12, 1999).

Medical Readiness: Issues Concerning the Anthrax Vaccine (GAO/T-NSIAD-99-226, July 21, 1999).

Contract Management: Observations on DOD's Financial Relationship With the Anthrax Vaccine Manufacturer (GAO/T-NSIAD-99-214, June 30, 1999).

Medical Readiness: Safety and Efficacy of the Anthrax Vaccine (GAO/T-NSIAD-99-148, Apr. 29, 1999).

Chemical and Biological Defense: Observations on DOD's Plans To Protect U.S. Forces (GAO/T-NSIAD-98-83, Mar. 17, 1998).

Defense Health Care: Medical Surveillance Improved Since Gulf War, But Mixed Results in Bosnia (GAO/NSIAD-97-136, May 13, 1997).

Chemical and Biological Defense: Emphasis Remains Insufficient to Resolve Continuing Problems (GAO/NSIAD-96-103, Mar. 29, 1996).

Chemical and Biological Defense: Emphasis Remains Insufficient to Resolve Continuing Problems (GAO/T-NSIAD-96-123, Mar. 12, 1996).

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Report to the Chairman and Ranking Minority Member, Committee on Veterans' Affairs, U.S. Senate

October 1999

MEDICAL READINESS

DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program

GAO/NSIAD-00-36

Contents

Abbreviations

CDC	Centers for Disease Control and Prevention
CHCS	Composite Health Care System
DEERS	Defense Enrollment Eligibility Reporting System
DOD	Department of Defense
DMDC	Defense Manpower Data Center
FDA	Food and Drug Administration
GAO	General Accounting Office
USAMMA	U.S. Army Medical Materiel Agency
VAERS	Vaccine Adverse Event Reporting System

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National Security and
International Affairs Division

B-283133

October 22, 1999

The Honorable Arlen Specter
Chairman
The Honorable John D. Rockefeller IV
Ranking Minority Member
Committee on Veterans' Affairs
United States Senate

The Department of Defense (DOD) regards the biological agent anthrax, an infectious disease that is 99-percent lethal if inhaled by unprotected humans, as the single greatest biological weapon threat to U.S. military forces. To counter this threat, the Secretary of Defense announced in December 1997 a plan to immunize all active and reserve military personnel with a licensed anthrax vaccine. The Secretary stipulated that immunizations would not begin until DOD (1) established a means of testing the vaccine over and above tests required by the Food and Drug Administration (FDA), (2) developed a system for tracking vaccinations, (3) approved operational and communication plans for the vaccination program, and (4) had an outside expert review the health and medical aspects of the program. In May 1998, the Secretary announced that his conditions had been met, and in August 1998, DOD began immunizations, giving first priority to personnel deployable to southwest and northeast Asia, areas where U.S. forces are considered at high risk of exposure to anthrax.

The vaccination program has been the subject of increasing controversy. Public debate has centered on whether the vaccine is safe and effective, and whether it is prudent to rely on only one vaccine manufacturer. Since the Secretary's announcement, we have reviewed various aspects of the program. In April 1999, we testified on research on the vaccine's safety and efficacy, noting the lack of studies on long-term safety and on human efficacy testing against inhaled anthrax.[1] In June 1999, we reported on DOD's financial relationship with the sole-source vaccine manufacturer

[1] *Medical Readiness: Safety and Efficacy of the Anthrax Vaccine* (GAO/T-NSIAD-99-148, Apr. 29, 1999).

and attributed the manufacturer's serious cash-flow problems to an overly optimistic business plan.[2] The following month, we reported that DOD's data on adverse reactions resulting from vaccinations indicated that female servicemembers reported such events in greater numbers than male servicemembers and that no studies had been done to determine the optimum number of doses of the vaccine.[3] We also noted that DOD had conducted some research on a second-generation anthrax vaccine but considered such research an unfunded requirement and that the Department of Health and Human Services had recently funded several research grants to develop a second-generation vaccine.

Although the policy to vaccinate the entire force has been questioned, our review focussed on the implementation of the vaccination program as established by DOD. Given the program's scope, DOD's poor medical record-keeping during the Gulf War, and serious previous shortcomings at the vaccine manufacturing facility, you asked us to review DOD's implementation of the vaccination program as it is currently structured. Specifically, as you requested, we assessed DOD's

- ability to maintain an adequate supply of anthrax vaccine for its immunization schedule,
- system for recording and tracking servicemembers' vaccinations,
- efforts to monitor possible adverse reactions to anthrax vaccinations, and
- steps to educate servicemembers about the program.

To assess the vaccine supply, we reviewed the quantity of vaccine in stockpile, the status of efforts to test the stockpiled vaccine, and schedules for producing new vaccine. To assess DOD's tracking of servicemembers' vaccinations, we compared electronic and paper records of vaccinations at four locations (one per service). To assess tracking of adverse reactions, we evaluated DOD's data on adverse reactions and interviewed medical personnel and vaccine recipients. Finally, to assess DOD's education efforts, we surveyed vaccine recipients during our four site visits and discussed education efforts with commanders and program officials. A detailed discussion of our scope and methodology is in appendix I.

[2] *Contract Management: Observations on DOD's Financial Relationship With the Anthrax Vaccine Manufacturer* (GAO/T-NSIAD-99-214, June 30, 1999).

[3] *Medical Readiness: Issues Concerning the Anthrax Vaccine* (GAO/T-NSIAD-99-226, July 21, 1999).

Results in Brief

As of July 1999, DOD had given about 1 million anthrax vaccinations to more than 315,000 servicemembers, but supply problems jeopardize its schedule for vaccinating all 2.4 million servicemembers, and DOD lacks a contingency plan in the event these problems are not resolved in time. Test failures[4] and problems in the testing itself have slowed or precluded release of 26 of the 40 vaccine lots since testing began in January 1998. In all, only 14 lots[5] have been released to DOD since January 1998, and most of these have already been used. Moreover, the manufacturer has yet to receive FDA permission to release lots produced after restarting operations in May 1999 following a 17-month shutdown for renovations. As a result, DOD has fallen behind its original schedule by 5 months, and it risks further disruption if more vaccine does not become available by August 2000. DOD's plans for maintaining an adequate supply of vaccine are optimistic, given testing problems, and assume that FDA will grant approval of tested lots in less time than in the past. Consequently, DOD may not be able to augment its stock of usable vaccine as currently planned. The manufacturer's financial problems, which had threatened vaccine supply, have been recently mitigated by a renegotiated contract, but financial concerns could re-emerge if there are further delays in releasing vaccine. Although DOD has considered options, should the vaccine manufacturer have further delays in or lose its ability to produce FDA-approved vaccine, DOD does not have a formal contingency plan to deal with such possibilities.

DOD has a new recording and tracking system for vaccinations that is better than the one used during the Gulf War and in Bosnia, but DOD is not meeting its requirement to record vaccination data consistently in paper records and in its central database. Our comparison of records from DOD's central database and files at three military installations showed that 85 to 97 percent of paper and electronic records agreed on the number of anthrax vaccinations given to servicemembers, but agreement was lower at two of those sites—ranging from 17 to 69 percent—for dates and lot numbers. Agreement in all categories was much lower at a fourth installation, with match rates of 8 to 22 percent, in part because individuals' duty stations had not been updated. This data is vital for (1) scheduling the

[4]Before some of the stockpiled lots can be released, FDA must approve the results of its required lab tests. Other stockpiled lots received FDA approval some years ago but must now pass supplemental tests before DOD can use them.

[5]Each lot includes roughly 200,000 doses.

FDA-licensed regimen of six vaccinations and boosters and (2) tracking who receives vaccinations from a specific lot, should health concerns about a lot later emerge. Delays in updating data on individuals' duty stations have impeded DOD's ability to use its central database to manage vaccination schedules and assess unit readiness. Commanders need updated duty station information to ensure their personnel receive vaccinations on time so that they may be ready for deployment. In addition, DOD does not collect data on those refusing vaccination or leaving the service to avoid vaccination. This leaves DOD without an important tool to gauge the extent of resistance to the program and target training resources to provide servicemembers with the information they want.

DOD has used data from the Vaccine Adverse Event Reporting System to monitor adverse reactions (or events) to anthrax vaccinations. The system relies on medical personnel or servicemembers to provide needed data. However, DOD has not systematically informed these personnel on how to provide needed data into the system. As a result, DOD may not have data on adverse reactions (or events) that is important for monitoring vaccine safety. DOD uses the number of data entries into the system to determine an adverse reaction rate. However, this data does not provide sufficient basis for reporting a reaction rate because the information is inadequate to directly link the health condition of a servicemember to the anthrax vaccination. Moreover, such events may be underreported. Further, preliminary data from DOD surveys of vaccine recipients indicates a greater rate of reaction than is indicated by the reporting system, which reported 215 adverse events after over 978,000 vaccinations as of July 1999. The reaction rates reported by DOD surveys varied (between 21 and 70 percent), in part due to methodological limitations such as lack of control groups or adjustments for factors such as physical activity and age. DOD has reported that there is no evidence of a pattern of serious, long-lasting adverse reactions.

DOD has employed a high-visibility campaign to educate servicemembers about the program and has taken steps to address the controversy surrounding the program. In addition, it recently expanded its communications efforts by updating the program's Internet site, opening a toll-free anthrax information line, and forming a speakers' bureau of anthrax experts. However, a survey we performed at four military installations, though not projectible beyond the 249 respondents, indicated that servicemembers want more information about some issues related to the program. More than two-thirds of survey respondents reported that the information they received on reasons for the program, shot requirements

and schedules, and consequences of refusals was at least moderately helpful. However, over half said they either received no information on possible long-term side effects and procedures for reporting side effects or found the information less than moderately helpful. Although many respondents wanted more information on long-term side effects, data on this topic is limited because no long-term studies have been carried out. DOD officials recently discussed conducting additional studies to increase their understanding of possible long-term health effects.

This report includes recommendations to the Secretary of Defense to develop plans in the event that the vaccine does not become available as currently anticipated, to provide guidance for the consistent reporting of adverse events, and to establish data collection measures that allow the program to monitor performance and target training and research resources.

Background

According to the Chairman of the Joint Chiefs of Staff, anthrax is the greatest biological weapon threat. DOD considers vaccination one of the measures critical to protecting U.S. forces against such weapons. As a result, it has begun immunizing all U.S. military personnel—about 2.4 million servicemembers, including all active and reserve—against anthrax. The Secretary of the Army is the Executive Agent of the program, which is being implemented in three phases to vaccinate the entire force by 2004.

- Phase 1—begun in 1998 and ongoing: 423,000 members assigned or rotating to high-threat areas have begun or will begin vaccinations.[6]
- Phase 2—slated to begin in January 2000: early deploying units—about 1 million personnel—begin vaccinations.
- Phase 3—the remaining approximately 1 million personnel begin vaccinations.

The regimen for this vaccine is an initial series of three vaccinations at 2-week intervals, followed by a series of three vaccinations at 6-month intervals, with annual boosters thereafter.

[6]DOD had planned to begin vaccinations in southwest and northeast Asia in the summer of 1998. However, in March 1998, when hostilities in southwest Asia seemed likely, DOD began vaccinating personnel stationed there ahead of schedule.

Production and Testing of Anthrax Vaccine

The anthrax vaccine was licensed in 1970 to protect occupational groups such as veterinarians, meat packers, wool workers, and health officials who might come into contact with the disease primarily through the skin. Its effectiveness against inhalation anthrax in humans has not been proven, as it would be unethical to conduct such studies on humans. However, as we reported in our April 1999 testimony,[7] studies on the efficacy of the vaccine in guinea pigs, rabbits, and monkeys support the view that the vaccine can protect against exposure to inhaled anthrax in these animals, but the correlation of that protection to humans has not been established. DOD recently sought to develop an animal model to establish such a correlation.

DOD currently procures the anthrax vaccine solely from one private manufacturer, BioPort Corporation. Formerly, the facility was known as the Biologic Products Division of the Michigan Department of Public Health, then the Michigan Biologic Products Institute. The manufacturer is the only FDA-licensed anthrax vaccine manufacturer in the United States. BioPort produces the vaccine in lots individually numbered for tracking purposes. Each lot generally consists of about 20,000 vials containing 10 doses each. The lots must be tested according to standard FDA protocols for purity, potency, sterility, and safety.[8] Successful results are then submitted to the FDA for review. If the test results satisfy FDA, it assigns each approved lot an expiration date and notifies the manufacturer that the lot can be released for use.

This vaccine has a 3-year shelf life, measured by FDA from the date it passed the FDA's potency test. The manufacturer can request a 3-year extension of the shelf life by retesting for potency and submitting passing results to FDA for approval. FDA also allows retesting of lots that initially fail potency tests, provided the reason for the failure is investigated and explained and the retested vaccine meets appropriate standards. Once a

[7] *Medical Readiness* (GAO/T-NSIAD-99-148, Apr. 29, 1999).

[8] According to the Code of Federal Regulations (21 C.F.R. section 600), purity is the relative freedom from extraneous matter in the finished product; potency is the specific ability or capacity of a product as indicated by appropriate laboratory tests or adequately controlled clinical data; sterility is the freedom from viable contaminating microorganisms; and safety is the relative freedom from harmful effects to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the recipient's condition at the time.

vial of vaccine is labeled for shipment, its expiration date is changed to a maximum of 1 year (not to exceed its 3-year shelf life).[9]

In March 1997, the FDA cited the manufacturer for repeated deviations from applicable standards. According to DOD, in January 1998 the manufacturer stopped production as part of a previously scheduled renovation plan to support the production, testing, and stockpiling of the anthrax vaccine. These renovations were largely funded by DOD. When the manufacturer suspended production, it still had 40 lots of anthrax vaccine stored at its plant. Of these, 31 had already passed all the tests and had received FDA approval for release.[10] Nine had not yet been tested. DOD decided to subject the 31 approved lots to a series of supplemental tests for purity, potency, sterility, and safety as a prudent safeguard.[11] DOD contracted with an independent firm to oversee the supplemental tests, which were conducted by BioPort. DOD also decided that the remaining nine lots would not need to undergo supplemental testing, as these had never been released and would be undergoing FDA-mandated testing for the first time.

BioPort resumed production of vaccine in the renovated facility in May 1999. As part of its effort to receive FDA approval of its renovations and operational changes, BioPort must submit test data to demonstrate that the lots produced are consistent with each other and with anthrax vaccine previously produced in the old facility. Once these new lots, called consistency lots, pass the FDA tests, and once FDA, upon inspecting the facility and operations and reviewing the test results, approves the renovations and consistency lots, BioPort will be permitted to resume full commercial operations—i.e., sell its newly produced vaccine. Without

[9]In April 1999, 59 Marines were notified that they had received vaccine three weeks after its expiration date. Both the FDA and the Armed Forces Epidemiological Board determined that there was no concern over the safety or effectiveness of the vaccine. Those notified were nonetheless given an option of receiving an additional vaccination if they had concerns about the vaccine's efficacy. The Marine Corps followed up with a message reminding Marine commanders of the procedures for checking expiration dates on all vials of vaccine. Further, refresher training was implemented at the base in question and was strongly recommended for other medical units.

[10]At the start of the program in March 1998, some of these 31 lots contained fewer than 20,000 vials because of previous commercial sales and military use.

[11]As we noted in our April 1999 testimony, quality cannot be guaranteed from final tests alone, only from a combination of in-process tests, end-product tests, and strict controls of the entire manufacturing process.

FDA's approval of its renovations and successful completion of tests on consistency lots, however, Bioport can produce vaccine but cannot release it for use.

Packing and Shipping the Vaccine

DOD manages the transport of anthrax vaccine from BioPort to initial military recipients. To obtain its goal of zero defects and to maintain vaccine accountability, DOD and BioPort designed a packing and shipping protocol that maintains the temperature-sensitive vaccine within a constant temperature range during transport.[12] Most anthrax vaccine is shipped via commercial carriers. It is packaged in temperature-monitored boxes for domestic shipments and in refrigerated containers for international shipments. Appendix II describes the packing and shipping protocol.

Recording, Tracking, and Reporting Immunizations

As of July 1999, DOD had given about 1 million anthrax vaccinations to over 315,000 servicemembers. To meet the requirement for a system to track servicemembers receiving anthrax vaccinations, DOD's Defense Manpower Data Center added anthrax data fields to an existing DOD-wide database of personal, service-related, benefits, and residence information. This database, the Defense Enrollment Eligibility Reporting System (DEERS), now includes fields to record, among other things, the date and lot number of each anthrax vaccination given to each servicemember. Also, each service developed its own interim database to fully document vaccination information at locations where vaccinations are performed and to electronically send the information to DEERS, the central repository for such information.[13] DOD planned to use an upgrade of its Composite Health Care System to replace the interim service-specific tracking systems. Both the service interim systems and DEERS were designed to be used by unit commanders to ensure that their personnel receive their vaccinations according to schedule and by the services to report vaccination rates in their joint monthly readiness reports.

According to the services' implementation guidelines, vaccination information is to be recorded on two paper forms—the servicemember's

[12]In June 1998, on the basis of temperature testing, BioPort increased the temperature range for safe shipment of the vaccine from 2° to 8° Celsius to 1° to 25° Celsius.

[13]The Marine Corps uses the Navy's database.

medical record and form PHS-731, commonly known as the yellow shot record. The medical record is the property of the government, and the yellow shot record belongs to the individual. Procedures for yellow shot records varied at the installations we visited. For example, at the Air Force location, servicemembers were not given their vaccination unless they had their yellow shot record, while other locations did not have this requirement. Planning guidance issued by the Joint Staff also required the Joint Staff Inspector General to review compliance with requirements to document anthrax vaccinations. The review includes a random sample of medical records for personnel who received vaccinations between March and August 1998. The Inspector General's review was assigned in May 1998, and a report is scheduled to be issued later this year, but preliminary results were not yet available at the end of our review.

Tracking Adverse Reactions to the Vaccine

DOD submits data on adverse events temporally associated with the anthrax vaccine to the Vaccine Adverse Event Reporting System (VAERS). VAERS is a passive surveillance system, meaning that it alerts FDA and the Centers for Disease Control and Prevention of adverse events that may be associated with licensed vaccines through information voluntarily reported by health care providers, patients, or families. VAERS also serves as a warning signal for detection of previously unreported, unusual adverse events and/or unexpected increases in reported events. A panel of experts commissioned by the program reviews all VAERS reports after they have been submitted to FDA to identify any signaling event that would identify problems stemming from the anthrax vaccine. As of July 1999, the panel had found no pattern of causality stemming from the use of the anthrax vaccine.

Supply Problems Jeopardize DOD's Vaccination Schedule

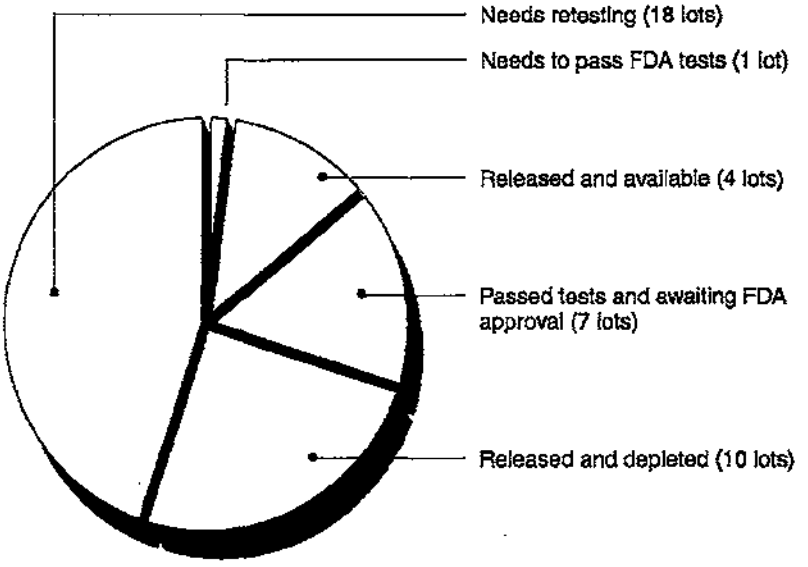
The most critical component of the program, an adequate supply of vaccine, is threatened by testing delays and possible loss of production capability. Testing problems have already delayed release of stockpiled vaccine,[14] many lots of which are still unavailable for use. BioPort has also fallen behind schedule in submitting to FDA test results on the lots produced after it resumed operations in May 1999. If testing problems are not resolved soon, or if FDA withholds approval of BioPort's renovations or newly produced lots, DOD will have difficulty in (1) providing phase 1 vaccinations beyond August 2000 and (2) beginning phase 2, which has already been delayed 5 months. BioPort also faces financial problems and some security weaknesses that put the supply of vaccine at risk. On the positive side, the program has nearly eliminated loss of vaccine in transit to the field thanks to a highly successful shipping and packing system. However, despite the risks to the vaccine supply, DOD has not prepared a formal, written contingency plan for vaccinating servicemembers should a steady supply be further delayed or disrupted.

Testing Problems Have Delayed Release of Vaccine

As of June 23, 1999, 26 of the 40 stockpiled vaccine lots were still not available for use (see fig. 1). Most of these—18 lots—had undergone but not passed all the supplemental tests or had to be retested. An additional lot needed to pass FDA-mandated tests. Seven other lots passed supplemental or FDA tests but had not yet received FDA approval. In all, of the original 40 lots, only 14 had been released for use since the program began, and 10 of these had been depleted.

[14]Although the original stockpile contained 31 lots, we use the term "stockpile" to refer to all anthrax vaccine—40 lots in all—stored at BioPort before production restarted in May 1999.

Figure 1: Status of Testing for 40 Lots Produced Prior to Shutdown for Renovations



DOD data as of June 23, 1999

When supplemental testing began in January 1998, program officials expected to receive the first positive results by April of that year. However, problems with testing processes, failure of vaccines to pass tests, and limited testing resources delayed or precluded the release of 18 lots. All 18 lots have passed safety tests but have at least one unresolved issue with purity, potency, or sterility.

- Nine lots failed purity tests because the amount of preservative used in the vaccine did not meet FDA standards.[15] DOD is considering permanently removing these lots from the stockpile, given the time and resources it would take to resolve the issue.

[15]BioPort has discussed with FDA completing studies that would enable the manufacturer to request FDA approval of release of those lots with less preservative (phemerol) than currently required. If these studies show that lower amounts of the preservative are effective, and if FDA, after reviewing the data, approves lowering the standard, DOD may be able to use some or all of these nine lots.

- Three lots initially failed sterility tests, then passed them, but FDA cited serious concerns about the lots. According to program officials, the lots will probably not be retested and will likely be withdrawn from the stockpile.
- Fourteen lots still need to pass potency tests. For two of these, test results were invalid due to problems in the test procedures, causing BioPort to suspend all further potency tests until the problems were resolved. At DOD's request, an outside scientific team reviewed the test procedures and recommended several corrective measures.[16] BioPort adopted the team's recommendations, which took several months to implement. In all, most potency testing was delayed 6 to 9 months. The remaining 12 lots have undergone valid testing but have not passed it.

Table 1 summarizes the tests needed for the 18 lots that have not yet passed supplemental testing.

Table 1: Status of 18 Stockpiled Lots Subject to Supplemental Testing

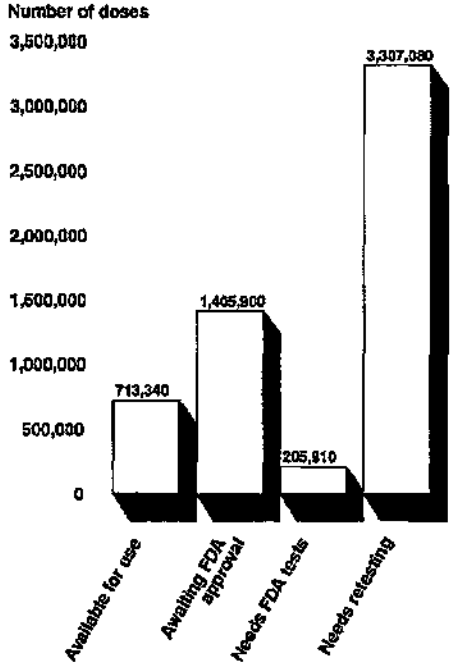
Supplemental tests needed	Number of lots
Potency	6
Potency and sterility	3
Potency and purity	5
Purity	4
Total	**18**

Source: DOD.

Although testing is performed by lots, vaccination schedules are predicated on the number of doses available. To understand the implications of these testing problems for DOD's vaccination program, therefore, it is necessary to assess available doses—especially because the number of doses in a lot varies. As of June 23, 1999, 5.6 million doses remained in the stockpile at BioPort, but 4.9 million (88 percent) of these were unavailable for use (see fig. 2).

[16]The team suspected but could not confirm that at least some of the variances were due to changes in (1) the size, age, and sex of the test subjects (guinea pigs); (2) a saline solution used in the tests; and (3) the strain of anthrax used in the control group.

Figure 2: Status of Doses Remaining in Stockpile



DOD data as of June 23, 1999

Note: Does not include almost 2 million doses that have been released and shipped to installations.

- More than 3 million doses cannot be released unless BioPort retests its lots, achieves successful results, and receives FDA approval to release them. According to program officials, lots containing a total of over 2.2 million of these doses are not likely to be ever retested due to the aforementioned purity and sterility test results.
- More than 1.4 million doses unavailable to DOD are awaiting FDA approval of successful testing, and program officials expected to successfully test and request FDA approval for an additional almost 206,000 doses needing FDA tests before October 1999.

In summary, as of June 23, 1999, only 713,000 doses in the stockpile were available for use, and more than half of them—about 416,000 doses—will expire in February and April 2000. On the basis of DOD's estimates of doses required per month, the 713,000 doses would sustain phase 1 of the program through December 1999. This estimate does not include doses

already delivered to the field and not yet administered. However, typically, no more than a 3-month supply of vaccine is delivered to a location, which means that the program could be sustained at best through March 2000, on the basis of both delivered and available stockpiled vaccine doses.

Program officials are not concerned about the status of the stockpiled vaccine. At the time of our review, they expected FDA to grant release of stockpiled lots containing a total of 1.6 million doses before October 1999, and they projected this would sustain the program through August 2000. This expectation assumes a quick and positive response by FDA. Program officials also expected to retest and submit some other lots in early 2000. However, this expectation seems optimistic. According to these same officials, BioPort's limited testing resources, overburdened by competing demands, are now being concentrated on obtaining FDA approval of renovations. Consequently, performing more supplemental tests is a far lower priority for both BioPort and DOD.

BioPort Renovations Are Behind Schedule and Have Delayed the Program's Second Phase

A 5-month delay in completing renovations caused BioPort to delay production startup from January 1999 to May 1999. This delay, coupled with testing problems and workload, have in turn delayed production and approval of vaccine consistency lots. Indeed, BioPort has not yet performed FDA-mandated testing on any of the consistency lots, and as a consequence, no test results have been submitted to FDA for approval.

In late July, program officials expected BioPort to submit successful results for the first consistency lots by September 1999 and expected FDA to approve renovations, which involves an inspection of the facility, and permit release of these lots by January 2000. This would allow the program to begin its second phase 5 months after its scheduled August 1999 starting date. Although BioPort officials say they are coordinating more closely with FDA now, this expectation seems optimistic. FDA is required to review and provide a response to the manufacturer regarding test results within 4 to 6 months, but approval is not automatic. Our analysis of past test approval periods for potency tests of stockpiled lots,[17] showed that the time from successful test completion to FDA approval has averaged 10 months. This period, which includes any delays between test completion

[17]The period measured was from the date the manufacturer completed lot potency tests to the date FDA approved the results of those tests. BioPort needs approval of potency test results as well as approval of its renovations which are separate FDA approval processes.

and the manufacturer's submission to FDA, ranged from 2 to 29 months and lasted more than 8 months for almost half of the lots analyzed. Should FDA question the test results or raise other production issues, release of new production could be delayed beyond January 2000. Indeed, FDA concurs that this date for approval of renovations and release of lots is optimistic.

BioPort's Finances and Physical Security Could Threaten Vaccine Supply

Although somewhat mitigated by recent contract renegotiations, BioPort's financial problems have reduced the program's vaccine supply in the short term and may threaten future supplies altogether if production does not resume. BioPort must improve its financial health if DOD is to retain this sole source of anthrax vaccine. In June 1999[18] we testified about several problems at BioPort: (1) renovation delays reduced expected revenues, causing a serious cash-flow problem; (2) the company lacked the cash reserves and the ability to obtain commercial financing at reasonable rates to cover operating expenses; (3) its accounting system was inadequate; and (4) the company projected a significant operating loss for the year ending December 1999. As a short-term measure to generate revenues to improve its financial health, BioPort received authorization from DOD to sell 70,000 doses of anthrax vaccine to other customers,[19] even though it was not fully meeting its contractual delivery requirements at the time. This action diminished the potential supply available to U.S. forces. Moreover, on the basis of renegotiation of its contract with DOD, BioPort (1) will provide DOD with fewer doses of the vaccine than its original contract stipulated to better reflect its production capabilities and (2) will be permitted to increase its private sales to increase revenues. DOD officials stated that this reduced availability will still meet the program's needs.

Although not as pressing as its financial problems, the physical security of BioPort's facility presents some risk to the vaccine supply. In 1998, the Defense Special Weapons Agency reviewed security at what was then the Michigan Biologics Products Institute and recommended numerous physical and operational measures to correct weaknesses. BioPort implemented many of these, including improvements of doors, locks, and fences, but rejected other measures it considered "beyond the scope of a

[18]*Contract Management* (GAO/T-NSIAD-99-214, June 30, 1999).

[19]BioPort sells these doses at a significantly higher price than the DOD contract price. DOD has approved the sale of 30,000 doses to the Canadian Armed Forces, and BioPort intends to sell the remaining 40,000 doses to other potential customers. These sales would also require approval under export control regulations.

biotechnology business." These included such measures as increasing surveillance and modifying existing structures. According to BioPort, if DOD considers further security measures important, it must also consider funding them. In the opinion of DOD's program officials, most of the remaining security recommendations are relatively minor in nature and of less concern than BioPort's production problems. DOD is determining the most effective means of addressing and funding any high-cost security measures at BioPort. At the time of our review, however, DOD did not have plans to implement these measures. Absent a specific implementation plan, it is unclear when or if these security weaknesses would be addressed.

Well Designed and Administered Packing and Shipping Eliminate Vaccine Losses in Transit

DOD and BioPort have worked closely together to solve the challenges of shipping the temperature-sensitive anthrax vaccine to all sorts of climates in all types of weather. Although a transport problem in the first shipment of vaccine (to a U.S. base in Germany) led DOD to destroy 20,000 vials rather than risk distributing vaccine that had been subjected to below-standard temperatures, the program has had extremely few losses since. Learning from this incident, program officials and the manufacturer developed a packaging protocol that maintains a safe temperature range that is continuously monitored from within the container. They also devised a shipping system that uses commercial carriers and constantly tracks packages in transit. Shipments are kept small to limit loss from misplacement or deliberate destruction. According to the program's data, 99.8 percent of all shipped vials arrived safely after the new procedures were implemented.[20] Given this excellent record, DOD is adapting the program's shipping protocol for other environmentally sensitive pharmaceuticals that it manages.

DOD Lacks Contingency Plans for Disruption or Loss of Production

Program officials acknowledge that BioPort has had testing, production, financial, and security problems, but they have developed no formal contingency plans to ensure that vaccinations continue if the supply of vaccine is disrupted or lost. These officials believe that enough stockpiled lots have been released to maintain phase 1 through August 2000. However, implementation of phase 2, which depends on new production and release of vaccine, has already been postponed by 5 months to January 2000, and

[20]This excludes the first shipment of 20,000 vials (464 vials destroyed of 197,487 shipped as of July 2, 1999). Including that first shipment, the program's total success rate is still 90.6 percent of shipped vials and 99.2 percent of all shipments.

even this new date may be unrealistic. If the testing and other problems continue to delay vaccine production and release, DOD will find it difficult to provide vaccinations in the latter part of 2000 and beyond.

Program officials have considered how to adjust for limited delays in releases of the current supply, but they have no formal back-up plans in case of major delays in release of new lots. Several alternatives to the current phase 1 schedule may be possible, should BioPort be seriously delayed in obtaining FDA approval of its renovations. These alternatives range from redistributing vials already sent to the field to suspending all further vaccinations except for forces in the highest-risk theaters. However, program officials could not provide formal criteria for implementing various alternatives, nor could they cite measures of potential advantages such as how long a specific alternative might extend the program or how many personnel it might maintain.

The program also has no contingency plan should BioPort lose its production capability outright, either through FDA rejection of its renovations, financial failure, or destruction by natural catastrophe or hostile agent. Program officials did consider construction of new and completely redundant production facilities, but this alternative was seen as too costly and time-consuming. As we noted in an earlier report, development of a second-generation vaccine that may provide other manufacturing alternatives has begun, but DOD research in the area remains unfunded.[21] The Department of Health and Human Services recently funded several research grants in the area. However, licensing a new facility or developing a second-generation vaccine would take several years—too long to offset any major loss of production by BioPort during the program's timeline. At present, DOD has no means of continuing immunizations with anything other than what is available from the BioPort stockpile, most of which still needs to pass tests before it can be used.

[21] *Medical Readiness* (GAO/T-NSIAD-99-226, July 21, 1999).

Recording and Tracking Vaccinations Has Improved, but Further Improvements Possible

DOD is more capable of recording and tracking vaccinations today than it was during the Gulf War in 1991 or the Bosnia operations in 1995. However, DOD is not meeting its requirement to consistently record vaccination data in its centralized database and paper records. Such inconsistencies could cause vaccinations to be given off schedule or hinder subsequent investigations should questions arise about a specific vaccine lot. Also, delays in updating data on servicemembers' duty stations, as well as shortcomings in how the services update the DEERS database, have limited the utility of the database for determining individual vaccination schedules and assessing unit readiness. While DOD tracks vaccination exemptions (including waivers and deferrals) for medical reasons such as pregnancy or administrative leave, it does not monitor refusals or voluntary departures from the service that may be due to vaccine-related concerns. As a result, DOD is not able to use the information to monitor all aspects of the program's implementation.

Vaccinations Recorded, but Some Data Is Incomplete

The Gulf War and the concerns it subsequently generated about Gulf War illnesses highlighted shortcomings in DOD's systems for recording and tracking medical data, including vaccination records. In 1997, we reported that DOD had improved its medical surveillance during operations in Bosnia but that documentation of vaccinations was one area still needing improvement.[22]

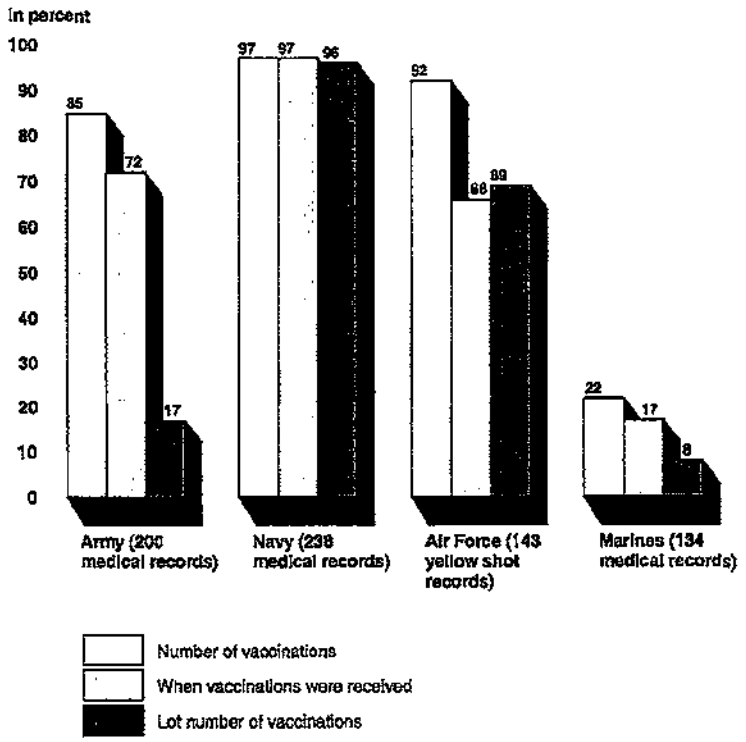
In following up on this deficiency, we found that DOD has improved its ability to record and centrally collect vaccination information. Our comparison of DEERS data and paper medical records at four military installations[23] (one per service) indicated that, except at the Marine Corps installation, the numbers of vaccinations were recorded consistently.

[22]*Defense Health Care: Medical Surveillance Improved Since Gulf War, but Mixed Results in Bosnia* (GAO/NSIAD-97-136, May 13, 1997). Our comparison of a centralized list of vaccine recipients with their medical records in five units revealed that vaccinations had not been recorded in 24 percent of medical records. Three of the five units failed to record vaccinations in more than 30 percent of medical records.

[23]We visited one location per service where a large number (more than 1,000) of vaccinations had been given: Fort Stewart in Hinesville, Georgia, for the Army; the USS Eisenhower, Norfolk Navy Shipyard, Portsmouth, Virginia, for the Navy; Langley Air Force Base, Hampton, Virginia, for the Air Force; and Camp Lejuene, Jacksonville, North Carolina, for the Marine Corps. Our sample of records cannot be generalized. See appendix I for more information on our scope and methodology.

However, agreement between the two systems was not as high when matching specific dates of vaccinations and vaccination lot numbers. Inconsistency in dates could lead to vaccinations being given off-schedule and to inaccurate readiness reports. Inconsistent or missing lot information could hinder investigations, should concerns arise about a specific lot. Also, information that is not recorded in paper records makes it difficult to address adverse reactions needing immediate care or determine the validity of subsequent claims for disability compensation. Figure 3 summarizes the agreement between electronic and paper information on vaccinations by service.

Figure 3: Comparison of Paper and DEERS Records



Source: GAO.

We made the following observations:

- The Army base's low match rate for lot numbers was due to the fact that lot numbers were not recorded in the medical records for about 60 percent of vaccinations. Despite this omission, the base did record lot numbers in DEERS, and only 1 percent of vaccinations recorded in DEERS were without lot numbers.
- The fact that almost all ship personnel received vaccinations on the same days while deployed at sea contributed to the high match rate between DEERS and medical records on the Navy vessel.
- As shown in figure 3, unlike the other installations we visited, the Air Force base relied primarily on the yellow shot record, not the medical record, for recording vaccinations on paper. Less than 5 percent of vaccinations, dates, or lot numbers in the medical records matched information in DEERS. Officials at the site said the yellow shot records were smaller and therefore easier to carry on deployment. However, unlike the yellow shot record, the medical record is government property and should be complete because it serves as evidence for determining veterans' disability compensation. The commander of the medical group at the base told us he planned to have the information in the electronic records printed and entered in the medical records, but this had not been done at the time of our review.
- Marine Corps officials were unable to provide specific reasons for the low match rate with DEERS but noted that (1) neither DEERS nor the Navy database are optimized to handle the frequent changes in units of the Marine Corps—as a result, DEERS did not list all the Marines deployed at Camp Lejeune; (2) lack of training on the Navy database—introduced to the Marine Corps in March 1998, the same month that anthrax vaccinations began—could have contributed to inconsistencies; and (3) the Navy system uses the date the vaccinations are entered into the system as the default, causing inaccuracies if vaccinations are not entered into the system the same day they are given.

Services' Use of DEERS Limits Its Utility

DEERS was envisioned as a major source of reports on program implementation. However, concerns about the timeliness and accuracy of data in DEERS have caused service representatives to rely on interim, service-specific tracking systems, and other systems to track and report vaccination information. For example, Army and Navy officials said they had concerns about DEERS data because duty station information was not updated, in some cases for as long as 6 to 9 months, in DEERS.

Problems we encountered obtaining medical records for our review also demonstrated some of the weaknesses in duty station information. For example, we found that DEERS did not list all servicemembers assigned to a particular duty station. We obtained personnel rosters for Fort Stewart and Camp Lejeune from Army and Marine Corps personnel databases. We compared a sample 300 records from these two lists with the DEERS roster of servicemembers assigned to the two duty stations and found that the DEERS database only listed 210 (70 percent) of Fort Stewart personnel and 111 (37 percent) of Camp Lejeune personnel.

Army and Air Force officials told us they rely on service-specific tracking systems rather than DEERS to obtain more timely information for both day-to-day management of vaccinations and quarterly servicewide readiness reports. Navy and Marine Corps officials told us that because of shortcomings in the Navy tracking system, they rely on reports from individual commanders to manage and obtain servicewide data. Officials from all four services and the program noted that since the start of the program, service-level systems have improved and are more responsive to commanders' reporting needs.

According to Defense Manpower Data Center (DMDC) officials, delays in updating DEERS are caused partly by service personnel systems not providing timely data to DEERS. In May 1999, the officials told us they and the services had taken steps to update duty station information more promptly. We were unable to test the effectiveness of these changes because they were instituted after our analysis. DMDC officials also noted that some data inconsistencies and delays in resolving errors could have been avoided if the services had followed the original design of the tracking system, which allows medical providers to be linked directly to DEERS through their service-level systems. Such direct linkage (1) ensures that servicemembers' vaccination records are updated regardless of whether they are vaccinated by their own or another service and (2) minimizes the impact of mistakes (such as entering the wrong social security number or recording the same vaccination twice) by providing immediate feedback to the user in case of error. However, the Army and Navy have adopted systems that do not directly link to DEERS. Instead, Army, Navy, and Marine Corps data are transmitted to central servers in their service-specific systems, which then upload the data to DEERS. This can cause delays in correcting errors. DMDC officials reported that the Air Force, thanks to its direct linkage to DEERS, receives far fewer error messages and has to do fewer follow-ups than the other services. DMDC

produces lists of errors each day but has not analyzed how frequently different errors occur.

DOD plans to eventually transition the service-specific databases to a common system. It has begun testing and in 2000 will install the Composite Health Care System II (CHCS-II), which, among other things, is designed to interface with DEERS for updating vaccination data. According to DMDC officials, the system will ensure consistent data quality across services. However, it is unclear when the services will abandon their interim, service-specific databases in favor of CHCS-II. Service officials said they were reluctant to move to the new system because it will rely on DEERS for vaccination and duty station data and will not be under the control of the individual services for program upgrades. Moreover, CHCS-II is not intended for use by deployed units, so it cannot be used on locations such as Navy ships. DOD has established a team with representatives from all services that meets regularly to address problems associated with vaccine tracking systems.

Goal Performance Measures Do Not Include Exemptions and Refusals

DOD set a timeliness goal of vaccinating 90 percent of all servicemembers no more than 30 days after their vaccinations are due according to the licensed regimen.[24] As of July 1999, all services (except the Army) had met or exceeded that goal. The Army had a 78-percent compliance rate at that time. The data used to calculate the percentage of "on-time shots," however, does not include exemptions or refusals.

Servicemembers can receive exemptions from vaccinations for medical reasons (e.g., pregnancy) or administrative reasons (e.g., extended leave to change duty stations). Exemptions accounted for about 5 percent or less of those who received at least one injection, according to service officials. As for refusals, the program collected anecdotal data on refusals until January 1999, but the effort was labor-intensive because it entailed surveying individual commanders. Due to the small number of refusals–82 after almost 172,000 servicemembers had received one or more injections–senior Army officials decided the effort was not productive and halted data collection. Moreover, reports of refusals did not list personnel who

[24]DOD's policy is to adhere to the approved immunization schedule and to make deviations to the schedule the exception rather than the rule. According to DOD policy, the effect of deviations from this schedule on the efficacy of the vaccine is unknown, but in general, the greater the deviation, the less certain the protective effect in humans.

voluntarily left the services due to concerns about the vaccine. Although the refusal number at the time may have been low, lack of data limits the program's ability to gauge the effectiveness of its education efforts and to effectively respond to any increase in opposition to the vaccine.

According to written guidance from the Army and Navy and our discussions with Air Force and Marine Corps officials, servicemembers who refuse vaccination are initially provided additional education. Servicemembers who continue to refuse are given a direct order, which, if disobeyed, can lead to disciplinary action—including discharge—at the commander's discretion. The Air Force, the only service with a database to track such information, plans to collect data on disciplinary actions taken against those who refuse vaccination, but it has not yet begun to do so. A provision in the National Defense Authorization Act for Fiscal Year 2000 requires an exit survey of all servicemembers leaving military service to collect data on, among other things, their reasons for leaving.[25] This is also a potential source of anthrax refusal data.

Possible Adverse Events Are Monitored, but DOD's Use of Data May Be Misleading

DOD monitors possible reactions (or adverse events)[26] to anthrax vaccinations primarily by using VAERS. However, reports of such events may be incomplete because servicemembers have not been fully informed about reporting procedures. Moreover, DOD has used the VAERS data to report a rate of reaction to the vaccine. This is misleading because of potential underreporting of events to VAERS, and the potential for overstating the reaction rate because reports sent to VAERS are not confirmed to be causally linked to the vaccination. Preliminary data from DOD studies of adverse events indicates a higher rate of possible reactions than is reported by VAERS, but the reporting rates in these studies varied and the studies have methodological limitations. Thus, DOD does not have reliable information on the extent of adverse reactions. DOD reported that adverse events have been few in relation to the number of vaccinations and that there is no evidence of a pattern of serious, long-lasting adverse

[25]See section 581 of Public Law 100-65, October 5, 1999.

[26]Adverse events are adverse outcomes for which a cause and effect relationship with an exposure (to a vaccine or a medication) has not yet objectively been determined. An adverse event becomes an adverse reaction once objective evidence is available to establish a cause-and-effect link between an exposure and an adverse outcome.

reactions. DOD medical personnel have drafted additional clarifying guidance on treating and reporting adverse reactions to the vaccine.

Medical Staff and Servicemembers Are Not Well Informed About Reporting Adverse Events

According to testimony by DOD officials, as of July 1999, 215 adverse events[27] had been reported to VAERS after about 978,000 vaccinations. VAERS is a so-called passive surveillance system, meaning that it relies on medical personnel or individuals to report adverse events they think resulted from a vaccination. DOD medical personnel are required to file a VAERS report for reactions that cause a servicemember either to lose more than 24 hours of duty time or to need hospitalization.[28] DOD reported, and FDA officials commented, that this requirement exceeds FDA requirements, which only require vaccine manufacturers, not physicians, to report to VAERS, though reporting by physicians is encouraged.

Nonetheless, VAERS data may be incomplete because DOD medical staff and servicemembers have not received the guidance needed to submit VAERS reports. Medical officials at a May 1999 conference convened by the program to discuss clinical issues expressed concern that they had not received clear guidance on how and when to complete VAERS forms. According to DOD officials, medical personnel may also report any other reaction they think might be caused by the vaccine, but because this is not stated explicitly in DOD's guidance on vaccinations, some medical personnel may be unsure about which reactions to report.

Servicemembers and their relatives may also report directly to VAERS any adverse events they suspect are related to a vaccine. DOD, however, prefers that VAERS reports be filed through its medical providers to ensure that data is sufficiently detailed to identify and understand trends. A program official acknowledged that anthrax vaccine educational materials initially did not explain how to self-report adverse events. Moreover, of the 249 servicemembers we surveyed,[29] 44 percent (110) told us they had received no information on how to report adverse reactions.

[27]Military medical personnel reported 109 of these.

[28]Of 174 reports reviewed by DOD, 20 met this criteria.

[29]As noted in appendix I, respondents were not randomly selected, and thus the data cannot be projected beyond those surveyed.

In April 1999, DOD updated its briefings to include information on reporting adverse events. It is also revising regulations to (1) make reporting requirements more inclusive, (2) clarify patient and provider roles and responsibilities, and (3) explain how to obtain and process VAERS forms. In addition, in July 1999, DOD disseminated draft clinical guidelines for the management of anthrax vaccine adverse events that outlines clinical protocols, pre-treatments, specialty referral processes, contraindications, categorization of local and systemic reactions and associated treatment algorithms, and directions for reporting to VAERS.

DOD Has Used Adverse Event Data Incorrectly

In presenting reaction rate data, program and DOD officials have shown reactions reported to VAERS as a percentage of all vaccinations. They did so in several briefings to GAO and congressional staff, in prepared testimony, and on the program's Internet site. However, according to FDA guidance, incidents in the VAERS database reflect a temporal, not necessarily a causal, relationship with vaccination and thus should not be used to calculate the incidence of reactions. DOD's use of such a percentage is an inaccurate representation of the true reaction rate because (1) not all adverse events prove to be adverse reactions and (2) studies have shown that reactions are often underreported in passive surveillance systems such as VAERS, though the extent of possible underreporting is unknown. As of July 1999, DOD updated its briefing information to more accurately describe adverse events reported to VAERS simply as a VAERS report rate.

Other Data on Adverse Events Varies

In studies where vaccine recipients were surveyed about their reactions to the vaccine, adverse reactions were reported at a much higher rate than adverse events reported to VAERS, though these studies have methodological limitations. A 1962 study of the vaccine indicated that mild local reactions (swelling of up to 5 centimeters) were reported in 30 percent of recipients and moderate local reactions (swelling of greater than 5 centimeters) were reported in 4 percent of vaccine recipients.[30] DOD has conducted several subsequent studies of adverse reactions using active

[30]As we testified in April 1999, data from this study was based on a different vaccine than the one eventually licensed. FDA reported that the method of preparing the licensed product was similar but not identical to the vaccine used in the study and that production changes for the licensed vaccine were "minor."

monitoring, and preliminary results vary.[31] For example, according to DOD testimony, 70 percent of respondents in a 1998 survey of 603 medical personnel who had received the vaccine reported a local reaction to the anthrax vaccine. In another 1997 study, 16 percent (81 respondents) of 508 servicemembers receiving the vaccine reported mild local reactions, while 5 percent (25 respondents) had moderate to severe local reactions. As we testified in July 1999, data from other DOD studies also indicated that women reported a higher rate of adverse reactions than men. These studies relied on self-reported data, did not use control groups, and were not adjusted for factors such as occupation, physical activity level, and age.

According to our survey, when asked if they had had any side effects due to the anthrax vaccine, 45 percent of recipients (111 respondents) reported they had,[32] and 30 percent (74 respondents) reported swelling at the injection site, the most frequently cited symptom. Of those who reported reactions, less than 5 percent (5 respondents)[33] said they had missed work or a planned activity due to the symptoms, and 13 percent (14 respondents) sought medical treatment. Further, the percentage of female servicemembers who reported side effects was considerably higher than that of male servicemembers (64 percent of the 36 women surveyed against 42 percent of the 210 men surveyed).

On August 24, 1999, the program convened a team of civilian and military experts to design a set of studies to assess the long-term safety of the anthrax vaccine. Another long-term study is underway to determine whether individuals who received multiple vaccines, including anthrax vaccine, during their past employment at Fort Detrick, Maryland, have had any long-term health effects. A total of 570 study and control volunteers have been enrolled in this case-control study that began in 1996.

[31]In active monitoring, vaccine recipients are contacted to ascertain if there were any adverse reactions to the vaccine after vaccine administration. See *Medical Readiness* (GAO/T-NSIAD-99-148, Apr. 29, 1999).

[32]Other reactions cited by the 111 respondents included redness at the injection site (12 respondents, or 11 percent), nausea (4 respondents, or 4 percent), loss of appetite (2 respondents, or 2 percent), headaches (6 respondents, or 5 percent),and infections (3 respondents, or 3 percent). Respondents were not limited to one response.

[33]The symptoms reported by these five individuals included burning sensations, colds, need for more sleep, memory problems, fevers, headaches, nausea, lower blood pressure, viral infections, fainting spells, chronic sinus problems never previously experienced, fevers, and blood in the stools.

DOD Has an Extensive Education Campaign but Has Not Systematically Monitored the Results of Its Efforts

DOD and the services have used a variety of measures to educate servicemembers about the program and have taken steps to address controversy surrounding the program. However, many respondents to our survey indicated that they had not received information on some topics related to the program and desired additional information. The program recently established a communications division to implement plans to address the expressed desire for more information. More effective monitoring of servicemembers' understanding of the program, including the number of refusals to take the vaccine, would help DOD redirect educational efforts to those areas where additional information is needed.

Many Servicemembers Have Received Some Information but Want More on Long-term Side Effects

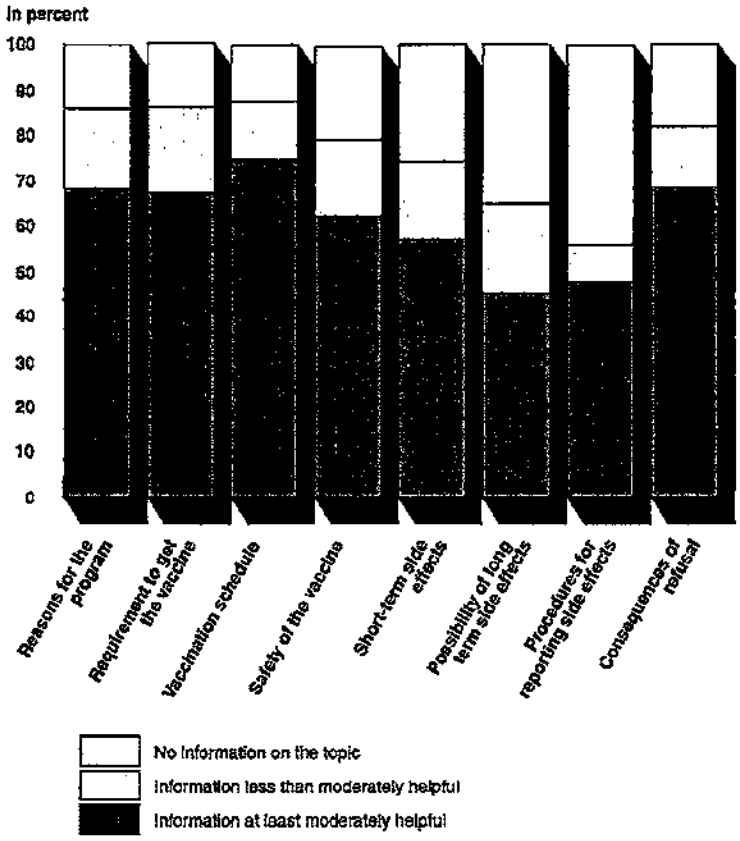
DOD and the services have made the vaccination program a high priority. At the four military installations we visited, the commanders established procedures for administering vaccinations and providing information. In addition to giving briefings and distributing pamphlets, the commanders expected health care professionals and staff to play key roles in providing expert advice to servicemembers. Further, after having briefed servicemembers about the threat of anthrax, the safety of the vaccine, and the requirement for the vaccine, commanders often highlighted the importance and safety of the vaccine by being among the first to receive it, often in the servicemembers' presence. As shown in table 2, according to our survey of 249 servicemembers (not projectible beyond those surveyed), respondents reported that command briefings and medical staff were their primary sources of information.

Table 2: Survey on Sources of Anthrax Vaccine Program Information

	Percentage of respondents reporting the following as their primary source of information				
	Command briefing	Medical staff	Radio, television, or print media	Other sources	Percentage reporting they received no information on the topic
Reasons for the anthrax vaccine program	41	19	11	15	14
Requirement for all servicemembers to get the anthrax vaccine	51	10	14	11	13
Vaccination schedule	30	47	2	9	11
Safety of the vaccine and the extent it offers protection against anthrax	20	29	9	21	21
Short-term side effects that may occur	13	38	6	18	25
Remote possibility of long-term side effects	9	23	8	16	44
Procedures for reporting side effects	16	35	1	4	44
Consequences of refusing the vaccine	54	3	14	12	16

Our survey also showed that for many topics, servicemembers found information they received at least moderately helpful, but information related to long-term side effects and procedures for reporting side effects was not as helpful to many respondents. Figure 4 shows how helpful respondents found information they received about each topic.

Figure 4: Respondents' Assessment of Helpfulness of Information



Source: GAO.

According to our survey, at least 57 percent of respondents reported that the information they received on the reasons for the program, the requirement for the vaccine, the consequences of refusing the vaccine, the vaccination schedule, the protection the vaccine offers against anthrax, and the short-term effects the vaccine may have was moderately or very helpful. There were some areas, however, where many servicemembers either received no information or desired additional information. Our survey showed that only 35 and 47 percent of respondents, respectively, said the information they received on the possibility of long-term adverse effects and on reporting adverse reactions was at least moderately helpful, and 44 percent said they had not received information on the remote

possibility of long-term side effects. Further, when asked what additional information they wanted, 43 percent (106 respondents) reported a desire for information on long-term side effects.

Many of the respondents who said they wanted information on possible long-term adverse reactions also reported experiencing some side effects. Fifty-nine of the 111 respondents (53 percent) who reported experiencing short-term reactions said they wanted information on the possibility of long-term adverse effects. Air Force servicemembers represented almost 70 percent of this group.

The wish for information on possible long-term adverse reactions was also highlighted in May 1999, when a commander temporarily halted anthrax vaccinations at Dover Air Force Base, Delaware, until he determined that servicemembers' questions on the vaccine's safety and its possible health risks had been satisfactorily addressed. The questions were spurred by a magazine article about an unauthorized additive, squalene, alleged to have been used in some vaccine lots and about the alleged relationship between the vaccine and Gulf War illnesses. Following an initial meeting at which servicemembers raised these questions but were unsatisfied with the responses, several DOD, Air Force, and Army personnel knowledgeable of the program, including the Air Force Surgeon General, provided responses in a second set of meetings. These experts reported that independent laboratory tests performed on the specific lots cited by the media had failed to find squalene. Subsequently, Dover officials resumed anthrax vaccinations. Further analysis of all of 13 additional lots also found no evidence of squalene.

Concerns similar to those expressed at Dover have been reportedly voiced at other installations. A primary reason for dissatisfaction with information about long-term side effects appears to be that research has not been done to address the topic. According to program officials, such studies have recently been discussed but are not yet funded or underway.

Program Recently Established a Communications Division

The program has recently established a communications division to focus on servicemembers' information needs. The division updated the program's Internet site and established a toll-free information line and a traveling speakers' bureau of experts on anthrax and the vaccine. The communications division was also instrumental in updating briefings for installation leaders and medical personnel to provide more detailed information on the threat of anthrax. DOD expects these briefings to

respond effectively to commanders' and medical staff's needs by countering misinformation in the media and on the Internet.

The communications division plans to periodically obtain feedback on implementation of its plan, which includes surveys carried out by DOD and service program staff while on site visits to convey key messages and ensure consistency of information. Program staff, including some from the communications division, conducted the first survey in July 1999 and plan to conduct surveys at seven other sites to be visited by December 31, 1999. The surveys will not be projectible but are expected to provide useful information on the implementation of the communications plan. In July 1999, the program submitted a budget proposal for program evaluation and research to include an annual evaluation of communications effectiveness and clinical issues. The proposal did not include linking vaccine refusals to program effectiveness.

Conclusions

DOD's policy decision to vaccinate the entire force against anthrax has presented many challenges. DOD has made progress in implementing the anthrax vaccination program, but several challenges remain. As of July 1999, DOD had administered more than 1 million vaccinations to over 315,000 servicemembers. DOD has taken steps to ensure that vaccine lots are recently tested for purity, potency, sterility, and safety before they are released for use. Vaccinations are recorded in a central database (an improvement over past record keeping); data on the program's implementation progress is collected; reported adverse events are monitored; servicemembers receive information on the program; and the manufacturer's contract has been restructured to help improve its financial condition.

The first challenge, however, is to develop a formal plan for vaccinating servicemembers should the anthrax vaccine supply not be available as currently anticipated. If BioPort, the sole-source supplier of the vaccine, is unable to obtain FDA approval to release stockpiled or newly produced vaccine, DOD will not be able to vaccinate the entire force as planned. Developing a formal plan would help DOD consider (1) various contingencies, including options for altering the three phases of the program, should the vaccine supply become limited and (2) strategies to mitigate the risk of loss of the sole-source manufacturer, including strategies to acquire a second production source or develop a second-generation vaccine.

Second, while DOD has improved its recording and tracking of vaccinations, shortcomings remain in documenting vaccinations in paper medical records and in establishing a DOD-wide database useful to commanders for tracking vaccinations. To ensure that servicemembers obtain the health care they need, especially if they experience short- or long-term adverse events associated with vaccinations, DOD must keep paper and electronic medical records accurate and current. Also, because the anthrax immunization regimen requires several vaccinations over a short period and annual boosters, it is critical that commanders have timely information about servicemembers in their units who are scheduled for vaccinations. Because the DOD-wide database, the Defense Enrollment Eligibility Reporting System, lacks current data on servicemembers' duty stations, commanders do not find it useful for scheduling individual vaccinations or determining the status of vaccinations for their unit as a whole. DOD's plan to incorporate vaccine tracking in an upgrade to its Composite Health Care System program will be of limited use to commanders if it does not give them some of the capabilities of the service-level systems.

Third, measures used to track program implementation omit important data needed to assess overall performance such as refusals. Program officials, however, have discontinued monitoring refusals, even though such data would help monitor possible lack of acceptance of the program. Moreover, previous reports of refusals did not include personnel leaving the services because of concern about the anthrax vaccine. If collected during exit interviews scheduled in 2000, this data could provide another indicator of possible resistance to the program.

Fourth, data on adverse events may be underreported, making it difficult to continuously monitor vaccine safety. DOD has updated educational material on reporting adverse events, and monitoring the effectiveness of efforts to distribute this information to servicemembers would help ensure adverse events are consistently reported.

Fifth, servicemembers clearly want more information on the possibility of long-term side effects. Because the vaccination program is a mandatory, servicewide program, it is essential that servicemembers be given the fullest information possible on these side effects. Although DOD officials have recently discussed potential studies on possible long-term side effects of the vaccine, none have been designed or funded.

Finally, program officials have not systematically monitored their education efforts. Informing servicemembers about the risks of anthrax, the protection the vaccine affords, and the vaccine's safety and efficacy is critical to the long-term success of the program. While the program has provided information on some of these topics and has established a communications division dedicated to improving communications with and education of servicemembers, monitoring the effectiveness of such efforts is important for allocating education resources. Officials plan to obtain feedback on their new efforts but have not yet designed and implemented a systematic strategy to help assess overall progress in meeting communications goals. Further, because data on refusals to receive the vaccine is no longer being collected, it is difficult to better target educational efforts and address emerging concerns.

These problems need to be resolved if the program is to succeed in vaccinating the entire force against anthrax.

Recommendations

To address the challenges DOD faces in vaccinating its total force against anthrax, we recommend that the Secretary of Defense direct the Secretary of the Army, as Executive Agent for the anthrax vaccination program, to

- prepare a formal, written plan that addresses strategies to deal with (1) contingencies for vaccinating servicemembers if the supply of anthrax vaccine is not augmented with new production and (2) the risks associated with reliance on a single vaccine manufacturer;
- routinely collect and report, among other program performance measures, data on the number of servicemembers refusing to take the vaccine;
- improve DOD guidance and training on how to report adverse events to the Vaccine Adverse Event Reporting System and refrain from inappropriately using data from the system to report an adverse reaction rate;
- design and conduct a study on possible long-term side effects of the anthrax vaccine and develop a communications plan to provide servicemembers information on the status of this effort; and
- continue improvements in educational efforts by regularly surveying vaccine recipients and addressing their educational needs.

In addition, we recommend that the Secretary of Defense direct the Defense Manpower Data Center to

- assess the timeliness of personnel duty station data in the Defense Enrollment Eligibility Reporting System to determine where time lags occur in obtaining data and take or recommend steps to resolve untimely submissions,
- review service requirements for recording and tracking medical data and incorporate plans to address these requirements in future upgrades of the Composite Health Care System, and
- include the response "to avoid the mandatory anthrax vaccine" (or words to that effect) among answers to questions on the reasons for resigning from the military in the DOD-wide exit survey to be administered in 2000.

Agency Comments

In written comments on a draft of this report, DOD generally concurred with the report findings and recommendations, emphasized several areas of concern, and described recent or proposed actions to implement recommendations made in our report. DOD also provided technical comments which we incorporated as appropriate.

DOD commented that we did not fully discuss some key aspects and successes of the anthrax immunization program. For example, DOD stated that it keeps three paper records to ensure that immunizations are documented and that no other organization in the world can match this accomplishment. Our report recognizes that DOD has made improvements to its systems for recording and tracking vaccinations but notes that further improvements are needed to ensure that data are recorded in an accurate and timely manner. DOD also stated that the report, "did not mention the excellent long-term safety record of the vaccine examined over a period of 44 years." Our report notes that GAO's recent work on this issue found that data on the vaccine's long-term safety is limited. In our previous work, we found that while some studies have spanned many years, they focus on short-term reactions to the vaccine. For example, a 20-year study on reactions to the vaccine only reported on symptoms that began within 48 hours of the vaccination. Moreover, DOD has indicated that additional data on the vaccine's long-term safety would be beneficial and has established a committee to identify and plan additional research on this issue.

Finally, DOD noted several actions it has taken or plans to take to implement our recommendations such as using existing data to develop a written plan to address possible vaccine shortages and improving DOD guidance and training on how to report adverse events to the Vaccine Adverse Event Reporting System. Regarding our recommendation that

DOD use a DOD-wide exit survey to query members whether the requirement to receive the vaccine affected their decision to resign, DOD noted that it is not appropriate to single out anthrax vaccinations as a potential reason for departing the military because it is a "leading" question and would produce survey bias. Rather, DOD believes that focus groups and surveys of individuals who refuse to take the vaccine are more appropriate assessment tools. We believe that DOD should pursue other methods, such as focus groups, to determine the possible impact of the anthrax vaccine program on retention but believe that a response category about the anthrax vaccine could be included on DOD's exit survey since it will be one of many possible reasons for leaving the military.

We are sending copies of this report to Representative Bob Stump, Chairman, and Representative Lane Evans, Ranking Minority Member, House Committee on Veterans' Affairs. We are also sending copies to the Honorable William S. Cohen, Secretary of Defense; the Honorable Louis Caldera, Secretary of the Army; the Honorable Richard Danzig, Secretary of the Navy; the Honorable F. Whitten Peters, Secretary of the Air Force; General James L. Jones, Commandant of the Marine Corps and Dr. Jane E. Henney, Commissioner of Food and Drugs. Copies will also be made available to others upon request.

Please contact me at (202) 512-3958 if you have any questions concerning this report. Key contacts and major contributors to this report are listed in appendix V.

Carol R Schuster

Carol R. Schuster
Associate Director, National Security
Preparedness Issues

Scope and Methodology

To conduct our review, we interviewed officials and obtained documents from the Army Office of the Surgeon General's Anthrax Vaccine Immunization Program; the Joint Program Office for Biological Defense; the Naval Medical Information Management Center; the Offices of the Judge Advocates General for the Army, the Navy, Marine Corps, and the Air Force; and the Joint Staff. We also obtained information and discussed the program with officials from the Defense Manpower Data Center (DMDC) in Seaside, California, and Arlington, Virginia; U.S. Air Force Air Combat Command, Langley, Virginia; U.S. Navy Space and Warfare Systems Command, Chesapeake, Virginia; medical and command personnel at Fort Stewart, Georgia; USS Eisenhower, Norfolk Naval Shipyard, Portsmouth, Virginia; Langley Air Force Base, Virginia; and Camp Lejeune, Jacksonville, North Carolina. In addition, we interviewed officials and obtained documents from BioPort Corporation in Lansing, Michigan; and the Food and Drug Administration (FDA) in Rockville, Maryland.

To determine the availability of the vaccine and its impact on program schedules, we reviewed and summarized data on vaccine lot status, including supplemental test results, lot quantities, lot expiration dates, and results of initial lot release testing. We analyzed assumptions of projections for vaccine production and usage and compared them with program schedules and past testing data. We also discussed measures for securing and shipping the vaccine with officials from BioPort, the U.S. Army Medical Materiel Agency, and one installation at each service.

To assess systems for recording and tracking vaccinations, we selected one installation from each service where a large number of vaccinations had been given (at least 1,000) and randomly selected 300 service members who had received at least one injection of the vaccination series.[1] We then compared the information on the paper records with data from the Defense Enrollment Eligibility Reporting System (DEERS). Table 3 summarizes the installations visited, records reviewed, and time frames of our collection of DEERS and paper data.

[1]Files for the Fort Stewart location inadvertently included the records for the first 300 social security numbers, and therefore were not random.

Table 3: Collection and Review of Electronic and Paper Records

Service location visited	Population that received at least one vaccination	Medical records reviewed	Yellow shot records reviewed	Date DEERS data was received	Date(s) paper record data was reviewed
Army: Fort Stewart, GA	8,751	200	197	1 Dec. 1998	14-17 Dec. 1998
Navy: *USS Eisenhower*, VA	2,108	238	1	2 Feb. 1999	16-17 Feb. 1999
Air Force: Langley AFB, VA	1,273	186	143	9 Nov. 1999	30 Nov. 1998
Marines: Camp Lejeune, NC	1,842	134	4	10 Mar. 1999	15-18 Mar. 1998

Source: GAO.

We compared the vaccination number, date, and lot number contained in the DEERS database with data on paper records—the medical record and yellow shot records available on site. A mismatch of any vaccination for each category was considered a mismatch for the entire record. Because our samples included only those who had received at least one injection, our analyses did not examine the possible condition that a servicemember received an injection but did not have it recorded in DEERS. Further, although our initial sample of records was designed to project our results to the installations we visited with a precision of ±5 percent at a 95-percent confidence level, operational limitations in the field—most notably the unavailability of some records because of deployments and transfers—did not allow us to review sufficient records to generalize our results to all personnel at the four installations with a reasonable level of confidence.

To evaluate the reporting of vaccine-related adverse events, we reviewed FDA requirements for the Vaccine Adverse Event Reporting System (VAERS), obtained reports of adverse events from the program, discussed reporting procedures with medical and command personnel at the four military installations we visited, and reviewed additional Department of Defense (DOD) studies on adverse events. In addition, we attended the May 1999 Annual DOD Conference for Biological Warfare Defense Immunizations.

To assess education initiatives of the program, we reviewed guidance and service plans to determine education requirements; collected and reviewed educational material used at the military installations we visited, discussed education efforts with command and medical personnel at each installation and with FDA officials, and surveyed a total of 249 servicemembers at those installations. We did not evaluate the accuracy of information

provided to vaccine recipients but used the survey to determine what information was available to servicemembers and how helpful they found the information. Questionnaire respondents were, with three exceptions, vaccine recipients who were available at the time of our site visits. Because the respondents were not randomly selected, their responses cannot be projected. Details of the questionnaire and responses are in appendix III. We also discussed program plans for future communications and education initiatives with program officials.

We conducted our review from July 1998 through July 1999 in accordance with generally accepted government auditing standards.

Packaging and Shipping Protocol

This appendix describes DOD's packaging and shipping protocol for transporting anthrax vaccine from BioPort to military sites. DOD's packing and shipping goals are to have zero defects (such as package damage that would ruin the vaccine) and zero loss of accountability (such as packages disappearing due to mishandling or theft).

Packaging

BioPort packages vials of anthrax vaccine according to the protocol designed by DOD and BioPort to maintain doses within an acceptable temperature range (1–25°C). The vials are shipped in an insulated container along with gelatin cold-packs, a digital monitor that records the temperature every 5 minutes throughout transit, an addressed envelope for return of the monitor, and an address label for return of the packaging materials to BioPort. In tests of the temperature monitor, DOD found its failure rate to be just under 1 percent—usually due to a mechanical or electrical problem. There are several layers in each container:

- The first layer is composed of two gelatin cold-packs. In spring and fall, one of the packs is frozen before packing; in summer, both are frozen. In winter, neither is frozen.
- The second layer is made of cold-packs that are never frozen before shipping. The vaccine vials and the temperature monitor are packed between the second and third layers.
- The third layer holds two more cold-packs cooled to 4°C.

The highest temperature recorded since use of this protocol began (in a shipment sent to southwest Asia) has been 16°C.

Shipping

DOD's shipments of anthrax vaccine are managed by the U.S. Army Medical Materiel Agency (USAMMA). Shipments in the continental United States, nearly all of which are by air, are performed by Federal Express. Some overseas shipments are also carried by Federal Express, but most are delivered by DHL World Wide Express. Should either Federal Express or DHL World Wide Express go on strike, the other carrier would take over delivery of shipments.

The shipping label on each box has a code to track the package, giving DOD "total asset visibility." As part of its Priority Alert program, Federal Express gives DOD's shipments priority and aggressively pursues solutions to problems that arise. The shipping box carries fluorescent "Priority Alert"

labels on all sides to notify handlers that the box must be moved first and never bumped. If a Priority Alert shipment is held up by problems with Federal Express' transportation vehicles, the company immediately arranges with a common carrier to move the shipment. Federal Express employees take procedural problems uncovered through this program directly to the company's managers for priority resolution.

Federal Express has given USAMMA a computer system to track shipments, and pagers are used for the two organizations to maintain 24-hour communication. BioPort enters information on an outgoing vaccine shipment into the Federal Express system, establishing instant visibility. The program can also generate reports that identify, among other things, systemic problems with shipments to a particular military installation. USAMMA, thus alerted, can check with the site and clarify the situation. Special software, PC Track, will soon link USAMMA to Federal Express' mainframe computer and provide more communication regarding shipments.

USAMMA notifies military recipients beforehand of imminent shipments and gives instructions to alert local security about the shipment and verify that proper refrigeration will be available in the receiving area. USAMMA also faxes them a checklist to be used when the shipment arrives. Upon receipt, the recipient visually inspects the package for damage. If damaged, the recipient is to refuse shipment and contact USAMMA. The military recipient then refrigerates the vaccine at 2–8°C in a restricted area and returns the monitor to USAMMA. The recipient awaits authorization from USAMMA, which checks that temperature data recorded by the monitor did not exceed temperature tolerances before releasing the vaccine. If the package's interior temperature has been too high or low at any point in transit, it shows up on the monitor's read-out as a positive or negative spike (if the box were opened en route, for example, a positive spike would be recorded). Any deviation is recorded on a special form and sent to BioPort for assessment.

When a shipping problem occurs, USAMMA conducts a risk analysis that runs through an "if/then" protocol. Also, whenever a route is changed, USAMMA runs a test shipment of one vial.

Survey of Servicemember Views of the Anthrax Vaccine Immunization Program

We surveyed vaccine recipients in all four services about the anthrax vaccine program and obtained responses from 249 active duty servicemembers: 18 percent (44) in the Army, 12 percent (31) in the Navy, 34 percent (85) in the Air Force, and 36 percent (89) in the Marine Corps. Because our survey participants were not randomly selected, the survey results cannot be projected to a larger military population.

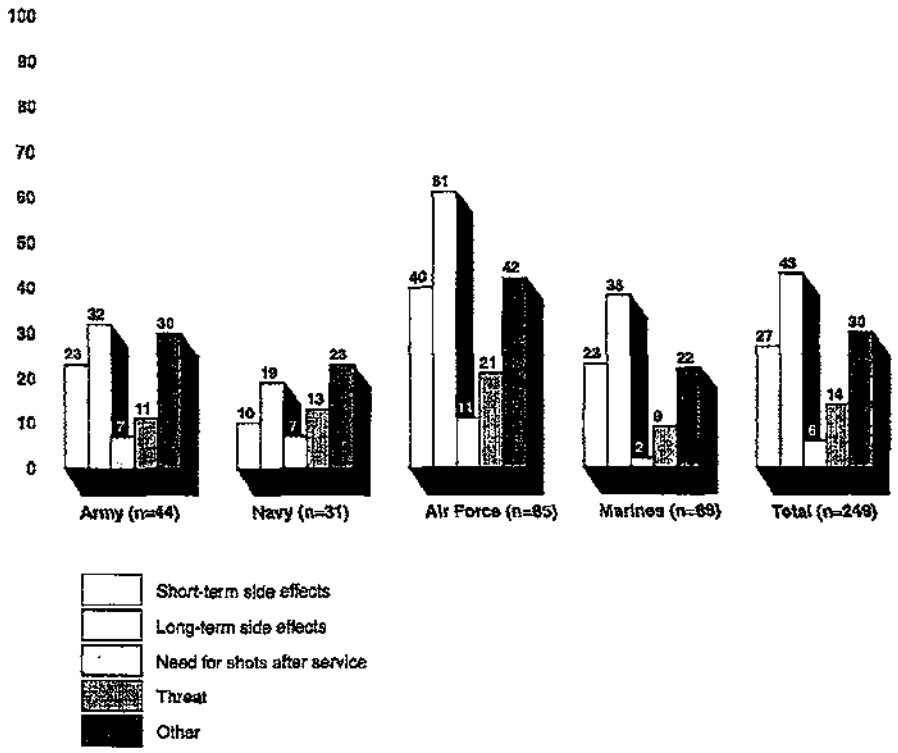
- About 89 percent (220) were enlistees and 11 percent (28) officers.[1]
- 56 percent (140) were between the ages of 18 and 25, the other 44 percent were almost equally distributed between the ages of 26 and 33 and 34 and 49. Most participants in the Army, the Navy, and the Marine Corps were between 18 and 25, while those in the Air Force tended to be older.
- About 86 percent (213) were men.
- Approximately 65 percent (162) identified themselves as Caucasian, 22 percent (54) as Black, and the remaining 13 percent (32) as either Hispanic American, Native American, or Asian American. One participant did not respond to the question.
- The number of respondents for each question varied because they were instructed to skip questions that did not apply to their individual case.

Servicemembers Wanted Information on Possible Long-term Effects of the Vaccine and Other Issues

Two-thirds (164) of survey participants said they wanted information they had not received, including information on temporary or short-term side effects of the vaccine, possible long-term side effects, the vaccination routine after active duty, the anthrax threat, or other information. Participants from all four services also said they wanted information they had not received, especially on possible long-term side effects (about 43 percent—106—of all participants). Relative to their peers from the other services, a higher proportion of Air Force participants expressed a need for information they had not received, particularly on possible long-term side effects (see fig. 5).

[1] One participant in the survey did not indicate military rank.

Figure 5: Percentage of Participants Wanting More Information

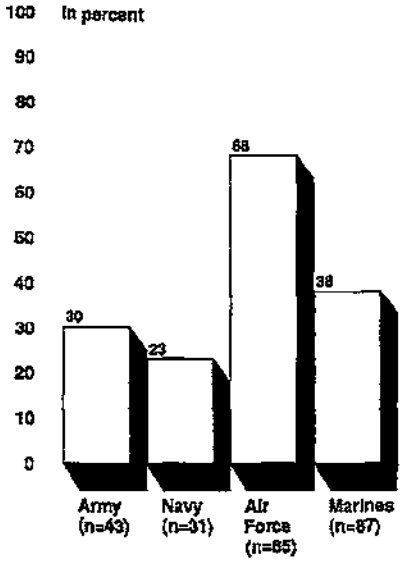


Source: GAO.

Examples of topics not listed in the survey about which respondents wanted more information included why more than three vaccinations are necessary, whether the vaccine has been tested by a qualified source, the history of the vaccine, the anthrax disease, and the extent to which the vaccine has been used to immunize humans.

Figure 6 shows the percentage of participants, by service, who responded that they experienced reactions. The Air Force had the highest rate (68 percent, or 58 out of 85 respondents).

Figure 6: Percentage of Respondents Reporting Short-term Adverse Effects, by Service



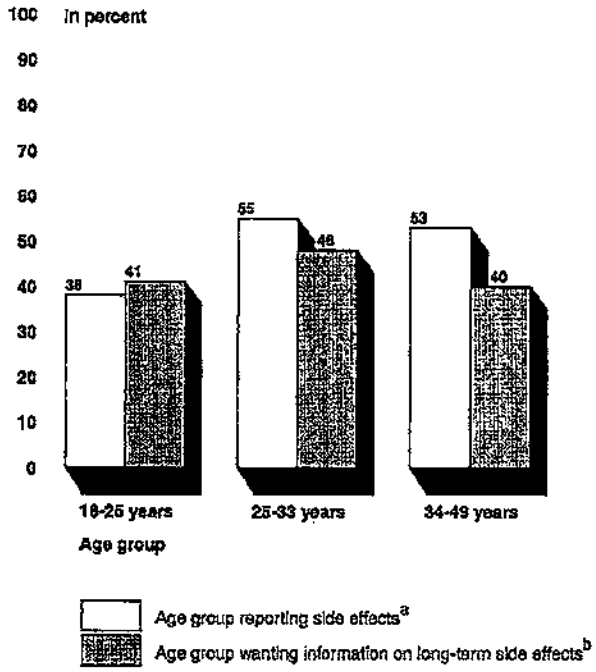
Note: Does not include three respondents who had not received their first shot.

Source: GAO.

Of the 111 survey participants who said they had experienced short-term reactions, 57 percent (59) said they wanted information on possible long-term adverse effects.

Figure 7 shows the percentage of participants in three age groups who reported having adverse effects and who said they wanted more information on possible long-term effects.

Figure 7: Percentage of Respondents Reporting Adverse Effects and Wanting Information, by Age Group



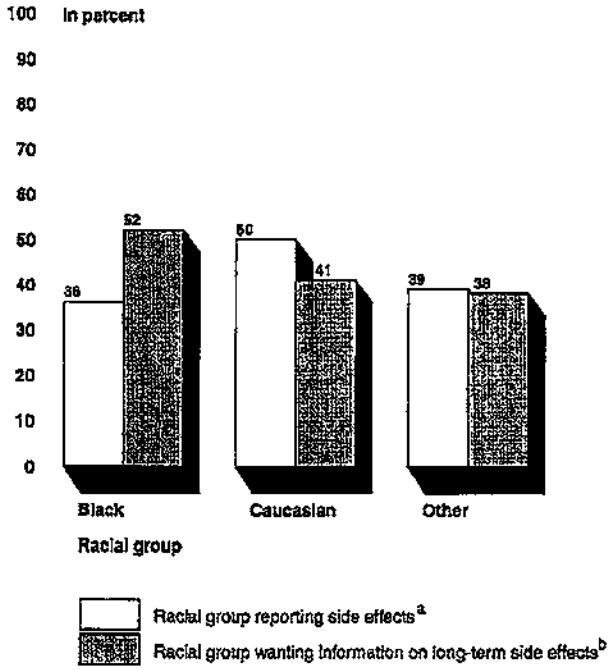
[a] Excludes three respondents who had not yet received their first vaccination. The numbers in each group are: 18 to 25 years, 138 respondents; 25 to 33 years, 55 respondents; 34 to 49 years, 53 respondents.

[b] Includes all respondents. The numbers in each group are: 18 to 25 years, 140 respondents; 25 to 33 years, 56 respondents; 34 to 49 years, 53 respondents.

Source: GAO.

As shown in figure 8, participants in all race categories said they had experienced adverse effects and wanted information on possible long-term adverse effects.

Figure 8: Percentage of Respondents Reporting Adverse Effects and Wanting Information, by Race



[a] Does not include one respondent who did not specify race and three who had not received their vaccination. The numbers for each group are: Black, 53 respondents; Caucasian, 161 respondents; other, 31 respondents.

[b] Does not include one respondent who did not specify race. The numbers for each group are: Black, 53 respondents; Caucasian, 162 respondents; other, 32 respondents.

Source: GAO.

Comments From the Department of Defense

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO ATTENTION OF

0 1 OCT 1999

Office of the Surgeon General

Mr. Norman J. Rabkin
Director, National Security Preparedness Issues
National Security and International Affairs Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Rabkin:

This is the Department of Defense (DOD) response to the GAO draft report "MEDICAL READINESS: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program", dated 3 September 1999 (GAO Code 703254/OSD Case 1688).

While DOD generally concurs with the draft report findings and recommendations, the report did not fully characterize some key aspects and successes of the AVIP. In 18 months of implementation, DOD immunized 340,000 Service Members representing over 1,121,000 immunizations. Although the GAO report focused on the DEERS data repository, it was the Service Immunization Tracking Systems, by design, which successfully tracked each of these immunizations from over 1,200 locations and 5,100 separate units worldwide. At least three paper records serve as redundant safety measures to ensure immunizations are documented. There isn't a State, Federal or private sector health agency in the world that can match this DOD accomplishment.

The GAO investigation acknowledged the grave and urgent danger facing Service Members from the lethal threat of anthrax, but did not mention the excellent long-term safety record of the vaccine, examined over a period of 44 years, in over nine studies or surveys, involving 14,284 patients and 45,742 administered doses. Adding the 1.1 million doses given since March 1998 and analysis of adverse events by an outside panel of national vaccine experts, using national reporting instruments, the vaccine demonstrates a compelling safety record. And while we did not produce a formal written "plan" dealing with an endless array of possible vaccine delivery events and contingencies, the AVIP Agency does have a March 1999 algorithm which addresses the trigger points and options for ensuring continued, measured implementation of the AVIP.

Additional technical comments have been provided directly to the GAO staff for incorporation into the report. Our specific responses to your recommendations are enclosed. We appreciated the opportunity to work with the GAO survey team and the ability to comment on the draft report.

Sincerely,

Ronald R Blanck

Ronald R. Blanck
Lieutenant General, US Army
The Surgeon General

Enclosure
As stated

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GAO DRAFT REPORT-DATED SEPTEMBER 3, 1999
GAO CODE 703254/OSD CASE 1888

"MEDICAL READINESS: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program"

DEPARTMENT OF DEFENSE COMMENTS

To address the challenges DOD faces in vaccinating its total force against anthrax, the GAO recommended that the Secretary of Defense direct the Secretary of the Army, as Executive Agent for the anthrax vaccination program to:

Now on p. 35.

Recommendation 1: Prepare a formal, written plan that addresses strategies to deal with (1) contingencies for vaccinating service members if the supply of anthrax vaccine is not augmented with new production and (2) the risks associated with reliance on a single vaccine manufacturer. (p. 29/GAO Draft Report)

DoD Response: Concur. DOD will transform the current contingency algorithm chart with trigger points and options for ensuring continued, measured implementation into a formal written plan to satisfy the GAO review.

Now on p. 35.

Recommendation 2: Routinely collect and report, among other program performance measures, data on the number of service members refusing to take the vaccine. (p. 29/GAO Draft Report)

DoD Response: A draft policy memorandum, subject: Reporting Service Members Refusing the Anthrax Vaccine, is currently being staffed with the AVIP Executive Agent's General Officer Synchronization Team.

Now on p. 35.

Recommendation 3: Improve DoD guidance and training on how to report adverse events to the Vaccine Adverse Event Reporting System, and refrain from inappropriately using data from the system to report adverse reaction rate (p. 29/GAO Draft Report).

DoD Response: Concur. DOD initiated several actions in the past six months:

1. Apr 99, updated DOD "Force Health Protection Against Anthrax Leaders Briefing", required to be given to all DOD Service Members and DOD Emergency Essential civilians by supervisors, commanders prior to receiving the anthrax immunization. Slides 12, 13, 14 clearly state, for both the AC and RC, "any vaccine associated adverse event may be reported through VAERS by either the patient or provider...in writing or by calling 1.800.822.7967...reporting instructions are available on the Internet at http://www.fda.gov/cber/vaers.htm."

1

2. Apr 99, updated DOD "Anthrax Vaccine Immunization Program Health Care Providers Briefing". Slides 31,32, 33 provide clinical guidelines for VAERS reporting in addition to the guidance provided in the Leaders Briefing above.

3. DOD Policy Memo "Policy for Reporting Adverse Reactions Associated with the Anthrax Vaccine Immunization Program (AVIP)" created 30 Jun 98, staffed with the Services 21 Apr 99, outlines clinical protocols and algorithms for submitting VAERS; also requires submission of an "Anthrax Vaccine Adverse Reaction Supplemental Form". The memo is currently at ASD (HA) for signature.

4. 20 Jul 99, ASD (HA) Memorandum - Ensuring Reservists Have Full Access to Department of Defense (DOD) Medical Treatment Facilities (MTF) for Treatment and Evaluation of Adverse Events from DOD Directed Immunizations, clearly outlines patient or provider submission of Form VAERS-1 with phone numbers, Internet address, etc.

5. DOD Clinician Anthrax Vaccine Guidelines FACT SHEET outlines anthrax vaccine clinical protocols, pre-treatments, specialty referral process, contraindications, categorization of mild, moderate, severe and systemic reactions and associated treatment algorithms. The FACT Sheet clearly outlines enhanced patient or provider Form VAERS-1 reporting with all associated phone and access numbers.

6. AVIP Agency prominently posts Form VAERS-1 reporting options, sources of information, downloadable copies of the form on the anthrax Internet website www.anthrax.osd.mil and silent training aids distributed to Service Members receiving the anthrax immunization.

7. AVIP Agency established links from the DOD anthrax web site to the Food and Drug Administration VAERS information page to facilitate direct FDA reporting.

8. AVIP Agency 1.877.GETVACC Anthrax Information Line, implemented 9 August 1999, routinely provides information on patient or provider reporting of adverse events and Form VAERS-1 access and processing.

9. AVIP Speaker's Bureau/Open House Site Visits prominently discusses patient or provider VAERS reporting access, options and process during their tour.

10. Revised and simplified the AVIP VAERS summary data chart posted on the www.anthrax.osd.mil Internet site.

11. Each of the Services disseminated Service-wide messages to the field outlining VAERS reporting procedures, encouraging Service Member, Health Care Provider or guardian submission of Form VAERS-1 for any vaccine adverse event.

2

12. Sep 99, updated the new DOD quad fold information brochure "What Everyone Needs to Know About The Anthrax Vaccine" (replaces the three current versions of the Tri-fold) given to every Service Member, family member and Civilian prior to immunization. Now provides updated VAERS reporting access, procedures, phone numbers and web site information.

13. The Service Surgeon Generals included VAERS reporting procedures in all major Service/Joint medical proceedings, conferences, etc.

14. Additionally, the Anthrax Vaccine Expert Committee (AVEC) continues to review every anthrax vaccine Form VAERS-1 submission to monitor the safety of the program.

Now on p. 35.

Recommendation 4: Design and conduct a study on possible long-term side effects of the anthrax vaccine and develop a communication plan to provide servicemembers information on the status of this effort. (p. 30/GAO Draft Report)

DoD Response: Concur. DOD established a Longitudinal Studies Concept Committee to explore relevant questions regarding the safety of the anthrax vaccine, define research needs and identify subsequent research design. The Committee consists of DOD, FDA, CDC and Armed Forces Epidemiological Board (AFEB) representatives and met on 24 Aug and 22 Sep 99. The Committee defined gaps in knowledge, set a research agenda and recommended appropriate scientific designs to answer these questions, including comparison groups, statistical methods and ethical oversight. These designs will draw from traditional scientific approaches: surveys, database studies, records reviews, or other methods, depending on the specific question to be answered. Some studies can likely be completed in a few months; others will require several years. DOD programmed $2M to fund this Longitudinal Studies concept in the fiscal year 2000 Program Objective Memorandum and appropriate amounts in subsequent years.

Now on p. 35.

Recommendation 5: Continue improvement of educational efforts by regularly surveying vaccine recipients and addressing educational needs. (p. 30/GAO Draft Report).

DoD Response: Concur. DOD recently sponsored development of a Public Health award winning educational survey for administration to service members who started or are scheduled to start the vaccination series. This survey collects information about the availability, timeliness and effectiveness of AVIP educational materials prior to and during the period that service members are receiving anthrax vaccinations. DOD already collected hundreds of surveys and continues to collect them through multiple venues. Additionally, the AVIP Agency collects informal survey information from telephone calls to the toll free information line and from emails received from AVIP web site users. Collectively,

this survey data is providing insightful information regarding the effectiveness of educational information efforts. DOD plans to expand survey collection and research efforts.

Now on p. 36.

Recommendation 6: Assess the timeliness of personnel duty station data in the Defense Enrollment Eligibility Reporting System to determine where time lags occur in obtaining data and take or recommend steps to resolve untimely submissions. (p. 30/GAO Draft Report)

DoD Response: Concur. We will take aggressive steps through the AVIP Executive Agent to ensure the timely and accurate updating of personnel data in both the Service Immunization Tracking Systems and DEERS.

Now on p. 36.

Recommendation 7: Review service requirements for recording and tracking medical data and incorporate plans to address these requirements in future upgrades to the Composite Health Care System. (p. 30/GAO Draft Report)

DoD Response: Concur. The Services have already developed/employed excellent automated systems for recording, managing and reporting immunization data at the unit level in the 18 months since AVIP execution. These Service systems allow us to track the over 340,000 Service Members and 1,120,000 immunizations given at 1,200 locations within 9,100 separate units worldwide. At least two or more paper back-up systems offer additional redundancy for assured recording of immunizations. DEERS serves AVIP as the final repository for this data. The AVIP Executive Agent will aggressively pursue standardization, simplification and training of all current Service Immunization Tracking Systems into a successor, joint service, long-term immunization tracking system. We have already identified the Service functional requirements needed by unit commanders, supervisors and medical personnel at both home station and deployed locations worldwide.

Now on p. 36.

Recommendation 8: Include response "to avoid the mandatory anthrax vaccine" (or words to that effect) among answers to questions on the reasons for resigning from the military in a DoD-wide exit survey expected to be administered in 2000. (p. 30/GAO Draft Report)

DoD Response: Partially concur. An exit survey to assess overall recruiting and retention issues should be conducted. However, it is not appropriate to single out anthrax vaccinations as a reason for departing the military any more than the potential hundreds of other reasons for leaving the service. A question of this nature is "leading", produces survey bias and fails to capture the multi-faceted and complex nature of why service members depart the military. Our survey construction experts indicate the use of "focus groups" and other population sampling vehicles to assess the impact of the AVIP on retention is a far more appropriate assessment process.

GAO Contacts and Staff Acknowledgments

GAO Contacts

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Acknowledgments

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Related GAO Products

Medical Readiness: Issues Concerning the Anthrax Vaccine (GAO/T-NSIAD-99-226, July 21, 1999).

Contract Management: Observations on DOD's Financial Relationship With the Anthrax Vaccine Manufacturer (GAO/T-NSIAD-99-214, June 30, 1999).

Combating Terrorism: Observations on Growth in Federal Programs (GAO/T-NSIAD-99-181, June 9, 1999).

Medical Readiness: Safety and Efficacy of the Anthrax Vaccine (GAO/T-NSIAD-99-148, Apr. 29, 1999).

Gulf War Illnesses: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved (GAO/NSIAD-99-5, Mar. 29, 1999).

Combating Terrorism: Observations on Biological Terrorism and Public Health Initiatives (GAO/T-NSIAD-99-112, Mar. 16, 1999).

Combating Terrorism: Observations on Federal Spending to Combat Terrorism (GAO/T-NSIAD/GGD-99-107, Mar. 11, 1999).

Chemical and Biological Defense: Observations on DOD's Plans To Protect U.S. Forces (GAO/T-NSIAD-98-83, Mar. 17, 1998)

Combating Terrorism: Efforts to Protect U. S. Forces in Turkey and the Middle East (GAO/T-NSIAD-98-44, Oct. 28, 1997).

Combating Terrorism: Status of DOD Efforts to Protect Its Forces Overseas (GAO/NSIAD-97-207, July 21, 1997).

Defense Health Care: Medical Surveillance Improved Since Gulf War, But Mixed Results in Bosnia (GAO/NSIAD-97-136, May 13, 1997)

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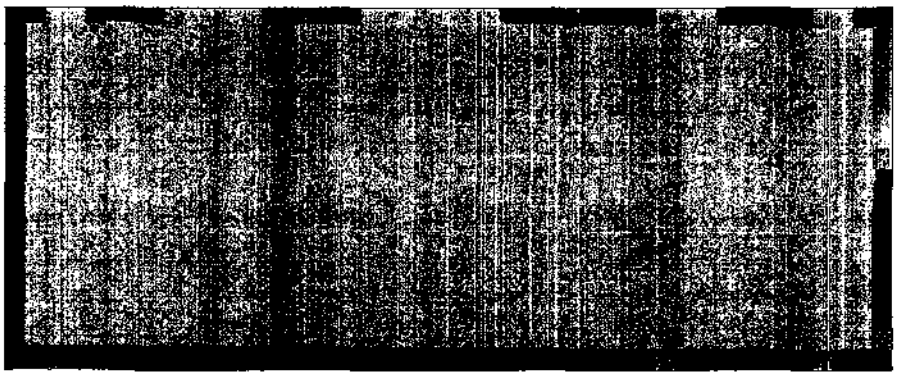

United States General Accounting Office

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Testimony

Before the Committee on Veterans' Affairs, U.S. Senate

For Release on Delivery
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CHEMICAL AND BIOLOGICAL DEFENSE

Observations on DOD's Plans To Protect U.S. Forces

Statement of Mark E. Gebicke, Director, Military Operations and Capabilities Issues, National Security and International Affairs Division

GAO/T-NSIAD-98-83

GAO Form 160 (12/91)
OPR:OIMC/PCC

Mr. Chairman and Members of the Committee:

We are pleased to be here today to discuss the Department of Defense's (DOD) continuing efforts to protect U.S. military forces against chemical and biological weapons, including its plan to inoculate all U.S. military forces against anthrax. As we learned from the Gulf War, U.S. forces were inadequately prepared for surviving and operating in a chemically or biologically contaminated environment. More recently, we found that deficiencies in medical record-keeping have hampered the conduct of epidemiological research to the point that DOD cannot provide precise, accurate, and conclusive answers regarding the causes of Gulf War veterans' illness.

Today, I will first briefly discuss the fundamental shortcomings in DOD's protection of its forces against chemical and biological warfare.[1] Then, I will discuss DOD's proposed anthrax immunization program.

SUMMARY

In examining DOD's experience in preparing its forces to defend against potential chemical and biological agent attacks during the Gulf War, we identified numerous problems. Specifically, we found shortages in individual protective equipment; inadequate chemical and biological agent detection devices; inadequate command emphasis on chemical and biological capabilities; and deficiencies in medical personnel training, and supplies.

While many deficiencies noted during the Gulf War remain unaddressed today, DOD has increasingly acknowledged and accepted the urgency of developing a capability to deal with the chemical and biological threat to its forces. Both the Congress and DOD have acted to provide greater protection for U.S. forces. Their actions have resulted in

[1]Appendix I provides a list of the unclassified GAO reports on DOD's chemical and biological capabilities. We have also issued three classified reports on this issue.

increased funding, and the fielding of more and better chemical and biological defense equipment. DOD must address remaining critical deficiencies if U.S. forces are to be provided with the resources necessary to better protect themselves. For example, DOD needs to decide on major policy and doctrine issues, improve and increase its capability to detect toxic agents, provide forces with improved and sufficient numbers of individual protective equipment, and deal with problems of collective protection and decontamination.

DOD is now embarking on a major effort to protect U.S. forces from the threat of the deadly biological agent anthrax. Its program to immunize millions of active and reserve forces against anthrax, ensuring that each receives the prescribed vaccinations in the proper time sequence, will be a challenge. However, if DOD considers lessons learned from previous, smaller-sized immunization programs and from the medical record-keeping errors in the Gulf War and in Bosnia in formulating detailed implementation plans, it can reduce the risks and improve the prospects for successfully managing the program.

PROTECTING FORCES AGAINST CHEMICAL AND BIOLOGICAL AGENTS POSES CONTINUING CHALLENGES

In 1996, we reported that military units then designated for early deployment faced many of the same chemical and biological defense problems that Gulf War veterans had experienced.[2] During the Gulf War, units and individuals deployed to the theater without all of the chemical and biological detection, decontamination, and protective equipment needed to operate in a contaminated environment. Some units did not have sufficient quantities or the needed sizes of protective clothing, and chemical detector paper and decontamination kits in some instances had passed their expiration dates. While the 6-month Operation Desert Shield buildup time allowed DOD to correct some of these

[2]Chemical and Biological Defense: Emphasis Remains Insufficient to Resolve Continuing Problems (GAO/NSIAD-96-103, March 29, 1996).

problems, had chemical or biological weapons been used during this period, some units might have suffered significant, unnecessary casualties.

We further reported that DOD's progress in chemical and biological research and development was slower than planned, training of Army and Marine Corps forces was inadequate, there was little evidence that joint training and exercises included chemical and biological defense elements, stocks of vaccines for biological agents were in short supply, and medical units lacked necessary chemical and biological defense equipment and training. We believe these deficiencies were a result of, and would not be corrected without, changes in emphasis on the part of senior military leadership.

We have also reviewed DOD's ability to protect critical ports and airfields overseas. Although I cannot fully discuss our findings in this open hearing because of their sensitive nature, I can say that there are deficiencies in doctrine, policy, equipment, and training for the defense of critical ports and airfields.

Congress and DOD have taken action that have improved U.S. forces' ability to survive and operate if chemical and biological agents are used against them. For example, DOD has requested and Congress has approved increased funding for chemical and biological defense. Numerous efforts are currently underway that should provide our servicemembers with new chemical and biological defense equipment and capabilities over the next 5 years. These include the production and fielding of improved protective masks, body garments, and systems to better detect biological and chemical agents. In addition, several commanders in chief recently increased their emphasis on various aspects of chemical and biological defense by, for example, increasing stocks of chemical defense equipment and incorporating more chemical and biological defense scenarios in major military exercises.

Still, DOD must address remaining critical deficiencies that affect its ability to protect forces from chemical and biological attack. DOD's doctrine and policy are inadequate

regarding responsibility for the chemical and biological defense of overseas airfields and ports critical to the deployment, reinforcement, and logistical support of U. S. forces in the event of a conflict. As a result, questions are unresolved regarding the provision of the force structure and equipment needed to protect these facilities. Also, unresolved doctrinal, policy, and equipment questions persist regarding the return of chemically or biologically contaminated strategic lift aircraft and ships and the protection of both essential and nonessential civilians in high-threat areas overseas. Moreover, DOD has insufficient quantities of biological agent vaccines to protect U.S. forces, and servicemembers deployed in high-threat areas overseas normally have no biological agent detection capability. Also, collective protection facilities and equipment and agent detection systems are generally insufficient to protect the force.

DOD's PROGRAM TO IMMUNIZE FORCES AGAINST ANTHRAX

Anthrax is an infectious disease that afflicts certain animals, especially cattle and sheep. The anthrax vaccine was licensed by the Food and Drug Administration (FDA) in 1970 to protect veterinarians, meat packers, wool workers, and health officials who might come in contact with anthrax. (FDA licensure of a vaccine means that it has been tested and proven to be safe and effective in humans.) The vaccine has been routinely administered to populations at risk for several years.

The Chairman of the Joint Chiefs of Staff considers anthrax to be the greatest biological weapons threat to U.S. military forces. After a 3-year study, the Secretary of Defense concluded that vaccination is the safest way to protect U.S. forces against a threat that is 99 percent lethal to unprotected individuals. Accordingly, in December 1997, DOD announced plans to vaccinate all U.S. military personnel (including active, reserve, and national guard servicemembers) against the biological warfare agent anthrax. The Michigan Biologic Products Institute is under contract with DOD to supply the vaccine for the DOD immunization program.

While the vaccine will be centrally procured, administering the vaccinations will be decentralized at multiple DOD facilities worldwide. Initially, DOD planned to begin administering the program in the summer of 1998 to about 165,000 servicemembers and DOD mission-essential personnel located in Southwest Asia and Northeast Asia, which are the areas with the greatest biological warfare threat from anthrax. Prior to beginning the immunizations, DOD wanted time to (1) perform testing of the vaccine to ensure its sterility, safety, potency, and purity; (2) implement a system to track personnel who receive the vaccinations; (3) approve plans to administer the immunizations and inform military personnel of the program; and (4) have the program reviewed by an independent expert. However, DOD accelerated the anthrax vaccination schedule. In March 1998, DOD began immunizing forces stationed in the Persian Gulf because of the possibility of hostilities occurring in that region. DOD plans to vaccinate the remaining active and reserve force over the next several years. In addition, DOD plans to decide whether the program should be extended to others, such as host nation personnel, civilian contractors, and dependents.

In accordance with the FDA licensure regimen for this vaccine, DOD plans to provide an initial series of three vaccinations at 2-week intervals, a second series of three vaccinations at 6-month intervals, and annual booster vaccinations to maintain immunity against anthrax. DOD recognizes that immunizing the entire force with multiple vaccinations will be difficult and involves significant administrative and logistical issues. DOD's program will involve administering anthrax vaccinations to about 2.4 million personnel around the world--a total of about 14.4 million vaccinations for the current force. In addition, personnel entering military service will also be immunized. Thus, DOD envisions the program to continue indefinitely.

Personnel Data Systems to Identify Servicemembers Requiring Vaccinations Must be Accurate

To ensure that all servicemembers receive the required vaccinations, it is important for DOD to have accurate and reliable personnel data systems showing where all servicemembers are located, especially those deployed to overseas locations.

Our work in examining the Operation Joint Endeavor medical surveillance program in Bosnia surfaced concerns about the accuracy of the deployment database used for determining which servicemembers required postdeployment medical assessments. More specifically, DOD officials expressed concerns about the accuracy of the DOD-wide database that was used to identify Air Force and Navy personnel who deployed to Bosnia. Air Force officials told us that the Air Force had supplied information to DOD's database on servicemembers it planned to deploy but that many of them never deployed and the database was not corrected. We were also told that data on servicemembers assigned to two Navy construction battalions that deployed to Bosnia did not appear in the database. DOD officials told us that they were concerned about the accuracy of the deployment database and planned to address the problem.

Sufficient Command Emphasis Needed to Ensure Program Implementation

Because DOD plans to administer anthrax vaccinations in a decentralized manner at multiple locations involving both operational and medical personnel, high-level commanders need to emphasize the importance of the program to ensure that it is carried out within the time schedule for administering the vaccinations. Careful attention to the administration of vaccines is critical because the vaccinations must be given at specific intervals over an 18-month period to achieve maximum protection.

In the past, a lack of command emphasis hindered DOD's successful implementation of medical programs. For example, we found that the Army had not done many postdeployment medical assessments of active duty personnel who had deployed to Bosnia. We also found that assessments done were, on average, not done within the 30-day time frame DOD established. Our work disclosed that it took an average of 98 days to complete the assessments.

In addition, the Bosnia medical surveillance plan also required servicemembers to undergo a tuberculin test at about 90 days following departure from the theater. Our work disclosed that the test took an average of 142 days.

These problems occurred because command officials did not emphasize the importance of the assessments and medical personnel did not have the authority to require servicemembers to go to medical clinics for assessments. Reliance upon unit commanders to require servicemembers to get the assessments was not effective for the Bosnia deployment.

Medical Records Documenting Vaccinations Must be Complete

Medical records documenting all care (including vaccinations) for servicemembers are essential for the delivery of high-quality medical care. DOD regulations require documentation in a servicemember's permanent medical record of all immunizations and visits made to health units.

The Presidential Advisory Committee on Persian Gulf War Veterans' Illnesses and the Institute of Medicine reported problems concerning the completeness and accuracy of medical record-keeping during the Gulf War. Research efforts to determine the causes of what has become known as veterans' Gulf War illnesses have been hampered by, among other things, incomplete medical records showing immunizations and other health services

provided to servicemembers while deployed. The Institute of Medicine characterized DOD's medical records as fragmented, disorganized, and incomplete.

We tested the completeness of medical records for selected active duty Army servicemembers who had deployed under Operation Joint Endeavor. We found that many of the medical records were incomplete in that they lacked documentation on (1) medical surveillance assessments conducted, (2) tick-borne encephalitis vaccinations given, and (3) visits made to in-theater health units. More specifically, we found that 19 percent of the post-deployment in-theater medical assessments and 9 percent of the postdeployment home unit medical assessments were not documented in the medical records. These documentation problems were attributed to the fact that this was a paper-based system that relied upon servicemembers to hand carry assessment forms from the theater to their home unit, which maintained the permanent medical record.

Regarding the documentation of tick-borne encephalitis vaccine in Bosnia, servicemembers deploying to regions where the threat of this disease was prevalent were given the choice of being inoculated with this investigational drug vaccine.[3] We found that 141 (24 percent) of the 588 medical records reviewed for servicemembers who had received the vaccine lacked required documentation.

Our tests of the completeness of the permanent medical records for servicemembers' visits made to battalion aid stations in Bosnia showed similar problems. Specifically, we found that there was no documentation in the medical records for 44 (29.3 percent) of the 150 visits we reviewed. Army officials mentioned that permanent medical records were still paper-based and that information was subject to being misfiled or lost. They also pointed out that servicemembers had deployed to the theater with only an abstract of their permanent medical records and that any medical documentation generated in the theater

[3]An investigational drug is a new drug or product regulated by FDA that has not been licensed for general use in the United States.

was to have been routed back to the servicemembers' home units for inclusion into their medical records.

DOD officials told us that a solution to these documentation problems would be the development of a deployable, computerized patient record. DOD has a project underway to have a paperless computerized medical record for every active duty servicemember by fiscal year 2000.

Centralized Database for Monitoring Program Implementation Must be Accurate

Without an adequate centralized monitoring system, DOD will not have reasonable assurances that the program is being implemented as planned. For Operation Joint Endeavor, DOD established a centralized database to track the services' progress in implementing its medical surveillance program. Medical units processing medical assessments were required to send copies of assessment forms to the DOD office maintaining the centralized database in the United States.

In testing the completeness of the centralized database for in-theater and home unit postdeployment medical assessments conducted for 618 servicemembers, we found that the database understated the number of assessments done. More specifically, it omitted 12 percent of the in-theater medical assessments and 52 percent of the home unit medical assessments.

DOD officials told us that they plan to use a new automated system for tracking implementation of the anthrax immunization program from locations around the world. The automated system is still being developed.

Efficient Inventory Controls Are Necessary to Ensure Sufficiency of Vaccine Supply

To ensure that military personnel will receive vaccinations in a timely manner and to effectively manage the program, it is important for DOD to maintain an efficient inventory control system. This system is needed to ensure that (1) sufficient supplies of vaccines will be available at the various worldwide immunization sites; (2) vaccines that are older than their 1-year shelf life are destroyed; and (3) records of vaccines received, administered, and destroyed are kept to allow for monitoring and tracking.

For the Bosnia deployment, DOD experienced problems in accounting for the inventory of the tick-borne encephalitis vaccine. DOD had to comply with strict FDA regulations regarding its use because it was still being tested as an investigational new drug. Regulations required DOD to fully account for vaccine inventories, including the number of doses administered and the number of doses destroyed.

In the spring of 1996, officials from the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) went to Bosnia to review the procedures being used to administer the tick-borne encephalitis vaccine. These officials found that no record of vaccine disposition was being maintained and recommended that all vaccination sites perform a physical inventory and maintain data on vaccines on hand, used, and destroyed. USAMRIID officials met with considerable resistance from some medical personnel responsible for administering the vaccine about the need to keep proper records. They told us that some of the personnel seemed more interested in administering the vaccine than in keeping necessary records.

Our work on the Bosnia deployment in 1997 showed that the problems identified by USAMRIID had not been corrected. More specifically, DOD could not account for more than 3,000 (20 percent) of the total number of doses sent to Bosnia. Since our report was issued in April 1997, officials from the Office of the Army Surgeon General informed

us that most of the missing doses had been destroyed and only 242 doses remained unaccounted for.

CONCLUSIONS

In conclusion, we believe that DOD has moved in the right direction in increasing its emphasis on improving its chemical and biological defense capabilities. Increased emphasis by the commanders in chief in their areas of responsibility, a DOD-wide spending increase leading to increased numbers of fielded chemical and biological detection and protective equipment, and planned procurements of equipment over the next several years will make U.S. forces better prepared to deal with chemical and biological weapons than in the past. However, greater diligence and more action is needed by DOD to maintain progress toward achieving a level of protection for our forces that will enable us to achieve wartime objectives. This latest initiative to immunize the forces against anthrax represents a clear recognition of this threat to U.S. servicemembers. But DOD must overcome past deficiencies in its medical record-keeping practices and make sure supplies of vaccine are available if this new program is to be successful. In this regard, we reiterate that DOD needs to have the means to (1) identify those servicemembers that require immunization, (2) ensure sufficient command emphasis to guarantee that those identified for immunization are immunized, (3) maintain accurate an accurate medical record of immunizations for each servicemember, (4) manage large-scale immunizations through accurate central databases, and (5) ensure that vaccine inventories are appropriately controlled to ensure that sufficient supplies are on hand.

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This concludes my prepared remarks. We would be happy to respond to any questions the Committee may have.

RECENT GAO REPORTS ON CHEMICAL AND BIOLOGICAL DEFENSE

Gulf War Illnesses: Public and Private Efforts Relating to Exposures of U.S. Personnel to Chemical Agents (GAO/NSIAD-98-27, Oct. 15, 1997) .

Combating Terrorism: Status of DOD Efforts to Protect Its Forces Overseas (GAO/NSIAD-97-207, July 21, 1997).

Gulf War Illnesses: Improved Monitoring of Clinical Progress and Reexamination of Research Emphasis Are Needed (GAO/NSIAD-97-163, June 23, 1997).

Defense Health Care: Medical Surveillance Improved Since Gulf War, but Mixed Results in Bosnia (GAO/NSIAD-97-136, May 13, 1997).

Chemical And Biological Defense: Emphasis Remains Insufficient to Resolve Continuing Problems (GAO/NSIAD-96-103, Mar. 29, 1996).

(703231)

Safety Review of Anthrax Vaccine, 2 April 2001
Compiled by the Anthrax Vaccine Immunization Program (AVIP) Agency

To date, 13 human studies have assessed the safety of anthrax vaccination. These studies, some stretching back almost 50 years, reported adverse events after vaccination in varying degrees of detail. The following paragraphs report, to the extent information is available, the design characteristics of these studies, the number of men and women participating, and specific findings.

Among the studies described below, one of two vaccine formulations was used. The Brachman study and the early Fort Detrick studies used anthrax vaccine manufactured according to the original 1950s formula developed at Fort Detrick, Maryland. Research on this vaccine has been repeatedly accepted by the Food & Drug Administration (FDA) as relevant to the understanding of the safety profile of the current anthrax vaccine, developed in the 1960s.

In the 1960s, the production process for anthrax vaccine was improved to increase the concentration of the active ingredient, known as "protective antigen" (increasing the vaccine's potency), and to decrease the amount of other bacterial components in the vaccine (eg, proteins called edema factor or lethal factor), thus increasing purity. This purer, more potent vaccine, manufactured in Lansing, Michigan, was licensed by the National Institutes of Health in 1970. This license was reaffirmed by FDA in 1985 (*Fed Reg* 1985;50:51002-117 http://www.anthrax.osd.mil/Site_Files/articles/Indexclinical/Fed_register.htm).

The CDC observational study involved people who received either the original vaccine or the improved vaccine, or both. The other studies described below used anthrax vaccine manufactured according to the improved 1960s formula, the same vaccine used throughout the United States today.

Details of each study appear on following pages. The 13 studies include:

a. The Brachman Study (pivotal field trial evaluating safety and efficacy).

b. The CDC Observational Study (the follow-on open-label study between the Brachman study and vaccine licensing in 1970).

c. Fort Detrick Multi-Dose, Multi-Vaccine Safety Studies (evaluations of Army laboratory workers vaccinated hundreds of times with dozens of vaccines).

d. Fort Detrick Special Immunization Program (SIP) Safety Study (continuation of the previous study among more workers into modern times).

e. Fort Bragg Booster Study (evaluation of additional doses of anthrax vaccine among soldiers vaccinated several years earlier during the Persian Gulf War).

f. USAMRIID Reduced-Dose / Route-Change Study (study of anthrax vaccine administered by two different injectable routes of administration).

g. Canadian Forces Safety Survey (study of Canadian Service Members).

h. TAMC-600 Survey (study of adverse events after anthrax vaccination of medical personnel at Tripler Army Medical Center).

i. U.S. Forces Korea Records (study of adverse events among personnel there).

j. USAF Vision Study (a study of visual acuity among vaccinated and unvaccinated air crew members).

k. USAF Air Combat Command Study, Langley Air Force Base (study of outpatient medical care among Air Force personnel after return from Southwest Asia).

l. Reports involving Anthrax Vaccine Submitted to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS).

m. Defense Medical Surveillance System (comparison of hospitalization and outpatient visit rates for those vaccinated and unvaccinated against anthrax).

SUMMARY: Anthrax vaccine prevents anthrax. Anthrax vaccine does not prevent other health problems. This is evident in the similar rates of hospitalization among Service Members vaccinated or unvaccinated against anthrax (section M).

Like all vaccines, anthrax vaccine may cause soreness, redness, itching, swelling, and lumps at the injection site. About 30% of men and 60% of women report mild local reactions, but these reactions usually last only a few days. Lumps can persist a few weeks, but eventually go away. For both genders, between 1% and 5% report moderate reactions of 1 to 5 inches in diameter. Larger reactions occur after about one in a hundred vaccinees or less. Beyond the injection site, from 5% to 35% will notice rashes (16%), headaches (14% to 25%), joint aches (12% to 15%), malaise (6% to 17%), muscle aches (3% to 34%), nausea (3% to 9%), chills (2% to 6%), fever (1% to 5%). Again, these symptoms usually go away after a few days.

The vaccine's product labeling ("package insert") indicates that systemic effects occur in 0.2% of vaccine recipients. This value of 0.2% is unusually low compared to other vaccines and compared to modern data collection with the licensed anthrax vaccine. The low value probably reflects a "threshold effect" of counting only cases of substantial adverse events, in contrast to mild adverse events.

To monitor rare or unexpected adverse events associated in time to any vaccine, DOD health care providers have participated in the Vaccine Adverse Event Reporting System (VAERS), since its inception in 1990. In addition, each VAERS report is reviewed by an independent panel of civilian physicians. To date, this panel has detected no patterns of unexpected adverse events related to anthrax vaccination.

There are no known long-term patterns of side effects from the anthrax vaccine, based on an ongoing series of studies at Fort Detrick, Maryland, and elsewhere. The first report in this series was published in 1958.

Despite the extensive body of knowledge regarding the safety of anthrax vaccine, safety monitoring continues, as is prudent for all vaccines and medications.

a. The Brachman Study

Citation: PS Brachman, H Gold, SA Plotkin, FR Fekety, M Werrin, NR Ingram. Field evaluation of human anthrax vaccine. *American Journal of Public Health* 1962; volume 52: pages 632-45. http://www.anthrax.osd.mil/site_files/articles/indexclinical/brachman.pdf

Investigators: Epidemiologists at the Communicable Disease Center, Johns Hopkins Hospital, Philadelphia Department of Public Health.

Period of Observation: 1955 to 1959

Participants: 1,249 people total, gender unspecified, of whom 379 received anthrax vaccine. At least 3 of the 26 cases of anthrax detected in this study occurred in women.

Vaccine Studied: Fort Detrick formulation

Study Design: Randomized, placebo-controlled trial of anthrax vaccine among mill workers in northeastern U.S. who processed raw imported goat hair.

Findings: "The typical reaction was mild and did not cause any interruption of work."

(a) Injection-site ("local") Reactions:

Mild local reactions, consisting of 1 to 2 cm of redness, plus slight local tenderness, occurred in about 30% of recipients within 24 hours after vaccination. Itching were noted less commonly. "In general, all signs and symptoms disappeared within the next 24 to 48 hours. In many of the cases, this minimal degree of local reaction would not have been noticed by the inoculee had not his arm been examined at 24 and 48 hours after inoculation."

Moderate local inflammation (a defensive reaction to irritation) (> 5 cm in diameter), occurred in 4% of recipients.

Large local reactions occurred less frequently and consisted of extensive swelling of the forearm, in addition to local inflammation. "Three individuals experienced edema extending from the deltoid to the mid-forearm and, in one case, to the wrist, with a definite collection of fluid in the bursa of the elbow. This extensive edema disappeared within three to five days."

(b) Events Beyond the Injection Site ("systemic"): Brachman, et al., did not differentiate between nonserious and serious events. Systemic events occurred in fewer than two per thousand (< 0.2%) recipients, including "...two individuals who experienced, along with the edema-producing local reactions, some malaise of 24 hours' duration." Even less frequently, fever and chills were noted.

(c) Events or effects by gender: Brachman, et al., did not differentiate between men and women in describing adverse events.

(d) Length of time to resolution: Brachman reported no adverse events persisting beyond five days, except that "A few inoculees developed small, firm, painless nodules at the site of injections which persisted for several weeks." They also noted that "Half of these edema-producing reactions were maximum at 24 hours, and the remainder at 48 hours.

b. The CDC Observational Study

Citation: FDA Panel on Review of Bacterial Vaccines & Toxoids: Food & Drug Administration. Biological products; Bacterial vaccines and toxoids; Implementation of efficacy review. *Federal Register* 1985; volume 50: pages 51002-117. <http://www.anthrax.osd.mil/Site_Files/articles/Indexclinical/Fed_register.htm>

Investigators: Data collected under DBS-IND#180 by CDC. Data submitted to NIH Division of Biological Standardization as part of the license application for anthrax vaccine. This license was granted in 1970.

Period of Observation: 1962 to 1972

Participants: about 7,000 people, gender unspecified, involving about 16,000 doses of anthrax vaccine. At least 227 of these people received 10 or more annual booster doses.

Vaccine Studied: Mixture of people receiving the Fort Detrick formulation and the Lansing formulation

Study Design: Observational study assessing use of vaccine in industrial high-risk settings. Side-effect data was collected on vaccinees, but not on any control subjects. CDC collected and analyzed reports of cases of anthrax disease from around the United States (which showed disease in unvaccinated people and no disease in vaccinated people).

Findings: "Local reactions are typically mild.... Only a few systemic reactions with marked chills and fever have been recorded. All reactions reported have been self-limited." "Severe local reactions and systemic reactions are relatively rare."

(a) Injection-site ("local") Reactions:
Mild local reactions ($\leq$ 3 cm) were reported after 3% to 20% of doses administered.
Moderate reactions ($>$ 3 cm to $<$ 12 cm) were reported after 1% to 3% of doses.
Large reactions ($\geq$ 12 cm) were reported after fewer than 1% of doses.

(b) Events Beyond the Injection Site ("systemic"): Report authors did not differentiate between nonserious and serious events. Systemic reactions, reported in four individuals (fewer than 6 per 10,000 doses), consisted of fever, chills, nausea and general body aches, which resolved spontaneously.

(c) Events or effects by gender: Report authors did not differentiate between men and women in describing adverse events.

(d) Length of time to resolution: Authors did not report persistent adverse events.

c. Fort Detrick Multi-Dose, Multi-Vaccine Safety Studies

Citation: Richard N. Peeler, Leighton E. Cluff, Robert W. Trever. Hyper-immunization of man. *Bulletin of the Johns Hopkins Hospital* 1958; volume 103: pages 183-98.
Investigators: Scientists at the Johns Hopkins University
Period of Observation: 1944 to 1956 (mean: 10.4 years)
Participants: 99 men (range: 28 to 65 years old, mean: 40.1 years), 0 women, 99 people total, recipients of multiple immunizations against anthrax, botulism, brucellosis, diphtheria, Eastern equine encephalitis, influenza, plague, poliomyelitis, psittacosis, Q fever, Rift Valley fever, Rocky Mountain spotted fever, smallpox, tetanus, tularemia, typhus, Venezuelan equine encephalitis, Western equine encephalitis, and yellow fever, totaling 36 to 74 milliliters of vaccines, plus multiple skin tests to detect hypersensitivity to microbial antigens. [For comparison, note that the six doses of anthrax vaccine in the primary series total 3 ml.]

* * *

Citation: Richard N. Peeler, Paul J. Kadull, Leighton E. Cluff. Intensive immunization of man: Evaluation of possible adverse consequences. *Annals of Internal Medicine* 1965; volume 63: pages 44-57.
http://www.anthrax.osd.mil/Site_Files/articles/INDEXclinical/anthraxlibrary/Intensive.pdf
Investigators: Scientists at the Johns Hopkins University
Period of Observation: 1944 to 1962 (mean: 15.3 years)
Participants: 76 men (subset of 99 reported above), who received 42 to 102 ml of vaccines (mean: 74 ml)

* * *

Citation: Charles S. White III, William H. Adler, Virginia G. McGann. Repeated immunization: Possible adverse effects: Reevaluation of human subjects at 25 years. *Annals of Internal Medicine* 1974; volume 81: pages 594-600.
http://www.anthrax.osd.mil/Site_Files/articles/INDEXclinical/anthraxlibrary/Repeated.pdf
Investigators: Scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland
Period of Observation: 1944 to 1971
Participants: 97 men (subset of 99 reported above), who received 52 to 134 ml of vaccines (mean: 97 ml), plus 6 to 93 skin tests (mean: 55), compared to 26 age- and gender-matched, unvaccinated control subjects
Vaccine Studied: Mixture of people receiving the Fort Detrick formulation and the Lansing formulation

Study Design: Cohort study, occupational setting. The third study includes a small control group.
Findings: While there were some minor elevations in liver and kidney function tests and white blood cell counts in these men, none of these men developed any unusual diseases or unexplained symptoms that could be attributed to the repeated doses of multiple vaccines.

(a) Injection-site ("local") Reactions: Not the subject of these studies.
(b) Events Beyond the Injection Site ("systemic"): Several laboratory abnormalities were noted (including elevated white blood cell counts and elevated liver function tests). Many of these abnormalities were transient and not detected in the 1974 study.

"It is of prime significance that long-term follow-up examination of these intensively immunized men failed to demonstrate any evidence of illness attributable to the immunizations. There is no indication that intensive immunization interfered with the ability to produce adequate antibody titers after antigenic challenge."

The 1974 study concluded "These data and the accompanying evaluation of an intensively immunized population provide evidence that no obvious adverse effects result from repeated immunization. ... Thus, this group provides reassurance that schedules for routine immunization with a diversity of vaccines should not produce untoward effects merely because of frequency of inoculation."

(c) Events or effects by gender: Not applicable.

(d) Length of time to resolution: Not applicable, no long-term health effects found.

d. Fort Detrick Special Immunization Program (SIP) Safety Study

Citation: None, data analysis in progress, manuscript in development
Investigators: Scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland
Period of Observation: 1973 to present
Participants: 1,255 men, 335 women, 1,590 people total, who received 10,451 doses of anthrax vaccine, assessed at the USAMRIID Special Immunizations Clinic (occupational-health clinic)
Vaccine Studied: Lansing formulation

Study Design: Cohort study of repeatedly vaccinated laboratory workers, with data based on visits to an occupational health clinic (the USAMRIID Special Immunizations Clinic).
Findings: All local and systemic events resolved without extensive time lost from work, hospitalization or long-term effects. These employees continue to be examined and tested annually for medical conditions since their last visit, yet no diseases or unexplained symptoms have been observed that would not be expected in an unvaccinated group of comparable age and other demographic characteristics.

(a) Injection-site ("local") Reactions: 4% of doses resulted in a local reaction consisting of redness, induration (an area of hardened tissue), itching, and soft or puffy swelling (edema) at the injection site. Mild, moderate, and Large reactions were not differentiated in this analysis.

(b) Events Beyond the Injection Site ("systemic"): Systemic reactions of headache, fever, chills, malaise (discomfort, uneasiness), muscle and joint aches occurred after 4 per 1,000 doses. Fifty systemic events noted above were classified as nonserious. One serious systemic event was reported in this study, a woman who developed multiple sclerosis. [Background: About 10,000 people are diagnosed with multiple sclerosis each year in the United States.] Her case resolved in 6 weeks and she returned to duty. All systemic events resolved without extensive time lost from work, hospitalization or long-term effects.

(c) Events or effects by gender: Adverse events were reported by 2% to 4% of men and 4% to 7% of women.

(d) Length of time to resolution: All local and systemic events resolved without extensive time lost from work, hospitalization or long-term effects.

e. Fort Bragg Booster Study

Citation: None, data collection and analysis in progress
Investigators: Scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland
Period of Observation: 1992 to 1993
Participants: 490 men, 0 women, 490 people total, U.S. Army Special Operations Command soldiers at Fort Bragg, North Carolina
Vaccine Studied: Lansing formulation

Study Design: USAMRIID investigators actively assessed the safety of booster doses of anthrax vaccine, given to Special Operations soldiers previously vaccinated against anthrax and botulism during the Persian Gulf War of 1990-91. All 490 were assessed for vaccine safety; 281 were assessed for immunogenicity.
Findings: No adverse event caused lost time from work or hospitalization and all reactions resolved without lasting consequences.
(a) Injection-site ("local") Reactions:
Mild: Of these soldiers, 21% had local redness and/or swelling in the arm where the booster vaccination was administered.
Moderate: In 5%, the redness and/or swelling was $\geq$ 5 cm.
Large: None described.
(b) Events Beyond the Injection Site ("systemic"): One or more systemic reactions occurred in 44% of recipients during the first 30 days after vaccination, most commonly muscle aches (30%), malaise (16%), headache (16%), rash (16%), or joint aches (12%). We should note that these troops were engaged in a field exercise at the time of this study. Therefore, the role of the anthrax vaccination cannot reasonably be separated from the rigorous physical exertion commonly associated with Special Forces field deployments.
(c) Events or effects by gender: Not applicable.
(d) Length of time to resolution: No adverse event caused lost time from work or hospitalization and all reactions resolved without lasting consequences.

f. USAMRIID Reduced-Dose / Route-Change Study

Citation: None. Technical report prepared for Food & Drug Administration. Manuscript in preparation
Investigators: Scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland
Period of Observation: 1998 (enlarged study in planning)
Participants: 109 men, 64 women, 173 people total
Vaccine Studied: Lansing formulation

Study Design: USAMRIID actively collected safety data during a pilot study to evaluate a reduced schedule for administering the anthrax vaccine. The safety of anthrax vaccination was studied in three groups of people: (1) some got the standard schedule of the first three doses (0, 2, 4 weeks) into the subcutaneous fat layer under the skin, (2) others received two doses given subcutaneously, (3) a third group received two injections into the muscle in the upper arm. All these volunteers gave informed consent for the procedure.

Findings: This study provides evidence that local adverse events are less common when the intramuscular route is used to administer anthrax vaccine, compared to the subcutaneous route.

(a) Injection-site ("local") Reactions: Redness and swelling at the injection site occurred more commonly among those given subcutaneous injections, compared to intramuscular injections. Male vaccine recipients developed injection-site reactions less frequently after subcutaneous injection (5% to 32%) than female vaccine recipients (39% to 69%), but the rates were comparably low for both genders when the vaccine was given by intramuscular injection (0% to 7%). Subcutaneous nodules, which resolved spontaneously, were common among recipients of subcutaneous injections, but were not observed among recipients of intramuscular injections. Subcutaneous nodules were usually not noticed by the vaccinee and resolved spontaneously.

(b) Events Beyond the Injection Site ("systemic"): Systemic adverse events were uncommon and their incidence did not differ among the three groups. After the first dose, the side effects noted were headache (14%); malaise (9%); loss of appetite (3%); nausea or vomiting (3%); muscle ache (3%); itching (3%) and low grade fever (3%). All of these reactions were graded as nonserious; none were serious events.

(c) Events or effects by gender: Male vaccine recipients developed injection-site reactions less frequently after subcutaneous injection (5% to 32%) than female vaccine recipients (39% to 69%), but the rates were comparably low for both genders when the vaccine was given by intramuscular injection (0% to 7%).

(d) Length of time to resolution: Not specifically described, but temporary duration was common, as in other studies.

g. Canadian Forces Safety Survey

Citation: None, unpublished
Investigators: Canadian military physicians, Canadian Forces Medical Group, Ottawa
Period of Observation: February to May 1998
Participants: 576 people total, gender unspecified, members of three Canadian Forces units deployed to the Persian Gulf during Operation Determination who received 1,676 doses of anthrax vaccine (1, 2, or 3 doses per person)
Vaccine Studied: Lansing formulation

Study Design: Actively monitored study of adverse events after anthrax vaccination.
Findings:

(a) Injection-site ("local") Reactions:
Mild (1 to 5 cm): after 4.4% of doses, reported by 12.7% of recipients
Moderate (> 5 to 12 cm): after 0.2% of doses, reported by 0.5% of recipients
Large: none reported

(b) Events Beyond the Injection Site ("systemic"): Systemic reactions occurred after 2.2% of doses, reported by 5.7% of recipients. Reported systemic events included headache (13 reports), flu-like gastrointestinal symptoms (9), fever with or without chills (5), fout taste in mouth (3), and neurologic symptom (1, temporary, not considered serious). Two individuals reported heartburn after each of three vaccine doses. . One individual reported a persistent lump (nodule) at the injection site and multiple nodules at several distant sites, but it is unknown whether those lumps existed unnoticed before the vaccination. One medical officer noted several cases of fever and chills, with or without malaise; in all cases these events resolved within 2 to 5 days.

(c) Events or effects by gender: Not described

(d) Length of time to resolution: In all cases except the persistent nodule, these events resolved within 2 to 5 days.

h. TAMC-600 Survey

Citation: Centers for Disease Control & Prevention. Surveillance for adverse events associated with anthrax vaccination - U.S. Department of Defense, 1998-2000. *Morbidity & Mortality Weekly Report* 2000;49(Apr 28):341-5. Reprinted in *JAMA* 2000;283:2648-9. http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4916a1.htm

Investigators: Preventive Medicine Division, Tripler Army Medical Center (TAMC), Honolulu, Hawaii

Period of Observation: 1998 to 2000 (and ongoing)

Participants: 418 men, 184 women, 602 people total; physicians, nurses, medics and other medical-support personnel who augment U.S. medical forces in Korea in military contingencies. Mean age 28 years.

Vaccine Studied: Lansing formulation

Study Design: Prospective, population-based, self-reported survey. The people surveyed are a highly educated, medically experienced population, more able than the norm to describe adverse events and with more ready access to care than other populations.

Findings: Regardless of gender, most adverse events after vaccination were mild and self-limited. The results for all systemic complaints did not substantially vary between dose #1, dose #2, dose #3, and dose #4.

(a) Injection-site ("local") Reactions:

Mild, redness < 5 cm (35% to 40%). Women reported more localized itching (39% to 63%), compared to men (25% to 28%). Women developed more subcutaneous nodules (73% to 90%), compared to men (61% to 66%).

Moderate, redness 5 to 10 cm (20% to 25%).

Large, redness > 10 cm (5% to 10%). Moderate to large injection-site reactions were more common among women (40% to 51%) than among men (17% to 32%). Women reported more swelling of the lower arm (8% to 14%), compared to men (7% to 10%)

(b) Events Beyond the Injection Site ("systemic"): Women reported muscle soreness more often (62% to 80%), compared to men (60% to 67%). About 20% of men and women reported symptoms that they personally judged could be ignored; 15% reported symptoms that affected their activity for a short time but did not limit their ability to perform duties; 8% reported symptoms that affected their activity for a short time that was relieved by self-treatment with nonprescription medication; and fewer than 2% reported that their symptoms were unrelieved by medication and that their ability to perform their duties was limited for a short time.

(c) Events or effects by gender: Injection-site and systemic events occurred more frequently among women than men, but events in both genders were similar in resolving on their own over the course of a few days without residual consequences. Between 4% and 14% of women had an outpatient medical visit, compared to 2% to 5% of men.

(d) Length of time to resolution: Muscle aches typically lasted between 7 hours and 3 days.

i. U.S. Forces Korea Records

Citation: Centers for Disease Control & Prevention. Surveillance for adverse events associated with anthrax vaccination - U.S. Department of Defense, 1998-2000. *Morbidity & Mortality Weekly Report (MMWR)* 2000;49(Apr 28):341-5. Reprinted in *JAMA* 2000;283:2648-9. http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4916a1.htm
Investigators: Department of Preventive Medicine, 121st Evacuation Hospital, Seoul, Korea
Period of Observation: 1998 to 1999
Participants: 2,036 men, 495 women, 2,531 people total
Vaccine Studied: Lansing formulation

Study Design: Systematic recording of self-reported surveys when personnel returned for subsequent doses of anthrax vaccine.
Findings: Regardless of gender, almost all reported events were localized or minor, self-limited, and did not lead to impairment of work performance.
(a) Injection-site ("local") Reactions: Women reported knots (nodules) more frequently (62% to 68%) than did men (42% to 44%).
Mild (redness < 5 cm): Women (12% to 14%), men (8% to 10%)
Moderate (redness 5 to 12 cm): Women (15% to 18%), men (5% to 8%)
Large (redness > 12 cm): Women (3% to 6%), men (1% to 3%)
(b) Events Beyond the Injection Site ("systemic"): Itching was reported by 22% to 40% of women and 7% to 9% of men. Fever was reported by 3% to 5% of women and 1% to 2% of men. Chills were reported by 4% to 6% of women and 2% of men. Malaise was reported by 15% to 16% of women and 6% to 7% of men. Overall, 1.9% reported that their work activity had been limited to some extent or were placed on limited duty. Only 0.3% reported losing one or more days of duty; 0.5% consulted a clinic for the reaction. One individual required hospitalization (analyzed under VAERS, below).
(c) Events or effects by gender: Overall, 72% to 74% of women and 42% to 44% of men reported at least one adverse event after the first or second doses of anthrax vaccine.
(d) Length of time to resolution: Almost all reported events were localized or minor, self-limited, and did not lead to impairment of work performance.

j. USAF Vision Study

Citation: None, manuscript under development
Investigators: Force Health Protection and Surveillance Division, Institute for Environment, Safety, & Occupational Health Risk Analysis (IERA/RSRH). Personnel were seen and the Aeromedical Consult Service, United States Air Force School of Aerospace Medicine (USAFSAM/AFC)

PHASE I
Period of Observation: 1998 to 1999
Participants: 178 case subjects with vision change (161 men and 17 women) and 1,803 control subjects without vision change (1,744 men and 59 women), 1,981 people total, USAF aircrew members, deployed worldwide
Vaccine Studied: Lansing formulation

Study Design: Aviators who suffered a change in vision sufficient to jeopardize flying status were enrolled as cases, with ten age-matched controls identified from automated records of physical examinations. Next, the vaccination status of cases and controls were determined from the anthrax vaccination database.
Findings: Seventeen of 95 cases (18%) had received at least one dose of anthrax vaccine, compared to 451 of 1,060 control aviators (43%). The resulting odds ratio of 0.30 (95% confidence interval: 0.18 to 0.52) suggests that vaccination is not associated with vision change. Technically, the value less than one (with a confidence interval that excludes one) implies that vaccination is protective against vision change, but such a phenomenon is not biologically plausible.
(a) Injection-site ("local") Reactions: Not applicable.
(b) Events Beyond the Injection Site ("systemic"): Vaccination is not associated with vision change.
(c) Events or effects by gender: Not applicable, no effect observed.
(d) Length of time to resolution: Not applicable, no effect observed.

PHASE II
Period of Observation: 1998 to 1999
Participants: 448 case subjects with vision change and 510 control subjects without vision change, 958 people total, USAF aircrew members, deployed worldwide
Vaccine Studied: Lansing formulation

Study Design: medical records with pairs of physical examination data were collected that recorded changes in visual acuity. Next, the vaccination status of cases and controls were determined from the anthrax vaccination database.
Findings: 109 of 448 aviators (24.4%) with visual acuity change had been vaccinated against anthrax, compared to 134 of 510 (26.3%) of aviators without visual acuity change. The resulting odds ratio of 0.90 (95% confidence interval: 0.68 to 1.20) suggests that there is no association between anthrax vaccination and changes in visual acuity.
(a) Injection-site ("local") Reactions: Not applicable.
(b) Events Beyond the Injection Site ("systemic"): Vaccination is not associated with vision change.
(c) Events or effects by gender: Not applicable, no effect observed.
(d) Length of time to resolution: Not applicable, no effect observed.

k. USAF Air Combat Command Study, Langley Air Force Base

Citation: None, manuscript under development
Investigators: USAF Air Combat Command, 1st Aerospace Medicine Squadron, Langley AFB, Virginia
Period of Observation: 1998
Participants: 1,130 vaccinated men, 212 vaccinated women, 1,342 total vaccinated personnel; compared to 3,231 unvaccinated men, 613 unvaccinated women, 3,845 total unvaccinated personnel, 5,187 people total, USAF personnel deployed to Southwest Asia between January and September 1998
Vaccine Studied: Lansing formulation

Study Design: Electronic records of anthrax vaccination were compared with electronic records of ambulatory medical visits among vaccinated and unvaccinated personnel who had returned from Southwest Asia in the previous 6 months.
Findings: No statistically significant associations between anthrax vaccination and any ambulatory diagnosis were found. These diagnoses included allergy, arthropathy, circulatory, dermatological, digestive, endocrine, headache/neurological, hearing, infectious/parasitic, injuries, mental health, musculoskeletal, nasal, neoplastic, ocular, reproductive, respiratory, sleep disorders, urinary, unexplained illness, or more than one diagnosis.
(a) Injection-site ("local") Reactions: Not applicable. No effects observed.
(b) Events Beyond the Injection Site ("systemic"): No effects observed.
(c) Events or effects by gender: Investigator reports no difference in findings when men and women are considered separately. No effects observed.
(d) Length of time to resolution: Not applicable. No effects observed.

I. Reports involving Anthrax Vaccine Submitted to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS)

Citation: Centers for Disease Control & Prevention. Surveillance for adverse events associated with anthrax vaccination - U.S. Department of Defense, 1998-2000. *Morbidity & Mortality Weekly Report (MMWR)* 2000;49(Apr 28):341-5. Reprinted in *JAMA* 2000;283:2648-9. http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4916a1.htm. Data collection and analysis ongoing, publication of an independent report is underway, under the aegis of DHHS.

Investigators: Civilian medical experts convened by DHHS Health Resources & Services Administration

Period of Observation: 1990 to present

Participants: 1,472 vaccine recipients reflected in 1,550 VAERS reports (1,530 when duplicates are omitted), as of April 3, 2001

Vaccine Studied: Lansing formulation

Note: The most detailed information on VAERS reports is maintained by the Food & Drug Administration (FDA) and the Centers for Disease Control & Prevention (CDC). The following analysis is based on VAERS information made available to the DoD. Questions involving more detailed analyses should be referred to DHHS.

Study Design: DoD relays all reports (whether initiated by vaccinee, guardian, health-care provider, or any other source) of adverse events after any vaccination to the Food & Drug Administration. FDA also receives VAERS reports from other sources. FDA's VAERS staff seeks additional medical records, if needed, and follows subjects of these reports to gather information about symptom resolution.

At the request of DoD, the Department of Health and Human Services (HHS) established an Anthrax Vaccine Expert Committee (AVEC) in October 1998 to review VAERS forms related to anthrax vaccine. The AVEC independently reviews all anthrax vaccine-related reports received by VAERS. The AVEC meets every 3 to 6 weeks, along with representatives of DoD, CDC, FDA, and HHS, to review all the new anthrax adverse events reports submitted in the interim. The AVEC reviews the quality of the submitted information, evaluates the reported event in the context of expected and unexpected adverse events to vaccines, and assesses the cause-and-effect relationship of the event with the anthrax vaccine. The AVEC also looks for any clinically significant patterns in the aggregate data.

Findings: To date, the AVEC reports that it has found nothing unexpected in the side-effect profile of anthrax vaccine. The chairman of the AVEC stated "Based on the review of these adverse events, it is apparent that it is safe to continue the anthrax vaccine immunization program of the Department of Defense and it is appropriate to continue to monitor the vaccine adverse events reports and review the safety of the vaccine on an ongoing basis."

As of April 3, 2001, the independent AVEC reviewed 1,530 unique VAERS reports related to anthrax vaccination. The 1,530 reports were grouped into three main categories, based on effect on the vaccine recipient's functional status: hospitalization, loss of duty $\geq$ 24 hours, and other (reports involving neither hospitalization nor loss of duty $\geq$ 24 hours).

Fifty-five of the 1,530 reports involved hospitalization; the civilian panel found that 11 of the 55 "very likely/certainly" or "probably" were caused by anthrax vaccine. All eleven involved allergic, inflammation reactions at the injection site.

For background, the other 44 hospitalizations (those not categorized as "very likely/certainly" or "probably" caused by anthrax) vaccine involved the following diagnoses:

Abdominal pain (1-"unclassifiable" according to AVEC)
Acute encephalitis (1-"unrelated" according to AVEC)
Angioedema (1-"unrelated" according to AVEC)
Aplastic Anemia (1- "unclassifiable" according to AVEC)
Atrial fibrillation (1-"unlikely," 1-"unclassifiable" according to AVEC)
Bipolar psychiatric disorder (1--"unclassifiable," 1-"unrelated" according to AVEC)
Black-out episode (1-"unrelated" according to AVEC)
Cardiac arrest (1-"unrelated" according to AVEC)
Cardiomyopathy with atrial fibrillation (1-"unlikely," 1-"unrelated" according to AVEC)
Diabetes mellitus, insulin-requiring (1-"unclassifiable" according to AVEC)
Diabetes mellitus, non-insulin-requiring (1-"unrelated" according to AVEC)
Dysethesias (T1 and below) (1-"unclassifiable" according to AVEC)
Dyspnea (2-"unclassifiable" according to AVEC)
Endocarditis with perirectal abscess (1-"unrelated" according to AVEC)
Fatigue and injection-site inflammation (1-"possible" according to AVEC)
Febrile illness (1-"unrelated" according to AVEC)
Guillain-Barré syndrome (GBS, 3-"unclassifiable," 2-"unrelated" according to AVEC)
Idiopathic thrombocytopenic purpura (ITP, 1-"unclassifiable" according to AVEC)
Inflammation over olecranon process (1-"unrelated" according to AVEC)
Liver abscess with *E. coli* septicemia (1-"unrelated" according to AVEC)
Intestinal surgery (appendectomy) (1-"unrelated" according to AVEC)
Meningitis, aseptic (1-"unrelated" according to AVEC)
Meningitis, viral (1-"unclassifiable" according to AVEC)
Meningitis, unspecified (1-"unrelated" according to AVEC)
Multiple sclerosis (1-"unlikely" according to AVEC)
Neurological symptoms (facial weakness, slurred speech) (1-"unlikely" according to AVEC)
Neutropenia, fever (2-"unclassifiable" according to AVEC)
Pemphigus vulgaris (1-"unlikely" according to AVEC)
Rash (1-"possible" according to AVEC)
Seizure (1-"unrelated" according to AVEC)
Syncope (1-"unrelated" according to AVEC)
Systemic lupus erythematosus (1-"unlikely" according to AVEC)
Toxic epidermal necrolysis syndrome (1-"unrelated" according to AVEC)
Viral-like syndrome (2-"unrelated" according to AVEC)

Another 146 reports involved loss of duty ≥ 24 hours (but did not involve hospitalization); the civilian panel found that 86 of the 146 certainly or probably were caused by anthrax vaccine. These 86 reports described injection-site reactions (50 reports), various rashes (9), acute allergic reactions (9), viral-like symptoms (8), itching (2), gastroenteritis (2), muscle aches (2), bronchiolitis obliterans (1), temporary tingling (1), photophobia (1), and swollen lymph nodes (1). Some reports described multiple symptoms.

The balance of the 1,530 reports, 1,329, involved neither hospitalization nor loss of duty ≥ 24 hours. All were reviewed by the AVEC, which found no patterns of unexpected adverse events.

* * *

Separate analyses performed by the Anthrax Vaccine Immunization Program Agency indicate there has been no clinically meaningful correlation between anthrax vaccine and reports of adverse events involving hospitalization (all 55 reports) or loss of duty ≥ 24 hours (all

186 reports) based on (a) geographic clustering, (b) vaccine lot (manufacturing batch), or (c) Active- vs. Reserve Component status.

No VAERS reports have been submitted regarding microbial contamination of vaccine vials.

(c) Events or effects by gender: A separate analysis performed by the Anthrax Vaccine Immunization Program Agency indicate that there has been no correlation between anthrax vaccine and reports of adverse events involving hospitalization (for any cause, not just reports judged by the AVEC to be caused by the vaccine), based on gender.

(d) Length of time to resolution: Based on information available to the Anthrax Vaccine Immunization Program Agency (some of which includes records with information redacted by the FDA), all personnel described by VAERS reports judged by the AVEC to be "very likely/certainly" or "probably" caused by anthrax vaccine have recovered or are recovering.

m. Defense Medical Surveillance System (comparison of hospitalization rates for selected diagnoses before and after introduction of Anthrax Vaccine Immunization Program)

The Defense Medical Surveillance System (DMSS) is a longitudinal, relational database of personnel and demographic data, augmented with military experience and medical event data for active-duty personnel in each of the military services. The DMSS is coordinated by the Army Medical Surveillance Activity (AMSA), a component of the US Army Center for Health Promotion & Preventive Medicine (USACHPPM).

I. *TRENDS OVER TIME*

The rate of hospitalization for any cause among Service Members assigned to US Forces Korea shows a steady decline since 1993, despite introduction of a hepatitis A vaccination program in 1996 and the anthrax vaccination program in 1998. These data are especially meaningful, given that all military personnel in Korea are now vaccinated against anthrax. The evidence shows that there has not been an increase in hospitalizations in a theater where all Service members were vaccinated against anthrax and all hospitalizations are recorded electronically.

The rate of death due to illness for any cause at any location among active-duty Service Members has stayed steady or declined slightly, despite introduction of a hepatitis A vaccination program in 1996 and the anthrax vaccination program in 1998.

The rates of hospitalization for diagnoses alleged to be related to anthrax vaccination (including leukemia, Guillain-Barré syndrome, erythema multiforme, thyroid disorders, multiple sclerosis, lupus erythematosus, and aortic aneurysm) are essentially unchanged since 1993, despite introduction of a hepatitis A vaccination program in 1996 and the anthrax vaccination program in 1998.

Analysis of trends over time is helpful, but is not as meaningful a comparison as when the health experiences of vaccinated and unvaccinated Service Members are contrasted directly. Such analyses appears in the next section.

II. *DIRECT COMPARISONS OF VACCINATED & UNVACCINATED PEOPLE*

The most scientifically powerful evidence for the safety of this vaccine comes from the Defense Medical Surveillance System which establishes that anthrax-vaccinated personnel and unvaccinated personnel are hospitalized and visit outpatient clinics at basically the same rates, both overall and for each organ system of the body. For example, one per 35 anthrax-vaccinated people are hospitalized each year, compared to one per 28 unvaccinated people hospitalized per year. Anthrax-vaccinated personnel are as healthy (and as sick) as unvaccinated personnel.

Automated records of immunization and hospitalization were linked electronically. This analysis consisted of 515,389 person-years of experience in the anthrax vaccinated group and 2,873,751 person-years experience in the unvaccinated group. A person-year is analogous to a man-hour. Effectively, it is the experience of one person followed for one year of time. Two people followed for 6 months each also constitutes a person-year.

Rates of hospitalization for each of 16 major diagnostic categories among anthrax vaccine recipients were contrasted with Service Members (SMs) who have not received anthrax vaccine. The rate of hospitalization for each of the 16 major diagnostic categories was the same for SMs vaccinated or unvaccinated against anthrax. These categories include Blood and Blood Formation, Circulatory, Complications of Pregnancy, Digestive, Endocrine / Immunology / Metabolic, Genitourinary-Female, Genitourinary-Male, Infectious Disease, Mental Health, Musculoskeletal / Connective Tissue, Neoplasms, Nervous System, Respiratory, Skin, Injury or Poisoning, and Ill-Defined Conditions.

The accompanying table shows the rate of hospitalization for each category per 100,000 Service Members per year, differentiating people vaccinated or unvaccinated against anthrax. The next column shows the ratio (the unadjusted ratio) of these two rates. If the rates among two groups are the same, the ratio is one.

The column labeled "adjusted ratio" uses the standard statistical method known as regression to remove the effects of age, gender, rank, deployment, service, ethnicity, previous hospitalization, calendar year, and occupation. Statistical adjustment simplifies the comparison to just the effect of the vaccine, holding other effects constant, providing an apples-to-apples comparison. The adjusted ratio is a more specific measure of the relationship between anthrax vaccination and hospitalization.

To account for the inherent variability in measures such as these, the 95% confidence interval is provided. The 95% confidence intervals (CIs) are the range of values within which the true value would lie 95% of the time, if you repeated the analysis multiple times. The 95% CIs shown are for the adjusted rate ratios. For a rate ratio to find a "statistically significant elevation," the confidence interval would have to be entirely above 1.00.

Finding: Assessing specific categories of hospitalization, rate ratios for vaccinated active-duty Service Members are comparable to SMs unvaccinated against anthrax. The rates of hospitalization are essentially the same for vaccinated and unvaccinated Service Members.

Within these 16 broad categories of hospitalization, specific diagnoses are of interest. Another accompanying table shows the rates of hospitalization for various disorders alleged to be associated with anthrax vaccination. The accompanying table shows data for lymphatic cancers (such as leukemia), thyroid disorders, multiple sclerosis, Guillain-Barré syndrome, disorders of the ear, asthma, ulcers or gastritis, joint problems (arthropathies), diffuse disorders of connective tissue (e.g., lupus erythematosus), heart rhythm, or complications of surgery or medical care not elsewhere classified. As with the major categories above, no rate ratio is elevated for vaccinated active-duty Service Members, compared to SMs unvaccinated against anthrax. Again, the rates of hospitalization are essentially the same for SMs vaccinated or unvaccinated against anthrax.

Similarly, rates of outpatient medical visits (ambulatory visits) for each major diagnostic category among anthrax vaccine recipients was contrasted with Service Members (SMs) who have not received anthrax vaccine. The rate of outpatient visits for each major diagnostic category was comparable for SMs vaccinated or unvaccinated against anthrax.

Again, within these broad categories of outpatient medical visits, specific diagnoses are of interest. Another accompanying table shows the rates of outpatient visits for various disorders alleged to be associated with anthrax vaccination. The accompanying table shows data for thyroiditis, hypothyroidism, multiple sclerosis, Guillain-Barré syndrome, visual disturbances,

vertigo, asthma, migraine, rheumatoid arthritis, lupus erythematosus, heart rhythm, atherosclerosis, diabetes mellitus, testicular dysfunction, ulcerative colitis, erythema multiforme. As with the major categories above, none of these rate ratios is elevated for vaccinated active-duty Service Members, compared to SMs unvaccinated against anthrax. The rates of outpatient medical visits are essentially the same for SMs vaccinated or unvaccinated against anthrax.

Gender-Specific Effects: When these analytic approaches are repeated looking at men and women separately, we again find that

a. anthrax-vaccinated women have comparable rates of hospitalization and outpatient medical visits, compared to unvaccinated women.

b. anthrax-vaccinated men have comparable rates of hospitalization and outpatient medical visits, compared to unvaccinated men.

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PHYSICIAN/HEALTH CAREY PROVIDER FACT SHEET'

Anthrax Vaccine & Antibiotic Availability Program

I. PROGRAM SYNOPSIS

The purpose of this program is to provide post-exposure prophylaxis for participants following suspected or confirmed exposure to ***B. anthracis*** spores. Under this program, Anthrax Vaccine Adsorbed (AVA) will be administered intramuscular (IM) for children (younger than 18 years old) and subcutaneous (SQ) for adults. All participants will have signed an informed consent form before being allowed to participate in the program.

The objectives of this program are: 1) to provide antibiotic, or anthrax vaccine and antibiotic (ciprofloxacin, doxycycline, or amoxicillin) for the treatment of suspected or confirmed exposure to ***B. anthracis*** spores; 2) to collect data on adverse reactions to the vaccine and/or the antibiotic ; and 3) to collect data on any anthrax-related infections in the Program population **after** administration of the anthrax vaccine and antibiotics.

This is an multi-site program for the administration of antibiotics or antibiotics with concomitant use of 3-doses of anthrax vaccine intended for implementation when an 'antibiotics only' post-exposure prophylaxis regimen for 60 days has been previously recommended. This is a regimen that is not licensed by the FDA. Enrollment in the program is open-ended. Because this program will be implemented only in a contingency, the specific number of participants to be enrolled cannot be projected, although a range of 100 to 10,000 participants has been adopted for planning purposes. This is a rough estimate and is not designed for the purpose of providing support for a labeling change for Anthrax Vaccine Adsorbed.

The rationale for the program is based not on controlled clinical studies but rather on highly controlled animal studies. Because exposure to ***B. anthracis*** during a contingency will not be similarly controlled, the outcome for humans receiving the antibiotic or antibiotic and vaccine regimen may not be comparable. The purpose of this program is to make antibiotics or antibiotics plus vaccine available for participants following exposure to ***B. anthracis*** spores. We do not know if there is a risk of disease among people who have been exposed to anthrax spores and have taken 60 days of antibiotics. However, if

[1] This fact sheet does not substitute for the "Clinical Procedure Manual," but serves as a brief summary of the program and critical vaccine safety issues. Participating physicians should contact their Site Coordinator for a procedure manual, if necessary.

there is such a risk, then either 40 days of additional antibiotics or 40 days of additional antibiotics and the vaccine may be of benefit in reducing this risk of disease.

The intent of this program is for contingency use of antibiotics or antibiotics with anthrax vaccine in a post-exposure setting, not to support a labeling change for the licensed anthrax vaccine.

The anthrax vaccine to be used under this program is classified as an Investigational New Drug (IND) because (1) the medical indication for post-exposure prophylaxis is not included in the approved package insert, (2) the dosing schedules include vaccination schedules that are outside the parameters of the approved package insert (3) unreleased lots of the vaccine may be used with this program, and (4) certain antibiotics are not approved for post-exposure prophylaxis for anthrax and (5) no antibiotics are approved for beyond 60 days of post-exposure prophylaxis for anthrax. The Food and Drug Administration (FDA) will review data provided by the Sponsor on specific lots of vaccine intended for use under this program. Only lots that meet the FDA criteria will be administered. The source of vaccine for this program will be from one of the following categories: unreleased lots from the original production facility that meet FDA criteria, or unreleased lots from the renovated production facility that meet FDA criteria. The program, consent form, and progress reports will undergo continual review by the CDC Investigational Review Board (IRB) at least annually in accordance with Title 2 1, Code of Federal Regulations (CFR) Part 56.109.

II. Counseling patients about participation in the program

This program is intended to make antibiotics or antibiotics and anthrax vaccine available to all people who may have been exposed to anthrax spores and who were advised to complete a 60-day course of drugs. DHHS is not making any recommendation whether an individual should or should not take this vaccine or additional antibiotics. DHHS is making the vaccine and antibiotics available to allow patients in consultation with physicians to decide whether or not they wish to participate.

Factors relevant to the decision to participate include exposure dose, risk of inhalation anthrax, antibiotic adherence, side effect tolerance, and overall health status. People who may have had exposure to higher numbers of anthrax spores include:

- People who had significant contact with an anthrax-laced powder or envelope.
- People who worked in areas where someone became infected with inhaled anthrax.
- People in environments heavily contaminated with anthrax.

These groups include 70 Capitol Hill workers exposed to the letter setn to Senate Majority Leader Tom Daschle as well as workers in Washington's central Brentwood and New Jersey's Hamilton Township postal facilities and AMI Building in Florida.

Individuals must carefully examine the risks and benefits of choosing to take the antibiotics and vaccine; or continue on an antibiotic for an additional 40 days; or cease taking antibiotics at this time. All persons should maintain close contact with their healthcare provider. A synopsis of adverse effects and possible benefits is presented in the patient "Informed Consent" document.

Antibiotic Safety Sheets are provided separately.

III. ANTIBIOTICS (PATIENT INFORMATION)

Neither ciprofloxacin nor doxycycline are licensed by the FDA for use beyond 60 days for post-exposure prophylaxis of inhalational anthrax. Amoxicillin is not licensed for any post-exposure prophylactic regimens for inhalational anthrax.

CIPROFLOXACIN

Ciprofloxacin (**CIPRO®**) is approved by the Food and Drug Administration (FDA) to treat and protect individuals who become exposed to ***Bacillus anthracis*** spores administered as an aerosol. The recommended treatment after exposure to inhalational anthrax is 500 mg given orally every 12 hours for 60 days. The antibiotic should not be given to anyone who has had a serious allergic reaction to ciprofloxacin or other antibiotics in the quinolone family.

How to take CIPRO: Take CIPRO with food (excluding milk or yogurt) and at least one large glass of water. The antibiotic works best when the amount of medicine in your body is kept at a constant level, so take 1 tablet every 12 hours for 60 days. If you take any of the following-zinc, iron, sucralfate, **Videx®** (didanosine), and antacids that contain magnesium, calcium, or aluminum-take them 6 hours before or 2 hours after taking CIPRO.

Side effects: CIPRO may cause stomach upset, loss of appetite, diarrhea, nausea, drowsiness, or headache during the first few days as your body adjusts to the medication. If these symptoms persist or become severe, inform your health care provider. Promptly report new pain or tenderness (tendonitis) in arms or legs. Ruptured tendons have been reported after administration of CIPRO. Also report any vision changes, restlessness, ringing in the ears, or mental changes. In the unlikely event that you have an allergic reaction to this antibiotic, seek immediate medical attention. Symptoms of an allergic reaction include rash, itching, swelling, fever, or trouble breathing. If you notice any other effects, contact your health care provider promptly.

Precautions: Before taking CIPRO, tell your health care provider if you have a medical history of epilepsy, kidney disease, tendon problems, nervous system disorders, liver disease, blood vessel problems, and any drug allergies. Use caution driving or performing tasks requiring alertness if this medication makes you dizzy or lightheaded. Alcohol can make the condition **worse.** CTPRO can increase sensitivity to sunlight, so avoid prolonged sun exposure. Wear protective clothing and a sunscreen to minimize sun sensitivity. The safety of ciprofloxacin, to the unborn baby is not known. However,

adverse drug effects have been reported in young animals given ciprofloxacin or doxycycline (such as bone and joint changes). If you are pregnant or could become pregnant you should inform program personnel.
Drug Interactions: Tell your health care provider of all medications that you are using (both prescription and nonprescription), especially of other antibiotics, theophylline, warfarin, cyclosporine, live bacterial vaccines, probenecid, sucralfate, quinapril, didanosine, iron, zinc, and antacids that contain magnesium, aluminum, or calcium.

Caution: CIPRO may increase or extend the effects of caffeine and theophylline.

DOXYCYCLINE

Doxycycline is approved by the FDA to treat anthrax disease but not explicitly for post-exposure prophylaxis. The recommended treatment is 100 mg given orally every 12 hours for 60 days after exposure to anthrax spores. The antibiotic should not be given to anyone who has had a serious allergic reaction to any tetracycline product.

How to Take Doxycycline: Take doxycycline with food and at least one glass of water. The antibiotic works best when the amount of medicine in your body is kept at a constant level, so take I tablet every 12 hours. Do not lie down for at least I hour after taking this drug.

Side Effects: Doxycycline may cause nausea or diarrhea. In the unlikely event that you have an allergic reaction to this antibiotic, seek immediate medical attention. Although the occurrence is unlikely, dark urine, yellowing of the eyes or skin, persistent sore throat or fever, unusual bleeding or bruising, unusual fatigue, white patches in the mouth, or unusual vaginal discharge/itching should be reported immediately to your health care provider. Use of tetracycline during the last half of pregnancy may cause permanent discoloration of the teeth of offspring. If you have an allergic reaction to this antibiotic, seek immediate medical attention. Symptoms of an allergic reaction include rash, itching, swelling, fever, or trouble breathing. If you notice any other effects, contact your health care provider,

Precautions: Before taking doxycycline, tell your health care provider if you have a medical history of yeast infections of the mouth, kidney or liver problems, esophagus problems or trouble swallowing (hiatal hernia or reflux/heartburn), and any drug allergies. Use of this antibiotic for prolonged periods may result in an infection (e.g., oral, bladder, or vaginal yeast infection). Doxycycline can increase sensitivity to sunlight, so avoid prolonged sun exposure. Wear protective clothing and a sunscreen to minimize sun sensitivity. Avoid taking antacids containing magnesium, aluminum, or calcium; sucralfate; iron preparations; or vitamin (zinc) products within 3 hours of taking this antibiotic.

Drug Interactions: Tell your health care provider of all medications that you are using (both prescription and nonprescription), especially antibiotics (penicillins/cephalosporins such as cefuroxime), antacids, vitamins/minerals (such as zinc), iron supplements, bismuth subsalicylate, sucralfate, carbamazepine, phenytoin, barbiturates like phenobarbital, blood thinners like warfarin, or methoxyflurane. Use of doxycycline may make birth control pills less effective.

AMOXICILLIN

This drug belongs to the broad class of penicillin drugs. You have been given this drug for protection against possible exposure to anthrax. You have been provided a limited supply of medicine. Local emergency health workers or your healthcare provider will inform you if you need more medicine after you finish this supply. If so, upon your follow-up visit, you will be told how to get more medicine. You will be told if no more medicine is needed. You may also be switched from this medicine to a different medicine.

Take this medicine as prescribed, This drug is usually given in three daily doses (500 mg in adults) and may follow you getting a 10-14 day course of another antibiotic for prevention of anthrax (ciprofloxacin or doxycycline). Amoxicillin is used for anthrax prevention when specific anthrax prevention drugs such as doxycycline and ciprofloxacin are contraindicated and there is low antimicrobial load (prophylaxis and localized cutaneous anthrax in pediatric, pregnant or lactating patients). Special dosing instructions for children are oral amoxicillin 80 mg/kg of body mass per day divided every 8 hours (not to exceed 500 mg three times daily).

Keep taking your medicine, even if you feel okay, unless your doctor tells you to stop. If you stop taking this medicine too soon, you may become ill.

Amoxicillin is assumed to be effective with penicillin-sensitive anthrax bacteria. There is only limited experience available using it to treat anthrax infection. In addition, the FDA has not approved its use specifically for prevention of this infection, and there is concern that standard oral doses may achieve less than desired drug levels.

How to take Amoxil ® Amoxil is available as capsules, tablets and powder for oral suspension intended for oral administration.
Capsules contain 250 mg or 500 mg amoxicillin. Tablets contain 500 mg or 875 mg amoxicillin. Chewable tablets contain 125 mg, 250 mg or 400 mg amoxicillin.

Side effects: As with other penicillins, amoxicillin may cause stomach upset, diarrhea, nausea and vomiting during the first few days as your body adjusts to the medication. If these symptoms persist or become severe, inform your health care provider. If you have an allergic reaction to this antibiotic, seek immediate medical attention. Symptoms of an allergic reaction include rash, itching, hives, fever, or trouble breathing. If you notice any other effects, contact your health care provider.

Precautions: Before taking amoxicillin, tell your health care provider if you have asthma, any other illnesses or any allet'gies, especially to penicillin or other antibiotics. Use of this antibiotic for prolonged periods may result in yeast or other infection.

Drug Interactions: Tell your health care provider of all medications that you are using (both prescription and nonprescription), especially tetracycline products.

IV. VACCINE

A. Anthrax Vaccine Adsorbed (AVA)

Anthrax Vaccine Adsorbed (AVA) is produced by BioPort Corporation (formerly Michigan Biologic Products Institute and Michigan Department of Public Health) in Lansing, Michigan. It has been licensed for pre-exposure prophylaxis by the U.S. Food and Drug Administration since 1970. AVA is a sterile product made from filtrates of microaerophilic cultures of an avirulent, nonencapsulated strain of Bacillus ***anthracis, which*** elaborates the protective antigen during the growth period. It contains no whole bacteria, neither live nor dead, so it is impossible to contract anthrax from the vaccine. The cultures are grown in a synthetic liquid medium and the final product is prepared from sterile filtered culture fluid. The protective antigen (PA) in the vaccine is the common disease-causing protein in all anthrax strains that cause disease; therefore, the vaccine is expected to provide protection against all strains of ***B. anthracis.*** The potency of FDA-licensed lots of AVA is confirmed according to the U.S. Food and Drug regulations (21 CFR 620.23). The final product contains no more than 2.4 mg aluminum hydroxide (equivalent to 0.83 mg aluminum) per 0.5 mL dose. The aluminum hydroxide adjuvant in the vaccine increases the number of antibodies that the body makes in response to vaccination. Formaldehyde, in a final concentration not to exceed0.02%, and benzethonium chloride, 0.0025%, are added as preservatives.

The anthrax vaccine is supplied in 5.2-mL vials containing approximately 10 doses each. Each vial of unreleased vaccine will be labeled for human administration and will include the following statement: "Caution: New Drug – Limited by Federal law to investigational use." This cautionary statement will not appear on vials of FDA-released vaccine. The vaccine should be stored at 2°C to 8°C (35.6°F to 46.4°F). It should not be frozen.

B. Efficacy of the Anthrax Vaccine

The efficacy of anthrax vaccine for **post-exposure prophylaxis has not been evaluated in** humans.

The effectiveness of the anthrax vaccine for pre-exposure prophylaxis is based on human and animal research. Although the number of subjects getting the vaccine in these pre-exposure studies has been small, they suggest efficacy of 90-95%.

C. Contraindications for Use of AVA

Contraindications for preexposure use of AVA include pregnancy, immunosuppression including HIV, hypersensitivity to AVA and age < 18 years.

FDA has allowed use of AVA for post-exposure prophylaxis in this program. The risks of instituting post-exposure prophylaxis with AVA in this program among people for whom pre-exposure AVA is contraindicated should be weighed against the risk of anthrax disease.

Precautions

1. General: Epinephrine solution, 1: 1000, should always be available for immediate use in case an anaphylactic reaction should occur, even though such reactions are rare.

2. Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies have not been performed to ascertain whether Anthrax Vaccine Adsorbed has carcinogenic action or any effect on fertility.

3. Pregnancy: Although unconfirmed, a recent preliminary study suggests that the vaccine may be linked with an increase in the number of birth defects when given during pregnancy. At this time no one knows for sure whether this vaccine can cause fetal harm.

D. **Safety of AVA**

Several studies have shown that anthrax vaccine is safe, with an incidence of side effects after injection similar to that of other common vaccines. As with any medication, all vaccines will occasionally cause adverse reactions. Usually these are mild, like a sore arm or "flu"-like symptoms.
Based on data obtained during 30 years of experience with anthrax vaccine, it is expected that up to 30% of men and 60% of women receiving the vaccine will experience some mild adverse effects, for example:

Redness: reddish discoloration around injection site, visible by sight;

Swelling: soft raised area on the skin, detectable by observation and/or touch;

Lump or "knot": hard spot on the skin, detectable by observation and/or touch;

Bruise: bluish/black discoloration of skin at injection site, visible by sight;

Warmth: area at injection site associated with elevated temperature, detectable by touch;

Soreness: a state of unusual sensitivity to touch or pressure;

Itching on arm: an unpleasant cutaneous sensation provoking the desire to scratch or rub the skin.

Arm motion limitation: unable to perform normal range of motions in the arm.

Loss of appetite: a lack of appetite even though there is a physical need for food, and sometimes associated with weight loss;

Headache: participantive feeling of sharp/dull throbbing/constant discomfort in head and/or neck;

Fatigue: a feeling of tiredness or exhaustion;

Muscle ache: participantive feeling of muscle pain;

Joint swelling or pain: participantive feeling pain or stiffness in a joint;

Itching: area other than injection site/more generalized associated with an itching sensation;

Nausea/Vomiting: feeling sick to the stomach; may be accompanied by vomiting (throwing up);

Diarrhea or stomach pains: watery or loose stools are passed more often then normal;

Chills: shivering, a sensation of cold or an episode of shivering with paleness and feeling of coldness;

Shortness of breath: participantive feeling of difficulty breathing;

Fever: elevated temperature (generally above 98.6); may be accompanied by chills;

Rash or Hives: an irritation on the skin (red bumps)

Fainting: temporarily unconscious

E. Serious Adverse Events

A serious adverse event (SAE) is any untoward medical occurrence that results in any of the following outcomes:

1. death
2. life-threatening adverse event
3. in-patient hospitalization or prolongation of existing hospitalization
4. persistent or significant disability/incapacitation
5. congenital anomaly/birth defect

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered **SAEs** when, based on appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent the occurrence of any of the five outcomes listed above.

In the event of an **SAE,** the Site Coordinator or their designee should notify the Clinical Project Manager with 24 hours of their notification of the **SAE.** Additionally, the Site Coordinator or their designee will Fax the VAERS Form and/or the MEDWATCH Form, with the appropriate cover sheet(s), to the CPC, CDC (FAX: 1-866-639-8548) and submit the form(s) either by mail and/or FAX to VAERS and or MEDWATCH (see forms for appropriate FAX number and address). The forms provided to the participants for reporting **AEs** have been specifically pre-labeled with their **IND** number, site code, and participant numbers. Only these pre-labeled forms should be used for reporting **AEs** under this program.

IV. Questions and Problems

For the period of the first 6-weeks after enrollment, the participants should direct questions to their Site Coordinators. If the Site Coordinators are unable to satisfactorily answer the question and/or need additional information, they should contact the Clinical Project Manager, Dr. McNeil. Additional questions may be directed to the CDC hotline: 1-888-246-2675 (English) or 1-888-246-2857 (Spanish).

On February 17, 2000, the Subcommittee on National Security, Veterans Affairs, and International Relations, Committee on Government Reform released a report prepared by the majority staff regarding the DoD Anthrax Vaccination Immunization Program. This report, which contains five findings and five recommendations, has been proposed for consideration and adoption by the full Committee. DoD's response follows:

February 17, 2000

ANTHRAX FACTS

- Anthrax is a deadly biological weapon that represents a real and present danger to U.S. service personnel.
- Anthrax vaccine was licensed by the FDA nearly 30 years ago as safe and effective in preventing this extremely lethal disease. It was revalidated in 1980 when biomedical responsibility was transferred from NIH to the FDA. The vaccine is neither "experimental" nor "investigational."
- The Secretary of Defense, after assuring a program of high quality, directed the Anthrax Vaccine Immunization Program for the Total Force.
- The number of vaccinations given to date exceeds 1.4 million doses, with few serious adverse events.
- Reports of adverse events are consistent with expectations based on previous research studies and in line with experiences with commonly used vaccines and compare favorably with those of other required vaccines, including those we give to our children.
- The evidence of vaccine protection in humans and animals against aerosol exposure to anthrax is persuasive and this has been so stated by the FDA.
- Concerns about previous deficiencies by the production facility in meeting current Good Manufacturing Practices have been addressed by FDA action, DoD assistance to the facility, and a supplemental testing program on the safety, sterility, purity, and potency of the vaccine. This is a totally new facility owned and operated by a new licensee. The inspections and certifications are very thorough, very demanding and are not accomplished overnight.
- Hypotheses and Internet rumors about squalene in anthrax vaccine are false.
- In balancing the risks of immunization versus risks from failing to vaccinate, the scales tip decidedly in favor of immunization.
- The United States government must protect the Armed Forces against clear biological-warfare threats, whenever safe and effective vaccines are available.

COMMENTS ON THE REPORT *FINDINGS*

REPORT FINDING 1. The AVIP is well intentioned, but it is an over broad response to the known threat.

KEY POINTS:

- We are pleased to note that the report recognizes the "known threat" and affirms the program as "well-intentioned."
- However, we disagree that it is "overbroad" -- unlike other vaccines which we can offer troops one dose as they deploy--with a 6-dose series over 18 months as the only licensed protocol. We MUST begin vaccinating NOW for FUTURE protection of the ENTIRE force. Before it's too late.
- Everyone is subject to future deployment/we depend highly on both active and reserve components -- anything other than vaccination of entire force is unwarranted risk.

BACKGROUND:

- Former Director of the CIA, James Woolsey, referred to it as "the single most dangerous threat to our national security in the foreseeable future."
- At least seven potential adversaries have an offensive capability to use or active R&D programs to obtain this biological weapon.
- Known intelligence subsequent to Desert Shield/Desert Storm confirms both Iraq's offensive BW capability to deliver anthrax and their intent to use it. Russia and some former Soviet states have an even greater capability.
- The former USSR in the post-Cold War era admitted that their anthrax production provided enough agent to kill every person on earth several times over.

FINDING 2. The anthrax vaccine is vulnerable to supply shortages and price increases.

KEY POINTS:

- SOLE SOURCE SUPPLIER IS NOT UNIQUE TO ANTHRAX VACCINE; 40% of US vaccines are sole source:
- Adult and deployment--Yellow Fever, Typhoid, Cholera, Plague
- Children et al--Measles, Mumps, Rubella, Chicken Pox, Polio
- The price paid by DoD per dose of Anthrax Vaccine Adsorbed (AVA) is cheaper than almost all civilian vaccine prices and is less expensive per dose than several CDC purchased doses for national childhood vaccine program.
- DoD is always cognizant of supply vulnerability. There is not enough anthrax vaccine to immunize everyone at once; therefore, the DoD has a phased implementation, starting with personnel at greatest risk, assigned and

deploying to the two high threat areas of Korea and SWA. Per the original AVIP Plan, Phase II will not be started until DoD has established assured production at BioPort.

BAGKGROUND:

- The management of production, supplemental testing schedules, labeling and other factors contributed to the phased schedule of vaccinations. This phased approach ensures that sufficient vaccine is first available to forces that are most at risk from a biological warfare attack, and that an adequate supply exists to support unexpected worldwide contingencies and international crises.

FINDING 3. DoD's execution of AVIP is logistically too complex to succeed.

KEY POINTS:

Yes, it is logistically complex, but WE ARE SUCCEEDING!

- 1.45M doses administered to over 400,000 service members, EE civilians
- Automated tracking system records it ALL (largest such successful effort by any health care organization world wide): every single dose administered by name, SSAN, date administered, lot number, health care provider, route of administration, dose amount
- World class shipping/distribution system has worldwide industry attention--we know location of every dose, by lot number-- unprecedented temperature controlled environment monitored throughout shipment
- Unprecedented education effort from the beginning continues to grow and mature consistent with service member feedback
- Unprecedented worldwide command attention supported by immunization tracking system focused on service members receiving all 6 doses consistent with package insert

BACKGROUND:

Immunizations are tracked and recorded in four places: the individual's shot record (PHS 731); the individual's health record; the Services' automated immunization tracking system; and the Defense Enrollment Eligibility Reporting System (DEERS) which is the central repository.

The DEERS repository provides a worldwide capability to download immunization data for all Service members. This is very unique to DoD. No other health care system can provide this type of data access for their customers.

FINDING 4. Anthrax vaccine safety is not monitored adequately.

KEY POINTS:

- DoD has aggressive, multi-faceted surveillance program to assess and monitor vaccine safety, which was presented in testimony to the Subcommittee on National Security, Veterans Affairs and International Relations Committee on Government Reform, July 21, 1999. DoD testimony on safety monitoring was not recognized in the subcommittee

report.
- DoD employs monitoring by three scientific method categories: clinical studies (ongoing and planned); database analysis of vaccine recipient automated medical records (ongoing); and spontaneous reports (VAERS).
- DoD employs FDA/CDC VAERS reporting with unprecedented redundant review and assessment by civilian expert medical panel--the Anthrax Vaccine Expert Committee.

BACKGROUND:

- Safety data to date includes at least 12 human studies assessing the safety of anthrax vaccine. These studies, some published, some unpublished, but all made available to the GAO, stretch back almost 50 years.
- Report acknowledges active monitoring in two of these studies: Tripler Army Medical Center and Pittman et al, Fort Detrick, both active surveillance, which are DoD directed studies.
- Like all vaccines, anthrax vaccine may cause soreness, redness, itching, swelling, and lumps at the injection site. About 30% of men and 60% of women report mild local reactions, but these reactions usually last only a few days. Lumps can persist a few weeks, but eventually go away. For both genders, between 1% and 5% report moderate reactions of 1 to 5 inches in diameter. Larger reactions occur after about one in a hundred vaccines or less. Beyond the injection site, from 5% to 35% will notice muscle aches, joint aches, chills, fever, headaches, nausea, loss of appetite, malaise, or related symptoms. Again, these symptoms usually go away after a few days.

To monitor rare or unexpected adverse events associated in time to any vaccine, DoD health care providers have participated in the Vaccine Adverse Event Reporting System (VAERS), established by the Department of Health and Human Services, since its inception in 1990. In addition, each VAERS report is reviewed by an independent panel of civilian physicians. To date, this panel has detected no patterns of unexpected adverse events related to anthrax vaccination.

FINDING 5. Vaccine efficacy against biowarfare is uncertain.

KEY POINTS:

- Anthrax vaccine is a FDA-licensed product: has been since 1970 and is neither "experimental" nor "investigational."
- FDA-approved package insert recommends usage in man to protect against Bacillus anthracis --not just cutaneous; all forms of the disease.
- FDA reaffirmed efficacy and safety of anthrax vaccine in multiple testimonies both to Congressman Shays' and Burton's committees during 1999--part of the Congressional Record.

BACKGROUND:

- The current U.S. licensed anthrax vaccine is considered to be highly effective against naturally occurring strains of anthrax, including antibiotic-resistant-strains. This is because anthrax vaccine targets the key disease-causing protein common to all strains of anthrax, the Protective Antigen.
- In a letter from the FDA to the Assistant Secretary of Defense (Health Affairs) dated March 13,1997, the FDA states:

> "While there is a paucity (scarcity) of data regarding the effectiveness of anthrax vaccine for prevention of inhalation anthrax, the current package insert does not preclude this use. The original efficacy trial clearly showed that the vaccine

conferred a high level of protection against cutaneous exposure. None of the 5 inhalation cases in this trial occurred in anthrax vaccine recipients, but these data alone are insufficient to allow definitive statistical conclusions. Results from animal challenge studies have also indicated that pre-exposure administration of anthrax vaccine protects against inhalation anthrax. Therefore, I believe your interpretation is not inconsistent with the current label."

COMMENTS ON THE REPORT *RECOMMENDATIONS*

RECOMMENDATION 1. Force-wide mandatory AVIP should be suspended immediately.

KEY POINTS:

- DoD is firmly committed to maintaining a healthy and fit force and preventing needless casualties—for the Total Force—not just part of the force.
- Vaccination with a FDA-licensed product is a pillar of our Force Health Protection Strategy.
- Like wearing body armor, mandatory protection through vaccination is not an individual decision—to do otherwise risks not only the individual, but his comrades serving with him, his unit, and its mission.

BACKGROUND:

- A partially vaccinated force that suffers half or one-quarter casualties after an anthrax attack virtually guarantees a failed mission and unconscionable combat losses.
- Anthrax vaccination is no different than any other Force Health Protection issue—like wearing armor, a protective mask, or receiving the dozens of other immunizations required of Service Members before deployment to foreign countries.

RECOMMENDATION 2. DoD should accelerate research and development of a second generation recombinant vaccine.

KEY POINT:

- Agree and ongoing: Research and development of a second generation recombinant vaccine has been accelerated and is currently ongoing.

RECOMMENDATION 3. DoD should pursue testing of shorter shot regimen.

KEY POINTS:

- Agree and ongoing.
- DoD has worked toward this goal for several years: US Army Medical Research Institute of Infectious Diseases (USAMRIID) actively collected data during a pilot study to evaluate a reduced dosing schedule and change in route of administration; findings presented to the FDA in Fall 1998.
- DoD, in collaboration with the CDC, with Congressional funding is now developing the

research protocols and design of the definitive clinical research to evaluate a reduced dosing schedule and change in route of administration.

RECOMMENDATION 4. DoD should enroll all recipients in comprehensive evaluation and treatment program for long-term studies.

KEY POINTS:

- Through its automated immunization tracking system database, ALL DoD anthrax vaccine recipients are recorded and anthrax vaccine doses tracked as they begin the anthrax vaccination series. This will facilitate all ongoing and planned evaluation and treatment programs for long-term studies.

BACKGROUND:

- The Department of Defense continues to monitor the safety of the vaccine during program execution. The Army is conducting a longitudinal, prospective study using a cohort of 600 soldiers stationed at Tripler Army Medical Center. The intent is to identify side effects that may be temporally associated with anthrax vaccinations. To date, the results have closely correlated with historical data in medical literature.
- The Anthrax Vaccine Expert Committee (AVEC), a panel of civilian physician experts convened by the Department of Health and Human Services Health Resources & Services Administration reviews all VAERS reports submitted to the FDA. This independent external review panel meets every 4-6 weeks. To date, the committee has identified no unexpected events after anthrax vaccination.
- The nearly 50 years of study experience with anthrax vaccine in the United States demonstrates the vaccine has a similar side-effect profile, compared to other commonly used vaccines.

RECOMMENDATION 5. Use of the anthrax vaccine for force protection against biowarfare should be considered experimental and undertaken only pursuant to FDA regulations for investigational new drugs.

KEY POINTS:

- **Anthrax vaccine is a FDA-licensed product; has been since 1970— neither "experimental" nor "investigational."**
- **FDA-approved package insert recommends usage in man to protect against *Bacillus anthracis*—not just cutaneous: all forms of the disease.**
- **FDA reaffirmed efficacy and safety of anthrax vaccine in multiple testimonies both to Congressman Shays' and Burton's committees during 1999—part of the Congressional Record.**

BACKGROUND:

- **The current U.S. licensed anthrax vaccine is considered to be highly effective against naturally occurring strains of anthrax, including antibiotic-resistant strains. This is because anthrax vaccine targets the key disease-causing protein common to all strains of anthrax, the Protective Antigen.**
- **In a letter from the FDA to the Assistant Secretary of Defense (Health Affairs) dated March 13, 1997 the FDA states "While there is a paucity of data regarding the effectiveness of anthrax vaccine for prevention of inhalation anthrax, the**

current package insert does not preclude this use. The original efficacy trial clearly showed that the vaccine conferred a high level of protection against cutaneous exposure. None of the 5 inhalation cases in this trial occurred in anthrax vaccine recipients, but these data alone are insufficient to allow definitive statistical conclusions. Results from animal challenge studies have also indicated that pre-exposure administration of anthrax vaccine protects against inhalation anthrax. Therefore, I believe your interpretation is not inconsistent with the current label."

BACKGROUND

TOTAL FORCE ANTHRAX VACCINATIONS as of: 9 February 2000

	ARMY	AIR FORCE	NAVY	MARINES	C G	TOTAL
DOSE #1	133,844	123,789	78,636	69,643	344	406,256
DOSE #2	124,036	117,920	70,561	65,718	328	378,563
DOSE #3	113,283	112,109	63,949	61,145	306	350,792
DOSE #4	84,343	80,151	28,763	35,224	133	228,614
DOSE #5	44,382	41,208	7,027	5,607	21	98,245
DOSE #6	8,238	9,394	667	738	8	19,045
BOOSTER	247	47	0	0	0	294
TOTAL	508,373	484,618	249,603	238,075	1,140	1,481,809

IN CONCLUSION

- The threat of anthrax is real. If exposed and unprotected, we will in all likelihood die.
- It is colorless, odorless, tasteless and very difficult to detect. Our Servicemen and women go to war every day under the delivery umbrella of weaponized anthrax. There is safe and effective vaccine that has been certified, re-certified, and reviewed many times, by the FDA, the agency our nation depends on to do so.
- No one has ever died from taking the anthrax vaccine shot; but many could die because they had not been vaccinated and were exposed.
- We agree with the sub-committee that a better version can be developed, probably requiring fewer shots.
- We are actively pursuing such a vaccine with a funded, aggressive program, but it will take several months to a few years to develop it and gain certification.
- We cannot send out troops into harm's way during that time without the safe and effective protection, which is available today.
- This is not an experimental program; it is protection by a properly proven product from a deadly threat.

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Anthrax And The Internet

By Colonel Mark F. Cancian, U.S. Marine Corps Reserve

"After three years of study it was found that vaccination was the safest way to protect a highly mobile military against a threat of anthrax spores that are 99% lethal for unprotected persons." --DoD Policy Statement (www.anthrax.osd.mil)

". . . .Vaccinating service members with a shoddily produced vaccine with a poor record of effectiveness and [which] may be dangerous is neither good medical practice nor sound military strategy. -- Dr. M. Nass (www.dissident.org)

What's going on here? Dueling web sites and dissenting opinions! In part, this is nothing new. Service members frequently have been caught up in policy debates, medical and otherwise. There is, however, a new facet: the rise of the Internet as a communications medium that amplifies other leadership challenges, skepticism about government, the widespread acceptance of conspiracy theories, the surge of issue activists, and the blurring of the line between fact and fiction, all occurring in a post-Cold War strategic situation where military needs are not as pressing. The environment for leadership is changing, and military leaders must change with it.

The Anthrax Debate

Anthrax is a highly lethal disease caused by bacteria and normally associated with plant-eating animals. Humans can be infected by direct contact with infected animals and animal products. Anthrax was weaponized about 50 years ago, and DoD believes about seven countries have anthrax as a biological weapon.

A vaccine against anthrax was developed about 40 years ago and has been in use since 1970 when it was licensed by the Food and Drug Administration. Annually, it is given to several thousand people who might be exposed to natural anthrax—veterinarians and people working with high-risk animal products.

In 1998, after a two-year review, the Secretary of Defense decided to inoculate service members against anthrax, beginning with those deploying to threat areas. His rationale was as follows[1]:

*Anthrax is highly lethal and likely to be used in future conflicts.[2]

*Passive measures such as gas masks are useful but do not provide sufficient protection.

*The vaccine is effective against all known strains of anthrax.

*The vaccine is safe, having been thoroughly tested. Acknowledged production problems are being fixed. Side effects are minor (sore arms, redness). There are no known fatalities from vaccination.

*Military and civilian society routinely inoculate against a variety of diseases. Failing to inoculate service members against a known threat would be irresponsible.

From the beginning critics have raised questions. These criticisms cover a lot of ground because they come from many different sources[3], but the main concerns are as follows:

*Anthrax has never been used in war and, even if used, is unlikely to be an effective weapon.

*Defensive measures like gas masks and antibiotics will provide sufficient protection.

*The vaccine is not effective against most strains of anthrax, especially bioengineered strains.

*The vaccine's long-term effects have not been adequately investigated.

*The vaccine's production facility is unsafe.

The impact of this debate is real. A few hundred service members have refused to take the vaccine and been disciplined. While representing only a small fraction of the total number inoculated, these "resistors" have received considerable media attention, magnified by antivaccination activists. For example:

*"A group of 23 sailors from a Norfolk-based aircraft carrier have refused to take anthrax shots ordered by the Pentagon, joining a small but growing number of servicemembers who have declined the inoculation. . . ." (Washington Post, 12 March 1999, www.washingtonpost.com)

*"A Marine has gone to federal court to seek a hardship discharge . . .[on account of] his mother [who] suffers severe anxiety, panic attacks and depression because she distrusted the anthrax vaccine. . . .el'm not going to let the government shoot my son up with poison and take him from me,' she said." (Pittsburgh Post-Gazette, 21 November, 1999, post-gazette.com/regionstate/19991123anthrax5.asp)[4]

As a result the case against the vaccine has received wide attention. Congress has held hearings on the issue, and a few members have recommended that the vaccination program be made voluntary.

The Internet

The Internet has been the catalyst for this controversy. Once limited to the technologically sophisticated, Internet access is now as common as the telephone. Usage has risen from just 300,000 in 1990 to 4.8 million in 1995 to 60 million today, and is increasing by 2 million per month.[5] Certainly the Internet has shaped the debate about anthrax vaccinations. "The Internet has brought the largest government agency to its knees," observed one Internet authority. "An Army of invisible detractors can keep the most powerful fighting machine in history on the defensive."[6] Then-Deputy Secretary of Defense John Hamre essentially agreed: "There's an awful lot of just absolute nothing but rumormongering [on the Net]."

The Web's openness is one of its most exciting qualities. Everything is there--the good, the bad, the interesting, and the mundane. Anyone can post anything. For a society that prizes the free flow of information and ideas, this is wonderful. The practical problem is that everything posted acquires a certain credibility just by being on the Web, clearly formatted and attractively presented. As a former Director of the National Security Agency once noted, "B.S. at the speed of light is still B.S."[7]

This unfiltered dissemination of information is new. Traditional communications media--like newspapers, magazines, and television--have certain standards about what they report. They may sometimes fail to meet these standards, but the standards about evidence, sources, and attribution are in place. There are no such standards for the Net. Further, if traditional communications media err, there are mechanisms for challenging them--letters-to-the-editor, ombudsmen, direct appeals to the editors. On the Net there is no presiding authority, no referee. Indeed, the problem of Net credibility has become serious enough that there are now sites dedicated to debunking net hoaxes.

The Navy and Marine Corps are wiring all bases for Internet access, with most offices already connected and even sailors aboard ship getting connected.[8] This not only promises to transform our way of doing business but also opens all the benefits of cyberspace to sailors and Marines, an important recruiting incentive and quality-of-life enhancement for a networked generation. It also, however, exposes sailors and Marines to all the messages in cyberspace. A search done on "anthrax vaccine" will turn up all the official sites as well as all the resistor sites. In the past it was possible, but difficult, for antimilitary groups to reach service members directly, and in every conflict they tried. Senior officers remember the antimilitary activities outside base gates during the Vietnam War, and the Marine Corps archives contain

antiwar leaflets given to troops headed for Nicaragua in the 1920s. Direct access, however, was difficult. Groups had to physically hand out pamphlets or take some other very direct, and visible, action. The Net goes around the traditional gatekeepers--base police, policy makers, department heads, NCOs, and petty officers. Groups can target service members on the Net without it being visible in the usual ways. There is a whole level of communications, like the barracks rumor mills, occurring below the level of the military leadership's visibility. The antivaccine movement delivered their message directly to service members and raised fears before the DoD realized it and fought back.

What happens on the Net is anonymous. People are known only by nicknames and cryptic e-mail addresses--"superdog" or "rspz123@aol.com." In traditional society, one could also maintain anonymity, but it took effort and was difficult. Now it is easy. People can hold conversations in chat rooms, explore Web sites, and exchange e-mail all without being known. Net posters are frequently anonymous as well. Some Web sites lack any attribution; others refer to obscure individuals or to vague organizations without any details except perhaps an e-mail address.

Speed and accessibility of information do not in themselves challenge military leadership. They do, however, facilitate and amplify certain social trends, such as distrust of government, that tend to undermine authority and that make military leadership more difficult.

Distrust of Government

The increasing distrust of government is a phenomenon that long has been recognized and that needs little elaboration. It is enough to say that in 1960 confidence in government was 75% while today it is 30%.[9] Vietnam, Watergate, oil crises, environmental alarms, and presidential impeachments have taken their toll. In the military specifically, activists point to nuclear weapons testing on troops, combat forces exposed to Agent Orange in Vietnam and the lingering mystery surrounding Gulf War disease as evidence that the government cannot be trusted.

Distrust of government can intensify a penchant for conspiracy theories. Although always present in the United States--suspicions about freemasons and the Catholic church were common in the 18th and 19th centuries--these have received a major boost in recent years, driven by various coverups: some real, others fanciful.

The Web abounds in conspiracy theories. Although Princess Diana and the CIA seem to have a special prominence here, the military is also a frequent subject. A few examples give a flavor for what is out there:

* "It is planned that the United States shall be permanently without an Army, Navy, and an Air Force. The Internal Security Forces that are to be assigned the duty of keeping order may or may not be U.S. citizens. Martial rule shall prevail throughout the United States." (www.libertygunrights.com)

* "'Operation Rain Dance' was set in motion by the Department of the Army, an Air Force Special Research Unit, and biomedics of the U.S. Navy. . . . SB-17 was a virus they were working on to target and kill only Native Americans. Do you remember the 7-9 Navaho Indians who died of mysterious circumstances? The experiment was a success." (ftp.shout.net/pub/users/bigred/vol11)

Anthrax is no exception. There is dark talk of "medical experiments" and corporate conspiracies. The broader point is that for any controversial public issue there will spring from the fertile mind of some citizens the very darkest interpretation, and that view will be on the Net for all to see.

Activists

To gain a political foothold in a democracy, an issue needs a group of activists who will take the time and invest the resources to get visibility for that issue. Articulate and energetic individuals, such as Rachel Carson (Silent Spring) and Upton Sinclair (The Jungle), always have had an impact on the politics of specific issues. The Internet now facilitates this process. A Web site puts out information for the curious. Chat rooms build awareness and make converts.[10] E-mail groups get people organized and

activated. Chain e-mails act like petitions with each addressee signing on if he or she agrees and forwarding it to others.[11] A recent example of this is Jody Williams and the effort to ban antipersonnel landmines. She built an international arms control movement in large part through the Internet (www.icbl.org). Indeed, there are Web sites dedicated to activism in general (www.berkshire.net/~ifas/activist). Anthrax too has its activists. Certain names keep popping up at "resistor" Web sites.[12]

The extreme version of activism is an inducement to hysteria. Activists have long known that publicizing mere "concerns" may not sufficiently energize an electorate, so they turn to more extreme measures. As a result many anti-anthrax vaccine Web sites contain extreme language: "human guinea pigs," "experimental drugs," and "poison." Even the scientific community is not immune. Though believing in the scientific method as an ideal, many scientists also hold strong political beliefs. As one scientist candidly stated,

On the one hand, as scientists, we are ethically bound to the scientific method, in effect promising to tell the truth, the whole truth and nothing but--which means we must include all the doubts, caveats, and ifs, ands, and buts. On the other hand we are human beings as well. . . . and like most people we'd like to see the world a better place. . . . To do that we need to get broad based support, to capture the public's imagination. . . . so we have to offer up scary scenarios, make simplified, dramatic statements, and make little mention of the doubts we have.[13]

Not surprisingly controversies have frequently erupted over "junk science"--the abuse of scientific evidence for political purposes (www.junkscience.com).

Hysteria, panic, and rebellion driven by rumor are nothing new. In 1789, the Great Fear gripped revolutionary France wherein thousands of peasants were convinced that angry mobs of Parisian revolutionaries were going to invade the countryside. In 1857, British native troops in India, the Sepoys, rebelled over rumors that the new Enfield cartridges were greased with pork fat (forbidden to Moslems) or cow fat (forbidden to Hindus) and that even touching them would make a trooper religiously unclean. What is new is the speed and reach that modern technology, especially the Internet and e-mail, bring to these fears, concerns and controversies.

The Challenge for Military Leadership

Politically, the Cold War spoiled the military. Certainly there were bitter debates about weapons, budgets, and policies. But underlying these debates was a shared and universal assumption that the dangers to the nation were great and immediate, the responsibilities of the military were immense and that, therefore, tinkering with military personnel policies was risky and best minimized. Today, although the world remains unstable and dangerous, the threats are less immediate to the average citizen. It is hard for Americans to imagine a really serious conflict such as Korea or Vietnam, to say nothing of a world war. The memories are instead of Desert Storm and Kosovo--apparently easy victories with few casualties. Anthrax and other threats seem abstract and unreal.

Further, fewer and fewer Americans have served in the military and therefore have a hard time seeing it as anything except an extension of their own civilian experience. As a result there seems little reason to compromise civilian standards for military necessity--whether regarding environmental laws, the role of homosexuals, or in this case, vaccination. Not only will this continue, it will become more acute as memories of the Cold War fade further. Military leaders will struggle to justify policies that require sacrifice in some dimension when the average citizen sees little need for compromise.

So what are military leaders to do? First, as long as a policy exists, leaders must firmly implement that policy. To do less invites anarchy. Resistors frequently complain, "I'm willing to face enemy fire, but I'm not willing to be a guinea pig in a medical experiment." One sympathizes with people facing the shock of the unexpected. Military history is full of examples where seasoned units broke in panic because of threat from an unexpected direction. But to sympathize is not to excuse. At commissioning and at every promotion an officer is charged "to observe and follow such orders and directions as may be given by the President of the United States of America or other superior officers. . . ." There is no fine print saying

that a member will only be asked to do "a," "b," and "c" but not "d," "e," and "f".

More harshly, there is a question about courage and reliability. Once someone indicates that they will only obey only the orders they regard as justified, reasonable, and safe, they have indicated their unreliability. And where does it stop? However much they protest that it is just this one order, the precedent is set. It is a slippery slope until all orders are second-guessed.

Leaders have a special responsibility. In some instances officers refusing the shots encouraged their troops to also refuse shots. This literally is mutiny, defined in the Uniform Code of Military Justice as, "refusing, in concert with any other person, to obey orders. . . ." Calling such behavior mutiny is politically incorrect, the term being so harsh. Nevertheless, that is what the behavior is, and it cannot be tolerated.

Merely implementing policy is not enough. Leaders also must recognize the new challenges and take steps to ensure voluntary and willing compliance with orders.

The first requirement is for education at the unit level. What frustrated British drill sergeants during the French and Indian War still frustrates military leaders: it is not enough just to give American troops an order. A leader must explain why. Conversely, this is the U.S. military's great strength--intelligent compliance, not just blind obedience. For controversial issues like anthrax shots this means that a conscious educational effort will be necessary. The leadership needs to take direct action to explain why a policy is being implemented; the troops will not absorb this by osmosis. For anthrax vaccinations this is now belatedly under way. Having the ship's doctor or the battalion surgeon talk with the troops for an hour before every shot of the series may be all that is needed. But clearly an order from the chief or the gunny to "line up and get your shot, it's good for you" is not enough.

The second requirement is Net presence. Information campaigns in cyberspace are the same as campaigns in traditional media. They require a broad approach, persistence, rapid reaction, and credibility. Such campaigns begin by producing one's own Web sites. The DoD, in general, and the Navy, specifically, have very sophisticated Web sites and are now aggressively defending anthrax vaccination on the web. Further, the DoD has recognized that one site is not enough. An effective campaign requires using multiple sites. A search on "anthrax vaccination" now turns up a dozen DoD sites, which overwhelm "resistor" sites. It is like a traditional media campaign where putting out a single press release is not enough. Further, Net presence must be part of a broad approach employing traditional media, hot lines, brochures, and op-ed pieces, all of which the DoD is now doing, though belatedly. Persistence and rapid reaction mean that this is an extended campaign, not a single battle. The Web is no different from traditional media campaigns where unfavorable or inaccurate stories require immediate response. Sites are not constructed once for all time, like a book, but need to be updated frequently in response to the latest events. Finally, credibility is vital. There's no substitute for clear facts, scientific evidence and specific citations.

Another requirement is advance warning. The DoD has a fairly sophisticated process for keeping an eye on what the traditional media are saying. Every morning the Current News[14] produces a compendium of major articles relating to national security. Public-affairs personnel participate in policy discussions and keep senior officials advised about media events and strategies. It is time to expand that effort to the Net. Whether this is part of "information operations" or "public affairs" is not important. What is important is to keep an eye on the Net and to react quickly to what is there. The first inkling of an unfavorable Net rumor should not be a newspaper headline.

Censorship is not an answer. It may be tempting to block access on government computers to dissident Web sites by using software filters. This is a hopeless task, like trying to control what books or newspapers the troops read. Which sites to block? It is impossible to separate "legitimate" policy discussion from "illegitimate" agitation and trying to do so will produce endless, and embarrassing, arguments. It is better to have rules about appropriate Web surfing during duty hours--and leave the policy at that.

Finally, there is the emotional aspect. In scientific arguments the discussions center around evidence,

facts and logical inference. Without question these are important. But the emotional side also is valid. People want to feel supported, cared for, and valued. This should not be overlooked in the scientific debate.

This discussion has looked at the institution's side of this phenomenon. What about individuals who face a policy they find intolerable? What recourse do they have? Today, for some, it is the anthrax vaccination, but tomorrow, for others, it could be another Balkans intervention or gays serving openly in the military. In the course of their careers many officers will face policies they find unwise, unjust, or even abhorrent.

As difficult as it may be practically, resignation should not be dismissed. There is too minor a tradition in the U.S. armed forces of resigning on principal. Many officers, particularly senior officers, convince themselves that they can do more on the inside. At bottom, there is a deep arrogance in such a belief, because it implies that those coming after would not have the same ability or commitment. General Harold K. Johnson, Army Chief of Staff 1964-1968, articulated this at the end of his life. When asked if he had any regrets about his career, he said he regretted not having resigned over the inept handling of the Vietnam War. "I made the typical mistake of believing I could do more for the country if I stayed in than if I got out. I am now going to my grave with that lapse in moral courage on my back."[15]

For many servicemembers, however, the responsibilities of family, lingering doubts about the absolute correctness of their views, and the love of service make resignation an unacceptable option. For them there is still the option of speaking out through professional writing. Proceedings, along with other professional magazines, publishes article after article taking issue with some element of established policy--warfighting doctrine, procurement plans, personnel policies, the entire gamut of military concerns. Indeed, professional magazines would have no role without this ability to raise issues and disagree with existing policies. The discussions in Proceedings about the role of women in the naval services and the conduct of senior leadership, sparked in part by James Webb's sharp commentaries, show that even sensitive and politically incorrect topics can be discussed. For anthrax vaccination, as with other cutting-edge policy issues, there is a legitimate policy debate. Are the risk and effort of giving the vaccines, however small, worth the gain in protection? How really likely and effective is biological warfare? There must be avenues for servicemembers to discuss important issues.

There is, nevertheless, a unwritten rule about what is discussed "inside the family" and what is discussed outside. It is one thing for active-duty personnel to make arguments in professional magazines and to use their ranks in signing them. It is another to write op-ed pieces for the local paper. This kind of public advocacy is really lobbying and is best left to retirees and civilians.

If the anthrax situation was unique--the result of special circumstances unlikely to be repeated--then it would be of narrow and limited interest. But it is not. The conditions that brought this controversy forth--skepticism about government, the widespread acceptance of conspiracy theories, the surge of issue activists, and the blurring of the line between fact and fiction--will go on. The Cold War consensus about the military will continue to fade. Most important, as the Internet becomes ever more accessible, it will bring on more controversies. They will become challenges for every military leader.

And this is a new kind of challenge--not visible in traditional ways, disseminated raw and unfiltered, sometimes going beyond data and facts. An effective response does not require a new kind of leadership but an extension of existing principles into a new realm.

1 -- See the official Department of Defense site, www.anthrax.osd.mil.

2 -- For discussion see LCDR Pietro Marghella, "December 7, 1999: The Second, Silent Attack on Pearl Harbor," United States Naval Institute Proceedings, May 1999, pp. 60-65.

3 -- For example, www.dissident.org, thinktwice.com, dallasnw.quick.com, www.gulfwarvets.com/anthrax.htm, marshealthnet.org/MGS/V5N2Anthrax, www.deizialoup.net/no2anthrax.

4 -- The Marine was eventually granted a hardship discharge.

5 -- onto.isoc.org/guest/zakon/internet/history.

6 -- John Aravosis, an online expert with Wired Strategies. Cited in USA Today, 19 October 1999, p. 8D.

7 -- Rear Admiral L.E. Jacoby, "Operational Intelligence: Lessons from the Cold War," United States Naval Institute Proceedings, September 1999, p. 103.

8 -- Through programs such as Navy-Marine Corps Intranet. See Admiral Archie Clemens, "It's More than E-mail," United States Naval Institute Proceedings, February 2000, pp. 56-58.

9 -- washingtonpost.com/wp-srv/politics/polls/vault/stories/data021599.htm

10 -- A ten-minute search on AOL revealed 7 chat rooms devoted to resisting anthrax vaccinations.

11 -- In November 199, senior officials received such an e-mail petition protesting the anthrax vaccination policy, with 2500 "signatures" on it.

12 -- What is interesting about these activists--and what might be a harbinger for the future--is that some of these activists seem to have left-wing credentials while others seem to have right-wing credentials.

13 -- Stephen Schneider, cited by Jonathan Schell, "Our Fragile Earth," Discover, October 1989, p. 47.

14 -- Also known as the Early Bird.

15 -- Lewis Sorley, Honorable Warrior (Kansas:University of Kansas Press, 1998), p. 304.

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INSTITUTE OF MEDICINE

Gulf War and Health

Volume 1. Depleted Uranium, Sarin, Pyridostigmine Bromide, Vaccines

Introduction

On a bright, clear morning on Friday, 24 August 1990, three Canadian ships slipped from their births in Halifax harbour to begin an historic voyage. Air and ground colleagues soon joined these 932 sailors in the hugest military deployment since the Korean War. The length of the mission was uncertain, with personnel being told to expect to be away for two years. They faced seasoned Republican Guards, with a promise of "the mother of all battles." Excitement blended with fear. The uncertainties and the threats were enormous. Their deployment marked a new beginning for the intensity of operational missions that Canadians were to embark upon over the next ten years. Life as a member of the Canadian Forces would never be the same.

Few sailors who left that day would ever have dreamed that a decade later the nature of what they had been exposed to and the consequences to their health of those exposures would be the subject of such an enormous controversy - the last battle of the Gulf War. Last month those same sailors gathered in Halifax to reminisce on what they had been through, both on their deployment and in the years that had followed. For many, questions and worries remained. Their future seemed clouded. As fate would have it, September 2000 saw the release of a comprehensive report into their health by one of the most prestigious medical bodies in the United States, the Institute of Medicine (IOM). Would the answers these veterans sought be finally given to them?

In the hours following the press conference, I was contacted several times by individuals from Canada and the United States as to what my impressions were of the report that had just been released. This was surprising and flattering at the same time. The miracles of modern technology had prevented us from establishing an electronic link with the authors at their press conference. Canadian investigators were blind as to what was said and what important points the authors wanted to emphasize with their very large audience. Further technological tribulations resulted in a delay of several hours before I could open the first attachment of the downloaded **prepublication** copy.

My impressions? Profound disappointment. I have only read the first few chapters, but the thread seems the same. This delay of several hours has given me a chance to sit back and reflect on what I have read, and how I should react to it. I am not naïve enough to believe that what I think will have any influence on how the medical and scientific community receives this report. Instead of a purely analytical approach, therefore, I believe I can indulge myself and be more philosophical. I can share my experiences with helping Gulf War veterans over the past decade and what I think this report will mean to

them. The report has generated many frustrations in me. I am sure it will be no better for my patients.

The Canadian Study

Two hundred and 71 words. A mail out questionnaire that tried to capture the entire Canadian Gulf War cohort rated 271 words in this comprehensive review. What is disheartening, is that with those 271 words, the authors still managed to miss the significance of what they had read in the Goss Gilroy Inc. study. In fact, in those 271 words, they even managed to get something wrong. The authors note "A subset of Canadian veterans who could not have been exposed to many of the agents because they were based at sea, reported symptoms as frequently as did land-based veterans in this study." The first crew of HMCS Protecteur was not, in fact, based at sea. By the time the air war began in January of 1991, these Gulf War veterans were already back in Canada. Their illness rate and symptom pattern is the same as all other Gulf War veterans. They were not exposed to depleted uranium, sarin, pyridostigmine bromide or novel vaccines such as anthrax or plague. This is surely not inconsequential information. That this fact is not even mentioned is puzzling and disappointing.

The only Canadians near the battlefields were the 536 personnel with 1 Canadian Field Hospital 80 kilometers from the Iraqi border at Al Qaysumah. The other 4000 Canadian Gulf War veterans were at least 400 kilometers away. The illness rate in all Canadian units is the same. In terms of putative "exposures," the fact that 4000 Canadian Gulf War veterans were at least 400 kilometers away when Iraqi vehicles were targeted by depleted uranium projectiles and yet have the same illness types and rate as their colleagues at 1 Canadian Field Hospital must be significant. In actual fact, to make the point even more forceful, there were only 2200 Canadian Gulf War veterans on the ground during the air and ground conflict. In other words, 2800 Canadian Gulf War veterans were back in Canada when the war was going on. This must have some meaning in terms of exposures and their alleged relationship to subsequent ill health.

Peer-Reviewed Published Literature

The IOM adopted a policy of using only peer-reviewed published literature to form its conclusions. They also note, however, that they consulted widely with interested groups and did use non-peer-reviewed publications for background. Canada, despite its small contribution to the Gulf War in terms of numbers has arguably some of the best information available of all the Coalition countries in terms of exposures and health outcomes. It is disappointing Canadian insights were not sought in researching this report. The significance of the Protecteur data might have been drawn to the author's attention and might have strengthened the conclusions they were able to make.

Focus Groups

Veterans and leaders of veterans' organizations were consulted many times during this study. The purpose of using focus groups is to ensure the investigators in fact address the

concerns of the population being studied. It is important that they receive answers to questions they might have. Their fears may not be valid, but they are legitimate. The IOM has done a commendable job in reaching out and ensuring the primary stakeholders were not forgotten.

There exists, however, another large group who also have legitimate concerns about the direction research has taken to date and the state of knowledge that currently exists with respect to Gulf War health issues. This group is the physicians who talk with, evaluate and manage Gulf War patients on a regular basis. Over the years this group has learned a lot. In particular, I believe they have insights into veteran issues that the veterans themselves may not be able to articulate. Peer-reviewed medical journals were consulted. The very same physicians who deal with patients on a daily basis often write these journal articles. There are impressions and opinions formed, however, that never make it into peer-reviewed medical journals. It is not clear that the authors of this report sought this invaluable experience. If not, I believe this to be a mistake.

Unexplained Illnesses

There existed in Ottawa, prior to the Gulf War, a clinic that saw patients with fatigue, memory and concentration difficulties, joint pains, sleep disturbances, headaches, abdominal pain and diarrhea, rashes and shortness of breath. This clinic had a national referral base. Such patients are perplexing to establishment medicine physicians who often have difficulties dealing with them. Physicians from mainstream medicine interested in seeing and following them are few and far between. I know this because it was I who had established this clinic.

I loathe the term chronic fatigue syndrome. It implies a homogeneity and understanding of this population that simply does not exist. In my previous life as a general practitioner I had attracted a large group of patients with non-specific somatic complaints that defied diagnoses. Following my specialty training it only seemed natural that my interest in this area would continue. That interest has now spanned 12 years.

When I finish what I believe are very comprehensive evaluations of these fatigue patients I sit down and talk to them. Often I gain valuable insights from their significant others. These significant others often have much to contribute as to what is going on and what their own concerns might be. By the time patients have reached me their problems often span several years. When they ask me what has caused their problems I have a simple answer. "I don't know."

That is not to say I am unfamiliar with their problems, that I do not understand the frustrations they have encountered seeking a diagnosis, or that I cannot help them. Indeed, in most cases I can. What I offer them is a very powerful therapeutic tool - reassurance. In many cases they are seeing a physician for the first time whose practice largely consists of patients with the same types of complaints. I will not abandon them, I will try to help, they will not die or even get worse, and they can get better. The strength of this therapeutic tool is awesome.

Dr Charles Engel has recently hypothesized that clinicians see patients through the lens of what they "know" and are familiar with. If a patient with multiple somatic complaints does not fit the construct of a standard psychiatric diagnosis then psychiatrists will view them as being within the "turf" of their internal medicine colleagues, and vice versa. The result? In many cases the patient does not fit into the standard shopping list of disorders for any specialty. They "belong" to no one.

It was not surprising that a Gulf War patient was referred to my chronic fatigue clinic in August of 1991. It was not surprising to me that I was asked to establish a separate Gulf War Clinic in April of 1995. I have seen and intensely investigated over 100 Gulf War patients since that time. I have never seen a Gulf War patient with a diagnosis that I have not also made in Canadians who never served in the Gulf. Through the "lens" of my own practice, Gulf War patients have the same types of problems as the majority of my non-Gulf War patient practice.

In a practice that consists largely of patients with non-specific somatic complaints, it is not hard to find a diagnosis that "fits." There are many broadly defined, poorly understood disorders such as chronic fatigue syndrome, fibromyalgia, soft tissue pain syndrome and myofascial pain syndrome that are suitable for the patients I have seen. The specific label attached is actually irrelevant because the management is virtually identical. No Canadian Gulf War veteran has ever left my clinic without a diagnosis.

The question remains: "Do these diagnoses 'explain' their problems." The answer of course is simple. No. That is not the same, however, as saying that there is no understanding, knowledge or predictability as to how the patient will do. In my fatigue practice, the diagnoses I make do not 'explain' the problems from an etiological perspective. These diagnoses do not prevent me from offering reassurance and comfort to my patients.

When I make a diagnosis of multiple sclerosis in patients, I cannot tell them why they were unfortunate enough to come down with this problem. I do not know what causes MS. The etiology is 'unexplainable' to me. There are, however, physical abnormalities that I can point to that somehow are reassuring to the patient and the public at large. This somehow 'demystifies' the diagnosis.

In my fatigue practice I cannot 'explain' to my patients what has caused them to be unwell. I have my own theories, but no proof. There are no physical abnormalities that I can point to; nevertheless, I do not find these diagnoses to be any more 'mysterious' than my MS patients' diagnoses. I have grown quite comfortable over the years managing my fatigue patients without benefit of absolute certainty. I can offer them reassurance. I can deal with their worries.

The term 'unexplained illness,' however, conjures up very different emotions and fears in non-physicians, especially in the context of the Gulf War. It equates to 'mysterious' and the 'unknown.' People are afraid of what they do not know or understand. This term, as innocuous as it may seem to clinicians, is anything but to a worried patient.

The Canadian Gulf War Clinic closed in December of 1997. Clinics were opened up across Canada in January of 1998 to assess veterans of any deployment, whether currently serving, or not. The reason? Gulf War diagnoses were no different from diagnoses being made in Canadian veterans of all Canadian deployments. In fact, I have seen more Somalia veterans with non-specific somatic complaints than Gulf War veterans. This is either because there is a previously undescribed "Somalia syndrome" or because I happen to run a satellite clinic at the base Somalia veterans deployed from. The point? Peacekeepers return with medical problems from the types of missions we currently send them on. These are perhaps 'unexplainable,' however; they are certainly not 'mysterious' or even unexpected. The only 'exposure' common to all is the fact these Peacekeepers have been sent to areas of conflict. I would hope each would not, in the future, rate is own 'syndrome' label.

Worry

Several expert scientific panels have reviewed the evidence regarding Gulf War health issues and have concluded that many of the diagnoses could be attributable to stress reactions. This is a concept many veterans cannot understand, and indeed, I believe there is a better term - worry. Veterans were worried when they went to the Gulf War. The extensive media coverage of their subsequent health issues, often sensational and rarely accurate, has only heightened this worry. I am convinced that worry can make people unwell. I can safely predict an influx of patients whenever the media carries another story telling Canadian veterans they are going to die a slow and horrible death. It does not matter the mission. Few Croatian veterans were seen at any of our clinics until the media raised the specter of 'red dirt contaminated with PCBs.'

In my practice, the greatest benefit I can offer my patients is to alleviate their worry. As a practitioner who continues to see Gulf War veterans, there was nothing in the Institute of Medicine Report that I could use to reassure them. Quite the opposite in fact. Ten years after the Gulf War and after some of the most intensive investigations ever undertaken it is a sad commentary that patients can be left with the feeling that we are almost right back at square one. I believe in fact there is much to reassure our patients about. Unfortunately, this does not seem to come through in the report.

Categories of Evidence

The IOM has assigned a weighting factor to the evidence it has reviewed with five subsequent categories of association. This is an attractive, time-honoured and valuable way to review scientific information. It is a system, however, that is not well understood by the layman. In the case of the IOM report, categories are assigned that may reflect the peer-reviewed articles published, but do not fully encompass the known epidemiological facts.

It is stated, for example, that for depleted uranium, there is no association between exposure to uranium and clinically significant renal dysfunction or lung cancer at cumulative internal radiation levels lower than 200 mSv. It states there is

inadequate/insufficient evidence to determine whether an association exists for virtually all other health outcomes. This does not, I think, reflect what physicians managing patients might advise them based on known exposure information or known health outcomes in Gulf War veterans.

Four thousand Canadian Gulf War veterans served at least 400 kilometers from the battlefields. This is a long way for dust to blow. Members of 1 Canadian Field Hospital, a group comprising only 12% of all our Gulf War veterans were 80 kilometers away. Most of the Iraqi vehicles hit by depleted uranium rounds were destroyed between February 24 and February 28, 1991. Even at the Field Hospital, the prevailing southwesterly winds meant the personnel were virtually always upwind. Even so, 80 kilometers is also a long way for dust to blow.

I follow a patient whose wife has had two children with minor congenital abnormalities of the genitourinary system. This patient served 400 kilometers from the battlefields. I feel quite comfortable in saying to this individual that these anomalies have nothing to with depleted uranium. Should the patient read the IOM report, he will note there is inadequate/insufficient evidence to say one way or the other as to whether this is true, or not. Should I testify in front of a National Inquiry into Gulf War health issues I will advise them that I am confident that this member's children were not adversely affected by the genotoxic effects of depleted uranium, the IOM report notwithstanding. I can state this because I believe Canadian epidemiological data with respect to unit locations makes depleted uranium an implausible culprit. Also, I am unaware of any data showing an increased incidence of congenital anomalies in Gulf War veterans in general. My "opinion" in this matter is certainly not likely to carry the cachet of the IOM in the eyes of a National Inquiry. My "opinion" is not likely to sway many journalists, either.

The Invisible Kitten

Absence of evidence is not proof of absence. This is a favorite line with special interest groups on a variety of health issues. In nicely captures the fact that scientists and clinicians avoid use of the terms "never" or "always." We can never know anything with certainty. I do not know if the comet Hale-Bopp was controlled by an alien space ship, or not. Members of the Heaven's Gate Cult were certainly convinced that it was. Based on what I know, I could be reasonably confident in counseling a member of this cult against committing suicide to attain a higher level of existence. My knowledge of this fact, however, is not absolute.

If someone were to tell me there was an invisible kitten outside my office window I am reasonably confidant that this is not likely. I cannot, however, prove that one is not there. In regards to depleted uranium and the health of Canadian Gulf War veterans, I am comfortable that depleted uranium is not a factor in any of their illnesses. I would suspect the IOM would hold a similar opinion. Unfortunately, this does not come across in their report. Too many doors are left wide open. Patients are not reassured about health issues that a review of the evidence would indicate are not likely related to Gulf War exposures.

Gulf War Research

Research is exciting and interesting. To researchers. My read of Gulf War veterans is they are tired of endless studies that conclude: "I don't know." Ten years have elapsed since the Gulf War. It is unfortunate the medical and scientific community cannot be more forthright in statements about which exposures are or are not likely to be associated with an adverse health outcome. Such forthrightness is, of course, not in keeping with an inquiring open scientific mind. Veterans are denied the reassurance they seek. They continue to worry. More research is funded which can be reasonably predicted will not categorically rule in or out any environmental exposure being associated with an adverse health outcome.

I enjoy research, especially when others do it. I can now be reasonably confidant that I will be reading about Gulf War research papers for many decades to come. I will never be out of a job in terms of responding to them. I will be paid a lot of money. My wife and children will be happy. The Gulf War veterans? They will remain worried.

Conclusions

I have not touched on other environmental exposures reviewed by the IOM. My comments would be the same. The first crew of HMCS Protecteur never took pyridostigmine bromide. The second crew did. The illness rate is the same. I am reasonably confident that PB is not a factor in the health of Gulf War veterans. There were no Canadian units within 300 miles of the Khamisiyah weapons depot when it was destroyed. I am reasonably confident that sarin is not a factor in the health of Canadian Gulf War veterans. The only Canadian unit to receive anthrax vaccine was 1 Canadian Field Hospital. The illness rate at 1 Canadian Field Hospital is identical to the illness rate of all other Canadian units. I am reasonably confident that anthrax is not a factor in the illnesses of Canadian Gulf War veterans. No Canadians received botulinum toxoid. I am reasonably confident that botulinum toxoid is not a factor in the illnesses of Canadian Gulf War veterans. Members of the second crew of HMCS Protecteur received all their vaccines in Canada before deploying to the Gulf. Members of 1 Canadian Field Hospital received multiple vaccines while in Saudi Arabia. The illness rate in both groups is the same. I am reasonably confidant that receiving multiple vaccines while deployed is not associated with adverse health outcomes.

My own ten-year anniversary of deploying to the Gulf War is coming up. It seems like a lifetime ago. I have learned much. That I would ever have embarked down such a path in life as fate has directed me would never have entered my wildest dreams. I continue to follow Gulf War veterans and give them as much reassurance as I can. It is disappointing that 10 years after this conflict a study is released that does not offer similar reassurance. A colleague of mine who has also reviewed the IOM report commented: "At least the special interest groups won't go away feeling happy about the report." This may in fact be true, but I am unconvinced. In any case, it is a sad day when the best that can be said is that no one will be happy about such a landmark report. Gulf War patients will not

have their worries relieved. Special interest groups will not be able to hold the study up as supporting their theories. Physicians will not be able to look to the report to offer their patients any reassurance. I will not be mentioning this report when I meet with my patients. That, in itself, says it all.

Tomorrow is another day. I will have a chance to review the report in the detail that it deserves. I do not see this report as being a tool I can use in helping my patients. I will move on and leave it behind. For those who asked, you have my thoughts.

Prepared by: Col Ken Scott
Position: Director of Medical Policy
Date: IOM Release Date +1 : 08 September 2000

Questions Concerning Anthrax Vaccine

Q1: What is in the Anthrax Vaccine?

A1: The Anthrax Vaccine is a sterile product made from filtrates of cultures of an avirulent, nonencapsulated, nonproteolytic V770-NP1-R strain of *Bacillus anthracis.* The cultures are grown in a synthetic liquid medium and the final product is prepared from sterile filtered culture fluid. These filtrates from the culture fluid are cell-free and contain the factor known as protective antigen (PA), which is produced by the bacteria during cell growth. Aluminum hydroxide gel adsorption is used to isolate the PA from the culture filtrate. The final product contains no more than 2.4mg aluminum hydroxide per 0.5ml dose (equivalent to 0.83mg of elemental aluminum per 0.05ml dose). Aluminum hydroxide is used as an adjuvant. The solvent used in the final product is 0.85% sodium chloride. Formaldehyde, in a final concentration not to exceed 0.02% and benzethonium chloride, 0.0025%, are added later in the process as preservatives. The final product is packaged in sterile multidose glass vials containing ten 0.5ml doses per 5ml. The product is produced in conformance with U.S. Food and Drug Administration regulations (21 CFR 620.34 - 620.24).[1, 2]

Q2: When the Anthrax Vaccine is injected into a person, what does the immune system produce?

A2: The body's first contact with an organism or a foreign material (antigen) such as a vaccine stimulates the body to activate its nonspecific and specific immune response systems.

The nonspecific immune response system consist of inflammation, phagocytosis, and complement production. Inflammation is a complex series of events that occur as the body attempts to maintain normal equilibrium. Vasoactive substances, including histamine, are released. These substances induce vasodilatation, increase local blood flow, and allow the release of fluid and protein into the tissues. The proteins help by clotting extracellular and lymphatic fluid to delay spread of bacterial or toxic products. The classic symptoms of inflammation are erythema (redness) from blood-vessel dilation, edema from excess fluids in the soft tissues, and swelling from accumulation of fluid and cells. Phagocytic cells are stimulated to mobilize to the site of the cell injury, or in this case, immunization. These phagocytic cells (monocytes and macrophages) adhere to the offending particles and ingest it (phagocytosis). Complement are proteins that circulate in the body in an inactive form. They can be activated to cause pooling of cells necessary for immune activity by attracting them to the area of inflammation.

If the nonspecific immune system does not completely protect the individual, the specific immune response system produces immunity primarily by the mechanisms of specificity and memory. The B and T lymphocytes are the major mediators of the specific immune response, and are told what to do by the macrophages. Macrophages

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[1] Package Insert, Anthrax Vaccine Adsorbed, BioPort Corporation, Lansing, Michigan, U.S. License No. 1260. Document 50483, Revised 3/99.

[2] Grabenstein J. Anthrax Vaccine, ImmunoFacts: Vaccines and Immunologic Drugs, Facts and Comparisons, August 1998, pp 33 - 35a.

process the antigen into a form that the components of the specific immune response system recognizes and presents the antigen to them. T lymphocytes are responsible for developing immunity to infections caused by microorganisms that live and multiply within the cells. T lymphocytes also help regulate the effects of B lymphocytes. B lymphocytes produce antibodies to the antigen. Specificity refers to the ability of T or B lymphocytes to react exclusively to the presence of a particular molecular configuration of a substance and not to react to other substances. Once a lymphocyte recognizes and reacts to an antigen, more of those specific lymphocytes are produced by the body. Memory is the property of evoking a more vigorous specific immune response upon reexposure to a particular antigen. This response has two processes. The first process is the proliferation of both B and T lymphocytes to the antigen on first exposure. Some of these lymphocytes go on to form sensitized lymphocytes or antibodies, which decrease with time. The second process occurs when other lymphocytes form a more persistent population of memory cells. Each reexposure causes a quicker and more intense response.

Inactive vaccines, such as the anthrax vaccine, do not replicate and are generally less efficient in inducing an immune response than live vaccines. Multiple doses of the inactive vaccine must be given to stimulate the primary and secondary responses necessary to produce long lasting immunity. This is why the anthrax vaccine must be given in the six dose series, with annual boosters.[3]

Q3: How does this then protect the person against anthrax infection in the future?

A3: Once a person has been immunized with the anthrax vaccine their immune response system will recognize the anthrax bacteria as an antigen. The non-specific and specific immune response systems respond immediately to begin to produce or activate monocytes, macrophages, phagocytes, complement, B and T lymphocytes, and antibodies.

Additionally, the body's first line of defense includes physical barriers, like intact skin, mucus, respiratory cilia, as well as biochemical defenses such as lysozyme, gastric acids, and lactic acid. The respiratory system has cilia (small hair-like structures) which work to try to sweep away inhaled substances. The membranes lining the interior surfaces of the body can trap foreign substances and inhibit them from penetrating the cells. These membranes produce mucus which contain enzymes (lysozyme) which breakdown the cell walls of bacteria, thus killing them. Acids in the gastric system and produced by the skin can also kill the bacteria.[4]

Q4: What happens to the ingredients in the anthrax vaccine after they are injected into the body?

A4: The main ingredient in the vaccine is 0.85% sodium chloride solution, which is absorbed into the cells. Water and salt (sodium chloride) are part of the normal body.

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[3] Koeller J and Tami J eds. Concepts in Immunology and Immunotherapeutics, 2nd Edition, American Society of Hospital Pharmacists, Bethesda, Maryland, 1992.

[4] Koeller J and Tami J eds. Concepts in Immunology and Immunotherapeutics, 2nd Edition, American Society of Hospital Pharmacists, Bethesda, Maryland, 1992.

The preservatives are recognized as non-self and are eliminated mainly by phagocytosis, due to their very low concentrations, although a small immune response could be produced. The PA and the aluminum hydroxide are immediately recognized by the body as antigens and thereby trigger the immune system to respond.

Q5: Are there, or can there be made, strains of anthrax that the immune response to the current anthrax vaccine will not protect against?

A5: Virulent strains of *Bacillus anthracis* produces two virulence factors. A bacterial capsule and a three-part exotoxin. The three distinct antigenic components of the exotoxin are:

Factor I is known as **edema factor (EF)** which is the protein necessary for the edema producing activity of the toxin.

Factor II is known as **protective antigen (PA)** because in induces protective antitoxin antibodies to be formed in guinea pigs. PA is the binder for the anthrax toxin.

Factor III is known as **lethal factor (LF)** because it is the protein necessary for the lethal effects of the anthrax toxin.

In order for either the EF or LF to produce their toxic effects, it must be combined with PA. PA+EF produce edema. LF+PA produces lethal activity. EF+LF is inactive. EF+LF+PA produces edema and necrosis and is lethal. Without PA the bacteria cannot produce toxin.

The Russians published a study indicating that genes transferred from the related *Bacillus cereus* bacteria can act to enable *Bacillus anthracis* to evade the protective effect of the live attenuated Russian vaccine in a rodent model. Genetic manipulation of the *Bacillus anthracis* bacteria is possible, however all virulent strains of the bacteria produce the three factors of the toxin (EF, PA, and LF). The current U.S. anthrax vaccine induces the human body to produce antibodies to PA. Which means that the vaccine would work against all virulent strains of anthrax.

Q6: Are there records on who/what organizations bought the anthrax vaccine since 1970?

A6: The manufacturer maintains records of who purchased the vaccine. Most of the vaccine since 1990 was purchased by the U.S. Army, including during and since Operations Desert Shield/Storm. The U.S. Army Medical Materiel Agency along with U.S. Army Medical Research Institute for Infectious Diseases have maintained records to whom they have distributed the vaccine.

Q7: How long must human recipients of an experimental vaccine be followed before FDA approves a vaccine? This assumes vaccinees have been shown to be protected from a naturally occurring disease.

A7: The FDA requires new drugs and vaccines to undergo several phases of clinical trials (testing in people) for safety and effectiveness. Each investigative protocol is unique, where the size of the patient population studies and their duration can differ

from product to product, or the disease state for which the drug/vaccine is being developed.

Phase I trials evaluate basic safety and identify only very serious or very common adverse events. These trials are small, with usually 20 to 100 patients enrolled. These trials last only a few months.

Phase II trials allows for more information on safety and preliminary information on effectiveness to be collected. Phase II trials include several hundred patients and last anywhere from several months to two years. The trials are discontinued if severe reactions or a lack of effectiveness surfaces during the first two phases.

Phase III trials expand to measure effectiveness and safety in several hundred to several thousand patients. Phase III may last months to years, depending on the product.

If the manufacturer believes that there is sufficient and adequate data to show that their product is safe and effective for its intended use, they may submit and application to the U.S. Food and Drug Administration for licensure of the product (product license) and for licensure of the manufacturing plant (establishment license).[5]

Q8: Why was the Michigan Biological/BioPort anthrax vaccine production facility shut down?

A8: The production plant was shut down to undergo a planned modernization of their equipment and to ensure that they were able to comply with the good manufacturing practices required by the U.S Food and Drug Administration, OSHA, and other state and local regulations imposed upon manufacturers of biological products. The new production line (equipment and process), as well as the lots of new product will have to be inspected and certified/licensed by the U.S. Food and Drug Administration before any newly produced lots can be sold.

Q9: How does the anthrax vaccine used in the United States differ/compare with the anthrax vaccine used by the British?

A9: The vaccine used by the British is an aluminum salts precipitated cell-free filtrate of Sterne strain cultures grown to as to maximize the PA content. It is produced by the Centre (sic) for Applied Microbiology and Research at Porton Down, Wiltshire. The vaccine was licensed by the Secretary of State for Health, as Medicines Control Agency product license 1511/0037, since 1979. The US vaccine is an aluminum hydroxide adsorbed cell-free filtrate of cultures of a noncapsulating, nonproteolytic derivative of strain V770. Both vaccines use the PA as the main component, therefore work identically. The main difference between the US and UK utilization of the vaccines was that the British administered their anthrax vaccine at the same time as a pertussis vaccine. This co-administration of anthrax and pertussis vaccines was intended to boost the response to the anthrax vaccine. The U.S. forces were not given the pertussis vaccine.[6]

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[5] Stehlin IB, How FDA Works to Ensure Vaccine Safety, found at http://www.fda.gov/fdac/features/095_vacc.html

[6] Turnbull PC. Anthrax vaccines: past, present and future. Vaccine. 1991;9:533-539.

Q10: What anthrax vaccine are the Israelis testing?

A10: The Israeli Ministry of Defense has purchased the anthrax vaccine produced by BioPort Corporation.

Q11: What were the four criteria Secretary of Defense Cohen placed on the anthrax vaccine before he ordered it to be mandatory?

A11: On 15 December 1997, Secretary of Defense Cohen approved the plan to immunize the total force against anthrax contingent on the successful completion of four conditions: (1) supplemental testing, consistent with U.S. Food and Drug Administration standards, of anthrax vaccine lots in the stockpile to assure their potency, purity, sterility, and general safety; (2) approval of the Services' implementation plans that describe how they plan to administer their respective anthrax vaccination program and communications plans to inform military personnel of the overall program; (3) implementation of a system for fully tracking anthrax vaccinations; and (4) review of the health and medical aspects of the program by an independent expert.

Q12: When and how were the criteria met?

A12: Secretary of Defense Cohen approved implementation of the Anthrax Vaccine Immunization Program for the total force on 18 MAY 1998, based upon successful completion of the Services implementation and communication plans, supplemental testing, tracking system, and independent review.

The supplemental testing was overseen by an independent, third party organization called Mitretek Systems, Incorporated. The testing included (1) General Safety, based upon the FDA's 21 Code of Federal Regulations (CFR) section 610.11 requirements; (2) Potency, based upon 21 CFR 620.23 requirements; (3) Sterility, based upon 21 CFR 610.12 requirements; and (4) Purity, there are no formal CFR requirements, however the lots were tested for their content of aluminum, phenol, chloride, and formaldehyde.

The independent review of the program was completed on 19 February 1998 by Dr. Gerard Burrow. In his report he concluded that the FDA licensed anthrax vaccine appears to be safe and offers the best available protection against anthrax as a biological warfare agent.

Q13: What were Dr. Burrow's qualifications to conduct an independent review?

A13: Dr. Gerard Burrow serves as the Special Advisor for Health Affairs to the President of Yale University. Dr. Burrow previously chaired the Institute of Medicine Committee on Health Consequences of Persian Gulf War Service.

Q14: Where and from whom did Dr. Burrow obtain data/information to decide the anthrax vaccine supply was safe?

A14: Dr. Burrow consulted with nationally recognized experts in allergy, immunology and infectious diseases. He met with, reviewed, and discussed the anthrax vaccine implementation plan with personnel from the Department of Defense.

Q15: How is the anthrax vaccine stored and how is the expiration date determined for each method of storage?

A15: The commercial packaging of the anthrax vaccine should be stored under refrigeration between 35 to 46 degrees Fahrenheit (2 to 8 degrees C). The vaccine should not be frozen. The vaccine is shipped under refrigerated conditions using specially designed refrigerated shipping containers (VaxiCool ®), which has a temperature monitoring device. The FDA has set the acceptable shipping range for the anthrax vaccine at 1 to 25 degrees C (34 to 77 degrees F). The vaccine is to be placed in refrigeration upon receipt at it's final destination. The U.S. Army Medical Materiel Agency (USAMMA) is responsible for shipping the anthrax vaccine to all DoD agencies and commands. USAMMA has developed standard operating procedures (SOP) for ordering, shipping, and final disposition of the vaccine. The SOP can be obtained from the USAMMA web page (http://www.armymedicine.army.mil/USAMMA)

Q16: What has to happen to a lot of anthrax vaccine to have the expiration date extended?

A16: The manufacturer may formally request and receive an extension of the expiration dating on individual lots of its products from the U.S. Food and Drug Administration. The FDA examines data provided by the manufacturer on the potency, sterility, and purity of the lot(s) for which the extensions are being requested. If the data supports the extension and all federal requirements have been met, the FDA can grant the extension.

Q17: Are the records from the testing to extend the expiration date for a lot of anthrax vaccine part of the public record?

A17: The records are not published in the public domain. These records are proprietary information held by the manufacturer. However, the manufacturer may provide the information to responsible organizations or persons on a case-by-case basis.

Q18: It has been alleged that several lots of anthrax vaccine were found to be contaminated. What are the facts on testing of those lots?

A18: A number of recent articles in magazines and newspapers have incorrectly reported that certain lots or vials of anthrax vaccine that were administered to our Service members or shipped to military facilities were expired or contaminated (i.e., anthrax vaccine lots FAV020, FAV030, and FAV016). At no time have expired or

contaminated lots or vials of anthrax vaccine been administered to our Service members or shipped by DoD to any military facilities.

Anthrax vaccine lot number FAV020 was originally approved for release by the FDA in 1994, with an expiration date in 1996. The manufacturer of the FDA-licensed anthrax vaccine, BioPort (MBPI), requested an extension of the expiration date and conducted additional potency testing on lot number FAV020 in 1996 in order to meet FDA's requirements for extending the expiration date. This potency testing was satisfactory and FDA subsequently re-released lot number FAV020 with the expiration date extended until 1999. The extension of the expiration date on anthrax vaccine lot number FAV020 involved the manufacturer, MBPI, and the FDA. The DoD was not involved in the extension of anthrax lot number FAV020. Any manufacturer of a pharmaceutical or biological product can request and receive an extension from the FDA on the expiration date of the product after federal requirements for product extension have been successfully met. It is not uncommon for a government or private-sector organization to use a pharmaceutical or biological product whose expiration date has been extended by the FDA.

Anthrax vaccine lot number FAV030 passed sterility testing conducted by the manufacturer and the data was provided to the FDA prior to lot release. The lot was subsequently approved for release by the FDA. The lot also underwent successful supplemental testing by the manufacturer, to include sterility testing. Supplemental testing by the manufacturer was overseen by a third party independent contractor and no evidence of contamination of any type was found.

Prior to shipment of anthrax vials to DoD, the manufacturer conducts routine 100 percent visual quality control checks on all anthrax vials as part of its Quality Assurance Program. It was during one of these routine quality control inspections that the manufacturer detected the presence of inert gasket or stopper material in a number of anthrax vials in lot FAV016. All anthrax vials in lot FAV016 that contained particulate gasket material were discarded. Lot release data on lot FAV016 was subsequently sent to the FDA and, upon review, the FDA released the lot for use. Prior to the decision to immunize US forces against anthrax and the initiation of DoD-mandated supplemental testing, a number of vials of lot FAV016 that were released by the FDA for use were shipped to DoD and used to immunize some Service members and DoD laboratory workers. At no time were any of the vials from lot FAV016 that were contaminated with particulate gasket material ever shipped to DoD as they had been previously discarded. During the FDA inspection of the manufacturer in February 1998, the FDA requested the manufacturer provide additional documentation on destruction of the original vials from lot FAV016 that contained the particulate material. As a good manufacturing practice, the manufacturer then quarantined all the remaining vials of lot FAV016 at the manufacturing facility pending collection of the documentation required by the FDA. In addition to meeting the FDA's requirement for documentation resulting from the February 1998 inspection, the remaining vials of lot FAV016 must also successfully complete supplemental testing before they will be removed from quarantine and shipped to the DoD for use. Since all vials of FAV016 previously shipped to DoD had been approved by the FDA for lot release and had been visually checked for particulate material by the manufacturer before shipment with those that were found to contain

particulate material discarded, no recall of vaccine lot FAV016 that had been shipped to DoD was instituted by the manufacturer nor was it requested by the FDA.[7]

Q19: Anthrax vaccine was tested and FDA approved to prevent cutaneous anthrax (skin infection), which is curable with antibiotic treatment. Why does FDA/DOD believe this anthrax vaccine will protect humans against inhalation anthrax, the most likely route of infection in a biological warfare/bioterrorism scenario?

A19: In 1985, a FDA Advisory Panel stated that there is sufficient evidence to conclude that the anthrax vaccine is effective under the limited circumstances for which this vaccine is employed. The FDA-approved package insert is silent on route of exposure, but recommends the vaccine for protection of individuals who may come in contact with animal products contaminated with *Bacillus anthracis* spores, or may be exposed to infected animals, or conduct research or diagnostic activities with *Bacillus anthracis*. In a March 13, 1997 letter to Dr. Stephen C. Joseph, then the Assistant Secretary of Defense for Health Affairs, the FDA confirmed that the pre-exposure administration of the FDA-licensed anthrax vaccine for the prevention of inhalation anthrax is not inconsistent with the current product label. The Committee on Infectious Diseases, American Academy of Pediatrics (1994), states that "the vaccine is effective in preventing or significantly reducing the occurrence of cutaneous and inhalation anthrax in adults."

Several studies performed at the USAMRIID have demonstrated the efficacy of the FDA-licensed anthrax vaccine against inhalation anthrax in rhesus monkey challenge studies. These animal studies showed that the FDA-approved anthrax vaccine provided greater than 95% protection against high-dose aerosol challenge with anthrax in the monkey model. Human antibody response to the FDA-licensed vaccine provides further suggestive evidence that the FDA-licensed anthrax vaccine will protect against inhalation anthrax.[8]

Q20: Why is the anthrax vaccine not FDA approved for use in individuals under 18, over 65, or who are pregnant or lactating?

A20: It is not recommended by the manufacturer for use in patients under 18 years old or over 65 years of age because no studies have been conducted in those populations, although there is no evidence of a lack of efficacy. Immunization of children and the elderly with the anthrax vaccine may be required in emergency situations.

The FDA places the anthrax vaccine in Category C for use in Pregnancy. It is not known if the anthrax vaccine or antibodies to the anthrax cross the placenta. Problems in pregnant women have not been documented and are unlikely. Use would be prudent in emergency situations. It is not known if the vaccine or it's corresponding

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[7] Office of the Assistant Secretary of Defense (Health Affairs), Information on General and Commonly asked Questions About the Anthrax Vaccine and the DoD AVIP, 05 April 1999.

[8] Office of the Assistant Secretary of Defense (Health Affairs), Information on General and Commonly asked Questions About the Anthrax Vaccine and the DoD AVIP, 05 April 1999.

antibodies are excreted in breast milk. Problems in humans have not been documented and are unlikely.[9]

Q21: How is the protection from anthrax vaccine changed if there are delays (one month or more) in getting the first three shots? The second three shots? The annual booster?

A21: It is DoD policy to follow the anthrax vaccine dosing schedule approved by the FDA. However, deviations from the schedule for the anthrax vaccine for medical reasons, such as pregnancy or active infection, must be documented in the patient's medical record. While the vaccine schedule should be followed as closely as possible, if an individual is late for one dose, the next dose should be given as soon as possible, and the series should continue. The effect of specific deviations from the approved schedule on the efficacy of the vaccine is unknown. Prolonging the interval between vaccine doses is not expected to interfere with immunity achieved after the concluding dose of the basic six-shot series, but may delay the induction of immunity. The entire six-shot series is required for full protection, as determined by the FDA. Booster doses are given at one-year intervals if continued immunity is needed.

Q22: How is the human anthrax vaccine made? How is this different from the animal anthrax vaccine?

A22: The Anthrax Vaccine is a sterile product made from filtrates of cultures of an avirulent, nonencapsulated, nonproteolytic V770-NP1-R strain of *Bacillus anthracis.* The cultures are grown in a synthetic liquid medium and the final product is prepared from sterile filtered culture fluid. These filtrates from the culture fluid are cell-free and contain the factor known as protective antigen (PA), which is produced by the bacteria during cell growth. Aluminum hydroxide gel adsorption is used to isolate the PA from the culture filtrate. The final product contains no more than 2.4mg aluminum hydroxide per 0.5ml dose (equivalent to 0.83mg of elemental aluminum per 0.05ml dose). Aluminum hydroxide is used as an adjuvant. The solvent used in the final product is 0.85% sodium chloride. Formaldehyde, in a final concentration not to exceed 0.02% and benzethonium chloride, 0.0025%, are added later in the process as preservatives. The final product is packaged in sterile multidose glass vials containing ten 0.5ml doses per 5ml. The product is produced in conformance with U.S. Food and Drug Administration regulations (21 CFR 620.34 - 620.24).[10, 11]

The animal anthrax vaccine is a live spore vaccine using strain 34F2 (Sterne's strain). The attenuated live spore vaccines suffer from potency problems and variations in virulence resulting in inadvertent deaths among the vaccinated animals. The animal

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[9] Grabenstein J. Anthrax Vaccine, ImmunoFacts: Vaccines and Immunologic Drugs, Facts and Comparisons, August 1998, pp 33 - 35a.

[10] Package Insert, Anthrax Vaccine Adsorbed, BioPort Corporation, Lansing, Michigan, U.S. License No. 1260. Document 50483, Revised 3/99.

[11] Grabenstein J. Anthrax Vaccine, ImmunoFacts: Vaccines and Immunologic Drugs, Facts and Comparisons, August 1998, pp 33 - 35a.

vaccine must be used with care in vaccinating some species of goats and llamas. The anthrax vaccines intended for use in animals should not be used in humans.[12]

[12] Turnbull PC. Anthrax vaccines: past, present and futrue. Vaccine. 1991;9:533-539.

RESEARCH WORKING GROUP

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PERSIAN GULF VETERANS COORDINATING BOARD

WHITE PAPER

SQUALENE

Human Adjuvant Disease among Gulf War Veterans

DRAFT
1 June 1999

February 05, 1999 / 48(04);69-74

Bioterrorism Alleging Use of Anthrax and Interim Guidelines for Management -- United States, 1998

From October 30 through December 23, 1998, CDC received reports of a series of bioterroristic threats of anthrax * exposure. Letters alleged to contain anthrax were sent to health clinics on October 30, 1998, in Indiana, Kentucky, and Tennessee. During December 17-23 in California, a letter alleged to contain anthrax was sent to a private business, and three telephone threats of anthrax contamination of ventilation systems were made to private and public buildings. All threats were hoaxes and are under investigation by the Federal Bureau of Investigation (FBI) and local law enforcement officials. The public health implications of these threats were investigated to assist in developing national public health guidelines for responding to bioterrorism. This report summarizes the findings of these investigations and provides interim guidance for public health authorities on bioterrorism related to anthrax.

Indiana

The threatening letter was opened by an administrative assistant, who called 911; police, fire, emergency medical services (EMS), and hazardous materials units (IIAZMAT) (i.e., first responders) were sent to the clinic, and the local FBI office was contacted. The letter was sealed in a plastic bag and collected by FBI. All 3 1 adults who were in the building when the letter was opened were considered possibly exposed to Bacillus anthracis spores and were detained for approximately 3 hours.

First responders in consultation with public health officials in the Marion County Health Department (MCHD) decontaminated the potentially exposed persons in a temporary shelter constructed on the scene. HAZMAT personnel used full protective gear with self-contained respirators (level A protection). The 3 1 occupants placed their clothing and personal effects in plastic bags and showered using soap and water plus a dilute bleach solution. The desktop where the letter *was* opened was washed with a 5% hypochlorite solution (i.e., standard household bleach). All 3 1 persons were transported to local emergency departments (EDs) to receive oral chemoprophylaxis with ciprofloxacin (500 mg twice daily); some underwent additional decontamination (i.e., showered again with soap and water) as required by hospital policy.

Public health officials from the MCHD collected contact information from all persons and informed them they would be notified when results from laboratory testing were available; arrangements also were made for counseling. The letter was taken by FBI to the Indiana State Department of Health Laboratory, where cultures for B. anthracis were negative. The next day, FBI transported the letter to the United States Army Medical Research Institute for Infectious

Diseases (USAMRIID), U.S. Department of Defense, in Ft. Detrick, Maryland, where direct fluorescent antibody testing and culture were negative.

Kentucky

The letter was opened by an administrative assistant; the assistant called the postal inspector and was advised to put the letter in a plastic bag. The postal inspector contacted the local FBI office and went to the clinic. FBI contacted the assistant fire chief who sent police, fire, EMS, and a HAZMAT unit to the clinic.

Jefferson County Health Department personnel recommended that the staff member and the postal inspector shower with soap and water at the clinic and obtain oral chemoprophylaxis (ciprofloxacin 500 mg twice daily) at a local ED. The Kentucky State Department for Public Health, FBI's Weapons of Mass Destruction Office, and USAMRIID advised that decontamination and oral chemoprophylaxis were not necessary for five other adults in the center who may have been exposed to the letter. The desktop where the envelope had been opened was decontaminated with a hypochlorite solution.

The letter was taken by FBI to a biosafety level 3 facility at the University of Louisville Hospital Clinical Microbiology Laboratory, where phase microscopy revealed no spores consistent with B. anthracis, and cultures were negative. The next day, FBI transported the letter to USAMRIID, where direct fluorescent antibody testing and culture were negative.

Tennessee

The letter was opened by an administrative assistant, who called the local police department; officers took custody of the letter and placed it in a plastic bag. A clinic administrator contacted CDC seeking advice about preventive health measures. CDC notified the local FBI field office and the Tennessee Department of Health regarding the threat. FBI took the letter from the local police department to USAMRIID, where tests were negative for B. anthracis. The administrative assistant and the responding police officer, both of whom had direct contact with the letter, received chemoprophylaxis.

California

During December 17-23, 1998, four threats alleging use of anthrax were reported in greater metropolitan Los Angeles. The response to all four threats involved the police and fire departments, EMS, HAZMAT, FBI, the County of Los Angeles Department of Health Services (CLADHS), the California Department of Health Services, and CDC.

The first threat was a letter mailed to a private business; all 28 adults considered at risk for exposure to B. anthracis were decontaminated at the scene and given chemoprophylaxis. The letter was transported by FBI to a CLADHS biosafety level 3 laboratory and cultured for B. anthracis; all cultures were negative.

In the second threat, a telephone caller to a government building claimed to have contaminated the building's air-handling system. Approximately 95 adults received chemoprophylaxis. First responders, FBI, and CLADHS jointly decided not to decontaminate involved persons.

In the third threat, a telephone caller to 911 claimed to have contaminated the air-handling system of a federal building with B. anthracis; 1200-1500 persons (at least one of whom was pregnant) and two children potentially were exposed. Contact information for potentially exposed persons was collected for follow-up. No one was decontaminated on the scene, and chemoprophylaxis was not recommended; all potentially exposed persons were asked to go home, wipe down the interiors of their potentially contaminated vehicles with a solution of one part bleach to 10 parts water, place their clothing in a plastic bag until results from laboratory testing were known, and then shower. Environmental samples taken from the air ducts of the building were cultured for B. anthracis at CLADHS; all cultures were negative.

In the fourth incident, an anonymous telephone caller to 911 claimed to have contaminated the air-handling system of an office building occupied by approximately 200 persons. FBI was contacted; the threat was deemed to have low credibility. FBI in conjunction with CLADHS decided that neither decontamination nor chemoprophylaxis was warranted. Environmental samples tested at CLADHS were negative for B. anthracis.

Reported by: Marion County Health Dept, Indianapolis; Indiana State Dept of Health. Jefferson County Health Dept, Louisville; Kentucky Dept for Public Health. Knox County Health Dept, Knoxville; Tennessee Dept of Health. County of Los Angeles Dept of Health Svcs, Los Angeles; California Dept of Health Svcs. Council of State and Territorial Epidemiologists, Atlanta, Georgia. Federal Bur of Investigation, Washington, DC. US Army Medical Research Institute for Infectious Diseases, US Dept of Defense, Ft. Detrick, Maryland. Office of Emergency Preparedness, US Dept of Health and Human Svcs. Emergency Response Coordinating Group, National Center for Environmental Health; Meningitis and Special Pathogens Br, Div of Bacterial and Mycotic Diseases, National Center for Infectious Diseases; and an EIS Officer, CDC.

Editorial Note

Editorial Note: Anthrax is an acute infectious disease caused by the spore-forming bacterium B. anthracis. It occurs most frequently as an epizootic or enzootic disease of herbivores (e.g., cattle, goats, and sheep), which acquire spores from direct contact with contaminated soil. Humans usually become infected through contact with or ingestion or inhalation of B. anthracis spores from infected animals or their products (e.g., goat hair). Human-to-human transmission has not been documented.

Although all the threats alleging use of anthrax described in this report were hoaxes, they demonstrate settings where bioterrorism can occur and the potential public health impact. These threats required prompt action by health, law enforcement, and laboratory personnel. Coordination and communication across agencies are necessary to protect the public and first responders from credible biologic warfare and bioterrorism agents such as anthrax.

The spore form of B. anthracis is durable and can be delivered as an aerosol (1). The incubation period for anthrax is 2-60 days. Inhalation causes the most serious form of human anthrax, and although contemporary experience in humans is limited, mortality may be high even with appropriate therapy (T.V. Inglesby, D.A. Henderson, J.G. Bartlett, et al., Working Group for Civilian Biodefense, personal communication, 1998). The likelihood of developing cutaneous disease is low after exposure of B. anthracis spores to intact skin. The risk for "secondary"

anthrax through reaerosolization appears to be low in settings where B. anthracis spores were released unintentionally or were present at low levels (2). In situations where the threat for transmission of B. anthracis spores is deemed credible, decontamination of skin and potential fomites (e.g., clothing or desks) may be considered to reduce the risk for cutaneous and gastrointestinal forms of disease.

Planning for Response to Threats

The public health response to bioterrorism requires communication and coordination with first responders and law enforcement officials. State and local health departments should work with these groups to ensure that local disaster preparedness plans address bioterrorism; define the roles of each agency, including protection of first responders; and are tested through simulations. FBI has jurisdiction for bioterrorism response but recognizes the need to conduct epidemiologic investigations, define at-risk groups, and rapidly implement potentially life-saving medical and public health responses. When bioterrorism alleging use of anthrax or other agents occur, the local emergency response system should be activated by dialing 911 in most communities; in communities without 9 11 systems, local law enforcement authorities should be notified. The local FBI field office and local and state public health authorities also should be notified.

FBI will coordinate the collection of evidence (e.g., letters, packages, or air-handling system samples) and deliver materials to an FBI or U.S. Department of Defense laboratory for testing. To guide decision-making, test results identifying B. anthracis should be available as soon as possible, at least within 24-48 hours. Efforts are under way to assess and enhance the capabilities of state and local health department laboratories to fulfill the need for rapid analysis. Planning for laboratory testing should be part of bioterrorism preparedness by state and local public health, law enforcement, and first responder authorities in consultation with federal officials.

Public health officials, working with law enforcement and first response personnel, should determine the need for decontamination and postexposure prophylaxis. In most of the recent hoaxes purporting anthrax exposure, immediate postexposure decontamination and prophylaxis have not been indicated because of the lack of credibility of the threat. Public health officials should collect contact information for potentially exposed persons for notification of laboratory results or other follow-up. Potentially exposed persons should be given information about the signs and symptoms of illnesses associated with the biologic agent and about whom to contact and where to go should they develop illness.

Recommendations for Postexposure Prophylaxis

Postexposure prophylaxis for exposure to B. anthracis consists of chemoprophylaxis and vaccination. Oral fluoroquinolones are the drugs of choice for adults, including pregnant women (T.V. Inglesby, D.A. Henderson, J.G. Bartlett, et al., Working Group for Civilian Biodefense, personal communication, 1998; 3) (Table 1). If fluoroquinolones are not available or are contraindicated, doxycycline is acceptable. Children should receive prophylaxis with oral ciprofloxacin or oral doxycycline (T.V. Inglesby, D.A. Henderson, J.G. Bartlett, et al., Working Group for Civilian Biodefense, personal communication, 1998; 3) (Table 1). Prophylaxis should continue until B. anthracis exposure has been excluded.

Postexposure vaccination with an inactivated, cell-free anthrax vaccine (Bioport Corporation,

formerly Michigan Biologic Products Institute **) is indicated in conjunction with chemoprophylaxis following a proven biologic incident (T.V. Inglesby, D.A. Henderson, J.G. Bartlett, et al., Working Group for Civilian Biodefense, personal communication, 1998; 4). Postexposure vaccination consists of three injections: as soon as possible after exposure and at 2 and 4 weeks after exposure. Anthrax vaccine can be requested through CDC. Although this vaccine is now being administered routinely to U.S. military personnel, routine vaccination of civilian populations is not recommended. This vaccine has not been evaluated for safety and efficacy in children aged less than 18 years or adults aged greater than 60 years.

If decontamination is appropriate, persons should remove their clothing and personal effects, place all items in plastic bags, and shower using copious quantities of soap and water (5). Plastic bags with personal effects should be labeled clearly with the owner's name, contact telephone number, and inventory of the bag's contents. Personal items may be kept as evidence in a criminal trial or returned to the owner if the threat is unsubstantiated. For incidents involving possibly contaminated letters, the environment in direct contact with the letter or its contents should be decontaminated with a 0.5% hypochlorite solution (i.e., one part household bleach to 10 parts water) following a crime scene investigation. Personal effects may be decontaminated similarly.

CDC and other offices in the U.S. Department of Health and Human Services are working with state and local health departments, federal agencies, and nongovernmental organizations to improve the public health capacity to address bioterrorism and develop locality-specific response plans. CDC also can assist public health officials with decision-making if a threat occurs alleging the use of a biologic agent.

References

1. Pile JC, Malone JD, Eitzen EN, Friedlander AM. Anthrax as a potential biological warfare agent. Arch Intern Med 1998;158:429-34.

2. Meselson M, Guillemin J, Hugh-Jones M, et al. The Sverdlovsk anthrax outbreak of 1979. Science 1994;266:1202-8.

3. Franz DR, Jahrling PB, Friedlander AM, et al. Clinical recognition and management of patients exposed to biological warfare agents. JAMA 1997;278:399-411.

4. Friedlander AM, Welkos SL, Pitt MLM, et al. Postexposure prophylaxis against experimental inhalation anthrax. J Infect Dis 1993; 167: 1239-43.

5. U.S. Army Medical Research Institute for Infectious disease&DC/Food and Drug Administration. Medical response to biological warfare and terrorism {Satellite broadcast}. Atlanta, Georgia: US Department of Defense/US Department of Health and Human Services, CDC, September 22-24,1998.

Infection caused by the bacterium Bacillus anthracis. ** Use of trade names and commercial sources is for identification only and does not imply endorsement by CDC or the U.S. Department of Health and Human Services.

Table-1

Note: To print large tables and graphs users may have to change their printer settings to landscape and use a small font size.

TABLE 1. Recommended postexposure prophylaxis for exposure to Bacillus anthracis*

Drug	Adults	Children+
Oral fluroquinolones		
One of the following:		
Ciprofloxacin	500 mg twice daily	20-30 mg per kg of body mass per day divided every 12 hours
Levofloxacin	500 mg once daily	Not recommended
Ofloxacin	400 mg twice daily	Not recommended
If fluoroquinolones are not available or are contraindicated		
Doxycycline	100 mg twice daily	5 mg per kg of body mass per day divided every 12 hours

* Prophylaxis should continue until exposure to B. anthracis has been excluded. If exposure is confirmed, prophylaxis should continue for 4 weeks and until three doses of vaccine have been administered or for 8 weeks if vaccine is not available.

+ Use of tetracyclines and fluoroquinolones in children has well-known adverse effects; these risks must be weighed carefully against the risk for developing life-threatening disease. If a release of B. anthracis is confirmed, children should receive oral amoxicillin 40 mg per kg of body mass per day divided every 8 hours (not to exceed 500 mg three times daily) as soon as penicillin susceptibility of the organism has been confirmed.

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INFORMATION PAPER

DASG-HCA

22 Feb 01

SUBJECT: Acute Allergic Reactions After Anthrax Vaccination

1. PURPOSE. To describe the incidence of acute allergic reactions (also called anaphylaxis, anaphylactic reactions, or immediate hypersensitivity) after anthrax vaccination.

2. FACTS.

a. Acute allergic reactions include a wide spectrum of clinical conditions, ranging from mild to life-threatening. Anaphylaxis is the term properly used for immediate-type hypersensitivity reactions ("allergic reactions") involving a type of antibody called immunoglobulin E (IgE). Allergists use the term "immediate" because these reactions typically begin within seconds to minutes after the drug is administered. The outer limit for "immediate" is generally set at 2 hours after drug administration. Other kinds of allergic or hypersensitivity reactions (that are not anaphylactic reactions) can occur at later time periods.

b. The most severe, life-threatening form of anaphylaxis is called anaphylactic shock, which involves airway and cardiovascular collapse. Anaphylactic shock can occur after administration of many medications, including insulin, penicillin, other antibiotics, other medications, insect stings, common foods (e.g., peanuts), most vaccines, and other substances (e.g., latex). Food allergies are the most common cause of anaphylaxis seen in emergency rooms.

c. The frequency of anaphylactic shock is estimated as follows:

. once per 10,000 people per year overall (United Kingdom)
. once per 4,000 to 25,000 people receiving anesthesia
. once per 10,000 uses of X-ray contrast material
. once per 100,000 courses of penicillin
. once per 1 million vaccinations (range: 1 per 600,000 to 10 million doses)
. death after anaphylactic shock is even more rare than the statistics cited above.

d. As of 13 Feb 01, the Anthrax Vaccine Expert Committee (AVEC) convened by the Department of Health & Human Services (DHHS) had reviewed 1,487 reports of adverse events after anthrax vaccination, submitted to the Vaccine Adverse Event Reporting System (VAERS). These reports were independently reviewed for symptoms of anaphylactic reactions and the time of their onset after vaccination. Reports were considered without regard to AVEC judgments regarding cause-and-effect association (i.e., casting a broad net).

e. Anaphylactic shock was defined in advance (in consultation with allergists at the Walter Reed Army Medical Center) as life-threatening airway and/or vascular collapse. Through 13 Feb 01, no cases of anaphylactic shock were reported to VAERS after anthrax vaccination, During this interval, more than 2.0 million doses of anthrax vaccine were administered to more than 502,000 people.

f. Acute allergic reactions were defined in advance (in consultation with allergists at the Walter Reed Army Medical Center) as generalized itching (beyond the injection site) with symptoms of chest tightness, with or without evidence of hives, that began within 2 hours after anthrax vaccination. These reactions are suggestive of anaphylaxis. VAERS reports that mentioned the administration of epinephrine or antihistamines were also counted, because it is not uncommon to administer epinephrine or antihistamines (e.g., diphenhydramine, Benadryl®) at the first sign of acute allergic symptoms, to preclude progression of symptoms. As of 13 Feb 01, 15 cases consistent with acute allergic reactions have been reported to VAERS after

anthrax vaccination, during the time when 2.0 million doses of anthrax vaccine had been administered. Each of these 15 vaccine recipients recovered after prompt treatment. No specific lot of vaccine was associated with significantly more of these reactions than other lots, nor was any geographic clustering apparent.

g. Conclusion: No cases of anaphylactic shock have been reported after anthrax vaccination. As is expected with other vaccines, antibiotics, and other medications, anthrax vaccine is associated rarely with acute allergic reactions. Each of the reported cases recovered fully.

3. References:

a. Ewan PW. Anaphylaxis. *British Medical Journal* 1998;316:1442-5.

b. Grabenstein JD. Anaphylaxis: Epinephrine and emergency responses. Hospital Pharmacy 1997;32(Oct): 1377-89.

c. Lieberman P. Anaphylaxis and anaphylactoid reactions. In: Middleton E Jr., Reed CE, Ellis EF, Adkinson NF Jr., Yunginger JW, Busse WW. *Allergy: Principles &* Practice, 5th ed. St. Louis: Mosby, 1998:1079-92.

LTC (b)(6) DASG-HCA/DSN (b)(6)

Approved by COL Randolph

INFORMATION PAPER

DASG-HCA
18 July 2000

SUBJECT: Antibody Response to Successive Doses of Anthrax Vaccine

1. PURPOSE. To describe the immune response to fewer than 6 doses of anthrax vaccine.

2. FACTS.

a. Many vaccines require multiple doses to achieve full immunity. With these vaccines, scientists recognize that each successive dose builds on the effect of earlier doses. Later doses build progressively higher levels of disease-fighting antibodies in the bloodstream, like climbing steps on a ladder or a staircase towards full protection.

b. Anthrax vaccine is administered in a six-dose basic series, with annual boosters thereafter, according to the dosing schedule approved by the Food & Drug Administration (FDA). Like other vaccines, each of the initial doses of anthrax vaccine stimulates increasingly higher amounts of anti-anthrax antibodies.

c. In early laboratory tests developed at the US Army Medical Research Institute of Infectious Diseases (USAMRIID) in the 1970s and 1980s, anti-anthrax antibodies developed in 47% of vaccine recipients after one dose of anthrax vaccine, 83% of vaccinees 2 weeks after the first three doses [Johnson-Winegar, *Journal of Clinical Microbiology* 1984;20:357-61], and 91% after 2 or more doses [Buchanon et al, *Journal of Immunology* 1971;107:1631-6].

d. In the late 1990s, USAMRIID developed a more sensitive test, a test able to detect smaller amounts of antibody. They found that one dose of anthrax vaccine produced detectable antibodies in 60% to 84% of recipients. After two doses, anti-anthrax antibodies were detected in 95% to 100% of anthrax vaccine recipients. These data are in a technical report submitted by USAMRIID via BioPort Corporation to the FDA. The data will be published in a series of scientific journals in due course. The first manuscript has appeared in the 15 Sep 2000 edition of the journal "Vaccine". See also: Brachman S, Friedlander AM. Anthrax. In: Plotkin SA, Orenstein WA, ed. *Vaccines*, 3rd ed. Philadelphia: W. B. Saunders, 1999:629-37.

e. In 1992-93, USAMRIID scientists drew blood on 281 Fort Bragg soldiers. These soldiers received 1, 2, or 3 doses of anthrax vaccine 18 to 24 months earlier during the Persian Gulf War of 1990-91. Next, these soldiers received one additional dose of anthrax vaccine. As depicted in the following table, 92% to 100% of these soldiers responded to a single dose of anthrax vaccine with increases in detectable antibody levels. A high antibody-response rate after a single booster dose of a vaccine shows that the immune system remembers the previous vaccinations, even if antibodies were not detected just before the booster dose.

Table 1. Proportion Of Troops Responding To One Dose Of Anthrax Vaccine in 1992-93, 18 To 24 Months After Previous Incomplete Doses Of Anthrax Vaccine

Category	1 previous vaccination	2 previous vaccinations	3 previous vaccinations	Total
	13 soldiers	197 soldiers	71 soldiers	281 soldiers
# with detectable antibodies before 1992-93 vaccination	3 soldiers (23% of 13)	47 soldiers (24% of 197)	36 soldiers (51% of 71)	86 soldiers (30% of 281)
# with detectable antibodies 30 days after 1992-93 vaccination	12 soldiers (92% of 13)	196 soldiers (99.5% of 197)	71 soldiers (100% of 71)	279 soldiers (99.3% of 281)

f. Antibody responses to anthrax vaccine require careful interpretation. The concentration of anti-anthrax antibodies that protects humans from anthrax disease is not precisely known. Similarly, the antibody level that protects against some other diseases is also unknown (e.g., pertussis, Lyme disease, meningococcal, pneumococcal, typhoid, mumps, poliovirus, yellow fever). The laboratory test that indicates whether someone is protected from disease is sometimes referred to as the "clinical correlate of immunity."

g. USAMRIID and the Centers for Disease Control & Prevention (CDC) are jointly investigating the clinical correlate of immunity for anthrax vaccine. Much of the effort involves animal research in which lab tests (such as antibody levels) will be evaluated to find the dividing line that separates survivors from the deceased.

LTC (b)(6) DASG-HCA/DSN (b)(6)
Approved by COL Randolph

INFORMATION PAPER

DASG-HCA
27 November 2000

SUBJECT: Information for Healthcare Providers on the Additional Temporary Slowing and Future Resumption of the Anthrax Vaccine Immunization Program (AVIP)

1. Purpose. To inform Immunization Clinic Staff and Vaccine Providers about the Further Revision of the AVIP.

2. Current Situation.

a. In 1996, the Department of Defense (DoD) identified anthrax as the number-one biological-warfare threat. To counter this grave and urgent threat, DoD implemented the AVIP. We are short of vaccine necessary to sustain the current program. Due to this, there will be a slow down of the execution of the program. DoD will continue to protect personnel at highest risk.

b. Effective 27 November 2000, DoD will further reduce the number of personnel receiving anthrax vaccination. Vaccination will now be limited to personnel assigned or deployed on the ground in Southwest Asia (Kuwait, Saudi Arabia, Bahrain, Jordan, Qatar, Oman, United Arab Emirates, Yemen, and Israel) for more than 30 consecutive days and those personnel afloat in the Persian Gulf who have the potential of being committed ashore. Anthrax vaccinations of other personnel will resume when adequate FDA-released supplies of vaccine become available.

c. On-hand, open anthrax vaccine vials will be used at their current location to continue the immunization series for individuals already in the program, until this category of supply is exhausted. The U.S. Army Medical Material Agency (USAMMA) will provide redistribution instructions to move un-opened vials to support the SWA mission. Follow shipping instructions carefully to prevent improper conditions during transit.

d. Some Service Members will have received fewer than the FDA-recognized 6-dose series. DoD wants its personnel to receive all six doses and to receive annual boosters. DoD is obliged by the shortage to defer additional vaccinations until vaccine supply is restored.

e. The six-dose basic series of anthrax vaccine, with annual boosters thereafter, provides full protection. Receiving fewer than six doses provides the recipient some level of anthrax-fighting antibodies, enhancing personal, around-the-clock immunity. Each dose of vaccine is like climbing another step in a staircase or a ladder. Getting several doses provides valuable, although partial protection.

f. It is not physically harmful to the individual to get less than the recommended number of doses in any vaccine schedule. Public-health experts agree on this. The only concern is that a person is not considered fully protected until after the six-dose basic series.

g. Once the anthrax vaccine supply is restored, people whose dosing schedule was interrupted will not need to start the series over from the beginning. Memory cells of the immune system remember how many shots people receive. One simply resumes the anthrax vaccination series where he or she left off and adjusts the timing for the next dose. This is a long-held finding of the CDC's Advisory Committee on Immunization Practice (ACIP), as well as that of our civilian advisors on the Armed Forces Epidemiological Board (AFEB). [*MMWR* 1994;43(RR-1):1-38 ftp://ftp.cdc.gov/pub/Publications/mmwr/rr/rr4301.pdf] DoD is also consulting with the FDA on planning resumption of full-scale program implementation.

h. All anthrax vaccinations must be entered into each Service's Immunization Tracking System (ITS). For the Army, this is MEDPROS; for the Air Force, MITS; and for the Navy and Marine

Corps, SAMS. As soon as possible, enter any backlog of immunizations that have not yet been entered.

i. Clinics must continue to perform quality-improvement evaluation of clinical practices that enhance immunization delivery.

j. To minimize waste in vaccinating, use a syringe and needle with little hub space. We recommend the following items:

NSN	Description	Unit of Issue
6515-00-655-5751	5/8 inch, 25 gauge needle	PG
6515-00-982-4206	Tuberculin, lcc syringe	PG
6515-00-982-4205	Needle and Syringe Hypo lcc	PG

For more detailed logistic information, consult with your service representatives, or contact the US Army Medical Material Agency's website: http://www.armymedicine.army.mil/usamma/anthrax/antxhome.htm.

k. We will rely on the other pillars of our Force Health Protection Program (i.e., protective gear, biological-agent detectors, and antibiotics) to help protect those Service Members who have not completed the anthrax vaccination series.

l. DoD is aggressively seeking a second U.S. source for anthrax vaccine. By having a second source, DoD can have greater confidence and comfort that a sufficient supply of safe and effective vaccine will be available in the future.

m. Clinical questions regarding anthrax vaccines can be addressed through immunology and/or preventive medicine consultants. Additional information is available from the Anthrax Vaccine Immunization Program Agency, www.anthrax.osd.mil, 877-GET-VACC, avip@otsg.amedd.army.mil.

3. Additional Background information.

a. The United States has confronted similar shortages of vaccine over the years. The United States experienced a delay in supply of influenza vaccine in Fall 2000 due largely to manufacturing issues. The CDC's Advisory Committee on Immunization Practices considered how best to prioritize a limited supply of influenza vaccine at its June 2000 meeting in Atlanta. There is currently a complete outage of adenovirus vaccine,, plague vaccine, and the intradermal form of rabies vaccine. This type of rabies vaccine is available to neither military nor civilian customers.

b. The most notable example of a similar U.S. vaccine shortage came in 1984-85 with the national shortage of diphtheria-tetanus-pertussis (DTP) vaccine given in a 5-dose series to the nation's children. Public health experts and pediatricians agreed that the proper thing to do was to administer the first three doses in the DTP series to infants, but to postpone doses given later in childhood until supply was restored." [*MMWR* 1984;33:695-6, 1985;34:103-4, 1985;34:231-2]

LTC (b)(6)
Approved by: COL Randolph

Anthrax Vaccine and Drugs Availability Program for Persons Possibly Exposed to Inhaled Spores

Consent Form (Adults)

Background:

People who breathe in large numbers of anthrax spores may be at risk for developing anthrax infections in their lungs. Such infections are very serious and possibly fatal. As you know, you may have been exposed to spores during the recent anthrax attack.

Antibiotics (drugs) can prevent anthrax infection in people exposed to spores. Not much is known about people who may have been exposed to very large numbers of spores, such as those in post offices or government buildings during the recent attacks, because this situation has never occurred before. The current recommendation to try to prevent infections in exposed individuals is to take drugs for 60 days. Some scientists and doctors have recommended the drugs be taken for longer than 60 days. Whether or not 60 days of drugs is enough is not known, because spores can stay in the body for a long time and may be hard to get rid of. FDA has not approved use of any drug for more than 60 days to prevent anthrax disease. There are risks from taking drugs for a long time.

There is also a vaccine for anthrax to immunize persons at risk of exposure to anthrax spores. We do not know if giving anthrax vaccine along with drugs after a person is exposed to anthrax spores is better than giving drugs alone to prevent the disease. The Food and Drug Administration (FDA) has not approved anthrax vaccine for this use. There are risks to taking the vaccine.

Because people like you may have been exposed to large numbers of anthrax spores, the Department of Health and Human Services (DHHS) is making anthrax vaccine available to those exposed who may want to take it to prevent anthrax disease, even though it has not been tested or shown to be effective for this use.

Purpose of the Program:

This program is intended to make the vaccine and additional drugs available to all people who may have been exposed to anthrax spores and who were advised to complete a 60-day course of drugs. It is very important that you understand that this use of the vaccine has never been tested in people and no one knows if it offers any additional protection from infection. The vaccine is only available through this program.

Description of the Program:

Although the current recommendation to prevent anthrax is to take drugs for 60 days, everyone who decides to take part in this program will receive an additional 40 days of drugs to try to reduce the chances of anthrax infection. You may also take the vaccine if you wish.

You do not need to take the vaccine to receive the drugs. In addition, you can choose to stop taking drugs at the end of 60 days and not take part in this program.

Before you decide to take part in this program, there are several important things that you should know. You should read this form very carefully with a member of the program staff or your doctor and make sure that you know the risks and possible benefits before you agree to take part in this program.

- **Anthrax vaccine has not been shown to prevent infection when given to people after exposure to anthrax spores.**
- **The FDA has not approved the use of any antibiotic for more than 60 days or the use of amoxicillin for the prevention of anthrax.**
- **The vaccine that you will receive in this program has not been approved by the Food and Drug Administration (FDA) for this use and is considered investigational.**
- **FDA has not approved this lot of vaccine (Lot FAV-063) because the company's license to produce the vaccine is under review. This lot of vaccine has passed all of the vaccine maker's tests for use in humans.**
- **You should not consider the vaccine as treatment for anthrax. The vaccine as given in this program has not been shown to give long term protection against anthrax.**
- **You may have undesirable side effects from taking the vaccine.**

Because the vaccine is not approved for this use, FDA considers this a clinical investigation and regulations require the collection of health information from you in order to watch for side effects or other problems. In addition, we will watch for any cases of anthrax.

DHHS is not making any recommendation whether you should or should not take this vaccine. DHHS is making the vaccine available to you to allow you to decide whether or not you wish to use the vaccine.

If you decide to take the vaccine, you will get three shots of vaccine under the skin of your upper arm. You will get one shot every two weeks. Each shot is small (0.5cc), one-tenth of a teaspoon. You will get all of your vaccine shots in one month.

In addition to the vaccine, you will also be given a 15-day supply of drugs. You will be asked to return for a follow-up visit two weeks later to get the rest of your 40-day supply.

Do not stop taking the drugs without first talking to program staff or your doctor.

Everyone in the program will be asked to keep a diary about their health for the first six-weeks after starting the program. You will also receive a phone call from the CDC staff at 2-months, 6-months, 1-year and 2-years after joining the program to keep track of how you are doing and any problems you may have.

You will be asked to take part in this program for a period of two years. Your taking part in this program is completely voluntary. You may drop out any time without penalty or loss of benefits to which you are entitled.

Possible Risks:

Anthrax Vaccine:
The most common side effects are a sharp stinging or burning in your arm right after the shot. This pain usually goes away within a minute. Like many vaccines, the anthrax vaccine can cause soreness, redness, itching, and swelling in the arm that can last up to a week. A lump at the site is common. It usually goes away in a few weeks without treatment. From 5% to 35% of people who get the vaccine will have muscle aches, joint aches, headaches, malaise, rashes, chills, low-grade fever, or nausea. These symptoms usually go away within a week.

Any vaccine can cause serious problems, which may require a hospital stay. For anthrax vaccine, these serious problems, such as allergic reactions, happen less than once in every 100,000 doses. Some people have reported serious chronic illnesses like Guillan-Barre Syndrome (a muscle weakness disease), chronic joint diseases or had miscarriages and infertility after getting the anthrax vaccine. Data from over 500,000 people worldwide who did get the anthrax vaccine so far suggests that people who get the vaccine have the same chance of getting these health problems as people who do not get the vaccine.

The anthrax vaccine cannot give you anthrax disease.

Although unconfirmed, a recent preliminary study suggests that the vaccine may be linked with an increase in the number of birth defects when given during pregnancy. At this time no one knows for sure whether this vaccine can cause fetal harm.

If you have the Human Immunodeficiency Virus (HIV) or another health problem that affects your immune system (such as if you are being given drugs to treat cancer), seek the advice of your program site coordinator or your personal doctor about how any medical problems you might have may be affected by receiving anthrax vaccine. New findings that we discover in this program will be reported to the site program coordinator and provided to you by them.

Antibiotic Use:
Drugs may have side effects. Read the fact sheets on the three drugs. These describe the risks from taking each drug. Women should take note of potential problems to use of drugs during pregnancy. Follow medical advice carefully.

Please report any side effects you have in the first 6 weeks to your site program coordinator (as listed on your emergency contact sheet). After 6 weeks, please report side effects that you have by mailing a Vaccine Adverse Events Reporting Form (VAERS) to the address on the form (PO Box 110 Rockville MD 20849-1100) and fax the VAERS form and Cover Sheet to the CDC's Central Processing Center at 1-404-639-8548. You will also need to report these side effects to MedWatch by calling1-800-FDA-1088 or by faxing the MedWatch form to 1-800-FDA-0178.

Possible Benefits:

We do not know if there is a risk of disease among people who have been exposed to anthrax spores and have taken 60 days of antibiotics. However, if there is such a risk, then either 40 days

of additional antibiotics or 40 days of additional antibiotics and the vaccine may be of benefit in reducing the risk of disease.

Alternatives:

Anthrax vaccine is only available to you at this time through this program.

If you do not want to take the vaccine, you may continue to take drugs either through this program or through your doctor.

You also have the choice to not take extra drugs.

Costs:

Participants in this program will receive free of charge the vaccine and/or drugs and all services necessary to administer the vaccine. You will be responsible for your routine medical costs and charges not related to this program.

Injury:

If you are hurt as a result of being in this program, treatment will not be provided by HHS and may not be provided by [this site]. You (or your insurer, Medicare, or Medicaid) will be expected to pay for any care that is needed. By signing this consent form and agreeing to be in this program, you are not giving up any of your rights. If you believe that you have been injured, please contact the National Immunization Information Hotline at 1-800-232-2522 (for Spanish speakers, call 1800-232-0233) for information on your rights and advice on how to proceed.

Privacy:

Your privacy will be protected to the extent legally possible. Information obtained from this program may be published. We would not publish your name or other information that would identify you personally. The CDC, (local site), the vaccine maker, and the FDA will be allowed to review medical and program records as part of their duty to protect people involved in this program.

<u>If you have any questions:</u>
If you have any questions about this program or want to report any side effects, you may contact the site program coordinator. If you have questions regarding your rights as a program participant, you may contact CDC Deputy Associate Director for Science (1-800-584-8814).

Consent:

A member of the program staff has explained this document in detail to me, and I freely consent to join this program. I understand the following:

- I may continue to take drugs alone to prevent anthrax disease and that these are likely to be effective so long as I continue medication.

- If I choose to receive the vaccine as given in this program, I am unlikely to develop long-lasting immunity to anthrax.
- There have been no human studies to date that have shown whether the vaccine can be effective when given after exposure to anthrax spores.
- The anthrax vaccine or the drugs can cause rare serious adverse reactions.
- The doctors in charge may remove me from the program without my consent, if it is in my best interest medically.
- The risks and benefits of taking this vaccine.
- That I may refuse to join or may drop out at any time without penalty or loss of benefits.

I have been given the time to ask questions freely and had them answered to my satisfaction. I have been given a copy of this informed consent form. I understand that nothing contained in this informed consent waives any of my legal rights as a volunteer.

Please check one:

___ I choose to be in the program and get 40 extra days of drugs

___ I choose to be in the program and get 40 extra days of drugs and vaccine

Printed Name of Volunteer Subject	Date of Birth (dd/mm/yy)	
Signature of Volunteer Subject	Date/Time	
Permanent Street Address of Volunteer Subject		
Permanent City, State, Zip Code of Volunteer Subject		
Printed Name of Person Conducting Consent Interview	Signature of Person Conducting Consent Interview *	Date
Printed Name of Witness	Signature of Witness **	Date

* **If the consent information was provided to a volunteer who does not speak or read English, the person conducting the interview should indicate that the information was presented in the subject's language: _____.**

** Witness should be able to understand both English and the volunteer's language.

CHARTER

DoD Select Agents Response Task Force

1. PURPOSE. The Department of Defense (DoD) Select Agents Response Task Force (SARTF) will develop near-term, detailed contingency medical plans for protecting against, and responding to a smallpox outbreak or influenza pandemic affecting DoD installations or units both in CONUS or OCONUS. These plans will be coordinated with response plans being developed by the Department of Health and Humans Services. The Task Force will be co-chaired by Health Affairs and the Anthrax Vaccine Immunization Program Agency.

2. BACKGROUND. In the May 28, 2002 memorandum (Subject: Support for an Accelerated Vaccine Planning Effort), the ASD(HA) tasked each Service to nominate one expert from clinical medicine, medical planning, and medical logistics by June 3, 2002 to be on the task force. HA will then select one person from each of the Services' nominees to be members of the task force on a full-time basis for 4 months. The task force will be established June 11, 2002 and end on October 11, 2002.

3. ASSUMPTIONS.

- The task force will operate from June 11, 2002 until October 11, 2002.
- Office space, automation and administrative support will be provided for the task force members.
- No TDY funds will be available for nominees from outside the DC-metropolitan area. TDY funds for such individuals nominated by the Services who are selected to serve on the task force will have to be provided by the nominating Service.
- TDY funds to support the activities of the task force members (e.g., any meetings at the Centers for Disease Control and Prevention in Atlanta) will be provided by Health Affairs.
- Task force members will have at least a "Secret" clearance.
- The vaccines available to be utilized in response to a smallpox event will be INDs. The contingency plans will be adjusted when approved vaccines become available.

4. GOALS. The goals of the DoD Select Agents Response Task Force are:

- Develop an executable, detailed DoD Smallpox Response Plan using the CDC Smallpox Response Plan as a template with details specific to DoD situations;

- Develop an executable, detailed DoD Pandemic Influenza Response plan using the CDC Pandemic Response Plan as a template with details specific to DoD situations;

- Initiate reiterative planning at the Service-level such that detailed, Service implementation plans in support of the DoD plan are complete by the end of the same 4-month period;

- Coordinate/integrate DoD plans with HHS/CDC plans as appropriate;

- Provide recommendations for institutionalizing the planning process for any other select agents;

- Provide final plans by October 1, 2002.

5. MEMBERSHIP. Membership will consist of 2 co-chairs and 1 selected nominee from each of the Services for a total of 5 members. Based on recommendations from the task force chairs, technical/expert working groups will be established as needed to assist the in the performance of its functions. In addition, the task force members may request the advice of DoD and non-DoD experts to enable it to carry on its work.

6. MEETINGS. Members selected to the task force will be temporarily assigned for a period of 4 months beginning June 11, 2002, and ending October 11, 2002. The co-chairs will determine formal meetings of the task force. The first meeting of the task force will be on June 11, 2002.

WORKING GROUPS. Continuing or ad hoc working groups shall be established as needed. The co-chairs of the SARTF shall appoint members and designate one of them to serve as the chairperson. When necessary, a work group may request the advice of DoD and non-DoD consultants to enable it to carry on its work.

7. SUPPORT AGENCY. The Anthrax Vaccine Immunization Program Agency, Office of the Surgeon General, Department of the Army, has agreed to, and the Deployment Health Support Directorate, Tricare Management Agency shall also be responsible for providing administrative and staff support of the DoD SARTF. Details of that support will be coordinated by the directors of those agencies. Administrative support is defined as budgeting, funding, fiscal control, manpower control and utilization, personnel administration, security administration, space, facilities, supplies automation support, and other administrative services.

8. REPORTING CHAIN. Members of the task force will report to the Health Affairs co-chair. The co-chairs will report to the Deputy Assistant Secretary of Defense for Force Health Protection & Readiness.

9. INDIVIDUAL PROCUREMENTS. The SARTF is not authorized to advise on individual procurement actions. No matter shall be assigned to the SARTF for its consideration that would require any member of the SARTF or working groups to participate personally and substantially

in the conduct of any specific procurement or place him or her in the position of acting as a "procurement official," as that term is defined pursuant to law.

10. DELIVERABLES.

- An executable, detailed DoD Contingency Smallpox Response Plan by October 1, 2002;
- An executable, detailed DoD Contingency Pandemic Influenza Response Plan by October 1, 2002;
- Recommendations to institutionalize this planning process for other select agents;
- At least monthly progress reports and briefings to the DASD(FHP&R) and others as directed;

11. DURATION OF THE DOD SELECT AGENTS RESPONSE TASK FORCE. This charter will expire on October 11, 2002, unless renewed, or terminated earlier, by the ASDHA.

William Winkenwerder, Jr., M.D.
Assistant Secretary of Defense for Health Affairs

ASD(HA) Approval Date:

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

MAY 2 8 2002

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)

SUBJECT: Support for an Accelerated Vaccine Planning Effort

REFERENCES: (a) DoD Directive 6205.3, "DoD Immunization Program for Biological Warfare Defense," November 26, 1993
(b) DoD Directive 5136.1, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," May 27, 1994
(c) DoD Instruction 6205.2, "Immunization Requirements," October 9, 1986

Action is under way to increase interagency vaccine policy coordination to support development, production, distribution and use of vaccines for protection against biological warfare agents and other threats to public health. Within DoD, the Deputy Secretary of Defense is directing our support. In anticipation of the establishment of a more formal structure, we must immediately accelerate DoD planning and actions necessary to protect against such threats. Our initial efforts will focus on establishing a near-term contingency plan for responding to select disease outbreaks.

In order to accelerate our work, I am, under the authorities of references (a), (b), and (c), establishing a task force with the objective of submitting detailed contingency plans by October 1, 2002, with monthly interim reports to the USD(P&R). There are two immediate actions that require your assistance and support:

1. The Army, as Executive Agent for the DoD Immunization Program for Biological Warfare Defense, will have the lead for supporting the task force. This builds upon the excellent work of the Anthrax Vaccine Immunization Program (AVIP) Agency, which has already taken on broader vaccine program roles.

2. The task force will be established June 11, 2002 to develop detailed contingency plans for addressing select disease outbreaks. This task force will work full-time for four months to produce the required plans. I request that each Military Department identify appropriate military medical experts to participate on this task force. Please nominate one expert for each of the following: clinical medicine, preventive medicine, medical planning, and medical logistics by Monday, June 3, 2002. We will select one individual from each Service for participation in the task force.

This task force will work closely with representatives from the Department of Health and Human Services, and with other representatives from across the federal government. The Deputy Assistant Secretary of Defense (Force Health Protection and Readiness) will oversee the task force and report to me. I plan to work in close collaboration with the Assistant Secretary for Health, Department of Health and Human Services who has expressed a strong interest to establish joint collaboration now. The Under Secretary of Defense (Personnel & Readiness) has asked for an initial report within 4 weeks.

A meeting will be held on June 11, 2002 with the task force to further outline the requirements and expectations. My POC is COL Terry Rauch, (b)(6).

William Winkenwerder, Jr., M.D.

cc:
USD(P&R)
USD(AT&L)
JCS (J-4)
Surgeons General
Director, Administration & Management

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

MEMORANDUM FOR SECRETARY OF THE ARMY

SUBJECT: Operational Planning for Smallpox Attack

Tom —

In your role as DoD Executive Agent for the Immunization Program for Biological Warfare Defense, I request your assistance in directing a tri-Service, multidisciplinary process team for operational planning of the Department's preparedness and response to a smallpox attack.

Our vaccine requirements and other medical assets must be correlated to a concept of operations that clearly defines our response to biowarfare attacks. Consequence management of a smallpox outbreak requires intense medical planning that is nested in an overarching operational plan. By defining our response based upon tactical assets, logistics, and doctrine, we can more effectively craft vaccine policies and other force health protection measures that support our operational objectives. In addition, it will be necessary to address how we will synchronize our efforts with other agencies involved in the Federal Response Plan. However, our initial focus should be upon the specific roles and responsibilities of DoD for ensuring the protection and readiness of the force.

In the near-term, this team should focus on the following subject areas:

- A review of existing doctrine that identifies appropriate combat health support for a smallpox attack, and the additional medical assets and policies necessary to effectively support this contingency.

- A concept of operations for DoD's medical response to domestic acts of bioterrorism involving smallpox and the necessary medical services—vaccines, evacuation assets, patient decontamination, medical logistics distribution, and other policies—that will effectively support this contingency.

- An outline of what protective measures we can implement immediately (within the next 30 days) with current resources and other constraints, and then what we can accomplish over time—3 months, 6 months, 1 year, 18 months, and 2 years.

While this initiative will focus on medical issues, it will benefit from a broad range of occupational expertise from the Services to address other relevant aspects of disaster consequence management. This planning will be valuable for the Department in shaping policy decisions, resource requirements, and training standards for these

scenarios. Additionally, it will create an operational template and planning guide for our interface with other federal agencies for responding to a biological warfare attack.

I request a concept and milestone presentation on these plans at the Executive Council for DoD Medical Programs (a regularly scheduled meeting involving medical leadership of the Services, TRICARE, Joint Staff, and Health Affairs Policy Staff) on March 6, 2002. My point of contact on this issue is Ms. Ellen Embrey, my Deputy Assistant Secretary of Defense (Force Health Protection and Readiness), at (b)(6) (b)(. I will continue to maintain oversight over this effort, and schedule subsequent meetings and planning sessions on this subject through direct coordination with the Army Surgeon General. Thank you for your assistance on this issue, and I look forward to continued dialogue on how we might proceed on this initiative.

David S. C. Chu

TRANSACTION REPORT

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MEMORANDUM FOR SECRETARY OF THE ARMY

THROUGH: USD (Personnel & Readiness)

SUBJECT: Force Health Protection Recommendations for Smallpox Virus

Reference: DoDD 6205.3 DoD Immunization Program for Biological Warfare Defense

In accordance with the above Directive, I request that the Secretary of the Army, as the DoD Executive Agent for the Immunization Program for Biological Warfare Defense, provide me with recommendations to enhance total force protection against smallpox virus. These recommendations will facilitate my subsequent instructions to the Military Departments on the immunization of DoD personnel. The recommendations should address information on obtaining a portion of the current licensed vaccine stockpile, storage and distribution of the vaccine, and a plan for its use and the use of Vaccinia immune globulin. I request this information be provided within 30 days of the date of this memorandum. My point of contact for this is COL Jerry Jennings, (b)(6).

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

cc:
USD(AT&L)

Myths and Facts About Anthrax Vaccine

- MYTH: Anthrax vaccine is dangerous and can cause death.
  FACT: Medical experts agree: no deaths and only rare serious side effects have been caused by anthrax vaccine. The Department of Defense, Food and Drug Administration, Centers for Disease Control and Prevention, and an independent panel of civilian physicians review reports of death or serious illness that might possibly be associated with anthrax vaccination. These groups all agree that anthrax vaccine is not associated with any unexpected patterns of adverse events. The National Academy of Sciences' Institute of Medicine reported in March 2002, "There is no evidence that life-threatening or permanently disabling immediate-onset adverse events occur at higher rates in individuals who have received AVA [U.S. anthrax vaccine] than in the general population." In rare cases, patients experience serious adverse effects; these are treated and followed appropriately.

- MYTH: Anthrax vaccine causes terrible side effects.
  FACT: Based on over 30 years of anthrax vaccine use, we know that severe, albeit transient, injection site reactions do occur. It is known that from 30 to 60 percent of people who receive anthrax vaccine will develop an injection site reaction (less than one inch). About 1 in 100 develops a reaction five inches in diameter or larger. The rate of side effects away from the injection site is about the same as other vaccines: from 5 to 35 percent, with these events going away within a few days. The National Academy of Sciences' Institute of Medicine reported in March 2002, "Local events, especially redness, swelling, or nodules at the injection site, are associated with receipt of AVA [U.S. anthrax vaccine], are similar to the events observed following receipt of other vaccines currently in use by adults, and are fairly common" and "There is no evidence that life-threatening or permanently disabling immediate-onset adverse events occur at higher rates in individuals who have received AVA than in the general population."

- MYTH: Women have long-term side effects from anthrax vaccine more than men.
  FACT: Women experience more small injection site reactions than men. For skin reactions smaller than one inch in diameter, the likelihood is 60 percent for women and 30 percent for men. For side effects away from the injection site, the rates for men and women are about the same.

- MYTH: Antibiotics are more effective than anthrax vaccine.
  FACT: There is no better round-the-clock protection against anthrax infection than the anthrax vaccine. Antibiotics are effective when started immediately or very soon after exposure. However, not all exposures can be predicted in advance or even determined in very early stages, particularly in certain military situations. In such situations, the consequences for military personnel and their mission could be dire. This is not a risk DoD can afford to take. DoD will therefore vaccinate ahead of time for the best protection.

- MYTH: Anthrax vaccine only protects against cutaneous anthrax.
  FACT: While no vaccine is 100% effective, this vaccine will greatly reduce the risk of contracting anthrax regardless of route of exposure. Based on human and animal data, the National Academy of Sciences' Institute of Medicine concluded in March 2002 that anthrax vaccine is "an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains of *Bacillus anthracis*."

- MYTH: Anthrax vaccine won't protect against all strains of anthrax.
  FACT: Every disease-causing strain of *Bacillus anthracis* produces the same protein, a protein that is required to cause disease. The vaccine induces the production of antibodies that neutralize that protein. The National Academy of Sciences' Institute of Medicine concluded in March 2002 that "it is unlikely that either naturally-occurring or anthrax strains with bioengineered protective antigen could both evade AVA [the U.S. anthrax vaccine] and cause the toxicity associated with anthrax."

- MYTH: Some lots of anthrax vaccine cause more problems than other lots.
  FACT: Based on self-administered surveys and spontaneous reports, lot-to-lot comparisons in the various human safety studies performed to date found no meaningful differences based on lot. No vial of anthrax vaccine was distributed by the manufacturer without lot-specific manufacturing and testing data, explicitly reviewed and approved by the Food and Drug Administration (FDA). The Department of Defense uses only vaccine lots that the FDA released as meeting all applicable standards.

- MYTH: The anthrax vaccine is based on old technology.
  FACT: Anthrax vaccine was invented using mid-century technology that also led to highly successful vaccines against tetanus, diphtheria, and other infectious diseases. Today's manufacturing of anthrax vaccine by BioPort meets all current Food and Drug Administration standards of production.

- MYTH: The Department of Defense added squalene, an oil naturally produced in the human body and by bacteria, to the vaccine in 1990-91 to stretch the supply.
  FACT: No one added squalene to anthrax vaccine. Food and Drug Administration (FDA) scientists found trace quantities of squalene in anthrax, diphtheria, and tetanus vaccines (less than the natural level of squalene in the human bloodstream). The FDA notes that these minute quantities could have come from the bacteria involved or from processing during FDA tests (squalene is present in the oil in fingerprints). The FDA called the squalene in vaccines "naturally occurring and safe."

- MYTH: The Food and Drug Administration revoked the license of BioPort, the Department of Defense's vaccine supplier, because of manufacturing problems.
  FACT: BioPort's predecessor, the Michigan Biological Products Institute (MBPI), owned by the State of Michigan, approved renovations in 1995 for the Lansing

facility. In 1997, the Food and Drug Administration (FDA) issued a notice of intent to revoke licenses issued to MBPI. MBPI responded within 30 days with a strategic plan for compliance to FDA standards. The manufacturer voluntarily closed the anthrax vaccine production line in January 1998 for renovation. BioPort submitted a highly detailed set of quality control documents to FDA in fall 2001. FDA approved BioPort's facilities and processes, as they relate to the manufacture of anthrax vaccine, on January 31, 2002.

- MYTH: The Centers for Disease Control and Prevention use of anthrax vaccine to Congressional staff and U.S. Postal Service workers was "experimental" and "investigational," requiring informed consent, so the Department of Defense's use of anthrax vaccine requires consent from servicemembers as well.
  FACT: The Department of Defense's use of anthrax vaccine in the Anthrax Vaccine Immunization Program for pre-exposure prevention using six doses over eighteen months is consistent with the Food and Drug Administration-licensed use of the vaccine. The Centers for Disease Control and Prevention offer of anthrax vaccine for Congressional and U.S. Postal Service workers used anthrax vaccine for "post-exposure prophylaxis" in three doses. This is not a Food and Drug Administration-licensed use of the vaccine, therefore, in that case (post-exposure), the vaccine was administered under an "investigational new drug" protocol, with informed consent.

- MYTH: The anthrax vaccine can cause miscarriages.
  FACT: There is no study to support this claim. Consistent with the national standard and the Centers for Disease Control and Prevention recommendation, the Department of Defense policy does not vaccinate pregnant woman. Women who receive the vaccine get pregnant and deliver children at the same rates as unvaccinated women. A preliminary report (not yet published, not reviewed by peer scientists) suggested that women vaccinated during pregnancy might have an elevated rate of birth defects. However, medical scientists and study experts who have reviewed this preliminary information expressed concerns about the study's methods, and recommended further analysis. The Department of Defense is working with the Centers for Disease Control and Prevention to see if these preliminary data are accurate, or if they are not.

COMMENTS ABOUT ANTHRAX VACCINE

SAFETY AND EFFECTIVENESS

"The committee finds that the available evidence from studies with humans and animals, coupled with reasonable assumptions of analogy, shows that AVA [anthrax vaccine adsorbed] as licensed is an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains of *B. anthracis*."

Institute of Medicine Report: *The Anthrax Vaccine: Is it Safe? Does it Work?* Washington, DC: National Academy of Sciences, March 6, 2002.

"The committee found no evidence that people face an increased risk of experiencing life-threatening or permanently disabling adverse events immediately after receiving AVA, when compared with the general population. Nor did it find any convincing evidence that people face elevated risk of developing adverse health effects over the longer term, although data are limited in this regard (as they are for all vaccines)."

Institute of Medicine Report: *The Anthrax Vaccine: Is it Safe? Does it Work?* Washington, DC: National Academy of Sciences, March 6, 2002.

"The range of reported side effects experienced by recipients of the anthrax vaccine are in line with previously published reports and compatible with similar vaccines. There are no convincing data demonstrating long-term adverse health impacts to recipients of anthrax vaccine, although additional studies are in progress."

Armed Forces Epidemiological Board (AFEB), civilian physicians and scientists advising the Surgeons General, report of March 1, 2002.

"The Food and Drug Administration's approval to resume production of the anthrax vaccine is welcome news for our fight against bioterrorism. For more than 30 years, the anthrax vaccine has been a safe and effective way to protect people from this deadly disease. Health officials did the right thing in providing vaccine to Congressional and postal workers. Anthrax spores can remain in the lungs for extended periods."

Louis W. Sullivan, M.D., president of the Morehouse School of Medicine, former secretary of health and human services from 1989-93, as published in *New York Times*, February 10, 2002.

"Evidence indicates that this vaccine is effective in preventing cutaneous and inhalational anthrax; it is recommended for laboratory workers who routinely work with *B. anthracis* and workers who handle potentially contaminated industrial raw materials. It may also be used to protect military personnel against potential exposure to anthrax used as a biological warfare agent. Annual booster injections are recommended if the risk of exposure continues."

James Chin, MD, MPH, Editor, *Control of Communicable Diseases Manual*, 17th Edition, 2000.

"The AFEB was concerned and somewhat surprised at the criticism surrounding the program given the high level of professionalism that had characterized this effort. ... Anthrax vaccine is a fully licensed FDA vaccine. The vaccine does cause local side effects, but has an excellent safety profile. The Anthrax Vaccine Immunization Program has carefully tabulated person-specific immunization data and has assiduously investigated reported complications associated with receipt of anthrax vaccine. These data have been regularly reviewed by the board and attest to the safety of the vaccine."

Armed Forces Epidemiological Board (AFEB), civilian physicians and scientists advising the Surgeons General (http://www.tricare.osd.mil/afeb/), report of March 29, 2000.

"I think what we can talk about is the vaccine and the studies that have been done to show both its safety and efficacy, and the FDA has been involved in those studies, and it is on that basis that we can say the vaccine is safe, and it's also effective."

David Satcher, MD, PhD, Surgeon General of the United States, To U.S. House of Representatives Committee on Government Reform, August 3, 1999.

"The only known effective prevention against anthrax is the anthrax vaccine. Treatment of cutaneous anthrax infection involves administration of antibiotics. In the case of pulmonary anthrax infection, therapy has been of limited benefit, except when given immediately after exposure."

Later, page 19, **"Mr. Chairman, we believe anthrax vaccine is a safe and effective vaccine for the prevention of anthrax disease – an often-fatal disease. Our confidence in this vaccine, like all vaccines, is based upon four components: first - the clinical trials and subsequent clinical laboratory experience with the vaccine; second - ongoing inspections of the manufacturing facility; third – our lot release requirements; and fourth - our ongoing collection of adverse event reports. We will continue our**

efforts in all four of these areas, with the anthrax vaccine and all vaccines, to assure that only safe products are on the market."

Kathryn C. Zoon, Ph.D., Director, Center For Biologics Evaluation And Research (CBER), Food & Drug Administration (FDA), To U.S. House of Representatives Subcommittee on National Security, Veterans' Affairs and International Relations, Committee on Government Reform, Hearing on DoD's Anthrax Vaccine Immunization Program, April 29, 1999.

"Mr. Chairman, we are aware that some people question the safety and efficacy of the anthrax vaccine. Let me be clear. We believe that for persons at high risk the licensed anthrax vaccine is safe and effective for the prevention of the often-fatal anthrax disease."

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"Killed anthrax vaccines appear to be effective in reducing the risk of contracting anthrax with a relatively low rate of adverse effects. Further research should be restricted to testing new vaccines only."

The Cochrane Collaboration, internationally respected group of scientists who apply principles called evidence-based medicine (http://www.cochrane.org), "The effectiveness and safety of vaccines against human anthrax: A systematic review," *Vaccine* 1998; volume *16:* pages 880-884

THREAT

"Anthrax represents the primary biological warfare threat to United States forces and interest. It is the most widely adopted agent in foreign biological warfare programs. An attack will likely come with little to no warning with potential catastrophic impact. Because of this, anthrax deserves its reputation as an effective and deadly biological warfare agent."

Rear Admiral Lowell Jacoby, United States Navy, Director of Intelligence, Joint Staff J2, To U.S. Senate Committee on Armed Services, Hearing to Review the DoD Anthrax Vaccine Immunization Program, April 13, 2000.

CONGRESSIONAL SUPPORT

"And in my view, there's no question when you move into an area of possible risk with anthrax that you should vaccinate."

Later. **"I've supported this program from that—from my perspective, my training and what I know about the disease. I think it would be unconscionable for us to knowingly allow our troops to be at risk from a credible, military threat of weaponized anthrax simply because misinformation and fear have seized control of this issue."**

Senator Wayne Allard, a veterinarian, U.S. Senate Committee on Armed Services, Hearing to Review the DoD Anthrax Vaccine Immunization Program, April 13, 2000.

COMMENTS FROM THE TROOPS

"I view the anthrax vaccine is similar to any other force protection measure that I receive or use. I may not need the protection every day, but I never know when I'll need it. Consequently, for my safety and the safety of my teammates, I want all the protection I can get."

Later. **"From my personal standpoint, and what I've observed in my team, taking the anthrax vaccine has not been an issue. I'm aware that there is information out that attempts to discredit this vaccine, however, I'm also aware that this is an FDA-approved vaccine and has been used successfully for years."**

Lieutenant (Junior Grade) Chris Rohrbach, United States Navy, Assistant Officer in Charge, Bravo Platoon, Special Warfare Group 8, Little Creek Virginia, To U.S. House of Representatives Subcommittee on Military Personnel, Committee on Armed Services, Hearing on the Anthrax Vaccine Immunization Program, September 30, 1999.

"I believe it's [the threat's] very real. In fact, I'd feel very uncomfortable going into, going in harm's way with a teammate of mine that hasn't been vaccinated against the anthrax. That is one more casualty I'll have to worry about. If he gets vaccinated for anthrax, that's, as far as I'm concerned, that's one less thing that I need to worry about."

Lieutenant James Randall, United States Navy, Head, Training Department, Special Warfare Group, To U.S. House of Representatives Subcommittee on Military Personnel, Committee on Armed Services, Hearing on the Anthrax Vaccine Immunization Program, September 30, 1999.

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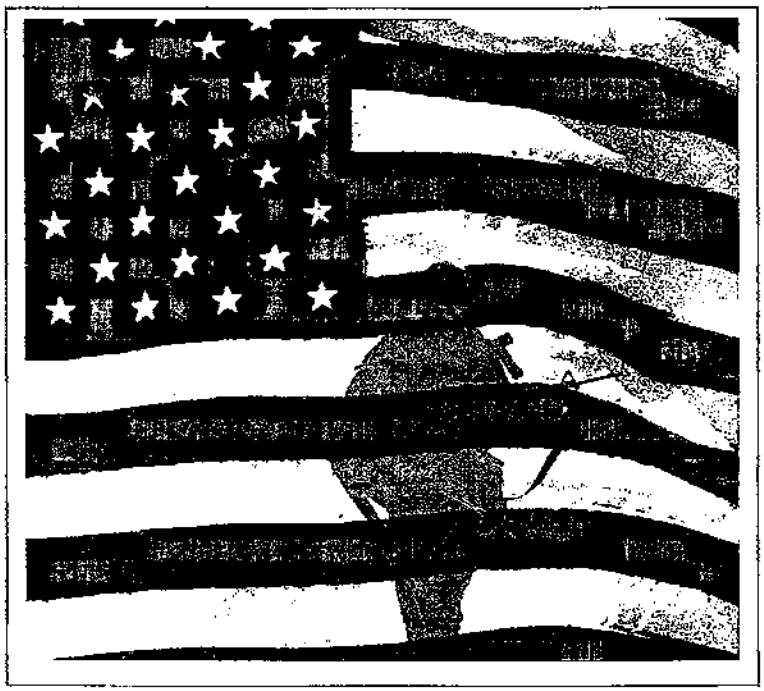

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- We provide many different vaccines and medical procedures on a mandatory basis, when it is known that the vaccine or medical measure is safe and effective, and exposure or possible exposure to an agent poses a real risk. Also, we fight and win as teams—if one or several team members in areas of higher risk are not vaccinated and fall victim to anthrax, they could jeopardize the lives of other team members and mission success.
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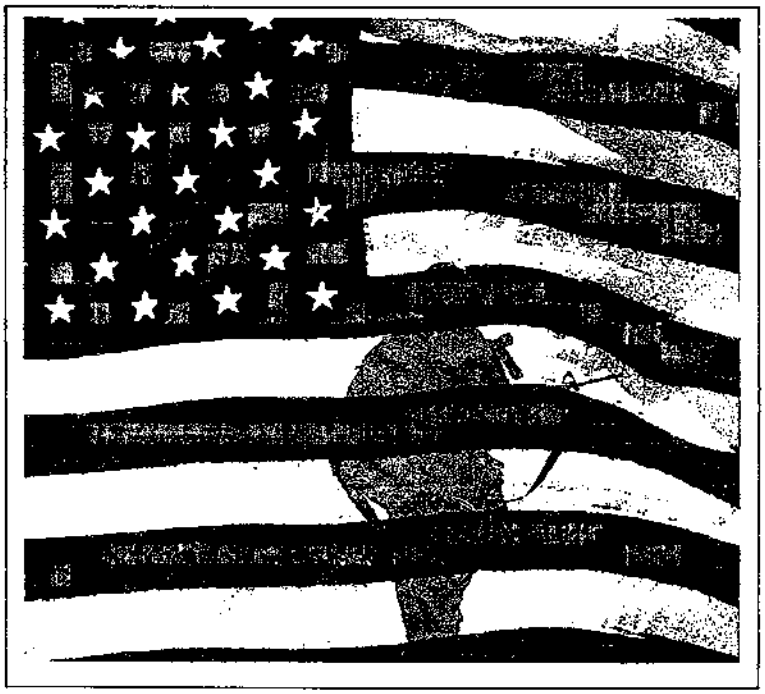

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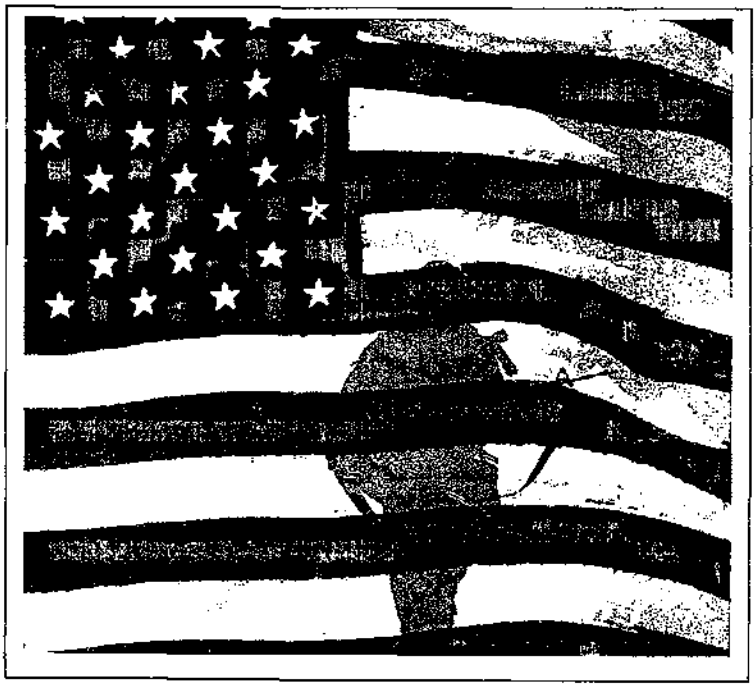

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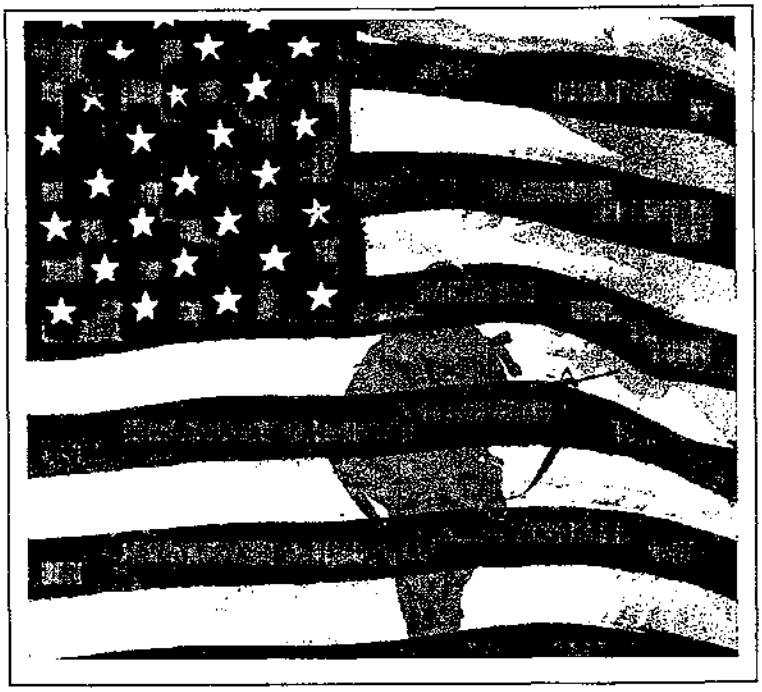
Department of Defense
Anthrax Vaccine Immunization Program

Information Pamphlet



"...I have a message for our military: Be Ready."

President Bush, September 20, 2001,
speech to the Joint Session of Congress
following attacks on America

Contact us at avip@amedd.army.mil or call 877-GET-VACC (877-438-8222)

Visit our website at www.anthrax.mil

Summer 2002

Department of Defense Policy

The Department of Defense will resume the Anthrax Vaccine Immunization Program (AVIP) consistent with U.S. Food and Drug Administration approved labeling and the best practice of medicine. Our policy is to immunize military personnel, Emergency-Essential DoD civilians and contractor personnel, assigned to or deployed for more than 15 days in higher threat areas whose performance is essential for certain mission critical capabilities.

Frequently Asked Questions

What Is Anthrax ?

- Anthrax is a robust spore-forming bacterium (*Bacillus anthracis*) that can be stored for years, loaded into a variety of weapons, and produced in large quantities without sophisticated equipment. Inhaled anthrax is 99% lethal in an unprotected, unvaccinated population, left untreated.

Is Anthrax A Biological Warfare Threat ?

- The threat is real and failure to prepare would result in grave consequences. A former Director of the Central Intelligence Agency, James Woolsey, referred to it as "the single most dangerous threat to our national security in the foreseeable future."
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THE DEPARTMENT OF DEFENSE
ANTHRAX VACCINE IMMUNIZATION PROGRAM:

UNPROVEN FORCE PROTECTION

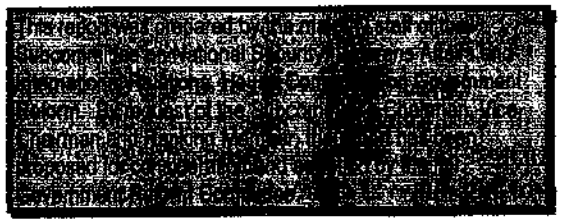
Summary

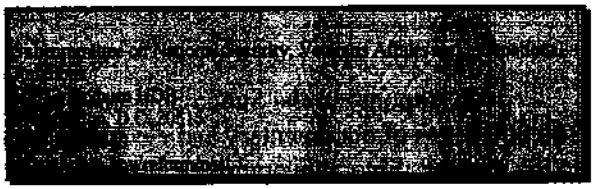
Findings in Brief
Recommendations in Brief

Background

Discussion

Findings
Recommendations





February 17, 2000 (2:27PM)

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Summary

Responding to service members= complaints of program insensitivity to adverse health effects, inadequate medical record keeping and heavy-handed program operation, the Subcommittee initiated an oversight investigation into the design and implementation of the Department of Defense (DOD) force-wide, mandatory Anthrax Vaccine Immunization Program (AVIP). Because the anthrax vaccine is still being studied as a potential causative or contributing factor in Gulf War veterans= illnesses[1], the Subcommittee measured the program against this standard: Any expanded use of the same vaccine should be undertaken only with the greatest care and only to the extent necessary.

As currently designed and implemented, the anthrax vaccine program fails on both counts. The AVIP lacks a consistent standard of care and is designed to reach far beyond those at risk.

Based on the testimonial and documentary record[2], the Subcommittee finds the AVIP a well-intentioned but overwrought response to the threat of anthrax as a biological weapon. Against the so-called Aasymmetric≅ threats to U.S. conventional military superiority posed by a growing range of chemical and biological weapons, the anthrax vaccine program represents a medical Maginot Line, a fixed fortification protecting against attack from only one direction.

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[1] P.L. 105-277, Title XVI, sec. 1603(d).

[2] In response to the Subcommittee=s investigative requests, DOD provided more than 100,000 pages of documentary and electronic records on the anthrax vaccine program from 1991 to the present. Five Subcommittee hearings were held in 1999, encompassing 20 hours of testimony from 46 witnesses. The full Committee on Government Reform also heard testimony on the subject of vaccines for military defense on October 12, 1999.

Unrealistic Program

As a mandatory, force-wide countermeasure to the real threat of weaponized anthrax on the battlefield, the vaccine effort is unrealistic. It expands and distorts the use of invasive, dated medical technology to address perceived weaknesses in detection technology and external physical protection against biological attack. Born of a post-Gulf War panic over apparent weaknesses in chemical and biological (CB) warfare defenses, the AVIP is an unmanageably broad military undertaking built on a dangerously narrow scientific and medical foundation.

At best, the vaccine provides some measure of protection to most who receive it. Just how much protection is acquired, by whom, for how long and against what level of challenge are questions DOD answers with an excess of faith but a paucity of science.

Many members of the armed forces do not share that faith. They do not believe merely suggestive evidence of vaccine efficacy outweighs their concerns over the lack of evidence of long term vaccine safety. Nor do they trust DOD has learned the lessons of past military medical mistakes: atomic testing, Agent Orange, Persian Gulf War drugs and vaccines. Heavy handed, one-sided informational materials only fuel suspicions the program understates adverse reaction risks in order to magnify the relative, admittedly marginal, benefits of the vaccine.

As a military operation, the AVIP rests on weak conceptual and logistical footing. It suffers from poor planning, inflexible execution and over-extended supply lines. As a health care effort, the AVIP compromises the practice of medicine to achieve military objectives.

The decision to use the 1950's era vaccine, which requires an elaborate inoculation regime of six shots over 18 months, presents daunting, perhaps insurmountable, logistical challenges to reach a force of 2.4 million active duty and reserve component members. Research to support a shorter, more manageable inoculation regimen was not completed before the AVIP was launched. Development of a purer, potentially less reactogenic anthrax vaccine using recombinant technologies was not pursued aggressively.

Unstable Supply

The sole-source procurement strategy leaves the program vulnerable to supply shortages and price increases. Because Food and Drug Administration (FDA) regulations require a dedicated production facility for spore-based biologics, other pharmaceutical firms will not commit the time and capital needed to manufacture an old vaccine for a very limited market. As a result DOD and the sole vaccine maker are locked in a mutually dependent relationship.

The manufacturer, struggling to reopen a plant with a checkered regulatory history, clings to a captive customer. Threats to stop production render DOD unable to resist demands for extraordinary financial relief and pressure to permit the use of publicly funded improvements to monopolize the private domestic and foreign markets as well.

Uncertain Safety

Incurious reliance on FDA approval of the vaccine as Asafe≅ for occupational exposure blinds the program to potential adverse reaction trends in a vastly expanded, demographically diverse population of vaccine recipients. Adverse events following vaccination are reported by women at twice the rate among men. The vaccine may be as safe as many other approved products, but valid data to support, or refute, that proposition will not come from the AVIP. Preposterously low adverse report rates generated by DOD point to a program far more concerned with public relations than effective force protection or the practice of medicine.

The AVIP raises an ominous question: Who protects the force from ill-conceived force protection? The anthrax vaccine effort is designated a Acommander=s program≅ not a medical program, so DOD doctors appear unable to act as advocates for individual patients in the face of command pressure to meet force-wide inoculation levels. FDA regulations reach only the vaccine producer, the BioPort Corporation, not the activities of the vaccine purveyor, the Pentagon, although for purposes of the AVIP the distinction is meaningless.

Untested Efficacy

Administration of the anthrax vaccine for mass prophylaxis against biological warfare should be considered an off-label use of the product to treat an indication for which it is not explicitly licensed. DOD=s operational use of a standard of Afunctional protection≅ after three inoculations constitutes a *de facto* alteration of the approved six shot regimen. Both the new indication and the new schedule should be undertaken only pursuant to FDA regulations governing clinical trials of investigational new drugs (IND).

Under supervision of the FDA and an Institutional Review Board (IRB), DOD would be required to inform vaccine recipients adequately, obtain informed consent and gather data on vaccine safety consistently. If necessary, DOD could request the president waive the informed consent requirement for certain deployed personnel under the statute, regulation and Executive Order that provide far greater protections to service members than the process used for similar waivers during the Gulf War.[3]

[3] 10 U.S.C. 1107(f); 21 CFR Part 50; Executive Order of September 30, 1999 (No. 13139).

Findings in Brief

1. **The AVIP is a well-intentioned but over-broad response to the anthrax threat.** It represents a doctrinal departure overemphasizing the role of medical intervention in force protection.

2. **The AVIP is vulnerable to supply shortages and price increases.** The sole-source procurement of a vaccine that requires a dedicated production facility leaves DOD captive to old technology and a single, untested company. Research and development on a second-generation, recombinant vaccine would allow others to compete.

3. **The AVIP is logistically too complex to succeed.** Adherence to the rigid schedule of six inoculations over 18 months for 2.4 million members of a mobile force is unlikely, particularly in reserve components. Using an artificial standard that counts only shots more than 30 days overdue, DOD tolerates serious deviations from the Food and Drug Administration (FDA) approved schedule.

4. **Safety of the vaccine is not being monitored adequately.** The program is predisposed to ignore or understate potential safety problems due to reliance on a passive adverse event surveillance system and DOD institutional resistance to associating health effects with the vaccine.

5. **Efficacy of the vaccine against biological warfare is uncertain.** The vaccine was approved for protection against cutaneous (under the skin) infection in an occupational setting, not for use as mass protection against weaponized, aerosolized anthrax.

Recommendations in Brief

1. The force-wide, mandatory AVIP should be suspended until DOD obtains approval for use of an improved vaccine. To accomplish this:

    2. DOD should accelerate research and testing on a second-generation, recombinant anthrax vaccine; and,

    3. DOD should pursue testing of the safety and efficacy of a shorter anthrax inoculation regimen; and,

    4. DOD should enroll all anthrax vaccine recipients in a comprehensive clinical evaluation and treatment program for long term study.

5. While an improved vaccine is being developed, use of the current anthrax vaccine for force protection against biological warfare should be considered experimental and undertaken only pursuant to FDA regulations governing investigational testing for a new indication.

Background

The Program

On December 15, 1997, after what DOD described as Aa detailed, deliberative process≅ spanning almost four years[4], Secretary of Defense William S. Cohen announced a program to immunize all active duty personnel against anthrax, a bacterial disease that in spore form can be used as a biological weapon. The effort is called the Anthrax Vaccine Immunization Program (AVIP).[5]

The program was designed to be implemented in three phases[6]:

Phase I	(3/98 - 1/00)	Forces assigned or rotating to high threat areas	400,000
Phase II	(1/00 - 1/04)	Early deploying forces into high threat areas	1,000,000
Phase III	(10/02 - 9/06)	Remainder of the total force, boosters, etc.	1,000,000

The AVIP is a medical force protection effort undertaken by DOD pursuant to a 1993 policy calling for immunizations Aagainst validated biological warfare threat agents, for which suitable vaccines are available, in sufficient time to develop immunity before deployment to high-threat areas...≅[7]

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[4] *Anthrax Immunization Program,* 106th Cong., 1st sess., p. 8 (1999) (Subcommittee on National Security, Veterans Affairs, and International Relations hearing of Mar. 24, 1999, No. 106-17) [hereinafter ANSVAIR Anthrax Hearing (I)≅] (prepared statement of Dr. Sue Bailey).

[5] DOD Media Release, ADefense Department to Start Immunizing Troops Against Anthrax,≅ No. 679-97, December 15, 1997.

[6] AVIP briefing slides (in subcommittee files).

[7] Department of Defense, DOD Directive 6205.3, ADOD Immunization Program for Biological Warfare Defense.≅ November 26, 1993. Other elements of force protection include

intelligence about threats, detection capability, physical protection (suits, masks, etc.), post-exposure treatment with antisera and antibiotics, and strategic deterrence. In the Gulf War, up to 150,000 U.S. service personnel received one or two doses of the anthrax vaccine along with other immunizations and medications. Due to poor or non-existent record keeping, however, DOD is unable to conduct a systematic follow-up on the health effects, if any, of the Gulf War vaccines.

According to the DOD news release announcing the vaccine program, AAfter a three year study, Secretary of Defense William S. Cohen concluded that the vaccination is the safest way to protect highly mobile U.S. military forces against a potential threat that is 99 percent lethal to unprotected individuals.≅[8] Cohen added, ATo be effective, medical force protection must be comprehensive, well documented and consistent. I have instructed the military to put such a program in place.≅[9]

Accordingly, Secretary Cohen set four conditions on the start of vaccinations:

1) supplemental testing to assure sterility, safety, potency and purity of the vaccine stockpile;
2) implementation of a system for fully tracking anthrax immunizations;
3) approval of operational plans to administer the vaccine and communications plans to inform military pers
4) review of medical aspects of the program by an independent expert.[10]

In 1998, supplemental testing of the anthrax vaccine stockpile began.[11] An elaborate interim record keeping and tracking system was designed to combine vaccination data from the three military services into an existing central data base, the Defense Enrollment Eligibility Reporting System (DEERS).[12] A more efficient, centralized immunization records system is under development.[13] Communication plans were approved centered around a Atri-fold≅ brochure to be given to service personnel.[14] An anthrax vaccine web site was also created.[15] A physician reviewed the AVIP program plans.[16]

In March 1998, at the request of the regional commander, 48,000 troops assigned to the Persian Gulf area began the vaccination series. On May 18, 1998, Secretary Cohen pronounced

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[8] See *supra* note 5, p.1.

[9] *Ibid.*

[10] *Ibid.*

[11] Letter from Anthony M. Lutrell, Vice President - Quality Assurance, BioPort Corp. to Dr. Michael Gilbreath, Joint Program Office for Biological Defense, DOD, January 8, 1999 (in subcommittee files).

[12] Major William Terry, ATracking Troops= Anthrax Shots,≅ (with charts), *ArmyLINK News*, March 1999.

[13] *Ibid.*

[14] Department of Defense, AVIP tri-fold brochure, AWhat Every Service Member Should Know About Anthrax≅ (undated) (in subcommittee files).

[15] Department of Defense web site on Anthrax Vaccination Immunization Program, http://www.anthrax.osd.mil.

[16] Letter from Dr. Gerard N. Burrow, Special Advisor to the President for Health Affairs, David Page Smith Professor of Medicine, Professor of Obstetrics and Gynecology, Yale University School of Medicine, to DOD Undersecretary Rudy de Leon, Feb. 19, 1998 (in subcommittee files).

the four conditions fulfilled and approved the total force program, which began in September with troops in Korea.[17]

DOD cited several factors to support the conclusion the anthrax vaccine is both safe for widespread use and effective against the most likely anthrax threat:

1) FDA approval and monitoring of the vaccine;
2) vaccine usage since approval;
3) assured production capacity;
4) independent medical review;
5) supplemental vaccine testing; and

[17] Steve Bowman, *Department of Defense Anthrax Vaccination Program* (98-873F) , Congressional Research Service Report (updated), October 28, 1998, p. 2.

6) vaccine tests in animals.[18]

FDA Approval of the Vaccine

The AVIP uses the only anthrax vaccine licensed for manufacture in the United States. Anthrax Vaccine Absorbed (AVA) was approved as safe in 1970 based on animal studies and one study of wool workers exposed to indeterminate levels of cutaneous (through skin) and airborne anthrax spores. The disease primarily infects grazing animals and the vaccine has been used since 1970 by some veterinarians, livestock workers and researchers at risk from exposure. The approved immunization process requires a fixed schedule of six injections over 18 months and an annual booster. The vaccine does not contain live anthrax bacteria, but challenges the immune system to mount a response to filtered elements of the killed bacteria absorbed into an adjuvant.[19]

Subsequent FDA review of the studies in 1985 concluded the vaccine was safe, Afairly well tolerated,= and effective against cutaneous anthrax, but that data from both human and animal tests was insufficient to support a finding of efficacy with regard to airborne exposure.[20] In analyzing the benefit/risk ratio of classifying the old vaccine as compliant under new FDA standards, the expert panel concluded, AThis vaccine is recommended for a ***limited, high-risk of exposure population*** along with other industrial safety measures designed to minimize contact with potentially contaminated material. The benefit-to-risk assessment is satisfactory *under the prevailing circumstances of use.*=[21] (emphasis added)

The sole producer of the vaccine is the Michigan Biologics Products Institute (MBPI), formerly the Michigan Public Health Department. Since licensure in 1970, FDA monitoring of the vaccine consisted of collecting adverse reaction data and conducting intermittent manufacturing plant inspections.

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[18] Prepared statement of Dr. Sue Bailey, Assistant Secretary for Health Affairs, DOD, NSVAIR Anthrax Hearing (I), p. 9 .

[19] The FDA-approved immunization schedule: Day 1, 2 weeks, 4 weeks, 6 weeks, 6 months, 12 months and 18 months. An adjuvant is an ingredient that modifies or enhances the effectiveness of the drug or treatment.

[20] Federal Register, 21 CFR Part 610, December 13, 1985, p. 51058.

[21] *Ibid.*

While detailed information on inspection activities prior to 1990 is not readily available, FDA regulatory scrutiny of the manufacturer has been increasing since then. The Lansing, Michigan facility has been cited repeatedly by the FDA for quality control deficiencies and Anumerous significant deviations from the Federal Food, Drug and Cosmetic Act, FDA=s regulations and the standards in MBPI=s license.≅[22] In March 1997, the FDA warned MBPI that steps would be taken to revoke production licenses, including anthrax vaccine, unless immediate actions were taken to correct longstanding deficiencies.[23] In March 1998 the plant was closed for $1.8 million in renovations and a $15 million expansion funded by DOD.[24] Vaccine production resumed in May 1999, but neither the renovated facility nor any newly produced vaccine lots have been approved by the FDA.[25]

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[22] *Safety and Efficacy of the Mandatory Vaccine*, 106th Cong., 1st sess., p. 58 (1999) (Subcommittee on National Security, Veterans Affairs, and International Relations hearing of Apr. 29,1999, No. 106- 26) [hereinafter ANSVAIR Anthrax Hearing (II)≅] (testimony of Dr. Kathryn Zoon, Director, FDA Center for Biologics Evaluation and Research).

[23] Center for Biologics Evaluation and Research, FDA, AFDA Warns Michigan Biological Products Institute of Intention to Revoke Licenses,≅ No. D0382, March 11, 1997.

[24] *Department of Defense=s Sole-Source Anthrax Vaccine Procurement*, 106th Cong., 1st sess., p. 8 (1999) (ANational Security, Veterans Affairs, and International Relations Subcommittee hearing of June 30, 1999) [hereinafter ANSVAIR Anthrax Hearing (III)≅] (testimony of Louis J. Rodrigues, Director, Defense Acquisitions Issues, National Security and International Affairs Division, U.S. General Accounting Office).

[25] DOD News Briefing, Monday, December 13, 1999 (available at

Deviations from good manufacturing practices can effect vaccine safety and effectiveness. FDA will not permit the release of vaccines not documented to meet approved potency, sterility and stability levels. Based on concerns over the impact of production process errors on vaccine quality, BioPort quarantined 11 lots of anthrax vaccine. Additional lots are being held pending resolution of questions about potency testing that arose during the supplemental review.[26]

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http://www.defenselink.mil and in subcommittee files).

[26] AMedical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program,≅ (GAO/NSIAD-00-36) U.S. General Accounting Office, October 22, 1999, p. 13. See also, Department of Defense Joint Program Office - Biological Defense, AInvestigation of Supplemental Potency Testing≅ JPO-0855 (undated) (in subcommittee files). See also, prepared statement of BG Eddie Cain, Joint Program Manager, Joint Program Office for Biological Defense, NSVAIR Hearing (II), p. 68.

Under FDA regulations, stockpiled lots must be tested for potency at predetermined intervals. Potency test are done using guinea pigs by comparing the survival rates of animals vaccinated with the test lot(s) against those vaccinated with a previously manufactured control or Areference≅ lot. Potency test failures during the DOD supplemental testing program have raised questions regarding the validity of test procedures and the selection of reference lots.[27]

Assured Production Capacity

MPBI was purchased in September 1998 by the BioPort Corporation, a new company formed by private investors, including former Joint Chiefs Chairman Adm. William J. Crowe. The next month BioPort was awarded a DOD contract valued at $29 million to produce anthrax vaccine for the AVIP.[28] The contract (DAMD17-98-C 8052) provides for a one year Base Period and two option years. The contract provides for a full-term, fixed price, fixed annual quantity because Athe Government currently requires all the AVA [anthrax vaccine absorbed] that BioPort can produce.≅ Under the agreement, BioPort will receive progress payments at various stages of the anthrax vaccine production process.

On August 5, 1999, DOD announced the contract had been Arestructured≅ to increase the price by $24.1 million, including $18.7 million of advance payments.[29]

This contract, and earlier contracts with MPBI and MDPH, were accompanied by a justification and authorization for other than full and open competition (sole source). The sole source procurement was authorized because AMichigan Biologics Products Institute (MBPI) is the only organization in the U.S. with a Food and Drug Administration (FDA) License to

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[27] Letter from Joseph S. Little, Contracting Officer, Department of the Army to Fuad El-Hibri, BioPort Corporation, Sept. 23, 19989 (in subcommittee files).

[28] Department of Defense (1998) Award/Contract: U.S. Army Medical Research ACQ Activity - BioPort Corporation, DAMD17-98-C-8052, Sept. 17, 1998.

[29] Department of Defense, Media Release, ADOD Announces Contract Restructuring,≅ August 5, 1999 (in subcommittee files).

manufacture AVA≅ and A[d]ue to the time and expense required to produce a licenced product, investing in alternate manufacturers is not considered to be an effective way of meeting the Government=s requirements.≅[30] DOD also indemnified MBPI/BioPort against liability arising from Athe risks of adverse reactions, or the failure to confer immunity against anthrax....≅[31]

[30] Joseph S. Little *A*Justification and Approval for Other than Full and Open Competition,≅ Anthrax Vaccine Absorbed, DAMD17-97-0014 (JPO 0836) May 20, 1997 (in subcommittee files).

[31] Memorandum of Decision, Secretary of the Army Louis Caldera, Authority Under Public Law 85-804 to include an Indemnification clause in Contract DAMD 17-91-C-1139 With Michigan Biologic Products Institute, September 3, 1998 (in subcommittee files).

Potential liability resulting from adverse events was a major issue for the anthrax vaccine manufacturer even when the vaccine was used by a only few hundred people each year. In 1986, Secretary of the Army John Marsh, Jr. authorized indemnification of the State of Michigan Department of Public Health, which would not provide the vaccine without indemnification due to Athe possibility that persons vaccinated may develop anaphylaxis or some unforeseen reaction of serious consequences, including death.≅[32]

In 1992, Secretary of the Army Togo West, Jr. approved a request to indemnify the anthrax vaccine manufacturer, the Michigan Biologics Product Institute (MBPI), against all liability arising from:

> Athe unusually hazardous risks associated with potentially severe adverse reactions and the potential lack of efficacy of the AVA. These concerns stem from: a) the *limited use of the vaccine to date*, i.e., tests prior to approval of the vaccine by the Food and Drug Administration are on *too small a scale to permit accurate assessment of types and severity of adverse reactions (only widespread use can provide this assessment)*; and b) insufficient experience in mass immunization programs to truly evaluate the efficacy of the vaccine. Moreover, there is no way to predict whether the pathogen against which the vaccine may be used will be sufficiently similar to the pathogen used in tests to ensure vaccine efficacy.≅[33] [emphasis added]

In 1998, Secretary of the Army Louis Caldera again authorized indemnification of MBPI because Athe size of the proposed vaccination program may reveal unforwarned idiosyncratic

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[32] Memorandum of Decision Secretary of the Army John O. Marsh, Authority under 50 U.S.C. 1431-1435 (P.L. 85-804) to Include an Indemnification Clause in Contracts or Purchase Orders with the State of Michigan, February 27, 1986 (in subcommittee files).

[33] Memorandum of Decision, Secretary of the Army Togo West, Jr., Authority under P.L. 85-804 to Include an Indemnification Clause in Contract DAMD17-91-C-1139 with the Michigan Biologic Products Institute [undated] (in subcommittee files).

adverse reactions.≅[34] The contracting officer justified the later indemnification request, in part, because, ASince 1990, approximately 600,000 doses have been issued from MBPI=s stockpile. The limited use of AVA to date versus the large number of doses that are being stockpiled and subject to use may expand the data base to a point where the statistical significance of a predicted adverse reaction may become a reality.≅[35]

[34] See *supra* note 31.

[35] Joseph S. Little, Contracting Officer, AContracting Officer=s Request for Authorization for Indemnification Under Authority of Public Law 85-804,≅ Oct. 8, 1997, p. 3 (in subcommittee files).

Following the Gulf War, and prior to adoption of the DOD immunization policy in 1993, and the mandated AVIP in 1998, Pentagon officials considered and rejected alternative anthrax vaccine production sites.[36] Instead, an acquisition strategy was adopted focusing solely on the MBPI/BioPort vaccine.[37]

Vaccine Usage and Safety

DOD literature says the anthrax vaccine Ahas been safely and routinely administered in the United States to veterinarians, laboratory workers, and livestock handlers for more than twenty-five years.≅[38] Testimony at the March 24 hearing indicated between 100 and 300 civilians may receive the vaccine each year. Since approval, and prior to the AVIP, fewer than 68,000 doses had been distributed apart from stocks used in Operation Desert Storm.[39]

As with any vaccine, anthrax inoculation can cause adverse health events in some individuals, ranging from soreness or swelling at the injection site (local reactions) to fevers, chills, muscle aches and anaphylaxis[40] (systemic reactions). Local reaction may be mild,

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[36] BG Eddie Cain, AProcurement of the Anthrax Vaccine-Single Source Versus Additional Site,≅ DOD Information Paper, JPO 0920, October 19, 1998 (in subcommittee files).

[37] BG John C. Doesberg, AAcquisition Strategy for the Procurement of Anthrax Vaccine Adsorbed,≅ Joint Program Office for Biological Defense, JPO 0120, February 1, 1997 (in subcommittee files).

[38] See *supra* note 14.

[39] Prepared statement of Dr. Kathryn Zoon, Director, FDA Center for Biologics Evaluation and Research, NSVAIR Anthrax Hearing (II), p. 52-53.

[40] Anaphylaxis is one form of hypersensitivity to a drug or antigen. Anaphylactic shock is an often severe, sometimes fatal, physical reaction characterized by respiratory symptoms,

moderate or severe enough to require medical attention. Systemic reactions are generally considered clinically more significant. Reactions may increase in severity after successive injections.[41]

fainting, swelling and itching.

[41] Michigan Biologic Products Institute, AAnthrax Vaccine Absorbed: How Supplied, References, Description, Clinical Pharmacology, Indications and Usage, Contraindications, Warnings, Precautions, Adverse Reactions, Dosage and Administration,≅ FDA License No. 99, Rev. Feb. 1998 (in subcommittee files).

The AVA has been described as a relatively crude, imprecisely characterized vaccine, and estimates of reaction rates vary widely.[42] According to the FDA-approved AVA product labeling, 30 percent of vaccine recipients can be expected to suffer mild local reactions, 4 percent will incur moderate local reactions and less than .2 percent will experience systemic reactions.[43] In 1994 and 1995, DOD considered the need for a new anthrax vaccine Abased on the reactogenicity of the current vaccine.≅[44]

To avoid adverse reactions, the vaccine should not be given to those who experienced a severe reaction to a previous dose or to those with acute respiratory disease or an active infection. Immune compromised persons (i.e. HIV infected) may not respond to the vaccine. It is not recommended for pregnant women or for those under 18 or over 65 years of age.[45]

The Army Anthrax Vaccine Immunization Plan directs medical personnel to report severe adverse reactions (resulting in hospitalization or more than 24 hours lost from duty) through the Vaccine Adverse Events Reporting System (VAERS) administered by the Department of Health and Human Services (HHS).[46] Within HHS, VAERS is a joint project of the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA).[47] VAERS guidance recommends recording any clinically significant symptoms occurring subsequent to vaccine administration, whether or not a causal relationship has been established between the vaccine and the adverse reaction.[48]

The Army Medical Surveillance Activity also receives copies of VAERS forms from all the uniformed Services and produces a quarterly report for the U.S. Army Medical Command.[49] The Army Surgeon General has requested the assistance of the HHS Vaccine Injury Compensation Program in evaluating all anthrax-related VAERS data.[50]

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[42] Phillip Brachman and Arthur Friedlander, *Vaccines*, 2d ed., pp. 729-739, Philadelphia, WB Saunders (1994).

[43] See *supra* note 41.

[44] LTC George W. Anderson, Jr.,Memorandum AMinutes of the FDA meeting of May 5, 1994 Concerning Production and Purification of PA from Delta Stern-1 (pPa102) CR4.≅ U.S.Army Medical Research Institute on Infectious Diseases, May 19, 1994 (in subcommittee files).

[45] See *supra* note 41.

[46] Gen. William W. Crouch, U.S. Army Vice Chief of Staff, MEMORANDUM AArmy Anthrax Vaccine Immunization Program Plan, Apr. 29, 1998, p. 3 and Annex C (in subcommittee files).

[47] FDA Center for Biologics Evaluation and Research, AVaccine Adverse Events Reporting System (VAERS)≅ available at http://www.fda/gov.cber/vaers/faq.htm.

[48] *Ibid.*

[49] See *supra* note 46, p. C-7.

[50] *Anthrax Vaccine Adverse Reactions* 106th Cong. 1st sess. (1999) (subcommittee on

National Security, Veterans Affairs, and International Relations hearing of July 21, 1999) [hereinafter ANSVAIR Anthrax Hearing (IV)≡] [The Subcommittee hearing has not yet been printed. Page numbers in this and subsequent references to statements at this hearing refer to individual prepared written statements or the unofficial transcript, held in subcommittee files.] (prepared statement of Gen. Robert Claypool, p. 13-14).

The AVIP convened a clinical conference in May 1999 to discuss anthrax issues, including adverse events. Col. Renata Engler, M.D., Chief, Allergy-Immunology Department, Walter Reed Army Medical Center, presented data from ongoing research and case studies showing higher adverse reaction rates in women.[51] Also discussed at the conference was the Army Surgeon General=s proposed longitudinal cohort study to assess near-term and long-term health effects of the anthrax vaccine.[52]

To convey important information about medical exemptions and adverse reactions, the Army implementation plan directs commanders and medical staff to provide recipients Aadequate information on the vaccine, its safety, its benefits, and the need for adherence to the immunization schedule prior to the first anthrax vaccination.≅[53] The other Service implementation plans contain identical or similar requirements.

On April 1, 1999, VAERS data (1990 to 1999) contained 101 reports of adverse events associated with anthrax inoculation, 14 of which were considered serious.[54] In May 1999, DOD reported a total of 123 VAERS filings with FDA, but included only 65 of those in the caculation of an adverse reaction rate of .007 percent of 890,888 vaccinations given to date. According to DOD, only 11 VAERS reports Amet strict reporting requirements.≅[55]

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[51] COL Renata Engler, MD., USA, Chief, Allergy and Immunology Department, Walter Reed Army Medical Center, APresentation-Anthrax Immunization: Challenges for the Future,≅ *Department of Defense Conference for Biological Warfare Defense Immunizations*, Fort Detrick, Maryland, May 25-27, 1999 (in subcommittee files).

[52] Department of the Army, Office of the Surgeon General, AMemorandum for Conference Participants,≅ Apr. 16, 1999, p. 2 (in subcommittee files).

[53] See *supra* note 46 p. C-5.

[54] Testimony of Dr. Kathryn Zoon, Director, FDA Center for Biologics Evaluation and Research, NSVAIR Anthrax Hearing (II), p. 55.

[55] Department of Defense, Briefing Slide:*A*Anthrax Vaccine Adverse Events-Vaccine Adverse Event Reporting System (VAERS) Military - Week Ending May 21, 1999" May 28,

1999 (in subcommittee files).

A review of the AVIP plans, and of basic literature on the anthrax vaccine, was conducted by Dr. Gerard N. Burrow, of the Yale University School of Medicine.[56] According to Dr. Burrow[57], he conducted his review over three months, read materials provided by DOD and interviewed Pentagon officials responsible for designing and implementing the program. On February 19, 1998, in a four page letter, he concluded, AThe anthrax vaccine appears to be safe and offers the best available protection against wild-type anthrax as a biological warfare agent.≅ The letter contains two paragraphs on safety and efficacy. Regarding the safety of the vaccine stockpile, all of which was manufactured under conditions cited by FDA as deficient, Dr. Burrow pointed to the DOD supplemental testing program, and the fact that AFDA directed MBPI to do a comprehensive review to demonstrate that deviations in biologic product lines did not impact anthrax vaccine quality and integrity. The results of this review should be available in the near future.≅[58] Regarding efficacy of the vaccine, the letter recites usage figures since approval in 1970 and cites the conclusion of an unpublished DOD study that Aunit effectiveness could best be preserved through the use of pre-deployment vaccination.≅[59]

In a letter to the Subcommittee in response to a request to testify on his review of the program, Dr. Burrow wrote:

> Unfortunately, I do not believe I can make a significant contribution to the work of your Committee. I chaired the Institute of Medicine Committee that reviewed the Defense Department program for clinical care of Gulf War veterans in active service and interacted with personnel in the Office of Health Affairs. The Defense Department was looking for someone to review the program in general and make suggestions, and I accepted out of patriotism. I was very clear that ***I had no expertise in Anthrax*** and they were clear that they were looking for a general oversight of the vaccination program.
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> I visited the Pentagon on a number of occasions, talked with a variety of people in and out of government and presented my report which you have to the Secretary on March 2, 1998. ***I had no access to classified information.*** ...≅[60] (emphasis added)

Supplemental Testing

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[56] See *supra* note 16.

[57] In an April 16, 1999 telephone conversation with Subcommittee staff, Dr. Burrow said his charge was a general review of the program, and that as an internist, he has little experience with vaccines. His primary recommendation was the use of focus groups of military personnel to determine appropriate communication strategies.

[58] See *supra* note 16.

[59] *Ibid.*

[60] Letter from Dr. Gerard N. Burrow, Yale University School of Medicine, to Rep. Christopher Shays, April 26, 1999 (in subcommittee files).

To address concerns over the age and quality of stockpiled vaccine, DOD undertook an effort to re-test the product before use. A contractor was retained to conduct supplemental testing of vaccine lots, all of which had been manufactured in an aging production facility, and some of which had been approved by the FDA for use beyond the initial expiration date.

Mitretek Systems Inc. reviewed vaccine production records and observed additional testing conducted by BioPort personnel.[61] Of the 31 vaccine lots[62] subjected by DOD to supplemental testing, 18 remained unavailable as of July, 1999 due to unresolved purity, potency or sterility issues.[63]

Some involved in the program opposed supplemental testing as redundant and likely to cause more problems than it solved by establishing a self-imposed vaccine safety standard in addition to FDA lot-release criteria.[64] Their concerns were validated when the supplemental testing program appears to have overwhelmed the MBPI/BioPort testing capabilities, producing anomalous results and delaying the program.[65] Once the testing problems became apparent, vaccine lots not technically in the stockpile when the AVIP was announced were not subjected to the supplemental assays under the rationale the FDA was requiring the same tests for lot release.[66] All the lots submitted for supplemental testing had also undergone the same FDA lot

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[61] See *supra* note 17, p. 3.

[62] Each lot contains approximately 200,000 doses of vaccine.

[63] See *supra* note 26, p. 13.

[64] Dr. Michael Gilbreath, Information Paper, JPO 0364, Feb. 4, 1998 (in subcommittee files); prepared statement of Dr. Robert C. Myers, Chief Operating Officer, BioPort Corporation, NSVAIR Anthrax Hearing (II), p. 83-84.

[65] *Ibid.* (Gilbreath Information Paper)

[66] Letter from Sec. of Defense William Cohen to Reps. Shays (CT), Gilman (NY), Kelly (NY), Souder (IN), Ose (CA), and Talent (MO), September 30, 1999, Attachment p. 1 (in subcommittee files).

release protocols.

Animal Data on Efficacy

DOD=s determination the vaccine affords protection against virtually all strains of airborne anthrax spores rests primarily on studies of vaccinated animals (guinea pigs, rabbits and monkeys) challenged with various strains of the disease.[67] But widely varied results within and between animal species suggest variable modes of protection not necessarily correlated to antibody levels stimulated by the vaccine.[68] Without a proven model in animals that is known to correlate to protection in humans, animal data remains only suggestive.

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[67] Testimony of Dr. Sue Bailey, DOD Assistant Secretary for Health Affairs, NSVAIR Anthrax Hearing (I), p. 11.

[68] Prepared statement of Dr. Meryl Nass, NSVAIR Anthrax Hearing (II) p. 108-111.

Vaccine-acquired anthrax immunity may also be limited or overwhelmed when the subject is challenged with variant anthrax stains.[69] A report by the Senate Committee on Veterans= Affairs concluded that:

> Adata suggests that the vaccine can protect humans against inhaled anthrax but to date there is inadequate information to judge how well it works, particularly against weaponized anthrax, which could cause exposure to greater concentrations of anthrax than has occurred among workers exposed on the job.≅[70]

In response to questions regarding the efficacy of the vaccine against antibiotic resistant or genetically altered anthrax strains, DOD said

> AThe current US-licensed anthrax vaccine is considered to be highly effective against naturally occurring strains of anthrax, including antibiotic resistant strains. The development of genetically engineered organisms using anthrax or any other biological warfare agent is a potential threat that must be evaluated carefully. We are not aware, however, of any information to suggest that these modified strains have been used in any context other than the research laboratory.≅[71]

When one U.S. laboratory studying the release of anthrax at Sverdlovsk implied the Russian mixtures of anthrax strains might overcome the protection afforded by the anthrax vaccine, DOD persuaded the author Ato correct the press release to make it more accurate. The modification stated, in part, Athere is no experimental data or evidence to suggest that such a mixture is resistant to the FDA-licensed anthrax vaccine used by the US military.≅[72]

Opposition to the AVIP

Some have refused the vaccine. Active duty personnel have been disciplined under service-specific policies for refusing a lawful order. Reservists and National Guard members have resigned or transferred to units or Anon-mobility≅ positions which do not require the vaccine. The DOD does not collect uniform records on refusals, but media reports indicate more than 300

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[69] *Ibid.*

[70] *Report of the Special Investigation Unit on Gulf War Illnesses*, Senate Committee on Veterans= Affairs, 105th Congress, 2nd Session, September 1998, S. Rpt. 105-39, p. 122. See aslo, AIs Military Research Hazardous to Veteran=s Health? - Lessons Spanning Half a Century,≅ Staff report prepared for the Committee on Veterans Affairs, United States Senate, p. 11, 103d Congress, 2d Session, S. Prt. 103-97, December 8, 1994.

[71] See *supra* note 66.

[72] *Ibid.* Nor is there data demonstrating the vaccine is effective against altered or mixed anthrax strains.

service men and women have refused to take the shot.[73]

[73] AVaccine Refused by 23 Aircraft Carrier Sailors,≅ *Associated Press*, March 11, 1999 (in subcommittee files). The reported number of vaccine refusers has remained fairly stable in public reports, between 200 and 300, for some months.

Hearing testimony and correspondence from Reservists and National Guard members suggests up to 30 percent of some units would resign or seek to transfer due to the anthrax program.[74] Their concerns focus on the lack of systematic, long-term studies on anthrax vaccine health effects.[75]

Safety is also an issue for some because the anthrax vaccine is one of the exposures under study by the National Academy of Science=s Institute of Medicine (IOM) pursuant to the Persian

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[74] *Impact of the Anthrax Vaccine Program on Reserve and National Guard Units*, 106th Cong., 1st sess., p. 57 (Subcommittee on National Security, Veterans Affairs and International Relations hearing, Sept. 29, 1999) [hereinafter ANSVAIR Anthrax Hearing (V)] [The Subcommittee hearing has not yet been printed. Page numbers in this and subsequent references to statements at this hearing refer to individual prepared written statements or the unofficial transcript, held in subcommittee files.] (testimony of Capt. David Panzera; testimony of Tech. Sgt. William Mangieri, NSVAIR (V), p. 58) See also, testimony of Capt. Thomas Rempfer, NSVAIR Anthrax Hearing (I), p.110; testimony of Maj. Redmond Handy, NSVAIR Anthrax Hearing (I), pp. 102-102. DOD does not collect data on refusals or resignations attributable to the vaccine. An informal survey of Reserve and Guard units shows more than 700 current or likely departures due to the AVIP. The survey can be found at: http://www.dallasnw.quik.com/cyberella/Anthrax/Chron_Info.html, p. 12-13.

[75] Testimony of Col. Redmond Handy, NSVAIR Anthrax Hearing (I), p. 91; prepared statement of Ms. Randi Martin-Allaire, NSVAIR Anthrax Hearing (II), p. 171; prepared statement of Sgt. Michael Shepard, NSVAIR Anthrax Hearing (II), p. 193; testimony of Major Cheryl Hansen, NSVAIR Anthrax Hearing (V), p. 31.

Gulf War Veterans Act of 1998, enacted as Title XVI of the 1998 Omnibus Appropriations Act, P.L. 105-277. The law directs IOM to review associations between illnesses and wartime exposures that warrant a presumption of service-connection for sick Gulf War veterans.[76] That study is ongoing.

Efforts to meet Secretary Cohen=s four preconditions to AVIP implementation, intended to address likely reservations about the program, have only served to intensify concerns:[77]

1. Problems with supplemental testing underscore vaccine safety and production issues. The failure to test all lots produced before the plant closed suggests to some the promise of supplemental testing was not fulfilled.

[76] P.L. 105-277, title XVI.

[77] Letter from Reps. Benjamin Gilman (NY), et. al. to Defense Secretary William Cohen, July 20, 1999, p. 1 (in subcommittee files).

2. The prerequisite communication effort engenders resentment and mistrust as simplistic DOD attempts at education and risk communication portray very limited vaccine use as Aroutine≅[78] and attack those with legitimate questions as Aparanoics≅[79] and simple-minded victims of Internet propaganda.[80]

3. Delays in posting data to the tracking system reduce its value as a real time indicator of medical readiness and increases tolerance of deviations in the FDA approved inoculation regimen.[81]

4. Contrary to subsequent DOD characterizations, the promised outside, expert, scientific review of the program was only very general in nature.[82]

Others question the necessity of the program, asking whether it betrays a lack of confidence in deterrence and other force protection elements, and suggesting a vaccine program makes anthrax attack more, not less, likely.[83]

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[78] See *supra* note 14.

[79] Lt. Gen. Ronald Blanck, AIgnore the Paranoics: The Vaccine is Safe,≅ *Army Times*, Feb. 2, 1999, p. 12.

[80]Douglas J. Gilbert, American Forces Press Service, AAnthrax Vaccine Called Effective Force Protection,≅ *DefenseLink*, Nov. 5, 1998 (in subcommittee files); *Washington Times*, AAnthrax Shots Drive Air Force Veteran From Service,≅ October 13, 1999, p. 18; *PBS New Hour*, AAnthrax Vaccine,≅ Oct. 21, 1999 (comments of Gen. Blanck) (transcript in subcommittee files); Col. Guy Strawder, AAVIP Director=s Newsletter≅ (in subcommittee files).

[81] Bradley Graham, AAnthrax Shots Missing Targets?≅ *Washington Post*, Sept. 29, 1999, p. A27.

[82] See supra note 60 and accompanying text.

[83] Testimony of Capt. Thomas Rempfer, NSVAIR Anthrax Hearing (I), p. 40-41; testimony of Maj. Russell Dingle, NSVAIR Anthrax Hearing (I), p.49.

Hearings and Legislative Proposals

On March 24, 1999 the Subcommittee on National Security, Veterans Affairs and International Relations held the first of five hearings on the Department of Defense (DOD) Anthrax Vaccination Immunization Program (AVIP). Entitled, AOversight of the Anthrax Vaccine Inoculation Program,≅ the hearing examined the effectiveness and efficiency of the AVIP as a medical force protection measure, a record keeping initiative and long term procurement. The Subcommittee heard testimony from Dr. Sue Bailey, Assistant Secretary for Health Affairs, U.S. Department of Defense, accompanied by, Lt. Gen. Ronald R. Blanck, U.S. Army; Rear Admiral Todd Fisher, Deputy Surgeon General U.S. Navy; and Lt. Gen. Charles H. Roadman, II, U.S. Air Force; Capt. Thomas Rempfer, Connecticut Air National Guard; Maj. Russell Dingle, Connecticut Air National Guard; Pfc. Stephen M. Lundbom, U.S. Marine Corps; Attorney Mark Zaid; Col. Redmond Handy, Member Reserve Officer Association; and Lorene K. Greenleaf.

On April 29, 1999, the Subcommittee held a hearing on the AVIP entitled, AAnthrax (II): Safety and Efficacy of the Mandatory Vaccine.≅ The purpose of this hearing was to examine the vaccine=s safety and effectiveness against an aerosolized biological weapons attack. Individuals who testified disputed the Department of Defense claim the vaccine is unquestionably safe for force wide use. Some who testified are experiencing serious illnesses they associate with the anthrax vaccine. Testimony was received from Kwai-Cheung Chan, Director, Special Studies and Evaluations Section, National Security and International Affairs Division, General Accounting Office; Dr. Katherine Zoon, Director, Center for Biologics Evaluation and Research, Food and Drug Administration; Dr. Michael Gilbreath, Medical Project Manager, Joint Program Office for Biological Defense; Dr. Robert Myers, Chief Operating Officer, BioPort Corporation; Dr. Meryl Nass; David Churchill; Randi Martin-Allaire; Roberta Groll; and Michael Shepard.

On June 30, 1999 the Subcommittee held a hearing entitled, A Oversight of DOD Sole Source Anthrax Vaccine Procurement.≅ The primary focus was to examine AVIP acquisition strategies and procurement activities pursued by the Department of Defense to purchase the vaccine. Issues examined included the technical and financial ability of BioPort to supply the vaccine at the contracted price, and the effect of management problems on the safety and the quality of the vaccine produced. Testimony was given by Louis J. Rodrigues, Director, Defense Acquisition Issues, National Security and International Affairs Division, General Accounting Office; David Oliver, Jr., Principal Deputy Under Secretary of Defense for Acquisition and Technology, Department of Defense; and Fuad El-Hibri, Chief Executive Officer, BioPort Corporation.

On July 21, 1999, the National Security Subcommittee held its fourth hearing on the AVIP. Entitled, AAnthrax Vaccine Adverse Reactions,≅ the hearing focused on the program=s willingness to recognize and ability to treat adverse reactions to the vaccine in military personnel.

[redacted]

the joint FDA/CDC Vaccine Adverse Event Reporting System (VAERS), under-reports adverse events and adverse vaccine reactions. Testifying at this hearing were CPT Michelle Piel, USAF; LT Richard Rovet, USAF; SGT Robert Soska, USA; CPT Jon Richter, USAR; Kwai-Cheung Chan, Director, Special Studies and Evaluations Section, National Security and International Affairs Division, General Accounting Office; MG Robert Claypool, Deputy Assistant Secretary for Health Operations Policy, Department of Defense accompanied by, RADM Michael Cowen, Deputy Director for Medical Readiness, Joint Staff, Department of Defense; and COL Renata Engler, Chief, Allergy-Immunology Department, Walter Reed Army Medical Center; and Dr. Susan Ellenberg, Director, Division of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, Food and Drug Administration.

The Subcommittee held its fifth hearing on the AVIP on September 29, 1999 entitled, AImpact of the Anthrax Vaccine Program on Reserve and National Guard Units.≅ The hearing examined the implementation of the AVIP in reserve component units and the impact of the program on retention, readiness and morale. Testifying at the hearing were Lt. Col. Thomas Heemstra, Indiana Air National Guard; Maj. Cheryl Hansen, Air Force Reserves; Capt. David Panzera, New York Air National Guard; Tech. Sgt. William Mangiere, New York Air National Guard; Charles Cragin, Acting Assistant Secretary for Reserve Affairs, Department of Defense, accompanied by, Maj. Gen. Paul Weaver, Jr., Director, Air National Guard, Department of Defense; Col. Frederick Gerber, Director, Health Care Operations, Office of the Army Surgeon General, Department of Defense; and Col. James Dougherty, Air Surgeon, National Guard Bureau, Department of Defense.

In the first session of the 106 Congress, two bills were introduced regarding the anthrax vaccine program:

Rep. Walter Jones (NC) introduced HR 2543 on July 16, 1999. Entitled AThe American Military Health Protection Act,≅ the bill would instruct the Department of Defense to make the anthrax vaccination immunization program voluntary for all members of the Armed Forces until the FDA has approved a new anthrax vaccine for humans or the FDA has approved a new, reduced course of shots for the current anthrax vaccine. This bill was referred to the Committee on Armed Services.

Rep. Benjamin Gilman (NY), introduced HR 2548 on July 19, 1999, cosponsored by Reps. Sue Kelly (NY) and Bob Filner (CA). HR 2548 would suspend further implementation of the Department of Defense anthrax vaccination program until the vaccine is determined to be safe and effective through a study by the National Institutes of Health. The Department of Defense Anthrax Vaccination Moratorium Act was referred to the Committee on Armed Services and to the Committee on Commerce.

The FY2000 Defense Appropriations Act (HR 2561) contained a provision directing the Comptroller General to report on: effects on morale, retention and recruiting; the civilian costs and burdens associated with adverse reactions for members of the reserve components; adequacy of long and short term health monitoring; assessment of the anthrax threat, including but not

limited to foreign doctrine, weaponization, quality of intelligence, and other biological threats. DOD was directed to contract with the National Research Council to conduct studies on: vaccine adverse events and adverse reactions, particularly among women; vaccine efficacy against inhalation anthrax; correlation of animal models to safety and efficacy in humans; research gaps; and other matters.

Discussion

Findings

1. The AVIP is a well-intentioned but over-broad response to the anthrax threat. It represents a doctrinal departure overemphasizing the role of pre-exposure medical intervention in force protection.

DOD bases the scope of AVIP on the scope of the threat, and the perceived need for additional, individual force protection to meet that threat. Threat assessment requires objective and subjective analyses of U.S. vulnerability, enemy capacity, and enemy intentions. AA threat analysis, the first step in determining risk, identifies and evaluates each threat on the basis of various factors, such as its capability and intent to attack an asset, the likelihood of a successful attack, and its lethality.≅[84]

Since the King of Athens poisoned his enemy=s wells in 600 BC and Alexander the Great hurled diseased animal corpses over the walls of a besieged city, ground forces have been vulnerable to casualties caused by natural or pernicious exposure to chemical and biological pathogens.[85] But in the absence of proven capability and intent to use biological weapons, vulnerability alone does not constitute a validated threat for purposes of determining appropriate and effective countermeasures.

Appropriately, much of the information regarding the BW capabilities and intentions of potential adversaries, and even allies, is classified. As a result, most public descriptions of the anthrax threat focus on the general vulnerability of unprotected forces to anthrax attack, the general ease and availability of anthrax production and the likely lethality of a successful anthrax attack.

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[84] *Combating Terrorism - Threat and Risk Assessments Can Help Prioritize and Target Program Investments*, U. S. General Accounting Office, GAO/NSIAD-98-74, April 1998 p. 3.

[85] Dr. Stephen C. Joseph, Assistant Secretary of Defense for Health Affairs, ABiological Warfare - INFORMATION MEMORANDUM≅ (undated) p.2 (in subcommittee files).

According to various unclassified DOD statements, more than ten countries Ahave, or are developing, a biological warfare capability.≅[86] Those nations are: China, Iran, Iraq, Israel, Libya, North Korea, South Korea, Syria, Taiwan and Russia. Other public lists also include Egypt, Cuba, Japan, and the former Soviet states in Eastern Europe that may have inherited bio-warfare capabilities.[87] For purposes of the AVIP, AThe high threat areas validated by our intelligence community for the potential use of anthrax as a biological weapon of mass destruction includes [sic] Korea, Israel, Jordan, Kuwait, Saudi Arabia, Bahrain, Qatar, Oman, UAE and Yemen.≅[88] Anthrax is not seen as a threat in the Balkans.[89]

Other descriptions of the anthrax threat focus on the relative ease of acquisition, mass production and weaponization of the stable, long-lasting anthrax microbe. According to DOD, production of biological warfare agents does not require specialized equipment or advanced technology. Biological agents are more potent and efficient than chemical weapons, and can be delivered through a variety of means. Legitimate uses (i.e. vaccine manufacture) for Adual use≅ production technologies make counter-proliferation strategies difficult to implement

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[86] DOD Information Paper, ADOD Biological Warfare Threat Analysis,≅ 12/15/97, p. 1. See also, *Proliferation: Threat and Response,* Department of Defense, November 1997.

[87] Office of Technology Assessment, U.S.Congress, AProliferation of Weapons of Mass Destruction: Assessing the Risks,≅ p. 65, OTA-15C-559, August, 1993 (in subcommittee files). Notably included among those nations are U.S. allies who, it must be presumed, pose less danger to U.S. forces than nations currently opposing U.S. policy goals.

[88] See *supra* note 66, Attachment p. 13.

[89] *Ibid.*

successfully.[90]

Secretary Cohen told Members, AAnthrax poses a clear and present danger to our armed forces. It is the weapon of choice for germ warfare because it is easy to weaponize and is as lethal as the Ebola virus. At least seven potential adversaries have worked to develop the offensive use of anthrax.≅[91]

In testimony before a subcommittee of the House Armed Services Committee, Deputy Secretary of Defense John Hamre said, ACurrently, at least ten nation states and two terrorist groups are known to possess, or have in development, a biological warfare capability.≅[92]

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[90]See *supra* note 86. The release of deadly chemical sarin gas in Tokyo by the Aum Shinrikyo cult highlighted the terrorist, and by implication, the military threat posed by chemical and biological weapons. But subsequently acquired information regarding the cult=s unsuccessful attempts to use biological agents is seen by some as a counter to the argument those agents are not technically challenging to produce and deploy.

[91]See *supra* note 66.

[92] Prepared statement of Hon. John J. Hamre, Deputy Secretary of Defense, submitted to the Subcommittee on Military Personnel, House Committee on Armed Services, p. 2, September 30, 1999.

DOD testimony to the Subcommittee portrayed the threat similarly: AAs identified by the Chairman of the Joint Chiefs of Staff, anthrax is a major threat to our troops. Anthrax is the primary biological warfare threat faced by U.S. forces. More than 10 countries, including Iraq, have or are suspected of developing this biological warfare capability. Anthrax is the biological weapon most likely to be encountered because it is highly lethal, easy to produce in large quantities, and relatively easy to develop as a weapon.≅[93]

The AVIP tri-fold brochure describes the threat as follows:

> ABiological weapons are maintained by several countries around the world. Use of these weapons could cause widespread illness among unprotected military forces.
>
> Anthrax is the biological weapon most likely to be encountered because it is:
> X Highly lethal
> X Easy to produce in large quantities
> X Relatively easy to develop as a weapon
> X Easily spread over a large area
> x Easily stored and dangerous for a long time≅[94]

Clearly, DOD has determined the threat is real and imminent, and has concluded it would be irresponsible not to deploy an available countermeasure to protect the lives and fighting capability of U.S. forces.[95]

But similar statements on the threat have been made by DOD for many years. According to GAO testimony, AThe nature and magnitude of the military threat of biological warfare (BW) has not changed since 1990, both in terms of the number of countries suspected of developing BW capability, the types of BW agents they possess, and their ability to weaponize and deliver those BW agents. Inhalation anthrax is considered by DOD to be the primary BW threat because

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[93] Prepared statement of Dr. Sue Bailey, DOD Assistant Secretary for Health Affairs, NSVAIR Anthrax Hearing (I), p. 8.

[94] See *supra* note 14.

[95] Prepared statement of Dr. Sue Bailey, DOD Assistant Secretary for Health Affairs, NSVAIR Anthrax Hearing (I), p. 13.

of its lethality, ease of production, and weaponization.≅[96]

[96] Prepared statement of Kwai-Cheung Chan, Director, Special Studies and Evaluation Section, National Security and International Affairs Division, U.S. General Accounting Office, NSVAIR Anthrax Hearing (II), p. 12.

According to unclassified briefing materials assessing the anthrax threat, anthrax stocks and weaponized anthrax have been confirmed only in Southwest Asia. A stock of anthrax has been confirmed in Northeast Asia. Capacity to produce and weaponize anthrax elsewhere (South Asia or transnational) is suspected but unconfirmed.[97]

Assessment of the Iraqi threat concludes that substantial anthrax production capacity exists but exceeds the ability to weaponize. While Iraq appears likely to be able to launch a BW attack using AL HUSSEIN ballistic missiles, aircraft delivery is seen as less likely due to U.S. and Coalition air superiority.[98] So Saddam would be Aunlikely to use WMD unless he perceives regime=s survival at stake.≅[99]

So the threat remains tactically limited and regional. The AVIP is universal.

Several factors appear to have fueled the 1997 decision to launch a mandatory, force-wide program to address a long acknowledged, regionally-based threat.

After the Gulf War, the Department of Defense undertook what is now characterized as Aa detailed, deliberative process≅[100] over more than three years that culminated in the conditional decision to implement a mandatory, force-wide anthrax immunization program. AAfter a three year study, the Department has concluded that the vaccination is the only safe way to protect highly mobile U.S. military forces against a potential threat that is 99 percent lethal to

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[97] DOD, Briefing Slide entitled AAnthrax Threat,≅ April 20, 1998 (in subcommittee files).

[98] DOD, Briefing Slide entitled AAssessment≅April 20, 1998 (in subcommittee files).

[99] *Ibid.*

[100] Prepared statement of Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs, NSVAIR Anthrax Hearing (I), p. 8.

unprotected individuals.≅[101]

That study was conducted, for the most part, behind closed doors. However, the documentation provided to the subcommittee by DOD[102] describes a process more predetermined than deliberative, as the obvious operational benefits of passive, pre-exposure protection (versus cumbersome protective masks and suits), and the Iraqi threat, drove the decision to use the only vaccine currently available.[103]

[101] Letter from Sandra K. Stuart, Assistant Secretary of Defense (Legislative Affairs) to The Honorable Christopher Shays (CT), p.1, December 15, 1997.

[102] Letter from Rep.Christopher Shays, Chairman, Subcommittee on National Security, Veterans Affairs and International Relations, House Committee on Government Reform to Secretary of Defense William Cohen, May 12, 1999 (in subcommittee files)

[103] Department of Defesne, Information Paper ADOD Biological Warfare Force Protection,≅ December 15, 1997, p. 2 (in subcommittee files).

In November 1993, DOD Directive 6205.3 set out a broad policy supporting immunization research, development, testing, acquisition and stockpiling of vaccines against current and emerging biological warfare threats. The directive required immunization only of Adesignated≅ or Aprogrammed≅ personnel against agents Afor which suitable vaccines are available, in sufficient time to develop immunity before deployment to high threat areas....≅[104]

With regard to anthrax, DOD conducted research and program planning to develop an Aimproved anthrax vaccine≅ (IAV) that would generate immunity against the known threat in a reasonable time. According to a DOD Operational Requirements Document (ORD), the need for an improved vaccine was identified in the MNS (Mission Needs Statement) for Medical Defense Against Chemical and Biological Warfare Agents in August 1994 and in the MNS for Department of Defense Biological Defense in August 1992.[105]

The mission profile for the improved vaccine called only for inoculation of deployed and rapid deployment units Abased on intelligence estimates of the potential for use of specific BW agents against U.S. forces. ... Other military personnel will be vaccinated prior to departure to BW threat areas. An accelerated immunization program will be conducted under certain alert or mobilization conditions.≅[106]

Shortcomings of the currently licensed vaccine were seen as the Aserious logistical obstacles, especially for reserve forces≅ posed by the approved six-shot schedule and reports that suggest Athis vaccine may not provide universal protection against all anthrax strains.≅[107] Minimum standards for the improved vaccine included generation of a protective immune response within 14 days of administering three inoculations.

Briefing materials produced by the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) in 1994 listed the following problems with the current vaccine:

Prolonged immunization schedule

Reactogenicity:

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[104] See *supra* note 7, p. 2.

[105] Department of Defense, AOperational Requirements Document (ORD) for Improved Anthrax Vaccine,≅ Oct. 2, 1995, p. 1 (in subcommittee files).

[106] *Ibid.*, p. B-1.

[107] *Ibid.*, p. 2.

Systemic reactions: .7 - 1.3%
Significant local reactions: 2.4 -3.9% (5.9%)

Vaccine components completely undefined in terms of characterization and quantitation of the PA, and other bacterial products and constituents present

Significant lot-to-lot variation in the PA immunogen content
Human trials with similar but not identical vaccine showed protection against cutaneous anthrax but insufficient data to show efficacy against inhalation anthrax

Made from spore-forming strain requiring dedicated production facility[108]

Minutes of a May 1994 USAMRIID meeting addressed Athe Army=s need for a new Anthrax vaccine. This need is based on reactogenicity of the current vaccine, the desire to make a vaccine with defined and well characterized components, and the need to produce a vaccine which does not require a BL-3[109] containment for production or a dedicated production facility, since *B. anthracis* is a spore former.≅[110]

Iraq=s 1995 declarations to the United Nations Special Commission (UNSCOM) described Aa substantial BW program≅[111] including 8,000 liters of anthrax, 6,000 of which Iraq claimed to have weaponized in missile warheads, aerial bombs, rockets, remote-control aircraft and agricultural sprayers mounted on planes and helicopters.[112] At the same time, DOD interest in an improved anthrax vaccine diminished sharply. Reservations about the suitability of the old vaccine were put aside once it was made the centerpiece of the proposed immunization effort.

The vaccine program is just one element of the Joint Biological Warfare Defense concept encompassing:

X detection and warning
X individual (masks, suits) and collective protection (sealed command and control facilities)
X medical (vaccines) countermeasures to prevent disease
X contamination avoidance

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[108] U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Briefing Slide AProblems with Current MDPH Vaccine,≅ (undated) (in subcommittee files).

[109] Bio-Safety Level 3, the second most stringent of the four levels of controls to protect persons handling infectious agents. For a description of current bio-safety standards see: http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s3t.htm

[110] See *supra* note 44, p. 1.

[111] See *supra* note 85, p. 5.

[112] *Ibid.*

X decontamination[113]

Treaties, anti-proliferation regimes, as well as the prospect of tactical and nuclear retaliation, are also meant to deter use of chemical an biological weapons.

[113] *Ibid.*, p. 7.

These are meant to be parts of an Aintegrated and overlapping systems approach to BW defense[114] in which both military and medical considerations dictate a hierarchy of force protection measures emphasizing contamination avoidance and physical protection over medical intervention and decontamination. One statement of chem/bio defense doctrine ranks force protection strategies as follows:

> A... The most effective and singularly most important prophylaxis in defense against biological warfare agents is physical protection. Preventing exposure of the respiratory tract and mucous membranes ... to infectious and/or toxic aerosols through use of a full-face respirator will prevent exposure, and should, theoretically, obviate the need for additional measures. Chemical protective masks effectively filter biological hazards.
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> ... All medical prophylactic modalities described should be viewed only as secondary (i.e. backup), and are not be relied upon as primary protective measures. Agent exposures near the source of dissemination will be high, and likely to overwhelm any medical protective measure.≅[115]

The AVIP makes medical prophylaxis a primary aspect of force protection and CBW deterrence. In testimony, the DOD Assistant Secretary for Health Affairs put the proposition quite directly: AOur greatest and prime biological enemy today is anthrax. And our strongest weapon against anthrax is vaccination.≅[116] The Navy=s Deputy Surgeon General added:

> AWe are fortunate to have a time tested, safe and effective vaccine to provide an

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[114]DOD, *Medical Defense Against Biological Material*, (undated) p. 1.

[115]*Ibid.* The section on Prophylaxis and Therapy continues: AThe precise efficacy of available medical countermeasures has, of course, never been evaluated in actual field circumstances, but is largely inferred from laboratory studies on nonhuman primates. While these extrapolations may be inexact, the strongly support the efficacy of vaccines and drugs at some agent dose.≅ (emphasis original)

[116]Testimony of Lt. Gen. Charles H. Roadman, Surgeon General, USAF, NSVAIR Anthrax Hearing (I), p.17.

important element of the body armor needed to defend our personnel against weaponized anthrax. Anthrax has now joined other immunizations received by our Service men and women to protect against disease threats just as important as wearing a gas mask or carrying a rifle when on the battlefield.≅[117]

[117]Testimony of R.Adm. Todd Fisher, Deputy Surgeon General, USN, NSVAIR Anthrax Hearing (I), p17.

The Air Force Surgeon General expressed a similar rationale: AIn addition to the potential human cost, mass casualties would degrade our military mission, military capability and mission accomplishment. We would not send people into battle without helmets and weapons. So we should also provide the best armor against biological dangers that we can. That armor is immunization.≅[118]

But some service members see an important difference between the physical body armor worn in battle, which can be removed, and medical prophylaxis, which cannot. AThe body armor that our Department of Defense refers to is perceived by many service members as >tin foil armor=.≅[119]

Primary reliance on medical intervention may also undermine confidence in other elements of the force protection hierarchy. One hearing witnesses asked if the vaccine might not Acreate a facade of force protection≅ provoking an adversary to even more lethal chem/bio or conventional attack.[120] He noted:

> AThese foundations of force protection rely on a credible willingness to use force. This resolve won the Cold War and it won the Gulf War. Abandoning this time tested doctrine and emphasizing the inevitability of biological attack to advocate a defensive anthrax vaccination policy may inadvertently result in legitimizing biological warfare.≅[121]

The vaccine policy also reflects a lack of confidence in current force protection equipment. Physical barriers, effective against all toxins and microbes if used properly and in time, are now viewed as Alikely to remain only partially effective for the foreseeable future.≅[122] Protective suits and masks Adegrade individual operating capabilities and force effectiveness ...≅[123] The

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[118] Testimony of Lt. Gen. Charles H. Roadman, II, Surgeon General, USAF, NSVAIR Anthrax Hearing (I), p. 18.

[119] Testimony of Captain Thomas Rempfer, NSVAIR Anthrax Hearing (I), p. 40.

[120] *Ibid.*

[121] *Ibid.*

[122] See *supra* note 85, p. 11.

[123] *Ibid.*

purpose of the current doctrine on bio/chemical defense Ais to maintain combat operations unencumbered by contamination and the wearing of the protective gear.≅[124]

[124]See *supra* note 103.

Even this doctrinal reliance on the primacy of medical protection does not necessarily demand the universal, pre-deployment inoculation that characterizes the AVIP. Throughout the policy deliberation process, the option was considered to hold vaccines in stockpiles and defer actual immunization until mobilization to a threat area.[125] As late as September 1997, decision memoranda to the Under Secretary of Defense contained a recommendation to: AMaintain the planning guidance for total force immunization as a contingency plan, ready for finalizing, coordination, and approval at the appropriate time based on: (a) resolution, in conjunction with the FDA, of facility production issues; and/or (b) changes in the validated anthrax biological warfare threat.≅[126]

The decision to launch the force-wide, mandatory immunization program, despite well documented misgivings about the vaccine and the capacity of the vaccine manufacturer, seems to have been driven by a genuine concern to avoid casualties, a military requirement for theoretically uniform protection within deployed units, an expansive view of demands on U.S. troop mobility, and the daunting logistics of the chosen vaccine.

AWhy is it essential that the anthrax immunization be mandatory? Military commanders have the responsibility to ensure the health and safety of their troops and to carry out their mission responsibilities. Anthrax is a serious threat. We have a safe and efficacious vaccine. To not use the vaccine constitutes a failure to protect our troops and a risk to carrying out military missions.≅[127] According to DOD, AWe are morally obligated to provide the best protection we are capable of providing to our troops -- in the case of protection against anthrax, there is a vaccine to provide individual immunity to this biological warfare agent.≅[128] According to Dr

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[125] Dr. Edward D. Martin, et. al., Acting Assistant Secretary of Defense (Health Affairs), Department of Defense, AMemorandum for Deputy Secretary of Defense - Anthrax Vaccination Implementation Plan - ACTION MEMORANDUM,≅ p. 1, Sept. 19, 1997 (in subcommittee files).

[126] *Ibid.*, p. 2.

[127] Prepared statement of Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs, NSVAIR Anthrax Hearing (I), p. 10.

[128] DOD, *Public Affairs Talking Points*, p. 1, December 15, 1997.

Bailey, ALike other vaccines that are required to prepare military personnel for deployment, the anthrax vaccine is mandatory.≅[129]

[129] Prepared statement of Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs, NSVAIR Anthrax Hearing (I), p. 10.

But the anthrax vaccine requirement differs from general military immunization and chemoprophylaxis policy in two significant respects. Other inoculations are required pursuant to medical, not military command authority,[130] and they are required primarily to maintain and protect the health of personnel from naturally occurring diseases or pathogens endemic to specific duty or deployment areas. Although the threat of natural anthrax Aremains a significant problem in numerous countries throughout Africa, the Middle East, Europe and Asia,≅[131] the general military immunization policy contains no reference to the anthrax vaccine.

When asked how the U.S. program compared to the approach of allied forces, such as Great Britain which began a voluntary program, or Israel which appears to rely primarily on antibiotic treatments, the Pentagon responded, ADOD does not base its policies on those of our allies or coalition partners.≅[132] Because Aour Armed Forces must be prepared to conduct successful military operations worldwide at a moments [sic] notice,≅ DOD believes the Amandatory AVIP is clearly in our best interests and strongly supports our national security and military strategies.≅[133]

But there will be exceptions. A July 1999 Defense Threat Reduction Agency policy on anthrax immunization says:

> ADeploying civilian employees who decline to participate in the DTRA-AVIP will be required to execute a AStatement of Informed Declination≅ attesting to the Agency=s offer of anthrax immunization and the individual=s decision to decline. By signing this statement, the employee acknowledges and willingly assumes the enhanced medical risk associated with travel to affected regions without receiving the recommended vaccinations. Hence, his/her deployment to these regions in support or mission requirements will not necessarily be precluded. This statement will become a part of the individual=s permanent Occupational Health Record.≅[134]

One of the primary reasons for the mandatory AVIP is the perceived need for consistent levels of force protection within and between deployed units to guarantee military effectiveness. Field commanders need to know the capabilities of their members. But even the force-wide, mandatory anthrax vaccine program is unlikely to meet that need. DOD concluded, but cannot

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[130] Department of Defense, *Medical Services - Immunizations and Chemoprophylaxis*, Army Regulation 40-562, NAVMEDCOMINST 6230.3, AFR 161-13, CG COMDTINST M6230.4D, October 7, 1988.

[131] See supra note 105, p. 1.

[132] See supra note 66, p. 14.

[133] *Ibid.*

[134] Defense Threat Reduction Agency, *Policy Memorandum 99-22*, July 23, 1999, p. 2 (in subcommittee files).

prove, that individual antibody response to the vaccine equals protection from anthrax attack. That is, DOD believes the more anthrax-fighting antibodies produced, the more medical Abody armor≡ has been acquired. Animal studies suggest this may be the case for some species, but no correlate has been found in humans to permit extrapolation of this conclusion.[135]

[135] Prepared statement of Kwai-Cheung Chan, NSVAIR Anthrax Hearing (II), p.17.

In any event, DOD does not test military personnel for antibody levels to determine the extent to which members of a unit may have acquired protection against anthrax. Uniform protection is also unlikely because individual immunological response to the vaccine can vary substantially due to a variety of factors, including gender, and contemporaneous administration of other vaccines or medicines.[136] Nevertheless, DOD concludes enrollment in the AVIP equals protection for purposes of satisfying the need for uniform force protection.[137]

And, the very factors cited by DOD as necessitating universal AVIP coverage may actually work against that goal. Rapid mobility and the mixture of active and reserve forces mean individuals bring variable levels of protection to their assignments, depending on the number of shots taken to date and their individual immune system response. Some people don=t respond to the vaccine at all.[138] So, beyond the general proposition that vaccinated individuals are likely to have some protection against some level of attack, the AVIP will not assure a commander that a unit is uniformly or even substantially protected. In tactical terms, the protection afforded by vaccination would be needed only during the time between detection and the order to deploy individual and collective physical protective measures (suits, masks, tents, etc.). Better detection capability, improved masks and a battlefield doctrine to deploy protective measures earlier could limit or eliminate the need even for that small window of protection provided by the vaccine.

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[136] Testimony of Col. Renata Engler, Chief, Allergy-Immunology Service, Walter Reed Army Medical Center, NSVAIR Anthrax Hearing (IV), p. 173.

[137] See *supra* note 46, p. 1.

[138] Investigational New Drug (IND) application for Anthrax Vaccine Adsorbed (AVA) submitted by Michigan Biologic Products Institute, Lansing, Michigan, September 20, 1996, pp. 28 -29 (in subcommittee files).

2. The AVIP is vulnerable to supply shortages and price increases. The sole-source procurement of a vaccine that requires a dedicated production facility leaves DOD captive to old technology and a single, untested company. Research and development on a second-generation, recombinant vaccine would allow others to compete.

DOD has built a force-wide program on the narrowest possible industrial base.

According to GAO, AThe most critical component of the program, an adequate supply of vaccine, is threatened by testing delays and possible loss of production capability.≅[139] Moreover, GAO found ADOD=s plans for maintaining an adequate supply of vaccine are optimistic ... and assume that FDA will grant approval of tested lots in less time than in the past.≅[140] Despite the possibility of further delays or a recurrence of financial problems at BioPort, ADOD does not have a formal contingency plan to deal with such possibilities.≅[141]

When DOD launched the AVIP, subject to the Secretary=s four conditions including supplemental testing, MBPI/BioPort held 40 lots of vaccine, roughly the equivalent of 8 million doses, or enough vaccine to provide 1.3 million people the full six-shot regimen (assuming all lots were used before the expiration of original or extended label dating). But problems in the supplemental testing program delayed or precluded release of 18 lots.[142] GAO found:

> AIn summary, as of June 23, 1999, only 713,000 doses in the stockpile were available for use, and more than half of them - about 416,000 doses - will expire in February and April 2000. On the basis of DOD=s estimates of doses required per month, the 713,000 doses would sustain phase 1 of the program through December 1999.≅[143]

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[139] See *supra* note 26, p. 12

[140] *Ibid.*, p. 5.

[141] *Ibid.*

[142] *Ibid.*, p. 13.

[143] *Ibid.*, p. 15; Including an estimated three-month supply already delivered to the field at

the time of this estimate, GAO concluded the program could be sustained at best through March 2000.

But even that delayed schedule may be optimistic. FDA inspectional findings on the renovated facility contain a number of observations repeated from the February 1998 inspection.[144] FDA considered those earlier findings Asignificant≅ and took issue with DOD officials characterizing cGMP matters as mere Abookkeeping difficulties≅ in public statements.[145] If problems with the renovated facility are determined to be significant enough to bar release of vaccine lots produced since May 1999,[146] DOD could face severe shortages.

Because resumption of vaccine production has been delayed longer than anticipated by plant renovations and efforts to meet FDA compliance requirements, implementation of Phase II of the AVIP, scheduled to begin in early 2000, has been delayed Ain the range of six to 12 months.≅[147]

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[144] FDA Form 483, November 15-23, 1999 (in subcommittee files). See also, *Stars and Stripes*, ACohen Defends Mandatory Anthrax Shots After Ordering FDA-Related Suspension,≅ p. 1, Dec. 20, 1999.

[145] E-mails between Food and Drug Administration and Department of Defense dated August 31 - September 1, 1999 (in subcommittee files).

[146] Production of consistency lots began in the renovated and expanded BioPort facility in May 1999. Data on consistency lots is submitted to FDA to validate the production process. Other lots have also been produced by BioPort in the expanded facility, but use of those at risk lots depends on FDA approval of the facility license supplement, an amendment to the license regarding the potency test and approval of test data on each lot.

[147] Dr. Sue Bailey, Department of Defense News Briefing, December 13, 1999, p.

In addition to production problems and delays, BioPort may not be a reliable financial partner in the vaccine enterprise. At the Subcommittee=s request, the General Accounting Office (GAO) examined the structure and status of the financial relationship between DOD and BioPort.[148] They reviewed the contract documents, proposals and analyses done in connection with DOD procurement of the anthrax vaccine.[149]

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2 (available at: http://www.defenselink.mil) (In subcommittee files).

[148]Letter to David Walker, Comptroller General, U.S. General Accounting Office from Rep. Christopher Shays, Chairman, Subcommittee on National Security, Veterans Affairs and International Relations, House Committee on Government Reform, May 13, 1999 (in subcommittee files).

[149]*Contract Management - Observations on DOD=s Financial Relationship with the Anthrax Vaccine Manufacturer*, Prepared statement of Louis J. Rodrigues, Director, Defense Acquisition Issues, National Security and International Relations Division, GAO, GAO/T-NSIAD-99-24, June 30, 1999.

Only nine months after entering into the agreement, BioPort=s ability to perform under the contract was in doubt.[150] In June 1999, the Defense Contract Audit Agency (DCAA) completed an audit of BioPort=s financial condition and reached a similar conclusion.[151] According to GAO, estimates contained in BioPort=s business plan and contract proposal have proven highly optimistic.[152]

As a result, BioPort had to request emergency assistance from DOD and major modifications to the contract.[153] In order to remain able to produce vaccine for the AVIP, BioPort sought and received an advance payment of $10 million, a significant per-dose price increase and DOD

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[150] Testimony of Louis J. Rodrigues, Director, Defense Acquisition Issues, National Security and International Affairs Division, U.S. General Accounting Office, NSVAIR Anthrax Hearing (III), p. 4.

[151] Defense Contract Audit Agency, Report No. 2261-97G21000018, Department of Defense, September 24, 1997 (in subcommittee files).

[152] Prepared statement of Louis J. Rodrigues, Director, Defense Acquisition Issues, National Security and International Relations Division, GAO, NSVAIR Anthrax Hearing (III), p. 7.

[153] DOD Briefing Slides, ABioPort Contract - Anthrax Vaccine,≅ June 2, 1999 (in subcommittee files). See also, BioPort Corporation media release, AAnthrax Vaccine Manufacturer Calls for Fair and Reasonable Cotract,≅ June 30, 1999 (in subcommitee files).

permission to sell up to 300,000 doses each year on the open market, despite the fact those doses would be produced using government furnished equipment under the DOD contract.[154] DOD also authorized BioPort=s sale of up to 70,000 doses from the vaccine produced under the prior contract but either released or deemed never part of the stockpile.[155]

This early, extraordinary relief was necessary because production delays reduced estimated income. And, the procurement had to be done by means of a fixed price contract because neither side to the contract knew what it actually cost to produce the vaccine.[156] In its transition from a state-owned facility to a private enterprise, MBPI/BioPort has not fully implemented promised cost control and cost accounting systems to support a more appropriate cost-reimbursement procurement.

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[154] Testimony of The Honorable David R. Oliver, Jr., Principal Deputy Under Secretary of Defense for Acquisition and Technology, NSVAIR Anthrax Hearing (III), p. 65.

[155] Testimony of The Honorable David R. Oliver, Jr., Principal Deputy Under Secretary of Defense for Acquisition and Technology, NSVAIR Anthrax Hearing (III), pp. 64-65. See also, DOD Briefing Slides, AAnthrax Vaccine Absorbed Information Brief,≅ June 4, 1999 (in subcommittee files). The briefing contained the following points: AMs. Spector advised that doese in the inventory that have been paid for cannot be used by BioPort for Private/Foreign Sales≅ and ARelease doses from stockpile for private sales - JPO/OSD action (very political).≅

[156] Testimony of Louis J. Rodrigues, Director, Defense Acquisition Issues, National Security and International Relations Division, GAO, NSVAIR Anthrax Hearing (III), p. 28.

GAO also found the dependent relationship between DOD and BioPort unusual and risky. While sole-source procurements for vaccines may be common, those producers usually have other product lines generating income from other customers. In this case, problems with the production and delivery of the one vaccine put the corporation in an extemely bad financial position.[157]

One vaccine producer operating a single production site also points to security risks. GAO observed, ABut if we are relying upon this vaccine as part of the backbone of our defensive biological program, the question of vulnerability to a single site becomes an issue. If you made a decision with respect to that vulnerability that led you to want to have an alternative site, then we probably should be looking at establishing a second source.=[158]

Following the Gulf War, and prior to adoption of the DOD immunization policy (1993) and the mandated AVIP (1998), Pentagon officials considered and rejected alternative anthrax vaccine production sites.[159] Instead, an acquisition strategy was adopted focusing solely on the MBPI/BioPort vaccine.[160]

Since 1993, DOD has focused almost exclusively on the older, FDA approved vaccine, to the exclusion of development work on newer, recombinant vaccine formulations. Not surprisingly, DOD market surveys detected little interest by other pharmaceutical or biologics companies in producing the older anthrax vaccine under a licence from MBPI. So it appears DOD=s sole source justification may be self-validating, in that there is only one AVA producer because the single largest vaccine customer has decided to deal with only one producer.

Other manufacturers would be more likely to express an interest in recombinant vaccine production because it can be done more safely and efficiently than older vaccine formulation methods involving live bacteria. But DOD decided not to emphasize recombinant anthrax vaccine development due to the lengthy (6 to 8 years) development and approval time, and potential high costs.

Yet, had DOD officials elected to pursue second-generation anthrax vaccine development aggressively six years ago, they would be nearing completion on a newer, purer anthrax vaccine. BioPort=s current financial demands, and the company=s power to hold the AVIP hostage in the future, appear to undermine DOD=s determination the MBPI/BioPort acquisition strategy would

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[157] *Ibid.*, p. 16.

[158] *Ibid.*, p. 15.

[159] See *supra* note 36, p. 1.

[160] See *supra* note 37.

prove more affordable than new vaccine development.

One legal review of the BioPort contract sole source justification suggested DOD add a reference to ways competition might be increased by utilizing alternative technologies to produce the anthrax vaccine. The suggestion was not incorporated in the final document.[161]

It appears the choice of the MBPI vaccine for use in the AVIP may also have been premised on DOD and the manufacturer obtaining FDA approval to reduce the lengthy shot course from 6 shots over 18 months, to just 2 or 3 inoculations over 6 weeks. DOD developed a detailed program to gain approval for a shortened AVA shot course due to problematic levels of systemic (0.7 to 1.3 percent) and significant local reactions (2.4 to 3.9 percent) associated with the prolonged immunization schedule.[162] An Investigational New Drug (IND) application was filed on September 20, 1996 at the FDA to study a reduced anthrax vaccine shot course, but design of a definitive comparison study has never been submitted.[163]

So now, having foregone opportunities to improve or diversify anthrax vaccine production capacity, both DOD and BioPort are in a fiscal squeeze. Having made a substantial investment in MBPI and BioPort, DOD now faces hard, costly choices between sustaining the sole FDA licensed manufacturer of the anthrax vaccine, which may prove inadequate, and/or embarking on the establishment and licensure of another. In future budgets, DOD must consider to fund Adeveloping a second source to BioPort or developing a different approach to solve the anthrax

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[161] Elizabeth Arwine, Legal Advisor, ALegal Review of Justification and Approval (J&A); Michigan Biologic Products Institute (MBPI), Jun. 3, 1997, p.1 (in subcommittee files). See also, Joseph S. Little, AResponse to JAG Comments,≅ Department of Defense Memorandum for Record, June 4, 1997 (in subcommittee files).

[162] See *supra* note 108.

[163] Letter from Melinda K. Plaisier, Interim Associate Commissioner for Legislative Affairs, Food and Drug Administration to Rep. Christopher Shays, Chairman, Subcommittee on National Security, Veterans Affairs and International Relations, House Committee on Government Reform, Mar. 15, 1999 (in subcommittee files).

problem and don=t take that money and put it against solving another bio-threatΨ.≅[164]

While these alternatives are being reviewed, the mandatory force-wide program to provide protection against what DOD characterizes as the pre-eminent biological warfare threat is on a very uncertain procurement footing. Without more extraordinary DOD assistance, BioPort appears financially incapable of capitalizing and sustaining a highly technical, heavily regulated manufacturing process. The same financial pressures that hindered MBPI=s ability to comply with FDA good manufacturing practices could also continue to affect BioPort=s capacity to produce a safe and effective product on schedule.

[164]Testimony of The Honorable David R. Oliver, Jr., Principal Deputy Under Secretary of Defense for Acquisition and Technology, NSVAIR Anthrax Hearing (III), p. 69.

3. The AVIP is logistically too complex to succeed. Adherence to the rigid schedule of six inoculations over 18 months for 2.4 million members of a mobile force is unlikely, particularly in reserve components. Using an artificial standard that counts only shots more than 30 days overdue, DOD tolerates serious deviations from the Food and Drug Administration (FDA) approved schedule.

No other vaccine required by DOD for force health or combat protection demands so complex an administration schedule.[165] The FDA approved inoculation regime is six shots over 18 months, with a subcutaneous injection of AVA to be given as follows:

#1 B start of series
#2 B two weeks later
#3 B one month after start of series
#4 B six months after start of series
#5 B one year after start of series
#6 B 18 months after start of series.
Booster B annually after completion of initial series.[166]

The ability to track immunizations and meet this schedule was one of Secretary Cohen=s four preconditions to the AVIP. But even the Secretary of Defense received his fourth inoculation three weeks before it was due.[167]

In an effort to comply with the elaborate timetable, DOD administers a three-tiered record keeping system. Each inoculation should be recorded on the individual service member=s shot record.[168] Data recorded should include the date and AVA lot number. The same data is also entered into one of the service branch medical systems.[169] Finally, the service branch systems periodically forward inoculation data to the Defense Enrollment Eligibility Reporting System

[165] See *supra* note 130.

[166] See *supra* note 41.

[167] E-mail from Col. Fred Gerber dated September 1, 1998 (in subcommittee files).

[168] Form #PHS-731, Department of Defense (in subcommittee files).

[169] Service-specific subsystems: the Army MEDPROS, Navy SAMS and R-STARS, Air Force MITS.

(DEERS), a pre-existing facility modified to serve as an interim access point for centralized AVIP data. In the future, DOD plans to centralize AVIP data using an upgrade of the Composite Health Care System now under development.[170]

[170] See *supra* note 26, p. 10.

This system was designed to address problems with medical record keeping encountered during Operation Desert Shield, Desert Storm and in Bosnia.[171] However, while GAO found some improvements in vaccination records, a sampling of AVIP tracking at four locations discovered varying levels of discrepancies between paper and electronic data. According to GAO:

> AInconsistency in dates could lead to vaccinations being given off-schedule and to inaccurate readiness reports. Inconsistent or missing lot information could hinder investigations, should concerns arise over a specific lot. Also, information that is not recorded in paper records makes it difficult to address adverse reactions needing immediate care or determine the validity of subsequent claims for disability compensation.≅[172]

GAO also found use of DEERS data more limited than anticipated. ADEERS was envisioned as a major source of reports on program implementation. However, concerns about the timeliness and accuracy of data in DEERS have cause service representatives to rely on interim, service-specific tracking systems, and other systems to track and report vaccination information.≅[173] Specific concerns centered on duty station data, found in some cases to be updated only six to nine months late.[174] This severely limits the utility of DEERS as a tool to generate unit compliance or readiness reports, since the database often does not reflect current unit membership. Readiness estimates based on AVIP tracking data are Astill suspect,≅ according to an internal DOD document.[175]

The difficulties of tracking anthrax vaccinations in the active force are compounded in

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[171] *Ibid.*, p. 20.

[172] *Ibid.*, p. 21.

[173] *Ibid.*, p. 22.

[174] *Ibid.*

[175] E-mails from Maj. Guy Strawder dated February 17, 1999 (in subcommittee files).

reserve component units,[176] given changing unit memberships and monthly training schedules unlikely to match the inoculation regime. This difficulty was anticipated,[177] but DOD acknowledged in testimony that compliance with the FDA inoculation schedule in reserve component units was lower than in the active force due to less frequent drill schedules and timing of access to military medical facilities for purposes of receiving the vaccine.[178]

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[176] Reserve components consist of Army, Navy, Air Force and Marine reserve units as well as Army and Air National Guard units. Reserve units are elements of the national military. National Guard units are state militias unless federalized.

[177] See *supra* note 108.

[178] Prepared statement of Charles L. Cragin, Acting Assistant Secretary for Reserve Affairs, DOD, NSVAIR Anthrax Hearing (V), p. 5-7; testimony of Charles L. Cragin, NSVAIR Anthrax Hearing (V), p. 150.

As the logistical challenges of vaccine compliance increase, so do the risks of deviations from the approved schedule. While the effect of schedule deviations is another unknown element of the AVIP, DOD concludes Athe greater the deviation the less certain the protective effect in humans.≅[179] Nevertheless, ADOD set a timeliness goal of vaccinating 90 percent of all service members no more than 30 days after their vaccinations are due....≅[180] DOD reports meeting that goal.[181]

On August 4, 1999 the Subcommittee requested data on vaccine regimen compliance in all reserve component units then enrolled in the vaccine program. The DEERS reports provided to the Subcommittee contained shot records on 32,681 individuals who had received one or more inoculations prior to July 31, 1999. Almost half (15,625) the individuals listed were overdue to receive an inoculation. In some cases, entire units had missed the schedule by a month or more. A summary of the data follows:

Branch/Res. Comp	# Enrolled	# Overdue	%Overdue
AFReserves	8931	2954	33
AIRNG	9246	2482	27
ArmyNG	2441	1443	59
ArmyReserves	5802	3661	63
MCReserves	2730	1967	72
USNReserves	3531	3118	88[182]

[179] Memorandum on APolicy Deviation from Anthrax Vaccine Immunization Schedule≅ from the Department of Defense dated September 11, 1998, p. 1 (in subcommittee files).

[180]See *supra* note 26, p. 24. See also, testimony of Charles L. Cragin, Acting Assistant Secretary for Reserve Affairs, DOD, NSVAIR Anthrax Hearing (V), p. 150.

[181] Department of Defense, AAnthrax Vaccine Immunization Program Quarterly Review,≅ Jan. 22, 1999, p. 9 (in subcommittee files).

[182] Letter and accompanying computer diskette from Charles L. Cragin to Rep. Christopher Shays dated August 23, 1999 (in subcommittee files).

The Air Surgeon, Col. James Dougherty, disputed the accuracy of the DEERS data. In an e-mail reacting to a media report of poor compliance in a Connecticut Air National Guard unit, he said Aall the data are inaccurate≅ because the DEERS system is updated weeks after shots are actually administered.[183] DOD also said the data showing overdue inoculations was inflated due to the inadvertent inclusion of Individual Ready Reserve forces, service members who are separated from military service but available for call-up.[184] Nevertheless, according to an internal DOD document, readiness estimates based on AVIP tracking data are Astill suspect.≅[185]

If the centralized tracking system cannot provide a real-time picture of the inoculation status of the entire force, or individual units, it fails to meet the operational standard set by the Secretary as a condition of AVIP implementation.

The data provided to the Subcommittee by DOD also showed most reserve component members receive the first three inoculations on schedule, with compliance deviations occurring with regard to subsequent shots.[186] That may not be entirely inadvertent. DOD documents contain the statement ASoldiers with 3 or more vaccinations are Protected.≅[187] The DOD position that Afunctional protection≅[188] is provided after only three of the six required inoculations sets a deployability standard against which reserve component commanders are measured. Once members of a unit have received three shots, there appears to be little incentive to press for further compliance with an increasingly unpopular program.

There is little scientific evidence to support the theory that three shots protect as well as six. DOD expended significant time and resources in 1994 and 1995 on plans and programs to demonstrate the safety and efficacy of a shorter anthrax inoculation regime, and a different route of administration. An Investigational New Drug (IND) application was filed to guide further animal studies and clinical trials in humans. But the effort appears to have all but abandoned when planning for the AVIP began. Support for the FDA application to reduce the shot course seems to have been redirected to vaccine acquisition and AVIP logistics.

In September 1999, the Director of the FDA Center for Biologics Evaluation and Research, Dr. Katherine Zoon, wrote to Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs

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[183] E-mails from James Dougherty dated September 1, 1999. (in subcommittee files)

[184] Testimony of Charles L. Cragin, Acting Assistant Secretary for Reserve Affairs, NSVAIR Anthrax Hearing (V), p. 104 (in subcommittee files).

[185] See *supra* note 175.

[186] See *supra* note 182.

[187] See *supra* note 134, p. 2, and e-mails from Department of Defense personnel dated February 17 - April 14, 1999 (in subcommittee files); If the manufacturer of a pharmaceutical or biologic product advised patients or physicians that half the FDA approved dosage or administration regimen was as effective against the labeled indication, it would be a serious violation of FDA regulations.

[188] See *supra* note 134, p. 2.

regarding data showing significant deviations from the AVA administration routine:

> A... Because we are unaware of any data demonstrating that any deviation from the approval intervals of doses found in the approved labeling will provide protection from anthrax infection, we strongly recommend that the Anthrax Vaccine Immunization Program follow the FDA approved schedule.≅[189]

Prior to the administration of each shot, medical personnel are directed to provide information on the vaccine and the program, and to inform each recipient regarding the health factors that should exclude a person.[190] Exclusionary factors include severe reaction to a previous shot, active infection, pregnancy, current immuno-suppression.[191] Service members should also be informed regarding the identification and reporting of adverse health events suffered subsequent to inoculation.[192]

But GAO found medical staff and service members were not well informed about reporting adverse events and found more than forty percent of those sampled had not received information on how to report vaccine related adverse events.[193] Testimony by service members reflected the GAO findings.

Ms. Randi Martin-Allaire, a civilian employee of the Michigan Air National Guard told the Subcommittee, AI was on antibiotics at the time I received by fourth injection, and was never asked if I was on any type of medication or antibiotics.≅[194] Her colleagues described similar miscues and confusion over the standards for identifying and treating vaccine adverse reactions.[195]

Service members report AVIP information and briefings seem designed to persuade, not educate. The inability of Air Force briefers to answer service members= questions led one commander to suspend the vaccination program until the Air Force Surgeon General personally intervened.[196] Vaccine recipients also report mass inoculations during which no questions

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[189] Letter from Dr. Katherine C. Zoon to Dr. Sue Bailey dated September 29, 1999 (in subcommittee files).

[190] See *supra* note 46, p. C-5.

[191] See *supra* note 41.

[192] Department of Defense, AClinical Practice Guidelines for Managing Adverse Events After Anthrax and Other Vaccinations,≅ Nov. 15, 1999 pp. 1-2. (in subcommittee files)..

[193] See *supra* note 26, pp. 24-26.

[194] Prepared statement of Randi J. Martin-Allaire, NSVAIR Anthrax Hearing (II), p. 170.

[195] Prepared statement of Roberta Groll, NSVAIR Anthrax Hearing (II), p. 176-179; and prepared statement of David Churchill, NSVAIR Anthrax Hearing (II), pp. 183-188.

[196] Debra Funk, AAir Guard Unit Delays Anthrax Inoculations,≅ *Air Force Times*, July 5, 1999, p. 29.

regarding current health status are asked and noVAERS forms made available.[197]

[197] E-mails and meeting notes (in subcommittee files).

The AVIP is made more complex by the need to address growing resistance to the vaccine, specifically in reserve component units. The impact of the AVIP on retention in reserve component units could be significant. Informal surveys by service members suggest the Air National Guard may suffer air crew attrition of thirty percent or more.[198] To date, the Defense Department has not acknowledged any unusual pattern of resignations attributable to the AVIP.[199]

It is not clear where the Department might look to discern such a pattern. DOD collects no centralized data on refusals or resignations attributable to the vaccine program. Some service members also said unit commanders openly discouraged attribution of resignations or transfers to the AVIP.[200] An Air Force Reserve Interim Anthrax Policy forbids the approval of transfer requests made by anyone scheduled or directed to begin the anthrax immunizations.[201]

GAO was critical of this lack of monitoring to determine the effectiveness of the AVIP communications effort.[202] Without data on refusals, AIt is difficult to better target educational efforts and address emerging concerns. These problems need to be resolved *if the program is to succeed* in vaccinating the entire force against anthrax.≅[203] (emphasis added)

DOD developed a detailed program to gain approval for a shortened AVA shot course to address the logistical challenge of the six-shot regime and to reduce problematic levels of systemic (0.7 to 1.3 percent) and significant local reactions (2.4 to 3.9 percent) associated with the prolonged immunization schedule.[204] An Investigational New Drug (IND) application was filed on September 20, 1996 at the FDA to study a reduced anthrax vaccine shot course, but

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[198] See *supra* note 74.

[199] Testimony of Maj. Gen. Paul Weaver, Director, Air National Guard, DOD, NSVAIR Anthrax Hearing (V), p. 118.

[200] E-mails (in subcommittee files).

[201] Command Anthrax Policy, U.S. Air Force Reserve, June 22, 1999 (in subcommittee files).

[202] See supra note 26, p. 35.

[203] *Ibid.*

[204] See *supra* note 108.

design of a definitive comparison study has not yet been submitted.

4. Safety of the vaccine is not being monitored adequately. The program is predisposed to ignore or understate potential safety problems due to reliance on a passive adverse event surveillance system and DOD institutional resistance to associating health effects with the vaccine.

Based on data gathered during limited occupational use since licensure, the AVA can be considered nominally safe. But the vastly expanded use of the vaccine for a new purpose requires a proactive approach to emerging safety issues. That approach is not now a part of the AVIP.

As with any vaccine, anthrax inoculation can cause adverse health events in some individuals, ranging from soreness or swelling at the injection site (local reactions) to fevers, chills, muscle aches and anaphylaxis[205] (systemic reactions). Local reaction may be mild, moderate or severe enough to require medical attention. Systemic reactions are generally considered clinically more significant. Reactions may increase in severity after successive injections.[206]

More inoculations means more reactions. An immunization program using a vaccine requiring six shots and annual boosters should be prepared to deal with some number and variety of adverse health effects. Despite having been licensed for almost 30 years, the vaccine had not been widely used prior to the Gulf War.[207] As noted previously, lack of adequate medical record

[205] Hypersensitivity to a drug or antigen. Anaphylactic shock is an often severe, sometimes fatal, physical reaction characterized by respiratory symptoms, fainting, swelling and itching.

[206] See *supra* note 41.

[207] Prepared statement of Kathryn C. Zoon, Ph.D., NSVAIR Anthrax Hearing (II), pp. 52-

keeping prevents systematic study of that cohort for health effects possibly associated with the anthrax vaccine and other medicines and toxins. The vaccine is being studied as a potential factor in Gulf War veterans= illnesses.[208] As GAO noted, AThe long term safety of the vaccine has not yet been studied.=[209]

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[208] See supra note 1.

[209] Prepared statement of Kwai-Cheung Chan, Director, Special Studies and Evaluation Section, National Security and International Relations Division, GAO, NSVAIR Anthrax Hearing (II), p. 11.

The AVA has been described as a relatively crude, imprecisely characterized vaccine, and estimates of reaction rates vary widely.[210] According to the FDA-approved AVA product labeling, 30 percent of vaccine recipients can be expected to suffer mild local reactions, 4 percent will incur moderate local reactions and less than .2 percent will experience systemic reactions.[211] In 1994 and `95, DOD considered the need for a new anthrax vaccine Abased on the reactogenicity of the current vaccine.≅[212]

In April 29, 1999 testimony[213] before the Subcommittee, the General Accounting Office (GAO) summarized studies of anthrax vaccine reactions, finding rates of systemic reactions ranging from .05 percent to 48 percent. (Table 1, below)

Table I: Reactions to Licensed Anthrax Vaccine Reported in Various Studies

Study	Type of Reporting	Number Vaccinated	Local reactions (percent)		Systemic reactions (percent)	
		(or doses)	Mild	Moderate / Severe	Mild	Moderate / Severe
IND	Active / Passive	3,984[a]	6 B 20[b]	1 B 10[b]	None[b]	.05[b]
Pittman (1997)	Active	508	16	5	29[c]	14
TAMC (1998)	Active	536	Not Addressed		43[d]	5
DOD (Current monitoring)	Passive	223,000[b]	[e]	[e]	[e]	[e]

[a]This number represents the number of study participants who received the first dose of the licensed vaccine.
[b]These figures represent the percentage of people who experienced this type of reaction during the study, even if they had previously been inoculated with the Merck vaccine.
[c]This figure also includes persons who had reactions of "unknown" severity.
[d]This figure represents the frequency of the most common side effect, myalgia.

[210] *Ibid.*, p. 16.

[211] See *supra* note 41.

[212] AMinutes of FDA Meeting of 5 May 94 Concerning Production and Purification of PA from Delta Sterne,≅ Department of the Army, May 19, 1994, p. 1.

[213] Prepared statement of Kwai-Cheung Chan, Director, Special Studies and Evaluation Section, National Security and International Relations Division, GAO, NSVAIR Anthrax Hearing (II), p. 16.

[9]DOD testified that as of March 16, 1999, more than 223,000 service member have been immunized. There had been 42 reports on adverse effects submitted to the FDA and CDC. Only seven service members required hospitalization or experienced loss of duty for more than 24 hours.

In later testimony, GAO also observed:

> In addition to reporting to VAERS, DOD has conducted three efforts to actively collect data on adverse reactions after service members received the anthrax vaccine. Data from these efforts show that women reported twice the rate of adverse reactions than men for both local (e.g. swelling) and systemic (e.g. malaise and chills) reactions. In addition, a higher proportion of women than men reported making an outpatient medical visit after a vaccination, and more than twice the percentage of women reported that they missed one or more duty shifts after their vaccinations than did men.[214]

Captain Michelle L. Piel believes she suffered an adverse reaction to the anthrax vaccine. Fatigue, dizziness, joint pain and severe cold-like symptoms following her first two inoculations resulted in the loss of flight status. When she suggested submitting a report to VAERS, she testified, AMy request met reluctance.≅[215] Because her symptoms did not fall within the range of expected vaccine reactions, doctors as Dover Air Force Base did not associate her illness to the AVA. She concluded, AThis is a major reason why adverse events from the anthrax vaccine are underreported.≅[216] She added, Alt didn=t make sense to me. I was too sick to fly. I was too sick to get another shot. But my illness wasn=t reportable on a VAERS form?≅[217]

When others at Dover suspected health effects might be linked to the vaccine, efforts to report a trend Awere met with resistance and discouragement from within Dover=s medical

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[214] Prepared statement of Kwai-Cheung Chan, Director, Special Studies and Evaluation Section, National Security and International Relations Division, GAO, NSVAIR Anthrax Hearing (IV), p. 3 (in subcommittee files).

[215] Prepared statement of Capt. Michelle L. Piel, NSVAIR Anthrax Hearing (IV), p. 3 (in subcommittee files).

[216] *Ibid.*

[217] *Ibid.*

community.≅[218] According to Capt. Piel, AIt took 6 months to reach the right, highly specialized doctors to begin to diagnose my immune system problems.≅[219]

[218] *Ibid.*

[219] *Ibid.*, p. 4.

At the reaction rates cited by the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID),[220] the anthrax vaccine program, when implemented across the entire 2.4 million member force, could produce 31,200 systemic reactions and up to 93,600 severe local reactions. Recently, the Army Surgeon General conceded that, ASystemic events occur in five to 35 percent of anthrax-vaccine recipients.≅[221] At the range of systemic reactions found by DOD in the Tripler Army Medical Center active surveillance study, the AVIP could generate over one million systemic reactions, many thousands of which will require medical management and treatment.[222]

Given that prospect, it might have been expected by service members that an integral part of the AVIP would be highly sensitive active and passive surveillance systems to Apermit accurate assessments of types and severity of adverse reactions≅[223] because Aonly widespread use can provide this assessment.≅[224] That was one factor which lead DOD to indemnify the vaccine manufacturer against the Aunusually hazardous risks≅ of vaccine production.[225]

To better quantify those risks, and to detect adverse reaction trends early, the program design could have included detailed medical protocols on screening, vaccine administration and adverse events. The AVIP could have assembled and trained a multi-disciplinary network of health professionals to manage the anticipated adverse event caseload. It could have provided each recipient with a simple, one page vaccine information sheet on adverse events and drug inter-actions of the type routinely provided with childhood vaccines. The AVIP could have designed and initiated the controlled, cohort studies only now being discussed to learn more about reaction rate differences by age and gender.[226]

The AVIP does not include those safety elements.

Instead, the program now relies primarily on an adverse event surveillance and reporting system known to understate the nature and extent of health effects associated with vaccine administration. Access to immunologists and allergists is limited geographically. Not until one year after the program began did DOD update briefing materials to include information on reporting adverse events and revise program regulations to make reporting requirements more inclusive, clarify patient and provider responsibilities, and explain how to process a Vaccine

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[220] See *supra* note 108.

[221] Letter from Lt. Gen. Ronald R. Blanck to Mark Zaid dated December 10, 1999, p. 1 (in subcommittee files).

[222] See *supra* chart at note 213.

[223] See *supra* note 33.

[224] *Ibid.*

[225] *Ibid.*

[226] Deborah Funk, AMilitary Officials Order Study to Determine Vaccine=s Safety, Long-term Side effects,≅ *Army Times*, July 12, 1999, p. 12.

Adverse Event Reporting System (VAERS) form. Only in July 1999 did DOD distribute draft clinical guidelines that outline clinical protocols, pre-treatments, specialty referral processes, contraindications, categorizations of local and systemic reactions and associated treatment algorithms.[227]

[227] Prepared statement of Maj. Gen. G. Robert Claypool, Deputy Assistant Secretary for Health Operations Policy, DOD, NSVAIR Anthrax Hearing (IV), p. 12 (in subcommittee files).

According to GAO testimony, studies have shown passive systems sometimes capture only one percent of adverse events temporally or causally related to use of a medical device or vaccine. Reports also vary in quality and utility due to inconsistencies in identifying and interpreting health effects as vaccine related. A passive system is useful as a Asentinel≅ to alert clinicians to unexpected events.[228] AIt does not tell you how often, with what severity, or does not establish causality. The limitations are very well accepted.≅[229]

Because passive systems are voluntary, the data generated are subject to a self-selection bias, in that trends in volunteered data cannot be extrapolated as if representative of an entire cohort or population. As a result, information from a passive reporting system, like VAERS, is not an appropriate source of data for use in generating adverse reaction rates.

Nevertheless, AVIP reports and DOD public statements portray the ratio of VAERS reports to inoculations given as an adverse reaction rate.

> AIn presenting reaction rate data, program and DOD officials have shown reactions reported to VAERS as a percentage of all vaccinations. They did so in several briefings to GAO and congressional staff, in prepared testimony, and on the program=s Internet site. However, according to FDA guidance, incidents in the VAERS database reflect a temporal, not necessarily a causal, relationship with vaccination and thus should not be used to calculate the incidence of reactions.≅[230]

GAO found, AThis is misleading because of potential underreporting of events to VAERS, and the potential for overstating the reaction rate because reports sent to VAERS are not confirmed to be causally linked to the vaccination.≅[231] The potential for overreporting is

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[228] Testimony of Kwai-Cheung Chan, Director, Special Studies and Evaluation Section, National Security and International Relations Division, GAO, NSVAIR Anthrax Hearing (IV), p. 125 (in subcommittee files).

[229] Testimony of Dr. Shushil K. Sharma, Special Studies and Evaluations Section, National Security and International Relations Division, GAO, NSVAIR Anthrax Hearing (II), p. 25.

[230] See supra note 26, p. 32.

[231] *Ibid.*

limited, however, by DOD screening of VAERS reports before inclusion in quarterly AVIP figures. In this regard, GAO concluded, AThus, DOD does not have reliable information on the extent of adverse reactions.≅[232]

[232] *Ibid.*

Even if useful to gauge short term reactions, passive reporting systems are also unlikely to capture long term or chronic health effects or syndromes, since providers and vaccine recipients do not generally associate an illness with an event far removed in time.[233] But many service members are concerned over possible long term health effects of the anthrax vaccine, alone or in combination with other treatments and exposures.[234] According to GAO, AA primary reason for dissatisfaction with information about long-term side effects appears to be that research has not been done to address the topic. According to program officials, such studies have recently been discussed but are not yet funded or underway.=[235]

The AVIP=s strict VAERS reporting requirements of hospitalization or more than 24 hours absence from duty limit the scope of any safety surveillance to severe, short term reactions. This overly narrow interpretation of adverse event data could result in DOD missing the types and severity of adverse reactions only widespread use would otherwise reveal. The Astatistical significance of a predicted adverse reaction=[236] will only become apparent if the statistics are permitted to capture the full range of available data.

A system already known for underreporting can be made even less reliable in the hands of an institutional culture resistant, even hostile, to reports attributing ill health to the anthrax vaccine. Air Force Lieutenant Richard Rovet, while serving as Health Care Integrator for the Flight Medicine Clinic at Dover AFB, noted a number of individuals reporting potentially vaccine-related symptoms: dizziness, ringing in the ears, joint pain, muscle aches, memory impairment, fatigue, numbness, prolonged fever and chills, localized and persistent rashes.[237] He said there was significant confusion in the field regarding reportable reactions Aespecially in

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[233] Prepared statement of Dr. Meryl Nass, NSVAIR Anthrax Hearing (II), p. 107.

[234] Prepared statement of Capt. Michelle L. Piel, NSVAIR Anthrax Hearing (IV) (in subcommittee files); prepared statement of Capt. Jon Richter, NSVAIR Anthrax Hearing (IV) (in subcommittee files); and e-mails sent to the subcommittee (in subcommittee files).

[235] See *supra* note 26, p. 32.

[236] See *supra* note 30.

[237] Prepared statement of Lt. Richard Rovet, NSVAIR Anthrax Hearing (IV), p. 2 (in subcommittee files).

regard to what constitutes systemic reaction.≅[238] Lt. Rovet testified medical providers saw the issue of identifying vaccine reactions Apolitically sensitive and like to avoid it.≅[239]

[238] Testimony of Lt. Richard Rovet, NSVIAR Anthrax Hearing (IV), p. 25 (in subcommittee files).

[239] *Ibid.*

That resistance reduces what few incentives already motivate military personnel to report sick. Particularly when complaining of symptoms of unknown origin, a service member risks the label Amalingerer≅ or Adepressed.≅[240] If seeking care seems a dead end, Awhy risk your flying status if you are just suffering some of the mild symptoms of joint pain or you feel a little bit tired? Why should you go to the doctor is you feel you can continue to operate an airplane? And that is why people don=t come forward.≅[241]

An Air Force Reservist, Capt. Jon Richter, also suffered chronic symptoms he attributed to the vaccine. While he came forward, he testified there is little incentive for others do so. AI was encountering more of my squadron mates who were vaccinated that said they too had experienced various reactions, including tinnitus, dizziness, muscle and joint pain, and, in one case, gray-outs. However, most were attempting to keep it low profile and did not readily discuss these matters for fear of reprisal.≅[242] AWord travels fast. Morale is at an all time low. People are trigger shy about coming forward with their symptoms. There is an air of fear and distrust prevalent throughout.≅[243]

A reluctance to acknowledge vaccine related health effects could also block access to the immunologists and allergists experienced in the diagnosis and treatment of adverse reactions. This can be a more acute problem for National Guard and Reserve members whose level of access to military medicine, particularly specialists, for vaccine matters is uncertain. Witnesses at the Subcommittee=s April 29 hearing from the Michigan Air National Guard described a difficult and time consuming process to gain access to medical personnel with relevant expertise.[244]

According to the Dr. Renata Engler, Chief Immunologist at the Water Reed Army Medical Center, and a consultant to the AVIP, AVaccine administration is serious business and deserves more care and training of those who deliver the service.≅[245] One critical issue, she said, Ais that stakeholders who understand the clinical issues have NOT been represented in the organizational policy development.≅[246] AThere is a problem that the organization does NOT

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[240] Prepared statement of Capt. Michelle L. Piel, NSVAIR Anthrax Hearing (IV) p.3 (in subcommittee files).

[241] Testimony of Capt. Michelle L. Piel, NSVAIR Anthrax Hearing (IV), p. 59 (in subcommittee files).

[242] Testimony of Capt. Jon Richter, NSVAIR Anthax Hearing (IV), p. 38 (in subcommittee files).

[243] Ibid, p. 41.

[244] Prepared statement of Roberta Groll, NSVAIR Anthrax Hearing (II), pp. 176-179; prepared statement of Randi Martin-Allaire, NSVAIR Anthrax Hearing (II), pp. 167-171; and prepared statement of David Churchill, NSVAIR Anthrax Hearing (II), pp. 183-188.

[245] E-mails from Col. Renata Engler dated December 4, 19998 (in subcommittee files).

[246] E-mail from Col. Renata Engler dated December 15, 1998 (in subcommittee files).

have a forum for experienced, ongoing clinical input into the many problems that surround immunization delivery and adverse reaction management.≅[247] (emphasis original)

[247] *Ibid.*

Those problems include recognition of potentially life-threatening hypersensitive reactions, use of pre-treatments to mitigate vaccine reactions and the criteria to be applied to determine temporary or permanent medical exemption, or waiver, from the AVIP. At the first DOD conference on biological warfare immunizations, held in May 1999, Dr. Engler made a presentation on the clinical challenges posed by the AVIP. She summarized several case studies of those who had suffered adverse reactions to the anthrax vaccine, with data from Walter Reed Army Medical Center, data from Dr. Hoffman=s study in Korea, and patient profiles from Dover AFB.[248] In her slide presentation, she noted a Afear of military medical establishment≅ and concluded the AVIP message should be, AEvery service member deserves the same quality of care as ANY OTHER PATIENT: investigate problems proactively & objectively, validate suffering, knowledge base and unknowns. Vaccines are drugs & NOT 100% safe.≅[249]

Regarding the availability of medical deferrals and waivers, Dr. Engler asked, AShould medical waivers become a punitive event? ... Do we want rigid administrative guidelines that polarize and antagonize service members with problems? Can we acknowledge risk & include choice of affected AD in final disposition? Does every service member have to be immunized or is there room for a benefit risk ratio discussion?≅[250]

Room for that discussion may be limited. The risk/benefit decision underlying the AVIP can conflict with the clinician=s duty to weigh the risks and benefits to the individual patient. In an e-mail exchange with Col. Fred Gerber, operational head of the AVIP, Dr. Engler posed the following example:

> AA rash within 2 hours of the vaccine could represent an increased risk for life threatening anaphylaxis with next dose - if you ignore this and do not handle it appropriately and a subsequent dose results in significant harm, you are outside the standard of care and would NOT be excused by the >active duty= blanket. Our specialty has worked with this type of patient and achieved successful and safe subsequent vaccination but this requires expertise and very carefully prepared informed consent. ETHICALLY, you cannot expose a soldier to a medical treatment if he/she is at increased risk for harm from it and yes we do waiver people for serious vaccine reactions from future reactions and they continue on active duty for the most part. Anthrax brings unique urgency to the scenario and a group discussion on these issues with an ethicist is crucial.≅[251] (emphasis original)

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[248] See *supra* note 51, pp. 3-7.
[249] *Ibid.*, p. 12.
[250] *Ibid.*
[251] See *supra* note 245.

Col. Gerber, while disclaiming any purview over clinical issues, was unwilling to acknowledge that safety considerations might need to overcome the AVIP imperative in some number of cases:

> ANot sure I agree with what you=ve presented Renata. If ... she had a rash within 2 hrs of shot #1 ... [w]hy would that exempt her from getting rest of series and going to Korea? Who should go in her place? Those become the issues. Korea is one of the two AVIP Phase I High Threat Areas ... everyone is at increased risk for exposure to anthrax there. By your algorithm, when we get to Phase II of the AVIP, new soldiers coming into service would be put out of service because of an adverse reaction to anthrax ... what about an adverse to any of the other 17 immunizations? ... Call it like you see it, but I wouldn=t quickly exempt soldiers from worldwide assignments who have rashes, pain, swelling, etc. Let=s face it, AVA is one of many soldiers have to take. The more exotic vaccines are yet to come. ... Does a rash in 2 hours mean you can=t get any more immunizations without additional clinical follow-up/eval? I=m not sure it does.≅[252]

Concerns about the short and long term safety of the anthrax vaccine are legitimate. It is disingenuous for DOD to say 30 years of use has seen no serious short-term or chronic adverse health effects associated with the vaccine. For most of that time, no one was looking.

The short-term adverse reaction rates contained in the FDA-approved labeling were derived from data gathered during testing of an earlier, less reactogenic anthrax vaccine. FDA only establish the Vaccine Adverse Event Reporting System in 1990. That passive surveillance system, while useful to detect sentinel events or clusters for further study, understates the extent of reactions. Limited use of the vaccine since licensure has yielded limited information that suggests higher reaction rates, particularly in women.[253]

Since the AVIP began, DOD has undertaken two active follow-up surveys of vaccine recipients, one in Korea and another at Tripler Army Medical Center, Hawaii. The results of both studies indicates both local and systemic reactions at generally higher rates than described in the product labeling. According to GAO, AThe data gathered in Korea also show that after the first two shots, more than twice the proportion of women than men reported systemic reactions of

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[252] E-mails from Col. Fred Gerber dated November 17, 1998 (in subcommittee files).

[253] AAnthrax Vaccine: Safety and Efficacy Issues,≅ (GAO/NSAID-00-48) U.S. General Accounting Office, October 12, 1999, pp. 1-7.

fever, malaise, or chills than did men.[254] The Tripler survey also demonstrates gender differences in reported reactions.[255]

[254] *Ibid.*, p. 3.
[255] *Ibid.*, p. 4.

Service members= concerns about the impact of manufacturing process lapses on vaccine quality and safety are well placed. For biological products, the process is the product. A[Q]uality cannot be guarantees from final tests on random samples but only from a combination of in-process tests, end-product tests, and strict controls of the entire manufacturing process.=[256] At BioPort, and its predecessor the Michigan Biologics Products Institute, those controls were found to be less than strict.

The long-term safety of the licensed vaccine has not been studied.[257] It is of little comfort to service members that no other vaccines have been subject to any post-licensure longitudinal study. Unlike more modern vaccines, the AVA was approved before animal toxicity studies were even required. As a result, Astudies have not been performed to evaluate the effect of AVA on carcinogenesis, mutagenesis or impairment of fertility. Animal reproduction studies have not been conducted with AVA. Neither is it known whether AVA can cause fetal harm when administered to a pregnant woman or whether it can affect reproductive capacity.=[258]

It is unlikely the current anthrax would be approvable under modern regulatory standards for the safety and efficacy of biological products. It seems unlikely BioPort will be able to achieve and sustain modern manufacturing standards for safe vaccines.

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[256] Prepared statement of Kwai-Cheung Chan, Director, Special Studies and Evaluation Section, National Security and International Affairs Division, GAO, NSVAIR Anthrax Hearing (II), p. 13.

[257] *Ibid.*, p. 11.

[258] See supra note 138, pp. 87-88.

5. Efficacy of the vaccine against biological warfare is uncertain. The vaccine was approved for protection against cutaneous (under the skin) infection in an occupational setting, not for use as mass protection against weaponized, aerosolized anthrax.

Uncertainties about safety might be more readily accepted if there were no questions about the effectiveness of the anthrax vaccine. Safety risks would be tolerable if the benefits were unquestioned. But there are questions. The proposition that the AVA will provide effective protection against the most likely form of weaponized anthrax, aerosolized spores in significant quantities, is unproven.

And, until there is an anthrax attack, the proposition must remain unproven. The industrial settings in which anthrax was a threat have all but disappeared.[259] It would be unethical to expose human test subjects to a lethal agent. So, based on proven efficacy against indeterminate levels of cutaneous exposure in a industrial setting, it can only be assumed the vaccine provides equivalent protection against high levels of inhalation exposure.

That assumption is supported by data from tests on vaccinated animals who survive aerosol challenge. But different survival rates between animal species, and between anthrax strains, raise more questions than the vaccine answers about the actual physiological mechanism of protection. Without a way to correlate animal data to human protection (i.e. PA antibody titers), efficacy of the vaccine may never be more than suggested or inferred.

According to GAO:

[259] Only research and testing facilities now present an occupational setting posing a danger of anthrax exposure.

AStudies on the efficacy of anthrax vaccine have been limited to a study of the efficacy of the earlier version for humans and studies of the efficacy of the licensed vaccine for animals. The only study of the efficacy of the vaccine for humans was performed by Brachman, using the original vaccine. The Brachman study claimed that the vaccine gave 93 percent (and a lower confidence limit of 65 percent) protection against anthrax penetrating the skin. It found that the number of individuals who contracted anthrax by inhalation was too low to assess the efficacy of the vaccine against this form. There has been no specific study of the efficacy of the licensed vaccine in humans. Rather, its efficacy in humans has been inferred from other data, including a reduction in the incidence of anthrax following immunization of at-risk individuals and from animal experiments.≅[260]

All the DOD animal studies support the view that the licensed vaccine can protect some animals against exposure to some strains of anthrax either by inoculation or inhalation. But animal species differ in susceptibility.[261] In testimony submitted to the Subcommittee, Dr. Meryl Nass summarized the available data from animal studies of anthrax vaccine efficacy. AOne can see varying survival rates from 0 - 100% depending upon the strain of anthrax used and possibly other parameters of the experiment. Survival rates in guinea pigs varied from 23% to 71% when they were exposed to inhaled anthrax.≅[262] Studies in mice showed survival rates between no higher than ten percent.[263]

In concluding the current vaccine is effective against aerosol challenge, DOD relies primarily on studies using rhesus monkeys. AThese animal studies showed that the FDA-approved anthrax vaccine provided greater than 95% protection against high-dose aerosol challenge with anthrax in the monkey model. Human antibody response to the FDA-licensed vaccine provides further suggestive evidence that the FDA-licensed anthrax vaccine will protect against inhalation anthrax.≅[264]

But, according to GAO, Aseveral studies have shown no direct comparison of immunity in humans to that in monkeys.≅[265] In fact, the one immunized monkey that died in the DOD studies Ahad a low antibody titer similar to other monkeys that lived following a lethal aerosol

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[260] Prepared statement of Kwai-Cheung Chan, Director, Special Studies and Evaluation Section, National Security and International Affairs Division, GAO, NSVAIR Anthrax Hearing (II), p. 16-17.

[261] See *supra* note 253, p. 8.

[262] Prepared statement of Dr. Meryl Nass, NSVAIR Anthrax Hearing (II), p. 108.

[263] *Ibid.*, p. 110.

[264] Prepared statement of Dr. Sue Bailey, Assistant Secretary for Health Affairs, DOD, NSVAIR Anthrax Hearing (I), p. 11.

[265] U.S. General Accounting Office, Correspondence to Rep. Steve Buyer from Kwai Cheung-Chan, ASummary of GAO=s Findings on the Safety and Efficacy of the Anthrax Vaccine,≅ (GAO-NSIAD-00-54R), November 4, 1999, p. 3.

challenge.=[266]

[266] See *supra* note 138, p. 90.

One study comparing the efficacy of a live spore vaccine to a PA-based vaccine, like the AVA, concluded, AImmunization with cell-free preparations which contained components of that anthrax toxin did not provide adequate protective response against some challenge isolates of *B. anthracis*. The fact that the spore vaccine provided protection against all isolates tested suggests that other antigens may play a role in active immunity.≅[267]

DOD resists that suggestion because confidence in the efficacy of the current anthrax vaccine in humans, against all known strains, depends heavily on the conclusions 1) that the antibody response to the one antigen, PA,[268] protects against the toxic mechanism of all natural anthrax, and 2) that the antibody response in animals correlates to a similar protective response in humans.

The lack of a immunological correlate of protection against anthrax limits the extent of efficacy claims that can be made about the current vaccine, and it poses a profound challenge to the studies needed to approve an improved vaccine or a shorter AVA shot course. In describing the challenges to demonstration of efficacy for proposed changes in the dose and use of the current anthrax vaccine, DOD noted:

> APresently there are no precise serological or other immunological correlates of protection to enable conclusions to be drawn from immunization studies in man. The extrapolation from animal studies to humans likewise is seriously complicated by this fact. ...≅
>
> AThe demonstration in some animal models that protection with the present vaccine varies across challenge strains further complicates studies and limits the breadth of efficacy claims that can be made.≅
>
> ATo date, no animal or other potency test has been demonstrated to be well correlated with protection of humans. ***The potency test required for the present vaccine[269] has not been well correlated to efficacy in humans and it is doubtful that it can be.***≅ (emphasis added)
>
> AIt has recently been stated that the antigenic components of the licensed vaccine are not well defined and that there is lot to lot variation in the level of protective antigen. Because of these points, efficacy studies will likely have to include

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[267] Stephen F. Little and Gregory B. Knudson, AComparative Efficacy of Bacillus anthracis Live Spore Vaccine and Protective Antigen Vaccine against Anthrax in the Guinea Pig,≅ *Infection and Immunity*, May 1986, Vol. 52, No. 2, p. 511.

[268] Protective antigen (PA) is one of three proteins involved in the mechanism of anthrax toxicity.

[269] The current potency test uses guinea pigs.

multiple lots to demonstrate consistency of protection.≅[270]

[270] See *supra* note 138, p. 45 (presentation slide entitled, AChallenges to Demonstration of Efficacy for the Proposed Changes in Dose and Use of Anthrax Vaccine,≅ included in supporting documentation to MBPI IND application) (in subcommittee files).

Regarding efficacy, one author of an anthrax vaccine study wrote, AMy concern is not the long-term health effects of this vaccine, but rather that it is not efficacious against all strains of *B. anthracis*. If I were the scientific director of an offensive BW program for a government hostile to the U.S., I would direct my investigators to repeat this experiment, screening a larger number of *B. anthracis* isolates until a strain was isolated that would kill immunized animals, and then use that vaccine resistant strain as the stock for producing spores to be used in filling BW submunitions.≅[271]

Genetically engineered anthrax strains could also defeat the current vaccine if the resulting organism caused disease in new ways. Reports that Russian scientists successfully inserted genes into a virulent anthrax strain were received by DOD with some skepticism. Col. Gerald Parker, then-commander of USAMRIID, was quoted as saying the claims needed to be evaluated Ato learn whether the advance is theoretical or practical, and whether it could sidestep the American anthrax vaccine.≅[272] Taking a more skeptical approach to threat assessment than DOD uses with regard to natural anthrax, Col. Parker added, AIt=s one thing to do this in the lab. But its a whole different thing to produce it in large quantities to be used as a weapon. That would be very difficult.≅[273]

Concerns about the efficacy, and by implication the necessity, of the vaccine are legitimate given the extent of unproven, unknown, and perhaps unknowable, aspects of the protection afforded. The vaccine almost certainly could be overwhelmed by a high-dose aerosol exposure. Immunized troops near an initial release point could still suffer significant casualties. The vaccine may have diminished effect against highly virulent strains, or combinations of strains. The vaccine may provide no protection against genetically engineered anthrax.

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[271] Memorandum from Gregory B. Knudson to Rep. Christopher Shay dated May 8, 1999. (In subcommittee files)

[272] William J. Broad, AGene-Engineered Anthrax: Is It a Weapon?≅ *New York Times*, February 14, 1998 (in subcommittee files).

[273] *Ibid.*

1. The force-wide, mandatory AVIP should be suspended until DOD obtains approval for use of an improved vaccine.

Recommendations

The anthrax vaccine program is not sustainable in its present form. Due to the lack of assured production, AVIP Phase II has already been delayed. Confidence in the quality of the vaccine stockpile is low and the capacity to procure sufficient new production remains highly doubtful. The program should be suspended while contingency plans for allocation of available vaccine are formalized and research is conducted to obtain a safer, more effective vaccine.

Signaling an awareness the anthrax immunization effort was on weak conceptual and logistical footing from the start, Secretary Cohen announced four preconditions to the start of the program: supplemental vaccine testing, an adequate tracking system, completed implementation and communication plans and an independent scientific review. Those were appropriate. Had they been more scrupulously addressed, the AVIP might be a very different, much better program.

The military anthrax immunization program should have been conditioned on completion of the same level of research and testing required of other battlefield systems. We would not ask U.S. forces to fight using rifles designed in the 1950's. We should not ask them to rely on 1950's era medical technology, when modern science has the capacity to produce an improved vaccine. Much has changed in the biologics industry since the AVA was first approved in 1970. As evidenced by FDA inspectional findings in 1998 and 1999, not enough has changed at the vaccine production facility to bring it into full compliance with modern manufacturing standards. It is doubtful the AVA would be approved by the FDA today.

As additional assurance the anthrax immunization program is as safe as possible, DOD should test the vaccine for toxicity, mutagenicity, carcinogenicity and reproductive effects in animals. The current AVIP should be suspended while those studies, and other steps recommended by the Subcommittee, are undertaken.

The AVIP should be suspended because it lacks an essential element in a medical program: trust. However well-intentioned, the anthrax vaccine effort is viewed by many with suspicion. It is seen as another chapter in a long, unhappy history of military medical malfeasance in which the healing arts are corrupted to serve a lethal purpose.

The fundamental rationale for the AVIP - that something, even an old, questionably effective vaccine, is better than nothing - gives little comfort to those who daily see their forebears and colleagues grow sicker from radiation testing, Agent Orange and Gulf War illnesses. If the noble experiment fails, if the vaccine ultimately causes more casualties than

weaponized anthrax, many men and women in uniform do not believe their government will acknowledge their sacrifice or treat their wounds.

Trust must be earned. It can be earned only with a degree of candor and openness that has not been the hallmark of the AVIP to date. While claiming a new awareness of the need for effective risk communication, the Pentagon still reverts to absolutist declarations, heavy handed propaganda, and *ad hominem* attacks whenever the risks of the anthrax vaccine are communicated too effectively or persistently. In a culture based on a chain of command and the power to compel, attempts at persuasion and education often devolve into intimidation. Labeling opponents Aparanoics≅[274] and ridiculing the intelligence or courage of those with legitimate questions[275] are not the methods of modern risk communication.

Nowhere is DOD=s failure to communicate the relative risks and benefits of the AVIP more obvious than in reserve component units. The bulk of vocal resistance to the AVIP has arisen in the few Reserve and National Guard units included in Phase I. Those service members have more options than active duty personnel. If they conclude the anthrax vaccine poses more risk than benefit to their civilian and military careers, they can resign, or seek a transfer to a non-mobility position. Many have done so.

DOD appears to be in denial on this issue, ignoring clear signs the anthrax program is having, and will certainly have, a substantial impact on retention and morale in reserve component units. At the Subcommittee=s September 29, 1999 hearing on the subject, Maj. Gen. Paul Weaver, Director, Air National Guard, testified there had been Aone known refusal documented.≅[276] Previously, the Subcommittee had received testimony and correspondence from several members of Air Guard units who had refused the vaccine, more than one of whom were in the hearing room when Gen. Weaver made that statement.

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[274] See *supra* note 79.

[275] See *supra* note 80.

[276] Testimony of MG Paul Weaver, Director, Air National Guard, NSVAIR Anthrax Hearing (V), p. 119.

Principal Deputy Assistant Secretary of Defense (Reserve Affairs) Charles Cragin testified the impact of the AVIP on retention was Anegligible≅[277] despite having been given information just days before that more than half the air crew in one unit has submitted resignations attributable directly to the anthrax program.[278] At the same hearing, Mr. Cragin conceded Athe Department=s efforts to inform and educate reserve personnel about the anthrax protection program were not initially as robust as they should have been.≅[279]

Until much more is known about the true impact of a mandatory vaccine program on retention, readiness and morale in the most voluntary sector of the all-volunteer U.S. armed forces, the AVIP should be suspended.

Rather than risk long term health impairment, some service members would be willing to consider the vaccine-preventable risk of anthrax among the inherent, unavoidable risks of military service. They do not have that option, an opportunity to assume risk made available to essential civilian employees of the Defense Threat Reduction Agency.[280]

Others view this force protection effort as an untested medical solution to a purely mechanical problem - contamination prevention and avoidance - better solved by physical rather than pharmacological technology. With regard to the anthrax vaccine, DOD appears to accept more unknowns and greater technological risks than would be tolerated in any combat weapon system. As a result, some service members are not convinced this Acommander=s program≅ is for their long-term protection as much as for battlefield convenience and the preservation of short-term mission capability while under anthrax attack. Suspension of the AVIP would allow DOD to focus more attention and resources on development and deployment of chemical defense doctrine, tactics, detection capability as well as individual and collective protection equipment effective against all threats.

The Subcommittee makes no recommendations regarding the status of those service members who left the armed forces voluntarily, or as the result of disciplinary actions, due to the

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[277]Prepared statement of Charles Cragin, Acting Assitant Secretary for Reserve Affairs, NSVAIR Anthrax Hearing (IV), p. 3.

[278]Letter (with attachments) from Charles Cragin to Rep. Christopher Shays, attachment p. 1, October 21, 1999. (in subcommittee files)

[279]Prepared statement of Charles Cragin, Acting Assitant Secretary for Reserve Affairs, NSVAIR Anthrax Hearing (IV), p. 4.

[280]See *supra* note 134.

anthrax vaccine program. Just as each service branch, operating under the Uniform Code of Military Justice, determined its own approach to vaccine refusals, each should determine through its own processes what appeals, if any, might be available in the event the AVIP is restructured or suspended.

recombinant anthrax vaccine.

Despite the Aclear and present danger≅[281] posed to U.S. troops by anthrax as a biological weapon, DOD considers development of an improved anthrax vaccine Aan unfunded requirement.≅[282] Had that requirement been addressed more aggressively after the Persian Gulf War, the eight to ten year development, testing and FDA approval process now posited by DOD as an potential barrier to a new vaccine could have already been breached.

Although an improved vaccine based on recombinant technology may not necessarily have better safety characteristics than the current vaccine,[283] it would address two other problems plaguing the AVIP. Production of a second vaccine, at a second site, would diversify the industrial capacity to support so critical a program, making vaccine supplies more abundant and more secure from attack. And, because recombinant techniques do not require extensive dedicated facilities, capital costs can be allocated across more than one product, increasing the likelihood other manufacturers would compete for DOD contracts.

The second generation vaccine studied by DOD was also more consistently characterized in terms of PA content than the AVA[284]. Lot-to-lot consistency would address one challenge noted by DOD to demonstrating efficacy of a vaccine that cannot be tested in humans.[285] It would also give commanders greater confidence that vaccinated troops, to the greatest extent possible, have achieved a more uniform level of protection.

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[281] See *supra* note 66, p. 1.

[282] Testimony of Kwai-Cheung Chan, Director, Special Studies and Evaluation Section, National Security and International Affairs Division, GAO, NSVAIR Anthrax Hearing (IV), p. 100.

[283] Testimony of Col. Renata Engler, Chief, Allergy and Immunology Department, Walter Reed Army Medical Center, NSVAIR Anthrax Hearing (IV), p. 155.

[284] Prepared statement of Kwai-Cheung Chan, Director, Special Studies and Evaluation Section, National Security and International Relations Division, GAO, NSVAIR Anthrax Hearing (IV), p. 13.

[285] See *supra* note 108.

David Oliver, Principal Deputy Under secretary of Defense for Acquisition and Technology, said in testimony that DOD would be reviewing procurement options with regard to a second AVA production site versus a new vaccine. He suggested, however, that funds spent on an improved anthrax vaccine would limit funds available to address other bio-threats.[286] That trade-off puts anthrax on a par with other biological agents in terms of threat, when in fact DOD considers anthrax the pre-eminent bio-threat. Budgets estimates for the Joint Vaccine Acquisition Program (JVAP) indicate DOD anticipates procurement of limited, deployment-contingent stocks of vaccines against other biological weapons, making anthrax the only agent targeted for universal immunization. Improving the medical prophylaxis against the primary threat should be a DOD funding priority.

DOD concedes, AIn the case of anthrax vaccine, the current FDA-licensed vaccine is not ideal. The vaccine was developed in the 1950's and 1960's by the state-of-the-art procedures at that time, and licensed in 1970. Advances in biotechnology and genetic engineering may enable improvements in the vaccine that allow fewer doses or use of highly purified protective antigen. The DoD scientists are pursuing both of these objectives. A highly-purified recombinant protective antigen vaccine has shown efficacy in animal models.≅[287]

But DOD is unwilling to wait for the research, development and FDA approval processes,[288] even though DOD believes Awithin a year we will get FDA approval for reduced dose based on the science.≅[289]

To address the domestic bioterrorism threat, the Department of Health and Human Services= National Institute of Allergy and Infectious Diseases formed a working group to develop and test a second generation anthrax vaccine, and the Institute has funded some research. DOD should support those efforts.

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[286] Testimony of The Honorable David R. Oliver, Jr., NSVAIR Anthrax Hearing (III), pp. 68-69.

[287] Department of Defense, AInformation About the Anthrax Vaccine and the Anthrax Vaccine Immunization Program,≅ prepared by the AVIP Agency, January 25, 2000, pp. 12-13 (available at: http://www.anthrax.osd.mil) (in subcommittee files).

[288] *Ibid.*

[289] Testimony of Col. Fred Gerber, Director, Health Care Operations, Office of the Army Surgeon General, NSVAIR Anthrax Hearing (V), p. 153.

With regard to an improved anthrax vaccine, the American Public Health Association adopted a policy statement in November 1999 urging DOD to Adelay any further immunization against anthrax using the current vaccine or at least to make immunization voluntary≅[290] and to convene a commission of military and non-military public health experts to review safety and efficacy evidence for the current vaccine, attempt to determine when an improved vaccine might be available, and make recommendations about continuation of the current program.[291] Their recommendations were based on the concern Athat mandatory immunization with a vaccine of unproved efficacy when an improved vaccine may soon be available, is contrary to public health principles and may adversely effect the acceptance of voluntary or mandatory immunization programs in which there is good evidence of efficacy and safety....≅[292]

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[290] AAnthrax Immunization,≅ American Public Health Association, Policy Statement No. 9930, Nov. 10, 1999.

[291] *Ibid.*

[292] *Ibid.*

3. DOD should pursue testing of the safety and efficacy of a shorter anthrax inoculation regimen.

A shorter shot course could reduce the cost of the immunization program, simplify delivery logistics, and lower the incidence of adverse reactions.

According to GAO testimony, ANo studies have been done to determine the optimum number of doses of the anthrax vaccine.≅[293] The original inoculation schedule of three doses was based on a regimen developed using animals in the early 1950s. However, three people who received three doses of a weaker formulation of the vaccine became infected after exposure to anthrax. The number of doses was then arbitrarily increased to six, the number used in the only human efficacy study published in 1962, and thus the number approved by FDA.[294]

Even if a prolonged, multi-shot regimen is necessary to generate an initial immune response, the annual booster may be unnecessary. GAO noted:

> AIn November 1971, the Division of Biologics Standards, NIH, noted an apparent increase in reports of adverse reactions after individuals received booster shots. The Division considered it advisable to reevaluate the need for annual boosters and possibly the amount of the booster dose. Although the record is unclear as to whether or not NIH requested a reevaluation, to date, no such reevaluation has been done.≅[295]

The 1993 DOD Directive on biological warfare defense mandates immunization Aagainst validated biological warfare threat agents, for which *suitable* vaccines are available, in sufficient

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[293]Testimony of Kwai-Cheung Chan, Director, Special Studies and Evaluation Section, National Security and International Affairs Division, GAO, NSVAIR Anthrax Hearing (IV), p. 97.

[294] Prepared statement of Kwai-Cheung Chan, Director, Special Studies and Evaluation Section, National Security and International Affairs Division, GAO, NSVAIR Anthrax Hearing (IV), p. 5.

[295] *Ibid.*, p. 6.

time to develop immunity before deployment to high threat areas....≅[296] (emphasis added) For this purpose, Asuitable≅ should not just mean FDA approved, but demonstrably as safe and effective as possible for the intended military use. A vaccine that takes 18 months, and annual boosters, to confer immunity should not be considered suitable under the policy.

[296] See *supra* note 7.

In 1995, the Joint Program Manager for Biological Defense reported, AThe immunization schedule of 6 shots over 18 months has stopped the approval process for an annual immunization program against this high threat biological warfare agent. Moreover, it has been used by critics to question the relevance of the biological defense (BD) vaccine program to the DOD.≅[297]

If the time to develop immunity could be reduced substantially, use of the anthrax vaccine would be safer and could be targeted far more effectively to forces deploying to high threat areas.

Based on animal studies and research into the immunological response to the vaccine in humans, DOD concludes most persons acquire the bulk of whatever protection is achieved after two or three shots.[298] DOD documents assert that three inoculations provide functional protection, and the services= AVIP implementation plans set as Adesirable≅ the goal that Aall personnel assigned to high threat areas receive their first three shots prior to deployment.≅[299] In the interest of reducing adverse reactions, particularly in persons whose immune systems have already mounted a complete response to the vaccine, DOD should put its belief in the efficacy of a reduced shot course to the test of rigorous scientific trials.

To the extent those efficacy studies were put aside due to the lack of a correlates of human immunity, that challenge will have to be overcome in any event as DOD attempts to develop and deploy other vaccines against other bio-threats. That work might as well be done in support of a safer vaccine against the primary biological warfare threat, anthrax.

In terms of increased safety, there is also some evidence an intravenous injection would

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[297] Col. John C. Doesburg, Joint Program Manager for Biological Defense, Memorandum on AUrgent Requirement for Integrated Command Support to Revise the Immunization Schedule for Anthrax Vaccine≅ (JPO 0045) from the Department of the Army, November 17, 1995 (in subcommittee files).

[298] Testimony of Maj. Gen. Robert Claypool, Deputy Assistant Secretary for Health Operations Policy, NSVAIR Anthrax Hearing (IV), p. 179; Arthur M. Friedlander, Philip R. Pittman, and Gerald W. Parker, AAnthrax Vaccine: Evidence for Safety and Efficacy Against Inhalational Anthrax,≅ The Journal of the American Medical Association, December 8, 1999, Vol. 282, No. 22, pp. 2104-2106.

[299] See *supra* note 46, p. 1, sec. 1(a)(8).

produce fewer side effects and adverse reactions than subcutaneous administration. DOD expended significant time and resources in 1994 and 1995 on plans and programs to demonstrate the safety and efficacy of a shorter anthrax inoculation regime, and a different route of administration, but appears to have all but abandoned those efforts when planning for the AVIP began. Support for the FDA application to reduce the shot course seems to have been redirected to vaccine acquisition and AVIP logistics.

4. DOD should enroll all anthrax vaccine recipients in a comprehensive clinical evaluation and treatment program for long term study.

DOD only recently began Ato design a set of studies to better evaluate the long term safety of the anthrax vaccine ... to conform with present-day, post-marketing practices≅[300] While employing active surveillance techniques, these will be cohort studies because A[i]t would be labor-intensive, cost-prohibitive, and would not conform to civilian expectations for us to use this in all 2.4 million service personnel whom we will administer the vaccine to.≅[301] According to Gen. Claypool, DOD will also use linked databases to conduct active surveillance of vaccine recipients, using DEERS and Athe large medical database residing at a tri-service defense medical surveillance system here in the National Capital region of the Walter Reed installation.≅[302]

But these steps, coming more than one year after AVIP implementation, are not enough to monitor the impact of the vaccine program on military health. Having missed the opportunity to study the large cohort of service members who received the AVA during Operations Desert Shield and Desert Storm, DOD has an obligation to reach beyond Acivilian expectations≅ to evaluate the safety of this vaccine.

Particularly for members of reserve component units, access to primary care and specialists at military facilities can be limited. According to DOD, adverse events after the anthrax vaccine are Aline of duty illnesses.≅[303] Therefore,

> Aa member of the Reserve Component may present themselves for initial treatment and evaluation at any military treatment facility, after vaccination during a period of duty. The member will be examined and provided necessary medical care. Once treatment is rendered or the individual=s emergent condition is stabilized, a Line of Duty and/or Notice of Eligibility status will be determined by the member=s unit, as required. No treatment beyond that justified to stabilize the condition or emergency is authorized until Service connection is validated.≅

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[300] Testimony of Maj. Gen. Robert Claypool, Deputy Assistant Secretary for Health Operations Policy, NSVAIR Anthrax Hearing (IV), p. 108.

[301] *Ibid.*

[302] *Ibid.*, p. 109.

[303] Dr. Sue Bailey, AWhat Everyone Needs to Know about the Anthrax Vaccine≅ quarterfold brochure, Department of Defense, November 1, 1999, p. 3 (in subcommittee files).

But requiring an immediate determination of service-connection for vaccine related health effects means many short term, and most long term, adverse reactions will not be monitored by DOD physicians. The causal attribution of health effects to inoculations is difficult, becomes more difficult over time, and remains unlikely in a military program institutionally resistant to any suggestion the vaccine is not safe. Service members should not bear the burden of proof the vaccine caused their ill-health subsequent to inoculation. The process of proving service-connection has frustrated Gulf War veterans= efforts to obtain accurate diagnoses, effective treatments and fair compensation for their unexplained illnesses. It should not be repeated in the AVIP.

Enrollment of every vaccine recipient in a clinical evaluation and treatment protocol would allow DOD to capture a unique and valuable data set for use in their longitudinal studies, avoiding disputes over cohort selection bias and other methodological issues. The evaluation and treatment program could also be the vehicle for assembly of the multidisciplinary teams envisioned by Dr. Engler[304] to develop and implement clinical protocols and maintain a consistent standard of care in the AVIP. It would also help assure service members the vaccine program, as a medical force protection effort, has as its primary purpose the protection of the health of the force.

[304] E-mails from Col. Renata Engler dated December 4-8, 1998 (in subcommittee files).

5. While an improved vaccine is being developed, use of the current anthrax vaccine for force protection against biological warfare should be considered experimental and undertaken only pursuant to FDA regulations governing investigational testing for a new indication.

Under FDA regulations, use of an FDA-approved product in an unapproved way, or for an unapproved purpose, can only be undertaken pursuant to clinical trial protocols contained in Investigational New Drug (IND) applications.[305] IND protocols must be approved by an Institutional Review Board charged to monitor the scientific credibility and ethical soundness (i.e. patient protections) of the trial. FDA must agree the trial proves the product is safe and effective for the proposed use. Informed consent must be obtained from persons enrolled in IND drug or vaccine trials.

If DOD proposed to use the anthrax vaccine against a disease or indication not currently described in the FDA-approved product labeling (i.e high blood pressure), an IND application would be required. If DOD proposed to alter the FDA-approved AVA inoculation regimen (i.e. by eliminating one or more of the six shots), and IND would be required.

Despite the fact the vaccine was approved as safe and subsequently deemed effective only against cutaneous anthrax infection, DOD asserts use of the FDA-approved AVA as prophylaxis against weaponized, inhalation anthrax does not constitute an off-label use against a new indication because A[w]hile the package insert for this vaccine is nonspecific as to the route of exposure, DOD has long interpreted the scope of the license to include inhalation exposure, including that which would occur in a biological warfare context.≅[306]

While some in DOD may have interpreted the scope of MBPI=s FDA license to include inhalation anthrax by implication, others proceeded as if explicit labeling for the indication would be necessary. Throughout development of the anthrax policy that eventually became the AVIP, some in DOD interpreted FDA regulations as requiring approval of both a reduced number of inoculations and the new indication. A 1995 memo states:

[305] 21 CFR Part 312.

[306] Letter from Dr. Stephen C. Joseph to Dr. Michael A. Friedman dated March 4, 1997 (in subcommittee files).

> AThe use of a reduced schedule to protect service members from aerosol exposure to anthrax can only legally be done if the FDA licenses the vaccine for that specific schedule and indication. ... Obtaining FDA license approval for a specific immunization schedule change and for a labeled indication change (aerosol challenge) must provide data that establish safety of two doses of the vaccine given at 0 to 4 weeks since this schedule does not mimic the current schedule of 0, 2 and 4 weeks. More extensive problems exist in demonstrating vaccine efficacy against an aerosol challenge.≅[307]

In September 1996, the vaccine manufacturer, MBPI, submitted an IND application which said, AThe ultimate purpose of this IND is to obtain a *specific indication for inhalation anthrax* and a reduced vaccination schedule.≅[308] (emphasis added) Briefing slides produced by USAMRIID in October 1997 reference two separate objectives to be met in a supplement to the AVA license:

X Supplement to AVA license to reduce the number of immunizations and change the route of immunization.

X Supplement AVA license to explicitly include inhalational anthrax as an indication.[309]

Since 1997, the *Department of Defense Nuclear/Biological/Chemical (NBC) Defense - Annual Report to Congress* has referred to medical CBW countermeasures proven safe because they have Abeen widely used to treat other medical conditions.≅[310] The report cites pyridostigmine

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[307] Micheal J. Gilbreath, Ph.D., AIs the current Anthrax vaccination regimen necessary?≅ Department of Defense Information Paper (JPO 0044), November 10, 1995, p. 1-2.

[308] See *supra* note 138, p. 1.

[309] Department of Defense, ASupplemental to AVA License≅ USAMRIID presentation slides, October 28, 1997 (in subcommittee files).

[310] *Department of Defense Nuclear/Biological/Chemical (NBC) Defense - Annual Report to Congress*, March 1999, pp. 3-3 to 3-4; *Department of Defense Nuclear/Biological/Chemical (NBC) Defense - Annual Report to Congress*, February 1998, pp. 3-4 to 3-5; *Department of*

bromide, the botulinum toxoid vaccine, both used for CB prophylaxis only pursuant to INDs, and the anthrax vaccine. But DOD=s interpretation of the current AVA labeling rests on the conclusion there is but one indication - anthrax infection acquired by any means. Against what Aother medical condition= was the anthrax vaccine used to prove its safety?

> When DOD asked the FDA to concur with the implicit inclusion of inhalation anthrax in the current product labeling, the response was affirmative but tepid. FDA Lead Deputy Commissioner Michael Friedman wrote: AWhile there is a paucity of data regarding the effectiveness of Anthrax Vaccine for prevention of inhalation anthrax, the current package insert does not preclude this use. The original efficacy trail clearly showed that the vaccine conferred a high level of protection against cutaneous exposure. None of the 5 inhalation cases in this trial occurred in Anthrax Vaccine recipients, but these data alone are insufficient to allow definitive statistical conclusions. Results from animal challenge studies have also indicated that pre-exposure administration of Anthrax Vaccine protects against inhalation anthrax.

Defense Nuclear/Biological/Chemical (NBC) Defense - Annual Report to Congress, March 1997, pp. 3-4 to 3-5.

Therefore, I believe your interpretation is not inconsistent with the current label.≅[311]

It was on this basis DOD proceeded to design the AVIP without informed consent procedures, or an informed consent waiver, and without other elements of a clinical trial such as consistent data gathering and detailed health outcome monitoring.

DOD was aware of the extensive problems confronting the effort to prove vaccine efficacy for the new indication, most notably that A...no animal or other potency tests has [sic] been demonstrated to be well correlated with protection of humans.≅[312] DOD conducted, and plans to continue, studies attempting to validate an animal model so findings can be extrapolated to humans.

In launching the AVIP, DOD did not confront those problems but sidestepped them by concluding use of the vaccine to prevent anthrax infection, however acquired, would not require an IND as long as the approved inoculation schedule was followed. So the AVIP=s cumbersome logistics, additional costs, and increased risk of adverse reactions all flow directly from an unwillingness to do the research and testing to develop a better vaccine or improve the safety and efficacy of the current AVA.

That research and testing will have to be done in any event. In 1997 DOD told Congress:

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[311] Letter from Dr. Michael A. Friedman to Dr. Stephen C. Joseph dated March 13, 1997 (in subcommittee files).

[312] See *supra* note 307, p. 2. The memo continues, AThe potency test required for the present vaccine has not been well correlated to efficacy in humans.≅ The current potency test uses guinea pigs. Tests challenging different animal species with a range of anthrax strains showed the vaccine provides varied levels of protection. Against some strains, vaccinated guinea pigs and mice suffered 100 mortality. In DOD studies using nonhuman primates (rhesus monkeys) between 88 and 100 percent of the vaccinated animals survived.

> ADOD complies with all Food, Drug and Cosmetic Act requirements. The Food and Drug Administration (FDA) requires large-scale field trials in human subjects to demonstrate efficacy of drug and biologicals prior to licensure. There are, however, legal and ethical constraints that preclude such efficacy studies for NBC countermeasures. Field studies of efficacy cannot be performed, since exposure to most NBC agents does not usually occur naturally. Moreover, the high lethality and/or toxicity of NBC agents also makes it unethical to expose human subjects in controlled efficacy studies usually required by the FDA for product licensure (*e.g.*, test of effectiveness of the product against the threat in humans). For these reasons, ***many NBC countermeasures are likely to remain in an Investigational New Drug (IND) status, requiring their administration under provisions of an approved protocol and with written informed consent*** from their service members. In contingency situations, DOD may request a waiver of informed consent from the FDA. DOD continues to work with the FDA to seek alternative methods for demonstrating safety and efficacy of NBC medical countermeasures and to obtain their licensure.≅[313] (emphasis added)

Given the predicted likelihood NBC vaccines will be available only in IND status for some years to come, DOD will need to develop the capacity to conduct broad-based clinical trials and effectively communicate risk/benefit assessments through informed consent processes. In the interests of deploying a safer, presumably more effective vaccine against the pre-eminent biological warfare threat, DOD should be willing to develop that capacity now. Instead, DOD has chosen to address the primary threat with a dated, secondary countermeasure with substantial unknowns regarding quality, safety and efficacy.

In prescribing the vaccine, DOD is engaging in the practice of medicine. AIt is true doctors can use drugs off label. It is never true they can do so without informed consent of the patient... You are not immunized from getting informed consent.≅[314] If DOD were to concede administration of AVA against inhalational battlefield exposure is an off label use, informed consent would be required. The AVIP could be transformed, for most, into a voluntary program, with limited mandatory usage of the vaccine possible only pursuant to a carefully monitored informed consent waiver.

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[313] See *supra*, note 310, 1998 Report, p. 3-4.

[314] Testimony of Arthur Caplan, Ph.D., *Force Protection: Improving Safeguards for Administration of Investigational New Drugs to Members of the Armed Forces*, 106th Cong. 1st sess. (1999), unofficial transcript, p. 77 (subcommittee on National Security, Veterans Affairs and International Relations hearing of November 9, 1999) (in subcommittee files).

In a statement submitted to the Subcommittee, the Association of American Physicians and Surgeons asserted:

> AA distinction must be made between treatment and experimentation. It may be asserted that anthrax vaccine (unlike pyridostigmine bromide as used in the Gulf War or anti-botulinum vaccine) constitutes >treatment,= or that it is not experimental because of being declared safe and effective by FDA. ... In fact, the anthrax vaccine was licensed by the FDA before efficacy studies were required. Its efficacy against inhalational anthrax has been questioned.... British epidemiologist suggested that troops be publicly randomized to receive active vaccine or placebo, clearly implying that many consider the vaccine to be experimental.≅[315]

The AAPS recommended a careful examination of the medical ethics involved in military, and civilian, vaccination efforts, noting the entire point of informed consent in combat is >not to prevent soldiers from obtaining whatever protection may be afforded them by an investigational agent that has not been adequately tested, but rather, it is to give them the choice of whether they think the >protection= is worth the risks of adverse effects= ≅[316]

Although DOD=s track record administering INDs or informed consent waivers is not exemplary,[317] current procedural safeguards, adopted since the Gulf War, provide far more

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[315] Submitted statement of Dr. Jane M Orient, Executive Director, Association of American Physicians and Surgeons, NSVAIR Anthrax Hearing (I), p. 119, citing the *European Journal of Epidemiology* 4:12-19, 1998 and Ness AR, Harvey I, Gunnell D, Smigh GD: AAll troops sent to Gulf should be randomized to receive anthrax vaccination or placebo.≅ *British Medical Journal* 316:1322, 1998.

[318] *Ibid.* (quoting Grodin MA, Annas GJ: *Journal of the American Medical Association* 277:712-713, 1997).

[317] In 1990, DOD requested authority to administer IND products, pyridostigmine bromide and botulinum toxoid vaccine, to certain military personnel. DOD also requested a waiver of informed consent requirements in connection with the use of those products by the armed forces. The FDA granted the DOD requests under the terms of an interim rule establishing the procedures and conditions under which informed consent waivers could be obtained by DOD. But DOD did not meet the conditions FDA placed on the waivers, failing to provide information to individual service members about the IND products and failing to keep the medical records necessary to fulfill the protocols and capture data about the safety of the drugs. Despite some improvements in medical record keeping, DOD=s next use of an IND vaccine showed similar problems. In 1997, the General Accounting Office observed Anearly one fourth of the soldiers who received an investigational tick-borne encephalitis vaccine before deploying to Bosnia did not have this information noted in their files.≅ (ADefense Health Care: Medical Surveillance Improved Since Gulf War, but Mixed Results in Bosnia,≅ [GAO/NSIAD-97-136] U.S. General

protection to service members receiving investigational products than the AVIP now provides.

Accounting Office, May 13, 1997, p. 33.)

In November, 1997 the Subcommittee proposed, and the full Government Reform and Oversight Committee approved, an oversight report on Gulf War veterans= illnesses containing 18 findings and 18 recommendations.[318] Among them was the finding that A[t]he FDA was passive in granting and failing to enforce the conditions of a waiver to permit use of PB by DOD≅ and the recommendation that AFDA should grant a waiver of informed consent requirements for the use of experimental or investigational drugs by DOD only upon receipt of a Presidential finding of efficacy and need.≅[319]

Legislation reflecting that recommendation was introduced in both chambers of Congress.[320] The 1999 Defense Authorization Act contained provisions, codified at 10 USC 1107(f), implementing the recommendation by strengthening notice requirements and by requiring a presidential authorization for any waiver of informed consent.

In view of the new statutory provision, FDA on October 5, 1999 revoked the 1990 interim final rule and issued a new regulation to govern DOD compliance with IND conditions and informed consent waivers.[321]

On September 30, 1999 the White House issued Executive Order 13139 establishing the procedures by which the president would comply with the new law.[322] The EO says A[w]aivers of informed consent will be granted only when absolutely necessary≅ and only upon a written determination by the president that obtaining consent is not feasible, is contrary to the best

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[318] *Gulf War Veterans= Illnesses: VA, DOD Continue to Resist Strong Evidence Linking ToxicCauses to Chronic Health Effects,* 2d Report by the Committee on Government Reform and Oversight, House Rpt. 105-388, November 7, 1997, pp. 3-6.

[319] *Ibid.*

[320] H.R.4035, 105th Congress, 2d Session; S.2057, 105th Congress, 2d Session

[321] Federal Register, 21 CFR Parts 50 and 312, October 5, 1999, p. 54180.

[322] Executive Order of September 30, 1999, AImproving Health Protection of Military Personnel Participating in Particular Military Operations≅ No. 13139, The White House, Washington, D.C.

interest of the service member or is not in the interest of national security. In the event a waiver is granted, the DOD Secretary must notify Congress and publish a notice in the Federal Register. No waiver may last more than one year. Waivers may be renewed based on a new, fully documented request.≅[323]

The statute establishes clear U.S. policy that waiver of informed consent in military operations is deemed appropriate and necessary under certain circumstances. The statute, the FDA interim rule and EO 13139 describe, and limit, those circumstances and attempt to ensure any decision to use IND drugs or vaccines without informed consent is as open as possible, supported by sufficient information and authorized at the highest level.

The new regime for waiving informed consent requirements appears far more rigorous and transparent than the system employed under the original interim rule. The statute is very explicit in describing the information that must be provided to each individual service member being given an IND drug or vaccine. The written information must include a clear statement the substance is investigational, the reason the drug or vaccine is considered necessary, information regarding possible side effects and drug interactions, and any other information FDA may require as part of the IND protocol.

That is more clinically useful information than the AVIP now routinely conveys. Consistently providing balanced risk/benefit assessments in an IND setting would also move DOD closer to its stated goal of more effective risk communication. According to an article linked to the DOD AVIP web site:

[323] *Ibid.*

APeople are different. One size does not fit all when it comes to explaining risk. Some prefer short, simple messages about a vaccine's benefits and risks.8,12,68 These people, presumably a majority of the population, will be satisfied with the summary information comprising the Vaccine Information Sheets (VISs) published by the Centers for Disease Control and Prevention. Others want more detailed information. Some will scour the literature to explore every fact they can find. The goal of risk communication involving vaccines should be informed consent.68 True consent to vaccination is only possible if the individual has received all the information he or she wants and understands that information. Then an informed vaccine decision can be made. Providing this information demonstrates respect for the individual. From the clinician's perspective, the consent process can be part of the efforts to identify contraindications to vaccination (e.g., severe hypersensitivity, immunodeficiency).≅[324]

The FDA Abelieves that exceptions from the informed consent requirement should apply rarely and only when sufficient additional protections are provided to the military personnel affected.≅[325] The agency also expresses the view that DOD should pursue drug development through normal regulatory procedures, despite the obvious difficulty of acquiring efficacy data regarding chemical and biological warfare exposures. In the future, requests for informed consent waivers must be accompanied by a history and projected time line for full scale development of the drug or vaccine in question.[326] No more waiting until the eve of war to shortcut a process that could have been underway for months or years.

Under the new law, only the president may waive prior consent requirements, and only after certifying in writing that obtaining consent is not feasible, is contrary to the best interest of the service member, or is not in the interest of national security. With regard to the first two

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[324] Department of Defense, AAnthrax Vaccine Immunization Program≅ at Internet page http://www.anthrax.osd.mil/ citing John D. Grabenstein and James P. Wilson, AAre Vaccines Safe? Risk Communication Applied to Vaccination,≅ *Hospital Pharmacy*, Vol. 34, No. 6, pp 713-729 (available at http://www.anthrax.osd.mil/SCANNED/ARTICLES/grabedocs/vaccines.htm).

[325] See *supra* note 321 p. 51484.

[326] *Ibid.*

justifications, the president must apply the standards and criteria used by the FDA for waivers. Those standards and criteria are detailed in the new FDA interim rule. To meet them, the Secretary of Defense must document for the president all the scientific data, threat assessment, lack of alternatives, and conditions under which the IND product will be used.

The FDA regulation strengthens the role of the Institutional Review Board (IRB) in approving and monitoring the IND protocols for which waivers are granted. IRBs are panels charged with assuring that clinical trials have legitimate scientific goals and that protocols protect human subjects. Under the regulation, an IRB must review all aspects of the proposed IND and waiver. Significantly, the IRB must include at least three members who are not employees of the federal government. This should add some element of independent review to DOD waiver requests. The rule also requires detailed certifications from DOD regarding record keeping systems, medical staff training, and communication of benefits and risks.

The Executive Order of September 30, 1999 mirrors the FDA regulation in many respects, requiring the DOD Secretary to support a waiver request with written justification, rationale, and proof of IRB review. The Assistant to the President for National Security Affairs and the Assistant to the President for Science and Technology must also review the request. After approval of a waiver, the EO requires monitoring and periodic reports on compliance with IND protocols and waiver conditions.

These more explicit and elaborate procedures address many of the problems noted in the execution of the Gulf War waivers. If applied rigorously, those safeguards could also form the basis for a mandatory anthrax vaccine program for certain deployed forces, Special Forces, or other elements determined by the president to warrant vaccination in the interests of national security. The remainder of the force could choose to enroll in an IND protocol[327] or assume the risks of biological warfare not addressed by individual and collective protection, detection, battle tactics and deterrence.

In July 1999, the *Air Force Times* editorialized it was time to AStop Mandatory Anthrax Inoculations≅ because the manufacturer appeared unreliable, and because:

[327] Open protocols could be established for the on-going trial of a reduced vaccine regimen or a trial of a purer vaccine.

AMore research is needed to understand the long-term risk of using the anthrax vaccine. And now, long after initiating the vaccination program, the Pentagon is finally planning such a long-term study of the vaccine=s health effects. That=s good, but until those risks are understood, the Pentagon should proceed with caution -- not reckless abandon.≅[328]

The editorial concluded Athe risks of the vaccine are outweighed by the risk of contracting anthrax≅[329] and advised service members to take the shots. ABut in the absence of empirical evidence proving the vaccine=s long-term safety, the troops should be given the chance to decline. Give them the information they need make wise, informed decisions for themselves. Let those who decline live with what they consider a reasonable risk.≅[330]

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[328]"Stop Mandatory Anthrax Inoculations,≅ *Air Force Times*, Army Times Publishing Co., Jul. 12, 1999, p. 44.

[329] *Ibid.*

[330] *Ibid.*

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(b)(6) 07/17/2001 04:21 PM

To: (b)(6) @OSAGWI
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Subject: FW: SJS 01-03248 (Review of Draft Contingency Protocol for AVA Us e in Volunteers Post Exposure)

Do what you need to administratively with this. I'm forwarding it to LCDR (b)(6) so he can start working on it

---------- Forwarded by (b)(6) on 07/17/2001 04:23 PM ----------

(b)(6) @otsg.amedd.army.mil> on 07/17/2001 03:09:15 PM

To: (b)(6) @OSAGWI
cc:

Subject: FW: SJS 01-03248 (Review of Draft Contingency Protocol for AVA Us e in Volunteers Post Exposure)

COL O'Donnell,

The office of the Assistant Secretary of the Army for Manpower and Reserve Affairs has requested that OSAGWI review the protocol and have the opportunity to provide comments. The draft protocol is attached and a brief history of the action below. Please let me know if you have any questions.

(b)(6)

CHIEF, SERVICE ANALYST DIVISION, EAGLE GROUP INTERNATIONAL
ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP) AGENCY
OFFICE OF THE SURGEON GENERAL
(b)(6) DSN (b)(6)
FAX (b)(6)

> -----Original Message-----
> From: (b)(6)
> Sent: Tuesday, July 10, 2001 3:40 PM
> To: (b)(6)
> Subject: RE: SJS 01-03248 (Review of Draft Contingency Protocol for
> AVA Use in Volunteers Post Exposure)
>
> Ladies and Gentlemen,
>
> Attached are the files for the updated Draft Contingency Protocol for
> Vaccination of Volunteers with Anthrax Vaccine Adsorbed (AVA) After
> Possible Exposure to Bacillus Anthracis Spores. This protocol was staffed
> earlier this year. Comments from that staffing and from a conference
> co-sponsored by the Joint Staff and the Army Office of The Surgeon General
> have been incorporated. Please review the draft protocol and forward your
> concurrence or additional comments electronically to me NLT COB 20 July.

I have not received the JS Form 136 or draft DJS comments (which will change based on your input), but wanted to get these documents out so that you can begin reviewing them.

Please note, the JS was asked to comment on the protocol (including all of the appropriate appendixes) and not on the implementation guidelines. A copy of the JS comments submitted on 4 Apr 01 with the actions taken by MRMC
is attached also.

Please let me know if you have any questions.

Thanks,

(b)(6)

CHIEF, SERVICE ANALYST DIVISION, EAGLE GROUP INTERNATIONAL
ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP) AGENCY
OFFICE OF THE SURGEON GENERAL
(b)(6) DSN (b)(6)
FAX (b)(6)

> <<AVA protocol restaffing memo to HA.doc>> <<0700012 - Anthrax
> Contingency Protocol 113000 (5-15-01).doc>> <<AppA - Logistics
> Annex1.doc>> <<AppB - Form 15721.doc>> <<AppC - Subj Resp Form1.doc>>
> <<AppD - Baseline Questionnaire1.doc>> <<AppE - Deviation Form1.doc>>
> <<AppF - cvr page.doc>> <<AppG - QCA.doc>> <<AppH - Info Papers.doc>>
> <<AppI - Consent Form.doc>> <<AppJ - Sample Instructional Manuals.doc>>
> <<lifesaving-brief.ppt>> <<JCS Memo 0400.doc>> <<Implementation
> Guidance-v3.doc>> <<Anthrax IND Protocol Memo July 3 revised.doc>> .

- AVA protocol restaffing memo to HA.doc
- 0700012 - Anthrax Contingency Protocol 113000 (5-15-01).doc
- AppA - Logistics Annex1.doc
- AppB - Form 15721.doc
- AppC - Subj Resp Form1.doc
- AppD - Baseline Questionnaire1.doc
- AppE - Deviation Form1.doc
- AppF - cvr page.doc
- AppG - QCA.doc
- AppH - Info Papers.doc
- Appl - Consent Form.doc
- AppJ - Sample Instructional Manuals.doc
- lifesaving-brief.ppt
- JCS Memo 0400.doc
- Implementation Guidance-v3.doc
- Anthrax IND Protocol Memo July 3 revised.doc

(b)(6)
Medical Readiness Division

Office of the Special Assistant to the Under Secretary of Defense
(Personnel and Readiness) for Gulf War Illnesses,
Medical Readiness and Military Deployments
(b)(6)

MCMR-UMP (70-1r)

MEMORANDUM FOR Dr. J. Jarrett Clinton, Assistant Secretary of Defense for Health Affairs, 1000 Defense Pentagon, Washington, D.C. 20301-1200

SUBJECT: Review of the Draft Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Absorbed after Possible Exposure to Bacillus Anthracis Spores

1. Reference memorandum, The Joint Staff, DJSM-0256-01, 4 April 2001, SAB.

2. Referenced memorandum included comments on subject protocol provided by the Joint Staff. The comments have been reviewed and incorporated, as applicable, into the contingency protocol. Additionally, comments received from representatives of the Services and Commanders in Chief during the Joint Staff/Army Office of The Surgeon General co-sponsored Joint Medical Nuclear, Biological, and Chemical (JNBC) Readiness Conference, 30 April-4 May, have been incorporated.

3. Enclosed for restaffing is the updated version of the protocol (enclosure 1). Enclosure 2 is an item-by-item summary of the review and disposition of comments received in referenced memorandum.

4. During the JNBC Readiness Conference, the attendees agreed that there should be a separation between the protocol and an implementation plan. Most of the concerns expressed by the representatives were not related to the protocol, but rather to how things would be done. Based on this concern, draft Implementation Guidance was prepared during the conference (enclosure 3). Suggest that this guidance be submitted for staffing along with the protocol.

5. My point of contact for this action is (b)(6) or DSN (b)(6), email: (b)(6)@amedd.army.mil.

3 Encls

JOHN S. PARKER
Major General, MC
Commanding

337

Reference: same as above

Background: The Assistant Secretary of Defense for Health Affairs (HA) requested that a protocol be prepared to allow the use of the Anthrax Vaccine Absorbed (AVA), in conjunction with antibiotics, for post-exposure to Anthrax. A protocol was prepared and staffed out to the Services and the CinCs by HA. Comments were received and incorporated into the protocol. Additionally, comments were received during a conference co-sponsored by the Joint Staff and the Army Office of The Surgeon General. These comments have also been incorporated. This document forwards the updated protocol, along with an item-by-item description of the resolution of the comments received back from the CinCs and Services. Additionally, during the Joint Conference (above), the CinC and Service representatives determined that their real concern was not with the protocol, but rather how they would implement it. A Draft Implementation Guidance document was prepared and is enclosed as well.

Recommendation: CG sign and forward package to HA.

Gere
Zadinsky
SGS

Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Adsorbed (AVA) to Protect against *Bacillus anthracis* Spores

Sponsor: Department of Defense
Office of the Surgeon General of the Army

Point of Contact, Coordinating Office: U.S. Army Medical Research and Materiel Command (USAMRMC)
Office of Regulatory Compliance and Quality (RCQ)
504 Scott Street
Fort Detrick, Maryland 21702-5012
301-619-2165

Sponsor's Representative: Ronald Clawson, Ph.D.
U.S. Army Medical Materiel Development Activity (USAMMDA)
622 Neiman Street
Fort Detrick, Maryland 21702-5012
(301) 619-7845

Clinical Project Manager: Philip R. Pittman, M.D., M.P.H., LTC
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
1425 Porter Street
Fort Detrick, Maryland 21702-5011
(301) 619-2997

JTF/Service Principal Investigators: TBD

Clinical Study Monitor: TBD

Medical Monitor: Anthrax Vaccine Expert Committee

Date of Issue:

This protocol will be conducted as written and in compliance with International Conference on Harmonisation Guidelines for Good Clinical Practice and other applicable regulatory requirements.

STUDY SYNOPOSIS

The purpose of this protocol is strictly to provide treatment for subjects following suspected or confirmed exposure to *B. anthracis* spores. The intent of this protocol is for contingency use of anthrax vaccine in a postexposure setting, not to support a labeling change for the licensed anthrax vaccine. All subjects will have signed an informed consent form before being allowed to participate in the protocol.

The endpoint of this protocol is the collection and analysis of all adverse events (AEs), including local and systemic reactions to the vaccine and clinical cases of anthrax in the study population after administration of the anthrax vaccine.

The anthrax vaccine to be used under this protocol is classified as an Investigational New Drug (IND) because (1) the medical indication for postexposure prophylaxis is not included in the approved package insert, (2) the dosing schedules described for certain anticipated circumstances include vaccination schedules that are outside the parameters of the approved package insert, and (3) some unreleased lots of the vaccine may be used with this protocol. The FDA will review and select each lot of vaccine that will be used under this protocol. The source of vaccine may be from one of the following categories: FDA-released lots of anthrax vaccine, unreleased lots from the original production facility that are acceptable to FDA for this protocol, or unreleased lots from the renovated production facility that are acceptable to FDA for this protocol. When available, licensed lots of vaccine will be used. The protocol will remain active up to a maximum of 5 years.

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ABBREVIATIONS/DEFINITIONS

ACIP	Advisory Committee on Immunization Practices
AE	Adverse Event
AFEB	Armed Forces Epidemiological Board
AITS	Automated immunization tracking system
AR	Army Regulation
AVA	Anthrax Vaccine Adsorbed
AVEC	Anthrax Vaccine Expert Committee
AVIP	Anthrax Vaccine Immunization Program
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CINC	Commander in Chief
cm	Centimeter
CRF	Case Report Form
DA	Department of the Army
DEERS	Defense Eligibility Enrollment Report System
DLA	Defense Logistics Agency
DMSS	Defense Medical Surveillance System
DoD	Department of Defense
EF	Edema factor
ELISA	Enzyme-linked immunosorbent assay
FDA	Food and Drug Administration
FDMB	Focused Distribution Management Branch
GBS	Guillain-Barré syndrome
GCP	Good Clinical Practice
GM	Geometric mean
GMT	Geometric mean titer
HSRRB	Human Subjects Research Review Board
HUC	Human Use Committee
ICF	Informed consent form
ICH	International Conference on Harmonisation
ID	Intradermal
Ig	Immunoglobulin
IM	Intramuscular
IND	Investigational New Drug
Investigator	Refers to both Principal Investigator and Investigator
IRB	Institutional Review Board
JTF	Joint Task Force
LF	Lethal factor

mL	Milliliter
mm	Millimeter
MOPP	Mission-Oriented Protective Posture
N	Number of subjects
NBC	Nuclear, Biological and Chemical
OPDRA	Office of Product Development and Regulatory Affairs
OTSG	Office of the Surgeon General
PA	Protective antigen
PI	Principal Investigator
RCQ	Regulatory Compliance and Quality
SAE	Serious Adverse Event
SIP	Special Immunizations Program
SOP	Standard Operating Procedure
SC	Subcutaneous
TBD	To be determined
µg/mL	Microgram per milliliter
USAMMA	U.S. Army Medical Materiel Agency
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC	U.S. Army Medical Research and Materiel Command
VAERS	Vaccine Adverse Event Reporting System
VIS	Vaccine Information Statement

1.0 GENERAL INFORMATION

Sponsor: Department of Defense
Office of the Surgeon General of the Army

Point of Contact, Coordinating Office: U.S. Army Medical Research and Materiel Command (USAMRMC)
Office of Regulatory Compliance and Quality (RCQ)
504 Scott Street
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JTF/Service Principal Investigators: TBD

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(301) 619-4883

Medical Monitor: Anthrax Vaccine Expert Committee

Contingency Sites: TBD based on particular contingency

Clinical Laboratory: Not applicable

2.0 BACKGROUND INFORMATION

Anthrax disease is a zoonotic infection caused by the spore-forming *Bacillus anthracis*. Depending on the route of infection, anthrax disease can occur in three forms: cutaneous, gastrointestinal, and inhalational [1]. Humans become infected by contact with infected animals or contaminated animal products [2, 3]. Inhalational anthrax is the most lethal form of the disease because of the difficulty in establishing the diagnosis and the rapid progression of the disease. Hemorrhagic mediastinitis, toxemia, and massive pulmonary edema give rise to a fatality rate of almost 100% if untreated [4]. Mortality may exceed 80% after symptoms occur, despite treatment.

Research on anthrax as a biological weapon (BW) began in the early 1900s [5]. *B. anthracis* is considered to be the most likely biological warfare agent because of the ability of *B. anthracis* spores to infect via the respiratory route, the high mortality of inhalational anthrax, and the greater stability of *B. anthracis* spores when compared with other potential biological warfare agents [4-8]. At least 17 nations are believed to have offensive biological weapons programs [5]; however, the number working with anthrax is unknown [9]. The lethal potential of aerosolized anthrax was demonstrated with 68 deaths and 79 cases of anthrax during the 1979 accidental aerosolized release of *B. anthracis* spores from a military microbiology facility in Sverdlovosk in the former Soviet Union [10].

The Persian Gulf War of 1991 heightened the military's awareness that anthrax spores could be used as an effective biological warfare agent. Lyophilized spores can be stored almost indefinitely, can be dispersed in air by a variety of weapons, and are difficult to detect because they are odorless, colorless, and tasteless. Iraq admitted to a United Nations inspection team in 1995 that it had secretly manufactured and stockpiled massive amounts of *B. anthracis* spores for an offensive biological warfare program prior to the Persian Gulf War [11]. Other countries hostile to Western democracies—Iran and North Korea—possess or are pursuing offensive BW capabilities.

According to the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) Recommendations for Use of Anthrax Vaccine in the United States, primary and secondary aerosolization of *B. anthracis* spores are important considerations in the deliberate release of *B. anthracis* spores [12]. Primary aerosolization results from the initial release of the spores; secondary aerosolization results from disturbance of the particles that have settled from the primary release by wind or human and animal activities. Service personnel may be exposed by direct aerosolization and then again by secondary aerosolization.

The infectious dose of *B. anthracis* in humans is not precisely known. Estimates based on data from primates for the infectious dose by the respiratory route are that 8,000 to 50,000 spores are required to cause inhalational anthrax in humans [13, 14]. The influence of strain or host factors on this infectious dose is not completely understood. The incubation period for inhalational anthrax in humans has been reported to range from 1 to 43 days [10]. Studies in nonhuman primates indicate that inhaled spores do not immediately germinate within the alveolar recesses but reside there potentially for weeks until taken up by alveolar macrophages. Spores then germinate and begin replication within the macrophages. Antibiotics are effective against

germinating or vegetative *B. anthracis* but are not effective against the spore form of the organism. The disease may be prevented as long as a therapeutic antibiotic level is maintained to kill germinating *B. anthracis* organisms [12].

Executive Order 13139 of 30 September 1999 [15] mandates that military personnel in operations where they could potentially be exposed to a range of weapons, including biological as well as endemic diseases, be provided with safe and effective vaccines and treatments to negate or minimize their effects. The Anthrax Vaccine Immunization Program (AVIP) sponsored by the Department of Defense (DoD) addresses the prophylactic immunization of military service personnel to protect them against anthrax. Anthrax Vaccine Adsorbed (AVA) is recommended for pre-exposure prophylaxis. The current regimen consists of three subcutaneous (SC) injections, 0.5 ml each, given 2 weeks apart followed by three additional SC injections at 6, 12, and 18 months.

Studies have shown that 83% of human vaccinees develop a vaccine-induced antibody response after two doses of the vaccine. Greater than 95% develop a fourfold rise from baseline in antibody titer after three doses [12]. In addition to an anthrax pre-exposure program, DoD believes that a treatment vaccination program is also needed for individuals who potentially have been exposed to *B. anthracis* spores. Such individuals could include

- Anthrax-vaccine naive personnel
- Personnel who have not completed the primary series of anthrax vaccinations at 0, 2, and 4 weeks
- Personnel who are due for a booster anthrax vaccination

For early treatment of exposure to *B. anthracis* spores, the CDC and ACIP [12, 16] recommends combined chemoprophylaxis and vaccination. This recommendation is based on an extensive review of the literature and professional opinion. The FDA has approved ciprofloxacin to reduce the incidence or progression of inhalational anthrax following exposure to aerosolized *B. anthracis* [17]. In addition, ciprofloxacin has shown in vitro activity against *B. anthracis* and has been shown to be effective when administered in combination with anthrax vaccine in postexposure studies in nonhuman primates [18, 19]. The FDA had previously approved penicillin and doxycycline for the treatment of symptomatic anthrax [7, 16, 20]. Antibiotics are effective against the germinated form of *B. anthracis*, but are not effective against the spore form of the organism.

This is an open-label (no control), multi-site contingency protocol for the administration of anthrax vaccine and concomitant use of antibiotics to treat volunteers following confirmed exposure to *B. anthracis* spores—a regimen that currently is not explicitly approved by the FDA. Enrollment in the protocol is open-ended. Because this protocol will be implemented only in a contingency, the specific number of subjects to be enrolled cannot be projected, although a range of 100 to 5,000 subjects has been adopted for planning purposes. This is a rough estimate and is not designed for the purpose of providing support for a labeling change for Anthrax Vaccine Adsorbed.

The rationale for the protocol is based not on controlled clinical studies but rather on highly controlled animal studies. Because exposure to *B. anthracis* during a contingency will not be similarly controlled, the outcome for humans receiving the antibiotic and vaccine regimen may not be comparable. The purpose of this protocol is strictly to provide treatment for subjects following suspected or confirmed exposure to *B. anthracis* spores. The intent of this protocol is for contingency use of anthrax vaccine in a postexposure setting, not to support a labeling change for the licensed anthrax vaccine. All subjects will have signed an informed consent form before being allowed to participate in the protocol.

The endpoint of this protocol is the collection and analysis of all adverse events (AEs), including local and systemic reactions to the vaccine and clinical cases of anthrax in the study population after administration of the anthrax vaccine.

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2.1 Product Description

Anthrax Vaccine Adsorbed (AVA) is produced by BioPort Corporation (formerly Michigan Biologic Products Institute and Michigan Department of Public Health), Lansing, Michigan [21]. AVA is prepared from a cell-free culture filtrate, which contains no bacteria. A toxigenic, nonencapsulated strain, V770-NP1-R, is used to prepare the vaccine [22]. The filtrate contains a mix of cellular products, including PA (protective antigen) [23, 24] and is adsorbed to aluminum hydroxide as an adjuvant [21]. The amounts of PA and other proteins per 0.5-mL dose are variable, and all three toxin components (lethal factor [LF], edema factor [EF], and PA) are present in the product [25]. The final product contains no more than 0.83 mg aluminum per 0.5 mL dose. Formaldehyde (final concentration ≤0.02%) is added as a stabilizer to the preservative, benzethonium chloride (0.0025%) [21].

The anthrax vaccine is supplied in 5.2-mL vials containing 10 doses each. Each vial will be labeled for human administration and will include the following statement: "Caution: New Drug – Limited by Federal law to investigational use." The vaccine should be stored at 2°C to 8°C (35.6°F to 46.4°F). It should not be frozen.

2.2 Summary of Nonclinical and Clinical Findings

2.2.1 Nonclinical Studies

2.2.1.1 Efficacy Studies

The efficacy of anthrax vaccines against challenge with *B. anthracis* spores has been tested in a limited number of studies using guinea pigs, nonhuman primates, and rabbits [27]. In a series of studies in the guinea pig model, AVA gave variable protection against intramuscular challenge (0%-100% survival) but modest protection against aerosol challenge (20%-26% survival) [26-31]. In studies conducted in the nonhuman primate model, 62 of 65 (95%) vaccinated with AVA survived an aerosol challenge, whereas 0 of 18 control (unvaccinated) animals did not survive [26, 32-37]. In two studies in the rabbit model, 114 of 117 rabbits (95%) survived lethal aerosol challenge, whereas 0 of 28 controls survived the challenge [32].

2.2.1.2 Postexposure Studies

In the mid-1950s, studies in monkeys demonstrated that treatment with penicillin for 5 or 10 days, beginning on day 1 after exposure to aerosolized anthrax spores, was protective during drug therapy [38]. However, the animals died when the antibiotic was discontinued because the antibiotic did not inhibit sporulation. Long-term protection was afforded only when penicillin therapy was combined with postexposure vaccination.

In response to the military's concern about a potential anthrax threat, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) undertook a study to determine whether a prolonged course of postexposure antibiotics with or without vaccination would protect monkeys exposed to a lethal aerosol challenge of *B. anthracis* spores when the antibiotic was discontinued [39]. Beginning on day 1 after aerosol exposure to *B. anthracis* Vollum 1B spores, six groups of 10 rhesus monkeys were given penicillin, ciprofloxacin, doxycycline, doxycycline plus vaccine, vaccine alone, or saline. The antibiotics were administered for 30 days, and the anthrax vaccine was given on days 1 and 15 of the antibiotic regimen.

As shown in Table 1, each antibiotic regimen completely protected animals while on therapy and provided significant long-term protection upon discontinuance of the drug. The results also showed that complete long-term survival, after discontinuance of antibiotics, occurred when postexposure antibiotic treatment was combined with vaccination, confirming previous reports [38, 40].

All animals survived while undergoing antibiotic prophylaxis. Three animals treated with penicillin died on days 9, 12, and 20 after antibiotics were discontinued (days 39, 42, and 50 after exposure). A single animal in the doxycycline group died of inhalation anthrax 28 days after discontinuing treatment (day 58), and one animal in the ciprofloxacin group died 6 days after discontinuation of therapy (day 36).

Table 1. Survival of Monkeys after Postexposure Treatment of Inhalational Anthrax

Treatment	Anthrax deaths	*P* vs. control
Control, saline	9/10	
Anthrax vaccine, 0.5 mL	8/10	>.1
Penicillin, 180,000 units	3/10	<.02
Ciprofloxacin, 125 mg	1/9*	<.002
Doxycycline, 30 mg	1/10	<.002
Doxycycline, 30 mg + anthrax vaccine, 0.5 mL	0/9**	<.0002

* One animal died 5 days after exposure from aspiration pneumonia, had no evidence of anthrax at autopsy, and was excluded from analysis.

** One animal died 6 days after discontinuing doxycycline with no evidence of anthrax on autopsy. Cause of death unknown; the animal was excluded from analysis.

None of the animals treated with antibiotics alone developed an immune response to anthrax. However, antibiotic treatment begun early after exposure did prevent infection from fully developing. Only animals that had been vaccinated seroconverted after aerosol challenge. A serologic response also has been observed in humans who recover from established clinical anthrax after treatment [41, 42] and in monkeys after vaccination. The only animals resistant to a second aerosol challenge were those that had been vaccinated and had seroconverted. Animals protected by antibiotic treatment against the initial infection were susceptible to reinfection. This agrees with a previous report in which animals treated with antibiotics after exposure and hyperimmunized with five doses of vaccine were protected upon rechallenge [42].

2.2.2 Clinical Studies

2.2.2.1 Efficacy Studies

The only clinical study conducted to evaluate efficacy used a vaccine similar to AVA [43]. Both that vaccine and the current vaccine contain protective antigen (PA) as the principal ingredient. A single blind, placebo-controlled study was conducted from 1955-1959 in goat hair workers at risk for cutaneous anthrax in one New Hampshire and three Pennsylvania mills. Vaccination resulted in a statistically significant reduction in the incidence of anthrax in the vaccinated (1 cutaneous and 0 inhalational cases) compared with the placebo group (13 cutaneous and 2 inhalational cases)—92.5% efficacy with a 95% confidence interval of 65% to 100%. An additional three cases of inhalational anthrax were reported in unvaccinated workers who did not participate in the study.

Five cases of inhalational anthrax occurred among 448 unvaccinated workers at the mill where the outbreak occurred (combining both placebo recipients and the unvaccinated observational group), with zero cases among 149 fully vaccinated workers. Despite the trend toward efficacy, the number of cases of inhalational anthrax was insufficient for the difference between the vaccinated and unvaccinated groups to be conclusive statistically (p = 0.34; a USAMRIID calculation, not included in original publication).

Further evidence of efficacy in humans was reported by an advisory panel to the FDA in 1985, based on CDC data collected between 1962 and 1974 [44]. The panel identified 27 cases of anthrax in at-risk industrial settings. Three cases occurred in unvaccinated persons who worked near a goat hair mill. The remaining 24 cases were mill workers; three were partially immunized (one with 1 dose, two with 2 doses); the remaining 21 were unvaccinated. Based on these data, no cases of anthrax have been reported in fully vaccinated subjects at risk of infection. These observations lend further support to the efficacy of the vaccine.

More recently, a Phase 2, open-label study of various dosing regimens of AVA was conducted [45]. The intent of the study was to compare (1) a reduced dosage regimen with the licensed (control) regimen (0.5 mL, subcutaneous (SC) injections given at 0, 2, and 4 weeks) and (2) intramuscular (IM) with SC administration. The results of the study that relate to the proposed contingency protocol are presented. They include the immunogenicity results of the initial SC three-dose series of AVA in the control group (21 men and 7 women) and the safety data on the 203 doses of AVA that were administered SC: 132 doses to men and 71 doses to women.

Immune response to AVA was determined by quantitation of antibody specific for *B. anthracis* PA using a validated enzyme-linked immunosorbent assay (ELISA). A PA-specific IgG concentration >25 µg/mL or a titer ≥1:200 was considered above the minimum limit of quantitation and indicative of an immune response. This assay was chosen because peak PA-specific IgG concentration correlated with protection against inhalational anthrax in a rabbit model [46].

Table 2 presents the antibody response rates in the control group after administration of the first three doses of the licensed regimen at 0, 2, and 4 weeks. The overall rates are cumulative (responded in at least a one time interval up to 8 weeks). The group demonstrated a rapid increase in antibody concentration after administration of the second dose of AVA and achieved 100% seroconversion after administration of the third injection.

Table 2. Antibody Response Rates after Administration of the First Three Doses of AVA at Weeks 0, 2, and 4

Schedule	N	Response	Number of Antibody Responses above Threshold (%)			
			0-2 weeks	3-4 weeks	5-8 weeks[a]	0-8 weeks
0-2-4 SC	28	Titer ≥1:200	10/28 (36)	26/28 (93)	26/26 (100)	28/28 (100)
	28	IgG 25 µg/mL	4/28 (14)	24/28 (86)	26/26 (100)	28/28 (100)

[a] Denominators differ from N values in some cases because samples were not collected from all volunteers at each interval.

Figure 1 presents the antibody response of the control group from 0 to 84 weeks. Based on this antibody response, three doses of vaccine administered at 0, 2, and 4 weeks should afford maximum protection in the shortest time interval.

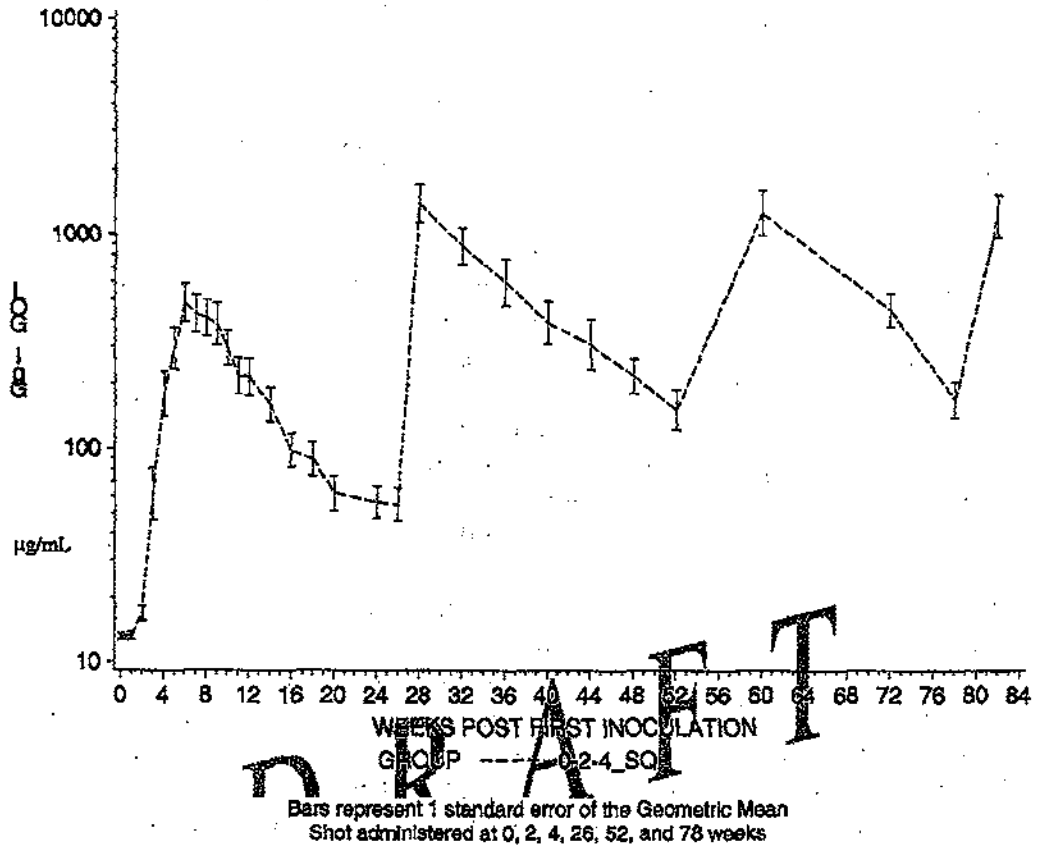

Figure 1. Anti-PA IgG Concentration: Licensed Vaccination Schedule (n = 28)

The duration of immunity is unknown in humans. Animal data suggest that the duration of efficacy of two injections may be between 1 and 2 years [24, 28, 29].

2.2.2.2 Safety Studies

Safety data for AVA are based on adverse event (AE) data, 13 clinical safety studies involving 366,000 vaccine recipients, including passive surveillance for AEs through the FDA's Vaccine Adverse Event Reporting System (VAERS), plus the concurrence of 5 independent review panels, as well as ongoing surveillance. Some of the most robust evidence of the safety of anthrax vaccine comes from the Defense Medical Surveillance System (DMSS), which shows that anthrax-vaccinated and unvaccinated personnel are hospitalized at the same rates.

In AVA prelicensure evaluations, 6,986 people received 16,435 doses—9,893 primary (6) doses and 6,542 annual booster doses [47].

Local reactions: Mild local reactions—erythema, edema, and induration <30 mm—occurred after 20% of vaccinations. Moderate local reactions—edema and induration of 30 to 120 mm—occurred after 3% of vaccinations. Severe local reactions—edema or induration >120 mm—occurred after 1% of vaccinations [47]. Brachman et al. [43] found mild reactions in 30% and

moderate local reactions in 4% of 379 vaccine recipients in their study of the alum-precipitated precursor vaccine to the AVA.

Systemic reactions: Systemic reactions, consisting of fever, chills, body aches, or nausea, occurred in less than 0.05% (4/~7,000) of vaccinees [47]. In the Brachman et al. study [43], systemic reactions occurred in 0.2% of vaccine recipients.

Safety data are available from AVIP. As of July 2000, nearly 460,000 service members had received 1,830,000 doses of AVA. The Morbidity and Mortality Weekly Report (MMWR) of 28 April 2000 [48] reported on three of DoD's completed or ongoing surveys. Based on results of the survey conducted in Korea, women tended to have higher rates of local reactions than men. A self-administered questionnaire was used to assess the frequency and nature of AVA adverse events in a cohort of U.S. military health care workers in the Korea Medical Augmentee Program. Results showed a gradual decline in the number of subjects experiencing systemic reactions from approximately 8% of 595 after the first dose, 5% of 585 after the second dose, and approximately 3% of 536 after the third and fourth doses.

DoD uses the FDA VAERS-1 form to report events potentially related to any vaccination to VAERS and to each military service's disease reporting system. VAERS reports related to anthrax vaccinations are consolidated for AVIP by the Defense Medical Surveillance System. At DoD's request, Department of Health and Human Services (DHHS) established the Anthrax Vaccine Expert Committee (AVEC), a panel of civilian academic medical experts, to review all VAERS-1 reports related to the anthrax vaccine, including those reported directly to FDA or CDC. As of September 2000, 1,152 VAERS-1 reports had been reviewed by AVEC [www.anthrax.osd.mil/Site Files/articles/INDEXclinical/safety_reviews.htm]. Of these, 46 involved hospitalization, 10 of which were "very likely/certainly" or "probably" caused by anthrax vaccine. All 10 involved allergic, inflammatory reactions at the injection site. The other 36 hospitalizations were categorized as unrelated, unlikely, or unclassifiable. Another 169 reports involved a loss of duty >24 hours (but did not involve hospitalization); the civilian panel found that 114 of the 169 certainly or probably were caused by anthrax vaccine. These 114 reports described injection-site reactions (71), various rashes (16), viral-like symptoms (9), acute allergic reactions (7), itching (4), gastroenteritis (2), angioedema (1), muscle aches (1), temporary tingling (1), photophobia (1), and swollen lymph nodes (1). Some reports described multiple symptoms. The balance of the 1,152 reports, 592, were categorized as other than serious, involving neither hospitalization nor loss of duty >24 hours.

Separate analyses performed by the AVIP indicated no correlation between anthrax vaccine and reports of significant adverse events (involving hospitalization or loss of duty) based on (a) geographic clustering, (b) vaccine lot (manufacturing batch), or (c) active vs. reserve component status. No VAERS-1 reports have been submitted that relate to microbial contamination of vaccine vials. No deaths have been causally linked to the anthrax vaccine.

A serious AE, as defined by the FDA (21 CFR 600.80), results in death, hospitalization, permanent disability, or is life threatening. Post-licensure VAERS reports of serious AEs have included cellulitis (3), pneumonia (3), Guillain-Barré syndrome (2), seizures (2), cardiomyopathy (2), systemic angioedema (1), transverse myelitis (1), and myelitis (1) [CDC and FDA,

unpublished data, 1999]. An analysis of VAERS data showed no pattern of serious AEs clearly associated with the vaccine.

In the Phase 2 study comparing dosing schedules, volunteers were monitored for AEs [46]. Specifically, each volunteer was scheduled for evaluation approximately 30 minutes after administration of AVA and 1-3 days, 1 week, and 1 month after vaccination. Reactions were reported up to 30 days after each dose. AE data on subjects in the control group (licensed, SC regimen) and subjects in the comparator study arms who received SC injections are presented. The most common local AE following administration of the first three doses was tenderness at the injection site (70%), followed by SC nodules (38%), and erythema (36%). No abscess or necrosis was observed at the injection site for any treatment group.

The rates of occurrence of local and systemic AEs after administration of AVA during this study are presented for both genders in Table 3. Although the number of AVA doses administered was too small for significance, a number of local reactions, including tenderness, SC nodules, erythema, and induration tended to decrease in frequency as the frequency of doses (up to three) increased. Pruritus and edema showed a slight tendency to increase as the number of doses (both genders) increased. No measurable trend was observed for the reactions warmth and edema. Systemic AEs after each dose of AVA were generally few with headache and malaise being the most common. No trend was noted regarding frequency of systemic AEs and number of doses (up to three) of AVA.

Table 3. Local and Systemic AVA-Related Adverse Events after SC Administration of AVA at Weeks 0, 2, and 4

Reaction	Dose*		
	1	2	3
Local			
Tenderness	74 (73%)	54 (71%)	15 (58%)
SC nodule	44 (44%)	32 (42%)	1 (4%)
Erythema	45 (45%)	26 (34%)	3 (12%)
Warmth	16 (16%)	12 (55%)	5 (19%)
Induration	17 (17%)	12 (16%)	2 (8%)
Pruritus	12 (12%)	12 (16%)	5 (19%)
Arm motion limitation	9 (9%)	6 (8%)	3 (12%)
Edema	3 (3%)	5 (7%)	2 (8%)
Axillary node, tender	1 (1%)	0	0
Systemic			
Anorexia	2 (2%)	1(1%)	0
Fever	2 (2%)	2 93%)	1 (4%)
General pruritus	3 (3%)	2 (3%)	0
Headache	13 (13%)	6 (8%)	1 (4%)
Malaise	8 (8%)	10 (13%)	1 (4%)
Myalgia	4 (4%)	4 (5%)	1 (4%)
Nausea	3 (3%)	2 (3%)	0
Respiratory difficulty	4 (4%)	1 (1%)	0

*Total number of doses administered: 203: dose 1, 101; dose 2, 76; dose 3, 26.

As shown in Table 4, the occurrence of local, vaccine-related adverse events was related to gender (doses 1, 2, and 3 combined). Local AEs associated with SC administration, such as SC nodules, erythema, induration, and edema were more common in females than in males, and systemic vaccine-related AEs after administration were independent of gender.

Table 4. Local and Systemic AVA-Related Adverse Events for Each Gender after SC Administration of the First Three Doses of AVA at Weeks 0, 2, and 4

Reaction	Gender	Reaction Present*
Local		
Tenderness	Female	60 (84.5%)
	Male	83 (62.9%)
SC nodule	Female	45 (63.4%)
	Male	32 (24.2%)
Erythema	Female	45 (63.4%)
	Male	29 (22.0%)
Warmth	Female	25 (35.2%)
	Male	8 (6.1%)
Induration	Female	27 (38.0%)
	Male	4 (3.0%)
Pruritus	Female	21 (29.6%)
	Male	8 (6.1%)
Arm motion limitation	Female	7 (9.9%)
	Male	11 (8.3%)
Edema	Female	7 (9.9%)
	Male	3 (2.3%)
Axillary node, tender	Female	0
	Male	1 (0.8%)
Systemic		
Headache	Female	8 (11.3%)
	Male	12 (9.1%)
Anorexia	Female	0
	Male	3 (2.3%)
Malaise	Female	6 (8.5%)
	Male	13 (9.8%)
Myalgia	Female	5 (7.0%)
	Male	4 (3.0%)
Nausea	Female	2 (2.9%)
	Male	3 (2.3%)
Respiratory difficulty	Female	1 (1.4%)
	Male	4 (3.0%)
General pruritus	Female	2 (2.8%)
	Male	3 (2.3%)
Fever	Female	1 (1.4%)
	Male	4 (3.0%)

*Total number of doses administered = 203: 132 to males and 71 to females.

A series of independent civilian review panels have confirmed the value of anthrax vaccination. The first was the Panel on Review of Bacterial Vaccines and Toxoids (advising FDA) [49]. The Armed Forces Epidemiological Board (AFEB) has repeatedly endorsed the anthrax vaccination of military service personnel. The Working Group on Civilian Biodefense issued recommendations for use of anthrax vaccine in response to terrorist incidents [7]. The Anthrax Vaccine Expert Committee (AVEC) found no unexpected adverse events in its review of VAERS reports involving anthrax vaccine for causal associations and reports [26, 48].

Adverse events following anthrax vaccination have been assessed in studies conducted by DoD in the context of the routine anthrax vaccination program. At U.S. Forces, Korea, data were collected at the time of anthrax vaccination from 4,348 service personnel regarding adverse events experienced from a previous dose of anthrax vaccine. Most reported events were localized, minor, and self-limited. After the first or second dose, 1.9% reported limitations in work performance or had been placed on limited duty. Only 0.3% reported ≥1 day lost from work; 0.5% consulted a clinic for evaluation; and one person (0.025) required hospitalization for an injection-site reaction. Adverse events were reported more commonly among women than among men.

A second study at Tripler Army Medical Center, Hawaii, assessed adverse events among 603 military healthcare workers. Rates of events that resulted in seeking medical advice or taking time off from work were 7.9% after the first dose; 5.1% after the second dose; 3.0% after the third dose; and 3.1% after the fourth dose. Events most commonly reported include muscle or joint aches, headache, and fatigue [48]. However, these studies are subject to several methodological limitations, including sample size, the limited ability to detect adverse events, loss to follow-up, exemption of vaccine recipients with previous adverse events observational bias, and the absence of unvaccinated control groups [49].

2.3 Risks and Benefits

2.3.1 Risks to Subjects

This vaccine has been safely administered in the United States since 1970. However, as with other vaccines, minor reactions are common. Serious adverse events occur rarely after any vaccination. A sharp, stinging sensation immediately upon injection of the anthrax vaccine is common; however, it generally dissipates within the first minute. Like all vaccines, the anthrax vaccine may cause soreness, redness, itching, and swelling at the injection site. Up to 30% of men and 60% of women report mild local reactions, but these reactions usually last only a few days. For both genders, between 1% and 5% report reactions of 1 to 5 inches in diameter. Larger reactions occur about once per 100 vaccinations. A lump at the site occurs commonly, usually lasting for a few weeks, before resolving without treatment.

Beyond the injection site, from 5% to 35% will notice muscle aches, joint aches, headaches, malaise, rashes, chills, low-grade fever, nausea, or related symptoms. These symptoms are usually resolved in less than a week.

Any vaccine can cause serious reactions, such as those requiring hospitalization. For anthrax vaccine, they happen less than once per 100,000 doses. Severe allergic reactions occur less than once per 100,000 doses.

Vaccinees should discuss with the military health care provider whether antihistamines or pain relievers before or after vaccination could help reduce erythema, induration, swelling, and itching at the site of injection. Vaccinees should be told to promptly report adverse events to a military health care provider before receiving additional vaccinations.

As for long-term effects, nearly 1,600 laboratory workers at Fort Detrick, Maryland, have received approximately 10,500 doses of anthrax vaccine since 1973 [Pittman, unpublished data] under the Special Immunizations Program at USAMRIID. Over 20 lots of vaccine have been used during this 25-year period, and a number of individuals have received over 20 doses of anthrax vaccine. None developed unexplained symptoms due to repeated doses of this or other vaccines they received. From this program and other monitoring, no patterns of delayed side effects to anthrax vaccine have been found. Monitoring continues.

A history of a severe reaction to a previous dose of anthrax vaccine is generally an exclusionary criterion. However, because of the nearly 100% fatality from inhalational exposure to anthrax, the vaccine could be administered in conjunction with symptomatic treatment.

While formal clinical studies have not been performed to determine whether this vaccine is carcinogenic or has any effect on fertility, it should be noted that no nonliving vaccine has been found to be carcinogenic or to affect fertility. Furthermore, observational studies of health effects manifested in military hospitalization databases indicate that anthrax vaccine has no effect on rates of cancer or reproductive health problems. The effects of AVA on animal reproduction have not been tested, and it is not known whether the vaccine can cause fetal harm when administered to a pregnant woman or affect reproductive capacity [20]. However, there has been no evidence of infertility, miscarriages, or other reproductive problems with the use of inactivated vaccines, beyond what is expected among unvaccinated individuals.

Vaccinations are routinely deferred until after pregnancy, unless, as in this contingency protocol, immunity is needed during pregnancy. Tetanus, meningococcal, hepatitis B, and influenza vaccines, for example, are specifically recommended for susceptible women during their pregnancy. As with many other vaccines licensed in the United States, specific studies of possible reproductive side effects from use of anthrax vaccine have not been performed.

Because the anthrax vaccine is a sterile, cell-free (filtered) bacterial vaccine, it is noninfectious and is not expected to cause any harm to a fetus. If the anthrax vaccine is inadvertently given to a pregnant woman, no adverse pregnancy outcome or fetal harm is expected. If a pregnant woman is known to have been exposed to *B. anthracis* spores, she will be given the opportunity to take the anthrax vaccine as a potential lifesaving measure.

Immunosuppressed individuals may not be adequately immunized. Also individuals receiving a concurrent course of therapy that depresses the immune response, such as corticosteroids, may not be adequately immunized if the recommended dosage schedule is followed.

As with any vaccine administration and no matter what precautions are taken, the risk of a serious, or even life-threatening, allergic reaction or infection with an unknown adventitious agent exists. To the extent possible during contingencies, emergency equipment will be available to handle acute adverse reactions as per standard medical practice.

Less likely, but possible, is the theoretical chance of Guillain-Barré syndrome (GBS). GBS was associated with campylobacter infections, as well as the influenza vaccine formulations in 1976, 1993, and 1994. CDC reports that 95% of GBS cases are not temporally associated with the administration of vaccines. Approximately 3,500 cases are recorded per year in the United States and Canada. Patients generally present with weakness and loss of lower extremity reflexes. GBS usually occurs as an ascending motor neuron process. The lower extremities are usually involved first and are more severely affected than the upper extremities. The bulbar musculature may be involved as well. GBS is a motor neuron disease, but sensory symptoms may occur along with radicular pain. With appropriate care, the death rate from GBS may be 3%-4%. Approximately 85% of patients make a complete or nearly complete recovery. Management includes supportive care, plasmapheresis, and administration of high-dose immunoglobulins.

No cause-and-effect relationship between anthrax vaccination and GBS has been found. Between March 1998 and January 2001, during the time when 2 million doses of anthrax vaccine were administered, five cases of GBS in subjects vaccinated with AVA were reported to VAERS. The independent civilian AVIP judged one of these cases unrelated to anthrax vaccine (due largely to an inconsistent time course) and the other four cases as unclassifiable (being indistinguishable from the rate of GBS expected in the general population).

2.3.2 Risks to Personnel and the Environment

This protocol presents no known hazards to the personnel other than those normally associated with routine vaccination of human subjects. The principal risks to personnel in the clinical setting are those associated with needle sticks. The risk of contracting anthrax from handling needles is nonexistent.

No risks to the environment are known other than those associated with the generation of biohazardous wastes attendant to vaccination. All biohazardous wastes will be disposed of as stipulated in the Logistics Annex (Appendix A).

2.3.3 Benefits to Subjects

Potential benefits of administration of the anthrax vaccine to previously unvaccinated people after potential exposure to anthrax is that vaccination may provide an additional degree of protection against relapse after discontinuation of antibiotic treatment and would likely protect against a subsequent exposure to *B. anthracis* spores. Previous recipients of anthrax vaccine could benefit against relapse if they are due for a vaccination or if they have not kept their vaccinations current. The benefit of adhering to the prescribed antibiotic regimen cannot be overstated. Strict compliance with both the antibiotic and vaccine dosing schedule could mean the difference between life and death.

2.3.4 Alternatives to Vaccination

Antibiotics, if taken as prescribed, can be effective if exposure to *B. anthracis* spores is detected. Once symptoms of anthrax develop, giving antibiotics reduces the risk of death only slightly—from 99% to 80% lethality. The ACIP recommends postexposure prophylaxis following aerosol exposure to *B. anthracis* spores. Prophylaxis may consist of antibiotic therapy alone or a combination of antibiotic therapy and vaccination.

Individual protective masks (gas masks) and collective protection systems (NBC MOPP suit) provide excellent front-line defense, but their effective use requires rapid and early detection of the agent. Current detection devices do not provide appropriate early warning to allow timely use of personal protective equipment.

2.4 Description of and Justification for Route of Administration, Dosage, Dosage Regimen, and Treatment Periods

Detailed instructions for the administration of the anthrax vaccine are provided in the package insert of the licensed product [22] and at www.armymedicine.army.mil/usamma/anthrax/antxhome.htm. The contents of each vial should be inspected for particulate matter or discoloration. Then each vial should be gently but thoroughly shaken to ensure homogeneous distribution of the contents. More agitation will be needed the first time the vial is used compared with subsequent uses. However, shaking to the point of foaming may degrade the vaccine. Vials should be shaken to resuspend their contents if they have not been moved for 30 or more minutes.

A 0.5-mL dose of vaccine should be drawn into a 1.0-mL tuberculin syringe using sterile technique. Other syringes may have a larger hub space, preventing 10 doses from being withdrawn from a 10-dose, 5.2-mL vial. For SC injections, 5/8-inch, 25- to 27-gauge needles are recommended. The prefilling of large numbers of syringes with anthrax vaccine is rarely advantageous. If prefilled syringes are used, they should be gently shaken if they have not been moved for 30 or more minutes.

The injection site should be cleaned per local procedures. Universal precautions should be observed for infection control. According to CDC, gloves are not required when administering injections, but local infection-control policies should be observed. The vaccine should be injected into the SC tissue of the deltoid or triceps area of the upper arm, typically with the needle at a 45° angle to the skin. Jet-injector immunization devices must not be used. To the extent possible, doses will be administered in alternate arms to minimize discomfort. Left-right-left is a common sequence. Properly stored vials may be used after opening until the labeled expiration date.

Although the primary focus of this protocol is the vaccination of AVA-naïve individuals, the protocol is also intended for individuals who are at various AVIP dosing points when they have been or are presumed to have been exposed to *B. anthracis* spores. Accordingly, anthrax vaccine-naïve subjects will receive three doses at weeks 0, 2, and 4 then continue with the FDA-labeled schedule

- Subjects who have had fewer than three doses will receive two more doses at weeks 0 and 2, then continue with the FDA-labeled schedule
- Subjects who have had three doses will receive an immediate booster dose, then continue with the FDA-labeled schedule
- Subjects who have received four or more doses will receive an immediate booster dose, then continue with the FDA schedule.
- If a subject's record (paper or automated record) is not available, the subject will be assumed to be unvaccinated. In such instances, vaccination will begin with dose 1. An antibiotic will be started as well. If a subject's records are subsequently located, the next dose will be given according to the licensed schedule.

Subjects who have been or potentially have been exposed to *B. anthracis* spores and who do not have their vaccination records immediately available should receive a single dose of vaccine, then continue with the FDA-labeled schedule once their records are obtained.

According to DoD Medical Considerations set forth in the AVIP plan [www.armymedicine.army.mil/usamma/anthrax/antxhome.htm], commanders are responsible for assuring that unit personnel are available at the appropriate times for vaccination. The timing of all subsequent doses must be based on the date the last dose was given, not when it was originally scheduled. It will not be necessary to restart the entire primary series (weeks 0, 2, and 4 and months 6, 12, and 18) due to any prolonged interval between doses. Subjects who risk potential re-exposure to *B. anthracis* spores will be advised to complete the FDA-labeled dosing schedule for the licensed vaccine after their participation in the protocol.

It is acknowledged that there may be some degree of "overimmunization." However, it is preferable to provide the best possible chance to protect each individual exposed to this deadly agent. Considering the risk of "underimmunization" versus the benefit of boosting the immune response by administering an extra dose, we believe strongly favors boosting.

2.5 Compliance Statement

This contingency protocol will be conducted as written and in compliance with the ICH Guideline for Good Clinical Practice (GCP) and other applicable regulatory, DoD, and FDA requirements.

2.6 Study Population

For this contingency protocol, service members include all medically deployable active and reserve component service members as well as U.S. government employees, contractors, other U.S. personnel, and dependents (>18 and <65 years of age) who potentially have been exposed to *B. anthracis* spores. Allied military forces and local nationals also will be eligible to receive the anthrax vaccine. Because this protocol will be implemented only in a contingency, the specific number of subjects to be enrolled cannot be projected, although a range of 100 to 5,000 has been adopted for planning purposes. However, there could be scenarios in which more than 5,000 individuals could be enrolled.

2.7 References

1. Koch R. The aetiology of anthrax based on the ontogeny of the anthrax bacillus. *Med Classics* 1937;2:787.
2. Lincoln RE, Walker JS, Kelin F, and Haines BW. Anthrax. *Adv Vet Sci* 1964;9:327-368.327-368.
3. Friedlander AM. Anthrax. In: Sidell FR, Takafugi ET, and Franz DR (eds): *Textbook of Military Medicine*; Medical Aspects of Chemical and Biological Warfare, Part 1. Washington DC, Walter Reed Army Medical Center, 1996, pp. 467-478.
4. Dixon TC, Meselson M, Guillemin J, and Hanna PC. Anthrax. *N Engl J Med* 1999;341(11):815-826.
5. Christopher GW, Cieslak TJ, Pavlin JA, and Eitzen EM. Biological warfare: a historical perspective. *JAMA* 1997;278:412-417.
6. Pile JC, Malone JD, Eitzen E, and Friedlander AM. Anthrax as a potential biological warfare agent. *Arch Int Med* 1998;158:429-434.
7. Inglesby TV, Henderson DA, Bartlett JG, et al. Anthrax as a biological weapon: medical and Public Health Management. *JAMA* 1999;281(18):1735-1745.
8. Franz DR, Jahrling PB, Friedlander AM, et al. Clinical recognition and management of patients exposed to biological warfare agents. *JAMA* 1997;278(5):399-411.
9. Cole LA. The specter of biological weapons. *Sci Am Dec* 1996:60-65.
10. Meselson M, Guillemin J, Hugh-Jones M, et al. The Sverdlovsk anthrax outbreak of 1979. *Science* 1994;266:1202-1208.
11. Zilinskas RA. Iraq's biological weapons: the past as future? *JAMA* 1997;278:418-424.
12. Advisory Committee on Immunization Practices for Use of Anthrax Vaccine in the United States. Control and Prevention of Anthrax: Recommendations of the Advisory Committee on Immunization Practices for Use of Anthrax Vaccine in the United States, December 15, 2000.
13. Brachman P. Inhalational anthrax. *Ann NY Acad Sci* 1980;353:83-93.
14. Albrink WS and Goodlow RJ. Experimental inhalation of anthrax following the administration of spores by inhalation in the chimpanzee. *Am J Pathol* 1959;35:1055-1065.
15. The President. Improving health protection of military personnel participating in particular military operations. Federal Register 1999;64(192):54175-54178.
16. Bioterrorism alleging use of anthrax and interim guidelines for management—United States, 1998. *CDC MMWR Morb Mortal Wkly Rep* 1999;48(04):69-74.
17. FDA. Approval of Cipro® for use after exposure to inhalational anthrax. FDA Talk Paper, Aug. 31, 2000.
18. Franz DR, Jahrling PB, Friedlander A, et al. Clinical recognition and management of patients exposed to biological warfare agents. *JAMA* 1997;278:399-411.
19. Doganay M, Aydin N. Antimicrobial Susceptibility.of *B. anthracis. Scand J Infect Dis* 1991;23(3):333-335.
20. Barnes JM. Penicillin and *B. anthracis. J Pathol Bacterol* 1947;194:113-125.
21. BioPort Corporation. Anthrax Vaccine Adsorbed Package Insert. March 1999.
22. Advisory Committee for Immunization Practices. Adult immunization. *MMWR* 1984;33:33-34.
23. Puziss M, Manning LC, Lynch JW, et al. Large-scale production of protective antigen of *Bacillus anthracis* in man. *J Bacteriol* 1963;85:230-236.

24. Turnbull PCB, Broster MG, Carman JA, et al. Development of antibodies to protective antigen and lethal factor components of anthrax toxin in humans and guinea pigs and their relevance to protective immunity. *Infect Immun* 1986;52:356-363.
25. Puziss M and Wright GG. Studies on immunity in anthrax. X. Gel adsorbed protective antigen for immunisation in man. *J Bacteriol* 1963;85:230-236.
26. Friedlander AM, Pittman PR, and Parker GW. Anthrax vaccine: Evidence for safety and efficacy against inhalational anthrax. *JAMA* 1999;282(22):2104-2106.
27. Little SF and Knudson GB. Comparative efficacy of *Bacillus anthracis* live spore vaccine and protective antigen vaccine against anthrax in the guinea pig. *Infect Immun* 1986;52:509-512.
28. Ivins BE, Welkos SL, Little SF, et al. Immunization against anthrax with *Bacillus anthracis* protective antigen combined with adjuvants. *Infect Immun* 1992;60:662-668.
29. Ivins BE, Fellows PF, and Nelson GO. Efficacy of a standard human anthrax vaccine against *Bacillus anthracis* spore challenge in guinea pigs. *Vaccine* 1994;12:872-874.
30. Fellows PF, Linscott MK, and Ivins BE. Anthrax vaccine efficacy against *Bacillus anthracis* strains of diverse geographical origin. Presented at 3rd International Conference on Anthrax, 1998, Plymouth, England.
31. Ivins BE, Fellows P, Pitt L, et al. Experimental anthrax vaccines: efficacy of adjuvants combined with protective antigen against an aerosol *Bacillus anthracis* spore challenge in guinea pigs. *Vaccine* 1995;13:1779-1784.
32. Pitt MLM, Little S, Ivins BE, et al. In vitro correlate of immunity in an animal model of inhalational anthrax. Presented at 3rd International Conference on Anthrax, Plymouth, England, 1998.
33. Fritz DL, Jaax NK, Lawrence WB, et al. Pathology of experimental inhalation anthrax in the rhesus monkey. *Lab Invest* 1995;73:691-702.
34. Ivins BE, Fellows PF, Pitt MLM, et al. Efficacy of a standard human anthrax vaccine against *Bacillus anthracis* aerosol spore challenge in rhesus monkeys. *Salisbury Med Bull* 1996;87:125-126.
35. Pitt MLM, Ivins BE, Estep JE, et al. Comparison of the efficacy of purified protective antigen and MDPH to protect non-human primates from inhalation anthrax. *Salisbury Med Bull* 1996;87:130.
36. Ivins BE, Pitt MLM, Fellow PF, et al. Comparative efficacy of experimental anthrax vaccine candidates against inhalation anthrax in rhesus macaques. *Vaccine* 1998;16:1141-1148.
37. Darlow HM, Belton FC, and Henderson DW. The use of anthrax antigens to immunize man and monkey. *Lancet* Sept. 8, 1956:476-479.
38. Henderson DW, Peacock S, Belton FC. Observations on the prophylaxis of experimental pulmonary anthrax in the monkey. *J Hyg* 1956;54:28-36.
39. Friedlander AM, Welkos SL, Pitt MLM, et al. Postexposure prophylaxis against experimental inhalation anthrax. *J Infect Dis* 1993;167:1239-1242.
40. Lincoln RE, Klein F, Walker JS, et al. Successful treatment of rhesus monkeys for septicemia anthrax. In: *Antimicrobial Agents and Chemotherapy*—1964. Washington, DC: American Society for Microbiology, 1965:759-763.
41. Sirisanthana T, Nelson KE, Ezzell JW, Abshire TG. Serological studies of patients with cutaneous and oral-oropharyngeal anthrax from northern Thailand. *Am J Trop Med Hyg* 1988;39:575-581.

42. Buchanan TM, Feeley JC, Hayes PS, Brachman PS. Anthrax indirect microhemagglutination test. *J Immunol* 1971;107:1631-1636.
43. Brachman PS, Gold H, Plotkin SA, et al. Field evaluation of a human anthrax vaccine. *Am J Publ Health* 1962;52:632-645.
44. Department of Health and Human Services. Biological products; bacterial vaccines and toxoid implementation of efficacy review: proposed rule. *Federal Register* 1985;50:51058.
45. Pittman PR. Comparative study to determine the best two-dose schedule and route of administration of human anthrax vaccine. Final Study Report. U.S. Army Medical Research Institute of Infectious Diseases, April 2000, 362 pp.
46. Department of Defense Animal Studies of Anthrax Vaccine Adsorbed (AVA). Development of in vitro correlate of immunity assays and scientific research on use of the rabbit animal model of inhalational anthrax. U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD, 4 September 1998, 36 pp.
47. Michigan Department of Public Health. BB-IND 180.
48. Centers for Disease Control and Prevention. Surveillance for adverse events associated with anthrax vaccination. U.S. Department of Defense, 1998-2000. *MMWR Weekly* April 28, 2000 49(16);341-345.
49. Advisory Committee on Immunization Practices. Use of anthrax vaccine in the United States. *MMWR* 2000;49:1-20.

3.0 PROTOCOL OBJECTIVES

The objectives of this protocol are:

- to provide anthrax vaccine to volunteers who are receiving an antibiotic (ciprofloxacin, doxycycline, or penicillin V potassium) for the early treatment of confirmed exposure to *B. anthracis* spores
- to collect data on local and systemic reactions to the vaccine and clinical cases of anthrax in the study population after administration of the anthrax vaccine.

4.0 PROTOCOL DESIGN

According to DoD Directive No. 6200.2 (August 1, 2000), if no FDA-approved biologic is available to counter a particular threat, DoD components may request approval of the Secretary of Defense (SecDef) to use an IND product. Such a request must be justified based on the available evidence of the safety and efficacy of the product and the nature and degree of the threat to personnel. The SecDef ordered the implementation of a plan to protect service personnel after exposure to *B. anthracis* spores. This protocol has been reviewed and recommended for approval by the USAMRIID Human Use Committee (HUC) and the Army Surgeon General's Human Subjects Research Review Board (HSRRB). If approved by the Surgeon General of the Army and in the absence of a clinical hold by the FDA, the SecDef may approve the use of the anthrax vaccine IND. The chain of command for this contingency protocol is shown in Figure 2.

Preparatory steps to administer vaccine under this protocol would commence on *possible, probable,* or *suspected* exposure to *B. anthracis* spores (Figure 3). Actual administration of

vaccine under this protocol would occur only upon *confirmed* exposure. According to the decision-making process shown in Figure 4, if exposure *to B. anthracis* is *possible*, the SecDef will direct affected unified commands to integrate the protocol into operational plans and the prepositioning of material (antibiotics and anthrax vaccine). The SecDef's order will be directed through the Chairman of the Joint Chiefs of Staff (CJCS), in coordination with the Assistant Secretary of Defense (Health Affairs), Under Secretary of Defense (Policy), Secretary of the Army as Executive Agent, and DoD General Counsel [DoD Directive 6200.2, Section 4.2.1]. If exposure to *B. anthracis* spores is *probable*, the Unified CINC will consult with the Joint Task Force (JTF)/Service Principal Investigator (PI) regarding a request to the SecDef for authority to initiate the protocol. A CINC's request will be made through the CJCS who will make the necessary coordinations as describe above.

Suspected exposure to *B. anthracis* spores would be based on evidence of use or on findings of field detectors or field laboratories. In the case of a suspected exposure, the Unified CINC, in consultation with the JTF/Service PI, will order the initiation of self-administered antibiotics, and advise the SecDef of the decision. In the event that the suspected exposure cannot be confirmed or is ruled out, the Unified CINC will order the JTF/Service PI to halt the self-administration of antibiotics and advise the SecDef of that decision.

Confirmed exposure to *B. anthracis* spores would be based on one or more of the following: classical clinical findings of exposure, casualties from exposure, laboratory confirmation of exposure, or environmental confirmation of exposure. In the case of confirmed exposure, the Unified CINC, in consultation with the JTF/Service PI, will order service members to complete the 60-day antibiotic regimen and order the implementation of the anthrax vaccination protocol. Preliminary laboratory identification can be made within 24 hours after receipt of specimens at USAMRIID with confirmation of results in 72 hours. Upon this determination, any eligible individual who is presumed to have been exposed and who has volunteered to participate will be vaccinated in accordance with this protocol.

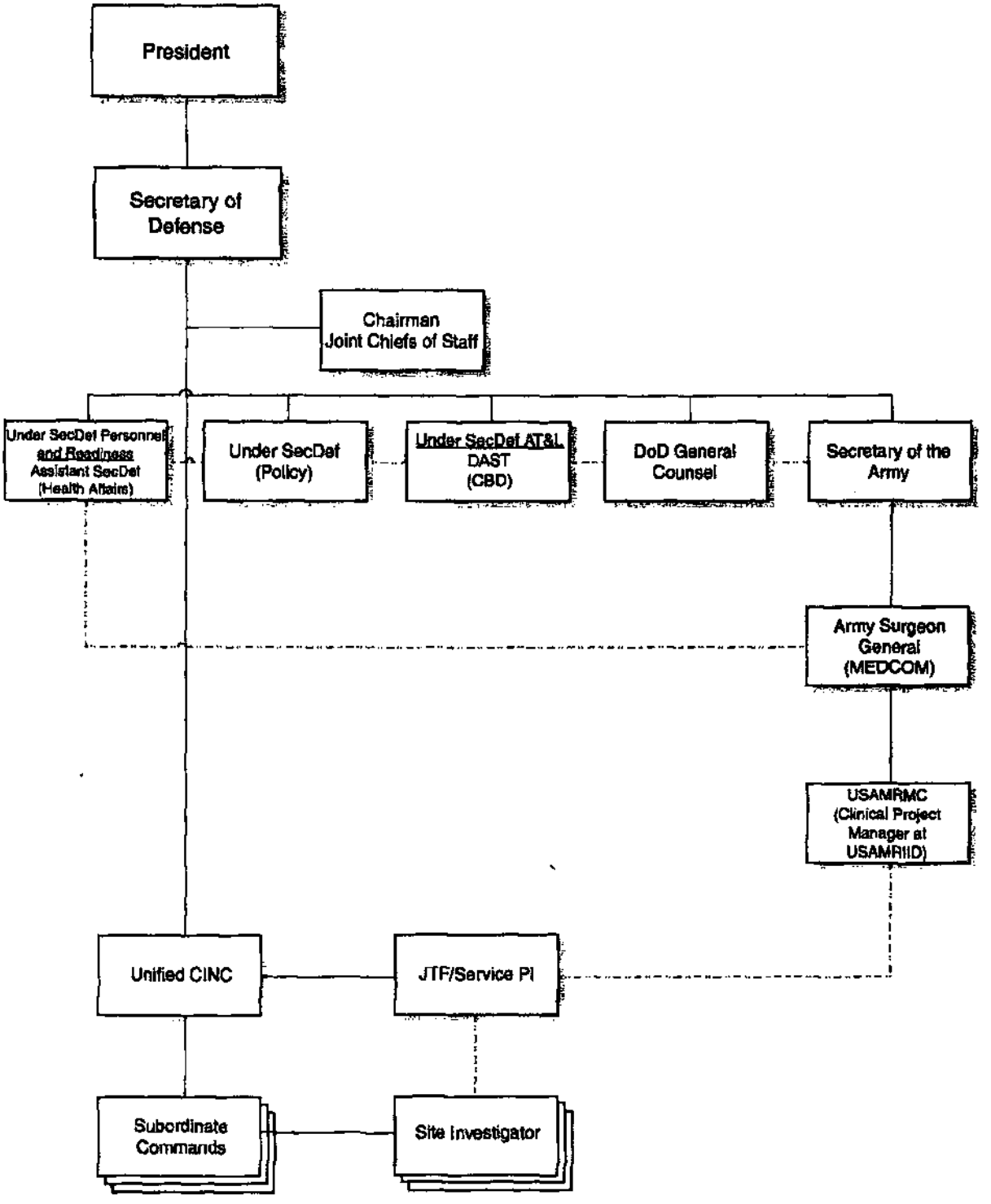

Figure 2. Chain of Command for Anthrax Vaccine Contingency Protocol

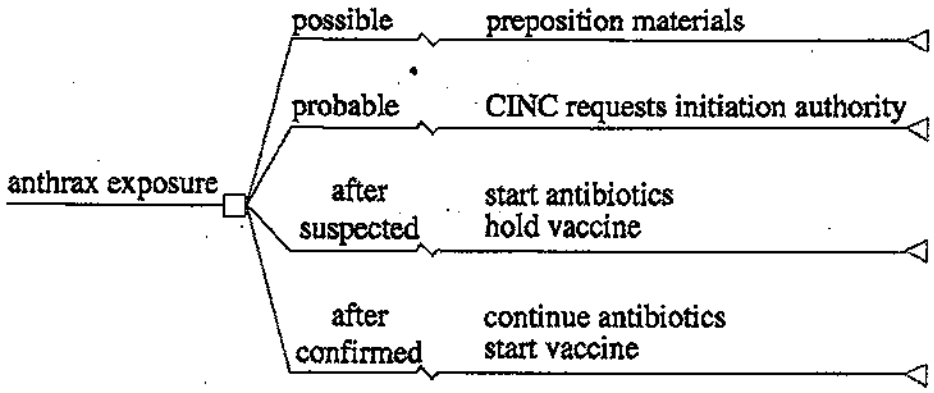

Figure 3. Decision Tree for Anthrax Vaccine Contingency Protocol

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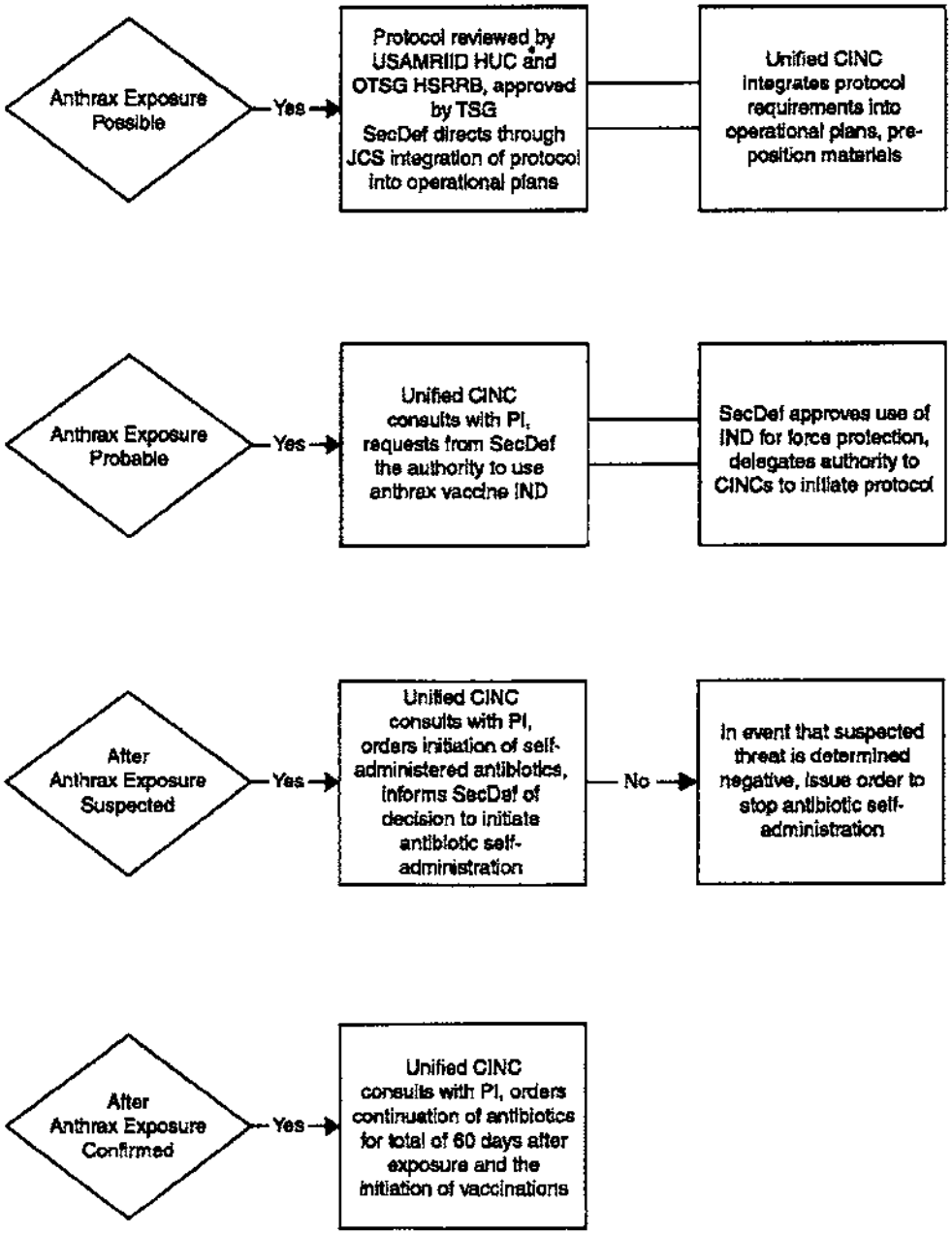

Figure 4. Decision-Making Process for Anthrax Vaccine Contingency Protocol

Responsibilities of Unified CINC:

1. Designate GCP-trained JTF/Service PIs who could be called upon immediately should a threat of exposure to *B. anthracis* spores necessitate activation of the anthrax vaccine contingency protocol
2. Assess the threat of exposure to *B. anthracis* spores of service personnel under the Unified CINC
3. Request approval from SecDef to implement the anthrax contingency protocol
4. Designate additional JTF/Service component PIs, if necessary
5. Order the JTF/Service PI to activate anthrax contingency protocol
6. Inform SecDef of decisions related to the execution of the protocol
7. If appropriate, request waiver of informed consent through SecDef to the President

Responsibilities of Services:

1. Provide uniform education to service members about the anthrax contingency protocol
2. Provide GCP protocol-specific training to JTF/Service PIs
3. Provide storage distribution, disposition, and accountability of anthrax vaccine
4. Provide QC/QA of protocol documentation

Responsibilities of JTF/Service PI:

1. Be trained in GCP (responsibility of USAMMDA)
2. Sign FDA Form 1572 (see Appendix B)
3. Upon being notified by Unified CINC of probable, suspected, or confirmed exposure to *B. anthracis* spores, order antibiotics to be dispensed and vaccination teams to be deployed
4. Assign Investigators to vaccination sites

Responsibilities of Site Investigator:

1. Be trained in GCP (responsibility of USAMMDA)
2. Assign an individual at the vaccination site responsibility for documenting vaccine storage, accountability, and distribution, and disposition.
3. Present or appoint GCP-trained designee to present informed consent information and sign ICF
4. Dispense or oversee dispensing of antibiotics
5. Administer or oversee administration of vaccine
6. Oversee or assign responsibility for ensuring subjects receive requisite vaccinations
7. Oversee entry of vaccination data into AVIP database
8. Complete or oversee completion of AE forms and protocol deviation forms
9. Report protocol deviations in accordance with protocol and JTF/Service PI
10. Report serious and unexpected AEs in accordance with protocol and JTF/Service PI
11. Submit SAE follow-up reports in accordance with protocol and JTF/Service PI

Figure 5. Responsibilities Associated with Anthrax Vaccine Contingency Protocol

Responsibilities of Clinical Project Manager:

1. Be trained in GCP
2. Be responsible for repository of all contingency protocol documentation, including Subjective Response Forms, vaccine accountability documents, informed consent forms, Six-Month Follow-up Questionnaire, protocol deviation forms, VAERS forms (AEs)
3. Submit safety reports to RCQ
4. Submit IND annual reports to the RCQ
5. Track data being entered in the service immunization tracking systems, which are compiled by the DEERS database
6. Retain sufficient data for subject follow-up (VRDB)
7. Oversee integration of original data entered by each service into a single database at USAMRIID
8. Forward copies of serious and unexpected AEs to the RCQ, HSRRB, and USAMRIID's Human Use Committee

Responsibilities of Secretary of Defense:

1. Approve/disapprove CINC request to implement the protocol. The SecDef has authority under DODD 6200.2, Section 4.2, to approve protocols for use on volunteers who give informed consent.
2. Request a waiver of informed consent from the President of the United States when necessary in accordance with DODD 6200.2, Section 4.3

Figure 5. Responsibilities Associated with Anthrax Vaccine Contingency Protocol (cont.)

Active monitoring will be accomplished by means of a Subjective Response Form (Appendix C), which will be given to each anthrax vaccine-naïve subject prior to administration of doses 2 and 3. The form will address the subject's state of health during the previous 2-week period. The form will also include a self-assessment of the subject's compliance with the concomitant antibiotic regimen. The forms will be addressed to the Clinical Project Manager, USAMRIID. The data will be entered into the study database and become part of the analysis of safety.

USAMMDA will conduct long-term safety follow-up of subjects who participated in this contingency protocol. Approximately 6 months after receiving the anthrax vaccine under the contingency protocol, 100% of vaccinees (up to a maximum of 3,000) plus 10% of the additional study population will be asked to complete a follow-up questionnaire (Appendix C) about their state of health since their participation in the protocol. They may be sent a postcard with a toll-free number to call, be surveyed by telephone, be mailed a questionnaire to complete, or be given an Internet site to complete the questionnaire on-line. As with the Subjective Response Form, responses to the Follow-up Questionnaire will be entered into the study database and become part of the analysis of safety.

4.1 Protocol Endpoint

The endpoint of this contingency protocol is the collection and analysis of all adverse events, including local and systemic reactions and clinical cases of anthrax disease in the study population after the administration of the anthrax vaccine.

4.2 Type of Protocol

This is an open-label, multi-site contingency protocol for the administration of antibiotics and anthrax vaccine designed for early treatment of volunteers after confirmed or presumed exposure to aerosolized *B. anthracis* spores.

4.3 Measures to Avoid Bias

Not applicable.

4.4 Description of Protocol Treatment

All individuals presumed to have been exposed to *B. anthracis* spores will be given a Baseline Health Questionnaire (Appendix D) to complete and up to a 60-day supply of antibiotic chemoprophylaxis (see Section 6.4, Concomitant Medications/Treatment). After signing an Informed Consent Form (ICF), they will receive anthrax vaccine according to the dosing schedule in Section 2.4.

4.5 Study Duration

The protocol will remain active up to a maximum of 5 years to enable DoD to protect the health of volunteers, including active and reserve component service members, as well as U.S. government employees, contractors, other U.S. personnel, dependents (>18 and <65 years of age), and allied military forces and local nationals who are presumed exposed to *B. anthracis* spores.

4.6 Protocol Termination

The protocol may be terminated at any time if the subjects' safety and health may be compromised by its continuation. The Principal Investigator or Sponsor may make this determination.

4.7 Product Accountability

4.7.1 Vaccine Accountability

The Sponsor will be responsible for distribution of the vaccine, through the Focused Distribution Management Branch (FDMB) of USAMMA, to all supporting medical supply activities of all services or organizations participating in this protocol. The sponsor will have ultimate responsibility for vaccine accountability. General procedures for vaccine ordering, shipping, storing, controlling, accounting, and disposition processes are described in the Logistics Annex, Appendix A. Additional information is available on the USAMMA AVIP web site at www.armymedicine.army.mil/usamma/anthrax/antxhome.htm.

The Investigator at each vaccination site will assign an individual the responsibility for documenting vaccine storage, accountability, and distribution, including maintenance of logs of

vaccine receipt, temperature maintenance, list of doses by vaccine lot administered (by subject), and amount of remaining vaccine before final disposition (Appendix A, Logistics Annex). These documents will be maintained in the protocol file, which will be sent to the Clinical Project Manager at USAMRIID at the termination of the contingency protocol.

All unopened vials will be accounted for and returned to the sponsor's representative (USAMMDA). After being properly documented, all used vaccine, partially used vials, and all paraphernalia used in the conduct of this protocol will be disposed of according to instructions in Appendix A for drug accountability and handling medical equipment or waste.

4.7.2 Antibiotic Accountability

The antibiotics to be distributed in this protocol are considered concomitant medications. The respective Services will manage the supply and distribution of these antibiotics within the normal medical supply channels in the same manner as all other pharmaceuticals (Appendix A).

4.8 Treatment Randomization Codes

All participants will receive a supply of antibiotics. All participants will receive the anthrax vaccine providing they have signed the ICF and meet eligibility criteria.

4.9 Source Data

The following data fields will be completed via service automated immunization tracking systems (AITSs) and will serve as the Case Report Form for subjects enrolled in the contingency protocol. The service AITSs are MedPROS (Army), SAMS (Navy & Marine Corps), and MITS (Air Force) tracking systems.

1. Immunization Table
   - Date of immunization
   - SSN of receiving individual
   - CDC code for immunization
   - CDC code for manufacturer
   - Volume of vaccine administered
   - Lot number of immunization batch
   - Delivery means of vaccine
   - Adverse reaction to immunization
   - Supervising medical individual
   - SSN for supervising medical individual
   - Location administered
   - Calculated next due date
   - Series number, route of administration (e.g., SC, ID, IM, etc.)

2. Temporary Personnel Table (for non-U.S. service volunteers)
   - Service or military personal class
   - SSN of soldier/individual
   - Unit identification code
   - Individual rank
   - Individual name
   - Date of birth
   - Job code
   - National identity number or other ID number

3. Immunization Validation Table
   - Descriptor code used in Service
   - CDC code for immunization
   - Short name for immunization (CDC)
   - Full immunization name (CDC)
   - Total immunizations in series
   - Number of immunizations
   - Standard dose for immunization
   - Standard route for administration
   - Booster requirement
   - Required interval for each immunization

The data will be integrated into the Defense Eligibility Enrollment Report System (DEERS) for subsequent analysis and long-term record keeping. Ethnicity and gender of service members will be captured at the DEERS level. Ethnicity and gender of non-service members will be captured on the Informed Consent Form. The forms will be forwarded to the Clinical Project Manager, USAMRIID, for entry into the contingency protocol database.

Each service has a back-up plan for data entry if the electricity fails or if a contingency precludes the use of computers. The required information will be entered in the individual paper medical record or paper shot record for subsequent entry into the service-specific electronic database.

Other source data include

- Baseline Health Questionnaire
- Informed Consent Form
- Patient Medical Records (including laboratory results)
- Subjective Response Form (record of reaction(s) after dose 1 and dose 2 of anthrax vaccine and compliance with antibiotic regimen)
- Six-Month Follow-up Questionnaire—internet web site, form letter, telephone contact
- VAERS-1 form

Because of the difficulty of maintaining case report files in a contingency, paper forms, e.g., Baseline Health Questionnaire and protocol deviation forms, will be prelabeled for forwarding directly to the Clinical Project Manager, USAMRIID.

5.0 SELECTION AND WITHDRAWAL OF SUBJECTS

5.1 Inclusion Criteria

Subjects must be presumed to have been exposed to *B. anthracis* spores.

Subjects either must have begun chemoprophylaxis with antibiotics (see Section 6.4, Concomitant Medications) or begin chemoprophylaxis concurrently with the administration of the first dose of anthrax vaccine.

Subjects, including dependents, must be between 18 (17 years old if active duty) and 65 years of age to receive anthrax vaccine.

Subjects must sign and date the ICF before receiving the anthrax vaccine.

5.2 Exclusion Criteria

A history of a severe reaction to a previous dose of anthrax vaccine is generally an exclusionary criterion. However, because of the nearly 100% fatality from inhalational exposure to *B. anthracis* spores, the vaccine can be administered with symptomatic treatment.

Pregnancy is also generally an exclusionary criterion. However, pregnant or lactating women should be given the option of taking the vaccine if the Investigator believes it is warranted because of probable exposure to *B. anthracis* spores (see Section 2.3, Risks and Benefits).

HIV infection is also an exclusionary criterion by current DoD policy. However, nonvaccinated individuals with HIV infection who are exposed to *B. anthracis* spores should be vaccinated, even though the adequacy of the immune response to the vaccine in these persons is unknown.

5.3 Voluntary Withdrawal

Subjects who refuse treatment may withdraw at any time without penalty or loss of benefits to which they are otherwise entitled. Counseling will be provided about the subject's health if he/she decides to discontinue participation in the protocol. Additional medical advice in the best interest of the individual subject will be provided. Specifically, subjects will be told *"Do not stop taking antibiotics on your own because this will allow the bacteria to emerge and cause potentially lethal disease."*

5.4 Removal of Subjects from Study

The Investigator or Medical Monitor will determine which subjects will be withdrawn from the contingency protocol.

6.0 TREATMENT OF SUBJECTS

6.1 Protocol Procedures

Prior to deployment and periodically during deployment, service members will receive standardized instruction on the potential need for the contingency protocol and information on the anthrax vaccine and each of the three antibiotics that could be administered in the event of exposure to *B. anthracis* spores. Medical personnel under the supervision of a GCP-trained Investigator will dispense the antibiotic either in advance of or concurrently with the administration of the vaccine at a designated military medical treatment facility. The individual dispensing the antibiotic will caution subjects that their lives could depend on the antibiotic being taken each day precisely as prescribed. Subjects experiencing a reaction to the antibiotic prescribed should report immediately to their health care provider. Under no circumstance should they discontinue taking the antibiotic until instructed by the health care provider.

Once anthrax exposure is considered **probable**, potentially affected individuals will be given the information paper on the anthrax vaccine and an information paper that describes each of three antibiotics that could be administered. Once anthrax exposure is **suspected**, potentially affected individuals will be asked to review the previously provided information papers. At this time, they will be given an ICF to read (ask questions and understand) and sign as per 21 CFR and ICH guideline for GCP. A copy of the signed and dated ICF will be given to each subject. The Investigator or designee will ask each subject to complete the Baseline Health Questionnaire (Appendix D) prior to administration of the first dose of anthrax vaccine. The subject will be told to present the signed copy of the ICF to the Investigator or designee prior to administration of each subsequently scheduled dose of anthrax vaccine. Subjects will have to sign and date a new ICF if they are not able to present a copy of the original signed and dated form. Once the Investigator or designee has determined that subjects have signed the ICF and are determined to be eligible to participate in the contingency protocol, they will be administered a dose of anthrax vaccine as per instructions in Section 2.4. A person on site will be assigned the responsibility of entering the data for each vaccination into the service-specific computerized database. Data on non-U.S. subjects will be collected by the respective service that administered the vaccine. Subjects will be observed for a minimum of 30 minutes, and any local or systemic reactions will be documented a VAERS-1 form, which will serve as the AE form for this contingency protocol (see Section 8).

Subjects scheduled to receive doses 2 and 3 at weeks 2 and 4 will be given a Subjective Response Form (Appendix B) to complete prior to receiving dose 2 and dose 3. Subjects will be asked to assess their reaction(s), if any, to the previous injection (dose 1 or 2). All vaccinees will be advised that they may also report adverse reactions that might be related to the vaccine to the Investigator or designee prior to completing the response form at the second or third visit. All subjects will have to report any reactions occurring after administration of all subsequent doses of anthrax vaccine directly to the Investigator or designee.

After concluding their participation in the contingency protocol, subjects who will be at risk of future exposure to *B. anthracis* spores will be advised to complete the FDA-labeled regimen of

the licensed product. All military personnel will be notified by means of the vaccination databases of their respective services when they are due for their next dose of anthrax vaccine.

Subjects will be advised in the ICF that they could be selected for a follow-up safety survey approximately 6 months after their participation in the contingency protocol. One hundred percent of vaccinees (up to a maximum of 3,000) will be asked to complete a questionnaire (see Section 4 and Appendix C for details).

6.2 Protocol Deviation Procedures

All deviations from the protocol and actions taken will be recorded on a Protocol Deviation Form (Appendix E) and placed in the regulatory file at the military medical facility administering the vaccine. The Investigator will be responsible for identifying and recording all deviations, which are defined as isolated occurrences involving a procedure that did not follow the protocol or protocol-specific procedure. These deviations will be reported to the Clinical Project Manager as soon after their occurrence as possible. The Clinical Project Manager will submit the deviations to Regulatory Compliance and Quality (RCQ), which will submit them in the IND annual report to the FDA.

At the end of the contingency protocol, vaccination records will be reviewed to determine which subjects were vaccinated off schedule and a follow-up plan will be formulated.

6.3 Protocol Modifications

Any change or modification to the protocol that affects participants, objectives, design, procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendments will be agreed upon and approved by the Sponsor, the USAMRIID HUC and the HSRRB prior to implementation. The ICF must be revised to concur with any amendment, as appropriate, and must also be reviewed and approved with the amendment. A subject already enrolled in the protocol will be informed about the revision and asked to sign the revised ICF if the modification directly affects the subject. A copy of the revised, signed (with date) ICF will be given to the subject. All original versions of the ICF will be retained as part of the subject's permanent record and a copy retained at USAMRIID.

Administrative changes to the protocol are corrections and/or clarifications that have no effect on the way the study is to be conducted. These administrative changes will be agreed upon by the Sponsor and the Clinical Project Manager and will be documented. The HUC/HSRRB will be notified in writing of administrative changes prior to implementation.

6.4 Concomitant Medications/Treatment

6.4.1 General

Restrictions on the use of concomitant medications or treatment during this protocol are related to the administration of ciprofloxacin, doxycycline, or penicillin and are presented in Section 6.4.2. Use of immune-suppressing medications should be annotated in the subject's records.

Other vaccines, if required, may be administered concurrently with the anthrax vaccine, using separate syringes and different anatomic sites. Expected reactions to vaccines may be additive when the anthrax vaccine is administered with other vaccines.

6.4.2 Antibiotics

Prior to or concurrently with the administration of the anthrax vaccine, the Investigator or designee will dispense up to a 60-day supply of antibiotic to individuals potentially exposed to *B. anthracis* spores. Recommendations for selecting an antibiotic in this protocol are listed in Table 5, and each antibiotic is discussed in the following sections.

Table 5. Recommendations in Order of Priority for Selecting an Antibiotic after Exposure to *B. anthracis* Spores

Antibiotic	Dose	Duration
1. Ciprofloxacin	500 mg every 12 hours	60 days postexposure
2. Doxycycline	100 mg bid every 12 hours	60 days postexposure
3. Penicillin V Potassium (PenVK)	500 mg every 6 hours	60 days postexposure

Notes:
1. If subject is allergic to the antibiotic initially prescribed, revert to the next available antibiotic.
2. If supply of antibiotic is insufficient, revert to the next available antibiotic.
3. If supplies of ciprofloxacin are exhausted, and subjects are started on doxycycline or PenVK, switch non-allergic subjects to ciprofloxacin when supplies of ciprofloxacin become available.

The antibiotic of choice is ciprofloxacin for postexposure to anthrax spores. Doxycycline is recommended as the second choice. These two antibiotics have the advantage of twice daily administration, which should increase compliance. For pregnant females and those allergic to ciprofloxacin and doxycycline, penicillin is recommended, although it must be administered four times daily. However, strict compliance with daily dosing will be emphasized for all regimens.

6.4.2.1 Ciprofloxacin

The FDA recently approved ciprofloxacin to reduce the incidence or progression of inhalational anthrax following exposure to aerosolized *B. anthracis* spores. The recommended adult dosage for postexposure inhalational anthrax is 500 mg given orally every 12 hours for 60 days. Ciprofloxacin is contraindicated in persons with a history of hypersensitivity to ciprofloxacin or any member of the quinolone class of antimicrobial agents.

Subjects are to take ciprofloxacin with food (excluding milk or yogurt) and at least 8 oz of water. Subjects taking zinc, iron, sucralfate, Videx® (didanosine), and antacids containing magnesium, aluminum, or calcium should take them 6 hours before or 2 hours after taking ciprofloxacin. Ciprofloxacin may be associated with hypersensitivity reactions, so skin rashes or other allergic reactions should be reported immediately. It can increase sensitivity to sunlight, so prolonged exposure to sunlight should be avoided. Ciprofloxacin may cause lightheadedness or dizziness,

so care should be taken when operating machinery or vehicles or engaging in activities requiring mental alertness. Pain, inflammation, and ruptured tendons have been reported after administration of ciprofloxacin. Of special note, ciprofloxacin also may increase the effects of caffeine and theophylline, which may result from reduced clearance and prolongation of their serum half-lives.

A more detailed description of the side effects, precautions, and drug interactions is included in the Antibiotic Information Paper (Appendix H).

6.4.2.2 Doxycycline

FDA has approved doxycycline for the treatment of anthrax disease but not for postexposure prophylaxis. Doxycycline is contraindicated in persons with a previous hypersensitivity reaction to any of the tetracyclines. Subjects are to take a 100-mg oral dose of doxycycline with food and at least 8 oz of water every 12 hours for 60 days after exposure to *B. anthracis* spores unless otherwise instructed by the Investigator. As with ciprofloxacin, doxycycline may be associated with hypersensitivity reactions, so skin rashes or other allergic reactions should be reported immediately. It can increase sensitivity to sunlight, so prolonged exposure to sunlight should be avoided. Subjects should drink fluids liberally and should not take antacids containing magnesium, aluminum, or calcium, products containing iron, or multivitamins containing zinc. Concurrent use of a tetracycline may render oral contraceptives less effective. In addition, use of a tetracycline during tooth development (last half of pregnancy) may cause permanent discoloration of the teeth of offspring.

A more detailed description of the side effects, precautions, and drug interactions is included in the Antibiotic Information Paper (Appendix H).

6.4.2.3 Penicillin V Potassium

Penicillin is approved by the FDA for the treatment of anthrax disease but not for postexposure prophylaxis. Penicillin is contraindicated in persons with a previous hypersensitivity reaction to any penicillin. Subjects are to take an oral dose of 500 mg on an empty stomach with 8 oz of water every 6 hours for 60 days after exposure to *B. anthracis* spores unless otherwise instructed by the Investigator. A previous hypersensitivity reaction to any penicillin is a contraindication. Penicillin should be used with caution in individuals with histories of significant allergies and/or asthma. The most common reactions to oral penicillin are nausea, vomiting, epigastric distress, diarrhea, and black hairy tongue. Hypersensitivity reactions include skin eruptions, urticaria, and other serum-sickness-like reactions. Penicillin may be taken with or without meals.

A more detailed description of the side effects, precautions, and drug interactions is included in the Antibiotic Information Paper (Appendix H).

6.5 Procedures for Monitoring Subject Compliance

After the administration of each of the first two doses of vaccine at weeks 0 and 2, each subject will be given a Subjective Response Form to document compliance with the antibiotic regimen as well as reaction to the anthrax vaccine (Appendix C) to complete just before the next vaccination. The service-specific databases being used for this protocol will automatically retrieve the names of personnel who are due to receive an anthrax vaccination. The Investigator at each vaccination site will assign a medical care giver the responsibility for ensuring that subjects complete the requisite number of vaccinations.

Monitoring/ensuring that subjects complete the requisite number of vaccinations must be a partnership among the subjects themselves, their commanders or other unit leaders, and the medical community, especially considering the stress of implementing this protocol within military operations.

7.0 ASSESSMENT OF EFFICACY

Assessing the efficacy of the anthrax vaccine for the early treatment of exposure to *B. anthracis* spores is not an endpoint of this protocol (see Section 9). The occurrence of any cases of anthrax disease during the contingency protocol will be evaluated as an adverse event (see Section 8). To the extent possible, the cause of any deaths that occur during the course of the protocol will be determined.

8.0 ASSESSMENT OF SAFETY

The Clinical Project Manager will be responsible for the real-time collection and evaluation of safety data. All AEs recorded during the protocol—whether or not considered to be related to administration of the anthrax vaccine—will be included in the data analysis. Each AE will be documented on a VAERS-1 form (Appendix F), which will be submitted from the field to the Clinical Project Manager. The project manager will report all AEs that are considered serious or unexpected that are considered to be associated with the use of the vaccine to RCQ, which will submit them to the FDA (see Section 8.5). The FDA will be advised of the aggregate incidence of injection site reactions albeit not on individual VAERS reports.

The frequency and incidence rates of all events that might be related to vaccine administration or prescribed antibiotics that are documented by the Investigator or designee on the VAERS-1 form and service-specific databases, as well as events recorded by subjects on Subjective Response Forms and Follow-up Questionnaires, will be analyzed. AE data recorded for the active monitoring group will also be included.

Possible occurrences of anthrax disease and all deaths occurring during the protocol will be recorded as AEs, and their relationship to demographic characteristics of the vaccinees, number of doses received, vaccine lots, and concomitant medications will be analyzed. The outcome of all AEs will be documented to the extent possible during a contingency. Investigators and their

designees will be instructed on the importance of recording the antibiotic prescribed to the subject in Block 17 of the VAERS-1 form for a subject experiencing an AE during the protocol.

Note: Although injection site reactions to the vaccine will be apparent, systemic reactions to the vaccine may not be distinguishable from the onset of the infection.

8.1 Definitions of Adverse Events

An AE is any untoward medical occurrence in a patient or clinical investigation subject administered an investigational drug (vaccine) that does not necessarily have a causal relationship with this treatment. An AE, therefore, can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of an investigational product (e.g., a specific lot of anthrax vaccine) whether or not causally related to the vaccine. Loss of duty greater than 24 hours is a mandatory VAERS reporting criterion.

A serious adverse event (SAE) is any untoward medical occurrence that results in any of the following outcomes:

1. death
2. life-threatening AE
3. in-patient hospitalization or prolongation of existing hospitalization
4. persistent or significant disability/incapacitation
5. congenital anomaly/birth defect

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered SAEs when, based on appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

An unexpected adverse event is an adverse reaction, the nature or severity of which is not consistent with the applicable product information or any AE that has not been documented previously as an event to be expected, i.e., nature, frequency, or intensity, with administration of this test article (vaccine).

8.2 Possible AEs with the Administration of the Anthrax Vaccine

The following statements about adverse reactions are paraphrased from the Package Insert for AVA (the licensed anthrax vaccine) and the previously cited DoD data:

- Like all other vaccines, the anthrax vaccine may cause soreness, redness, itching, and swelling at the injection site. Up to 30% of men and 60% of women report mild local reactions, which usually last only a few days and consist of a small ring of erythema, 1-2 cm in diameter, plus slight local tenderness. For both genders, between 1% and 5% report reactions of 1 to 5 inches in diameter. Larger reactions occur in about one per

100 vaccinees. A lump at the site occurs commonly, usually lasting a few weeks before resolving without intervention.

- From 5% to 35% of vaccinees will experience systemic reactions, including muscle aches, joint aches, headaches, malaise, rashes, chills, low-grade fever, nausea, or related symptoms. However, these symptoms usually resolve in less that a week.
- Any vaccine can cause serious reactions requiring hospitalization. For the anthrax vaccine, they happen <1 per 100,000 doses.

Before administering the anthrax vaccine, the Investigator should determine the type of reaction the volunteer experienced after previous anthrax vaccination(s). The Investigator or designee and the volunteer should assess whether antihistamines or pain relievers before or after vaccination would help reduce bothersome symptoms. In addition, epinephrine or other suitable emergency medications will be available for treating acute allergic adverse reactions.

8.3 Assessing AEs

Volunteered and observed AEs will be recorded in the volunteer health records, in addition to any protocol-specific records. These include AEs that the subject reports spontaneously and those observed by the Investigator. Figure 6 is a decision tree for the Investigators to use in assessing AEs that may occur during the contingency protocol.

8.3.1 Intensity

Regardless of the classification of an AE as serious or not, its severity must be assessed according to the following categories:

- Mild — Does not interfere with routine activities
- Moderate — Interferes with routine activities
- Severe — Unable to perform routine activities

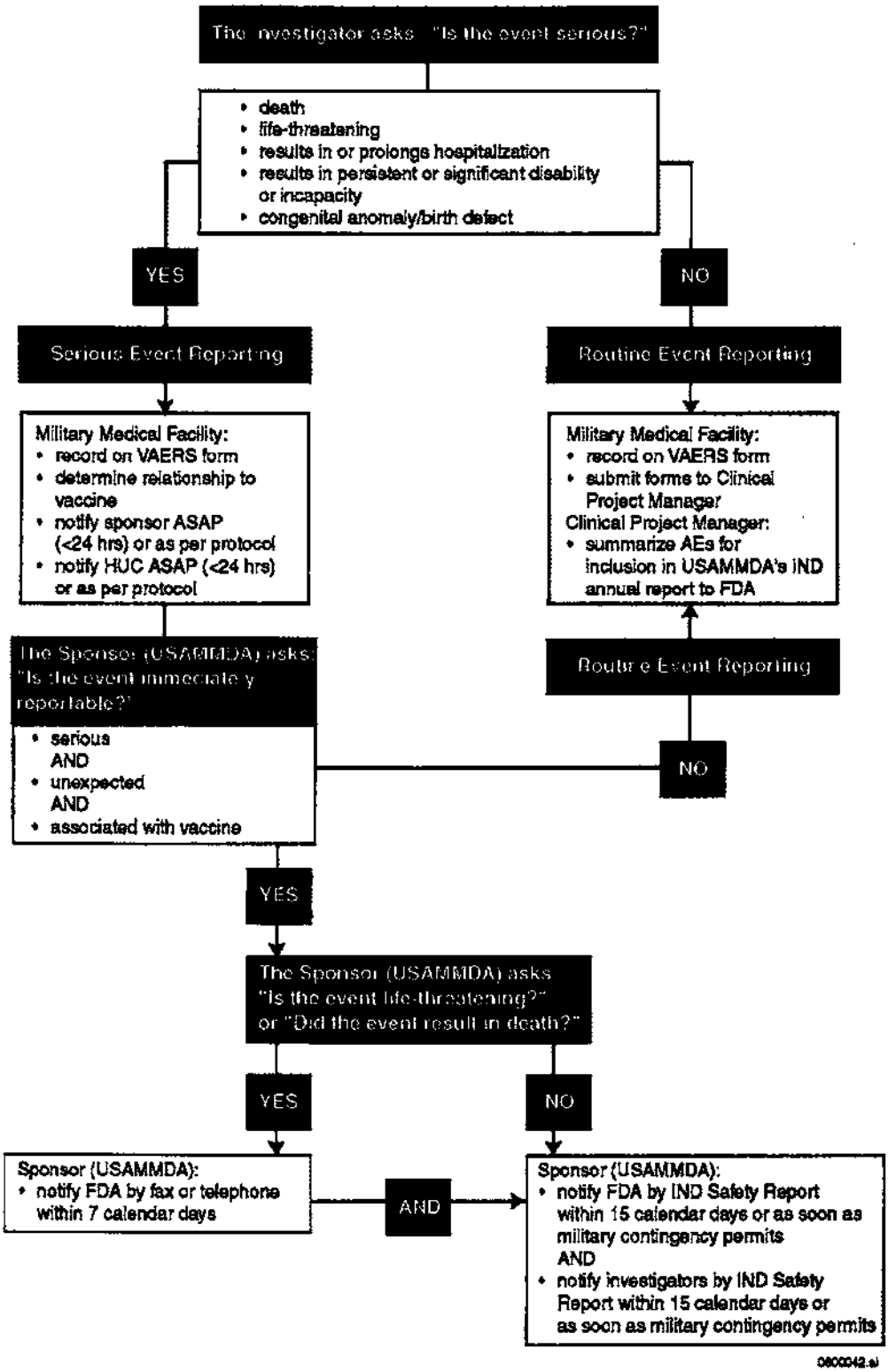

Figure 6. Decision-Making Diagram for the Reporting of Adverse Events—Anthrax Vaccine Contingency Protocol

8.3.2 Causality

Categories of interrelationship between administration of the vaccine and a given or observed reaction are defined in Table 6.

Table 6. AE Causality Assessment Criteria

Category	Definition
Definite	Events occurring within a timely manner after administration of the vaccine that are known sequelae to the administration of the vaccine and follow a previously documented pattern of reaction but for which no other explanation is known. This category applies to those AEs that the investigator believes are incontrovertibly related to the vaccine.
Probable	Any event occurring in a timely manner after administration of the vaccine that follows a known pattern of reaction to the vaccine and for which no other explanation is known. This category applies to those AEs that, after careful medical consideration at the time they are evaluated, are believed with a high degree of certainty to be related to the vaccine.
Possible	Any event occurring in a timely manner after administration of the vaccine that does not follow a known pattern of reaction and for which no other explanation is known. This category applies to those AEs that, after careful medical consideration at the time they are evaluated, are considered unlikely to be related but cannot be ruled out with certainty.
Unlikely	In general, this category can be considered applicable to those AEs that, after careful medical consideration at the time they are evaluated, are considered to be unrelated to administration of the vaccine.
Not related	Any AE for which there is evidence that an alternative etiology exists or for which no timely relationship exists to the administration of the vaccine and the AE does not follow any previously documented pattern. This category applies to those AEs that, after careful medical consideration, are clearly and incontrovertibly due to causes other than the vaccine.
Unclassifiable	There is insufficient information about the AE to allow for an assessment of causality.

The criteria to be used in making the assessment are:

- temporal relationship between administration of the vaccine and the AE
- known safety profile of the vaccine
- evidence of alternative cause(s)

Note: Only a physician can make this determination.

8.4 Recording AEs

The following information must be recorded for each AE on the VAERS-1 form in the designated blocks (in brackets), and SAEs will be reported as per instructions in Section 8.5:

- Subject's name and SSN (add to address line)
- Investigator's name and name of medical treatment facility
- Subject's date of birth [3], age [4], gender [5], and ethnicity (add to [7])
- Vaccine lot [13] and dates of administration [10]
- Date and time of onset [11]
- Signs, symptoms, and severity [7, 8]
- Continuous vs. intermittent reaction [7]
- Relationship to vaccine [7]
- Intervention/treatment [7]
- Concomitant medication(s), including dose, route, frequency, and beginning and ending dates [7]
- Date and time of resolution [7]

All blocks on the VAERS-1 form that are relevant to the AE should be completed.

Limited AE data will also be entered into the service-specific databases (MEDPROS, Army; SAMS, Navy/Marines; and MITS, Air Force).

8.5 Reporting AEs

An Investigator must telephone, fax, or e-mail SERIOUS and UNEXPECTED AEs within 24 hours (or as soon as possible given the contingency) to:

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
Clinical Project Manager
Telephone:
Fax:
e-mail:

The Clinical Project Manager will forward AE information to:

U.S. Army Medical Research and Materiel Command (USAMRMC)
Office of Regulatory Compliance and Quality
Telephone: (301) 619-2165
Fax: (301) 619-7803
e-mail:

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
Chairman, USAMRIID Human Use Committee
Telephone: (301) 619-4723
Fax: (301) 619-2312
e-mail:

An Investigator must submit a written follow-up report within 3 working days (or as soon as possible given the contingency) of the onset of an SAE to:

U.S. Army Medical Research and Materiel Command (USAMRMC)
Office of Regulatory Compliance and Quality
504 Scott Street
Fort Detrick, MD 21702-5012
Fax: (301) 619-7803
e-mail:

The Sponsor's Representative, USAMMDA, will prepare a form 1571 and forward it along with the safety report to RCQ. RCQ with notify the FDA by phone or fax within 7 calendar days of receipt of an initial report of an SAE and also must notify the FDA (through RCQ) and all PIs in writing within 15 calendar days of being notified of an SAE.

An attempt will be made to follow up subjects for whom an AE was reported but whose resolution was not documented during the contingency in order to ascertain the status or resolution of the AE.

8.6 AE Follow-Up

All AEs will be followed to resolution to the extent possible given the contingency regardless of whether the subjects are still participating in the contingency protocol. For all individuals who can be followed, outcomes may be classified as recovered, persists (i.e., chronic condition diagnosed, other infectious disease, trauma), died, or lost to follow-up.

Nonserious AEs will be reported to the FDA in the IND annual report prepared by the Clinical Project Manager.

8.7 AE Monitoring

A Medical Monitor (Unit Medical Officer [Army] or equivalent organizational medical officer for Navy, Air Force, and Marine Corps units) at each site is required to investigate all serious and unexpected AEs associated with the contingency protocol and provide an unbiased written report of the event within 10 calendar days of the initial report (unless contingencies delay it) to the Clinical Project Manager at USAMRIID. At a minimum, the Medical Monitor should also indicate whether he/she concurs with the details of the report provided by the Investigator. The Medical Monitor is also required to submit AE findings to the HSRRB. The specific functions of the Medical Monitor are described in Section 11.2.

Representatives of the Army, Navy, and Air Force Offices of the Surgeons General and USAMMDA, as the Sponsor's representative, are also entitled to review research records as part of their responsibility to protect human subjects in research.

9.0 STATISTICS

All subjects enrolled in this contingency protocol will be included in the evaluation of safety.

The number of subjects will depend on the documented or perceived exposure to *B. anthracis*.

Data entered into the MEDPROS, SAMS, and MITS databases will be evaluated for compliance with the vaccination schedule and the relationship of AEs to vaccine doses. The analysis will include standard tabulation of demographic, vaccination, and AE data, as well as the antibiotic administered. All AE data entered into the VAERS-1 forms including Investigator-determined causality, will be analyzed.

Assessment of vaccine efficacy is not a major objective of this protocol. However, as part of the assessment of safety, the number of doses of anthrax vaccine received, the vaccine production lot, and the temporal relationship to onset of disease will be studied in subjects who develop anthrax disease while participating in this contingency protocol.

10.0 DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

Representatives of the Army, Navy, and Air Force Offices of the Surgeons General, USAMMDA as the Sponsor's representative, and the FDA will be permitted to photocopy and review medical and protocol records related to this protocol as part of their responsibility to protect human subjects enrolled in DoD-sponsored clinical studies.

11.0 QUALITY CONTROL AND QUALITY ASSURANCE

11.1 Clinical Study Monitor

The Quality Assurance Division, USAMMDA, will provide retrospective monitoring of the anthrax vaccine contingency protocol (Appendix G). No prospective monitoring is planned. The study will be monitored for GCP compliance, verifying adherence to the protocol and the completeness and exactness of data entry at the conclusion of the contingency protocol. The monitor will audit the investigation study files, volunteer consent forms, service-specific databases (i.e., case report forms), VAERS-1 forms, original source documents, and logistical records upon their arrival at the permanent record site (USAMRIID). Upon completion of each review, the monitor will brief the Clinical Project Manager and PIs of findings and issues in need of resolution for future contingencies requiring the use of IND products. A written report of the findings and recommendations will be circulated and provided to USAMMDA, as the Sponsor's Representative.

11.2 Medical Monitor

The Unit Medical Officer (or equivalent organizational medical officer for Navy, Air Force, and Marine Corps units) will assume the role of Medical Monitor at the vaccination sites for subjects enrolled in this protocol. Unit Medical Officers will provide care (as they would for any other

medical necessity) for volunteers experiencing AEs associated with the anthrax vaccine. Situations permitting, a person from USAMMDA could conduct an on-site audit. The AVEC will assume the role of Medical Monitor (data safety monitoring board)—reviewing all adverse events that are reported during the execution of the contingency protocol. This is the role that the committee currently performs for the AVIP.

12.0 ETHICS

12.1 Good Clinical Practice

The procedures set forth in this protocol are designed to ensure that the Sponsor and all protocol personnel abide by the Code of Federal Regulations (in particular, 21 CFR, Parts 56, 312, 314, and 601) and ICH Guideline for GCP. All Principal Investigators and Investigators will receive GCP instruction. The PI for each JTF/Service confirms this by signing this protocol and FDA Form 1572.

12.2 Informed Consent

Written informed consent, in compliance with 21 CFR 50, will be obtained before any protocol-related procedures are initiated. Subjects will receive information papers (Appendix H) about the anthrax vaccine and the antibiotics together with the ICF (Appendix I). Instructions about the uses of IND products during a military contingency, in general, and the anthrax vaccine, specifically, will be given to service members prior to deployment and periodically post-deployment. Appendix J contains samples of standardized instructional manuals that will be given to service members. DoD's quadfold brochure and CDC's Vaccine Information Statement (VIS) on anthrax vaccination may be used as training aids to provide additional information. A GCP-trained investigator will present the protocol in lay terms to the subject singly or in groups. Questions will then be solicited on the nature of the protocol, the means by which it is to be accomplished, and the risks to the participants. Any question that cannot be answered will be referred to another Investigator. Informed consent will be obtained from each subject. No subject will be expected to grant consent until questions have been answered to his/her satisfaction. Subjects should understand that the lots of anthrax vaccine to be administered postexposure to *B. anthracis* spores under this protocol are considered to be an investigational drug. Informed consent includes the principle that it is critical that the subject be informed about the principal potential risks and benefits. This information will allow subjects to make a personal risk-versus-benefit decision and understand the following general principles:

1. Participation is entirely voluntary.
2. Subjects may withdraw from participation at any time without penalty or loss of benefits to which they are otherwise entitled.
3. Refusal to participate involves no penalty.
4. The individual is free to ask any questions that will allow him/her to understand the nature of the protocol.

Before being enrolled in this contingency protocol, all subjects will sign (with date) an ICF prior to undergoing any protocol-related procedure. This consent form must include the subject's full

name, home of record, telephone number, social security number or local identification number, gender, and date of birth. The ICF must be dated, witnessed, and retained by the Investigator as part of the protocol records at the military medical facility administering the vaccine. Should the protocol be modified, the subject consent form may be revised to reflect the changes of the protocol. Each volunteer will receive a copy of the signed ICF and any revised ICF, read and signed (with date) by the subject. This copy should be presented at the subject's next duty station if transferred before receiving the requisite number of doses of vaccine. If the signed form is lost, the volunteer will be required to sign and date a new ICF before receiving subsequent doses.

12.3 Approval of Study Protocol

Before a clinical protocol can be initiated, the protocol and other required documents will be submitted to the OPDRA Quality Assurance Unit, the Sponsor's Representative, and USAMRIID Scientific Review Committee; approved by the USAMRIID HUC Institutional Review Board (IRB) and the HSRRB; and submitted to the FDA for consideration and acceptance.

12.4 Confidentiality

Subjects will be identified in the service-specific databases by their personal social security number, date of birth, home of record, and telephone number. Subjects will be advised that they could be contacted at later dates for follow-up. This follow-up includes safety surveillance for the benefit of service members. The Privacy Act (5 USC § 552a) statement related to the establishment of a database with information retrievable by the Social Security number of service members is included in the ICF.

Representatives of the Army, Navy, and Air Force Offices of the Surgeons General, USAMMDA as the Sponsor's representative, and the FDA are eligible to photocopy and review medical and research records related to this protocol as a part of their responsibility to protect human subjects in clinical research.

No personal data will be used in any external communication or publication.

12.5 Confidential Follow-Up

The Clinical Project Manager is responsible for retaining sufficient information about each subject (i.e., name, home of record, telephone number, social security number, date of birth, and identity in the protocol, dates of participation) so that USAMMDA as the Sponsor's representative, representatives of the Army, Navy, and Air Force Offices of the Surgeons General, and the FDA may access this information if necessary. This information will be captured and retained in the database at USAMRIID dedicated for this protocol. The Clinical Project Manager will maintain protocol records in accordance with GCP and ICH guidelines.

Information on individual subjects needed to support the Volunteer Registry Database will be maintained by the respective services for a minimum of 75 years.

13.0 DATA HANDLING AND RECORDKEEPING

All protocol data will be handled in compliance with ICH Guideline for GCP. Clinical data, if collected during the course of a subject's participation in the protocol, will be entered into the individual's protocol record. All original data entered by each service into its database will be forwarded for integration into a single database.

14.0 FINANCING AND INSURANCE

The Department of Defense is funding this clinical protocol. Should a subject be injured as a direct result of participating in this protocol, he/she will be entitled to medical care at no cost for that injury. Injury compensation is based on the "personnel" status of the volunteer. Military personnel are generally eligible for disability compensation for any injuries or illnesses incurred in the line of duty. Civilian personnel of the U.S. Government and of contractors are generally eligible for disability compensation for injuries or illnesses incurred within the scope of employment. Injury compensation beyond the scope of these disability compensation programs is not available. Injury compensation for volunteers who do not have a personnel status that includes compensation coverage is not available. The subject should understand that this does not constitute a waiver or release of legal rights. This issue is addressed in the ICF and will be discussed with the subject by the Investigator or designee at the vaccination site.

15.0 PUBLICATION POLICY

All data collected during the course of this protocol may be published in the open medical or military literature with the identity of the volunteers protected.

16.0 WAIVER REQUESTS UNDER 21 CFR 312

16.1 21 CFR 312.53 (b) – Control of Drug

A waiver has been requested in a separate letter to the FDA of the requirement for the Sponsor to ship investigational new drugs (anthrax vaccine) only to Investigators participating in the investigation.

The Logistics Annex (Appendix A) includes a system for control of the anthrax vaccine that will allow a retrospective analysis of records (at the termination of the contingency protocol) to track the disposition of all vaccine.

16.2 21 CFR 312.64 (a) and (c) – Investigator Reports

A waiver has been requested in a separate letter to the FDA of the requirement for submission of annual progress reports and a final report from individual Investigators.

The Clinical Project Manager will collect data and submit adequate reports as described in 21 CFR 312.62.

17.0 SIGNATURE OF JTF/SERVICE PRINCIPAL INVESTIGATOR

Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Adsorbed (AVA) after Possible Exposure to *Bacillus anthracis* Spores

I have read the foregoing protocol and agree to conduct the protocol as outlined herein in accordance with the ICH Guideline for GCP and applicable FDA, DoD, and U.S. Army regulations.

_____ _____
Name Date

_____
Title

_____
Location

APPENDIX A

Logistics Annex

APPENDIX A

LOGISTICS ANNEX

1. General. The Focused Distribution Management Branch (FDMB) at the U.S. Army Medical Materiel Agency (USAMMA) will coordinate the distribution of the Anthrax Vaccine to all supporting medical supply activities of all Services or organizations participating in this protocol. All activities must become familiar with the vaccine ordering, shipping, storing, controlling, accounting, and disposition processes discussed in this annex. Additional information is available on the USAMMA AVIP web site at http://www.armymedicine.army.mil/usamma/anthrax/antxhome.htm.

The Anthrax Vaccine to be used under this protocol is considered an investigational new drug. It must be handled using strict procedures meeting rigorous regulatory requirements for logistical tracking. Activities will track the issuing of this vaccine like a controlled substance and must be capable of documenting all issuing of vaccine from the wholesale level down to vaccination sites. Vaccination sites will employ the Services vaccination tracking systems to document administration of Anthrax Vaccine to subjects under this protocol. This annex presents information pertaining to all portions of the logistical tracking process beginning with requisitions and ending with disposition of expired/suspended vaccine.

2. Requisitioning. The FDMB will not accept automated requisitions for Anthrax Vaccine being requested under this protocol. Vaccination centers must submit requests to their supporting logistics activity, which will validate the requirements and submit the formal requisition to their strategic logistics agency, which serves as their Service Anthrax Vaccine Control Center using a DD Form 1348-6 or acceptable alternative. A sample DD Form 1348-6 is attached. Service Anthrax Vaccine Control Centers are as follows: Navy and Marine Corps – Navy Medical Logistics Command (NAVMEDLOGCOM), Air Force – Air Force Medical Logistics Office (AFMLO), Army – U.S. Army Medical Materiel Agency (USAMMA).

a. Vaccination Centers must request vaccine through their supporting medical supply channels. Medical supply officers must prepare the appropriate request for faxing to their Service Anthrax Vaccine Control Center.

b. The following information must be provided on the DD Form 1348-6 or appropriate alternative: NSN – 6505-01-399-6828; Document Number (including requisitioner, date, and serial number); priority – 02; Name of item requested – Anthrax Vaccine for IND, 5.2ml vial; unit of issue – VI; Quantity – enter quantity required. Additionally, provide the following additional information to ensure proper delivery:

1) Requester's name,
2) Requester's telephone number (commercial and DSN if available),
3) Requester's fax number,
4) Person who will be the shipment point of contact (POC),

5) POC telephone number (commercial and DSN if available),
6) POC fax number,
7) POC e-mail (if available),
8) Alternate POC information (identical information as requested for the primary POC), and
9) Shipping address (unit or facility, street address, city, state and zip code). Individuals experiencing difficulties providing this information should contact USAMMA at (301) 619-4121/4128/4411/4318/4198/4320. DSN is 343.

c. Navy & Marine Corps requesters must submit their requisitions to NAVMEDLOGCOM. Air Force requesters must submit their requisitions to AFMLO. Army and non-DoD requesters must submit their requests via fax to USAMMA at (301) 619-4468.

d. USAMMA will contact customers immediately if requests are incomplete or illegible to complete to requisition process.

e. Anthrax Vaccine Points of Contact:

Army (Executive Agent)
USAMMA web site: http://www.armymedicine.army.mil/usamma/anthrax/poc.stm
USAMMA Pharmacy Consultant: MAJ Marc Caouette, DSN 343-4307, Comm 301-619-4307, FAX x4189. Email: Marc.Caouette@dot.amedd.army.mil
Focused Distribution Management Branch:
Kandi Barnhart, DSN 343-4411, Comm 301-619-4411,
Email: Kandi.Barnhart@amedd.army.mil
Jackie Graff, DSN 343-4198, Comm 301-619-4198
Email: Jackie.Graff@amedd.army.mil
Bonnie Pereschuk, DSN 343-4121, Comm 301-619-4121,
Email: Bonnie.Pereschuk@amedd.army.mil
Toscha Stanley, DSN 343-4318, Comm 301-619-4318,
Email: Toscha.Stanley@amedd.army.mil
Kitty Reese, DSN 343-4320, Comm 301-619-4320,
Email: Kitty.Reese@amedd.army.mil
David Orgler, DSN 343-619-4128, Comm 301-619-4128,
Email: David.Orgler@amedd.army.mil

Air Force
Air Force web site: https://afml.ft-detrick.af.mil/afmlo/index.htm
MSgt Dale Clark, DSN 343-4172, Comm 301-619-4172
Email: Dale.Clark@Ft-Detrick.af.mil
MSgt Shelia A. Brown, DSN 343-4122, Comm 301-619-4122
Email: Shelia.Brown@Ft-Detrick.af.mil

Navy and Marine Corps
Navy and Marine Corps web site: nmic-web@us.med.navy.mil
LCDR Brad Homman, DSN, 343-3065, Comm 301-619-3065
Email: bhomman@us.med.navy.mil
Lt Scott Spratt, DSN 343-3086, Comm 301-619-3086
Email: smspratt@us.med.navy.mil
HMC Marvin Brown, DSN 343-7248, Comm 301-619-7248
Email: mbrown@us.med.navy.mil

3. Shipping.

a. The FDMB will contact the receiving units prior to their scheduled shipment. At the time of this call, the FDMB and the receiving unit will discuss all handling requirements for the Anthrax vaccine. The activity should notify all personnel in their receiving area and central receiving mail drop-off area. They should clear all gate or Post requirements. The FDMB advises the activity to track the shipment using the DHL or Federal Express web site (www.DHL.com or www.fedex.com) or by calling 1-800-345-3579 (DHL) or 1-800-463-3339 (Fed Ex). The FDMB also tracks each shipment. The FDMB provides the activity their DHL tracking numbers upon notification from the manufacturer (BioPort Corp). Customers must ensure they have appropriate refrigeration available for storage of the vaccine or the FDMB cannot ship to the site. After calling the activity, the FDMB will fax them a copy of the vaccine receipt matrix and handling instructions. A sample of each is attached. The receiving activity must complete all requirements specified on the receiving matrix.

b. The FDMB will release the vaccine from the manufacturer (BioPort Corp) and have it packaged and shipped directly to the vaccination center requesting the vaccine.

c. Upon receipt of the vaccine, the activity must inspect the package for damage before release from DHL or Federal Express. If the package is damaged, the activity should refuse the shipment and call the FDMB immediately.

d. If the receiving activity has an urgent need to vaccinate its personnel immediately upon receipt of the vaccine, then the following steps must be followed.

1) Upon receipt of the shipment the receiving site must contact the FDMB **before opening the package.**
2) The FDMB staff will explain procedures for conducting a check on the shipment's cold-chain maintenance status, which is recorded by the TempTale temperature-monitoring device, enclosed in each Anthrax vaccine shipment.
3) After completing this procedure the receiving activity must promptly remove the TempTale from the shipping container and follow the steps exactly as described by the FDMB staff (within 5 minutes of opening the shipping container).
4) The response from the TempTale (either Green Light or Red Light) will be relayed back to the FDMB staff person, who will either provide verbal

authorization to release the vaccine for immediate use, or will tell the receiving activity that further inspection is required.

5) The receiving activity will inspect the vaccine, and place it in an approved storage refrigerator.

e. If immediate release of the vaccine is not necessary, activities should remove the vaccine, inspect it, and store as above and then contact the FDMB to acknowledge receipt of the shipment and quantity received, and confirm the express-mail air bill number for the return envelope.

f. The receiving site must express mail return the TempTale monitor to USAMMA using the enclosed pre-addressed, overnight express mail envelope.

g. Upon receipt, USAMMA will download the temperature data from the TempTale. Once validated the vaccine will be released by the FDMB, first telephonically, then with a follow-up faxed confirmation.

h. The receiving site must repack all other contents of the box, attach the pre-addressed shipping label to the box and send it back to BioPort via FedEx/DHL.

i. USAMMA will not provide release of vaccine for administration unless a proper green light release is performed on the TempTale monitor or the monitor is received, downloaded and approved by the USAMMA Pharmacy Consultant.

4. Storing. Like most vaccines, anthrax vaccine must be stored in the refrigerator at 2 to 8 degrees Celsius (36 – 46 degrees Fahrenheit). DO NOT FREEZE. If Anthrax vaccine is exposed to temperatures above or below this level for >1 hour, contact USAMMA at DSN 343-4128/4121/4411/4198/4318/4320 or 301-619-4128/4121/4411/4198/4318/4320 for disposition instructions. Anthrax vaccine is particularly susceptible to freezing temperatures, which rapidly make the vaccine unusable. Anthrax vaccine can tolerate short exposures to other temperatures without degradation. USAMMA provides guidance on unusual storage conditions or distribution emergencies.

5. Emergency Storage.

a. During situations when normal refrigeration systems break down, every effort must be taken to minimize loss of vaccine due to breaks in the cold-chain.

b. In the case of power failure or breakdown of proper storage facilities, the FDMB will assist in establishing alternative emergency storage plans. The FDMB has several Vaxicools, approved temporary storage refrigeration units, located around the world. These Vaxicools can be utilized until existing storage facilities are returned to proper operating order or replaced. When a power failure or loss of storage is discovered, the FDMB must be notified immediately. FDMB personnel will assist with risk assessment, recommend actions to be taken, and assist with redistribution of vaccine or delivery of a Vaxicool to temporarily store the vaccine. Service POCs should be

contacted shortly after the initial contact with the FDMB to inform them of the situation.

Redistribution. Guidance for redistribution can be obtained from www.armymedicine.army.mil/usamma. The Focused Distribution Management Branch (FDMB) must be contacted prior to redistribution of the Anthrax vaccine. FDMB personnel must ensure maintenance of cold-chain throughout redistribution and will provide release authorization when redistribution is completed. The effective movement of the vaccine requires constant maintenance of the appropriate storage temperature. To ensure this requirement, the vaccine will be moved in a refrigerated container. Information on these containers can be obtained from the above mentioned web site.

a. The FDMB will provide the losing activity detailed packing instructions for the VaxiCool® or VaxiPac® container; gaining activities will be provided receiving and processing matrix for the transported vaccine.

b. An empty VaxiCool® or VaxiPac® container with shipping labels and a serial numbered security band will be sent to the losing activity. If the container is damaged, refuse receipt and notify FDMB immediately with details of refusal.

c. If the container is in satisfactory condition, receive and process documents and pack vaccine in accordance with information provided.

d. With the provided pre-addressed, overnight express-mail label, send the VaxiCool® or VaxiPac® to the gaining unit. Call FDMB to confirm overnight express-mail label account number, airbill and security band serial number for the shipment.

e. Upon receipt of the vaccine, the gaining activity will immediately inspect the VaxiCool® or VaxiPac®, security band for serial number accuracy and contents for damage. If the container or contents are damaged, refuse shipment and notify the FDMB immediately with details. If container is in satisfactory condition, receive and immediately secure vaccine in the required refrigerated storage environment (2° to 8° Celsius or 36° to 46° Fahrenheit). **DO NOT FREEZE.** Call FDMB to confirm receipt.

f. Process documents and vaccine in accordance with the information provided. **Request commercial carrier to wait for the VaxiCool® or VaxiPac®.** Ship container back to FDMB, USAMMA using the provided pre-addressed, overnight, express-mail label. Call FDMB, USAMMA, to confirm overnight express-mail label account number and air bill serial number for the VaxiCool®.

g. Establish stock record accountability of vaccine IAW Service regulations.

h. **DO NOT RELEASE THE VACCINE TO END-USER UNTIL AUTHORIZED BY THE FDMB.**

7. Control and Accountability. Because this product is not FDA-approved it must be handled in accordance with the control and accountability procedures of an investigational pharmaceutical.

   a. Logistics activities must maintain readily retrievable records showing receipts and issues to supported activities/clinics/vaccination sites. This information must include the lot number and expiration date of the vials received or issued. Logistics sites not possessing an automated method that can readily retrieve reports of this information should implement manual procedures as would be used for controlled substances.

   b. Immunization sites must also maintain readily retrievable records showing receipts from their supporting logistics activities, including lot number and expiration date, and local administration records showing consumption of the vaccine they have received (i.e., number of doses administered). Individual dosage administration will be recorded in the Service-specific AVIP systems in operation at the vaccination sites. Vaccination sites not possessing an automated method that can readily retrieve reports on the receipt and gross usage of vaccine should implement manual procedures as would be used for controlled substances.

   c. The FDMB and all other activities receiving anthrax vaccine must provide hard copy supply status reports to USAMMDA on a monthly basis. These data will include the information discussed above (receipts, issues and immunization documentation) as well as an updated, validated inventory and will be gathered with a closing date of the last day of each month. Activities will forward/fax these data to USAMMDA for inclusion in the protocol case files NLT the 7th of each month. The USAMMDA fax number is (301) 619-2304 (DSN – 343).

8. Disposal. Activities have responsibility for disposal and destruction of unusable vaccine. The FDMB must be contacted prior to destruction of any vaccine issued under this protocol. Activities will report on-hand vaccine inventories to be destroyed to their respective logistic agencies. The report will include information regarding lot numbers and quantities. The Anthrax vaccine is considered non-hazardous waste. DO NOT DISCHARGE THIS ITEM INTO A SANITARY SEWER.

   a. The disposal code for item 6505-01-399-6828 (Anthrax Vaccine Adsorbed) is CA01 (provided by U.S. Army Center for Health Promotion and Preventive Medicine, Aberdeen Proving Ground, MD).

   b. Methods for disposal are as follows:

      1. AUTOCLAVE/SANITARY LANDFILL. Autoclave this item at 120 degrees Celsius for 60 minutes at 15 psi prior to burial in a permitted sanitary landfill.

      2. INCINERATION. Mix this disposal item and incinerate. To prevent the production of excessive air pollutants, the disposal item or combination of similar

items shall not exceed 10 percent by weight of the total waste load charged to the incinerator at any one time.

3. CONTRACTOR. In accordance with local policy and procedures for contractor-designated medical waste disposal. The activity will prepare a certificate of destruction to document disposal actions before handoff to a local contractor for final disposition.

4. The following procedures are in place in the event the aforementioned disposal methods are not available or immediate disposal is necessary:

    (a) Contact the FDMB and provide information regarding lot numbers and quantities. The FDMB will provide a pre-addressed, overnight, express-mail container with packing procedures.
    (b) Remove each vial from its package.
    (c) Tear or shred the insert and package and dispose of as regular waste.
    (d) Deface the label on each vial with red permanent marker.
    (e) The activity will pack the container according to instructions provided and mail the container to FDMB.
    (f) The activity will call FDMB, USAMMA, to confirm overnight express-mail account number and air bill serial number for the container.

c. Activities will prepare a certificate of destruction to document disposal actions and fax a copy to the FDMB and to USAMMDA within 24 hours after final disposition. Activities must also prepare an executive summary that documents the circumstances surrounding the wasting of the vaccine and what actions have been taken to prevent loss of vaccine in the future.

d. Those charged with the disposal and destruction should address all questions or concerns to USAMMA Pharmacy Consultant.

Anthrax Vaccine Receiving and Processing Matrix for Receiving Official

1. **PURPOSE:** To give detailed instructions on the receiving and processing of the Anthrax Vaccine.
2. **GENERAL INFORMATION:** The Secretary of Defense has assigned the Army as the Executive Agent for the Anthrax Immunization Program. The Surgeon General of the Army is responsible for command and control of this program. The delegated receiving Official or Authorized Alternate is responsible for the receipt, processing, storage, security, and subsequent release to the end-user of this vaccine. This matrix details the necessary receiving and handling instructions to be followed by each Receiving Official or Authorized Alternate. This vaccine must be handled as a critical medical materiel item requiring the utmost control. **Due to the sensitivity of this vaccine, the Receiving Official or Authorized Alternate may be held pecuniarily liable for any damage or spoilage caused by negligence.**

STEP	CRITICAL EVENT
1	Receiving Official contacted prior to shipment from their Medical Logistics Agency (USAMMA/ AFMLO/NAVMEDLOGCOM) to verify ship-to address and convey any special preliminary receipt instruction to the Focused Distribution Management Branch (FDMB).
2	Receiving Official faxed a copy of this matrix and handling instructions a day prior to shipment.
3	FDMB calls Receiving Official or Authorized Alternate prior to shipment and verifies: 1. Address and any other alternate receiving officials 2. Receipt time of vaccine (1000-1200 the next day). 3. Expected time of phone call (1500-1630 day of shipment) from FDMB w/FedEx/DHL tracking/airbill#. 4. They have been contacted by their Medical Logistics Agency (AFMLO/NAVMEDLOGCOM/USAMMA) to confirm vaccine delivery.
4	FDMB provides the Receiving Official a brief on the details and potential risk associated with receipt of this shipment: 1. All personnel in receiving area are aware of the incoming vaccine shipment and a policy is put in to place to contact the Receiving Official or Authorized Alternate immediately for signature. 2. Clear all facilities (Post/Camp/Clinic) security requirements (gate guards notified). 3. Notify central receiving mail drop off locations of incoming vaccine shipment from FedEx/DHL. 4. Verify that proper refrigeration is available in the receiving area with constant temperature monitoring capability and proper backup if necessary. 5. Start tracking and call FedEx or DHL by 0800 the next day (www.DHL.com and/or 1-800-345-3579 or www.fedex.com and/or 1-800-463-3339). 6. Contact FDMB if delivery is not made by 1200.
5	Upon Receipt of the vaccine, the Receiving Official or Authorized Alternate will: 1. Call FDMB to confirm receipt. 2. Check for damage (If damaged then refuse shipment contact FDMB). 3. Remove handling instruction information paper, FedEx/DHL envelope (for TempTale return to USAMMA), and FedEx/DHL label (addressed to BioPort for box return) from the box. Request FedEx/DHL carrier wait for TempTale. 4. Put TempTale in the FedEx/DHL envelope and hand back to FedEx/DHL carrier. Send via Priority Overnight. 5. Immediately secure vaccine in the required refrigerated storage environment (2 to 8° Celsius, which is equivalent to 36 to 46° Fahrenheit). DO NOT FREEZE. 6. Provide FDMB with TempTale FedEx/DHL tracking/airbill #. 7. Enclose all packaging contents in shipping box and put FedEx/DHL label on box (for return to BioPort). Call FedEx/DHL for pickup. Send via Priority Overnight **8. Assure stock record accountability for the vaccine is established IAW Service regulations.** **9. DO NOT RELEASE THE VACCINE TO END-USER UNTIL AUTHORIZED BY THE FDMB.**
6	FDMB will upon receipt and examination of the TempTale: 1. Phone Receiving Official or Authorized Alternate with results. 2. Fax Anthrax Document Release Form to Receiving Official.
7	Receiving Official will close shipment with their Medical Logistics Agency.

ARMY: *USAMMA Focused Distribution Management Branch (FDMB):* Mr. David Orgler, Mrs. Bonnie Pereschuk, Mrs. Kandi Barnhart, Mrs. Jackie Graff, Mrs. Tosha Stanley, and Mrs. Kitty Reese DSN 343-4128/4121/4411/4198/4318/4320 (301) 619-4128/4121/4411/4198/4318/4320, FAX x4468*USAMMA, Pharmacist/COR: MAJ Marc Caouette, DSN 343-4309 (301)-619-4309, FAX x4189*

DOCUMENT IDENTIFIER			ROUTING IDENTIFIER			M & S	ITEM IDENTIFICATION* (NSN, FSCM/Part No., Other)														UNIT OF ISSUE		QUANTITY				DOCUMENT NUMBER					
							FSCM					PART NUMBER															SERV	REQUISITIONER				
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DOCUMENT NO. (Cont.)							DEMAND	SUPPLEMENTARY ADDRESS						SIGNAL	FUND CODE		DISTRIBUTION CODE			PROJECT CODE			PRIORITY		REQUIRED DELIVERY DAY OF YEAR			ADVICE CODE		BLANK				
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											REJECT CODE (FOR USE BY SUPPLY SOURCE ONLY)		IDENTIFICATION DATA
70	71	72	73	74	75	76	77	78	79	80	65	66	*1. MANUFACTURER'S CODE AND PART NO. (When they exceed card columns 8 thru 22)
													2. MANUFACTURER'S NAME

3. MANUFACTURER'S CATALOG IDENTIFICATION	4. DATE (YYMMDD)	5. TECHNICAL ORDER NUMBER
6. TECHNICAL MANUAL NUMBER	7. NAME OF ITEM REQUESTED Anthrax Vaccine for IND	
8. DESCRIPTION OF ITEM REQUESTED		8a. COLOR 8b. SIZE
9. END ITEM APPLICATION		9a. SOURCE OF SUPPLY
9b. MAKE	9c. MODEL NUMBER / 9d. SERIES	9e. SERIAL NUMBER
10. REQUISITIONER (Clear text name and address)	11. REMARKS	

FOLD LINE

FOLD LINE

DD FORM 1348-6, FEB 85 *Edition of Apr 77 may be used until exhausted*

DOD SINGLE LINE ITEM REQUISITION SYSTEM DOCUMENT *(MANUAL - LONG FORM)*

USAPPC V1.00

HANDLING INSTRUCTIONS OF ANTHRAX VACCINE SHIPMENT INFORMATION PAPER

1. **PURPOSE:** To give detailed instructions on the receiving and processing of the Anthrax Vaccine.

2. **GENERAL INFORMATION:** The Secretary of Defense has assigned the Army as the Executive Agent for the Anthrax Immunization Program. The Surgeon General of the Army is responsible for command and control of this program. This paper details the necessary receiving and handling instructions to be followed by each activity. This vaccine must be handled as a critical medical materiel item requiring the utmost control.

3. **ANTHRAX VACCINE INFORMATION:** The vaccine must be refrigerated and maintained at temperatures between 2 to 8 degrees Centigrade (36 to 46 degrees Fahrenheit). DO NOT FREEZE. The refrigerator must be monitored electronically or manually and recorded on a routine basis. The stock number for this vaccine is 6505-01-399-6828.

4. **SHIPPING INFORMATION:** All shipments will originate from Bio Port, in Lansing, MI. The carrier will be DHL or FedEx. Shipment tracking information for DHL is available via the Internet at www.DHL.com or 1-800-225-5345 and for Federal Express at www.fedex.com or 1-800-463-3339. USAMMA will notify each receiving activity with the shipment tracking number (air bill number).

5. **RECEIPT INFORMATION:** Upon receipt of the package:
   1. Inspect the package and contents for damage.
      a. If contents are damaged, refuse receipt and notify USAMMA immediately with details of refusal.
      b. If contents are in satisfactory condition, receive and process documents in accordance with local procedures.
      c. Open shipping container and remove the digital temperature control monitor (TempTale©) included in every container. Place vaccine in Refrigerator.
      d. In the provided pre-addressed, DHL envelope, send the monitor back to USAMMA using Priority Overnight. **Return the provided envelope Priority Overnight before COB the day of receipt.**
      e. Call USAMMA to confirm receipt of vaccine and provide the priority overnight airbill number for the TempTale.

   2. **DO NOT RELEASE VACCINE TO END-USER UNTIL AUTHORIZED BY USAMMA.** (Release authorization will be electronically transmitted to the receiving activity once the temperature control monitors are received, downloaded and approved by USAMMA staff pharmacist.)

6. **SECURING SHIPMENT:**
   1. **DO NOT FREEZE!** Vaccines must be refrigerated at temperatures between 2 to 8 degrees Celsius (36-46 degrees Fahrenheit).
      a. **The receiving activity will not release the vaccines from refrigerated storage until they receive authorization from USAMMA.**

7. **POINTS OF CONTACT:** Mr. Dave Orgler, Mrs. Bonnie Pereschuk, Mrs. Kandi Barnhart, Mrs. Toscha Stanley, Mrs. Jackie Graff and Mrs. Kitty Reese. Focused Distribution Management Branch, DSN 343-4128/4121/4411/4318/4198/4320 or COMM (301) 619-4128/4121/4411/4318/4198/4320, FAX 301-619-4468, cell phone 301-676-0857.

ARMY (Executive Agent)

USAMMA Focused Distribution Management Branch (FDMB)
DSN 343-4128/4121/4411/4198/4320/4318 or COMM (301) 619-4128/4121/4411/4198/4320/4318,
FAX DSN 343-4468 or COMM 301-619-4468

AIR FORCE

MSgt Shelia A. Brown
DSN 343-4122 or COMM (301) 619-4122 or PAGER (888) 485-3221, FAX 301-619-2557

MSgt Dale Clark
DSN 343-4172 or COMM (301) 619-4172 or PAGER (888) 587-9892, FAX 301-619-2557

NAVY

LCDR Homman
DSN 343-3065 or COMM (301) 619-3065

LT Byron Owens
DSN 343-3086 or COMM (301) 619-3086

U.S. DEPARTMENT OF STATE

Michael Wertz
Office: 202-663-1486
Fax: 202-663-1613
Mobile: 410-382-2119
E-mail: WertzMM@state.gov

ANTIBIOTIC LOGISTICS FOR THE ANTHRAX VACCINE CONTINGENCY PROTOCOL

The antibiotics employed in this protocol are considered concomitant medications. The Services will manage the supply and distribution of these antibiotics within the normal medical supply channels in the same manner as all other pharmaceuticals. These agents are incorporated as part of the Army Division-Ready Brigade Sets, which are designed to support 5,000 troops each and are included in Army Prepositioned Stocks. The other Services have similar Prepositioned stocks of materiel to support rapid deployment to multiple theaters of operation.

Ciprofloxacin is approved to reduce the incidence or progression of inhalational anthrax following exposure to aerosolized *B. Anthracis* spores, whereas doxycycline and penicillin are approved for treatment of anthrax disease but not for post-exposure prophylaxis. As such they are not considered investigational agents under this protocol. These antibiotics are also indicated for many other diseases and as such are not solely designated as Medical Biological Defense Materiel. These agents will be managed within normal medical logistics channels down to the Division (Division Medical Supply Office) level, and then further issued to line as well as medical units for eventual issue/prescribing at the battalion/company level. These products are purchased in several package sizes and configurations; therefore, repackaging for individual issue, including appropriate labeling for individual issue, must be completed at the unit level.

When employed under this protocol, the antibiotic issued to an individual will be documented on the informed consent form. Prescriptions will contain appropriate labeling to ensure directions for use are clearly conveyed to the individual, with emphasis placed on continuing therapy until directed to stop by medical authorities, and to seek medical care should adverse reactions occur. The gathering of safety information concerning the combination of vaccine and antibiotics is a key component of this protocol; therefore, troops must be vigilant in their detection and reporting of adverse events.

APPENDIX B

FDA Form 1572

APPENDIX C

Subjective Response Form
Six-Month Follow-Up Questionnaire

Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Adsorbed (AVA) to Protect against *Bacillus anthracis* Spores

Subjective Response Form

PLEASE USE BLACK INK ONLY

Last Name | First Name | MI

SSN | Rank | Age | Gender ☐ Male ☐ Female | Race:_____

Anthrax Vaccination No. ☐

Did you have any reaction at the injection site? ☐ Yes ☐ No

Use the rulers below to answer questions about size of redness:

5 cm ——————

10 cm ——————————

Redness <5 cm (less than 2 inches)	☐ Yes	☐ No
Redness 5 – 10 cm (2 to 4 inches)	☐ Yes	☐ No
Redness >10 cm (more than 4 inches)	☐ Yes	☐ No
Swelling of arm below elbow	☐ Yes	☐ No
Pain that limited motion of elbow	☐ Yes	☐ No
Localized itching	☐ Yes	☐ No
Lump or "knot"	☐ Yes	☐ No
Muscle soreness	☐ Yes	☐ No

Did you have any other kind of reaction within 3 days after vaccination: ☐ Yes ☐ No

Loss of appetite	☐ Yes	☐ No
Headache	☐ Yes	☐ No
Fatigue	☐ Yes	☐ No
Muscle aches	☐ Yes	☐ No
Joint aches	☐ Yes	☐ No
Itching over entire body	☐ Yes	☐ No
Nausea and/or vomiting	☐ Yes	☐ No
Diarrhea	☐ Yes	☐ No
Chills	☐ Yes	☐ No
Shortness of breath	☐ Yes	☐ No
Fever	☐ Yes	☐ No

For 2 weeks after receiving the anthrax vaccine:

Were you hospitalized for any reason in those 2 weeks?	☐ Yes	☐ No
Did you go to sick call or for an outpatient medical visit for any reason in those 2 weeks?	☐ Yes	☐ No
Did you miss one shift or more of work in those 2 weeks due to illness?	☐ Yes	☐ No

Indicate number of days of work missed in those 2 weeks due to illness: _____

Reaction (_____) went away within: ___24 hrs ___48 hrs ___7 days ___14 days ___other _____
Reaction (_____) went away within: ___24 hrs ___48 hrs ___7 days ___14 days ___other _____

Which antibiotic did you take? ☐ Ciprofloxacin ☐ Doxycycline ☐ PenVK ☐ Other _____
Did you experience any problems taking the antibiotic since your last vaccination? ☐ Yes ☐ No
If yes, describe:

Comments:

Signature _____ Date _____

Dear Service Member,

You participated in a ***Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Adsorbed (AVA) to Protect against* Bacillus anthracis *Spores***

at _____
Theater of Operation

We would appreciate your assistance in evaluating any side effects that you may have experienced within 48 hours after receiving anthrax vaccine.

_____ _____
Print Name Social Security Number

Number of anthrax vaccinations received: _____

INSTRUCTIONS: write the dose number (1, 2, 3, 4, 5, 6, 7, etc.) that you had a reaction against in the boxes under Dose No. for local reactions and for systemic reactions. Check small box below that number for reactions associated with that shot. You can write reactions to as many as four doses of anthrax vaccine.

Local reactions:

Dose No.	
	Enter the anthrax vaccine dose number(s) in the boxes to the left.
	None
	Redness and/or swelling less than 2 inches in any direction.
	Redness and/or swelling 2 to 4 inches in any direction.
	Redness and/or swelling more that 4 inches in any direction.
	Pain or swelling that limited but did not prevent your using your arm.
	Incapacitating pain, swelling, or tenderness that prevented you from using your arm.
	Other (please describe) _____

Generalized reactions:

Dose No.	
	Enter the anthrax vaccine dose numbers(s) in the boxes to the left.
	None
	Fever, fatigue, muscle aches, nausea, or headaches that did not limit your activity.
	Fever, fatigue, muscle aches, nausea, or headaches that did limit your activity.
	Severe incapacitating reaction that resulted in quarters or hospitalization.
	(please describe) _____

Resolution of reaction(s):

Dose No. _____ Reaction (_____) went away within: __ 24 hrs __ 48 hrs __ 7 days __ 14 days __ other _____
Dose No. _____ Reaction (_____) went away within: __ 24 hrs __ 48 hrs __ 7 days __ 14 days __ other _____
Dose No. _____ Reaction (_____) went away within: __ 24 hrs __ 48 hrs __ 7 days __ 14 days __ other _____
Dose No. _____ Reaction (_____) went away within: __ 24 hrs __ 48 hrs __ 7 days __ 14 days __ other _____

Experience with antibiotic:

What antibiotic did you take? ☐ Ciprofloxacin ☐ Doxycyline ☐ PenVK ☐ Other

Did you take all doses of the antibiotic?

___<5 ___5-10 ___11-20 ___21-40 ___41-60 ___61-80 ___81-100 ___101-120 ___>120

Did you experience any reaction to the antibiotic? ___ Yes ___ No

If yes, describe: _____

_____ _____
Signature Date

APPENDIX D

Baseline Health Questionnaire

Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Adsorbed (AVA) to Protect against *Bacillus anthracis* Spores

Baseline Health Questionnaire

PLEASE COMPLETE USING BLACK INK ONLY

DEMOGRAPHIC INFORMATION

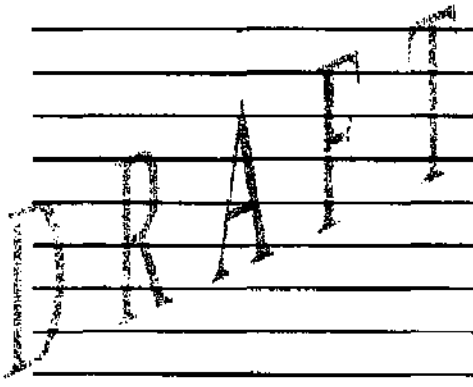
Last Name | First Name | MI | SSN

Rank | Age | Gender: ☐ Male ☐ Female | Race:_____

Allergies: Medication ☐Yes ☐No If yes, identify_____

MEDICAL HISTORY Identify any history of or current conditions to the best of your knowledge.

		Explain	Date of Onset/ Diagnosis
Cardiac (Heart)	☐Yes ☐No		__/__/__
Respiratory (Breathing)	☐Yes ☐No		__/__/__
Gastrointestinal (Stomach)	☐Yes ☐No		__/__/__
Musculoskeletal	☐Yes ☐No		__/__/__
Psychiatric (Depression)	☐Yes ☐No		__/__/__
Neurological (Seizures)	☐Yes ☐No		__/__/__
Genitourinary (Kidney)	☐Yes ☐No		__/__/__
Gynecologic (incl. pregnancy)	☐Yes ☐No		__/__/__
Integumentary (Skin)	☐Yes ☐No		__/__/__
Any other chronic illness	☐Yes ☐No		__/__/__



Do you currently take any medications? ☐ Yes ☐ No If yes, list_____

Do you take nutritional supplements? ☐Yes ☐ No If yes, list_____

Do you smoke? ☐Yes ☐No If yes, how much (packs/day) _____ and how long (No. of years)?_____

Do you use smokeless tobacco? ☐Yes ☐ No If yes, how long (No. of years)?_____

Rate your overall health: ☐ Excellent ☐ Good ☐ Fair ☐ Poor

Have you ever had a reaction to an antibiotic? ☐Yes ☐ No If yes, describe _____

How many doses of anthrax vaccine have you received? ☐ None ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐__

Have you ever had a reaction to an anthrax vaccination? ☐Yes ☐No If yes, describe _____

Have you been given an antibiotic for this protocol? ☐Yes ☐No If yes, which? ☐ Ciprofloxacin ☐ Doxycyline ☐ PenVK ☐ Other

How many doses have you taken? __<5 __5-10 __11-20 __21-40 __41-60 __61-80 __81-100 __101-120 __>120

Volunteer Signature	Date	Witness Signature	Date

APPENDIX E

Clinical Protocol Deviation Form

Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Adsorbed (AVA) After to Protect against *Bacillus anthracis* Spores

CLINICAL PROTOCOL DEVIATION FORM

Military Medical Facility _____ Principal Investigator _____

Initials/ Date	Volunteer SSN	Description of Deviation	Action Taken

Signature of Principal Investigator _____ Date _____

APPENDIX F

VAERS-1 Form

APPENDIX G

Quality Control and Assurance

APPENDIX G
QUALITY CONTROL AND ASSURANCE

1. GENERAL

The Quality Assurance Division, U.S. Army Medical Materiel Development Activity (USAMMDA) will provide retrospective monitoring for the anthrax vaccine contingency protocol. No prospective monitoring is planned. The protocol will be monitored for GCP compliance, verifying adherence to the protocol and the completeness and exactness of data entry at the conclusion of each contingency. The monitor will review the protocol files, volunteer consent forms, service-specific databases (case report forms), original source documents, and logistical records upon arrival at USAMRIID, the permanent record site. Upon completion of each review, the monitor will brief the Clinical Project Manager of findings and issues in need of resolution. A written report of the findings and recommendations will be circulated and provided to USAMMDA, the Sponsor's Representative.

2. SUBJECT DOCUMENT FILE REVIEW PLAN

USAMMDA's Quality Assurance Division personnel will monitor the protocol records at Fort Detrick, Maryland. The records will be reviewed at the completion of the protocol for each contingency, with each monitor reviewing no more than 50 records per day.

3. QUALITY ASSURANCE MONITOR

USAMMDA's Quality Assurance Division will monitor items listed on the Quality Assurance Office Anthrax Contingency Protocol, see Attachment I.

APPENDIX H

Anthrax Vaccine Information Paper
Antibiotic Information Paper

ANTHRAX VACCINE INFORMATION PAPER

Background on Anthrax

Anthrax has been recognized as an illness for centuries. The spores that cause anthrax can survive in soil for decades. The disease used to be common where livestock grazed. Animal anthrax is controlled with a vaccine for cattle and other animals. Natural human infection usually results from people touching infected animals or animal by-products. In addition, rarely, there are occupational cases of inhalational anthrax due to the inhalation of aerosolized anthrax spores. Inhalational anthrax is the most lethal form of anthrax, because it is difficult to diagnose and because it progresses so rapidly.

Threat

Anthrax spores are a known biological weapon. In fact, anthrax tops the Department of Defense (DoD) biological threat list. An aerosol of anthrax is odorless, colorless, tasteless, and difficult to detect. It is easy and cheap to produce. Anthrax spores can be stored for a long time and can be dispersed by a variety of weapons. Small amounts of anthrax can produce large numbers of casualties among unprotected people. For example, the accidental aerosolized release of anthrax spores from a military microbiology facility in the former Soviet Union in 1979 resulted in at least 79 cases of anthrax infection and 68 human deaths.

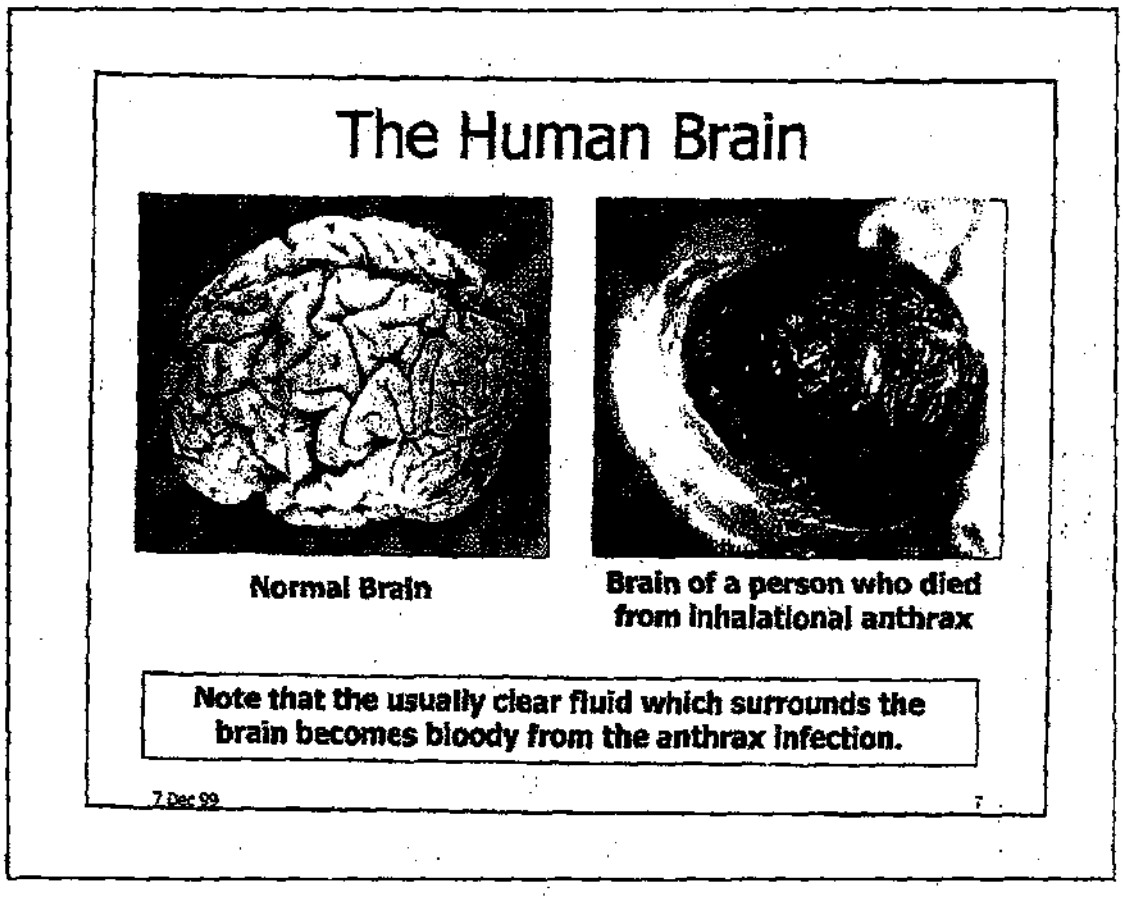
Inhalational Anthrax

Inhalational anthrax occurs when anthrax spores enter the body through the lungs. Spores go to the lymph system where bacteria multiply and produce deadly toxins. The toxins cause bleeding and destruction of the brain or vital organs in the chest. Most people die as a result. Figure 1 compares a normal brain with a brain of a person who died from inhalational anthrax. The initial symptoms of inhalational anthrax include sore throat, mild fever, and muscle aches. Symptoms can rapidly progress to severe difficulty breathing and shock. After symptoms appear, about 80% of people with inhalational anthrax die, even if they get treated with antibiotics. Inhalational anthrax does not spread from person to person.

Anthrax Vaccine

The anthrax vaccine (Anthrax Vaccine Adsorbed) is manufactured by BioPort Corporation, Lansing, Michigan. It has been licensed for preexposure prophylaxis by the U.S. Food and Drug Administration since 1970. The vaccine is a sterile product made from bacteria (*Bacillus anthracis)* that are avirulent (cannot cause disease themselves). It contains no whole bacteria, neither live nor dead, so it is impossible to contract the disease from the anthrax vaccine. The vaccine contains protective antigen (PA), which is the common disease-causing protein in all anthrax strains that cause disease, so the vaccine is expected to provide protection against all strains. The vaccine is deposited on the surface of a chemical called aluminum hydroxide to increase the number of antibodies that the body makes in response to vaccination. Benzethonium chloride and formaldehyde are added as preservatives.

The anthrax vaccine to be used in the contingency protocol is classified as an Investigational New Drug (IND) because (1) administration after exposure to anthrax spores has not been approved by the FDA, (2) some of the dosing schedules include vaccinations at times that are outside the schedule approved by the FDA, and (3) some unreleased lots of the vaccine may be used with this protocol. The FDA will have reviewed the safety and potency of and accepted any unreleased lots used in this protocol.



The standard dosing schedule of anthrax vaccine involves three doses at 2-week intervals, followed by three more doses given at 5- to 6-month intervals, plus annual boosters. Subjects participating in the contingency protocol will be given the number of doses sufficient for post-prophylaxis treatment rather than the complete series of vaccinations needed for protection. As few as two doses produce a rapid increase in the number of protective anti-anthrax antibodies in the bloodstream. Three doses of vaccine given 2 weeks apart should provide antibodies in the shortest period of time. Antibiotics protect against anthrax in the short term, whereas vaccination provides more durable protection.

Efficacy of the Anthrax Vaccine

The potential effectiveness of the anthrax vaccine for treatment after aerosolized exposure to anthrax spores is based on human and animal research. The only clinical study to evaluate

protection of a vaccine containing protective antigen was conducted from 1955 to 1959 in goat hair workers at risk for anthrax. People who were fully vaccinated developed anthrax disease 92.5% less often than those not vaccinated. An outbreak of inhalational anthrax occurred at one mill during the study. Five cases of inhalational anthrax occurred among 448 unvaccinated workers at that mill (combining both placebo recipients and the unvaccinated observation group), compared to no cases among 149 fully vaccinated workers at that mill. Despite the trend toward efficacy, the number of cases of inhalational anthrax was too low for the difference between the vaccinated and unvaccinated groups to be conclusive statistically.

The anthrax vaccine provided more than 95% protection in rhesus monkeys against inhaled anthrax spores. In five studies of rhesus monkeys given either one or two doses of anthrax vaccine, 62 of 65 vaccinated animals (95%) survived a lethal aerosol challenge with hundreds of times the median fatal dose. In the various studies in monkeys, 18 unvaccinated animals were challenged, but none survived.

Safety of Anthrax Vaccine

Several studies have shown that anthrax vaccine is safe, with an incidence of side effects after injection similar to that of other common vaccines. As with any medication, all vaccines will occasionally cause adverse reactions. Usually these are mild, like a sore arm or "flu"-like symptoms. No deaths have been caused by anthrax vaccination.

Based on data obtained during 30 years of experience with anthrax vaccine, it is expected that up to 30% of men and 60% of women receiving the vaccine will experience some mild adverse effects at the *injection site*, for example:

- A sharp, stinging or burning sensation immediately upon injection is common, usually lasting less than 1 minute
- Redness, itching, swelling (lasting a few days):
  - Less than 1 inch: men up to 30%, women up to 60%
  - 1 to 5 inches: 1% to 5%
  - Greater than 5 inches: up to 1%; in these cases, swelling may extend below the elbow
- Soreness, tenderness, or local pain in 8% to 19%
- Lump: 30% to 90% (may persist a few weeks)
- Women tend to have higher rates of local reactions than men
- For both men and women, most injection-site reactions last 1 to 3 days and go away on their own.
- The frequency of tenderness, lumps, and redness tends to decrease as the frequency of injections (up to three) increase, whereas itching and swelling tend to increase.

These rates of adverse reactions are similar to those for other vaccines, including the generally mandatory childhood vaccines, DTP (diphtheria-tetanus-pertussis), MMR (measles-mumps-rubella), and other vaccines, such as hepatitis A and yellow fever, administered to military personnel.

The following *systemic events* (reactions away from the injection site) have been reported:

- From 5% to 35% will notice:
  - Muscle aches, joint aches, chills, low-grade fever, no appetite, headaches, nausea, malaise, related symptoms
  - These symptoms usually go away in a few days, less than a week
- Serious allergic reactions occur (less than 1 per 100,000 doses)
- Reactions requiring hospitalization occur less than once per 100,000 doses.

In a study conducted in Hawaii, the number of subjects experiencing systemic reactions declined from about 8% after the first dose, to 5% after the second dose, and 3% after the third and fourth doses. These systemic reactions are similar to those experienced by recipients of other vaccines, such as the hepatitis A vaccine (pain in 22% to 51%, headache in 15%) and the typhoid Vi vaccine (pain in 27% to 56%, malaise in 4% to 37%, fever in 2% to 11%, and headache in 11% to 27%).

As for long-term effects, nearly 1,600 laboratory workers at Fort Detrick, Maryland, have received approximately 10,500 doses of anthrax vaccine since the early 1970s. A number of individuals have received over 20 doses of anthrax vaccine. None developed unexplained symptoms due to repeated doses of this or other vaccines they received. No patterns of delayed side effects to anthrax vaccine have been found.

As of January 2001, about 2 million doses of anthrax vaccine had been administered to about 500,000 service members.

The Department of Defense uses the FDA's Vaccine Adverse Event Reporting System (VAERS) to report events potentially related to any vaccination. The Anthrax Vaccine Expert Committee, (AVEC), a panel of civilian academic medical experts, reviews all VAERS reports related to anthrax vaccine. As of October 2000, AVEC had reviewed 1,203 VAERS-1 reports. Of these, 48 involved hospitalization, 10 of which were certainly or probably caused by anthrax vaccine. All 10 involved allergic, inflammatory reactions at the injection site. Another 172 involved loss of duty for more than 24 hours, and the remaining 983 were categorized as other than serious, involving neither hospitalization nor loss of duty of more than 24 hours.

Use of Vaccine as Part of Post-Exposure Treatment

The use of anthrax vaccine after a person is exposed to anthrax spores is not specifically identified in the product labeling approved by the FDA. This means that the FDA has not evaluated the safety and efficacy of anthrax vaccine for the prevention of anthrax disease when used after exposure to anthrax spores. However, because the objective of producing anthrax antibodies in the blood stream is the same both before and after exposure, the Advisory Committee on Immunization Practices of the Center for Disease Control and Prevention recommends a combination of antibiotic therapy and vaccination according to a standard schedule (0, 2, and 4 weeks). The Committee's recommendation is based on studies in monkeys that have shown antibiotics in combination with post-exposure vaccination to be effective in preventing disease after exposure to anthrax spores. In one study, groups of monkeys received

(a) one of three antibiotics, (b) vaccine alone, or (c) an antibiotic and anthrax vaccine. Antibiotics were given for 30 days, and the anthrax vaccine was injected on days 1 and 15 of the antibiotic schedule. Two important points: first, in each group where an antibiotic alone was given (without vaccine), once the antibiotic was stopped, some animals died from inhalational anthrax as far out as 28 days after stopping the antibiotic (58 days after the exposure). Secondly, none of the monkeys given antiobiotics alone developed antibodies to anthrax although antibiotics did prevent infection from fully developing. Only the vaccinated monkeys survived exposure to anthrax spores after the antibiotics were stopped. When exposed to anthrax spores a second time, only animals that were vaccinated and had antibodies to anthrax survived. Because the duration of protection from vaccination is not known, persons at risk may require additional vaccinations should subsequent exposures occur. The side effects associated with using the anthrax vaccine after exposure should be the same as those associated with pre-exposure administration. In the monkey studies, adverse reactions with the antibiotic-vaccine treatment did not differ from those that occurred when either was administered alone.

Conclusion

Anthrax is a deadly biological weapon. For 30 years, the anthrax vaccine has been used to prevent this extremely lethal disease. The number of vaccinations given to date exceeds 2 million doses, with few serious adverse events. The reports of adverse events are consistent with expectations based on previous research studies and in line with experiences with commonly used vaccines. The risks of using anthrax vaccine in combination with antibiotics should not differ from the risks of receiving the antibiotic and the vaccine alone. Efficacy of the post-exposure antibiotic-vaccine regimen has been shown to result in long-term survival in studies conducted in rhesus monkeys.

You may obtain additional information about the anthrax vaccine from your health care provider or the AVIP web site: http://www.anthrax.osd.mil

Individuals who decide not to participate in or to withdraw from the anthrax vaccine contingency protocol are advised to complete the antibiotic prescribed to prevent *B. anthracis* spores from emerging and causing potentially lethal disease.

ANTIBIOTIC INFORMATION PAPER
for
ANTHRAX VACCINE CONTINGENCY PROTOCOL

The antibiotics ciprofloxacin, doxycycline, or penicillin are the drugs of choice for the treatment of anthrax, including inhalational anthrax, which is the most lethal form of the disease. Treatment needs to begin before symptoms appear. Use of the antibiotics can keep individuals alive until their bodies can build a long-lasting immunity to anthrax via vaccination. After symptoms appear, however, inhalational anthrax is almost always fatal, regardless of treatment. Because taking an antibiotic could be the difference between life and death, each dose must be taken as ordered for 60 days unless otherwise instructed by a health care provider.

CIPROFLOXACIN

Ciprofloxacin (CIPRO®) is approved by the Food and Drug Administration (FDA) to treat and protect individuals who become exposed to *Bacillus anthracis* spores administered as an aerosol. The recommended treatment after exposure to inhalational anthrax is 500 mg given orally every 12 hours for 60 days. The antibiotic should not be given to anyone who has had a serious allergic reaction to ciprofloxacin or other antibiotics in the quinolone family.

How to take CIPRO: Take CIPRO with food (excluding milk or yogurt) and at least one large glass of water. The antibiotic works best when the amount of medicine in your body is kept at a constant level, so take 1 tablet every 12 hours for 60 days. If you take any of the following—zinc, iron, sucralfate, Videx® (didanosine), and antacids that contain magnesium, calcium, or aluminum—take them 6 hours before or 2 hours after taking CIPRO.

Side effects: CIPRO may cause stomach upset, loss of appetite, diarrhea, nausea, drowsiness, or headache during the first few days as your body adjusts to the medication. If these symptoms persist or become severe, inform your health care provider. Promptly report new pain or tenderness (tendonitis) in arms or legs. Also report any vision changes, restlessness, ringing in the ears, or mental changes. In the unlikely event that you have an allergic reaction to this antibiotic, seek immediate medical attention. Symptoms of an allergic reaction include rash, itching, swelling, fever, or trouble breathing. If you notice any other effects, contact your health care provider promptly.

Precautions: Before taking CIPRO, tell your health care provider if you have a medical history of epilepsy, kidney disease, tendon problems, nervous system disorders, liver disease, blood vessel problems, and any drug allergies. Use caution driving or performing tasks requiring alertness if this medication makes you dizzy or lightheaded. Alcohol can make the condition worse. CIPRO can increase sensitivity to sunlight, so avoid prolonged sun exposure. Wear protective clothing and a sunscreen to minimize sun sensitivity. This medication may be taken during pregnancy.

Drug Interactions: Tell your health care provider of all medications that you are using (both prescription and nonprescription), especially of other antibiotics, theophylline, warfarin, cyclosporine, live bacterial vaccines, probenecid, sucralfate, quinapril, didanosine, iron, zinc, and antacids that contain magnesium, aluminum, or calcium.

Caution: CIPRO may increase or extend the effects of caffeine and theophylline.

DOXYCYCLINE

Doxycycline is approved by the FDA to treat anthrax. The recommended treatment is 100 mg given orally every 12 hours for 60 days. The antibiotic should not be given to anyone who has had a serious allergic reaction to any tetracycline product.

How to Take Doxycycline: Take doxycycline with food and at least one glass of water. The antibiotic works best when the amount of medicine in your body is kept at a constant level, so take 1 tablet every 12 hours. Do not lie down for at least 1 hour after taking this drug. Avoid taking antacids containing magnesium, aluminum, or calcium; sucralfate; iron preparations; or vitamin (zinc) products within 3 hours of taking this antibiotic.

Side Effects: Doxycycline may cause nausea or diarrhea. In the unlikely event that you have an allergic reaction to this antibiotic, seek immediate medical attention. Although the occurrence is unlikely, dark urine, yellowing of the eyes or skin, persistent sore throat or fever, unusual bleeding or bruising, unusual fatigue, white patches in the mouth, or unusual vaginal discharge/itching should be reported immediately to your health care provider. Use of tetracycline during the last half of pregnancy may cause permanent discoloration of the teeth of offspring. If you have an allergic reaction to this antibiotic, seek immediate medical attention. Symptoms of an allergic reaction include rash, itching, swelling, fever, or trouble breathing. If you notice any other effects, contact your health care provider.

Precautions: Before taking doxycycline, tell your health care provider if you have a medical history of yeast infections of the mouth, kidney or liver problems, esophagus problems or trouble swallowing (hiatal hernia or reflux/heartburn), and any drug allergies. Use of this antibiotic for prolonged periods may result in an infection (e.g., oral, bladder, or vaginal yeast infection). Doxycycline can increase sensitivity to sunlight, so avoid prolonged sun exposure. Wear protective clothing and a sunscreen to minimize sun sensitivity.

Drug Interactions: Tell your health care provider of all medications that you are using (both prescription and nonprescription), especially antibiotics (penicillins/cephalosporins such as cefuroxime), antacids, vitamins/minerals (such as zinc), iron supplements, bismuth subsalicylate, sucralfate, carbamazepine, phenytoin, barbiturates like phenobarbital, blood thinners like warfarin, or methoxyflurane. Use of doxycycline may make birth control pills less effective.

PENICILLIN V POTASSIUM

Penicillin V Potassium (Pen VK) is approved by the FDA to treat anthrax. The recommended treatment is 500 mg given orally every 6 hours for 60 days. The antibiotic should not be given to anyone who has had a serious allergic reaction to any penicillin.

How to Take Pen VK: Take Pen VK on an empty stomach (1 hour before or 3 hours after meals) with at least one glass of water. The antibiotic works best when the amount of medicine in your body is kept at a constant level, so take 1 tablet every 6 hours.

Side Effects: Pen VK may cause stomach upset, diarrhea, nausea, and vomiting during the first few days as your body adjusts to the medication. If these symptoms persist or become severe, inform your health care provider. If you have an allergic reaction to this antibiotic, see immediate medical attention. Symptoms of an allergic reaction include rash, itching, hives, fever, or trouble breathing. If you notice any other effects, contact your health care provider.

Precautions: Before taking Pen VK, tell your health care provider if you have asthma, any other illnesses or any allergies, especially to penicillin or other antibiotics. Use of this antibiotic for prolonged periods may result in an infection (e.g., oral, bladder, or vaginal yeast infection). Use of penicillin may make birth control pills less effective.

Drug Interactions: Tell your health care provider of all medications that you are using (both prescription and nonprescription), especially tetracycline products. Use of penicillin may make birth control pills less effective.

Do NOT stop these antibiotics without the approval of your health care provider.

APPENDIX I

Informed Consent Form

INFORMED CONSENT FORM

Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Adsorbed (AVA) to Protect against *Bacillus anthracis* Spores

A. Basis for Participation

You are being asked to provide your consent to an investigational treatment for your exposure to anthrax spores. According to current recommendations from the Centers for Disease Control and Prevention (CDC), the best treatment after exposure to anthrax is a combination of an antibiotic and anthrax vaccine. The Food and Drug Administration (FDA) has licensed Anthrax Vaccine Adsorbed (AVA) to be given to people before they face potential exposure to *Bacillus anthracis* spores (the cause of anthrax disease). However, FDA has not licensed the vaccine for post-exposure treatment or for use in combination with antibiotics. Such use is, therefore, considered investigational and requires your consent to receive the anthrax vaccine.

The basis for recommending antibiotic and vaccine together comes from strictly controlled studies in monkeys, not from studies in humans. Because human exposure to anthrax spores cannot be controlled, the survival of people receiving the antibiotic and vaccine together may not be the same as in the animal studies. The studies in monkeys showed antibiotics in combination with post-exposure vaccination to be effective in preventing anthrax disease. After exposure to anthrax spores, monkeys given antibiotics alone were only protected from disease during treatment (some animals died after stopping the antibiotic), whereas monkeys given antibiotics and vaccine survived after they stopped receiving antibiotics. This means that these animals developed immunity against anthrax and continued to be protected even after stopping the antibiotic.

The anthrax vaccine to be used in this study is classified as an Investigational New Drug (IND) because (1) administration after exposure to anthrax spores has not been approved by the FDA, (2) some of the dosing schedules include vaccinations at times that are outside the schedule approved by the FDA, and (3) some unreleased lots of the vaccine may be used with this protocol.

You are being asked to volunteer to be vaccinated with doses of AVA that the FDA has not released. These doses will be replaced with FDA licensed and released doses of anthrax vaccine as soon as they become available. All antibiotics to be used in this protocol have been approved by the FDA: ciprofloxacin for treatment and prevention of anthrax after exposure to aerosolized anthrax spores and doxycycline and penicillin V potassium for treatment of anthrax.

You have been given information papers on the anthrax vaccine and the three antibiotics that may be used in this protocol. If you have questions about anything in them, ask your health care provider for an explanation. This Informed Consent Form (ICF) explains the purpose of the protocol, the procedures involved, information on the potential benefits and risks, and alternatives to participation. Your rights as a participant in this protocol are outlined. Please read this document thoroughly and ask any questions that may occur to you relating to your participation. Your signature on this document indicates that you agree to participate in the protocol.

It is essential that you understand that:

- Taking part in this protocol is entirely voluntary.
- Refusal to participate will involve no penalty or loss of any benefits to which you are otherwise entitled.
- You may withdraw from the protocol at any time without penalty or loss of benefits to which you are otherwise entitled.

If you decide to withdraw from the protocol, you will be encouraged to complete the antibiotic prescribed for treatment of exposure to *B. anthracis* spores.

B. Principal Investigator/Investigator

_____
(Name, Title, Location)

Note: This section must be filled in before you sign this form.

C. Purpose of the Study

- To provide anthrax vaccine to volunteers who are receiving antibiotics for the early treatment of exposure to *B. anthracis* spores.
- To collect data on all adverse events, including local and systemic reactions to the vaccine and clinical cases of anthrax in the study population after administration of the vaccine.

D. Anthrax Vaccine

The vaccine to be used in this study (described in the Anthrax Vaccine Information Paper) was manufactured by BioPort Corporation, Lansing, Michigan. The schedule for giving the vaccine under this protocol is the same as the schedule for the licensed vaccine. AVA has been licensed by the FDA since 1970 to be given to people before they face potential exposure to anthrax spores. In this protocol, the vaccine is considered to be investigational because (1) it is being given after potential exposure to anthrax spores and along with an antibiotic, (2) the dosing schedule has been modified, and (3) unreleased lots of vaccine may be used. The FDA will have reviewed the safety and potency of and accepted any unreleased lots used in the protocol.

E. Alternatives to Receiving Anthrax Vaccine

Protective clothing and gas masks can provide excellent frontline defense, but their effective use requires rapid and early detection of the anthrax spores. Clothing and masks do not protect the body from spores that have been inhaled. Current detection devices are not sufficient to completely protect against the threat.

Ciprofloxacin, doxycycline, or penicillin V potassium, if taken as prescribed, can be effective if exposure to anthrax spores is detected. The CDC recommends post-exposure prophylaxis after aerosol exposure to anthrax spores. This may consist of antibiotic therapy alone or a combination of antibiotic therapy and vaccination. This recommendation is based on an extensive review of studies conducted in monkeys, and professional opinion. The recommended antibiotics include ciprofloxacin, doxycycline, and penicillin V potassium. FDA has approved ciprofloxacin to reduce the incidence or progression of inhalational anthrax following aerosol exposure to anthrax spores. FDA also has approved doxycycline and penicillin V potassium for treatment of anthrax disease.

Once symptoms of anthrax develop, giving antibiotics reduces the risk of death only slightly.

F. Potential Benefit

The benefit of following the prescribed antibiotic regimen cannot be overstated. Strict compliance with both the antibiotic and vaccine dosing schedule could mean the difference between life or death. If you have never received the anthrax vaccine, vaccination may provide an additional degree of protection against relapse after you discontinue antibiotic treatment. In addition, vaccination could protect against a subsequent exposure to anthrax spores. Previous recipients of anthrax vaccine could benefit against relapse if they are due for a vaccination or if they have not kept their vaccinations current.

G. Study Procedures

You must be at least 18 years of age (17 years old if active duty) and presumed to have been exposed to anthrax spores. You must have read the Anthrax Vaccine and Antibiotic Information Papers, and you must sign and date this Informed Consent Form before you can receive the anthrax vaccine.

Before or at the same time that you receive the first dose of the anthrax vaccine, you will be given a 60-day supply of an antibiotic (check the one you have been asked to take): ☐ ciprofloxacin, ☐ doxycycline, or ☐ penicillin V potassium (PenVK). You may receive the 60-day supply of antibiotics in one or several increments, depending on supply levels. You must tell the health care provider if you are allergic to any of the antibiotics being used in this protocol. It will be your responsibility to complete the 60-day supply of antibiotic.

If you decide not to participate in or to withdraw from this contingency protocol, you will be advised to complete the antibiotic prescribed for treatment of exposure to *B. anthracis* spores because stopping the antibiotic would allow the bacteria to emerge and cause potentially lethal disease.

In this protocol, you will not receive the full 18-month vaccine regimen needed for protection, but only those doses sufficient for post-prophylaxis treatment. You will be injected under the skin (subcutaneous) in the upper arm (deltoid region) with 0.5 mL of the anthrax vaccine. To the extent possible, doses will be administered in alternate arms to minimize discomfort. If you have never received anthrax vaccine, you will be given an initial dose, then one dose at week 2, and one dose at week 4. If you have received fewer than three doses, you will receive an initial dose and another dose at week 2. If you have received three doses, you will receive an immediate booster dose, then continue with the FDA-labeled schedule (at 6, 12, or 18 months or an annual booster). You will remain at the vaccination site for at least 30 minutes after each injection to be observed for any immediate adverse reactions to the anthrax vaccine. You are instructed to report adverse reactions that you think might be related to the administration of the vaccine to your health care provider.

If this is the first time you have been given the anthrax vaccine, you will receive a survey form so you can report any reactions you might have after vaccination. We also want to know whether you took the antibiotic as prescribed. You will be asked to complete the form before you receive your next scheduled vaccination (at weeks 2 and 4). You are instructed to report any adverse reactions that affect your ability to carry out your duties to your health care provider.

H. Duration of the Study

You will remain in the contingency protocol until the contingency protocol has ended, until you have completed the required number of vaccinations, or as instructed by your health care provider. Six months after the protocol has ended, you may be among approximately 3,000 volunteers to be sent a follow-up form to report the experience with the antibiotic-vaccine regimen. You will receive instructions via mail, telephone, or e-mail for completing and submitting the form.

I. Potential Risks and Discomforts

Antibiotics: Take ciprofloxacin with food (excluding milk or yogurt) and at least one large glass of water. Do not drink liquids that contain caffeine because the antibiotic can increase the effect of the caffeine. Do not take ciprofloxacin with sucralfate, Videx® (didanosine), magnesium/aluminum antacids, or products containing calcium, iron, or zinc (take 6 hours before or 2 hours after taking ciprofloxacin). Immediately contact your medical care provider at the first sign of a rash or other allergic reaction. Report any pain, inflammation, or rupture of a tendon. Ciprofloxacin can increase sensitivity to sunlight, so avoid excessive exposure to sunlight. Ciprofloxacin may cause dizziness, so you should know how you react to the antibiotic before engaging in activities requiring mental alertness or coordination.

Take doxycycline with food and at least one large glass of water. Do not take doxycycline with magnesium/aluminum antacids or products containing calcium, iron, or zinc. Immediately contact your medical care provider at the first sign of a rash or other allergic reaction. Doxycycline can increase sensitivity to sunlight, so avoid excessive sunlight. Oral contraceptives may be less effective when taken with this class of drug. Use of doxycycline during the last half of pregnancy may cause permanent discoloration of the teeth of offspring.

Take PenVK on an empty stomach with at least one large glass of water. You should not take PenVK if you have had a previous reaction to any penicillin. Let your medical care provider know if you have a history of allergies or asthma. Immediately contact your medical care provider at the first sign of a rash or other allergic reaction. Other reactions that you might experience include nausea, vomiting, stomach upset, and diarrhea. Oral contraceptives may be less effective when taken with this class of drug.

Do not stop taking antibiotics on your own because this will allow the bacteria to emerge and cause potentially lethal disease. Volunteer initials: _____

Vaccine: The anthrax vaccine has been safely administered in the United States since 1970. As with other vaccines, minor reactions are common. A sharp stinging or burning sensation immediately upon injection of the anthrax vaccine is common; however, it generally goes away within the first minute. Serious adverse events occur rarely after any vaccination. Like all vaccines, the anthrax vaccine may cause soreness, redness, itching, and swelling at the injection site. Up to 30% of men and 60% of women report mild local reactions, but these reactions usually last only a few days. For both men and women, between 1% and 5% report reactions of 1 to 5 inches in diameter. Larger reactions occur about once per 100 vaccinees. A lump at the site occurs commonly, usually lasting for a few weeks, before resolving without treatment.

Beyond the injection site, from 5% to 35% will notice muscle aches, joint aches, headaches, malaise, rashes, chills, low-grade fever, nausea, or related symptoms. These symptoms usually disappear in less than a week. Any vaccine can cause serious reactions, such as those requiring hospitalization. For anthrax vaccine, they happen less than once per 100,000 doses. Severe allergic reactions occur less than once per 100,000 doses.

Discuss with your health care provider whether antihistamines or pain relievers before or after vaccination might help reduce bothersome symptoms. Promptly report adverse reactions to your health care provider before receiving additional vaccinations.

If you had an acute allergic reaction to a previous dose of anthrax vaccine, you would generally be excluded from future vaccinations. A severe reaction is defined as an acute allergic reaction consisting of

a rash, swelling of the face and mouth, and difficulty in breathing. However, because of the high fatality rate from inhalational exposure to anthrax spores, you would still qualify for this protocol. Vaccinations are routinely deferred until after pregnancy, unless, as in this contingency protocol, immunity is needed during pregnancy. If you are pregnant, you will be given the opportunity to take the anthrax vaccine, along with the antibiotic, as a lifesaving measure to protect you and your unborn baby.

If you are HIV-positive or are otherwise immunosuppressed, you may not be adequately protected with the proposed vaccination schedule. Check with your health care provider. Also if you are receiving any therapy such as corticosteroids that depresses the immune response, you may not be adequately protected by the recommended dosage schedule. Please inform your health care provider and ask for specific advice.

Formal studies have not been conducted to determine whether anthrax vaccine is carcinogenic or has any effect on fertility. No nonliving vaccine has been found to cause cancer or to affect fertility. Furthermore, there has been no evidence of infertility, miscarriages, or other reproductive problems with the use of the anthrax vaccine.

There is a theoretical chance of Guillain-Barré syndrome (GBS), which is an inflammation of nerves that can cause muscle weakness and/or paralysis. However, the CDC reports that 95% of GBS cases are not associated in time with vaccination. No cause-and-effect relationship between anthrax vaccination and GBS has been found. Between March 1998 and January 2001, during the time when 2 million doses of anthrax vaccine were administered, five cases of GBS in anthrax-vaccinated people were reported to VAERS. The independent civilian Anthrax Vaccine Expert Committee judged one of the cases as unrelated to anthrax vaccine and the other four cases as unclassifiable (not different from the rate of GBS expected in the general unvaccinated population).

J. Safeguards for Your Protection
Good clinical practices and professional patient care will be used during this protocol. The medical personnel are trained to treat vaccine-related emergencies should any occur. Significant new findings discovered during the course of your participation that may relate to your willingness to continue participation will be provided through the chain of command or through other information channels as appropriate.

K. Compensation
You will not be paid for participating in this protocol.

The U.S. Department of Defense is funding this contingency protocol. Should you be injured as a direct result of participating in this research project, you will receive medical care, at no cost to you, for that injury. Injury compensation is based on the "personnel" status of the volunteer. Military personnel are generally eligible for disability compensation for any injuries or illnesses incurred in the line of duty. Civilian personnel of the U.S. Government and of contractors are generally eligible for disability compensation for injuries or illnesses incurred within the scope of employment. Injury compensation beyond the scope of these disability compensation programs is not available. Injury compensation for volunteers who do not have a personnel status that includes compensation coverage is not available. You should also understand that this is not a waiver or release of your legal rights.

L. Confidentiality
All information collected during this protocol will be confidential. No information such as your name or Social Security number that identifies you specifically will be made public. The U.S. Army Medical Materiel Development Activity (the study Sponsor's representative); representatives of the Army, Navy,

and Air Force Offices of the Surgeons General; and the FDA will be permitted to photocopy and review medical and study records related to this protocol as part of their responsibility to protect human subjects enrolled in clinical protocols. The information about your participation in this protocol will be retained in a DoD database for a minimum of 75 years.

M. Consent

I have read this informed consent document and freely consent to participate in this contingency protocol. I have read the information papers given to me on anthrax vaccine and the antibiotics to be used in this protocol. I have been told the nature of the protocol and that I am a voluntary participant. I agree to adhere to the procedures outlined in this consent form. I have been told how long I will be expected to participate. I also have been told that the physician in charge may remove me from the protocol without my consent either because of my failure to follow the protocol requirements or if the physician believes it is in my best interest medically. I understand the risks and benefits associated with my participation in this protocol. I further understand that I may refuse to participate or may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled. I have been given the opportunity to ask questions freely and had them answered to my satisfaction. I acknowledge that I have been given a copy of this signed and dated informed consent form.

I understand that nothing contained in this informed consent waives any of my legal rights as a volunteer.

If I have any questions regarding my rights as a volunteer, I may contact the Chairman, Human Use Committee (301) 619-4723 or:

_____

If I have questions regarding my safety or health, I may contact

_____

(Name of Investigator at Military Medical Facility)

or U.S. Army Medical Research and Materiel Command, Office of Regulatory Compliance and Quality, 504 Scott Street, Fort Detrick, MD 21702-5012, (301) 619-2165.

In the event of a protocol-related injury, I may contact:

_____

(Name of Investigator at Military Medical Facility)

or Office of Regulatory Compliance and Quality (301) 619-2165.

N. Privacy Act Information, Authority: 10 USC 3013, 44 USC 3101, 10 USC 1071-1087

PRINCIPAL PURPOSE: To document the provision of educational information on the use of anthrax vaccine and for participation in the "Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Adsorbed (AVA) to Protect against *Bacillus anthracis* Spores."

ROUTINE USES: The SSN and home address will be used for identification and locating purposes. Information derived from the protocol will be used to document your participation. This information will be retained by the respective military services for a period of at least 75 years. Information will also be used to allow follow-up evaluation and analysis of medical conditions resulting from your participation.

DISCLOSURE: The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected.

Your signature below constitutes consent to disclosing data to the U.S. Army Medical Materiel Development Activity (the study Sponsor's representative); representatives of the Army, Navy, and Air Force Offices of the Surgeons General; and the FDA.

Printed Name of Volunteer Subject	Date of Birth
	SSN
Signature of Volunteer Subject	Date/Time
Permanent Address of Volunteer Subject	Ethnicity of Non-Service Personnel: White, Black, Hispanic, Asian, Other (specify)
Printed Name of Person Conducting Consent Interview	Gender of Non-Service Personnel
Signature of Person Conducting Consent Interview*	Date
Printed Name of Witness	
Signature of Witness**	Date

*If the consent information was provided to a volunteer who does not speak or read English, the person conducting the interview should indicate that the information was presented in the subject's language: _____.

**Witness should be able to understand both English and the volunteer's language.

APPENDIX J

Sample Instructional Materials

ENCLOSURE

JOINT STAFF COMMENTS ON THE CONTINGENCY PROTOCOL FOR VACCINATION OF VOLUNTEERS WITH ANTHRAX VACCINE ADSORBED (AVA) AFTER POSSIBLE EXPOSURE TO *BACILLUS ANTHRACIS* SPORES.

1. Section 2.0

a. Page 3, first paragraph, last sentence. Change as follows: "Anthrax Vaccine Adsorbed (AVA) . . . ."

REASON: Completeness. This is the first time the abbreviation is used within the document.

Changed

b. Page 3, third paragraph, first sentence. Change as follows: ". . . the CDC and ACIP (12, 16) . . . ."

REASON: Completeness

Changed

c. Page 3, fifth paragraph, fourth sentence. Delete and substitute the following:

"The intent of this protocol is for contingency use of anthrax vaccine in a post-exposure setting, not to support a labeling change for the licensed anthrax vaccine."

REASON: Allows the use of information collected while stating the proper intent of the protocol.

Changed

d. Page 4, first paragraph. Comment: Define the timeframe and when data collection will cease, so that analysis and reporting to FDA can begin and end.

REASON: Clarity of the research design.

Added: Upon termination of the contingency, a cohort of volunteers will be sent a follow-up questionnaire to describe their experience during implementation of the protocol. The Clinical Project Manager will analyze the questionnaire data as well as the protocol data and prepare a final report for submission to the Food and Drug Administration (FDA).

2. Section 2.2.2.2

a. Page 8, first paragraph. Add to the end of paragraph the following statement: "Some of the most robust evidence of the safety of anthrax vaccine comes from the Defense Medical Surveillance System (DMSS), which shows that anthrax-vaccinated and –unvaccinated personnel are hospitalized at the same rates."

Added

b. Page 9, fourth paragraph, last sentence. Change as follows: "No deaths have been causally linked to the ~~resulted from~~ anthrax vaccine."

Changed

c. Page 12, first paragraph, last sentence. Change as follows: "Anthrax Vaccine Expert Committee (AVEC) found no . . . ."

REASON: Accuracy. The DMSS constitutes a capability more robust than VAERS for post-marketing surveillance of health events potentially associated with the anthrax vaccine. The ACIP recommendations note two deaths were reported through VAERS as of publication date, but were not "causally associated".

Changed

3. Section 2.3.4

a. Page 14, first paragraph, third line. Change as follows: ". . . .The ~~AVIP~~ ACIP recommends . . . ."

REASON: The ACIP is a more authoritative reference than the AVIP and adds credibility to the statements as a civilian advisory group.

Changed

b. Page 14, second paragraph. Change as follows: "~~Protective clothing and gas masks can~~ Individual protective masks (gas masks) and collective protection systems (NBC MOPP suit) provide excellent . . . ."

REASON: Protective clothing provides minimal protection against anthrax spores. However individual protective masks and collective protection systems provide inhalation protection against anthrax spores. The correct terminology should be used, however the document should also be written in lay language.

Changed

4. Page 16, Table 5, Anthrax Vaccine Administration Guideline for Post-Exposure Prophylaxis

a. Page 16, doses 4 through 6, second and third columns. Change as follows: "~~14 days~~6 month" and "~~2 weeks~~6 months."

b. Page 16, dose 7, second and third columns. Change as follows: "~~14 days~~ 12 months" and "~~2 weeks~~ 12 months."

REASON: Consistency with the current anthrax program. The current dosage schedule for doses 4 through 6 are given at a 6 month interval with subsequent doses being required annually.

c. Page 16, Notes section. Add the following:

"In a "vaccine tight" environment, triage emphasis should be given to those who have not received doses 1, 2, and 3 before considering boosting of those who have received four or more doses of the vaccine."
Changed

REASON: Large amounts of vaccine might be squandered by boosting of those who have nearly completed the full vaccine schedule.

No changes made: The table was deleted. The new schedule is described on page 16, Post-NBC Conf. Version.

5. Page 17, section 2.7, References, item 13. Change as follows: "United States, 2000 (~~draft~~December 15, 2000)."

REASON: Accuracy

Changed

6. Section 4.0

a. Page 20, first paragraph, third sentence. Change as follows: "The Secretary of Defense ordered the implementation of a plan ~~(contingency protocol under an IND)~~ to protect service . . . ."

Changed

b. Page 20, first paragraph, fifth sentence. Change as follows: ". . . The Surgeon General of the Army and the absence . . ."

Changed

c. Page 24, Figure 5, Responsibilities Associated with Anthrax Vaccine Contingency Protocol

(1) Responsibilities of the Combatant CINC section: Add the following:

"3. Request approval from SECDEF to implement the anthrax contingency protocol.

Added

4. Inform SECDEF of decisions related to the execution of the protocol."

REASON: IAW DODD 6200.2 the implementation authority rests with SECDEF, not the CINC. The CINC is responsible for informing the SECDEF of any decision made after the SECDEF gives approval to execute the protocol.

Added

(2) Page 24, Responsibilities of Site Investigator, item 11. Change as follows: ". . . AEs to ~~RCQ, USAMRIID Human Use Committee, and~~ Clinical Project Manager."

Changed

(3) Page 24, Responsibilities of Clinical Project Manager section. Add the following: "8. Forward copies of serious and unexpected AEs to the RCQ, HSRRB and USAMRIID's Human Use Committee."

REASON: The Clinical Project Manager should be responsible for forwarding the information to the RCQ and USAMRIID Human Use Committee. This will reduce the reporting requirements for the Site Investigator and require him/her to only have one primary office to report all information/reports. By centralizing the reporting, this will help to ensure the information is forward to the proper agencies/committees.

Added

(4) Page 24, end of figure. Add the following:

"Responsibilities of the Secretary of Defense:

1. To approve/disapprove CINC request to implement the protocol. The Secretary of Defense has the authority under DODD 6200.2 Section 4.2 to approve protocols for use on volunteers who give informed consent.
2. Request a waiver of informed consent from the President of the

3. United States when necessary IAW DODD 6200.2 Section 4.3."

Added

d. Page 25, end of paragraph 2. Add the following:

"To reduce bias, a comparable control group of personnel who did not participate in the protocol will be surveyed six months after receiving the influenza vaccine, for comparison."

REASON: Clarity, completeness and consistency. Avoids confusion with other Service Surgeons General. This portion of the protocol should show all of the key responsibilities. Under DODD 6200.2, the SECDEF does have the ability to request the President waive the requirement for informed consent. The SECDEF must personally request the waiver. The protocol should recognize this option and address the steps when necessary. Improves study design by adding a bias control measure for the survey.

Not added: Will be tasked to an epidemiology group; not to be incorporated in IND

7. Section 4.9

a. Page 27, 4.9 Source Data section, first paragraph. Delete and substitute the following:

"The following data fields will be completed via Service automated immunization tracking systems (AITSs) and will serve as the Case Report Form for subjects enrolled in the contingency protocol: The Service AITSs are: MEDPROS (Army), SAMS (Navy & Marine Corp), and MITS (Air Force)."

Changed

b. Page 27, Immunization Table, subparagraph 1. Add the following:

"Series Number, Route of administration (e.g., SC, ID, IM, etc.)."

Added

c. Page 27, Temporary Personnel Table, subparagraph 2. Add the following:

"National Identity Number or other ID number."

Added

d. Page 27, subparagraph 3, first bullet. Change as follows: ". . . used in ~~MODS~~Service AITS."

Changed

e. Page 28, subparagraph 4, first bullet. Change as follows: "used in ~~MODS~~Service AITS."

REASON: Accuracy, completeness and clarity. The protocol can be given to non-US service volunteers. Thus the protocol must comply with the requirements of DODI 6205.4, Section 5.5.4.1 Immunization of Other Than US Forces for Category 2 through 4 personnel.

NOT CHANGED: Items 4 and 5 (Lot Validation Table and Manufacturer Validation Table) were deleted from Post-HSRRB version.

8. Page 29, section 5.3. Comment: Clearly define the withdrawal (voluntary and involuntary) criteria for the protocol. Identify the documentation requirements when an individual is withdrawn from the protocol. Individuals who do not desire to take non-FDA-released AVA will be allowed (indeed, encouraged) to take the antibiotic regimen. Added as per Info Papers and ICF

Added the following:
5.3 Voluntary Withdrawal

Subjects who refuse treatment may withdraw at any time without penalty or loss of benefits to which they are otherwise entitled. Counseling will be provided about the subject's health if he/she decides to discontinue participation in the protocol. Additional medical advice in the best interest of the individual subject will be provided. Specifically, subjects will be told "*Do not stop taking antibiotics on your own because this will allow the bacteria to emerge and cause potentially lethal disease.*"

5.4 Removal of Subjects from Study

The Investigator or Medical Monitor will determine which subjects are to be withdrawn from the contingency protocol.

9. Page 30, section 6.1, third paragraph, first sentence. Change as follows: ". . . further exposure to *B. anthracis* spores ~~should~~ will be advised to complete the FDA . . . ."

REASON: Clarity

Changed

10. Page 33, section 6.5, end of paragraph. Add the following:

"Monitoring/ensuring that subjects complete the requisite number of vaccinations must be a partnership among the subjects, themselves, their commanders or other unit leaders, and the medical community, especially considering the stress of implementing this protocol within military operations."

REASON: Accuracy

Added

11. Page 34, section 8.0. Comment: Describe plans that establish accountability for documentation of protocol treatments in individual medical records of vaccine recipients. Address the documentation of adverse events during a military operation in the health record. The protocol must establish accountability for tasks. As written, this section loosely requires AE outcome documentation (paragraph 3).

To be incorporated in the Implementation Plan.

12. Page 34, section 8.1, end of first paragraph. Add the following:

"Loss of duty greater than 24 hours is a mandatory VAERS reporting criteria."

REASON: Accuracy

Added

13. Page 35,section 8.3. Add the following:

"Volunteered and observed AEs will be recorded in the volunteer health records in addition to any protocol specific records."

REASON: Clarity

Added

14. Section 8.5

a. Page 38, Clinical Project Manager. Change as follows: Move the Clinical Project Manager at USAMRIID to the top of the addressee list for serious and unexpected AEs.

Added

b. Page 38, after the Clinical Project Manager. Add the following statement: "The USAMRIID Clinical Project Manager will forward AE information to:"

Added

c. Page 38, Clinical Project Manager. Add the telephone #, fax #, and email address information to the Clinical Project Manager after the position has been filled.

REASON: The Clinical Project Manager works within the same organization as the US Army Medical Research and Materiel Command (USAMRMC) Office of Regulatory Compliance and Quality and the US. Army Medical Research Institute of Infectious Diseases (USAMRIID) Chairman, USAMRIID Human Use Committee. He/she can forward this information to these committees. This will reduce administrative burden on deployed operational units and help to ensure each committee receives the necessary information. Deployed operational units will not be able to forward AE information for central collection without it.

To be added when protocol is finalized.

15. Page 39, section 8.7, first sentence. Change as follows: "review." Replace with "investigate." Delete "Human Subjects Research Review Board (HSRRB)." Replace with "Clinical Project Manager at the USAMRIID."

REASON: Accuracy. The medical officer will likely be called on to examine and possibly treat the affected individual. This is not a technical review. To help ensure compliance with the protocol, the deployed operational units should deal with only one office. The Clinical Project Manager at USAMRIID will need to have this information anyway and can forward the report to the HSRRB. This change will simplify the flow of information from the deployed unit to the central collection point.

Changed

16. Page 40, section 12.1, first sentence. Change as follows: ". . . by the Code of Federal Regulations (in particular parts 21, 56, 314, and 601 of CFR 312) and ICH . . . ."

REASON: The protocol should clearly identify applicable CFRs.

Changed

17. Page 41, section 12.2, paragraph 1, second sentence. Add the following:

"DoD's quad-fold brochure and CDC's Vaccine Information Statement (VIS) on anthrax vaccination may be used as training aids to provide additional information."

REASON: Uniformity and consistency of information by utilizing existing resources.

Added

18. Sections 12.4 and 12.5 (Confidentiality and Confidential Follow-up)

a. Page 42. Comment: Ensure compliance with the Privacy Act (5 U.S.C § 552a) if establishing any database of service members with data retrievable by their social security numbers. See AR 340-21, The Army Privacy Program, 5 July 1985, paragraph 4-6.

Added the following to the ICF:
N. Privacy Act Information, Authority: 10 USC 3013, 44 USC 3101, 10 USC 1071-1087
PRINCIPAL PURPOSE: To document the provision of educational information on the use of anthrax vaccine and for participation in the "Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Adsorbed (AVA) to Protect against *Bacillus anthracis* Spores."
ROUTINE USES: The SSN and home address will be used for identification and locating purposes. Information derived from the protocol will be used to document your participation. This information will be retained by the respective military services for a period of at least 75 years. Information will also be used to allow follow-up evaluation and analysis of medical conditions resulting from your participation.
DISCLOSURE: The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected.

Your signature below constitutes consent to disclosing data to the U.S. Army medical Materiel Development Activity (the study Sponsor's representative), representatives of the Army, Navy, and Air Force Offices of the Surgeons General, and the FDA.

b. Page 42. Comment: Ensure that the listing in sections 12.4 and 12.5 of those individuals who will have access to these records is the same as that on the Informed Consent Form.

Added the following:

The U.S. Army Medical Materiel Development Activity (the study Sponsor's representative), representatives of the Army, Navy, and Air Force Offices of the Surgeons General, and the FDA are entitled to photocopy. . . .

c. Page 42. Comment: Explicitly state on the informed consent form all of the parties who will have access to the data (consistent with sections 12.4 and 12.5).

Stated

d. Page 42. Comment: The Privacy Act also requires that a Privacy Act statement be furnished to individuals whenever personal information is requested from them that will become part of a system of records retrievable by their names or personal identifiers. See AR 340-21, paragraph 4-2 for a list of required data. See also AR 15-6, Appendix B for additional guidance on drafting a systems notice.

Issue addressed (see above)

e. Page 42. Add the following:

"Your signature below constitutes consent to disclosing this data to these individuals."

REASON: Accuracy, consistency and to ensure compliance with the Privacy Act. Per AR 340-21, Chapter 3, the Army is prohibited from disclosing a record from a system of records without obtaining the prior written consent of the data subject, except, for example, when disclosure is made to officers and employees of DOD who have a need for the record in the performance of their duties (the so-called "need-to-know" exception to the Privacy Act), or permitted by a routine use that has been published in the Federal Register. Any invocation of the "need-to-know" exception must be documented by the official responsible for invoking it.

Added

19. Page 42, section 14.0 and section K of the Informed Consent Form. Comment: Consult with US Army Medical Research and Materiel Command (USAMRMC) legal counsel to determine whether the passage "Should a subject be injured as a direct result of participating in this protocol, he/she will be entitled to medical care at no cost for that injury. The subject will not receive any injury compensation, only medical care" should be changed to "The subject will not receive any injury compensation beyond that provided by law."

The sentence was revised as follows: ...at no cost for that injury. Injury compensation is based on the "personnel" status of the volunteer. Military personnel are generally eligible for disability compensation for any injuries or illnesses incurred in the line of duty. Civilian personnel of the U.S. Government and of contractors are generally eligible for disability compensation for injuries or illnesses incurred with the scope of employment. Injury compensation beyond the scope of these disability compensation programs is not available. Injury compensation for volunteers who do not have a personnel status that includes compensation coverage is not available. The subject should understand. . .

Further, request USAMRMC counsel coordinate with the Office of Workers Compensation to determine if they have any provisions affecting civilians who are exposed to anthrax and to develop plans to accommodate medical care for civilian and contractor personnel who are injured as a direct result of participating in the protocol. It is likely that questions about such care will arise during the briefing for the informed consent and unit support personnel will need to know how to care for members who need to exercise this component of the protocol.

Revision incorporates civilian requirements.

20. Appendix Section. Comment: Add a copy of the FDA Form 1572, instructions on how to fill this form out, and how to obtain a copy of the form through the internet and/or mail. The protocol should be inclusive and provide the Principal Investigators a copy of each form they must complete.

Added as Appendix B

21. Appendix A, Logistic Annex

a. Page A-2, second paragraph, first line. Change as follows: ". . . Vaccine to be used under this protocol may not have ~~not~~ been released . . . ."

REASON: Accuracy. If vaccine which has been released is available, then this vaccine will be used. If FDA released vaccine is not available, then non-FDA released vaccine will be use.

The post-HSRRB version of the first line was changed to "The Anthrax Vaccine to be used under this protocol is considered an investigational new drug."

b. Pages A-3 and A-4. Comment: Provide an agency email account when possible.

(1) Add the following: "Navy and Marine Corps".

Added

(2) Change as follows: ". . . "bhomman@~~nml10~~us.med.navy.mil"; "Lt ~~Byron Owens~~ Scott Spratt"; ". . ~~bowens@nml10.med.navy.mil~~ smspratt@us.med.navy.mil"; and "mbrown@~~nml10~~us.med.navy.mil".

REASON: Accuracy. The vaccine may or may not have been released. Avoids any unnecessary limitations on the protocol. Providing agency email accounts will allow field units to forward the necessary information once individuals PCS.

Changed

c. Page A-3, subparagraph e. Comment: Ensure a mechanism is in place to keep the POC listing current and accurate.
Recommend referencing the USAMMA website (http://www.armymedicine.army.mil/USAMMA/anthrax/poc.stm) in the protocol.

Added as first item under Anthrax Vaccine Points of Contact

USAMMA must ensure changes and updates are posted on the website in a timely manner as necessary.

Web site updated regularly

d. Page A-13, paragraph 2. Comment: The first sentence states: "The antibiotics Ciprofloxacin, Doxycycline and Penicillin are all approved by the FDA for either the prevention or treatment of disease caused by *B. Anthracis*. As such, they are not considered investigational agents under this protocol." This statement is contradictory to the statement on page 33 (6.4.2.3.), "Penicillin is approved by the FDA for the treatment of anthrax disease but not for post-exposure prophylaxis." Clarify which statement is correct and then make necessary changes to ensure consistency throughout the protocol.

REASON: Accuracy and clarity

Revised wording: Ciprofloxacin is approved to reduce the incidence or progression of inhalational anthrax following exposure to aerosolized *B. anthracis* spores, whereas doxycycline and penicillin are approved for treatment of anthrax disease but not for post-exposure prophylaxis.

22. Appendix B

a. Page B-3, after "Number of anthrax vaccinations received:" Change the blank line with check boxes, indicating the number of potential doses. "__1 __2 __3 __4 __5 __6 __7 or more."

In post-HSRRB version, blank line replaced with "enter the anthrax vaccine dose number(s) in the boxes to the left."

b. Page B-3, "Experience with antibiotic" section. Delete "Yes No". Replace with check boxes listing "__<5 __5-10 __11-20 __21-40 __41-60 __61-80 __81-100 __101-120."

REASON: Check boxes give more easily analyzed information than free text entries. An estimate of the total number of antibiotic doses taken is more informative assessment of compliance than a simple yes or no answer.

Replaced and added +120 (to accommodate PenVK dosage schedule)

23. Appendix C

a. Page C-2, after the line "Do you smoke?" Add the following: "Do you drink alcohol? How many drinks per week?" Then list in check box format several options.

Reference to alcohol was deleted in earlier version.

b. Page C-2, after last question, "How many doses have you taken? Add the following check boxes "<5, 5-10, 11-20, 21-40, 41-60, 61-80, 81-100, and 101-120."

REASON: Alcohol use is an important contributor to the overall health status along with tobacco use. Check boxes give more easily analyzed information than free text entries.

Replaced and added +120 (to accommodate PenVK dosage schedule)

24. Appendix G

a. Page G-6, Precaution paragraph. Comment: Include information about avoiding excessive sunlight/photosensitivity while taking Doxycycline.

Added: "Doxycyline can increase sensitivity to sunlight."

b. Page G-6, Drug Interactions paragraph. Add the following: "Doxycycline can increase sensitivity to sunlight."

This section addresses drug-drug interactions and Precaution section address sun sensitivity.

c. Page G-6. Comment: Include a summary paragraph to summarize the important points at the end of the consent form (e.g. how to avoid excessive sunlight, be aware of dizziness, decreased effectiveness of birth control pills, how and when to take the medications).

Already stated in Information Papers and relevant section of the ICF

d. Page G-7, Drug Interactions paragraph. Add the following: "Penicillin can increase sensitivity to sunlight."

Added this statement to Precautions section, but not to Drug Interactions

e. Informed Consent Form

(1) Comment: Create three separate Informed Consent Forms. Version 1 is for use of FDA released vaccine, version 2 is for use with non-FDA released vaccine, and version 3 is for when either FDA released or non-FDA released vaccine will be available. In each case the third paragraph under sub-paragraph A must be adjusted to correctly identify which vaccine (FDA released or non released) is being used. The third version could use a check box style question such as: "You will be given a dose of vaccine from (check the one that describes the vaccine) __ FDA released AVA vaccine or __ non-FDA released AVA vaccine but which the FDA agrees may be used in this protocol." For version 2 and 3, add a paragraph that describes why the protocol is using non-FDA release AVA vaccine.

Three ICFs not prepared: As released lots of vaccine become available, the ICF can be revised during the annual review of the protocol.

(2) Paragraph G, subparagraph 3. Delete "or triceps."

Deleted

(3) Comment: Add the risks of no treatment.

New third Paragraph: If you decide not to participate in or to withdraw from this contingency protocol, you will be advised to complete the antibiotic prescribed for treatment of exposure to *B. anthracis* spores because stopping the antibiotic would allow the bacteria to emerge and cause potentially lethal disease.

(4) Second page (page unnumbered), paragraph 2. Comment: The protocol addresses taking all the antibiotics together. This part of the form suggests that volunteers may take any one antibiotic only. The protocol and consent form must be consistent.

Protocol and ICF made consistent

Section 6.4.2, , Paragraph 1, second sentence: Recommendations for selecting an antibiotic. . . . ICF, Section E, Paragraph 2, First sentence: Cirofloxacin, doxycycline, or penicillin V potassium, if taken as prescribed. . . .

Deleted sentence 3: The recommended antibiotics include. . . .

(5) Third page (page unnumbered). Comment: Ensure information on the antibiotics is consistent with the previous antibiotic information. Each drug that imposes effects from excessive sunlight and affects the effectiveness of oral contraceptives needs to so state at every point these drug factors are mentioned. Include tips on managing oneself when taking these drugs (e.g. use of sunscreen, coincident use of supplemental contraceptives, etc.).

Information stated in Information Papers

(6) Fifth page (page unnumbered). Comment: Add information about how the volunteer may get the information about his/her participation.

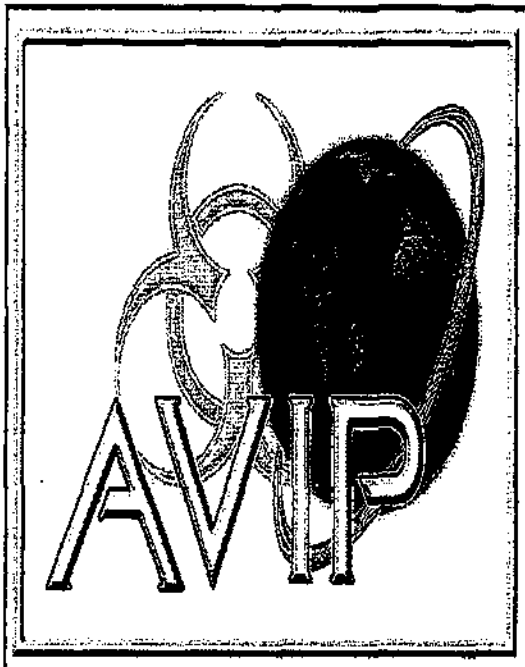
Under Section M, referred volunteers to RCQ

(7) Section N, fifth page (page unnumbered). Comment: List the organization and address for the Regulatory Compliance and Quality Office. Added

(8) Comment: Add to the protocol a discussion of the status of participants while they are under treatment (e.g., need for isolation of those exposed, hazardous material management).

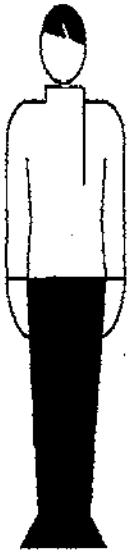
REASON: Completeness and accuracy. The precautions for use of Doxycycline are not correct. As per the Physician Desk Reference 2001, sun exposure (photo-sensitivity) is a possible side effect from the use of quinolones however it is a warning in Doxcycline use and should be included in all antibiotic precautions. The injection should be into the deltoid area stated in protocol to avoid possible ulnar neuropathy. The protocol can be used with either FDA release or non-FDA release vaccine. Recipients need to be aware of which category of vaccine they are receiving and why they are receiving non-FDA released vaccine.

Not added: Not within the scope of the protocol.



Anthrax Vaccine Immunization Program

Life-Saving Treatment after Anthrax Exposure:



Important Information About Anthrax Vaccine

Anthrax

- Natural anthrax is primarily a disease (
- Anthrax is a known biological weapon.
- Inhalational anthrax is highly lethal.
- Antibiotics plus vaccination against ant
  critical for <u>your</u> protection.
- Anthrax vaccine is safe and effective a
  series, based on decades of experi
- Independent panels of civilian physicia
  anthrax vaccine is safe and effecti

15 Jun 01

Anthrax Vaccine After Exposure

- You may have been exposed to anthrax, a lethal disease.
- The Centers for Disease Control & Prevention (CDC) recommends that people in your situation receive antibiotics, plus at least 3 doses of anthrax vaccine.
- The Food & Drug Administration (FDA) has not yet licensed the use of 3 doses of anthrax vaccine for protection after exposure to anthrax (POST-exposure use). Therefore, FDA considers using anthrax vaccine in a 3-shot series an Investigational New Drug (IND) use.
- Depending on supply, the anthrax vaccine available for you may have passed some or all of the usual tests FDA requires. These tests are required before FDA permits manufacturers to ship vaccines under normal conditions.

Protection from Anthr
Antibiotics Plus Anthrax \

- Take 30 to 60 days of antibiotics (eg, cip as directed by your medical personnel.
- Previously unvaccinated people can choo or not to take the IND anthrax vaccine.*
- Antibiotics PLUS vaccine provides the bes long-term protection, the best chance of
- We HIGHLY encourage you to take the v

* unless the President invokes Executive Order 13139

15 Jun 01

Antibiotics Plus Anthrax \

- Anthrax bacteria "hibernate" inside spore
  When these bacteria come out of the spores, it's called "germination."
- Antibiotics kill the bacteria form of anthra
- Antibiotics do not kill anthrax spores.
- When you stop taking antibiotics, anthrax spores remaining in the lung could germinate into growing bacteria. These bacteria could kill you.
- Anthrax vaccine can protect you over the long term from any anthrax spores remaining in your lungs after you stop taking the antibiotics.

15 Jun 01

Anthrax Vaccine

- Licensed by the FDA since 1970
  - Administered in the U.S. to at-risk veterin laboratory workers, and livestock handler
  - More than 2 million doses administered tc 511,000 Service Members since 1998
  - 13 safety studies
  - 6 reviews by independent panels of civilia and scientists
- Any whole anthrax bacterium, whethe dead
  - Can cause anthrax disease
  - Does not contain protective antigen (PA)

15 Jun 01

Injection-Site Reacti
After Anthrax Vaccina

- From Hawaii, Korea, Ft. Bragg, Ft. Detr

2000: Redness, itching, swelling (lasting

  - Less than 1 inch: men up to 30%, won
  - 1 to 5 inches: 1% to 5%
  - Greater than 5 inches: up to 1%
  - Swelling may extend below elbow
- Soreness or local pain in 8% to 19%
- Lump: 30% to 90% (may persist a f

- For both genders, most injection-site re

1 to 3 days and go away on their own

15 Jun 01

Systemic Events After Vac

(Events Away from the Injection S

- From 5% to 35% will notice:
  - Muscle aches, joint aches, chills, low-grac no appetite, headaches, nausea, malaise, symptoms
  - Women report these symptoms more ofte
  - These symptoms usually go away in a fev than a week
- Serious allergic reactions occur after a

  < 1 per 100,000 doses

Injection-Site Reaction Systemic Events

- Ask your health-care provider whethe acetaminophen, antihistamines, or oth medications may help reduce bothersc symptoms.
- Report adverse events after vaccinatic care provider promptly, before additio vaccinations.

Adverse Event Reporting

- Vaccine Adverse Event Reporting System (VAERS)
  - FDA reviews 100% of adverse-event reports submitted to either FDA or DoD
  - Anyone can submit a Form VAERS-1
- DoD requires a Form VAERS-1 submission for:
  - Loss of duty greater than 24 hours
  - Hospitalization
  - Suspected vaccine vial contamination
- Other submissions permitted
- Form VAERS-1 may be obtained from:
  - 1-800-822-7967 or www.vaers.org

Information Sources

- Chain of command
- http://www.anthrax.osd.mil
- http://www.defenselink.mil
- http://www.cdc.gov
- http://www.aviationmedicine.com
- Call toll-free 1-877-GET-VACC

  (1-877-438-8222)

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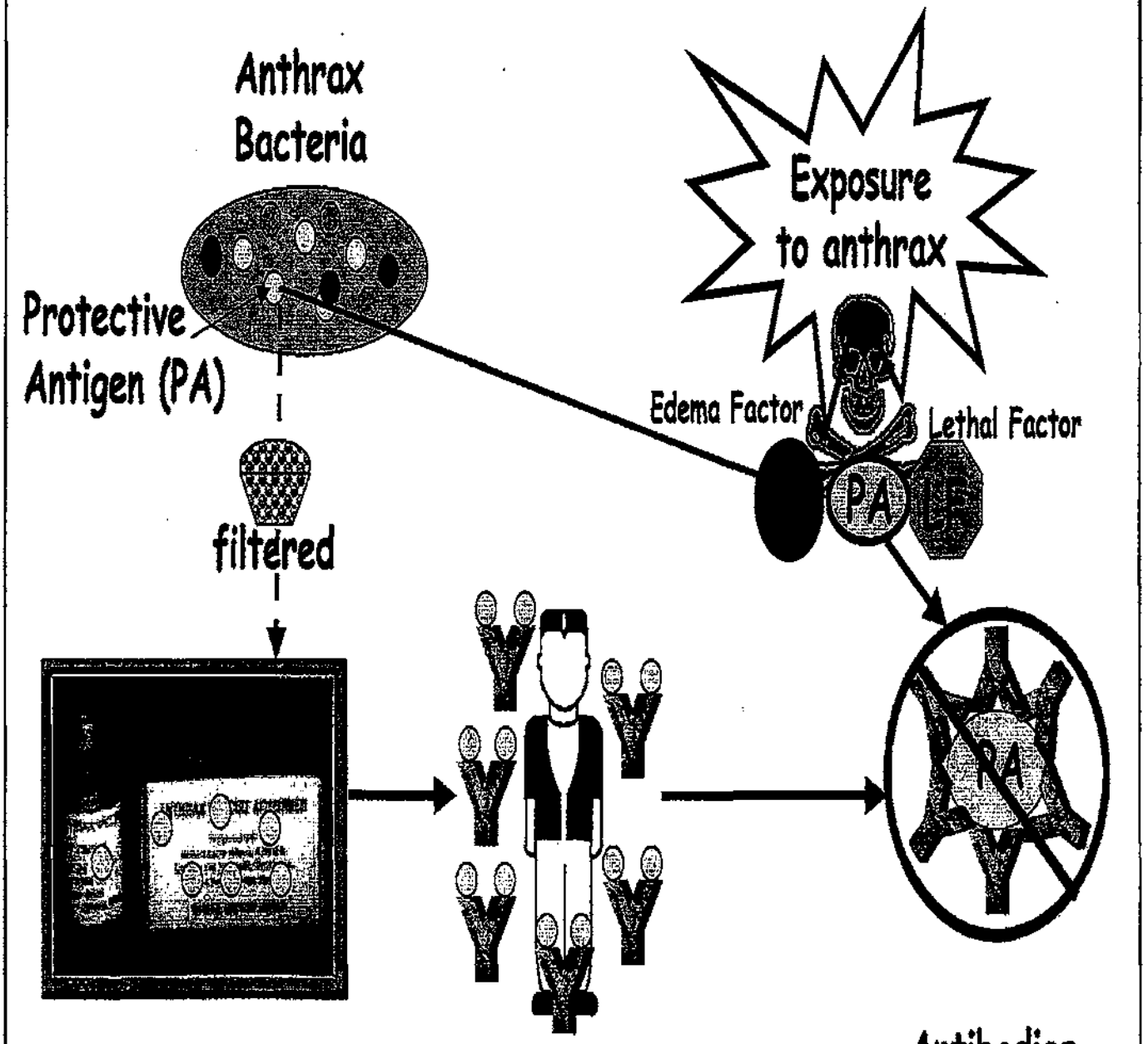
Background Slides

Inhalational Anthrax

- Inhalational anthrax occurs when spores enter the body through the lungs
- Not transmitted person to person
- Spores migrate to lymph system where bacteria multiply and produce lethal toxins
- Toxins cause bleeding and destruction of the brain or vital organs in the chest, resulting in death

How Anthrax Vaccine Prevents Disease



Vaccine contains PA, extracted from anthrax bacteria.

Immune system develops antibodies (Y) to PA, protection from disease.

Antibodies "neutralize" PA, common part of anthrax toxins.

Long-Term Studies

- More than 1,500 Fort Detrick laboratory workers vaccinated against anthrax
  - Followed for up to 10 - 20 years
  - None developed unexplained symptoms due to repeated doses of anthrax vaccine or any other vaccines they received
  - Employees followed annually
- Additional studies are underway to gather more information

MEMORANDUM FOR DIRECTOR, JOINT STAFF
DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE (CHEMICAL AND BIOLOGICAL DEFENSE)
GENERAL COUNSEL (ATTENTION: Mr (b)(6))

SUBJECT: Review of the Draft Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Absorbed after Possible Exposure to Bacillus Anthracis Spores

The Assistant Secretary of Defense for Health Affairs (HA) requested that a protocol be prepared to allow the use of the Anthrax Vaccine Absorbed (AVA), in conjunction with antibiotics, for post-exposure to Anthrax.

A protocol was prepared, and staffed by OASD(HA)to the Services and the Commanders in Chief (CINCs) through J-4, Medical Readiness. Comments were received and incorporated into the protocol. Additionally, comments were received during a conference co-sponsored by the Joint Staff and the Army Office of The Surgeon General. These comments have also been incorporated.

This document forwards the updated protocol, along with an item-by-item description of the resolution of the comments received back from the CINCs and Services. Additionally, during the Joint Conference (above), the CINC and Service representatives determined that their real concern was not with the protocol, but rather how they would implement it. A Draft Implementation Guidance document was prepared and is enclosed as well.

Request your review and comment or concurrence with the attached protocol so that it can be forwarded for final approval to the Food and Drug Administration and the Human Subjects Research Review Board. The coordination is required NLT July 31, 2001. My point of contact is (b)(6) , Program Director for Health Science Policy. He can be reached at (b)(6) or by e-mail at (b)(6) @ha.osd.mil.

Robert S. Driscoll, COL, MS, USA
Acting Deputy Assistant Secretary of Defense
Health Operations Policy

Attachments
As stated

July 3, 2001

MEMORANDUM FOR ACTING DEPUTYASSISTANT SECRETARY OF DEFENSE (HA) HEALTH OPERATIONS POLICY

FROM: (b)(6), Program Director, Health Science Policy

SUBJECT: Review of the Draft Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Absorbed after Possible Exposure to Bacillus Anthracis Spores - ACTION MEMORANDUM

- **DISCUSSION:**. The Assistant Secretary of Defense for Health Affairs (HA) requested that a protocol be prepared to allow the use of the Anthrax Vaccine Absorbed (AVA), in conjunction with antibiotics, for post-exposure to Anthrax.

- A protocol was prepared and staffed out to the Services and the CINCs by HA. Comments were received and incorporated into the protocol. Additionally, comments were received during a conference co-sponsored by the Joint Staff and the Army Office of The Surgeon General. These comments have also been incorporated.

- This document forwards the updated protocol, along with an item-by-item description of the resolution of the comments received back from the CINCs and Services. Additionally, during the Joint Conference (above), the CINC and Service representatives determined that their real concern was not with the protocol, but rather how they would implement it. A Draft Implementation Guidance document was prepared and is enclosed as well. The coordination is required NLT July 31, 2001.

RECOMMENDATION: Sign the memorandum.

MEMORANDUM FOR DIRECTOR, JOINT STAFF
DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE (CHEMICAL AND BIOLOGICAL DEFENSE)
GENERAL COUNSEL (ATTENTION: Mr. (b)(6))

SUBJECT: Review of the Draft Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Absorbed after Possible Exposure to Bacillus Anthracis Spores

The Assistant Secretary of Defense for Health Affairs (HA) requested that a protocol be prepared to allow the use of the Anthrax Vaccine Absorbed (AVA), in conjunction with antibiotics, for post-exposure to Anthrax.

A protocol was prepared, and staffed by OASD(HA)to the Services and the Commanders in Chief (CINCs) through J-4, Medical Readiness. Comments were received and incorporated into the protocol. Additionally, comments were received during a conference co-sponsored by the Joint Staff and the Army Office of The Surgeon General. These comments have also been incorporated.

This document forwards the updated protocol, along with an item-by-item description of the resolution of the comments received back from the CINCs and Services. Additionally, during the Joint Conference (above), the CINC and Service representatives determined that their real concern was not with the protocol, but rather how they would implement it. A Draft Implementation Guidance document was prepared and is enclosed as well.

Request your review and comment or concurrence with the attached protocol so that it can be forwarded for final approval to the Food and Drug Administration and the Human Subjects Research Review Board. The coordination is required NLT July 31, 2001. My point of contact is (b)(6) , Program Director for Health Science Policy. He can be reached at (b)(6) or by e-mail at (b)(6) @ha.osd.mil.

Robert S. Driscoll, COL, MS, USA
Acting Deputy Assistant Secretary of Defense
Health Operations Policy

Attachments
As stated

July 3, 2001

MEMORANDUM FOR ACTING DEPUTYASSISTANT SECRETARY OF DEFENSE (HA) HEALTH OPERATIONS POLICY

FROM: (b)(6), Program Director, Health Science Policy

SUBJECT: Review of the Draft Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Absorbed after Possible Exposure to Bacillus Anthracis Spores - ACTION MEMORANDUM

- **DISCUSSION:**. The Assistant Secretary of Defense for Health Affairs (HA) requested that a protocol be prepared to allow the use of the Anthrax Vaccine Absorbed (AVA), in conjunction with antibiotics, for post-exposure to Anthrax.

- A protocol was prepared and staffed out to the Services and the CINCs by HA. Comments were received and incorporated into the protocol. Additionally, comments were received during a conference co-sponsored by the Joint Staff and the Army Office of The Surgeon General. These comments have also been incorporated.

- This document forwards the updated protocol, along with an item-by-item description of the resolution of the comments received back from the CINCs and Services. Additionally, during the Joint Conference (above), the CINC and Service representatives determined that their real concern was not with the protocol, but rather how they would implement it. A Draft Implementation Guidance document was prepared and is enclosed as well. The coordination is required NLT July 31, 2001.

RECOMMENDATION: Sign the memorandum.

IMPLEMENTATION GUIDANCE
USE OF INVESTIGATIONAL DRUGS FOR FORCE HEALTH PROTECTION

Purpose: To provide guidance to CINCs and Services for the implementation of investigational new drug (IND) protocols required for force health protection.

Scope: Guidance provided is intended to serve as a range of potential solutions to assist in the development of implementation plans for force protection protocols. CINCs are responsible for requesting use of INDs in accordance with DoD Directive 6200.2. CINCs are also responsible for providing broadly defined requirements for use of INDs in OPPLANS. Service components are responsible for resourcing and executing IND protocols required to fulfill assigned missions identified in OPPLANS.

Background: According to Department of Defense Directive 6200.2, Use of Investigational New Drugs for Force Health Protection, it is the policy of the Department of Defense to make preferential use of products approved by the FDA to provide needed medical countermeasures against to chemical, biological, or radiological warfare and endemic disease threats. However, when no safe and effective FDA-approved drug is available against a particular health threat, DoD components may request approval of the Secretary of Defense to use an investigational product. It is DoD policy that the use of investigational drugs will comply with applicable laws and regulations. Furthermore, any request for a waiver of informed consent must be approved by the President in accordance with procedures described in Executive Order 13139 and 21 CFR 50.23(d).

FDA-required protocols have been written for the use of two investigational new drug products. The protocol is written in the common format of drug research that describes rationale, objectives for using the product, the statistical design, and methodology for the distribution of the medicine and collection of information. To assist military planners in the use of these investigational products, implementation guidance is provided that describes procedures to follow with products that are either medic administered (e.g., anthrax vaccine) or service member administered (e.g., pyridostigmine bromide for pretreatment against the nerve agent soman).

The anthrax vaccine protocol describes procedures for the administration of anthrax vaccine adsorbed in combination with ciprofloxacin as an early treatment for personnel exposed to the anthrax virus to prevent the onset of symptoms. Anthrax vaccine will be used under investigational status if approved lots of vaccine are not available and because the use of anthrax vaccine after exposure is not an approved use of the product. Regardless of prior immunizations with the anthrax vaccine, all exposed personnel are to receive at least one immunization. The schedule for immunizations is described in paragraph 2.4 of the protocol. Anthrax vaccine is being provided under an investigational drug status because the use of anthrax vaccine for early treatment is not an FDA approved indication and because vaccine lots used for this purpose may not have passed all criteria for release. However, animal studies provide strong evidence that the

use of anthrax vaccine in combination with ciprofloxacin may be effective in humans. Informed consent is to be obtained from individuals prior to immunization with the anthrax vaccine.

The pyridostigmine bromide protocol describes procedures for the use of PB as a nerve agent pretreatment to protect service members from the nerve agent soman. PB is to be taken when there is an imminent threat of nerve agent exposure to pre-treat nerve endings to allow the antidotes of 2-PAM and atropine to work effectively. The dose of PB is one tablet every eight hours. Administration is not to go beyond 14 days. Service members are to discontinue use of PB after exposure to nerve agents. Specific procedures are described in the information sheet (pages 1-8 of the protocol). PB is provided under an investigational drug status because the use of PB for nerve agent pretreatment is not an FDA approved indication. PB is approved by the FDA for use in a disease called myasthenia gravis. Animal studies provide strong evidence that the use of PB may be effective in humans in the pretreatment against soman.

Guidance:

1. Considerations for requesting use of IND protocols (CINC responsibilities):

- CINCs should identify whether INDs are required for AOR OPPLANS. Consideration should be given to the expected potential benefit (lives saved, mission completion, etc.) as compared to costs associated with the use of INDs (personnel, time, and fiscal resources).
- Develop mechanism to request authority for use of INDs consistent with requirements identified in DoD Directive 6200.2 (Figure 1).
- Identify broadly stated criteria for initiation of INDs in operational plans (Figure 2).
- Identify a Principal Investigator (PI) for JTFs organized for contingency OPPLANS (Figure 3).
- For protocols in which a waiver of informed consent is warranted, submit request through the Joint Chiefs of Staff to the Secretary of Defense.
- Cost/Benefit considerations for use of INDs
  - Benefits
    - Potential to save lives
    - Potential to maintain unit integrity to fulfill mission accomplishment
  - Costs
    - Logistical support required for implementation
    - Document education and informed consent in medical record
    - Information system updates to record IND use
    - Training investigators
    - Training service personnel
    - Public Affairs support
    - Time required for implementation and time required to obtain waiver of informed consent
    - Any potential for long term health consequence from use of the IND product

2. Service and CINC responsibilities -- Education of military leadership

- Inform leaders at all levels of the basic requirements for use of INDs (as described in Executive Order 13139 (section 5) and DoD Directive 6200.2 (section 4.8.4)).
- Make execution of IND protocols a Commander's program.

3. Service responsibilities

- Education of service members
    - Services will develop mechanisms to provide any protocol specific briefings or videotapes developed as part of the protocol to inform service members and other potential protocol participants of the purpose of using the investigational product.
    - Services will identify trained health care providers to be available to answer service member questions regarding the particular investigational product.
    - Services will communicate to service members the availability of any protocol specific telephone "hot-lines" and e-mail addresses available for additional questions.
    - Services will "market" the use of the investigational product well in advance (to the extent possible) to combat the challenges of negative perceptions and potential negative information programs from organizations traditionally opposed to use of INDs (e.g., Citizen-Soldier).
    - Services should develop systems to educate early and often. Start with general information regarding use of INDs in military operations as part of normal health care briefings. Provide more specific information on annual basis as part of regularly scheduled threat or NBC briefings. Information to be updated as required based on threat or new knowledge about IND products.

- Education of health care providers
    - Institute training in Good Clinical Practices (GCP) that will be developed for specific military contingency IND protocols
    - Provide GCP training through variety of sources, e.g., web-based, CD-ROM, training institutions, incorporated into USAMRICD and USAMRIID satellite courses, and as part of organizational training.
    - Document GCP training in credentialing files.
    - Allow a protocol specific SMART team to assist in implementation and execution of protocol if military mission allows sufficient time and prioritization in TPFDL for insertion. Include quality assurance (QA) component as part of SMART team.

- Documentation of informed consent
    - Provide informed consent as part of pre-deployment health assessment when possible.
    - A signed copy of the consent form must be given back to the service member, a copy is also to be included in the service member health records and the original

is to be forwarded back to the U.S. Army Medical Research and Materiel Command for inclusion in the study records. Specific details regarding routing of informed consent forms are described in each protocol.

- Forward deployed forces should be provided informed consent on regular basis for threats in the AOR.
- For service members that refuse informed consent at time of pre-deployment or health assessment, provide opportunity for them to change mind when faced with threat.
- Informed consent to be obtained by a GCP-trained health care provider (physicians, physician assistants, nurses, pharmacists, and licensed practical nurses should be trained in GCP to facilitate this process).
- When the use of an investigational product is to be voluntary, the availability of an ombudsman to ensure voluntary consent should be considered. Unit chaplains are well suited to fulfill this role.
- When the use of the investigational product is voluntary, services should not differentiate service members who refuse consent when assigning missions.

- Documentation of participation, control, and accountability -- For self-administered products, e.g., pyridostigmine bromide (PB).

  - Current solutions

    - Differences among service components with regard to issuing PB – some units issue through medical channels and others issue through NBC channels; therefore, follow service specific procedures.
    - Use paper system for recording participation until automated systems are available for deployed forces – Use unit rosters to document that service members were provided the product at any of the following points:
    - Point of issue – can be issued at NBC Room as forward deployed unit or at theater in-processing for deploying units or individuals
    - For medical channel controlled – document via medical/corpsman/or medical treatment facility
    - Use SF600 for initial recording, transfer information to existing automated system at later date if not readily available. Use overprinted SF600 with stamp of data fields to be collected to document participation. File the SF600 in the medical record upon return to home station.
    - Record how many tablets are returned at end of operation and record the difference between amount issued and returned as the amount taken.

  - Future solutions. As the use of medical information technologies mature, many manual tasks may be automated to include the use of bar-coded packages of investigational products to record distribution, receipt and administration of investigational products.

- Documentation of Administration -- For Medic-Administered Products, e.g., anthrax vaccine, absorbed (AVA)
  - Current solutions – Use existing service data systems (MedPROS, SAMS, MITS) to record administration of AVA. This solution may be complicated due to the availability and functionality of data terminals as well as the ability to enter data in a timely manner.
  - Future solutions – Next generation medical information systems may be employed as fielded (e.g., Joint Services Automated System in combination with the Personal Information Carrier).
- Other considerations for recording participation – Participation lists may be classified. Hold list until end of operation; grant access to lists based on security clearance. Organizations maintaining classified lists will need to maintain system to allow for long-term follow-up consistent with other protocol requirements.
- Collecting adverse event information
  - Per instructions in specific protocol, use existing FDA forms such as VAERS and MEDWATCH to collect information on investigational vaccines and drugs. Protocols to reflect routing of adverse event forms to Service PI. Each service to identify methods to record adverse events in medical records.
- Long-term follow-up
  - Use existing requirements for health status assessment as identified in DoD Directives for collecting information on long-term health effects.
  - USAMRMC to collect protocol specific information after completion of military operations using subjective response forms identified in protocol. Services will provide resources necessary to allow collection of follow-up information (e.g., updated address rosters for location purposes).
- Designating PI
  - CINC surgeon coordinates identification of PIs. Identify PI overall in charge per JTF. Identify PI for each service component based on size and scope of operation. Physicians at lower levels of care are classified as sub-investigators (not required to sign FDA Form 1572).
- Quality Assurance
  - To the maximum extent that operational plans allow, services need to consider the presence of QA personnel in each phase of protocol execution.
    - QA personnel can identify problems in execution and correct deficiencies early.
    - QA presence at education and informed consent process to ensure appropriate provision and documentation of education and consent.

    - QA presence during execution to ensure appropriate documentation.
    - QA presence during follow-up phases to audit documentation and follow-up on missing data.
- QA plans should include self-assessment based on forms provided and use of existing QC personnel assigned to MTFs in event that QA personnel are not deployed early enough due to competing TPFDL requirements.
- Plan to insert QA personnel with SMART teams. QA is force-multiplier for protocol execution and should be early in TPFDL.

Figure 1. Criteria for Requesting Authority to Use INDs.

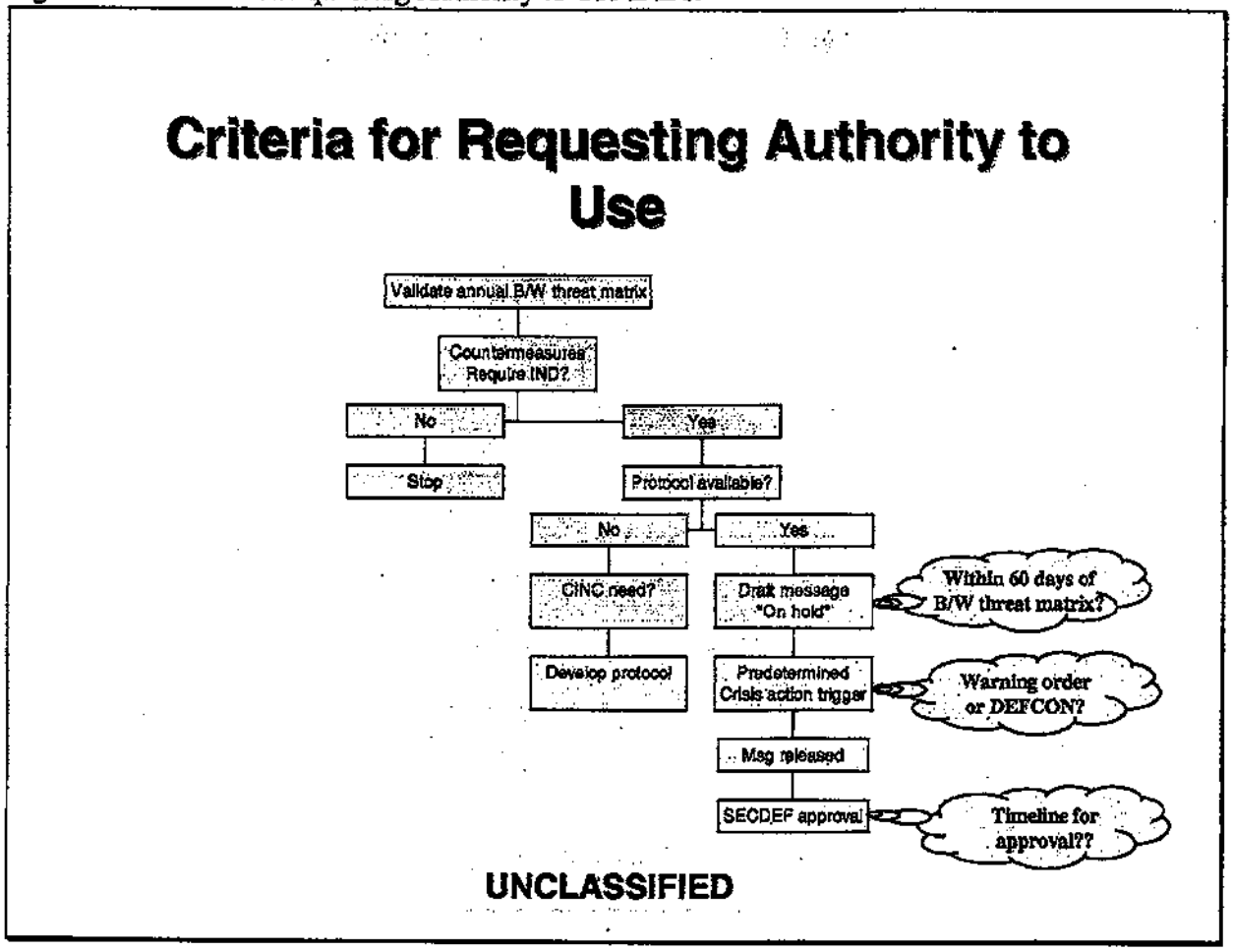


Figure 2. Approval Process for Use of INDs.

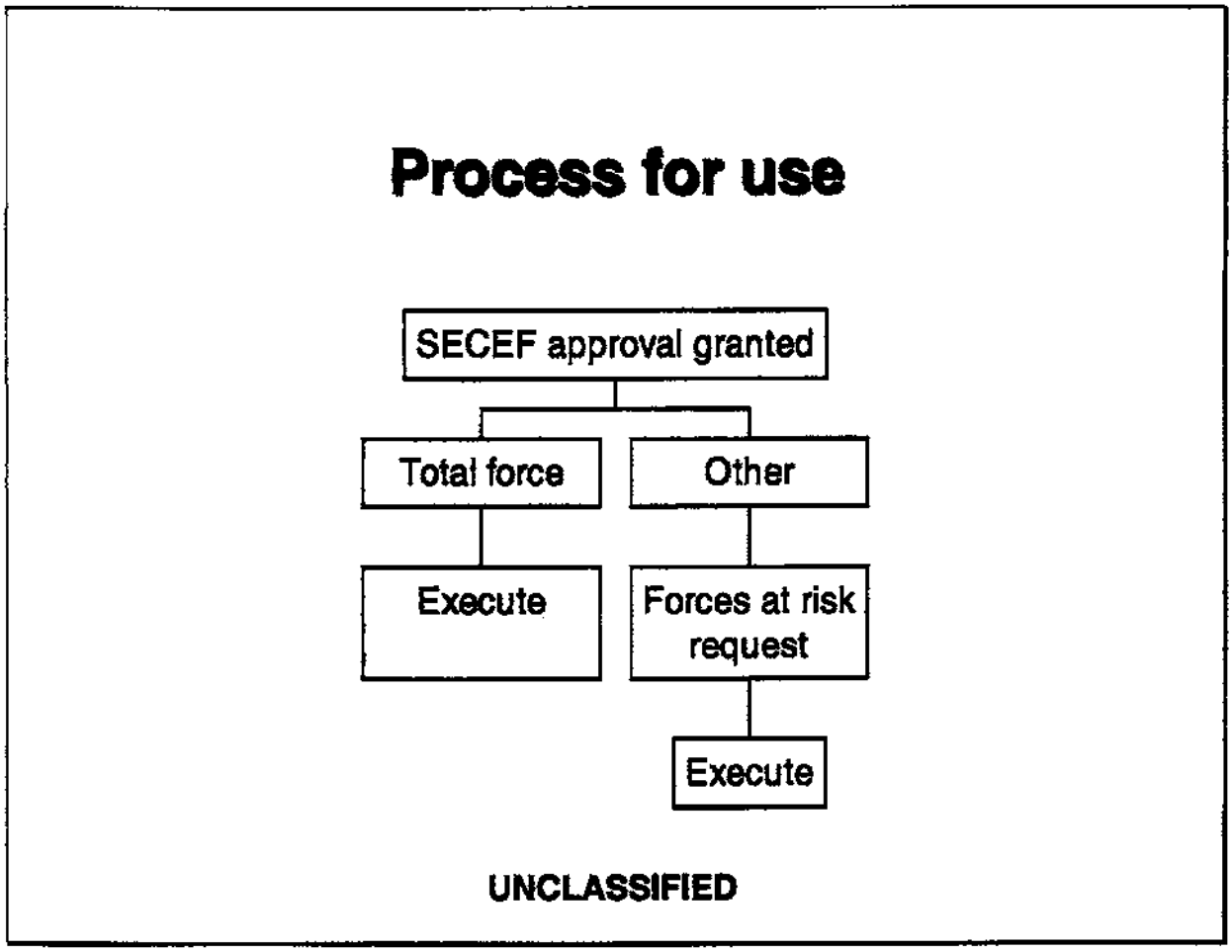
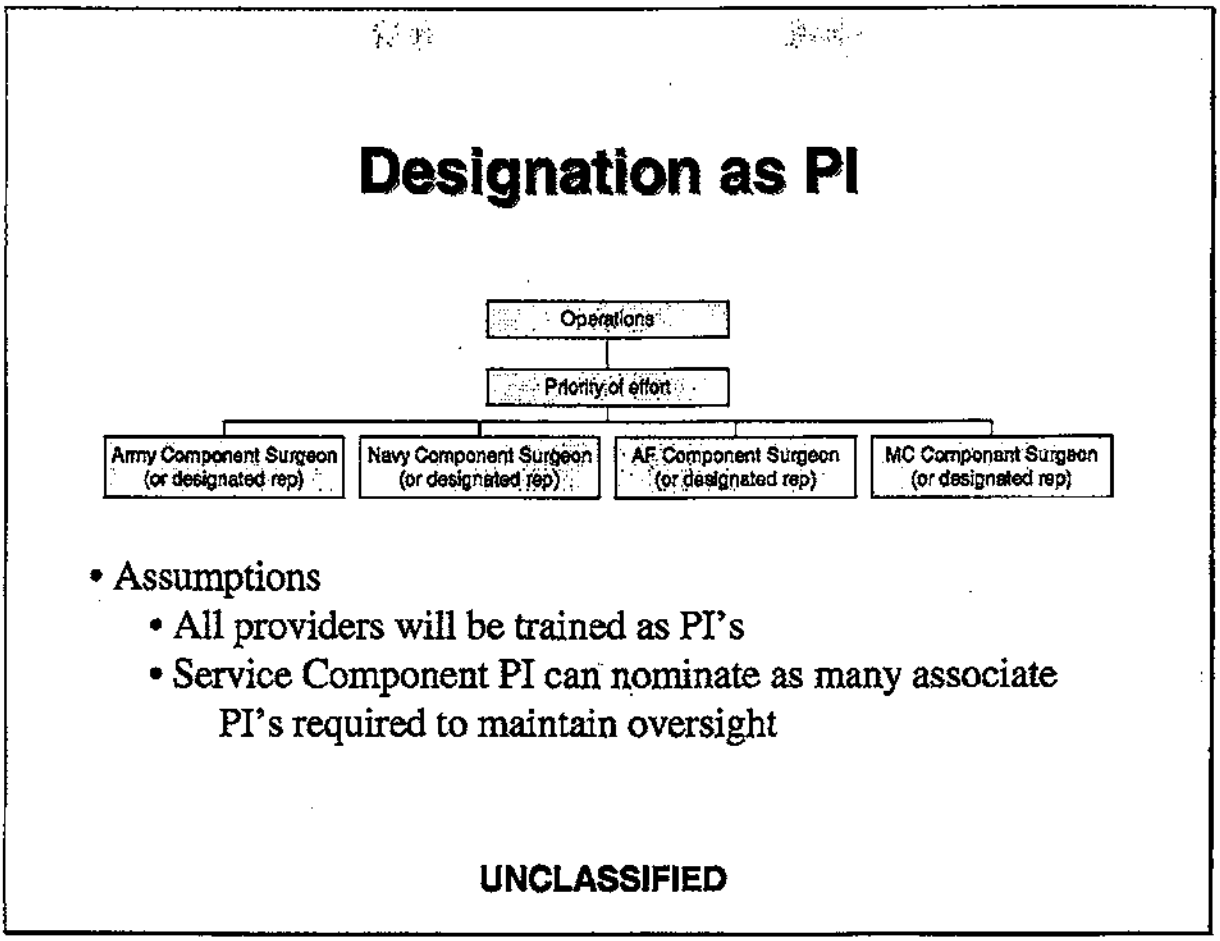


Figure 3. Identification of Principal Investigator.



(b)(6)
07/23/2001 09:07 AM

To: (b)(6) @OSAGWI
cc: (b)(6)

Subject: anthrax vaccine protodol
Document is set for Permanent Archival

(b)(6)

Attached below are the comments provided by (b)(6), which I have forwarded to the AVIP office. One set pertains to an earlier version that (b)(6) provided in March and the other attachment contains his most recent comments. In addition to these comments, I attended the videoteleconference on Friday at which I orally reinforced the written comments and discussed some other items of interest to the participants. The VTC included the AVIP office, MRMC (LTC (b)(6)), and ASA (M&RA). This action is now closed, although we may see a revised protocol later.

FO'D

---------- (b)(6) on 07/23/2001 09:00 AM ----------

From: (b)(6) on 07/19/2001 04:49 PM
To: (b)(6) @OSAGWI
cc:

Subject: anthrax vaccine protodol

Frank: My quick comments on the newer draft attached. Also the old comments on the earlier one (b)(6

more comments on anthrax post-exp pro comments on anthrax post-exp proto

(b)(6)
Office of the Special Assistant to the Under Secretary of Defense
(Personnel and Readiness) for Gulf War Illnesses,
Medical Readiness and Military Deployments

Francis L. O'Donnell, COL, MC
Director, Medical Readiness
Office of the Special Assistant to the Under Secretary of Defense
(Personnel and Readiness) for Gulf War Illnesses,
Medical Readiness and Military Deployments
(b)(6)

Requested comment on **Contingency Protocol for Vaccination of Volunteers with Anthrax Vaccine Adsorbed (AVA) to Protect against *Bacillus anthracis* Spores,** 5/15/01 draft, received July 19, 2001.

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- Record keeping. (See also my earlier comments.) There may be weaknesses in the reliance on automated recordkeeping for vaccine administered under these circumstances. To the best of my knowledge, the services automated recordkeeping systems are not all up to this task. Even if they could (amidst the anticipated chaos) capture the active duty personnel this way, could you rely on these systems for the reserve personnel? And how about the civilians? The services paper record systems, both individual records and rosters, proved inadequate during the Gulf War for a variety of reasons. One suggestion for a more suitable "back-up" is to create a *simple* roster template (only spaces for the information you *must* have) that can be distributed to the points of administration, completed, and collected, with the data transferred to your electronic database at another time. Sorry to be so simplistic, but I have yet to find a Gulf War immunization roster with the essential information, and documentation of administration is, after all, the starting point for this study. Finally, you may also need to detail the collection and forwarding system, since recording the event is only one part of the problem.
- Informed consent. (See also my earlier comments.) This proposal still mentions only voluntary use accompanied by informed consent. If it is clear that a request for waiver of informed consent will not be requested under these conditions, I would delete mention of it under *Responsibilities of the Secretary of Defense* (p. 25, par. #2). (There might be some degradation of the military operation if there were failures to volunteer. On the other hand, there would probably not be any shortage of volunteers under the circumstances of a confirmed exposure.) If there is a chance that a waiver may be requested, the entire protocol would have to better reflect this possibility.
- Age inclusion and exclusion. Have you considered adding the young and old to the *Exclusion Criteria* (p. 29, par. 5.2), then adding an option for them to take the vaccine as you did with pregnant women? After all, it may be difficult to deny the ambassador, or perhaps the young military or civilian dependents under these circumstances.
- Purpose. From conversations with (b)(I understand there are problems in stating what would seem to be the real usefulness of the study, i.e., the effects of post-exposure vaccination on the reduction/prevention of anthrax disease. (There are already far easier and more controllable ways to expand the information on acute adverse effects.) But do you have to consider the occurrence of anthrax disease as an *adverse event* (p. 34, par. 7.0)? Like studying an investigational meningococcal vaccine in the midst of an epidemic and saying you are just looking for adverse reactions?
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(b)(6)
Medical Issues
July 19, 2001

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Comments from OSAGWI experience:

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General Comments: (The authors may already have these comments from other reviewers.)

- The purpose of the study is confusing to me. For whatever reason, there seems to be a preoccupation with the study of short-term adverse events from the vaccine and less interest in the study of the post-exposure vaccination on the reduction/prevention of anthrax disease. The investigators indicate that the protocol is strictly to provide treatment, that the study data is not intended to support a labeling change, that the efficacy of anthrax vaccine for early treatment of exposure is not an endpoint of the study, and that the occurrence of any cases of anthrax disease will be evaluated as an adverse event (?). The distinction between treatment and research is an old and not very productive argument, unless this protocol can be classified under a Treatment IND. To me there is valuable information to be gained on the effectiveness of anthrax vaccine given in addition to antibiotic in preventing disease following anthrax inhalational exposure. Even if animal investigation and surrogate markers will allow approval for use in these indications, we should not pass up the opportunity to accomplish careful research in humans under conditions not otherwise possible.
- Presumably this will be use of an approved product for an unapproved indication, and so would require IND status for this approved product. It seems this will be further complicated by the intention to use existing lots of vaccine that have not been released by the FDA, at least until there are sufficient stocks of released vaccine. The reasons why the vaccine lots have not been released may be of importance for both the safety of the subjects and the validity of the study results (E.g., if these preparations are more or less immunogenic or reactogenic, study results may be more difficult to interpret.)

- Th investigators may want to ensure that the methods of observing and recording adverse reactions/events are similar to those of earlier and ongoing studies, so that the information can be validly compared. There seems to be no provision for long term follow-up of the subjects. This might be an opportunity to study both short and long term adverse reactions/events in a group of subjects who will be in stress at the time of vaccination, and perhaps (and this is a long shot) shed some additional light on the hypothesis and limited research about the potential additive health effects of stress and immunizations. If we are just talking acute effects of the vaccine, there are already far easier and more controllable ways to expand this information.

(b)(6)

Medical Issues
March 29, 2001, revised (for typos only) April 2, 2001

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(b)(6)

Medical Issues
July 19, 2001

- Specify OMSS-based f/u at 3000 recipients.
- Monitoring: OMSS would work for death hosp. Toleration. For rare events, would not suffice. N/3 is detectable.
- Survey will screen for non-serious events.
- Long term follow-up? Use OMSS
- Sent to MVNCB?

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- Informed Consent. There was confusion during the Gulf War about whether investigational products were mandatory or voluntary, and a negative impact from that confusion. This proposal mentions only voluntary use accompanied by informed consent. It is not clear whether a request for waiver of informed consent is anticipated. If a waiver is anticipated, or may be requested at the time of use, this should be stated in the protocol. In this case, the research proposal should include an *information sheet* rather than a *consent form* (perhaps both if there is uncertainty about the requirement for informed consent), and some preconditioning risk communication. If the vaccine is only to be given on a voluntary basis, there might be concerns about degradation of the military operation by vaccine refusals, one reason for creating a mechanism for the waiver of informed consent during the Gulf War deployment. All of this, of course, applies only to military personnel; the inclusion of other than military subjects would further complicate this issue. Finally, it is questionable whether one could truly satisfy the elements of informed consent under the anticipated chaotic scene of a confirmed exposure, although this might be lessened in some study subjects by earlier risk communication. Fear alone would probably drive most subjects to the vaccine.

General Comments: (The authors may already have these comments from other reviewers.)

- The purpose of the study is confusing to me. For whatever reason, there seems to be a preoccupation with the study of short-term adverse events from the vaccine and less interest in the study of the post-exposure vaccination on the reduction/prevention of anthrax disease. The investigators indicate that the protocol is strictly to provide treatment, that the study data is not intended to support a labeling change, that the efficacy of anthrax vaccine for early treatment of exposure is not an endpoint of the study, and that the occurrence of any cases of anthrax disease will be evaluated as an adverse event (?). The distinction between treatment and research is an old and not very productive argument, unless this protocol can be classified under a Treatment IND. To me there is valuable information to be gained on the effectiveness of anthrax vaccine given in addition to antibiotic in preventing disease following anthrax inhalational exposure. Even if animal investigation and surrogate markers will allow approval for use in these indications, we should not pass up the opportunity to accomplish careful research in humans under conditions not otherwise possible.
- Presumably, this will be use of an approved product for an unapproved indication, and so would require IND status for this approved product. It seems this will be further complicated by the intention to use existing lots of vaccine that have not been released by the FDA, at least until there are sufficient stocks of released vaccine. The reasons why the vaccine lots have not been released may be of importance for both the safety of the subjects and the validity of the study results (E.g., if these preparations are more or less immunogenic or reactogenic, study results may be more difficult to interpret.)

- Th investigators may want to ensure that the methods of observing and recording adverse reactions/events are similar to those of earlier and ongoing studies, so that the information can be validly compared. There seems to be no provision for long term follow-up of the subjects. This might be an opportunity to study both short and long term adverse reactions/events in a group of subjects who will be in stress at the time of vaccination, and perhaps (and this is a long shot) shed some additional light on the hypothesis and limited research about the potential additive health effects of stress and immunizations. If we are just talking acute effects of the vaccine, there are already far easier and more controllable ways to expand this information.

(b)(6)

Medical Issues
March 29, 2001, revised (for typos only) April 2, 2001

46025

THE JOINT STAFF
WASHINGTON, DC

Reply ZIP Code
20318-0300

DJSM-0109-03
06 February 2003

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

Subject. Exception to Policy for Priority II Anthrax Vaccinations for Selected AMC Personnel

1. Recommend approval of AMC's request (Enclosure A) that selected personnel be approved for anthrax immunizations as an exception to policy.

2 Personnel to be vaccinated under the exception would include strategic airlift crews, Ravens (security forces that travel with the aircraft and protect crews while on the ground at foreign airfields) and tactical airlift control elements (TALCEs) -- an estimated 4,250 personnel, including Active and Reserve Component personnel.

3 Service members are expected to deploy to designated higher-threat areas (HTAs) for more than 15 cumulative days in a 12-month period and are at heightened risk of anthrax exposure This request is supported by USCENTCOM, USEUCOM and USTRANSCOM

4. The Army, as the executive agent for the DOD Immunization Program for Biological Warfare Defense, concurred with critical comment (Enclosure B) Although vaccination of personnel who are in an HTA for cumulative deployments of greater than 15 days in a 12-month period was supported, the Army indicated that vaccinations should begin on an individual basis when the individual is first notified of a deployment or deploys into one of the HTAs for the first time

5 While this approach may be feasible for some Active Component personnel, significant advance planning is required to administer vaccinations to Reserve Component personnel Combined with the relatively short notice inherent in many airlift missions, it seems prudent to give the AMC commander discretion to vaccinate these personnel prior to actual notice of a deployment if it is deemed that they have a high probability of being deployed to an HTA. Furthermore, many of these personnel are expected to require smallpox immunizations under the current smallpox vaccination policy, and it will be much simpler logistically to administer both vaccinations at the same time.

6 TALCE personnel are subject to deployment at less than 12 hours notice to austere fields where medical logistic support to conduct vaccinations is often lacking. Therefore, immediate vaccination of those who are deemed to have a high probability of deploying to an HTA should be authorized.

7 Other Active personnel who have deployed to one of the designated HTAs within the past 12 months should also be authorized for immediate vaccination All other personnel should begin vaccinations as soon as they are designated for deployment to an HTA

8. The Joint Staff points of contact for this issue are (b)(6) (b)(6) (b)(6), (b)(6)

JAMES A. HAWKINS
Major General, USAF
Vice Director, Joint Staff

Enclosures

Copy to
HQ USAF, Attn Deputy Chief of Staff for Air and Space Operations

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

AFODM 001-03
16 Jan 03

MEMORANDUM FOR DIRECTOR, JOINT STAFF

SUBJECT Exception to Policy for Priority II Anthrax Vaccinations for Selected AMC Personnel

Request Joint Staff action on the attached Exception to Policy (ETP) request from AMC/SG (Attachment 1) Current DoD policy for requesting ETP for Priority II anthrax vaccinations requires recommendation from Combatant Commander, with final approval from ASD/HA in consultation with the Chairman, Joint Chiefs of Staff (USD/P&R Memo, 6 Aug 02) (Attachment 2)

Current DoD policy for Priority II anthrax vaccination requires personnel to be assigned or deployed to a higher threat area (HTA) greater than 15 consecutive days AMC strategic airlift aircrews, Ravens and Tactical Airlift Control Elements (TALCEs) are not usually in a HTA greater than 15 *consecutive* days, and therefore, are not authorized to receive anthrax vaccine under Priority Group II However, since many of the designated AMC personnel are in a HTA greater than 15 *cumulative* days, their risk for possible anthrax exposure is increased Therefore, request an ETP for AMC strategic airlift aircrews, Ravens and TALCEs (an estimated 4,250 personnel, including AD and ARC personnel) to receive anthrax vaccine now

Air Staff POCs on this issue are Brig Gen Robert Smolen, HQ USAF/XON (DSN (b)(6) , e-mail: (b)(6) @pentagon af mil) and Col Deneice Van Hook, HQ USAF/SGZP (DSN (b)(6) 5, e-mail (b)(6) @pentagon af mil)

Attachments
1 AMC Request for ETP w/ Bulleted Point Paper
2 6 Aug 02 USD/P&R Memo

RONALD E. KEYS, Lt Gen, USAF
Deputy Chief of Staff
Air & Space Operations

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS AIR MOBILITY COMMAND

29 OCT 2002

MEMORANDUM FOR HQ AFMOA/SG

FROM HQ AMC/SG
203 West Losey Street, Suite 1600
Scott AFB IL 62225-5219

SUBJECT Request for Strategic Airlift Mission Exception to Policy Anthrax Vaccine Implementation Plan (AVIP)

1 Strategic air mobility assets routinely transit geographic areas identified as higher threat areas (HTAs) for anthrax, but are not included in the Air Force AVIP plan Due to their unique missions, AMC/SG requests an Exception to Policy, in accordance with Annex B of the Air Force AVIP 2002 Implementation Plan AMC has identified three specific missions for ETPs Tactical Airlift Control Elements (TALCEs), Strategic Airlift Aircrew Members, and Ravens

2 TALCFs, including their associated Global Reach Liaison (GRL) teams, are subject to rapid deployment (less than 12 hours notice) to austere fields in HTAs on average for 45 days TALCEs lack adequate pre-deployment time to provide an initial anthrax vaccination series (i e shots 1, 2 and 3) Additionally, they often lack the medical logistics support necessary to vaccinate in the field due to their far forward laydown Because of their mission criticality and logistical circumstances, TALCEs should be identified as Priority Two personnel

3 Due to the nature of strategic airlift, aircrew members assigned to this mission are unlikely to remain in place for 15 days or longer, but can be reasonably expected to exceed 15 cumulative days in a 12-month period IAW with instructions in Annex B of the Air Force AVIP 2002 plan, request that AMC and AMC gained C-5, C-17 C-141, and special airlift mission (C-32, C-37, C-40) crewmembers be granted an ETP to initiate immediate anthrax vaccination In addition, ETP to vaccinate Security Forces Ravens is also requested Ravens are specially trained security forces that travel with these aircraft and protect them while on the ground at foreign airfields These flyers and security forces should be identified as Priority Two personnel

4 The Command Surgeon, Headquarters Air Mobility Command, estimates the total number of affected personnel as 4,250 Please refer to the attached point paper for further details Should your staff have any questions, my POC is Lt Col (b)(6) DSN (b)(6) or (b)(6) @scott.af.mil

CHARLES B. GREEN
Brigadier General, USAF, MC, CFS
Command Surgeon

Attachment:
AVIP ETP Point Paper

POINT PAPER

ON

ANTHRAX VACCINE FOR STRATEGIC AIRLIFTERS

- The Air Force AVIP 2002 Implementation Plan directs anthrax vaccination for personnel assigned 15 consecutive days or longer to Higher Threat Areas (HTAs)
  - AVIP Plan specifically identifies vaccination policy for special missions and those assigned to HTAs and deployed as part of AEF buckets
  - AVIP Plan does not address those military personnel frequently transiting HTAs but not residing for ≥ 15 consecutive days – a frequent occurrence for strategic airlifters
  - AVIP Plan Annex B allows MAJCOM to submit Exception to Policy (ETP)
    - Plan specifically suggests strategic airlift personnel be considered for ETP when personnel can be expected to accumulate 15 days in a 12-month period
- C-5, C-17, C-141 and special airlift mission crewmembers routinely fly into the HTAs and are expected to exceed 15 days in a 12-month period It would be appropriate to vaccinate them based on their frequent exposure/rotation through these HTA
- Ravens, security forces accompanying these aircraft, provide aircraft security at off-station airfields, are also expected to exceed 15 days cumulative days in HTAs, and require similar anthrax vaccine protection
- Tactical Airlift Control Elements (TALCEs) and Global Reach Laydown teams provide initial aerial port, aircraft maintenance, and C2 for strategic airlift at far forward bases
  - Demanding mission has 12-hour deployment notice for 45-day missions
  - Do not have robust medical support, including routine access to vaccinations
  - They are AEF enablers, not tied to an AEF bucket, subject to deployment at any time
- Based on AMC functional inputs, AMC/SG estimates total AMC and AMC-gained personnel included in these proposals to be 4,250
  - Aircrew (1,000 Active Duty/ 2,350 Air Reserve Component), Ravens (250/220), TALCEs (430 all AD)
- Recommendation. Identify Strategic Airlift Aircrew, Ravens, and TALCEs as AVIP priority two personnel for immediate vaccination to adequately protect them prior to deployment

Lt Col (b)(6) AMC/SGPA/DSN (b)(6) @scott af mil/dob/18 Oct 02

HEADQUARTERS DEPARTMENT OF THE ARMY
ASSISTANT DEPUTY TO THE ARMY OPERATIONS DEPUTY
(JOINT AFFAIRS)
OFFICE OF JOINT AND DEFENSE AFFAIRS

03 FEB 2003

ARMY PLANNER DACS-ZD-JDA
Memorandum Number 085-03

MEMORANDUM FOR SECRETARY, JOINT STAFF, ATTN: J-4 (Health Service Support Division), LTC (b)(6)

SUBJECT: Exception to Policy for Anthrax Vaccination for Selected AMC Personnel. (SJS 03-00355)

1. Concur only subject to the following critical comment

2. Critical comment We agree that certain personnel of the USAF Air Mobility Command (AMC) may be at increased risk of *Bacillus anthracis* exposure based on cumulative deployments of greater than 15 days in a twelve-month period; however, anthrax vaccinations should not begin to the entire force of 4,250 personnel immediately on approval of this request. Vaccinations should only begin on an individual basis, when that individual is first notified of deployment or deploys into one of the CJCS-designated High Threat Areas (HTA) for the first time Any deviation from this concept will result in a non-concurrence.

Rationale: The alert status of AMC's subject personnel does not justify immediate vaccination Their alert status is no different than other Services' alert forces (e.g., Division Ready Brigades within Army Divisions), which are not being vaccinated. Rather, on notice of actual deployment these forces begin vaccinating if they fall within the other parameters of the DoD Anthrax Vaccine Immunization Program policy.

Further, current DoD contingency AVA requirements, coupled with competing AVA requests from both U S Federal Agencies and foreign nations, constrain DoD's anthrax vaccine supplies until May 03

3 POC is COL Randy Randolph or MAJ (b)(6), at (b)(6)

RANDY C WRIGHT
Colonel, GS
Deputy to the ADCSOPS (JA)

OPTIONAL FORM 99 (7-90)
FAX TRANSMITTAL # of pages ▶
(b)(6)
(b)(6)
Phone # (b)(6)
Fax #

SUBJECT: Exception to Policy for Priority-2 Anthrax Vaccinations for Selected Air Force Air Mobility Command (AMC) Personnel.

COORDINATION

		Non-concur	Concur
Director MILVAX-AVIP Agency	COL Randolph	_____	_____
DATSD(CBD)	Dr. Anna Johnson-Winegar	_____	_____
DUSD (TSP&CP)	Lisa Bronson	_____	_____

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

February 27, 2003, 4:00 P.M.

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: Request for Coordination on Exception to Policy for Priority-2 Anthrax Vaccinations for Selected Air Force Air Mobility Command (AMC) Personnel.

- The Director, Joint Staff endorsed a recommendation by the Air Force to vaccinate selected AMC personnel against anthrax as an exception to policy (TAB B).
- This request includes 4,250 personnel, including strategic airlift crews, Ravens (security forces that protect aircraft and aircrews while transiting foreign airfields), and tactical airlift control elements (TALCEs).
- MILVAX is concerned that all personnel will be immediately vaccinated.

RECOMMENDATION: Sign memorandum requesting coordination at TAB A.

COORDINATION: TAB C.

ATTACHMENTS:
As stated

Prepared by: CDR (b)(6), DHSD/ODASD(FHP&R), (b)(6) PCTOTS# 46025, 46421
46421.

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR DEPUTY UNDER SECRETARY OF DEFENSE (TSP&CP)
DEPUTY TO THE ASSISTANT SECRETARY OF DEFENSE (CBD)

SUBJECT: Exception to Policy for Priority-2 Anthrax Vaccinations for Selected Air Force Air Mobility Command (AMC) Personnel.

Request coordination no later than COB Friday, February 28, on the attached draft action memo and exception to policy memorandum for selected AMC personnel.

The draft memorandum grants an exception to policy for priority-2 anthrax vaccinations that was requested by the Air Force and endorsed by the Joint Staff for selected Air Mobility Command personnel. These selected mission personnel may be in high risk threat areas for a 15-day cumulative or greater time frame.

If you have any questions regarding this matter, please contact CDR (b)(6) at (b)(6) Please fax your coordination to (b)(6).

William Winkenwerder Jr., MD

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR DIRECTOR, THE JOINT STAFF
COMMANDER, AIR MOBILITY COMMAND

SUBJECT: Exception to Policy for Priority-2 Anthrax Vaccinations for Selected Air Force Air Mobility Command (AMC) Personnel.

REFERENCE: Under Secretary of Defense (Personnel and Readiness) memorandum, "Policy on Administrative Issues Related to the Anthrax Vaccine Immunization Program (AVIP)," August 6, 2002.

In accordance with the above reference, an exception to policy is approved for Tactical Airlift Control Elements (TALCEs), Strategic Airlift Aircrew Members, and Security Forces Ravens. Begin vaccinating strategic airlift crews now, and Raven security and Tactical Airlift Control Element personnel when they receive their first order to a designated high threat area.

Execution of this vaccination program is per previously published clinical and administrative guidelines and consistent with existing Service implementation plans. The Secretary of the Army remains the Executive Agent for the Anthrax Vaccine Immunization Program (AVIP). Questions regarding this matter shall be directed to COL Gaston Randolph, Director of the MILVAX-AVIP agency a(b)(6).

William Winkenwerder Jr. MD

(253)

HA/TMA Document Profile

CMAT Control #
2003050-0000014

46025

Subject:	Exception to Policy for Priority II Anthrax Vaccinations for Selected AMC Personnel
Author:	Hawkins, James A. Maj Gen
Date of Document:	2/6/2003
OSD # :	
PR # :	
Organization:	The Joint Staff
Department:	
Assigned To:	DHS
Prepared For:	ASD
Suspense Date:	3/5/2003
Coord Office(s):	
Congressional Name:	
Input By:	(b)(6)
Profiler's Directorate:	Admin, HA
Response Signed By:	
Dt Response Signed:	
Doc Type:	MEMO
Application:	DOCSIMAGE
Previous Documents:	
Related Documents:	
Notes:	

Beneficiary Info

Beneficiary Name:	
Address 1:	
Apartment #	
Phone #	
Email Address:	
City:	
State:	**Zip**

History

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Status: Available

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46714, 46715

46025

THE JOINT STAFF
WASHINGTON, DC

Reply ZIP Code
20318-0300

DJSM-0109-03
06 February 2003

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

Subject. Exception to Policy for Priority II Anthrax Vaccinations for Selected AMC Personnel

1. Recommend approval of AMC's request (Enclosure A) that selected personnel be approved for anthrax immunizations as an exception to policy.

2 Personnel to be vaccinated under the exception would include strategic airlift crews, Ravens (security forces that travel with the aircraft and protect crews while on the ground at foreign airfields) and tactical airlift control elements (TALCEs) -- an estimated 4,250 personnel, including Active and Reserve Component personnel.

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4. The Army, as the executive agent for the DOD Immunization Program for Biological Warfare Defense, concurred with critical comment (Enclosure B) Although vaccination of personnel who are in an HTA for cumulative deployments of greater than 15 days in a 12-month period was supported, the Army indicated that vaccinations should begin on an individual basis when the individual is first notified of a deployment or deploys into one of the HTAs for the first time

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7 Other Active personnel who have deployed to one of the designated HTAs within the past 12 months should also be authorized for immediate vaccination All other personnel should begin vaccinations as soon as they are designated for deployment to an HTA

8. The Joint Staff points of contact for this issue are (b)(6)
(b)(6)

JAMES A. HAWKINS
Major General, USAF
Vice Director, Joint Staff

Enclosures

Copy to
HQ USAF, Attn Deputy Chief of Staff for Air and Space Operations

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

AFODM 001-03
16 Jan 03

MEMORANDUM FOR DIRECTOR, JOINT STAFF

SUBJECT Exception to Policy for Priority II Anthrax Vaccinations for Selected AMC Personnel

Request Joint Staff action on the attached Exception to Policy (ETP) request from AMC/SG (Attachment 1) Current DoD policy for requesting ETP for Priority II anthrax vaccinations requires recommendation from Combatant Commander, with final approval from ASD/HA in consultation with the Chairman, Joint Chiefs of Staff (USD/P&R Memo, 6 Aug 02) (Attachment 2)

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Air Staff POCs on this issue are Brig Gen Robert Smolen, HQ USAF/XON (DSN 225-5833, e-mail: (b)(6) @pentagon af mil) and Col Deneice Van Hook, HQ USAF/SGZP (DSN (b)(6) e-mail (b)(6) @pentagon af mil)

Attachments
1 AMC Request for ETP w/ Bulleted Point Paper
2 6 Aug 02 USD/P&R Memo

RONALD E. KEYS, Lt Gen, USAF
Deputy Chief of Staff
Air & Space Operations

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS AIR MOBILITY COMMAND

29 OCT 2002

MEMORANDUM FOR HQ AFMOA/SG

FROM HQ AMC/SG
203 West Losey Street, Suite 1600
Scott AFB IL 62225-5219

SUBJECT Request for Strategic Airlift Mission Exception to Policy Anthrax Vaccine Implementation Plan (AVIP)

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CHARLES B. GREEN
Brigadier General, USAF, MC, CFS
Command Surgeon

Attachment:
AVIP ETP Point Paper

POINT PAPER

ON

ANTHRAX VACCINE FOR STRATEGIC AIRLIFTERS

- The Air Force AVIP 2002 Implementation Plan directs anthrax vaccination for personnel assigned 15 consecutive days or longer to Higher Threat Areas (HTAs)
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  - Aircrew (1,000 Active Duty/ 2,350 Air Reserve Component), Ravens (250/220), TALCEs (430 all AD)
- Recommendation. Identify Strategic Airlift Aircrew, Ravens, and TALCEs as AVIP priority two personnel for immediate vaccination to adequately protect them prior to deployment

Lt Col (b)(6) /AMC/SGPA/DSN (b)(6) @scott af mil/dob/18 Oct 02

HEADQUARTERS DEPARTMENT OF THE ARMY
ASSISTANT DEPUTY TO THE ARMY OPERATIONS DEPUTY
(JOINT AFFAIRS)
OFFICE OF JOINT AND DEFENSE AFFAIRS

03 FEB 2003

ARMY PLANNER DACS-ZD-JDA
Memorandum Number 085-03

MEMORANDUM FOR SECRETARY, JOINT STAFF, ATTN: J-4 (Health Service Support Division), LTC Jones

SUBJECT: Exception to Policy for Anthrax Vaccination for Selected AMC Personnel, (SJS 03-00355)

1. Concur only subject to the following critical comment

2. Critical comment We agree that certain personnel of the USAF Air Mobility Command (AMC) may be at increased risk of *Bacillus anthracis* exposure based on cumulative deployments of greater than 15 days in a twelve-month period; however, anthrax vaccinations should not begin to the entire force of 4,250 personnel immediately on approval of this request. Vaccinations should only begin on an individual basis, when that individual is first notified of deployment or deploys into one of the CJCS-designated High Threat Areas (HTA) for the first time Any deviation from this concept will result in a non-concurrence.

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3 POC is COL Randy Randolph or MAJ (b)(6), at (b)(6).

RANDY C WRIGHT
Colonel, GS
Deputy to the ADCSOPS (JA)

OPTIONAL FORM 99 (7-90)
FAX TRANSMITTAL # of pages ▶
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Phone # (b)(6)
Fax #

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

MAR 10 2003

MEMORANDUM FOR DIRECTOR, THE JOINT STAFF
COMMANDER, AIR MOBILITY COMMAND

SUBJECT: Request for Exception to Policy for Priority II Anthrax Vaccinations for Selected AMC Personnel

REFERENCE: Under Secretary of Defense (Personnel and Readiness) memorandum, "Policy on Administrative Issues Related to the Anthrax Vaccine Immunization Program (AVIP)," August 6, 2002

In accordance with the above reference, an exception to policy is approved for Tactical Airlift Control Elements (TALCEs), Strategic Airlift Aircrew Members, and Security Forces Ravens to be immediately vaccinated against anthrax.

Execution of this vaccination program is per previously published clinical and administrative guidelines and consistent with existing Service implementation plans. The Secretary of the Army remains the Executive Agent for the Anthrax Vaccine Immunization Program (AVIP). Questions regarding this matter shall be directed to COL Gaston Randolph, Director of the MILVAX-AVIP agency. He can be reached at (b)(6).

William Winkenwerder, Jr., MD

254

HA/TMA Document Profile

CMAT Control # 2003050-0000012

45855

2002331-0000005

Subject: Designation of US Coast Guard's National Strike Force as an Anthrax Vaccination Immunization Progra

Author: (b)(6) Joint Staff

Date of Document: 2/5/2003

OSD # :

PR # :

Organization: The Joint Staff

Department:

Assigned To: DHS

Prepared For: ASD

Suspense Date: 2/20/2003

Coord Office(s):

Congressional Name:

Input By: (b)(6)

Profiler's Directorate: Admin, HA

Response Signed By:

Dt Response Signed:

Doc Type: MEMO

Application: DOCSIMAGE

Previous Documents:

Related Documents:

Notes: Task by Dr. Winkenwerder 1. Prepare Package w/response to DJS and implementing document (if FHP&R Concurs) 2.Coordinate action with MILVAX

Beneficiary Info

Beneficiary Name:

Address 1:

Apartment #

Phone #

Email Address:

City:

State: **Zip**

History

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(b)(6) –

Forward to Ms Embrey's office
FOR AC:
(1) Prepare package w/ response to DJS and implementing document (if Fed Reg, concurs).
(2) Coord action w/ MLCVAX

Dir. W wants turnaround NLT 20 FEB – based on the date of the USCG originating document.

(b)(6)

THE JOINT STAFF
WASHINGTON, DC

Reply ZIP Code:
20318-0300

DJSM-0100-03
05 February 2003

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

Subject: Designation of US Coast Guard's National Strike Force as an Anthrax Vaccination Immunization Program (AVIP) Special Mission Unit

1. The US Coast Guard has requested that the members of its National Strike Force be designated as a Special Mission Unit (Priority 1) under the DOD AVIP (enclosure).

2. The Coast Guard has assigned 213 active duty personnel into three National Strike Teams (NSTs) capable of providing critical response and decontamination support to facilities contaminated with anthrax spores. In the past, this unit has deployed and supported activities such as decontamination of the Hart building in Washington, D.C. The Coast Guard has stated that the NSTs will continue to respond to anthrax contamination in the foreseeable future.

3. This request was coordinated with the Army as the executive agency for the DOD Immunization Program for Biological Warfare Defense.

4. I concur in this request and recommend that the USCG National Strike Force be designated as a special mission unit and that all personnel assigned to this unit receive anthrax immunizations based on that priority.

JAMES A. HAWKINS
Major General, USAF
Vice Director, Joint Staff

Enclosure

Copy to:
Commandant, US Coast Guard

U S Department of Transportation
United States Coast Guard

Commandant
United States Coast Guard

2100 Second Street, S W
Washington, DC 20593-0001
Staff Symbol G-WK
Phone (202) 267-1098
Fax (202) 267-4512
Email

6230

DEC 13 2002

MEMORANDUM

TJ BARRETT
Acting

From THOMAS H COLLINS
COMDT (G-C)

Reply to G-WK
Attn of. RADM Joyce Johnson
(b)(6)

To Department of Defense, Joint Staff, ATTN Joint Staff Surgeon

Subj DESIGNATION OF U.S COAST GUARD'S NATIONAL STRIKE FORCE AS AN AVIP SPECIAL MISSION UNIT

Ref (a) COMDTINST M6230 3A, Coast Guard Anthrax Vaccine Immunization Program (AVIP), page 2
(b) CDC document, Antimicrobial Prophylaxis to Prevent Anthrax Among Decontamination/Cleanup workers Responding to an Intentional Distribution of *Bacillus anthracis*, dtd 22 Oct 01

1 I request that the U S Coast Guard's National Strike Force be designated as an AVIP Special Mission Unit As per reference (a), this will mandate anthrax immunization as a priority 1 unit The U S Coast Guard's National Strike Force includes 213 deployable active duty members divided into three different response teams (National Strike Teams (NSTs)). One mission performed in October-December 2001 was to respond to and perform decontamination efforts in areas known to be contaminated with anthrax Under current mission profiles, the NSTs will respond to anthrax contamination sites for the foreseeable future

2 Reference (b) describes the potential for breaches of protection and the contamination of workers using appropriate personal protection equipment Due to this potential for increased exposure during repeated deployments into contaminated anthrax areas, we request Anthrax vaccine to immunize Strike Team members that are at-risk of exposure due to mission requirements Designation as a Special Mission Unit will allow these at-risk military members to receive licensed anthrax vaccine IAW reference (a), thus ensuring maximum protection for our personnel with the potential to be repeatedly exposed to anthrax contaminated sites.

3 It is our intention to utilize only NST members who have been immunized with the anthrax vaccine as our primary responders to anthrax decontamination sites in the future. Currently, only six Strike Team personnel have begun the anthrax vaccine series Immunizing all Strike Team personnel will ensure that we are ready to respond immediately to any future anthrax contamination site Current projections to start most personnel with three doses of vaccine and bring those previously started in the program up-to-date would require 633 doses

4 My Point of Contact for this matter is RADM Joyce M Johnson at (b)(6)

#

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D C 20301-1200

HEALTH AFFAIRS

MAR 1 8 2003

MEMORANDUM FOR DIRECTOR, THE JOINT STAFF
COMMANDANT OF THE U S COAST GUARD

SUBJECT Designation of U S Coast Guard's National Strike Force for Anthrax Vaccine Immunization Program (AVIP)

REFERENCE: Deputy Secretary of Defense "Reintroduction of the Anthrax Vaccine Immunization Program (AVIP)," June 28, 2002

The referenced memorandum authorizes inclusion in the AVIP of additional personnel at higher risk of exposure to anthrax based on performance of critical capabilities.

The increasing threat of the use of weapons of mass destruction makes it essential that we have a critical response and decontamination capability like the U S Coast Guard's National Strike Force.

Therefore, I approve inclusion of the U.S Coast Guard's National Strike Force, involving approximately 213 active duty members, in current AVIP implementation. Execution of the AVIP for these personnel is under the authority of the Commandant of the Coast Guard.

This determination is effective immediately COL Gaston Randolph, Director of the AVIP-MILVAX Agency is the point of contact for any question on this matter He can be contacted at (b)(6)

William Winkenwerder, Jr.

William Winkenwerder, Jr., MD

cc.
Surgeon General of the Army

2002331-0000005

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OFFICE OF TKE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

December 4, 2002, 11:00 AM

FOR: DEPUTY ASSISTANT SECRETARY OF DEFENSE (FORCE HEALTH PROTECTION & READINESS)

FROM: COL David Adams, Program Director, Strategic Plans and Policy

SUBJECT: Joint Operational Concept for Biological Warfare Defense

- The Joint Staff/J8 is staffing a proposed joint staff policy memo (TAB B) containing an operational concept for biological warfare defense. This appears to be bridge guidance until a formal joint doctrine publication is produced. There are many areas that impact the health service support capabilities of the DoD. While the document presents a good first start, it has some serious shortcomings. TAB A provides our comments on the document.

RECOMMENDATION: FHP&R sign the memo at TAB A to forward our comments to the J8.

COORDINATION: TAB C

ATTACHMENT:
As stated

Prepared by: COL Dan Sulka, DHSD, (b)(6), PCDOCS #43605

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

DEC 0 4 2002

MEMORANDUM FOR JOINT STAFF/J8 (JRO-CBRND)

SUBJECT: Joint Operational Concept for Biological Warfare Defense

Thank you for the opportunity to review the Joint Operational Concept for Biological Warfare Defense document provided in your memorandum dated November 8, 2002. We believe that the document contains the basis for a useful operational concept, but it requires some additional work. The document should not only bridge the guidance shortfall until the publication of a revised Joint Publication 3-1 1, but should also provide the justification and framework for joint tactics, techniques, and procedures on biological warfare defense.

Our specific comments are attached. My point of contact is COL Dan Sulka, Program Director, Operational Health Support, (b)(6)

Ellen P. Embrey
Deputy Assistant Secretary of Defense
Force Health Protection and Readiness

Attachment: As stated

Comments: Joint Operational Concept for Biological Warfare Defense

General

(Critical) There are numerous areas in the main body and in the appendixes where "issues" are raised but not resolved. To be consistent with the stated purpose of the document, any text that raises issues or identifies shortfalls must be re-written to provide policy guidance or a solution.

(Critical) Appendix D contains an exhaustive list of statements of shortfalls or actions that must be accomplished in order for this policy and concept of operations to be successfully applied. These "assumptions," for which the CONOPS will not be executable, must instead be stated in a directive manner with specific responsibility for the enabling task identified. The joint staff can do this for the Combatant Commanders and to a degree the service components. However, OSD and Defense Agencies' responsibilities should be stated up front in the main document in a section titled "assumptions."

(Major) Overall structure of the document is flawed. The appendixes contain critical information that should be in the body of the document and the main document contains details that should be addressed in an appendix.

(Major) It is way too long and should be edited and structured to focus the appropriate content to the appropriate audience. As it stands, responsibilities for activities are unclear. It should be organized to state specific responsibilities and activities of:

- OCONUS (deployed) combatant commanders and their service components executing current bio-defense activities during contingency operations.

- OCONUS combatant commanders and service components in garrison/training to include responsibility for overseas family members, DOD civilians and support contractors.

- CONUS (but including AK and HI combatant commanders/ Service components) and the military services executing Title 10 base operations and domestic force protection.

- CONUS (including AK and HI) Combatant Commanders (NORTHCOM, STRATCOM, JFCOM) and military services for support of Homeland Defense and DOD support of Department of Homeland Security and other federal agency bio-defense missions and responses.

(Major) The document does an inadequate job articulating the intelligence function and assigning responsibilities at the strategic, operational and tactical levels for biological warfare intelligence. The intelligence prep of the battle space should be part of the "Sense" grouping of activities.

(Major) The document should have a single comprehensive and integrated threat section; currently, discussion of the threats, means of dispersal, agent effectiveness, and vulnerabilities is scattered throughout the document. It should be organized based on the structure suggested above.

(Major) Although the document is comprehensive and touches on the things that it needs to touch on, it does not tie together the roles and responsibilities that the operational, training and doctrine, materiel development and medical communities all have in executing a coordinated whole. As written, each would appear to be able to execute their roles and responsibilities independently and perhaps at odds with the others.

(Major) There are a number of "The Commander/Combatant Command will determine their capability to" or "their priority for" statements throughout the document along with a clear admission (page 14) that these organizations do not have the personnel qualified to do either task. If this is the case, this operational concept needs to articulate the linkages and assist in determining achievable capability (there aren't enough detectors to go around, regardless of how important a particular commander feels his particular mission is) and a meaningful and executable priority list.

(Major) The document does not address patient evacuation guidelines.

(Significant) Throughout the document there is reference to the JCS Threat list. Since this is a classified document, there should be instruction in the document on how to gain access.

(Administrative) There should be a reference section. There should be a glossary because many terms are introduced or used that may not be familiar to the general audience for this policy memo.

Specific:

(Major) Page 1: The use of the term "principle" is overused, incorrect, and confusing. Sense, Shape, Shield, and Sustain are major groupings of activities; the categories of other actions listed under each of these should be called "components." There are a number of true strategic/operational principles buried in the document that should be elevated. These include "maintain and maximize mission accomplishment" (Page 2), "simultaneous execution of B W activities" (Page 2), "BW defense is an ongoing process not just a contingency mission for overseas deployed forces" (Page 2), "must include integration of military and civilian elements, local and federal agencies as well as allied or host nation" (Page 2.), "situational awareness" (Page 3), and "non-proliferation and counter-proliferation" (Page 4).

(Significant) Page 1, "SHAPE": Include a discussion or the model of operational risk management found in a variety of current DoD publications, to include Joint Staff memorandum MCM 0006-02 dated Feb 02, 2002, to describe the "implications to the joint force commander."

(Critical) Page 1, "SHAPE": There appears in the fifth line the phrase, "...envisions critical sense, shield, and sustain end states." Neither in this paragraph nor elsewhere in the document are these "end states" clearly articulated. This is absolutely critical later (page 12) in the discussion of "Commander's Guidance" and "commanders intent" of which end state is the most critical element.

(Significant) Page 4, "SHAPE": Vaccines should be included in this list because they also shape vulnerabilities.

(Major) Page 4, para a: "Move Intelligence Preparation of the Battle Space (Strategic/ Operational biological warfare Vulnerability Analysis)" from "SHAPE" to the "SENSE." This will be consistent with page 1 treatment of intelligence. In addition, split this into two functions: "Intelligence Preparation of the Battle Space" and "Strategic /Operational Biological Warfare Vulnerability Analysis." There are more functional inputs in the vulnerability analysis business than intelligence. These include operational, political, and medical. Also, keep "vulnerability analysis" in "SHAPE."

(Significant) Page 5, "SHIELD": Include Medical Countermeasures.

(Critical) Page 5, para b: There needs to be a much more comprehensive albeit generic articulation of the threat. The critical problem with the current text is that it only addresses characteristics of scale and effectiveness of a "biological attack." This policy memo is titled "biological warfare"; the level of discussion of threat should be at the warfare theory level initially and then address the current strategic/political nature of BW, e.g. use by nation states through non-nation actors. The anthrax "attacks" in the fall of 2001, for example, may have been a criminal act but not biological warfare. For the echelons of DoD and other federal agencies this memo touches, these are critical distinctions.

(Critical) Page 6, first line: The idea of BW fusion centers appears for the first time here and follows many other times in the document. As this memo intends to establish a concept of operation for BW defense and this element appears to be a critical component of it, this document must better define what this fusion center does, how and where it is organized in the joint force commanders headquarters, and establish staff leadership/responsibility for B W defense operations.

(Significant) Page 6, para c: Re-title this paragraph to "environmental surveillance." Preventive medicine personnel do many types of this work, but in some Services, other communities are involved. This will also help distinguish this function from Page 7, para d, titled "Medical Surveillance," much of which is also the responsibility of the preventive medicine community.

(Significant) Page 8, "Biological Detection Operations": This section should address false alarms and/or alarm verification.

(Administrative) Page 11: "ATP-45" is not defined.

(Major) Page 12, para a: Disassociate "Intell Prep of the Battle Space" from vulnerability analysis and move it to "SENSE" discussion. Include discussion of operational risk management paradigm in the remaining text of this paragraph.

(Major) Page 12, para a, third paragraph: Delete the word "permanent" from the description of the biological warfare red team unless the document here or somewhere else assigns this responsibility for organizing and resourcing this capability to an organization.

(Major) Page 13: "Specific biological warfare medical and technical defense priorities for mission accomplishment must be established before the actual initiation of biological warfare" sounds very much like we intend to initiate offensive biological warfare. This sentence should be rewritten.

(Critical) Page 14, para f: There is inadequate description of readiness measures and reporting requirements and associated metrics. This needs to be a more important, probably stand-alone, portion of the document.

(Critical) Page 14 para h: Delete "information management" from the title as it will confuse the IT community. More importantly, this paragraph must briefly discuss the concept of risk communication as a function of command information and public affairs.

(Major) Page 14, para i, last two lines: These state the Services and Combatant Commanders establish requirements for BW defense experts. Instead, it should state that the Combatant Commanders, through the current requirements generation process (e.g. JWCA / JROC) establish requirements for "biological warfare defense capabilities." The Services must develop the force structure, materiel, and personnel to fulfill the requirements.

(Major) Page 16: Vaccinations and public knowledge of the use of countermeasures may have a deterrent effect on enemy biological agent use.

(Major) Page 16: This section should address plans for mortuary services for contaminated bodies.

(Major) Page 18: At this point in the document it is clear the concept of operations has not fully recognized the seminal difference between chemical and biological weapons, i.e. the time between exposure and onset of effects. It is difficult to point out each instance that leads up to this cumulative sense, but it is most obvious in the area of physical collective and individual protection. The discussions of physical protection do recognize, in passing, that for biological weapons, wearing a mask or remaining in a collective shelter will be a long-term experience. However, they then launch into the resource constraints of providing this for all who need it rather than the wholesale impracticality of determining when to start and stop providing protection or how to control the resulting panic. Appendix A does a better job of facing this head on, but still glosses over the previous threat assessment that any attack will be covert rather than obvious.

(Major) Page 18-19: There may be a need here for guidance on sanitizing the mask and changing filters.

(Significant) Page 21, 4th para: Incorrect use of the term "levels of care" despite the attempt in a footnote to clarify. Should not attempt to create a new definition, instead replace with phrase "standards of care" here and in paragraph above.

(Major) Page 23, **para** e: This paragraph should briefly articulate the conceptual difference between chemical warfare decontamination and biological warfare restoration (cleaning/ disinfecting) to establish the foundation later for the joint tactics, techniques, and procedures. It is a good discussion of standards, but must be placed in the context of a CONOPS for restoring the environment back to a "safe" condition, whether that is a building, a room, or a base.

(Critical) Appendix A, "Near Term Implementation": If this appendix is retained substantially, it must be formatted to specifically identify organizational and /or command responsibility for each of the actions.

(Significant) Page A-4, **para** b: Use of the term "units" is confusing. The document should indicate the size of unit as companies or squadrons that may not **resourced** to execute the tasks that follow.

(Major) Page A-5, **para** e: The policy must define what "detection of a biological attack" means in order to start the six-hour prophylaxis clock. Does it involve laboratory confirmation?

(Major) Page A-5, **para** e: Remove the example for smallpox; too much detail for this section. If the JCS policy needs to address specific biological warfare agents, it should do so in an appendix or annex and reference any OSD policy details/guidance on the particular vaccine.

(Major) Page A-6, **para f:** This paragraph introduces a "waiver" without explanation. The waiver process should be included. It is unclear if the paragraph refers to the waiver of informed consent (which requires presidential action), waiver of restrictions on reporting, or what.

(Major) Page A-6, **para** h: This paragraph addresses quarantine. There should be similar discussion concerning evacuation or non-combatant evacuation operations as options to protect forces/DOD members from BW attack.

(Critical) Page A-7, **para** j : As written, this paragraph states that "until medical surveillance in **DoD** is standardized and **routine...all MTFs** will sample **from** 10 percent of all persons exhibiting non-specific flu-like symptoms, and analyze . . . samples for the agents on the JCS threat list." This is an onerous and unreasonable requirement knowing that the majority of visits to treatment facilities fall into the "non-specific flu-like symptoms" category. If the intent of the paragraph is to have this occur only when directed by the Commander, it should be rewritten. It should also clarify which commander.

(Significant) Page A-7, **para** k: There should be discussion and guidance on writing Status of Forces Agreements and alliance procedures to permit transportation of biological samples.

(Major) Page A-8, **para** n: The concept should define "first responders" in both a domestic operations context as well as in a military context, i.e. define of a military first responder.

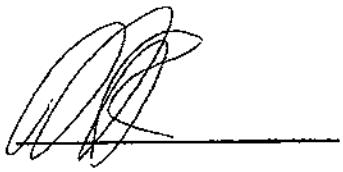
(Major) Page A-9, **para** b: There is no day-to-day garrison /training base DNBI reporting. The requirement exists only in JCS MCM 0006-02 for contingency/deployed operations. There is, however, a reportable medical events system based on the HHS model.

(Major) Page A-l 1, **para** 5: This post-attack list omits the critical function of cleaning, disinfecting, and validation/confirmation of these efforts.

(Significant) Page B-1&2: Increase the scale of the graphic and provide step-by-step guidelines for use of the scale. Suggest doing a single page for each BW agent and include other **agent-**spccific information such as agent characteristics, possible delivery mechanisms, health effects, etc. Then, rename the appendix.

SUBJECT: Joint Operational Concept for Biological Warfare Defense

COORDINATIONS



COL Rauch CoS/DASD(FHP&R)

THE JOINT STAFF
WASHINGTON, D.C.

Action No. J8A 00603-02

Date: 11/8/02

MEMORANDUM FOR:

☑ ACTION OFFICERS

☐ PLANNERS (SERVICES)/DIVISIONS CHIEFS (OTHERS)

USA		USAF	
USN		USMC	
J-1		J-3	
J-4		J-5	
J-7		Editors	
CENTCOM		PACOM	
EUCOM		TRANSCOM	
JFCOM		STRATCOM	
SOCOM		NORTHCOM	
		KOREA	
OSD (TSP/IP)		ODATSD (CBD)	
OSD (HA)		LC	

Subject: Joint Operational Concept for Biological Warfare Defense

1. The attached JS Form 136 is forwarded for:

☑ Preliminary Coordination

☐ Final Coordination

☐ Information

2. Request a response by 2 Dec 02 Respond to (b)(6) (b)(6) (b)(6) (b)(6)

3. Please review attach document and provide critical, major, and substantive utilizing the JS comment form.

(b)(6)

JOINT STAFF ACTION PROCESSING FORM

CLASSIFICATION	UNCLASSIFIED	ACTION NUMBER	J8A 00603-02
TO DJS	THRU	ORIG SUSPENSE	20 Dec 02

SUBJECT Joint Operational Concept for Biological Warfare Defense

EXECUTIVE SUMMARY

1. Purpose. To obtain the **DJS** signature on Memorandum for the Chairman, approving the release of the Joint Operational Concept for Biological Warfare (BW) Defense.

2. Discussion

a. The DPG-04 tasked the CJCS with the development of a BW CONOPS. The J8/ JRO and the J5/ Nuc&CP contracted with the Institute for Defense Analysis (IDA) to facilitate the development of a BW Defense Operational Concept, which better meets the DPG intent. The DPG-04 also tasks the USD (AT&L), in conjunction with the Joint Staff, with developing alternative funding strategies to allow the implementation of the BW defense concept.

b. The completed Joint Operational Concept for BW Defense is broad enough to be applied to military operations, force protection, and homeland security but is primarily focused on the Joint Force Commanders' operations. It creates an operational framework that permits the Services and Combatant Commands to develop more detailed CONOPS and doctrine, while also delivering the USD (AT&L) the operational requirements to initiate development of funding strategies.

3. Recommendation. DJS sign Memorandum for the Chairman, approving the release of the Joint Operational Concept for Biological Warfare (BW) Defense.

COORDINATION

NAME	AGENCY	DATE	NAME	AGENCY	DATE
	J1			[illegible]	
	J3			USAF	
	J4			USN	
	J5			USMC	
	J7			EUCOM	
	CENTCOM			JFCOM	
	Editors			SOCOM	

AO/L/DIV/EXT	(b)(6)	Date Prepared: 8 Nov 02

CLASSIFICATION	CLASSIFICATION/DECLASSIFICATION INSTRUCTIONS
UNCLASSIFIED	

COORDINATION					
NAME	AGENCY	DATE	NAME	AGENCY	DATE
	TRANSCOM			OSD PSP	
	STRATCOM			OSD (HA)	
	NORTHCOM			ATSD(CBD	
	KOREA				
	LC				

Reply ZIP Code:
203 18-0300 {DATE 1}

MEMORANDUM FOR: Distribution List

Subject: Joint Operational Concept for Biological Warfare Defense

1. The Joint Operational Concept for Biological Warfare (BW) Defense is based on broad principles, not on specific capabilities. This interim guidance is provided under the guidance of the Chairman of the Joint Chiefs of Staff. It sets forth guidance to supplement existing doctrine to govern joint activities and performance of the Armed Forces of the United States in joint operations and multinational and interagency operations. This fills a current void in joint doctrine and will serve as the initial concept that will formalized through a follow-on revision of Joint Publication 3- 11 "Joint Doctrine for Operations in a Nuclear, Biological, and Chemical (NBC) Environments."

2. The scope of this document is to provide an operational framework that assist the Joint Force Commander and their staff in successfully conducting military operations and providing force protection for forces that are both mobile (air, sea, and land) and positioned at fixed sites against an adversary's use of biological weapons. This concept addresses issues involving biological agents directed against the US armed forces personnel and equipment, not those employed specifically against civilian populations, crops, and livestock. The principles contained within apply to joint, multi-national, and interagency operations.

3. The purpose of this document in Enclosure A is to provide joint force commanders with a guide to facilitate successfully plan and execute operations in a biological environment. It also provides the foundation for future joint, multi-service, service doctrine, and tactics, techniques, procedures (TTPs). Additionally, it supports developing future operational capabilities. This concept enables the identification of integrated solutions across the Joint Doctrine, Organization, Training, Material, Leader Development, Personnel, and Facilities (DOTMLPF) domain.

4. The document is organized under four operational principles for Chemical, Biological, Radiological, and Nuclear (CBRN) defense; SENSE, SHAPE, SHIELD, and SUSTAIN. These principles provide a framework that support joint operations more effectively that the current doctrinal framework of "Avoid – Protect – Decon" which does not fully incorporate the challenges of biological warfare defense, nor does it provide the necessary flexibility to address the challenges that a capabilities based force could face on a future battlefield. SENSE, SHAPE, SHIELD, and SUSTAIN are more overarching and flexible and will be incorporated into future CBRN doctrinal revisions.

5. The Joint Staff points of contact is [redacted] (b)(6)

For the Chairman of the Joint Chiefs of Staff:

{NAME 1}
{Rank1}
{Title1}

Enclosure

References:
1 x X x X x

copy to:
Secretary of the Army
Secretary of the Navy
Secretary of the Air Force

DISTRIBUTION LIST

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Under Secretary of Defense for Acquisition, Technology, and Logistics
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Commander, US Special Operations Command
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Commander, US Transportation Command
Commander, Combined Forces Command

AN OPERATIONAL CONCEPT FOR BIOLOGICAL DEFENSE

NOVEMBER 5, 2002

TABLE OF CONTENTS

1. Introduction

This document recommends an initial operational concept for biological defense. While biological agent may be directly introduced into food and water or delivered by a vector; this concept concentrates on **aerosolized** biological agent defense. The concept melds existing medical and veterinary procedures for food, water, and vectors into the overall biological defense operational concept. This operational concept organizes biological defense under four principles: Sense, Shape, Shield, and Sustain. The definitions of these principles follow.

Sense

Provides the current biological warfare situation by collecting operational, intelligence, and logistical information, by detecting sampling, and by identifying biological agents in air, water, on land, and on surfaces in flora, fauna, and personnel. This principle includes the capability to diagnose and quantify the hazard. The capability also enables the continued monitoring and identification of biological agent hazards in support of operational planning and execution, shielding, and sustaining decisions. Sense is the key enabler for shaping the battlespace, using knowledge-based human and artificial intelligence.

Shape

Provides the capability to characterize the biological hazard, and its implications to the joint force commander. This biological hazard characterization is the process by which the joint force commander develops a clear understanding of the current and predicted biological warfare defense situation; envisions critical sense, shield, and sustain end states; and visualizes the sequence of events that moves the joint force from its current state to those end states. The shaping process assimilates manually and automatically collected information from military forces, coalition allies, host nation, and non-governmental organizations in near real time to inform operational courses of action. Shaping the battlespace accomplishes the mission.

Shield

Prevents or reduces biological casualties by reducing and/or preventing exposure to biological agent through physical protection or by providing medical prophylaxis from the agent effects. Shielding maintains force capability.

Sustain

Maintains combat power. Capabilities identified in this area are applicable to medical and non-medical operations. Sustain the force recognizes that personnel/units may become exposed to, or have to operate in, a contaminated environment, thus requiring the ability to treat ill personnel or reconstitute units/facilities to pre-incident operational capability as soon as possible.

These principles are not listed in any priority, and they must be executed simultaneously. Each principle has several individual elements under it (see section 2.a., Organization). For example, under the principle of Sense are the elements of medical surveillance and biological detector operations. Note from Figure 1 (page 3) that all principles are interconnected:

2. Operational Concept

For maximum effectiveness, a biological warfare defense operational concept must be standard among the Combatant Commands and Services, and must be well coordinated with other military and civilian entities. The operational concept objective is to maintain and maximize mission accomplishment in the face of biological warfare attacks. Implementing this operational concept requires joint standards, joint actionable criteria, and joint. procedures for biological defense and biological attack warning. The concept must be implemented through all levels of command. This implementation will be costly (in dollars and people) and will require time. Biological warfare has enormous potential to negate military and civilian capability. It will have significant national and international political impact, as well as a public relations or public confidence impact. The use of biological weapons may change public responses or population behavior in a time of crisis.

The implications of biological warfare defense are much broader than just defending the active military. The use of biological agents[1] against military installations will expose civilians and family members on the installation, as well as civilians and/or non-U.S. forces in the surrounding area. Biological defense is more than a joint and combined operation; it is an ongoing process that includes all members of the U.S. military, family members, civilian employees, and local, state, and national government agencies of the United States, as well as the military and civilian elements of other countries, especially allies.

[1] In this operational concept, biological agents are any preparation of disease-causing organisms or toxins that can be disseminated into the environment to affect humans, plants, or animals. Additionally, in some cases the disease itself can be spread by vectors, which are living hosts such as mosquitoes or humans, and which can transmit a disease to other humans, plants, or animals.

CONOPS

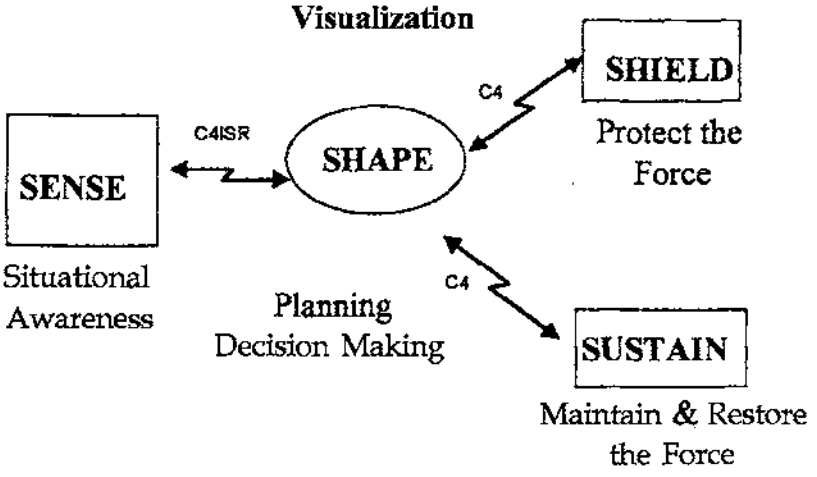

Figure 1. Operational Concept Principles

In today's asymmetric environment, the highest probability of biological weapon use will likely be covert release, as opposed to use of standard military delivery systems2 (e.g., aircraft and missiles). Attacks on civilian targets also can have significant impact on military effectiveness without causing military casualties. These effects could range from denial of civilian facilities and movement restrictions to loss of infrastructure and industrial base.

The principles of biological defense stated in this document – Sense, Shape, Shield, and Sustain – apply across the spectrum of combat and non-combat operations, from a major theater of war (joint maneuver forces and facilities in active combat) to CONUS installations in peacetime.

Implementation of the principles and elements at the tactical level will vary by priority, resources, and mission. For example, biological warfare situational awareness in some units or installations may be more heavily focused on epidemiological detection due to the scarcity of technical detection devices. Counterproliferation and non-proliferation actions, while not 100 percent effective , defend the force and civilians against biological warfare. This operational concept recognizes the contribution of major, more conventional counterproliferation actions such as missile defense and counter-force operations, but does not address them specifically. It also recognizes that,

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[2] The United States' overwhelming technical and operational military capability will most likely cause a potential enemy to choose covert delivery systems, such as special operations personnel on foot or using cars or small private craft for sea or air delivery.

across the Combatant Commands and Services, there are many biological defense initiatives under way.

Non-proliferation and counterproliferation plans and policies are an integral part of defeating the biological warfare threat. These actions, normally in the purview of regional Combatant Commands, national level government agencies, and the senior political leadership of the country, are essential to all biological warfare defense capabilities. Any actions that prevent the possible initiation of a biological warfare capability or remediation of an attack enhance the biological warfare defense capability of the force.

a. Organization. The following sections of this document discuss the four principles and their included elements. These principles, and the elements of each, are listed below.

- **SENSE: Gain and Maintain Biological Warfare Defense Situational Awareness**

  Environmental surveillance
  Medical surveillance
  Epidemiological analysis and detection
  Conventional combat surveillance and intelligence
  Biological agent detection operations
  sampling
  Identification
  Warning and reporting

- **SHAPE: Minimize U.S. vulnerabilities to Biological Warfare Agents by influencing U.S., Allied, and opponent capabilities**

  Intelligence Preparation of the Battle Space (Strategic/ Operational biological warfare Vulnerability Analysis)
  Commanders Guidance
  Planning
  Prioritization
  Alternative Courses of Action for Mission Accomplishment
  Readiness
  Information Operations
  Public Relations, Media Relations and Information Management
  Education, Training, and Exercise
  Liaison and Communication
  Decision-making and criteria
  Non-proliferation and counterproliferation
  Biological Defense
  Operational/ Fusion Centers
  Special Considerations

- SHIELD: **Protect the Force**

  Individual protection
  Collective protection
  Medical Protection
  Conventional Defense

- SUSTAIN: **Maintain or restore military operations; focused logistics**

  Medical treatment
  Quarantine
  Individual Replacement and Unit Replacement
  Logistics
  Decontamination
  Mortuary Affairs

b. Threat. The scale of biological attacks can vary from a biological agent employed as an assassination weapon against an individual; in food and water against a limited target; in a covert aerosol against a fixed facility; or released as a long-line-source, eventually covering thousands of square kilometers. The primary threat to military operations is aerosolized biological agent. The effectiveness of an aerosol attack can vary enormously (see Appendix C for technical considerations). This variability is, in general, unpredictable. Commanders should assume that third world countries and non-state actors are at least as capable as the U.S. biological warfare program was in the 1960s.

3. Sense: Gain and Maintain Biological Warfare Defense Situational Awareness

The elements of sensing the battle space for biological warfare defense operations are discussed below. Situational awareness, as with all military actions, is required for mission success. Situational awareness for biological defense derives from several sources: aerosol background surveillance, meteorological surveillance, medical surveillance, conventional combat situational awareness (air defense radars, etc.), intelligence, logistical status, force readiness status, and technical biological detection (biological detection devices). Situational awareness specifically includes awareness of possible attacks against agricultural or other economic targets. Biological warfare defense situational awareness must be established and maintained by Commanders at all levels.

Biological warfare situational awareness requires the dedication of assets to maintain a current picture, as close to real time as possible, of any indicator of biological warfare use, as well as a worldwide picture of background events and environments that may hide or indicate biological weapon use. Data must be

collected, processed, correlated, and reviewed in central fusion centers to integrate multiple and unique indicators of biological weapon use. These data must be recorded and validated for potential forensic use or for determining attack attribution. These same centers must be able to differentiate endemic disease outbreaks from biological attacks.

The elements of biological warfare situational awareness are detailed below. The assets required vary from biological detection units to epidemiologists, meteorologists, veterinarians, physicians, specialized biological warfare defense experts, unique intelligence and environmental collection systems, laboratories, and logistical support for systems, units, and personnel. Personnel assets include appropriate liaison to and from other nations, other U.S. government agencies, and state and local authorities, etc.

a. Aerosol Background Surveillance

Current and future biological detection and identification capability is and will be affected by the environmental background; for example, the amount of organic and inorganic material in the air. Aerosol background data are required to support the implementation of detection plans within areas of responsibility (AORs) and will assist in determining detection strategies and tactics, techniques, and procedures (TTPs) at the operational and user level. The interaction of environmental background must be understood and defined to maximize the capability of technical detection and identification systems.

b. Meteorological Surveillance

Meteorology- is a significant variable in biological warfare offense and defense planning. Meteorological conditions determine where and if an agent cloud will travel significant distances downwind (10 -100 kilometers (km)) or only cover a local area (less than 10 km downwind travel). Changes in wind speed and humidity may change detector system performance; changes in humidity can change agent characteristics such as particle size or decay rate. Commanders and staffs must be aware of meteorological conditions at their level, the level above and the level below their commands. As well as comprehensive real-time meteorology, detailed meteorological records must be maintained for post-attack analysis.

c. Preventive Medicine Surveillance

Non-aerosol risks from biological agent include contamination of food and water and other items that personnel regularly come into contact with. Monitoring these potential routes of entry, which we term "preventative medicine surveillance," must be conducted on a regular basis. The Services currently field teams that test air, water, soil, flora and fauna for endemic disease hazards. Information from these activities must be fused with traditional biological weapon intelligence and information to provide a more

complete biological hazard picture, as well as to guard against non-aerosol attacks.

d. Medical Surveillance

As part of their routine operations, Combatant Commands, with their components, must conduct AOR-wide medical surveillance. Medical surveillance is a feature of biological warfare defense situational awareness. The "background" level of illness must be known to determine changes indicative of a biological warfare attack. The medical surveillance system will be standardized throughout the AOR, and to the extent possible coordinated with existing U.S. regional and national system(s) and those of other countries. At a minimum, input from other non-U.S. national systems will be collected and monitored as a source of medical surveillance. The medical surveillance system must provide timely information on the specifics of morbidity in the U.S. and allied force structure, the U.S. population, and the population of other nations as appropriate to the AOR.

e. Epidemiological Analysis and Detection

Epidemiological analysis is the study and processing of data/indications provided by medical surveillance. This analysis processes the surveillance data provided and determines when there are "anomalies" in the normal or expected incidents of disease. Epidemiological detection – the outcome of the analysis – is the identification of a pattern of disease within a population of people as a result of a biological attack. For the near future, epidemiological detection will be the most likely source of information on forces exposed to biological agents.

The actions possible after an epidemiological detection are more limited than those taken after a technical detection since operational reaction time is lost and personnel are already casualties. The response options are prophylaxis, treatment, and alternative courses of action for mission accomplishment. In general, prophylaxis will be ineffective for those personnel already showing signs of disease. There already will be a demand on the medical treatment system without the opportunity to prepare for the initial influx of casualties. Although casualties are the first indication of a biological warfare attack, other units or areas may be protected by immediate prophylaxis, or medical treatment responses may be initiated.

There must be initial standard criteria – common among the Combatant Commands and Services – that define and determine that an attack has occurred, based on epidemiological analysis of medical surveillance data. The number of criteria must be limited and rapidly available for decision-making. Reaction to a biological warfare attack must be rapid. The more numerous and more complex the criteria, the longer the reaction time before response may be initiated, and the less effective the response.

f. Conventional Combat Surveillance and Intelligence

Conventional combat indications and warning (such as an air defense attack warning, increased meteorological radar activity, etc.) must be collected and monitored as part of biological warfare situational awareness. While not definitive, when fused with other data, such as current meteorology, this level of information can contribute to indications and warning of a biological agent release.

Biological agents may be effectively delivered by any conventional military system. However, larger, longer-range systems such as aircraft and missiles are more efficient than are small arms and artillery. Current information on aircraft flight paths, ship tracks, and missile paths also may provide an indication of a biological weapon attack and the basis for initiating protection. For example, an aircraft or a ship track perpendicular to the wind and upwind of the force may be a biological agent release indicator. Detection units may then be placed on a different collection schedule,3 or forces may assume a higher physical protection level. As an example, current Air Force doctrine tells all airbase personnel to take protection in the event of an enemy missile launch. Other installations or units may be directed to adopt the same doctrine given the short flight time for missile impact in AORs.

Commanders routinely access and use intelligence and, in general, understand the process for establishing collection requirements and the sources of intelligence. Biological defense requires more emphasis on the unique area of medical intelligence and personnel who understand the field.

g. Biological Agent Detection Operations

Biological agent detection operations consist of the employment of biological detection devices. Current biological detectors are limited in number and capability. Once the operational and strategic vulnerability analysis is completed, employment of these limited assets may be planned for greatest operational payoff (see section 4. 3.). Other issues for detection include detector capability in the local AOR environment, forward positioning of detection assets in peacetime, and scheduling detection units in the strategic flow of forces.

The Combatant Commands should prioritize the employment of available biological detection capability. Currently, there is no DoD process or system that provides information on the configuration and density of biological agent

[3] This operational concept recommends continuous use of all available biological detection assets. Depending on the technology in use, Commanders may wish to change the normal processing and analytical cycle for samples within a time-distance proximity to a suspicious conventional delivery system (aircraft missile etc.).

detection assets and the resulting effectiveness. Joint and Service analytical resources should be tasked to assist in detector placement guidance.

When a biological detection system indicates the presence of a biological agent, either by specific identification or by generic agent[4] presence indicators, response must be initiated based on pre-existing criteria. Current systems such as the BIDS, BIDS P3I, IBDS, Portal Shield, and JBPDS[5] provide agent-specific identification as an output. The BIDS and BIDS P3I can provide generic information of possible agent presence. The M-94 LRBSDS provides generic attack indication based on aerosol cloud shape. Recently, a commercial off-the-shelf (COTS) collection process has been established using a dry filter aerosol collector called a Dry Filter Unit (DFU). The aerosol material is continuously collected and then manually dissolved into liquid and tested by a DoD detector kit (hand held assay) or forwarded to a laboratory for testing. Laboratory testing of DFU samples provides greater sensitivity and specificity than does the hand-held assay.

There is no standard for response based on type and number of biological detection system indications. Guidance must be provided on number and type of indications for action, and what action to take. For example, to reduce false alarm rates, some current systems require two positive identifications before declaring a biological attack. Currently, the action then is to assume MOPP 4 (Mission-Oriented Protective Posture-4). Given the time lag of todays biological point detection capability, Commanders may wish to consider different actions, e.g., not masking but initiating immediate prophylaxis.

h. Sampling

Sampling is the process of collecting material from the environment or from personnel. Environmental samples will likely provide agent (the organism or toxin) along with growth media, fillers, natural background material, etc. Medical samples taken from exposed personnel will likely provide the organism, toxin, or markers of their presence. The reasons for sampling range from agent/ disease identification to providing senior political leaders with scientific evidence of a biological agent attack.

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[4] For the purposes of this paper, identification means specifying the pathogen or toxin to the disease level; e.g., botulinurn toxin, not botulinum toxin type A. A generic agent presence indicator is a single or multiple set of device outputs, such as the presence of organic particles; size, shape, and distribution of organism sizes; etc.; that could indicate the presence of agent in the environment.

[5] BIDS, Biological Detection System; BIDS P3I, BIDS Preplanned Product Improvement; IBDS, Interim Biological Detection System; JBPDS, Joint Biological Point Detection System; LRBSDS, Long Range Biological Stand-off Detection System.

Within the AOR and across the Components. Commanders must establish standard procedures for sample collection, handling, chain of custody, transportation, and processing. The preparation, preservation, and transportation of samples and the material required to do so must beavailable and standardized throughout the force. Allies should be encouraged to adopt the U.S.-defined method. Allied laboratories offer additional capabilities that the Commander should consider. Guidance for sampling must be promulgated and implemented throughout the force.

i. Identification

For operational purposes, identification means specifying the disease-causing organism or toxin at the "disease level," e.g., anthrax, plague, SEB toxin, etc. Identification is important for all aspects of biological warfare defense because it is the start of effect characterization and specific countermeasures. Currently, there is an informal hierarchy of identification definitions within DoD. Terms such as "presumptive," "silver standard," and "gold standard" identification are used, but not defined. Further, there are no criteria for action based on this informal identification hierarchy. The Services and Combatant Commands should consider standardizing technical detector identification and medical identification with the national laboratory response network. For example, an automated detector or a hand-held assay might be comparable to a level A laboratory, while the USAMRIID laboratory would be a level D facility. This congruence between the military and civilian systems will avoid possible confusion and enhance both homeland defense and military-oriented biological defense.

The definition- of identification must be standardized. Because identification can come from multiple technical or medical sources, the definition must be keyed to its source and must include such information as sensitivity, probability of false positive/false negative identification, etc. Within the AOR, these standards are necessary to provide information with a known confidence level that will assist Commanders in developing actionable criteria.

The identification of the agent, the source of the identification, and when it occurs drive the options available to the Combatant Commander. For example, if a technical detector indicates anthrax, there is some period of time to implement prophylaxis. Additionally, since the agent/disease is known, the best available prophylactic can be chosen, and disease-specific treatment preparations can be initiated. If the identification is for an agent that does not have prophylaxis available, alternative courses of action for mission accomplishment may be implemented and agent-specific personnel treatment regimes may be prepared. If the Commander must wait for identification from epidemiological or medical sources, the same actions generally apply, except the options for response are now time-constrained; alternate courses of action for mission accomplishment and casualty treatment become priorities.

Laboratory assets are the most reliable contributors or enablers of identification. Given the political sensitivity of nations when addressing the transport and analyses of potential biological agent samples, laboratory capability must be available in each country within the AOR where significant U.S. forces are deployed.

j. Warning and Reporting

Warning and reporting are required to coordinate and enhance surveillance, detection, and identification, as well as to take advantage of information to minimize personnel exposure.

Within the AOR, a standard joint system of reporting suspected and actual biological attacks must be established. The Commander must specify what information is required, who issues warnings and reports, whom they should be sent to, and what circumstances require the issuance of warnings and reports. For example, under current ATP-45 procedures, biological agent detection in one city or area of the AOR would not be forwarded throughout the entire AOR. **While the Regional Command or Theater Commander may have** such procedures, there is no overall standard. Further, within the AOR, this system must be capable of incorporating *warnings* **from** non-DoD and non-U.S. sources as *well as warning* non-DoD and non-U.S. organizations, e.g., local U.S. civilian organizations, coalition allies, other non-allied countries, etc.

The Combatant Commands must determine criteria for issuing warnings and reports. These criteria are a basis for actions taken, and are based on situational awareness.

The ability to conduct warning and reporting requires that warning and reporting centers be established (see page 16, section m.). These centers also can serve as or be part of the data/intelligence fusion centers for all information/data that contribute to the determination of biological weapon use. At the theater level, there must be a specified warning and reporting center for biological warfare defense, empowered to provide information to senior DoD leadership. Warnings and reports, if inadvertently made public, could influence policy, resources, and politics.

4. Shape: Minimize U.S. Vulnerabilities to Biological Warfare Agents by Influencing U.S., Allied, and Opponent Capabilities; Shape the Battle Space by Biological Defense Actions and Plans

The elements of shaping the battle space for biological defense are discussed below. Shaping is much broader and more detailed in implementation than can be described here. While this operational concept specifically addresses how to shape biological defense, biological defense shapes the overall battle space. Shaping is the command, leadership, planning, and intellectual aspect of biological defense

a. Intelligence Preparation of the Battle Space (Strategic/ Operational Biological Warfare Vulnerability Analysis)

All operations involve intelligence preparation of the battle space. In the case of biological weapons, the force must look at strategic mission accomplishment and how biological warfare could be used to counter strategic success, as well as more detailed vulnerability analysis at operational and tactical levels. Within a specific AOR, the effects of terrain, climatology,. population demographics, and time must be analyzed to determine potential impacts on missionaccomplishment.

These vulnerability analyses should examine all facets of the operational plans (OPLANS), assigned and implied missions, and how, where, and when mission accomplishment could be negated or disrupted by biological agent attacks. Examples could include the loss of an early deploying carrier, or an attack on a continental United States (CONUS) facility, such as a force projection node, a satellite control center, or a long-range bomber base. It is important to note that some key operational facilities are not DoD controlled, but nonetheless require biological defense protection.

As the Combatant Commands and Components conduct their vulnerability analyses, the Commands should coordinate with OSD and JS to conduct an overarching review of OPLAN interaction, as well as other biological warfare vulnerabilities of the national military strategy. This must be an ongoing process with a permanent biological warfare red team in place to identify military vulnerabilities. An example of a red teams investigation might be the effect of biological agent release on the national/international civil air transportation system while the U.S. is conducting or preparing to conduct a major theater deployment.

b. Commanders Guidance

The Commanders guidance or intent is integral to military planning and operations. All Services, all Soldiers, Sailors, Airmen, and Marines are familiar with the concept and the implementation of Commanders guidance. In the case of biological warfare defense, this is a new and unique area for Commanders to state their intent. Few Commanders have a true working knowledge of biological warfare weapons and agent effects. Further, few Commands have staffs with adequate expertise to assist Commanders in biological warfare defense. Not only does the Commander have to critically assess and determine risk from biological warfare, but also he/she must be able to understand the technical and medical implications of biological warfare defense. Commanders, particularly at the operational level, will be required to provide guidance for biological warfare defense operations across the Service Components and subordinate units that have varying biological warfare defense capability. Ultimately it is the Commander who decides the level of

biological warfare defense and asset allocation. Specific areas that could be included in the Commanders guidance are detailed in the section 4.k. below.

c. Planning

For biological defense as with all other activities, planning is central to the successful initiation and continuity for all operations. Biological defense planning must be integrated throughout the planning cycle, taking into consideration threats and vulnerabilities. It is critical in addressing the logistical, medical, host nation, and coalition issues that will arise and it must extend down from the strategic/operational level to the tactical implementation level. Plans must include sufficient guidance to standardize biological warfare defense operations, including medical operations, across the AOR and Component Commands. Depending on the AOR, both U.S. and non-U.S. forces, other government agencies, non-government agencies, and state and local agencies may have to be involved in biological warfare defense planning and execution.

d. Prioritization

While normally conducted in the planning process, operational prioritization is emphasized separately in this operational concept because of the potential for disruption as a result of a biological attack. While mission accomplishment priorities are not expected to change in a biological environment, operational and logistical priorities may. Specific biological warfare medical and technical defense priorities for mission accomplishment must be established before the actual initiation of biological warfare, remembering that such warfare can be delivered covertly by non-traditional systems in "peacetime." Priorities could include placement of medical and detection units earlier in the time-phased force deployment list (TPFDL), allocating air defense, allocating additional ground security forces, or assigning mobile detection units.

e. Alternative Courses of Action for Mission Accomplishment

In addition to planning for the implementation of biological defense measures, plans also must be in place to continue mission accomplishment and to assure a strategic force flow, despite a successful attack. Mission accomplishment contingency plans must begin with those elements (personnel, units, facilities, schedules) identified in vulnerability analyses and the potential effect of biological weapon attacks on those elements and on mission accomplishment. Once this has been done, alternative courses of action must be prepared and resourced. Biological warfare may require unit replacement of U.S. or coalition forces, the use of alternative facilities, or the substitution of capabilities on a large scale; alternative courses of action also must address the loss of allied or neutral bases or over-flight routes.

f. Readiness

Within the AOR and extending to supporting Commands and Services, a system must be established for measuring and reporting biological defense readiness. This readiness-reporting requirement may be combined with or integrated into existing procedures or systems. What constitutes biological warfare defense readiness must be defined and promulgated; example readiness indicators could include: prepared and resourced plans and current operations; status of situational awareness capability; the ability to provide prophylaxis; the ability to treat biological casualties; and the status of biological warfare defense personnel.

g. Information Operations

Information Operations (IO) are applied to all realms of combat and peacetime operations. Biological defense IO missions range from depriving an opponent the capability to develop and target biological weapons to depriving the opponent any information on the effectiveness of an attack.

h. Public Relations, Media Relations, and Information Management

Because of the uniqueness of biological warfare and the associated fear of the unknown, information management must be in place, and releasable information must be prepared and standardized before any incident takes place. Information must be internally coordinated across DoD and with U.S. local, state, and federal agencies; standardized and coordinated nationally with other organizations, such as the Center for Disease Control and Prevention (CDC) and state and local authorities; consistent and objective in its dissemination to the force, and to the public; and available to the public in the area of responsibility. Commanders must establish criteria and guidelines for what is releasable and when to release information.

i. Education, Training, and Exercise

Implementing the operational concept presented in this paper requires personnel specifically educated and trained in biological defense and supporting academic disciplines, such as meteorology, medicine, and biology. Once the biological defense operational concept is implemented, it must be aggressively, realistically, and regularly exercised and translated throughout multi-Service and Service-specific doctrine.

The Services have dedicated NBC defense personnel, but no biological defense experts per se; rather, current NBC defense personnel are generalists, or specialists in chemical warfare defense. The DoD has a limited expertise, generally found in highly qualified medical or acquisition personnel.

The Services and the Combatant Commands must establish requirements for biological warfare defense experts and associated personnel, to include the

number of positions to be filled, position/performance criteria, and requisite education.

The Combatant Commands, the Components, and the Services must ensure that adequate and realistic biological warfare defense exercises are adequately resourced and conducted, and that biological warfare defense is properly integrated into other exercises. Exercising responses to biological warfare attack can be extremely difficult; large numbers of personnel are required to act as patients or to support medical operations. While not all biological warfare defense exercises are conducive to the general training of the entire force, they are extremely important to the realistic training and appraisal of biological defense capability.

j. Liaison and Communication

Liaison is a normally implemented military process; however, for biological defense, the liaison and communication requirements may be quite different. Many biological warfare defense issues will be medical and may involve the CDC, the Department of Health and Human Services (DHHS), and the Food and Drug Administration (FDA) in the U.S. and similar national organizations through out the AOR. Liaison for biological warfare defense will call for special talents (infectious disease physicians, epidemiologists, etc.) and also will require language skills or translators. Because of the sensational nature and fear associated with biological warfare effects, special liaisons may be required at the national political level, as well as with the media, across the AOR.

k. Decision-making Criteria

Decision (or action) criteria must be established and standardized before any biological warfare attack; some of the more important decision criteria, and related decisions Commanders must make, follow:

- Establish criteria for action, based on:
  - o epidemiological detection
  - o the output of technical biological detection devices
  - o indications and warning
  - o identification.
- Establish a set of standard definitions and performance descriptors for identification.
- Determine warning and reporting criteria, based on current capabilities[6] and mission risk tolerance.

[6] Current capabilities mean those assets, systems, doctrines, units, personnel, etc., in the force today.

- Establish physical protection criteria, based on mission accomplishment and risk and criteria for masking and unmasking.
- Maintain a list of approved and investigational new drugs (IND), as well as standard guidance for such issues as informed consent. Maintain planning guidance on the expected effectiveness of prophylaxis.
- Deterrnine the requirements for prophylaxes, resource the capabilities to prophylax personnel, and establish criteria for administration.
- Establish requirements for and capabilities to treat personnel at all levels of care (e.g., from heroic care to field expedient care; this criterion refers to the quality and quantity of care provided the patients, not level 1,2,3 medical facilities). This operational concept assumes the medical system will be overwhelmed and unable to provide the normal high. quality of care planned for "conventional" warfare, with respectively fewer trauma cases. Combatant Commands and the Services must plan for and resource the medical treatment of mass biological casualties.
- Establish criteria for residual biological agent safety and contamination determination.

Before and during the decision-making process, Commanders should realize that there always will be considerable uncertainty in a biological warfare situation. Unknowns and assumptions must be explicitly specified. For example, the extent of the attack, the infectivity of the agent, and the effectiveness of prophylaxis and treatments all will be unknown to different degrees. More information will become available over time, allowing refinement or reconsideration of actions;. however, actions must be implemented early, taking into account this high level of uncertainty.

1. Non-proliferation and Counterproliferation

Non-proliferation and counterproliferation plans, policies, and actions are an integral part of shaping the environment. These actions – normally within the purview of Regional Combatant Commands, national level government agencies, and the senior political leadership of the country – are essential to the shaping process. Counter force and active defense resources provide significant capability; these capabilities and the plans for their employment must be considered and coordinated with biological defense capabilities and plans.

m. Biological Defense Operational/ Fusion Centers

Commanders should establish biological warfare defense centers as a critical component of existing operations centers in the force, maintaining the common biological defense operational picture and manned with biological warfare defense experts who can analyze relevant data and provide the Commander recommendations on appropriate countermeasures taken in response to an attack. These centers should be the Commanders primary advisors for implementing the elements within the principles of sense, shape, shield, and sustain.

n. Special Considerations

Although the Regional Commands are guided by the requirements of their specific AORs, TRANSCOM has uniquely broad concerns encompassing not only the biological defenses of each theater, but also the health and safety standards of the U.S., countries through which personnel and materiel must transit, and countries from which the United States requires overflight permission. In order to carry out the missions of moving personnel and equipment to and from the region of conflict, TRANSCOM will have to apply the principles and elements of this operational concept to its facilities worldwide. This will entail especially broad coordination with all Combatant Commands, as well as with U.S. and foreign governmental agencies.

5. Shield: Protect the Force

Shielding encompasses those direct physical measures that *prevent exposure* ofpersonnel to agent and/or disease, and direct medical actions that *prevent the occurrence of* the disease. The requirements to protect active military forces, family members, civilian employees, contract employees, etc., regardless of location and nationality, must be taken into account. This operational concept supports implementation of DoD Memorandum September 5, 2002; Subject: Preparedness of the U.S. Military Installations and Facilities Worldwide Against Chemical, Biological. Radiological, Nuclear and High-Yield Explosive (CBRNE) Attack [Reference 1].

Physical protection describes any means of preventing direct physical exposure from agent; it normally is composed of individual protection and collective protection. For biological agents, the primary goal of physical protection is the prevention of agent inhalation since, for most agents, inhalation exposure causes the most severe manifestation of the disease. Physical protection, particularly individual physical protection, may degrade task performance, thus degrading unit and facility performance; the degree of degradation depends on the type of physical protection, level of training, acclimatization, duration of protection, work activity, and meteorological conditions.

Once the vulnerability analyses are completed and those personnel, units, and facilities critical for mission accomplishment have been identified, the mission-specific requirements for physical protection must be determined. For example, based on vulnerability and mission criticality, units or facilities that currently do not have collective or individual protection could be issued DoD individual protective equipment or provided COTS equipment to reduce exposure and risk.

a. Individual Protection

Traditionally, individual protection has been synonymous with MOPP gear. MOPP gear provides extremely good protection from biological agents but, in fact, only the mask is normally required. The most important aspect is timing: when to put it on and when to take it off.

The criteria for masking must consider the threat, the source of the biological agent warning, meteorological conditions, the agent, and the mission risk. Masking after epidemiological identification has no benefit unless the agent is contagious[7]; masking after point sensor identification may have benefit, depending on meteorological conditions, position of detection, position of personnel, and the time elapsed between when warning was received and the individual masked.[8]

Currently, there are no standard unmasking procedures after a biological attack. Unmasking guidance must be developed based on source of warning, point(s) of detection, time since warning, unit position, etc. Criteria should be standard among the Combatant Commands and Services, except for the mission risk component.

Commanders may opt for COTS individual protection devices such as dust masks, surgical masks etc.; if properly chosen and worn during an attack, these devices will reduce the level of exposure. COTS protective equipment will not prevent all causalities but, depending on the agent, may reduce the number of lethalities and the total number of affected personnel. Since it is unlikely that personnel will know an attack is occurring, individual protection may have to warn on a continuous basis (see Appendix A for near-term guidance.) The decision to utilize commercial off-the-shelf masks requires further technical analysis to ensure adequate protection and the development

[7] Masks will limit exposure from airborne particulate matter. AOR and local medical and operational SOPs are required to address the procedures for contagious personnel/ agents in operational settings.

[8] If the weather is extremely calm, agent may stay in the area of release for hours; masking would reduce initial exposure. For other than "calm" conditions, masking in the immediate area following warning likely does not reduce exposure. Masking personnel in downwind areas should reduce exposure given adequate warning time.

of TTPs. *The best respiratory protection is the standard military issue protective mask.*

Because individual protection also is the first response for chemical warfare and radiological warfare protection, masking and unmasking procedures for chemical, biological, and radiological (CBR) defense must be coordinated across Combatant Commands and Services to ensure proper protection from all three threats, while at the same time avoiding confusion.

b. Collective Protection

Traditionally, collective protection describes the prevention of biological agent entry into facilities, rooms, or vehicles. Collective protection systems normally provide filtered air with sufficient over-pressure to prevent agent seepage into the protected space; collective protection facilities require air locks and entry-exit procedures.

Unless the facilities are operational at all times, the issue of when to start and when to stop operating collective protective systems, or when to enter and when to exit such facilities, is paramount. The best way to avoid exposure is to operate collective protection continuously and have as many personnel in collective protection as possible. Given resource limitations and mission accomplishment requirements, the Commander should publish priorities for collective protection installation and guidance for operation.

c. Medical Protection

Given the capability of biological weapons to cause mass casualties and the limitations of technical detection, medical protection will be the primary biological warfare defense response. These measures must be planned, prepared, and, in some cases, implemented prior to exposure.

Prophylaxes are those medical measures taken to prevent the occurrence of a disease; they may be administered pre- or post-exposure, depending on the particular agent and specific medical countermeasure(s). For example, the anthrax vaccine is a prophylaxis administered pre-exposure. Ciprofloxicin, administered post-exposure but before symptoms appear, also is an accepted prophylaxis for anthrax. Administering prophylaxes requires careful planning and preparation, not just from an operational and logistical perspective but also for medical and legal reasons.[9] (See Appendix B for graphics portraying

[9] Law and regulation approve drugs for a specific "purpose and application." Before a particular drug has full FDA approval, it is described as an "investigational new drug" (IND). Using a drug for a purpose for which it was not approved is considered "off label." IND and off-label use require the informed and voluntary consent of the person receiving the drug.

information on the course of diseases and time windows for detection and prophylaxis administration.)

There is no standard reference for the effectiveness of prophylaxis (how often the disease is prevented or to what degree symptoms are reduced). Standard accepted planning guidance is required to estimate the effectiveness of prophylaxis. Each Command should develop planning information that includes the expected percent of personnel casualties avoided given administration of prophylaxis, by time after exposure (one day, two days etc.) and by agents, relevant to their AOR, from the JCS threat list.

A list of approved drugs and investigational new drugs for prophylaxis and treatment of biological agent exposure must be centrally maintained and coordinated among the Combatant Commands and the Services. It is imperative that OSD and JS maintain ongoing coordination with the FDA and other government agencies as required, thus ensuring the best and most timely information is available to the Commands and Services who will have to execute prophylaxis. Plans must be in place that address all aspects of prophylactic implementation, conform with the requirements for informed consent, state how much material is required, where it is stored, how soon can it can be administered, what the possible side effects are, what might be possible political considerations to U.S. implementation, etc. Prophylaxis includes pre-exposure vaccination; given the threat of biological weapon use, the pre-exposure administration of an effective vaccine to the force enhances mission accomplishment, increases survival, and reduces logistical demands.

d. Conventional Defense

All aspects of conventional defense shield the force from biologic&l warfare attacks; each aircraft or missile destroyed before reaching the target eliminates a potential biological warfare threat. Local security, physical security, and patrolling all deter covert releases or increase the chance of intercepting the release before it happens. Security forces, military and civilian, must be educated on biological warfare agents and possible covert or field-expedient release mechanisms.

6. Sustain: Maintain or Restore Military Operations

Restoration operations encompass those actions required to bring the force, or portions of the force, back to pre-biological attack capability. These operations include actions ranging from medical treatment of personnel to unit replacement to decontamination..

a. Medical Treatment

Medical treatment describes those medical measures taken when personnel show signs of illness. Treatments vary for different diseases; some diseases caused by biological agents have no specific treatments. For example, the agent

SEB, a toxin of *Staphylococcus Aureus* bacteria, was weaponized in the now-defunct U.S. offensive program and still has no specific treatment. Where there is no specific treatment to counter a disease, medical personnel treat to alleviate or lessen symptoms. Toxins, with the exception of botulinum, and viral diseases generally are treated symptomatically rather than with agent/ disease-specific medical countermeasures. Antibiotics are typically used to treat bacterial infections.

The current military medical system has a dual mission: to maintain the health of the peacetime force, including family members and retirees, and to support the force in wartime by saving life and limb and, where possible, returning personnel to duty. The current medical force structure and procedures are based on historical trauma workloads and are not designed to support mass casualties from infectious agents or toxins. For example, all personnel on fiied facilities such as air-bases or base clusters, or amphibious forces afloat, could be exposed to agent and require treatment; ground maneuver forces'treatment requirements could range from a battalion to major portions of a deployed corps.

The requirements for and the capability to treat patients at the various levels of care, in terms of required medical personnel, units, and material, must be determined, as a successful biological attack will dramatically increase medical requirements. The capability to provide care and the level of care provided must be balanced against the vulnerability analysis, available resources, mission accomplishment, and medical treatment requirements.

Levels of care[10] must be established and standardized throughout the AOR. Current military medical assets could and would provide "heroic" care to a small number of biological casualties, but the potential for biological warfare mass casualties is so great and so varied that Commanders must recognize that, at some level of resources, care must be constrained. Medical planners also should anticipate an increase in the "worried well" – those persons who are concerned but are not suffering psychological effects – as well as those persons exhibiting the psychological effects of biological warfare on the force. Medical doctrine must specifically address the response to mass biological warfare casualties.

Once capability and planning requirements are determined, medical contingency planning must be initiated. As a minimum, plans must address the capabilities to treat personnel, requirements for force structure, evacuation policy/ capability, quarantine, and the resulting effect on mission accomplishment. Evacuation of personnel exposed to biological warfare agents or potentially exposed to biological warfare agents also may be a sensitive political issue: while most biological warfare agents are not contagious, there is a generalized fear of biological warfare. Non-U.S. national and/or U.S. state

[10] As stated earlier, level of care refers to quality and quantity of care, not the facility level.

and local authorities may deny passage of patients through territories pending some assurance of safe passage, etc. Commanders may be required to maintain large numbers of casualties or potentially exposed personnel in theater (in medical facilities or transient facilities), increasing the demand for force structure and resources. Additionally, depending on the agents and course of disease, evacuation assets may be extremely limited due to requirements for specialized equipment, such as respirators onboard aircraft or limitations on contracted commercial assets to transport biological warfare casualties.

Additionally, medical facilities/units may require augmentation by non-medical personnel to provide non-medical support, e.g., laundry, cleaning, feeding, etc. Augmentation of medical assets must be factored into biological warfare defense planning and other operational requirements. A further, consideration should be the possible use of "in-unit care," defined as supporting sick personnel with food, shelter, sanitation, and medication (if available and feasible) without the supervision of medical personnel within the individual's assigned unit.[11]

b. Quarantine

Quarantine of a facility or a unit poses a diverse set of challenges, from the national political level through the tactical level. Combatant Commands not only will have to establish and maintain quarantine, they also will have to deal with the political and public reactions and ramifications in their respective AORs. Contingency plans for quarantine should consider mission accomplishment, legal status of civilians in quarantine area, support for the quarantined areas or organizations, quarantine enforcement, and public relations.

c. Individual Replacement and Unit Replacement

Depending on the scale of the attack, the agent, its effectiveness, etc., Commands may be faced with the requirement to replace individual personnel or entire units to maintain mission capability. Commanders should establish key individual and unit skills' and capabilities' replacement priorities, as well as plans to replace such individuals or units.

d. Logistics

There is a logistical component to all elements of this operational concept. Some elements, such as biological detection operations and prophylaxis, may have special requirements for timeliness and storage/ transportation conditions; for example, refrigeration may be required to maintain shelf life. Medical treatments for mass biological warfare casualties

[11] By definition, this is not "military medical care," Medical care is provided within the military medical system.

will create a logistical demand not normally planned for or resourced. Additionally, conducting logistical operations in a biological warfare environment may be constrained or complicated by medical and legal requirements in addition to the effects and risks of biological warfare on logistical capability.

e. Decontamination

The issue of decontamination and risk standards are not new or unique to biological warfare defense. DoD-wide and perhaps DOD/national interagency standards must be established. Biological safety and exposure standards pose a difficult problem: the DoD standard must be acceptable and scientifically defensible in the U.S. and among other nations. And whatever standards are eventually adopted, there must be a commensurate public relations effort to ensure public acceptance and acceptance of risk for military operations. These standards must be thoroughly coordinated and interwoven through the operational concept to ensure all facets are executable. In the absence of DoD standards, Combatant Commanders should establish AOR-specific standards and coordinate among the Commands and Services.

f. Mortuary Operations

Fatalities caused by biological warfare may have unique mortuary requirements. There is the possibility of negative public and other non-U.S. government reaction to the handling and transport of these casualties due to the fear of the unknown, and biological warfare in general. All Commands and agencies must have plans and resources to properly process, inter, and transport mass fatalities while considering operational necessity, human dignity, and family and public feelings and emotions.

APPENDIX A

NEAR-TERM IMPLEMENTATION

1. Introduction

This Appendix summarizes aspects of the operational concept and is designed to apply to current operations; it recommends specific actions and criteria based on current biological warfare defense capabilities.

A current capability approach to biological defense and a chronology is presented below; specific actions then are presented. The key issues discussed are before exposure/ attack planning; resourcing; and rehearsing.

2. Kev Points

The importance of actions taken before the event cannot be over-emphasized. Prior planning and rapid execution are imperative; it is better to act and be wrong than not to act. Even if prophylaxis is under way, it can be halted if there is a subsequent determination of no agent exposure/attack.

Large numbers of increasingly ill and dying personnel and the resulting degradation of operational capability likely will characterize biological attacks. Effects of biological attacks can be mitigated by:

- 3 pre-exposure prophylaxis that provide immunity for some agents
- the use of collective and individual protection during the attack
- 3 prompt post-exposure prophylaxis for some agents.

Maintaining key military capability requires that units/facilities plan for and implement protective measures in advance of need.

Biological agents are invisible and have no taste, smell, or other obvious signature. Moreover, because small amounts of agent can have widespread effects, it is particularly suitable for covert dissemination. Currently, the only way to know that biological agents are present is through the use of tactical point detectors. Several types of detectors exist, but all operational detectors provide indication that an attack has taken place, rather than warning of approaching agent. Hence, current detectors cannot be used to trigger the use of individual or collective protection systems. For some agents, however, this indication is sufficiently rapid that post-exposure medical measures can be effective if implemented quickly. In the absence of tactical detectors, the fact that an attack occurred will be apparent only when increasing numbers of individuals become sick and are diagnosed with agent-induced diseases. At this point, it usually will be too late to preserve unit operational capability. Unit replacement or alternative courses of action are required for mission accomplishment.

A current capability approach to biological defense is outlined here:

- 3 Identify and prioritize key units and facilities that must be protected from biological agents to help guide the allocation of resources.

- Plan against biological attacks. Planning encompasses use of detection systems, laboratory support, medical preparations, and determination of actions to be taken in the event of biological attack. Identify those events that would signal a biological attack has occurred. For all units, but especially for those units for which prompt detection and protection might be lacking, prepare contingency plans in the event that a biological attack renders the unit non-mission-capable.
- Vaccinate or pre-treat all personnel against threat agents where such measures can be taken.
- Deploy and operate tactical detectors at critical sites. Because of the covert threat, operate those detectors continuously.
- Where collective protection exists, operate it continuously.
- Conduct medical surveillance and epidemiological analysis continuously
- Establish a biological warfare identification laboratory capability in each country within each AOR. An in-country laboratory capability eliminates the need for cross-border transportation of suspected biological warfare agent samples.
- Ensure that post-exposure prophylaxes are available and can be applied to potentially exposed personnel within no more than six hours after detection, including the decision time to use them.
- For critical units and facilities, consider the continuous or shift-based use of respiratory masks to protect against agents for which treatments are not available or where detectors are not present.
- Be prepared to handle mass biological casualties, prep&e medical contingency plans, exercise and rehearse the plans, and stock the required material.
- Tram all personnel, military and civilian, on biological warfare threats consequences, and response plans.

2. Before

This section is a summary of actions taken before the attack. Planning, resourcing, and exercising these actions/procedures will allow immediate and more effective transition to immediate after the attack actions.

a. Knowledge / People

Commanders will establish a core of personnel with the appropriate knowledge to plan and execute biological defense (including medical) through consequence management. Personnel should be organic to the facility and/or the organization and be full time, as opposed to part time or additional duty.

b. Establish Current Biological Warfare Defense Capabilities

Commanders of installations and units will establish their current biological defense capabilities; this includes the ability to determine an attack has occurred and to respond to such an attack. Evaluation for consequence management will be conducted on the basis of assumed exposure for the personnel at the unit and/or facility, as required by Reference 1. This assessment will be conducted for the agents on the JCS threat list that apply for the specific AOR, and should establish criteria for requesting augmentation as required.

c. Threat, Risk, and Response

It is imperative to establish a threat and response process based on the capability to defend against biological warfare, the mission, and acceptable risk. Response must include alternative operational courses of action to replace functions, facilities, or units not operationally ready because of a biological attack. Traditional physical security measures should always be included in assessing and countering the risk of a biological warfare attack.

Today, there is no standard DoD threat assessment for biological attacks. Given this, biological warfare defense options are extremely limited. At least in the near- and mid-term, Commanders will not be able to sense a biological attack in sufficient time to protect most personnel before exposure. (Units and installations that are exceptionally large may be able to warn some personnel who are a great distance downwind, based on the reaction time of current sensors. See Figure A-1 .) For installations/ units with technical biological detection capability, the determination of detection duty cycle and risk is imperative. Current technical detection capability will, at best, provide after-the-fact exposure information. For small installations, e.g., a small Air Force Base or Kaserne 3 km by 5 km, assuming collective or individual protection is likely a moot point after an attack has been determined. However, for a large deployed formation such as an Army Corps or Marine Corps Expeditionary Brigade, a warning from detection that results in assuming protection may avoid and or at least reduce exposure levels.

For small installations and facilities, there are very few sets of meteorological conditions that would negate a biological attack. There is no current method to determine the metrology and attack characteristics (type release, agent, decay rate, etc.) combinations that could negate the effectiveness of a potential biological release. If the Commanders estimate that the risk of biological attack is significant enough to employ a detector, then all detectors available should be employed, and if detection operations are warranted, all collective protection systems should be employed. Reducing the number of functioning detectors at any installation, even in non-optimal meteorological conditions, only decreases the chances of detection.

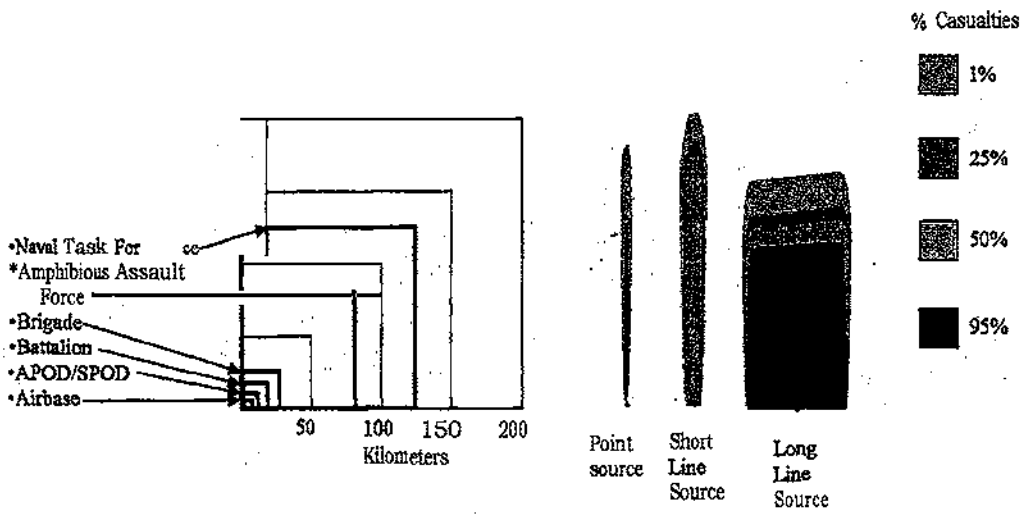

Figure A- 1. Attack and Target Size Example

If the risk of personnel degradation is considered unacceptable, Commanders should consider masking personnel by shift, or maintaining personnel in masks continuously to retain mission capability. DoD standard issue chemical biological radiological (CBR) protective masks provide the best respiratory protection in any operational CBR defense effort; however, if Commanders opt for COTS masks, they should have a protection factor of at least 100. Dry agents and highly infectious agents demand higher protection factors. Standard protective masks, when properly fitted, provide sufficient protection to avoid almost all exposures; COTS masks, depending on the type and fitting, will reduce exposure but not as effectively as military issue protective masks.[1] For installations/units without technical detection, with the exception of collective protection and shift or continuous masking, biological warfare defense response is limited to medical surveillance and consequence management.

For units, installations, and facilities without biological detection capability, planning and preparation for consequence management are the best near-term

[1] ECBC Interim Technical Memorandum Protection Factor and Saturation Testing of Commercial Negative Pressure Half Mask Respirators 9 November 2001; Defense Research Establishment Suffield Ralston, Alberta, Suffield Memorandum No 187, Assessment of Commercial Alternatives to the C4 Mask for use in Moderate to High Risk Biological Scenarios) In the limited test cites, surgical-type masks have been shown to have a protection factor of from 3-7. More sophisticated commercial dust/vapor masks can have a protection factor in the 100s to 1000. Protection factor is the ratio of outside to inside concentration for the particulate matter of interest.

courses of action. Commanders must always assume that biological warfare agents can be used covertly and successfully to attack their units/facilities.

d. Prioritize

Based on assigned mission, Commanders of installations and units will prioritize biological warfare defense to provide maximum mission accomplishment when resources are not available to prevent 100 percent exposure, or to provide 100 percent prophylaxis and treatment in a consequence management response. Prioritization also should include continuity of command and control, maintenance of biological defense capabilities, and the continuation of essential services. At operational levels, prioritization should focus on mission accomplishment and support of the attacked units.

e. Prophylaxis

Commanders will plan for, preposition resources for, and initiate administration of prophylaxis for bacterial agents/diseases within six hours after detection of a biological attack. Detection, even though it currently will not provide warning to prevent exposure, will provide sufficient warning to administer prophylaxis for bacterial agents with prior preparation and stockpiling. For those units without detection, or for attacks below the sensitivity level of the detectors, casualties will be the first indication of an attack. When this occurs, an especially rapid response is required; therefore, a six-hour criterion is chosen.

For viral agents, the only available non-IND prophylaxis is for smallpox. CDC maintains the vaccine and will issue/ship in the instance of a confirmed smallpox outbreak. Commanders will plan for and resource the administration of smallpox vaccine immediately upon receipt from the CDC; i.e., 24 hours after identification of the attack.

Combatant Commands must prepare, resource[2], and exercise plans for the distribution and administration of smallpox vaccine in OCONUS. As required,

[2] Note that smallpox inoculations are administered differently from current 'injection'-type inoculations (intra-muscular or sub-cutaneous). The process of scarification administers smallpox vaccine. Scarification requires personnel trained to 'scarify' (make small cuts in the skin) an inoculation area with a bifurcated (two pronged) needle, thus introducing the 'vaccine' into the body. The site, when properly inoculated, elicits a local immune response. The inoculation site must be 'read' several days later to verify the proper immune reaction. Administration of the smallpox vaccine to a population requires medical personnel trained in proper administration and follow-on confirmation of this vaccine.

these plans should address the stockpiling of the smallpox vaccine in the AOR, or AOR/Command-specific plans to move vaccine from CDC facilities to the AOR. Commands should assume and execute the requirement to vaccinate all personnel rather than wait for epidemiological determinations; vaccination priority should be to the facility/unit with known cases, by order of mission accomplishment priority and by epidemiological evidence.

There is a limited capability response for botulinum toxin using an IND antitoxin or the toxoid. Response time to deliver the material to any installation in the AOR should be twelve hours. Each installation/unit will have in place the appropriate IND protocols, supporting plans, and resources to administer the antitoxin/toxoid. Planning for the quantities of botulinum antitoxin should be based on 10 percent of the population of the largest facility or unit.

f. Investigational New Drugs

The prophylactic use of some drugs has not yet been approved by the FDA for that specific purpose; it is considered "off label use;" further, some other medical countermeasure may be investigational and not yet FDA approved. In all IND cases, without wavier or specific legal circumstance, individual notification and consent forms (informed consent) are required prior to administering the drugs under the supervision of a principle investigator (could be a Command surgeon). Individual records and follow-up medical assessment are required after the administration of IND drugs. Combatant Commands and Services must prepare, coordinate, and plan for implementation to the tactical level.

g. Treatment

Local Commanders will plan for and resource, within their capabilities, the ability to treat all personnel enumerated in Reference **1.** Operational level Commanders will plan for and resource for the treatment of all personnel, based on the largest eligible population in their AOR. Resource and capability requirements will be based- on the consequence management assessment discussed above.

h. Quarantine

Each installation/unit will plan for quarantine; this planning should include, but not be limited to, legal authority; personnel tracking and accountability; ensuring continuity of essential services; criteria to initiate quarantine; extent of quarantine; enforcement of quarantine interaction with local, state, and federal agencies and /or their host nation equivalents; support of quarantined personnel; legal issues; mission impact; etc. Operational and strategic level Commanders will plan for mission accomplishment in quarantine situations and to support quarantined units/facilities. Strategic

level and operational level Commanders will designate lower level Commanders with authority to implement quarantine on military facilities and provide policy for quarantine implementation.

i. Liaison

Each installation/unit will establish the appropriate liaison with higher, lower, and adjacent units. More importantly, liaison and points of contact must be established, documented, and exercised with the appropriate local, state, and federal officials who may assist in the detection of or response to a biological attack. OSD/JS will establish and promulgate standard procedures for federal-level coordination with Service entities and other federal or non-U.S. national, state, and local agencies. The Services and operational level Commanders will implement these procedures.

j. Medical Surveillance and Medical Sampling

Until medical surveillance in DoD is standardized and routine as a biological warfare detection system, and when directed by the Commander, all **MTFs** will sample from 10 percent of all persons exhibiting non-specific flu-like symptoms, and analyze (or forward to the appropriate laboratory for analysis) samples for the agents on the JCS threat list. Many military installations do not have U.S. military treatment facilities on site; installation Commanders, operational level Commanders, and Services that have forces and facilities not served by an MTF will determine if sampling is necessary based on the mission priority of the facility/unit, and will establish an interim medical surveillance system. Additionally, Commanders must review mutual support agreements with off-installation support activities and identify requirements in the event of a biological attack. Mutual support agreements must be exercised regularly.

Operational level Commanders and the Services will establish procedures for the surveillance of Reserve and National Guard units based on their priority to mission-essential OPLAN execution.

k. Establish Laboratory Capability

The issue of transporting suspected or confirmed biological agent samples across international boundaries becomes more problematic every day. The denial of landing/movement rights for vehicles (air/land/water) transporting samples could, at a minimum, delay definitive defensive actions or, at worst, render the samples useless. Initial sample analysis results, produced by a technology more sensitive and more specific than fielded DoD tactical identification systems, must be available no latter than 12 hours after receipt of the sample. The Combatant/Regional Commands should establish sufficient laboratory capability in each country where U.S. forces are deployed to enable all defense operational and medical actions/decisions. Commanders should

consider the use of ship laboratory capability as a possible political and operational solution.

1. Actions and Criteria for Actions

Each facility/organization will establish an action list or standard operating procedure (SOP) for identification of a biological attack, and the response to such an attack. This should be synchronized with the installations anti-terrorism/force protection weapons of mass destruction plan. Examples of material included in this SOP include biological detector employment procedures; medical surveillance procedures; point of contact for information; prophylaxis and treatment regimes; assistance augmentation; notification and warning procedures; public relations guidance; physical security; initial quarantine preparation actions; etc. An action list should be prepared for each specific agent on the AOR/JCS threat list and should be standardized across the AOR to the extent possible. All procedures, SOPs, etc., will be included in installation/unit operational or emergency operations centers.

m. Exercise and Training

Each installation/unit will plan and execute exercises for all aspects of biological defense at least once every 12 months; this includes all interactions with the local, state, and federal agencies. Operational level Commanders will exercise all support plans and alternative mission accomplishment plans.

Training requirements – individual, group, and unit – will be identified, resourced, and executed. The planning, training, and exercise for biological warfare defense must be integrated into all aspects of operations. Response will vary in scale from procedures for handling suspicious packages to enforcing and supporting quarantine for large units or groups of units, as well as civilian interface.

n. First Responders

This operational concept does not specifically address the role of first responders in biological warfare defense; while they have a role, it is well documented for normal operations and there has been copious guidance published recently for such personnel at the TTP level.

3. Daily Activities

This section discusses actions that should occur daily. Each facility/unit should include biological warfare defense and consequence management in all daily operations, briefings, and staff meetings.

a. Detection Duty Cycle

Detector duty cycle will be reviewed at least daily for those units/facilities with the capability; detector duty cycle and readiness states will be included in daily situational and staff briefings at all levels.

b. Medical Surveillance

Medical surveillance will be executed daily for those units/facilities with the capability. If necessary, facilities and units will maintain internal records of disease and non-battle injury (DNBI) rates on a daily basis and institute a system to analyze the data daily. Combatant Commanders will establish criteria for action based on change in these rates.

In general, eligible personnel usually refrain from attending sick call, acute minor illness clinics, etc., on an individual basis until they decide they really need medical advice. For biological defense, all personnel should be encouraged to seek medical assistance at the earliest opportunity. This greatly increases medical workload but may be the only way to increase the probability of early clinical detection and identification of a biological attack. Commands may wish to encourage a "if you feel sick, go to the clinic" approach to facilitate early medical screening.

c. Collective Protection Duty Cycle

Collective protection duty cycle and readiness states will be included in daily situational and staff briefings at all levels.

d. Operational and Physical Security Emphasis on Biological Warfare Defense

All normal operational security, conventional defensive actions, and physical security actions enhance biological warfare defense. Commanders should ensure that physical security personnel are particularly knowledgeable on the possible indicators/means of covert biological warfare dissemination. Operational and physical security are executed daily and reviewed daily as threat levels (conventional) change.

e. Environmental Monitoring and Archiving

All meteorological data and any other environment data must be preserved, on a daily basis, for use in forensic and post exposure operational decision-making. There- should be standard data recording and preservation procedures throughout the AOR.

4. During

Actions taken during an attack are limited to those cases where there is evidence of a possible attack; this includes overt attacks by a conventional delivery system or conventional munitions. For example., if there is a ballistic missile or aircraft attack warning, personnel should be masked or enter collective protection as a precaution against biological attack. Local Commanders should establish "all-clear" criteria based on cloud time of arrival and pass time assumptions for agents derived from Allied Technical Publication 45. Placing personnel in field-expedient collective or individual protection may be effective in reducing exposure. Personnel must leave the field-expedient enclosure after the all-clear (using the ATP-45 assumptions). While tests indicate field-expedient measures may reduce exposure, they do not eliminate exposure. There is no current system to assess the effectiveness of field-expedient measures other than in a laboratory. Such measures may be employed as required, but protection assumptions should not be included in consequence management requirements planning.

a. Alert and Warning to Others

All attacks by conventional delivery systems or conventional munitions are reported throughout the chain of command, as well as laterally. Units/facilities should initiate biological warfare defense actions based on possible biological warfare inclusion in "conventional" attacks; as an example, activating the sampling team given the possibility of SCUD impacts. Commanders with biological detection assets will warn other units and organizations based on procedures outlined in ATP-45. Civilian entities in the U.S. and, where applicable, foreign civilian and military authorities must be warned as well. Operational level commanders will publish guidance for issuing warning, both in CONUS and OCONUS.

b. Sample Collection, Transportation, and Analysis

Commanders at all levels will establish, resource, tram, and exercise for the collection of possible biological warfare samples. SOPs for existing military detectors and detection kits will be formalized by operational Commanders and coordinated across AORs. Procedures also must be established to sample during any event that could cause the dissemination of a biological agent;

these include but are not limited to bomb, missile impact, high explosive covert detonations, unusual spray devises, etc. Across the AOR, laboratory support must be in place and managed to serve units as they deploy or maneuver. Transportation of samples across international boundaries or in some instances between states/local jurisdictions may be politically sensitive.

5. After

The list below enumerates actions taken after an attack (these actions have been discussed in the "Before" section of this Appendix). The list is provided as the basis of a checklist for unit or facility use.

Attack determination

- Detection
  - Medical surveillance disease or symptoms
  - Other warning, explosion scud etc

ID agent / disease

- Detectors
- Clinically
- Sampling

Warn as appropriate

Initiate prophylaxis as appropriate

Initiate treatment as appropriate

Coordinate and communicate; Up chain of command; Outward liaison local, etc.

PR, internal and external

Ensure operational infrastructure

Mission triage reassignment

Obtain augmentation

Contagion control

Control access

Enforce hygiene and safety awareness

APPENDIX B

AGENT RESPONSE TIME LINES

The relative times of occurrence pictured in the accompanying figures are not precise. For example, in a best-case scenario, technical detectors provide information at 1 hour and 24 hours,[1] as shown. Realistically, there is some unknown probability that the devices will detect the agent release. Similarly, the time range for onset and outcome of the disease are approximate and shown in the absence of treatment. Data on the effects of these agents on humans from a biological agent instead of the naturally induced form of the disease are sparse. Secondary infections from contagious agents are not shown.

Note the time ranges for medical detection. These time ranges include detection based on surveillance of disease incidence, clinical diagnosis, and clinical laboratory identification. The actions of medical personnel and their ability to commit resources can move the "detection" along this continuum.

Finally, the figure displays the significance of post-exposure prophylaxis by indicating the timeframe during which it is effective. The earlier prophylaxis is implemented, the more successful it will be at preventing disease.

The information presented is for that portion of the exposed population that is infected/intoxicated by an attack, i.e., those personnel who will eventually become casualties or fatalities. The actual number of personnel affected by any attack will vary greatly. In each figure, the green portion of the bar represents those who are not sick but will become ill; the yellow represents those who are ill; the red represents those who become fatalities. Note that in several cases, a second green portion on the right side of the bar shows recovery. Technical detection times are indicated on the horizontal time axis and a black line above each agent bar represents medical detection times. The "prophylaxis window" is shown in purple. For agent such as anthrax and plague, when prophylaxis becomes less effective with the passage of time, the bar is shown diminishing at an angle. Where prophylaxis may be administered effectively any time within a window, as shown for smallpox and Q fever, the bar is as a rectangle. Where there is no bar, the administration of prophylaxis is ineffective

The rule of thumb for biological defense is: take action as early as possible, whether it is protection, prophylaxis, or implementing alternative courses of action for mission accomplishment.

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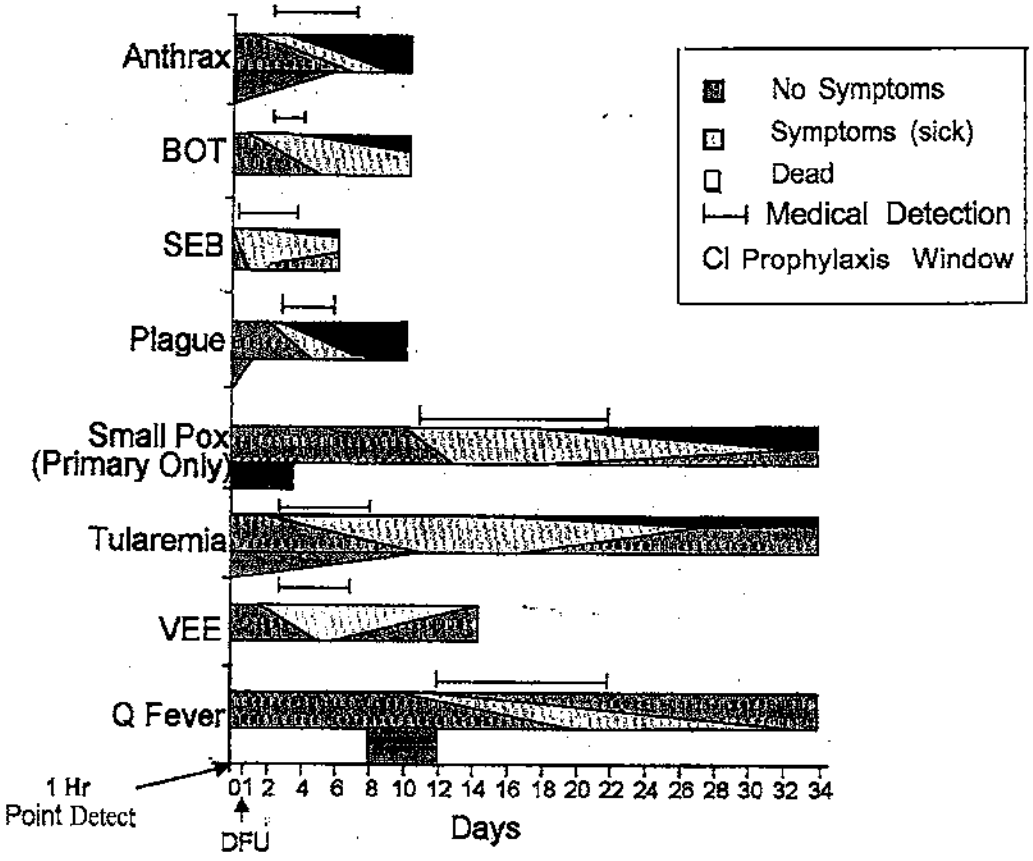
[1] Automated biological detection systems such as the BIDS and Portal Shield are assumed to provide hourly output, while systems such as the dry filter unit (DFU) are assumed to provide output every 24 hours (12 hour collection and 12 hours to transport and analyze).

Time Course of Disease:
Indicating Detection and Prophylaxis Window



APPENDIX C

TECHNICAL DESCRIPTION OF BIOLOGICAL AGENTS

This Appendix is extracted from "Force Protection And Operations In a Biological Warfare Environment, Commanders Guidelines," dated 18 June 2002, pages 5 through 15 and has been modified for presentation. It is used by permission of the Policy Division, Directorate of Nuclear and Counter proliferation, Deputy Chief of Staff, Air and Space Operations, HQ USAF.

1. Understanding the Characteristics of the Biological Threat

Because BW events and agents vary so dramatically, a "one size fits all" response to a BW event will not work. The Commander must be conversant with the basic technical parameters associated with BW in order to think through and to shape an effective response.

To aid in developing this understanding, this section covers:

- **Basic inforination on biological agents, including the types of agents, their characteristics, and how agents incapacitate or kill**
- **Likely delivery systems**
- **Operational impacts, including conditions that affect the potential intensity and duration of an event, and the number of personnel likely to be affected**
- **Trigger events indicating that a BW event has likely occurred**
- **Mitigation strategies and their limitations**

a. Agent Characteristics

Biological agents are organisms or chemicals produced by organisms that affect humans in different ways. Some kill while others incapacitate; some act quickly while others incubate for several weeks; and some are contagious while others are not. Vaccinations, prophylaxis (medicines given before sickness), and treatments (after sickness) exist for some, but not for other. Before assessing impacts of biological weapons, one must first understand the nature of likely biological agents and how they work.

Types of Agents

Biological agents are either pathogens or toxins. Pathogens are microorganisms that directly attack human tissue and biological processes and include three categories: bacteria, viruses, and Rickettsia.

Pathogens vary **in their characteristics and in their treatments.**

- *Bacteria (e.g.,* **anthrax, tularemia, plague) are living single cell organisms, which can grow and reproduce in the environment, in plants, animals, or humans. Bacteria are susceptible to antibiotics, but can develop resistance to antibiotics as strains evolve in nature, or as the result of the intentional genetic manipulation of strains. Vaccines exist for some bacteria as well.**
- *Viruses (e.g.,* **VEE, smallpox) are smaller than bacteria, do not grow, and require a living host cell to make new copies of themselves. Antibiotics have no effect on viruses, but anti-viral agents such as vaccines can limit some viral illnesses.**

- *Rickettsia (e.g.,* **Q-fever, Rocky Mountain Spotted Fever) are intermediate in size, contain nearly everything necessary to make new copies of themselves, but rely on infected cells to make new copies. Antibiotics are effective against Rickettsia.**

- *Toxins are* **poisonous substances naturally produced by bacteria, plants, fungi, snakes, insects, and other living organisms. Common toxins include Botulinum toxin (produced by bacteria); Staphylococcus Enterotoxin B, or SEB (produced by bacteria); and ricin (produced by a plant). Toxins act to destroy organisms by overwhelming the organism's ability to rid itself of the poison it produces (intoxication). Bacteria can destroy organism via both infection and intoxication. Plants, fungi, snakes, insects, and other living organisms intoxicate their victims via more direct means (injection, contact, ingestion), while viruses have no ability to intoxicate whatsoever.**

Agent Effects

How devastating a BW agent will be on the human body depends on a number of variables. Note: minor changes in any one variable can result in a significant difference in the effectiveness of the attack, as well as in the effectiveness of the appropriate response.

Key variables include:

- ***Exposure levels.*** Since many medical countermeasures are time sensitive, how much of a particular pathogen or toxin an individual is exposed to affects both the lethality and the timing of the onset of symptoms.

- **How *the biological agent enters the body.*** The point of entry of the pathogen or the toxin often determines the lethality of the disease or poison. For example, anthrax has three possible points of entry: openings in the skin (cutaneous anthrax), ingestion (gastrointestinal anthrax), or inhalation (inhalational or pulmonary anthrax). The three forms of anthrax differ in number of organisms necessary to cause infection, fatality rate, and responsiveness to antibiotic therapy after onset of symptoms.

- ***Time to onset of symptoms and incubation periods.*** Some agents work within hours while others have incubation periods as long as several weeks. This matters because it complicates determining whether or when an attack occurred, how widespread are the effects, and what are the available treatment strategies.

- ***Extent of communicability.*** Certain diseases, such as smallpox and hemorrhagic fever, which are contagious, pose a greater challenge. These

challenges include the risk to those in close contact – including medical caregivers and the problems of separating the ill from those susceptible to becoming ill if exposed.

- ***Incapacitation v. lethality.*** Some agents kill while others only incapacitate their victims. Again, treatment and operational strategies are influenced by these factors. Where fatalities occur, there are varying periods of incapacitation prior to death.

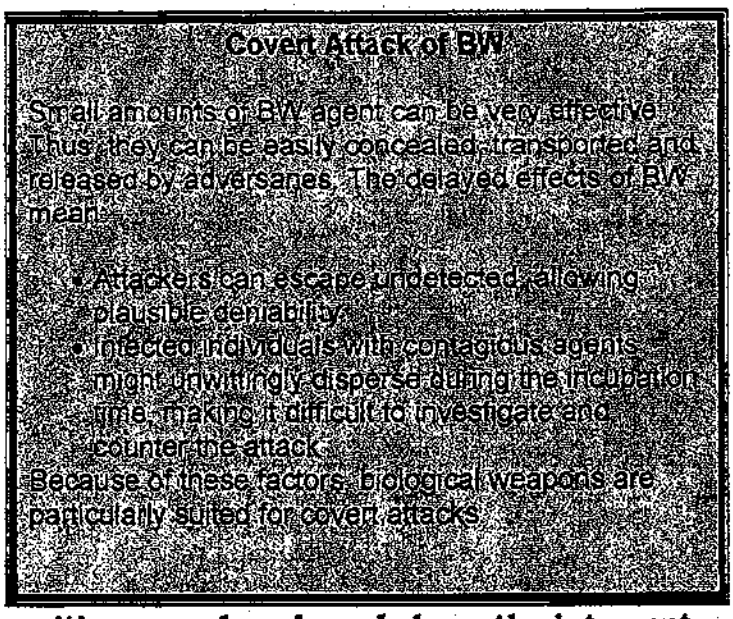
b. Weaponization and Dissemination

Knowing how an agent can be disseminated is critical to shaping an effective response because the size, shape, intensity and overall effectiveness of the agent deposition pattern is influenced by the delivery method. The attacker is likely to consider a number of issues when choosing a means of delivery, including ease of accessing and cost of weapons systems, size of targeted area, likelihood of successful delivery (i.e. penetration of defenses, susceptibility to meteorological uncertainties), covertness, and safety to the delivery tear-n.

Weaponized BW Deliver-v

- **Theater** ballistic missiles *(TBMs)* **are a viable delivery means for many agents. With bulk warheads, release can be explosive or line release.**

- *Submunitions* **The size of the submunition pattern allows area targets to be more effectively contaminated. Coordinated salvos of TBMs, which would likely ensure at least one missile penetrating active defenses, pose even a greater challenge. Intercepted bulk-filled missiles do not affect the targeted airbase. However, in many designs, the submunitions may be released above the intercept altitude – or only a small number of the submunitions become damaged by current active defense systems.**



- *Ground sprayers can also* **be used to deliver agent. Because ground sprayer attacks will be initiated relatively close to the target, precise, real-time wind data can be used to select a place and time of release to optimize accuracy. Ground sprayers can be stationary or vehicle-mounted. If released from a moving vehicle, the resulting line source can cover a very large area, but attackers risk being detected.**
- *Aircraft sprayers,* **as an airborne line source, can yield dosage patterns that cover very large areas. Since these patterns can be several hundred kilometers long, agents can be released far upwind of the intended target area. Remote releases may allow attackers to avoid having to penetrate air defenses. Warning and alert of attacks of this type depend on the ability to closely monitor enemy air traffic patterns and identify suspicious flight profiles.**
- *Mortar, artillery, and multiple rocket launchers (MRLs) are* **well suited to deliver biological agents. Artillery attacks can deliver an extremely large amount of agent very accurately. Shells filled with biological agents can be used in a combined attack with chemical and conventional explosive shells, making it difficult to recognize the event as a BW attack.**

Other Means of BW Delivery

In addition to weapons-associated delivery of BW, BW can be disseminated through other means.

- ***Vector-mediated delivery*** occurs when insects or other animals are utilized to disseminate BW agents. Vector-mediated delivery allows for clandestine release that is hard to identify or to attribute to a specific adversary. The Japanese used plague-infected fleas with devastating effect against the Chinese. As recently as 2000, there was concern that West Nile Encephalitis was a deliberate biological event until it was proven to be an endemic event.
- ***Fomite spread.*** Using inanimate objects (fomites) to spread agents is another potential way to disseminate biological agents, such as smallpox. Evidence suggests that while the primary means of transmission of smallpox is person-to-person contact, smallpox virons can also be spread via human contact with contaminated surfaces or by aerosolization, increasing the hazard of the spread of contagion. The recent case of anthrax-mixed powders shows the efficacy of fomite spread.
- ***Food or consumer product contamination.*** Food or other products for human consumption are also a group vulnerable to BW contamination. Many can be laced with pathogens, such as the

salad bar contaminated with Salmonella to keep voters away from the polls. Another example would be the inadvertent contamination in a meat processing plant utilized by a food chain for their hamburger supply that resulted in E. coli illnesses. Other products can be spiked with poisons, as was the case with the injection of Chilean grapes with cyanide in March, 1989 or the Tylenol product tampering cases of in the 1980s.

- ***Water contamination.*** Water supplies are a potential means for biological attack since some pathogens can grow in water, survive for considerable lengths of time, or survive normal chlorination and filtration treatments in municipal water supply systems. Similarly, toxins, which are generally unresponsive to normal water treatment, can be transported via water supplies. However, the amount of agent required having an operational impact make this a less likely means of delivery. On the other hand, attacking a specific building by creating a high-pressure "tap" of the water supply is technically straightforward and requires less agent.

c. Operational and Force Protection Impacts

It is critical to note that biological weapons differ from chemical weapons in operationally significant ways that dictate different responses and risk trade-offs. A few key differences are illustrated in the following table.

		BIOLOGICAL
Release/Site of Weapon	Quickly discovered, possible to cordon off contaminated/ attack areas	Difficult to identify, probably not possible or useful to cordon off area of attack
Manifestation of Symptoms	Rapid, usually minutes to hours after an attack	Delayed, usually days to weeks after an attack (except toxins)
Distribution of Affected Patients	Downwind area near point of release	Widely and rapidly spread, difficult to track or predict
Signatures	Easily observed (colored residue, dead foliage, pungent odor, dead insect and animal life)	Typically no characteristic signatures immediately after attack
Medical Counter-	Chemical antidotes	Limited vaccines, antibodies, and/or antitoxins and

[redacted]		antivirals for some agents
[redacted]	After decontamination and or weathering, no further need for protective measures or risk of further contamination	Patient isolation / quaran tine crucial if communicable disease is involved

A biological attack is a very complex process that depends on several technical factors, all of which determine its operational impact. These factors fall into three categories: lethality factors, environmental factors, and source factors.

Lethality

The lethality of an agent, or the rate at which it kills its victims, has an obvious impact on force protection and operations. Many factors contribute to the lethality of event, including agent effects, discussed in Section A above. Of additional note:

- Potency. The potency of the agent will partially dictate the number of casualties relative to agent delivered. Highly infective agents are more lethal because less mass is required.
- ***Particle*** Size. Only small particles (1-10 microns) will reach the lower lungs, where they can cause harm. Size is a function of how the agent is manufactured and processed for weaponization.
- ***Means of entering the body.*** Almost all BW agents are more effective if inhaled. For physical reasons, different sized particles will become embedded in different parts of the respiratory system. Therefore, for any batch of agent, the distribution of particle size is a key lethality factor. Anthrax is a good example. The lower respiratory system provides the conditions for anthrax to survive, grow, and multiply. Anthrax spores must reach this area to cause inhalational anthrax and only particles from 1-5 microns will reach these areas with high efficiency. Therefore, lethal dose is dependent on particle size distribution. Other agents infect different sections of the respiratory system and must be released in appropriate particle sizes to be effective.

Source Factors

Source factors expand the number of possible scenarios that must be considered before a response is structured. More specifically, source factors include fill type (or how the agent is manufactured) and release mechanism.

- ***Fill*** type. Agents can be produced in a variety of forms depending on the manufacturing process. For example, anthrax can be manufactured as a

wet slurry or as a dry powder. Anthrax transport and diffusion is much more efficient as a dry powder than as a wet slurry, but it is more difficult to weaponize and to handle. Thus, how it is manufactured depends on the expertise of the attacker and his equipment/infrastructure.

- ***Release mechanism.*** The mechanism for release has a significant impact on how much of the agent survives the release event and the size, shape and concentration of the pattern of dispersion.

Environmental Factors

Environmental factors encompass agents' interaction with the ambient environment, from the point of release until inhaled by a human. Environmental factors will dictate the size, shape, dosage at inhalation, height of agent deposition, and concentration of agent deposition patterns on the ground. Thus, environmental and weather conditions can be extremely critical to determining how effective the attack will be, particularly with certain delivery systems. Some have suggested that this factor is so critical that weather and time of day can provide a guide to protection options in a high threat situation. More specifically:

Environmental and weather conditions can be extremely critical to determining how effective the attack will be, particularly with certain delivery systems. Some have suggested that this factor is so critical that weather and time of day can provide a guide to protection options in a high threat situation.

- ***Wind speed and direction. Since*** BW agents are released as small particles and aerosols, they tend to move with the winds. Stronger winds move the clouds faster, resulting in lower exposure. In calm conditions, **the** agent cloud stays close to the release site. This results in a significantly higher risk of exposure, which lasts until the wind speed increases enough to move the agent containing air package downwind. However, these wind conditions can actually lead to larger casualties depending on position of personnel and the type agent. A very infectious agent moving rapidly over terrain will expose more people but at an effective level to cause casualties. The same release, lingering in a smaller area will effect less personnel overall. All interactions for BW are agent specific
- ***Atmospheric stability, layering and mixing.*** A successful attack requires the agent mixing with air. This is caused by turbulence in the atmosphere. Stable layers restrict vertical movement of agent particles, **so** agent released below an inversion remains available for inhalation, and causes a higher likelihood of exposure. Agent released above an inversion may not be able to penetrate the inversion layer, so mixing

down to the ground would occur only when the inversion layer is broken-- perhaps at dawn-- well downwind from the release point.

- ***Terrain.*** Landforms, buildings and surface coverings (trees, brush, sand, asphalt) influence the channeling of local wind, and affect spatial agent distribution.

- ***Rates of biological decay or inactivation in the atmosphere.*** Biological agents decay in the atmosphere at different rates based on heat, humidity, and exposure to UV light, but most will survive for relatively short periods (minutes to hours) in the open atmosphere. The relatively low rate of biological decay of anthrax spores makes anthrax an attractive BW agent. Anthrax can survive between 1 and 2 days in the air. Since UV light is the primary cause of anthrax spore decay, night attacks would likely be most effective, but daytime attacks can still be effective on a fixed site target. SEB and Ricin decay very little. Ricin is not very toxic, so this benefit is offset.

- **Rates of decay in soil, water, and on surfaces.** In a weaponized release, the level of deposition onto ground surfaces is very low. Agent survival on surfaces is an important characteristic for considering the risk from reaerosolization and the need for decontamination. Anthrax spores and smallpox virons have been found to be quite stable in soil (many years).

- ***Time of day.*** Because each agent biologically decays at a different rate depending on temperature, humidity, and UV light intensity, the time of day affects the operational impacts of an attack. In general, nighttime or early morning, with its lower temperatures and UV light, provides the best conditions for successful BW attacks because of lower biological decay – and because neutral and inversion conditions – especially with low wind speeds – result in agent clouds which maintain lower physical decay (i.e. spreading of the biological agent over time.)..

- *Potential for reaerosolization.* **Most biological agents are not persistent, and will decay within hours or days under exposure to the environment. However, anthrax spores can survive in a non-vegetative state for years if embedded just beneath the surface where they would be shielded from W radiation, temperature, and humidity effects. Some evidence, including the recent experience with anthrax, suggests that, if disturbed, anthrax can reaerosolize, possibly generating a local dosage hazard.**

APPENDIX D

HIGH-LEVEL AND CROSS-CUTTING ACTIONS REQUIRED TO IMPLEMENT A DOD-WIDE OPERATIONAL CONCEPT FOR BIOLOGICAL DEFENSE

Traditionally, operational concepts, doctrine, tactics, techniques, and procedures have been a Service responsibility. As warfare became global (e.g., total war, attacking civilian population centers and strategic industries) and military technology became more complex and capable (ballistic missiles, nuclear weapons, stealth, biological weapons, etc.), more and greater multi-Service and joint doctrine has evolved. Biological defense particularly calls for broad, all-encompassing doctrine. However, to effectively derive and implement such a doctrine and then implement it at the TTP level; many issues must be addressed at the senior policy and joint operational level. This Appendix lists many of the issues that must be addressed from the top down, and standardized across the Department of Defense, for both operational warfare and homeland defense/force protection. Today, there is no one center of operational and scientific expertise responsible for biological defense. Without such an operationally empowered focal point, it will be difficult if not impossible to implement the operational concept described in the body of this paper.

- OSD and the JS must establish a central point of expertise for biological defense operations and leadership at the national military level.
- OSD, Joint Staff, Combatant Commands, and the Services must conduct strategic vulnerability analyses, identifying those assets that must be protected from biological warfare effects.
- OSD and JS must establish a biological warfare red team capability to identify national military vulnerabilities to biological warfare attacks.
- OSD, JS, Combatant Commands, and Services must establish appropriate biological warfare surveillance assets (personnel, units, and systems), processes, and fusion centers.
- JS and Combatant Commands must implement a system to characterize the worldwide environmental background as it pertains to biological defense/ detection, with initial priority based on current threat information and OPLANS.
- OSD and JS must provide the Combatant Commands standardized decision aids to assist in epidemiological detection.
- OSD, JS, Combatant Commands, and Services must implement a single, worldwide medical surveillance system.
- The Combatant Commands must establish common criteria for action, based on indications and warning.
- The Combatant Commands and Services must plan for the deployment and support of biological detection systems. Additionally, specific common biological detection doctrine and decision aids relating risk, technical capability, cost, and operational effectiveness,

etc., must be developed/ coordinated by OSD and JS and provided to the Combatant Commands and Services.

- JS, Combatant Commands, and Services must establish common criteria for action, based on the output of technical biological detection devices.
- JS, Combatant Commands, and Services must establish criteria for action, based on epidemiological detection.
- OSD and JS must establish standard procedures for sample collection, handling, transportation, and processing. The Combatant Commands and the Services must implement the sampling procedures as established by OSD/ JS.
- OSD and the JS must establish a set of standard definitions and performance descriptors for identification.
- Combatant Commands and Services must establish common criteria for action, based on identification.
- OSD and JS must establish and maintain a worldwide joint military biological warfare warning and reporting system above and beyond that specified in the U.S.-approved version of the Allied Technical Publication-45.
- Combatant Commands and Services must determine warning and reporting criteria, based on current capabilities and mission risk tolerance.
- OSD, JS, the Services, and the Combatant Commands must establish and maintain biological warfare warning and reporting centers.
- Combatant Commands and Services must develop physical protection criteria based on mission accomplishment and risk.
- Combatant Commands and Services must establish criteria for masking and unmasking.
- Combatant Commands and the Services must maintain collective protection in continuous operation, or establish standard criteria for initiating and ceasing collective protection.
- OSD and JS must develop and provide the Combatant Commands and Services with a list of approved and investigational new drugs for prophylactic use, as well as standard guidance for such issues as informed consent. Additionally, this document should include planning guidance on the expected effectiveness of prophylaxis.
- OSD and JS, in coordination with the Combatant Commands and Services, must determine the requirements for prophylaxes, resource the capabilities to prophylax personnel, and establish criteria for administration.

- 3 Combatant Commands and the Services must plan for and resource the medical treatment of mass biological casualties.
- 3 Combatant Commands and the Services must establish their requirements for and their capabilities to treat personnel at the various levels of care (heroic, optimal, etc.)
- 3 OSD, JS, and Combatant Commands assess the requirement for replacements, individual and unit, in coordination with the Services. This action should be linked to the strategic vulnerability analysis, resources, and mission accomplishment
- 3 OSD and JS, in coordination with the Combatant Commands, Services, and concerned federal agencies, must develop standards for biological warfare agent decontamination, risk guidance, and, as required, guidance for the retrograde of personnel and material from an active biological warfare theater.

❖ OSD and JS must prepare the overall information plan for biological warfare defense and coordinate with the Services and Combatant Commands for implementation.

- 3 Combatant Commands, in coordination with OSD, JS and the Services, must develop and resource alternative operational plans to maintain mission accomplishment within a biological warfare environment.
- 3 OSD, JS, and the Services must establish and resource the appropriate professional education and provide the Combatant Commands, OSD, JS, and the Services qualified biological warfare defense experts.
- 3 OSD, JS, the Combatant Commands, and the Services must ensure adequate and realistic biological warfare defense exercises are conducted and biological warfare defense is properly integrated into other exercises.
- 3 OSD, JS, the Combatant Commands, and the Services must establish a system for measuring and reporting biological defense readiness.
- :* OSD, JS, Combatant Commands, and the Services must track personnel movements (units, groups, or individuals) in sufficient time and detail to implement medical countermeasures.
- 3 JS must establish a set of unique and standard definitions for biological warfare defense terms, a lexicon, and update the JCS Pub 1-02, The Dictionary of Military Terms, accordingly.
- 3 OSD, JS, Combatant Commands, and the Services need to understand, assess, and plan for the implications of biological warfare attacks on agriculture or other economic targets such as fuel; DoD specialty manufacturing facilities, etc.

- OSD must publish comprehensive guidance for mortuary affairs; the JS, Combatant Commands and Services must implement the guidance.
- OSD must establish and publish a comprehensive vaccine policy.
- OSD must obtain the required Service end strength increases to support implementation of this operational concept.
- Combatant Commanders and Services must publish priorities for collective protection installation and guidance for operation.
- The Combatant Commands, Services, JS, and OSD must derive standard planning guidance to estimate the effectiveness of prophylaxis.

STANDARDIZED COMMENT MATRIX PRIMER

The matrix below is a Word document table to be used as a template for submitting comments on draft publications and draft program directives. Except as noted below, an entry is required in each of the columns. To facilitate consolidating matrixes from various sources, do not adjust the column widths. Use the column headings in the document header as a guide to adjust column widths.

Column 1 – ITEM
Numeric order of comments. Accomplish when all comments from all sources are entered and sorted. To number the matrix rows, highlight this column only and then select the numbering ICON on the formatting tool bar.

Column 2 - #
Used to track comments by source. Manually enter numbers from the first comment to the last comment. These numbers will stay with the comment and will not change when consolidated with other comments.

Column 3 – SOURCE

J1 -J-1
J2 - J-2
J3 - J-3
J4 - J-4
J5 - J-5
J6 - J-6
J7 - J-7
J8 - J-8
USA – US Army
USN – US Navy
USMC – US Marine Corps
USAF - US Air Force
USCG – US Coast Guard
CENTCOM - US Central Command
EUCOM - US European Command
JFCOM - US Joint Forces Command
PACOM - US Pacific Command
SOCOM - US Special Operations Command
SOUTHCOM - US Southern Command
SPACECOM - US Space Command
STRATCOM - US Strategic Command
TRANSCOM - US Transportation Command
DTRA – Defense Threat Reduction Agency
DIA – Defense Intelligence Agency
DLA – Defense Logistics Agency
MDO – Missile Defense Organization
NSA – National Security Agency
DISA – Defense Information Systems Agency
NIMA – National Imagery and Mapping Agency
LC – Joint Staff Office of Legal Counsel

Column 4 – TYPE
C – Critical (Contentious issue that will cause non-concurrence with publication)
M – Major (Incorrect material that may cause non-concurrence with publication)
S – Substantive (Factually incorrect material)
A Administrative (grammar, punctuation, style, etc.)

Column 5 – PAGE
Page numbers expressed in decimal form using the following convention:
(Page I-2 = 1.02, Page IV-56 = 4.56, etc.) Enables proper sorting.

0 – General Comments
0.xx - Preface, TOC, Executive Summary (Page i = 0.01, Page XI = 0.11)
1.xx – Chapter I
2.xx – Chapter II
3.xx - Chapter III
x.xx – Chapter x, etc.
51.xx – Appendix A
52.xx – Appendix B
52.01.xx - Annex A to Appendix B
53.xx – Appendix C, etc.
99.xx – Glossary

NOTE: For Program Directives enter the page number as a whole number, (1, 2, 3, etc.) PDs are normally sorted by paragraph and line number and the page number helps to find the paragraph.

Column 6 – PARA
Paragraph number that pertains to the comment expressed. (i.e. 4a, 6g, etc.)

NOTE: An entry in this column should be used when commenting on draft program directives. An entry is optional for comments on draft joint publications.

Column 7 – LINE
Line number on the designated page that pertains to the comment, expressed in decimal form (i.e., line 1=1, line 4-5 = 4.5, line 45-67 = 45.67, etc.) For figures where there is no line number, use "F" with the figure number expressed in decimal form (i.e. figure II-2 as line number F2.02). For appendices, use the "F" and the appendix letter with the figure number (i.e appendix D, figure 13 as line number FD. 13; appendix C, annex A, figure 7 as line number FCA.07)

Column 8 – COMMENT
Comment text in line-in-line-out format according to JSM 57 11.01A, *Joint Staff Correspondence Preparation* (Examples are provided in JP 1-01, Annex A to Appendix E). To facilitate adjudication of comments, copy complete sentences into the matrix so that it may not be necessary to refer back to the publication to understand the rationale for the change. Do not use Tools, Track Changes mode to edit the comments in the matrix. Include deleted material in the comment in the strike through mode. Add material in the comment with underlining. Do not combine separate comments into one long comment in the matrix, (i.e. 5 comments rolled up into one).

Column 9 - RATIONALE
Provide concise objective explanation of the rationale for the comment.

Column 10 - DECISION
A - Accept
R – Reject (Rationale required for rejection.)
M - Accept with modification (Rationale required for modification.)

NOTE: This column is for the LA and JSDS use only. No rationale required for accepted items. Rationale for rejection is placed in the rationale comment box and highlighted for clarity. For modifications, the complete modified language will be placed (and annotated) as the bottom entry for that item in the "Comments" column and the rationale for the modification placed in the rationale comment box and highlighted for clarity.

TIPS AND TRICKS OF **THE** TRADE

Headers and Footers

1. Publication name
2. Classification (Unclassified/Secret/ etc.)
3. Column headings
4. Filename (insert **from** header/footer drop down menu)
5. As of "date" (insert from header/footer drop down menu-manually enter date when **finalized** for tracking purposes)
6. Page X of Y (insert from header/footer drop down menu-manually enter last page number for Y when finalized-tracks total # of pages and does not default back to actual page #)

Combining Matrixes

1. Select all and correct for font and font size (Times New Roman, #10).
2. Copy one entire matrix and paste it a few lines below the last row of another matrix.
3. Adjust column widths as necessary to match one matrix with the other (use the column headings in the document header as a guide).
4. Merge the matrices into one by deleting the lines between the two.

Item (row) numbering (automatic numbering)

1. Highlight column number 1 from top to bottom.
2. Delete the existing number and then renumber by selecting automatic line numbering on the formatting tool bar.

Sorting

1. Select: "Table" on top menu **toolbar**.
2. Select: "Sort."
3. Select: "Sort by, Column 5 (Page column), Number, Ascending."
4. Select: "Then by, Column 7 (Line column), Number, Ascending."
5. Select: "Then by, Column 4 (Type column), Text, Descending."

Executive Summaries

Do not make comments on the executive summary until the FC. Main body text will be copied and pasted into the executive summary reducing the amount of time spent on making the two accurate. The contractor with LA and/or JSDS input will include an executive summary in the FC released for review and comment.

[illegible]		UR		[illegible]	[illegible]	[illegible]	COMMENT	RATIONALE	DECISION (A/R/M)
1.	1	J7	M	0.0			General Comment. The definition of "apportionment (air)" was changed in the revision to JP 3-0. This new definition is provided in the glossary but it is not used in the text. The text still speaks of apportionment by geographic areas. This should be corrected throughout the text. Specific comments will follow.	Consistency with JP 1-02 and 3-0.	A
2.	2	J7	A	1.01	1	19	Change to read as follows: "The ~~J~~joint ~~F~~force ~~C~~commander (JFC) may retain C2 of joint air operations and use the joint staff to plan, and execute on the JFC's behalf. The JFC may also organize and conduct air operations through the Service Component Commanders ~~to the joint task force (JTF)~~. This publication addresses **operational relationships, policies and procedures** for C2 of joint air operations through the **designation of a joint force air component commander (JFACC) or use of the JFC's staff.**"	Correctness. This publication applies to all levels of JFCs. The publication does address the JFC staff option.	A
3.	3	J7	A	1.01	1	28	Change to read as follows: ". . .the designation of a joint force air component commander (JFACC). Commanders of unified commands, subordinate unified commands, and ~~joint task forces (~~JTFs~~)~~ should establish implementation policies . . ."	Add period for correctness. Correct use of acronym. R-Acronym established earlier.	R
4.	4	J7	C	1.11	2	51	Change to read as follows: "Joint forces are organized on the principles of centralized planning and direction and decentralized execution. ~~However, in joint air operations, unity of effort is accomplished through centralized control coupled with decentralized execution. Centralized control amplifies on 1's key consideration of centralized planning places the responsibility and authority planning, directing and coordinating a military operation or group/category of operations under a single commander.~~ Centralized ~~control~~ planning and direction does not confer command authority over assets. Command authorities are defined by the JFC. Centralized ~~control~~ planning and direction is essential for ~~effective employment of all available forces~~ controlling and coordinating the efforts of the forces." **Modify to read as follows**: "Joint forces are organized on the principles of centralized planning and direction and decentralized execution. However, in joint air operations, unity of effort is accomplished through centralized control coupled with decentralized execution. Centralized planning and direction does not confer command authority over assets. Command authorities are defined by the JFC. Centralized	Consistency with JP 1, Chapter V, para 5c, JP 0-2, Chapter V, para 1c, and JP 3-0, Chapter II, para 6a. This concept has been changed in joint doctrine and must be changed in this publication. **LA/JSDS Mod**: The correct joint doctrine terminology is centralized planning and direction and decentralized execution.	M

ITEM	#	SOURCE	TYPE	PAGE	PARA	LINE	COMMENT	RATIONALE	DECISION (A/R/M)
							planning and direction-is essential for effective employment of all available forces."		
5.	1	JCS/LC	S	2.04		F2.02	Change figure and caption of figure to read: "Objectives of Air Space Control."	Accuracy and consistency with Fig. II-3 on page II-5.	A
6.	2	JCS/LC	A	2.06		80	Change to read "(IOs) s, PVOs . . ."	Typo.	A
7.	3	JCS/LC	A	3.02		F3.01	Replace "objectives" with "objectives;" change to read: "JFACC/JFC"; and replace "Attach" with "Attack."	Typos.	
8.	4	JCS/LC	A	3.10		1	Change to read: ". . . assigns weights to the criteria for comparison."	Correct grammar.	A
9.	5	JCS/LC	A	3.10		2	Replace "principals" with "principles."	Typo: **R** -Original language is correct.	R
10.	6	JCS/LC	A	3.13		33	Add colon after "following"	Typo. **R** -Colon is incorrect.	R.
11.	7	JCS/LC	A	3.20		80.82	Change to read: "(within Combat Plans). The GAT identifies and prioritizes ~~which will identify and prioritize~~ specific targets that meet the JFC's objectives and the component's subobjectives . . ."	As drafted, sentence is a confusing run-on sentence. Edited for clarity and typos.	A
12.	5	J7	S	52.02	3b	71	Change to read as follows: "The JFACC must **exploit the unique characteristics of all air capabilities and/or forces made available for tasking** to achieve assigned objectives as rapidly and as effectively as possible."	Consistency with previous sentence.	A
13.	6	J7	A	53.03	Quote	40	Change to read as follows: "**. . .and** to spark the advance of our ground troops by visual and radar **cooperation**."	Correctness.	A
14.	8	JCS/LC	S	99.02		4	Add "IPB Intelligence preparation of the battlespace."	Acronym is used, but not explained.	A
15.	9	JCS/LC	S	99.06		17	Add definition for intelligence preparation of the battlespace.	Acronym is used, but not defined. R -Acronym use alone does not demand a glossary definition.	R
16.									

256

SECRETARY OF DEFENSE CORRESPONDENCE ACTION REPORT

This form must be completed and forwarded to the Correspondence Control Division (CCD), WHS Room 3A948. Suspense Desk: (b)(6) FAX Number: (b)(6) Email: (b)(6)@osd.pentagon.mil

Action Agency	SMD
Suspense Date	05/17/01

1. ACTION TAKEN (Check one)

- [ ] a. ACTION HAS BEEN COMPLETED (Copy attached)
- [ ] b. REQUEST EXTENSION OF SUSPENSE DATE TO _____ *(Justify below)*
- [ ] c. INTERIM REPLY HAS BEEN SENT (Copy attached) EXTEND SUSPENSE TO _____ *(Justify below)*
- [ ] d. REQUEST CANCELLATION *(Justify below)*
- [x] e. REQUEST TRANSFER TO USD P&R *(Justify below /include POC Name & Phone Number)*
- [ ] f. REQUEST DOWNGRADE TO _____ *(Justify below)*

2. JUSTIFICATION

USD P&R will provide a copy of our response.

3. REPORTING AGENCY

a. ACTION AGENCY: OSAGWI/MR/MD

b. NAME OF ACTION OFFICER: (b)(6)

c. TELEPHONE NO.: (b)(6)

d. DATE: 09/07/2001

e. APPROVING AUTHORITY (Service Secretary/Under Secretary/ASD/Military/Executive Assistant Level)

Signature: (b)(6)

Date Signed: 9/7/01

4. CCD CONTROL

W00554-01

5. ACTION TAKEN (For EXSEC/ Correspondence Control Division Use Only)

a. EXT	Approved	Disapproved
b. CANX	Approved	Disapproved
c. DWNGRD	Approved	Disapproved
d. TRANSFER	Approved	Disapproved
e. OTHER (Specify)		

Signature: _____ Date Signed: _____

SD FORM 391, JAN 2000

SECRETARY OF DEFENSE CORRESPONDENCE ACTION REPORT

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Action Agency	SMD
Suspense Date	05/17/01

1. ACTION TAKEN (Check one)

- [x] a. ACTION HAS BEEN COMPLETED (Copy attached)
- [ ] b. REQUEST EXTENSION OF SUSPENSE DATE TO _____ *(Justify below)*
- [ ] c. INTERIM REPLY HAS BEEN SENT (Copy attached) EXTEND SUSPENSE TO _____ *(Justify below)*
- [ ] d. REQUEST CANCELLATION *(Justify below)*
- [ ] e. REQUEST TRANSFER TO _____ *(Justify below* /include POC Name & Phone Number)
- [ ] f. REQUEST DOWNGRADE TO _____ *(Justify below)*

2. JUSTIFICATION

Our response is attached.

3. REPORTING AGENCY

a. ACTION AGENCY: OSAGWI/MR/MD

b. NAME OF ACTION OFFICER: (b)(6)

c. TELEPHONE NO.: (b)(6)

d. DATE: 05/08/2001

e. APPROVING AUTHORITY (Service Secretary/Under Secretary/ASD/Military/Executive Assistant Level)

Signature

Date Signed

4. CCD CONTROL

W00554-01

5. ACTION TAKEN (For EXSEC/ Correspondence Control Division Use Only)

a. EXT	[ ] Approved	[ ] Disapproved
b. CANX	[ ] Approved	[ ] Disapproved
c. DWNGRD	[ ] Approved	[ ] Disapproved
d. TRANSFER	[ ] Approved	[ ] Disapproved
e. OTHER (Specify)		

Signature

Date Signed

SD FORM 391, JAN 2000

CORRESPONDENCE TASKER

CMAT Control #
2001121-0000001

Classification: UNCLASSIFIED

Date: 04/30/2001

Control Number: 0093596

Route To: USD P&R

External Reference: WE 00554-01

Controlling Organization: ADMIN/CCO

Document Date: 04/25/2001

Original Suspense Date: 05/17/2001

Document Originator: KARL ROVE

Current Suspense Date: 05/17/2001

Create Date: 04/30/2001

Signature Level:

Subject: GULF WAR SYNDROME AND ANTHRAX

Action: Reply Direct

ADDITIONAL INSTRUCTIONS:

COORDINATIONS

Signature: _____ **Date/Time:** _____

Printed Name: _____

MAR 23 2001

H. R. PEROT
(b)(6)
DALLAS, TEXAS 75251

March 22, 2001

Mr. Karl Rove
Senior Advisor to the President of the United States
The White House
West Wing, 2nd Floor
1600 Pennsylvania Avenue, NW
Washington, DC 20502

Dear Karl,

Attached (Exhibit A) is the information you requested about the people in the Pentagon whose mission has been to ignore the Gulf War illnesses and label them as stress.

On page 22, the last page, I have included a list of all the acronyms of the different units in the Pentagon.

I suggest that as you read this document, you put the last page beside it so you can easily identify the acronyms.

In addition, I have included (Exhibit B), a booklet prepared by two Air Force Academy graduates on the anthrax vaccine problem, and a packet of news stories (Exhibit C) that reveals a great deal about the company in Michigan, Bioport.

Sincerely,

Ross Perot

RP/bc
Enclosures

UPR

SECRETARY OF DEFENSE CORRESPONDENCE ACTION REPORT

This form must be completed and forwarded to the Correspondence Control Division (CCD), WHS Room 3A948. Suspense Desk: (b)(6) FAX Number: (b)(6) (b)(6) Email: (b)(6) @osd.pentagon.mil

Action Agency	UPR
Suspense Date	05/07/2001

1. ACTION TAKEN (Check one)

- ☐ a. ACTION HAS BEEN COMPLETED (Copy attached)
- ☐ b. REQUEST EXTENSION OF SUSPENSE DATE TO _____ *(Justify below)*
- ☐ c. INTERIM REPLY HAS BEEN SENT (Copy attached) EXTEND SUSPENSE TO _____ *(Justify below)*
- ☐ d. REQUEST CANCELLATION *(Justify below)*
- ☐ e. REQUEST TRANSFER TO _____ *(Justify below)* (Include POC Name & Phone Number)
- ☐ f. REQUEST DOWNGRADE TO _____ *(Justify below)*

2. JUSTIFICATION

3. REPORTING AGENCY

a. ACTION AGENCY: UPR	c. APPROVING AUTHORITY (Service Secretary/Under Secretary/ASD/Military/Executive Assistant Level)
b. NAME OF ACTION OFFICER	Signature / Date Signed
c. TELEPHONE NO.	
d. DATE	

4. CCD CONTROL

W00554-01

5. ACTION TAKEN (For EXSEC/ Correspondence Control Division Use Only)

a. EXT	☐ Approved	☐ Disapproved
b. CANX	☐ Approved	☐ Disapproved
c. DWNGRD	☐ Approved	☐ Disapproved
d. TRANSFER	☐ Approved	☐ Disapproved
e. OTHER (Specify)		

Signature / Date Signed

WHITE HOUSE

SD FORM 391, JAN 2000

SECRETARY OF DEFENSE CORRESPONDENCE ROUTING SLIP

Action Agency: **UNDER SECRETARY FOR PERSONNEL & READINESS**
Action Required: **APPROPRIATE ACTION**
Coordinate With:

Remarks:

Special Instructions:

Suspense Date: **May/7/2001**	Routing Date: **April/27/2001**	OSD CONTROL: **W00554-01**

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EXECUTIVE SECRETARY REAR
Senior Advisor to DSD for Chemical & Biological Protection
SMD

EXHIBIT D

Information Paper on the DoD Anthrax Vaccine Immunization Program (AVIP)

Updated: 18 FEB 2001

A. Executive Summary

B. Chronology

C. Legal issue #1 – Informed consent

- Law on informed consent for servicemembers – 10 USC 1107
- Clinton's Executive Order 13139 and DoD Directive 6200.2
- Examples of false testimony by senior military officials

D. Legal issue #2 – Adulteration

- History of AVA
- Adulteration
- Misbranding

E. Legal issue #3 – On-going litigation

- Ft. Hood soldier – Charges dropped
- Ft. Bragg soldier – Convicted and jailed
- Imprisonment of Marines in January/February 2001, and the pending court-martial of Dr. John Buck, MD, USAF – Keesler AFB, MS.

F. Food and Drug Administration

- Food, Drug and Cosmetic Act and Public Health Service Act
- FDA Center for Biologics Evaluation and Research Division
- FDA culture

G. Medicine

- Gulf War Illness -- Previous investigations of a link to vaccines
- Gulf War Illness – UK study linking vaccination to GWI
- Gulf War Illness-- Kansas study linking vaccination to GWI
- Gulf War illness -- French study
- Institute of Medicine -- Studies and conflicts of interest
- Centers for Disease Control Advisory Committee on Immunization Practices
- Command Influence and the Practice of Military Medicine
- Office of the Special Assistant for Gulf War Illness -- Report on vaccine use in the Gulf War and its relationship to "Force Health Protection" doctrine

H. Risk/benefit analysis

- Threat of biological warfare and/or bioterrorism
- Deployment to high-threat areas without anthrax vaccine immunization

I. Policy

- Policy -- Origins and evolution
- Ethics and examples of the breakdown
- Impact of AVIP on military culture and on civil-military relations

J. Recommendations

Section A
Executive Summary

Excerpt from the Feb. 17th, 2000 National Security Subcommittee's Report –HR 106-556 –"Unproven Force Protection:"[1]

"The AVIP should be suspended because it lacks an essential element in a medical program: trust. However well-intentioned, the anthrax vaccine effort is viewed by many with suspicion. It is seen as another chapter in a long, unhappy history of military medical malfeasance in which the healing arts are corrupted to serve a lethal purpose."

The Anthrax Vaccine Immunization Program (AVIP) is a Department of Defense (DOD) force protection program designed to counter the use of anthrax as a biological weapon by America's enemies. However, the program is rife with problems, foremost being the mandated use of an antiquated vaccine, not properly licensed to protect against biological warfare exposures, and originating from a manufacturer failing to garner FDA approval. An orderly, scientific, and medically sound approach to force protection against anthrax was abandoned in 1997. As a result, a poorly designed and inadequate vaccine became the centerpiece of the AVIP.

By using the vaccine Servicemembers rights under the law, previously acknowledged by Senate Report 103-97 and internal DoD review, were ignored. Critical and highly trained personnel were forced to leave the services, despite serious safety, efficacy and legal issues being raised in the field concerning the vaccine. Others who partook of the AVIP became ill, some severely, many testifying to Congressional committees. An unprecedented and expensive education campaign was launched rivaling the budget of the vaccine program itself.

Senior military and defense department officials often unknowingly compromised their integrity due to a lack of knowledge of the critical issues and facts in order to prop up the seriously flawed program. Throughout the dilemma rhetoric and spin supplanted the critical analysis of the legitimate safety and legality issues presented by the anthrax vaccine. These events have made the AVIP a number one topic of discussion throughout military ranks. Accordingly, AVIP represents a top priority for the new administration in an effort to secure modern force protection measures for our troops, and restore the crucial element of trust required within our fighting force.

Force protection against biological weapons is a laudable goal. For many years, DOD officials and military medical experts worked on developing such a program for the biological agent anthrax. U.S. Army researchers first developed the anthrax vaccine absorbed (AVA) in the 1940's, with continuing work and refinement of the vaccine formula throughout the 1960's. AVA was licensed in 1970, although the normal licensing procedures and requirements were never met. From 1970 until just prior to the Gulf War

[1] House Committee on Government Reform report, "Unproven Force Protection", 17 Feb 2000, p.95
See: http://www.house.gov/reform/ns/reports/anthrax1.pdf

AVA was rarely manufactured and used almost exclusively for military research. Reports indicate a total production in those twenty years of less than 70,000 doses.

A 1985 FDA review of AVA published in the Federal Register found that little data supported the safety and efficacy of the vaccine, in fact there was no clinical evidence for the licensed vaccine, only for a similar, but earlier version of the vaccine. Regardless, FDA found that based on the extremely small and specific group of individuals requiring the vaccine, it was safe and effective. The review also noted that there was no scientific data to show effectiveness against inhalation exposure.

Coincidentally, at the same time as the 1985 FDA review, the U.S. Army sent out a Request for Proposal (RFP) for a contract to develop a new anthrax vaccine, because the current vaccine had too many adverse reactions and was not suitable to a biowarfare environment. In 1989, the U.S. Army again stated these limitations in answering questions before Senate Government Affairs Committee hearings (Sen. Glenn) on the escalation of the biowarfare threat.

Realizing that the current vaccine was inadequate for use as a force protection measure, DOD and the manufacturer set out to reduce the adverse reaction rate and to license the vaccine for inhalation exposure. The U.S. Army developed a plan in 1995 for just those purposes. Explaining the reason for this plan the U.S. Army writes that the current vaccine "is not licensed" for inhalation exposure. The appropriate paperwork was submitted to FDA in 1996 and remains unapproved to this day.

Shortly after SECDEF Cohen arrived, this methodical, scientific, and lawful approach was abandoned, either for expediency or because of insurmountable regulatory and scientific hurdles. In an unprecedented move, an Assistant Secretary of Defense for Health Affairs circumvented the regulatory process and obtained a legally irrelevant memo from a new "acting" FDA Commissioner to provide a basis or approval for commencing the AVIP. The process was circumvented because the legally required data for approving a vaccine, a controlled human field trial, could not be ethically gathered. In order to commence a mandatory program, absent a regulatory approval, the FDA memo was the expedient solution.

AVA, long known to be a highly reactive and unlicensed vaccine of limited effectiveness, became the centerpiece for the AVIP. A vastly larger population would use AVA, despite strict limits in its license according to the Federal Register and product label, and further, the use against inhalation anthrax was previously acknowledged as unlicensed. As a "commander's program" the military medical community was effectively taken out of the loop and discouraged from practicing medicine. The administration of the vaccine was an order to be followed, not a medical treatment to be discussed in a classic doctor/patient relationship. Informed consent for the "off label" use of the vaccine was not an option.

Because of the exponentially greater need for vaccine, the manufacturer quadrupled production capacity. This was accomplished by replacing the existing licensed facility with all new and unlicensed equipment. Additionally, key production methods changed,

namely in the sterility and protective antigen extraction steps. Many of these changes were approved after the fact, contrary to FDA regulations. Others were never approved, as is reported in the several FDA Inspection Reports from 1990 onward. A long litany of other FDA regulatory infractions adds to the list of violations, whether scientific or compliance, that render this vaccine an adulterated and illegal product.

Servicemembers who became aware of these issues of non-compliance or of the off-label use have been systematically punished for discovering what was previously DOD's official medical and scientific position on the vaccine. In the small percentage of Guard and Reserve units to mandate the vaccine, large numbers have opted to leave, rather than risk the illnesses occurring amongst the various services. Active duty members, without the option of leaving, are being sent to jail and dishonorably discharged for taking the position previously held by the most senior of DOD's medical and science officials.

The Food and Drug Administration has been less than consistent in its position on AVA and the AVIP. Its inspection reports are scathing, and the plant was shut down as a result, yet the vaccine that came from this unacceptable facility was previously labeled as "approved." It would appear that FDA is using its discretion to overlook numerous violations in the production of the vaccine and the inappropriate and haphazard manner in which the vaccine program is being implemented.

The program is so sensitive that any appearance of a 'PR' problem is fought aggressively. Adverse reactions are high (known prior to the implementation of the program), as evidenced by the highest percentage of Vaccine Adverse Event Reports (VAERS) for any vaccine in history. Many Servicemembers are referred to clinics, hospitals, even Walter Reed Medical for treatment of unknown ailments. When AVA is mentioned as a possible cause, servicemembers are treated as disloyal soldiers because their medical conditions are a threat to the program.

Ask the DOD however, and they deny anything out of the ordinary, as noted by Senator Richard Shelby's previous investigation of Gulf War Illness[2]:

"While I have not yet determined the reason for this apparent aversion to full disclosure by DOD, the staff working on this issue from our committee has been constantly challenged by the Department's evasiveness, inconsistency, and reluctance to work toward a common goal here."
"I can only conclude, Mr. President [of the Senate], that when dealing with the Department of Defense on this issue, you have to ask the right question to receive the right answer. I do not believe they understand that we are only seeking the truth in a way to help our veterans."

The AVIP, as with any other force wide program, must be assessed for the risks versus the benefits of such a program. DOD's stated reason for this program is the increased

[2] Senator Shelby's Conclusions On The Persian Gulf Syndrome, US Senate, 17 Mar 1994, Congressional Record page S3098.
See: http://www.gulflink.osd.mil/czech_french/czfr_refs/n08en014/s3098.htm

threat of an aerosolized anthrax attack on U.S. Forces. GAO and others disagree. Their assessment is that the threat has not changed since before the Gulf War. The risk of adverse reactions to the loss of troops from an attack must also be considered. Again, DOD and GAO disagree. DOD insists the loss of highly skilled pilots and others has not impacted the readiness of the military. Again, GAO disagrees. Morale has plummeted since 1998 with the anthrax vaccine surfacing as a primary cause. DOD's abysmal history of care for its' own troops is captured in the 1994 Senate Hearing (SR103-97):[3]

"For at least 50 years, DOD has intentionally exposed military personnel to potentially dangerous substances, often in secret."

"DOD has repeatedly failed to comply with required ethical standards when using human subjects in military research during war or threat of war."

In early 1999, Army Surgeon General, LTG (Dr.) Ronald Blanck (D.O.) clearly acknowledged DoD's credibility problems[4]:

"I think it speaks to the undercurrent of distrust of the government and the military," said Lt. Gen. Ronald R. Blanck, the surgeon general of the Army, the service that oversees the vaccination program. "Agent Orange. Nuclear tests in the '50s. People say, 'How can you say this is safe?' Clearly, we have a credibility problem."

Opposition to the anthrax vaccine policy has arisen as military members, legislators, and citizens -- often parents, have discovered that the foundations of the DoD's Anthrax Vaccine Immunization Program (AVIP) are not based on the truth. Contrary to DoD assertions, the anthrax vaccine was never tested and approved according to standards in federal law, was modified without FDA approval, and was not approved for the use or indication the DoD is mandating under AVIP.

Questions about the inconsistencies in the DoD's mantra of safety and effectiveness were met with denials, discipline and discharges. These actions contrast with the ethical and safety standards to which military members are accustomed when dealing with issues that affect the well being of the troops. To this day most military commanders are not aware of these truths about the vaccine as the DoD's propaganda efforts to educate the troops label all opposition as "internet misinformation."

To the contrary, Congressional, GAO, State, and Institute of Medicine investigations have validated the concerns of military servicemembers opposed to the anthrax vaccine policy. The reality is that the anthrax vaccine plant remains closed today, just as it was in 1998 when the shots and controversy began.

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[3] Senate Report 103-97, "Is Military Research Hazardous To Veterans' Health? Lessons Spanning Half A Century", A Staff Report Prepared For The Committee On Veterans' Affairs, United States Senate, 8 Dec 1994

See: http://www.gulfwarvets.com/senate.htm

[4] Steven Lee Myers, "Armed Services opt to discharge those who refuse vaccine", NY Times, 11 Mar 1999

Section B
Chronology[5]

1970 government approval. 2 November 1970. Despite a lack of efficacy testing, the Public Health Service (FDA predecessor) licensed the anthrax vaccine.[6]

- **Anthrax vaccine license granted despite not conducting a valid controlled human field trial.** Data from an earlier trial (known as the Brachman Study, using a different vaccine prepared by Merck, Sharp, & Dohme) was provided to satisfy the efficacy requirements established by the Public Health Service (PHS), but after the license was granted. Federal law required testing for efficacy in humans before licensure. The Michigan Department of Public Health attempted an efficacy study of the anthrax vaccine being used by DoD today that Public Health Service found unsatisfactory.

- **The GAO has reported that the current vaccine differs from the vaccine used in the Brachman efficacy studies in three ways[7].**

  - First, the Michigan Department of Public Health (MDPH) manufacturing process differs from that used for the Brachman Study vaccine.

  - Second, the strain of anthrax used to grow the MDPH vaccine is different form the strain used for the Brachman Study vaccine.

  - Finally, to increase the yield of protective antigen (believed to be an important part of the vaccine's protective effects), the ingredients and/or formulation used to make the vaccine were changed.[8]

1980's DoD statements. DoD documentation in the 1980's, absent the political pressure associated with AVIP, contains objective statements about the safety and efficacy of the anthrax vaccine being used today:

- **1985 US Army RFP.** A 1985 Army "request for proposal" to solicit a new anthrax vaccine from the biologics industry candidly discussed the safety and

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[5] For a more detailed chronology see the House Government Reform Committee website version at: See: http://www.house.gov/reform/hearings/healthcare/00.10.03/timeline.doc

[6] Written Testimony attachments (Public Health Service memorandums) to Dr. Claussen's testimony, 12 OCT 1999, Government Reform Committee hearing on force protection vaccines.

[7] GAO, 29 Apr 1999. See: http://www.gao.gov/AIndexFY99/abstracts/ns99148t.htm

[8] FDA's predecessor's letters - http://www.house.gov/reform/hearings/healthcare/00.10.03/timeline.doc

efficacy of the MCPH vaccine, its high adverse reaction rate, and its questionable efficacy against different strains of anthrax[9]:

*"There is an operational requirement to develop a safe and effective product which will protect US troops against exposure from virulent strains of Bacillus anthracis. **There is no vaccine in current use which will safely and effectively protect military personnel against exposure to this hazardous bacterial agent.**"*

*"A licensed vaccine against anthrax, which appears to afford some protection from the disease, is currently available for human use...**The vaccine is, however, highly reactogenic, requires multiple boosters to maintain immunity and may not be protective against all strains of the anthrax bacillus.**"*

1985 FDA Product Review -- Given the lack of a controlled human field trial noted in the original 1968 to 1970 correspondence (despite the NIH and PHS requesting this required data), **a proposed rule for a specific product review of the anthrax vaccine absorbed was published in the Federal Register on 13 December 1985. However, a final rule fully licensing the vaccine has never been published,** ostensibly because no human efficacy data on this vaccine was ever provided to the FDA as requested by the PHS in 1970[10]:

- December 13, 1985 -- FDA Specific Product Review of the Anthrax Vaccine Absorbed as printed in the Federal Register, CFR 620 -- *"Anthrax vaccine ... **efficacy against inhalation anthrax is not well documented.**"*

*"**The vaccine manufactured by the Michigan Department of Public Health has not been employed in a controlled field trial. Brachman employed a similar vaccine prepared by Merck Sharp & Dohme for Fort Detrick in a placebo-controlled field trial in mills processing imported goat hair. ... No meaningful assessment of its value against inhalation anthrax is possible due to its low incidence.**"*

1989 Office of the Secretary of Defense (OSD) letter to Senator Glenn. A 1989 letter from then-Assistant Secretary of Defense Robert B. Barker to Senator John Glenn reiterated the safety and efficacy problems with the vaccine[11]:

*"**Current vaccines, particularly the anthrax vaccine, do not readily lend themselves to use in mass troop immunization for a variety of reasons: the***

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[9] Request for Proposals (RFP) No. DAMD 17-85-R-0078, US Army Medical Research Acquisition Activity, Fort Detrick, Frederick, MD, 16 May 1985

[10] 13 December 1985 FDA Product Review and Proposed Rule, CFR 620; http://www.house.gov/reform/hearings/healthcare/00.10.03/timeline.doc

[11] Letter from former Assistant Secretary of Defense Robert B. Barker to former U.S. Sen. John Glenn, chairman of the Senate Governmental Affairs Committee, 24 Aug 1989, transcript of Senate Hearing 101-744. The letter and quotes from Barker to Glenn are on page 474 and 480.

requirement in many cases for multiple immunizations to accomplish protective immunity, a higher than desirable rate of reactogenicity, and, in some cases, lack of strong enough efficacy against infection by the aerosol route of exposure."

March 1990 – Army Doctors describe the anthrax vaccine as an "unlicensed experimental vaccine."

- Col. (Dr.) Takafuji of the Army Surgeon General office and Col. (Dr.). Philip K. Russell of Fort Detrick, in an article titled "Military Immunizations," describe the anthrax vaccine as a ***"limited use vaccine ... unlicensed experimental vaccine"*** (Infectious Disease Clinics of North America, 3/90, p. 156)

- **This description of the anthrax vaccine by key US Army physicians means that its use requires informed consent or a Presidential waiver of informed consent.** Yet in the Gulf War and in the current AVIP program DoD asserts that the vaccine is "FDA-approved" and therefore does not require informed consent.

1994 Senate Report 103-97. In February 1994 then-MG Ronald Blanck (later Army Surgeon General) acknowledged a possible link between the anthrax vaccine and Gulf war Illness to Senate Veterans Affairs Committee investigators[12]:

- ***"Although anthrax vaccine had been considered approved prior to the Persian Gulf War, it was rarely used. Therefore, its safety, particularly when given to thousands of soldiers in conjunction with other vaccines, is not well established. Anthrax vaccine should continue to be considered as a potential cause for undiagnosed illnesses in Persian Gulf military personnel because many of the support troops received anthrax vaccine, and because the DoD believes that the incidence of undiagnosed illnesses in support troops may be higher than that in combat troops."***

The Senate Veterans Affairs Committee concluded in their Dec 1994 report[13]:

- ***"Records of anthrax vaccinations are not suitable to evaluate safety...However, the vaccine's effectiveness against inhaled anthrax is unknown. Unfortunately, when anthrax is used as a biological weapon, it is likely to be aerosolized and thus inhaled. Therefore, the efficacy of the vaccine against biological warfare is unknown. ... The vaccine should therefore be considered investigational when used as a protection against biological warfare."***

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[12] Maj. Gen. Ronald Blanck, Commanding General, Walter Reed Army Hospital, to Committee staff, 414 Russell Senate Office Bldg., Washington, DC, 4 Feb 1994, from Senate Report 103-97, 8 Dec 94, page 35.
[13] Senate Veterans Affairs Committee staff report 103-97, 414 Russell Senate Office Bldg., Washington, DC, 4 Feb 1994, from Senate Report 103-97, 8 Dec 94, Note 61-63.

After the implementation of AVIP, LTG Blanck disavowed his testimony to the Senate Veterans Affairs Committee.[14]

1994 and 1999 -- Medical textbook "Vaccines". In 1994, Col. (Dr.) Arthur Friedlander, the Army's chief anthrax vaccine researcher at Ft. Detrick, co-authored a chapter on the anthrax vaccine in a medical textbook, "Vaccines", and acknowledged the shortcomings of the vaccine used for AVIP, including its high reactogenicity[15]:

- ***"The current vaccine against anthrax is unsatisfactory for several reasons. The vaccine is composed of an undefined crude culture of supernatant adsorbed to aluminum hydroxide. There has been no quantification of the protective antigen content of the vaccine or of any of the other constituents, so the degree of purity is unknown. Standardization is determined by an animal potency test. The undefined nature of the vaccine and the presence of constituents that may be undesirable may account for the level of reactogenicity observed. The vaccine is also less than optimal in that six doses are required over 18 months, followed by annual boosters. There is also evidence in experimental animals that the vaccine may be less effective against some strains of anthrax. Clearly a vaccine that is completely defined, that is less reactogenic, and that requires on or two doses to produce long-lasting immunity would be highly desirable."***

1995 SAIC Corporation contracted to develop an Army plan to obtain FDA approval for a license amendment to include aerosolized anthrax exposure. In September 1995 the Army contracted SAIC Corporation to submit a plan to the Army that would enable them to obtain FDA licensure of the vaccine for inhalation anthrax. **SAIC's plan clearly identified the legal status of the vaccine -- which inferred a substantial informed consent obstacle for DoD unless scientific tests were developed to satisfy federal regulatory requirements** pertaining to the safety and efficacy of the vaccine[16]:

- ***"This vaccine is not licensed for aerosol exposure expected in a biological warfare environment."***

1995 JPOBD (Joint Program Office for Biological Defense) meeting. In October 1995 the Army held its first meeting to develop a course of action to obtain FDA licensure of the vaccine for inhalation anthrax so that they could begin a mass immunization program. The meeting minutes clearly indicate that the Army knew it

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[14] LTG Ronald Blanck, U.S. Army Surgeon General, letter to the editor, Washington Times, 14 Mar 2000.
[15] A.M Friedlander and P.S. Brachman, "Vaccines", ed. Plotkin and Mortimer, 1994 edition chapter 26, pg. 737
[16] SAIC Corporation plan, 29 Sep 1995, enclosure to memorandum from Dr. Anna Johnson-Winegar (US Army) to Dr. Robert Myers (MDPH), US Army Medical Research and Material Command, Fort Detrick, Frederick, MD, 5 Oct 1995.

had to obtain FDA approval of a new licensed indication for inhalation anthrax, that the efficacy tests used to license the vaccine were for a different vaccine, and that there was no scientific data to support this change by FDA.[17]

- *"A meeting was held on 20 Oct 1995 to discuss the process for modifying the MDPH anthrax vaccine license to indicate a reduced number of injections and to expand the indication to include protection against aerosol challenge of spores."*

- *"COL Friedlander said that the original series of 6 doses was established in the 1950's for an anthrax vaccine similar to but not identical with the MDPH vaccine."*

- *"Studies of vaccine (not MDPH product) effectiveness in humans working in tanneries showed protection against cutaneous disease, but there was insufficient data to demonstrate protection against inhalation disease."*

BG Busby, the Joint Program Manager for Biological Defense, concluded the meeting with comments that allude to the doctrinal motivations Army personnel had in implementing the AVIP program and identifies the start of an aggressive campaign to sell the policy and the vaccine on which it is based.

- *"BG Busby addressed a need to make the case that anthrax is currently the principal biological warfare threat. By protecting against anthrax and other BW threats, the vaccines serve as a deterrent."*

1996 IND (Investigational New Drug) Application submitted by MBPI, the anthrax vaccine manufacturer, to obtain inhalation anthrax approval. **This IND application is still pending with the FDA.** The Investigational New Drug application was specifically for anthrax vaccine absorbed (AVA) and the modification sought by the manufacturer, at the request of and with DoD assistance, will apply regardless where the anthrax vaccine is manufactured. The IND lists three reasons for the application: a change in indication to include inhalation anthrax, a change of dosage, and a change in route of administration.

Summary: The IND application was submitted following an Army, Joint Staff, and OSD staff process in which there was concurrence that it was necessary to obtain FDA approval of a new licensed indication for inhalation anthrax before DoD could

[17] LTC David Danley, "Minutes of the Meeting on Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements", held on 20 Oct 1995 meeting; Joint Program Office for Biological Defense memorandum, 13 Nov 1995.

start mass anthrax vaccinations.[18] That consensus was reversed within a month of Mr. Cohen being confirmed as SecDef, following DoD pressure on FDA to give permission to begin use of the anthrax vaccine for inhalation anthrax without obtaining a new licensed indication or completing the scientific investigation proposed by the Army in the IND application.[19]

1993 - 1999 FDA Inspections: DoD and the Army have long been aware of the anthrax vaccine's significant shortcomings, and the FDA began its reporting of problems with a series of inspections in the post-Gulf War era that continue to this day. According to the GAO, the FDA did not inspect the anthrax vaccine manufacturing facility from 1970 when the vaccine was licensed until 1993. Both the former and current anthrax vaccine production facility have consistently failed FDA inspections with "significant deviations" from current good manufacturing practices (CGMPs) required by FDA regulations on the following inspection dates:[20]

- May 4 - May 7, 1993
- May 31- June 3, 1994
- April 24 - May 5, 1995
- Nov 18 - Nov 27, 1997
- Feb 4 - Feb 20, 1998
- Nov 15 - Nov 23, 1999 (current facility)

Before the announcement of the AVIP policy, FDA had communicated the seriousness of these deficiencies to the manufacturer (MDPH, MBPI and Bioport) and to the US Army in:

- An FDA letter dated 22 Dec 1993.
- An FDA Warning Letter dated 31 Aug 1995
- An FDA "Notice of Intent to Revoke" (NOIR) MBPI's license dated 11 Mar 1997.

19 Feb 1998 -- DoD's "independent expert" review of anthrax program is announced as complete.

- DoD received a report on the anthrax vaccine policy from Dr. Gerard Burrow of Yale University. Dr. Burrow, a professor of gynecology, had been asked by now-Deputy Secretary of Defense Rudy DeLeon to act as an "independent expert" to review the proposed AVIP, and Burrow's "approval" was made a prerequisite by Secretary of Defense Cohen for DoD to proceed with immunizations. Dr. Burrow

[18] LTC David Danley, "Minutes of the Meeting on Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements", held on 20 Oct 1995 meeting; Joint Program Office for Biological Defense memorandum, 13 Nov 1995.
[19] Dr. Stephen C. Joseph, DoD ASD/Health Affairs, letter to FDA Lead Deputy Commissioner Michael Friedman, 4 Mar 1997
[20] FDA/CBER Office of Compliance and Biologics Quality, inspections of Bioport -- http://www.house.gov/reform/hearings/healthcare/00.10.03/accountability.doc

concluded, *"The anthrax vaccine appears to be safe and offers the best available protection against wild-type anthrax as a biological warfare agent."*[21]

- Yet when Dr. Burrow was asked by Congress to testify about his review at a 29 April 1999 hearing, he declined. In a 26 April 1999 letter to Representative Christopher Shays (R-CT), Burrow stated: *"The Defense Department was looking for some [sic] to review the program in general and make suggestions, and I accepted out of patriotism. I was very clear that I had no expertise in Anthrax and they were very clear they were looking for a general oversight of the vaccination program."*

20 Feb 1998 FDA inspection report begins: "The manufacturing process for Anthrax Vaccine is not validated."[22]

- The FDA report documented numerous instances of redating vaccine lots that had either expired or failed potency testing. All of the vaccine given to US troops under the AVIP to-date has come from a stockpile that was manufactured or re-dated during the 1993-1998 period of repeated failed FDA inspections.

- In January 1998, just a few weeks before the FDA was to return to the anthrax vaccine manufacturer, MBPI (now Bioport, Inc), unilaterally stopped production of the anthrax vaccine -- according to DoD because of "renovations". However, in testimony before the House Armed Services Committee on 13 Jul 2000, DoD representatives acknowledged that the FDA would not have allowed any more anthrax vaccine production from the former Michigan production line.[23]

1998 Secretary of the Army Indemnification Letter – In September 1998 DoD granted indemnification to the anthrax vaccine manufacturer. While DoD press statements implied that indemnification was common practice, this had last occurred with the Swine Flu vaccine in 1976.[24]

- *"The obligation assumed by MBPI under this contract involves unusually hazardous risks associated with the potential for adverse reactions in some recipients and the possibility that the desired immunological effect will not be obtained by all recipients. Although AVA has been extensively tested under the auspices of the Food and Drug Administration, the size of the proposed vaccination program may reveal unforewarned idiosyncratic adverse reactions.*

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[21] See: http://www.defenselink.mil/other_info/burrows.html

[22] FDA/CBER Office of Compliance and Biologics Quality, inspections of Bioport – http://www.house.gov/reform/hearings/healthcare/00.10.03/accountability.doc

[23] Excerpted House Armed Services Committee (Military Personnel Subcommittee) transcript, sections 62-63, discussion between Representative Christopher Shays (R-CT), DepSecDef Rudy DeLeon, and Anna Johnson-Winegar Ph.D., Deputy Assistant Secretary of Defense for Chemical and Biological Defense. See: http://commdocs.house.gov/committees/security/has195020.000/has195020_0f.htm

[24] 3 September 1998 DoD indemnification of anthrax vaccine manufacturer, http://www.house.gov/reform/hearings/healthcare/00.10.03/timeline.doc

Moreover, there is no way to be certain that the pathogen used in tests measuring vaccine efficacy will be sufficiently similar to the pathogen that U.S. forces might encounter to confer immunity. These concerns, coupled with the uncertain and evolving state of product liability law with regard to vaccines, lead me to the conclusion that the performance of this contract will subject MBPI to certain unusually hazardous risks."

1999 update of 1996 Investigational New Drug (IND) Application – On 29 Jan 1999 BioPort Corporation submitted a progress report containing meeting minutes referring to studies related to the 1996 Investigational New Drug (IND) application. The FDA Form 1571 on which the submission is made lists "inhalation anthrax" (not a change in dosage or route of administration) as the only reason covered under this submission.[25] The form also lists Army personnel at Ft. Detrick who are responsible for the investigation supporting the changed indication.

One year after the announcement of a mandatory anthrax vaccination program the new owner of the anthrax vaccine plant, BioPort, acknowledged in their update to the FDA that the vaccine was not licensed for the purpose for which DoD was using it. This acknowledgement means that DoD's use of the anthrax vaccine required informed consent. Despite this, DoD officials have repeatedly attempted to infer that the IND application submitted to FDA was only for a change of dosage and route of administration -- not a new indication for inhalation anthrax. BioPort's CEO also failed to mention this primary reason for the IND application during his 30 Jun 1999 testimony before Congress.

5 Oct 1999 FDA Notice of Proposed Rulemaking (NPRM)[26] -- proposed, never enacted -- On 5 Oct 1999 FDA issued a Notice of Proposed Rulemaking (NPRM) to change the licensing requirements for biowarfare drugs and vaccines. During Congressional testimony on 9 Nov 1999 William Raub, Ph.D., HHS Deputy Assistant Secretary For Science Policy, explained why[27]:

"...FDA is proposing to amend its new drug and biological product regulations to identify the information needed to provide substantial evidence of the efficacy of new drug and biological products used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances. This proposal would apply when the traditional efficacy studies in humans are not feasible and cannot be ethically conducted under FDA's regulations for adequate and well-controlled studies in humans...In these situations, certain new drug and biological products that are intended to reduce or prevent serious or life-threatening conditions could be approved for marketing based on evidence of effectiveness derived

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[25] FDA Form 1571, Investigational New Drug Application, 29 Jan 1999.
[26] http://www.fda.gov/cber/rules/lethtox.pdf
[27] William Raub, testimony, 9 Nov 1999. See: http://www.fda.gov/search/advsearch.html

from appropriate studies in animals, without adequate and well-controlled efficacy studies in humans (21 CFR 314.126)[28]."

The FDA NPRM is a tacit admission that anthrax vaccine is an investigational new drug, because it cannot meet FDA regulatory requirements for progressing to a fully licensed status for its intended use by DoD.

FDA's proposal to introduce a different licensing standard for biowarfare drugs and vaccines is in concert with a recommendation made by two Army doctors in a 1992 article. They explained[29]:

"For products designed to product against chemical and biological agents, a clear demonstration of efficacy would require exposure to humans to these lethal agents. Since this practice would be unethical and immoral, these products never advanced beyond the investigational stage."

Two years after the Anthrax vaccine policy was announced the FDA took steps to legally sanction it, and other drugs and vaccines likely to be developed under the $325 million Joint Vaccine Acquisition Program. Despite proposing a new rule, however, FDA has taken no further action to enact it in federal law. Until it does, use of the anthrax vaccine for inhalation exposure is not recognized or approved as one of its' intended uses and therefore requires informed consent.

23 Nov 1999 – FDA inspects BioPort's new manufacturing facility – <u>again</u> begins: "The manufacturing process for the production of Anthrax Vaccine Adsorbed is not validated." – An FDA inspection of the anthrax vaccine manufacturer conducted 15-23 Nov 1999 reiterated once again the failure to meet FDA standards.

- The FDA <u>again</u> begins: *"The manufacturing process for the production of Anthrax Vaccine Adsorbed is not validated."*

- At a 13 Apr 2000 Senate Armed Services Committee hearing DoD officials admitted that they do not expect the FDA to certify the new anthrax vaccine production facility until late 2000 – nearly three years after the old facility was shutdown.[30]

- By the fall of 2000 the manufacturer's certification is slipped at least an additional year to mid to late 2001 based on problems in the manufacturer's packaging and labeling operation discovered during an October 2000 FDA inspection. The FDA also noted the manufacturer had failed to investigate adverse reactions.[31]

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[28] 21 CFR 314.126, "Adequate and well-controlled studies."
See: http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=314&SECTION=126&YEAR=1999&TYPE=TEXT

[29] Col. Garland E. McCarty and Lt. Col. Gregory P. Bereaux, Military Medicine, Vol. 157, (August 1992)

[30] FDA/CBER Office of Compliance and Biologics Quality, testimony to SASC – http://www.house.gov/reform/hearings/healthcare/00.10.03/accountability.doc

[31] http://www.fda.gov/ora/frequent/bioport483.pdf

3 April 2000 Congressional Report (draft released on 17 Feb 2000)– After multiple Congressional hearings concerning the AVIP controversy, the full Committee on Government Reform adopts the National Security Subcommittee report, titled "Unproven Force Protection", recommending suspension of the experimental anthrax program.[32]

- House Government Reform Committee Findings:

  *1. **The AVIP is a well-intentioned but over-broad response** to the anthrax threat. It represents a doctrinal departure over emphasizing the role of medical intervention in force protection.*
  *2. **The AVIP is vulnerable to supply shortages and price increases.** The sole-source procurement of a vaccine that requires a dedicated production facility leaves DOD captive to old technology and a single, untested company. Research and development on a second-generation, recombinant vaccine would allow others to compete.*
  *3. **The AVIP is logistically too complex to succeed.** Adherence to the rigid schedule of six inoculations over 18 months for 2.4 million members of a mobile force is unlikely, particularly in reserve components. Using an artificial standard that counts only shots more than 30 days overdue, DOD tolerates serious deviations from the Food and Drug Administration (FDA) approved schedule.*
  *4. **Safety of the vaccine is not being monitored adequately.** The program is predisposed to ignore or understate potential safety problems due to reliance on a passive adverse event surveillance system and DOD institutional resistance to associating health effects with the vaccine.*
  *5. **Efficacy of the vaccine against biological warfare is uncertain.** The vaccine was approved for protection against cutaneous (under the skin) infection in an occupational setting, not for use as mass protection against weaponized, aerosolized anthrax.*

- House Government Reform Committee Recommendations:

  *1. **The force-wide, mandatory AVIP should be suspended** until DOD obtains approval for use of an improved vaccine. To accomplish this:*
  2. DOD should accelerate research and testing on a second-generation, recombinant anthrax vaccine; and,
  3. DOD should pursue testing of the safety and efficacy of a shorter anthrax inoculation regimen; and,
  4. DOD should enroll all anthrax vaccine recipients in a comprehensive clinical evaluation and treatment program for long term study.
  *5. **While an improved vaccine is being developed, use of the current anthrax vaccine for force protection against biological warfare should be considered***

[32] House Committee on Government Reform, "Unproven Force Protection", 17 Feb 2000 http://www.house.gov/reform/ns/reports/anthrax1.pdf

experimental and undertaken only pursuant to FDA regulations governing investigational testing for a new indication.

1999-2000 General Accounting Office reports -- all critical of the safety and efficacy of the vaccine, DoD's lax contract relationship with BioPort, and impact of the AVIP:

- 11 Oct 2000 -- ANTHRAX VACCINE: Preliminary Results of GAC's Survey of Guard/Reserve Pilots and Aircrew Members. GAO-01-92T. [33]
- 14 Apr 2000 -- "Contract Management: DOD's Anthrax Vaccine Manufacturer Will Continue to Need Financial Assistance", testimony before the Subcommittee on Personnel, Senate Committee on Armed Services. GAO/T-NSIAD-00-140[34]
- 13 Apr 2000 -- "Medical Readiness: DOD Continue to Face Challenges in Implementing Its Anthrax Vaccine Immunization Program," testimony before the Senate Committee on Armed Services. GAO/T-NSIAD-00-157[35]
- 12 Oct 1999 -- Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program (22Oct99) GAO/NSIAD-00-36[36]
- 21 July 1999 -- Medical Readiness: Issues Concerning the Anthrax Vaccine (07/21/1999), T-NSIAD-99-226 [37]
- 30 June 1999 -- Contract Management: Observations on DOD's Financial Relationship With the Anthrax Vaccine Manufacturer (06/30/1999), T-NSIAD-99-214[38]
- 29 Apr 1999 -- Medical Readiness: Safety and Efficacy of the Anthrax Vaccine (04/29/1999), T-NSIAD-99-148 [39]
- 29 March 1999 – Gulf War Illnesses: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved (03/29/1999), NSIAD-99-5 [40]

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[33] http://www.gao.gov/new.items/d0192t.pdf
[34] http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi?IPaddress=162.140.64.21&filename=ns00140t.pdf&directory=/diskb/wais/data/gao
[35] http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi?IPaddress=162.140.64.21&filename=ns00157t.pdf&directory=/diskb/wais/data/gao
[36] http://www.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=gao&docid=ns00036.txt
[37] http://www.gao.gov/AIndexFY99/abstracts/ns99226t.htm
[38] http://www.house.gov/reform/ns/hearings/testimony/contract_management_630.htm
[39] http://www.gao.gov/AIndexFY99/abstracts/ns99148t.htm
[40] http://www.gao.gov/AIndexFY99/abstracts/ns99005.htm

Section C

Legal issue #1 – Informed consent

The first legal issue will be explored based on violations of existing law, Presidential executive order, regulations and directives; and further by the false testimony under oath by senior DoD officials and experts to possible obscure the relevant issues.

Illegal Program: AVIP in its mandatory form is in violation of 10 USC 1107, EO 13139, and DODD 6200.2 by failing to provide US armed forces members informed consent with the use of an experimental or investigational vaccine. Both SR 103-97 and HR 106-556 deemed the use of the anthrax vaccine as "experimental" and / or "investigational" following lessons learned from the Gulf War. DoD recognized the experimental nature of the anthrax vaccine before the 1997 initiation of the AVIP. The subsequent policy process behind the implementation of the AVIP clearly attempts to circumvent the requirements of the regulations, and later the specific requirements of the US Code, Executive Order, and DoD Directive, as well as the rights of US Servicemembers under these laws, regulations or directives.

False statements: False statements have been made under oath by at least two senior military officers, LtGen. Ronald Blaack, US Army, Retired; and Colonel Arthur Friedlander, US Army. These officer's false testimony regarding the IND (Investigational New Drug Application) for the Anthrax Vaccine Absorbed (AVA) obstructed the regulatory and legal bodies receiving the testimony from accurately assessing the legal issues involved. Further, Col. Friedlander's false testimony occurred across international borders as a representative of the US Military, tarnishing our nation's and military's reputation and credibility. Both officers have testified to Congress and sacrificed our nation's armed forces creditability and integrity in the eyes of our Congressional representatives and its military members.

Charge 1: AVIP violates Informed Consent rights of US Armed Forces members, contrary to US Law, Executive Order and DoD Directive:

1. 1999 Law on informed consent for US Servicemembers – 10 USC 1107.

2. September 29, 1999 Executive Order by President Clinton – EO 13139.

3. August 1, 2000 DoD Directive 6200.2 codifies USC and EO requirements.

Background:

Statement of John J. Michels, Jr. – before the House Government Reform Committee, 3 Oct 2000[41]:

"The 1970 NIH-approved license for AV indicates that it was approved as a prophylaxis only against cutaneous exposure to anthrax for a specific methodology of administration, and a specific vaccination schedule. (See: PHS / NIH approval paperwork submitted in Congressional Testimony by Dr. Claussen, October 12, 1999; House Committee on Government Reform; also See: Federal Register, December 13 1985, previously provided to the DoD IG on 16 JAN 01).

Recognizing the need for certification for pulmonary infections, in 1995 the Michigan Department of Public Health ("MDPH") and the Army discussed establishing a plan for Investigational New Drug approval by the FDA. [See: Anthrax Vaccine License Amendment Project Plan briefing slides (October 20, 1995]. The briefing slides clearly show that the Army was well-aware that the AV, in order to meet the above-described legal requirements for licensure, had to pass through the IND application process in order to become fully licensed as a prophylaxis for pulmonary anthrax. The focus of the proposed plan was to get approval from the FDA for a change to the immunization schedule (in this case to a series of three doses of vaccine versus the prescribed six) and to change the labeling to reflect that the vaccine was properly administered as protection against pulmonary or airborne anthrax.

In fact, less than one year from the date of the briefing, on September 20, 1996, MBPI filed an Investigational New Drug application with the FDA. The application identified the three areas where the current license would be modified – showing a new designation for "inhalation anthrax", changing the "route of administration", and changing the "vaccination schedule". The application indicates that it is an "initial" investigational new drug application. (See: Previously provided IND Application, dated September 20, 1996, to DoD IG on 16 JAN 00).

Thus, as the DoD was preparing to kick-off its anthrax vaccination program, the sole producer of anthrax vaccine recognized that its product, as labeled, was not legally viable and undertook the appropriate steps to change product use labeling, method of administration, and vaccination schedule. These substantial changes in how this drug was to be used rendered it an IND. This is explicitly acknowledged by the September 20, 1996 application by MBPL MBPI or Bioport has never withdrawn that application, nor has it ever been modified or acted on in any way. In fact the application was modified / updated in Jan. 1999 to include a single indication change: "Inhalation Anthrax."

[41] John J. Michels, Esq., testimony before the House Government Reform Committee, 3 Oct 2000. See: http://www.house.gov/reform/hearings/healthcare/00.10.03/michels.htm

The formal record of the anthrax program is littered with references to the vaccine's IND status. For example, as the Army began to move forward to try and license the vaccine as a prophylaxis against inhaled or pulmonary anthrax, it followed up its October 1995 meeting with a series of meetings designed to request that MBPI file an IND application for the vaccine. On November 13, 1995 the Joint Program Manager for Biological Defense, Army Brigadier General Walter L. Busbee, instructed the Joint Program Office for Biological Defense that the DoD needed to "...develop a ... package for initiating and completing an amendment to MDPH anthrax license for: (1) reduced immunization schedule, (2) immunization by the intramuscular route, and (3) indication for protection against an aerosol challenge". Minutes of the Meeting on Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements (November 13, 1995), Atch. 6. As late as June 30, 1999, in testimony before the House Subcommittee on National Security, Veterans Affairs and International Relations, Atch 7, at 12, Mr. Fuad El-Hibri, President and CEO of Bioport, stated

> [w]e continue to hold an Investigational New Drug application - IND 6847 – to improve administration of the anthrax vaccine.

The use of the AV as currently contemplated by DoD is a clear change in how the drug was to be originally used and for which it was licensed, rendering the AV an IND. There can be no doubt that "administration of the anthrax vaccine for mass prophylaxis in Biological Warfare should be considered an off-label use of the product to treat an indication for which it is not explicitly licensed... both the new indication and the new schedule should be undertaken only pursuant to FDA regulations governing clinical trials on investigational new drugs". The Department of Defense Anthrax Vaccination Immunization Program: Unproven Force Protection, p.3, House of Representatives Government Oversight Committee (March 9, 2000) Atch. 8.

This current vaccine is obviously a "new" drug under any FDA standard. Moreover, the Anthrax Vaccine is apparently is not even the same substance originally tested and approved by NIH. This bizarre conclusion is borne out in a GAO report dated April 29, 1999, entitled Medical Readiness: Safety and Efficacy of the Anthrax Vaccine, Atch. 9 where, at p. 3, it was revealed that the AVIP vaccine being administered to DoD members is not the same vaccine as originally tested prior to 1970. The import of this fact cannot be emphasized enough; the vaccine in current DoD inventories is NOT the same chemical compound as the original compound tested in advance of the 1970 NIH approval.

Accordingly, there can be absolutely no claim by DoD that the AV is anything but an IND. This fact is recognized by the AV's manufacturer, Bioport, in its IND application, which is still current and pending, and by the complete failure of Bioport, DoD or any other entity to provide verifiable clinical testing showing that the AV is either safe or effective, in humans, as a prophylaxis to pulmonary anthrax. The FDA testing regimen, which has not been waived or excepted for the AV, federal statutes,

and federal case law, all point to the inescapable determination that the AV is an IND as it is currently being used on members of the Armed Forces without their informed consent.

As a work around, it becomes apparent that the Department of Defense recognized that the manufacturer's inability to gain certification for its manufacturing process from the FDA due to failure to comply with CGMPs (current good manufacturing practices), as well as the inability to gain IND approval due to lack of efficacy testing against inhalation anthrax IAW regulations. As a result the Assistant SECDEF for Health Affairs, Mr. Stephen Joseph wrote a letter to FDA Lead Commissioner Michael Friedman on 4 Mar 1997 maintaining that Anthrax Vaccine Absorbed had been long recognized as approved for inhalation anthrax protection. This new commissioner accepted the DoD's request. On 13 Mar 1997 FDA Lead Commissioner Michael Friedman offered to ASD/Health Affairs Stephen Joseph a letter on FDA letterhead with the language DoD felt they needed to circumvent the regulatory requirements – the language specifically said the the DoD's use for the vaccine, "was not inconsistent" with the product's license. As the GAO noted in House Congressional Hearing on 11 October 2000, this also did not maintain that the use was "consistent" with the AVA's label or license.

Further, the Code of Federal Regulations, specifically 21 CFR 10.85 – Advisory Opinions – explains precisely why the 13 Mar 1997 letter by FDA Lead Deputy Commissioner is legally irrelevant – yet this is the primary justification the DoD uses to maintain product approval:

> *"A statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this section or Sec. 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."*[42]

The FDA personal memo of 13 March 1997 didn't proceed through this or any other process that complies with the requirements of the regulations or current laws. It appears to be a quick fix for a vaccine that was to be the foundation of a multi-level biowarfare vaccine force protection program."

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[42] 21 CFR 10.85, "Advisory Opinions"
See: http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=10&SECTION=85&YEAR=1999&TYPE=TEXT

Specific Background on Charge 1, Item 1 – 1999 Law on informed consent for US Servicemembers – 10 USC 1107:

A determination that the AVA is an IND renders inescapable the conclusion that service members as a consequence of federal law and service regulations must give their informed consent prior to submitting to vaccinations. Despite the complexities of these requirements, Servicemembers cannot be denied this right unless the President waives their informed consent. This has not happened. This argument is codified in the laws of the land as of 1999 and the passage of Title 10, Section 1107 of the US Code:

The Federal Statute:

10 U.S.C. § 1107 (1999) entitled "Notice of Use of an Investigational New Drug or a Drug Unapproved for its Applied Use" specifically provides:

> A – Notice Required. - (1) Whenever the Secretary of Defense requests or requires a member of the armed forces to receive an ***investigational new drug or a drug unapproved for its applied use***, the Secretary shall provide the member with notice containing the information specified in subsection (d).
>
> ***E – Limitation and Waiver. - (1) In the case of the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation, the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) may be waived only by the President.*** The President may grant such a waiver only if the President determines, in writing, that obtaining consent –
>
> 1. Is not feasible;
> 2. Is contrary to the best interests of the member; or
> 3. Is not in the interests of national security. (Emphasis added).

Specific Background on Charge 1, Item 2 – The Executive Order of the President:

An Executive Order is a lawful order of the Commander-in-Chief of the United States Armed Forces. On September 30, 1999, the President issued Executive Order 13139, entitled "Improving Health Protection of Military Personnel Participating in Particular Military Operations". EO 13139 reiterates many of the requirements of federal law and specifically provides in part:

> Sec. 2. Administration of Investigational New Drugs to Members of the Armed Forces. (a) The Secretary of Defense (Secretary) shall collect

intelligence on potential health threats that might be encountered in an area of operations. The Secretary shall work together with the Secretary of Health and Human Services to ensure appropriate countermeasures are developed. ***When the Secretary considers an investigational new drug or a drug unapproved for its intended use (investigational drug) to represent the most appropriate countermeasure, it shall be studied through scientifically based research and development protocols to determine whether it is safe and effective for its intended use.*** (b) It is the expectation that the United States Government will administer products approved for their intended use by the Food and Drug Administration (FDA). However, in the event that the Secretary considers a product to represent the most appropriate countermeasure for diseases endemic to the area of operations or to protect against possible chemical, biological, or radiological weapons, but the product has not yet been approved by the FDA for its intended use, the product may, under certain circumstances and strict controls, be administered to provide potential protection for the health and well-being of deployed military personnel in order to ensure the success of the military operation. The provisions of 21 CFR Part 312 contain the FDA requirements for investigational new drugs.

Sec. 3. Informed Consent Requirements and Waiver Provisions.

A -- Before administering an investigational drug to members of the Armed Forces, the Department of Defense (DoD) must obtain informed consent from each individual unless the Secretary can justify to the President a need for a waiver of informed consent in accordance with 10 U.S.C. 1107(f). Waivers of informed consent will be granted only when absolutely necessary. (Emphasis added).

In addition, the provisions of 21 C.F.R. §§ 50, 312 (October 5, 1999) support both the federal statute and the Executive Order by specifically noting situations where the informed consent requirements may be waived. Echoing 10 U.S.C. § 1107, the Regulations note that only the President of the United States may waive the informed consent requirements mandated by his Executive Order and federal law. Waiver is allowed only if one of three preconditions is met -- if obtaining informed consent is not feasible; if obtaining informed consent is contrary to the best interests of the recipient; or if informed consent is contrary to national security interests. The President has yet to issue any such waivers, or even initiate action to do so regarding the AVA.

Specific Background on Charge 1, Item 3 – DoD Directive 6200.2:

Reiterating both Federal Law, Executive Order and standing FDA Regulations, the Department of Defense coordinated it's own Directive in August of 2000, which DoD is also in violation of by using AVA without informed consent or with a Presidential waiver:

Department of Defense DIRECTIVE – NUMBER 6200.2 – SUBJECT: Use of Investigational New Drugs for Force Health Protection – i.e., requirements to comply with Federal Law and applicable Executive Orders.

References: (a) Section 1107 of title 10, United States Code (b) Executive Order 13139, "Improving Health Protection of Military Personnel Participating in Particular Military Operations," September 30, 1999 (c) Title 21, Code of Federal Regulations, Parts 50, 56, 312, Subpart I of Part 314, Subpart G of Part 601, current edition (d) House Report No. 105-736, Conference Report to Accompany Proposed Strom Thurmond National Defense Authorization Act for Fiscal Year 1999, page 685 (e) through (f), see enclosure

1. PURPOSE – This Directive: 1.1. Establishes policy and assigns responsibility for compliance with references (a) through (c) for the use of investigational new drugs for force health protection. 1.2. Designates the Secretary of the Army as the DoD Executive Agent for the use of investigational new drugs for force health protection.
2. APPLICABILITY AND SCOPE – This Directive: 2.1. Applies to the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities and all other organizational entities within the Department of Defense.
2.2. Applies to all uses of investigational new drugs by the Department of Defense for force health protection.
3. DEFINITIONS – 3.2. Investigational New Drug (IND). A drug or biological product subject to the FDA regulations at 21 CFR Part 312 (reference (c)), including: 3.2.1. A drug not approved or a biological product not licensed by the FDA. 3.2.2. A drug unapproved for its applied use.

Charge 2: False Testimony

False testimony to Congress and to a Canadian Courts-martial concerning the IND issue misrepresents the issue surrounding AVA's use without informed consent:

#1 – COL Arthur Friedlander's false testimony to a Canadian court-martial

COL Friedlander's vague answers in his trial testimony (below), while under oath, consistently attempt to deny any knowledge of the primary purpose of the 20 Sep 1996 Investigational New drug application prepared by USAMRIID for the anthrax vaccine manufacturer – to obtain a new licensed indication for inhalation anthrax.

Excerpted testimony from 30 Mar 2000, questioning by Assistant Defence Counsel Jill Duncan and answers by Colonel (Dr.) Arthur Friedlander, U.S. Army (USAMRIID, Ft. Detrick, MD):[43]

MINUTES OF PROCEEDINGS
STANDING COURT MARTIAL

For the trial of K72 142 802 Ex-Sergeant Michael Richard KIPLING, Canadian Forces, Regular Force, held at 17 Wing Winnipeg, Manitoba on the 15th, 16th, 17th, 22nd, 23rd, 24th, 25th, 28th and 29th days of February 2000; and the 27th, 28th, 29th, 30th and 31st days of March 2000; and the 26th day of April 2000; and the 5th day of May 2000.

MILITARY JUDGE
F26 089 814 Colonel G.L. Brais, Office of the Chief Military Judge.

Assistant Defence Counsel Duncan:
Q.**If I'm going to suggest to you, sir, that the drug was licenced for cutaneous anthrax only and that there has been a subsequent amendment for coverage for inhalation anthrax, would you agree with me or disagree with me?**

Colonel Friedlander:
A. I'm not aware of that.

Q. Okay. I'm going to show you something, sir, that seems to suggest at least--I'll give you a copy.

[43] Canadian court-martial trial transcript, Judge G.L. Brais, 30 Mar 2000, Office of the Chief Military Judge, Canadian Forces

A. Uh-huh.

ASSISTANT DEFENCE COUNSEL: Oh, I've given you the copy for the judge. I'll just refer, Your Honour, if I might to where I want the witness to attend to and then I'll show it to Your Honour.

MILITARY JUDGE: Yeah, but I'd like to know what it is first, before you have the witness ...

ASSISTANT DEFENCE COUNSEL:
Q. It's off of the web and it indicates that it's an article from the *Belleville News-Democrat* newspaper, March 27th, the year 2000?

A. Uh-huh.

Q. Have you seen this newspaper article, sir?

A. No, no.

Q. In particular, the fifth paragraph, it says that the office, and this is referring to the Joint Program Office for Biological Defense, quote: "managed and funded efforts leading to the submission of a Biologic Licensure Application amendment to the FDA,' including data to support its proposal 'to license the vaccine to provide protection against aerosol exposure to anthrax.'". Is that something you're familiar with, sir, or would you disagree with that statement?

A. I'm not sure the details of this, I do know that there were questions that were raised, since there are no direct studies in humans with this vaccine, and that a statement was made by the FDA that the use of the vaccine in the Gulf War against the threat of aerosol use of spores was not inconsistent with the product licence.

ASSISTANT DEFENCE COUNSEL: Okay. I don't know whether my learned friend has any objection to tendering this into evidence; the witness has referred to it.

MILITARY JUDGE: Well, you've, sort of, put the cart before the horse. But, you know, I mean, I wanted to see the document before you questioned the witness on it. I guess there was no objection, so now it's done.

PROSECUTOR: Your Honour, I would object to this. He has responded to ...

MILITARY JUDGE: Well, it's too late, its done, I've heard it. I've heard it, now it's a question of weight.

PROSECUTOR: Well, ...

ASSISTANT DEFENCE COUNSEL: Okay, I'll proceed then. This is not a document that was offered by this gentleman, so I'll just leave it at that.

Q. But, sir, when you say that it's not inconsistent with inhalational anthrax, that's something slightly different than saying it was licenced for inhalational anthrax, wouldn't you agree?

A. I can read to you what it says in the product insert about anthrax, and I think that the question is what you mean by "contact".

Q. Okay. Well, my question to you actually, sir, was: To say that it's not inconsistent with inhalational anthrax is different than saying this drug is--or this vaccine is for inhalational anthrax?

A. That's for the person who wrote that statement to--I mean, the interpretation of that, I'm not here to interpret that statement, I didn't make that statement.

Q. If I was to suggest to you, sir, that we've heard evidence that the vaccine was licenced for cutaneous anthrax and that there was an application placing the drug into IND status with the FDA for three reasons: one, is to change for inhalational anthrax; two, was to change the route of administration; and, three, to change the scheduling of the drugs, would you agree with that or do you know?

A. I know that there have been studies dealing with trying to reduce the number of doses and to look at the route of administration.

Q. So are you saying, sir, that you're not familiar with what I've said, or you disagree with it?

A. No, no. I don't know that--I'd have to look back at the documents that you're referring to.

Q. Okay. So you're not saying the drug is not in an IND status for those three variations?

A. You know, I'm not clear what you're saying in terms of--I mean, I'm not quite clear what that means, in other words. There are studies that have been done, that I'm involved with, looking at reducing the number of doses and changing the route of administration.

Q. Okay. That's not actually what I'm asking, sir?

A. Yes.

Q. Okay. Maybe if I can make myself clearer: We've heard evidence that the drug was licenced for cutaneous anthrax and that it's now been proposed, presumably by DOD, to make three changes: one, is make it a countermeasure for inhalational anthrax as opposed to cutaneous; two, change the route of administration; and, three, the schedule of dosages, and that because it's an amendment, the drug has gone into IND status for that purpose?

A. You know, I can't answer that question. You have to talk to the people actually directing that study.

Q. So you're saying you're not sure?

A. That's right.

Comment: The DoD documents provided to the DoD IG, and detailed in the previously listed chronology, reflect that despite Col. Friedlander assertion that he was "not aware" of the purpose of the Investigational New Drug application filed on 20 Sep 1996, on at least three occasions he was present at DoD meetings during which he specifically briefed the three reasons for the IND application, including an FDA license amendment to add an indication for inhalation anthrax:

1. **20 Oct 1995 briefing.** Colonel Friedlander presented a briefing at a meeting held by the Joint Program Office for Biological Defense on 20 Oct 1995. The meeting was a strategy session held by DoD and manufacturer representatives to develop a gameplan for "Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements."[44] According to the meeting minutes, Col Friedlander:

   - *"...presented a briefing covering the three topics: (1) evidence for a reduction in the number of doses of anthrax vaccine, (2) evidence for vaccine efficacy against an aerosol challenge [inhalation anthrax], and (3) progress towards an in vitro correlate of immunity."*

   - ***"Dr. Friedlander agreed that the surrogate animal model needed to be established", which followed his acknowledgment that "there was insufficient data to demonstrate protection against inhalation disease."***

[44] LTC David Danley, "Minutes of the Meeting on Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements", held on 20 Oct 1995 meeting; Joint Program Office for Biological Defense memorandum, 13 Nov 1995.

- Last, a briefing slide from this meeting titled, "Immediate Objectives for Anthrax Vaccine Licensure", explained the purpose of the IND to be prepared by the Army: *"To obtain a [FDA] Product License Application Supplement approval for a specific immunization schedule change...and for a labeled indication change [such as the indication for use in protection against aerosol challenge)."*

2. **9 Feb 1996 briefing.** At a follow-up meeting on 9 Feb 1996 Col. Friedlander presented another briefing titled "Research Plan to Support Reduction in Dosage of Licensed Anthrax Vaccine (AVA) and Indication for Aerosol Exposure". This clearly demonstrates that Col. Friedlander was integrally involved in the preparation of the investigation protocol prepared by the US Army, and which the manufacturer ultimately submitted to the FDA on 20 Sep 1996. The meeting minutes show that Friedlander discussed the need for the study to show a correlation between animal and human immune response to the vaccine – a recognition that the anthrax vaccine had never demonstrated efficacy for inhalation anthrax in humans which is the legal requirement for licensure.[45]

3. **10 Nov 1997 briefing.** Col. Friedlander presented another briefing to DoD and contractor representatives on 10 Nov 1997 titled: "Supplement to AVA License". This was 14 months after the submission of the IND application by the manufacturer. The briefing slides clearly show the three changes sought (including an indication for inhalation anthrax] and that Col. Friedlander was responsible for the pre-clinical portions of these studies intended to obtain FDA approval for these changes.[46]

4. **15 Dec 1998 briefing** concerning the update to the IND application. A meeting was held and Col. Friedlander was listed as an attendee in which the IND application status was the primary topic. The only reason listed as a new "indication" on the IND application was "inhalation anthrax."

Col. Friedlander's testimony stands contrary to his presence at these meetings and his intimate knowledge of the IND application. This IND application update, dated 29 January 1999, was submitted in the very month military pilots in the Connecticut Air National Guard were being forced out of their combat positions due to their unanswered questions about the illegal nature of the AVIP mandate.

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[45] Col (Dr.) Arthur Friedlander, Minutes of the Anthrax License Amendment Issues Meeting, briefing titled "Research Plan to Support Reduction in Dosage of Licensed Anthrax Vaccine (AVA) and Indication for Aerosol Exposure", 9 Feb 1996.

[46] Col (Dr.) Arthur Friedlander, briefing titled "Supplement to AVA License" (slides), meeting attended by USAMRIID and contractor representatives, 10 Nov 1997

#2 – LTG Ronald Blanck false testimony to Congress

Further evidence of attempts to deny knowledge of the IND application came in testimony to the Senate Armed Service's Committee on 13 April 2000. **In testimony before Congress LTG Ronald Blanck, then-Army Surgeon General, misrepresented the purpose of the Investigational New Drug application prepared by the Army for the manufacturer.** The Senator who queried LTG Blanck was unfamiliar with the Food, Drug, and Cosmetic Act and accepted LTG Blanck's testimony without question. Therefore, he did not pursue the fundamental issue – that the Army knew that the anthrax vaccine is not licensed for inhalation anthrax and that it had prepared an IND application for the vaccine manufacturer to submit to the FDA on 20 Sep 1996 to satisfy a legal standard that it later ignored.

Excerpted verbatim testimony before the Senate Armed Services Committee, 13 Apr 2000:

> SEN. ROBERTS: General Blanck, the annual Congressionally mandated chemical and biological defense program report to Congress submitted on March 15, 2000, states: "The Department submitted data to the FDA last year to license the vaccine to provide protection against aerosol exposure to anthrax." My question is why is the Department seeking a license for the vaccine when the license for the anthrax vaccine has existed since 1970?
>
> GEN. BLANCK: It is really for the facility, not for the vaccine per se.
>
> SEN. ROBERTS: Oh, I see, okay. All right. That clears that up.

Legal Issue #1 – Informed Consent – Conclusion:

To the contrary, these two examples of misleading and false testimony do not clear things up. These examples of false testimony over the pivotal issue of the IND status of the anthrax vaccine go straight to the core of the legal issues involved. By not answering these questions in a forthright manner the legal concerns of both the Canadian Court and the US Congress were obstructed by these US Army officers. Further, the chain of events in the chronology and the awareness by the US Army that the anthrax vaccine was inadequate and unlicensed make it painfully clear that the Anthrax Vaccine Absorbed and the Anthrax Vaccine Immunization Program, testimonials, education programs, and UCMJ action against US Servicemembers all stand contrary to the Law, Executive Order, DoD Directives, and every military member's oath to uphold the Constitution and the laws of the land.

Section D
Legal Issue #2 – Adulteration

History of Anthrax Vaccine Adsorbed.

The Search. The search in the Western hemisphere for a vaccine protective against *Bacillus anthracis* began in earnest in the mid-1940's with Gladstone[47] in the United Kingdom and Cromartie[48] in the United States. Identification studies, production studies, and animal trials continued through the 1940's and into the early 1960's. The first human use of an anthrax vaccine in the United States was chronicled in 1954[49].

The Vaccine.

The first field trial of a human anthrax vaccine, known as the Brachman Study, was conducted from 1955-1959 at four goat hair-processing mills in the Northeast U.S. The findings were published in 1962[50]. Development of the vaccine continued unabated during this time and in 1965 a patent was granted to the U.S. Army[51] for an anthrax antigen [vaccine]. ***It is this vaccine, not the vaccine used in the Brachman study for which a license was sought.***

An application to license this vaccine was submitted in 1967. A study was conducted in Talladega using this patented vaccine (the results have never been published). Correspondence between the investigators and the National Institutes of Health indicate problems with the study. In January 1968 the Acting Chief of the study, Dr. Philip Coleman, wrote[52]

- ***"As to the efficacy of the vaccine, we have no real method of determining the protection afforded."***

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[47] Gladstone, GP. Immunity to Anthrax: Protective antigen Present in Cell-free Culture Filtrates. The British Journal of Experimental Pathology. Vol. 27 pp394-418

[48] Cromartie, WJ. Et al. Studies on infection with Bacillus anthracis. The Journal of Infectious Diseases. Vol. 80 No. 1 pp14-52

[49] Wright, GG. Et al. Studies on Immunity in Anthrax. The Journal of Immunology. Vol. 73 No. 6 pp387-391

[50] Brachman. PS. Et al. Field Evaluation of a Human Anthrax Vaccine. American Journal of Public Health. Vol. 52 pp632-645

[51] Puziss, M. Wright, GG. Anaerobic Process for Production of a Gel-adsorbed Anthrax Immunization Antigen. United States Patent Office Record. September 28, 1965. page 1471

[52] Philip Coleman, Acting Chief, Investigational Vaccines Activity , letter to Division of Biologics Standards, National Institutes of Health, 25 January 1968.

A 6 February 1969 memorandum from the licensing oversight committee to Dr. Margaret Pittman, of HEW, chides the study efforts by stating[53]:

- *"The lack of cases of anthrax in an uncontrolled population of approximately 600 persons in the Talladega mill can hardly be accepted as scientific evidence for efficacy of the vaccine."*

On 10 February 1969 Dr. Pittman recommended licensure of the vaccine but wrote[54]

- ***"It was noted also that clinical data establishing efficacy of the product had not been submitted and that data be requested from NCDC*** [National Communicable Disease Center]."

On 2 November 1970 license approval was recommended by the Department of Health, Education, and Welfare **without any efficacy data.**[55] The License was granted on 10 November 1970. At some point the efficacy data from the earlier Brachman Study was submitted and accepted (no documentation of this has been uncovered). The Brachman Study is referenced on the approved package insert. **It is important to realize that the vaccine used in the Brachman Study differed from the licensed vaccine in strain, formulation, and production method.**

The license for biologic products actually consists of two separate applications, the establishment license application (ELA), and the product license application (PLA). FDA requires that both applications be approved simultaneously for a license to be granted.

The vaccine was ostensibly developed to protect mill workers in danger of contact with anthrax spores from handling contaminated animal products. Shortly after the vaccine was licensed, the mills began closing as the garment industry changed. The risk of exposure and infection from anthrax spores by the general public disappeared. **The vaccine's use became limited to experiments on laboratory animals, the researchers conducting the experiments, and the staff at the manufacturing plant.**

The FDA and Anthrax Vaccine Adsorbed.

The FDA completed a review of biologic products (vaccines) in 1985 and published a Proposed Rule in the Federal Register on 13 December 1985.[56] This proposed rule was the result of a review of the safety, efficacy, and labeling of bacterial vaccines and toxoids with standards of potency. AVA is such a product. The FDA review of AVA severely limits its endorsement of the product.[57]

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[53] Ad Hoc Committee letter to Dr. Margaret Pittman, 6 February 1969.
[54] Dr. Margaret Pittman, letter to Dr. Sam Gibson, 10 February 1969.
[55] HEW memorandum from Margaret Pittman to Reference No. file 67-70. 2 November 1970.
[56] Federal Register, Vol. 50, No. 240, pp51002 et seq.
[57] Federal Register, Vol. 50, No. 240, page 51038.

- *"In general, safety of this product is not a major concern, especially considering its very limited distribution..."*

- *"Immunization with this vaccine is indicated only for certain occupational groups with risk of uncontrollable or unavoidable exposure to the organism. It is recommended for individuals who come in contact with imported animal hides, furs, wool, hair (especially goat hair), bristles, and bone meal, as well as laboratory workers involved in ongoing studies on the organism."*

- *"Anthrax vaccine poses no serious special problems other than the fact that its efficacy against inhalation anthrax is not well documented."*

- *"The Panel believes that there is sufficient evidence to conclude* that *anthrax vaccine is safe and effective under the limited circumstances for which this vaccine is employed."*

The FDA made the following critique of the licensed vaccine in the 1985 review.

- *"The vaccine manufactured by the Michigan Department of Public Health has not been employed in a controlled field trial."*

- *"The labeling seems generally adequate. There is a conflict, however, with additional standards for anthrax vaccine. Section 620.24(a) defines a total primary immunizing dose as 3 single doses of 0.5 mL. The labeling defines primary immunization as 6 doses..."*

- *"Labeling revisions in accordance with this Report are recommended."*

FDA recognized a discrepancy and recommended that the labeling be changed. The additional standards, published in the Code of Federal Regulations, were the standard approved by FDA. FDA noted that the labeling indicated six doses where the additional standards indicated three doses.

A review of late-1960's Annual Progress Reports on the licensing study indicates that the primary dosing schedule was three doses.[58] **The labeling has never been changed, the DOD has followed the six-dose schedule, and the FDA has not commented on or corrected this glaring discrepancy.**

The Manufacturer.

The Michigan Department of Public Health (MDPH), holder of the one U.S. license for anthrax vaccine adsorbed, produced the vaccine sporadically throughout the 1970's and

[58] NCDC Annual Progress Report to the Director, Division of Biologic Standards, 1 October 1968.

1980's. The first large DOD contract occurred in 1988, with three additional DOD contracts through 1998. The Michigan Department of Public Health semi-privatized its Biologics Division into the Michigan Biologic Products Institute in 1997. They in turn sold the facility and its licenses to BioPort in 1998. During the Gulf War there was an effort by the US Army to obtain FDA approval of other manufacturer's under the MDPH license. Although at least on contract was awarded and the manufacturer was indemnified by the Secretary of the Army[59], the Army claims these entities made no vaccine.

Until the 1988 contract with DOD, production of AVA was infrequent, a batch being produced every three to four years, the largest being 7500 doses. MDPH had one production line that they alternately used for other vaccine products. A requirement to drastically increase production for the DOD contracts required an expansion of the production facility.

Originally one production line was built around a 100-liter glass-lined fermentor. Two new stainless steel fermentors (production lines) were added in 1990. The original production line was replaced in 1991 with two additional stainless steel fermentors (production lines). These four fermentors produced AVA until the facility was shut down in January 1998.

The new production lines used different equipment than that approved for the original facility. **The manufacturer was aware of the need to gain FDA approval for this new equipment and an FDA official communicated to Dr. Myers, Responsible Head for MDPH, that the new equipment was considered a major change to the ELA.**[60] MDPH applied for an amendment to the ELA in December 1990[61], after the first two fermentors had been installed. The FDA approved this amendment to the ELA in 1993.[62] **No ELA amendment for the two fermentors installed in 1991 was ever sought or made. Additionally, MDPH did not seek to amend their PLA with this change of equipment.**

The type of filter used in the sterilization process was also changed at this time. There were no amendments sought to the ELA or PLA.

Once the additional production lines became operational, MDPH mixed the batches coming off the lines to form a final anthrax vaccine (FAV). Prior to the additional lines the vaccine was merely called Lot3, Lot4, etc. After the new lines were operational, the vaccine released for distribution was called Lot FAV001, FAV002, etc.

Throughout this time frame, MDPH made other changes, to include changing the reference standard, applying for a change to the potency test, changing the amounts of

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[59] SecArmy memorandum of decision, "Authority Under Public Law 85-804 to Include an Indemnification Clause in Contract DAMD17-91-C1086 with Program Resources, Inc., 3 Sep 1991 http://www.dallasnw.quik.com/cybercila/Anthrax/Mem_D_91.html

[60] Conversation record memo from Rebecca Devine to Dr. Myers, 9 July 1990.

[61] MDPH letter to CBER seeking to amend establishment license for new equipment, 6 December 1990.

[62] CBER letter to MDPH granting approval of new equipment, 27 July 1993.

preservative, etc. FDA approved most of these changes. However, an application to change the reference standard was never made.

Plans for a new facility began during the mid-1990's and in January 1998, BioPort stopped producing AVA. The production facility was razed shortly thereafter. BioPort has made AVA in the new facility, but awaits FDA approval of the new facility and the vaccine produced there.

The FDA and the Manufacturer.

FDA regularly inspected MDPH. These inspections document a pattern of non-compliance with current good manufacturing practices (cGMP), not only with AVA, but also with every product the manufacturer made. **Every inspection of MDPH resulted in discrepancies ranging from unsanitary conditions and unapproved procedures to non-compliance with current Good Manufacturing Practices (GMP), contaminated products, and changing equipment and products without approval.** For example:

1988.[63]

- *"There is no written procedure for assessing stability characteristics of final biological products."*

- *"No direct physical accountability for packaged undated anthrax vaccine which was stored alongside of packaged and dated vaccine with the same lot number. Nine hundred and six vials of unfinished vaccine were distributed freely in 3 cardboard boxes with unknown number of vials in each carton. Removal of vials as needed was not indicated."*

1990.[64]

- *"Anthrax prod. fac. was observed to be in a state of general disrepair in that there was: (A)Paint peeling from the walls (B)Exposed light fixtures (C)Cracked ceiling (D)Exposed raceways (E)Dirt & filth & dust on overhead pipes (F)Cluttered work space."*

- *"Anthrax prod. records are inconsistent in that procedures used to formulate Lot #21 are different from those used to formulate Lots #25, 26 & 27 in that media is autoclaved for sterilization for Lot #21 and filtered for sterilization for Lots #25, 26 & 27."*

1992.[65]

- ***"Changes in the manufacturing methods for...were not submitted as amendments to the product license application prior to releasing the material for distribution..."***

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[63] FDA Form 483 Inspectional Observations, 26-27 April 1988.
[64] MDPH letter to CBER responding to FDA inspectional observations made on 12-13 September 1990, 10 October 1990.
[65] FDA Form 483 Inspectional Observations, 29-31 July 1992.

- *"No SOP* [standard operating procedure] *exists to describe procedures for handling potentially infectious material..."*

1993.[66]

- ***"There are insufficient personnel to assure compliance with current GMP regulations, e.g., failure to report changes in manufacturing, failure to maintain calibration records adequately, failure to adequately validate equipment used in the formulation or testing of product."***

1994.[67]

- ***"There are insufficient personnel to assure compliance with current GMP regulations, e.g., failure to maintain calibration records adequately, failure to maintain environmental controls adequately in that production area temperatures were above 80°F, and failure to submit changes to CBER."***

- *"There is no annual review of production batch records* [anthrax]*."*

- *"Raw material* [anthrax vaccine materials] *stored in an unapproved warehouse, building (redacted) i.e., no ELA* [establishment license application] *supplement has been submitted for this area."*

1995.[68]

- ***"the company did not inform FDA of the procedural and equipment change during the production of..."***

- *"facilities and equipment were not adequate."*

- *"SOP's did not exist for many procedures."*

- *"SOP's were incomplete or incorrect."*

- *"SOP's were not adhered to."*

- *"Frequent contamination during vaccine manufacturing was documented but not investigated."*

The CBER Inspection Task Force recommended the issuance of a Warning Letter to MDPH on 22 June 1995. A Warning Letter was issued to MDPH on 31 August 1995.

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[66] FDA Form 483 Inspectional Observations, 4-7 May 1993.
[67] FDA Form 483 Inspectional Observations, 31 May – 3 June 1994.
[68] FDA Form 483 Inspectional Observations, 23 April 1995 – 5 May 1995.

1996.[69]

- *"The firm had not completed cleaning validation studies for routine cleaning procedures on multi-use equipment."*

- *"Validation studies to demonstrate microbial retention and compatibility have not been conducted for sterilizing filters..."*

- *"There was condensate dripping onto open* (redacted) *tanks..."*

- *"There was no procedure for clean-up of live rabies virus spills..."*

The anthrax production facility was not inspected because "*It comes under military Inspection.*"[70]

1997.[71]

- CBER issues a "Notice of Intent to Revoke" citation to Michigan Biologic Products Institute on 11 March 1997. The Army responds by sending in a team to assist the manufacturer develop a "strategic compliance plan."

1998.[72]

- In anticipation of an FDA inspection following up on their threat to revoke the manufacturer's license, MBPI "voluntarily" shut down production in January 1998. On 4 February 1998 the FDA returned to inspect the facility, and issued a report concluding: ***"The manufacturing process for Anthrax Vaccine is not validated."***

- *"There are no written procedures , including specifications, for the examination, rejection, and disposition of Anthrax and Rabies."*

- *"Prior to August 1997, the (redacted) filters used for harvest of Anthrax vaccine were neither validated nor integrity tested. This filter is the only sterile filtration step in the Anthrax manufacturing process."*

- *"There is no written justification for redating lots of Anthrax vaccine that have expired."*

- *"The firm does not trend multiple contaminations with microorganisms in sublots."*

As a result of this inspection, MBPI "voluntarily" quarantined 11 lots of AVA. The failure of FDA to recall the quarantined vaccine and order it destroyed resulted in some of it being shipped to the Canadian military and being used on their servicemembers.[73]

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[69] FDA Form 483 Inspectional Observations, 18-27 November 1996.
[70] Summary of Findings Report, 14 January 1997.
[71] CBER NOIR letter to MBPI, 11 March 1997.
[72] FDA Form 483 Inspectional Observations, 4-20 February 1998.
[73] Ann Rees, "Their Dangerous Dose", The Province [Vancouver, Canada], 25 Jun 2000

Another inspection took place in October 1998, finding:[74]

- *"Stability testing has not always been performed in accordance with stability protocols, for example..."*

- *"CBER has not been notified in accordance with Error and Accident reporting of the following..."*

- *"On 6/30/98, the firm installed a new reaction tank mixer on Tank (redacted). There is no data documenting that the new mixer is equivalent to the old mixer, including mixing profiles. In addition, CBER has not been notified of this change."*

1999.[75]

- FDA finding: ***"The manufacturing process for Anthrax Vaccine Adsorbed is not validated."***

Thirty observations were noted. The inspection report ends with this comment.

- ***"The observations noted in this FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the GMP regulation."***

2000.[76]

- *"The design and construction...do not assure sterility of products filled..."*

- *"The following product lots failed initial sterility testing for release or for stability testing...Investigations into these initial sterility failures are incomplete..."*

- *"Investigations are incomplete, inaccurate, or not conducted."*

- ***"There is no assurance equipment is operating as designed."***

Adulteration.

a) The law.

Anthrax Vaccine adsorbed is a biologic product designed for human consumption. Biologic products are regulated by the Public Health Service Act (PHS) and the Federal Food, Drug, and Cosmetic Act (FDCA). 42 USC Section 262 describes the regulation of

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[74] FDA Form 483 Inspectional Observations, 19-23 October 1998

[75] FDA Form 483 Inspectional Observations, 25-23 November 1999.

[76] FDA Form 483 Inspectional Observations, 10-26 October 2000.

biologic products according to the PHS. Chapter 9 of Title 21 of the U.S. Code contains the FDCA. The FDCA provides the following definition of an adulterated drug:[77]

- *"A drug shall be deemed to adulterated (a)(1) (A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess"*

The Federal Food, Drug, and Cosmetic Act provides a definition of a misbranded drug:[78]

- *"A drug or device shall be deemed to be misbranded – (a) False or misleading label. If its labeling is false or misleading in any particular."*

The Federal Food, Drug, and Cosmetic Act also establishes prohibited acts related to adulteration and misbranding:[79]

- *"The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."*

The Code of Federal Regulations set forth the current good manufacturing practice regulations in manufacturing, processing, packing, and holding of drugs. 21 C.F.R. § 210.1(b) describes the status of the current good manufacturing practices regulation.

- *"The failure to comply with any regulation set forth in this part and in parts 211 through 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action.*

21 C.F.R. § 210.2(a) describes the applicability of the current good manufacturing practices regulation.

- *"The regulations in this part and in parts 211 and 226 of this chapter as they may pertain to a drug and in parts 600 through 680 of this chapter as they may pertain to*

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[77] 21 U.S.C. § 351
See: http://www4.law.cornell.edu/uscode/21/351.html
[78] 21 U.S.C. § 352
See: http://www4.law.cornell.edu/uscode/21/352.fest.html
[79] 21 U.S.C. § 331
See: http://www4.law.cornell.edu/uscode/21/331.html

a biologic product for human use, shall be considered to supplement, not supersede, each other, unless the regulations explicitly provide otherwise."

Part 600 of 21 C.F.R. deals with Biologics. The only portion of Part 600 that "*explicitly provides otherwise*" concerns applications for the establishment and product licenses for a therapeutic DNA plasmid product, therapeutic synthetic peptide product of 40 or fewer amino acids, monoclonal antibody product for in vivo use or therapeutic recombinant DNA-derived products. All other biologics regulations are supplemented by the current good manufacturing practices regulations cited above.

21 C.F.R. § 601.12 reads in part:

- *"(a) General. As provided by this section, an applicant shall inform Food and Drug Administration (FDA) about each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling, established in the approved license. **Before distributing a product made using a change, an applicant shall demonstrate through appropriate validation and/or other clinical and/or non-clinical laboratory studies, the lack of adverse effect of the change on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.**"*

- *"(b) Changes requiring supplemental submission and approval prior to distribution of the product made using the change (major changes). (1) A supplement shall be submitted for any change in the product, production process, quality controls, equipment, facilities, or responsible personnel that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety and effectiveness of the product. (2) These changes include but are not limited to: (i) Changes in the qualitative or quantitative formulation or other specifications as provided in the approved application or in the regulations; (vi) Changes which may affect product sterility assurance, such as changes in product or component sterilization method(s), or an addition, deletion or substitution of steps in a aseptic processing operation."*

Adulteration.

b) The Fermentors.

The anthrax vaccine (AVA) produced by MDPH since 1990, by MBPI when they took over the operations in 1996, and the stockpile currently owned by BioPort is adulterated. **The product is adulterated for many reasons.**

The fermentors added in 1990 were considered a major change. Ms. Devine, an FDA employee, informed MDPH's executive director, Dr. Myers, of this in the summer of 1990. The request to amend the ELA was made in December 1990. This amendment was finally approved in July 1993, two and one half years after the facility had been modified.

During this time frame, MDPH was producing and *distributing* AVA without the *prior approval* required IAW 21 C.F.R. § 610.12 above.

The fermentors added in 1991 are also considered a major change. An independent review of the facility by a DoD contractor in February 1996 noted that two of the fermentors had not been supplemented [approved], and if FDA found out they could expect severe consequences.[30] This means that ***all the AVA produced and distributed since these two additional fermentors were installed in 1991 is adulterated.***

Adulteration.

c) The Filters.

Along with the new fermentors came new filters. As referenced in the above CFR, *"Changes which may affect product sterility assurance, such as changes in product or component sterilization method(s)" require prior approval.* No such amendment was sought. FDA made note of this in their February 1998 inspection report:

- *"Prior to August 1997, the* [redacted] *filters used for harvest of Anthrax vaccine were neither validated nor integrity tested. This filter is the only sterile filtration step in the Anthrax manufacturing process."*

- *"I questioned W. White, D. Slabbekoorn, and T. Wilsey regarding the filters used prior to this validation. Each reported that the filters used prior to the introduction of the* [redacted] *filters had not been integrity validated nor were they routinely integrity tested."*

Filters were approved in August 1997. However, the February 1998 inspection revealed that the validation process used to gain the approval was not valid.

- *"Validation of microbial retention by the* (redacted) *filters used for harvest of Anthrax vaccine was performed only with* (redacted) *media, which is used in tetanus production. Studies were not performed using Anthrax product or media."*

Adulteration.

d) Redating.

Biologic products have expiration dates as described in Part 600 of 21 C.F.R. Modifications to the expiration dates shall be made only upon written approval, in the form of a supplement [amendment] of the product license, issued by the Director of the Center for Biologics Evaluation and Research. Expiration dates are also regulated under the current good manufacturing practices as described in 21 C.F.R. § 211.137, which states in part:

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[30] Kenner Associates report to SAIC, 26 February 1996.

- *"To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in §211.166."*

21 C.F.R. § 211.166 states in part:

- *"There shall be a written stability testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates."*

In 1997, MBPI relabeled 1.5 million doses of AVA. MBPI took vials of AVA that were already labeled with an expiration date and soaked the labels off. They then relabeled the vials with new expiration dates. ***These 1.5 million doses of AVA are adulterated for several reasons.***

- MBPI had no approved stability testing program at the time this relabeling occurred, as observed in the February 1998 FDA inspection.

- MBPI had no approved procedures for removing and relabeling filled vials of vaccine.

- MBPI had no procedure, approved or otherwise, for reconciling the vials with the original Lot once the labels were removed. In other words, MBPI could not assure that the vials would be re-identified correctly, i.e. FAV008, or FAV009, etc.

MBPI also redated bulk vaccine that had expired without justification or approved procedures. ***These doses, too are adulterated.***

Both of these practices, relabeling and redating, require a supplement to the product license IAW 21 C.F.R. § 610.53(d). No supplement was sought or approved at the time of these events. Current good manufacturing practice regulations require compliance with these parts of the C.F.R.. As stated above, non-compliance renders the drug adulterated.

Adulteration.

e) Mislabeling.

The Lot number or control number of a drug is an important regulatory requirement. As such 21 C.F.R. § 202.18 states the requirements.

- *"The lot number on the label of a drug should be capable of yielding the entire manufacturing history on the package. An incorrect lot number may be regarded as causing the article to be misbranded."*

Additionally, the current good manufacturing practices regulation defines "Lot number" as:

- *"any distinctive combination of letter, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined."*

On several occasions, MBPI sought and CBER approved the extension of the expiration date of a Lot of AVA. CBER's approval notice amended the Lot number. For example, MBPI sought to redate Lot FAV020. CBER approved the extension of the expiration date and renamed the Lot FAV020a, to indicate this Lot as different from the original FAV020.

MBPI failed to put the correct Lot number on the labels of the redated vaccine. This failure to correctly identify the vaccine contained within makes it difficult if not impossible for the label to provide *"the entire manufacturing history"* as required by § 202.18, ***causing the vaccine so labeled to be considered misbranded,*** or as required by the current good manufacturing practices regulations ***causing the vaccine so labeled to be considered adulterated.***

Both of these acts are prohibited under the U.S. Code § 331 as described above.

Adulteration.

1) New Drug Application requirement.

The FDCA defines "new drug" in two ways. 21 U.S.C. § 321(p)(2) states:

- *"Any drug... the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions."*

21 C.F.R. § 310.4 (h) further defines "new drug" as:

- ***"The newness of a drug may arise by reason (among other things) of (5) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of the drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug."***

AVA has been licensed since 1970. In the first twenty years approximately 70,000 doses were made. The use of the vaccine was essentially limited to military researchers and test

animals. With the use of the vaccine for inhalation anthrax during the 1990-91 Gulf War, a vastly larger population began taking the drug. This new "application", or use, is an example of the US Code definition of a new drug.

In addition to a new population, the drug was being used (applied) for an indication that was not "*prescribed, recommended, or suggested in the labeling.*" This, too, renders the vaccine a "new drug".

The rules and regulations for new drugs are lengthy and involved. Suffice to say that MDPH, MBPI, and BioPort are not in compliance with these rules and regulations.

The manufacturer has produced and distributed to the DOD an unlicensed and unapproved new drug from 1990 to the present.

Adulteration.

g) The patent.

The AVA license is based on United States Patent, No. 3,208,909. This patent specifies the equipment used in the manufacture of AVA. When the facility was enlarged and the type of equipment used to produce AVA was changed, the vaccine was no longer being made in accordance with the patent (license). The AVA produced without a patented procedure is considered a new drug. Section 355 of the U.S. Code describes such a drug and the requirements for approval and licensure. MDPH and MBPI did not file applications based on this section of the Code. To date, BioPort has not done so either.

Section E
On-going litigation

Background: Cases run the gamut from all charges being dropped to currently imprisoned US Marines, to an on-going General Court-Martial of an Air Force officer and physician.

1. **Ft. Hood soldier** – charges dropped in October. Army doctor had attempted to ascribe soldier's adverse reaction to an allergy after a possible causal relationship to the vaccine had been noted in the soldier's medical records. Doctors at Walter Reed advised Army prosecutors they had limited chance of success because the vaccine is contraindicated following an adverse reaction, so the soldier should not have been ordered to get any more shots.

2. **Ft. Bragg soldier** – convicted in October, imprisoned in a high-security jail at Camp Lejeune for 30 days, given a bad conduct discharge, reduction in rank and forfeitures of pay, and loss of all GI Bill benefits.[81]

3. **Comparative punishments:** anthrax refusal vs. other offenses. Refusal to take the anthrax vaccine is being punished more severely than first-time illegal drug offenses. Where active duty soldiers have been imprisoned, members of the Guard and Reserve have been coerced out of their positions without due process or discharge boards.

4. **Ruling by Navy Marine Corps Court of Criminal Appeals.**

   NMCCA heard five different cases on extraordinary writ. All five of the writs were heard and the cases stayed pending the ruling by the appeals court. Ultimately the court denied the writs, lifted the stays, and the cases docketed for court so that the court-martials may proceed. David Ponder, Jason Stonewall, Vitalino Arroyo, Ocean Rose, and Matthew Perry were all docketed for the month of January 2001. The NMCCA essentially decided in all of the cases that it was not a judicial usurpation of power for the judge to decide that the order is lawful as a matter of law. Court held that all of the petitioners had failed to show a clear and indisputable right to the relief requested. The appeals court did not preclude direct appellate review of the issue, but did tip their hand as to their view of the vaccine's status.

   Defense counsel believes that the court erred in several respects in its analysis of the Executive Order (EO 13139) and in the way that it ignored the federal statutes. Additionally, there is no analysis on the issue of military precedents and the fact that the DoD has internal regulations requiring informed consent for use of an IND or a drug unapproved for its applied use. See 32 CFR 219.[82] Also, there are numerous

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[81] J.S. Newton, Anthrax vaccine opponents firm, Fayetteville Observer, 17 Nov 2000.
See: http://205.107.108.244//cgi-bin/news/display.pl?month=10&index=n17thrax.htm&year=2000

[82] 32 CFR 219, "Protection of Human Subjects"
See: http://www.access.gpo.gov/nara/cfr/waisidx_00/32cfr219_00.html

DoD and BUMED Instructions that address IND's and the right every servicemember has to informed consent to medical treatment (See BUMED Inst and DoDD 6200.2, etc.).

5. **Status of appeal by Seaman David Ponder and the case of Dr. John Buck, USAF** – and additional USMC cases:

The ruling by the military judges on the Navy Marine Court of Criminal Appeals is subject to appeal to the Court of Appeals for the Armed Forces (CAAF), a panel of civilian federal judges. In late December 2000 defense counsel filed a writ-appeal of the NMCCA decision. In this petition, counsel is again asking for a stay of the proceedings until the case can be decided, as well as dismissal of the charge, or at least, an opportunity to put on evidence in court that establishes the drug as investigational or unapproved for its applied use.

The plethora of cases and UCMJ action just prior to the change of administrations is problematic for the new Secretary of Defense. By upholding the imprisonments that occurred prior to the 20th of January 2001, the new administration carries the risk of being implicated in the implementation and UCMJ action surrounding an illegal order. *The sheer quantity of cases and unprecedented terms of imprisonment after no* imprisonments for since the summer of 1999 are equally troubling.

The current case and pending court-martial of Dr. John Buck, USAF MD and Emergency Room physician, presents an impasse for the new leadership in the Department of Defense. To allow a UCMJ action to proceed that began in the previous administration's tenure, and to allow for the first time all the arguments about the illegality of the vaccine and the order to be presented by the defense, affords an opportunity to let the UCMJ make a ruling based on the full set a facts.

If the case of Dr. John Buck finds the order to be in violation of the US Code, the Executive Order, and DoD Directive, through the use of a suspect and possibly adulterated product, the case can serve as a precedent for the new civilian leadership in the Department of Defense to reverse all previous adverse personnel actions caused by the AVIP.

By allowing disciplinary action set forth by the previous SECDEF, the current leadership can finish the AVIP ethical dilemma once and for all by allowing the UCMJ to vindicate the servicemembers involved in this travesty.

Section F
Food and Drug Administration

Introduction. The regulatory system that governs new drug development is relatively new. Prior to 1906, there was no effective regulation in existence. From 1938, when the Food and Drug Administration first received broad statutory authority to regulate interstate shipment of unapproved new drugs for investigational use, until 1962, when the Kefauver-Harris Amendments were enacted, the FDA exercised virtually no direct control over the clinical development of new drugs.

Initial Regulation. The purpose of the Federal Food, Drug and Cosmetic Act is to limit interstate commerce in drugs to those that are safe and effective.

Originally enacted as the Federal Food and Drugs Act of 1906, the act prohibited adulterated or misbranded food or drugs from interstate commerce. However, the 1906 Act was very inadequate. False statements made about a drug by its manufacturer (i.e., public advertising) were not considered as misbranding by the courts. Additionally, the Act did not grant authority to ban unsafe drugs. For a drug to be legal under the 1906 law, it only had to meet the standards for composition of the United States Pharmacopoeia or the National Formulary. The Bureau of Chemistry enforced this law.

Sulfanilamide Disaster of 1937. It was not until after the sulfanilamide disaster of 1937 that the Act was modified. Soldiers originally used sulfanilamide. As a powder, it was sprinkled over a wound to prevent infection. A manufacturer decided to expand the antiinfective use of the drug by mixing the sulfanilamide with diethylene glycol, the same substance used today as antifreeze in car radiators, and marketed it as an elixir for sore throats. No clinical tests were performed prior to marketing. There were 107 reported deaths from this product.

Food, Drug, and Cosmetic Act of 1938. Subsequently, the Federal Food, Drug, and Cosmetic Act of 1938 was enacted which extended government's control over advertising and labeling. More importantly, it authorized the Food and Drug Administration (for the first time) to establish a regulatory system for obtaining pre-marketing clearance of an investigational new drug. Manufacturers were now required to submit a new drug application (NDA) containing evidence that a drug was safe for its intended use.

However, the FDA established a system of minimal regulation. These regulations, which remained in effect without change until 1963, left the protection of human subjects almost entirely to the discretion of sponsors and investigators. For example, it did not require a notice for conducting investigational trials to be submitted to the FDA, it did not require pre-clinical safety studies prior to administration of a drug into humans, and it did not require informed consent of test subjects.

There was a continued lack of adequate control over advertising. More importantly, there continued to be no government control over investigational plans prior to the submission

of a new drug application. As a result, abuses occurred. For example, people were administered investigational drugs without being told that they were participating in an experiment.

Role of the American Medical Association in Legislative Actions. The American Medical Association (AMA) had campaigned vigorously for the first food and drug law of 1906. They were a powerful force in achieving the passage of strong legislation. Relationships between the AMA and federal agencies regulating drugs were very close as they lobbied together to advance legislative decisions regarding the regulation of new drug development. When the 1938 Act was passed, the AMA was disappointed that it was not stronger. In 1953, it proposed a bill that eventually passed, authorizing the FDA to inspect pharmaceutical laboratories without first obtaining permission from the proprietor.

In 1959, Senator Kefauver began his hearings on the prices of drugs and the practices of the drug industry. The AMA, however, totally opposed the proposals for a change in the laws. **Specifically, the AMA was against the provision that a drug manufacturer had to prove claims of efficacy before he could market the drug.** They also were against the provision requiring the Secretary of Health, Education and Welfare to make determinations of what was the relative efficacy of structurally related drugs. **Relationships with the federal agencies disintegrated. The AMA became increasingly critical, especially of over-regulation.**

Thalidomide Disaster of 1962. In 1962, thalidomide, a sleeping pill developed and widely used abroad for several years, was being studied for use in the United States. The FDA did not approve this drug for marketing in the U.S. because of the safety clearance requirements in the Federal Food, Drug, and Cosmetic Act, and because of the refusal of an FDA medical officer, Dr. Frances Kelsey, to clear the drug on what she believed to be inadequate safety evidence provided by the manufacturer.

However, although the drug was restricted to investigational use in the U.S., the sponsoring pharmaceutical company widely distributed it to doctors for their use. Subsequently, it was reported to clearly be a human teratogen which caused malformations in many European children. Children were being born without arms or with other severe deformities. A series of lawsuits demonstrated that, in general, prescribers of drugs had been relying on manufacturers for information pertaining to the drugs, and that this information in some instances had been based on inadequate testing, or even on deliberate falsification and deception. **The Kefauver-Harris amendments of 1962 were finally enacted as a result of this incident.**

Kefauver-Harris Amendments of 1962. The Drug Amendments of 1962 included several important policy innovations.

First, it required that all clinical testing of investigational drugs be conducted under applications submitted to the FDA (Investigational New Drug Applications). Additionally, sponsors were required to submit reports of pre-clinical studies to justify

their proposed clinical testing in humans, obtain informed consent from test subjects prior to their entry into a study, and report all findings resulting from the investigational studies to the FDA.

Second, Good Manufacturing Practices (GMP) were established. Any drug would be considered adulterated if a manufacturer produced the drug without adhering to such practices.

Prescription drug advertising was placed under the supervision of the FDA.

Third, the 1962 amendments required that all new drugs must be shown to be effective, in addition to being safe, for their intended use, prior to marketing. The standard for scientific evidence acceptable for demonstrating substantial effectiveness was defined by Congress as:

- *"adequate and well controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could be fairly and responsible be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling."*

The FDA had actually proposed new regulations before the 1962 amendments were enacted, and it issued final rules three months after the new law took effect. These regulations are the broad outlines of the investigational drug regulatory system that remains in effect today.

Note that despite the 1962 amendments, until 1973 when DBS was put under FDA, they did not necessarily require efficacy data for approval, and this is how anthrax vaccine slipped in without good efficacy data, despite Congress's explicitly instructing otherwise in law a decade beforehand.

FDA Culture and Vaccines.

The former DBS (Division of Biologics Standards) was involuntarily transferred to FDA from the Public Health Service in 1973. Its transfer was triggered by the failed Polio vaccine release, on the grounds that old world style management encumbered it. The DBS was viewed as incapable of protecting the public health because it was too closely involved with the industry it was supposed to regulate ("unholy marriages"). That merger only lasted a few years and resulted in de-merging and the reestablishment of a Center for Biologics Evaluation and Research (CBER).

When the FDA assumed responsibility for regulation of vaccines in the early 1970's, there were clearly two cultures in the FDA. These were driven by two statutes, one for the regulation of pharmaceutical drugs (Food Drug and Cosmetic Act) and one for the

regulation of biological products such as vaccines and blood and blood products (Public Health Service Act).

The FDA's vaccine culture was based on a dual mandate to both promote public health and to regulate vaccine manufacturers. This culture is analogous the culture within the FAA before the ValuJet crash in the Everglades: the regulatory entity, FAA, only knew how to regulate companies that self-regulated and sought to nurture weak, start-up airlines. The FDA's ambivalent regulatory relationship with a state-owned manufacturer (MDPH) of the limited-use anthrax vaccine used almost solely by the military, and which no private company would produce, represented an inherent conflict between the FDA's dual role.

Licensing.

In the drug process, a firm (1) Registers, and (2) Lists its products. This is covered under section 510 of the FD&C Act. The C.F.R. covers the requirements for changes, the frequency for updating drug lists, etc. Biological manufacturers are required to Register and List, but in addition, the Product License and Establishment License are mandatory. This is a quirk in the dual-statutes involved – FD&C Act for both drugs and biologicals, and Sec. 351 of the PHS Act for Biologicals.

Summary: There are no inherently safe (safety: 1938) or effective (efficacy: 1962) prescription drugs or vaccines, only those which are not "*adulterated*" or "*misbranded*" within the *meaning of the Act when* labeled, *used or administered in* accordance with an FDA approved New Drug Application (IND/NDA) or FDA approved Product License Application (PLA) for marketed biologicals.

Investigational New Drug Applications and Product License Amendments.

Anthrax Vaccine Adsorbed is not an Investigational New Drug (IND). ***It is a licensed biological product legally marketed for the uses and indications in its approved labeling.*** The problem arises for DOD in that aerosolized exposure is not included in the currently approved labeling. The manufacturer needs to gain approval for the aerosolized exposure indication through a supplement to the Product License Amendment (PLA).

The regulatory scheme calls for a supplemental PLA to be approved by FDA to permit distribution for use under certain conditions, in this case, aerosol exposure. This is supposed to be approved ***before*** such use. ***This has not been done, and under normal enforcement procedures such a firm would be ordered by FDA to cease and desist, or action would be taken to revoke its license.***

The IND/NDA or PLA supplement is the mechanism whereby those prescription drugs "*not generally recognized, among experts qualified by scientific training and experience*" are evaluated with respect to "*the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof.*" (FD&C Act Section 201 (p)(1)).

A PLA or an NDA is like a contract with the FDA. Compliance with the terms and conditions specified within the PLA or NDA is the assurance that the firms' product will not be considered to be (1) adulterated, or (2) misbranded, within the meaning of the FD&C Act.

If the firm or establishment does not comply with the PLA or NDA, then the firm can be subject to (1) License revocation for a biological, or (2) withdrawal of an NDA.

In addition, the firm can be prosecuted for non-compliance with Current Good Manufacturing Practices (CGMP), or products manufactured during a period of non-compliance with CGMP may be considered to be adulterated, and subject to seizure (a court ordered action accomplished by a US Marshall).

New Drug Applications (NDAs).

Twice during the history of the FD&C Act amendments (1938 and 1962) provisions were made for the so-called "Grand fathering" or exemption of drugs from the New Drug Provisions of the Act for those prescription drugs which were marketed prior to the effective dates of the amendments (1938 & 1962). This would have "Grand fathered" or declared such drugs as Not-New Drugs; however these provisions have never been used.

There are no prescription drugs or biologicals on the market that are grandfathered as "Not-New Drugs" therefore, there are no inherently safe or effective drugs.

Only the FDA can make a determination as to whether or not a drug (or vaccine) is a "new drug". This decision was rendered by the Supreme Court in one of several landmark cases decided back in the 1970's.

Section G
Medicine

Gulf War Illness – DoD has avoided investigations of a link to vaccines. At least four panels, the Defense Science Board, the National Institute of Health, the Institute of Medicine, and later, the Presidential Advisory Commission on Gulf War Illness reviewed possible causal factors in Gulf War Illness. Although the IOM recommended further study on vaccines, none was funded.

An August 1995 report by the federal interagency (DoD, HHS, DVA, and EPA) Persian Gulf Veterans Coordinating Board observed[83]:

- *"...approximately 150,000 troops received at least one dose of anthrax vaccine and about 8,000 received at least one dose of botulinum toxoid. Both vaccines have been used for many years without adverse effects. **All three review panels stated that no long-term adverse effects have been documented or would be expected. Further study of the potential adverse effects of vaccines in this population is not recommended by any of the three panels, nor is it endorsed in this plan.**"*

DoD has misrepresented previous reviews as scientifically valid investigations when no research was ever conducted. DoD has consistently defended the anthrax vaccine by stating that these groups have "found no evidence" of a causal relationship between anthrax vaccine and Gulf war Illness. Former Army Surgeon General LTG Ronald Blanck, publicly defending the anthrax vaccine in a March 2000 op-ed, stating[84]:

- *'These panels have included the Presidential Advisory Commission, the Defense Science Board, the National Institutes of Health and the Institute of Medicine. They all have concluded that there is no evidence of a connection between the illnesses and any of the vaccines, either singly or in combination."*

Statements by LTG Blanck and other DoD officials incorrectly imply that these panels' conclusions were based on scientific investigation. **The panels "found no evidence" because neither they, nor DoD, have ever published the results of a scientific investigation to determine whether a link exists between anthrax vaccine and Gulf War Illness in US troops.**

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[83] A Working Plan For Research On Persian Gulf Veterans' Illnesses, Persian Gulf Veterans Coordinating Board, Aug 1995
See: http://www.gulflink.osd.mil/vargt/framing.html

[84] LTG Ronald Blanck, U.S. Army Surgeon General, letter to the editor, Washington Times, 14 Mar 2000.

Gulf War Illness– UK (Unwin) study linking vaccination to GWI. The US Department of Defense funded a study (for over $1 million) of 8,195 British Gulf War-era veterans. Its findings included[85]:

- *"The Gulf War cohort reported symptoms and disorders significantly more frequently than those in the Bosnia and Era cohorts, which were similar...Gulf War veterans were more likely than the Bosnia cohort to have substantial fatigue, symptoms of post-traumatic stress, and psychological distress, and were twice as likely to reach the CDC case definition [of Gulf War Illness.]...Vaccination against biological warfare and multiple routine vaccinations were associated with all outcomes."*

- *"Service in the Gulf War was associated with various health problems over and above those associated with deployment to an unfamiliar hostile environment. Since associations of ill health with adverse events and exposures were found in all cohorts, however, they may not be unique and causally implicated in the Gulf War-related illness. A specific mechanism may link vaccination against biological warfare agents and later ill health, but the risks of illness must be considered against the protection of servicemen."*

During testimony before the Senate Armed Services Committee on 13 Apr 2000, then-Army Surgeon General LTG Ronald Blanck denied knowledge of the Unwin study.[86] He was not asked, nor did he explain why DoD has never funded a similar study.

Gulf War Illness– Kansas study linking vaccination to GWI. The state of Kansas Commission of Veterans Affairs funded a study of 2,030 Gulf War era veterans. Despite over $150 million spent on Gulf War Illness research, DoD has never conducted a comparable study on US servicemembers. The Kansas study concluded[87]:

- *'Gulf War Illness, defined as having chronic symptoms in three of six domains, occurred in 34% of PGW veterans, 12% of non-PGW veterans who reported receiving vaccines during the war, and 4% of non-PGW veterans who did not receive vaccines. The prevalence of Gulf War illness was lowest among PGW veterans who served on board ship (21%) and highest among those who were in Iraq and/or Kuwait (42%). Among PGW veterans who served away from battlefield areas, Gulf War Illness was least prevalent among those who departed the region prior to*

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[85] Catherine Unwin, et.al., "Health of UK servicemen who served in Persian Gulf War", The Lancet, 16 Jan 1999, page 169.

[86] Transcript, Senate Armed Services Committee hearing, "Subject: Department Of Defense Anthrax Vaccination Program", Federal News Service, Inc., 13 Apr 2000. Question about the Unwin study posed by Sen Olympia Snowe.

[87] Lea Steele, "Prevalence and Patterns of Gulf War Illness in Kansas Veterans: Association of Symptoms with Characteristics of Person, Place, and Time of Military Service", American Journal of Epidemiology, Vol. 152, No. 10 : 992-1002, page 1 of 14 (online).
See: http://aje.oupjournals.org/cgi/content/full/152/10/992

the war (9%) and most prevalent among those who departed in June or July of 1991 (41%). Observed patterns suggest that excess morbidity among Gulf War veterans is associated with characteristics of their wartime service, and that vaccines used during the war may be a contributing factor."

- *"A relation between vaccinations and illness has been observed among Gulf War veterans from the United Kingdom and Canada, and a mechanism for an association of illness with multiple vaccinations has been proposed. The prevalence of multisymptom illness was associated with reports by veterans from the United Kingdom of receiving vaccines against biologic warfare agents (anthrax, plague, pertussis adjuvant) and with receiving multiple vaccinations during deployment. A 1998 study of Canadian Gulf War veterans found a significant association between receiving "nonroutine immunizations" (anthrax, plague) and several symptom-defined outcomes."*

Gulf War illness – French study. On 13 Sep 2000 Defense Minister Alain Richard announced the creation of an independent commission into the health of the French military servicemembers who participated in the Gulf War. The commission's first hearing occurred on 2 Nov 2000 and it is tasked to investigate all health risks that French soldiers were exposed to during the Gulf War.[88]

- *"Armed forces medical corps spokesman Colonel Michel Estripeau, himself a doctor, said France's belief that allied troops were victims of their own protective measures were based on a long series of meetings with U.S. medical experts..."About 100,000 of the 600,000 Americans who served in the Gulf complain of ailments that have tentatively been lumped under the Gulf War syndrome heading. No one has yet come to definitive conclusions but we note that of 25,000 Frenchmen who served in the Gulf, only 180 have ailments whose origin could be in question. The only really major difference between the two groups is vaccinations," he said."*[89]

Institute of Medicine studies. Three studies – one complete. One already standing IOM committee issued a letter report on the safety of the anthrax vaccine in March 2000. Two additional IOM study panels have been convened in response to a mandate from Congress in the FY2000 defense legislation for a National Research Council study of the safety and efficacy of the anthrax vaccine.

1. **Committee on "Health Effects Associated with Exposures During the Gulf War".** Because of immediate concern over anthrax vaccine safety issues, the IOM offered to draw relevant information from an ongoing study of Gulf War exposures funded by the Department of Veterans Affairs. With the agreement of the Department of

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[88] "France Investigates Gulf War Syndrome", The Lancet, 18 Nov 2000, page 1747.
[89] "French to Check Liaison Officers for Gulf Syndrome", Reuters, 14 Sep 2000.

Veterans Affairs, the IOM was able to produce this letter report that summarizes the committee's literature review on the safety of the anthrax vaccine. Its findings were[90]:

- *"There is a paucity of published peer-reviewed literature on the safety of the anthrax vaccine.'*
- *"The published studies have found transient local and systemic effects (primarily erythema, edema, or induration) of the anthrax vaccine. There have been no studies of the anthrax vaccine in which the long-term health outcomes have been systematically evaluated with active surveillance."*
- *"The committee concludes that in the peer-reviewed literature there is inadequate/ insufficient evidence to determine whether an association does or does not exist between anthrax vaccination and long-term adverse health outcomes."*

2. **Committee on "The Safety and Efficacy of Anthrax Vaccine for the U.S. Military."** The committee will analyze available information, hold workshops and make specific recommendations on technical aspects regarding the safety and efficacy of the licensed anthrax vaccine. The issues addressed in this 24 month study include: the types and severity of adverse reactions, including gender differences; long-term health implications; inhalational efficacy of the vaccine against all known anthrax strains; correlation of animal models to safety and effectiveness in humans; validation of the manufacturing process focusing on, but not limited to, discrepancies identified by the Food and Drug Administration in February 1998; definition of vaccine components in terms of the protective antigen and other bacterial products and constituents; and identification of gaps in existing research.[91]

Significantly, this committee will neither conduct, nor sponsor, any research.

3. **Committee on "Review of the CDC Anthrax Vaccine Safety and Efficacy Collaborative Research Program.** This committee will advise the Centers for Disease Control and Prevention (CDC) on the completeness and appropriateness of the CDC plan to respond to the Congressional mandate to study the safety and efficacy of anthrax vaccine, addressing: (1) risk factors for adverse reactions, including gender differences; (2) determining immunologic correlates of protection and documenting vaccine efficacy; (3) optimizing the vaccination schedule and routes of administration to assure efficacy while minimizing the number of doses required and the occurrence of adverse events. The CDC, the National Institutes of Health (NIH), and the Department of Defense (DOD) are directed by Congress to collaborate and cooperate fully in this 24-month study.[92]

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[90] "An Assessment of the Safety of the Anthrax Vaccine", A Letter Report, Committee on Health Effects Associated with Exposures During the Gulf War, Institute of Medicine, 30 Mar 2000
See: http://www.nap.edu/html/anthrax_vaccine/

[91] See: http://www4.nas.edu/cp.nsf/Projects+_by+_PIN/MFUA-H-00-01-A?OpenDocument

[92] See: http://www4.nas.edu/webcr.nsf/ProjectScopeDisplay/MFUA-H-00-02-A?OpenDocument

Significantly, this committee will only provide advice for the Centers for Disease Control's study of the anthrax vaccine, conducted in concert with DoD. There will be no independent, non-governmental study by an outside entity.

Potential conflict of interest on two IOM study panels. Two researchers who conducted and authored the original efficacy study of a similar anthrax vaccine in New England mills in the 1950's were named to the IOM study committees. Additionally, a study director of one panel has co-authored a recent study with Army medical researchers. These personnel assignments place the researchers in a position to control the study agenda and influence the discussion in ways that those opposed to the anthrax vaccine cannot.

1. **Concerns about the Committee on "The Safety and Efficacy of Anthrax Vaccine for the U.S. Military."** The IOM preliminarily named Dr. Stanley Plotkin to the advisory committee that provides expert advice to this study committee. After an objection by Rep. Dan Burton, Dr. Plotkin was removed from the committee before its first meeting. Congressman Burton wrote[92]:

   - *"To alleviate concerns that may be raised about your study's results, I strongly encourage you to insure that no member of the IOM Anthrax Vaccine Committee has the slightest appearance of a conflict of interest. In particular, I am concerned about the inclusion of Dr. Stanley Plotkin on the study's advisory committee. I am aware of Dr. Plotkin's distinguished career in vaccine research and his role in developing the rubella vaccine. However, **Dr. Plotkin was also one of the authors of the only peer-reviewed anthrax vaccine efficacy study, published by Dr. Brachman, et.al., in 1962. Dr. Plotkin's inclusion in your advisory committee allows him an opportunity to influence your committee's analysis of the original efficacy study of the anthrax vaccine that opponents of the vaccine will not be afforded.** This could place in jeopardy the credibility of the results of the IOM's two-year study."*

   - Further, the study director of this committee, Dr. Lois Joellenbeck, co-authored a study last year with the former director of the Army's medical research establishment at Ft. Detrick, MajGen (Dr.) Philip Russell. Her close collaboration with DoD medical personnel again raises concerns as to whether dissenting views will be given the opportunity for a fair unbiased hearing during the IOM's review of the safety and efficacy of the anthrax vaccine.[93]

2. **Concerns about the Committee on the "Review of the CDC Anthrax Vaccine Safety and Efficacy Collaborative Research Program."** The IOM named Dr.

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[92] Letter from Rep Dan Burton to Dr. Kenneth Shine, President, Institute of Medicine, 2 Oct 2000.

[93] Joellenbeck, Lois M., Philip K. Russell, and Samuel B. Guze, eds., Institute of Medicine, "Strategies to Protect the Health of Deployed U.S. Forces: Medical Surveillance, Record Keeping, and Risk Reduction", Washington, DC: National Academy Press, 1999, p. 103.

Philip Brachman to chair the committee which will oversee the review of unpublished CDC and DoD safety and efficacy data on the anthrax vaccine. Despite an objection by Rep. Dan Burton, Dr. Brachman remains on this committee. Congressman Burton wrote[95]:

> *"Dr. Philip Brachman has been selected to chair the second IOM anthrax vaccine committee. I am aware of Dr. Brachman's distinguished career at CDC and Emory University. However, Dr. Brachman was also the lead author of three of four papers describing the only human anthrax vaccine efficacy study in the published medical literature. **Dr. Brachman also has had a long professional relationship with key Army researchers at Ft. Detrick, MD, including co-authoring the chapter on anthrax vaccine in the medical textbook "Vaccines" [ed. Plotkin, et.al.] with Colonel (Dr.) Arthur Friedlander. According to IOM's Dr. Lois Joellenbeck, Dr. Plotkin was removed from participating in the first IOM Committee because "the IOM and National Academies had decided that Dr. Plotkin should not serve as a member of the committee because of his role as an author on a paper important to the committee's work." How then can it be appropriate for Dr. Brachman – the lead author of the same study – to be chosen to chair this second committee which will review the work of those with whom he has a close professional relationship?"***

Institute of Medicine – 1999 Report on "*Strategies to Protect the Health of Deployed U.S. Forces*". This report is the result of a three-year study by the Institute of Medicine in response to a 1996 request by former Deputy Secretary of Defense John White to the leadership of the National Research Council. One of the two co-authors of the study was Dr. Philip Russell (MajGen, USA, ret.), former commander of the Army's medical research facility at Ft. Detrick and assistant Surgeon General of the Army before he retired. Dr. Russell's report makes the following frank assessment of the anthrax vaccine and its manufacturer[96]:

> ***"The manufacturer of the current anthrax vaccine, BioPort, has had problems meeting regulatory requirements and standards, resulting in a costly program to upgrade the manufacturing process and facility so that it meets U.S. Food and Drug Administration (FDA) standards. Since this vaccine is made by a process devised more than 40 years ago, it is far from the optimal product possible today using modern biotechnology production and purification methods. The current vaccine requires multiple doses and contains many extraneous proteins. A much more efficient vaccine that has a uniform content and that requires fewer doses can be developed. The Committee on R&D Needs for Improving Civilian Medical Response to Chemical and Biological Terrorism Incidents recommended that a second-generation vaccine be developed for civilian use (Institute of Medicine,***

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[95] Letter from Rep Dan Burton to Dr. Kenneth Shine, President, Institute of Medicine, 30 Oct 2000

[96] Joellenbeck, Lois M., Philip K. Russell, and Samuel B. Gaze, eds., Institute of Medicine, "Strategies to Protect the Health of Deployed U.S. Forces: Medical Surveillance, Record Keeping, and Risk Reduction", Washington, DC: National Academy Press, 1999, p. 105.
See: http://books.nap.edu/books/0309066379/html/105.html#pagetop

*1999c). **Developing a second-generation anthrax vaccine would be an appropriate action for DoD as well.**"*

Centers for Disease Control -- December 2000 recommendations of the Advisory Committee on Immunization Practices (ACIP). The ACIP is a standing committee tasked by the Centers for Disease Control to issue recommendations on the appropriate use of vaccines in the United States. **Ignoring the UK (Unwin) and Kansas (Steele) studies, CDC incorrectly claims that there is no scientific evidence of a correlation between anthrax vaccine and Gulf War Illness.** Further, neither of the studies cited by CDC below looked at anthrax vaccine as a potential causal factor. Claiming an absence of specific scientific studies that might provide scientific evidence of a correlation, CDC then recommends the use of the vaccine on the basis that "scientific evidence does not support" a connection between anthrax vaccine and Gulf War Illness. It recently issued recommendations on the use of anthrax vaccine.[97]

*"CDC has conducted two epidemiologic investigations of the health concerns of Persian Gulf War (PGW) veterans that examined a possible association with vaccinations, including anthrax vaccination. The first study, conducted among Air Force personnel, evaluated several potential risk factors for chronic multisymptom illnesses, including anthrax vaccination. Occurrence of a chronic multisymptom condition was significantly associated with deployment to the PGW but was not associated with specific PGW exposures and also affected nondeployed veterans (79). **The ability of this study to detect a significant difference was limited.** The second study focused on comparing illness among PGW veterans and controls. The study documented that the self-reported prevalence of medical and psychiatric conditions was higher among deployed PGW veterans than nondeployed veterans. **In this study, although a question was asked about the number of vaccinations received, no specific questions were asked about the anthrax vaccine. However, the study concluded that the relation between self-reported exposures and conditions suggests that no single exposure is related to the medical and psychiatric conditions among PGW military personnel (80). In summary, current research has not documented any single cause of PGW illnesses, and existing scientific evidence does not support an association between anthrax vaccine and PGW illnesses.**"*

CDC tries to have it both ways: claiming that in two studies they have "examined a possible association with vaccinations, including anthrax vaccination", then admitting that neither study was capable of detecting a relationship, then finally asserting without adequate data that "no single exposure is related to [GWS]" and "existing scientific evidence does not support an association between anthrax vaccine and PGW illnesses." **CDC's attempt to bolster the claim that anthrax vaccination cannot be related to GWS by citing two studies, which lacked the power to explore the issue, is not good science.**

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[97] Centers for Disease Control, "Use of Anthrax Vaccine in the United States, Recommendations of the Advisory Committee on Immunization Practices", 15 Dec 2000
See: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4915a1.htm

CDC does not recommend anthrax vaccine for civilian "first-responders" to bioterrorism incidents, but states vaccination of military personnel "may be indicated." Significantly, the criterion CDC used to determine whether vaccination is indicated is "a calculable risk assessment."[98] CDC does not address the contradiction between their recommendation not to vaccinate the civilians most at risk of anthrax exposure versus DoD's plans to immunize all military personnel against anthrax, regardless of location or deployable status.[99]

> *"Although groups initially considered for preexposure vaccination for bioterrorism preparedness included emergency first responders, federal responders, medical practitioners, and private citizens, vaccination of these groups is not recommended. Recommendations regarding preexposure vaccination should be based on a calculable risk assessment. At present, the target population for a bioterrorist release of B. anthracis cannot be predetermined, and the risk of exposure cannot be calculated. In addition, studies suggest an extremely low risk for exposure related to secondary aerosolization of previously settled B. anthracis spores (28,83). Because of these factors, preexposure vaccination for the above groups is not recommended. For the military and other select populations or for groups for which a calculable risk can be assessed, preexposure vaccination may be indicated."*

CDC acknowledges lack of efficacy data. Significantly, the co-author of the recent ACIP recommendations, Dr. David A. Ashford (D.V.M.) made the following statement about the anthrax vaccine's efficacy during a CDC-sponsored conference in July 2000[99]:

> *"For those of us working with the vaccine, we do not have specific information on the efficacy of the existing vaccine for the prevention of inhalational anthrax and we probably never will."*

This admission by a CDC staff member means that DoD's use of the anthrax vaccine for inhalation anthrax exposure in a biowarfare environment is investigational, and therefore, is subject to the informed consent requirements in federal law (10 USC 1107).

Adverse reaction reporting and the willingness of the DoD medical community to proactively acknowledge and treat medical problems caused by the anthrax vaccine have been constrained by command influence. For example, Secretary of Defense Cohen, stated[100]:

> *"The vaccinations begun in 1998 after these four conditions were met. Gen. Hugh Shelton, the Chairman of the Joint Chiefs, and I were among the first to receive the*

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[98] Ibid.
[99] Eliza Bussey, "Anthrax Vaccine Is Safe, U.S. Health Experts Say", Reuters Health, 10 Jul 2000
[100] William S. Cohen, " Defense Leaders Commentary: Protecting Our Military", DoD News
See: http://www.defenselink.mil/news/Feb2000/n02072000_2000207l.html

shots. We experienced the same mild side effects, such as temporary soreness or a small bump on the arm, that many others feel. Indeed, the side effects are frequently less than those caused by other routine vaccinations that most Americans routinely receive. Our careful monitoring of the program reveals no unexpected side effects. Nevertheless, if our troops experience a negative reaction, we provide quality medical care."

The House Committee on Government Reform report on the DoD anthrax vaccine policy, titled "Unproven Force Protection", debunks this statement by SecDef Cohen, but also recognized the impact DoD's senior leadership has had on the treatment of servicemembers who have adverse reactions to the anthrax vaccine.

The Government Reform Committee report found that no meaningful effort was made to meet the "four conditions" stipulated by Cohen when the AVIP policy was announced in 1997[101]:

"Signaling an awareness the anthrax immunization effort was on weak conceptual and logistical footing from the start, Secretary Cohen announced four preconditions to the start of the program: supplemental vaccine testing, an adequate tracking system, completed implementation and communication plans and an independent scientific review. Those were appropriate. Had they been more scrupulously addressed, the AVIP might be a very different, much better program." (p.95)

The Government Reform Committee report documented the impact of command pressure on the military medical community[102]:

"Preposterously low adverse report rates generated by DOD point to a program far more concerned with public relations than effective force protection or the practice of medicine. The AVIP raises an ominous question: Who protects the force from ill-conceived force protection? The anthrax vaccine effort is designated a commander's program not a medical program, so DOD doctors appear unable to act as advocates for individual patients in the face of command pressure to meet force-wide inoculation levels." (p.3)

The House Government Reform Committee report found that military servicemembers with adverse reactions have consistently met resistance from a DoD medical community that will not accept the possibility that their administration of the political sensitive anthrax vaccine could be the cause of potentially life-threatening illnesses[103]:

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[101] House Committee on Government Reform report, "Unproven Force Protection", 17 Feb 2000. See: http://www.house.gov/reform/ns/reports/anthrax1.pdf

[102] Ibid.
[103] Ibid.

"A system already known for underreporting can be made even less reliable in the hands of an institutional culture resistant, even hostile, to reports attributing ill health to the anthrax vaccine." (p.81)

Secretary Cohen's assertion that the military will provide "quality medical care" to those made ill by the anthrax vaccine has yet to occur. The military medical community has only responded to the medical needs of ill servicemembers when they are under pressure from Congress or the media. Their response to the ill has been to convene medical discharge boards to get rid of seriously ill servicemembers, rather than to treat them.

DoD cannot accept the failure of the anthrax vaccine policy, or objectively view its flaws, because it is the centerpiece of a new military doctrine.

Taken at face value, DoD's decision not to pursue studies appears to be based simply on accepting inaccurate assumptions about the safety of the vaccine that do not comport with pre-Gulf War acknowledgements of the anthrax vaccine's reactogenicity or anecdotal experience during the Gulf War.

Yet, the December 2000 report on vaccine use during the Gulf War by the Pentagon Office of the Special Assistant for Gulf War Illness clearly demonstrates DoD's motivation not to explore the safety of the anthrax vaccine[164]:

"Vaccines are an integral part of DoD's new strategy of force health protection, which was developed in part from lessons learned from the Gulf War."

In fact, the link between the anthrax vaccine and DoD's new doctrine, Joint Vision 2010, was made clear by a flag officer in the first press briefing on the AVIP program in December 1997[165]:

"If you look at the national military strategy right now, we have four strategic concepts...Given those concepts, the vaccination is the only way to accommodate a force that is very mobile...I think it was more of a reflection, and the other briefer can comment on this, in the context of Joint Vision 2010, the whole idea of force protection, what do we mean by it and what needs to be done to make it work was relooked at."

The consequence of vaccines being the keystone of the military's "force health protection" doctrine, and the anthrax vaccine being a prototype of the much more ambitious Joint Vaccine Acquisition Program, is that bureaucratically DoD cannot afford to scientifically determine if a connection between anthrax vaccine and Gulf War Illness exists. The latest report by the Office of the Special Assistant for Gulf War Illness, ten years after the war, admits they have once again avoided a scientific

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[164] "Vaccine Use During the Gulf War", DoD Office of the Special Assistant for Gulf War Illness, Dec 2000. See: http://www.gulflink.osd.mil/va/vs_s03.htm

[165] See: http://www.defenselink.mil/news/Dec1997/x12181997_x1215mfp.html

investigation while simultaneously justifying the continued use of the anthrax vaccine because of an absence of evidence which a scientific investigation might disclose. [106]

> *"No individual health records were reviewed and this paper cannot provide detailed information on the specific vaccines that an individual servicemember may have received."*

[106] "Vaccine Use During the Gulf War", DoD Office of the Special Assistant for Gulf War Illness, Dec 2000. See: http://www.gulflink.osd.mil/va/va_s02.htm#I1 . INTRODUCTION

Section H
Risk/benefit analysis

The Clinton Administration has exaggerated the threat of biological warfare and bioterrorism.[107]

> *"Although the absence of those types of* [bioterrorism] *cases over the past twenty-five years does not preclude their occurrence in the future, analysis of terrorist behavior with chemical and biological substances does not provide much backing for the not-if-but-when catastrophic terrorism school of thought... Conventional terrorism was far more prevalent, far more harmful, and far more deadly than chemical or biological terrorism. Therefore, if the past is any predictor of the future, terrorist incidents involving chemical and biological substances will continue to be small in scale and far less harmful than conventional terrorist attacks."*

The current Administration's bioterrorism threat response assessment has lacked empirical validity.[108]

> *"...instead of examining historical cases in which terrorists sought to acquire and use such agents, the Clinton administration, as well as many outside analysts, developed their threat assessments and response strategies in an empirical vacuum. Lacking solid data, they fell back on worst-case scenarios that may be remote from reality."*

SecDef Cohen is personally responsible for exaggerating the threat and has been inconsistent in his statements.

- Mr. Cohen's five-pound bag of sugar[109]:

> *"In a television appearance in 1997, Defense Secretary Cohen held up a 5-pound sugar bag that he said was big enough, if filled with anthrax spores, to wipe out half the population of Washington, D.C. A group of government experts later wrote in a scholarly journal, the Archives of Internal Medicine, that Cohen's estimate had overshot the mark by 100 times."*

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[107] Amy Smithson, "Ataxia: The Chemical and Biological Terrorism Threat and the US Response", The Stimson Center, Report No. 35, October 2000.
See: Chapter 2: http://www.stimson.org/pubs/cwc/ataxchapter2.pdf

[108] Jonathan Tucker and Amy Sands, "An Unlikely Threat", Bulletin of Atomic Scientists, Jul/Aug 1999
See: http://www.bullatomsci.org/issues/1999/ja99/ja99tucker.html

[109] Paul Richter, "Experts Assess Risk of 'New Terrorism' Threat", Los Angeles Times, 7 Feb 2000

- Mr. Cohen's Jul 1999 Washington Post op-ed[110]:

"At least 25 countries, including Iraq and North Korea, now have -- or are in the process of acquiring and developing -- weapons of mass destruction...This is not hyperbole. It is reality...The race is on between our preparations and those of our adversaries. We are preparing for the possibility of a chemical or biological attack on American soil because we must. There is not a moment to lose."

- Mr. Cohen's Jul 2000 Army Times op-ed[111]:

"At least 10 countries have or are developing anthrax as a weapon."

Statements by DoD officials indicate a premeditated effort to hype the biowarfare threat:

- *"BG Busbee addressed a need to make the case that anthrax is currently the principal biological warfare (BW) threat."*[112]

- *"The hype, I think, was necessary to get our attention," said David R. Franz, former head of the U.S. Army Medical Research Institute of Infectious Diseases. "But we have to be careful to deal with facts rather than hype, or we will be expending unnecessary resources."*[113]

Objective analysis of the biowarfare threat indicates that it has not changed significantly in the last decade.

An April 1999 General Accounting Office report concluded[114]:

"The nature and magnitude of the military threat of biological warfare (BW) has not changed since 1990, both in terms of the number of countries suspected of developing BW capability, the types of BW agents they possess, and their ability to weaponize and deliver those BW agents..."

DoD testimony to Congress on the threat substantiates the static nature of the biowarfare threat:

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[110] William S. Cohen, " Preparing for a Grave New World ", Washington Post, 26 Jul 1999
[111] William S. Cohen, "Force Protection is My Priority", Army Times, 31 Jul 2000
[112] LTC David Danley, *"Minutes of the Meeting on Changing the Food and Drug Administration License* for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements", held on 20 Oct 1995 meeting; Joint Program Office for Biological Defense memorandum, 13 Nov 1995.
[113] Steve Goldstein, "Clouded by a Fear of Bioterrorism", Philadelphia Inquirer, 14 Nov 1999
[114] GAO report, 29 Apr 1999: Medical Readiness: Safety and Efficacy of the Anthrax Vaccine (04/29/1999), T-NSIAD-99-148 See: http://www.gao.gov/AIndexFY99/abstracts/ns99148t.htm

- 1988 DoD testimony to Congress on the number of threat countries[115]:

  "...what has happened is that we have seen the number of nations possessing biological agents increase from 4 to 10 that we know of – there are probably more – and this drove us to approach the Armed Services Committee asking for increased funding for biological defense."

- April 2000 DoD testimony to Congress on the number of threat countries:

  - Written testimony of Joint Staff Director of Intelligence, J-2: *"At least 10 countries have or are developing a biological warfare capability. Several of these countries are suspected of developing anthrax as a biological warfare agent."*[116]

  - Verbal testimony of Joint Staff Director of Intelligence, J-2, indicates just two countries with weaponized anthrax capability[117]:

    SEN. WARNER: *"Do you know whether or not any military has formally weaponized these systems? You have covered that pretty well, but I am talking about do we have positive knowledge of that?"*

    ADM. JACOBY: *"Very clear and positive knowledge that the former Soviet Union and Iraq have weaponized and had operational systems to deliver anthrax, yes, sir."*

Credible experts dispute the notion that Iraq has an effective aerosol biowarfare capability.

- Dr. Raymond Zilinskas, Center for Public Issues in Biotechnology, University of Maryland[118]:

  "Anthrax slated for weapons may be produced as slurry (an insoluble liquid mixture) or dry powder. Anthrax slurry, while easier to manufacture than powder, is less efficient for biological warfare purposes; agents in slurry lose virulence relatively quickly and, more importantly, slurry is troublesome to disperse as an aerosol with particles of optimal size. Yet, although Iraq possessed dryers and grinders that could have been used to produce dry anthrax, all of its deployed biological warfare munitions were filled with wet

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[115] Thomas J. Welch, PH.D., Deputy Asst to the Secretary of Defense for Chemical Matters, testimony before the Subcommittee on Oversight of Government Management, Committee on Government Affairs, US Senate, 28 July 1988.

[116] Rear Admiral Lowell Jacoby, Director of Intelligence, Joint Staff, J-2, testimony before the Senate Armed Services Committee, 13 Apr 2000.
See: http://www.senate.gov/~armed_services/statemnt/2000/000413lj.pdf

[117] Jacoby, testimony, 13 Apr 2000. (Federal News Service transcript)

[118] Zilinskas, Raymond A., "Iraq's Biological Weapons; The Past as Future?," JAMA August 6, 1997 – Vol 278, No. 5, p. 421.

anthrax. The Iraqis may have been unable to overcome either the technical difficulties or the safety problems inherent in dry anthrax production."

Other credible experts dispute the hyped-portrayal of the biowarfare threat.

- Milton Leitenberg, Senior Fellow at the University of Maryland Center for International and Security Studies, commenting on the Secretary of Defense Cohen's bioterrorism pronouncements[119]:

  "They are exaggerated and alarmist. They are probably even dangerous and counterproductive, since they virtually solicit and induce precisely what they portray as fearing...No agency of the U.S. government has prepared a threat analysis that provides indications that these events are imminent or even likely. Instead, various analysts have provided vulnerability projections and scenarios, which are always easy to concoct in the abstract...Either the advice reaching the secretary of defense and other senior officials on this subject is extraordinarily poor, or they are intentionally disregarding real-world experience."

- Professor Jeanne Guillemin, Sociology Department, Boston University, Anthrax, The Investigation of a Deadly Outbreak, documenting the 1979 accidental release of anthrax in Sverdlovsk, Russia from a biowarfare facility[120]:

  "Based on experiments with hundreds of monkeys done at Fort Detrick in the 1950s, the U. S. army standardized a value of eight thousand inhaled spores as the dosage lethal for 50 percent of a human population receiving it, the so-called LD_{50}. But nowhere in Sverdlovsk was the case fatality rate 50 percent. Even at the ceramics factory pipe shop, apparently right on the centerline of the passing spore cloud, only ten of about four hundred and fifty workers fell ill and died, a fatality rate of 2 percent."

- State Department Fact Sheet, Chemical - Biological Warfare[121]:

  "The Department of State has no information to indicate that there is a likelihood of use of chemical or biological agent release in the immediate future. The Department believes the risk of the use of chemical/biological warfare (CBW) is remote, although it cannot be excluded. There are, of course, no guarantees. Until a threat becomes know, American citizens must make their own decisions with regard to those precautions they might take to avoid injury."

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[119] Lietenberg, Milton, "False Alarm," The Washington Post, August 14, 1999; Page A15.

[120] Guillemin, Jeanne, Anthrax, The Investigation of a Deadly Outbreak, University of California Press, Berkely, CA, 1999, p. 241.

[121] US Department of State, Fact Sheet Chemical - Biological Warfare, See: http://www.travel.state.gov/cbw.html

- Ed Regis, in his book, The Biology of Doom, documenting American germ warfare projects (concluding paragraph)[122]:

> *"An effective weapon stunned, stupefied, and bullied the enemy into submission with a sudden manifestation of overwhelming power. Biological weapons did none of those things. And that was why no one had ever used them."*

- Dr. Raymond Zilinskas, Monterey Institute of International Studies[123]:

> *"... what I try to make clear...is that there is need for placing the threat of bioterrorism in perspective – the greater biological threat facing the U. S. is not terrorists armed with biological weapons, it is, as it always has been, diseases of natural origin. If we can successfully meet and defeat the real threat of emerging, re-emerging, and transported infectious diseases, then we have also gone a long way toward being able to handle whatever manifestation of bioterrorism that will occur."*

Public exaggeration of the threat is fear-based, opportunistic, inaccurate and costly.

General

- Noted science journalist Daniel Greenberg[124]:

> *"No doubt there are nuts and demons out there planning evil things. But it should be noted that there's a whiff of hysteria-fanning and budget opportunism in the scare scenarios of the saviors who have stepped forward against the menace of bioterrorism."*

- Rutgers University political science professor Leonard Cole[125]:

> *"...the number of false bioterrorism threats has mushroomed in the past year, costing taxpayers millions of dollars and disrupting the lives of more than 13,000 potential victims. . . The suddenness of the hoax phenomenon is underscored by the fact that in the years before October 1998, fewer than a half-dozen anthrax threats had been recorded. Since then, according to the FBI, more than 200 threats have been logged. The cost of police, fire and emergency medical responses for a single incident runs as high as $500,000 . . . The most compelling explanation for the rash of bioterrorism threats has been the ballooning of publicity and hype, especially about anthrax. The (reported)*

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[122] Regis, Ed, TheBiology of Doom: The History of America's Secret Germ Warfare Project, Henry Holt and Company New York, NY, 1999, p. 222.
[123] Zilinskas, Raymond A., "Assessing the Threat of Bioterrorism," Written testimony before the House National Security Subcommittee, October 20, 1999, p. 15.
[124] Greenberg, Daniel S., "The Bioterrorism Panic, Washington Post, March 16, p. A21.
[125] Cole, Leonard A., "A Plague of Publicity," Washington Post, Monday, August 16, 1999; Page A15.

number (of incidents) mentioning "anthrax" grew from seven in 1996 to 122 in 1998. . . The trend began in April 1997 with the nation's first major bioterrorism hoax, at the B'nai B'rith building in Washington. An anthrax threat there disrupted the downtown area as TV news cameras caught naked people being decontaminated outdoors. In a highly publicized performance in November, Cohen hoisted a five-pound bag of sugar on national TV, warning that an equivalent amount of anthrax could kill half the population of Washington."

Media exploitation

- Boston College Sociology Professor Jeanne Guillimen[126]:

  "In modern time...the media profitably market the risks that confront society, whether or not those risks materialize. In this regard, biological weapons offer almost unlimited potential for exploitation."

- Comments on ABC Nightline series on Bioterrorism, 1-8 Oct 1999:

  ➢ Donald A. Henderson, Director of the John Hopkins Center for Civilian Biodefense Studies[127]:

  "Biological terrorism is a hot media topic these days, but by confusing fact and fiction, coverage could cause more harm than good. . . misleading stories are appearing – including the recent anthrax scenario on ABC's 'Nightline' . . . 'Nightline incorrectly portrayed medical and public health intervention as ineffectual...antibiotics were erroneously depicted as being of little value. . . ... 'Nightline's' story ended at Day Seven, implying – incorrectly -- that no further interventions would be useful. . . These efforts (at awareness) should be improved by increasing public understanding of the true threat of bioterrorism – a result that can only come from careful media coverage of this easily sensationalized topic."

  ➢ Professor Jeanne Guillemin[128]:

  "Cohen has said publicly that a bioterrorism attack is a question of 'when,' not 'if.' This is surely one of the most irresponsible statements of our times from a government official. . . the American public deserves better than being manipulated by the military-media scare industry. And maybe a future 'Frontline' [sic: should say 'Nightline'] *will educate us on how that $10 billion against terrorism is really getting spent."*

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[126] Guillemin, Jeanne, Anthrax: The Investigation of a Deadly Outbreak, University of California Press, Berkely, CA, 1999, p. 248.
[127] Henderson, Donald A, "Dangerous Fictions About Bioterrorism," Washington Post, November 8, 1999, p. A 21.
[128] Guillemin, Jeanne, "Scare Campaign about Biological Weapons is Itself a Threat," Boston Globe, December 2, 1999, p. A27.

Victims. DoD has been unwilling to acknowledge that there are chronically ill victims of the anthrax vaccine and possibly deaths.

- DoD has established a presumption against any adverse reaction being caused by the anthrax vaccine, despite repeated acknowledgment of the vaccine's high reactogenicity during the pre-Gulf War period and in medical texts written by Army physicians as recently as 1999.

- Testimony before the House Government Reform Committee has provided compelling evidence of a safety problem with the vaccine. While DoD reacts quickly to any safety issue (for instance, by grounding aircraft) it has not applied the same standard to safety risks associated with the anthrax vaccine. This includes continuing to administer the vaccine to servicemembers who have experienced adverse reactions.[129]

[129] House Government Reform Committee hearings, 3 Oct 2000, 21 Jul 1999, 29 Apr 1999
See: http://www.house.gov/reform/hearings/healthcare/00.10.03/index.htm
See: http://www.house.gov/reform/ns/hearings/testimony/july_21.htm
See: http://www.house.gov/reform/ns/hearings/testimony/witnesses4-30.htm

Section I
Policy

Policy Origins.

Clinton Administration bioterrorism policies. Terrorist incidents were a catalyst for the policy -- but bureaucratic, political, and budget factors provided momentum. These policies had bipartisan support through legislation such as the 1996 Nunn-Lugar-Domenici amendment to the FY1997 Defense bill, which passed in the Senate by a 96-0 vote[130]:

- *"Several factors inflamed the tenor of the US debate. The problem of terrorism truly began to crystallize for Americans when prominent buildings in New York City and Oklahoma City were bombed, sinking in even further with bombings of US targets in Saudi Arabia and Africa. The backdrop for these events was the revelation of frightening details about the extent of the bioweapons programs in Iraq and the former Soviet Union. Adding to the tinder, international terrorist Osama bin Laden threatened to acquire mass destruction weapons specifically to use against Americans. Other, more political factors, also fanned the debate, such as the vested interests of defense contractors and government offices in larger budgets, not to mention the desire of elected officials to be perceived as "doing something" about the problem."*[131]

Both Administration and DoD biowarfare policy-making has been the result of narrowly-focused staff processes relying on a limited number of "experts", who may have bureaucratic or financial interests in the outcome of a policy decision.

- *"A review of events leading to the Clinton vaccine decision reveals that the proposal was pushed by a small group of scientists, businessmen and policy makers who largely shared the same views as they struggled to do something, anything, about a threat whose dimensions were potentially terrifying but frustratingly unclear. Working in Washington's frenetic, often insular world, they tended to overwhelm or sidestep doubters, and failed to see warning signs."*[132]

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[130] Debate Nunn-Lugar-Domenici amendment to the National Defense Authorization Act For Fiscal Year 1997, US Senate, 26 Jun 1996, Congressional Record, page S6988, et.seq.
See: http://www.stimson.org/cwc/sen96.txt

[131] Amy Smithson, "Ataxia: The Chemical and Biological Terrorism Threat and the US Response", The Stimson Center, Report No. 35, October 2000, pg 12.
See: Chapter 2: http://www.stimson.org/pubs/cwc/atxchapter2.pdf

[132] William J. Broad And Judith Miller , "Germ Defense Plan In Peril as Its Flaws Are Revealed", New York Times, 7 Aug 1998

- *"But some senior civilian Defense Department officials, who ardently support the vaccination plan, ultimately convinced the military leaders...senior defense officials eager to institute a broad vaccination program departed from normal departmental practice this spring and organized two meetings that included vice chiefs of the Army, Navy, Air Force and Marine Corps and civilian experts. "The meetings were unusual in that we were starting at the top instead of trying to staff an issue from the bottom up," said one of the organizers."*[133]

President Clinton's personal involvement, and desire for a "legacy" issue, precluded an objective policy-making process.

- *"Clinton became fixated on the emerging germ threat and ways to counter it among civilians, aides said. Influences are said to have included the Iraqi crisis, the Russian claims, the intelligence reports and a novel, "The Cobra Event" (Random House, 1997), about a terrorist attack on New York City with a genetically engineered mix of the smallpox and cold viruses."*[134]

- *"Clinton said he hoped that a major legacy of his Presidency would be to stave off unconventional attacks."*[135]

- *"...abandoning the vaccination program could unravel the administration's entire response to biological threats, discrediting a major element of Clinton's self-described legacy."*[136]

Within DoD, a new standard of accountability provided support for "force protection" policies. Secretary Cohen set his standard for accountability for the military when he ended the career of an Air Force general over the Khobar Towers terrorist bombing in July 1997. Cohen, judging a terrorist incident that occurred on his predecessor's watch, said[137]:

> *"Personal accountability is not simply a question of assigning blame. It involves understanding the obligations of leadership, defining command responsibility, and clarifying the high standards of performance that we expect from commanders who are entrusted with the safety of our troops...force protection is first and foremost the responsibility of the commander on the scene."*

For the military leadership the lesson was clear: casualties were no longer an acceptable consequence of sending troops in harm's way -- and their job security depended upon embracing force protection policies. Compare the earlier treatment of the USS Vincennes,

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[133] Bradley Graham , "Military Chiefs Back Anthrax Inoculations - Initiative Would Affect All of Nation's Forces", Washington Post, 2 Oct 1998

[134] Broad and Miller, 7 Aug 1998

[135] William J. Broad And Judith Miller ; "Clinton Describes Terrorism Threat for the 21st Century", New York Times, 22 Jan 1999

[136] Andrew J. Bacevich, Ph.D., "Bad Medicine for Biological Terror", Orbis, Spring 2000, p.224

[137] DoD press briefing, 31 Jul 1997
See: http://www.defenselink.mil/news/Jul1997/b0731j1997_t0731cgh.html

USS Stark, and Beirut bombing with Cohen's treatment of the Khobar Towers, A-6 ski-gondola in Italy, and USS Cole incidents.

The DoD anthrax vaccine policy, often ascribed by senior civilian defense officials as driven by regional CINCs' concerns, was a visible symbol of a broad Administration counterterrorism policy, PDD-63, that anticipated heavy DoD involvement in a "consequence management" (civil defense) role.

- Although shots were already being given in Southwest Asia (USCENTCOM), full-scale AVIP implementation was announced on 22 May 1998, the same day the President announced PDD-63, his new counter-terrorism policies, in a speech at the Naval Academy.[138]

- As part of PDD-63, DoD also announced the formation of weapons of mass destruction (WMD) rapid assessment elements using National Guard personnel. The teams are part of DoD's effort to support local, state and federal civil authorities in the event of an incident involving the use of on U.S. soil.[139] (These teams are now called WMD Civil Support Teams.)

The White House announced a new "Medical Force Protection" policy concurrent with the deployment of US forces to Southwest Asia in late 1997.

- First announced by President Clinton in Nov 1997 – it created a rationale for the AVIP policy decision that had actually already been made a year earlier, but not yet announced.[140]

- Implemented with a White House policy directive, PRD-5, in August 1998, six months after anthrax vaccine shots started. This policy document anticipated the problems incurred by the anthrax vaccine policy:[141]

  "...efforts to protect, preserve, or enhance the health of military members may be viewed with suspicion if such measures appear to restrict retention in the military, infringe on freedom of choice, limit personal or career opportunities, pose a

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[138] Remarks By The President At The United States Naval Academy Commencement, Office of the Press Secretary, The White House, 22 May 1998
See: http://www.pub.whitehouse.gov/uri-res/I2R?urn:pdi://oma.eop.gov.us/1998/5/26/18.text.1

[139] See: http://www.defenselink.mil/news/May1998/b05221998_bt254-98.html

[140] Statement By The President, Special Report of Presidential Advisory Committee on Gulf War Veterans' Illnesses, White House Press office, 8 Nov 1997
See: http://www.pub.whitehouse.gov/uri-res/I2R?urn:pdi://oma.eop.gov.us/1997/11/12/5.text.1

[141] Presidential Review Directive 5, "Planning for Health Preparedness for and Readjustment of the Military, Veterans, and Their Families after Future Deployments", August 1998, Executive Office of the President, Office of Science and Technology Policy.
See: http://209.207.236.112/irp/offdocs/prd-5-report.htm

potential adverse health effect, or exceed current civilian norms regarding risk and benefit..."

- PRD-5 indicates that "medical force protection" policy is driven by casualty aversion concerns within the Administration.

  "The military and civilian leadership of the government is being held to the extremely high standard of avoiding adverse health effects subsequent to military service—service that by definition, tradition, and reality is inherently hazardous."

  While laudable, recent research shows this casualty aversion to be out of sync with the expectations of the American people.[142]

- **PRD-5 contained extensive communications guidance that DoD AVIP officials have not followed:**

  "Health risk messages and supporting materials should not minimize the existence of the scientific uncertainty of a given risk from an identified hazard. Research needs and data gaps should be acknowledged up front, as should any disagreement among experts."[143]

Objective policy evaluations of the anthrax vaccine policy find it doctrinally flawed:

- Bulletin of Atomic Scientists (Nov/Dec 1998) – authored by a former UN weapons inspector in Iraq.[144]

- Orbis (Spring 2000) – authored by a retired US Army colonel and director of the International Relations at Boston University.[145]

Ethics.

Senior officers have hidden behind anonymity during three critical AVIP briefings

- 15 Dec 1997 – announcement of AVIP policy.[146]
- 22 May 1998 – announcement of full-scale implementation of AVIP.[147]
- 5 Aug 1999 – announcement of more than doubling of the price of vaccine and 18.7 million dollar interest-free loan by DoD to BioPort.[148]

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[142] "A Look At...Casualty Aversion: How Many Deaths Are Acceptable? A Surprising Answer", by Peter D. Feaver and Christopher Gelpi, Washington Post op-ed, November 7, 1999; Page B03
[143] PRD-5, Appendix A. See: http://209.207.236.112/frn/offdocs/prd-5-report.htm#_Toc426272947
[144] Jonathan Tucker and Amy Sands, "An Unlikely Threat", Bulletin of Atomic Scientists, Jul/Aug 1999 See: http://www.bullatomsci.org/issues/1999/ja99/ja99tucker.html
[145] Andrew J. Bacevich, Ph.D., "Bad Medicine for Biological Terror", Orbis, Spring 2000, p.221-236
[146] See: http://www.defenselink.mil/news/Dec1997/x12181997_x1215mfp.html
[147] See: http://www.defenselink.mil/news/May1998/x05281998_x0522mfp.html
[148] See: http://www.defenselink.mil/news/Aug1999/x08051999_x0805ant.html

AVIP has been characterized by slogans repeated by DoD officials defending the program that have little basis in fact or which are simply moralistic appeals to emotion.

- Why AVIP? "we believe it's the right thing to do"
- Why AVIP? "this is classic deterrence"
- Anthrax vaccine is "widely" or "routinely" used by veterinarians
- Helmet analogy -- 'this is no different than an order to wear a helmet'
- Independent medical expert from Yale "reviewed" the anthrax vaccine policy
- Vaccine has been supplementally tested to insure its safety
- SecDef: "I would be derelict in my duty not to vaccinate the troops."
- General officer: "It would be unconscionable not to vaccinate the troops"
- "This is a commander's program, not a medical program."
- General officer on MBPI/BioPort problems: "An urban legend."
- "Emergency stockpile" of vaccine is readily available
- General officer, et.al.: "I would give it to my child."
- Indemnification of contractor: "A misreading of a routine contracting procedure"
- Reactions "very similar to other vaccines"
- "There have been no deaths and no long-term chronic or life-threatening illness"
- General officer: "Only one known refusal in the ANG out of 10,700 vaccinated."
  - 'Refusals number in the hundreds'
- Animal studies have proven the safety and efficacy of the anthrax vaccine

DoD's tactics equate to an information warfare campaign ("psyops") against their own troops, frequently blaming the internet for their problems, while aggressively spending millions to promote the policy on their own internet site and in DoD publications.

- The Army AVIP Agency exists solely for the promotion of the anthrax vaccine. It is budgeted at $74 million over a six year period (FY99-FY05).[149] No other military medicine program needs to be forced on servicemembers with an orchestrated campaign of this type.

- William Arkin, a defense writer and former Army intelligence officer observed[150]:

  "...this is the Pentagon versus its own service members. It is a depressing window into the breakdown of discipline and basic confidence in the political and military leadership. That has nothing to do with the Web."

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[149] Charles Cragin, PDASD Reserve Affairs, testimony, 3 Oct 2000.
See: http://www.house.gov/reform/hearings/healthcare/00.10.03/cragin.htm

[150] William Arkin, "Bogged by the Net", Washington Post online, 27 Sep 1999
See: http://www.washingtonpost.com/wp-srv/national/donmil/arkin092799.htm

Untruthful testimony to Congress by a general officer and senior political appointee prompted a DoD IG complaint by 73 officers against a senior DoD political appointee and the Director of the Air National Guard.

- DoD IG attempted to drop complaint without investigation in May 2000.
- Representative Christopher Shays pressured the DoD Inspector General to resume an investigation that continues at a very slow pace.

2 officers submitted to the DoD IG on 22 Jan 2001 documented false testimony to Congress by Lt Gen Blanck and to the Canadian Court-martial by Col. Friedlander. The complaint was subsequently referred to the "Senior Advisor to the Deputy Secretary of Defense for Biological and Chemical Protection."

- DoD IG relegated this complaint of false testimony to Congress and across an international border back to the organization responsible for the AVIP and the senior officer in charge of the policies' defense and promotion, MG Randall West.

Two additional Examples of ethical lapses by military officers:

In addition to the ethical issues present in the false testimony of LtGen Blanck and Col. Friedlander concerning the IND arguments and the lack of informed consent in the "inhalation anthrax", additional breakdown are represented in two more examples. While these are far from exclusive of the questionable statements made by senior military officials under oath in defense of the anthrax program, they are representative a the larger concern -- When did it become acceptable for military members to not testify truthfully to the Congress of the United States?

- **#1 – MGen Paul Weaver, ANG (USAF) – Director of the Air National Guard.**

Director of the Air National Guard MGen Paul Weaver's statement
On the retention impact of the anthrax vaccine on the ANG

***Finding:* MajGen Weaver's made misleading statements to the House Government Reform Subcommittee on International Relations and Veterans Affairs and to the entire Air National Guard about the retention impact of the AVIP policy.**

The statements of concern occurred during the 29 September 1999 hearing before the U.S. House of Representatives Subcommittee on National Security, Veterans' Affairs and

International Relations (Government Reform Committee). Major General Paul Weaver, Director of the Air National Guard, made the following statement[151]:

> *"So, when I hear all of these other figures about these mass resignations, and what not, they're just not there. There are challenges with explaining, with discussing, as they all are, with the members of their unit, on the anthrax issue. But when it really gets down to it, we've had 18,700 people inoculated for anthrax in the Air National Guard, with one known refusal."*

Months prior to his testimony, however, eight pilots from the Connecticut Air National Guard and seven from the Wisconsin Air National Guard refused the anthrax vaccine. MGen Weaver first became aware of the imminent departure of these pilots from warnings forwarded to the Air National Guard headquarters by the commander of the Connecticut ANG 103rd Fighter Wing in October 1998 – nearly one year prior to his testimony. Subsequently, on 21 January 1999 Assistant Secretary of Defense Mr. Bacon acknowledged the departures from the Connecticut ANG by stating "eight or nine people have resigned rather than take the shot."[152] These resignations were also covered in media reports beginning on 15 January 1999.[153] The Wisconsin ANG pilot losses that occurred months before MGen Weaver's testimony were also widely publicized.[154]

Further, on 26 October 1999 during a live nationwide close circuit television briefing to the Air National Guard, MGen Weaver was asked why he stated to Congress, under oath, that only one person had refused the anthrax vaccine. MGen Weaver was reminded about the pilots who resigned over the vaccine at Connecticut and Wisconsin. Here is an excerpt of MGen Weaver's response:

> *"So, I was very much aware, when I said one refusal...that was a refusal of a person who had a commitment to the Air National Guard. My additional testimony also reflects that I was also very much aware that people did...did walk who...again...were volunteers of our Air National Guard Family."*

Despite this statement to the entire Air National Guard, MGen Weaver did not qualify his remarks in any way in his 29 September testimony before Congress. He said nothing of "one refusal with a commitment." Nor did he acknowledge that other members of the Air National Guard had "walked".

Upon publication of the preliminary findings of the GAO in October of 2000 in their report, 11 Oct 2000 – ANTHRAX VACCINE: Preliminary Results of GAO's Survey of Guard/Reserve Pilots and Aircrew Members, GAO-01-92T, it became apparent that

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[151] House Government Reform Committee testimony, 29 Sep 1999 and VHS Tape Segment #1 of The Jim Lehrer News Hour's Oct 1999 broadcast on the "Anthrax Dilemma."

[152] http://www.defenselink.mil/news/Jan1999/b012119991_t121asd_.html

[153] Thomas D. Williams, Hartford Courant, 15 Jan 1999

See: http://courant.ctnow.com/projects/anthrax/anth5.stm

[154] "6 Guard Pilots Might Refuse Anthrax Vaccine", by Richard W. Jaeger Wisconsin State Journal, 19 Jan 1999

indeed a major negative readiness impact was inherent in implementation of the Anthrax Vaccine Immunization Program (AVIP)[155]:

> "While many factors can influence an individual's decision to leave the military, surveyed Guard and Reserve pilots and aircrew members cited the anthrax immunization as a key reason for leaving or otherwise changing their military status. Since September 1998, an estimated 25 percent of the pilots and aircrew members of the Guard and Reserve in this population transferred to another unit (primarily in a non-flying position), left the military, or moved to inactive status. While several reasons influenced their decision, when asked to rank the one most important factor, the anthrax immunization was the highest, followed by other employment opportunities, and family reasons. Further, about one in five (18 percent) left before qualifying for military retirement benefits. Additionally, 18 percent of those still participating in or assigned to a unit reported their intentions to leave within the next 6 months. These individuals also ranked the anthrax immunization as the most important factor for their decision to leave, followed by unit workload and family reasons. Each of these groups—those who have left and those who plan to do so–had accumulated an average of more than 3,000 flight hours, which symbolizes a seasoned and experienced workforce.
>
> On our survey, most Guard and Reserve pilots and aircrew members expressed a positive view toward general immunizations. Almost three out of four believe that immunizations are effective (74 percent), and more than half believe immunizations to be safe (60 percent). However, their views on the anthrax immunization program and potential biological warfare immunizations in the future are very different. For example, two out of three reported little or no support for the anthrax program (65 percent). Despite DOD's high-visibility campaign to educate servicemembers about the anthrax immunization program, only about one in four believes that the information provided on DOD's anthrax Web site is timely (25 percent), 19 percent believe it to be complete, and 17 percent believe it to be accurate. Just 1 in 10 (11 percent) believe the information to be unbiased. Further, three out of four indicated they would not or probably would not take the shots if the anthrax immunization program were voluntary (76 percent). Eighty-seven percent, or almost 9 out of 10, indicated they would or probably would have safety concerns if additional vaccines for other biological warfare agents were added to the military immunization program.
>
> Forty-two percent of the respondents reported that they had received one or more anthrax shots. Of those taking the shots, 86 percent reported experiencing some type of local or systemic reactions, for example, a knot in the arm or joint pain. For some reactions, the reported duration was more than 7 days (for example, limited arm/body motion and joint pain). Some of these reactions could have implications for work performance."

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[155] http://www.gao.gov/new.items/d0192t.pdf

- **#2 – Colonel Gaston Randolph, USA – director of the US Army AVIP Agency.**

COL Gaston Randolph on the reason vaccine production was suspended

Finding: Colonel Gaston Randolph, Director of the DoD AVIP Agency, and other senior military officers have repeatedly made misleading statements regarding the reason anthrax vaccine production was suspended in January 1998. His statements are in conflict with testimony of senior defense officials, which he witnessed, and statements made by FDA officials.

The statements below infer the closure of the anthrax vaccine manufacturing facility was due to "renovations", rather than the real reason – multiple failures of FDA inspections leading to the FDA to conclude in a 20 Feb 1998 report: "The anthrax vaccine manufacturing process is not validated."

1. **DoD press briefing, 15 Dec 1997 – "problems found were not in the anthrax production line".** On the day the AVIP policy was announced a general or flag officer who declined to be named made the following false statement about the FDA's March 1997 Notice of Intent to Revoke the anthrax vaccine manufacturer's license[156]:

   *"Last spring the Food and Drug Administration notified the producer of the vaccine -- the Michigan Biological Laboratory -- that they had some production problems with regard to quality assurance and production practices and they needed to fix these. Those were identified, a management plan was put in place, we worked closely with the lab to do that. **The problems found were not in the anthrax production line, they were in other areas of other products being produced in the lab.**"*

2. **DoD press briefing, 5 Aug 1999 – "urban legend".** A general officer who declined to be named was a briefer at a press conference held to announce Secretary Cohen's first bailout of BioPort, including a more than doubling of the price of the vaccine and an $18.7 million interest-free loan. The anonymous general made the following statement[157]:

   *"The first [issue] that's sort of hanging in the background and I think needs a direct answer is the FDA having to shut the plant down for renovations. **That's another one of those urban legends or something that just keeps cropping up. We planned to shut the plant down to modernize it...**"*

3. **Air Force Magazine, December 2000.** Colonel Gaston Randolph, Director of the DoD AVIP Agency, was quoted in the December 2000 edition of Air Force Magazine

[156] See: http://www.defenselink.mil/news/Dec1997/x12181997_x1215mfp.html
[157] See: http://www.defenselink.mil/news/Aug1999/x08051999_x0805ant.html

making a statement about the closure of the anthrax vaccine manufacturing that is inconsistent with the admission before Congress by senior DoD officials that the FDA would not have allowed the Michigan plant to manufacture any more vaccine[158]:

> *"The decision to halt production of the vaccine also was taken by some critics as evidence that the shots are risky. But Randolph insists it was not FDA that ordered the interruption in delivery of the shots. "Early on," he said, "we realized that the original facility would not be large enough to handle the volume of production we needed and approved an expansion of what then was [Michigan Biologics Product Institute]. It is the renovation, which requires new FDA approvals, that has caused the vaccine shortage."*

4. **House Armed Services Committee testimony, 13 Jul 2000.** Colonel Randolph was sitting with Deputy Assistant Secretary of Defense for Chemical and Biological Defense Dr. Anna Johnson-Winegar and DepSecDef Rudy DeLeon when they admitted, in the testimony quoted below, that the FDA would not have allowed the Michigan plant to manufacture any more vaccine.[159] This testimony clearly rebuts statements made by Colonel Randolph in the December 2000 Air Force Magazine:

Mr. SHAYS. And the FDA basically shut down the old plant. Isn't that correct?

Secretary DE LEON. I would ask Dr. Johnson-Winegar, since she has been our action officer.

Dr. JOHNSON-WINEGAR. Sir, the FDA did not shut down the plant. The plant was scheduled for renovation and upgrade and that was initiated. In the meantime, these lots—

Mr. SHAYS. Didn't the FDA make it clear that they would not approve any more from this old plant and that they needed to upgrade it?

Dr. JOHNSON-WINEGAR. Yes.

Mr. SHAYS. And that is a matter of public record, correct?

Dr. JOHNSON-WINEGAR. Yes.

Secretary DE LEON. **Correct.**

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[158] Bruce D. Callander, " The Anthrax Issue ", Air Force Magazine, December 2000, Pg. 46
See: http://www.afa.org/magazine/Dec2000/1200anthrax.html

[159] Excerpted House Armed Services Committee (Military Personnel Subcommittee) transcript, sections 62-63, discussion between Representative Christopher Shays (R-CT), DepSecDef Rudy DeLeon, and Anna Johnson-Winegar Ph.D., Deputy Assistant Secretary of Defense for Chemical and Biological Defense.
See: http://commdocs.house.gov/committees/security/has195020.000/has195020_0f.htm

Mr. SHAYS. Didn't the FDA make it clear that they would not approve any more from this old plant and that they needed to upgrade it?

Dr. JOHNSON-WINEGAR. Yes.

Mr. SHAYS. And that is a matter of public record, correct?

Dr. JOHNSON-WINEGAR. Yes.

End of excerpted testimony.

5. **FDA's position on plant closure.** The FDA's position was made clear in a 25 June 2000 article in the Vancouver, Canada, newspaper *The Province*. The article quoted below was the result of an extensive interview with Mr. Mark Elengold, the deputy director for operations at the FDA's vaccine division, the Center for Biologic Evaluation and Research. The reporter asked Elengold to explain the significance of the FDA's March 1997 "Notice of Intent to Revoke" letter to the manufacturer, and the subsequent closure of the vaccine production line in January 1998:

"In 1997, the FDA gave notice that it would revoke the manufacturer's licence if it did not comply with regulations..."

"...In the three years I have been in this job, I have done it about three times," said Elengold, deputy director for operations for the FDA's Centre for Biologic Evaluation Research."

"It is a very serious tool. We view it . . . to be equivalent to an injunction . . .where we get a court to order compliance."

"The company failed to comply completely and a year later still faced the possibility of losing its licence, according to Elengold."

"The FDA held off pulling the licence, in part because it would have left the U.S. Department of Defence -- which had just announced that all soldiers were to receive anthrax vaccine -- with no domestic source."

"This is a one-source product so we tend to try to work with firms and put additional monitoring steps in to avoid revoking the licence," said Elengold.
The prestigious British medical journal Lancet reported at the time that "a plea from the Pentagon has prevented an 'eleventh-hour' closure of the only U.S. producer of anthrax vaccine," according to an e-mail to DND medical headquarters in February 1998."

"Elengold confirmed the Pentagon sat in on a crucial call to the company in which he discussed revoking the licence."[160]

6. **National Academy of Science/Institute of Medicine position on the anthrax vaccine manufacturer shutdown.** In a 1999 report co-authored by Dr. Philip Russell (MajGen, USA, ret.), the former commander of the US Army medical research facility at Ft. Detrick, the following reason is given for the shutdown[161]:

   "The manufacturer of the current anthrax vaccine, BioPort, has had problems meeting regulatory requirements and standards, resulting in costly program to upgrade the manufacturing process and facility so that it meets U.S. Food and Drug Administration (FDA) standards."

Impact of the anthrax vaccine policy (AVIP) on military culture:

The House Government Reform Committee report on the DoD anthrax vaccine policy made the following observation about the interplay between the policy and military culture.

> *"Trust must be earned. It can be earned only with a degree of candor and openness that has not been the hallmark of the AVIP to date. While claiming a new awareness of the need for effective risk communication, the Pentagon still reverts to absolutist declarations, heavy handed propaganda, and ad hominem attacks whenever the risks of the anthrax vaccine are communicated too effectively or persistently. In a culture based on a chain of command and the power to compel, attempts at persuasion and education often devolve into intimidation. Labeling opponents paranoiacs and ridiculing the intelligence or courage of those with legitimate questions are not the methods of modern risk communication."* (p.96)

An example of the unprofessional actions of those charged with implementing the anthrax vaccine policy is this ad hominem attack on opponents of the anthrax vaccine by the former director of the Army's AVIP Agency, which was posted on DoD's anthrax vaccine website from June-October 1999[162].

> *"Much of the hand-wringing and bizarre allegations about the vaccine is coming from a vocal minority of people who think the "field" is where a farmer works and "Gortex" is one of the Power Rangers. Most of these folks have never spent a*

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[160] Ann Rees, "Their Dangerous Dose", The Province [Vancouver, Canada], 25 Jun 2000

[161] Joellenbeck, Lois M., Philip K. Russell, and Samuel B. Guze, eds., Institute of Medicine, "Strategies to Protect the Health of Deployed U.S. Forces: Medical Surveillance, Record Keeping, and Risk Reduction", Washington, DC: National Academy Press, 1999, p. 105.
See: http://books.nap.edu/books/0309066379/html/105.html#pagetop

[162] Major Guy Strawder, former director of the US Army AVIP Agency. Posted Jun-Oct 1999 at: http://www.anthrax.osd.mil/

single moment in harm's way and have no appreciation of what that sacrifice means--and they openly resent the limited budget currently used to finance our nation's defense."

This statement was removed from the DoD anthrax vaccine website after Chairman Dan Burton of the House Government Reform Committee made note of it during a hearing on 12 Oct 1999.

Impact of AVIP on civil-military relations.

The anthrax vaccine policy has highlighted the inherent conflict between active duty military officers' blind obedience to a commander-in-chief and citizen-soldiers who place their first loyalty to the Constitution -- the rule of law. The framers of the Constitution, who created two Armies --one federal and one state -- to act as a check and balance, anticipated this conflict.[163] Increased reliance on the Guard and Reserve in the post-Cold War era has increased the likelihood of these types of conflicts.

Actions by senior military officers to defend a clearly political policy were evident when a two-star Marine general publicly dismissed a bipartisan Congressional committee report critical of the anthrax vaccine policy, dangerously blurring the lines of responsibility between civilian political appointees and military officers.[164]

The anthrax vaccine has placed the American citizen-soldier in conflict with senior military leaders who increasingly equate their oath to support and defend the Constitution with supporting and defending the executive branch. On a political level, the anthrax vaccine policy represents a conflict between the Congress, which passed a new law requiring informed consent for military servicemembers in 1998 and an executive branch, which has willfully disregarded that law. Unfortunately, the armed services committees in both the Senate and the House -- staffed by many former military officers -- appear reluctant to enforce this law *(10 USC 1107)*.

The consequence of senior military officers supporting a mandatory anthrax vaccine policy without informed consent is that they have shielded the President and commander-in-chief from having to assume the political liability, required of him in law, of waiving servicemembers' rights of informed consent.

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[163] Alexander Hamilton, commenting on the U.S. Constitution, Article 1, Section 8, Federalist Papers #29, 9 Jan 1788

[164] MGen Randall West, USMC, DoD press briefing, 17 Feb 2000
See: http://www.defenselink.mil/news/Feb2000/t02172000_t0217asd.html

Conclusion: the anthrax vaccine policy is an American "Dreyfus Affair."[165]

> *"Nearly 12 years passed before Dreyfus' conviction was reversed. Despite what he had endured, the stoic captain never lost faith and returned to the army: he was promoted to the rank of major and given the Legion of Honor. Still, like other great divisions among the French, the Dreyfus case lives on because it remains viscerally political. Among the anti-Dreyfusards were conservatives still opposed to the outcome of the French Revolution. Dreyfusards saw in the case a major issue, individual rights, trampled in the name of national security."*

Just as the Dreyfus Affair dishonored the French military 100 years ago, the American military leadership's passive acquiescence to Mr. Cohen's force protection panacea has revealed an epidemic of careerism and moral decay in the American officer corps. Then, a dogmatically Catholic French military leadership defensively persisted for eight years in falsely accusing a Jewish officer as a spy; today, America's generals blindly blame internet disinformation for opposition to the anthrax vaccine. The senior leaders have been aided by line commanders who have cooperated in shielding from Congress both adverse reactions and the retention impact of the vaccine. Military leaders have placed results before process by either acceding to the breaking of the law or by willfully subverting the Congress' Constitutional oversight responsibility. In time this will come to be seen as a stain on an American officer corps that collectively refused to expose a falsehood – that risk can be inoculated away -- to protect their careers.

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[165] Professor Michael Sinclair, "The Affair – The Case of Alfred Dreyfus", Wake Forest University See: http://www.wfu.edu/~sinclair/dreyfus.htm
See also Professor Jean-Max Guieu, "Chronology of the Dreyfus Affair", Georgetown University, May 2000. at http://www.georgetown.edu/guieu/chronology.htm

Section J
Recommendations

- Stop the anthrax vaccine immunization program immediately until the FDA specifically licenses the anthrax vaccine for inhalation anthrax or the Commander-in-Chief (President) waives servicemembers' right of informed consent in accordance with federal law.

- Stop the anthrax vaccine immunization program immediately until the FDA certifies that the manufacturer has met all federal regulatory standards and only newly - produced vaccine is used or the Commander-in-Chief (President) waives servicemembers right of informed consent in accordance with federal law.

- Congress should establish a presumption of service-connected injury for certain medical conditions resulting from the anthrax vaccine and direct both the DoD and DVA to acknowledge the sick and to provide adequate long-term medical care and disability payments for those made sick by the vaccine.

- Congress should establish independent, civilian oversight of the military practice of medicine. The DoD-sponsored Armed Forces Epidemiological Board has proven inadequate to this task.

- Congress should change federal law to delineate that promotion of public health is the sole the responsibility of the Centers for Disease Control, that the FDA is solely responsible for the regulation of drugs and biologics (vaccines), and, specifically, that FDA is responsible for regulating DoD's use of drugs and biologics (vaccines).

- The new Secretary of Defense should direct DoD to correct the military records of Servicemembers punished, discharged, or court-martialed for opposition to the DoD anthrax vaccine immunization program and compensate them for all fines, garnished pay, legal costs, and medical bills they have incurred.

- The new Secretary of Defense and Secretary of Health and Human Services should request a Department of Justice-led investigation of the DoD and FDA officials responsible for implementation of the anthrax vaccine immunization program. The investigation should recommend administrative action or indictments of officials who have misled Congress about the impact of the AVIP policy on the health and retention of Servicemembers; for violations of the federal law on informed consent, the Food, Drug, and Cosmetic Act, federal contracting regulations, and DoD and Service regulations.

THE WHITE HOUSE

WASHINGTON

2001 APR 27 PM 3:54

OSD
WHITE HOUSE SECTION

April 25, 2001

MEMORANDUM FOR PAUL WOLFOWITZ

FROM: KARL ROVE

SUBJECT: GULF WAR SYNDROME AND ANTHRAX

Here is material which has been sent to me by Ross Perot regarding the Gulf War Syndrome, as well as some material on the Anthrax vaccine problem.

He also offered me a packet of materials from the Lydon LaRouche crowd about Richard Armitage, but I turned him down.

I do think we need to examine the issues of both Gulf War Syndrome and the Anthrax vaccine and how they can be dealt with. They are political problems for us.

W00554 01

EXHIBIT A

Players in the Clinton Administration's Program
to Cover up the Gulf War Illness Problem
(See list of organization abbreviations attached.)

After expending $500 million over the past eight years in the Clinton Administration's response to the Gulf War illness, the massive government effort led by the Clinton White House has, by their own repetitive admission, made no progress in understanding the disease or helping the injured veterans. All positive contributions have come from outside the government by research groups funded privately and working at odds with, and often under duress from, the government effort. Early in the investigation, Clinton officials established a policy that the soldiers were suffering from the effects of stress and have attempted to make the science conform to this conclusion. The effort has involved scientific and financial corruption on a massive, systemic scale involving high level officials in numerous agencies -- all directed at creating the outward appearance of a large scientific effort, all the while obscuring the problem and dismissing the ill veterans.

The immediate reason for the lack of progress has been negative, defeatist and obstructive leadership by government officials in positions that oversee the research. This leadership has consistently expressed the view, "There is no Gulf War syndrome, and we will never know what caused the illness." All officials who came into positions of responsibility over this issue during the Clinton Administration had to subscribe to the view as a loyalty test. Not unexpectedly, this attitude in leadership has resulted in a large portfolio of research intended to disprove the presence of an illness, to attribute the symptoms to "stress," and to cover up in-theater chemical exposures that may have caused the problem. Most

scientists who could have contributed positively were repelled initially, and the few who ventured into the research were either subjected to harassment and loss of funding or were unfairly discredited.

Most of the negative research leaders are still in place. In the final months of the Clinton Administration, many of them were moved from appointed positions to permanent civil service jobs, where they can continue to obstruct the investigation. Others have moved out to consulting positions in universities and military contractors, such as RAND, where they continue to influence policy and orchestrate the cover up under lucrative consulting agreements or grants from their former colleagues.

In contrast, over the past 15 years under positive, enlightened research leadership at NIH and CDC, understanding of the HIV/AIDS problem has progressed from nil where virtually all sufferers died, to today's nearly complete medical understanding of the disease, highly effective treatment and a promising vaccine. If our country can do that for HIV/AIDS, surely we can do even better for the equivalent of five divisions of U.S. service men and women who were chemically wounded on the field of battle, serving their country.

To do this will require a complete change in research leadership, replacing the negative, defeatist echelon with a new cadre of positive, encouraging leaders who will take responsibility to achieve progress. *It should be made clear that their future performance will be measured by their ability to involve top scientists around the country to achieve a deep scientific understanding of the problem, develop effective treatment and devise practical means of preventing this problem in the future, just as NIH has successfully managed the HIV/AIDS research initiative.* (I understand that a couple of years ago there was a move to transfer the

entire Gulf War illness investigation to NIH where positive leadership might produce a research breakthrough, but NIH declined fearing harassment and retribution from VA and DoD if they got involved.)

The following is the best list of the negative leadership that can be put together. Suffice it to say that this is not all of the hidden obstructionists planted in key positions as the Clintons left office. However, moving these key people out of positions of influence over this issue will not only remove the most visible problems but will serve notice to others that the new administration will not tolerate negative, defeatist leadership when it comes to ensuring the health of our military force. Note that this list includes both current and retired government officials, all of whom appear to be either directing the research programs or strongly influencing them through outside consulting roles. DoD corruption was allegedly orchestrated through Rudy DeLeon, Deputy Secretary of Defense under Cohen; whereas, VA corruption was allegedly managed through Frances Murphy and John Feussner. Corruption in funding was managed through Army Surgeon General Ronald Blanck and Ft. Detrick's USAMRAA operation. Negative leadership in these areas appears to be the most critical obstructions at this time.

VA Central Office

From the beginning VA has played the predominant role in negative scientific leadership in understanding the illness. Now as more and more Gulf War veterans leave military service, the problem is increasingly a VA concern. Of the three divisions of VA, the Health Division is where the greatest obstruction has resided; the Benefits Division has generally been helpful as far as their limited resources go.

Frances Murphy, MD, MPH

Murphy has been the undisputed principal leader of the negative research policy throughout the Clinton Administration. With no research expertise, from the beginning she has promulgated the doctrine that the problem is unsolvable and exerted strong influence throughout the government. To ill veterans she is a central symbol of the government's duplicity in its research effort. Her departure is essential.

John R. Feussner, MD

Head of VA Research, Feussner has done the most to discourage productive researchers and unfairly influence research funding to favor stress researchers. An outspoken proponent of the "we'll never know what it is" doctrine, he is known as a research leader who rewards his research friends and quietly disposes of his research enemies by undermining their grant funding, regardless of scientific merit. For two years Murphy and Feussner have suppressed publication of a large VA study that clearly demonstrates a unique new Gulf War syndrome with a strong causal link to nerve gas exposure, while they continue stating publicly that there is no Gulf War syndrome. Feussner is tight with Rep. Christopher Smith, new chair of the House Veterans Affairs Committee, but quietly continues to do the most damage of anyone to research on Gulf War illness. His departure is essential.

Kelley A. Brix, MD

Devoid of research experience or credentials, Brix was Bernard Rostker's personal assistant while OSAGWI (see below) was covering up chemical exposures and harassing productive researchers. With the change in administration, Feussner brought her into VA as chief of research on Gulf War illness (the fox guarding the hen house). Her departure is essential.

Roger Kaplan

Formerly a public relations officer with OSD in the Clinton Administration, Kaplan was detailed to PSOB to assist Rudman in exonerating Rostker and OSAGWI. His outspoken motto has been, "The only problem with Gulf War veterans is that we didn't manage the press soon enough." He is a master of spin with no concern for scientific accuracy or truth. From inside VA, he continues feeding inaccurate information to the press to misrepresent research findings and disturbing VA disability data. With the change in administration, Feussner brought him over to VA to spread disinformation as PR director under Brix. His departure is essential.

Mark Brown, PhD

Brown is head of environmental research for the VA system. Although he may be a salvageable research leader, he has shown negative leadership under his mentors, Murphy and Feussner.

Robyn Y. Nashimi

Nashimi was a highly negative and manipulative staff of the PAC in the 1995-1998 time frame (see PAC below). After playing a major negative role in determining the direction of Gulf War illness research

in that time frame, she took a permanent position in the VA Central Office, where her negative influence is ever present.

Timothy R. Gerrity, PhD

Gerrity was Brix' predecessor in directing Gulf War illness research for the VA Central Office. After years of harassing researchers to look only at stress, a veritable psychological reign of terror in research circles, he retired from VA and joined Georgetown University, where he directs a large grant that was negotiated during his VA tenure. He continues to consult and play a role in Gulf War illness research leadership as a consultant. This relationship should end.

Office of Secretary of Defense, DoD

The OSD coordinated activities of all DoD agencies and offices and interfaced with VA Central Office by means of the Persian Gulf Veterans Coordinating Board (PGVCB).

Rudy DeLeon

Deputy Secretary of Defense DeLeon was ostensibly the top policy person in DoD on Gulf War illness. Rostker took his orders from DeLeon in shaping OSAGWI and the cover up. It is not clear whether DeLeon answered to Cohen, to Busick in the White House, or elsewhere. DeLeon allegedly was involved in other financial corruption involving large defense contracts. This should be investigated.

OSAGWI, OSD, DOD (RAND)

In early 1996 when the media was pressing VA and DoD to find the cause of Gulf War illness, the Clinton Administration created OSAGWI (Office of the Special Assistant to the Sec. Def. for Gulf War Illness) to "take the issue out of the media." While VA led the cover up of the illness, OSAGWI led the cover up of the chemical exposures that appear to have caused it. OSAGWI thus became a 200-person, $35 million per year public relations operation, whose mission was to "investigate" every report of chemical exposure in the war and manufacture an investigation to refute it and discredit the soldiers or researchers making the report, regardless of the true circumstances. Scientists staffing the Presidential Special Oversight Board (PSOB) to investigate OSAGWI's reports, found them to be thinly veiled propaganda devoid of scientific merit, although PSOB head Warren Rudman successfully obscured the criticism (see below). Although OSAGWI's charter has been renewed for five more years, there is a real question of whether OSAGWI is needed, and an investigation into corruption should be conducted.

Bernard Rostker, PhD

Rostker, a 30+ year Democratic political appointee, has regularly worked for the Pentagon during Democratic administrations and for the RAND Corporation when the Democrats are out of power. For example, he was head of the draft board in the 1970s. He is a tenacious propagandist with no concern for truth or the interest of injured soldiers. A whistleblower has stated that when Rostker came into his OSAGWI office in 1996, he held a meeting with Sue Bailey and other key DoD officials and announced that the new policy is that the Gulf War illness is due to stress and any who stay must agree to enforce this policy. His office unabashedly manipulated the truth to

cover up the widespread chemical exposures and illness of U.S. troops in the Gulf War. He let allegedly illegal sole-source contracts to his cronies at RAND to produce "scientific reports" giving cover to his positions and activities. The RAND report on stress was the subject of a scientific misconduct accusation. On the charge RAND officials admitted guilt but never corrected it; instead, they published a public attack to discredit the accuser. With the change of administrations, Rostker just moved back to RAND where he continues directing his former colleagues still in positions in the VA Central Office and OSAGWI.

Kelley A. Brix, MD

Brix was Rostker's personal assistant and policy analyst at OSAGWI. She was ever-present in Gulf War research forums, taking notes, developing propaganda, and engineering efforts to discredit productive researchers. With the change of administration, she moved to a permanent position under Feussner in the VA Central Office.

Retired Admiral Vesser

Another of Rostker's long-time deputies in OSAGWI, he is acting director of OSAGWI until a new director comes aboard. He has been a loyal Rostker lieutenant in the cover up, and is continuing the program. Since Rostker's replacement will have been chosen by the same leadership, the person should be evaluated carefully before perpetuating him.

Michael Kilpatrick, MD

A retired military physician, Kilpatrick has been the public spokesman

for OSAGWI, espousing the "we'll never know what this is" doctrine and traveling around the country trying to convince ill veterans that the government is doing everything it can to help them, when in fact it is doing nothing productive. To the ill veterans, he is a symbol of the government's contempt for military veterans.

William Spance, JD

Lead attorney for OSAGWI, Spance was instrumental in crafting the legal strategy to give Rostker cover in his activities to obscure the Gulf War illness. Recently Spance has had a change of heart and has become very negative on Rostker. Under oath and with pressure, he might be willing to tell how the cover up was orchestrated.

Presidential Special Oversight Board for Department of Defense Investigations of Gulf War Chemical and Biological Incidents (PSOB)

In 1998 President Clinton appointed former Senator Warren Rudman to form the PSOB to quell the mounting criticism of OSAGWI by veterans who were accusing them of covering up chemical exposures underlying the Gulf War illness. Scientific staffers from EPA and NIH, assigned to review OSAGWI's reports for the PSOB, wrote devastating criticisms of them. Rudman intimidated the scientist staffers, altered their reports, ignoring their objections, and concluded that the work of OSAGWI and Rostker was valid and credible and that stress is the main cause of the Gulf War illness. One of the scientist staffers, William H. Taylor, PhD, a toxicologist detailed from EPA, wrote a lengthy resignation letter accusing Rudman and colleagues on the PSOB of specific counts of altering reports and covering up. Under threats of dismissal from the PHS arranged by Rudman, Taylor

was forced to write an apology, and the outrageous PSOB falsifications stand.

Warren B. Rudman

Rudman is known to act as a front man for intelligence. Over the past several years he was put in charge of the Los Alamos security lapse and the PSOB investigation on the Gulf War illness. In the Los Alamos investigation he pinned the lapses on Win Ho Lee, who was later exonerated by a court. In the PSOB he appears to have openly and brazenly falsified reports to maintain the cover up of the role of chemical exposures in causing Gulf War illness and to exonerate Rostker and OSAGWI.

RADM Alan M. Steinman, MD

A retired Coast Guard and Public Health Service admiral, Steinman took the main role of altering the scientific staff reports and developing the false final report in praise of OSAGWI and Rostker and advocating the stress theory. He served an understudy role to Rudman, who is grooming him to collaborate in lucrative consulting jobs with government agencies.

RADM Paul E. Busick

Another retired Coast Guard admiral, Busick was the overall director of the Clinton Administration's entire response to the Gulf War illness problem. As a White House fellow reporting to Hillary Clinton, he coordinated the research and political activities of VA, DoD, CDC, NSC, IOM and various appointed advisory committees (PAC, PSOB, etc.) on this issue. He worked closely with Rudman and served on the PSOB.

Michael E. Naylon

A retired army colonel, Naylon was the executive director of the PSOB, carrying out Rudman's orders, including the intimidation of the scientist staffers. After his role in the cover up, he received a promotion to another job in the Pentagon.

Roger Kaplan

Served as the PR director of PSOB. When PSOB ended, he moved to a key PR position overseeing Gulf War illness research in the VA Central Office (see VA Central Office above).

Office of the Assistant Secretary of Defense, Health Affairs

In the early years of the Gulf War illness investigation (1992 - early 1996), OASD-HA was the lead office in coordination with the VA Central Office (Frances Murphy and Tim Garrity).

Stephen Joseph, MD, MPH

As ASD-HA from 1994-1996, Joseph was among the first to press the stress theory and advocate discouraging other lines of research. He is known to have called in both DoD and university researchers who were exploring chemical theories to berate and intimidate them. He basically shut off all meaningful epidemiologic and laboratory research on Gulf War illness in the government and instituted the $150 million CCEP program, meaningless physical examinations and routine laboratory tests for 60,000 ill soldiers. By relying on superficial test, this program was calculated to show nothing and thus confirm that the soldiers had no real illness. When his inept

management of the problem led to persistent fire from the media, Joseph was asked to resign, and OSAGWI was established to mount a more effective cover up under Rostker's leadership. Joseph left the government in 1996.

Sue Bailey, MD

Assistant Secretary of Defense, Health Affairs, after Joseph and personal friend of Hillary Clinton, Bailey has worked closely with Bernard Rostker to ensure that DoD personnel supported the stress theory in all research and political interactions with Congress. She was allegedly in the 1996 meeting when Rostker is said to have declared the stress policy. She reportedly has left office with large financial grants approved under her tenure. This should be investigated.

David H. Trump, MD

Naval captain Trump has been a central operative in executing the Gulf War policy, working closely with Bernard Rostker and Sue Bailey.

James R. Riddle, DVM, MPH

As an up-and-coming Pentagon operative in OSD, Riddle has been all too eager to disparage legitimate research toward understanding the Gulf War illness and collaborate with Murphy, Feussner, Rostker, Brix and others leading the negative research doctrine. He has little research training or experience but has become leader of research on force readiness. He is a highly negative influence.

Edward D. Martin, MD

Martin has been an outspoken and aggressive spokesman for the stress theory and the negative approach to research on Gulf War illness. He has been the public defender of the government's failed research program, particularly in relations with Congress.

Naval Health Research Center, Center for Deployment Health Research (San Diego)

This organization conducts epidemiologic research for DoD. Although this could be useful, the organization has been under extremely inept scientific leadership. Consequently, its products have been largely a waste of time and money. After millions of dollars of research on Gulf War illness, no positive findings have resulted, and yet this group is celebrated by the negative research leadership. The group collaborates with an inept statistician from UC San Diego, James D. Knoke, located nearby. Currently, the center has suppressed the results of a large study from his organization demonstrating adverse effects on reproductive function of Gulf War veterans compared with soldiers who did not serve.

Gregory C. Gray, MD, PhD

As director of research at the San Diego Naval research program, Captain Gray, has directed a large staff of researchers, all dedicated to disproving the association of all illnesses with service in the Gulf War. His prolific reports have been refuted by scientists in the private sector. He is to retire from the Navy this summer, but has already arranged extensive consulting relationships with the Naval Health Research Center, his current military research organization. Because of his pervasive negative leadership, these consulting relationships and

all further contact with Gray should be eliminated. Because of the likelihood that he has handpicked his successor for the same ideology, his successor's appointment should be held up pending an investigation of his suitability to exert positive leadership to find meaningful answers.

Ft. Detrick Procurement Activity

Virtually all funding for R&D on the Gulf War issue and anthrax immunization have been funded through the U.S. Army Materiel and Acquisition Activity (USAMRAA and USAMRAMC). This activity has been thoroughly corrupted to control the direction of science by funding scientific investigators and projects that can be counted on to support the stress theory and dispel the presence of real disease in Gulf War veterans and to deny funding to those who would explore the disease with scientific honesty. To accomplish this control while maintaining a veneer of scientific integrity, USAMRAA routinely submits all grant proposals to "peer review" by a private contractor, the American Institute of Biological Sciences (AIBS). In contrast to the NIH peer review process, where reviews are done by standing "study sections" whose members' identities are regularly published and open, AIBS reviews are done by secret panels of hand-picked people whose names are never revealed. Government policy supporters, such as Kelley Brix (see above), are known to have served on the secret AIBS review panels. This unaccountable, secret system has opened the door to wholesale corruption, not only using the public funding mechanism to control the direction of science but also to channel large grants to retiring government officials as a reward for conformity. Government research leaders have vehemently criticized any researcher who

receives private or government funding outside of their "peer review" process, because this threatens their control over the research direction. Other means of controlling research have included the ability to slow and withhold human subjects' protection approvals and to use audits to threaten or embarrass nonconforming scientists.

Gen. Ronald Blanck, DO

As Medical Director of Walter Reed Army Hospital in the early 1990s and Army Surgeon General from 1996 to 2000, Blanck was a central figure in the medical preparations for the Gulf War and for the investigation after the war. He was a member of the PGVCB and worked closely with Rostker, Bailey, Murphy, Feussner and others in orchestrating the stress theory and the effort to constrain research to the policy line. He was ultimately responsible for all procurement through Ft. Detrick and personally controlled human subject's protection reviews and audits. After retiring in 2000, Blanck is rumored to have taken large Ft. Detrick grants and contracts to the Univ. of North Texas medical school where he became president. A whistleblower has implicated Blanck in wrongdoing. Blanck's current grants and contracts should be investigated, and the role being played by his successor should also be studied.

Gen. John S. Parker, MD

Assistant Surgeon General of the Army under Blanck, Parker has headed the Ft. Detrick procurement system and has been instrumental in translating Blanck's policy into contracting practice. He directly supervises Lebo, Friedl, Little and others in the contracting operation.

Craig Lebo

Long time head of contracting for USAMRAA, civilian Lebo is a professional contracting officer, who runs an efficient contracting operation according to directions from Parker. He seems to be a good civil servant caught in a corrupt system but generally discharging his duties impartially.

Lt. Col. Karl Friedl, PhD

Contracting specialist Friedl has been in charge of Gulf War research contracting since the mid 1990s. He has shown extreme zeal in soliciting stress researchers and discouraging others. He is the hatchet man for ensuring that research follows policy and appears extremely clever and devious.

Joe Little

A contracting technician under Friedl, Little has been the one to execute much of the Gulf War contracting. Though only a functionary, he probably knows how the corruption works and, if placed under oath with some pressure, would probably tell all.

General Accounting Office

Over the past eight years, three GAO investigators (Drs. Sharma and Chen and Ms. Zukerman) have led the only investigation that has consistently uncovered the truth about what is going on in Gulf War illness research. They have consistently exposed wrongdoing and accurately informed Congress of the problems. I recently wrote a letter to the head of GAO congratulating him for the work of these three fine GAO investigators. Shortly after I wrote the letter I found that the head of

GAO had just removed these three individuals from investigating the problem and appointed two DoD-friendlies to succeed them. I fear that GAO has succumbed to the negative policy, and will no longer contribute to a positive solution. I realize that GAO is Congress' responsibility, but someone needs to clean house there too.

David M. Walker

Clinton-appointed U.S. Comptroller General Walker, head of GAO, made the decision to take Sharma, Chen and Zukerman off the Gulf War investigation.

Henry Hinton

Hinton was apparently GAO's quiet liaison with Deputy Sec. Def. Rudy DeLeon who was coordinating DoD responses to Gulf War illness. Hinton allegedly negotiated many GAO positions on DoD issues before the fact.

Uniformed Services University of the Health Sciences, Bethesda

Gary D. Gackstetter, DVM, MPH, PhD

Former chief of staff for Stephen Joseph, MD, Asst. Sec. Def. Health Affairs from 1994 to 1996, Gackstetter has been a constant organizer of policy and research to disprove the Gulf War illness. After Joseph was fired for allowing the problem to grow in the media, Gackstetter joined the faculty of the USUHS, where he continues to dabble in research toward negative conclusions.

Centers for Disease Control and Prevention (Atlanta)

From the early Clinton administration, CDC has been largely kept out of the

investigation despite its preeminence in investigating epidemics of this sort. They were asked, however, to provide a liaison to the Persian Gulf Veterans Coordinating Board (PGVCB), which coordinated the activities of all agencies in the matter.

Drue H. Barrett, PhD

Dr. Barrett has been the CDC representative since about 1998, after the first representative resigned in quiet protest at what was happening. She has embraced the government stress theory and worked enthusiastically to sustain the view.

William Reeves, MD

Around 1994 Congress mandated that CDC conduct an epidemic investigation in five Pennsylvania Reserve units. Drs. Keiji Fukuda and William Reeves headed the study. They eventually published a paper that, uncharacteristic for CDC, went beyond their data to claim that the illness was due to stress. Subsequently Fukuda asked for a transfer out of the Gulf War project, leaving Reeves to represent the stress theory in congressional hearings and scientific meetings.

Presidential Advisory Committee on Gulf War Illness (PAC)

In 1995 President Clinton appointed the PAC to study all scientific information on the Gulf War illness and evaluate the government's response. The chairman, Joyce Lashof, had been a long-time colleague of Stephen Joseph, ASD-HA (see above), who was instrumental in her appointment. She, along with Landrigan and Hamburg, relentlessly pushed the stress theory and belittled other ideas. Initially the other PAC members went along. However, as the PAC's term was expiring in

1998, the other seven PAC members broke with the three stress advocates and formed their own subcommittee. When U.S. troops were again deployed to Kuwait, this group wrote a dissenting letter to the President warning of the possible effects of low-level nerve gas. The three stress advocates continued beating the stress drum and were rewarded with further consulting opportunities in the administration; whereas, the other PAC members returned to obscurity.

Joyce C. Lashof, MD

A 30-year bureaucrat with the Office of Technology Assessment and formerly supervised by Stephen Joseph, around 1994 Lashof retired from government service to the Berkeley School of Public Health as president and fundraiser, only to be appointed by the Clintons to head the PAC. In that position she railroaded the stress theory through the committee and has tenaciously promoted it ever since. When the most recent IOM committee was formed to review Gulf War illness issues, her close colleague Patricia Buffler of Berkeley was named to the panel, where she is said to have exerted vigorous influence for the stress theory.

Philip Landrigan, MD

An academic scientist involved in occupational diseases at Columbia University medical school, Landrigan served on the PAC as one of the main proponents of the stress theory of Gulf War illness. He is an active government consultant and aspiring government agency head, who recently finished second for the appointment to head NIOSH. He appears to have been willing to support the stress theory vigorously to climb up the lucrative consultant ladder.

David A. Hamburg, MD

A highly respected staffer for the Institute of Medicine, Hamburg was the third stress theory advocate on the PAC. As a longtime leader in the Institute of Medicine, Hamburg was in a position to influence the membership of IOM committees of scientists appointed to review scientific evidence on Gulf War illness.

Robyn A. Nashimi

Former associate of Lashof at OTA and head staffer for the PAC, she orchestrated the stress theory support during two years of PAC activities. When the PAC ended, she took a job in VA Central Office (see above).

RAND Corporation

Bernard Rostker, a former RAND employee, directed allegedly illegal contracts to RAND to obtain predictable "scientific opinions" in support of his nefarious activities. RAND's activities should be investigated and greater scrutiny given to any government contracts they receive in the future.

University Researchers Playing Major Roles in the Cover up

As early as 1994 when Joseph arrived, DoD and VA have been searching for scientists who would investigate only stress or obtain negative results on chemical experiments and thus sustain their policy position. The following are a few of the more notorious such collaborators.

Simon Wessley, MD and colleagues at Kings College London

A well known psychiatrist who developed a reputation for attributing

chronic fatigue syndrome to psychological causes, Wessley has been the darling of the Defense Department in the Gulf War illness investigation. He has been heavily funded for studies that would never have passed peer review at NIH.

Barry W. Wilson, PhD

UC Davis professor and long time DoD contractor, has been awarded contracts to study the effects of low-level nerve gas on brain function. Years have passed since he received funding and little has come out of his laboratory. Other qualified researchers who proposed the same experiments but who had less government connections were denied funding. Given the central importance of this line of research and the difficulty of the problem, numerous parallel research efforts should have been funded and set to work rapidly years ago. This smells like a setup to reach a false conclusion.

Bradley N. Doebbeling, MD, Msc

University of Iowa medical school and Iowa City VA medical center associate professor, Doebbeling and colleagues were originally funded outside peer review by an Iowa senator. Although their findings do not support the stress theory, they have claimed that to be the case and have received generous refunding.

While a more complete list could be generated, these examples suggest the need to review of the many grants and contracts that have been funded by the Clinton Administration to determine which are likely to be productive.

List of Organizational Abbreviations

AIBS American Institute of Biological Sciences (private contractor)

ASD-HA	Assistant Secretary of Defense, Health Affairs (top medical office in Pentagon)
CCEP	Comprehensive Clinical Evaluation Protocol or Program
CDC	Centers for Disease Control and Prevention (Atlanta)
DoD	Department of Defense
EPA	Environmental Protection Agency
GAO	General Accounting Office (reports to Congress)
IOM	Institute of Medicine, National Academy of Sciences ("supreme court" of medical research)
NIH	National Institutes of Health
OSD	Office of the Secretary of Defense, DoD
PAC	Presidential Advisory Committee on Gulf War Veterans' Illnesses (Joyce Lashof, chair)
PGVCB	Persian Gulf Veterans' Coordinating Board (coordinates research on among agencies)
PSOB	Presidential Special Oversight Board for Department of Defense Investigations of Gulf War Chemical and Biological Incidents (Warren Rudman, chairman)
OSAGWI	Office of the Special Assistant (to the Secretary of Defense) on Gulf War Illness (Bernard Rostker, head)
OTA	Office of Technology Assessment, HHS
RAND	RAND Corporation (private think tank, supported mostly by DoD contracts)
USAMRAA	U.S. Army Materiel and Acquisition Activity, Ft. Detrick, Md, DoD
VA	Department of Veterans Affairs

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** WHITE HOUSE BULK REFERRAL **

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SUBJECT: CONCERNING GULF WAR SYNDROME.

********** PROCESSING INSTRUCTIONS **********

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102-17.1

(b)(6)

GWI

OSAGWI

NOV 12 1998

October 9, 1998

The President
The White House
Washington, DC 20500

Dear Mr. President:

The military should study the effects of chemical weapons on humans, make vaccines, keep up-to-date medical records of exposures,and research the chemicals used in the weapons.

Seven years after the Gulf War with Iraq, veterans started showing signs of a serious illness. Some think this illness was caused by nerve gas but that has not been proven as the key factor. However one of the definate factors in causing this outbread was the chemicals that they were subjected to while in Iraq. This illness that some call "Gulf War syndrome" could have been prevented if the military would have developed vaccines, kept medical records of soldjers exposures, or even researched biological weapons more closely. Due to this lack of preparation many veterans suffer daily with an illness that could have been prevented. This costly mishap couldbe prevented in the future if our military would take time to research and study chemical and biological weapons.

In conclusion, our military should take serious action such as: studing the effects of chemical weapons on humans, making vaccines, keeping up-to-date records of exposures, and research the chemicals used in the weapons the soldjers will be subjected to. This should all be taken into consideration to insure or at least limit the possibility of this ever happening again.

Respectfully yours,

(b)(6)

CONGRESSIONAL or SPECIAL CORRESPONDENCE

8317-029

CMAT: 8237-023
8349-022
8349-033
~~8349-FOOT~~ Rewrite
Date: 23-Dec-98

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action	Info	Comments
SK	Special Assistant	(SA)			signature OSAGWI
LY	Deputy Special Assistant	(DSA)	✓ 12/31		
TB	Executive Assistant to SA	(EA)			JAN 07 1999
	Executive Assistant to DSA	(EADSA)			
5	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____		12/31		
	Dir Lessons Learned Implementation	(LLI)			
2	Dir Public Affairs & Outreach	(PA)			98123D
	Dir Legislative Outreach	(LA)			
	Dir Quick Reaction Team	(QR)			
4	Dir Medical-Health & Benefits Collab	(MHB)			could need some work!
	Legal Advisor	(LGL)			
3	PM, Gulf War Illnesses Support	(PM)		31 Dec	
1	Editorial Review ☐ AMB ✓ ☒ Editors	(ER)			see edits - A, B,
	CMAT	(CMAT)			
Drink	Action Management Call 845-8369 ☒ COMEBACK COPY TO: (Sheet letter to Bob's Desktop) ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☒ CHRON FILE				

SUSPENSE:

Prepare reply for signature of:

☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

☐ Congress ☐ SOB ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO
☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

KEYWORDS:

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

JAN 1 1 1999

(b)(6)

Frankenmuth, Michigan 48734

Dear (b)(6) :

Thank you for your recent letter to President Clinton regarding Gulf War illnesses. As the Special Assistant to the Deputy Secretary of Defense appointed to oversee the Department of Defense (DoD) investigation of Gulf War illnesses. let me assure you that my number-one priority is the health and welfare of our Gulf War veterans. We are committed to a thorough, complete, and public investigation.

In your letter, you stated that you believe the illnesses our Gulf War veterans are experiencing are a result of exposure to chemicals and that such exposures could have been prevented with better preparation.

First, the United States military is always evaluating the weapons available to our potential enemies and the threat these weapons pose to our personnel. We continuously train to fight in all types of environments, and that training includes the possible use of chemical and biological weapons. Additionally, the forces's chemical agent detection capability is strong. Military units are equipped with active chemical alarms and passive detection kits designed to detect a broad range of chemical agents. Units are also staffed with personnel trained in defensive measures for countering a chemical threat.

During the war, false alarms did occur. Detection equipment is, by design, extremely sensitive to any suspected chemical warfare agent. allowing sufficient time for troops to respond to a chemical threat. When the alarm sounds, troops put on protective clothing and masks and trained personnel double check the detection equipment for the presence of chemical warfare agents. While this procedure may result in some false alarms, the overall result is a forewarned and protected force. Part of our investigation includes verifying the final analysis of the false alarms.

The military has an active vaccination program. In general, before deploying to the Gulf, veterans were required to have a limited number of vaccines. Most veterans would have received a specific vaccine only if required for the deployment, a booster dose was due, or if they lacked a record of having received a needed vaccination. Service members received other vaccines during recruit training or for previous deployments. A table of common vaccinations for military personnel is enclosed.

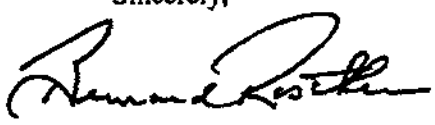
In the Gulf War Theater of operation, anthrax vaccine and botulinum toxoids were given to a limited number of service members for protection against biological warfare agent attack. For your reference, we have enclosed the sections on vaccines and preventive treatment from the Institute of Medicine's 1996 report, *Health Consequences of Service During the Persian Gulf War: Recommendations for Research and Information System.* Further, we are in the process of providing anthrax vaccinations to all our service members as a preventative measure.

We have used what we have learned from veterans of Korea, Vietnam, and in particular, the Gulf to provide better healthcare for our troops deploying throughout the world today. Now, prior to deployment, troops undergo a full medical assessment and serum collection process. Doctors use this assessment to establish a baseline health record which can be compared to the soldier's post-deployment health condition. We have plans to implement soldier-carried computer-based medical identification tags. A deployment and post-deployment surveillance system is now in place to identify health problems early enough to allow for better, more timely recognition of medical problems.

We are disclosing everything we find, do and learn. To ensure this information is available to the public, we publish all of our reports and other documents on our Internet website, GulfLINK (*http://www.gulflink.osd.mil*). Currently, GulfLINK contains all of the public information we have collected related to Gulf War illnesses. We have e-mail communications as a part of our website (*brostker@gwillness.osd.mil*). Through this service we are able to quickly respond to inquiries from veterans and the public. We hope you will be able to use this resource to monitor our progress. We have also enclosed an information packet that includes a copy of our annual report and the latest issues of our bi-monthly newsletter, *GulfNEWS.*

You have my assurance we are doing everything possible to investigate and explain Gulf War illnesses – we owe it to our brave men and women who served our country. Unless we understand what went on in the Gulf and what may be making our veterans sick, we will never be able to make the changes necessary to ensure our forces are protected in the future. Thank you for the opportunity to respond to your concerns. I hope this information is helpful to you.

Sincerely,



Bernard Rostker

Enclosures

Presidential Advisory Committee on Gulf War Veterans' Illnesses
Final Report

Chapter Four

GULF WAR RISK FACTORS

U.S. service members potentially were exposed to a broad range of risk factors during the Gulf War. The Committee evaluated the potential health effects of several suspected risk factors, which were selected based on our charter, previous reports on Gulf War veterans' illnesses, and expert and stakeholder testimony at meetings held nationwide. We also have attempted to analyze the extent and likelihood of exposure to these risk factors during the Gulf War. In most instances, however, exposure data have been difficult to obtain or nonexistent. This chapter reports the Committee's findings on the following risk factors:

- pesticides,
- chemical warfare agents,
- biological warfare agents,
- vaccines,
- pyridostigmine bromide,
- infectious diseases,
- depleted uranium,
- oil-well fire smoke,
- petroleum products, and
- psychological and physiological stress.

The chapter first reports what is known currently about possible U.S. troop exposure to each risk factor. Following this analysis, we discuss health effects known to date, and we present our findings and recommendations in the final section of this chapter.

EXPOSURE TO RISK FACTORS IN THE GULF

As described in the Committee's *Interim Report*, few exposure data exist on many key Gulf War risk factors. In fact, for most of the risk factors we analyzed, the only exposure information available today is anecdotal recollections of Gulf War veterans. As a consequence, it will be difficult to link, in a scientifically valid manner, any adverse health outcomes detected by ongoing research to specific exposures or risk factors. As noted in chapter 2, the Committee has concluded that DOD's Persian Gulf Registry of Unit Locations will be of little use for investigating questions about Gulf War veterans' health issues and is certainly an inadequate substitute for missing exposure data.

Exposure to Pesticides

Precise records exist for pesticides DOD shipped to the Gulf region (table 4-1). All pesticides shipped were approved by EPA or FDA for general use in the United States at the time of the Gulf War. U.S. consumers can purchase these at grocery, gardening, and other stores in products such as: OFF® and Cutters® (DEET), Raid® Ant and Roach Killer Spray and Raid® Yard Guard (permethrin), Black Flag® Insect Spray (Baygon), permethrin spray for treating clothes, and a variety of Ortho® brand and other name brands of gardening products containing carbaryl, diazinon, malathion, chlorpyrifos, and permethrin.

While DOD can document what pesticides were shipped-and how much-there are virtually no records available today on how these pesticides were used in the Gulf region. DOD made no provisions for collecting or keeping distribution or use records of U.S.-shipped and approved products. Reports from a few veterans about the use of other, locally obtained, unapproved pesticides are impossible for the Committee to followup.

Assuming DOD adhered to its policies on pesticide use, its programs closely parallel those established by EPA and FDA regulations for domestic pesticide use. According to DOD policy, the majority of U.S. service members had access to two pesticides: permethrin in a spray can (for treating uniforms) and DEET liquid or stick as a personal mosquito and fly repellent. DOD reports about 2.2 spray-cans of permethrin and 2.0 tubes of DEET (33 percent formulation) were shipped to the Gulf for each U.S. service member. According to DOD, U.S. troops were not provided with permethrin pretreated uniforms. All other pesticides shipped to the Gulf region were to be used only by specifically trained individuals or for special applications. For example, lindane apparently was used nearly exclusively on Iraqi prisoners of war as a delousing agent.

Exposure to Chemical Warfare Agents

DOD has fully acknowledged one case of CW agent exposure. U.S. Army Sergeant Fisher was exposed to a small amount of mustard agent while patrolling an Iraqi bunker during the war. Diagnosis was made on the basis of small chemical burns on his arms consistent with mustard exposure.[52] DOD also has confirmed nerve agent detections by Czech units, but has identified neither sources nor potentially exposed U.S. troops.[13,19] DOD has confirmed release of nerve agent at Khamisiyah in March 1991, and the Committee has concluded that troops near the demolition activity should be presumed to have been exposed to some level of nerve agent (see chapter 2). The Committee does not presume, however, that this implies long-term health effects in those exposed. DOD continues to investigate other reported CW agent detections.

Except for the Fisher incident, DOD reports in-theater medical surveillance observed no immediate or characteristic poisoning symptoms from any exposure to CW agents. According to representatives from the U.S. Army Medical Corps, which was responsible for training medical personnel to be alert during the war for signs and symptoms of CW agent exposures, characteristic poisoning from nerve agents such as sarin and soman were not seen by medical personnel during the Gulf War.[52] At least one other DOD medical repre

sentative, however, posits that a presumption of low-level exposure to OP nerve agents should be made when evaluating unexplained medical problems reported by some Gulf War veterans.[13]

Exposure to Biological Warfare Agents

Based on classified and public information currently available, the Committee has concluded there is no persuasive evidence that U.S. troops were exposed to BW agents during the Gulf War.[35,51,52,119,148,274] We note our determination is based on imperfect information. For instance, the United Nations cannot verify the quantities and weaponization status of Iraqi BW products because Iraq claims it unilaterally destroyed all its biological weapons. Additionally, the United States did not deploy a real-time BW agent detection system during the war.

Two salient factors, however, led to the Committee's conclusion. First, there were no verified detections of anthrax or botulinum toxin during the war. Second, stateside examination of soil samples and enzyme assays did not reveal the presence of BW agents. The Committee's review of U.S. Army hospital admissions records identified one admission for anthrax (a disease indigenous to the Gulf region) and none for botulinum poisoning.[342,343] DOD has investigated reports of dead animals that might have succumbed to biological agents, and we concur with the finding that the evidence does not implicate BW agents. Finally, UNSCOM reported to the Committee that Iraqi officials have denied any use of biological weapons during the war and that its own assessment supports this claim.

Exposure to Vaccines

DOD estimates approximately 150,000 U.S. military personnel received at least one anthrax vaccination, and about 8,000 service members received at least one dose of BT vaccine during the Gulf War. As noted in the Interim Report, however, medical recordkeeping on these and other matters was woefully inadequate.

Exposure to Pyridostigmine Bromide

All U.S. troops received blister packs containing PB pills during the Gulf War. The pills were intended to be self-administered upon a unit commander's order. DOD estimates approximately 250,000personnel took at least some PB during the Gulf War.[118] As noted in the Interim Report, accurate assessment of PB exposure of U.S. troops is not possible today because no records were kept of self-administered medications.

Exposure to Infectious Diseases

Infectious diseases endemic to the Gulf region include shigellosis, malaria, sandfly fever, and cutaneous leishmaniasis.[6,65,90,187] Along with

these infectious diseases, DOD medical personnel also monitored troops for dengue, Sindbis, West Nile fever, Rift Valley fever, and Congo-Crimean hemorrhagic fever.[90,293]

According to DOD, no cases of sandfly fever were reported during Operations Desert Shield/Desert Storm. Medical personnel saw seven individuals with malaria, one with West Nile fever, and none with rickettsial or other arthropod-borne viral illnesses; arthropod-borne viral diseases endemic to the Gulf are not known to cause chronic infection or disease. The documented low rates of infection among U.S. troops suggest exposures were minimal and/or preventive measures were effective.

Exposure to Depleted Uranium

According to the Office of the Army Surgeon General, 36 U.S. service members are known to have been exposed to DU when wounded in "friendly fire" incidents involving DU munitions.[112,267] VA reports it believes about two dozen of these individuals retain embedded DU shrapnel in their bodies.

In addition to exposure through "friendly fire" incidents, a review by the U.S. General Accounting Office concluded that several dozen service members were exposed to DU while retrieving or servicing vehicles damaged by DU munitions.[267,306] This number comprises about two dozen Army National Guard soldiers from the 144th Service and Supply Company who have reported they were unknowingly exposed to DU-contaminated debris while working with combat vehicles hit by DU munitions. Another two dozen soldiers from the 24th Infantry Division have reported they were unknowingly exposed to such debris in the course of vehicle recovery and maintenance operations.[96,97,267,306]

Although DOD had appropriate procedures for protecting personnel who worked with DU contaminated vehicles during the Gulf War, apparently few U.S. service personnel were adequately trained in these procedures. U.S. service personnel also could have been exposed to DU if they inhaled DU dust particles during incidental contact with vehicles destroyed by DU munitions, or if they lived or worked in areas contaminated with DU dust from accidental munitions fires. Thus, unnecessary exposure of many individuals could have occurred.[15,18,20,27,42,44,57,141,142,161,186,191,203,226,260,267,306]

With the exception of individuals who retain embedded DU munitions fragments, it is not possible to use *in vivo* monitoring today to develop accurate assessments of DU exposure in the Gulf. Whole-body counting to detect photons of x-ray or gamma radiation cannot be used to test for DU: The equipment is not designed to detect the low energy photons associated with DU decay.87 Moreover, the time that has elapsed since the Gulf War is long compared to the body's retention rate of uranium-i.e., it would be difficult to detect DU even with more sophisticated equipment performing specialized tests such as lung counts.[87,259]

Exposure to Oil-well Fire Smoke

In contrast to other risk factors, exposure to oil-well fire smoke is better characterized. Many U.S. service members who remained in the Gulf after the oil well fires started could have been exposed to oil-well fire smoke. The burning wells were located in eastern Kuwait, with the majority to the south of Kuwait City. Smoke plumes rose and combined in a "superplume" that could be seen for hundreds of kilometers and sometimes even partially blocked out the sun. Occasionally, smoke plumes touched down to the ground, sometimes enveloping nearby troops. Exact exposure levels for individual soldiers are not certain, but local and regional exposure information is available for oil well fires.

Multiple U.S. and international agencies performed extensive air monitoring during the fires and did not find pollutant levels likely to cause long-term health effects:

- A U.S. Interagency Air Assessment team-comprised of scientists from EPA, the National Oceanographic and Atmospheric Administration, and DHHS-arrived in Kuwait in March 1991 to assess the potential health effects of the oil well fires.[311]
- Scientists from 12 countries, including Kuwait and neighboring countries, were involved in a data collection effort overseen by the World Meteorological Organization.[339]
- The U.S. Army's Environmental Hygiene Agency carried out the largest effort, collecting nearly 4,000 ambient air and soil samples from May to December 1991.[265]

The data indicate that, despite the dramatic appearance of the oil plumes, pollutant levels were surprisingly low. All groups found that levels of nitrogen oxides, carbon monoxide, sulfur dioxide, hydrogen sulfide, other pollutant gases, and polycyclic aromatic hydrocarbons (PAHs) were lower than anticipated and did not exceed those seen in urban air in a typical U.S. industrial city.[89,289,302,339]

High levels of airborne particulate matter (sand and soot), however, were observed frequently at several monitoring sites. Analysis of samples suggested particles were mostly sand-based materials; high levels of airborne sand particulates are typical for this region of the world. Within the samples of particulate matter, levels of PAHs and toxic metals were low.[84,265]

Samples were collected during at least one instance when the smoke plume had touched down, providing "worst case" exposure data. Although airborne contaminants were detectable, they were surprisingly low compared to current U.S. occupational standards for these contaminants-even within the plume touchdown.[84,265,266]

Various biological samples also were collected from troops or other personnel working in Kuwait while the fires burned. One CDC study found blood levels of volatile organic compounds (VOCs) in firefighters were significantly higher than those in a U.S. reference population,[55] but individuals in Kuwait City, about 20 km from oil fires, had VOC levels approximately that of the reference group. These data are limited by small sample size and the short half-life of VOCs in service members' blood, but they suggest oil-well fire smoke did not significantly increase VOC exposures in troops in the Kuwait City area when most of the fires were active.

Blood and urine samples collected from a group of U.S. service members before, during, and after their 1991 deployment to Kuwait were analyzed for VOCs, PAH-DNA adducts, metals, and sister chromatid exchange (SCE) frequency in lymphocytes.[265] Pulmonary function tests and questionnaires also were administered. Levels of metals, VOCs, and PAH-DNA adducts showed no changes or showed decreases in troops living in Kuwait compared to troops living in Germany, with few exceptions. Lead levels in blood were not statistically significantly altered during deployment to the Gulf region.[9]

Exposure to Petroleum Products

Few specific data exist about possible exposures of U.S. service members to petroleum fuels or their combustion products. Operating the vehicles and machinery used in the Gulf War involved exposure to petroleum-based material. Petroleum fuels also were used for burning wastes and trash, dust suppression, and fueling stoves and tent heaters; none of these uses is unique to the Gulf War. Such uses, however, probably led to increased petroleum vapor and combustion product exposures. Thus, some U.S. service members were exposed to petroleum materials, including benzene, toluene, xylene, ethyl benzene, and combustion products including carbon monoxide, sulfur dioxide, nitrogen dioxide, particulates, lead, and other pollutants.

The U.S. Army's air monitoring (and blood monitoring done by CDC in a small study) found no evidence of elevated exposure to VOCs (including petroleum materials).[55,265] Still, some service members clearly experienced short-term, elevated exposures to petroleum fuels. For example, diesel was sprayed on the ground to suppress dust from the fine sand found in the Gulf region. A U.S. Central Command document lists crude oil/waste oil as the least desirable option for dust suppression, but does not mention diesel fuel.[280] One U.S. Army sanitary engineer testified to the NIH Technology Assessment Panel in 1994 that units used water or diesel fuel for dust suppression during the war.[100] He described one brigade dumping 30,000 gallons of diesel fuel on the roads daily, and said U.S. service members living in tents near the roads-and particularly truck drivers carrying out the spraying-complained of nausea from breathing the resulting fumes. As a result, the preventive medicine person to whom they complained obtained respirators for the drivers' use.[101] Another occupational group that could have experienced some risk of elevated exposures to petroleum products during the Gulf War were those who worked at military "Petroleum, Oils, and Lubricants" points where these materials were distributed.

The fuel used most widely during the war for both vehicles and equipment was Jet A-1, an internationally used kerosene-based aviation fuel provided at no cost by the Saudi Arabian government. Of the 1.8 billion gallons of fuel used during Operations Desert Shield/Desert Storm, roughly 75 percent was jet fuel (mostly Jet A-1), 24 percent was diesel fuel, and 1 percent was gasoline.[248] The gasoline used during Operations Desert Shield/Desert Storm was commercial leaded gasoline refined to Saudi Arabia's national standard.[135]

Combustion products from heaters used in poorly ventilated areas also are a general exposure concern for Gulf War participants. Burning leaded fuels indoors without proper ventilation-e.g., heaters in tents-could have caused increased lead exposure. Kerosene heaters, widely used in the United States, also could have been significant sources of exposure to nitric oxides, sulfur dioxide, inorganic combustion gases, carbon monoxide, and particles when used with inadequate ventilation.[165] During the war, four hospitalizations in U.S. Army field hospitals occurred because of asphyxiation from carbon monoxide.[342,343]

Exposure to Psychological and Physiological Stress

U.S. service members encountered many stressors during the Gulf War, including short deployment notice, uncertainty about length of deployment, isolation and separation from family, a polluted environment, poor living conditions with little privacy or social outlets, prolonged work hours, decreased income and worry about job retention, fear of SCUD missile and chemical and biological weapon attacks, anticipation of high casualty rates and torture, frequent CW agent alarms

that often required a defensive posture and full chemical gear, and dealing with casualties and dead bodies.

Even when the war was over, many veterans experienced postdeployment stress on their return from the Gulf. These included financial and employment difficulties, unresolved military pay issues, the revelation of cases of leishmaniasis and the consequent temporary ban on blood donations, increasing numbers of health complaints and "unexplained illnesses," and media accounts of apparent increased numbers of birth defects and cancer.

HEALTH EFFECTS OF GULF WAR RISK FACTORS

The Committee undertook a comprehensive analysis of the health effects of the ten Gulf War risk factors for which we examined possible exposures. Our analysis of possible health effects was performed independently of whether exposures were undocumented, imprecise, or known. That is, we considered the possible health consequences of a range of scenarios from high-level to low-level exposure and from single to multiple event and chronic or continuing exposure. The Committee also considered short-term and long-term health effects, including symptoms that might have appeared while service members were still in the KTO and symptoms that might not have appeared until sometime after the service members left the Gulf. The Committee's search for possible health effects extended to all organ systems and to cancer and noncancer outcomes.

Our examination of health effects drew on three types of sources: scientific literature; briefings and workshops with recognized experts; and information presented at Committee meetings. The Committee reviewed human exposure (mostly occupational) data and laboratory animal data. We found extensive scientific literature describing the human health effects for all the risk factors investigated, including CW agents, for which we initially had anticipated would have significant data gaps. The breadth and depth of information generally were sufficient** to make conclusions about the short- and long-term health effects that would be anticipated for U.S. service members exposed to a particular risk factor during the Gulf War.The information available in these sources, however, represents the boundaries of the Committee's investigation. We conducted no primary research and elected not to base our findings on research not yet subjected to peer review.

Finally, the Committee drew conclusions about the role of each risk factor in Gulf War veterans' illnesses based on comparison of the known health effects of the risk factor to the symptoms reported by Gulf War veterans. Symptoms reported by Gulf War veterans used in these comparisons were based on DOD's CCEP and VA's Persian Gulf Health Registry (see table 3-2).

Pesticides

As noted earlier in this chapter, pesticides DOD shipped for use during the Gulf War fell into five major categories: OP pesticides, methyl carbamate pesticides, organochlorine pesticides (lindane), pyrethroid pesticides (chiefly permethrin), and DEET.

Organophosphorus pesticides. Several OP pesticides were used during the Gulf War, including chlorpyrifos, diazinon, dichlorvos, and malathion. When administered in high doses, OP pesticides cause irreversible inhibition of acetylcholinesterase, an enzyme crucial to normal nerve and nerve/muscle function. Inhibiting acetylcholinesterase leads to unique and highly characteristic poisoning symptoms. Immediate symptoms of OP poisoning in humans usually develop within four hours of exposure and include narrowing of the pupil of the eye (miosis), headache, nausea, dizziness, anxiety, and restlessness. Severe and rapid onset poisoning symptoms include muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps, diarrhea, sweating, salivation, tearing, runny nose, and production of phlegm. Life-threatening symptoms include unconsciousness, incontinence, convulsions, and depression of breathing function. According to DOD, its medical monitoring and surveillance efforts reported no cases of immediate and severe OP poisoning symptoms in U.S. military personnel during the Gulf War.

Some individuals who recover from immediate and severe OP poisoning show long-term (lasting more than a year), subtle, neuropsychological abnormalities that can be detected using a battery of standardized neuropsychological tests. In an epidemiologic study of such long-term effects, severely poisoned individuals showed clear but subtle differences in intellectual functioning, academic skills, abstraction and flexibility of thinking, and simple motor skills. For example, about a five point difference in IQ was measured in severely poisoned versus control subjects.

Neurophysiologic effects were less apparent; abnormalities were found only in measurements of memory, abstraction, and mood and on one test of motor reflexes.221 These effects could not be detected, however, in a subset of the same worker population that had been exposed to doses of OP pesticides that were too low to cause the symptoms of immediate and severe poisoning.241 Other studies of low-level occupational exposures reinforce the finding that these types of long-term effects present solely in the aftermath of severe and immediate OP agent poisoning.[4,241]

Some OP pesticides that are no longer sold in the United States have been associated with human cases of a second type of delayed toxic effect called organophosphate-induced delayed neurotoxicity (OPIDN, sometimes referred to as delayed neuropathy). Initial symptoms are muscular incoordination progressing to numbness, tingling, fatigue or a cramp-like pain in the calf muscles, and even moderate to severe muscular weakness and paralysis.[7,117] Typically, effects occur 7 to 14 days following recovery from immediate and severe poisoning by the OP pesticide and involve neuropathologic lesions and degeneration of the nerve axon and myelin nerve sheath in both the central and peripheral nervous systems;[117] these effects are easy to measure in a clinical setting. In general, OPIDN caused by OP pesticide poisoning is associated with immediate poisoning symptoms.

All OP pesticides sold in the United States today are routinely screened for OPIDN toxicity with a standardized hen assay used by EPA; the hen is a laboratory animal especially sensitive to OPIDN effects. For some OP agents, these effects only can be observed by giving the hen extremely high doses that would rapidly lead to death, but then keeping the hen alive through the use of protective drugs such as atropine. Many investigators conclude any OP agent theoretically could cause this effect at sufficiently high doses, but that, in fact, immediate toxic effects cause death before delayed effects can be seen.[117]None of the pesticides DOD shipped to the Gulf War test positive for OPIDN in standard EPA screens.

Methyl carbamate pesticides. Methyl carbamate insecticides shipped for use during the Gulf War included propxur (Baygon®), carbaryl (Sevin®), and methomyl (Lannate®). These insecticides reversibly inhibit acetylcholinesterase, which leads to poisoning effects similar to OP poisoning. Poisoning with methyl carbamates tends to be of much shorter duration-with a greater margin of safety between symptom-producing and lethal doses-compared to OP pesticides, which bind permanently with acetylcholinesterase.

Pyrethroid pesticides. DOD shipped the pyrethroid insecticide permethrin to the Gulf for use as an insect repellent. Permethrin is used widely in the United States as the active ingredient in personal care products, such as shampoos and lotions, and for treating clothes to make them insect repellent. There are few reported poisonings of humans by permethrin, most likely because such a large dose is required to cause poisoning. Humans rapidly detoxify and excrete permethrin. Clinical signs of immediate permethrin poisoning following large oral doses become evident within two hours and include incoordination, ataxia, hyperactivity, and convulsions, followed by prostration, paralysis, and death.[171] Unlike OP pesticides, the Committee found no reports of long-term effects from permethrin poisoning in humans.

A National Research Council (NRC) subcommittee that reviewed possible health problems for military personnel wearing permethrin-treated military clothing concluded it is unlikely that soldiers using such uniforms would experience adverse health effects at the suggested exposure levels. The subcommittee concluded, "the weight of evidence shows that permethrin is unlikely to be a skin irritant or skin sensitizer for military personnel who are exposed to it dermally from wearing permethrin impregnated [uniforms]." The estimated "no observable adverse effect level" for immediate neurotoxic effects in humans from daily exposure is 200 milligram (mg)/kilogram, which is approximately three million times greater than estimated dermal exposure from permethrin treated uniforms.[171] NRC's worst-case estimate of lifetime carcinogenicity risk for humans wearing permethrin treated uniforms was less than 2 in 1,000,000.

In laboratory animal studies, dermal absorption of permethrin is low, although scientists observe neurotoxic effects if the substance is injected.[171,301] Most, but not all, studies have reported permethrin does not cause damage to genetic material in a wide variety of standard measurement systems. Permethrin is neurotoxic to laboratory animals at high oral doses. Rats fed permethrin at 6,000 mg/kg for 14 days showed fragmented and swollen sciatic nerve axons and myelin degeneration. However, nerve conduction studies in 23 permethrin workers showed no evidence of nerve impairment associated with permethrin exposure.[171] Rodent bioassays of chronic exposure to permethrin showed carcinogenic effects, such as liver and lung adenomas and lung carcinomas in mice, but data on human carcinogenicity of permethrin are lacking.

Organochlorine pesticides. DOD shipped one organochlorine pesticide, lindane, to the Gulf region. Lindane, once widely used as an agricultural insecticide in the United States, is still available as a lotion to treat head and body lice and scabies.[283,301] Lindane is dermally absorbed, stored in body fat, and only slowly leaves the body. Reports document that a few people who have used large amounts of lindane on their skin have had blood disorders and even seizures. Under conditions of extremely high exposure, lindane can cause liver and kidney disease.

Some pregnant laboratory animals orally treated with the maximum tolerated dose (the dose just below that causing immediate and severe toxicity) showed a statistical increase in the number of fetuses with extra limbs, indicating that lindane is a teratogen for this laboratory animal strain. Lindane has not been shown to be a human carcinogen, although long-term oral exposure of lindane to certain species and strains of laboratory rodents has been reported to cause liver cancer.[283] Hence, DHHS has determined that lindane should be viewed as a human carcinogen.

DEET. DEET, first introduced in 1955, continues to be a widely used liquid insect repellent in the United States, and DOD shipped approximately two 2-oz tubes per U.S. service member during the Gulf War. According to EPA, 50 to 100 million Americans use DEET-containing insect repellents annually. Relative to most pesticides, DEET has notably low immediate toxicity.[190,301] Although generally well tolerated when used as an insect repellent applied to human skin, about five to nine percent is absorbed through skin, and reports exist of tingling, mild irritation, and occasional skin peeling following repeated application.[301] Topically applied DEET is rapidly eliminated, mostly in the urine. In the past 35 years a few reports in the medical literature suggest rare neurotoxic effects.[190] In adult humans, ingestion of enormous doses of DEET has been associated with immediate toxic effects, including tremors, generalized seizures, and coma, although no long-term effects of poisoning have been reported.[320] (For possible synergistic effects, see section on PB later in this chapter.)

Rats continuously fed DEET up to the maximum tolerated dose over three generations showed a slight increase in the high-dose animals in a single neurological abnormality-a slight increase in exploratory locomotor activity-and no histopathologic central nervous and peripheral nervous system changes of significance.[190] Other reports indicate that rats fed the maximum tolerated dose of DEET can show severe and often fatal prostration accompanied by a brain myelinopathy.[320]

What do we conclude about the risks of pesticides to Gulf War veterans? According to DOD, after-action reports from in-theater medical personnel did not reveal any U.S. troops reporting symptoms that would indicate pesticide poisoning. Evidence from studies of humans poisoned by OP pesticides suggests that low-level exposures that do not cause signs and symptoms of immediate and severe poisoning will not result in long-term health effects. Thus, the Committee concludes it is unlikely that health effects and symptoms reported today by Gulf War veterans are the result of exposure to pesticides during the Gulf War. Lindane is an animal liver carcinogen, but it is too early to see an elevated liver cancer rate in Gulf War veterans.

Chemical Warfare Agents

At the time of the Gulf War, the U.S. military believed Iraq had weapons that could deliver OP nerve agents, including sarin, soman, and VX, and mustard (blister) agents. Hence, U.S. forces were supplied with protective gear, detectors, and prophylactic drugs to protect against the known consequences of exposure.

Immediate signs and symptoms of nerve agent poisoning. OP nerve agents are designed to incapacitate and kill humans. Inhalation exposure to these agents leads to immediate effects, including miosis, runny nose, and increased salivation. Immediate effects following skin exposure include local sweating and muscle twitching. Eye exposure rapidly produces miosis, which often is associated with eye pain, headache, and blurred vision.[264] In fact, miosis is the most sensitive and specific immediate response to acute poisoning in humans, and this reaction has served as the basis for establishing allowable occupational concentrations for CW nerve agents. Higher doses of these agents cause more severe effects, including convulsions, neuromuscular blockage, profuse airway obstruction and apnea-developing within one to two minutes of exposure.[77] Death occurs due to respiratory paralysis. The effects of nerve agent poisoning (figure 4-1) are virtually identical to those of severe OP-pesticide poisoning.

Data on human effects of CW nerve agent poisoning derive largely from human experiments carried out by the U.S. Army from the 1940s to the 1960s. Table 4-2 illustrates the type of information on immediate poisoning effects from low-level exposures to the OP nerve agent sarin.

Immediate signs and symptoms of mustard agent poisoning. With mustard agents, poisoning symptoms are severe irritation and tissue damage to eyes, skin,

and respiratory and gastrointestinal (GI) tracts. Usually the onset of symptoms is delayed for some hours after exposure.

One report of Iraqi use of mustard agent against Iranian troops in 1984 documented health effects in more than 5,000 Iranian casualties. Affected individuals had first to third degree burns over 20 to 70 percent of the total skin surface. Eye exposure caused tearing, severe conjunctivitis, and temporary loss of vision. Corneal abrasion was nearly always present, and photophobia and blurred vision developed in some cases. Upper airway involvement due to chemical burning of the throat led to pharyngitis and tracheobronchitis. These effects were quite severe, and this group suffered approximately 15 percent mortality. Those who survived the initial symptoms later experienced various GI complaints, including nausea, vomiting, and diarrhea. After five to seven days, hematologic problems were the greatest health threat to survivors.[105]

Long-term health effects of exposure to CW nerve agents. Two NRC reports addressed possible long-term morbidity and mortality in about 1,400 servicemen intentionally exposed to CW nerve agents in experiments conducted over a 20-year period ending in 1975. The possibilities of excess cancer risk and adverse mental, neurologic, hepatic, and reproductive effects were reviewed. Both NRC analyses concluded that no evidence exists that CW nerve agents cause long-term, adverse human health effects at the doses tested. The doses were nonlethal, but were high enough to cause clinical effects (such as miosis). NRC reported that both analyses had the power to detect any major health effects had they been present. A statistically significant increase in admissions to VA hospitals for malignant neoplasms was detected, with the caveat that admission numbers were small, showed no dose relationship, and no clustering of specific chemicals in relation to tumor site.[174,175]

Numerous studies in humans and animals report that survival from severe, immediate poisoning by OP nerve agents (including OP pesticides) can be associated with measurable, long-term neurological effects. One study of 77 industrial workers exposed to levels of sarin that caused immediate toxicity showed slight alterations in electroencephalograms (EEGs) one year after exposure. The study also reported, however, that trained experts could not distinguish an individual EEG from an exposed individual from an EEG of a person who had not been exposed, and that no clear relationship existed between alterations in EEG frequency spectrum and alterations in brain function.[22] A 1975 review by Lohs of the effects of CW agents in humans similarly reported long-lasting effects following severe, immediate OP pesticide and CW agent poisoning.[140]

CW nerve agents do not show OPIDN toxicity as measured in EPA's standardized hen bioassay for evaluating OP pesticides, except with extremely high doses (10 to 100 times the lethal dose) where immediate and severe toxic effects, including death, are seen.[117] Because OP CW nerve agents are chemically similar to OP pesticides and affect the same enzyme system in the body, similar long-term health effects would likely occur in the aftermath of immediate, severe poisoning with sarin, soman, or VX-i.e., the subtle, but measurable, neurophysiological and neuropsychological effects described earlier in this chapter. Again, these health effects did not occur in populations that had been exposed to subclinical amounts of OP pesticides. Current scientific evidence suggests that subclinical exposure to OP CW nerve agents does not result in long-term neurophysiological and neuropsychological health effects. Ongoing research at the Boston and Portland Environmental Hazards Research Centers is investigating the possibility of such effects in Gulf War veterans.

Long-term health effects of exposure to mustard agents. Based on epidemiologic research, humans exposed to mustard agent are at increased risk for lung cancer.[98,287] Several other reviews of human exposure to mustard agent during World War I (WWI) and other wars also indicate veterans exposed to mustard agents during the Gulf War could experience other respiratory problems as well.[98,287]

During World War II (WWII), more than 60,000 U.S. service members were used as human test subjects and exposed to mustard agents, including at least 4,000 individuals exposed to high concentrations of these agents.[98] An Institute of Medicine (IOM) review concluded that several specific chronic diseases are causally associated with mustard agent exposure. These include various respiratory cancers, skin cancer, chronic skin ulceration and scar formation, chronic respiratory disease including asthma, chronic bronchitis, emphysema, chronic eye diseases, and various psychological disorders including PTSD. IOM also found suggestive evidence (weaker than the associations for the conditions just mentioned) that exposure to mustard agent was associated with leukemia. Finally, IOM also analyzed two studies that examined the link between mustard and reproductive dysfunction, but determined that the database could not be used to make conclusions about human reproductive health effects.[98]

What do we conclude about the risks of CW agents to Gulf War veterans? Current scientific literature indicates that when exposure to OP CW agents results in immediate and severe poisoning, long-term, subtle neuropsychological and neurophysiological effects could occur. Available scientific evidence does not indicate that such long-term effects occur in humans following low-level exposures, but the amount of data from either human or animal research on low-level exposures is minimal. Long-term effects in humans exposed to mustard agents include an elevated risk of lung cancer beginning decades after exposure. Based on available data, it is unlikely the health effects reported by Gulf War veterans today are the result of exposure to OP or mustard CW agents during the Gulf War. Ongoing or planned federally-funded studies focused specifically on low-level exposures and delayed neurotoxicity of CW agents should elucidate gaps in knowledge and eliminate uncertainty and/or identify new directions for research.

Biological Warfare Agents

The U.S. military prepared for the possibility that Iraq might use two BW agents-anthrax and botulinum toxin-against U.S. service members during the Gulf War. After the war, new data revealed Iraq had also weaponized aflatoxin. The Committee evaluated the potential health effects of these three BW agents on the long-term health of Gulf War veterans.

Anthrax. Anthrax is a bacterial disease most often found in cattle and sheep. Human infection can occur by contact with infected animals or by inhalation of spores from infected animal products (e.g., as hides or wool). Left untreated the disease usually is fatal. After exposure, the anthrax bacteria travel to the intestines and other areas where they cause severe tissue damage. Initial symptoms include nonspecific malaise, low grade fever, and nonproductive cough. Initially, anthrax can be difficult to diagnose because symptoms, although severe, are not specific.[103] As the disease progresses, symptoms include high fever, labored breathing, choking cough, and vomiting; death usually occurs within four days.[276] Terminal symptoms include abrupt onset of shortness of breath, harsh breathing, skin turning blue, excessively rapid heartbeat, and rapid progression to shock and death. Cases of pulmonary anthrax caused by inhalation of aerosolized spores (which would be the case in a military use) are almost invariably fatal if not treated immediately with antibiotics. Exposure to small numbers of infecting spores can increase the incubation time of the disease from a few days to several weeks, but if infection occurs, the disease progresses toward death in the same manner as for high-level exposure.[103,276] No long-term effects have been reported in persons successfully treated for anthrax.

Botulinum toxin. Botulinum toxin is a group of related, highly poisonous protein agents isolated from fermentation of the bacterium *Clostridium botulinum*, which naturally occurs in soil and can grow in many meats and vegetables. Botulinum toxin is fast-acting, usually producing symptoms within 18 to 36 hours after ingestion. Death occurs in 80 percent of an exposed population after one to three days.[276] Botulinum toxin blocks neuromuscular conduction by binding to receptor sites on motor nerve terminals and by inhibiting the release of acetylcholine. Symptoms at high exposure levels can include respiratory distress and respiratory paralysis, which may persist for six to eight months.[117] Disability progresses from difficulty in walking and swallowing and impaired vision and speech to convulsions. Ultimately, symptoms include paralysis of the respiratory muscles, suffocation, and death-all within a few hours or days, depending on the amount of toxin ingested.[276] In cases of accidental exposure in the general population, the fatality rate is 35 to 65 percent and is fatal in three to ten days.[117] Botulism antitoxin can be effective if administered within days of exposure.[276] The Committee found no scientific literature suggesting adverse long-term health effects from low-level exposure to botulinum toxin.

In fact, botulinum toxin has conventional medical therapeutic uses. Botox® is an FDA-approved, purified, type A botulinum toxin, and injecting it into the muscle of patients causes a localized, temporary denervation and muscle paralysis. Such an effect is therapeutically useful for treating a number of conditions, including blepharospasm (an involuntary recurrent spasm of both eyelids) and for use in certain types of eye surgery. Studies on thousands of adults treated with Botox® have shown only mild side effects-e.g., a diffuse skin rash lasting several days-as a result of the localized muscle paralysis effects of the toxin. The only long-term effect reported is a slight reduction in the effectiveness of Botox® due to a person's natural immune responses.

Aflatoxin. Aflatoxin is a naturally occurring toxic metabolite from certain fungi that sometimes occur on grains, peanuts, and other foods stored under certain conditions.[117] Aflatoxin ingestion can result in immediate, toxic effects in many different species, and death results from acute liver toxicity.[29,117] Aflatoxicosis in humans has been reported following ingestion of aflatoxin contaminated food, and symptoms include vomiting, abdominal pain, pulmonary edema, gastrointestinal hemorrhage, convulsions, coma, and death.[29] Several epidemiologic studies suggest aflatoxin causes liver cancer in humans. The only documented health effect that could be expected from low-level exposure to aflatoxin would be an increased prevalence of liver cancer years to decades after exposure.

What do we conclude about the risks of BW agents to Gulf War veterans? In cases where an individual survives exposure to anthrax or botulinum toxin, no known, long-term health consequences exist. The Committee concludes it is unlikely the health effects reported today by Gulf War veterans are the result of exposures to BW agents. Aflatoxin, however, is a liver carcinogen, and increased rates of liver cancer could result decades following low-level exposure, although available evidence reviewed by the Committee does not indicate such exposures occurred during the Gulf War (see chapter 2).

Anthrax and Botulinum Toxoid Vaccines

Before U.S. troops deployed to the Gulf region, they received a standard series of inoculations against infectious diseases-e.g., cholera, typhoid, tetanus, diphtheria, polio, and measles-that might be given to any U.S. citizen traveling to these regions. After arriving in the Gulf War region, some U.S. service members received two additional vaccines for protection against the BW agents anthrax and botulinum toxin.

Anthrax vaccine. In 1970, FDA licensed anthrax vaccine to protect civilian workers against possible infection by anthrax bacteria. Since 1967 and before the Gulf War, more than 20,000 inoculations had been routinely administered to at-risk populations, including laboratory personnel who work with the bacteria that causes anthrax, persons in industries that work with animal hides and wool (which can be a source of anthrax infection), and veterinarians who come in contact with anthrax-infected animals.

Although active long-term safety surveillance is not generally part of the FDA vaccine licensing process, the FDA encourages U.S. health care providers and the law requires manufacturers to report serious adverse reactions for all licensed vaccines.[305] FDA has not received data that raise concerns about the safety of the anthrax vaccine.

Historical data for short-term health effects of the anthrax vaccine indicate up to six percent of recipients experience mild discomfort, including tenderness, redness, swelling or itching at the inoculation site for up to 72 hours. Fewer than one percent experience a more severe local reaction that potentially limits the use of the arm for one to two days. Systemic reactions, e.g., fever, malaise, are uncommon (about 0.1 percent).[102,103]

According to DOD, medical monitoring and surveillance conducted during the Gulf War found the expected short-term side effects of anthrax vaccines occurring at approximately the historical rates.[53] A single hospitalization for a vaccination site infection was reported. DOD points out that precise information about all possible short-term side effects is unknown, however, because of difficulties in collecting such data during and after the Gulf War.

Botulinum toxoid vaccine. Botulinum toxoid (BT) vaccine has been used for more than 25 years to protect industry and laboratory workers from occupational exposure to the extremely poisonous botulinum toxins. All civilian vaccinations have been administered under an investigational new drug (IND) application sponsored by CDC. For both civilian and military use, BT vaccine remains in "investigational" status-i.e., not yet licensed by FDA.

Since 1970, as part of the IND evaluation, FDA has reviewed information from CDC about the cumulative safety record for BT vaccine. Records of more than 10,000 administered vaccine doses (including approximately 2,200 in the five years before the Gulf War) indicate that treated individuals experience only local side effects often associated with many types of vaccinations. These effects, primarily at the injection site, include local pain, tenderness, swelling, redness, and itching. Systemic reactions such as temporary fever, tiredness, headache, or muscle pain also can occur. Rarely, reactions include soreness of the arm sufficient to leave individuals unable to perform duties for a day or two or development of a lump at the injection site that generally resolves within several weeks. Such adverse reactions also are observed with other licensed toxoid vaccines, such as diphtheria and tetanus toxoids.[53,102]

The U.S. Army examined the frequency of side effects of BT vaccinations seen in some U.S. service members. In one report of 237 Gulf War veterans who had received BT vaccine, 2.5 percent had systemic reactions. This rate parallels that recorded by the U.S. Army and CDC prior to the Gulf War.[127]

Precautions against contaminants. The Committee examined the hypothesis that Gulf War veterans' illnesses could be the result of contamination of anthrax

vaccine lots by *Mycoplasma incognitus*.[182] Discussions with staff of FDA, Walter Reed Army Medical Center, U.S. Army Medical Research and Materiel Command, academic experts, and the manufacturer of the vaccines indicate that *Mycoplasma* could not survive in the anthrax and BT vaccines.[136,138,168,303] *Mycoplasma* is difficult to grow, and the culture media used to produce Anthrax and BT vaccines do not contain serum, an essential ingredient for *Mycoplasma* growth. In addition, the vaccines are preserved and/or processed with other products that create a hostile environment for *Mycoplasma*, including:

- formaldehyde (anthrax and BT vaccines),
- benzethonium chloride (anthrax vaccine only),
- isotonic saline solution (BT vaccine only), and
- Thimerosal (BT vaccine only).

The Committee concludes it is unlikely that *Mycoplasma* organisms contaminated anthrax vaccine or BT vaccine.

Health effects of multiple vaccines. The human immune system has evolved the capability to deal with thousands of foreign substances, to sort them out, and to regulate immune response. Humans live among a vast population of hostile microorganisms, and vaccinations-even multiple, contemporaneous vaccinations-are a small part of total immune stimulation. Individual vaccines can cause adverse effects, but several studies of the effects of giving multiple vaccinations at one time have found no adverse effects associated with the practice. Research on this issue continues, but based on available evidence, the Committee believes it is unlikely that multiple vaccines are responsible for illnesses reported today by Gulf War veterans.[202,219,268]

What do we conclude about the risks of vaccines to Gulf War veterans? The Committee concludes it is unlikely that health effects reported by Gulf War veterans today are the result of exposures to the BT or anthrax vaccines, used alone or in combination.

Pyridostigmine Bromide

PB is a pretreatment drug used to protect against the CW nerve agent soman. By itself PB is not protective against CW nerve agent poisoning. Used as a pretreatment, however, PB might enhance the antidote effects of the standard atropine and 2-PAM treatments used by the U.S. military for nerve agent poisoning.[269]

Since 1955, FDA has approved PB for use by persons suffering from myasthenia gravis. No long-term health problems thought to be associated with PB have been reported for persons with myasthenia gravis who regularly take PB over many years or decades.[196,220] DOD filed a New Drug Application in May 1996, but PB currently has the status of an IND for nerve gas pretreatment use.

According to FDA, its conclusion that PB was safe for use by U.S. service members during the Gulf War was based largely on the extensive cumulative experience with this drug in patients with myasthenia gravis. Typically these patients are treated with PB doses of up to 1,500 mg per day for many years, compared to the prescribed dose of 90 mg per day for a maximum of seven days use during the Gulf War. Reported side effects of PB include increased salivation, increased tearing, urinary urgency and frequency, nausea, vomiting, muscle weakness, abdominal cramps and diarrhea.[167] These effects disappear when individuals stop taking PB.

Data from one DOD retrospective study on 30 medical support officers of the 18th Airborne Corps reveal a similar range of short-term health effects from PB. The 18th Airborne Corps instructed 1,650 soldiers (6.5 percent women) to take PB tablets at the onset of Operation Desert Storm in January 1991. Half those surveyed reported gastrointestinal symptoms, 5 to 30 percent reported increased urinary urgency and frequency, and fewer than 5 percent reported headaches and tingling of extremities. The need for a medical visit was reported by less than 1 percent, and the decision to discontinue use based on medical advice was reported by less than 0.1 percent. As with myasthenia patients, DOD reported that side effects ceased when PB use was discontinued.[110] Other retrospective studies found similar results.[32,270]

A survey of 213 Israeli soldiers asked about possible symptoms of PB and their severity. The most frequent health complaints reported were generally mild and nonspecific, including dry mouth, general malaise, fatigue, and weakness, which appeared about 1.6 hours after taking the medication and recurred after each intake. For this group the typical side effects associated with PB, such as nausea, abdominal pain, frequent urination and runny nose, were infrequent.[228]

DOD recently completed a study begun in November 1994 that looked at differential tolerances to PB between women and men.[128,296] Ninety subjects, equally divided by gender and in three weight classes, took 30 mg of PB every 8 hours for 21 days (plus one dose). PB was found to be safe and well-tolerated. All side effects were mild and resolved with no intervention. Headaches, dizziness, nausea, rash, and hair loss were reported in both drug and placebo groups. Diarrhea and abdominal pain were reported in the PB group only (four study participants). Overall, the occurrence of adverse effects did not differ between active and placebo subjects, nor were differences observed among gender or weight groups. Results from a 1-year followup, indicated no long-term effects except possibly a skin rash that resolved with treatment.[128]

DOD continues to seek FDA approval to use PB for the protection of U.S. troops against CW agents. To support this approval process, DOD has sponsored various research efforts since 1984 to gather information on the effects of PB pretreatment on healthy individuals. To date, DOD reports no serious or long-term reactions from this research.

Genetic predisposition to PB sensitivity. Some scientists suggest that persons who are genetically unable to produce the plasma enzyme butyryl cholinesterase (BuChE) could be more sensitive to PB's known side effects, and at least one apparent case has been reported.[139] The estimated frequency in the general population of persons unable to produce BuChE is about 0.03 percent. Exposure to PB (or similar compounds) could causeimmediate and marked health effects in these individuals. Based on studies of PB-related compounds in BuChE deficient individuals, however, symptoms vanish when exposure to PB is removed. Limited population genetic data indicate that about four percent of all people have slightly reduced ability to produce functional BuChE. It is unclear whether these individuals could be more susceptible to temporary PB side effects.[1,67,68,71,139,192,193,224,269]

Synergistic effects. Concern has been raised about the possibility of increased health problems from PB when it is combined with other risk factors. Some

researchers have hypothesized that PB in combination with stress may create central nervous system effects.[59,170,228] The insect repellent DEET and the insecticide permethrin are most often mentioned as cofactors with PB for Gulf War illnesses.

After the Gulf War, one U.S. Department of Agriculture researcher conducted a study on synergistic effects of various chemicals, including DEET and PB, on cockroaches. DEET showed a four-fold increase on the lethality of PB-i.e., it took one fourth as much PB to kill cockroaches in the presence of a sublethal dose of DEET.[314] In 1996, another researcher reported that PB given at near lethal levels to chickens could increase the toxicity of DEET and permethrin.[1] Under these conditions, nervous system damage to the chickens was reported. A 1995 DOD study with rats reported that PB caused a slight increase in lethality of DEET and permethrin when compared to expected additive values.[263]

These three studies report enhanced toxic effects from PB, DEET, and permethrin in combination. However, doses used in the laboratory experiments were far greater than exposures U.S. service members could have experienced during the Gulf War. Moreover, for DEET and permethrin, the routes of administration were not comparable to that used by U.S. service members in the Gulf War. For example, in the chicken model, DEET and permethrin were injected underneath the skin and, in the rat study, they were administered orally. During the war, DEET should have been applied to the skin, and permethrin should have been applied to the uniform.

These studies did not address the effect PB, DEET, and permethrin-individually or in combination-would have on morbidity in humans and what illnesses might be induced by such use. Neither did the studies answer whether there would have been detectable harmful effects in humans in-theater under the likely operational use by U.S. troops.

Some researchers suggest the immediate toxicity of the OP pesticides available to Gulf War veterans could have been increased from coexposure to PB,[1,150,151] leading to the well-characterized, long-term signs and symptoms of immediate and severe poisoning described earlier in this chapter. As previously mentioned, however, DOD reports that on-site medical personnel did not observe any immediate and severe effects of OP poisoning among U.S. service members, and the current scientific knowledge base indicates that long-term health effects do not occur in the absence of immediate poisoning.

In setting priorities for new research projects on Gulf War veterans' health issues, a subcommittee of the RWG of the Coordinating Board gave priority to toxicology studies on subtoxic exposures to PB and pesticides, either alone or in combination. Several federally funded studies now underway are assessing combined exposure to PB and other chemical risk factors.

What do we conclude about the risks of PB to Gulf War veterans? Given the extensive cumulative experience with the use of PB in patients with myasthenia gravis and data collected from military personnel, the Committee concludes it is unlikely that health effects reported today by Gulf War veterans are the result of exposure simply to PB. Ongoing federally funded studies should help the scientific community draw conclusions about the synergistic effects of PB and other risk factors.

Endemic Infectious Diseases

During WWII, British military units were stationed in the Gulf region and based on this experience documented the nature of endemic infectious diseases. Thus, the U.S. command was concerned about diseases, including shigellosis, malaria, sandfly fever, and cutaneous leishmaniasis.[6,65,90,187] For example, cutaneous leishmaniasis, known locally as the Baghdad boil, is endemic to that area; 80 to 90 percent of people in some parts of Southwest Asia have scars from previous attacks.[187] During WWII, rates of sandfly fever were 3 to 10 percent of all troops in the Middle East, and in some units it exceeded 50 percent.[187] Infectious diseases during the Gulf War, however, were not a major cause of sickness or lost work time.[90] During the Gulf War, only one death due to infectious disease (meningococcal meningitis) was reported.[342,343]

Experts attribute the lack of a problem with infectious diseases during the Gulf War to a comprehensive infrastructure of medical care and preventive medicine efforts.[90,185,271,273,293] DOD took measures to minimize infectious disease risk, including strict monitoring of drinking water purity, inspecting food sources and supplies, maintaining field camp sanitation, and instituting an insect vector control program. U.S. service members received booster doses of routine vaccinations, including typhoid, meningococcus and, during the fall, influenza. Immune gamma globulin was used to prevent Hepatitis A, and the small number of troops who entered Iraq near the Euphrates River valley received drug prophylaxis for malaria.

Most of the combat troops were isolated in barren desert locations, distant from rivers, oases, and urban areas. Additionally, maximum troop deployment occurred during the cooler winter months, which provided the least favorable conditions for the transmission of insect-borne diseases.[90,185] Indeed, the majority of the 12 individuals who developed viscerotropic leishmaniasis had been deployed to urban areas.[145]

Diagnosis of infectious diseases in-theater. Short-term diarrhea was a common symptom among troops in-theater. Most cases were mild, traveler's-type diarrhea that resolved spontaneously without antibiotics after a few days.[64,90] Gastroenteritis among outpatients decreased from four percent per week early in the deployment to less than 0.5 percent per week after U.S. medical command tightened control of food sources-especially imposing a ban on locally-grown fresh fruits and vegetables. The most common organisms identified in service members with diarrhea severe enough to warrant cultures were *Shigella sonnei* and *Escherichia coli*. DOD reports no confirmed cases in-theater of food-borne, diarrheal diseases, such as cholera, typhoid fever, or giardiasis.[90]

DOD medical personnel evaluated U.S. service members for several diseases transmitted by insects, including leishmaniasis, sandfly fever, malaria, dengue, Sindbis, West Nile fever, Rift Valley fever, and Congo-Crimean hemorrhagic fever.[90,293] As noted, sandfly fever had been a major concern, but no cases were seen during the Gulf War. DOD reports detecting seven cases of malaria and one case of West Nile fever, a mosquito-borne viral illness. No rickettsial illnesses and no cases of other arthropod-borne viral illnesses were identified.

Viscerotropic leishmaniasis (VL) and cutaneous leishmaniasis (CL) are the only endemic infectious diseases demonstrated to cause chronic morbidity among a number of Gulf War service members. These diseases are transmitted through the bites of sand flies; person-to-person infection does not occur. Thirty-two cases of leishmaniasis were diagnosed among U.S. troops, consisting of 12 cases of VL and 20 cases of CL.[145,277] CL causes a characteristic ulcerative or nodular skin rash that can persist for more than a year without treatment. And, while VL can be difficult to confirm, it is not considered to be a cause of widespread illness in

Gulf War veterans. All veterans diagnosed with VL, except one, have experienced the signs characteristic of the disease.[90,146,293]

It is unlikely that veterans in the Registry or CCEP who have unexplained illnesses are suffering from VL. The incidence of VL during the Gulf War and the five years since has been low (12 of 697,000), and other sandfly-borne infectious diseases in the troops have been absent.[90,278] Additionally, individuals with unexplained illnesses also lack signs and symptoms characteristic of VL. VL can sometimes occur following a prolonged incubation period (more than 18 to 24 months); there is also a risk of activation of latent infections in immunosuppressed persons.[65,90,146] To date, DOD and VA report that delayed onset of VL has not occurred.

From August 1990 through July 1991, the U.S. Army deployed approximately 347,000 individuals to the Gulf region. Based on information from U.S. Army field hospitals, the only infectious diseases that caused 30 or more each of approximately 14,000 admissions were pneumonia, intestinal infections, inflammation of the testes and/or epididymus, chicken pox, and kidney infections.[342,343]

What do we conclude about the risks of infectious diseases to Gulf War veterans? Based on a review of the rates and types of the diseases diagnosed during and after the Gulf War, the Committee concludes it is unlikely that infectious diseases endemic to the Gulf region are responsible for long term health effects in Gulf War veterans, except in a small, known number of individuals.

Depleted Uranium

Uranium is a naturally occurring, chemically toxic, and radioactive element composed of three isotopes. Relative to other radionuclides, natural uranium is only slightly radioactive because of its low specific activity.[288] When the uranium isotope used for nuclear reactors and weapons is extracted from natural uranium, DU is the byproduct.

DU is nearly twice as dense as lead-a property used to improve the performance of both armor and armor penetrating munitions. During the Gulf War, some U.S. tanks and U.S. aircraft fired DU munitions, which produced shrapnel and an aerosolized dust on impact with armor or on ignition in accidental munitions fires. DU retains natural uranium's toxicological properties and approximately half its radiological activity.[267] Most of DU's radiation cannot penetrate skin, and DU poses little threat to human health while it is external to the body.[288]

Because it is slightly radioactive, natural uranium is considered to be a potential carcinogen-albeit with a small cancer risk relative to other radionuclides.[288] Taken together, human and animal studies do not indicate conclusively that natural uranium causes cancer in humans. Epidemiologic studies of uranium miners experiencing extremely high, lifetime, occupational exposures to uranium show an increase in mortality due to lung cancer, but such cancers are thought to be caused by miners' concurrent exposures to radioactive radon gas and its decay products, tobacco smoke, silica and other dusts, or exhaust fumes from diesel engines.[172,321] Animal studies conclude that exposure to uranium for long periods of time does not result in increased incidence of cancer, except in the case of one study. This study found prolonged (more than five years) inhalation of high levels of uranium dioxide led to lung neoplasms in dogs.[130,131]

The chemical toxicity of uranium as a heavy metal is well characterized. In fact, the kidney is the most sensitive organ affected by exposure to uranium and is the critical target organ for risk assessment.[133,218,322,341] For this reason, uranium exposure is regulated based on its chemicaltoxicity and not its radiological properties.[129,156] Even so, more than 50 years of occupational health data from uranium miners reveal little epidemiologic evidence of excess kidney disease among workers exposed for years or decades.[322]

The health risks of internalized uranium or DU particles depend on dose, exposure pathway, and solubility of the ingested particle. Ingestion of insoluble uranium compounds poses little health hazard because they pass rapidly through the body and are eliminated in the feces. However, animal studies have shown that ingestion of large doses of relatively soluble uranium compounds are associated with kidney toxicity.[129,288] Inhaled uranium particles that are nonrespirable are cleared from the respiratory tract and either expelled from the body (cough) or swallowed and passed to the GI tract. Respirable and relatively soluble particles are cleared to blood and can affect kidney toxicity.[14,129] Less soluble particles can remain in the lung longer and in theory could pose a radiological hazard. The U.S. Army has conducted tests to characterize aerosols associated with DU munitions impacts with armor and with accidental DU munitions fires; it concluded a service member's risk exceeds civilian safety standards only when he or she is inside a vehicle when it is penetrated by DU munitions.[39,96,97] The adequacy of the research supporting this conclusion has been questioned by some reviewers.[229,267]

No studies of long-term human health effects of uranium metal implanted in tissue exist. Nevertheless, toxic effects are likely to be similar to the kidney toxicity observed from inhaled or ingested uranium. To date, VA has reported no kidney toxicity among soldiers wounded by DU fragments in friendly fire episodes.[112] VA currently monitors the health of approximately 30 veterans suspected of retaining embedded DU fragments, and the U.S. Army Medical Research and Materiel Command is funding animals studies to investigate the health hazards associated with short- and long-term exposure to DU metal fragments.[296]

What do we conclude about the risks of DU to Gulf War veterans? The Committee concludes it is unlikely that health effects reported by Gulf War veterans today are the result of exposure to DU during the Gulf War. Since uranium is a potential carcinogen, it is possible that exposure to DU during the Gulf War could lead to a slight increase in the risk for lung cancer after decades following the end of the war.

Oil-well Fire Smoke

At the end of the Gulf War, more than 600 Kuwaiti oil wells and several pools of spilled oil were left burning after being ignited by retreating Iraqi troops. Huge, dramatic plumes of billowing smoke from these fires rose high into the atmosphere. Occasionally the smoke remained low to the ground, in some cases enveloping U.S. military personnel.

Some chemicals contained in oil-well fire smoke, such as benzene and PAHs, are human carcinogens. As described earlier in this chapter, the amounts of these pollutants in the air were low. Hence, their contribution to excess cancer risk would be expected to be small and increased rates of cancers likely would not result.

The U.S. Army used EPA's standardized methodology to estimate cancer and noncancer risks from the oil-well fire smoke.[265] It concluded "the potential for significant long-term adverse health effects for the exposed DOD troop or civilian employee populations is minimal." Risks from cancers were estimated not to exceed two excess cancers per one million people exposed, a value well within EPA's acceptable range.

Noncancer risks from smoke exposure were calculated as Hazard Indices (HI). When the HI exceeds 1.0, there can be concern about potential noncarcinogenic health effects. In Saudi Arabia, the HI ranged from 0.6 to 2.0, while in Kuwait it ranged from 2.0 to 5.0. Most of this noncancer risk was contributed by inhalation of VOCs, particularly benzene. The U.S. Army concluded that risk of noncarcinogenic health effects among the U.S. service members was low since HIs are based on EPA toxicity values that are set far below levels thought to cause health effects and that also account for sensitive subpopulations such as children and the elderly. A congressional Office of Technology Assessment analysis of the U.S. Army's risk assessment methods and findings concluded "the risks to health from exposure to the smoke and the background air contaminants in the Persian Gulf are likely to be extremely small."[275]

Oil-well fire smoke appears not to have caused observable changes in lung tissue. Researchers at the Armed Forces Institute of Pathology found no significant differences when they compared lung tissue from autopsies of 33 U.S. service members who died after the start of the oil well fires to lung tissue from autopsies of soldiers who died before the fires.[164]

Information has been gathered from 110 firefighters working for private companies in the Kuwaiti oil fields in 1991. Individuals were deployed for 28-day periods, working daily at the well heads without breathing-protection equipment. Most were over 30 years old and had 10 or more years experience fighting similar well fires, many of them in Kuwait and elsewhere in Southwest Asia. No cases of illnesses resembling those reported by Gulf War veterans were reported, nor have such complaints been observed among thousands of oil-well firefighters who have spent years experiencing similar exposures.[60,61]

Known immediate health effects from inhaling large amounts of smoke and particulates are primarily respiratory, including coughing, wheezing, increased airway resistance, and respiratory infections. Toxic gases that can be found in oil-well fire smoke-such as hydrogen sulfide and sulfur dioxide-can cause eye and nose irritation, decreased pulmonary function, and increased airway reactivity.[312,315] Nevertheless, these toxic gases were not detected at high levels during the fires.[89,289,302,339] High levels of airborne particulates, which sometimes occurred in the Gulf region, are associated with increased rates of asthma and can exacerbate other chronic respiratory conditions. With chronic (months or years) exposure to particulates, there is increased risk of some loss in lung function or chronic bronchitis, especially in cigarette smokers.

What do we conclude about the risks of oil-well fires to Gulf War veterans? Based on research on human and animal health effects of exposure to air pollutants and on currently available exposure data, the Committee concludes it is unlikely exposure to oil-well fire smoke is responsible for symptoms reported today by Gulf War veterans. Although smoke from the oil-well fires did not include levels of carcinogens that would be expected to increase cancer rates among Gulf War participants, VA mortality studies will include cancer surveillance.

Petroleum Products

Diesel, kerosene, gasoline, jet fuel, and other petroleum-based fuels were widely used during the Gulf War for dust suppression, waste incineration, and for fueling vehicles, stoves, heaters and generators. U.S. service members in certain jobs were occupationally exposed to petroleum fuel vapors and combustion products, such as toluene, xylene, benzene, ethyl benzene, carbon monoxide, sulfur dioxide, nitrogen dioxide, particulates, lead, and other pollutants. Additionally, in some areas near the Kuwaiti oil-well fires, unburned crude oil drizzled down, covering the ground and troops below.[242]

Petroleum fuels are a complex mixture of aliphatic hydrocarbons and aromatic hydrocarbons such as benzene and PAHs. These fuels also commonly contain various additives, like lead. When burned, petroleum fuels produce a variety of potentially hazardous combustion products. High-level, short-term exposures to fuel solvents can cause immediate effects. In most cases, however, complete recovery occurs when the exposure ceases.[5,286]

U.S. service members could have been exposed to petroleum fuels by inhalation, ingesting contaminated water or dust, and skin contact. Inhalation exposure could depress the central nervous system (CNS). Symptoms include short-term effects ranging from fatigue, headache, nausea, blurred vision, and dizziness, to convulsions, paralysis, and loss of consciousness depending on the dose.[282,312] Again, exposure to high, nonlethal levels usually is followed by complete recovery, although rare cases of permanent brain damage after massive exposure have been reported.[117,205,282]

Prolonged breathing of diesel fuel vapors can damage kidneys or lower blood clotting ability.[284] Studies of workers occupationally exposed to certain hydrocarbon solvents in petroleum fuels suggest that long-term high-dose exposure over 12 to 14 years can lead to neurotoxic effects.[117,285] For example, psychomotor disturbances, visual memory and perception, and visuomotor learning ability were significantly affected in exposed gasoline-pump workers compared to matched controls, particularly workers exposed for more than a year.[125] Some studies suggest there are neurotoxic effects from long-term exposure, including decrements in memory, cognitive functioning, and sometimes neuromotor functions.[117] Other researchers, however, have challenged the existence of what is sometimes referred to as "chronic toxic encephalopathy," and uncertainty exists about CNS effects from long-term, low-level exposures to solvents.[69]

Benzene makes up about one percent of U.S. gasoline and up to five percent of European formulations. It is a known human carcinogen that is associated with certain types of leukemia. Nevertheless, more than 55 published epidemiologic studies of workers exposed occupationally to hydrocarbons such as gasoline generally do not replicate the carcinogenic effects reported for experimental animals.[157,282] Recent studies of refinery workers also do not reveal a clear association between gasoline production and leukemia.[88,282] Still, based on the limited evidence from animal studies and the presence of benzene in gasoline, the International Agency for Research on Cancer (IARC) concluded that gasoline is possibly carcinogenic to humans. It is not known if other petroleum products cause cancer in humans. IARC believes there are insufficient data to assess whether light fuel oils or light diesel fuels cause cancer in humans. However, IARC has determined that occupational exposure to fuel oils during petroleum refining is probably carcinogenic to humans.[284]

Although ingesting small amounts of fuel oils is unlikely to cause significant symptoms, ingesting fuel oils in larger quantities can cause vomiting, diarrhea, swelling of the stomach, stomach cramps, coughing, drowsiness, restlessness, irritability, and unconsciousness.[284] Ingestion of fuel oils can be accompanied (during vomiting) by aspiration of some of the material into the lungs, which can produce a chemical pneumonitis.

Skin exposure to large amounts of oil can physically clog pores and hair follicles, compromising body heat loss. Long-term exposure can cause acne and other skin problems. With high concentration or extended exposure, lighter components of crude oil or other fuel oils can defat the skin, leading to redness and itching or dermatitis.[284,312]

Exposure to the normal combustion products of petroleum fuels is also a health concern. Limited epidemiologic evidence indicates daily use of kerosene stoves for cooking or heating does not cause breathing problems for most people.[284] If insufficiently vented, however, carbon monoxide generated from fuel oil combustion can build up, causing drowsiness, nausea, and even asphyxiation. Individuals exposed to unvented combustion of fuels containing lead could experience health effects ranging from subtle biochemical changes in blood to severe CNS effects at high doses. Occupational exposure to inorganic lead is associated with subjective signs of neurotoxicity such as forgetfulness, lethargy, and weakness. These neurological signs and symptoms occur at about the same blood lead levels as other overt signs of lead intoxication, such as gastrointestinal complaints like abdominal pain, nausea, and vomiting.[286]

What do we conclude about the risks of petroleum products to Gulf War veterans? While certain subsets of Gulf War service members could have experienced occupational exposures to petroleum products that would entail increased risks of health effects, it is unlikely that health effects reported today by Gulf War veterans are due to exposure to petroleum products during the war.

Psychological and Physiological Stress

Virtually all Gulf War participants were exposed to a wide range of stressors associated with the war. Throughout human history, observers have noted a correlation between the horrors of war and "mysterious" illnesses in soldiers and veterans.[91] Only recently, however, have the broad range of symptoms for such illnesses been recognized as serious, physiological effects of stress.

Unexplained illnesses in soldiers were widely interpreted as a form of malingering until the 1940s. When WWII veterans experienced many of the same symptoms seen in WWI, Charles Samuel Dyers coined the term "shell shock." He began to study and write about what actually happened to the minds and bodies of soldiers on and off the battlefield. Physicians began to describe psychosomatic symptoms-physical disorders caused or influenced by a psychological state-as the normal and expected consequences of experiencing fear and fright, and recognized the relationship between intense emotion and bodily changes.

During this period, a telling example came to light that illustrated how traumatic experience can lead to a decline in physical health. A group of merchant marines in Norway during WWII were preselected for their excellent physical and mental health. Yet after exposure to extraordinary stress, they showed a sharp decline in their health. Many had symptoms of chronic fatigue, chronic pain, impotence, and irritability.

Today, scientists are beginning to unravel the physiological connection between the brain and various other parts of the human body. Recent animal and human studies reveal numerous pathways connecting the brain to the rest of the body, through which psychological stress can be physically expressed.[31] Animal studies demonstrate that stress can have measurable effects on the brain, immune system, cardiovascular system, and various hormonal responses. Although the human body can adapt to normal stresses, if the stress lasts longer it can be expressed in a variety of physical illness symptoms.[155] Some researchers suspect that the inadequate production of stress hormones and stress response occurs in some (not all) humans with CFS and PTSD.[31]

Based on this understanding and supported by decades of clinical observations, physicians recognize that many physical, as well as psychological, diagnoses are the consequences of stress. This connection is not limited to soldiers only. Experts now know that conventional stressors, such as bereavement, family problems, financial and job problems, domestic or other violence, can cause significant and long-term physical health effects.[26,184]

Physicians and scientists also note substantial variability in the human response to stress. One individual's reaction to trauma could be hypertension; in another individual, the reaction to similar trauma might be severe anxiety. A number of medical diagnoses are linked with stress, including somatoform disorders, CFS and FM. These conditions share many overlapping features, and each diagnosis depends on meeting specific case definitions. Significant evidence supports the likelihood of a physiological, stress-related origin for many of these ailments.

What do we conclude about the risks of stress to Gulf War veterans? The Committee concludes that stress does not cause a unique illness or set of symptoms. Stress can contribute to a broad range of physiological and psychological illnesses. Stress is likely to be an important contributing factor to the broad range of illnesses currently being reported by Gulf War veterans.

SUMMARY

The Committee has examined exposure and, independently, expected health effects for ten Gulf War risk factors: pesticides, CW agents, BW agents, vaccines, PB, infectious disease, DU, oil-well fire smoke, petroleum products, and psychological and physiological stress. In our evaluation, we used the substantial amount of relevant scientific information available in published peer reviewed literature, interviews with experts, invited testimony, public comment, and discussions with scientific experts in academic and government agencies. For most of the risk factors evaluated, the Committee has determined-even in the absence of exposure data-they are unlikely to be associated with the health problems currently reported by Gulf War veterans. Based on its review, the Committee makes the following findings and recommendations.

FINDINGS

- Although some veterans clearly have service-connected illnesses, current scientific evidence does not support a causal link between the symptoms and illnesses reported today by Gulf War veterans and exposures while in the Gulf region to the following environmental risk factors assessed by the Committee: pesticides, chemical warfare agents, biological warfare agents, vaccines, pyridostigmine bromide, infectious diseases, depleted uranium, oil-well fires and smoke, and petroleum products. Some of these risk factors explain specific, diagnosed illness in a few Gulf War veterans, for example, leishmaniasis has been diagnosed in 32 individuals. Prudence requires further investigation of some areas of uncertainty, such as the long-term effects of low-level exposure to chemical warfare agents and the synergistic effects of exposure to pyridostigmine bromide and other risk factors.
- A number of Gulf War risk factors-e.g., mustard agent, aflatoxin, and certain petroleum products-are potential human carcinogens that could cause

increased rates of cancer beginning decades after exposure.
- Stress is known to affect the brain, immune system, cardiovascular system, and various hormonal responses. Stress manifests in diverse ways, and is likely to be an important contributing factor to the broad range of physiological and psychological illnesses currently being reported by Gulf War veterans.

RECOMMENDATIONS

- DOD and VA should perform long-term mortality studies of Gulf War veterans appropriate for investigating cancer rates in the Gulf War veteran population in the coming decades.
- The entire federal research portfolio should place greater emphasis on basic and applied research on the physiologic effects of stress and stress-related disorders.

*As noted, individuals in this group also were assessed for SCEs, which were found to increase with deployment to Kuwait and remain elevated even after the return to Germany.[154] SCEs are a sensitive measure of DNA damage and repair and occur at a background rate in normal cells, but increase with exposures to DNA damaging agents. It is not clear what exposures in Kuwait could have led to the observed increases, since elevated SCEs are a nonspecific measure that can reflect exposure to infections and vaccinations, or to dietary, occupational, or environmental mutagens.

**In chapter 2, we identify those areas for which we believe new research data could fill in current gaps in knowledge.

KEYWORD PAGE.

CMAT NUMBER: 2000109-0000013

MOI FILING
LETTER TO CHRISTOPHER SHAYS
DATED FEBRUARY 29, 2000
DOD REVIEW OF SUBCOMMITTEE STAFF'S REPORT OF
FEBRUARY 15, 2000 ON ANTHRAX VACCINATION
IMMUNIZATION PROGRAM

CMAT Control #
2000109-0000013

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

FEB 2 9 2000

The Honorable Christopher Shays
Chairman
Subcommittee on National Security,
Veteran's Affairs and International Relations
Committee on Government Reform
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Shays:

The Department of Defense has completed a review of your Subcommittee staff's report of February 15, 2000, on the Department's Anthrax Vaccination Immunization Program. We were surprised that the report seemed to ignore a vast amount of the information presented as sworn testimony to your subcommittee by witnesses that appeared at some seven hearings last year.

You will find enclosed a point-by-point comment on suppositions contained in the report. We believe that a majority of these comments are backed by solid scientific studies and meet the test of medical responsibility. We also believe that if a committee of the Congress was to conduct a study of the anthrax vaccine issue as detailed and extensive, as DOD's has been, that the Committee's conclusion, too, would be that it is safe, effective, and the right thing to do.

We remain of the opinion that it would be wrong to cancel our program, make it voluntary, or treat the anthrax vaccine as if it were an investigative new drug. Doing so would leave our force unprotected from a deadly threat. It is important to recall that the Chairman of the Joint Chiefs, all four Service Chiefs and two major theaters CINCS have asked specifically for anthrax vaccination protection. If we denied them this requested and available protection, the potential exists for massive future casualties as the result of such a decision.

Sincerely,

Dr. Sue Bailey
Assistant Secretary of Defense
Health Affairs

Randy L. West
MajGen, USMC
Special Advisor for Anthrax
and Biological Defense Affairs
Under Secretary of Defense (P&R)

cc: Members of Government Reform Committee

MEMORANDUM FOR DEPUTY ASSISTANT SECRETARY OF DEFENSE (FHP&R)

SUBJECT: Deployment Health Support Directorate (DHSD) Weekly Activity Report.
~~3-6~~ 9-13 September 2002

Operational Health Support (OHS)

- **Meeting with the Joint Requirements and Integration Office (JR&IO).** Members ofthc Deployment Health Support Directorate (DHSD) attended a demonstration of PeopleSOFT software hosted by OUSD (P&R), Defense Human Resource Activity, JR&IO. on 6 September 2002, to examine the potential of long term solutions for the deploy-cd individual: and unit locations challenges he/she may encounter. The DHSD representatives saw a number of capabilities of the PeopleSOFT application, including the capability to record individuals and their units of assignment during deployments, to document pre-deployment processing activities, and to record a variety of medically related personnel management information. PeopleSOFT data, however, will have to be matched with operational unit data to meet the deployment personnel data needs of the medical health system (MHS). The JR&IO gave a brief overview of how PeopleSOFT will form the basic software architecture for the Defense Integrated Military Human Resource System (DIMHRS). The JR&IO has met with each of the Services to familiarize them with PeopleSOFT and to build business rules for adjusting the functionality of DIMHRS. DHSD's presentation/demo was an extract of what the Services saw during their familiarization. In addition, tho JR&IO presented the briefing to Dr. Chu during the week of 19 August 2002. DHSD provided the JR&IO a copy of the executive level trip report of DHSD's visit to DMDC West (30 April – 1 May 2002), and a draft copy of DHSD's working strawman for personnel and operational data needed to meet MHS individual and unit deployment location needs (POC (b)(6) (b)(6)).

- **USCENTCOM Depleted Uranium Support.** Over the last year, DHSD has responded to several requests for help from USCENTCOM on issues related to the Gulf War use of depleted uranium munitions. Recently. DHSD received a classified request. in response to which it is assisting USCENTCOM in identifying and assembling a team ofdeplcted uranium experts to go to the Gulf in early October 2002 to address the Host Nation concerns. At this point. it does not appear as though the delegation will include a DHSD representative. The DHSD coordinated the receipt of this follow-on USCENTCOM request with DUSD Installations and Environment's Safety and Occupational Health office as well as with the appropriate point of contact in ASD (ISA) for Near East and South Asian affairs (POC (b)((b)(6)).

- **Depleted Uranium Health Risk Assessment Funding.** In 1999, DoD initiated the CAPSTONE research program to evaluate depleted uranium aerosol levels inside Abrams Ml Al tanks and Bradley Fighting Vehicles hit by friendly fire. The CAPSTONE was jointly funded by the Office of the Special Assistant for Gulf War Illnesses. Medical Readiness. and Military Deployments ($2.8M) and the US Army ($1.3M). The scope and funding of CAPSTONE did not include preparation of a final health risk assessment (HRA). A health

risk assessment evaluates the possible exposure **scenarios,** develops estimates of potential exposure levels, combines the exposure estimates with knowledge of the toxicity of depleted uranium to estimate possible health effects, and communicates those findings in a way that would be understandable to servicemembers, veterans, and the public. The HR4 will address a major depleted uranium analysis gap identified by veterans: Congress, the GAO, the Presidential Special Oversight Board, and other countries. The Deployment Health Support Directorate worked closely with the US Army Medical Command and the US Army Center for Health Promotion and Preventive Medicine to establish an unfunded requirement for $1.98 1 M to complete the CAPSTONE HRA. The requirement has been funded with end-of-year FY02 Defense Health Program funds (POC (b)(6)).

Population Health Support (PHS)

- **GAO Review of Deployment Health Surveillance.** The GAO held meetings on 9 and 10 September with the following offices: DHSD (subjects: feedback from Fort Drum visit and DoD initiatives to track deployed service members); TMA Information Management, Technology & Reengineering Directorate (subject: status of TMIP and other information technology initiatives to support deployment health surveillance); and Air Force Preventive Medicine Division (subject: deployment health surveillance programs and implementation monitoring). DHSD staff members are continuing to coordinate with the Army, Navy, and Marine Corps on finalizing their responses to the GAO's request for data on deployed units and service members. The GAO indicated that their preliminary impressions of the review thus far would include deployment health surveillance policies that are in place but for which implementation has not been assessed. In addition, there appears to be heavy reliance on information systems to fix problems. but these systems are not yet fully developed or close to full implementation (POC (b)(6) (b)(6))

- **VA-DoD Health Care Task Force. On** 1 1 September 2002, a DHSD staff member attended a meeting of the President's Task Force to Improve Health Care Delivery for Our Nation's Veterans (PTF). The PTF heard from Dr. Robert Roswell, VA Under Secretary for Health, and received presentations from consultant staff on four themes or "calls for action" to create a seamless transition to veteran status; to improve beneficiary access to health care; to resolve the health care funding and demand mismatch; and to enable improved collaboration between VA and DoD. These themes form the preliminary **construct** for the PTF's Final Report, which is scheduled for release in March 2003. The PTF's Interim Report. released late July 2002, addressed seven key issue areas: leadership. benefits. resources. pharmaceuticals, procurement, facilities: and information systems (POC (b)(6) (b)(6)).

- **Anthrax Vaccine Immunization Resumption.** Representatives from DHSD have been working with the Anthrax Vaccine Immunization Program (AVIP) office and the Services' representatives to coordinate their respective Anthrax Vaccine Implementation plans with the Assistant Secretary of Defense for Health Affairs (HA) and the Assistant Secretary of Defense for Force Management Policy (FMP). Guidance from USD Personnel and Readiness (P&R) designated FMP as the approval authority for the Services' respective implementation plans, which were reviewed for their thoroughness in addressing the

following issues: 1) Concept of Operations. 2) Education and Communication. 3) Immunization Tracking, 4) Medical Guidance, and 5) Administrative Guidance. The plans were then approved 10 September 2002 for Service-wide distribution and execution (POC CDR (b)((b)(6)

Total Keported Number of Hours that DHSD Personnel Worked an SHAD Issue (29 August - 4 September 2002):

- 207.4 hours

Deployment Health Support Directorate Upcoming Travel and Events:

September

12	VSO/MSO Meeting, 1100, Pentagon, Rm. 2C 1061.
13	Award Ceremony for CAPT Matthews: 1030, Large Conference Room.
16-18	Air Force Association Aerospace Technology Exposition, Marriott Wardman Park Hotel. Washington, DC. DHS display to be provided.
17-18	Autumn 2002 Meeting of the Armed Forces Epidemiological Board (AFEB). Thayer Hotel, United States Military Academy. West Point. NY. Dr. Kilpatrick to attend.
23-24	National Syndromic Surveillance Conference. New York, NY. COL Gardner to attend.
29-4 (Oct)	Military Infectious Diseases Research Program (MIDRP). King of Prussia. PA. Dr. Kilpatrick, Ms. Embrey and (b)(6) to attend.

October

10	Force Health Protection Council Meeting, 1400-1530, Sky 4. Suite 901, Lrg. Conf. Rm.

November

10-15	Association of Military Surgeons of the United States (AMSUS), Louisville. KY Dr. Kilpatrick to attend, PAO and Web Development to exhibit.

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Subject DHSDs Weekly Activity Report

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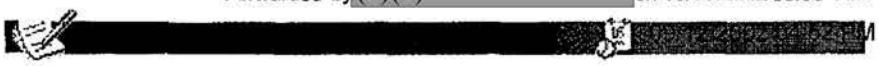

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Subject: DHSDs Weekly Activity Report
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Attached, please find the Deployment Health Support Directorate Weekly Activity Report

FHP&R WAR 09.12.02

Deployment Health Support Directorate

(b)(6) (b)(6)
Chief, Case Management Assignment Team
Deployment Health Support Directorate
(b)(6)

MEMORANDUM FOR DEPUTY ASSISTANT SECRETARY OF DEFENSE (FHP&R)

SUBJECT: Deployment Health Support Directorate (DHSD) Weekly Activity Report, 28 October – 1 November 2002

Population Health Support (PHS)

- **GAO Review of Deployment Health Surveillance.** GAO team members are at Travis AFB, CA, this week to review medical records for deployment-related documentation, associated with Operation Enduring Freedom. Preliminary feedback indicates that there are some problems with the Air Force personnel deployment data, which apparently included service members who deployed to locations with permanent US military medical treatment facilities (and for whom pre- and post-deployment health assessments, therefore, would not have been required). Although plans for GAO visits to additional military installations have not been finalized, dialogue is currently underway with the Army and the Marine Corps to identify appropriate locations, as well as to ensure the accuracy and applicability of the personnel databases used to select medical records for review (POC (b)((b)(6 (b)(6)

- **Anthrax Vaccine Research Program.** A representative from DHSD provided an update to the Deputy Assistant Secretary of Defense for Chemical and Biological Defense on 5 November 2002. Information for this update was obtained from the 3rd Annual Anthrax Vaccine Research Program (AVRP) Investigators' Meeting, held the week of 21 October 2002 at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. The update covered the primary aspects of the AVRP, focusing on human clinical trials, non-human (primate) studies, and correlates of protection. The ultimate goal of this research is to obtain the data and information that will support Food and Drug Administration (FDA) approval for changing the route of administration (from under the skin, into the muscle) and reducing the dosage (to fewer than six injections) of the current anthrax vaccine. The CDC has projected that an interim analysis will be available for review by September 2004. DASD (ChemBio Defense) meetings are held bimonthly (POC CDR (b)(((b)((b)(6)

Public Affairs Office (PAO)

- **October VSO/MSO Roundtable Meeting Held.** Nine representatives from veterans and military service organizations and the Interagency Community attended the roundtable meeting. No significant issues were raised (POC (b)(6) (b)(6) (b)(6) (b)(6)).

- **Media Response to DTC Announcement.** Thom Shanker of the *New York Times* asked for additional information on the Red Oak Phase I test. In particular, he asked how and where the test was conducted, and whether any civilians were in danger. He also asked how long it would impact the environment, and whether the longevity of the chemical sarin would remain a danger. PAO explained that the test

was conducted in a remote area, far from any population center. The shells were fired individually, and dissemination of the agent was monitored. Also, sarin is one of the least persistent agents, and loses its toxicity within hours of release. PAO also described in detail the follow-on work, to ensure that all environmental considerations were addressed (POC (b)(6) (b)(6) (b)(6)

- ***Times News Service* asks for Comment on VVA Lawsuit.** Debbie Funk, *Times News Service*, requested an interview and/or comment from Dr. Kilpatrick, in response to the lawsuit filed by VVA and several SHAD veterans. DHSD denied the request, explaining that it is inappropriate to comment on matters of current litigation. Ms. Funk also asked if DHSD knows whether Dr. Kilpatrick is named as an individual in the case. PAO explained that it does know, but that it still has no further comment (POC (b)(6) (b)(6) (b)(6)

- **NBC-4, KAMR-TV, Amarillo, Texas, asks for DTC Background.** Reporter Subha Ravindhran asked for background on the Project 112/Project SHAD for a news story this evening. PAO faxed a copy of the state/country matrix, today's press release and the 9 October press release. It also provided contact phone numbers and web information. Prior to this call, Ravindhran had contacted (b)(6) requesting comment on the pending lawsuit, on which (b)(6) declined to comment (POC (b)(6) (b)(6) (b)(6)

- **Is "Gulf War Syndrome" linked with homicides?** Sarah Edmonds of Reuters has contacted a number of researchers who have told her that a personality change is one of the symptoms of the "syndrome." She provided a list of seven names and asked if DHSD could verify three things – whether they are Gulf War veterans, and if so, in which services, and whether they participated in the CCEP. All seven individuals appear to have been involved in homicides or attempted homicides; several also have committed suicide; records confirm that six of teh seven were Gulf War veterans. Edmonds stated that she is working on a "balanced" story, and that she is including input from several experts. Based on her questions, PAO referred her to Jim Benson, VA Public Affairs. In a follow-up call, Edmonds asked for similar Gulf War service information on four servicemembers involved in the Fort Bragg murder-suicides. Following coordination with Army Public Affairs, advised Edmonds that three of the four people on her list were Gulf War veterans. Also told her that the Department of Defense, the Department of Veterans Affairs and the Department of Health and Human Services and several independent medical entities have looked at health status of Gulf War veterans very carefully. This is an ongoing effort and to date, there is no evidence to support the notion that Gulf War veterans are more violent than any other group. We should be careful not to jump to conclusions. Approximately 697,000 veterans served their country in Operations Desert Shield and Desert Storm. It would be an injustice to them to automatically link the aberrant acts of a few to their military service. Anticipate a news story that presents the typical Gulf War veteran in a negative light (POC (b)(6) (b)(6) (b)(6)

- **Association of Military Surgeons of the United States (AMSUS) Outreach.** An outreach

team will participate in the Association of Military Surgeons of the United States annual conference next week (10-15 November). In preparation for the meeting, the team created a new 8x8 display with tailored medical information and forwarded for distribution 250 each of the DHSD tri-fold, 800 Hotline cards, DeploymentLINK cards, MedSearch fact sheet, and 300 copies of the summer issue of *Deployment Quarterly*. Approximately 6,000 members of the 12,000+-member organization are expected to attend the meeting (POC (b)(6) (b)(6) (b)(6)

- **Media Query.** Johnny Edwards of the *Augusta Chronicle* requested a list of standard vaccines given to service members. In response, PAO forwarded a copy of the regulations and joint instructions used by the services to determine required vaccinations. In follow-up inquiries he asked about the anthrax and smallpox vaccines, as both issues had been in the news. PAO advised him that the anthrax vaccine was not a "routine" vaccine and provided information released earlier this year. With regard to the smallpox vaccine, advised him that it would be premature to discuss the issue as a final decision has not been made (POC (b)(6) (b)(6) (b)(6)

- **Product Request.** In response to a request by Shannon Middleton, American Legion Washington office, on 7 Nov. forwarded 50 copies of the current issue of the *Deployment Quarterly* (POC (b)(6) (b)(6) (b)(6)

- **Disaster News Network sought Comment.** Travis Dunn, Disaster News Network (*Disasternews.net*), asked for a comment on the VA's recent decision to double its GW-related research. Dunn had also contacted Jim Benson, VA Public Affairs. Benson explained the long-term research effort and DoD's support of all actions focused on achieving a better understanding of the illnesses of Gulf War veterans. To that end, DoD has been involved in a collaborative effort with the departments of Veterans Affairs and Health and Human Services since 1994. PAO noted that over time the research portfolio has evolved, and that studies have addressed a wide variety of health issues. The investigative effort has not been restricted; in fact, the changing nature of the studies reflects an effort to build on the findings of earlier research, scientific breakthroughs and improved technologies. Expect balanced coverage (POC (b)(6) (b)(6) (b)(6)

- **Smallpox Vaccine Communications Planning Continues.** In support of HA's upcoming policy announcement, team members have continued participation in smallpox communication planning meetings, prepared supporting documentation and incorporated revisions from policy and subject-matter experts (POC (b)(6) (b)(6) (b)(6)

- **Gulf War Research.** Ken Guggenheim, filling in for *AP* reporter Suzanne Gamboa, asked for DoD's comment on the VA's increased Gulf War research funding. He asked if anything new has happened, and if it is true that DoD no longer finds stress to be the cause of the illnesses of Gulf War veterans. Guggenheim asked about the significance of the research in light of future deployments. In an approximate 20-minute discussion, Dr. Kilpatrick explained that understanding chronic, debilitating symptoms is extremely important. In

addition to permitting DoD to address the concerns of individuals, it enables appropriate preparation for and ensured protection of those deployed. Guggenheim then asked if the latest funding announcement is a change from the past, to which Dr. Kilpatrick replied that this is rather a matter of what has changed over time. The Department of Defense has established three deployment-focused centers: clinical health, clinical research and surveillance. These centers allow for continued awareness and add a proactive side to the effort. In other words, DoD is not just focused on the battle wounds, it is also concerned with understanding all facets of deployment health, to identify the best options for prevention and treatment. To date, DoD, VA and HHS have provided more than $200 million for more than 200 projects. It is important to look at the entire portfolio – these projects address a myriad of issues (POC (b)(6) (b)(6) (b)(6)

- **Reuters asks about Depleted Uranium Health Effects in Iraq.** *Reuters* is preparing a book looking at the pros and cons of military action against Iraq. A small section of the book includes claims by the government of Iraq that cancer rates, congenital deformities and abnormalities significantly increased in children born after 1991, in areas where the munition was used. Via the DoD Press Office, Reuters requested DoD comment on this statement. DHSD provided the following statement to OASD (PA): "In contrast to Iraqi claims, the Department of Health and Human Services says, 'No human cancer of any type has ever been seen as a result of exposure to natural or depleted uranium.' Also, since 1993, a Veterans Affairs medical follow-up program has performed medical evaluations on 60 U.S. veterans exposed to DU friendly-fire, many with embedded DU fragments. The results of these medical evaluations indicate that even veterans with elevated levels of urine uranium ten years after the Gulf War have not developed kidney abnormalities, leukemia, bone or lung cancer, or any other uranium-related adverse outcome. PAO anticipates that the brief comments will be included in the book (POC (b)(6) (b)(6) (b)(6)

Health Doctrine Support (HDS)

- The Deseret Test Center investigation team revisited the Edgewood Technical Library last week. Based on additional search terms, the team was able to locate reports dealing with two tests known to have been completed that had not been previously located. The team has also reestablished a relationship with the chemical and biological researchers at the Naval Surface Warfare Center at Dahlgren, VA. Those researchers have located a number of potentially relevant documents and files based on the investigation team's expanded list of test names and keywords; the team plans to visit Dahlgren next Wednesday to assess their value to the investigation. Work to extract land-based test participant names from the records retrieved from Dugway is progressing, with approximately 65 new participants identified to date.

Operational Health Support (OHS)

- **Best Practices in Occupational Safety and Health, Education, Training, and Communication: "Ideas that Sizzle" Conference.** (b)(6) of DHSD attended this international conference, which was sponsored by the national Institute for Occupational

Safety and Health and a number of other federal agencies, including the Department of the Army (USACHPPM) and the Department of the Navy. Several hundred people from 15 different federal agencies attended the conference, which also had large international representation. (b)(6) of DHSD delivered a 30-minute presentation at a break-out session (attended by approximately 40 people), entitled "Health Risk Communication: A DoD Perspective." The presentation had previously been approved and presented at the International Society for Exposure Analysis in Vancouver, Canada, this past August. His key message was that the perceptions, concerns, and fears of stakeholders who are not knowledgeable with the scientific risk assessment process, must be treated as valid assessments of risk from the stakeholders' perspectives. Thus, it is critical that risk communicators and others take the necessary time to fully acknowledge and empathize with stakeholders, regarding their concerns, before attempting to alter those concerns to match more closely with the scientific assessment of risk. The presentation was well received, and it generated a number of questions especially from Canadian representatives (POC COL Sulka (b)(6)).

- **US Central Command (USCENTCOM) Visit.** On 23 October 2002, DHSD representatives attended discussions and office calls with the ADUSD (Safety and Occupational Health), Mr. (b)(6) at USCENTCOM, Tampa, Florida. (b)(6) invited DHSD to travel with him because it shares mutual areas of concern for force health protection. The overarching purpose of the meetings was to update Mr. Bowling and his staff on the current efforts of the intelligence and environmental communities (in particular USACHPPM and NIMA) in providing medical intelligence and environmental surveillance support to USCENTCOM's contingency operations. (b)(6) and his staff wanted to ensure that previous coordination efforts to protect this strategic command and critical infrastructure in the region were still relevant and working. Office calls included the Command Surgeon, the Deputy J-4 Engineer, the J-4, and the Deputy J-5. Other topics discussed were depleted uranium, future regional engagement projects, WMD, K2, recording locations for deployed units and individuals during a deployment, and the Combatant Command Surgeon Portal (POC COL Sulka (b)(6)).

- **Visit to USACHPPM.** On 24 October 2002, Ms. Embrey, accompanied by members of DHSD staff visited the US Army Center for Health Promotion and Preventive Medicine where they received a command brief from Brigadier General Bester and members of his staff. Major briefing topics included:
    - Smallpox Epidemiological Response Team program,
    - Garrison Disease Outbreak Response,
    - Chemical Agent Standards Development,
    - Defense Occupational & Environmental Health Surveillance,
    - Injury Prevention and Control,
    - West Nile Virus Surveillance Efforts, and
    - The Entomology Laboratory

  Major issues discussed included incorporation of biomarker analyses in the CTF Campaign

Plan, revisions to DoD Directive 6490.2 and DoD Instructive 6490.3, fitness programs for the reserve component, the operation of smallpox response teams, and acute exposure guideline levels and detector level settings for chemical warfare agents. In addition, Brigadier General Bester recommended that Ms. Embrey visit the Walter Reed Army Medical Center to receive a briefing on the Defense Medical Surveillance System (DMSS) (POC COL Sulka/(b)(6) (b)(6)).

- **Exercise *DILIGENT WARRIOR 03.*** From 22 to 25 October 2002, an Office of the Secretary of Defense (OSD)-directed, Joint Staff (JS)-coordinated, and Defense Threat Reduction Agency (DTRA)-sponsored exercise tested federal, state, and local response capabilities to a nuclear weapons accident. This year's exercise combined a field training event in Wyoming replicating an accident involving a weapon in transit with a command post-style exercise extending through the National Military Command Center (NMCC) to the OSD Crisis Coordination Center (OSD CCC). Local and national USAF and civilian responders reacted to the simulated incident near Guernsey, Wyoming, while reporting systems and processes from local to national levels were used to coordinate responses. Health Affairs staff officers (the Gold Team) manned the CCC throughout the exercise, gaining valuable command post experience and training in providing linkage to OSD medical policy and in coordinating the guidance of senior DoD leadership in radiological incidents. Because the exercise incident did not involve catastrophic damage or a release of radiation, there were no national level medical issues. (b)(6) , DATSD(NCB) received the After Action Review briefing that identified some overarching issues such as the role/relationship between the OSD CCC and the NMCC. During the exercise and during the after action review, it became clearer that the HA representatives to the CCC tracked or were expected to address issues not in the medical functional area, e.g., casualty reporting, mortuary services, and evacuation (determining whether or not to evacuate). FHP&R will review HA's role in the CCC. The DHSD will revise HA's input to the current draft DoD Manual 3150.8-M, *Nuclear Weapon Accident Response Procedures (NARP)* based on this exercise experience (POC COL Sulka/ (b)((b)(6)).

- **GAO Audit 460530, "Review of Nuclear, Biological, and Chemical Plume Analysis."** DHSD completed collecting documents and answering a second set of GAO questions for this audit. In addition, DHSD received a request for 269 additional documents that it has in its files. This list resulted from DHSD's answer to the first set of GAO questions in which their investigators asked about which documents it has that mention modeling. From that list, the GAO chose 269 that it wants DHSD to provide (POC COL Sulka/(b)(6)).

Total Reported Number of Hours that DHSD Personnel Worked on SHAD Issue (31 October – 6 November 2002):

- 129.2 hours

Deployment Health Support Directorate Upcoming Travel and Events:

November

8	Navy/Marine Corps Birthday Celebration, 1000-1100, Sky 4, Suite 901.
10-15	Association of Military Surgeons of the United States (AMSUS), Louisville, KY. Dr. Kilpatrick to attend; PAO and Web Development to exhibit.
1-15	Joint Doctrine Working Party Conference, Joint Warfighting Center, Suffolk, VA. Hank Hodge, LtCol Charleston to attend.
14	Force Health Protection Council Meeting, 1400-1530, Sky 4, Suite 901, Lrg. Conf. Rm.
18-20	Mobilization Symposium, Alexandria, VA. Hank Hodge, LtCol (b)(6) and (b)(6) to attend.
20	The Board of the Medical Follow-up Agency (MFUA) Advisory Panel Meeting, National Academies Building, 500 Fifth Street, NW, Room 101, Washington, D.C., POC (b)(6)

December

3	VSO/MSO Meeting, Pentagon (Rm. TBD), POC (b)(6) (b)(6) (b)(6)
5	Sergeant Majors Briefing, Ft. Bliss, TX.
20	FHP&R and DHSD Holiday Party, 1130-1530, Army Navy Country Club, Arlington, VA.

January

1-21	Reserve Officers' Association Conference, Washington Hilton and Towers, Washington D.C. PAO and Web Development to exhibit.
27-30	TRICARE Conference, Marriott Wardman Park Hotel, Washington, DC. COL Gardner to present; attendees TBD.

(b)(6) (b)(6)
12/02/2002 11:36 AM

To: (b)(6) @OSAGWI
cc:

Subject: DHSD's Weekly Activity Report

2b atch please

---------- Forwarded by (b)(6) on 12/02/2002 11:39 AM ----------

[redacted]

To: (b)(6) @ha.osd.mil
cc: (bcc: (b)(6) (b)(6)

Subject: DHSD's Weekly Activity Report
Document is set for Permanent Archival

Attached, please find the Deployment Health Support Directorate Weekly Activity Report.

FHP&R WAR 11.07.02

Deployment Health Support Directorate

(b)(6) (b)(6)
Chief, Case Management Assignment Team
Deployment Health Support Directorate
(b)(6)

2002340-0000005

HA/TMA Document Profile

43633

Subject:	Report to Congress on Anthrax Vaccine Supply Preparedness
Author	(b)(6)
Date of Document:	
OSD # :	
PR # :	
Organization:	
Department:	
Assigned To:	FHP&R
Prepared For:	ASD
Suspense Date:	12/13/2002
Coord Office(s):	
Congressional Name:	
Input By:	ASARDO
Profiler's Directorate:	HA
Response Signed By:	
Dt Response Signed:	
Doc Type:	102-18
Application:	DOCSIMAGE
Previous Documents:	
Related Documents:	
Notes:	On 12/6/02 rec'd tasker, scanned and routed to DHS. (aas)

Beneficiary Info

Beneficiary Name:	
Address 1:	
Apartment #	
Phone #	
Email Address:	
City:	
State:	**Zip**

History

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☐ **From External Source?**

Access Control

☐ **Secure Document**

☐ **Enable Content Searching**

ASSISTANT TO THE SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

NUCLEAR AND CHEMICAL
AND BIOLOGICAL DEFENSE
PROGRAMS

MEMORANDUM FOR UNDER SECRETARY OF DEFENSE (COMPTROLLER)
DEPUTY UNDER SECRETARY OF DEFENSE (INDUSTRIAL POLICY)
ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
ASSISTANT SECRETARY OF DEFENSE (LEGISLATIVE AFFAIRS)
DEPARTMENT OF DEFENSE GENERAL COUNSEL
DIRECTOR, ACQUISITION RESOURCES AND ANALYSIS
DIRECTOR, DEFENSE PROCUREMENT
JOINT REQUIREMENTS OFFICE (CBRN DEFENSE)

SUBJECT: Report to Congress on Anthrax Vaccine Supply Preparedness as Required by the FY03 Appropriation Report, Public Law 107-732

Request coordination NLT **noon Friday, December 13,** on the attached draft Action Memo and Report to Congress from Dr. Winegar to Mr. Aldridge. The report addresses "anthrax vaccine supply preparedness" as required by FY 03 Appropriations Report, Public Law 107-732. This represents an unfunded requirement.

If you have questions regarding this matter, please contact (b)(6) at (b)(6). Please fax your coordination (TAB E) to (b)(6)

Anna Johnson-Winegar, Ph.D.
Deputy for Chemical/Biological Defense

Attachments:
As stated

ASSISTANT TO THE SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

NUCLEAR AND CHEMICAL
AND BIOLOGICAL DEFENSE
PROGRAMS

ACTION MEMO

December 2, 2002, 7:30 AM

FOR: UNDER SECRETARY OF DEFENSE (ACQUISITION, TECHNOLOGY, AND LOGISTICS) ATSD(NCB) Action _____

FROM: Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense

SUBJECT: Report to Congress on Anthrax Vaccine Supply Preparedness as Required by the FY03 Appropriation Report, Public Law 107-732

- Forward the letters to the congressional defense committees (TAB A).
- The FY03 Appropriations Act, Public Law 107-732 (TAB B), requires a report to Congress by January 23, 2003.
- The Report to Congress on Anthrax Vaccine Supply Preparedness (TAB C).
- The Secretary of Defense has delegated authority to Under Secretaries (DoD Directive 5545.2) to submit reports to Congress in a memo dated July 26, 2002 (TAB D).
- Specific report requirements are:

  (1) Assess the immediate and short-term preparedness and potential future total biowarfare defense need for the FDA-licensed anthrax vaccine.
  (2) Assess the potential capacity to meet that need, and the need for a separate production capacity to mitigate risks of an event which could halt current vaccine production.

- None of the options discussed in the draft Report are funded in the POM, or officially submitted as an unfunded requirement.

RECOMMENDATION: Sign the letters (TAB A).

COORDINATIONS: ODoD(GC), ASD(HA), ASD(LA), DIR(ARA), USD(C), DIR(DP), DUSD(IP), JRO(CBRN) (TAB E)

Attachments:
As stated

CC: PDUSD(AT&L)
Prepared by: LTC (b)(6), ODATSD(CBD), Medical Advisor (b)(6)

TAB A

THE UNDER SECRETARY OF DEFENSE
3010 DEFENSE PENTAGON
WASHINGTON, DC 20301-3010

ACQUISITION,
TECHNOLOGY
AND LOGISTICS

The Honorable Robert Byrd
Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510-6025

Dear Mr. Chairman:

The National Defense Appropriation Act for Fiscal Year 2003, Public Law 107-732, requires the enclosed report be submitted to the congressional defense committees on the Department of Defense's Anthrax Vaccine Supply Preparedness. A similar letter has been provided to the other congressional defense committees.

Sincerely,

E. C. Aldridge, Jr.

Enclosures:
As Stated

cc: The Honorable Ted Stevens
Ranking Member

THE UNDER SECRETARY OF DEFENSE
3010 DEFENSE PENTAGON
WASHINGTON, DC 20301-3010

ACQUISITION,
TECHNOLOGY
AND LOGISTICS

The Honorable Bob Stump
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515-6035

Dear Mr. Chairman:

The National Defense Appropriation Act for Fiscal Year 2003, Public Law 107-732, requires the enclosed report be submitted to the congressional defense committees on the Department of Defense's Anthrax Vaccine Supply Preparedness. A similar letter has been provided to the other congressional defense committees.

Sincerely,

E. C. Aldridge, Jr.

Enclosures:
As Stated

cc: The Honorable Ike Skelton
Ranking Member

THE UNDER SECRETARY OF DEFENSE
3010 DEFENSE PENTAGON
WASHINGTON, DC 20301-3010

ACQUISITION,
TECHNOLOGY
AND LOGISTICS

The Honorable Carl Levin
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510-6050

Dear Mr. Chairman:

The National Defense Appropriation Act for Fiscal Year 2003, Public Law 107-732, requires the enclosed report be submitted to the congressional defense committees on the Department of Defense's Anthrax Vaccine Supply Preparedness. A similar letter has been provided to the other congressional defense committees.

Sincerely,

E. C. Aldridge, Jr.

Enclosures:
As Stated

cc: The Honorable John Warner
Ranking Member

THE UNDER SECRETARY OF DEFENSE

3010 DEFENSE PENTAGON
WASHINGTON, DC 20301-3010

ACQUISITION,
TECHNOLOGY
AND LOGISTICS

The Honorable C.W. "Bill" Young
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515-6015

Dear Mr. Chairman:

The National Defense Appropriation Act for Fiscal Year 2003, Public Law 107-732, requires the enclosed report be submitted to the congressional defense committees on the Department of Defense's Anthrax Vaccine Supply Preparedness. A similar letter has been provided to the other congressional defense committees.

Sincerely,

E. C. Aldridge, Jr.

Enclosures:
As Stated

cc: The Honorable David Obey
Ranking Member

TAB B

CHEMICAL AND BIOLOGICAL DEFENSE

The conferees agree to establish a "Chem-bio Defense Initiatives Fund" within the Department of Defense's Chemical and Biological Defense program, and provide an increase of $25,000,000 for this purpose. The Secretary of Defense is directed to allocate these funds among the program proposals listed below in a manner which yields the greatest gain in our chem-bio defensive posture. The program proposals to be considered are:

The National Center for Biodefense;
Chem-bio Threat Mitigation technologies;
Global Pathogen Science Portal;
Advanced Sensors for Chem-bio Agents;
Rapid Sensitive Biowarfare Protection;
Diagnostic Tool for Biowarfare;
Ultra-High Field Instrumentation;
Urban Security Initiative;
Chemical Imaging Birthreat Detection;
Biological Agent Sensor/Detection System;
Chem-bio Air Filtration System;
Food Safety and Security Sensors;
Bioinformatics;
Phylogenetic- and PCR-based Detector System;
Field Portable Nucleic Acid Bioterrorism Detection;
CBIA-Inspector Transportable Chem-bio Detection System;
Distributed Chemical Agent Sensing and Transmission;
Wide-Area Standoff Chem-bio Agent Detection System;
Air Purification for Protection System;
Rapid Antibody-based Countermeasures;
Oral Anthrax Antibiotic;
Plant Vaccine Development;
Rapid Response Senior Networking for Multiple Applications; and
Chemical Biological Incident Response Force (CBIRF).

ANTHRAX VACCINE SUPPLY PREPAREDNESS

The conferees are concerned about the adequacy of the supply and production capacity for the only FDA-licensed anthrax vaccine currently available in the U.S. to protect our military and civilian defense personnel from the demonstrated and potential future threat of anthrax. The Secretary of Defense is directed to provide a report which assesses the immediate and short-term preparedness and potential future total biowarfare defense need for the FDA-licensed anthrax vaccine, the potential need for expanded production capacity to meet that need, and the need for a separate production capacity to mitigate risks of an event which could result in a halt to current vaccine production. The Secretary shall submit this report to the congressional defense committees within 90 days after enactment of this Act.

CHRONIC MULTI-SYMPTOM ILLNESSES

The conferees have provided $6,200,000 to extend research on chronic multi-symptom illnesses with a special focus on the relationship between Gulf War illnesses and other diseases,

TAB C

Report on Preparedness of the Anthrax Vaccine Supply

This report is the response to the requirement of the House of Representatives October 9, 2002, Conference Report 107-732 for the FY03 Department of Defense Appropriations Act.

"The conferees are concerned about the adequacy of the supply and production capacity for the only FDA-licensed anthrax vaccine currently available in the U.S. to protect our military and civilian defense personnel from the demonstrated and potential future threat of anthrax. The Secretary of Defense is directed to provide a report which assesses the immediate and short-term preparedness and potential future total biowarfare defense need for the FDA-licensed anthrax vaccine, the potential need for expanded production capacity to meet that need, and the need for a separate production capacity to mitigate risks of an event which could result in a halt to current vaccine production. The Secretary shall submit this report to the congressional defense committees within 90 days after enactment of this act."

Assessment of the immediate and short-term preparedness and potential future total biowarfare defense need for the FDA-licensed anthrax vaccine, and the potential need for expanded production capacity to meet that need:

The Department of Defense (DoD) has conducted an evaluation of projected Anthrax Vaccine Adsorbed (AVA) requirements and the industrial base; it concludes that the capacity at the BioPort facility in Lansing, Michigan, given present capabilities and absent major manufacturing interruptions, is adequate to meet currently projected DoD immunization requirements and other validated Federal agency requirements by September 2006. However, the Department has received additional requests for AVA, from other domestic and foreign sources, that are not addressed in this analysis because they have not yet been validated as requirements. If these additional requests increase the requirement, the current capacity at the Lansing facility would not be sufficient.

Assessment of the need for a separate production capacity to mitigate risks of an event which could result in a halt to current vaccine production:

In addition to the potential for additional requirements, there is a need for a separate production capability to mitigate the vulnerability associated with reliance upon a single source for AVA. The risk of losing production capability, whether as a result of industrial issues, natural disasters, or terrorism, must be reduced. Establishment of a second production source will accomplish that objective, and may likewise condense the timetable for eventual manufacturing of a Next Generation Anthrax Vaccine (NGAV). Because of the extensive lead times associated with the regulatory process of validating manufacturing facilities for biological drugs, licensure by the Food and Drug Administration (FDA) and other market-related barriers to the entry of new AVA suppliers, the DoD has only a limited number of meaningful options to diminish the risk inherent in the existence of a sole manufacturer for AVA.

The DoD strategy proposes development of an alternative production source in alliance with BioPort who, as the license-holder, would secure additional manufacturing capability at a second site. The participation of BioPort mitigates risk by minimizing the learning curve of knowledge and experience, thereby reducing the time necessary to obtain FDA approval of the second facility. An evolutionary acquisition strategy will be pursued; such an incremental approach should lessen the overall financial investment required by the DoD and allay sole reliance on a single manufacturing facility until NGAV is approved by the FDA and is in full-scale production.

Efforts are currently underway to establish interim redundancy. The four phases are listed below:

- As the first phase of an incremental approach, an alternate testing site for potency testing and the qualification of a secondary vaccine filling facility are currently being sought; this will provide back-up capability for these two essential operations and reduce risk until a full-scale second-source facility can be established or NGAV becomes available.

- The second phase would involve securing the additional production facility, installation of fermentors, and obtaining FDA approval to conduct bulk manufacturing and formulation at that location. The bulk vaccine would then be transferred to the other sites for testing and filling.

- The third, and most critical phase would be establishment of an independent production infrastructure at the new facility, with the expertise in quality assurance and regulatory affairs necessary to obtain facility licensure from the FDA and to establish a full manufacturing capability at the autonomous location.

- The fourth phase would comprise installation of new fermentors and modification of the production suite(s) in order to manufacture NGAV. This would provide a primary facility or second source facility to be available to the companies who will compete for development and production of the NGAV..

This new production facility would strengthen the industrial base, significantly reduce the risk of losing the BioPort-Lansing facility, and provide a manufacturing capability for NGAV. This phased approach minimizes risk while maximizing financial flexibility since it does not require early and untimely commitment to full scale-construction of a second facility and its infrastructure. The approach provides the agility to modify direction as requirements change, whether as the result of earlier-than-anticipated availability of NGAV or because of a reduced demand for the current AVA product.

The various options discussed in this report are not currently funded in the Program Objective Memorandum nor submitted as an official Unfunded Requirement. In addition, they have not been fully coordinated within the DoD

TAB D

THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

July 26, 2002

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
UNDER SECRETARIES OF DEFENSE
DIRECTOR, DEFENSE RESEARCH AND ENGINEERING
ASSISTANT SECRETARIES OF DEFENSE
GENERAL COUNSEL OF THE DEPARTMENT OF DEFENSE
INSPECTOR GENERAL OF THE DEPARTMENT OF DEFENSE
DIRECTOR, OPERATIONAL TEST AND EVALUATION
ASSISTANTS TO THE SECRETARY OF DEFENSE
DIRECTOR, ADMINISTRATION AND MANAGEMENT
DIRECTOR, PROGRAM ANALYSIS AND EVALUATION
DIRECTOR, FORCE TRANSFORMATION
DIRECTORS OF THE DEFENSE AGENCIES
DIRECTORS OF THE DOD FIELD ACTIVITIES

SUBJECT: Expeditious Submission of Reports to Congress and Congressional Committees

In order to expedite the submission of required reports to the Congress, officials assigned responsibility by the Under Secretary of Defense (Comptroller) under DoD Directive 5545.2, "DoD Policy for Congressional Authorization and Appropriations Reporting Requirements," for preparing Secretarial Reports are delegated the authority to submit reports directly to the Congress or its Committees. This delegation of authority may be redelegated in writing to the Heads of DoD Components and to other civilian officials of the Department of Defense appointed by the President with the advice and consent of the Senate.

Notwithstanding the foregoing, when deemed appropriate, a report may be forwarded to the Secretary or Deputy Secretary of Defense for review and submission to the Congress or its Committees. Such reports shall be forwarded in sufficient time to permit review and submission before the report due date.

All Secretarial Reports required by law shall be coordinated with the Under Secretary of Defense (Comptroller), the Assistant Secretary of Defense (Legislative Affairs), the DoD General Counsel and, as appropriate, other DoD officials having collateral or related responsibilities.

U11837-02

All Secretarial Reports requested in committee or conference reports shall be coordinated with the Under Secretary of Defense (Comptroller), the Assistant Secretary of Defense (Legislative Affairs), the DoD General Counsel, and, as appropriate, other DoD officials having collateral or related responsibilities.

U11837-02

TAB E

Anthrax Vaccine Supply Preparedness - Report to Congress

Coordination*

	Concur	Non-concur	Concur with Comments
USD(C)			
DUSD(IP)			
ODoD(GC)			
ASD(HA)			
ASD(LA)			
DIR(ARA)			
DIR(DP)			
JRO(CBRN)			

* Please print the name of the principal responding on this action.

ACTION MEMO

December 11, 2002, 1000 AM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: Coordination of Draft Report to Congress - Anthrax Vaccine Supply Preparedness

- The draft Report to Congress on Anthrax Vaccine Supply Preparedness was sent to ASD (HA) for coordination (TAB B).

- The draft has been reviewed and there are no statements, findings, or recommendations of issue. The draft Report to Congress is consistent with the Department of Defense Force Heath Protection and Readiness policies.

- It is recommended that ASD (HA) concur as written.

RECOMMENDATION: That ASD(HA) sign memo at TAB A.

COORDINATION: TAB C

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD/ODASD (FHP&R), (b)(6) PCDOCS# 43633,43827

MEMORANDUM FOR DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE FOR CHEMICAL AND BIOLOGICAL DEFENSE

SUBJECT: Coordination of Draft Report to Congress - Anthrax Vaccine Supply Preparedness

Thank you for the opportunity to coordinate on the subject draft Report to Congress. The Assistant Secretary of Defense for Health Affairs (ASD (HA)) has reviewed the document and concurs with draft report as written.

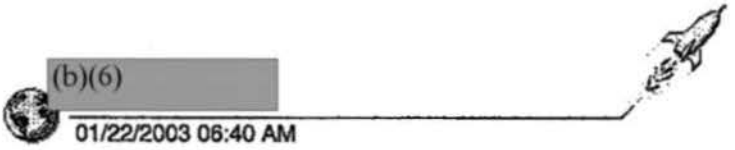
The ASD(HA) point of contact is Commander (b)(6) at (b)(6)

William Winkenwerder Jr., MD

SUBJECT: Coordination of Draft Report to Congress - Anthrax Vaccine Supply Preparedness

COORDINATIONS

Deputy Director, DHSD	Dr. Kilpatrick	Concur 12/11/02
PD, Preventive Medicine, FHP/R	COL Ben Diniega	Concur 12/11/02
Director, DHSD	Ms. Embrey	_____
C of S (HA)	Ms. Tabler	_____
PDASD (HA)	Mr. Wyatt	_____



(b)(6)

01/22/2003 06:40 AM

To: (b)(6)
cc:

Subject: FW: Hearing Preparation for Dr. Chu - Tasking for Info Papers - D UE NOON 1/22

Hear was the task. Will forward the papers to you next. (b)(6)

---------- Forwarded by (b)(6) on 01/22/2003 06:44 AM ----------

"Rauch, Terry, COL, OASD(HA)" (b)(6) @ha.osd.mil> on 01/17/2003 05:26:32 PM

To: (b)(6)

cc:

Subject: FW: Hearing Preparation for Dr. Chu - Tasking for Info Papers - D UE NOON 1/22

Alcon: See below, please.

(b)(6): You've got GW and SHAD

Anthrax and Smallpox - work with AVIP

PB: (b)(6)

Please get to me for Ms E review by cob 21 Jan.

Thanks

(b)(6)

-----Original Message-----
From: (b)(6)
Sent: Friday, January 17, 200312:31 PM
To: (b)(6)
(b)(6)

Subject: Hearing Preparation for Dr. Chu - Tasking for Info Papers - DUE NOON1/22
Importance: High

Please see the list of information papers below that we need to provide to Dr. Chu in preparation for the Congressional hearings. Attached is the sample format from P&R. Please forward your information papers to (b)(6) **and** (b)(6) (b)(6) **by Noonon 1/22. Thanks very much for your assistance.**

(b)(6)

FHP&R

Force Health Protection (FHP) - How are we doing better since the Gulf War?

Anthrax

Smallpox

SHAD

Pyridostigmine Bromide

CAPT (b)(6)

DoD/VA Joint Strategic Planning

(b)(6)

Regional Governance

Ops:

Next Generation of TRICARE Contracts (T-Nex) - How this is better from current Contracts

Provider Reimbursement/Network Adequacy

TRICARE For Life (TFL)

Pharmacy - Retail Contract/T-Nex

Claims Processing Performance

Reserve Health Care (including demo)

DoD/VA Collaboration (one page summary for P&R that addresses highlights of resource sharing, Federal Health Information Exchange, Joint Procurement and CMOP)

Regional Ops

Puerto Rico- Plan for Under-65 Retirees

RM:

Special Pay

DHP FY2004

Accrual Fund

Flexibility to Manage Military Health Care System

Response to GAO report regarding Third Party Collections, eligibility etc...

IMT&R:

Theater Medical Information Program (TMIP)

Information Security - TriWest Incident

 - budgetissuepaperformat.doc

(b)(6)
Project Support Manager
Deployment Health Support Directorate
(b)(6)

Pyridostigmine bromide

MESSAGE:

- The Department of Defense (DoD) has pre-positioned, for force health protection purposes, several million doses of pyridostigmine bromide (PB) labeled as an investigational new drug (IND) as a nerve agent pretreatment against soman.
- As background, soman is an extremely lethal nerve agent, confirmed or strongly suspected to be in the arsenal of a number of potential adversaries. Standard treatments for other nerve agents must be administered within two minutes of exposure to soman to be effective. There is currently no effective pre-treatment approved by the Food and Drug Administration (FDA) for exposure to this agent. However, the results of animal tests suggest that use of PB as a pretreatment adjunct, coupled with standard post-exposure treatments, may be protective. PB is approved by the FDA as safe and effective treatment of certain neuromuscular disorders, but has not been approved in the U.S. for marketing as a nerve agent pre-treatment.
- On January 6, 2003, the Department submitted a New Drug Application (NDA) to the Food and Drug Administration (FDA) for approval of PB for this indication.

FY 2004 Program/Budget Impact:

- In the U.S., PB is classified as an "investigational new drug" for this medical purpose. PB was widely used during the Gulf War under special procedures approved by the FDA. In the aftermath of the Gulf War, concerns have been expressed as to whether PB may have contributed to Gulf War veterans' illnesses. Reviews conducted by the Institute of Medicine and the Presidential Advisory Committee on Gulf War Veterans' Illnesses did not consider PB a likely cause, but a Rand report concluded that medical research to date has not ruled out some hypotheses of PB as a possible contributor. The Rand report was the subject of further independent review by the Armed Forces Epidemiology Board and the Institute of Medicine. DoD has funded over $20 million for research concerning the safety and efficacy of PB as a nerve agent pretreatment adjunct. Data from some of these studies was submitted to the FDA for approval of PB under the newly established animal efficacy rule.

- Evidence of the effectiveness of PB as a pre-treatment for soman was based solely on animal studies because it is unethical to expose people to lethal nerve agents in order to test the effectiveness of a drug.

Issues:

- The DoD must always balance the risks of war, to include the potential for use of deadly nerve agents such as soman, with the possible side effects from drugs such as PB. Currently, PB is thought to be an essential part of the medical protection our troops have for soman, which is extremely lethal. However, PB does have known short-term side-effects, such as diarrhea, and some veterans remain concerned that hypotheses regarding long term effects have not been disproved. We must continue our efforts to improve how we protect our troops against deadly nerve agents. Providing the best protection to our troops sometimes involves balancing several issues. The benefits of pyridostigmine far outweigh the risks

Subject: Shipboard Hazard and Defense

MESSAGE:

- Project SHAD (Shipboard Hazard and Defense) was a chemical and biological weapons vulnerability testing program in the 1960's that was part of a larger Deseret Test Center program.
- The DoD conducted SHAD tests primarily using substances believed to be safe in place of chemical or biological warfare agents to simulate the dispersion of harmful agents in a chemical or biological attack.
- A few veterans have expressed concern that they may have been exposed to harmful substances during these classified tests. At the request of the Department of Veterans Affairs, DoD investigators are searching through classified technical documents archived in various locations to identify reports about SHAD testing. Information provided to the VA is intended to allow them to verify specific servicemember involvement, and clarify possible exposure substances.
- Congress has directed completion of the DoD's investigation by the end of the summer and publication of an interim and final reports.

Issues:

- Congress provided no specific funding for the SHAD investigation, or for the required reports.
- SHAD investigations and reporting should be completed in FY03, so there are no issues for FY04.

(b)(6) DHSD, January 22, 2003

Subject: Force Health Protection (FHP) –
How are we doing better since the Gulf War?

MESSAGE: The DoD has applied medical lessons learned from the Gulf War in the following programs to help protect the health of military personnel before, during, and following deployments.

- **Force Health Protection Strategy:** DoD has developed a Force Health Protection strategy that promotes the health of servicemembers before deployment, protects personnel during deployment, and provides treatment for deployment-related health conditions.
  - **Initiatives:** The ASD(HA) with support of the Joint Staff and the Military Services is developing individual medical readiness standards and developing a new Force Health Protection directive to institutionalize our emphasis on force health protection.
- **Deployment Health Surveillance:** The DoD instituted a deployment health surveillance program that includes pre-and post-deployment health assessments, which validate individuals' medical readiness to deploy and address health concerns upon their return; individual serum specimens maintained in the DoD Serum Repository; and improved occupational and environmental health surveillance programs that help protect service members' health during deployment.
  - **Initiatives:** The ASD(HA) is developing streamlined deployment health assessments, implementing an interim system like the Theater Medical Information Program for medical surveillance, and establishing a management structure for comprehensive medical surveillance needs, along with comprehensive policies for deployment occupational and environmental health surveillance.
- **Deployment Health Centers:** The DoD has established three deployment health centers (for health surveillance, health care, and health research) that focus on the prevention, treatment, and understanding of deployment health concerns, including development of a post-deployment health clinical practice guideline.
  - **Initiative:** The ASD(HA) is developing metrics for assessing the effectiveness of the deployment health centers and the post-deployment clinical practice guideline.
- **Health Risk Communication:** The DoD has improved health risk communication through the provision of regionally-specific medical intelligence, environmental risk assessments, medical threat briefings, outreach programs, and deployment web sites.
  - **Initiative:** The ASD(HA) is developing metrics to assess the effectiveness of outreach programs that provide information exchange with veterans, their families, and the public.

- **Coordination with the Department of Veterans Affairs (VA):** The DoD coordinates with the VA on deployment health concerns through a DoD/VA Deployment Health Working Group.
  - **Initiative:** The ASD(HA) is working with the VA to ensure the effectiveness of the DoD/VA Deployment Health Working Group to resolve DoD and VA deployment health-related issues.
- **Medical Record Keeping:** The DoD is developing the Composite Health Care System II and the Theater Medical Information Program to create electronic medical records and improve deployment medical record-keeping.
  - **Initiative:** The ASD(HA) is working with the Military Services to develop an improved process for incorporating individual servicemember medical records from deployments into permanent health records.

COL John Gardner/Mr. (b)((b)(6 DHSD, January 22, 2003

ISSUE PAPER

DOD Smallpox Vaccination Program

MESSAGE: The DoD Smallpox Response Plan was signed on 30 Sep 02 and distributed throughout DoD. The plan provided guidelines so that DoD could respond appropriately to a smallpox event against DoD personnel/units/installations in CONUS or OCONUS and minimize the impacts of such attacks. The response plan includes the use of smallpox vaccine post-attack. The President announced the DoD Smallpox Vaccination Program on 13 Dec 02. This policy provides for the use of recently licensed smallpox vaccine in a pre-attack scenario for members of smallpox response teams, hospital-based health care teams, and specified deployed and deploying units and their critical support personnel. The SVP began in mid-December 2002 with the vaccination of response team and health care team personnel. Vaccination of select deployed personnel began in early January 2003. A total of about 500,000 personnel will be vaccinated.

FY 2004 Program Impact:

- The SVP supports current war efforts and contingency readiness. Evidence of biological weapons and training has been found in areas where US Forces are deployed or planning to deploy. Pre-vaccination will ensure military survival in a smallpox outbreak, but will also preserve military capability to respond. Sole dependence on post-attack vaccination would have severely impacted on our ability to operate during contingencies.

Issues:

- Smallpox vaccination could result in death (1-2 per million vaccinations) or other severe adverse effects (e.g., severe skin reactions) requiring treatment with vaccinia immune globulin (VIG) (100 per million vaccinations). DoD is monitoring personnel vaccinated for adverse events and is prepared to manage and treat adverse events that may occur. Additional VIG is being manufactured.
- Supplies of licensed smallpox vaccine are limited, and any major expansion of the SVP will have to be done using vaccine under an Investigational New Drug (IND) protocol (cumbersome requirements), or be delayed until additional licensed vaccine becomes available. Both DoD and HHS efforts to develop additional vaccine have been accelerated.
- Service members injured by smallpox vaccine would receive care from DoD hospitals and be eligible for the military or Veterans Affairs disability systems. Family members would receive care from DoD hospitals. Civilian employees (mostly healthcare workers) would be evaluated at DoD medical facilities and eligible for worker's compensation under the Federal Employees Compensation Act. Contractor personnel would be evaluated at DoD medical facilities; their eligibility for worker's compensation would be determined under their State worker's compensation program. With respect to potential liability of those who administer smallpox vaccinations, military members, civilian employees, or personal-services contract personnel are protected from law suits and personal liability under Federal law; the only litigation remedy is against the Federal Government under the Federal Tort Claims Act.
- The SVP is an unfunded program to date. Implementation costs have been absorbed by the Services.

COL Benedict M. Diniega/OASD(HA/FHP&R)/(b)(6) */January 21, 2003*

ISSUE PAPER

Anthrax Vaccine Immunization Program

MESSAGE:

- Anthrax is readily weaponized and highly lethal. It poses a clear threat as demonstrated by the anthrax terror attacks along our eastern seaboard in the fall of 2001 when five people were killed and 13 others infected by this deadly biological agent. The results of those attacks disrupted government operations and threatened the US Postal Service.

- Since March 1998, the Department of Defense has protected its personnel against anthrax weapons by means of the Anthrax Vaccine Immunization Program. To date, more than 2 million doses of anthrax vaccine have been given to more than 565,000 Service Members.

- Current policy requires mandatory protective vaccination of selected personnel who are assigned to, deployed to designeated higher-threat areas.

- After an exhaustive review, the National Academy of Sciences concluded that anthrax vaccine is effective against all forms of anthrax and is as safe as other vaccines commonly given to adults.

- Anthrax vaccine is a critical component in our arsenal against bioterrorism.

- DoD is working with the Department of Health and Human Services and other federal agencies to develop a next generation anthrax vaccine that is expected to offer a more user-friendly regimen than the current vaccine which requires six shots with yearly boosters.

FY 2004 Program/Budget Impact:

- Current intelligence assessments indicate that the anthrax threat to DoD forces is real.

- The Department's goal is to protect all forces against anthrax as a part of the Department's Force Health Protection program.

- Current scope of the immunization program encompasses personnel assigned to or deployed for more than 15 consecutive days in higher threat areas whose performance is essential for certain mission critical capabilities.

COL Denise Baken/OASD(HA/FHP&R) (b)(6) /January 21, 2003

Issues:

- Present funding supports current and estimated future needs.
- Budget and Program Data ($ in millions)

	Prior Yr (FY02)	Current (FY03)	Budget (FY04)	FYDP (FY05-09)	Total
DHP[1]	14.4	16.1	16.8	90.9	138.2
Army Procurement[2]	49.5	42.7	63.3	290.8	446.4

[1] Funds the Army's AVIP Agency Operations
[2] Funds vaccine procurement- transfer from Chemical and Biological Defense Program

HA/TMA Document Profile

46207

Subject: Anthrax and Smallpox Vaccines to DoD Personnel and Family Members Overseas

Author: Armitage, Richard L.
Date of Document: 2/21/2003
OSD # : U02290-03
PR # : 0105173
Organization: Department of State
Department:
Assigned To: DHS
Prepared For: ASD
Suspense Date: 3/6/2003
Coord Office(s):

Congressional Name:
Input By: (b)(6)
Profiler's Directorate: Admin, HA
Response Signed By:
Dt Response Signed:
Doc Type: LETTER
Application: DOCSIMAGE
Previous Documents:
Related Documents:
Notes:

Beneficiary Info
Beneficiary Name:
Address 1:
Apartment #
Phone #
Email Address:
City:
State: **Zip**

History
Created: 2/24/2003 HA PCDOCS Adr
Edited: 2/24/2003 HA PCDOCS Adr
Status: Available

Retention Schedule
Type: Archive
Retention Days: 365

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Access Control
☒ **Secure Document**
☐ **Enable Content Searching**

ACTION MEMO

May 23, 2003, 7:15 AM

FOR: UNDER SECRETARY OF DEFENSE (PERSONNEL AND READINESS)

FROM: William Winkenwerder Jr., MD, Assistant Secretary of Defense (Health Affairs)

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Offered Anthrax and/or Smallpox Vaccines on a Voluntary Basis Because of Location in a High Threat Area.

- Attached is a supplemental policy memorandum for individuals receiving anthrax and/or smallpox vaccines on a voluntary basis because of location in a high threat area (HTA).

- The policy provides a matrix graphically explaining those categories of personnel, the general locations, and circumstances in which a person may receive anthrax and/or smallpox vaccinations in accordance with existing OSD policies.

- The Services agree the intent of policy; however, they recommend the immediate declassification of Dr. Chu's memo listing the countries considered a DoD high-threat area and to include these countries in the policy document. These recommendations were not accepted due to the dynamic nature of the DoD HTA list, which would require a continual updating of policy.

RECOMMENDATION: Sign policy memorandum at TAB A

COORDINATION: TAB C

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD, (b)(6) PCDOCS#46207

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
UNDER SECRETARIES OF DEFENSE
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
INSPECTOR GENERAL, DEPARTMENT OF DEFENSE
COMMANDANT OF THE COAST GUARD
DIRECTOR, JOINT STAFF

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Offered the Anthrax and/or Smallpox Vaccines on a Voluntary Basis Because of Location in a High Threat Area.

The February 14, 2003, Deputy Secretary of Defense memorandum, Subject: Vaccinating Department of Defense (DoD) Personnel and Dependents Assigned to Department of State (DoS) Missions in High-Threat Areas, and the March 13, 2003, Assistant Secretary of Defense (Health Affairs) memorandum, Subject: Clarification of Service Responsibilities in Vaccinating Department of Defense (DoD) Personnel and Dependents Assigned to Department of State (DoS) Missions or Residing in Higher-Threat Areas, directed the Military Departments to provide anthrax and smallpox vaccinations on a voluntary basis to categories of persons in certain overseas high threat areas. This memorandum provides supplementary administrative guidance for individuals offered the anthrax and smallpox vaccines on a voluntary basis because of location in a high threat area.

In an effort to support the DoS, their measures to protect personnel, and DoD personnel supporting the DoS mission, policies were issued to delineate these efforts. However, other categories of individuals, locations, and circumstances were identified as not being specifically addressed. Table 1 (attached) is a matrix explaining those categories of personnel and the locations and circumstances in which a person may receive anthrax and /or smallpox vaccinations.

The Services are directed to meet all the same educational, clinical, and administrative requirements to administer vaccinations for these categories of personnel as directed in previous administrative and clinical policies for both the DoD Anthrax Vaccine Immunization Program and the Smallpox Vaccination Program.

It is essential that individuals receiving the Anthrax and/or Smallpox Vaccines on a voluntary basis complete an acknowledgement form prior to receiving these immunizations. These forms can be found on DoD's MILVAX website: www.vaccines.army.mil. The signed form must be entered into the individual's medical record.

The Services are directed to document all immunizations, preferably in their service's automated immunization tracking system, as each system's capability allows. At a minimum, immunizations should be documented in the individual health record and the International Certificates of Vaccination, PHS-731.

When practicable, adverse events in any individual receiving immunizations on a voluntary basis should be evaluated at the closest Medical Treatment Facility (MTF). Vaccine Adverse Events Reporting System (VAERS) forms should be submitted in accordance with existing Service reporting procedures. VAERS forms are available at www.vaers.org or by calling VAERS at 1-800-822-7967.

This policy is effective immediately and should be communicated to appropriate commanders, healthcare providers, and others involved in the implementation of the anthrax and smallpox immunization programs. Questions regarding this memorandum should be directed to the Director, Military Vaccine Agency at (703) 681-5101.

David S. C. Chu

Attachment:
As stated

ANTHRAX AND /OR SMALLPOX VACCINATIONS MATRIX

Table 1

Personnel Category	Located in DoD HTA	Located in a Non-DoD HTA; but in DoS HTA; assigned to DoS mission	Located in a Non-DoD HTA; but in DoS HTA; not assigned to DoS mission	Conditions:
	Vaccination is:	**Vaccination is:**	**Vaccination is:**	
Military	Mandatory	Permitted, Voluntary	Not Permitted	
Adult FM of Military member	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Emergency Essential DoD Civilian (E-E)*	Mandatory	Permitted, Voluntary	Not Permitted	Civilian Personnel Procedures Apply
Non-E-E	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	Civilian Personnel Procedures Apply
Adult FM of DoD Civilian (E-E and Non-E-E)	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Mission Essential Contractor (MEC)**	Mandatory	Permitted, Voluntary	Not Permitted	If mandatory, must be stated in contract
Non-MEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Adult FM of Contractor (MEC and Non-MEC)	Not Permitted	Not Permitted	Not Permitted	

* DoD civilian personnel classified as emergency-essential under DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees," April 10, 1999

** Contractor personnel performing mission essential services as described in DoDI 3020.37, "Continuation of Essential DoD Contractor Services During Crisis," November 6, 1990

SIGNED RESPONSE

ACTION MEMO

April 15, 2003, 2:15 p.m.

FOR: William Winkenwerder Jr., MD, ASD (Health Affairs)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness
//s//4/14/03

SUBJECT: Request for Coordination on Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program

- Attached is a draft supplemental policy memorandum for individuals receiving anthrax and/or smallpox vaccines under the Department of Defense Voluntary Immunization Program to forward for coordination with the Services, Joint Staff, and appropriate offices (TAB B).

- The policy provides a matrix graphically explaining those categories of personnel, and the locations and circumstances in which they may receive anthrax and/or smallpox vaccinations in accordance with existing Office of the Secretary of Defense policies.

- Coordinating offices will be given two weeks from the date of the coordinating letter to respond.

RECOMMENDATION: That the ASD (HA) sign the memorandum at TAB A

COORDINATION: TAB C

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD, (b)(6), PCDOCS# 48381

ACTION MEMO

FOR: UNDER SECRETARY OF DEFENSE (PERSONNEL & READINESS)

FROM: William Winkenwerder Jr., MD, ASD (Health Affairs)

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

- Attached is a draft supplemental policy memorandum for individuals receiving anthrax and/or smallpox vaccines under the Department of Defense Voluntary Immunization Program to forward for coordination with the Services, Joint Staff, and appropriate offices (TAB A).

- The policy provides a matrix graphically explaining those categories of personnel, and the locations and circumstances in which they may receive anthrax and/or smallpox vaccinations in accordance with existing Office of the Secretary of Defense policies.

- Coordinating offices will be given two weeks from the date of the coordinating letter to respond.

RECOMMENDATION: That the USD(P&R) sign the policy memorandum at TAB A and forward for coordination.

COORDINATION: TAB B

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD, (b)(6) , PCDOCS# 48381

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D C 20301-1200

HEALTH AFFAIRS

APR 2 2 2003

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETRAY OF THE AIR FORCE (M&RA)
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
DIRECTOR, JOINT STAFF

SUBJECT. Request for Coordination on Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program

Request your coordination not later than two weeks from the date of this memorandum on the attached draft policy memorandum delineating those categories of personnel, locations, and circumstances in which a person may receive anthrax and/or smallpox vaccinations under the Voluntary Immunization Program

My point of contact for this matter is CDR (b)(6) who may be reached at (b)(6) Coordination may be faxed to (b)(6) No response will be taken as concurrence

William Winkenwerder, Jr., MD

Attachments
As stated

cc
J-4 (DHS)
Surgeon General, Army
Surgeon General, Navy
Surgeon General, Air Force
Medical Officer, HQ, US Marine Corps
Director of Health and Safety, US Coast Guard

DRAFT

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETRAY OF THE AIR FORCE (M&RA)
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
GENERAL COUNSEL, DEPARTMENT OF DEFENSE

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program

The February 14, 2003, Deputy Secretary of Defense memorandum, Subject: Vaccinating Department of Defense (DoD) Personnel and Dependents Assigned to Department of State (DoS) Missions in High-Threat Areas, and the March 13, 2003, Assistant Secretary of Defense (Health Affairs) memorandum, Subject: Clarification of Service Responsibilities in Vaccinating Department of Defense Personnel and Dependents Assigned to Department of State Missions or Residing in High-Threat Areas, directed the services to provide anthrax and smallpox vaccinations on a voluntary basis to categories of persons in certain overseas high-threat areas. This memorandum provides supplementary administrative guidance for a Voluntary Immunization Program (VIP) with anthrax and smallpox vaccines.

In an effort to support the DoS measures to protect personnel, and DoD personnel supporting the DoS mission, policies were issued to delineate these efforts. However, other categories of individuals, locations, and circumstances were identified as not being specifically addressed.

Table 1 (attached) is a matrix graphically explaining those categories of personnel and the locations and circumstances in which a person may receive anthrax and/or smallpox vaccinations in accordance with the above Office of the Secretary of Defense (OSD) policies.

The Services are directed to meet all the same educational, clinical, and administrative requirements to administer vaccinations in these categories of personnel as directed in previous OSD administrative and clinical policies for both the DoD Anthrax Vaccine Immunization Program and Smallpox Vaccination Program.

It is essential that individuals receiving the anthrax and/or smallpox vaccines on a voluntary basis be required to complete an acknowledgement form prior to receiving any immunization. These forms can be found on DoD's MILVAX website: www.vaccines.army.mil. The signed form must be entered into the individual's medical record.

The Services are directed to document all immunizations; preferably in their service's automated immunization tracking system, as each system's capability allows. At a minimum, immunizations should be documented in the individual health records, PHS 731.

Adverse events in any individual receiving immunizations under the voluntary immunization program should be evaluated at the closest medical treatment facility. Vaccine Adverse Events Reporting System (VAERS) forms should be submitted in accordance with existing service reporting procedures. VAERS forms are available at www.vaers.org or by calling VAERS at 1-800-822-7967.

This policy is effective immediately and should be communicated to appropriate commanders, healthcare providers, and others involved in the implementation of the anthrax and smallpox immunization programs.

David S. C. Chu

Attachment:
As stated

Table 1

Personnel Category	Located in DoD HTA	Located in a Non-DoD HTA; but in DoS HTA; assigned to DoS mission	Located in a Non-DoD HTA; but in DoS HTA; not assigned to DoS mission	Conditions:
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Military	Mandatory	Permitted, Voluntary	Not Permitted	
Adult FM of Military member	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Emergency Essential DoD Civilian (EEC)*	Mandatory	Permitted, Voluntary	Not Permitted	
Non-EEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Adult FM of DoD Civilian (EEC and Non-EEC)	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Mission Essential Contractors (MEC)**	Mandatory	Permitted, Voluntary	Not Permitted	Must be Stated in Contract
Non-MEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	Must be Stated in Contract
Adult FM of Contractor (MEC and Non-MEC)	Not Permitted	Not Permitted	Not Permitted	

* DoD civilian personnel classified as emergency-essential under DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees," April 10, 1999.

** Contractor personnel performing mission essential services as described in DoDI 3020.37, "Continuation of Essential DoD Contractor Services During Crisis," November 6, 1990.

Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

COORDINATION

	Concur	Non-concur	Comment
Assistant Sec of the Army (M&RA)	____	_____	_____
Assistant Sec of the Navy (M&RA)	____	_____	_____
Assistant Sec of the Air Force (M&RA)	____	_____	_____
OSD (OGC)	____	_____	_____
Dir, Joint Staff	____	_____	_____

Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

COORDINATION

DASD, FHP/R	Ms. Ellen P. Embrey	Concurred 4/14/03
DoD, OGC	(b)(6)	_____
CoS, HA		_____
PDASD, HA		_____

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Offered the Anthrax and/or Smallpox Vaccines on a Voluntary Basis Because of Location in a High Threat Area.

COORDINATIONS

DOD, OGC	(b)(6)	Concur 5/8/03
Army (M&RA)	MG Kendall Farmer	Concur 5/7/03 (not attached - classified)
Navy, (M&RA)	(b)(6)	Concur 6/4/03
Air Force, (M&RA)		Concur 5/8/03 With Comments Attached
DASD, FHP&R	Ms. Ellen P. Embrey	_____
CoS, HA	(b)(6)	_____
PDASD, HA		_____

ACTION MEMO

April 11, 2003, 10:00 AM

FOR: UNDER SECRETARY OF DEFENSE (PERSONNEL & READINESS)

FROM: William Winkenwerder Jr., MD, ASD (Health Affairs)

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

- Attached is a draft supplemental policy memorandum for individuals receiving anthrax and/or smallpox vaccines under the Department of Defense Voluntary Immunization Program to forward for coordination with the Services, Joint Staff, and appropriate offices (TAB A).

- The policy provides a matrix graphically explaining those categories of personnel, and the locations and circumstances in which they may receive anthrax and/or smallpox vaccinations in accordance with existing Office of the Secretary of Defense policies.

- Coordinating offices will be given two weeks from the date of the coordinating letter to respond.

RECOMMENDATION: Sign policy memo at TAB A and forward for coordination.

COORDINATION: TAB B

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD, (b)(6), PCDOCS# 48381

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETRAY OF THE AIR FORCE (M&RA)
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
DIRECTOR, JOINT STAFF

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

Request your coordination not later than two weeks from the date of this memorandum on the attached draft policy memorandum delineating those categories of personnel, locations, and circumstances in which a person may receive anthrax and/or smallpox vaccinations under the Voluntary Immunization Program.

My point of contact for this matter is CDR (b)(6) who may be reached at (b)(6). Concurrence may be faxed to (b)(6). No response will be taken as concurrence.

William Winkenwerder Jr., MD

Attachments:
As stated

cc:
J-4 (DHS)
Surgeon General, Army
Surgeon General, Navy
Surgeon General, Air Force
Medical Officer, HQ, US Marine Corps
Director of Health and Safety, US Coast Guard

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETRAY OF THE AIR FORCE (M&RA)
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
GENERAL COUNSEL, DEPARTMENT OF DEFENSE

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

The February 14, 2003, Deputy Secretary of Defense memorandum, Subject: Vaccinating Department of Defense (DoD) Personnel and Dependents Assigned to Department of State (DoS) Missions in High-Threat Areas, and the March 13, 2003, Assistant Secretary of Defense (Health Affairs) memorandum, Subject: Clarification of Service Responsibilities in Vaccinating Department of Defense Personnel and Dependents Assigned to Department of State Missions or Residing in High-Threat Areas, directed the Services to provide anthrax and smallpox vaccinations on a voluntary basis to categories of persons in certain overseas' high threat areas. This memorandum provides supplementary administrative guidance for a Voluntary Immunization Program (VIP) with anthrax and smallpox vaccines.

In an effort to support the DoS measures to protect its personnel, and DoD personnel supporting the DoS mission, policies were issued to delineate these efforts. However, other categories of individuals, locations, and circumstances were identified as not being specifically addressed.

Table 1 is a matrix graphically explaining those categories of personnel and the locations and circumstances in which a person may receive anthrax and/or smallpox vaccinations in accordance with the above Office of the Secretary of Defense policies.

Category	HTA	Non-DoD HTA; but in DoS HTA; assigned to DoS mission	Non-DoD HTA; but in DoS HTA; not assigned to DoS mission	
	Vaccination is:	Vaccination is:	Vaccination is:	
Military	Mandatory	Permitted, Voluntary	Not Permitted	
Adult FM of Military member	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Emergency Essential DoD Civilian (EEC)*	Mandatory	Permitted, Voluntary	Not Permitted	
Non-EEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Adult FM of DoD Civilian (EEC and Non-EEC)	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Mission Essential Contractors (MEC)**	Mandatory	Permitted, Voluntary	Not Permitted	Must be Stated in Contract
Non-MEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	Must be Stated in Contract
Adult FM of Contractor (MEC and Non-MEC)	Not Permitted	Not Permitted	Not Permitted	

* DoD civilian personnel classified as emergency-essential under DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees," April 10, 1999.

** Contractor personnel performing mission essential services as described in DoDI 3020.37, "Continuation of Essential DoD Contractor Services During Crisis," November 6, 1990.

The Services are directed to meet all the same educational, clinical, and administrative requirements to administer vaccinations in these categories of personnel as directed in previous OSD Administrative and Clinical policies for both the DoD Anthrax Vaccine Immunization Program and Smallpox Vaccination Program.

The signed form must be entered into the individual's medical record.

The Services are directed to document all immunizations: minimally in the individual health records, PHS 731, and preferably in their Service's automated immunization tracking system, as each system's capability allows.

Adverse events in any individual receiving immunizations under the voluntary immunization program should be evaluated at the closest Medical Treatment Facility. Vaccine Adverse Events Reporting System (VAERS) forms should be submitted in accordance with existing Service reporting procedures. VAERS forms are available at www.vaers.org or by calling VAERS at 1-800-822-7967.

This policy is effective immediately and should be communicated to appropriate commanders, healthcare providers, and others involved in the implementation of the anthrax and smallpox immunization programs.

David S.C. Chu

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

COORDINATION

	Concur	Non-concur	Comment
Assistant Sec of the Army (M&RA)	_____	_____	_____
Assistant Sec of the Navy (M&RA)	_____	_____	_____
Assistant Sec of the Air Force (M&RA)	_____	_____	_____
OSD (OGC)	_____	_____	_____
Dir, Joint Staff	_____	_____	_____

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

COORDINATION

DASD, FHP/R	Ms. Ellen P. Embrey	4/14/05
DoD, OGC	(b)(6)	
CoS, HA		
PDASD, HA		

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

April 15, 2003, 2:15 p.m.

FOR: William Winkenwerder Jr., MD, ASD (Health Affairs)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness
//s//4/14/03

SUBJECT: Request for Coordination on Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program

- Attached is a draft supplemental policy memorandum for individuals receiving anthrax and/or smallpox vaccines under the Department of Defense Voluntary Immunization Program to forward for coordination with the Services, Joint Staff, and appropriate offices (TAB B).

- The policy provides a matrix graphically explaining those categories of personnel, and the locations and circumstances in which they may receive anthrax and/or smallpox vaccinations in accordance with existing Office of the Secretary of Defense policies.

- Coordinating offices will be given two weeks from the date of the coordinating letter to respond.

RECOMMENDATION: That the ASD (HA) sign the memorandum at TAB A

COORDINATION: TAB C

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD, (b)(6), PCDOCS# 48381

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

APR 2 2 2003

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETRAY OF THE AIR FORCE (M&RA)
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
DIRECTOR, JOINT STAFF

SUBJECT: Request for Coordination on Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program

Request your coordination not later than two weeks from the date of this memorandum on the attached draft policy memorandum delineating those categories of personnel, locations, and circumstances in which a person may receive anthrax and/or smallpox vaccinations under the Voluntary Immunization Program.

My point of contact for this matter is CDR (b)(6) who may be reached at (b)(6). Coordination may be faxed to (b)(6) No response will be taken as concurrence.

William Winkenwerder, Jr., MD

Attachments:
As stated

cc:
J-4 (DHS)
Surgeon General, Army
Surgeon General, Navy
Surgeon General, Air Force
Medical Officer, HQ, US Marine Corps
Director of Health and Safety, US Coast Guard

DRAFT

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETRAY OF THE AIR FORCE (M&RA)
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
GENERAL COUNSEL, DEPARTMENT OF DEFENSE

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program

The February 14, 2003, Deputy Secretary of Defense memorandum, Subject: Vaccinating Department of Defense (DoD) Personnel and Dependents Assigned to Department of State (DoS) Missions in High-Threat Areas, and the March 13, 2003, Assistant Secretary of Defense (Health Affairs) memorandum, Subject: Clarification of Service Responsibilities in Vaccinating Department of Defense Personnel and Dependents Assigned to Department of State Missions or Residing in High-Threat Areas, directed the services to provide anthrax and smallpox vaccinations on a voluntary basis to categories of persons in certain overseas high-threat areas. This memorandum provides supplementary administrative guidance for a Voluntary Immunization Program (VIP) with anthrax and smallpox vaccines.

In an effort to support the DoS measures to protect personnel, and DoD personnel supporting the DoS mission, policies were issued to delineate these efforts. However, other categories of individuals, locations, and circumstances were identified as not being specifically addressed.

Table 1 (attached) is a matrix graphically explaining those categories of personnel and the locations and circumstances in which a person may receive anthrax and/or smallpox vaccinations in accordance with the above Office of the Secretary of Defense (OSD) policies.

The Services are directed to meet all the same educational, clinical, and administrative requirements to administer vaccinations in these categories of personnel as directed in previous OSD administrative and clinical policies for both the DoD Anthrax Vaccine Immunization Program and Smallpox Vaccination Program.

It is essential that individuals receiving the anthrax and/or smallpox vaccines on a voluntary basis be required to complete an acknowledgement form prior to receiving any immunization. These forms can be found on DoD's MILVAX website: www.vaccines.army.mil. The signed form must be entered into the individual's medical record.

The Services are directed to document all immunizations; preferably in their service's automated immunization tracking system, as each system's capability allows. At a minimum, immunizations should be documented in the individual health records, PHS 731.

Adverse events in any individual receiving immunizations under the voluntary immunization program should be evaluated at the closest medical treatment facility. Vaccine Adverse Events Reporting System (VAERS) forms should be submitted in accordance with existing service reporting procedures. VAERS forms are available at www.vaers.org or by calling VAERS at 1-800-822-7967.

This policy is effective immediately and should be communicated to appropriate commanders, healthcare providers, and others involved in the implementation of the anthrax and smallpox immunization programs.

David S. C. Chu

Attachment:
As stated

Table 1

Personnel Category	Located in DoD HTA	Located in a Non-DoD HTA; but in DoS HTA; assigned to DoS mission	Located in a Non-DoD HTA; but in DoS HTA; not assigned to DoS mission	Conditions:
	Vaccination is:	Vaccination is:	Vaccination is:	
Military	Mandatory	Permitted, Voluntary	Not Permitted	
Adult FM of Military member	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Emergency Essential DoD Civilian (EEC)*	Mandatory	Permitted, Voluntary	Not Permitted	
Non-EEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Adult FM of DoD Civilian (EEC and Non-EEC)	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Mission Essential Contractors (MEC)**	Mandatory	Permitted, Voluntary	Not Permitted	Must be Stated in Contract
Non-MEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	Must be Stated in Contract
Adult FM of Contractor (MEC and Non-MEC)	Not Permitted	Not Permitted	Not Permitted	

* DoD civilian personnel classified as emergency-essential under DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees," April 10, 1999.

** Contractor personnel performing mission essential services as described in DoDI 3020.37, "Continuation of Essential DoD Contractor Services During Crisis," November 6, 1990.

Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

COORDINATION

DASD, FHP/R	Ms. Ellen P. Embrey	Concurred 4/14/03
DoD, OGC	(b)(6)	_____
CoS, HA		_____
PDASD, HA		_____

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

COORDINATION

DASD, FHP/R	Ms. Ellen P. Embrey	EPE 4/14/03
DoD, OGC	(b)(6)	
CoS, HA		
PDASD, HA		

TRICARE

TRICARE Management Activity

DOCUMENT MANAGEMENT DIVISION
ADMIN OFFICE

ACTION OFFICE DHS DATE 4-22-03 PCDOCS # 48741

ATTN: CDR (b)(6) (R) 48381

The attached correspondence is returned for the following reason(s):

- ☐ **Distribution**
- ☐ **Coordination**
- ☐ **Revision**
- ☐ **Correct Signature Block**
- ☐ **Correct Envelope Size**
- ☐ **Correct Letterhead**
- ☐ **Provide Original/Supporting Documents**
- ☐ **Provide SD 391**
- ☐ **Retain for your Files**

Additional Comments:

Signed Response Scanned into PCDocs # 48741

Health Affairs

ROUTING AND TRANSMITTAL SHEET

TRICARE Management Activity

	Sign	Coord		Sign	Coord
4/22 ASD, HA BW	✓	✓	____ Dir, TMA		
____ PDASD, HA					
____ DASD, C&PP			____ CMO		
4/14 DASD, FHP&R		✓	____ Dir, DHS		
____ DASD, HB&FP			____ CFO		
____ DASD, HPA			____ COO		
			____ Dir, Regional Operations/PEO		
____ CIO, MHS			____ Dir, IMT&R		
____ OGC, DoD			____ OGC, TMA		
____ LA					
4/18/03 CoS, HA	✓✓		____ Dir, A&M		
____ Military Assistant			____ CoS, TMA		
____ Dir, PI, HA			____ Dir, PI, TMA		
____ Dir, P&S			____ Dir, Admin		
____ Other (Specify)			____ Other (Specify)		

DMD (SKY) ____ Date: ____ **DMD (PNT)** A Date: 4/14/03

Date Received: 4/15/03 **Suspense Date:** N/A

Subject: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under DOD Voluntary Immunizatio Program

PCDOCS #: 48381, 48741 **OSD/P&R #:** ____

AO: QDR (b)(6) **Office:** DHS **Phone #:** (b)(6)

NOTES:

04/30/03 15:00 FAX (b)(6) COUGHLIN MRA MD

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2118
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	USA MRA
ST. TIME	04/30 14:59
USAGE T	01'11
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:59:04 PM

TO: HONORABLE PATRICK HENRY

FROM: (b)(6)

ORGANIZATION: ASA (M&RA)

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: (b)(6)

SENDER'S PHONE NUMBER: (b)(6)

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTIMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

(b)(6)

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2119
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	USN MRA
ST. TIME	04/30 15:00
USAGE T	01'20
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:59:04 PM

TO: HONORABLE WILLIAM NAVAS, JR ***FROM:*** (b)(6)

ORGANIZATION: ASN (M&RA)

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: (b)(6)

SENDER'S PHONE NUMBER: (b)(6)

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

04/30/03 15:04 FAX (b)(6) USAF/ MRA/ MD 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2120
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	USAF MRA
ST. TIME	04/30 15:03
USAGE T	00'46
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:59:04 PM

TO: HONORABLE MICHAEL DOMINGUEZ ***FROM:*** (b)(6)

ORGANIZATION: ASAF (M&RA)

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: (b)(6)

SENDER'S PHONE NUMBER: (b)(6)

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

04/30/03 15:03 FAX (b)(6)

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2121
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	
ST. TIME	04/30 15:04
USAGE T	00'43
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:52:06 PM

TO: ***FROM:*** (b)(6)

ORGANIZATION: GENERAL COUNSEL

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: (b)(6)

SENDER'S PHONE NUMBER: (b)(6)

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

04/30/03 15:01 FAX (b)(6) USAGI/17 AMY BD 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2122
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	
ST. TIME	04/30 15:05
USAGE T	01'32
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:52:30 PM

TO: DIRECTOR	***FROM:*** Freddie Anderson
ORGANIZATION: DIRECTOR, JOINT STAFF	
FAX NUMBER: (b)(6)	***TOTAL NO. OF PAGES INCLUDING COVER:*** 5
PHONE NUMBER: (b)(6)	***SENDER'S PHONE NUMBER:*** (b)(6)

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

04/30/03 15:13 FAX (b)(6) JOINT STAFF SG 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2127
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	JOINT STAFF SG
ST. TIME	04/30 15:13
USAGE T	01'33
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:53:33 PM

TO: SURGEON GENERAL ***FROM:*** (b)(6)

ORGANIZATION: JOINT STAFF SURGEON

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: (b)(6)

SENDER'S PHONE NUMBER: (b)(6)

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTIMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Please confirm receipt

04/30/03 15:15 FAX (b)(6) SURGEON GEN JS

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2126
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	J HAMRE
ST. TIME	04/30 15:12
USAGE T	00'45
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:53:33 PM

TO: SURGEON GENERAL

FROM:
Freddie Anderson

ORGANIZATION: JOINT STAFF SURGEON

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: (b)(6)

SENDER'S PHONE NUMBER: (b)(6)

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:
Please confirm receipt

04/30/03 15:00 FAX (b)(6) USAGH-17 MKT MD 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2123
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	USA-SG.Rev
ST. TIME	04/30 15:07
USAGE T	00'46
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:53:33 PM

TO: SURGEON GENERAL ***FROM:*** (b)(6)

ORGANIZATION: SURGEON GENERAL OF THE ARMY

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: (b)(6)

SENDER'S PHONE NUMBER: (b)(6)

SUBJECT: *REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM*

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

04/30/03 15:13 FAX (b)(6) [illegible]

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2124
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	NAVY SG
ST. TIME	04/30 15:09
USAGE T	00'43
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:53:33 PM

TO: ***SURGEON GENERAL*** ***FROM:*** (b)(6)

ORGANIZATION: SURGEON GENERAL OF THE NAVY

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: (b)(6)

SENDER'S PHONE NUMBER: (b)(6)

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2125
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	USAF SG
ST. TIME	04/30 15:10
USAGE T	01'12
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:53:33 PM

TO: ***SURGEON GENERAL*** ***FROM:*** Freddie Anderson

ORGANIZATION: SURGEON GENERAL OF THE AIR FORCE

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: (b)(6)

SENDER'S PHONE NUMBER: (b)(6)

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PERSONNEL AND READINESS

THEUNDERSECRETARYOFDEFENSE
WASHINGTON, D.C. 20301-4000

MAR 30 1999

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE

SUBJECT:>Change to Anthrax Vaccine Immunization Program (AVIP) Operational Procedure (One Day Policy)

Effective immediately, the **AVIP** will be applied to all U.S. military personnel and Department of Defense (DoD) emergency essential civilian employees and contractor personnel assigned, deployed or on temporary duty in the high threat areas and contiguous waters of Southwest Asia (Kuwait, Saudi Arabia, Bahrain, Jordan, Qatar, Oman, UAE, Yemen, and Israel) and the Korean Peninsula for any period of time. Prior to entry into the **designated** high threat areas these personnel must initiate vaccination against anthrax in accordance with the prescribed Immunization schedule. Ideally, personnel should receive at least the first three vaccinations in the series. In those rare circumstances when an Individual is not able to take or continue with the anthrax vaccination for medical or administrative reasons, they will be evaluated for deployability in accordance with Service criteria. Neither this policy nor the requirement to participate in **AVIP** is applicable to civilian employees or contractor personnel who are not designated as emergency essential.

Services will emphasize this policy immediately in all appropriate communications. Programs to educate and inform personnel about the threat and the anthrax vaccine, prior to being immunized will continue as directed. Services will ensure that your activities meet labor relations obligations and contracting requirements prior to implementing this policy with respect to civilian employees and contractor personnel. The Military Health System shall support provision of anthrax immunizations.

Our continued success in executing the **AVIP** depends greatly upon meticulous execution of communication and compliance programs.

KEYWORD PAGE. USE/VIEW PDF DOCUMENT FOR COMPLETE DOCUMENT INFORMATION.

KEYWORD

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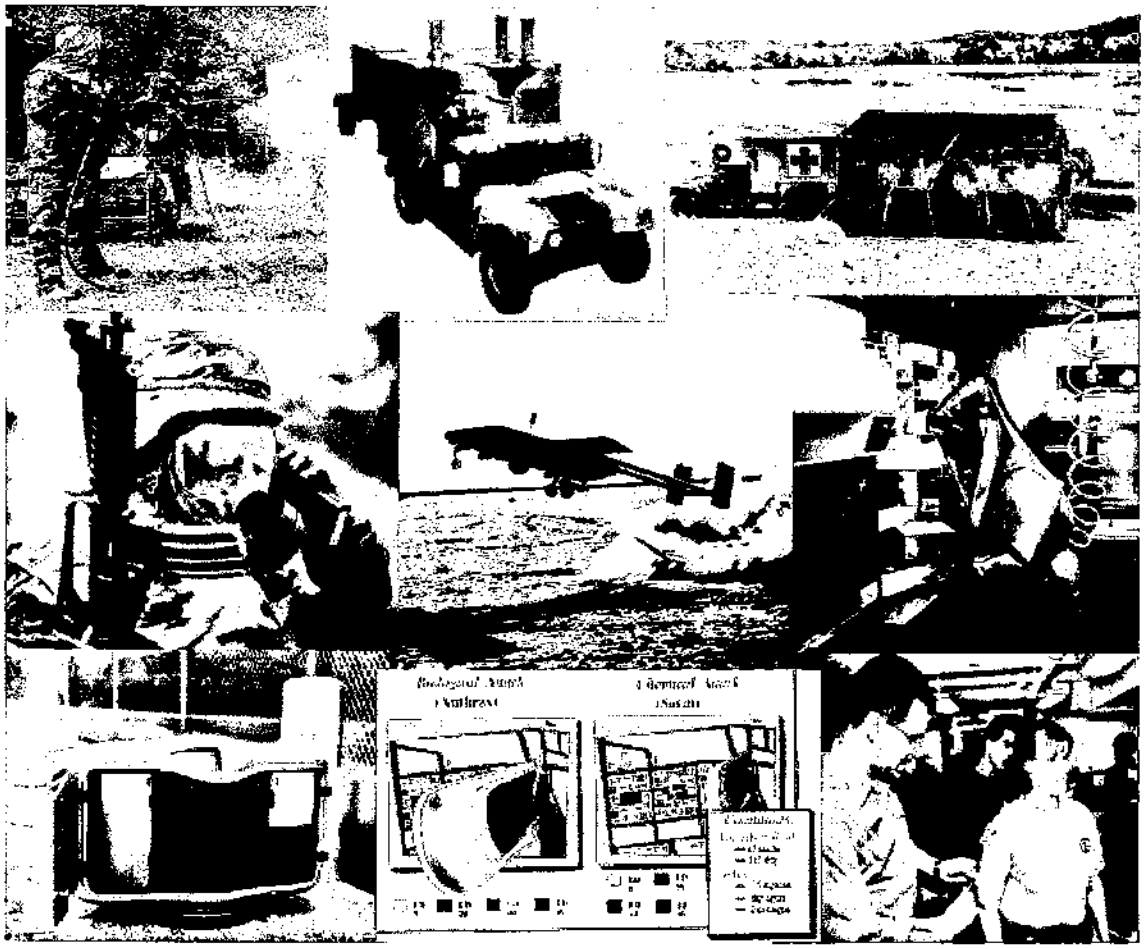
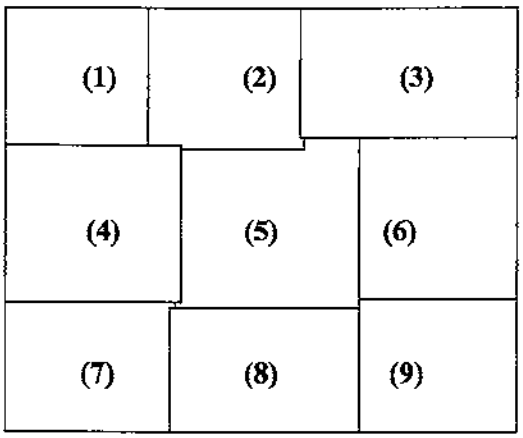
DEPARTMENT OF DEFENSE NUCLEAR/BIOLOGICAL/CHEMICAL (NBC) DEFENSE
ANNUAL REPORT TO CONGRESS
MARCH 1999

DEPARTMENT OF DEFENSE NUCLEAR/BIOLOGICAL/CHEMICAL (NBC) DEFENSE

ANNUAL REPORT TO CONGRESS MARCH 1999





Cover images:

(1) Crew spraying decontaminant solution on vehicle
(2) M31 Biological Integrated Detection System (BIDS) - Non-Developmental Item (NDI)
(3) Chemical Biological Protective Shelter (CBPS)
(4) Member of the 51st Security Forces Squadron, talks to other search team members via radio while conducting a search during exercise Beverly Midnight 99-1
(5) Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD) mounted on Unmanned Aerial Vehicle
(6) Researcher in overpressured protective suit in biosafety level 4 (BL-4) laboratory at the U.S. Army Research Institute of Infectious Diseases (USAMRIID)
(7) Prototype Portal Shield biological detector
(8) Simulated biological and chemical dosage distribution patterns
(9) Sailor receiving shot of the anthrax vaccine

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Executive Summary

The National Defense Authorization Act for Fiscal Year 1994, Public Law No. 103-160, Section 1703 (50 USC 1522), mandates the coordination and integration of all Department of Defense chemical and biological (CB) defense programs. As part of this coordination and integration, the Secretary of Defense is directed to submit an assessment and a description of plans to improve readiness to survive, fight and win in a nuclear, biological and chemical (NBC) contaminated environment. This report contains modernization plan summaries that highlight the Department' s approach to improve current NBC defense equipment and resolve current shortcomings in the program. *50 USC 1522 has provided the essential authority to ensure the elimination of unnecessarily redundant programs, focusing funds on DoD and program priorities, and enhancing readiness.*

The objective of the Department of Defense (DoD) Chemical and Biological Defense Program (CBDP) is to enable our forces to survive, fight, and win in a chemically or biological ly contaminated warfare environment. The DoD CBDP provides development and procurement of systems to enhance the ability of U.S. forces to deter and defend against CB agents during regional contingencies. The probability of U.S. forces encountering CB agents during world wide conflicts remains high. An effective defense reduces the probability of a CB attack, and if an attack occurs, it enables U.S. forces to survive, continue operations, and win. Scientific, technological, and resource limitations remain in preventing U.S. forces from having complete full dimensional protection and meeting all requirements for two nearly simultaneous Major Theater Wars. The unique physical, toxicological, destructive, and other properties of each threat requires that operational and technological responses be tailored to the threat. Nevertheless, significant progress has been made in overcoming these limitations since the establishment of the DoD CBDP. Still, U.S. forces remain the best protected forces in the world for surviving and conducting operations in chemically or biologically contaminated environments.

During the past year, DoD took several steps to ensure the protection of U.S. forces against both immediate and future chemical and biological threats. This report details DoD' s current and planned capabilities. However, highlights from the past year include initiating immunization of all U.S. forces with the licensed anthrax vaccine–a deadly biological warfare agent, deployment of advanced biological detection equipment during Operation Desert Thunder, and continued enhancement of DoD CBDP funds to protect against validated and emerging threats through the far-term future.

Numerous rapidly changing factors continually influence the program an d its management. These factors include declining DoD resources, planning for warfighting support to numerous regional threat contingencies, the evolving geopolitical environment resulting from the breakup of the Soviet Union, the entry into force of the Chemical Weapons Convention, and continuing proliferation of NBC weapons. To minimize the impact of use of NBC weapons on our forces, the DoD CBDP will continue to work towards increasing the defensive capabilities of Joint Forces to survive and continue the mission during conflicts that in volve the use of NBC

weapons. NBC defense programs are managed jointly under the oversight of a single office within DoD.

The program continues to implement congressional direction to improve jointness and reflects an integrated DoD developed program. This year' s program continues funding to support the highest priority counterproliferation initiatives. During the past year, the Depart ment reviewed its capabilities to protect against the asymmetric threats from chemical and biological weapons. As a result of the review, funding was identified to enhance and accelerate high-payoff technologies and advanced CB defense systems. The FY00–01 President' s Budget Submission includes $380 million in increased research and development funding for biological warfare defense and vaccines over the FY 2000-05 Future Years Defense Program (FYDP), as well as additional FY 1999 Emergency Supplemental funding to procure CB defense equipment for the Guard and Reserves to support the Consequence Management mission. Moreover, the Department continues to procure new CB defense equipment for our forces, due in large measure to the May 1997 *Report of the Quadrennial Defense Review* (QDR) recommendation to increase planned spending on counterproliferation by $1 billion over the FY 1999–2003 program period, of which $732 million was allocated to the DoD CBDP.

The DoD CBDP invests in technologies to provide improved capabilities that have minimal adverse impact on our warfighting potential. Joint and Service unique programs provide capabilities to support the framework of the three commodity areas of CB defense: Contamination Avoidance (detection, identification, warning/reporting, reconnaissance), Protection (individual, collective, medical support), and Decontamination. All of these capabilities integrated together as a system-of-systems are essential to avoid contamination and to sustain operational tempo on an asymmetric battlefield. Moreover, sound Joint doctrine and realistic training remain fundamental to our defense against chemical and biological weapons. In summary, the DoD CBDP is focusing on a jointly integrated, balanced approach to obtaining needed capabilities for our forces within affordability constraints.

OVERVIEW OF REPORT

The ***INTRODUCTION*** provides a background of the rationale and purpose of the DoD Chemical and Biological Defense Program (CBDP). This section summarizes the key counter-proliferation priorities and the current chemical and biological warfare threats to U.S. force s. Intelligence documents tailored to the threat are essential for developing and updating requirements for chemical and biological defense programs. Each chemical and biological de fense research, development, and acquisition effort funded within the program responds to a defined or validated threat. Variations among chemical and biological agents and each agent' s unique physical, toxicological, destructive, and other properties such as means of delivery re quire that operational and technological res ponses be tailored to the threat. Intelligence efforts continue to emphasize collection and analysis of nations' "dual-use" chemical and biological industrial capabilities and develop the indications and warning of adversarial use of dual-use capabiliti es.

CHAPTER 1 describes the accomplishments, processes, and issues related to DoD CBDP management and oversight. Since the program' s inception, DoD has made significant progress in improving the overall joint management and coordination of the NBC defense program, including integration of medical and non-medical chemical and biological defense programs. *50 USC 1522 has been a critical tool for ensuring the elimination of redundant programs, focusing funds on program priorities, and enhancing readiness.* This chapter outlines the changes within the oversight and management structure that have occurred as a result of the Defense Reform Initiative and the establishment of the Defense Threat Reduction Agency.

CHAPTER 2 provides information on non-medical NBC defense requirements and research and development programs. Requirements and the status of research and development assessments are described within the framework of the functional areas of NBC defense.

CHAPTER 3 provides information on medical NBC defense requirements and on research and development programs. Medical technologies are an integral part of providing individual protection both prior to, during and after a chemical or biological attack.

CHAPTER 4 provides an analysis of NBC defense logistics posture. The analysis reviews the status of quantities, characteristics, and capabilities of all fielded NBC defense equipment, industrial base requirements, procurement schedules, and problems encountered. Much of the information is based on the model of Joint Chemical Defense Equipment Consumption Rates (JCHEMRATES IV). Additional information is derived from the Joint NBC Defense Logistics Support Plan.

CHAPTER 5 assesses the status of NBC defense training and readiness conducted by the Services. Each of the Services' training standards and programs is reviewed. In accordance with Section 1702 of P.L. 103-160 (50 USC 1522) all chemical and biological warfare defense training activities of the Department of Defense have been consolidated at the United States Army Chemical School. This chapter also provides information on the move of the Chemical School from Fort McClellan, Alabama to Fort Leonard Wood, Missouri.

CHAPTER 6 provides information on the status of DoD efforts to implement the Chemical Weapons Convention (CWC), which was ratified by the United States and entered into force during 1997. This chapter also includes a summary of plans and activities to provide assistance to other countries in response to an appeal by another State Party to the CWC, pursuant to Article X of the CWC.

Finally, there are several ***ANNEXES*** to this report. ***Annexes A through D*** provide detailed information on Joint and Service-unique NBC defense equipment, including contamination avoidance, protection, decontamination, and medical programs. Detailed descriptions are provided for systems and equipment that have been fielded, are in production, or under development. ***Annex E*** provides a summary of funds appropriated, budgeted, and expended by the DoD CBDP. One of the successes of the DoD NBC Defense Program has been the consolidation of all DoD NBC Defense RDT&E and procurement program funds under defense-wide program elements, rather than throughout numerous Service accounts. ***Annex F*** provides a reference to NBC defense related sites on the internet. ***Annex G*** provides a statement regarding chemical and biological defense programs involving human subjects as required by 50 USC 1523. As detailed in the annex, no such testing has been conducted in over two decades and none is planned. ***Annex H*** provides the text of the Congressional language requiring this report. ***Annex I*** provides a list of the many acronyms and abbreviations that are used throughout this report.

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Introduction

I. PURPOSE

This report provides Congress with an assessment of the overall readiness of the Armed Forces to fight in a nuclear, biological, and chemical (NBC) warfare environment in accordance with 50 USC 1523. This is the sixth report submitted under 50 USC 1523.*

The objective of the Department of Defense (DoD) NBC defense program is to enable our forces to survive, fight and win in NBC-contaminated environments. In addition to the continuing requirement to respond to two simultaneous Major Theater Wars, numerous rapidly changing factors influence the program and its management. These factors include a new defense strategy, an era of declining DoD resources to include force structure reductions, planning for warfighting support to regional threat contingencies, the effects of the breakup of the Soviet Union, the entry into force of the Chemical Weapons Convention (CWC), and continued proliferation of NBC weapons.

The President' s October 1998 report,*A National Security for a New Century,* emphasizes the three key elements of the executive branch' s strategy as (1) to enhance our security with effective diplomacy and with military forces that are ready to fight and win; (2) to bolster America' s economic prosperity; (3) to promote democracy abroad. U.S. forces must have numerous capabilities in order to respond and deploy quickly to various worldwide needs. Counterproliferation capabilities are required by forces to meet worldwide needs, and NBC defense is integral to counterproliferation capabilities. The Commanders-in-Chief have identified their priorities for counterproliferation capabilities. These priorities are shown in Table I-1. Capa bilities which are supported by the NBC defense program are highlighted in **bold.**

Table I-1. Required CINC Counterproliferation Capabilities

1. **Provide individual protection to forces and assist allies/coalition partners**
2. Intercept conventional delivery of WMD and control collateral effects
3. **Provide collective protection to forces and assist allies/coalition partners**
4. **Mitigate the effects of WMD use**
5. **Detect** and monitor development, production, deployment, **employment of WMD**
6. Communicate the ability/will to employ interdiction/response capabilities
7. Determine vulnerabilities in WMD development, production, transfer, deployment, and employment
8. Conduct off-site attack to destroy, disable, and deny WMD targets
9. Establish and maintain relations with allies, and potential adversaries to discourage development, production, and use of WMD
10. Seize, destroy, disable, and deny transport of WMD
11. Communicate the ability/will to employ defensive capabilities
12. Determine vulnerabilities in decision making process related to WMD
13. Conduct information warfare to destroy, disable, and deny WMD

* The text of 50 USC 1523, *Annual report on chemical and biological warfare defense,* (implemented as part of Public Law 103-160, the FY94 National Defense Authorization Act) is included at Annex G.

14. Support treaties, export controls, and political/diplomatic efforts
15. Provide alternatives to the pursuit of WMD
16. Provide intelligence collection capabilities in support of USG non-proliferation efforts
17. Conduct on-site attack to seize, destroy, disable, and deny WMD targets
18. Provide personnel, training, materiel, equipment to support security assistance
19. Destroy, disable, and deny actor's non-WMD resources and capabilities

The response to the threat of NBC weapons must be based on the nature of this threat, not just where the threat occurs. A key part of DoD' s strategy is to stem the proliferation of such weapons and to develop an effective capability to deal with these threats. To focus the response to the threat, DoD and the intelligence community have completed several classified reports providing threat assessments on chemical and biological threats to U.S. forces. To minimize the effect of these threats to our forces, we need to continue improving our NBC defensive capabilities. These continuing improvements also contribute to our overall deterrence by demonstrating to an adversary that use of NBC weapons provides no military advantage. The DoD NBC defense program continues to work towards increasing the capabilities of Joint Forces to survive and continue their mission during conflicts which may involve the use of NBC weapons.

The number of nations with chemical and biological weapons (CBW) capabilities is increasing. Similarly, the sophistica tion of CBW capabilities is increasing. Proliferation of weapons technology, precision naviga tion technology, nuclear (medical, power, and industrial applications), and CBW technology to developing nations presents the United States with a complicated national security challenge. Intelligence efforts include collection and analysis of nations' "dual-use" nuclear, chemical and biological industrial capabilities, and development of the indications and warning of adversarial use of dual-use capabilities. Tailored intelligence documents are essential for developing and updating requirements for CB defense programs. Numerous threat documents tailored to the CB threat have been produced and are updated periodically. The Intelligence Community continues to review U.S. chemical and biological warfare intelligence requirements and assess the adequacy of those assets to execute the required intelligence program.

The DoD NBC defense program invests in technologies to provide improved capabil ities that have minimal adverse impact on our war fighting potential. Our goals are to provide:

- improved capabilities to detect NBC agents in order to avoid their effects;
- lighter, less burdensome protection;
- decontamination systems with reduced logistical burden;
- decontaminants that are less toxic and environmentally safe;
- integrated, balanced system of force protection; and
- medical casualty care and management.

All of the capabilities integrated together as a system-of-systems are essential to avoid contamination and to sustain operational tempo on an asymmetric battlefield. Sound Joint doctrine and realistic training remain fundamental to our defense against NBC weapons.

II. THE CURRENT CHEMICAL AND BIOLOGICAL WARFARE THREAT

Northeast Asia

North Korea has been pursuing research and development related to biological warfare since the 1960s. Pyongyang' s resources presently include a rudimentary (by Western stan dards) biotechnology infrastructure that is sufficient to support the production of limited quan tities of toxins, as well as viral and bacterial biological warfare agents. In the early 1990s, an open press release by a foreign government referred to applied military biotechnology work at numerous North Korean medical institutes and universities dealing with pathogens such as anthrax, cholera, and plague. North Korea possesses a sufficient munitions-production infra structure to accomplish weaponization of BW agents. North Korea acceded to the Biological Weapons Convention (BWC) in 1987.

By comparison, North Korea' s chemical warfare program is believed to be mature and includes the capability, since 1989, to indigenously produce bulk quantities of nerve, blister, choking and blood chemical agents as well as a variety of different filled munitions systems. North Korea is believed to possess a sizable stockpile of chemical weapons, which could be employed in offensive military operations against the South. North Korea has also devoted considerable scarce resources to defensive measures aimed at protecting its civilian population and military forces from the effects of chemical weapons. Such measures include extensive training in the use of protective masks, suits, detectors, and decontamination systems. Though these measures are ostensibly focused on a perceived threat from U.S. and South Korean forces, they could also support the offensive use of chemical weapons by the North during combat. North Korea has yet to sign the Chemical Weapons Convention (CWC) and is not expected to do so in the near-term, due to intrusive inspection and verification requirements mandated by the agreement.

China possesses an advanced biotechnology infrastructure as well as the requisite munitions production capabilities necessary to develop, produce and weaponize biological agents. Although China has consistently claimed that it has never researched or produced biological weapons, it is nonetheless believed likely that it retains a biological warfare capability begun before acceding to the BWC.

China is believed to have an advanced chemical warfare program that includes research and development, production and weaponization capabilities. Its current inventory is believed to include the full range of traditional chemical agents. It also has a wide variety of delivery systems for chemical agents to include artillery rockets, aerial bombs, sprayers, and short-range ballistic missiles. Chinese forces, like those of North Korea, have conducted defensive CW training and are prepared to operate in a contaminated environment. As China' s program is further integrated into overall military operations, its doctrine, which is believed to be based in part on Soviet-era thinking, may reflect the incorporation of more advanced munitions for CW agent delivery. China has signed and ratified the CWC.

South Asia

India has a well-developed biotechnology infrastructure that includes numerous pharmaceutical production facilities bio-containment laboratories (including BL-3) for working with lethal pathogens. It also has qualified scientists with expertise in infectious diseases. Some of India' s facilities are being used to support research and development for BW defense purposes. These facilities constitute a substantial capability for offensive purposes as well. India is a signatory to the BWC of 1972.

India also has an advanced commercial chemical industry, and produces the bulk of its own chemicals for domestic consumption. New Delhi ratified the CWC in 1996. In its required declarations, it acknowledged the existence of a chemical warfare program. New Delhi has pledged that all facilities related to its CW program would be open for inspection.

Pakistan has a capable but less well-developed biotechnology infrastructure than India. Its facilities, while fewer in number, could nonetheless support work on lethal biological pathogens. Moreover, Pakistan is believed to have the resources and capabilities necessary to support a limited offensive biological warfare research and development effort. Like India, Pakistan is a signatory to the BWC.

Pakistan has a less-well developed commercial chemical industry but is expected to eventually have the capability to produce all precursor chemicals needed to support a chemical weapons stockpile. Like India, Pakistan has numerous munitions systems which could be used to deliver CW agent, including artillery, aerial bombs, and missiles. Pakistan has ratified the CWC.

The Middle East and North Africa

*Iran' s*biological warfare program, which began during the Iran-Iraq war, is now believed to generally be in the advanced research and development phase. Iran has qualified, highly trained scientists and considerable expertise with pharmaceuticals. It also possesses the commercial and military infrastructure needed to produce basic biological warfare agents and may have produced pilot quantities of usable agent. Iran is a signatory to the BWC of 1972.

Iran initiated a chemical weapons program in the early stages of the Iran-Iraq war after it was attacked with chemical weapons. The program has received heightened attention since the early 1990s with an expansion in both the chemical production infrastructure as well as its munitions arsenal. Iran currently possesses munitions containing blister, blood, and choking agents and may have nerve agents as well. It has the capability to deliver CW agents using artillery shells and aerial bombs. Iran has ratified the CWC under which it is obligated to open suspected sites to international inspection and eliminate its CW program.

Prior to the Gulf War, *Iraq* developed the largest and most advanced biological warfare program in the Middle East. Though a variety of agents were studied, Iraq declared anthrax, botulinum toxin, and aflatoxin to have completed the weaponization cycle. During the Gulf War, coalition bombing destroyed or damaged many key facilities associated with BW activity.

However, it is suspected that a key portion of Iraq' s BW capability, in the form of agent-filled munitions, was hidden and may have subsequently escaped damage. Nonetheless, Iraq declared, after the war, that all BW agent stockpile and munitions were unilaterally destroyed. United Nations Special Commission (UNSCOM) activity has, however, revealed this assertion as well as many others related to BW activity, to be inaccurate and misleading. As with its chemical program, Iraq intends to re-establish its BW capabilities if afforded the opportunity by the relaxation or cessation of UNSCOM inspection activity.

Iraq had a mature chemical weapons program prior to the Gulf War that included a variety of nerve agents, such as tabun (GA), sarin (GB), and GF, as well as the blister agent mustard, available for offensive use. Iraq also undertook a program, begun in 1985 and continuing uninterrupted until December 1990, to produce the advanced nerve agent VX. Recent UNSCOM findings indicate that Iraq had weaponized VX in Al Hussein missile warheads. Although Iraq' s chemical warfare program suffered extensive damage during the Gulf War and subsequently from UNSCOM activity, Iraq retains a limited capability to re-constitute key parts of its chemical warfare program. Moreover, UNSCOM is still unable to verify elements of Iraqi declarations such as the disposal of chemical precursors, as well as the destruction of all chemical munitions. The comprehensive nature of Iraq' s previous chemical warfare activity and the consistent pattern of denial and deception employed by Iraqi authorities indicate a high-level intent to rebuild this capacity, should Iraq be given the opportunity.

Syria has a limited biotechnology infrastructure but could support a limited biological warfare effort. Though Syria is believed to be pursuing the development of biological weapons, it is not believed to have progressed much beyond the research and development phase and may have produced only pilot quantities of usable agent. Syria has signed, but not ratified, the BWC.

Syria has a mature chemical weapons program, begun in the 1970s, incorporating nerve agents, such as sarin, which have completed the weaponization cycle. Future activity will likely focus on CW infrastructure enhancements for agent production and storage, as well as possible research and development of advanced nerve agents. Munitions available for CW agent delivery likely include aerial bombs as well as SCUD missile warheads. Syria has not signed the CWC and is unlikely to do so in the near future.

*Libya' s*biological warfare program is believed to remain in the early research and development phase. Progress has been slow due in part to an inadequate scientific and technical base. Though Libya may be able to produce small quantities of usable agent, it is unlikely to transition from laboratory work to production of militarily significant quantities until well after the year 2000. Libya acceded to the BWC in 1982.

Libya has experienced major setbacks to its chemical warfare program, first as a result of intense public scrutiny focused on its Rabta facility in the late 1980s and more recently on its Tarhuna underground facility. Nevertheless, Libya retains a small inventory of chemical weapons, as well as the a CW agent production capability. Prior to closing its Rabta plant in 1990, Libya succeeded in producing up to 100 tons of blister and nerve agent at the site. Although the site was re-opened in 1995, ostensibly as a pharmaceutical plant, the facility is still believed

capable of producing CW agents. CW-related activities at the Tarhuna site are believed to be suspended. Libya has not ratified the CWC and is not likely to do so in the near future.

Independent States of the Former Soviet Union

The former Soviet offensive biological warfare program was the world' s largest and consisted of both military facilities and nonmilitary research and development institutes. Non-military activity was centrally coordinated and performed largely through a consortium of institutes known as Biopreparat. This network of facilities was created in 1973 as a cover for activity related to biological warfare. This huge organization at one time employed up to 25,000 people and involved nearly 20 research, development and production facilities. The Russian government has committed to ending the former Soviet BW program, although serious questions about offensive BW capabilities remain. Key components of the former program remain largely intact and may support a possible future mobilization capability for the production of biological warfare agents and delivery systems. Moreover, work outside the scope of legitimate biological defense activity may be occurring at selected facilities within Russia. Such activity, if offensive in nature, would contradict statements by top Russian political leaders that offensive activity has ceased.

While former Soviet biological warfare facilities existed in Ukraine, Kazakhstan, and Uzbekistan, none are currently active. Moreover, the governments in these new republics are not believed to have plans to establish any future BW capability. Also, Belarus has no program and no intention of establishing one. Ukraine, Belarus, and Uzbekistan have ratified the BWC, while Kazakhstan has not yet signed it.

Russia has acknowledged the world' s largest stockpile of chemical agents, amounting to approximately 40,000 metric tons. This stockpile, consisting mostly of weaponized agent includes artillery, aerial bombs, rockets, and missile warheads. Actual agents include a variety of nerve and blister agents. Additionally, some Russian chemical weapons incorporate agent mixtures, while others have added thickening materials in order to increase agent persistence. Russian officials do not deny that CW research has continued but claim that it is for defensive purposes and therefore not proscribed by the CWC. Many of the components for new binary agents developed under the former-Soviet program have legitimate civilian applications and are not considered on the CWC' s schedule of chemicals.

PROLIFERATION

The United States faces a number of regional proliferation challenges. Many of these are detailed in the November 1997 report published by the Office of the Secretary of Defense, *Proliferation: Threat and Response*. In the Middle East, Iran continues with a concerted effort to acquire an independent production capability for all aspects of its chemical weapons pro gram. Nonetheless, for the time being, it remains dependent on foreign sources for many chem ical warfare-related technologies. China, as a key supplier of technologies and equipment for Iran' s chemical war fare program, will play a pivotal role in deter mining whether Iran attains its long-term goal of independent production for these weapons. Iran is also pursuing a program to

purchase dual-use biotech equipment from other countries, ostensibly for civilian uses. Russia is a key source of biotechnology for Iran. Russia is an especially attractive target for Iranians seeking technical information on BW agent production processes.

Proliferation of chemical and biological warfare technology in South Asia also raises several important issues. India has exported a wide array of chemical products, including Australia Group-controlled items, to numerous countries of proliferation concern in the Middle East. The controlled items include specific chemical agent precursors, pathogens with biological warfare applications, and dual-use equipment which can be used in both chemical and biological warfare programs. Pakistan, on the other hand, may be seeking to upgrade key parts of its biotechnology infrastructure with dual-use equipment and expertise. Such acquisition efforts would reflect Pakistan's less-well developed biotechnology infrastructure.

Australia Group

The proliferation of chemical and biological warfare related technology remains a critical threat to peace and stability throughout the world. One mechanism through which industrialized countries have agreed to control the proliferation of key chemical and biological warfare-related technologies is the Australia Group. The Australia Group (AG) is a consortium of countries organized to slow the proliferation of chemical and biological warfare programs through the imposition of multilateral export controls. Initial efforts of this group began in June 1985 and focused on precursor chemicals used in the manufacture of chemical agents. However, convinced of the threat posed from biological weapons, AG countries subsequently agreed, in December 1992, to also control the sale of items that most likely could be used to develop biological agents and weaponry. The AG adopted a list of human pathogens consisting of 37 organisms, 10 toxins and associated genetically modified organisms, and a seven-item BW dual-use equipment list. In addition, the AG later adopted animal and plant pathogen lists in recognition of the threat posed from anti-crop and anti-animal biological warfare.

In North Africa, Libyan efforts to acquire foreign equipment and expertise related to biological warfare have been dealt a severe blow, largely because of UN sanctions. Due to the international community's encompassing restrictions on exports to Libya, efforts to proceed beyond laboratory-scale research and development related to biological warfare will be difficult.

OUTLOOK

In the next 10 years, the threat from the proliferation of CBW weapons will certainly increase. This will result from the development of chemical and biological agents that are more difficult to detect and from the adoption of more capable delivery systems. * We expect that more states with existing programs will master the production processes for complete weapons and will be less dependent on outside suppliers. States will be more proficient at incorporating chemical or biological agents into delivery systems and will be focusing on battlefield training as well as employment strategy and doctrine. Therefore, the threshold of some states to consider using these capabilities may be lowered.

* An assessment of potentially new biological agents that may challenge U.S. forces is in a DoD report to Congress entitled *Advances in Biotechnology and Genetic Engineering: Implications for the Development of New Biological Warfare Agents*, June 1996.

DoD does not expect significant increases in the number of government-sponsored offensive CBW programs. Nevertheless, the United States and its allies must be alert to this possibility as well as to the apparent growing interest in CBW on the part of sub-national groups such as terrorist organizations. Any nation with the political will and a minimal industrial base could produce CBW agents suitable for use in warfare. Efficient weaponization of these agents, however, does require design and production skills usually found in countries which possess a munitions development infrastructure or access to such skills from cooperative sources. On the other hand, crude agent dispersal devices could be fabricated by almost any nation or group. Such weapons might be capable of inflicting only limited numbers of casualties; nevertheless, they could have significant operational repercussions due to the psychological impact created by fears of CBW agent exposure.

Chapter 1

DoD Chemical and Biological Defense Program Management and Oversight

1.1 MANAGEMENT IMPLEMENTATION EFFORTS

The Department of Defense (DoD) implemented a process to consolidate, coordinate, and integrate the chemical and biological (CB) defense requirements of all Services into a single DoD CB defense program. Additionally, DoD continues to refine organizations and processes to ensure close and continuous coordination between the Chemical Biological Warfare Defense program and the Medical Chemical Biological Defense program.

1.1.1 Management Reviews

DoD has continued to use the Defense Acquisition Board (DAB) process to conduct oversight of the consolidated CB defense program in accordance with public law. Integrated product team working groups and overarching integrated product team meetings are conducted throughout the process to review progress concerning current actions, discuss new management issues, and develop recommendations for DAB decisions.

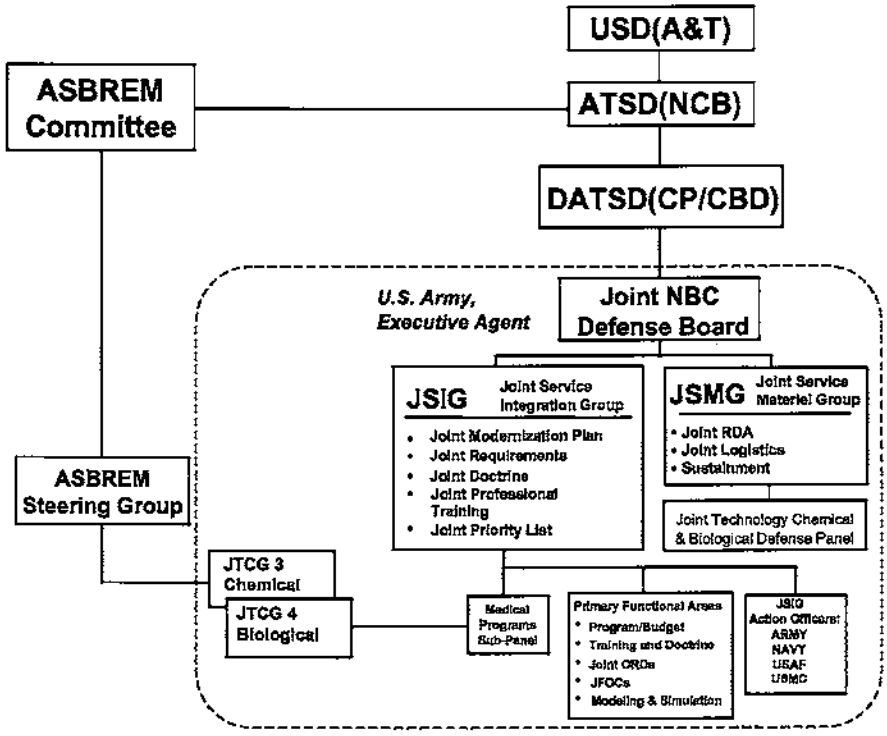
In developing the FY00–01 budget, the OSD Director for Program Analysis and Evaluation conducted a Program Review Group (PRG) assessment of DoD' s chemical and biological defense programs,with emphasis on biological defense measures. The Defense Resources Board (DRB) reviewed and approved the results of the assessments. A Program Decision Memorandum (PDM) incorporated the DRB decisions into the development of the FY00–01 budget request. The PDM added approximately $380 million over the future years defense plan (FYDP) for research and development of medical and non-medical biological warfare defense countermeasures.

1.1.2 Coordination and Integration of the Program

Through the Joint Service Agreement on NBC Defense, the Military Services have established a viable structure that ensures that Service operational needs are fully integrated and coordinated from their inception and that duplication of effort is eliminated from NBC defense research, development, and acquisition. The series of reviews conducted by the Joint Service Integration Group and the Joint Service Materiel Group, both separately and together, have proved to be an appropriate organizational method to accomplish the coordinating and integrating function.

1.2 ORGANIZATIONAL RELATIONSHIPS

The overall CB Defense Program management structure, portrayed in Figure 1-1, represents how the program was coordinated and integrated at the beginning of calendar year 1998. This management and oversight structure was developed in late 1996 to provide integration of medical and non-medical CB defense efforts at the Service level. Integration of CB defense efforts continued in 1998.



ASBREM - Armed Service Biomedical Research Evaluation and Management
ATSD(NCB) - Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs
DATSD(CP/CBD) - Deputy Assistant to the Secretary of Defense for Counterproliferation and Chemical / Biological Defense
DDR&E - Director, Defense Research and Engineering
JFOCs - Joint Future Operational Capabilities
JTCG - Joint Technical Coordinating Group
USD(A&T) - Under Secretary of Defense for Acquisition and Technology; serves as the chairman of the Defense Acquisition Board

Figure 1-1. Chemical and Biological Defense Program Management and Oversight Structure (At Beginning of Calendar Year 1998)

Throughout FY98 the Deputy Assistant to the Secretary of Defense for Counter-proliferation and Chemical/Biological Defense, DATSD(CP/CBD), as a deputy to ATSD(NCB), was responsible for the overall coordination and integration of all CB defense research, development, and acquisition (RDA) efforts. DATSD(CP/CBD) provided the overall guidance for planning, programming, budgeting, and executing the CB defense program.

DATSD(CP/CBD) remains the single office within OSD responsible for oversight of the DoD CB Defense Program. DATSD(CP/CBD) also retains approval authority for all planning, programming, and budgeting documents. DATSD(CP/CBD) is responsible for ensuring coordination between the medical programs and the non-medical CB defense efforts, and management oversight of the DoD CBDP in accordance with 50 USC 1522.

The DATSD(CP/CBD) is also the Executive Secretary of the OSD NBC Defense Steering Committee (see Figure 1-2.) The OSD NBC Defense Steering Committee provides direct oversight of the DoD Chemical and Biological Defense Program in accordance with Public Law 103-160. It provides the fiscal and programming guidance to the Joint NBC Defense Board (JNBCDB) to develop the POM. The Joint NBC Defense Board issues POM Preparation Instructions to the subordinate groups which review the validated requirements and build the POM strategy recommendations. The CB Defense Program is divided into the following commodity areas: contamination avoidance, individual protection, collective protection, decontamination, medical chemical d efense, medical biological defense, and modeling & simulation. These commodity areas correspond to the projects under the budget program elements. There is also a program budget element to support program management and oversight, user testing (*i.e.*, Dugway Proving Grounds), and doctrine development in accordance with the Joint Service Agreement and in compliance with 50 USC 1522. The JSIG is the principal steering group that oversees the coordination and integration of Service and CINC requirements and priorities for RDT&E and initial procurement. The JSMG is the principal steering group that manages the execution of RDT&E materiel development efforts to ensure that program risk is mitigated across commodity areas, and the ongoing efforts are complementary but not duplicative. The OSD NBC Defense Steering Committee is composed of the following members: (1) DDR&E, (2) Director, Defense Threat Reduction Agency (DTRA), (3) Director, Chemical Biological Defense Directorate, DTRA, (DTRA(CB)), and (4) DATSD(CP/CBD), who serves as the executive secretary.

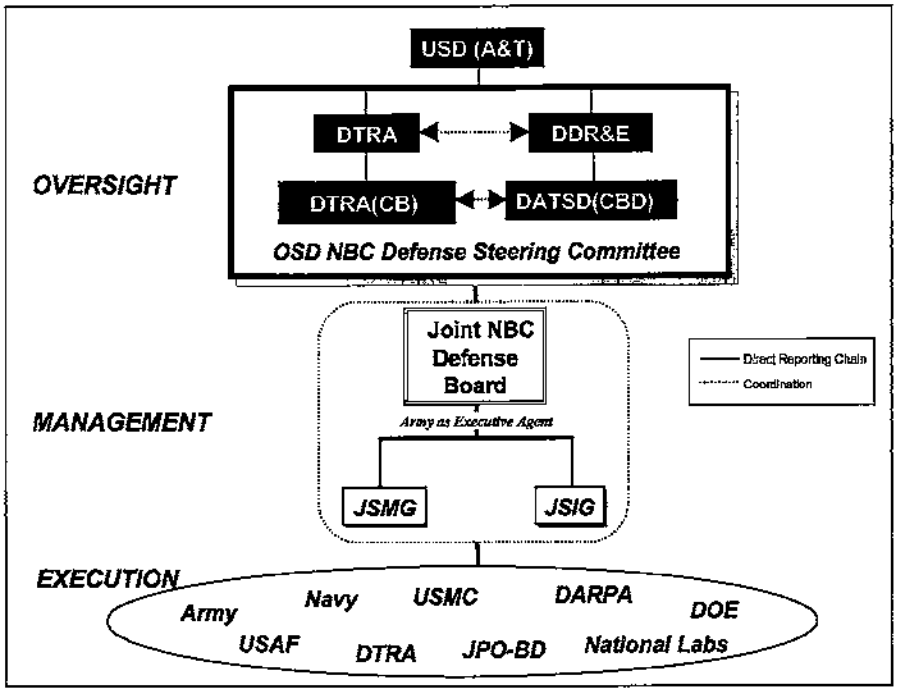


Figure 1-2. Chemical and Biological Defense Management and Oversight Structure

A Medical Program Sub-Panel (MPSP) has been implemented as part of the JSIG. The first multi-Service action officer meeting for the MPSP was held on 6 January 1998 and was chaired by the Senior Clinical Consultant for the Army Medical Department Center and School (AMEDDC&S). A second meeting on 10 September 1998 finalized a draft charter for the

implementation of the MPSP. The MPSP Service Principals met for the first time on 17 December 1998 and concurred on the charter. They recommended forwarding it to the JSIG with a recommendation that it be sent to the Joint NBC Defense Board for approval. The Joint NBC Defense Board approved the charter for the implemen tation of the MPSP. The MPSP is chaired by the Commander, AMEDDC&S. The purpose of the MPSP is to identify medical program needs and requirements as developed by the AMEDDC&S, CINCs, Services, Joint Staff, the ASBREM Committee, and other users. The MPSP has the primary responsibility for prioritizing medical CB defense requirements. The users and Joint Technology Coordinating Group (JTCG) 3 (Medical Chemical Defense Research Program) and JTCG 4 (Medical Biological Defense Research Program) provide input of medical requirements (separate from non-medical requirements) to the MPSP. The MPSP coordinates, integrates, and prioritizes all of the user requirements input. It provides the consolidated, integrated, and prioritized list of medical CB defense requirements to the JSIG. The JSIG then submits an integrated list of medical and non-medical requirements to the JNBCDB. The JSIG provides comments but makes no changes to the list when submitting the medical requirements to the JNBCDB. The JNBCDB and the OSD NBC Defense Steering Committee may make changes to the medical or the non-medical requirements and priorities list.

The Secretary of the Army is the Executive Agent responsible to coordinate, integrate, and review all Services' CB defense requirements and programs. The Secretary has delegated this responsibility to the Assistant Secretary of the Army for Research, Development and Acquisition, ASA(RDA), who along with the Vice Chief of Staff of the Army, co-chairs the Joint NBC Defense Board. The military departments' acquisition organizations execute the individual CB defense programs according to Service and DoD directives.

1.3 TECHNOLOGY BASE REVIEW AND ASSESSMENT

The DATSD(CP/CBD), the DDR&E office responsible for chemical and biological defense programs, provides technical oversight of all Service and Defense Agency chemical and biological defense science and technology base (S&T) programs and reviews these programs at least annually. DTRA(CB) performs program execution of CB tech base activities for DATSD(CP/CBD) through the Joint Technology Panel for Chemical and Biological Defense (JTPCBD). The JTPCBD coordinates all Service science and technology base activities for the JSMG. By March of each year, DTRA(CB) prepares the relevant NBC defense portions of three key documents detailing DoD S&T efforts, which are submitted to Congress separately in accordance with public law:

- the Joint Warfighting S&T Plan (JWSTP)
- the Defense Technology Area Plan (DTAP), and
- the Basic Research Plan (BRP).

1.4 DARPA BIOLOGICAL WARFARE DEFENSE PROGRAM MANAGEMENT

The Defense Advanced Research Projects Agency (DARPA) is charged with seeking breakthrough concepts and technologies. DARPA' s Defense Sciences Office (DSO) manages

its Biological Warfare (BW) Defense Program, which is intended to complement the DoD CB Defense Program by anticipating threats and developing novel defenses against them, and pursues the development of technologies with broad applicability against classes of threats. DARPA invests primarily in the early, technology development phases of programs, with rapidly decreasing involvement in the succeeding stages that lead to system development.

The FY98 National Defense Authorization Act directed the Secretary of Defense to ensure that the DARPA biological warfare defense program is coordinated and integrated under the program management and oversight of the DoD CBDP. The DARPA BW Defense Program coordinates its efforts with DATSD(CP/CBD) through regular briefings to both DATSD(CP/CBD) and DTRA(CB). The Advanced Diagnostics portion of the DARPA BW Defense Program is closely coordinated with the U.S. Army Medical Research and Materiel Command (MRMC) and maintains rep resentation on the recently formed Common Medical Diagnostic Systems Executive Committee. A panel of chemical/biological defense experts is routinely consulted by DARPA to evaluate programs and to ensure that National Institutes of Health (NIH) efforts are not being duplicated. The DARPA Defense Sciences Office is represented on the Joint Services Technical Panel for Chemical and Biological Defense (JSTPCBD) and maintains representation at CBD Program committee meetings, such as ASBREM sub-committee meetings. DARPA also participates in the BW Seniors Group, which provides Government coordination outside of DoD.

1.5 FUNDS MANAGEMENT

Figure 1-3 describes the funds management and execution process for the CB defense program and the coordination between funding and executing organizations. The key organizations in this process are: DATSD(CP/CBD) as the OSD focal point; the JNBCDB Secretariat representing the Executive Agent; the funds manager was the Ballistic Missile Defense Organization (FY96-FY98) and is now currently the Defense Threat Reduction Agency (DTRA); the JSMG as coordinator and interface between the participating organizations; and the operating agencies and performers which execute the programs. For budget distribution, the JNBCDB Secretariat provides funds distribution information to DATSD(CP/CBD) based on the appropriated budget. The DATSD(CP/CBD) prepares funds suballocation instructions (with support provided by DTRA(CB)) and submits them to the DTRA Comptroller for distribution to the operating agencies.

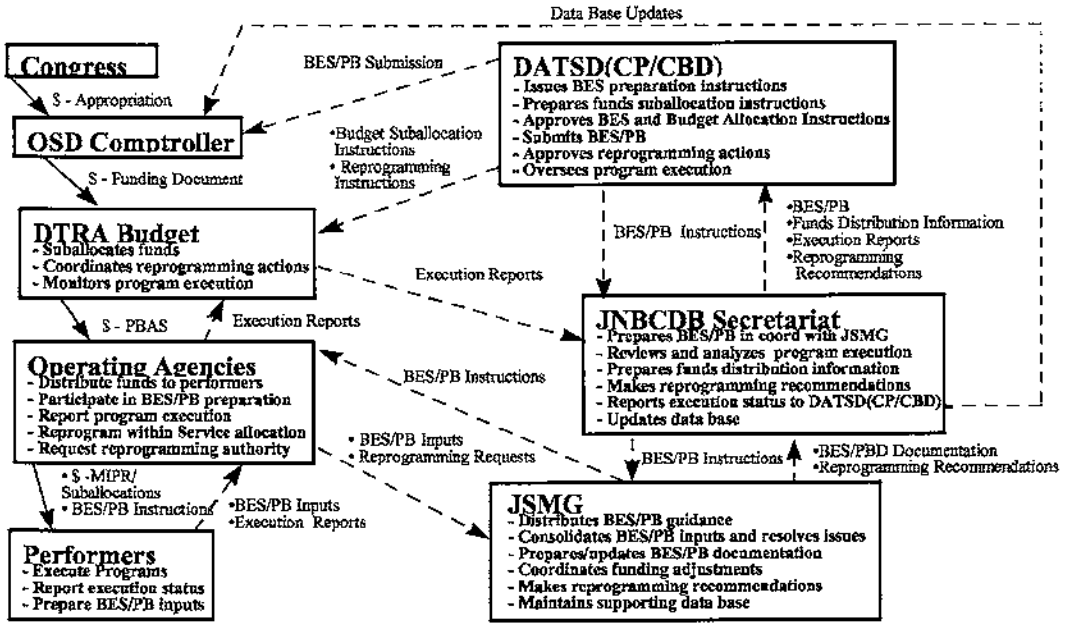


Figure 1-3. Chemical and Biological Defense Funds Management Process

The lead components or operating agencies provide notification of all funding adjustments to the JSMG Executive Office. The JSMG Executive Office, in turn notifies other components and agencies and the JNBCDB Secretariat (to update the database). For minor adjustments other than reprogramming actions, this is the only necessary action. The JSMG Execu tive Office forwards to the JNBCDB Secretariat the reprogramming requests with recom mendations and any concerns raised by the other components and operating agencies. The JNBCDB Secretariat reviews the reprogramming actions and forwards recommenda tions to DTRA(CB) for DATSD(CP/CBD) approval. Once approved, DATSD(CP/CBD) authorizes the DTRA Comptroller to execute the reprogramming. During the execution year for medical pro grams, the Headquarters, U.S. Army Medical Research and Materiel Command staffs all actions resulting from the requirement to reallocate funds between the Services.

DATSD(CP/CBD), with the support of DTRA(CB), instructs the DTRA Comptroller to issue execution and program status reporting instructions to the operating agencies. The operating agencies report execution status to the DTRA Comptroller on a monthly basis. The DTRA Comptroller forwards all program funds execution reports to the JNBCDB Secretariat and DTRA(CB) for program and budget database update and analysis, respectively. DTRA(CB) reports execution status to DATSD(CP/CBD) on a quarterly basis. It is the DTRA(CB)' s responsibility to notify the DATSD(CP/CBD) when programs deviate from or are in danger of not meeting OSD obligation and execution goals.

The DTRA Comptroller serves as the funds manager for the CB defense program. This office issues funding documents, per DATSD(CP/CBD) direction, and performs all required

accounting functions, with the assistance of the Army staff which represents the Executive Agent. The JNBCDB Secretariat updates the OSD comptroller program and budget databases as necessary after the POM, Budget Estimate Submission (BES), and President' s Budget (PB). DATSD(CP/CBD), with support provided by DTRA(CB), ensures that the JNBCDB Secretariat is kept informed of all OSD comptroller guidance, directives, and schedules.

1.6 NBC DEFENSE PROGRAM MANAGEMENT ASSESSMENT

ISSUE: **Oversight and management of the DoD NBC defense program continues to mature. It is imperative that the management system produces joint NBC defense requirements and NBC defense equipment that can be used by all forces. Public Law 103-160 (50 USC 1522) has provided a key tool for ensuring a jointly focused NBC defense program. The continued support of Congress and implementation of current plans will continue to improve jointness and readiness.**

SOLUTION: DoD has completed implementation of 50 USC 1522:

- DoD has developed an organizational structure ensuring close and continuous coordination of CB warfare defense and CB medical defense programs.
- The DoD CB Defense Program is fully integrated and coordinated and is based on validated Service requirements generated in response to defined threats. In addition, the Services now jointly prepare (i) Modernization Plans, (ii) Research, Development and Acquisition (RDA) Plans, and (iii) Joint Logistics Support Plans for NBC defense programs.
- Responsibility for the CB Defense Program is vested in a single office in OSD (DATSD(CP/CBD)) and oversight is conducted using the DAB process in coordination with the Director, Strategic & Tactical Systems.
- The overall integrity of the CB Defense Program' s organizational structure has been maintained throughout implementation of the Defense Reform Initiative (DRI) and establishment of the Defense Threat Reduction Agency through establishment of the OSD NBC Defense Steering Committee.
- A key DoD action in response to the GAO report (GAO Report NSIAD-96-103, "Chemical and Biological Defense: Emphasis Remains Insufficient to Resolve Continuing Problems" March 29, 1996) was the development of an immunization program for biological warfare defense. A description of this program is provided in Chapter 3 (p. 3-16).

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Chapter 2

Non-Medical Nuclear, Biological, and Chemical (NBC) Defense Requirements and Research, and Acquisition Program Status

2.1 INTRODUCTION

This chapter describes the consolidation of Joint Service non-medical NBC defense requirements and assesses how these programs meet the needs of U.S. forces. The discussion of requirements and the status of research and development assessments is conducted within the framework of the three principles of NBC defense doctrine for the mission area:

- Contamination avoidance
- Protection
- Decontamination

As defined in Joint Pub 3-11, *Joint Doctrine for Nuclear, Biological, and Chemical Defense,* contamination avoidance includes detecting, avoiding, and bypassing contaminated areas. Protection consists of individual and collective protection. Decontamination restores combat power and is essential for sustaining operations in a contaminated environment. Medical programs support these areas and are discussed in Chapter 3.

The threat from the continued proliferation of NBC weapons–as described in the Introduction–creates a continuous need to ensure that U.S. forces can survive, fight, and win in an NBC threat environment. The increasing danger from these weapons demands that we look for every opportunity to avoid technological surprises. Evolving operational requirements demand that the joint program progressively capture and leverage advances in technology to provide the best in NBC defense equipment for the forces.

Our research, development, and acquisition (RDA) goal is to equip the force with sufficient quantities of world-class equipment and in the shortest time possible in order to win decisively, quickly, and with minimal casualties. As authorized under the Joint Service Agreement for non-medical programs and in cooperation with the Armed Services Biomedical Research, Evaluation and Management (ASBREM) Committee for medical pro grams, the Army as executive agent coordinates, integrates, and reviews the DoD CB Defense Program. The results of these reviews, conducted with all Services participating, are docu mented in the Joint Service Modernization and Joint Service RDA Plans. These documents form the basis for the consolidated CB Defense Program Objectives Memorandum (POM).

The Services in coordination wit h the Commanders-in-Chief (CINCs) decide if a mate rial solution is needed to satisfy a requirement for a war fighting capability. They first look at doctrinal, training, or organizational solutions (non-material solutions), and when these cannot be found, they seek equipment solutions through the materiel acquisition cycle. If a valid need exists, then the research and development modernization process will identify technological approaches which may provide a new system or upgrade an existing system.

During FY98 the Joint Service Integration Group documented the Joint Future Operational Capabilities (JFOC). The purpose of the JFOC is to identify and prioritize Joint User (Services and CINCs) far-term future operational capabilities as expressed in the emerging Joint NBC Defense Concept. The overall intent is to provide enhanced user guidance to the Joint NBC Defense Science and Technology (S&T) community to assist in the NBC S&T program formulation and program execution process. The JFOC will also support the development of new NBC Defense Joint Mission Needs Statements (JMNSs) and future Joint Operational Requirement Documents (JORDs). The prioritized list of JFOCs establishes a clear link between near and long term Joint NBC Defense research and development efforts and user needs. Table 2-1 provides a synopsis of the current JFOC priorities, descriptions, and objectives. The JFOC has become an integral part of the Joint Service NBC Defense Modernization Plan and related science and technology plans, including the Joint Warfighting Science and Technology Plan (JWSTP) and the Defense Technology Area Plan (DTAP).

Table 2-1. Prioritized Joint Future Operational Capabilities

1: Contamination Avoidance —An enhanced capability to detect, locate, identify, and confirm the presence or absence of any standard or non-standard NBC hazard. Significantly improve tactical, operational, and strategic NBC situational awareness by rapidly detecting, locating, identifying, confirming and disseminating NBC and toxic industrial material (TIM) detection information to the joint force.
2: NBC Battle Management — Capability to access, assimilate and disseminate NBC information from throughout the battlespace via standard, joint service and automatic information/data transmission systems. Enhance warfighter protection by providing the critical link between detection and protection. Commanders at all levels will be provided sufficient, timely information through early and direct warning. Commanders will be able to quickly and effectively quantify the risk associated with various courses of action and provide real-time display with local 3-D digital terrain graphics to portray the current status of the NBC battlespace.
3: Collective Protection —To protect the joint force by allowing it to operate safely, at near-normal levels of effectiveness, while under NBC threat, or in NBC, TIM or other environmental hazards area. Enhance filter systems on existing vehicles, aircraft, shipboard, communications vans and other static/mobile structures.
4: Restoration Capability —Enhanced capability to provide rapid, effective, and safe removal/neutralization of hazards resulting from NBC or TIM contamination to enable restoration of unit operational capabilities. Protect and sustain the Joint force by rapidly returning equipment and personnel to normal operating modes/efficiencies after exposure to an NBC or TIM contaminated environment.
5: Individual Protection —To protect the joint force by allowing it to operate safely, at near-normal levels of effectiveness, while under NBC threat, or in NBC, TIM or other environmental hazards area.

In accordance with our national strategy of achieving and applying technological superiority, several underlying concepts form the foundation of acquisition modernization. The first is the need to reduce cycle time in the acquisition of new systems or the integration of emerging technologies into existing systems. The use of Advanced Concept Technology Demonstrations (ACTDs), open systems and architectures, along with the new emphasis on commercial standards and practices, allow us to shorten the acquisition cycle time. The program acquisition process reduces lifecycle costs through practices such as design-to-cost and concurrent engineering to ensure that equipment is easy to maintain and repair even with the inherent complexity in most new systems.

2.2 NBC DEFENSE MISSION AREA REQUIREMENTS AND RDA SUMMARY

NBC defense programs are categorized broadly under three operationally oriented areas: contamination avoidance, protection, and decontamination. The Services have been working

closely together to increase jointness in ongoing programs for each of these areas. This report highlights improvements during FY98 and discusses coopera tive efforts for further Joint development of requirements. This section summarizes the require ments in each of the mission commodity areas. Tables 2-2 through 2-10 display requirements and acquisition strategies. Since the focus of this chapter is on research and development efforts, fielded items are not included in these tables. Descriptions of developmental and fielded equipment can be found in Annexes A–C of this report.

2.3 CONTAMINATION AVOIDANCE (Detection, Identification and Warning)

The operational concept of contamination avoidance includes NBC reconnaissance, detection, identification, warning and reporting. Earliest possible warning is the key to avoid ing NBC contamination. For fixed sites where contamination cannot readily be avoided and for missions requiring operations in a contaminated environment, detection, identification, and warning are equally critical to ensure that forces can (1) assume the optimal protective posture so that they can continue to sustain operations and (2) rapidly identify and decontaminate affected areas, equipment, and personnel. Sensors for the individual warfighter and systems capable of detecting multiple agents and characterizing new agents are being developed. Advances in technology are being pursued in chemical and biological standoff, early warning detection, miniaturization, interconnectivity, improved detection sensitivity, improved logistics supportability, and affordability. The following sections detail contamination avoidance science and technology efforts, modernization strategy, and Joint Service programs.

2.3.1 Contamination Avoidance Science and Technology Efforts

2.3.1.1 Goals and Timeframes. The goal of contamination avoidance is to provide real-time capability to detect, identify, characterize, locate, and warn against all CB warfare agent threats below threshold effects levels (see Table 2-2). To meet near term needs a number of sensor technologies are being optimized while alternative detection technologies mature. Mid-term technologies focus on developments to improve tactical detection and identification capabilities for both chemical and biological warfare agents. Far-term science and technology efforts focus on multi-agent sensors for biological agent detection and remote/early warning CB detec tion. These far-term objective technologies seek to integrate chemical and biological point and remote/early warning detection modules into a single system. Research and Development (R&D) efforts seek to optimize and balance system sensitivity, size/weight, cost, power consumption, signature and false alarm rate. Ultimately the goal is direct integration of CB detectors as a single system into various platforms, and command, control, communication, computer, and intelligence (C^4I) networks.

Table 2-2. Contamination Avoidance Science and Technology Strategy

By 1999	By 2005	By 2009
• Complete installation of the Portal Shield ACTD biological and chemical detection network at CINC air bases and ports • Complete demonstration of integrated point biodetection capability (Advanced Technology Demonstration)	• Field upgrade (eye safe) Long Range Bio Stand-off Detector in FY00-02. • Joint Biological Remote Early Warning System (JBREWS) ACTD with fielding of ACTD systems to selected CINCs by FY01 • Complete development of Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD) • Initiate development of Joint Service Warning and Identification LIDAR Detection (JSWILD) • Complete development of Joint Chemical Agent Detector (JCAD) • Complete development of Block II Joint Biological Point Detection System (JBPDS)	• Demonstrate integration of chemical and biological agent detection modules into a single sensor suite • Initiate development of hand-held equipment chemical contamination scanner • Complete development of CB water monitor • Complete development of JSWILD

2.3.1.2 Potential Payoffs and Transition Opportunities. Future CB detection systems will provide the capability to detect, identify in real time, map, and track all CB contamination in a theater of operations. This will enable commanders to avoid CB contamination or to assume the appropriate protection required to continue fighting and sustain their mission with minimal performance degradation and casualties. The program seeks to develop small, lightweight chemical detectors to provide an individual chemical detection capability. CB detection technologies have dual use potential in monitoring air pollution, noxious fumes inside enclosed areas, and municipal water supplies.

2.3.1.3 Major Technical Challenges. The major technical challenges are in the areas of biological collection, detection and identification, including remote/early warning sensing, improved agent discrimination and quantification, sample processing, interferent and ambient biological background rejection, and genetic probe development. Size, weight, and power reduction of detectors, power generation and consumption, development of integrated biological and chemical detection systems, and the fusion of sensor data with map ping, imagery, and other data for near real-time display of events are other areas of challenge.

There are two critical needs, both are focused on biological agent detection. Current technologies require a *high level of logistical support* and *lack discrimination in biological standoff detection.* The challenge in reducing logis tical support stems from the dependence on reagents and size, weight, and power requirements of the systems. Several efforts address these issues and can be broken out as efforts in minimizing reagent requirements with higher sensitivity, better stability, and fewer supporting reagents, and scientific/engineering strategies to reduce size, weight, and power requirements, especially in the sample collections components. There are several factors directly limiting the ability to discriminate biological agents using standoff (laser) detection technologies. Key factors include: (1) a lack of fundamental data in understanding the spectral properties of biological warfare agents, (2) range limitations of lasers due to atmospheric absorption, and (3) natural background interference. Over the last two years, a number of strategies and concepts have been developed to improve the discrimi nation capability of standoff detection for biological materials. Preliminary data developed this past year has shown the potential feasibility of two of these concepts. Further efforts in FY02 and FY03 will

begin to validate the feasibility of providing an enhanced level of discrimination of biological material using standoff detection.

2.3.2 Contamination Avoidance Modernization Strategy

The increased lethality and heightened operational tempo of the future battlefield demand responsive NBC detection and warning capabilities in order to reduce force degra dation caused by contamination. These capabilities—which also encompass NBC reconnais sance, detection, identification, and reporting—are critical for force readiness and will continue to be emphasized by the DoD community in the near and distant future. Table 2-3 shows the roadmap of DoD requirements for contamination avoidance.

Table 2-3. Contamination Avoidance Modernization Strategy

	NEAR (FY99-00)	MID (FY 01-05)	FAR (FY 06-15)
Chemical Point Detection	• **Surface sampling capability (ICAM)** • **Automatic point detection of nerve and blister agents (ACADA)** • Navy-*Ship based improved automatic point detection of nerve/mustard (IPDS)* • Navy-*Automatically detect liquid agent (SALAD)*	• **Improved, all-agent programmable automatic point detection; portable monitor, miniature detectors for aircraft interiors; interior ship spaces; individual soldiers (JCAD)**	• **Improved surface contamination monitor** • **Low dosage miniature detector; specific identification; personal monitor** • **Detection of CB contamination in water (Joint Chemical Biological Agent Water Monitor)**
Biological Point Detection	• **Automatic long line source and point/mobile biodetection to detect and identify bio-agents; programmable (JBPDS Block I)** • Navy-*Ship based Interim Biological Agent Detector (IBAD)* • Army-*Biological Integrated Detection System (BIDS)*	• **Automatic point biodetection, to detect and identify; programmable (JBPDS Block II)** • **Joint Biological Remote Early Warning System (JBREWS) - A distributed network of fully automated lightweight sensors.**	• **Automated detection of all validated biological threat agents (Joint Biological Universal Detector, JBUD)** • **Automated, integrated detection of both biological and chemical agents in a single sensor package (Joint Chemical and Biological Universal Detector, JCBUD)**
NBC Reconnaissance and CB Remote and Stand-off Detection	• **Improved NBC Reconnaissance Vehicle with remote/early warning and data infusion capabilities (JSNBCRS)** • Army - *Long Range Stand-off detection and mapping of aerosol clouds (LR-BSDS)*	• **Biological remote detection and early warning capabilities (JBREWS)** • **Lightweight passive stand-off detection for chemical agent vapors (JSLSCAD)** • **Addition of biological detection and identification capabilities (JSNBCRS P3I)** • **Light reconnaissance vehicle (JSLNBCRS)**	• **Stand-off detection, ranging, and mapping of chemical vapors and aerosols (JSWILD)** • **Wide area detection** • **Automated standoff detection of biological agents (JBSDS)**
Warning and Reporting	• **Automated warning and reporting (JWARN Phase I)**	• **Automatic NBC warning and reporting interoperable with all Services (JWARN Phase II)**	• **Integrated and automatic warning and reporting (JWARN Phase III)**
Radiation Detection	• Army-*Compact, digital whole body radiation measurement (AN/VDR-13)*		• **Stand-off radiation detection and measurement** • **Portable radiation meter**

1. Joint Service programs are highlighted in **BOLD**; Service unique efforts are *italicized.*
2. Where applicable, systems which meet requirements are liste d following the entry.

Early detection and warning is the key to avoiding NBC contamination. As a result, DoD is concentrating RDA efforts on providing its warfighters real-time capabilities to detect, identify, quantify, and warn against all CB warfare threats below threshold effects levels. Real

time detection of biological agents below threshold effects levels is unlikely in the near to mid-term. Current emphasis is on developing lightweight, automated CB sensors capable of providing enhanced detection and early warning, capable of detecting all known biological and chemical agents. To meet the needs in the near to mid term, several stand-alone detectors and sensors are being developed. Developmental efforts are focusing on system miniaturization, improved sensitivity and specificity, agent characterization and range, decreased false alarm rate, and decreased operation and support costs. This focus will facilitate the integration of chemical detectors into personal warfighter gear, chemical and biological detectors onto various air, sea, and ground platforms, and integration of detectors into automated warning and reporting networks. Table 2-4 provides an overview of RDA efforts and Service involvement.

Table 2-4. Contamination Avoidance RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
Automatic Detectors and Monitors	- M22 Automatic Chem Agent Detection Alarm (ACADA)	Production	Joint	Joint	Joint	Rqmt
	- Shipboard Automatic Liquid Agent Detector (SALAD)	LRIP				Rqmt
	- Improved Point Detection System (IPDS)	Production				Rqmt
	- Improved CAM (ICAM)	Production	Rqmt	Interest	Rqmt	Interest
	- Joint Chemical Biological Agent Water Monitor (JCBAWM)	RDTE	Joint*	Joint*	Joint*	Interest
	- Joint Chemical Agent Detector (JCAD)	RDTE	Joint*	Joint*	Joint*	Joint*
	- Biological Point Detection					
	–Interim Biological Agent Detector (IBAD)	Fielded				*Rqmt*
	–Biological Integrated Detection System (BIDS NDI)	Fielded	*Rqmt*			
	–BIDS P3I	Production	*Rqmt*			
	- Portal Shield	Production	Joint	Joint	Joint	Joint
	- Joint Bio Point Detection System (JBPDS)	RDTE	Joint	Joint	Joint	Joint
Remote/ Early Warning	- Joint Service Lightweight Stand-off Chemical Agent Detector (JSLSCAD)	RDTE	Joint	Joint	Joint	Joint
	- Joint Service Warning and Identification LIDAR Detector (JSWILD)	RDTE	Interest	Interest		
	- Biological Stand-off					
	–Joint Remote Biological Early Warning System (JBREWS)	RDTE	Joint	Joint	Joint	Joint
	–Long Range Bio Stand-off Detection System-NDI (LRBSDS-NDI)	Fielded	*Rqmt*	*Interest*		*Interest*
	–LRBSDS	RDTE	*Rqmt*	*Interest*		*Interest*
NBC Recon	- Joint Service NBC Reconnaissance System (JSNBCRS)	RDTE				
	–M93A1 NBCRS/CB Mass spectrometer (See BIDS)	*	*Rqmt*		*Rqmt*	
	–Joint Service Light NBCRS/Lightweight Recon System (JSLNBCRS)	*	Joint*	Joint*	Joint*	*Interest*
Warning and Reporting	- Joint Warning and Reporting Network (JWARN)	RDTE/Prod	Joint*	Joint*	Joint*	Joint*
	– Multipurpose Integrated Chemical Agent Detector (MICAD)	*	*Rqmt*		*Rqmt*	
Radiation Detection	- AN/UDR-13 Pocket Radiac	Production	Joint	Interest	Joint	

Joint= Joint Service requirement — Joint*=Draft Joint Service requirement
Rqmt= Service requirement — Int-NIR= Service interest, no imminent requirement
Rqmt, Interest= sub-product requirement or interest *= Sub-product(s) of a Joint project
LRIP= Low Rate Initial Production

The management challenge involves the coordination and consolidation of dozens of detection and warning RDA efforts across the Services. This strategy, led by the JSMG through the Contamination Avoidance Commodity Area Manager, resulted in the initiation of RDA efforts which shared common technical goals, but were constrained to Service unique requirements. Management organizations and initiatives, such as the Joint Program Office for Biological Defense (JPO-BD) and the Joint NBC Defense Board are building Joint Service coordination across the mission area.

Over the past several years, the JSMG and JSIG, through the Contamination Avoidance Commodity Area Manager, with assistance from JPO-BD transformed and consolidated 44 separate contamination avoidance developmental efforts into nine fully coordinated joint projects. The Joint Programs are:

- Automatic Chemical Agent Detection Alarm (ACADA)
- Joint Chemical Agent Detector (JCAD)
- Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD)
- Joint Service Warning and Identification LIDAR Detector (JSWILD)
- Joint Biological Point Detection System (JBPDS)
- Joint Biological Remote Early Warning System (JBREWS)
- Joint Service Light NBC Reconnaissance System (JSLNBCRS)
- Joint Warning and Reporting Network (JWARN)
- Joint Chemical Biological Agent Water Monitor (JCBAWM)

2.3.3 Joint Service Contamination Avoidance Programs

The consolidation of Joint Service contamination avoidance programs has been completed. All detection programs have been restructured to meet current multi-Service needs. Bolded entries in Table 2-3 highlight Joint programs. Detailed descriptions of Joint contamination avoidance programs are provided in Annex A.

Chemical Warfare Agent Contamination Avoidance. An ACADA non-developmental item (NDI) is being procured for point detection of chemical agent vapors. ACADA is suitable for many vehicle-mounted and man-portable applications. A ship board version of ACADA that addresses unique shipboard interferents is being built to provide the Navy with an interim monitoring capability until JCAD is fielded. JCAD provides point chemical vapor detection and is in Phase II (Engineering and Manufac turing Development, EMD) of the acquisition cycle . JCAD will function as a chemical point detection system in order to accomplish a variety of mission requirements on multiple service platforms. It will be considerably smaller and lighter than the ACADA and can be configured for a variety of applications, such as individual soldier detec tors, shipboard chemical agent monitoring, special operations forces (SOF) applications, and aircraft interior detection JSLSCAD provides passive standoff, on-the-move detection of chemical agent vapor and is in Phase II (EMD) of the acquisition cycle. The JSLSCAD program is a joint program with a JORD being approved by all Services. The basic JSLSCAD system (detector, scanner and electronics module) will weigh less than 50 pounds and occupy approximately one cubic foot. The system may be modi fied to accommodate a variety of requirements, including the addition of a 360° x 60° scanner for Armored Systems Modernization applications (tracked and wheeled vehicles), and a gimbal mount for Marine Corps helicopters and unmanned aerial vehicle (UAV) contamination avoid ance roles. The Air Force' s primary use for this system will be in air base defense. The Navy will install JSLSCAD on shipboard and airborne platforms and at high priority oversea instal lations. This system will be fully evaluated by all the Services during EMD.

In the near-term, the Army, Air Force, and Marine Corps have agreed to focus on the development of a Joint Service Light NBC Reconnaissance System (JSLNBCRS). The pro posed system will consist of a suite of detectors required for a specific mission that could be easily integrated into the platform of choice. Currently two configurations are proposed: a light and a medium version, to fulfill expeditionary and armored mission profiles, respectively. The FOX NBCRS would fulfill heavy requirements. The FOX NBCRS is being upgraded to include a chemical standoff detection capability and other electronic improvements including data fusion.

In the far-term, the Army, Air Force, and Marines have agreed to a Joint Chemical Biological Agent Water Monitor (JCBAWM). JCBAWM is a system that will detect the presence of contaminants in potable water. A requirement for an agent water monitor has been identified by the Army, Air Force, and Marines–a tech base program is underway. The operational scenarios defined in the JCBAWM Operational Requirements Document (ORD) include source water, water distributions systems, and verification of water treatment. The Army and Air Force have identified a need for a warning and identification detector. The Joint Service Warning and Identification LIDAR Detector (JSWILD) is a technology base effort to address this problem. JSWILD is a laser-based stand off detection system being developed to meet the need for the detection of chemical liquids, aerosols, and vapors. Although this system is much heav ier than its passive counterpart (JSLSCAD), it provides the ability to detect chemical agents in all forms—liquids, vapors, aerosols–as well as mapping and ranging information. In addition, JSWILD will provide similar but shorter range (1–5 km) capabilities in biological standoff detection as those developed and fielded for the Long Range Biological Standoff Detection System.

Biological Warfare Agent Contamination Avoidance. Currently, there are nine biological detection efforts being managed under the Joint Program Office for Biological Defense (JPO-BD):

(1) Interim Biological Agent Detector (IBAD);
(2) Joint Biological Point Detection System (JBPDS);
(3) Biological Integrated Detection System (BIDS);
(4) Long Range Biological Stand-off Detection System (LR -BSDS);
(5) Air Base/Port Biological Detection (Portal Shield) Advanced Concept Technology Demonstration (ACTD);
(6) Portal Shield Production;
(7) Joint Biological Remote Early Warning System (JBREWS) ACTD;
(8) Critical Reagents Program;
(9) Technology Transfer Program.

Currently fielded systems include the Navy' s shipboard detection system (IBAD) and the Army' s land-based system (BIDS-NDI). The Army' s LR-BSDS is a helicopter mounted infrared LIDAR system for the detection, ranging and tracking of aerosol clouds that may indicate a biological warfare (BW) attack.

In the near-term, the Air Base/Port Biological Detection (Portal Shield) ACTD has developed and demonstrated the capability of networked sensors to protect high value fixed sites against BW attacks. Portal Shield has transitioned into production to meet urgent Joint Chiefs of Staff (JCS) directed buy. JBPDS will be produced to meet each of the four Services' needs for an integrated biological point detector. This program is developing a standard bio detection suite that will be integrated on Service designated platforms. Fielding of the BIDS P3I to the 7 th CML CO began in 1QFY99 and will be completed by 4QFY99. In addition, the Critical Reagents Program consolidates all DoD antibody, antigen and gene probe/primer developments and requirements. This program will ensure the quality and availability of reagents that are critical to successful development, test, and operation of biological warfare detection systems and medical biological products. The Technology Transfer program will ensure the successful and rapid transition of DARPA and other Service breakthrough biological detection technologies into DoD fielded systems.

In the mid-term, the JPO-BD will demo nstrate the Joint Biological Remote Early Warning Advanced Concept Technology Demonstration (ACTD). This tactical distributed network system of lightweight, automated sensors will use fusion to reduce false alarms. The ACTD demonstration test in FY00 will demonstrate enhanced capabilities in detection, identification, and advanced warning of BW attacks.

In the far-term, the concept for the ultimate, joint service chemical and biological detector is the Joint Chemical Biological Universal Detector (JCBUD). JCBUD is envisioned to be a miniaturized, multi-technology, automatic system that may be manned or unmanned, capable of detecting all CW/BW agents, and able to automatically warn troops and report pertinent data relative to a CW/BW attack.

2.3.4 Warning and Reporting

Warning and reporting is a critical capability in contamination avoidance. The Services have agreed to expedite development of this capability by integrating ongoing hardware and software into a Joint Warning and Reporting Network (JWARN). This network will be compatible with, but not duplicate, all C^4I equipment both current and developmental. The JWARN Phase I effort began fielding the first version of software in FY98. The JWARN Phase II effort will be initiated in FY99 into EMD for hardware and software integration onto Service designated platforms and installation at fixed sites.

2.3.5 Other Contamination Avoidance Programs

Various detection and warning requirements have unique mission profiles and technical specifications. While in some instances the development effort may leverage the technical achievements of a closely related detection and warning project, the application beyond its intended mission is limited and accordingly supports a specific requirement. The Navy award ed a production contract in FY97 for the Improved (chemical agent) Point Detection System (IPDS), and will begin installation in FY99. IPDS will be used to automatically detect and alarm in the presence of chemical agents in vapor form and will provide continuous detec tion and alarm capability in the harsh shipboard environment. The IPDS replaces the existing ship board Chemical Agent Point Detection System (CAPDS) improving detection thresholds, response time, immunity to shipboard interferents, and adding the capability to detect mustard agents. The Navy is also planning on fielding the Shipboard Automatic Liquid Agent Detector (SALAD) in fiscal year 2000. This shipboard system will be used to auto matically detect and alarm in the presence of liquid chemical agents. By detecting automatically, it will minimize the sailor' s exposure to contamination. As with the IPDS, it will provide continuous detection and alarm capability in the harsh shipboard environment. A performance-based contract for the low rate initial production of SALAD will be awarded in FY99.

2.3.6 Defense Advanced Research Projects Agency (DARPA) Programs

There are two related BW sensor programs currently ongoing within DARPA: the BW defense environmental sensors programs and the tissue-based biosensors program.

DARPA BW Defense Environmental Sensors Program. DARPA is developing technologies that will enable a multiplexing capability for bioagent identification. Technologies using up-converting phosphors provide improved detection sensitivity, and enhanced multiplexing is being developed that can reveal BW agent family, genus, and species on a single chip. A mass spectrometer is being miniaturized and ruggedized for battlefield use in identifying BW agents and contaminants without the use of liquids. These systems will be automated for unattended operations. Detection technologies that provide information on BW agent pathogenicity and viability are also being developed under the DARPA biological detection program.

DARPA Tissue-Based Biosensors Program. DARPA is exploring the use of biological cells and tissues as detector components for sensor devices that will report on chemical and bio logical toxins. Cells and tissues can be used to report on the functional consequences of exposure (mechanism and activity) to a wide spec trum of chemical and or biological toxins, whether they are living or dead, or whether they have been bioengineered and are currently undetectable by other means (antibodies, nucleic acid sequencing). Technical issues that are being addressed in the program include, (1) the fabrication of biocompatible matrices and interfaces for the long-term retention of cell and tissue function, (2) pattern recognition from critical pathways responsible for the processing of toxins, (3) sampling strategies to accurately extract and pre sent the toxin from air, liquid, or solid samples, and (4) systems integration into a functional device. The current focus of the program is on the use of neuronal and immunological cells and tissues as detectors for such devices. Engineering of cells and tissues of these origins, including stem cells, is proceeding in order to optimize sensor performance requirements and fabricate prototype devices for testing and evaluation.

2.4 PROTECTION

When early warning is not possible or units are required to occupy or traverse contaminated environments, protection provides life sustainment and continued operational capability in the NBC contaminated environment. The two types of non-medical protection are individual and collective.

- ***Individual protective equipment*** includes protective masks and clothing. Protective masks that reduce respiratory stress on the user while improving compatibility with weapon sighting systems and reduce weight and cost are being developed. Technology advances are being pursued to produce mask systems that provide fully compatible vision capabilities, laser/ballistic protection, and further reduction in logistics and physiological burden. Protective clothing is being developed that will reduce the physiological burden, have extended durability and have less weight and heat stress burden than present equipment.

- ***Collective protection equipment*** consists of generic NBC protective filters and air movement devices that provide filtered air to a wide range of applications, transportable shelter systems equipped with NBC filtration systems and, in selected cases, environmental control. Collective protection, *i.e.*, overpressure, can be applied to mobile and fixed command posts, medical facilities, rest and relief shelters, buildings/fixed sites, vehicles, aircraft, and ships. Lightweight shelters integrated with NBC filtration, environmental control and power generation facilities for medical treatment facilities have been developed and are in production. Technology improvements are being pursued to reduce power requirements and improve filtration capacity against current and future NBC agents. Technologies that reduce weight, volume, cost, and improve the deployability of shelters and filtration systems are also being pursued.

2.4.1 Protection Science and Technology Efforts

2.4.1.1 Individual Protection Goals and Timeframes. The goal of the individual protection area is to reduce the physiological burden associated with wearing protective equipment while maintaining, and potentially improving, the already high level of protection against CB warfare agents and radiological particles (see Table 2-5). To achieve these goals, key physiological performance requirements to the design and evaluation of clothing and respirators are being established. New barrier and filtration materials and selectively permeable materials are being developed and evaluated to accommodate these performance requirements.

2.4.1.2 Collective Protection (CP) Goals and Timeframes. The goals of the collective protection area are to (1) reduce the weight, size and power requirements of CP systems, (2) reduce the logistical burdens associated with the maintenance of CP filters, (3) improve protection capabilities against current and emerging threat agents and (4) improve the deployability of trans portable shelter systems (see Table 2-5). To achieve these goals, improvements to system (including transportable shelters) components are being investigated along with improvements to the current vapor and particulate filtration media. Regenerative vapor and particulate filtration materials processes are being investigated to eliminate the need for filter change and improve the capability against any battlespace NBC threats.

Table 2-5. Protection Science and Technology Strategy

By 1999	By 2005	By 2009
• Prototype mask with 50% reduced breathing resistance and 50% improved field of vision • Joint Service Lightweight Integrated Suit Technology (Overgarment and MULO), extended durability, reduced heat stress, increased protection • Demonstrate regenerative filtration pre-prototype for collective protection applications • Complete evaluation of low cost and lightweight CB tentage materials	• Demonstrate advanced adsorbents to enhance or replace carbon • JLIST P3I, Joint Chemical Ensemble, chemical protective garments, gloves and footwear that are lightweight, and have extended durability and reduced heat stress • Demonstrate a duty uniform utilizing selectively permeable membrane tech nology that provides integrated environmental protection • Demonstrate new collective protection shelters utilizing low cost and lightweight CB tentage materials and novel CB resistant tentage closures	• New transportable shelter system (JTCOPS) • Improvements to collective protection systems (JCPE) • Continuous operation filter technology • Demonstrate lightweight, self-detoxifying clothing

2.4.1.3 Potential Payoffs and Transition Opportunities. Individual protection investments will result in improved respiratory and percutaneous (skin) protection with reduced physiological and psychological burden to the individual warfighter. Improved air filtration systems and/or technologies for collective protection applications will allow for extended operation, in an NBC contaminated environment, reduce the logistics burden associated with filter replacement, reduce weight, volume and power requirements, and improve the capability against current and emerging threats. Filtration technology has commercial application to the chemical industry and automotive applications.

2.4.1.4 Major Technical Challenges. Integrating CB protection into future weapon systems necessitates tradeoffs between performance requirements and limitations of materials and designs. Integral respiratory protection requires tradeoffs between physiological performance parameters such as pulmonary function, field of view, speech intelligibility and anthropometric sizing against cost, size/weight, protection time, and interfacing with other equipment. CB protective clothing development requires balancing the physiological burden imposed upon the warfighter with maximum obtainable CB agent protection. Significant advancements have been made in improving the weight/bulk and power requirements of personal cooling systems, but further work in this area is needed. Air purification systems require tradeoffs with respect to performance, user requirements, size, weight and power constraints, as well as longer life.

2.4.2 Protection Modernization Strategy

Forces cannot always avoid NBC hazards, therefore, individual warfighting units must be provided materiel to protect them from the effects of these lethal agents. Protection must be effective against all known threats with minimal degradation to the performance of personnel, weapons, or equipment. Total NBC protective measures allow our forces to maintain combat superiority in contaminated environments. A summary of protection modernization require ments is provided in Table 2-6. Chemical defense capabilities are routinely demonstrated against actual chemical agents in the Chemical Defense Training Facility (CDTF), U.S. Army Chemical School.

The goal of the protection RDA area is to provide equipment that allows U.S. forces to operate in a NBC contaminated environment with minimal degradation of the warfighters' performance. Near-, mid-, and far-term objectives are to reduce physiological and logistical burdens while maintaining current protection levels. Table 2-7 provides an overview of individual and collective protection RDA efforts and Service involvement.

Protective masks will be improved to provide greater user comfort and to reduce breathing resistance. Mask systems will require increased NBC survivability and compatibility with combat or personal equipment. Future respiratory systems, such as the Joint Service Aviation Mask (JSAM) and Joint Service General Purpose Mask (JSGPM) will require enhanced compatibility with life support equipment, tactical sys tems, and fixed and ro tary wing aircraft. In the future, the focus will be on integrated respira tory protective ensembles which offer optimal compatibility with personal, tactical, and crew support systems.

Future protective clothing ensembles for U.S. forces will require re ductions in bulk and weight without any loss of protection or durability. To satisfy these needs, the Services have consolidated their mission specific requirements into a first truly joint program for the next generation chemical garments—the Joint Service Lightweight Integrated Suit Technology (JSLIST) program. The JSLIST program developed and is fielding the JSLIST Overgarment and Multi-purpose Overboots (MULO). The JSLIST Pre-Planned Product Improvement (P3I) will develop improved chemical protective overgarments, duty uniforms, undergarments, gloves, and socks that will increase protection, reduce physiological burden, and have increased durability beyond those items fielded in the baseline JSLIST program. New accessories, such as gloves and footwear, are required to execute missions and tasks which require greater tactility and traction. The Joint Protective Aircrew Ensemble (JPACE) will be developed to provide aviators with the same advantages and improved protection as JSLIST provides to other warfighters. Similarly, clothing systems for Explosive Ordnance Disposal (EOD) personnel and firefighters are required to enhance existing chemical protection systems without undue physiological burdens.

Table 2-6. Protection Modernization Strategy

	NEAR (FY99-00)	MID (FY01-05)	FAR (FY06-15)
Individual Eye/ Respiratory	• **Voice amplification; laser/ballistic eye protection; improved decontamin-ability, better comfort (M40A1/M42A1)** • Army - *Aircrew mask compatible with Apache helicopter systems with a significantly lighter motor/blower unit (M48/M49)* • Army -*Improved compatibility with aviation sighting/night vision systems; reduced logistics burden using non-blower systems, selected for Land Warrior (M45)*	• **Reduced physiological burden, improved comfort, enhanced optical and communications, improved compatibility** • **New mask systems for general purpose and aviation masks (JSGPM, JSAM)** • Navy -*Improved complete protection for all aircrews (CB Respiratory System)*	• **Advanced Integrated Individual Soldier Protection system (Future Soldier System)** • **Improved multiple agent protection**
Individual Clothing	• **Advanced protective suit technology; lighter, improved agent and flame protection; reduced heat stress integrated with all respiratory systems.** **- Improved foot protection (MULO)** • **Improved protection, less burdensome, protective suits; Improved foot and hand protection/less burdensome; Flame protection (JSLIST P3I)** • Army -*Improved protection for short term use for special purposes (ITAP)* • Army -*Improved protection with self contained breathing capability for special purposes (STEPO)*	• **Improved protection (Joint Service Chemical Ensemble)** • **Improved protection for aviators (JPACE)** • **Service Life Indicator and CB duty uniform**	• **Integrated multiple threat modular protection (chemical, biological, environmental, ballistic direct energy and flame)** • **Self-detoxifying clothing**
Collective Protection	• **Chemically Protected Deployable Medical Systems (CP DEPMEDS)** • **Chemically Hardened Air Transportable Hospital (CHATH)** • **Lighter, more mobile, easier setup, more affordable shelters (JTCOPS)** • **Improved current collective protection filters and equipment (JCPE)** • Marine Corps -*Protection for all combat vehicles and unit shelters* • Army -*NBC protection for tactical Medical units (CB Protective Shelter, CBPS).* *- Apply regenerable vapor filter to Comanche,* *- Apply collective protection to advanced vehicle concepts.* *-Modular, reduced size, weight and power for vehicle/ shelter collective protection - Advanced Integrated Collective Protection Shelter (AICPS)* • Air Force - *Upgrade/install collective protection into existing rest/relief shelters.*	• **Improved filters to extend filter life, reduce maintenance and reduce logistical burden** • **Regenerable/advanced protective filtration for vehicles/vans/shelters; reduce logistics burden, improved protection against current and future threats** • **Support medical treatment in a CB environment for Airborne, Air Assault, and Heavy Divisions (CBPS)** • Navy - *Backfit ships with contamination free protected zones - (Selected Area Collective Protection System, SACPS), Integrate collective protection system into V-22*	• **Family of advanced protective filtration systems for vehicles, shelters, ships, and light forces**

1. Joint Service programs are highlighted in **BOLD**, Service unique efforts are *italicized*.
2. Where applicable, systems which meet requirements are listed following the entry.

Table 2-7. Protection RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
	INDIVIDUAL PROTECTION:					
Integrated	- Force XXI Land Warrior	RDTE	Rqmt	Interest	Interest	Interest
Eye/ Respiratory Protective Masks	- MBU-19/P Aircrew Eye/Respiratory Protection (AERP)	Production	Interest	Fielded	Interest	
	- M48/49 Aircraft Mask	Production	Rqmt			
	- CB Respiratory System (A/P22P-14(V))	RDTE			Rqmt	Rqmt
	- M45 Aircrew Protective Mask (ACPM)	Production	Rqmt		Interest	
	- M40A1/M42A1	Fielded	Rqmt		Rqmt	
	- MCU-2A/P	Production		Fielded		Rqmt
	- Joint Service Aviation Mask (JSAM)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
	- Joint Service General Purpose Mask (JSGPM)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
Ancillary Equipment	- Protection Assessment Test System (PATS)	Production	Rqmt	Fielding	Fielded	Interest
	- Voice Communication Adapter	Production	Rqmt	Rqmt	Fielded	Fielded
Battlefield Protective Suits	- CB Protective Overgarment Saratoga	Fielded	Interest		Fielded	Interest
	- Chemical Protective Undergarment (CPU)	Fielded	Rqmt		Int-NIR	
	- Joint Service Lightweight Integrated Suit Technology (JSLIST/JSLIST P3I)					
	-- Overgarment	Prod.*	Rqmt	Rqmt	Rqmt	Rqmt
	-- Undergarment (P3I)	RDTE	Interest	Interest	Interest	
	-- Duty Uniform (P3I)	RDTE	Interest	Interest	Rqmt	
	-- Boots (MULO)	MS III*	Rqmt	Rqmt	Rqmt	
	-- Gloves (P3I)	RDTE	Rqmt	Rqmt	Rqmt	
	-- Socks (P3I)	RDTE	Interest	Interest	Interest	
	-Battledress Overgarment (BDO)	Fielded				
Specialty Suits	-Self-Contained Toxic Environment Protective Outfit (STEPO-I) Interim	Fielded	Rqmt			
	- STEPO	MS III	Rqmt			
	- EOD Ensemble	Production	Rqmt			
	- Improved Toxicological Agent Protective (ITAP)	RDTE	Rqmt		Interest	Interest
	- Joint Firefighter Integrated Response Ensemble (JFIRE)	Production	Rqmt	Rqmt		
	COLLECTIVE PROTECTION:					
Tentage and Shelter Systems	- M20A1/M28 Simplified CP Equipment (CPE)	Fielded	Rqmt	Interest		Rqmt
	- CB Protective Shelter (CBPS) (Medical)	Production	Rqmt		Interest	
	- Portable Collective Protection System (PCPS)	Fielded			Rqmt	
	- CP Deployable Medical System–Chemically/ Biologically Hardened Air Transportable Hospital (DEPMEDS/CHATH)	Production	Rqmt	Rqmt		
	- Joint Transportable CP System (JTCOPS)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
Collective Protection (CP) Systems	- Shipboard Collective Protection System (CPS)	Production	Interest	Interest		Rqmt
	- Shipboard CPE	RDTE	Interest	Interest		Rqmt
	- Modular Collective Protection System (MCPE)	Fielded	Rqmt	Interest		Interest
	- Advanced Integrated Collective Protection System (AICPS) for Vehicle, Vans, and Shelters	RDTE	Rqmt		Interest	
	- Selected Area Collective Protection System (SACPS)	Production			Interest	Rqmt
	- M8A3 GPFU	Fielded	Rqmt			
	- M13A1 GPFU	Fielded	Rqmt	Rqmt		Rqmt
	Joint Collective Protection Equipment (JCPE)		Rqmt		Rqmt	
Generic Filters	- M48/M48A1 (100 cfm)	Fielded	Rqmt		Rqmt	Rqmt
	- M56 (200 cfm)	Fielded	Rqmt	Rqmt	Interest	Rqmt
	- Fixed Installation Filters	Fielded	Rqmt	Rqmt		

Rqmt = Product requirement
Interest = Product Interest
Int-NIR = Product Interest, No Imminent Requirement

* - Sub-Product(s) of a Consolidated Joint Service Project
Rqmt, Interest = Sub-Product requirement or Interest

Collective protection equipment (CPE) development efforts are focused on NBC protection systems at the crew, unit, and platform level. New CPE systems will be smaller, lighter, less costly, and more easily supported logistically. New systems are required to provide clean environments for critical operations (*i.e.*, where individual protective equipment (IPE) otherwise places an unacceptable burden upon the warfighter in performing duties) and for essential rest and relief. Modernization efforts will concentrate on: (1) improvements to current vapor and particulate filtration media to extend filter life and to offer improved performance against current and/or emerging threats, (2) advanced air filtration (vapor and particulate) technologies, integrated with environmental control, to greatly reduce the logistical burden and offer greatly improved performance against current and postulated threats, (3) increased application of collective protection systems onto vehicles, vans, shelters, fixed sites, and ships, within the Joint Services, (4) improved transportable shelter system with integrated power/environmental control/filtration, (5) improvements to current collective protection systems to reduce weight, volume, and power requirements, and (6) standardization of filters within the joint services to address storage and procurement concerns. Efforts are in place to support major weapons systems developments, such as the U.S. Navy V-22 Osprey, the U.S. Army's Comanche, Crusader, Bradley, Breacher, Heavy Assault Bridge, Future Scout and Cavalry System, the USMC Advanced Amphibious Assault Vehicle (AAAV), and other advanced weapons platforms.

2.4.3 Joint Service Protection Programs

Joint programs are shown in Table 2-6 as bolded entries. A detailed description of Joint IPE and CPE programs is provided in Annex B. Section 2.7 provides a response to specific Congressional concerns regarding materials used in the JSLIST program.

Individual Protection

Eye/Respiratory. The M40 and M42 masks (for individuals and armored vehicle crewmen, respectively) are undergoing the final stages of fielding to replace their M17 and M25 series counterparts. The new masks offer increased protection, improved fit and comfort, ease of filter change, better compatibility with weapon sights, and a second skin which is compatible with Army and Marine Corps protective ensembles. The second skin design also is being reviewed by the Navy and Air Force for potential adoption. The Army, Marines, and Air Force are also fielding the Protection Assessment Test Systems (PATS) to provide users of the M40, M42, and MCU-2/P series masks with a rapid and simple means for validating the fit and function of the mask to ensure readiness. The Navy is evaluating the use of PATS with its MCU-2/P series mask.

The Navy, in coordination with the Marine Corps, is leading an effort to equip all forward deployed fixed and rotary wing aircrew with improved chemical, biological, and radiological (CBR) protection. The CBR ensembles will feature off-the-shelf items, such as the CB Respiratory System. The Army, in cooperation with the Marine Corps, recently completed a product improvement program for the M40 series mask that allows ground crew to aircrew communication. The Air Force continues to field Aircrew Eye-Respiratory Protection (AERP) systems to protect aircrews from CB hazards. This system complements the recently fielded lighter weight aircrew ensemble.

Mid- and far-term research is focused on improved vapor and particulate filtration technology, as well as improved masks for light and special operations forces (SOF). Development will be completed in the mid-term for the Joint Service Aviation Mask and Joint Service General Purpose Mask, which will provide improved eye, respiratory, and face protection against current and future agents. It will maximize compatibility with future weapon systems, be lightweight, and offer modular facepieces to accommodate a variety of mission profiles. Protective mask efforts will focus on supporting specific needs of the Joint Services and integrated warrior programs (Land Warrior, Air Warrior, Mounted Warrior, and Force XXI).

Clothing. In the area of full body protection, the JSLIST program coordinated the selection of advanced technology chemical protective materials and prototype materials. The JSLIST Overgarment was adopted by all four services, and the Multipurpose Overboot (MULO) was adopted jointly by the Army, Air Force, and Marines. The JSLIST Overgarment is a 45 day garment that provides 24 hours of chemical protection. It is launderable and lighter weight than the Battle Dress Overgarment (BDO). The MULO will replace the black vinyl overboot/green vinyl overboot (BVO/GVO). The MULO is a 60 day boot that provides 24 hours of chemical protection. The boot has increased traction, improved durability, petroleum, oil, and lubricant (POL) and flame resistance, and better chemical protection than the BVO/GVO.

The JSLIST Pre-Planned Product Improvement (P3I) will address requirements not met through the baseline JSLIST program. This program will obtain new material technologies for overgarments and duty uniforms using the existing JSLIST design. Fabric technologies for a chemical protective undergarment and materials and designs f or chemical protective gloves and socks will also be addressed. This program will develop a 60 day overgarment with desired flame resistance (FR), a 30 day overgarment with required FR, a 30 day duty uniform with desired FR, a 7 day overgarment with desired FR, a 7 day undergarment with desired FR, general purpose gloves, high tactile gloves, and socks. Materials that meet Service' s requirements will be placed on a qualified materials list to encourage multi-source competition and to provide surge capability. In addition, the Army is working with the Air Force on a chemical protective firefighter' s ensemble, leveraging the technology from the JSLIST program.

In the far-term, efforts will focus on integrated protection. Next generation technology will be directed toward integrating CB protection into a system that will also provide environmental, ballistic, directed energy, and flame protection, as well as reduced physiological burden. A strong emphasis on supporting technologies must continue. Materials that detoxify a broad range of chemical and biological agents on contact, which can be incorporated into fibers, fabrics, and selectively permeable membranes are being developed using biotechnology, as well as more conventional approaches.

Collective Protection (CP)

The Army has produced the M20A1 Simplified CPE and the M28 shelter liners to provide CP collective protection to existing structures. Environmental control is also being added to selected applications. The new CPE provides liquid agent resistance and allows expansion of protection area. The M20A1 has been fielded. The M28 Simplified CPE has been integrated into CP DEPMEDS and CHATH field hospitals.

CHATH and CP DEPMEDS are joint programs to integrate environmentally controlled collective protection into already fielded Army and Air Force field hospitals in order to sustain medical operations in a CB contaminated environment for 72 hours. Chemical protection is integrated into existing medical tents and shelters through addition of M28 Simplified CPE, chemically protected heaters, air conditioners, water distribution and latrine systems and alarms. CP DEPMEDS successfully completed an Operational Test 4Q97, with type classification in 4Q99 and fielding in FY00.

The Chemically and Biologicall y Protected Shelter (CBPS) is a highly mobile, rapidly deployable shelter system designed to be used for Echelon I and II forward area medical treatment facilities. The system is self contained/self-sustaining. It is permanently mounted onto a M1113 Expanded Capacity Vehicle (ECV) with a Lightweight Multipurpose Shelter. The vehicle tows a trailer and generator set. The vehicle transports a CB protected airbeam supported soft shelter, self-contained environmental support and power generation system, a crew of four and gear, and medical equipment. The CBPS presently is in limited production with initial fielding scheduled for 4Q99 to meet an urgency of need requirement. A subsequent Operational Test will be performed in 1QFY00 with full type classification following. A preliminary Operational Test was completed 3QFY98. Mid-term objectives are to initiate development of CBPS to support medical treatment for Airborne, Air Assault and Heavy Divisions.

Other near to mid-term collective protection efforts, such as the Advanced Integrated Collective Protection System (AICPS) will provide a compact, integrated package for power, filtration, and environmental control (heating/cooling). AICPS will provide transport ability and maintainability enhancements and decrease system set-up times. Joint Collective Protection Equipment (JCPE) will use the latest technologies in filtration, environmental controls, and power generation to improve and/or standardize current collective protection equipment so that it is lighter, more efficient, more affordable and less logistically burdensome. The Joint Transportable Collective Protection System (JTCOPS) will be the next generation lightweight, modular, easily trans portable, self-supporting collective protection shel ter that will provide relief from psychological and physiological stresses during sustained operations in a contaminated environment. JCPE and JTCOPS will initiate engineering development in FY00. Redesign and concept tradeoff assistance regarding advanced filtration technologies, such as Pressure Swing Adsorption (PSA) and Catalytic Oxidation (CatOx) has been provided to the Comanche, Crusader, USMC AAAV, and U.S. Army advanced vehicle efforts. The USAF is currently upgrading their collective protective fixed site capabilities.

2.4.4 Other Protection Programs

Program supporting requirements of a single service are shown in Table 2-6 as italicized entries. A detailed description of IPE and CPE projects is presented in Annex B.

Individual Protection

Eye/Respiratory. The Army is developing the M48/49 protective masks to replace the M43 series masks. The M48 will be for Apache pilots and the M49 for general aviator use. They will be lighter and offer enhanced protection and compatibility with night vision and aircrew systems.

In the near-term, the Army will replace the M43 mask for the general aviator with the Aircrew Protective Mask, M45. The M45 is lighter and less expensive than the M43 and features CB protection without the aid of force ventilated air.

Clothing. The Army has approved fielding of the Self-Contained Toxic Environment Protective Outfit (STEPO). STEPO provides OSHA level A protection for Army Chemical Activity/Depot (CA/D), Explosive Ordnance Disposal (EOD), and Technical Escort Unit (TEU) personnel. In the near to mid-term, the Army is developing an Improved Toxicological Agent Protective (ITAP) ensemble for short term operations in Immediately Dangerous to Life and Health (IDLH) toxic chemical environments (up to 1 hr), emergency life saving response, routine Chemical Activity operations, and initial entry and monitoring. The ITAP ensemble will incorporate improvements in material and design. It includes a one-hour supplied air bottle system, which can be switched to a filtered air respirator when operators exit the area of high contamination. A Personal Ice Cooling System (PICS) is being developed for use with both the ITAP and STEPO.

Collective Protection

The Navy now includes the Collective Protection System (CPS) on al l new construction ships. Currently the DDG-51, LHD-1, AOE-6, and LSD-41 ship classes are being built with CPS. The Navy also has the capability to backfit CPS on ships already in Service. The Selec ted Area Collective Protective System (SACPS) has been installed on selected LHA-1 class ships. Air inside the zone is maintained at a higher pressure than the outside air to prevent leakage of contaminants into the protected zone. In the mid-term, the Navy is designing the V -22 Osprey to be the first Naval aircraft to incorporate CBR protection for both aircrew and passengers. The ability to provide a pressurized, contamination free environment is a design requirement. The Navy Shipboard Collective Protection Equipment (CPE) effort will increase the shipboard particulate filter life (from the current one or two years) to at least a three year service life, through the use of new particulate pre-filter materials and the use of new high efficiency particulate (HEPA) filter media. The Shipboard CPE will thus provide millions of dollars of savings in life cycle costs by reducing shipboard maintenance requirements and providing energy efficient fans.

2.5 DECONTAMINATION

When contamination cannot be avoided, personnel and equipment must be decontaminated to reduce or eliminate hazards after NBC weapons employment. Decontamination systems provide a force restoration capability for units that become contaminated. Modular decontamination systems are being developed to provide decontamination units with the capability to tailor their equipment to specific missions. Technology advances in sorbents, coatings, catalysis, and physical removal will reduce logistics burden, manpower requirements, and lost operational capability associated with decontamination operations. The following sections detail CB decontamination science and technology efforts, modernization strategy, and Joint Service programs.

2.5.1 Decontamination Science and Technology Efforts

2.5.1.1 Goals and Timeframes. The goal of decontamination science and technology is to develop technologies that will eliminate toxic materials without performance degradation to the contaminated object and be environmentally safe (see Table 2-8). This area includes decontamination of personnel, individual equipment, tactical combat vehicles, aircraft, facilities, and fixed sites. Decontamination technologies currently being pursued include enzymes, catalysts that improve reactivity, decontaminants that are effective in both fresh and brackish water, and improved reactive sorbents. Supercritical fluid technology and non-ozone depleting fluorocarbons are being investigated for sensitive equipment decontamination, while gaseous ozone is being evaluated as a reactive decontaminant for interior spaces of vehicles such as aircraft. Contamination control involves investigating procedures that minimize the extent of contamination pickup and transfer, and maximize the ability to eliminate the contamination pickup on-the-move as well as during decontamination operations.

Table 2-8. Decontamination Science and Technology Strategy

By 1999	By 2005	By 2009
• Demo improved sorbent delivery systems • Aircraft Interior Decon procedures (non-system, Project DO-49)	• Sensitive Equipment Decon Systems • Demonstrate enzymatic decon • Fixed Site decon systems	• Demonstrate environmentally safe, sensitive equipment decon materials • New self-decontaminating materials • Improved decon material to replace DS 2 • Aircraft and other vehicle interior decontamination

2.5.1.2 Potential Payoffs and Transition Opportunities. The payoff from enhanced decontaminants and decontamination systems will be new non-corrosive, non-toxic, non-flammable, and environmentally safe decontamination systems suitable for a timely elimination of CB agents from all materials and surfaces. This ability will allow the forces to reconstitute personnel and equipment more quickly to increase combat efficiency and lessen the logistic burdens. In the future, reactive coatings may allow the continuation of combat operations without the need to disengage for decontamination. Dual use potential for environmental remediation, especially those dealing with pesticide contamination, is being exploited.

2.5.1.3 Major Technical Challenges. There are two principle technical difficulties associated with this effort. The first is the development of decontaminants that are reactive, non-aqueous, non-corrosive, safe to use on sensitive equipment, decontaminate a broad spectrum of chemical and biological agents, and environmentally safe. The second technical difficulty is the development of decontamination systems that effectively clean all surfaces and materials, while at the same time reduce the manpower and logistics burden. Also, new concepts or technologies for decontamination of fixed sites are needed.

2.5.2 Decontamination Modernization Strategy

Decontamination systems provide a force restoration capability for units that become contaminated. Existing capabilities rely upon the physical application and rinse down of decontaminants on contaminated surfaces. Existing systems are effective against a wide variety of threat agents, yet are slow and labor intensive and present logistical, environmental, material,

and safety burdens. In addition, existing systems are inadequate for electronic equipment decontamination, deficient for large area, port, and airfield decontamination, and rely on DS2 and water. To improve capabilities in this functional area, the Joint Services have placed emphasis upon new decontaminating technologies that reduce existing manpower and logistics requirements. These technologies are safer on the environment, the warfighter, and equipment. Table 2-9 shows the roadmap for modernizing decontamination systems in DoD.

The goal of the NBC decontamination program area is to provide technology that removes and detoxifies contaminated material without damaging combat equipment, personnel, or the environment. The RDA community is working with the Joint Staff and Services' operations community to prepare a roadmap that will integrate RDA efforts with non-RDA efforts. Other effort include policy, doctrine, standards, and revised tactics, techniques & procedures. Research and development of non-corrosive, all-agent multipurpose decon taminants and decontaminating systems for combat equipment, aircraft, and personal gear remains a priority. Alternative technologies, such as sensitive equipment decontam ination methods and large scale decontamination systems attract interest across the four Services. Table 2-10 provides an overview of Joint Service RDA efforts and Service involvement.

Table 2-9. Decontamination Modernization Strategy

	NEAR (FY99-00)	MID (FY01-05)	FAR (FY06-15)
Personal Equipment Decontaminants	• **More reactive, high capacity adsorbent (M291/M295)**	• **Non-caustic, non-corrosive decontaminant for personnel and equipment** • Army-*Higher efficiency decon methods (Sorbent Decon)*	
Bulk Decontaminants	• **Non-caustic, non-corrosive, easy to store and manufacture multipurpose decontaminants**	• **Decontaminants for fixed facilities** • Army -*Environmentally acceptable replacement for DS-2* • Army -*Enzymes for chemical agent decontamination* • Navy -*Less caustic capability*	• **Mission tailored decontaminants** • Navy -*Contamination resistant shipboard materials*
Expedient Delivery Systems		• **Auto-releasing coatings; reduces skin contact hazard & labor requirements**	• **Self-decontaminating auto releasing coatings; reduces manpower and logistic requirements eliminates skin contact hazard**
Deliberate Delivery Systems	• **High pressure water wash; mechanical scrubber; improved decontaminant dispenser (increased vehicle throughput)** • Army -*High pressure hot water washing and decontaminate scrubber capability; reduced water, labor, and logistic burden (M21/M22 Modular Decon System)*	• **Rapid large scale decon capability for fixed sites; reduced manpower and logistic burden** • **Non-aqueous capability for electronics, avionics and other sensitive equipment** • Air Force - *Sensitive equipment decontamination system for aircraft interiors*	• **Vehicle interior decon capability** • **Supercritical fluid decontamination apparatus** • Army -*Waterless decon capability for electronics and avionics*

1. Joint Service programs are highlighted in **BOLD** while Service unique are *italicized.*
2. Where applicable, systems which meet requirements are listed following the entry.

Table 2-10 Decontamination RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
Personnel	- M295 Individual Equipment Decontaminating Kit	Production	Fielded	Fielded	Interest	Interest
	- M291 Skin Decontaminating Kit	Production		Fielded	Fielded	
Combat Equipment, Vehicles, and Aircraft	- M17A2/A3 Lightweight Decontamination System	Production	Fielded	Rqmt	Fielded	Interest
	- M21/M22 Modular Decontamination System (MDS)	RDTE	Rqmt	Int-NIR	Int-NIR	Int-NIR
	- M17 Diesel Lightweight Decontamination System	RDTE		Int-NIR	Rqmt	Interest
	- Sensitive Equipment Decon	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
	- Joint Service Fixed Site Decon	RDTE		Rqmt	Rqmt	
Decontaminant Solutions and Coatings	- Sorbent Decontamination System	RDTE	Rqmt	Interest	Rqmt	Interest
	- Solution Decontaminants					

Rqmt = Product Requirement
Interest – Product Interest
Int-NIR = Product Interest, No Imminent Requirement

* = sub-Product(s) of a Consolidated Joint Service Project
Rqmt, Interest = Sub-Product Requirement or Interest

2.5.3 Joint Service Decontamination Programs

The Army has developed the M291 skin decontamination kit as a replacement for the M258A1 decontamination kit for all Services, and has introduced the M295 for improved personal equipment decontamination. The M295 provides the warfighter a fast and non-caustic decontamination system for personal gear. A new adsorbent which is more reactive and has higher capacity is being developed to improve the performance of the M295 kit.

In the near- and mid- term, DoD continues to research new multi-purpose decontaminants as a replacement for bulk caustic Decontamination Solution 2 (DS2) and corrosive Super Tropical Bleach (STB). New technologies, such as sorbents, enzymatic foams, and reactive decontaminating systems are being explored and may offer operational, logistics, cost, safety, and environmental advantages over current decontaminants. It should be noted that present shipboard chlorine-based decontaminant solutions pose an unacceptable corrosion risk to Naval aircraft. Current procedures require the use of fresh water and normal aircraft detergent solutions.

In the far-term, the Services are seeking non-aqueous decontamination systems to provide for sensitive equipment decontamination at mobile and fixed sites. Additionally, there is interest and research in coatings which can reduce or eliminate the necessity of manual decontamination. A detailed description of the decontamination projects is provided in Annex C.

2.5.4 Other Decontamination Programs

In the near- and mid-term, the Army is developing the Modular Decontamination System (MDS) to enhance vehicle and crew weapon decontamination. The MDS will support thorough decontamination for ground forces and possess mechanical scrubbing and improved decontaminant dispensing capabilities. It will also offer a reduction in size, weight, logistics burden, and workload requirements over existing decontamination systems. Similarly, the Marine Corps has explored an alternative man-portable decontamination system and is in the process of procuring an M17 Lightweight Decontamination System (LDS) with a diesel engine. The Air Force is upgrading existing M17 LDS to M17A2 versions and expanding sorbent kit inventories to improve operational and personnel decontamination programs.

2.6 NON-MEDICAL CB DEFENSE REQUIREMENTS ASSESSMENT

ISSUE: **Advanced technologies and new methods are currently being examined for fixed site decontamination. Follow-up investigations are planned over the next year to determine the requirements necessary to perform decontamination of large areas, including cleaning area to sustain cargo handling operations. Over the past year, the Services have worked together to improve the Joint orientation of NBC defense requirements. The work being accomplished will improve the equipment fielded in the near future. More emphasis needs to be placed on the Warfighting CINCs' requirements as input for equipment research and development. This is necessary to ensure that future equipment meets the needs of the Joint battlespace environment.**

SOLUTION: Areas of concern which are addressed under the management improvement initiatives include the following:

- Identifying baseline capabilities as a measure for determining what tactics, techniques, and procedures may be required.
- Focusing and prioritizing chemical and biological detector programs to ensure that resources are leveraging the most promising technologies and are not diluted by excessive Service unique requirements.
- Developing advanced individual protection ensembles that minimally degrade an individual' s performance for all tasks performed in contaminated environments.
- Identifying requirements for collective protection programs to ensure that enough assets are available to complete missions in a CB contaminated environment.
- Developing advanced detection capabilities for the purpose of directing decontamination efforts and monitoring the effectiveness of those efforts.
- Identifying an environmentally safe decontaminant and development of a capability to accomplish fixed site and sensitive equipment decontamination.

ISSUE: **"The conferees understand that the Department of Defense is currently dependent upon a single source of supply for permeable chemical protective garment materials used in the joint service chemical protective suit and related chemical protective garments, and believe that the Department of Defense should consider taking actions necessary to qualify additional sources of supply for these materials. The conferees direct the Secretary of the Army, as executive agent for the chemical-biological defense program, to report to the congressional defense committees on any plans to qualify additional sources for these materials."** (Source: H.R. 1119, Conference Report, National Defense Authorization Act for Fiscal Year 1998 Page 649.)

SOLUTION: The primary goal of the Joint Service Lightweight Integrated Suit Technology (JSLIST) program is to provide the best chemical protective ensemble to the individual Soldier, Sailor, Airman and Marine, leveraging state-of-the-art materials and design through joint service management with close industrial partnership. There can be no compromise in this standard. JSLIST successfully completed a Milestone III decision in April of 1997. JSLIST is presently funded and in production. User requirements are stated in the JSLIST

Joint Operational Requirements Document (JORD). Table 2-11 shows several of the *key* requirements.

Table 2-11. Selected JSLIST Operational Requirements

- Protection against specified levels of liquid agents;
- Protection against specified concentration of agent vapor;
- Protection against specified levels of agent aerosols;
- Protection for specified durations;
- Compatibility with the use of individual and crew-served weapons, all commonly issued protective masks and handwear, footwear and all standard chemical individual equipment in temperate to hot climates at all Mission Oriented Protective Posture (MOPP) levels so that the performance of combat tasks pertinent to mission completion are comparable to the currently approved garment;
- Greater freedom of movement and reduced performance degradation as compared to existing chemical protective garments;
- Not cause significant noise when in a combat environment.

Through comprehensive developmental and operational testing, and an independent assessment, The JSLIST program identified only one material combination that passed all testing. As a result, JSLIST production material is sole source.

The JSLIST Pre-Planned Product Improvement (P3I) program is a follow-on to JSLIST. The program includes participation by all Services and Special Operation Forces. The goal of the JSLIST P3I program is to increase the capabilities of the current chemical protec tive items. Desired requirements that were not achieved by the JSLIST pro gram will be addressed. The JSLIST P3I program is leveraging industry for improved fabric tech nologies for use in garments. The existing JSLIST design is used as the baseline, with minimum modifications, as necessary for improve ment. In order to address the Services' requirements for socks and gloves, state-of-the-art fabric technolo gies and designs for socks and gloves have been sought. The goal of the JSLIST P3I program is to initiate a qualification list for chemical protec tive socks, gloves, and fabrics for garments. The qualification list will be used to procure the items.

The program is being conducted in three phases. In phase I, there are two screening periods: phases Ia and Ib. Fabrics, socks, and gloves submitted by interested firms will be evaluated for minimum cha racteristics, all of which must be met in order to remain in the evaluation. By using two screening peri ods, manufacturers are provided an opportunity to participate in the initial screening period and then to improve their fabrics, gloves, and socks that did not meet the minimum criteria, and to resubmit during the second period. In addition, manufacturers that did not submit in screening phase Ia, can submit in phase Ib. Data obtained from both screening periods will be used in the selection process, which will occur after the completion of both screening periods. In phase II, developmental/operational testing (DT/OT) will be conducted to assess the field performance of the selected items. In phase III, technical data packages for the successful candidate fabrics, gloves, and socks will be provided to the procuring agency for insertion in the scheduled JSLIST production buys.

A market survey announcement was published in the Commerce Business Daily on 24 June 1997. An information packet detailing the Users' requirements, test criteria, test

methods, and the overall program schedule was provided to companies responding to the source sought announcement and expressing interest in participating in the program.

Phase Ia is completed. Phase Ib began on 7 May 1998 and was completed in 1QFY99. Phase II will be from 1QFY99-4QFY99. JSLIST P3I is scheduled for a Milestone III review in late 1999 or early 2000. The program goal remains the same, provide the best protection ensemble to our warfighters. The program may identify additional materials to accomplish this end. The program recognizes the importance of multi- sourcing and the business impacts on JSLIST ensemble production. Achieving addi tional material sources via the JSLIST P3I effort is a goal, though achieving the best protection as estab lished by the JORD is the primary goal.

Chapter 3

Medical Nuclear, Biological, and Chemical (NBC) Defense Requirements and Research and Development Program Status

3.1 REQUIREMENTS

3.1.1 Introduction

Many countries and terrorist groups have acquired the means to produce chemical, biological and radiological weapons and the means to deliver them. Nuclear, biological, and chem ical (NBC) proliferation increases the threat to deployed U.S. forces. In response, our medical chemical, biological, and radiological defense research programs' (MCBRDRP) mission is to preserve combat effectiveness by timely provision of medical countermeasures. Counter measures are developed in accordance with joint service mission needs and requirements in response to chemical warfare (CW) threats, biological warfare (BW) threats, and threats associated with radiological/nuclear warfare (RW) devices. The MCBRDRP has three goals:

(1) Provide individual level protection and prevention to preserve fighting strength.
(2) Maintain technological capabilities to meet p resent requirements and counter future threats.
(3) Provide medical management of CW, BW, and RW casualties to enhance survivability, and expedite and maximize return to duty.

Chemical warfare agents are available worldwide and include vesicants (blister agents), nerve, blood, and respiratory agents. Biological threat agents include bacteria, viruses, rickettsiae, and toxins that can be produced by any group with access to a scientific laboratory or a pharmaceutical industrial facility. The primary nuclear threat is the use of conventional explo sives to spread nuclear contamination over a limited area or strategic terrain (including usage against reactors or industrial radiation sources) and potentially the use of a single or a small number of crude, Hiroshima-type nuclear weapons. Exposure to multiple threats may result in synergistic effects. Assessment methodologies enable threat evaluation and injury prediction. Medical prophylaxis and treatment strategies reduce the performance decrement, injury, and death of military personnel in the field, thereby enabling them to accomplish their missions as well as reducing the need for medical resources.

DoD has maintained a medical research and development program for NBC for many years. This program has resulted in the fielding of numerous products to protect and treat service members. The DoD program to stockpile biological defense products has been smaller than the chemical defense effort, but has received greater emphasis in recent years.

Specific initiatives programmed to improve NBC defense medical readiness include:

- Continued emphasis on NBC medical countermeasures research.
- Identification and testing of medications and therapeutic regimens that reduce the effect of radiation on both bone marrow and the intestinal tract.
- A biological defense immunization policy for U.S. forces and for other-than-U.S. forces.
- Cooperative initiative with the U.S. Food and Drug Administration (FDA) for acceptance of efficacy data derived from animal studies as surrogates for large -scale human efficacy trials to license drugs and biological products that cannot be ethically tested for efficacy in humans.
- A prime systems contractor initiated effort to develop, license, produce, and store biological defense vaccines.
- Enhanced medical diagnostic capability for diseases/injuries caused by all agents.
- Definition of low-dose-radiation interaction on susceptibility to biological and chemical agents.

3.1.2 Challenges in the Medical NBC Warfare Defense Programs

Medical prophylaxes, pretreatments, and therapies are necessary to protect personnel from the toxic or lethal effects of exposure to all validated threat agents, as well as other anticipated threats. DoD has fielded a number of medical countermeasures that greatly improve individual medical protection, treatment, and diagnoses.

The DoD complies with the Food, Drug and Cosmetic Act for Drugs and Public Health Services Act Section 351 for biologics to ensure that drug products are safe and efficacious and biological products are safe, pure, and potent. DoD is working closely with the FDA to amend the Code of Federal Regulations (CFR) for New Drug and Biological Products that cannot meet the efficacy studies required by the FDA for product licensure because they are either not feas ible and/or cannot ethically be conducted under the FDA' s regulations for adequate and well controlled studies in humans. (See 21 CFR Sec 312.21(2)(b).) DoD presented a proposal to the FDA' s Vaccines and Related Biological Products Advisory Committee to use animal efficacy data as evidence demonstrating the efficacy of the Pentavalent Botulinum Toxoid (ABCDE). The Advisory Committee recommended that the FDA accept DoD' s proposed animal surrogate data for licensure of the Pentavalent Botulinum Toxoid (ABCDE). The FDA drafted a proposed rule that allows the use of animal efficacy data for those products that either cannot be tested ethically in humans or it is unfeasible to test. This proposed rule is expected to be published in the Federal Register in the near future.

Medical NBC defense products are thoroughly evaluated and tested for their safety in accordance with FDA guidelines before administration to *any* personnel. All NBC defense medical products must be safe to use and not degrade operational performance. In cases where adverse effects are known or are possible, a decision must be made–and a risk accepted–of the real or potential effects of a medical product versus the catastrophic effects of NBC weapons. In those cases where efficacy is not understood, the safety profiles of the products are well delineated. In many cases, the safety is well understood because the medical products have been widely

used to treat other medical conditions. (The anthrax vaccine is licensed and has been used since the 1970s to vaccinate veterinarians, textile workers, and others. The Pentavalent Botulinum Toxoid (ABCDE) was administered safely over 10,000 times to laboratory workers prior to its use for military personnel during the Gulf War. Various anti-emetics to protect against radiological threats have been used to treat cancer patients undergoing radiation therapy.) Several studies performed at the U.S. Army Medical Research Institute of Infectious Diseases demonstrated the efficacy of the anthrax vaccine against inhalation anthrax in the monkey model. Rhesus monkeys were vaccinated with one or two doses of the anthrax vaccine and then challenged with highly lethal levels of spores from the Ames strain of anthrax, the most virulent strain tested. In all these studies, the anthrax vaccine protected 42 of 43 monkeys against inhalation anthrax while none of a total of 14 controls used in these experiments survived.

The acquisition life cycle of medical products developed by DoD is normally m anaged in accordance with the guidelines found in DoD Regulation DoD 5000.2-R. However, since DoD also complies with FDA requirements, it also must follow the requirements of Title 21, Food & Drugs, Code of Federal Regulations for the manufacture, testing, and licensing of medical products. The following chart illustrates the correlation of FDA requirements for product development with the requirements of DoD 5000.2-R for the life cycle of product development in accordance with DoD acquisition policy:

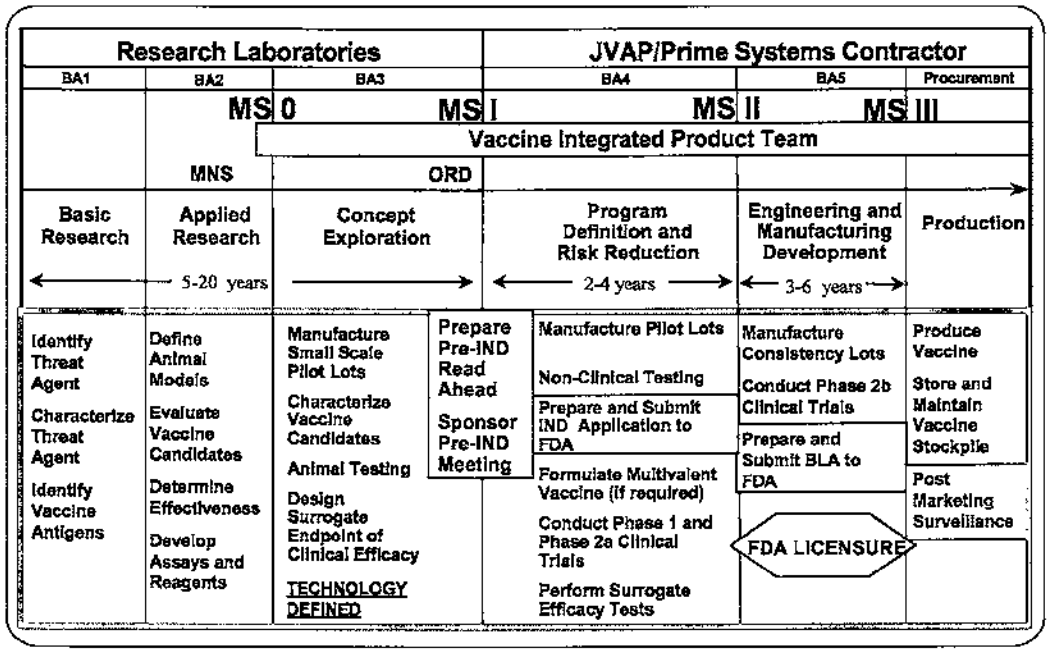

Figure 3-1. Integration of FDA and DoD Milestone Requirements

The medical NBC defense research programs discussed in this section are divided into chemical, biological, and nuclear areas of research. Table 3-3 (on page 3-15) provides a sum mary of the medical NBC defense programs and the planned modernization strategy over the next fifteen years.

3.1.3 Reducing Reliance on Research Animals

In accordance with the FY95 National Defense Authorization Act, which directed DoD to establish aggressive programs to reduce, refine, or replace the use of research animals, the MCBRDRP utilizes and develops technologies that will reduce reliance on animal research. In FY98, the MCBRDRP utilized computerized molecular modeling, computer predictions, *in vitro* cell cultures, a cell-free reaction system, and a lipid bilayer system to replace the use of animals when possible. All research proposals that use animals are evaluated by a statistician to ensure that the minimum number of animals required to obtain scientific validity are used. Animals lower on the phylogenetic scale (or the least sentient species) are used if the selection will permit attainment of the scientific objective. Additionally, all procedures that might cause pain or distress in laboratory animals are reviewed by a veterinarian with expertise in laboratory animal medicine to determine the procedural modifications, analgesics and/or anesthetic regimens to be incorporated to minimize pain or distress.

DoD policy states that animal use will be conducted in full compliance with the Animal Welfare Act and that animals are to be used in research only when scientifically acceptable alternatives are not available.

3.1.4 Medical Program Organization

Chemical/Biological. The U.S. Army is the Executive Agent for the Medical Chem i-cal and Biological Defense Research Program as prescribed in DoD Directive 5160.5 and, as such, is the lead requirements coordinator. The programs are integrated DoD in-house and ex ternal efforts. The Joint Technology Coordinating Group (JTCG) 3 (Medical CW Agent Defense) and JTCG 4 (Medical BW Agent Defense) of the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee are responsible for the programs' joint consolidation, coordination, and integration. The ASBREM Committee maximizes efficiency by coordinated planning, and minimizes unnecessary program overlaps and costly materiel retrofits. (The integration of program management and oversight of medical and non-medical NBC defense programs is described in Chapter 1.) The Army Science and Technology Base Master Plan, the Defense Technology Area Plan, the Joint Nuclear Biological Chemical Defense Research, Development, and Acquisition Plan, and the Medical Science and Technology Master Plan are the program drivers for the chemical and biological research programs. The Joint Service Integ ration Group (JSIG) established a Medical Program Sub-Panel (MPSP), which is the user rep resentative from the medical community, to establish and direct joint service NBC medical defense program requirements. The science and technology base is managed through the development and execution of Defense Technology Objectives (DTOs) and Science and Technology Objec tives (STOs). The predevelopment program (basic research, exploratory development, and concept exploration and definition) is directed by the U.S. Army Medical Research and Materiel Command (USAMRMC) through its lead laboratories for medical chemical defense, biological defense, and infectious disease research, U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID), and Walter Reed Army Institute of Research (WRAIR), respectively. The

advanced development program (Program Definition and Risk Reduction [PDRR]) and Engineering and Manufacturing Development (EMD) for medical *chemical* defense products is directed by the U.S. Army Medical Materiel Development Activity (a USAMRMC asset). The ad vanced development program (PDRR and EMD) for medical *biological* defense products is directed by the Joint Program Office for Biological Defense (JPO-BD). The Joint Vaccine Acquisition Program (JVAP) acts as a subordinate element of JPO-BD to transition candidate biological defense vaccines from research laboratories to the Prime Systems Contractor for the development, testing, licensure, production, and storage of vaccine stockpiles.

Nuclear. The study of the medical and biological effects of ionizing nuclear radiation is performed by the tri-service Armed Forces Radiobiology Research Institute (AFRRI). AFRRI programs are integrated into other DoD in-house and external efforts under the coordination of ASBREM. Specific requirements and tasking for AFRRI research comes from the individual services, Joint Staff, and the Defense Technology Objectives (DTOs) through the authority of a Board of Governors (BOG) with funding from the Director, Defense Research and Engineering (DDR&E) under the Secretary of Defense for Acquisitions and Technology. AFRRI is under the administrative control of the Uniformed Services University of the Health Sciences (USUHS). Members of the AFRRI BOG include representatives of Under Secretary of Defense for Acquisition and Technology (USD(A&T)), the Assistant Secretary of Defense for Health Affairs (ASD(HA)), the Surgeons General of the Army, Navy, and Air Force, and the Deputy Chiefs of Staff for Operations of the Army, Navy, and Air Force, or their designated representatives. Major inputs to AFRRI research requirements are driven by the biennial Army Qualitative Research Requirements (QRR) compiled by the U.S. Army Nuclear and Chemical Agency (USANCA) and AFFRI' s four DTOs. Currently there is no established advanced development (PDRR and EMD) process for the nuclear medical program.

3.2 MEDICAL CHEMICAL DEFENSE RESEARCH PROGRAM

The mission of the Medical Chemical Defense Research Program (MCDRP) is to preserve combat effectiveness by timely provision of medical countermeasures in response to joint service chemical warfare defense requirements.

3.2.1 Goals

The goals of the MCDRP are the following:

- Maintain technological capability to meet present requirements and counter future threats:

  - Determine sites, mechanisms of action, and effec ts of exposure to chemical warfare agents with emphasis on exploitation of neuroscience technology and dermal pathophysiology.
  - Identify sites and biochemical mechanisms of action of medical countermeasures.
  - Exploit molecular biology and biotechnol ogy to develop new approaches for medical countermeasures.
  - Exploit molecular modeling and quantitative structure-activity relationships

supporting drug discovery and design.

- Provide individual-level prevention and protection to preserve fighting strength:

  - Develop improved prophylaxes, pretreatments, antidotes, and therapeutic countermeasures.
  - Develop skin protectants and decontaminants.
  - Identify factors that influence safety and efficacy properties of candidate countermeasures.
  - Develop and maintain preformulation, formulation, and radiolabeling capabilities.

- Provide medical management of chemical casualties to enhance survival and expedite and maximize return to duty:

  - Develop concepts and recommend therapeutic regimens and procedure s for the management of chemical casualties.
  - Develop diagnostic and prognostic indicators for chemical casualties.
  - Provide education on medical management of chemical casualties.

3.2.2 Objectives

The objectives of the MCDRP differ with the vary ing threats:

- For vesicant (or blister) agents, the objective is to develop a pathophysiological database on vesicant chemical agents and a working hypothesis on how damage occurs at the cellular level. Used with associated technologies, this approach will enable the formulation of definitive pretreatment and treatment strategies, and is expected to produce a realistic concept for medical prophylaxis, immediate post exposure therapy, and topical protection. Alternatively, in dealing with liquid agent threat, reactive topical skin protectants (rTSPs) can be developed that will protect the skin and simultaneously detoxify the agent.

- For nerve agents, the objective is to field a safe and effective advanced anticonvulsant nerve agent antidote, and to field an advanced pretreatment based on biological scavengers like human enzyme butyrylcholinesterase (BuChE). Like acetylcholinesterase, the target enzyme for nerve agents, native BuChE is also inhibited by nerve agents. Through bioengineering efforts in the technology base, human BuChE has been mutated to a form that catalyzes the breakdown of nerve agent. The concept of using a catalytic BuChE to protect against large doses of nerve agent has been established in laboratory animals, indicating that this approach is feasible in humans. Although both offer poten tial long term protection, the enzyme pretreatment requires a single dose rather than three doses daily of pyridostigmine bromide.
- For blood agents, the objective is to develop and field a safe and effective cyanide pretreatment.
- For respiratory agents, the objective is to develop prophylaxes and therapies by understanding pathophysiological changes after agent exposure.

3.2.3 Threats, Countermeasures, Technical Barriers, and Accomplishments

The chemical warfare threats and countermeasures, as well as chemical defense research and development technical barriers and accomplishments, are outlined in Annex D (Section D.1).

3.3 MEDICAL BIOLOGICAL DEFENSE RESEARCH PROGRAM

The mission of the Medic al Biological Defense Research Program (MBDRP) is to develop medical countermeasures to protect U.S. forces and thereby deter, constrain, and defeat the use of biological agents against them (DoD Directive 5160.5, May 1985). The program is directed against agents of biological origin that are validated military threats. A primary concern is the development of vaccines, drug therapies, and diagnostic tools, and other medical products that are effective against agents of biological origin (see Table 3-1).

3.3.1 Goals

Goals of the MBDRP include the following:

- Protecting U.S. forces' warfighting capability during a biological attack.
- Reducing vulnerability to validated and novel threats by maintaining a strong technology base.
- Providing education on medical management of BW casualties.

3.3.2 Objectives

In accomplishing the goals of the MBDRP, efforts are focused on three objectives:

- Maintaining technological capability to meet present requirements and counter future threats:
  - Determine sites, mechan isms of action, and effects of exposure to biological warfare agents with emphasis on exploitation of molecular science.
  - Identify sites and biochemical mechanisms of action of medical countermeasures.
  - Exploit molecular biology and biotechnology to de velop new approaches for medical countermeasures.
  - Exploit molecular modeling and quantitative structure-activity relationships supporting drug discovery and design.

- Providing individual-level prevention and protection to preserve fighting strength:
  - Develop improved vaccines, pretreatments, antidotes, and therapeutic countermeasures.
  - Identify factors that influence safety and efficacy properties of candidate countermeasures.

- Providing training in medical management of biological casualties to enhance survival and

expedite and maximize return to duty:

- Develop concepts and recommend therapeutic regimens and procedures for the management of biological casualties.
- Provide education on medical management of biological warfare casualties

The MBDRP responds to requirements from the DoD as identified in the Joint Service Agreement on Biological Defense, the Joint Warfighting Science and Technology (S&T) Plan, the Defense Technology Area Plan, the Defense S&T Strategy, and DoD Directive 6205.3, "Biological Defense Immunization Program".

Highly sophisticated technology base efforts for medical biological defense hold the promise of yielding important new products to protect our troops against a wide range of biological weapons and naturally occurring diseases. These products include multi-agent vaccines that will reduce costs of vaccine production and simplify immunization schedules, and a common diagnostic kit, a hand-held device that can be deployed at forward sites to rapidly analyze clini cal samples for the presence of biological warfare agents as well as infectious diseases of mili tary importance. The development of these products, as well as the complementary technology-based research and development to enhance and expand these capabilities and to identify and develop new capabilities, is also being supported by collaboration with other agencies, such as the Defense Advanced Research Projects Agency (DARPA) and the Department of Energy (DOE).

Projects and technologies shared with the DOE are related to the strengths of DOE laboratories in developing advanced technologies in order to enable rapid detection of and response to a chemical or biological incident. While DOE focuses internal technology development efforts on the domestic threat, they actively support the DoD. The work spans DNA sequencing and biodetection to modeling and simulation, collaborating on projects such as x-ray crystallography and nuclear magnetic resonance imaging of BW agent antigens. The DNA sequencing efforts have led to advances in developing "lab on a chip" diagnostic technology for several BW threat agents. DOE is not involved in protection and treatment of personnel, but they are assisting DoD with drug/chemical database searches with the intent of identifying novel inhibitors of pathogens.

The DARPA BW defense program includes collaborating with USAMRMC on new platforms to enhance delivery and effectiveness of multi-agent vaccines (for example, stem cells genetically programmed to express antigens sequentially in order to provide automatic boosters in the body). Multi-agent vaccines are similar to the measles-mumps-rubella vaccine admin istered to children except that the technologies being explored for producing these new vaccines are more advanced, relying on bioengineering technologies such as naked DNA and the replicon-based delivery systems. Research in both the naked DNA and replicon approaches is advancing rapidly, and transition of a multiagent vaccine to advanced development (post Milestone I) is scheduled for FY 02.

Bioengineering techniques are also being used to prepare a variety of recombinant vaccines against single threat agents that will be produced without the need to grow the actual threat agent during the vaccine production process. Several recombinant vaccines are scheduled to be fielded over the next 10 years.

Development of a common diagnostic kit is proceeding with two state-of-the-art technologies. In the antibody-based system, a membrane platform will detect biological warfare threat agents in biological specimens. The second system relies on detecting the DNA of a variety of biological warfare threat agents or natural infectious diseases by a hand-held polymerase chain reaction (PCR) technique. With these tools, clinical diagnoses will be made much faster (less than 30 minutes) and farther forward than is possible now. The development of technologies for common diagnostic systems is jointly supported by DARPA.

The MBDRP includes the following areas of research:

Pre-exposure Countermeasures: This area involves prophylactic measures undertaken to prevent illness and injury associated with exposure to bacterial, viral, and toxin threat agents. The primary focus of pre-exposure therapy is efforts to produce effective vaccines. The roles of various factors in stimulating cellular and humoral immunity are determined through study of specific genes or properties of threat agents. This knowledge provides tools for development of second-generation recombinant or multi-agent vacci ne candidates as well as pretreatment therapies to intervene in the pathogenic effects of threat agents.

Post-exposure Countermeasures: Research efforts in this area are focused on developing safe, effective treatments to alleviate disease or injury associated with exposure to bacterial, viral, or toxin threat agents. Therapeutic measures may involve administration of antimicrobials, anti-toxins or generic compounds formulated to intervene at the pathogen' s site of action. The know-ledge necessary to develop such products requires in-depth research in the basic pathogenesis and physiology of the BW agents. These analyses will afford researchers tools to create a universal approach in treating post-exposure casualties of a BW attack.

Diagnostics: Diagnostics research involves the investigation and evaluation of sensitive and specific methods for detection of infectious organisms, toxins, antigens and antibodies in biological materials to include the application of nucleic acid probes or synthetic antigens. Rapid identification tests and diagnostic methods for the assay of toxins, metabolites, and analogs in clinical specimens are major goals of this program area.

3.3.3 Threats, Countermeasures, Technical Barriers, and Accomplishments

A biological th reat agent is defined as an intentionally disseminated living micro organism or toxin that can cause disease or death in humans, animals, or plants. Threat agents include a broad range of microorganisms (bacteria, rickettsiae, and viruses) and toxins of biological ori gin. Biological weapons are easy to make, difficult to detect, and can be very effective. Defense against this class of weapon is difficult, particularly when biological agents can produce casual ties over an area of thousands of square kilometers. Biological agents could also be used with devastating effect in combination with nuclear, chemical, or conventional weapons.

Countermeasures and diagnostic techniques for biological weapons are shown in Table 3-1. Critical elements of medical biological defense include the ability to protect U.S. forces from

BW agents, to rapidly diagnose (in clinical specimens) infection or intoxication from agents, and to treat casualties. Currently, the most effective countermeasure is pre-deployment active immunization. Future threats, however, may involve genetically engineered biological weapons that may be easily produced, highly lethal, difficult to detect, and resistant to conventional therapies.

The current MBDRP includes the following research a reas for the development of medical countermeasures:

- Characterize the biochemistry, molecular biology, physiology, and morphology of BW threat agents.
- Investigate the pathogenesis and immunology of the disease.
- Determine the mechanism of action of the threat agent in an animal model system.
- Select antigen(s) for candidate vaccines.
- Develop and compare potential vaccine candidates and characterize their effects in animal models.
- Establish safety and efficacy data for candidate vaccines.
- Develop medical diagnostics to include far forward, confirmatory, and reference lab.
- Develop chemo/immunotherapeutic agents and preparations.

Technical shortcomings in the private sector include the lack of high -level biological containment (BL-3 and BL-4) laboratory facilities to support biological defense research and scientific expertise in biological defense. These factors restrict the depth of expertise, facilities, and support available. A recent redress of funds and authorizations over a six year period (FY99-05) will be used for DoD facility upgrades and to maintain scientific and technological expertise.

Details of the biological warfare threats and countermeasures, as well as biological defense research and development technical barriers and accomplishments , are presented in Annex D (Section D.2).

Table 3-1. Medical Biological Defense Countermeasures and Diagnostic Techniques

VACCINES

- *Killed* – killed or inactivated microorganism that is incapable of replicating but stimulates immunity.
- *Live, attenuated* – live organism, genetically selected not to cause disease but able to stimulate immunity.
- *Toxoid* – toxin protein treated to inactivate its toxicity but retains its ability to stimulate immunity.
- *Recombinant* – gene coding for a protein that stimulates specific immunity to a BW agent is inserted into biological vector for production. Protein may be produced in high yields through bioengineering.
- *Deoxyribonucleic Acid (DNA)* – section of DNA that codes for protein that stimulates specific immunity to a BW agent. DNA produces the desired protein in recipient which stimulates immunity.
- *Polyvalent* – mixture of antigens that protects against a number of different BW agents.
- *Vectored* – carrier organism bioengineered to confer immunity against an unrelated BW agent or multiple agents.

ANTIBODY (ANTISERUM, ANTITOXIN)

- *Heterologous* – antibodies collected from animals (*i.e.*, different species than the recipient) repeatedly immunized against the BW threat. These antibodies must be treated to reduce the human immune response to them (serum sickness).
- *Homologous* – antibodies of human origin (*i.e.*, same species as the recipient) that provide protective immunity against the BW threat. These antibodies are not prone to stimulating serum sickness.
- *Monoclonal* – a cell culture technique for producing highly specific antibodies against a disease agent.
- *Bioengineered* – antigen binding site on the variable portion of an antibody elicited in a nonhuman system is combined with the nonvariable portion of a human antibody to produce a "humanized" antibody.

DRUGS

- *Antibiotics* – very effective against bacteria, but are ineffective against viruses and toxins .
- *Antiviral compounds* · Promising drugs in development by the pharmaceutical industry are being evaluated against biological threat viruses
- *Others* – compounds that offer new possibilities for protecting against and treating exposure to BW agents (such as drugs to treat toxins or nonspecifc treatments such as immunomodulators.)

DIAGNOSTIC TECHNOLOGIES

- *Immunological technologies* – These tests rely on antibodies for detecting the presence of proteins associated with the BW agent. They are easy to use, compact, rapid (minutes), and require little logistic support. This technology is currently used in out-patient clinics and doctor's offices.
- *Nucleic acid technologies* – nucleic acid tests, specifically the polymerase chain reaction (PCR), rely on segments of genes unique to BW agents to detect the presence of those agents. These tests are extremely sensitive and specific, but currently require more support to perform.

3.3.4 Defense Advanced Research Projects Agency (DARPA) Programs

As one of the major program areas conducted under its Defense Sciences Office, DARPA is pursuing the demonstration and development of new biological warfare defense capabilities. Major thrusts include real-time (environmental) sensing (described in Chapter 2); medical countermeasures (developing barriers to prevent entry of pathogens into the human body and developing pathogen countermeasures to block pathogen virulence and to modulate host immune response); Advanced Medical Diagnostics for the most virulent pathogens and their molecular mechanisms; and Consequence Management Tools.

Medical countermeasures to be developed include: (1) multi-agent therapeutics against known, specific agents, and (2) therapeutics against virulence pathways (mechanisms of disease) shared by broad classes of pathogens. Specific approaches include modified red blood cells to sequester and destroy pathogens, modified stem cells to detect pathogens and to induce immu nity or produce appropriate therapeutics within the body, identification of virulence mechanisms shared by pathogens, development of novel therapeutics targeting these mechanisms, and efficacy testing in cell cultures and animals.

Early diagnosis is key to providing effective therapy against BW agents since many of these agents cause early nonspecific flu-like symptoms. The goal of the DARPA Advanced Medical Diagnostics thrust is to develop the capability to detect the presence of infection by biological threat agents, differentiate from other significant pathogens, and identify the pathogen, even in the absence of recognizable signs and symptoms (when the pathogen numbers are low).

Mission effectiveness requires rapid, correct medical responses to biological threats. The objective of the Consequence Management thrust is to provide comprehensive protocols to protect or treat combatants by using current and emerging biological countermeasures. It will provide accelerated situational awareness for biological agents events by detecting exposure to agents through an analysis of casualty electronic theater medical records, and will locate and determine the most effective logistical support for providing appropriate treatment and pathogen-specific resources required to mitigate effects of the attack.

3.4 MEDICAL NUCLEAR (RADIOLOGICAL) DEFENSE RESEARCH PROGRAM

The mission of the Medical Nuclear Defense Research Program (MNDRP) is to conduct research in the field of radiobiology and related matters essential to the support of DoD and the Military Services. The sole repository of defense radiobiology expertise is AFRRI.

3.4.1 Goals

The goals of the MNDRP are the following:

- Develop medical countermeasures for the acute, delayed, and chronic effects of radiation.
- Identify and quantify hazards of embedded depleted uranium shrapnel to military casualties, both female and male.
- Develop rapid bioassay for radiation injury suitable for field deployment.
- Produce improved chelating agents for use in treating internal contamination by radioactive heavy metals.
- Sustain combat capability, increase survival, and minimize short- and long-term health problems associated with ionizing radiation alone, and when radiation is combined with other weapons of mass destruction.
- Respond to immediate operational requirements that require expertise in either radiation medicine, health physics, or radiobiology.
- Maintain core of scientific expertise necessary to meet current research requirements and to counter current and future radiological threats.

- Provide nuclear radiation weapon effects medical training for DoD medical personnel.

3.4.2 Objectives

The primary objective of this research group is to address the major aspects of military operational requirements for dealing with radiation injuries. A nuclear threat agent is any weapon that causes detrimental medical effects by either direct external irradiation or by internal contamination with radioactive material. These agents include radiation dispersal weapons, which scatter radioactive material with conventional explosives; deliberate area contamination; destruction of a nuclear power plant; improvised nuclear devices; and traditional nuclear weapons. Operational requirements include programs in casualty management, medical radioprotectants to diminish radiation injury, medical therapeutic regimens, maintenance of performance, and radiation hazards assessment.

3.4.3 Threats, Countermeasures, Technical Barriers, and Accomplishments

The deployment of a relatively low-yield nuclear device is increasingly possible by a terrorist or third-world country. If counterproliferation and intelligence efforts fail to deter deployment, medical remediation of casualties must be available. Such a device would most likely be utilized against either a military installation or a political target (*e.g.*, the seat of government, large population center, or commercial port city). In such a scenario, citizens outside the immediate lethal area would be exposed to the prompt radiation of the initial explosion as well as to chronic exposures resulting from the residual radioactive fallout.

The nuclear weapons inventory of current adversaries is thought to be small, but if a weapon is used for military advantage, concomitant use of biological or chemical weapons should be anticipated. A radiation dispersal device could include the destruction of a nuclear reactor, contamination of a battlefield with nuclear waste, or deliberate radioisotope contamina tion of a terrorist car bomb-type conventional explosives attack. Most casualties in these sce narios would suffer non-lethal doses of external irradiation. This would complicate the manage ment of their conventional injuries and could cause internal contamination with radionuclides. Early radiation injury diminishes the soldier' s ability to fight and survive. Effective radiation countermeasures must protect the soldier from performance decrement and simultaneously dim inish lethality and the long-term effects of radiation injury. Therapeutic measures will increase the survival and diminish the morbidity of individual soldiers who are wounded by radiation. A research program to understand molecular and cellular damage induced by radiation is needed to determine the best medical countermeasures for the new radiogenic wounding agents on the modern battlefield. Table 3-2 presents an overview of countermeasures to radiological exposure and research accomplishments during FY 98.

Table 3-2. Medical Nuclear Defense Countermeasures

PRETREATMENTS

Multidrug combinations: Enhanced survivability has been shown in animal models using a combined aminothiol and cytokine treatment modality. Sustained and effective delivery of prophylactic drugs was demonstrated in animal models using implanted capsules.

Antiemetics: Granisitron (Kytril®) has been adopted as the NATO standard pretreatment antiemetic medication to significantly block performance-degrading early symptoms of radiation injury. This allows mission completion and consequently diminishes the overall casualty rate.

DEPLETED URANIUM TOXICITY

Metabolism of metallic uranium fragments: Prior to the wounding of soldiers in Desert Storm, very little was known about the toxicity of implanted metallic uranium fragments. Previous uranium toxicity studies had been limited to inhaled uranium oxides in uranium workers. Preliminary aspects of animal studies indicate distribution to depot sites throughout the body and potential risks of late effects. Adequate chelation therapy does not exist at this time to increase excretion of this material.

Fetal metabolism of depleted uranium: During the next conflict it is anticipated that young female soldiers will be wounded by enemy depleted uranium weapons. No knowledge exists of the effects of this material on subsequent pregnancies.

MEDICAL THERAPIES

Specific Cell Line Stimulants: Granulocyte-Macrophage Colony Stimulating Factor has been demonstrated to be highly effective in restoring the immune competence of the bone marrow and allowing survival from radiation injuries previously considered lethal. The cytokine thrombopoietin has been developed as a therapeutic agent and is undergoing further trials as a platelet-formation stimulant.

Broad Range Cellular Recovery Stimulants: Research continues into biologically stable compounds that stimulate recovery of multiple hematopoietic cell lines.

Susceptibility to Infectious Agents and Efficacious Therapy: Research continues to assess susceptibility and resistance to infectious agents in conjunction with use of prompt and chronic sublethal irradiation, and to develop combined modality therapies that attack microorganisms and enhance innate immune response in irradiated personnel. A significant reduction in mortality was shown in animal models using a clinical support protocol based on antibiotic and platelet transfusion regimens.

DIAGNOSTIC TECHNIQUES

Biodosimetry and Dose Assessment: No dose-assessment method other than individual physical dosimeters can be made available currently to deployed soldiers. Automated chromosome dicentromeric analysis has been developed and can be made deployable to the Echelon 3 medical care level, and other, more rapid, methods are being evaluated.

CHEMICAL AND BIOLOGICAL WARFARE INTERACTIONS WITH RADIATION

Increased lethality of biological weapons after low level irradiation: Ongoing studies indicate even low levels of radiation exposure will markedly increase the infectivity of biological weapons. Existing data suggest synergistic interactions of mustard and nerve agents with ionizing radiation.

Significant progress has been made in prophylactic and therapeutic measures that will reduce mortality and morbidity in high -dose radiation environments. During the Cold War, the number of casualties resulting from the large -scale deployment of nuclear weapons would have easily overwhelmed the medical assets of NATO forces. In the current threat environment, adequate planning for medical response to a very limited nuclear attack is mandatory. While casualty numbers from a nuclear detonation will still be large, countermeasures have been developed that will significantly limit the morbidity and the secondary mortality. These modalities

will be particularly important in the likely scenario of terrorist use of radiation weapons. If the attack is limited to one or, at worst, a small number of events, the ability to provide intensive, sophisticated medical and other support is highly credible because of the availability of uncompromised treatment/research centers and medical evacuation capabilities.

Details of the radiological threats and countermeasures, as well as nuclear defense research and development technical barriers and accomplishments, are presented in Annex D (Section D.3).

3.5 MEDICAL NBC RESEARCH PROJECTION

Table 3-3 presents a projection of the medical NBC defense programs and modernization strategy for the next 15 years.

Table 3-3. Medical NBC Defense Programs and Modernization Strategy

	NEAR (FY99-00)	MID (FY01-05)	FAR (FY06-15)
Medical Chemical Defense	Licensed topical skin protectant	Licensed advanced anticonvulsant Licensed cyanide pretreatment Licensed multichambered autoinjector	Licensed reactive topical skin protectant Licensed advanced prophylaxis for chemical warfare agents Licensed specific protection and treatment for blister agents (vesicant agent countermeasures) Licensed vesicant agent prophylaxis
Medical Biological Defense	Anthrax vaccine Amendment for new dosing schedule Licensure of Pentavalent Botulinum Toxoid (ABCDE) Adsorbed	Licensed Q fever vaccine Licensed tularemia vaccine Licensed Vaccinia, cell culture derived vaccine Licensed Botulinum A/B/E/F monovalent vaccines Licensed new Venezuelan Equine Encephalomyelitis (VEE) vaccine Licensed brucellosis vaccine	Licensed staphylococcal enterotoxin B (SEB) vaccine Licensed new plague vaccine Licensed combined VEE, Western Equine Encephalomyelitis (WEE), & Eastern Equine Encephalomyelitis (EEE) vaccine Multiagent vaccine delivery system Hand-Held Common Diagnostic System Licensed Botulinum Tetravalent vaccine Licensed Ricin vaccine
Medical Nuclear Defense	Depleted uranium fragments toxicity assessment Multidrug radioprotectants validated Combination cytokine therapy validated Risk assessment for low dose, low dose-rate radiation effect	Radioprotectant transdermal patches New-generation prophylactic and therapeutic immunomodulators for multiorgan injuries Computer models to understand effects resulting from combined NBC attacks Echelon 3 biodosimetry system Carcinogenicity assessment of DU	Licensed radiation-induced cancer/mutation preventive techniques Licensed countermeasure for chem-bio-radiation interaction Echelon 2 biodosimetry system

3.6 MEDICAL R&D REQUIREMENTS ASSESSMENT

ISSUE: **DoD does not have a current approved mechanism for licensure of chemical and biological defense medical products (*i.e.*, drugs and vaccines) because legal and ethical constraints prevent adequate full testing in humans.**

SOLUTION: The FDA and DoD are working together to amend the Code of Federal Regulations to allow animal efficacy data to be used in lieu of large -scale human clinical efficacy trials. This mechanism of licensure is vital to provide military service personnel with licensed products. This rule will also establish requirements for licensure and allow the DoD to plan and conduct the appropriate studies to obtain product approval for the products planned for production and licensing. A proposal for the licensure of Botulinum Pentavalent Toxoid using the guinea pig as a surrogate model in lieu of human tes ting was accepted by a FDA Advisory Committee. The DoD is completing the clinical testing of Botulinum Pentavalent Toxoid for submission of this data to the FDA with projected licensure of this product in FY00.

ISSUE: **DoD lacks FDA-licensed vaccines against BW threat agents.**

SOLUTION: DoD awarded a prime systems contract to DynPort LLC. This contract establishes a single integrator to develop, license, produce, and maintain a stockpile of BD vaccines for protection against BW agents. DynPort LLC is required to obtain and maintain FDA licensure for all the vaccine products developed and produced under this contract by conducting clinical trials and establishing manufacturing procedures.

The contract was awarded in November 1997 and begins with the development and licensure of three vaccines: Q fever, Tularemia, and Vaccinia, and the storage of the current unlicensed BD vaccine stockpile (IND products). There are options for the development and licensure of ten other BD vaccines, which are programmed for development and licensure by FY10.

ISSUE: **Anthrax vaccine issues. Anthrax vaccination currently requires a primary series, six dose regimen spaced out over the course of 18 months, with an annual booster to maintain immunity. The timetable for the vaccination series makes it difficult to complete before deployment of forces or to ensure that mobile forces, once deployed, are administered the proper regimen.**

SOLUTION: On 18 May 1998, DoD decided to systematically vaccinate all U.S. mili tary personnel against anthrax. Current plans call for personnel serving in high threat regions to receive vaccinations, which began in summer 1998. The manufacturing pro cess for the anthrax vaccine has met all FDA requirements for producing and shipping the vaccine safely and contaminant-free. As of February 1999, more than 184,000 mil itary personnel have received shots of the anthrax vaccine. Total force vaccination will follow according to a schedule. This decision is crucial for developing a strategy to maintain the industrial base capability for vaccine production.

A firm fixed price contract to purchase Anthrax Vaccine Adsorbed for the continued supply of anthrax vaccine was awarded negotiated and signed for a 2 year period. DoD continues to work with BioPort to meet the more stringent requirements the FDA has imposed on all vaccine manufacturer. DoD has provided technical guidance on testing and evaluation and the auditing of quality systems. DoD conducted preliminary testing of a reduction of the dosage regime for Anthrax Vaccine Adsorbed from six vaccinations to five over an 18 month period. The results of this study will be presented to the FDA in FY 99. For more information on the DoD anthrax vaccine program, visit "Concerning the Anthrax Threat" on the Internet at http://www.defenselink.mil/specials/Anthrax.

ISSUE: **The effects on humans resulting from the exposure to low doses of chemical agents, particularly organophosphate (nerve) agents, are not clearly understood.**

SOLUTION: Beginning in FY96, DoD, in association with the Research Working Group of the Interagency Persian Gulf Veterans' Coordinating Board, DoD dedicated $5 million to evaluate the chronic effects of low-dose level exposure to chemical agents. Studies are underway since 1QFY97 to develop highly specific and sensitive assays, preferably forward-deployable, to detect and potentially quantify low-level exposure to chemical agents. These ongoing studies may also identify any long-lasting and toxic metabolites of chemical agents that could account for delayed and long-term health consequences. In addition, studies to look at the impact of possible genetic polymorphisms of cholinesterase enzymes upon individual response to nerve agents are underway. Additional funds have been committed and contracts are being awarded to evaluate potential chronic health complaints resulting from exposure to nerve agents. These contracts were begun 1QFY98.

ISSUE: **Radiation exposures below a level that cause acute effects predispose military personnel to injury from other battlefield agents. The magnitude of this interaction has not been fully evaluated.**

SOLUTION: Definitive assessment of NBC threat interactions and NBC agent modeling will support the strategic design and development of specific preventive and treatment countermeasures.

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Chapter 4

Nuclear, Biological, and Chemical (NBC) Defense Logistics Status

4.1 INTRODUCTION

The overall logistical readiness of the Department of Defense' s NBC defense equip ment continues to improve. The Services have increased stock of most NBC defense equip ment, and the overall requirements have decreased as a result of a smaller force. Both factors have improved the overall DoD readiness and sustainment status. Asset visibility initiatives continue to increase the ability to manage what is becoming an increasingly joint collection of NBC defense end items and consumables. A number of items continue to pose a moderate to high risk challenge due to low inventories and continued modernization efforts.

The DoD Chemical and Biological Defense Program jointly manages the research, development, and procurement of major end items of NBC defense equipment. These items are funded through defense-wide funding accounts. Consumable NBC defense items are managed by the Services and the Defense Logistics Agency (DLA) in accordance with Title X responsibilities of the Services and their desires to manage their own operations and maintenance funds. Under the provisions of Title X of the FY95 Defense Authorization Act, Service Secretaries are responsible for, and have the authority to conduct, all affairs of their respective departments including supplying, researching, developing, training, and maintaining equipment. The existence of defense-wide (rather than Service-specific) funding accounts has ensured the joint integration of NBC defense programs. However, no defense-wide (that is, joint) funding mech a-nism exists for the NBC defense logistics area. Because of this, the *joint* NBC defense community is limited to tracking the status of the DoD NBC defense logistics readiness and sustainment program and making recommendations to correct funding shortfalls.

The Joint Service Materiel Group (JSMG) coordinates NBC defense logistics issues. The JSMG, established by the Joint Service Agreement (JSA), works to ensure a smooth transition through the phases of NBC defense equipment life cycles. It is also charged with developing and maintaining an annual Joint Service NBC Defense Logistics Support Plan (LSP). This LSP forms the basis for the analysis found later in this chapter.

During the past year, increased focus by all Services and DLA on NBC defense logistics has visibly improved the overall program. Estimates are that the risk posed by weapons of mass destruction to early deploying units and special operations forces has been considerably reduced. Readiness shortfalls have been identified and addressed to the degree that full sustainment through a one Major Theater War (MTW) scenario is reasonably assured. The ability to sustain a second nearly simultaneous MTW scenario is not fully assured, due to current and potential critical shortfalls of specific program areas. The Services are programming funds for the FY02-07 POM to specifically address these problem areas. Additionally, the services are formulating

doctrine, tactics, techniques, and procedures for domestic response to terrorist incidents involving weapons of mass destruction.

The Joint Chemical Defense Equipment Consumption Rates (JCHEMRATES) IV study is in the final stages of validation and Service staffing. This study is being sponsored by the Joint Services Coordination Committee and executed through the U.S. Army Center for Army Analysis (CAA). The goal of the JCHEMRATES study is to define the parameters of future chemical warfare scenarios and determine the consumption rates for consumable DoD chemical defense equipment. Using the current Defense Planning Guidance and Quadrennial Defense Report, the JCHEMRATES study is developing consumption rates for the two MTW scenarios. These consumption rates will include both medical and non-medical chemical defense items for each Service and overall DoD roll-ups for both scenarios. They include both initial issue of chemical defense equipment and sustainment through the 120-day period. Once validated by the Services, these rates will form an important basis for determining future Service purchases and their readiness to go to war. As of the writing of this document, the JCHEMRATES IV study results are still in draft.

The JCHEMRATES IV study' s two MTW requirement is not and should not be considered a procurement target. This study did not fully consider certain factors such as air trans port into theaters of conflict or Navy fleet requirements for ships at sea. While the Services agree with the methodology and intent of the study, the study may require further refinement prior to becoming a fully accepted planning tool. The MTW requirement does not consider peacetime training requirements, sizing requirements, or full procurement to the entire active and Reserve forces. The MTW requirement denotes a *minimum planning number*, which if the total DoD inventory drops below, may represent a critical shortfall for that particular item, which should be immediately addressed to avoid diminishing the force' s NBC defense capa bility. Because of this limitation in the study, the Services have identified their total Service requirements as their procurement targets, while acknowledging JCHEMRATES as a necessary step in joint service management of the NBC defense program.

The Services continue to have issues regarding the accountability and management of NBC defense item inventories. Limited asset visibility of consumable NBC defense items below the wholesale level remains a problem due to the lack of automated tracking systems at that level (the exception being the Air Force). This has the full attention of the senior NBC defense managers. Improvement in this area is dependent on the progress of the DoD Total Asset Visibility (TAV) project.

The Services still procure consumable NBC defense items through multiple, separate, and distinct funding authorizations, as discussed in Section 4.6 of this chapter. Each Service is addressing secondary item procurement policies independently. However, there continues to be a shortfall of specific NBC items when measured against DoD requirements of a two MTW scenario.

The process by which the Services and DLA fund and store war reserve materiel has been hampered by differing definitions, different deployment strategies, and a lack of validated

requirements for jointly managed items. JCHEMRATES IV, once validated, will create a solid foundation for providing a basis for the common planning of future requirements.

The JSMG initiated its third Joint Service NBC Defense Logistics Support Plan (LSP) in September 1998. This report focuses on identifying the current on-hand stores of the Ser vices' and DLA' s NBC defense equipment, and matching these numbers against the require ments generated from the recently completed draft JCHEMRATES IV study (results as of March 1998). The LSP' s aim is to identify the Services' readiness and sustainment capability, maintenance sustainment, and industrial base issues in the area of NBC defense. The data call conducted for the FY99 LSP was used to develop the findings in this chapter.

4.2 NBC DEFENSE LOGISTICS MANAGEMENT

NBC defense logistics management remains in transition. The Joint NBC Defense Board has begun to exercise full authority in this area, and the JSMG, which reports to the Joint NBC Defense Board, has been charged with coordinating and integrating logistics readiness. The JSMG' s role is to identify current readiness and sustainment quantities in the DoD NBC logistics area, with respect to the two MTW scenario outlined in the Quadrennial Defense Review. Developmental NBC defense programs that will be fielded within the POM time period are addressed to identify modernization efforts that are underway.

As currently envisioned, all Services retain "starter s tocks" of NBC defense equipment that will support immediate deployments and initial operations. The length of time that these stocks will last each unit depends on the respective parent Service. Air Force units deploy with 30 days of NBC defense consumables. Army divisions use a planning figure of 45 days, while Marine Corps forces and Navy shore units use 60 days as the basis for their plans. As a matter of policy, Navy ships stock 90 days of consumable material. However, these values are notional in that they are based on peacetime demand and/or projections of wartime demand as contained in pertinent allowance documentation. For NBC defensive material, and particularly in the case of individual protective equipment (IPE), the days of supply represent a minimum stockage position based on current investment guidelines for such material. In most cases, the Services will first redistribute any available uncommitted assets to provide sustainment before sourcing elsewhere. Once these starter stocks are depleted, the military force turns to the DoD NBC defense item managers for "swing stocks," also known as "sustainment stocks."

DLA and the Army Materiel Command (AMC) are the item managers, or National Inventory Control Points (NICP), for the vast majority of NBC defense items in all four Services. They are responsible for industrial base development, acquisition, and storage of wholesale peacetime and sustainment wartime stocks. They buy (process procurement actions) and, if requested, store NBC defense materiel (swing stocks) for the Services. However, the Services must provide funding to DLA and AMC for the procurements.

Currently, only Army owned sustainment stocks are stored in DLA and AMC depots, providing limited back-up for deployed forces during a contingency. Because of a lack of visibility of NBC defense items, unclear wartime requirements (given the post-Cold War

environment), scarce Operations and Maintenance funds, and low priorities given to NBC defense stocks, the current quantity of DLA and AMC NBC defense war reserves have been reduced and will not support sustainment requirements for the entire DoD force during a full two MTW scenario. These numbers are reflected in the tables of this chapter.

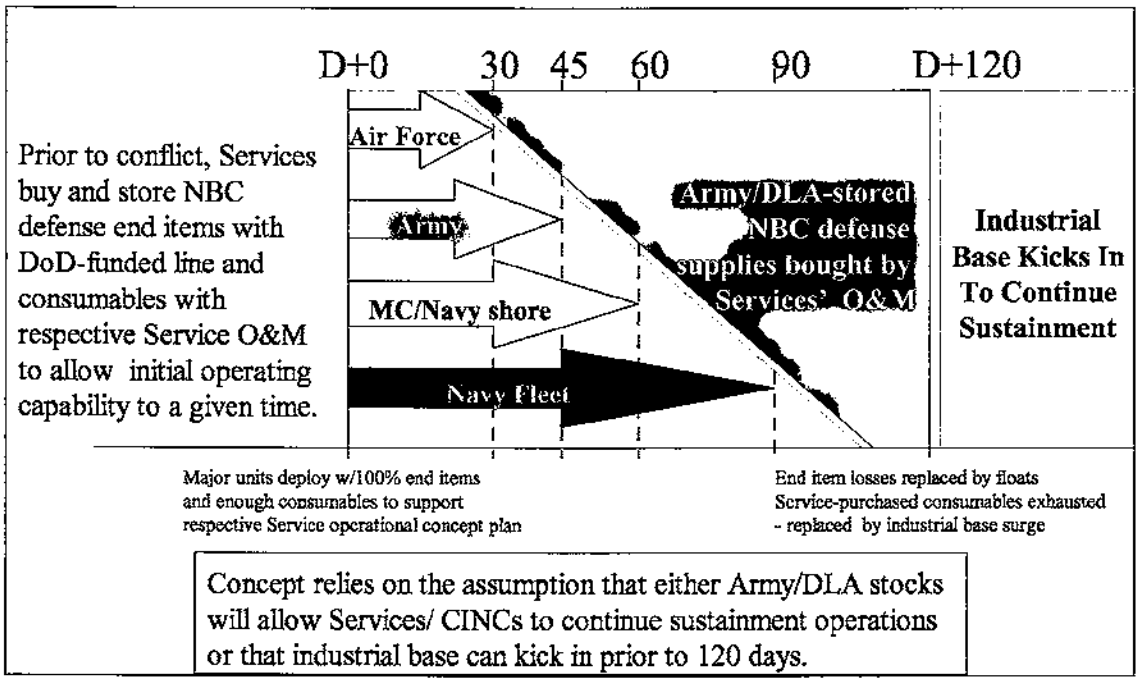

Figure 4-1. War Reserve Requirements and Planning

Service inventories of NBC defense items maintained at unit level use either manual records or a semi-automated tracking system. Stocks held at wholesale level are maintained using a separate automated system. Currently, there is little connectivity between the two systems. As a result, there is limited Service level asset visibility for NBC defense items. The Services are addressing this deficiency under the auspices of TAV, a long-term initiative that will link existing DoD logistics automated systems.

The Army has improved its visibility through an initiative to standardize individual issue of eleven critical NBC defense items across all major commands. In addition, consumable chemical defense equipment for all forces other than Force Package I and other early deploying units will be centrally stored at Bluegrass Army Depot. This seven-year execution plan is managed by HQ AMC and will enable better visibility and rotation of NBC defense consumable items. The Air Force has a similar program that consolidates stocks of NBC defense items for deployment in support of contingency operations. These initiatives have also reduced surveillance costs and improved overall management of NBC defense stocks. The Marine Corps has been leading a joint surveillance Technical Working Group, whose initiatives have been increasing cooperative efforts in surveillance and shelf life programs.

Both DLA and AMC will remain key players in the future NBC defense logistics management system. The Joint NBC Defense Board, through the JSMG, provides coordination and integration based upon the input of all Services' and commanders-in-chief' s (CINCs'). DLA and AMC will continue to provide services such as raw data collection, inventory control, and a distribution infrastructure. Upon the validation of JCHEMRATES IV, the Services and DLA can immediately begin plans to improve their readiness and sustainment status based on a common understanding of post-Cold War requirements.

4.3 QUANTITIES, CHARACTERISTICS, AND CAPABILITIES

The results of the data collection efforts are compiled in Tables 4-2 through 4-5 in Appendix 1, Logistics Readiness NBC Report Data, located at the end of this chapter. A table is included for each of the four Services and DLA.

The items listed under "Nomenclature" in Tables 4-2 through 4-5 of Appendix 1 are the currently fielded NBC defense items in the Services. "Total Service Requirements" include the quantity required for the entire Service (to include active and reserve forces), and includes peacetime replacements (wear and tear) and training requirements. The two MTW requirement quantities are those computed by the draft JCHEMRATES IV study (November 1998 data). Materiel requirements for training, sizing variations and peacetime replacements are *not* included in the wartime requirements. This number represents an average expenditure calcula ted among four scenarios: chemical defense equipment expenditures under low chemical weap ons use during favorable and marginal weather conditions; and of chemical defense equipment expenditures of high chemical weapons use during favorable and marginal weather conditions. All sets of conditions were run for the North-East Asia and South-West Asia scenarios.

The "Stocks On-Hand" represents the total of all serviceable NBC defense materiel available in each of the Services (stocks positioned with troops, stocks in the supply system and stocks stored in depots/facilities, both peacetime stores and war reserve). This number includes quantities for which a Service or agency has submitted a funded requisition or purchase order in FY98, but has not received the requisitioned items. Finally, the quantities depicted as "Projected Due-Ins" are quantities the Services plan to buy to replace peacetime consumption of NBC defense assets (to include training use and shelf-life expiration), and to buy wartime sustainment stocks. It must be emphasized that these numbers are based on major command estimates of requirements. Actual procurements will be based on available funding.

4.4 LOGISTICS STATUS

During data collection for the FY98 report, information on the inventory status of 123 fielded NBC defense equipment was compiled. While radiacs have not traditionally been a part of this chapter, they have been added as an effort towards continuity with other chapters and annexes of this report. NBC defense items such as batteries, spare parts, and sub-components were considered a subset of the primary item for risk assessments, and were not reviewed separately. Trainers were not included in the assessment process, since they do not reflect wartime service requirements. We then compared quantities required for wartime needs to

quantities currently on-hand. Characteristics and capabilities of selected fielded NBC defense items are discussed in detail in Annexes A-D of this report. The following items have been added to the current FY98 report:

- AN/VDR-2 Radiac Set
- AN/PDR-75 Radiac Set
- AN/PDR-77 Radiac Set
- AN/UDR-13 Radiac Set
- ADM-300 series Radiacs
- Older radiac sets still in service with the Navy include the AN/PDR-27, AN-PDR-43, AN/PDR-56, AN/PDR-65, CP-95 Radiac Computer-Indicator, CP-95 Radiac, DT-60 and IM-143 Dosimeters (also used by the USAF), and PP-4276/PD charger
- Chemically/Biologically Hardened Air Transportable Hospital/Chemically Protected Deployable Medical System
- Decontaminable Folding Litter
- Medical Equipment Set, Chemical Agent Patient Decontamination Kit
- Patient Chemical Wraps
- Medical antibiotics and chemical defense treatments, to include ciprofloxacin, doxycycline, sodium nitrite and sodium thiosulfate

The Army' s M51 Protective Shelter and the Marine Corps' s Portable Collective Protection Shelter (PCPS) were dropped from the Report as they were considered unserviceable and no longer in use, respectively. The Marine Corps' s Individual Chemical Agent Detector (ICAD) was also dropped as they no longer employ this detector.

Two changes involved standardizing names among the Services. The Air Force Chemical Outfit was retitled with the same name as the DLA' s Impregnated Chemical Protective Undergarment, as both had the same NSNs. The Air Force CPO Foot Covers were retitled as the Chemical Protective Footwear Covers in a similar fashion. This creates the perception of eliminating two items, but it is in reality consolidating NBC defense items with the same NSNs.

Of the 123 items extensively reviewed, we developed risk assessments for 50 items based on data gathered as of 30 September 1998 (see Table 4-1). These items were singled out because of their critical role or their ability to represent the general state of their respective commodity area. While some of the items assessed changed from the previous year' s report due to obsolescence, assessed items remained as constant as possible to provide for a trend analysis. These were rated as being in a low, moderate, or high risk category. "Risk" is defined as the probability that a shortage in the wartime requirement would exist, severely impacting DoD' s ability to respond to a contingency. Shortages were calculated by comparing the two MTW requirements (draft JCHEMRATES IV average requirements as of November 1998) to on-hand quantities, as shown in Tables 4-2 through 4-5.

RISK ASSESSMENT:

Low –	Services have at least 85 percent of wartime requirement on-hand to support two nearly simultaneous major theater wars
Moderate –	Services have between 70 to 84 percent of wartime requirement on-hand to support two nearly simultaneous major theater wars
High –	Services have less than 70 percent of wartime requirement on-hand to support two nearly simultaneous major theater wars

Table 4-1 provides the results of the assessment. Programs rated as high or moderate risk are discussed in greater detail in Appendix 2. A four-year comparison of data assessments is shown in Figure 4-2. In comparison to FY97 report data, the percentage of the FY98 report' s items in the low risk category dropped from 61 percent to 58 percent. The percentage of items in moderate risk rose from 17 percent to 20 percent, while the percentage of items in the high risk category remains steady at 22 percent.

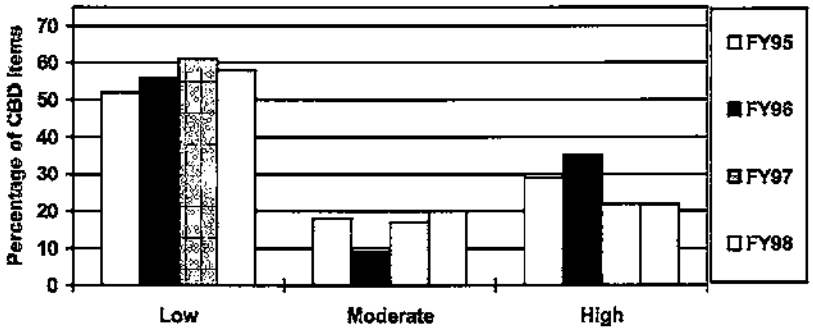

Figure 4-2. Logistic Risk Assessments: 50 NBC Defense Items

While there are only minor changes overall, the fol lowing items are highlighted:

- The status of M8A1 chemical agent detectors has improved due to downsized units turning in their equipment, thus resulting in lower overall requirements. The Army' s assessment and rebuild program returned 1,600 detectors to units, and another 1,500 are being repaired. The M8A1 detector will remain in the field until its successor, the M22 ACADA, is available in quantities to avoid any shortfalls.
- Limited quantities of M93A1 NBC Recon Systems and M21 RSCAALs continue to constrain early warning chemical reconnaissance and detection capabilities. Continued purchases through FY06 and acquisition of the JSLSCAD and JSLNBCRS will reduce this risk.
- Quantities of BDOs are not adequate to fill the Air Force requirement. The Air Force developed a mitigation plan in concert with procurement of the JSLIST ensembles to minimize risk. The recent plus-up of procurement funds for protective suits has aided in plans to transition to the JSLIST program. Due to the overall DoD WRM stockage of BDOs, the immediate risk is assessed as low. The BDOs will remain in inventory until they reach maximum shelf life.

- With the fielding of JSLIST overgarments, there is a need for additional personnel protection similar to the Army' s Second Skin to be applied to the MCU-2/P series masks.
- CWU 66/77P remains the only Air Force capability for air crew ensembles with the end of the Chemical Protective undercoverall procurement, and are assessed at moderate risk. Continued planned procurements should correct this assessment in the short term. The Joint Protective Aircrew Ensemble (JPACE), being procured in FY03, will replace this suit.
- The collective protection area is assessed as high risk at this time, in part due to the continued high emphasis on contamination avoidance and individual protection, which overshadows this area. As the procurement cycle in these two latter areas matures, the risk assessment of collective protection systems will lessen slightly.
- With the expiration of M258A1 kits beginning in FY99, the status of M291 kits will become a moderate risk area. Production issues have delayed the delivery of M295 kits to the Services. Inventories remain low. The status of the M291 and M295 kits will improve as procurement funds are released, but this area requires careful monitoring.
- Medical chemical defense materiel remains in low risk. The shortage of Nerve Agent Antidote Kits (NAAK) can be supplemented with existing supplies of atropine and 2-PAM autoinjectors, reducing its risk from moderate to low. These items will gradually be replaced by the Nerve Agent Antidote Delivery System (NAADS) beginning about FY04.
- Execution of the Joint Vaccine Acquisition Program (JVAP), combined with adequate stores of vaccine for the major BW threats, resulted in a lowering of the risk category from high to moderate risk. Continued vigilance is necessary to ensure that the contractors retain FDA-approved capabilities to produce and store vaccines in quantities required to protect the force.

Table 4-1. Logistic Risk Assessments: 50 NBC Defense Items

CONTAMINATION AVOIDANCE/DETECTION EQUIPMENT

Items	Risk Assessment	Remarks
Radiological		
AN/VDR-2 Radiac Set	Low	USMC is short 22% of requirements
AN/PDR-75 Radiac Set	Low	USMC has less than half of requirements (in both above cases, USA quantities offset risk)
AN/UDR-13 Pocket Radiac	High	Low inventory, still fielding
Biological		
Biological Integrated Detection System (BIDS)	Moderate	Low inventory, still fielding
Chemical		
M256A1 Chemical Agent Detector Kit	Low	Shelf life expiration may reduce stocks in future
M8 Detection Paper	Low	
M8A1 Automatic Chemical Agent Alarm	Low	DoD downsizing has reduced total requirements
M1 Chemical Agent Monitor (CAM)/Improved CAM	Moderate	Low inventory; still fielding
Chemical Agent Point Detection System (CAPDS)	Low	
AN/KAS-1 Chemical Warfare Directional Detector	Low	
M21 Remote Sensing Chemical Agent Alarm (RSCAAL)	High	Low inventory, not being procured
M22 Automatic Chemical Agent Detector/Alarm	High	Low inventory; still fielding
M93A1 NBC Reconnaissance System "Fox"	High	Low inventory; still fielding
Automatic Liquid Agent Detector (ALAD)	Moderate	Low inventory
M272A1 Water Testing Kit	Low	
M274 NBC Marking Set	Low	Meets minimum 2 MTW avg. requirements

INDIVIDUAL PROTECTION

Items	Risk Assessment	Remarks
Masks		
MCU-2/P-series Mask	Low	USAF/USN mask
M40-series General Purpose Mask	Low	USA/USMC mask
M42-series Tank Mask	Low	
M48 Apache Mask	Moderate	Replaces M43-series mask, still fielding
MBU-19/9 Aircrew Eye/Resp. Protection (AERP)	Moderate	Replaces MBU-13/P; still fielding
Suits		
JSLIST protective suits	Moderate	In process of fielding to all Services
Battle Dress Overgarment (BDO)	Low	No further production – being replaced by JSLIST
Saratoga Suit	Low	No further production – being replaced by JSLIST
CWU 66/77P	Moderate	Low inventory; augmented by USAF CPU
Chemical Protective Undercoverall	Low	
Mark III Suit, Collective Protection, Overgarment	Low	No further production – being replaced by JSLIST
Aircrewman Cape	Low	
Gloves/Overboots		
Chemical Protective Gloves (7/14/25-mil)	Low	
Green/Black Vinyl Overshoes (GVO/BVO)	Low	Risk lowered due to chemical protective footwear
Chemical Protective Footwear Covers	Low	cover stocks
Disposable Chemical Protective Footwear Covers	Low	Replaced by GVO/BVO

Note - Only selected Low Risk programs are displayed for information purposes.

COLLECTIVE PROTECTION

Items	Risk Assessment	Remarks
Chemical and Biological Protective Shelter (CBPS)	High	Low inventory, still fielding
M20A1 Simplified Collective Protective Equipment (SCPE)	High	Low inventory, not in production
M28 CPE HUB	High	Low inventory, still in production
M48A1 General Purpose Filter	High	Low inventory
Filter For (M59, M56, Shipboard) (200 CFM)	High	Low inventory

DECONTAMINATION EQUIPMENT

Items	Risk Assessment	Remarks
M258A1 Skin Decontaminating Kit	Low	Stocks will expire in FY99
M291 Skin Decontaminating Kit	Moderate	M258A1 stocks no longer augment M291
M295 Individual Equipment Decontamination Kit	High	Low inventory, still in production
DS-2, M13 Can	High	Low inventory
M11 Decontaminating Apparatus	Low	
M13 Decontaminating Apparatus, Portable	Moderate	Low inventory
M17-series Lightweight Decontamination System (LDS) (to include the A/E32U-8 Decontamination System)	Low	
M12A1 Power Driven Decontamination Apparatus (PDDA)	Moderate	Risk increased due to maintenance rqmts

MEDICAL DEFENSE

Items	Risk Assessment	Remarks
Mark 1 Nerve Agent Antidote Kit (NAAK)	Low	Risk lowered based on autoinjector stocks
Atropine Autoinjector	Low	
2-PAM Chloride Autoinjector	Low	
Nerve Agent Preventative Pyridostigmine (NAPP) Tablet	Low	
Convulsant Antidote Nerve Agent (CANA) Autoinjector	Low	
Biological Warfare Vaccines	Moderate	Prime contract awarded for development, production, FDA licensure, and storage

Note - Only selected Low Risk programs are displayed for information purposes.

Based on the average two MTW requirements identified in the draft JCHEMRATES IV study as of November 1998, the Services continue to exhibit shortages in certain critical areas. Shortages of chemical and biological agent detection systems, collective protection shelters and their respective filters, and biological warfare vaccines may have a serious impact on the joint force' s ability to survive and sustain combat operations under NBC warfare conditions operating in two nearly simultaneous MTWs. The extent of the operational impact of NBC defense equipment shortages is under review in several classified studies.

4.5 PEACETIME REQUIREMENTS

In peacetime, quantities of NBC defense equipment are necessary to train personnel in NBC defense and to build confidence that NBC equipment will provide the necessary protec tion when used correctly. The two most critical areas of peacetime stocks are individual protec tive equipment and medical chemical defense materiel. The Services have indicated that adequate NBC defense equipment is on-hand to conduct training.

Generally, items used in peacetime for training are drawn from wholesale stocks, requiring units to maintain both training and contingency stocks. For selected items, such as

protective clothing, contingency utility is lost when the item is used (or consumed) for training. Because peacetime training requirements are met in this manner, major commands do not track training equipment in their estimates of on-hand requirements.

4.6 FUNDING

In accordance with the NBC defense management initiatives outlined in Chapter 1, funding of RDT&E and procurement was centralized in a DoD defense-wide account beginning in FY96. Operations and maintenance (O&M) funding for NBC defense materiel is not consolidated at the DoD level. Therefore, for non-major (secondary) end items (*e.g.*, consumables such as decontamination kits, detection kits, and filters), each Service continues to separately fund replenishment and sustainment of NBC defense equipment. Depot maintenance and contractor logistics support for some low density major items are also O&M funded. These appropriations are not included in the joint NBC defense program.

Funding of NBC defense items classified as war reserves secondary items (WRSI) remains a significant issue. The Services are responsible for developing the requirements and funding items in war reserve stocks. Funding of WRSI comes from Congressional appro priations made into the Working Capital Fund (WCF) from the transfer of Services' O&M funds. For example, replenishment of NBC defense items in Army war reserves will require substan tial funding from 1999 through 2006 as these items reach their maximum extended shelf lives. Funding will be required to replace the Army and Air Force' s current inventories of BDOs with the Joint Service Lightweight Integrated Suit Technology (JSLIST). The Marine Corps, through its normal requirements generation and acquisition process, was able to obtain 100% war reserve of Saratogas for initial projected war reserves requirement (the Marine Corps views the BDO as a secondary protective ensemble). The recent plus-up of funds for protective suits will assist in building an initial stockage and minimum sustainment (war reserve) stock to meet the current defense planning guidance.

Under the current acquisition procedures and DoD guidance to minimize wholesale stockpiles, procurements are based only on funded Service requisitions. The Services remain responsible for program funding to replace NBC defense equipment wartime stocks. Procurement is usually based on economic buy quantities (a consolidation of all Service requisitions) to provide the best value to the government. Some procurements, however, suffer significant delays in delivery because of the time required to accumulate sufficient requisitions to produce economic buy quantities. This situation occurs when item managers try to plan purchases of consumable items that have a low peacetime consumption but high wartime consumption (such as decontamination kits, large collective protection filters and M256A1 detector kits). The result is a low purchasing history with a small industry production capability, which in turn causes a very low war reserve status with minimal industry surge capability. The draft JCHEMRATES IV model will identify more accurate requirements on which the Services can base their planning, once the study is validated and approved.

4.7 INDUSTRIAL BASE

With the end of the Cold War, a smaller DoD force, and subsequently reduced requirements for NBC defense items, lowered purchases of NBC defense consumables continue to threaten the industrial viability of this sector. While the sector is improving, vulnerabilities still exist. Collective protection systems (filters in particular) continue to be the most critical sub-sector in the NBC defense area. Additionally, protective clothing procurement continues to receive intense scrutiny due to the possibility of industrial base shortfalls in satisfying requirements during a contingency. The reluctance of pharmaceutical industries to support DoD CB defense medical programs, coupled with a lack of government vaccine production, represents a serious medical industrial base shortcoming.

These assessments indicate that the NBC defense industrial base sector is primarily supported by small- to medium-sized highly specialized companies dedicated to producing military unique products with little or no commercial utility. These companies have become dependent on Service demands and sales for their financial survival. Selected NBC defense items (BDOs, chemical gloves, and nerve agent autoinjectors) have been designated as critical to combat operations because of low peacetime demand, high wartime use, and the fragile supporting industrial base. As a result, DLA established, with OSD approval, a "War Stopper" program to sustain key industrial base capabilities, utilizing industrial preparedness funding under PE 07080110.

The mission of the Joint Service Integrated Product Team (IPT) for Industrial Base Management and Planning is to assist the Services in identifying problems and issues associated with implementing and executing a Joint Service NBC Defense Industrial Base Management Plan. The IPT will be able to provide DoD decision makers with accurate industrial base information and analyses. It consists of representatives from the JSMG and JSIG, Joint Staff, Office of the Secretary of Defense, logistics representatives and Commodity Area Managers from the four Services and DLA.

The IPT is addressing issues from across the Services for more than 128 items/systems and spare parts critical to readiness. The IPT is conducting analyses to include industrial and technology capabilities, alternative sources of supply, and a financial and economic analysis. These analyses will provide the NBC management structure with alternatives and recommendations within the sub-sectors of NBC defense. To date, all systems were evaluated, with most identified as having no need for further assessments, and 37 as requiring action of some sort. The results of the initial screenings indicate that the M293 Maintenance Kit, the M40 Universal Second Skin, the CWU-66/77 protective suit, the M295 decontamination kit, and diazepam injections require further industrial base studies.

4.8 NBC DEFENSE LOGISTICS SUPPORT ASSESSMENT

ISSUE: **The Department of Defense' s NBC Defense Program has a full capability to support and sustain the first of two MTWs. Readiness shortfalls that would preclude full support of a second MTW have been identified and will be addressed in the next POM (FY02-07). The Services' modernization efforts and common war reserve requirements will lessen the overall risk over the near term.**

SOLUTION: The Services continue to increase their readiness and sustainment status by consolidating common stocks and increasing visibility of their wholesale stocks. In most cases, accelerated procurement of critical items into war reserves will increase readiness against the potential use of weapons of mass destruction.

During 1998, all four Services participated in the continued development of the JCHEMRATES IV study, which is providing a more accurate prediction of the initial issue and sustainment quantities required for each Service. The use of this common methodology will allow the presentation of joint service requirements in future reports and facilitate improved joint logistics management.

ISSUE: **DoD continues to lack a joint, integrated system to maintain asset visibility of NBC defense equipment below wholesale level, and lacks a standardized war reserve program for NBC defense equipment. Resourcing the procurement and sustainment of wartime stocks of individual protective equipment, decontamination kits, and detector kits remains the responsibility of the Services.**

SOLUTION: DoD established the requirement for asset visibility and reviewed existing systems and procedures, both for peacetime reporting and war time reporting. The Services and DLA are addressing the NBC defense asset visibility deficiency under the auspices of the Total Asset Visibility initiative.

ISSUE: **NBC defense industries have a limited ability to augment specific shortfalls during any future contingency, in part due to lowered DoD procurements and the inability to retain warm production lines in critical areas. Without the introduction of significant plus ups or the use of innovative business practices (such as the use of performance specifications and use of ALPHA contracts), many of the small firms that make up this sector may choose to focus entirely on the commercial market place.**

SOLUTION: The Department of Defense continues to pursue innovative strategies to maintain a responsive industrial base, especially those strategies that decrease industry reliance on DoD procurement for industrial base survival. Strategies may include tapping into independent research and development (IR&D) conducted by universities and corporations, increasing reliance on dual-use technologies, and pursuing strategies that will encourage companies to decrease dependency on DoD requirements for their survival.

APPENDIX 1.
BREAKOUT OF SERVICE WAR REQUIREMENTS, STOCKS ON-HAND, AND PLANNED ACQUISITIONS

The following tables display NBC defense equipment total Service requirements, their wartime requirements, stocks on-hand quantities to include FY98 quantities on contract, and FY99–00 planned procurements for each of the four Services and Defense Logistics Agency. As mentioned earlier in this chapter, the two MTW requirements are based on the average requirements developed under the draft JCHEMRATES IV study, updated as of November 1998. This study has not yet been approved, but formal acceptance by the Services is anticipated in 1999.

It should be emphasized that the JCHEMRATES IV study' s two MTW requirement is not and should not be considered a procurement target. This study did not fully consider air transport into theaters of conflict or Navy fleet requirements for ships at sea. While the Services in general agree with the methodology and intent of the study, it may require further refinement prior to becoming a fully accepted planning tool. The MTW requirement does not consider peacetime training requirements, sizing requirements, or full procurement to the entire active and Reserve forces. The MTW requirement does denote a minimum planning number, which if the total DoD inventory drops below, may represent a critical shortfall for that particular item, which should be immediately addressed to avoid diminishing the force' s NBC defense capability.

Because of this limitation in the study, the Services have identified their total Service requirements as their procurement targets, while acknowledging JCHEMRATES as a necessary step in joint service management of the NBC defense program. The Services continually update these data call sheets on a frequent basis and consider these working papers rather than a static set of figures. The Services and DLA are working through the FY99 Joint Service NBC Defense Logistics Support Plan to update all figures and to provide 100% of the information required for logistics readiness and sustainment assessments.

Table 4-2a. Army Logistics Readiness Data - Nonconsumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE INS					
					FY99	FY00	FY01	FY02	FY03	FY04
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, CB, M17A2	4240-01-143-2017-20	218,274	0	733,806	0	0	0	0	0	0
MASK, CB, M40/M40A1	4240-01-258-0061-63	508,832	308,295	1,036,297	0	0	0	0	0	0
MASK, M24, AVIATOR	4240-00-776-4384	46,391	0	53,530	0	0	0	0	0	0
MASK, M25A1, TANK	4240-00-994-8751-52	17,642	0	132,138	0	0	0	0	0	0
MASK, M42, TANK	4240-01-258-0064-66	96,249	18,514	208,977	0	0	0	0	0	0
MASK, M43, APACHE	4240-01-208-6966-69	4,553	710	3,127	0	0	0	0	0	0
MASK, M45, AVIATOR	4240-01-141-4034-52	9,500	1,844	13	0	0	0	0	0	0
MASK, M48, APACHE	4240-01-386-0198	5,801	1,844	191	0	0	0	0	0	0
MASK, M49	4240-01-413-4095-99	12,744	1,844	13,591	0	0	0	0	0	0
MISC PROTECTION										
PATS, M41	4240-01-365-8241	2,534	3,334	5,523	0	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
RADIOLOGICAL DETECTION EQUIPMENT										
AN/PDR-75	6665-01-211-4217	6,039	5,445	7,378	0	0	0	0	0	0
AN/PDR-77	6665-01-347-6100	685	532	1,131	0	0	0	0	0	0
AN/UDR-13	6665-01-407-1237	1,861	26,901	458	2,376	2,863	2,926	4,211	8,673	12,849
AN/VDR-2	6665-01-222-1425	36,974	33,405	47,320	39	0	0	0	0	0
BIOLOGICAL DETECTION EQUIPMENT										
BIDS, M31	6665-01-392-6191	124	85	55	28	21	20	0	0	0
LR-BSDS, M34	6665-00-422-6605	24	10	4	0	4	4	3	0	0
CHEMICAL DETECTION EQUIPMENT										
ACADA, M22	6665-01-348-6963	28,839	28,839	1,724	1,540	4,668	7,274	0	0	0
ALARM, CAA, M8A1	6665-01-105-5623	27,755	28,000	29,958	0	0	0	0	0	0
CAM/ICAM	6665-01-357-8502	18,817	18,817	9,391	839	2,239	2,974	0	0	0
M21 RSCAAL	6665-01-334-6637	123	123	97	0	0	0	0	0	0
NBC RECON SYS, M93A1	6665-01-372-1303	123	123	43	12	15	15	4	4	17
DECONTAMINATION COMMODITY AREA										
DECON APPAR, M11	4230-00-720-1618	18,980	37,287	32,274	0	0	0	0	0	0
DECON APPAR, M13	4230-01-133-4124	226,800	111,125	31,338	16,653	0	0	0	0	0
DECON APPAR, PDDA, M12A1	4230-00-926-9488	682	129	477	0	0	0	0	0	0
L/WT DEC SYS, M17A1	4230-01-303-5225	1,327	2,516	2,598	30	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
CP DEPMEDS (HUB, CP, M28)	4240-01-395-5179	17	16	5	1	1	1	1	1	1
SHELTER, CB PROTECT	5410-01-441-8054	792	792	95	41	36	39	43	43	57
SHELTER, CP, M20/M20A1	4240-01-166-2254	2,019	1,747	626	23	0	0	0	0	0
MEDICAL COMMODITY AREA										
LITTER, DECONTAMINABLE	6530-01-380-7309			6,026	1,052	0	0	0	0	0

Table 4-2b. Army Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE INS	
					FY99	FY00
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
CHEM PROT UNDERGARMENT	8415-01-363-8692--00 8415-01-363-8683--91	728,718	254,312	132,757	173,413	169,464
JSLIST (ABDO) 45 DAYS	8415-01-444-1163 8415-01-444-5902	2,346,809	1,582,994	619	0	0
SCALP (TAN AND GREEN)	8415-01-364-3320--22 8415-01-364-3458--60	10,065	122,256	3,122	0	0
SUIT, CP CAMO (BDOs)	8415-01-137-1700-07	0	0	4,727,163	106,852	0
OVERBOOTS/GLOVES						
BLK/GRN VINYL OVERBOOTS	8430-01-317-3374-85	7,412,697	2,242,434	2,678,278	3,041	0
CP FOOTWEAR COVERS	8430-01-021-5978	1,028,707	0	641,791	7,094	0
CP GLOVES 7 MIL	8415-01-138-2501-04	473,041	121,741	254,204	0	0
CP GLOVES 14 MIL	8415-01-138-2497-00	1,067,558	486,963	797,789	0	0
CP GLOVES 25 MIL	8415-01-033-3517-20	6,270,220	3,368,247	5,702,880	5,718	0
MISC PROTECTION						
2D SKIN, M40 SERIES	4240-01-413-1540	812,709	354,231	194,415	10,081	0
CP HELMET COVER	8415-01-111-9028	1,320,556	4,085,749	530,325	35,575	0
FILTER CAN, C2A1	4240-01-361-1319	1,764,884	710,196	1,464,905	58	0
FILTER CAN, M10A1	4240-00-127-7186	196,464	0	77,969	1,523	0
FILTER ELEMENT, M13A2	4240-00-165-5026	584,511	0	377,722	0	0
HOOD, M40	4240-01-376-3152	3,534,562	1,046,139	1,401,518	15,252	0
HOOD, M5 (FOR M25A1)	4240-00-860-8987	46,316	0	24,902	0	0
HOOD, M6A2 (FOR M17)	4240-00-999-0420	733,910	0	491,311	0	0
HOOD, M7 (FOR M24)	4240-00-021-8695	44,172	0	45,514	2,424	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
DET KIT, M256A1	6665-01-133-4964	198,290	38,587	64,689	2,462	0
DET PAPER, M8	6665-00-050-8529	1,348,777	1,840,515	1,621,206	14,852	0
DET PAPER, M9	6665-01-226-5589	1,797,646	1,817,497	538,915	5,026	0
MAINT KITS, M293/M273	5180-01-379-6409 5180-01-108-1729	93,422	37,708	15,168	2,261	0
NBC MARK SET, M274	9905-12-124-5955	38,733	2,986	46,087	8	0
WATER TEST KIT, M272A1	6665-01-134-0885	8,778	7,730	7,956	4	0
DECONTAMINATION COMMODITY AREA						
DECON KIT, M258A1	4230-01-101-3984	834,253	0	250,577	136	0
DECON KIT, M291	4230-01-276-1905	1,147,688	150,511	284,162	4,050	0
DECON KIT, M295	4230-01-357-8456	752,595	150,441	63,143	0	0
DS2, 1 1/3 QT	6850-00-753-4827	224,797	625,770	200,061	0	0
DS2, 5 GAL	6850-00-753-4870	314,155	4,852,261	315,910	7	0
DS2, M13 CAN	4230-01-136-8888	154,609	1,971,215	109,962	68	0
STB, 50 LB	6850-00-297-6653	7,321	4,651	12,110	14	0

Table 4-2b. Army Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE INS	
					FY99	FY00
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP M12A2 (M14 GPFU)	4240-01-365-0981	12,180	8,342	4,726	0	0
FILTER, CP M13 SERIES (M14 GPFU)	4240-00-368-6291	11,200	8,342	3,638	0	0
FILTER, CP M18A1	4240-00-365-0982	32,370	40,196	15,264	0	0
FILTER, CP M19	4240-00-866-1825	19,236	34,779	8,364	0	0
FILTER, GP M48A1	4240-01-363-1311	10,350	10,553	2,499	0	0
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533	218	687	125	0	0
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	99,666	1,055,520	1,260,789	0	0
ATROPINE AUTOINJ	6505-00-926-9083	99,666	1,055,520	561,732	0	0
CANA AUTOINJ	6505-00-274-0951	290,106	1,228,345	558,656	185,187	185,187
NAAK, MKI	6705-01-174-9919	504,878	1,885,775	923,410	222,189	0
PYRIDOSTIGIMINE TAB	6505-01-178-7903	76,254	1,408,778	421,470	11,866	11,866
PATIENT WRAPS	6530-01-383-6260		58,176	9,175	0	0
MES CHEM AG PAT DECON	6545-01-176-4612			394	104	0
OTHER TREATMENTS						
CYPROFLOXACIN	6505-01-272-2385 6505-01-273-8650 6506-01-333-4154			42,270 27,622 398	0	0
DOXYCYCLINE CAPS	6505-01-153-4335			96	0	0
SODIUM NITRITE	6505-01-206-6009			20,034	0	0
SODIUM THIOSULFATE	6505-01-334-8781			1	0	0

Table 4-3a. Air Force Readiness Data – Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE INS					
					FY99	FY00	FY01	FY02	FY03	FY04
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, AERP	8475-01-339-9782(S)	29,879	29,879	21,542	6,068	200	112	0	0	0
MASK, CB, M17A2	4240-01-143-2017-20	1,625	5,132	2,600	0	0	0	0	0	0
MASK, MCU-2/P, MASK, MCU-2A/P	4240-01-415-4239-41 4240-01-284-3615-17	345,856	345,856	344,880	20,002	2,045	0	0	0	0
MISC PROTECTION										
PATS, M41	4240-01-365-8241	1,208	1,208	500	112	258	435	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
RADIOLOGICAL DETECTION EQUIP										
ADM 300-A KIT	6665-01-362-6213NW	300	117	265	20	20	0	0	0	0
-B KIT	6665-01-342-7747NW	800	597	899	25	39				
-C KIT	6665-01-320-4712NW	750	518	900						
-E KIT	6665-01-426-5071NW	250	119	239	10	20				
CHEMICAL DETECTION EQUIP										
ACADA, M22	6665-01-348-6963	2,140	2,140	177	220	50	25	0	0	0
ALARM, CAA, M8A1	6665-01-105-5623	423	331	0	0	0	0	0	0	0
CAM/ICAM	6665-01-357-8502	125	108	98	8	10	0	0	0	0
CHEM AGENT MONITOR/ICAM	6665-01-199-4153	1,000	1,960	450	838	672	10	0	0	0
M90 CWA	6665-01-408-5108	65	58	60	0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA										
A/E32U-8 DECON SYS	4230-01-153-8660	175	0	169	8	0	0	0	0	0
L/WT DEC SYS, M17	4230-01-251-8702	299	0	300	0	0	0	0	0	0
L/WT DEC SYS, M17A1	4230-01-303-5225	50	0	48	0	0	0	0	0	0
L/WT DEC SYS, M17A2	4230-01-	380								
L/WT DEC SYS, M17A3	4230-01-346-3122	100	157	100	0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
CHATH (SHELTER, CP, M28)	NOT ASSIGNED	21	20	1	10	10	0	0	0	0
KMU-450 SHEL MOD KIT	4240-01-044-7659	25	16	25	0	0	0	0	0	0

Table 4-3b. Air Force Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE INS	
					FY99	FY00
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
AIRCREWMAN CAPE	8415-01-040-9018	290,014	278,664	300,001	5,000	12,012
CLOTHING TEST KIT	6630-00-783-8192	200	167	9	0	0
CP UNDERCOVERALL	8415-01-040-3141	75,000	67,376	95,777	500	258
IMPREG UNDERGARMENT	8415-00-782-3242-5	5,000	5,000	4,925	0	0
JSLIST (ABDO) 45 DAYS	8415-01-444-1163 8415-01-444-5902	1,220,638	1,220,638	0	125,000	125,000
SUIT, AIRCREW, CWU-66/77P	8475-01-328-3454(S)	96,545	96,545	65,000	30,000	15,000
SUIT, CP CAMO (BDO)	8415-01-137-1700-07	0	801,167	558,701	54,425	17,252
SUIT, CP CAMO-DESERT 3 clr	8415-00-327-5347-53	0	13,878	57	0	0
SUIT, CP CAMO-DESERT 6 clr	8415-01-324-3084-91	0	23,656	36,085	1,996	0
OVERBOOTS/GLOVES						
BLK/GRN VINYL O/BOOTS	8430-01-317-3374-85	1,012,127	556,574	1,442,927	84,283	27,002
CP FOOTWEAR COVERS	8430-01-118-8172 (S) 8430-01-021-5978 (L)	154,802	106,612	200,005	2,005	5,697
CP GLOVES 7 MIL	8415-01-138-2501-04	226,002	167,619	341,003	21,006	7,014
CP GLOVES 14 MIL	8415-01-138-2497-00	1,834,565	653,715	2,279,351	537,229	106,024
CP GLOVES 25 MIL	8415-01-033-3517-20	90,000	12,960	122,380	3,056	90
CP SOCKS	8415-01-040-3169	200,056	170,768	199,070	3,111	787
DISP FOOTWEAR COVER	8430-00-580-1205	201,980	185,771	225,000	15,000	2,903
GLOVE INSERTS	8415-00-782-2809 (S)	2,245,876	1,688,335	2,441,469	330,002	75,000
MISC PROTECTION						
FILTER CAN, C2/C2A1	4240-01-119-2315	1,998,925	407,526	2,776,246	300,900	132,977
FILTER ELEMENT, M13A2	4240-00-165-5026	6,500	41,056	2,567	0	0
HOOD, M6A2 (FOR M17)	4240-00-999-0420	95,093	76,707	69,357	0	0
HOOD, MCU-2/P	4240-01-189-9423	2,225,189	851,056	3,071,242	49,707	81,000
MICS (COOL SYSTEM)	4240-01-298-4140YR	100	21	0	59	35
MICS VEST	8415-01-217-5634	1,110	80	1,410	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECT EQUIP						
DET KIT, M18A2 KIT	6665-00-110-9492	100	37	62	29	38
DET KIT, M256A1	6665-01-133-4964	50,123	1,300	25,045	490	122
DET PAPER, M8	6665-00-050-8529	454,096	209,953	992,378	10,890	7,888
DET PAPER, M9	6665-01-049-8982 6665-01-226-5589	50,606 310,345	249,650	40,308 300,090	302 30,000	16,699 12,090
MAINTENANCE KIT, M293	5180-01-379-6409	90	0	65	39	25
NBC MARK SET, M274	9905-12-124-5955	725	2,200	700	55	100
WATER TEST KIT, M272A1	6665-01-134-0885	100	445	115	10	19

Table 4-3b. Air Force Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE INS	
					FY99	FY00
DECONTAMINATION COMMODITY AREA						
CALCIUM HYPOCHLORITE	6810-00-255-0471	625	625	55	0	0
DECON KIT, M258A1	4230-01-101-3984	725,370	0	521,675	200,180	199,000
DECON KIT, M291	6850-01-276-1905	1,800,000	1,800,000	274,080	250,000	250,000
DECON KIT, M295	6850-01-357-8456	1,000,000	1,000,000	41,840	150,000	150,000
DRY SORBENT POWDER	6850-01-262-0484	1,150	100	55	992	194
SODIUM HYPOCHLORITE	6810-00-589-7316	100	625	100	0	0
STB	6850-00-297-6653	350	440	300	0	0
COLLECTIVE PROTECTION COMMODTY AREA						
FILTER, CP M13 SERIES (M14 GPFU)	4240-00-368-6291	0	0	0	0	0
FILTER, GP M48A1	4240-01-363-1311	0	4	0	0	0
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533	0	0	0	0	0
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248 6505-01-080-1986	84,951	316,716	769,903 14,616	185,376 3,782	159,213 3,066
ATROPINE AUTOINJ	6505-00-926-9083 6505-00-299-9673	184,860	316,716	805,462 18,138	178,315 5,505	163,963 7,881
CANA AUTOINJ	6505-00-274-0951	64,620	105,572	265,339	155,295	140,211
NAAK, MKI	6705-01-174-9919	2,947	0	140	0	16
PYRIDOSTIGMINE TAB	6505-01-178-7903	26,731	50,272	71,845	0	0
TETRACYCLINE	6505-00-655-8356	0	44,311	40,821	10,029	8,475
OTHER TREATMENTS						
CIPROFLOXACIN	6505-01-273-8650 6505-01-333-4154			27,530 9,059	76,403 6,504	34,644 4,854
SODIUM NITRITE	6505-01-206-6009			0	60	20
SODIUM THIOSULFATE	6505-01-206-6010			32	21	13

Table 4-4a. Navy Logistics Readiness Data - Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE INS					
					FY99	FY00	FY01	FY02	FY03	FY04
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, MCU-2/P	4240-01-173-3443	8,863		4,601	0	0	0	0	0	0
MASK, MCU-2A/P	4240-01-284-3615/17	3,928	27,576	3,093	0	0	0	0	0	0
MASK, MCU-2A/P (WR) USN	4240-00-327-4148-50	189,094		200,086	0	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
RADIOLOGICAL DETECTION EQUIP										
AN/PDR-27	6665-00-543-1435	1,642	953	1,556	0	0	0	0	0	0
AN/PDR-43	6665-00-580-9646	3,782	948	3,022	0	0	0	0	0	0
AN/PDR-56	6665-00-086-8060	163	76	218	0	0	0	0	0	0
AN/PDR-65	6665-01-279-7516	370	299	436	0	0	0	0	0	0
CP-95	6665-00-526-8645	29,782	386	20,031	0	0	0	0	0	0
PP-4276	6665-00-489-3106	6,054	377	4,009	0	0	0	0	0	0
IM-143	6665-00-764-6395	10,734	6,679	17,692	0	0	0	0	0	0
DT-60	6665-00-978-9637	135,344	74,686	112,957	0	0	0	0	0	0
BIOLOGICAL DETECTION EQUIP										
IBAD	NOT ASSIGNED	25	25	20	0	0	0	0	0	0
CHEMICAL DETECTION EQUIP										
ACADA, M22	6665-01-348-6963	300	300	0	142	80	78	0	0	0
ALARM, CAA, M8A1	6665-01-105-5623	262	128	262	0	0	0	0	0	0
CAPDS	6665-01-294-2556	230	230	225	0	0	0	0	0	0
CHEM AGENT MONITOR/ICAM	6665-01-199-4153	545	250	0	250	0	0	0	0	0
CWDD, AN/KAS-1	5855-01-147-4362	376	401	366	0	0	0	0	0	0
IPDS	NOT ASSIGNED	234	234	32	28	28	45	43	40	38
M21 RSCAAL	6665-01-334-6637	142	98	0	0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA										
DECON APPAR, M11	4230-00-720-1618	2,078	1,250	960	0	0	0	0	0	0
L/WT DEC SYS M17A3 DIESEL	4230-01-346-3122	138	137	5	0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
SHELTER, CP, M20/M20A1	4240-01-166-2254	670	40	205	40	0	0	0	0	0

Table 4-4b. Navy Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE-INS	
					FY99	FY00
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
IMPREG UNDERGARMENT	8415-00-782-3242-5	240	240	0	0	0
JSLIST (ABDO) 45 DAYS	8415-01-444-1163	319,000	69,768	2,800	0	0
	8415-01-444-5902	339,000	339,000		81,504	88,121
SUIT, CP, OG MK3	8415-00-214-8289-92	0	289,665	214,556	0	0
OVERBOOTS/GLOVES						
BLK/GRN VINYL O/BOOTS	8430-01-317-3374-85	168,846	109,519	175,534	0	0
CP FOOTWEAR COVERS	8430-01-118-8172 (S)			13,058	0	0
	8430-01-021-5978 (L)	339,000	339,000	121,993		
CP GLOVES 7 MIL	8415-01-138-2501-04	0	56,472	0	0	0
CP GLOVES 25 MIL	8415-01-033-3517-20	339,000	339,000	330,782	0	0
CP SOCKS	8415-01-040-3169	0	177,248	0	0	0
DISP FOOTWEAR COVER	8430-00-580-1205	0	177,248	0	0	0
GLOVE INSERTS	8415-00-782-2809	478,000	478,000	254,739	0	0
MISC PROTECTION						
CP HELMET COVER	8415-01-111-9028	0	55,152	0	0	0
FILTER CAN, C2/C2A1	4240-01-119-2315	480,000	480,000	315,204	0	0
HOOD, MCU-2/P	4240-01-189-9423	0	63,408	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECT EQUIP						
DET KIT, M256A1	6665-01-133-4964	10,235	159	10,077	0	0
DET PAPER, M8	6665-00-050-8529	91,567	49,220	48,059	0	0
DET PAPER, M9	6665-01-226-5589	30,902	68,132	36,569	0	0
NBC MARK SET, M274	9905-12-124-5955	522	22	480	0	0
TUBE PHOSGENE	6665-01-010-7965	1,207	1,596	1,750	0	0
WATER TEST KIT, M272A1	6665-01-134-0885	421	77	290	0	0
DECONTAMINATION COMMODITY AREA						
CALCIUM HYPOCHLORITE	6810-00-255-0471	9,001	9,001	3,618	0	0
DECON KIT, M258A1	4230-01-101-3984	26,402	0	19,944	0	0
DECON KIT, M291 (20 PER)	4230-01-276-1905	124,410	3,170	156,188	0	0
DECON KIT, M295 (20 PER)	4230-01-357-8456	0	1,585	0	0	0
DS2, 5 GAL	6850-00-753-4870	0	12,160	0	0	0
SODIUM HYPOCHLORITE	6810-00-598-7316	0	613	0	0	0
STB	6850-00-297-6653	37	1,437	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, GP M48A1	4240-01-363-1311	0	293	0	0	0
FILTER SET (FOR M59, M56, SHIPBOARD)	4240-01-369-6533	0	586	0	0	0
PRE-FILTER, SHIPBOARD CPE	4240-01-066-3266	23,655	293	9,176	1,848	1,428

Table 4-4b. Navy Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE-INS	
					FY99	FY00
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	19,521	95,112	227,529	0	0
ATROPINE AUTOINJ	6505-00-926-9083	19,521	95,112	337,580	0	0
CANA AUTOINJ	6505-00-274-0951	6,507	31,704	38,984	0	0
NAAK, MK1	6705-01-174-9919	19,521	95,112	17,384		
PYRIDOSTIGIMINE TAB	6505-01-178-7903	65,068	15,097	50,696	0	0
TETRACYCLINE	6505-00-655-8356	0	3,271	0	0	0
OTHER TREATMENTS						
CIPROFLOXACIN	6505-01-273-8650 6505-01-333-4154			540 239	0	0
DOXYCYCLINE CAPS	6505-00-009-5060 6505-00-009-5063			2,214 7,811	0	0
SODIUM NITRITE	6505-01-206-6009			4	0	0
SODIUM THIOSULFATE	6505-01-334-8781			4	0	0

Table 4-5a. Marine Corps Logistics Readiness Data – Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE INS					
					FY99	FY00	FY01	FY02	FY03	FY04
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, CB, M40/M40A1	4240-01-258-0061-63		71,474	199,137	30,000	0	0	0	0	0
MASK, CB, M17A2	4240-01-143-2017-20		0	19,737	0	0	0	0	0	0
MASK, M24, AVIATOR	4240-00-776-4384		0	4,307	0	0	0	0	0	0
MASK, M25A1, TANK	4240-00-994-8750-52	227,069	0	612	0	0	0	0	0	0
MASK, M42, TANK	4240-01-258-0064-66	(total roll-up of	4,174	5,214	0	0	0	0	0	0
MASK, MCU-2/P	4240-01-415-4239-41	mask rqmts)	0	98	0	0	0	0	0	0
MISC PROTECTION										
MASK COMM ADAPTOR	5996-01-377-9695	50,000	50,000	21,393	34,000	0	0	0	0	0
PATS, M41	4240-01-365-8241	258	258	258	0	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
RADIOLOGICAL DETECTION EQUIP										
AN/PDR-75	6665-01-211-4217	1,203	1,203	681	0	0	0	0	0	0
AN/VDR-2	6665-01-222-1425	2,343	2,343	1,826	0	0	0	0	0	0
CHEMICAL DETECTION EQUIP										
ACADA, M22	6665-01-348-6963	579	579	0	460	119	0	0	0	0
ALARM, CAA, M8A1	6665-01-105-5623	28	28	20	0	0	0	0	0	0
CAM/ICAM 1.5	6665-01-359-9006	1,854	1,854	1,854	0	0	0	0	0	0
CAM/ICAM 2.0	6665-99-725-9996	875	875	875	0	0	0	0	0	0
M21 RSCAAL	6665-01-334-6637	151	472	125	0	0	0	0	0	0
NBC RECON SYS, M93	6665-01-323-3582	10	10	10	0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA										
DECON APPAR, M11	4230-00-720-1618	21,050	7,056	43,271	0	0	0	0	0	0
DECON APPAR, M13	4230-01-133-4124	1,600	16,864	17,555	0	0	0	0	0	0
DECON APPAR, PDDA, M12A1	4230-00-926-9488	0	0	70	0	0	0	0	0	0
L/WT DEC SYS, M17A1	4230-01-303-5225	344	0	344	0	0	0	0	0	0
L/WT DEC SYS, M17A3	4230-01-346-3122	884	1,350	884	0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
**										

** - Note: The Marine Corps has stopped using the Portable Collective Protection System; therefore there are no collective protection systems to report.

Table 4-5b. Marine Corps Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE INS	
					FY99	FY00
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
JSLIST (ABDO) 45 DAYS	8415-01-444-1163 8415-01-444-5902	696,000	286,457	23,905	7,000	7,000
SUIT, CP CAMO (BDO)	8415-01-137-1700-07	(total roll-up of	0	174,020	0	0
SUIT, CP, SARATOGA	8415-01-333-7573-76	rqmts)	596,131	629,776	0	0
SUIT, CP, SARATOGA DESERT	8415-01-333-7577-80		50,000	0	0	0
OVERBOOTS/GLOVES						
BLK/GRN VINYL O/BOOTS	8430-01-317-3374-85	654,000	505,812	273,846	0	0
CP FOOTWEAR COVERS	8430-01-021-5978	0	0	368,825	0	0
CP GLOVES 25 MIL	8415-01-033-3517-20	654,000	646,820	715,125	0	0
MISC PROTECTION						
2D SKIN, M40 SERIES	4240-01-413-1540	277,069	109,514	23,696	51,000	0
CP HELMET COVER	8415-01-111-9028	0	425,531	0	0	0
FILTER CAN, C2/C2A1	4240-01-119-2315 4240-01-361-1319	554,246	152,546	206,845	0	0
FITLER CAN, M10A1	4240-00-127-7186	2,468	0	2,468	0	0
FILTER ELEMENT, M13A2	4240-00-165-5026	27,766	0	27,766	0	0
HOOD, M40	4240-01-376-3152	0	197,065	199,137	0	0
HOOD, M5 FOR M25A1	4240-00-860-8987	867	0	867	0	0
HOOD, M6A2 FOR M17	4240-00-999-0420	25,973	0	29,753	0	0
HOOD, M7 (FOR M24)	4240-01-021-8699	323	0	323	0	0
HOOD, MCU-2/P	4240-01-189-9423	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECT EQUIP						
DET KIT, M256A1	6665-01-133-4964	6,324	19,493	4,841	0	0
DET PAPER, M8	6665-00-050-8529	12,654	201,547	12,654	0	0
DET PAPER, M9	6665-01-049-8982 6665-01-226-5589	189,747	317,903	10,565	0	0
MAINTENANCE KIT, M293	5180-01-379-6409	0	0	0	0	0
NBC MARK SET, M274	9905-12-124-5955	2,286	2,204	209	0	0
WATER TEST KIT, M272A1	6665-01-134-0885	3,159	920	776	0	0
DECONTAMINATION COMMODITY AREA						
DECON KIT , M258A1	4230-01-101-3984	201,568	0	88,627	0	0
DECON KIT, M291	4230-01-276-1905	408,220	25,826	340,876	0	0
DS2, 1 1/3 QT	6850-00-753-4827	4,453	14,112	13,648	0	0
DS2, 5 GAL	6850-00-753-4870	7,252	289,223	5,359	0	0
DS2, M13 CAN	4230-01-136-8888		23,920		0	0
NITROGEN CYLINDERS	4230-00-775-7541	2,316	15,847	13,081	0	0
STB	6850-00-297-6653	7,410	1,202	401	0	0

Table 4-5b. Marine Corps Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE INS	
					FY99	FY00
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP M12A2 (M14 GPFU)	4240-01-365-0981	115	847	0	0	0
FILTER, CP M13 SERIES (M14 GPFU)	4240-00-368-6291	115	847	0	0	0
FILTER, CP M18A1	4240-00-365-0982	437	2,352	0	0	0
FILTER, CP, M19	4240-00-866-1825	219	1,176	0		
FILTER, GP M48A1	4240-01-363-1311	233	488	0	0	0
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533	0	0	0	0	0
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	291,216	271,135	291,216	0	0
ATROPINE AUTOINJ	6505-00-926-9083	205,344	271,135	205,344	0	0
CANA AUTOINJ	6505-00-274-0951	93,336	66,026	93,336	0	0
NAAK, MKI	6705-01-174-9919	0	354,800	0	0	0
PYRIDOSTIGIMINE TAB	6505-01-178-7903	93,336	0	93,336	0	0

Table 4-6. Defense Logistics Agency Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE INS	
					FY99	FY00
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
AIRCREWMAN CAPE	8415-01-040-9018	N/A	N/A	27,534	0	0
IMPREG UNDERGARMENT	8415-00-782-3242-5	N/A	N/A	6,226	0	0
JSLIST SUITS	8415-01-444-1200-70 8415-01-444-5504-98	N/A	N/A	0	42,000	41,000
SCALP (TAN AND GREEN)	8415-01-364-3320-22 8415-01-364-3458-60	N/A	N/A	1,248 27,113	0	0
SUIT, AIRCREW, CWU-66/77P	8475-01-328-3454(S)	N/A	N/A	0	4,000	25,000
SUIT, CP CAMO (BDO)	8415-01-137-1700-07	N/A	N/A	34,010	0	0
SUIT, CP CAMO-DESERT - 3 color	8415-00-327-5347-53	N/A	N/A	142,498	0	0
SUIT, CP CAMO-DESERT - 6 color	8415-01-324-3084-91	N/A	N/A	0	0	0
SUIT, CP, OG MK3	8415-00-214-8289-92	N/A	N/A	13,671	0	0
SUIT, CP, SARATOGA	8415-01-333-7573-76	N/A	N/A	0	0	0
OVERBOOTS/GLOVES						
BLK/GRN VINYL O/BOOTS	8430-01-317-3374-85	N/A	N/A	264,229	105,000	154,000
CP FOOTWEAR COVERS	8430-01-118-8172 (S) 8430-01-021-5978 (L)	N/A	N/A	0	0	0
CP GLOVES 7 MIL	8415-01-138-2501-04	N/A	N/A	147,482	0	0
CP GLOVES 14 MIL	8415-01-138-2497-00	N/A	N/A	649,542	0	0
CP GLOVES 25 MIL	8415-01-033-3517-20	N/A	N/A	1,211,189	0	0
CP SOCKS	8415-01-04-3169	N/A	N/A	271,667	0	0
DISP FOOTWEAR COVERS	8430-00-580-1205-06	N/A	N/A	50,579	13,455	14,052
MISC PROTECTION						
CP HELMET COVER	8415-01-111-9028	N/A	N/A	188,704	0	0
HOOD, MCU-2A/P	4240-01-189-9423	N/A	N/A	846,411	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIP						
MAINT KIT, M293	5180-01-379-6409	N/A	N/A	2,374	0	0
TUBE PHOSGENE	6665-01-010-7965	N/A	N/A	48	196	196
DECONTAMINATION COMMODITY AREA						
CALCIUM HYPOCHLORITE	6810-00-255-0471	N/A	N/A	103,612	27,752	55,504
DRY SORBENT POWDER	6850-01-262-0484	N/A	N/A	80	0	0
STB, 50 LB	6850-00-297-6653	N/A	N/A	540	1,380	1,380
COLLECTIVE PROTECTION COMMODITY AREA						
PRE-FILTER, SHIPBOARD CPF	4240-01-348-8785	N/A	N/A	554	588	588

Table 4-6. Defense Logistics Agency Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMT	NUMBER REQUIRED FOR 2MTW	STOCKS ON HAND TO INCLUDE FY98 DUE INS	PROJECTED DUE INS	
					FY99	FY00
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE, AUT	6505-01-125-3248	N/A	N/A	237,887	250,000	250,000
ATROPINE AUTOINJ	6505-00-926-9083	N/A	N/A	375,172	340,000	340,000
CANA	6505-00-274-0951	N/A	N/A	267,034	300,000	300,000
DIAZEPAM	6505-00-137-5891	N/A	N/A	5,588	0	0
NAAK, MKI	6705-01-174-9919	N/A	N/A	552,000	0	0
PYRIDOSTIGIMINE TABLETS	6505-01-178-7903	N/A	N/A	256,196	100,000	100,000
LITTER DECONTAMINABLE	6530-01-380-7309	N/A	N/A	3,500	1,518	0
MES CHEM ACT PAT TR	6545-01-141-9469	N/A	N/A	164	0	0
MES CHEM AG PAT DECON	6545-01-176-4612	N/A	N/A	108	0	0

APPENDIX 2
FIELDED NBC DEFENSE ITEMS - ISSUES AND CONCERNS

NBC defense items are generally used in combination to form a system or subsystem for a particular function. Therefore, this report will address items used as a system. These systems are categorized into five functional areas:

- Contamination Avoidance
- Individual Protection
- Collective Protection
- Decontamination
- Medical

1. CONTAMINATION AVOIDANCE

Contamination avoidance programs generally include equipment that is used to conduct NBC agent reconnaissance, detection, and identification. This area represents approximately half of the annual DoD NBC defense RDT&E budget. Due to recent type-classification of several programs that are intended to modernize contamination avoidance programs, this area has an unusually high number of developmental programs, as compared to other commodity areas. Many programs will complete their fielding beyond FY04.

Current numbers of biological detection devices, to include the Biological Integrated Detection System (BIDS) and Interim Biological Agent Detector (IBAD), are sufficient as measured against the draft average MTW requirements. Automatic biological agent point detectors and stand-off detectors are currently in development, and will not be deployed in significant numbers prior to FY02. The USAF has no fielded biological agent detection capability other than the limited quantities of Portal Shield ACTD biological detectors.

The combined total of chemical agent detection systems remains at moderate risk, but will improve slowly with the M22 Automatic Chemical Agent/Detector (ACADA) supplementing the M8A1 Automatic Chemical Agent Alarm. An Army initiative to inspect and repair M8A1 alarms at Anniston Army Depot has resulted in the quick assessment and return of 1,600 units to the field. Another 1,500 alarms were coded as requiring depot maintenance and are undergoing repairs. As a result of this program, the Army has no shortage of alarms for training purposes and there is no longer an acquisition gap between the combined acquisition of M8A1 and M22 alarms.

The M21 Remote Sensing Chemical Agent Alarm (RSCAAL) is at moderate risk with 82 percent two MTW fill projected by FY04. Technology from this system will be applied to the JSLSCAD, now under development. The M93A1 NBCRS is currently fielded at less than half of its projected requirements. This system adds improved mass spectrometer sampling system along with stand-off chemical vapor detection. Several units continue to use trained reconnaissance personnel in HMMWVs and APCs, thus moderating this risk as continued fielding and developmental systems enter the inventory.

Traditional consumables in this commodity area (M8 and M9 detection paper, M256A1 kits and M272A1 water test kits) are available in sufficient quantities to meet wartime requirements. Some shortages exist in individual Services, but overall there is little risk. Shelf life concerns may change this projection; this area remains under review.

The Army and Air Force radiac programs are expected to meet the two MTW scenario average requirements. The Army National Guard still has a large number of obsolete radiacs. These will be replaced in the near future by the AN/VDR-2 which is available in sufficient quantities through the depot system. The Navy has a small quantities of older radiacs still in the inventory, which should be replaced through a modernization program currently underway. The Marine Corps has about three-quarters of the required AN/VDR-2s and less than half of its AN/PDR-75s as compared to the MTW requirements. While Army stores or industry could compensate for this shortfall, it represents a potential risk, especially at the onset of any contingency.

2. INDIVIDUAL PROTECTION

Currently fielded protective suits and masks were primarily designed for use in the European environment against a Soviet threat. Equipment in this area is designed to protect against all known CB threat agents. Past Service-unique requirements led to Service-specific procurements and some duplication in capability resulting in the procurement of six different chemical protective suits and six different masks. This has caused difficulties in meeting current needs and exacerbated logistics planning. Fielding of the M40/42 protective masks, JSLIST protective suits and the MULO boot has begun to resolve many of these former challenges.

2.1 Protective Ensembles

The Services have initiated acquisition of the Joint Services Lightweight Integrated Suit Technology (JSLIST) suits as a replacement for the BDO and other chemical protective suits. As such, the protective suits should be viewed as a system with the older suits providing readiness stocks until the end of their service life. Contracts placed for the JSLIST program have begun delivery, equating to about 260,000 suits. The initial contracts did not include surge option clauses. Defense Supply Center Philadelphia (DSCP) took management of JSLIST in FY98, whose solicitations include the surge option as a requirement. By examining the year-by-year status of protective suits, we added the number of older suits still within service life to the number of JSLIST suits purchased by that year and matched the total against the requirements. In FY03, the services have sufficient protective suits to meet requirements as projected for the average two MTW requirements. However, beginning in FY05, the number of suits on hand will fall below total Service requirements, as the service life of older protective suits expires in large quantities. These calculations include the approximately $58 million plus-up per year allocated to purchasing protective suits beginning in FY98 (average plus-up between FY98-03).

The Battle Dress Overgarment (BDO) is reaching its maximum extended shelf life limit (14 years), and the Services have no plans for new production. There are no companies currently

manufacturing the BDO. The Army and Air Force have sufficient suits on hand in war reserves to sustain its requirements for the near term. The Saratoga suit, purchased by DSCP for the Marine Corps, is also out of production, but current stocks will sustain the Marine Corps until the JSLIST is available in adequate numbers. The Navy is relying on existing stocks of their Mark III chemical protective suit (also out of production) as stocks of JSLIST are being procured.

Armor crews and aircrews require special protective ensembles to integrate with their weapon systems. Services have sufficient numbers of aircrew suits to meet requirements, given the smaller total requirements for aircrews (relative to ground troops). The only exception is the CWU-66/77, which is supplemented by the Chemical Protective Undercoverall to result in a moderate risk rating. To protect armor crewmen when they exit their vehicles, the Services have developed the Suit Contamination Avoidance Liquid Protection (SCALP). This suit is rated as high risk because the Services have less than 25 percent of MTW requirements on hand. Increased procurements would reduce both risks in the short term.

The Services have adequate stocks of 7, 14, and 25-mil chemical protective gloves on-hand for contingency use. Recent DoD surveillance tests have validated the protective qualities of the existing butyl rubber glove stocks. The results from calculating the number projected to be on hand for FY04 exceeds the projected average MTW requirement. The status of the Services on-hand inventories has allowed DLA to pursue an Industrial Base Maintenance Contract (IBMC) with both current manufacturers (Siebe North, Inc., Charleston, SC, and Guardian Corp., Willard, Ohio) to sustain the industrial base with "War Stopper" funding.

Chemical Protective Footwear Covers, also known as the "fishtail" boot, have been out of production for several years. Their shortages are supplemented by the Black/Green Vinyl Overboot (BVO/GVO), which is the interim chemical protective footwear until the JSLIST MULO boots have been fielded (FUE expected in FY99). Because the GVO' s primary purpose is not chemical protection, current contracts do not include surge option clauses. Again, one should view protective footwear as a system with older GVOs providing readiness stocks until the MULO is fielded in sufficient quantities. Currently, the total DoD inventory shows adequate quantities of protective footwear, resulting in low risk assessment. The USMC is the only service reporting a shortage of footwear, but DLA can fill their shortfall.

2.2 Eye/Respiratory Protection

The Services continue modernizing their chemical protective mask inventories. Different versions of the protective mask were developed to meet the requirements of different military occupational specialties (*e.g.*, air crew, tank crew, *etc.*). For the Army and Marine Corps, the M40 (for generic use) and M42 (for armor crew members) series masks are replacing the M17 and M25-series masks, respectively. Some Army aviation units are still equipped with the old M24 mask, which will be replaced by the M45 mask. The M43-series mask, designed to be used by Apache equipped units, was in fact issued to all types of aviation units. It is being replaced by the M48 (Apache) and M49 (general aviation) series mask. The M45 will replace the M49 as the general aviation mask. This modernization effort is still ongoing; not all units have replaced their M43-series masks. All of these masks are at low risk, as the combined numbers of all

aviator masks on hand exceeds the requirement. These newer masks provide increased protection, improved fit and comfort, and compatibility with most Services' weapons systems' optics and sights.

The MCU-2A/P mask is designed to meet the needs of the Air Force ground crews, Navy shipboard and shore-based support missions, and Marine Corps rotary wing forces. The number of these masks on hand generally exceeds the requirement. The USAF has some shortages in masks and does not have second skins to provide complete personal protection. It will continue to be the mainstay of these units until the Joint Service General Purpose Mask is fielded, which will also replace the M40/42 masks. The Aircrew Eye/Respiratory Protection (AERP) mask is specially designed to enable pilots of high performance aircraft to conduct mission in a contaminated environment. Quantities of this mask are at 80% of the draft MTW requirements, making this a moderate risk.

In order to provide complete protection to our forces on the contaminated battlefield, particularly from liquid chemical agents, protective hoods and helmet covers are required as part of the individual protective ensemble. The protective hood for the M40 is rated as low risk. It is being replaced by the second skin for the M40 series mask, which is a high risk program with only 60 percent of requirements on hand by FY04. The MCU-2P hood is at low risk with an abundant inventory. Protective hoods for the M17-series, M24, and M25A1 masks are not a readiness issue, as these masks are leaving the inventory. The Chemical Protective Helmet Cover is a moderate risk with 66 percent of FY04 requirements expected to be on hand.

Filters and canisters provide the active ingredients that absorb the chemical and biological agents and provide the essential protection required. The C2/C2A1 canister is used with the M40, M42, M43, M45, M48, M49 and MCU-2/P masks. The number on hand currently exceeds requirements through FY04. The M13A2 filter element also exceeds requirements, but as stated will be leaving the inventory with the retirement of the M17-series mask. The M10A1 filter canister used on the M24/25 is short of the requirement, but these masks will leave the inventory and will not be a readiness problem.

3. COLLECTIVE PROTECTION

There are two general categories of collective protection: stand-alone shelters and integrated systems. Integrated collective protection equipment is component equipment designed to provide protection against CB agents through the use of filtered air under positive pressure to a variety of facilities, vans, vehicles, aircraft and ships. Filters for these integrated collective protection systems (CPS) are in short supply due to low peacetime demand and low production quantities. The increased emphasis on procuring individual protection and contamination avoidance equipment has resulted in a corresponding decrease in procurements of shelters and large collective protective filters.

The Air Force has expressed interest in a greater collective protective shelter capability. Combined with the Navy' s increasing shipboard collective protection filter requirements and the Army and Marine Corps traditional integrated vehicular systems and tactical shelter

requirements, the near-term MTW requirements for large carbon-based filters have outpaced current inventories even aided by industrial surge capability. As a result, much of this sector is assessed as high risk, though the risk is primarily due to the level of funding rather than technical shortfalls.

In the near term, the M51 shelter will be replaced by the new Chemical and Biological Protective Shelter (CBPS). All Army M51 shelters have been coded as unservicable. The CBPS is presently in production with fielding to initiate in 1QFY99. Both Army and Air Force field hospitals are being integrated with environmentally controlled collective protection. The Army' s Chemically Protected Deployable Medical Systems (CP DEPMEDS) achieves collective protection through the integration of the M28 Simplified CPE, chemically protected air conditioner, heaters, water distribution and latrine and alarm systems. The M28 Simplified CPE is in production and chemically protected heaters and air conditioners will initiate production before FY99. However, M28 components produced will not be enough to field 18 complete hospitals as originally planned, and all these components are not funded to meet Force Package I requirements. The effort to complete development and production of chemically protected latrine and water distribution systems and alarms remains unfunded.

The M20-series Simplified CPEs are used to provide a contamination-free, environmentally controlled work space for Echelon I and II forward area medical treatment facilities. Current funding levels, however, only will meet Force Package I requirements. There are some Force Package II units designated for deployments into high threat regions that will not be equipped with M20 shelters. This leads to an assessment as high risk. Current policy is that the M20/M20A1 Simplified CPE is a free issue item with no requirement to stock other than spares replenishment. The Marine Corps has Portable Collective Protection Shelters (PCPS) but does not plan to field them. The M20A1 SCPE is by default the only modern collective protection stand-alone shelter outside of the medical community in the inventory.

The Services have continued to improve integrated collective protection systems in armored vehicles and vans. All modern armored vehicles and armored vehicles in development have either filtered air systems, hybrid collective protection or full collective protection systems designed into their chaises. Notable progress has been made in providing shipboard collective protection. By the year 2000, most Naval ships that have close-in support roles (including amphibious ships, gunfire support combatants, and new logistics support ships) will contain significant CPS capabilities.

Collective protection filters for integrated systems (such as armored vehicles, ships and planes) continue to suffer from low stocks. While the Services have been proactive in selecting more capable industrial sources, actual procurement and storage of these filters to MTW requirements has not yet been initiated. As a result, stocks of filters (in particular those associated with the 200 CFM Particulate Filter Set for Shipboard Collective Protection Systems) remain at a critically low level. Continued difficulties in obtaining a strong industrial base in this field compound the issue of fielding and sustaining these items.

4. DECONTAMINATION

Current decontaminants are highly effective against all CB agents, but most present environmental hazards and are manpower intensive. The services are attempting to find environmentally safe decontaminants that are less labor intensive.

Basic soldier skills for decontamination of vehicle and crew-served weapons rely on the M11 Decontamination Apparatus, Portable (DAP) and M13 DAP. While the M11 is assessed as posing low risk, there are insufficient quantities of the M13 DAP as measured against the MTW requirements. The 1½ quart M11 can be used in place of the 14-liter M13 DAP, but they do not fulfill the same exact capability (in part due to the volume of DS-2).

The M17-series Lightweight Decontamination System (LDS) is used to provide operational equipment decontamination in many battalion-level units and dual-purpose (smoke/ decontamination) chemical companies. The Air Force employs the M17 at the squadron level for operational equipment decontamination. The M17 is assessed as a low risk, but may be increased due to a delay in rebuilding several hundred systems caused by a lack of funding since 1990. There is still a large mix of different models in the inventory, forcing the Services to retain a large number of differing spare parts to maintain the different models. Based on projected inventory, should spare parts become difficult to obtain for the different models, the risk may become high. Overall, this risk should drop as more systems are produced and the older models are upgraded or replaced. The Marine Corps is upgrading all of their LDS to the diesel engine. The Air Force is deleting stocks of A/E32-U systems by attrition, modifying existing M17s to M17A2s, and procuring additional M17A3s to satisfy shortages.

In the Army, the M12A1 Power-Driven Decontamination Apparatus (PDDA) and the M17A3 LDS are the primary pieces of equipment used to decontaminate vehicles, crew-served equipment and large areas of terrain. The M12A1 is assessed as moderate risk. Although the quantities on-hand of the M12A1 would normally result in a low risk assessment, the maintenance requirements, due to the age of this item, limit its full utilization. The M21/M22 Modular Decontamination System will displace 200 M12A1 PDDAs over the POM period, resulting in a high-low mix of technology. By FY02, the on-hand quantities of the M21/M22 MDS alone should satisfy the two MTW requirement. Additionally, the Marine Corps is replacing their M12A1 PDDAs with the M17-series LDS.

Although sufficient quantities of bulk DS-2 are available, the Army and Marine Corps plans for stocking containers of DS-2 (5-GAL and M13 Can) are below the MTW requirements expected for decontamination operations. While less hazardous replacement decontaminants are being developed, the quantities and packaging of current decontaminants present potential risk. The projected stockage of STB meets average MTW requirements, but has been considered a high-risk category in the past. Slight shortages in calcium hypochlorite and sodium hypochlorite can be made up by the industrial base, using commercially available alternatives. These increased requirements come as a result of increased attention to the need for decontamination capabilities in the 2 MTW scenario, and will be further refined. Continued monitoring is recommended.

The M258A1 Skin Decontamination Kit is the primary item used in personnel decontamination. The replacements for the M258A1 is the M291 Skin Decontaminating Kit. Although the M291 would be assessed as high risk, the availability of M258A1 decontam ination kits still in the inventory helps steady overall readiness stocks. These M258A1 kits are expected to expire in FY99, which will raise the risk assessment next year if procurements of the M291 kit are not increased. Rohm & Haas, Co., the sole supplier of the resin, sold the mixing and packaging equipment they used to manufacture the M291 Decontaminating Kit. Pine Bluff Arsenal, Arkansas, set up a production line and began to manufacture the M291 Decontaminating Kit in October 1996. Rohm & Haas continues to provide the XE-555 resin components. True Tech Inc. is blending the components to make the XE-555 resin. Alternatives to producing a kit that does not use the XE-555 resin are being studied. There are a number of options being explored to retain this "at risk" technology.

The projected stockage of the M295 Individual Equipment Decontamination Kit puts it in a high risk category when compared with 2 MTW requirements. The M295 Decontamina tion Kit uses the same resin mix as the M291 Decontaminating Kit, and began delivery in December 1997. True Tech Inc. has been producing this item in quantities of 760 kits per month for the past year. Increased funding for its procurement would alleviate the risk.

5. MEDICAL

Medical NBC defense items are used to counteract the effects of exposure to chemical or biological agents through pre-treatments, vaccines, or post-treatments. Current projections for medical chemical defense material indicates that sufficient quantities should be on hand through the POM years and present low risk. Quantities of Nerve Agent Antidote Kits (NAAK), Convulsant Antidote Nerve Agent (CANA), and Nerve Agent Pyridostigmine Pretreatment (NAPP) tablets now support two MTW requirements. The overall status of medical CB defense programs has not changed since last year, but this year' s report has expanded its scope to include medical treatments for biological warfare agents and a cyanide exposure.

NAAP is still an Investigational New Drug (IND) for the use as a nerve agent pretreatment. The U.S. Army Medical Materiel Development Activity (USAMMDA) has continued to work with the FDA for approval. Roche manufactures NAAP in Great Britain. Roche has sold this production line to ICN. Defense Supply Center –Philadelphia (DSCP) is working with ICN to establish a requirements contract for the manufacturer of NAAP.

The sole supplier to DoD for NAAK, atropine autoinjectors, pralidoxime autoinjectors and CANA is Meridian Medical Technologies, St Louis, Missouri. The medical chemical defense production line is being maintained with an IBMC. Meridian is an U.S. company but it obtains its atropine for the autoinjectors from a German supplier. Currently there is no domestic source for this drug. Pralidoxime and diazepam (CANA) for the autoinjectors is available from U.S. sources.

Patient Chemical Wraps have not been procured since 1991 and are made of the BDO materiel. USAMMA and the AMEDDC&S are currently assessing several versions of the patient wrap before initiating new procurement of this item. All services are procuring the new decontaminable litter, but in limited quantities, for first line units. There is a very large stockpile of canvas litters that can be used once in a NBC environment and then destroyed. As the canvas litters are depleted, they will be replaced with the new nylon decontaminable litter.

The Army has centrally funded, procured, stored, and managed Medical Chemical Defense Materiel since 1994 at Surgeon General designated storage locations. The U.S. Army Medical Materiel Agency (USAMMA) is the project manger for this materiel. Materiel is stored at strategic locations as Division Ready Brigade sets (DRBs), which support 5000 service members or by lot, manufacturer and product at Meridian Medical Technologies under an IBMC. The Air Force, Navy and Marine Corps maintain their medical CB materiel in decentralized unit locations. Visibility of on-hand assets has been improved with the release of the Joint Medical Asset Repository (JMAR) which is the Class VIII (medical) portion of JTAV.

Medical research programs continue to explore medical countermeasures to deter and defeat the use of biological warfare agents against U.S. forces. The Joint Program Office for Biological Defense (JPO-BD) has awarded a prime systems contract through the Joint Vaccine Acquisition Program (JVAP) for the development, FDA licensure, storage, and production of vaccines against DoD' s identified potential biological warfare agents. Currently, the U.S. total force (active and reserve forces) is being vaccinated against the primary high-threat BW agent, anthrax. The anthrax vaccination program is a three-phase program, starting with the troops serving in-or identified to deploy to-the two high-threat areas where hostile anthrax-use poses the greatest potential danger. The vaccination program is on-schedule and will take between seven and eight years to complete for all service members (to include new personnel acquisitions as the program extends over the entire period).

JPO-BD has assisted the sole domestic supplier of anthrax vaccine to maintain its FDA licensure and transition the production facility to private ownership in FY98. A follow-on contract was also awarded in FY 98 to ensure sufficient anthrax vaccine to meet the DoD vaccination program. Other vaccines (or combinations) are currently in various stages of development and testing to protect against other BW agents identified in the Chairman of the Joint Chiefs of Staff (CJCS) validated BW threat list. In the area of medical therapeutics, the Department is maintaining a stockpile of antibiotics (*e.g.*, ciprofloxacin, doxycycline, etc.) sufficient to address the treatment needs of potential BW exposures, where such treatment is medically indicated.

Chapter 5

Nuclear, Biological, and Chemical (NBC) Defense Readiness and Training

5.1 INTRODUCTION

The Services' vision for Joint NBC Defense Management is: *America' s Armed Forces trained and ready for the 21st Century, protecting our nation and its forces against nuclear, biological and chemical threats.* The Joint NBC Defense Program builds on the successes of each Service to develop a viable Joint orientation to NBC defense capabilities, which include Joint requirements documents; Joint doctrine and tactics, techniques, and procedures; Joint modeling, simulation, and wargaming; and Joint professional training.

5.2 NBC DEFENSE DOCTRINE

Joint Doctrine. Joint Pub 3-11, *Joint Doctrine for Nuclear, Biological, and Chemical (NBC) Defense*, provides guidelines for the planning and execution of NBC defensive operations. Its focus is on the NBC threat, national policy, and considerations peculiar to the preparation and conduct of NBC defense. These considerations include principles of theater NBC defense, logistics support, medical support, training, and readiness.

Multi-National Doctrine. The U.S. Army Nuclear and Chemical Agency (USANCA) has been delegated the DoD representative for international standardization of NBC operational matters. USANCA participates in the following North Atlantic Treaty Organization (NATO) groups:

- NBC Defense Interservice Working Party (NBCWP) under the Military Agency for Standardization,
- Land Group 7 (LG. 7)—NBC Equipment—under the NATO Army Armaments Group (NAAG),
- Working Group 2 (LG. 7)—Low Level Radiation in Military Environments,
- Challenge Subgroup (LG. 7)—Chemical/Biological Toxicity Challenge Levels,
- Technical Subgroup (LG. 7)—Nuclear Weapons Defense, and
- ATP-45 (NBCWP) NBC Warning/Reporting.

The USANCA also has been delegated as the representative in the ABCA Quadripartite Alliance (US, UK, Canada, Australia) in the Quadripartite Working Group (QWG) for NBC Defense. In that group, USANCA also participates in the RADIAC Information Exchange Group (IEG). The US Army Chemical School (USACMLS) participates with USANCA to incorporate NBC group agreements in revising existing manuals.

The USACMLS has been delegated as the representative at the NATO Training Group (Joint Services Subgroup) in addition to providing representation and subject matter expertise to support USANCA at NATO/QWG meetings as required. This includes consultation to coordinate the official US position on NBC defense issues prior to international meetings.

5.2.1 Joint NBC Defense Doctrine Program Management

The NBC defense program management strategy described in Chapter 1 provides the mechanism to assist the Joint Staff in the further development of the Joint NBC defense doctrine program. The Joint Service Integration Group (JSIG) coordinates with the Services to ensure the program is realistic and meets the needs of the Joint community.

5.2.2 Joint NBC Defense Doctrine Development Program

The US Army Chemical School (USACMLS) has the task from the Joint Staff to revise Joint Pub 3-11, *Joint Doctrine for Nuclear, Biological, and Chemical (NBC) Defense*. The title of the Joint Pub will be changed to Operations in an NBC Environment. This change reflects an increased emphasis on sustaining operations in a contaminated environment. An initial draft was staffed with all Services, comments consolidated, and recommendations for changes recorded. A second draft was published and distributed to the combatant Commands, Services, and the Joint Staff for comment in March 1999.

The JSIG is working with the Air Land Sea Application (ALSA) Center and the Joint Warfighting Center to lead the effort in the development of multi-service NBC defense doctrine. Currently ALSA is revising FM 3-4-1, *Multi-Service Procedures for NBC Defense of Fixed Sites, Ports, and Airfields*, in coordination with all the Services.

The USACMLS also provided exercise and training support to CINCs and various organizations throughout the year. Subject matter experts were provided to the Army War College for their Crisis Action Exercises, to the Atlantic Command (ACOM) for Joint Task Force (JTF) training, and to Exercise Silent Breeze II for briefing support.

The U.S. Army Medical Department Center and School (USAMEDDC&S) has been tasked to revise Joint Publication 4-02, *Doctrine for Health Service Support in Joint Operations*. The revision contains additional information on the medical aspects of NBC defense. USAMEDDC&S is assisting OSACMLS in revising the medical support aspects of Joint Pub 3-11.

5.2.3 Army Medical Doctrine Development Program

Multi-Service Doctrine. The FY98 effort consisted of initiatives to develop new Army Medical Department (AMEDD) NBC defense doctrine products, provide AMEDD input to other service NBC doctrine publications, and provide input to multinational medical NBC procedures. The initial draft of the FM 8-284, *Treatment of Biological Warfare Agent*

Causalities is completed. The draft has been distributed for review. Development of a new manual, FM 8-283, *Treatment of Nuclear Warfare Causalities and Low-Level Radiation Exposure* will be initiated when FM 8-284 is in the advanced stages of completion. These two manuals will be developed as multiservice publications. FM 8-10-7, *Health Service Support in a Nuclear, Biological, and Chemical Environment* is being revised and reviewed as a multiservice publication. Doctrine for nuclear, biological, and chemical-environment (NBC-E) will be developed and incorporated into current and new manuals as the technology allows. The area of NBC-E is not new, but emphases is being increased on the effects of long-term exposure to low-levels (subclinical levels) of NBC agents, industrial radiation, biological, and chemical hazards.

Multi-National Doctrine. The Office of The Surgeon General (DASG-HCO) has been designated the head of Delegation for the NBC Medical Working Group for standardization of NBC Medical operational matters. OTSG, DASG-HCO participates in the NATO groups shown in Table 5-1. The AMEDD participated in numerous NATO medical NBC procedural product reviews, resulting in several NATO Standardization Agreements (STANAGs) being updated. Further, the AMEDD participated in a Quadripartite Working Group to develop and update additional Quadripartite Standardization Agreements (QSTAGs), which are medical NBC procedural products. STANAGs and QSTAGs are reviewed for integration of these agreements into Army-specific doctrine literature products as well as multiservice medical doctrine products for which the AMEDD is the proponent.

Table 5-1. Selected NATO Groups

- NBC Defense Working Group
- NBC Medical Working Group – Head of Delegation
- Land Group 7 (LG.7) – Joint NBC Defense
- Working Group 2 (LG.7) – Low Level Radiation in Military Environments
- Challenge Subgroup (LG.7) – Chemical/Biological Toxicity Challenge Levels
- General Medical Working Party, Aeromedical Working Group
- Research Technology Area/Human Factors Medical (RTA/HFM) Panel NB&C Medical Subgroups.

5.2.4 Air Force Medical Doctrine Development Program

HQ USAF/SGXR has been participating with the Army in development of a doctrine field manual, *Treatment of Biological Warfare Agent Casualties*. A CONOPS was completed that standardized wartime medical contamination control operations. During FY98 SGXR has also participated in the review of numerous NATO Standardization Agreements that were updated during the year.

5.2.5 Marine Corps Doctrine

The Marine Corps continues to systematically review multi-service NBC doctrine. The Marine Corps has reviewed a number of NATO Standardization Agreements as well as multi-service doctrine with both the U.S. Army and the U.S. Navy. The Marine Corps has completed a new Marine Corps Warfighting Publication (MCWP) 3-37, *Marine Air Ground Task Force (MAGTF) NBC Defense*.

5.3 STANDARDS/PROFICIENCY AND CURRENCY

Each service establishes standards of proficiency and currency for NBC defense training.

5.3.1 Army

Army Regulation 350-41, *Training in Units*, establishes Army standards for pro ficiency for NBC defense training. NBC defense training is conducted at schools and in units. The USACMLS is responsible to train and sustain Chemical Corps soldiers and leaders and provide task/condition/standard limits, suggested training products, and oversight in the areas of NBC matters. Although the U.S. Army Chemical School (USACMLS) is neither designated nor resourced to be the DoD Executive Agent for joint NBC defense training, it has initiated several actions to counter NBC threats, including:

(1) assisting CINCs, Major Commands, and their staffs in assessing and providing reference materials regarding the NBC threat and recommending actions to reduce the NBC threat in their areas of operations;
(2) providing broad-based joint NBC defense doctrine and joint doctrine development support;
(3) introducing and upgrading instructional aids and training support material for war colleges and command and staff colleges for all services; and
(4) developing, evaluating, and fielding advanced instructional capabilities for both resident and nonresident instruction;
(5) conducting the Joint Senior Leader Training Course – A Focus on Weapons of Mass Destruction, intended to provide leaders from all Services with an understanding of joint NBC defense operations, training, readiness, threat, doctrine, and capabilities.

The initiatives have not been completed due to lack of resources.

Individual Training. At the initial training level, NBC defense tasks are taught to students wearing Mission Oriented Protective Posture (MOPP) gear during Basic Soldier Training and Warrant Officer Candidate Training to satisfy Initial Entry Training Requirements. Common core qualification is achieved from NBC tasks training during Officer (basic and advanced) and Warrant Officer (basic) training. NCOs train on leader NBC skills during their NCO development courses. Other Officer and NCO courses require training in NBC as a condition that effects the performance of branch specific tasks. At the company level each unit has an NBC NCO specialist and at the battalion or higher level most units have an NBC Officer and Senior NCO.

Unit Training. The Army is constantly challenged to improve its training of NBC battlefield hazards by integrating such training into unit mission training as well as individual and leader training. It is required that the NBC protective mask be worn during weapons qualification training at least twice a year, depending on the unit category within the Standards in Training

Commission (STRAC). Additionally, essential Army civilians are trained in NBC survival skills. Because of today' s battlefield complexities, the Army takes a systems approach to its training. NBC tasks for individuals are published in Soldiers' Training Publications and trained in the Army School System. Sustainment training occurs in the unit. NBC collective tasks are published in Army Training and Exercise Plan (ARTEP) Mission Training Plans. The highest level of NBC training recognizes NBC as a battlefield condition and units train to execute their Mission-Essential Task List (METL) while under NBC conditions.

Mobilization Training. In February 1998, the 20th Chemical Detachment (BIDS) deployed in support of Operation Desert Thunder. Additionally, the 310th Chemical Company (BIDS) was mobilized from the Army Reserve for mobilization training during March-June 1998 to support Operation Desert Thunder.

The USACMLS Move to Fort Leonard Wood. Construction of facilities at Fort Leonard Wood is on schedule. Completion and availability dates are shown as follows.

Facility	Construction Completion	Available for Occupancy
CDTF Admin Building	30 September 1998	15 November 1998
CDTF Training Building	7 January 1999	12 February 1999
Chemical Applied Training Facility	13 October 1998	8 January 1999
General Instruction Facility	17 May 1999	21 July 1999
Unaccompanied Enlisted Housing	17 May 1999	2 July 1999

In preparation for the move, the first individuals departed Fort McClellan in October 1998 and will be assigned to the CDTF at Fort Leonard Wood. A second large group left during February through March 1999. These include the combat developers, the training developers, and portions of the Chemical Brigade staff. The training departments will move to Fort Leonard Wood during May to August 1999 upon completion of scheduled training at Fort McClellan.

The USACMLS expects to stand up the 3d Chemical Brigade at Fort Leonard Wood during April through May 1999. This brigade will be responsible for all training activities at the Chemical School after the move is complete. Additionally, the brigade will provide command and control for the 82d Chemical Battalion (OSUT), the 84th Chemical Battalion, and the 58th Transportation Battalion.

All personnel and equipment that belong to the USACMLS must be on the way to Fort Leonard Wood by 30 September 1999.

Medical Training. The U.S. Army Medical Department Center and School (AMEDDC&S) conducts Medical NBC Defense Professional Training at Fort Sam Houston, Texas consisting of four Soldier/Noncommissioned Officer (NCO) courses, two Officer courses, and various related professional short courses.

AMEDD sergeants attend a 17 week Basic NCO Course (BNCOC) where NCOs with the MOS 91B (combat medic) are trained to be medical platoon treatment/evacuation team leaders. AMEDD BNCOC provides the NCO with the technical and tactical skills to conduct field medical operations and to treat, manage, and evacuate battlefield casualties. The NBC Sciences Branch provides classes and practical exercises in the skills necessary to perform battlefield medical operations in an NBC environment, to decontaminate, manage and treat contaminated casualties, and to train non-medical soldiers in casualty decontamination procedures. In FY98, more than 350 junior NCOs were trained in this course.

All AMEDD officers begin training in the Offic er Basic Course (OBC). This 11 week course prepares them with the fundamental knowledge to conduct medical operations in an NBC environment and to advise company, battalion, and medical treatment facility commanders about NBC contamination avoidance and the medical implication of NBC exposures. This experience includes 39 hours of classroom instruction and 12 hours of field training exercises, which emphasize confidence building, hands-on equipment training, and management of NBC contaminated casualties. There are six courses annually for active Army components and five courses for Reserve/National Guard components. In FY98, over 1,550 officers were trained in these courses.

The AMEDD Officer Advance Course (OAC) is designed to provide advanced militar y education for officers with 3–9 years of military service. This course provides the AMEDD officer with skills necessary for command, leadership, and staff positions of greater responsibil ity in both peacetime and times of hostility. The AMEDD officer participates in a group of 12–18 officers led by one experienced officer. The small group leader facilitates discussions and assignments with emphasis on sharing individual experiences for the collective good of the group. NBC subject matter expertise is provided by the NBC Sciences Branch, with emphasis on the supervision of medical operations in NBC-contaminated environments during a cap stone, Corps level, field training exercise, Medical Unit Staffs in Operations. In FY98, over 490 officers were trained in this course.

The Medical Management of Chemical and Biological Casualties Course (MCBC) provides DoD personnel, primarily physicians, physician assistants, and nurses with a working knowledge of the potential threat of chemical and biological weapons and the status and scope of medical defense strategies. It combines classroom instruction and field experience to estab lish essential skills, instill confidence, and define limitations in therapeutic modalities with each type of medical setting. The course also provides instruction on the use of specialized equip ment and skills required for safe, long distance evacuation. First-hand experience in triage, decontamination, and medical operations on the integrated battlefield is stressed. This course is offered fours times annually at the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), Aberdeen Proving Ground, Maryland and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Ft. Detrick, Maryland in addition to the three day exportable course provided on-site for individual units or posts.

In FY 98, 38 courses were taught consisting of:

- Three (3) MCBC in house courses
- Three (3) Field Management of Chemical and Biological Casualties Courses (FCBC)
- Five (5) Train the Trainer Courses
- One (1) Video Teleconference (VTC)
- Twenty-one (21) MCBC offsite courses
- Five (5) FCBC offsite courses.

2,525 students attended these courses. The student breakdown is as follows: Army (2,108), Navy (201), Air Force (124), Civilians (67), and Foreign Nation Students (25).

The MCBC course was taught twice at the AMEDD Officer' s Advanced Course and will be taught four times during the next fiscal year. A two-hour block of instruction on depleted uranium was added to the MCBC in-house course. The in-house MCBC course has doubled in size from 70 students to approximately 140 students. The offsite courses are now being replaced with distance learning VTC, satellite broadcasting, and CD-ROM. USAMRICD conducted five "train-the-trainer" courses in FY98, training twenty Army, Navy, and Reserve personnel to be utilized as instructors for offsite courses.

USAMRIID' s Operational Medicine Division, in conjunction with USAMRIID scientists, CDC experts, and nationally known leaders in Public Health, have just completed a 12-hour, fully accredited satellite distance learning program on Medical Defense against Biological Warfare and Terrorism. This educational outreach program, funded by the Office of the Army Surgeon General, trained 18,167 healthcare professionals at 583 down-link sites in CONUS and overseas from 22–24 September 1998. Army, Air Force, Navy/Marine Corps, Veterans Administration, and Public Health Service medical care providers were trained, as were personnel in Canada, the United Kingdom, Germany, Saudi Arabia, and several other overseas sites. This live interactive educational experience provided thousands of healthcare personnel with the information needed to prevent, diagnose, and treat biological casualties in both military warfare and civilian bioterrorism scenarios. The program was broadcast from the FDA' s television studio in Gaithersburg, Maryland to sites around the world. The broadcast was taped and then re-broadcasted the weekend of 3 and 4 October, 1998 to reach primarily Reserve and National Guard medical personnel. The cost effectiveness of this type of education is staggering: the program cost $69.29 per healthcare professional, or a cost of $5.77 per CME credit hour, compared to the traditional way of training students at Fort Detrick, with a cost per student of approximately $1,000. Further decreases in the cost per provider educated are possible with wider dissemination of the program in future years. This type of education also is an excellent way for providers to update their skills on a regular basis without ever leaving their home station or community.

Specific nuclear training is addressed through the Medical Effects of Ionizing Radiation (MEIR) course. This one-week course is designed to provide military health care providers and operational planners with background material relating to human injury and combat effective ness in a nuclear weapons detonation or accident scenario. The course introduces the physical

principles of nuclear weapons and ionizing radiation and the effects of nuclear weapons. The medical problems associated with radiation, including external exposure and internal contam i-nation are investigated. This course is offered twice annually at the Armed Forces Radio biology Research Institute (AFRRI), Bethesda, Maryland along with shorter "road" courses provided on-site for individual units or installations. In FY98, 502 Army, 137 Navy, 161 Air Force, and 51 Non-DoD Civilian personnel trained in this course, for a total of 851 personnel.

The focus of the Medical NBC Readiness Course (formerly the Medical NBC Professional Filler (PROFIS) Course) is on medical NBC battlefield operations, humanitarian operations, standards, and the threat. The intent of this course is to inform and educate military medical and preventive medicine professionals about the medical response in the event of an intentional NBC attack. The course addresses response to, and new standards for, peacetime operations in areas contaminated with low levels of radioactive material or industrial chemicals. This course is sponsored by the US Army Office of the Surgeon General and hosted by the AMEDDC&S. The course is open to Department of Defense preventive medicine officers and professionals assigned to deployable units or positions who are directly responsible for NBC consequence management (*i.e.*, military environmental scientists, health physicists, preventive medicine physicians, environmental engineers, medical operations officers, *etc.*)

The Medical NBC Defen se Training and Education Network provides distributed learn-ing and digital references via the Internet. The focus of this web site is to improve the overall awareness of medical NBC issues and to enhance sustainment training capabilities. The "home page" [http://www.nbc-med.org/] provides doctrinal publications that are inter-connected by keywords to allow for quick searches of topics. For training purposes, the user can download these documents. In addition to the internal search capability, this site has a state of the art internet search engine that allows the user to explore all electronic information in support of medical NBC training. Training using multimedia technology is also being developed for use with this network. Currently, the Management of Chemical Warfare Injuries interactive training package and Medical Management of Biological Casualties Manual is accessible through the site with nuclear training to be added as they become available. Future improve ments to this network include: expanding connectivity to other military, governmental and private agencies; scheduling interactive training and education events; and adding related video, video conferences, and training seminars to enhance training.

The Center for Health Promotion and Preventive Medicine sponsors a *Transportation of Biomedical Materials (TBM)* course and a *Refresher TBM* course. The purpose of these courses is to certify personnel to package infectious samples and specimens for transport IAW with requirements of 49 CFR Transportation, Air Force Regulation 71-4, and 42 CFR Centers for Disease Control. The course is interactive and practical exercises are used throughout. The course objectives are as follows:

- Identify and classify infectious substances, diagnostic specimens, biological products, and regulated medical waste (Department of Transportation).
- Use of hazardous materials table (49 CFR Part 172, 101) to prepare these items for transport.

- Package infectious substances, diagnostic specimens, biological products, and medical waste.

5.3.2 Air Force

Air Force policy is to provide initial and annual refresher training to personnel in or deployable to NBC high threat areas (HTAs). The Air Force standards of proficiency are based on two international standardization agreements: NATO Standardization Agreement 2150 (NATO Standards of Proficiency for NBC Defense) and Air Standardization Coordinating Committee (ASCC) Air Standard 84/8 (Initial, Continuation and Unit NBC Standards). Both agreements are implemented through Air Force Instruction 32-4001, *Disaster Preparedness Planning and Operations*. The Air Force ensures proficiencies and currency of NBC warfare defense training through classroom training, unit level training, and exercises. NBC Defense Training (NBCDT) is required only for military personnel and emergency essential civilians in or deployable to NBC threat areas. Major Commands (MAJCOMs), the Air Reserve Component, and Direct Reporting Units may tailor their NBCDT programs to meet their specific mission requirements. The subjects presented in the classroom follow the three principles of NBC defense (avoidance, protection, and decontamination) as identified in Joint Pub 3-11. Unit level training follows the classroom training on wartime mission critical tasks. Supervisors train personnel to complete mission critical tasks while the workers are wearing their full complement of individual protective equipment. Exercises are used for training and evaluation purposes. Instructors at base level receive their professional training through Air Force courses at Ft. McClellan, Alabama.

Individual Training. There are two types of individual training. The first is general equipment and procedures training that enables personnel to recognize and protect themselves and others from NBC hazards. The second is individual proficiency training that enables personnel to perform their wartime tasks in a NBC-contaminated environment. Detailed training comes with assignment to a threat area or to a deployable unit. Personnel receive the following NBC defense training courses:

AUDIENCE[1,2]	TYPICAL INITIAL INSTRUCTION TIME	INITIAL (FREQUENCY)	REFRESHER (FREQUENCY)	REMARKS
Low threat	6 hours	Within 90 days of assignment to mobility positions or 90 days prior to PCSing to a CB HTA.	Annual show of competency or as directed by MAJCOM.	Allow extra time for quantitative fit testing (QNFT)/ confidence exercise and CCA training.
Medium threat	6 hours	Within 90 days of arrival	Within 90 days of arrival	See Note 2
High threat	6 hours	Within 90 days prior to PCSing to HTA.	Within 30 days of arrival - topics should only include theater specific procedures and QNFT.	See Note 2

NOTES:

1. NBC Defense Training is required for military personnel and emergency essential civilians in or deployable to chemical-biological medium and high threat areas.
2. Initial training is required if there has been a break of 36 months or more in NBC defense training.

NBC refresher training is at the discretion of the MAJCOMs, with the majority opting for annual refresher training through classroom training and exercise participation. Individual NBC proficiency training occurs through on-the-job-training and exercise participation. In addition, aircrews are required to conduct a one-time flight while wearing chemical defensive equipment.

Unit Training. Units in or deployable to NBC threat areas must conduct the following training:

CB Threat Area	MINIMUM EXERCISE REQUIREMENTS
Low	**Annually** - Conduct attack response exercise implementing the base OPlan 32-1 and other contingency plans (*i.e.*, NBC, terrorist, or conventional attack). **AND** - Conduct an attack response exercise for units' mobility commitments based upon the threat at deployment locations.
Medium	**Semiannually** - Conduct attack response exercise implementing the base OPlan 32-1, BSP, and other contingency plans (*i.e.*, NBC, terrorist, or conventional attack). One exercise can be satisfied by a tabletop exercise. **AND** - Conduct attack response exercise for unit mobility commitments based on the threat at deployment locations. One exercise can be satisfied by a tabletop exercise.
High	**Semiannually** - Conduct attack response exercises implementing the base OPlan 32-1, BSP, and other contingency plans.

Air Force major commands have reported significant increases over the last three years in the number of people receiving equipment and procedures training as well as the number of hours spent for that training.

Medical Training Initiatives. Following the Air Force Medical Service (AFMS) NBC Warfare Defense Training Workshop in 1998, several training initiatives were prepared to meet gaps in Air Force chemical and biological medical defense training. Computer-based training tools for the AFMS re-engineered unit type codes, such as: (1) Patient Decontamination Teams, (2) Chemically Hardened Air Transportable Hospital, (3) Preventive and Aerospace Medicine (PAM) team training, (4) Bioenvironmental Engineering NBC team training, (5) PACAF AFMEDPAC 2000, (6) Continuing Medical Readiness NBC training, (7) NBC CD-ROM Toolboxes, (8) ACC/Force Protection Battlelab – Bio Agent detection training, and (9) NBC Defense Leadership Skills training were identified for contractor development. The Army (funded by the AF) is the OPR for two other initiatives: Medical Management of Chemical Casualties and the NBC CD-ROMs. Care providers who have not been afforded the opportunity to attend the Army MCBC Course will receive an instructor based course on medical management of chemical and biological casualties training at their units. Overseas locations have priority over CONUS bases for this initiative. In addition, identified medical UTC teams will receive medical reference materials developed by the US Army and civilian contractors for training.

5.3.3 Navy

Navy CBR-D training is conducted in two phases: individual and unit training. Individual training consists of attendance at formal school courses and completion of basic and advanced CBR Defense Personnel Qualification (PQS) training. Navy personnel also conduct periodic unit CBR Defense training and pre-deployment unit training exercises.

Individual Training. The Navy provides initial entry-level CBR defense training to all officers and enlisted personnel in the accession programs. Enlisted personnel receive three hours of training (two hours in the classroom; one hour in the lab) focused on the use of personal protection equipment and survival skills, including a CBR-D "confidence" chamber exposure. Officers receive two hours of class time focused on personal protection equipment and survival skills. After reporting to designated units, Navy personnel also are required to complete basic and advanced CBR-D PQS training.

Officer and Enlisted Personnel assigned to ship and shore billets requiring CBR-D expertise receive additional CBR-D related courses. These courses include the Disaster Preparedness Specialist Course and the CBR-D Operations and Training Specialist Course conducted at the U.S. Army Chemical School. Additional CBR-D training is covered in the Repair Party Leader Courses conducted at various Fleet Training Centers. Officers receive additional CBR-D related training at the Damage Control Assistant Course, the Shipboard Department Head Course, the Prospective Executive Officer Course, and the Prospective Commanding Officer Course held at the Naval Education and Training Center Newport, RI.

Navy medical providers attend the Management of Chemical and Biological Casualties Course at the U.S. Army Medical Research Institute for Chemical Defense, Aberdeen Proving Grounds, Maryland and the U.S. Army Medical Research Institute of Infectious Diseases, Ft. Detrick, Maryland.

Unit Training. Proficiency training is conducted at the unit level by Navy instructors who are graduates of the CBR-D Operations and Training Specialist Course conducted at the U.S. Army Chemical School. Navy units conduct basic, intermediate, and advanced training exercises as part of the Training and Readiness Cycle prior to deployment. During the basic training phase, CBR-D training exercises are overseen by the appropriate Type Commander and may involve additional unit training by CBR-D specialists from an Afloat Training Group (ATG). During the intermediate and advanced phases of the training cycle, combat readiness is reinforced through Composite Training Unit Exercises (COMPTUEXs) and Fleet Exercises (FLEETEXs).

5.3.4 Marine Corps

The Marine Corps' NBC training focuses on the ability to conduct operations throughout the battlespace with particular emphasis on amphibious deployment, littoral, and air/ground operations. The Marine Corps views NBC as an environment, similar to daylight/darkness and cold/heat.

Training requirements are derived from the Force Commander' s Mission Essential Task Lists, Joint Universal Lessons Learned, Marine Corps Lessons Learned, Mission Need Statements, and Fleet Operational Needs Statements. Once validated, the training requirements are introduced into the Systems Approach to Training (SAT) Process.

One of the results of the SAT process is the development of training tasks and standards that will fulfill the training requirements. These task lists and standards are incorporated into Individual Training Standards (ITSs) for individual Marines and Mission Performance Standards (MPS) for Marine units. These ITSs and MPSs are published as Marine Corps Orders for standardization and compliance throughout the Marine Corps.

The Marine Corps conduct training in two categories: Individual Training based on ITSs and Collective (unit) Training based on MPSs. Figure 5-1 shows the individual NBC training provided to all Marines.

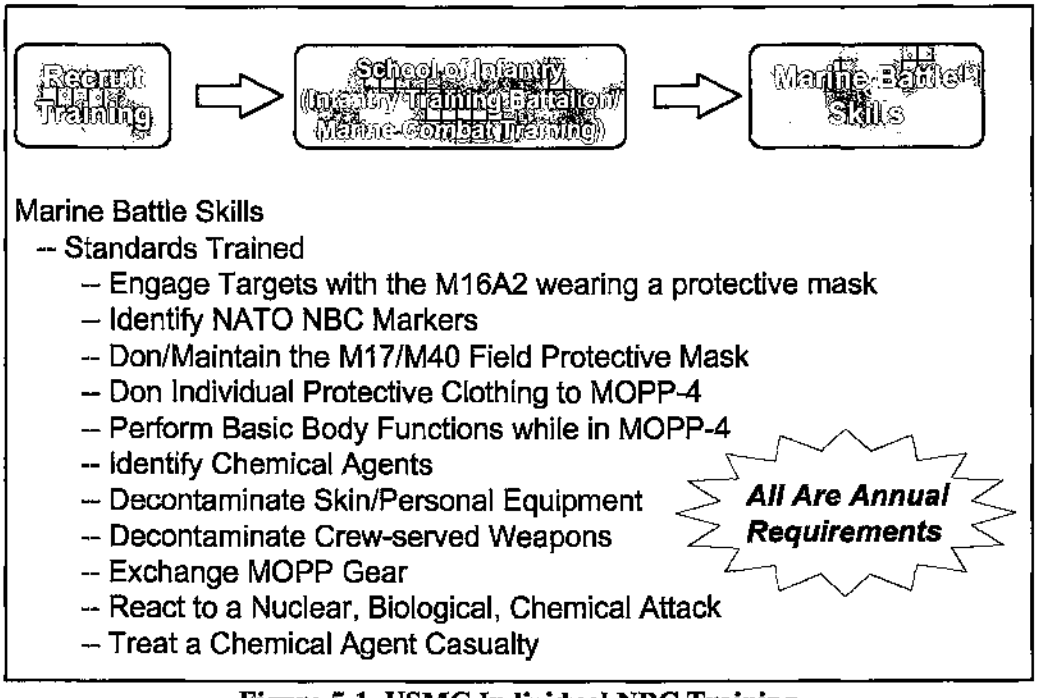

Figure 5-1. USMC Individual NBC Training

Individual Training. Enlisted Marine entry level training begins at recruit training or "Boot Camp" where Marines are introduced to the field protective mask and the gas chamber. All enlisted Marines then proceed to the School of Infantry (SOI). The training focus is surviving and functioning in an NBC environment. Training transitions from a classroom/academic environment to practical application/field environment to provide students more hands-on experience.

Once Marines reach their units they begin the Marine Battle Skills Training program. Marine Battle Skills is a set of tasks which all Marines are required to be proficient in and are

evaluated annually. Marine Battle Skills NBC training focuses on providing Marines the capability to survive as well as function in an NBC environment.

Unit Training. Unit level (or collective) training includes classroom and field training and is included in unit training exercises and plans. (See figure 5-2.) Units are also required to meet very specific training standards. These requirements take the form of Mission Performance Standards (MPSs). Each type of unit in the Marine Corps has a set of MPSs assigned to it. These MPSs are published as 3500 Series Marine Corps Orders.

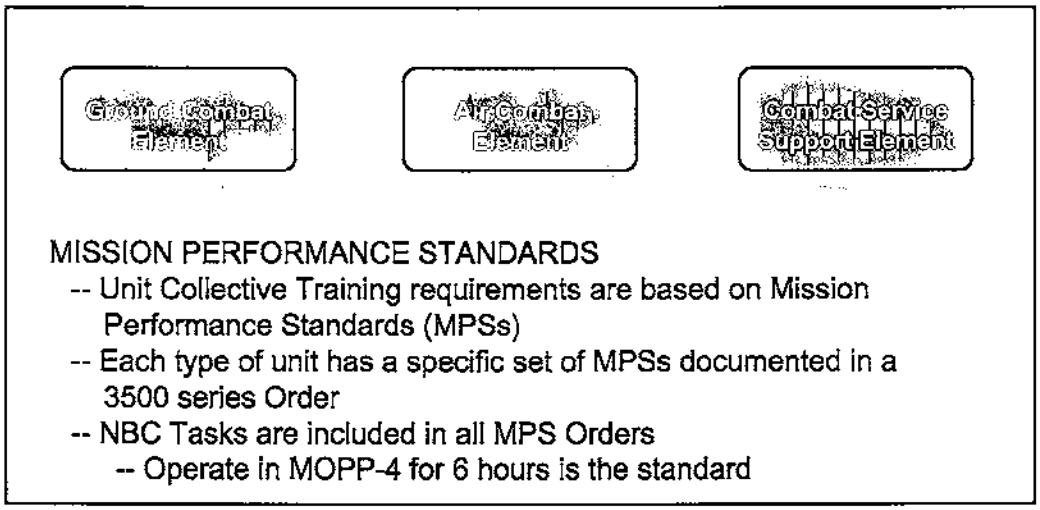

Figure 5-2. USMC Collective Training, NBC Requirements

Each MPS Order includes NBC Tasks which the unit must accomplish. However, each set of requirements varies from unit to unit. For example, a Tank Battalion must be able to utilize the vehicle' s NBC filtration system, decontaminate tanks, and operate tanks under NBC conditions. An Infantry Battalion on the other hand has no requirement to decontaminate tanks, but does have to decontaminate crew served weapons. NBC evaluations are conducted annually for all Marine Corps units. Those units that are part of the Marine Corps' Unit Deployment Program (UDP) and designated Marine Expeditionary Units (MEUs) are required to undergo an NBC evaluation prior to deployment.

5.4 NBC DEFENSE PROFESSIONAL TRAINING

Public Law 103-160 requires all Services to conduct NBC defense professional training at the same location. Currently, all Service training is co-located at the United States Army Chemical School at Fort McClellan, Alabama. Fort McClellan is scheduled for closure in FY99 and new training facilities are planned to open at Fort Leonard Wood, Missouri. Each Service conducts their training with their own Service instructors. The experts who graduate from the Service' s technical training and the Army' s Chemical Defense Training Facility become instructors for their Service' s unit training. The Defense Weapons School attached to the Field Command, DTRA at Kirtland AFB, New Mexico, conducts a nuclear hazards training course.

5.4.1 Joint NBC Defense Professional Training

The JSIG has established a Joint Training Council (JTC) comprised of Service detachment representatives at the USACMLS to discuss issues pertaining to facilities and range scheduling and any other training issues that impact the ability of the Services to conduct effective professional training.

Information exchanges between the Services were facilitated by the JSIG and plans put in place to review future doctrine and new equipment training plans. Discussion concerning a Joint instructor pool was shelved due to unique training requirements each Service possesses. The Army plans to consolidate common and shared (Chemical, Military Police, and Engineer) training. During consolidation training sessions, students from professional development courses conducted by all three schools will start at the same time, straining classroom and billeting resources.

Joint Professional Military Educa tion, Phases I and II, currently contains no NBC defense considerations or requirements. It is essential that officers of all Services assigned to joint staffs understand the NBC threat, are familiar with U.S. capabilities to detect and mitigate the threat, and comprehend their staff roles and responsibilities in dealing with NBC issues. The JSIG, along with the Services, Joint Staff, and CINCs will address these important shortfalls and requirements in the coming year.

Within the joint medical arena, the US Army Medical Department sponsors the Medical Management of Chem ical and Biological Casualties (MCBC) course, which provides training to DoD personnel. Additional information on this course can be found in Section 5.3.1. Based on guidance contained in DoD Directive 6025.3, *Clinical Quality Management Program in the Military Health Services* (signed 20 July 1995), health care providers are directed to receive certification for assignments during military operations. This certification includes NBC defense training and provider courses where applicable. The medical commander will review certification annually. In addition, on 20 December 1995 the DoD completed DoD Instruction 1322.24, *Military Medical Readiness Skill Training*, which implements policy, assigns responsibility, and prescribes procedures for developing and sustaining comprehensive systems for providing, assessing, and monitoring military medical skills training essential for all military personnel, health care personnel, and medical units. NBC defense training, to include chemical and biological warfare defense measures and medical specialty training such as casualty man agement, are specifically articulated in the instruction.

All Medical Nuclear Casualty Training has been consolidated under the Armed Forces Radiobiology Research Institute in Bethesda, Maryland, where radiobiology education is made available in a Tri-Service format.

5.4.2 Army NBC Defense Professional Training

US Army NBC Defense Professional Training presently takes place at Fort McClellan, Alabama. In June 1999, this training will begin moving to Fort Leonard Wood, Missouri.

Training consists of three enlisted/noncommissioned officer courses and two officer courses. At initial entry, enlisted soldiers receive training in chemical and biological agent characteristics and hazards, smoke and decontamination operations, chemical and radiological survey procedures, and individual protective clothing and equipment. This program provides 18 weeks of intensive training, culminating in live/toxic agent training in the Chemical Defense Training Facility. Toxic agent training is an integral, mandatory component of all professional courses. In October 1998, the initial entry enlisted training program was extended to 19 weeks to accommodate Army Values training.

Initial Entry Training
19 Weeks

Standards Trained:

- Radiological Survey
- Radiological Defense
- Chemical and Biological Agent Characteristics and Hazards
- Chemical and Biological Defense
- Decontamination Operations
- Smoke Operations
- Individual NBC Protection
- Chemical Defense Training Facility

Figure 5-3. U.S. Army Entry Training

Chemical Corps sergeants attend the 15 week Chemical Basic Noncommissioned Officer Course (BNCOC) where they are trained to be an NBC company squad leader and a non-chemical company or battalion NBC NCO. Chemical BNCOC provides the NCO with the technical and tactical skills needed to advise company/battalion commanders in NBC operations and procedures, to train non-chemical soldiers in NBC avoidance, decontamination, and protective measures and to lead smoke/decontamination squads.

Chemical Corps staff sergeants and sergeants first class attend the 13 week Chemical Advanced NCO Course (ANCOC) where they are trained to be an NBC platoon sergeant, an NBC NCO at brigade level, and an NBC NCO in a division or Corps level NBC element. During training they receive advanced technical operations, hazard estimates, logistics and maintenance management, combined arms operations, smoke and flame support, and training management.

Chemical Corps lieutenants attend a 19-week officer basic course, 10-weeks during mobilization. Reserve Component officers must attend the resident course. The Maneuver Support Center (MANSCEN), to be established at Fort Leonard Wood, will instruct the 3-weeks of common lieutenant training from the Chemical, Engineer, and Military Police schools. The Chemical Officer Basic Course (COBC) prepares lieutenants to serve as a Chemical Corps platoon leader or as a non-chemical battalion chemical staff officer/assistant operations officer. This course provides them with a fundamental knowledge of NBC agent characteristics and hazards, NBC recon (non-FOX), decon, and smoke operations, NBC staff functions, individual and unit tactical operations, and biological detection operations. This course includes classroom

instruction, hands-on equipment training, and field exercises. Completion of live/toxic agent training is a prerequisite for graduation.

Chemical Corps captains attend the 20-week officer advanced course where they are trained to serve as the commander of a Chemical Company and as NBC staff officers at the brigade and division level. Instruction focuses on leadership, Army operations, hazard pre diction, planning and conducting NBC reconnaissance, decontamination, biological detection operations, and smoke and flame operations in support of maneuver units. Additionally, officers receive training in nuclear target analysis/vulnerability analysis, operational radiological safety, and environmental management. Extensive use is made of computer simulations to reinforce the application of NBC assets in support of tactical operations. The duration of this course will be cut to 18 weeks, beginning in October 1998. In the MANSCEN configuration due to begin in March 1999 at Fort Leonard Wood, Missouri, the Chemical Officer will share training with Military Police and Engineer Officers in Common Training, Shared Tactical Training, and Battle Lab exercises.

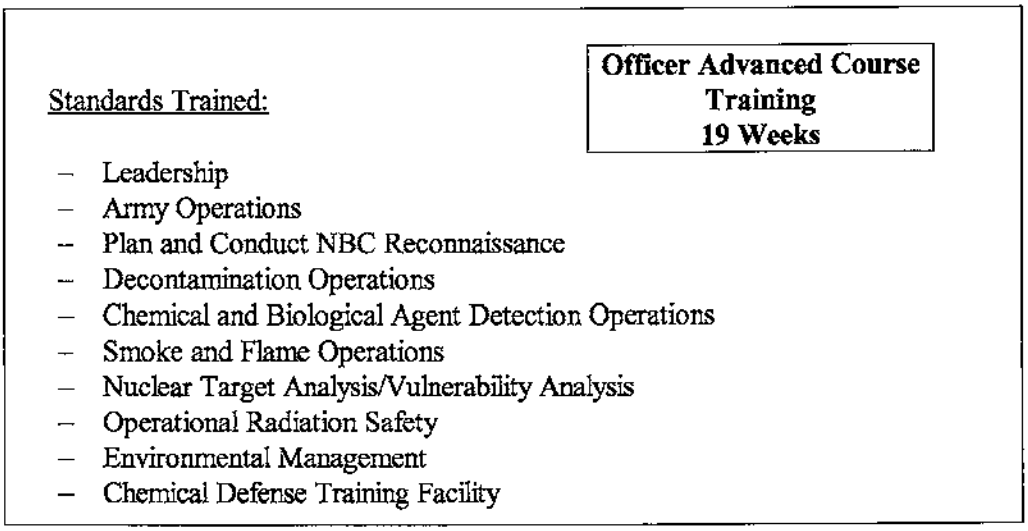

Figure 5-4. U.S. Army Officer Advanced Training

Specialized professional training is conducted in stand-alone courses attended by DoD, Allied, and international students. These courses include:

NBC Reconnaissance Operations (FOX)	(5 weeks)
Radiological Safety (Installation level)	(3 weeks)
Chemical Weapons Inspector/Escort (OSIA)	(1 week)
Chemical Weapons Convention Module II	(6 weeks)
Decon Procedures (Non-US) (GE, UK, NE)	(1 week)
RADIAC Calibrator Custodian	(1 week)
Biological Detection Specialist (BIDS)	(5 weeks)
Master Fox Scout	(2 weeks)
Long Range Biological Standoff Detection	(2 weeks)

5.4.3 Air Force NBC Defense Professional Training

The Air Force training detachment at Ft. McClellan offers six separate in-residence courses designed to enhance the NBC proficiency of primary-duty AF Civil Engineer Readiness Flight personnel. These courses fulfill the differing needs of the total force, including Active Duty, Air National Guard, and Air Force Reserve. Further, the Air Force administers a career development correspondence course and two mobile courses in airbase operability and NBC cell operations.

Each course contains a wide range of materials covering c ritical aspects of Readiness Flight operations in situations ranging from peacetime, military operations other than war, through wartime. The following is a synopsis of the NBC aspects of these courses.

Training for personnel being assigned primary readiness duties includes comprehensive coverage of agent characteristics and hazards (to include determination of incapacitation/ lethality levels); nuclear weapons effects and other specific hazards associated with ionizing radia tion; NBC detection and decontamination; contamination control and avoidance techniques; plotting and reporting procedures; detailed NBC persistency and duration of hazard calcula tions; the inter-relationship between NBC defense and other passive defense activities (*e.g.*, camouflage, concealment, and deception, (CCD), dispersal, and hardening, *etc.*); and systematic analysis procedures for assessing the hazard and providing credible advice to commanders.

Air Force learning theory emphasizes hands-on training, and the school makes extensive use of available training ranges and equipment. The school includes Chemical Defense Training Facility (CDTF) live agent training in five of six in-residence courses. Training is provided on every major piece of equipment available in the field today, including state-of-the-art items currently being fielded.

The CE Readiness Flight Officer and 7-level Craftsman courses provide flight leaders and mid-level NCOs with the background and technical information that is necessary for effective management of the CE Readiness Flight and contingency response operations.

Readiness is the key to successful Air Force operations. Consequently, the various aspects of CE Readiness Flight operations, including NBC defense and depleted uranium awareness, are also topics of instruction at briefings for Air War College, Air Force Institute of Technology, or Joint Senior Leaders Course.

The School of Aerospace Medicine at Brooks AFB teaches a variety of readiness courses to medical personnel. Courses–such as Bioenvironmental Engineering, NBC Battlefield Nursing, Preventive and Aerospace Medicine contingency training, Global Medicine, Military Tropical medicine, Medical Survival training, plus many others–are provided at the San Antonio, TX base.

5.4.4 Navy CBR Defense Professional Training

The Navy Construction Training Center Detachment at the U.S. Army Chemical School offers two courses of instruction for Navy Chemical, Biological and Radiological Defense

(CBR-D) specialists. The courses are open to Navy, Coast Guard, Military Sealift Command, and foreign military personnel, E-5 and above. Courses are designed to provide both afloat and ashore commands with individuals who can successfully perform their requisite duties in a CBR contaminated environment. In addition, the training enables CBR-D specialists to act as the primary CBR-D trainers for their respective commands.

The training capitalizes on the unique capabilities of the Army Chemical School. In addition to classroom instruction, the Navy Detachment utilizes the CDTF for live agent train ing and the Bradley Radiological/Laser Laboratory for training in theory and equipment opera tion for radiological defense. Approximately 200 students graduate annually from the Detach ment' s courses. In addition to being fully qualified to conduct training using the Army' s facil ities, the Navy Detachment actively participates as part of the Joint Training Council (JTC).

In addition to CBR-D Specialist courses conducted at the US Army Chemical School, the Navy has incorporated CBR-D readiness training into courses that are attended by personnel at all levels of professional development.

Course Name	**Course Location**
Recruit Training CBR-D	Naval Training Center Great Lakes, IL
Damage Control "A" School	Naval Training Center Great Lakes, IL
Senior Enlisted Damage Control	Fleet Training Center San Diego, CA
Hospital Corpsman "A" School	Naval Training Center Great Lakes, IL
Independent Duty Corpsman	Naval School of Health Sciences San Diego, CA and Naval School of Health Sciences Portsmouth, VA
Management of Chemical Casualties	U.S. Army Medical Research Institute for Chemical Defense, Aberdeen Proving Ground, MD
Medical Affects of Ionizing Radiation	Armed Forces Radiobiology Research Institute Bethesda,MD
Radiation Health Indoctrination	Naval Undersea Medical Institute Groton, CT
Radiation Health Officer	Naval Undersea Medical Institute Groton, CT
CBR-D Command Center	Naval Construction Training Center Gulfport, MS
CBR-D Personnel Protection	Naval Construction Training Center Gulfport, MS
CBR-D Team Training	Naval Construction Training Center Gulfport, MS and Naval Construction Training Center Port Hueneme, CA
Repair Party Leader	Fleet Training Center San Diego, CA Norfolk, VA Mayport, FL Ingleside, TX Pearl Harbor HI Yokosuka, Japan
Repair Party Officer Short Course	Surface Warfare Officers School Newport, RI
Division Officer	Surface Warfare Officers School Newport, RI
Damage Control Assistant	Surface Warfare Officers School Newport, RI
Department Head	Surface Warfare Officers School Newport, RI
Executive Officer	Surface Warfare Officers School Newport, RI
Commanding Officer	Surface Warfare Officers School Newport, RI

5.4.5 Marine Corps NBC Defense Professional Training

The Marine Corps NBC Defense School at Ft. McClellan consists of an Enlisted Basic NBC Defense Course, and an Officer Basic NBC Defense Course. In addition to the courses conducted by the Marine Corps NBC Defense School, Marines attend three other functional courses (Chemical Officer Advanced Course, NBC Reconnaissance Course, and the Radiological Safety Officer Course) conducted by the Army Chemical School.

The USMC Enlisted Basic NBC Defense Course trains approximately 200 NBC specialists in a comprehensive 10 week program covering all the ITSs specified in MCO 1510.71. The curriculum includes 108 hours of instruction on how to conduct NBC training. This training provides Marines with the tools they will need on a daily basis as they perform their primary peacetime mission of conducting NBC Defense training to their units. The course is divided into six blocks of instruction as shown in Figure 5-5.

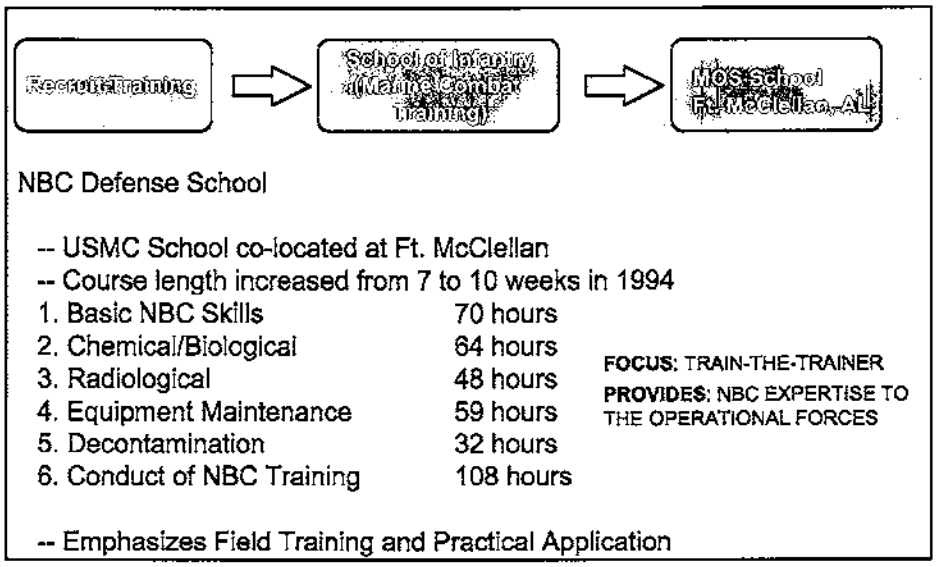

Figure 5-5. USMC Individual Training (Enlisted NBC Specialists)

Training For NBC Officers. Establishment of a Marine Corps Basic NBC Officer Course is complete. This course, shown in Figure 5-6, provides the requisite NBC skills to newly selected Marine Corps NBC Defense Officers. The first course will begin began in June 1997. All Marine NBC Officers are Warrant Officers, usually selected from NBC Defense specialist enlisted ranks. As Warrant Officers, they focus entirely on technical expertise, NBC Defense training, and supervision of enlisted NBC Defense specialists. In the past, Warrant Officers relied on the training they had received as enlisted NBC Defense Specialists and on-the-job training. However, the new NBC Defense Officers Course will be focused specifically towards Warrant Officers and will build on previous training received. NBC Officers also attend the Army' s Chemical Officer Advanced Course and Joint NBC courses as part of advanced Military Occupational Specialist (MOS) training.

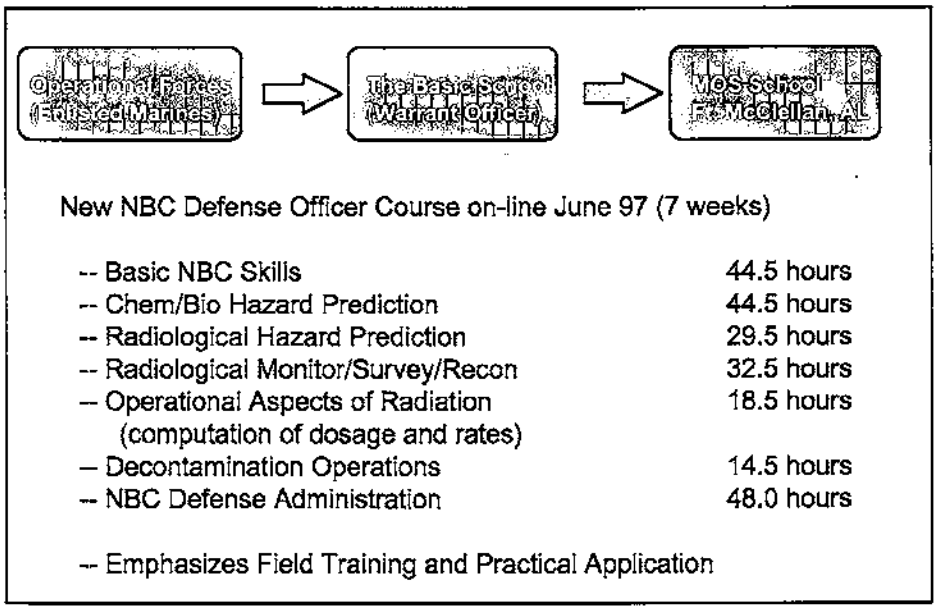

Figure 5-6. USMC Individual Training (Training for NBC Officers)

5.5 TRAINING IN A TOXIC CHEMICAL ENVIRONMENT

In 1987 the Army established the Chemical Defense Training Facility (CDTF) at Fort McClellan, Alabama. (A discussion of the transfer of the CDTF from Fort McClellan to Fort Leonard Wood is provided in Section 5.3.1 above.) The CDTF allows personnel to train in a real toxic agent environment. Since its opening, the Army has used this valuable resource to train over 47,000 U.S. and Allied members from all Services. Training philosophy demands that the military train the way it fights. The CDTF promotes readiness by providing realistic training in the areas of detection, identification, and decontamination of chemical agents. The training develops confidence in chemical defense tactics, techniques, procedures, and chemical defense equipment. Instructors ensure that trainees can adequately perform selected tasks on a chemically contaminated battlefield. To date, the CDTF has maintained a perfect safety and environmental record.

Enrollment at the Joint Senior Leaders Course and the Toxic Agent Leader Training Course at Fort McClellan continues to be in demand. Over 1,200 active and reserve commanders, service leaders, and toxic agent handlers from each of the services have attended. These personnel become very familiar with NBC considerations. In addition to this training opportunity, toxic chemical environment training provides senior officers, commanders, and future specialists confidence in their doctrine, warfighting techniques, and the equipment they fight with in the face of challenges presented by NBC contamination.

There is growing international interest in CDTF training participation. Germany has been taking advantage of this training opportunity for about six years. The United Kingdom now uses this facility for training. Law enforcement agencies and other first responder-type agencies have also participated in the training.

5.6 INTEGRATION OF REALISM/WARGAMES/EXERCISES

5.6.1 Simulations and Wargames

Incorporation of NBC features into relevant simulations, including portrayal of NBC weapons effects is essential. Currently, there are several engineering level models available that represent the fluid dynamics of NBC contamination. However, relatively few robust represen tations of NBC effects have been fully implemented in wargames and analytical models used by DoD. The Concepts Evaluation Model (CEM), used by the Army Concepts Analysis Agency, captures NBC effects off-line. Corps level models such as Vector-In-Command (VIC) and Division models such as Combined Arms and Support Task Force Evaluation Model (CASTFOREM) have some NBC capabilities that must be continually improved. JANUS, a division BDE level model, also has some NBC capabilities that are being improved and upda ted. Force Evaluation Model (FORCEM) has been modified for theater level effects. The configuration controlled version of Tactical Warfare (TACWAR) has within it a chemical module for theater level chemical effects that is under examination by the Joint Staff and OSD for its ability to accurately model the effects of chemicals on a theater level war.

Incorporation of NBC features in relevant models, including faithful portrayal of CB aerosolization and electromagnetic pulse (EMP) effects is essential. The incorporation of CB weapons into Janus-A for the Louisiana Maneuvers (LAM) and the ongoing iteration of the Army' s Total Army Analysis (TAA) process using FORCEM, mark the first time major decisions have considered CB weapons as a part of the standard battlefield. ACES, an Air Force Command Exercise System, is a family of joint wargames which currently has robust nuclear simulations with chemical and biological planned for the near future. All existing models need to be modified in the biological area. To date, there has been limited model modification for biological effects except for the current modifications ongoing to Janus.

Each of the services conducts wargames, which incorporate NBC in the scenarios, in their respective senior level service schools. The Joint Land, Aerospace, and Sea Simulation (JLAS), a joint exercise with all the senior service schools participating, and hosted by the Air Force Wargaming Center at Maxwell AFB, Alabama, incorporates electronic simulation of the NBC environment. EUCOM conducted AGILE LION 97 exercise in a Marine led JTF that dealt with a nuclear reactor accident humanitarian assistance operation in Lithuania. The Navy has conducted a Naval Battle Analysis to provide a tool to analyze the effects of CB agents on Naval operations and permit the incorporation of realistic assessments of CB warfare effects into Naval wargames. As a result, the Vapor, Liquid, and Solid Tracking (VLSTRACK) Model has been integrated into selected wargames and demonstrated to participants. In conjunction with the U.S. Army Center for Army Analysis (CAA), USANCA sponsored ATOMIUM 97, a NATO Partnership for Peace (PfP) political military game involving low-level radiation which included the participation of PfP nations and Russia.

Current training exercise gaming simulations have not received sufficient funding to adequately portray and challenge commanders and staffs to apply NBC defense training doc trine

and leader-development training strategies to prepare their forces to maintain operational continuity and achieve mission success in an NBC and smoke/obscurant environment. To be an effective training mechanism, these simulations must challenge training audiences to under stand adversaries' NBC intent and capabilities. Simulations must also allow players to visualize how NBC capabilities affect the battlespace, friendly courses of action, and operation plans. Additionally, effective simulations must allow players to apply NBC defense principles and capabilities to set conditions for mission success against NBC capable threats. Gaming simulations (Joint Simulation, Warfighter Simulation 2000, and Combined Arms Tactical Trainer) are being developed that will accurately replicate the NBC hazards and smoke conditions of future battlefields and their effects on friendly systems. Only then can commanders and staffs train and develop required high order battlefield cognitive skills that will allow full integration of enemy intent and capabilities, NBC environment effects, and friendly force capabilities into the development of a winning plan.

There is currently no standardized instru mentation system (IS) that can realistically portray all facets of Nuclear, Biological and Chemical training to train the total force. The U.S. Army Chemical School is developing NBC Recon training devices for the detection and track ing of simulated NBC contamination at Maneuver Combat Training Centers (CTCs) and home station training areas. Proposed training IS will retrieve, process, and calculate digital contamination data for maneuver units and will also include AAR feedback in the areas of NBC casualties, change of custody, and reaction procedures during NBC attacks and operations. This IS would provide a realistic replication of NBC contamination as portrayed on the battlefield. Resourcing will be pursued to field proposed training devices at CTCs and other locations.

5.6.2 Joint NBC Training/Joint and Combined Exercises

Chairman of the Joint Chiefs of Staff (CJCS) Exercise Program. Joint NBC defense training objectives must be incorporated into the CJCS Exercise Program. This program includes three different types of exercises:

(1) **Positive Force** (PF) exercises are large scale Command Post Exercises that normally consider national level issues such as mobilization and deployment. During PF 98 (Mobilization) and PF 99 (Deployment), Atlantic Command (ACOM), in its role as the force provider, ensures that deploying units and personnel are certified as combat ready. Although an integral part of this certification procedure is determining unit, personnel, and equipment operational readiness under NBC conditions, ACOM is not adequately staffed or organized to perform this certification.

(2) **Positive Response** (PR) exercises normally consider strategic level nuclear issues. In addition to considering command and control of nuclear forces, these exercises deploy and backup national command and control personnel and systems annually. Capabilities of these redundant systems are equally applicable during chemical and biological scenarios as they are during nuclear scenarios, but chemical and biological scenarios are not adequately exercised.

(3) The **No-Notice Interoperability Exercise (NIEX)** program continues to focus on our ability to interdict the proliferation of nuclear, chemical, and biological weapons. In

1995, the NIEX required the interagency process to respond to a foreign nation' s request to interdict and recover three stolen nuclear weapons. National level forces were deployed in response to this crisis. The 1996 NIEX tested our nation' s ability to respond to a crisis involving biological weapons. The Chairman of the Joint Chiefs' 1998 requirement for immediate action on WMD and NBC defense operations mandates integration of these topics into all futures NIEXs.

Joint Vision 2010 provides the operational based templates for the evolution of our Armed Forces to meet challenges posed by an adversary' s use of weapons of mass destruction. JV 2010 serves as the Doctrine, Training, Leader-development, Organization, and Material requirements (DTLOM) benchmark for Service and Unified Command visions. The NBC defense cornerstone resource for this vision of future warfighting embodies three required operational imperatives:

First, and most importantly, CJCS and Service leaders should recognize that NBC strategic and operational level of war expertise is an essential resource requirement in the Joint Warfighter Center (JWFC) and USACOM Joint Training and Analysis Center (JTASC). Success for Joint Vision 2010, a strategy centered on capabilities-based forces, requires these organizations to successfully accomplish their respective joint NBC defense doctrine, training, and leader development roles, and for USACOM to accomplish its NBC defense mission as force provider, force trainer, and force integrator. NBC expertise at all levels and from all Services is paramount.

Second, Unified Commands should staff their organization appropriately with the right expertise to meet current and future requirements to shape and respond to NBC challenges.

Third, doctrine, training, and leader-development training strategies should facilitate sophisticated battlefield visualization and situational awareness proficiency, allowing commanders and staffs to conduct service, joint, and combined operations in an NBC environment.

The Chairman of Joint Staff published Master Plan Exercise Guidance in May 1998. This guidance provides exercise objectives to the CINCs. This guidance provided specific counterproliferation objectives. NBC Defense and Force Protection were identified as the Chairman' s top training issues. This guidance will influence and guide development of CINC exercises and training, which will be conducted in Fiscal Year 2000.

Army. The Army emphasizes integration of NBC defense training in unit rotations at the Combat Training Centers (CTCs). These centers include the National Training Center (NTC), Joint Readiness Training Center (JRTC), the Combat Maneuver Training Center (CMTC), and the Battle Command Training Program (BCTP).

The Army continues to see negative NBC training trends at the company, battalion, and brigade level. This inferior performance at the CTCs is directly attributable to the lack of homestation NBC training. These results clearly indicate that there is a dire need to educate

senior leaders on influencing homestation training through providing command emphasis *and* dedicated resources to conduct NBC training. Conversely, units that (1) have the necessary command support and equipment, (2) balance NBC within their overall training requirements, and (3) execute according to approved training plans, are able to survive and continuously operate in a simulated NBC environment. However, increasingly constrained training resources limit NBC training to fundamentals. This often means training consists only of NBC survival and not training for continuous operations in an NBC environment.

Air Force. NBC warfare defense preparedness is an integral part of periodic Operational Readiness Inspections conducted by MAJCOM Inspectors General. Realism is injected into these scenarios using a simulated wartime environment including the use of bomb simulators, smoke, and attacking aircraft. Personnel are tasked to perform war skills while in their full complement of protective equipment. Additionally, Air Force units participate in major joint and combined exercises that incorporate realistic NBC situations. Following are examples that describe exercises incorporating NBC situations:

- TEAM SPIRIT - Pacific Air Forces (PACAF) Joint/combined large-scale air, sea, land exercise to demonstrate US resolve in South Korea.
- ULCHI FOCUS LENS - PACAF Joint/combined command and control exercise conducted in conjunction with the Republic of Korea' s national mobilization exercise "ULCHI."
- FOAL EAGLE - PACAF Joint/combined rear area battle and special operations field training exercise.
- EFX – Air Combat Command sponsored expeditionary force projection exercise.

Navy. Due to the unique nature of Naval force deployments, CBR defense training is conducted whether platforms are operating independently or in a group. During scheduled CBR defense training periods, realism is stressed and CBR defense equipment is used extensively.

Naval units conduct basic, intermediate, and advanced training CBR-D exercises prior to deployment. During the basic training phase, CBR-D training exercises are overseen by the appropriate Type Commander and may involve additional unit training by CBR-D specialists from Afloat Training Groups (ATG). During the intermediate and advanced phases of the training cycle, combat readiness is reinforced through Composite Training Unit Exercises (COMPTUEXs) and Fleet Exercises (FLEETEXs).

The exercises conducted by deploying Battle Groups and Amphibious Readiness Groups during pre-deployment Composite Training Unit Exercises and Fleet Exercises are designed to meet CINC training requirements for forces in the deployment area of responsibility.

Naval CBR-D scenarios are also incorporated into the "Global" Wargame conducted annually at the Naval War College in Newport, RI. The CBR-D scenarios addressed at "Global" are directed at strategic decisionmakers and National Command Authorities.

Marine Corps. The Marine Corps incorporates NBC training into combined arms exercises at the Marine Corps Air Ground Combat Center in Twenty Nine Palms, California. Battalion level unit exercises are also conducted during Korea and Thailand Incremental Training Programs where units deploy and exercise various tasks. Like the Air Force and Army, the Marine Corps also participated in major joint/combined exercises. Mission, threat, and task organization determine the level. During FY98, the Marine Corps incorporated NBC defense training into the following exercises:

- JTF Exercise United Endeavor
- Ulchi Focus Lens 98
- Foal Eagle
- IMEFEX
- Keystone 98
- Global 2000
- Bio 911
- Azure Haze
- Urban Warrior
- ChemWar 2000
- Brave Knight
- Agile Lion

It should be noted that all Marine Corps units must also conduct quarterly NBC exercises. Evaluations include operational, administrative, and logistical functional areas. These exercises incorporate realistic NBC defense training into the exercise scenario to enhance the value of the exercise.

5.7 INITIATIVES

5.7.1 Joint

Doctrine. Initiatives in Joint NBC defense doctrine are detailed in section 5.2.

Modeling. At the request of the Deputy Assistant Secretary of Defense for Counterproliferation and Chemical and Biological Defense, DATSD(CP/CBD), the JSIG has established a Commodity Area (CA) for CB M&S and appointed the Navy to be the lead service. Unlike other commodity areas, which manage advanced development programs, the M&S CA will primarily develop joint requirements, identify funding requirements to improve training and doctrine development, and promote standardization.

To support the M&S CA, the JSIG has tasked a contractor to develop a CB M&S Master Plan. When completed and approved, the plan will form the basis for future M&S R&D conducted by both the JSIG and JSMG. Initial findings from the Master Plan will be used to refine the M&S portion of the Modernization Plan in the second quarter FY99.

The DATSD(CP/CBD) has initiated a study to evaluate the suitability of VLSTRACK and HPAC for operational analysis. A study advisory group has been formed to evaluate the study and recommend how to consolidate the capabilities of the two models into a single system and reduce future duplication of developmental effort.

The Counterproliferation Review Council (CPRC) V&V Standards Working Group will be initiating a process in FY99 to standardize the V&V of CB models. This effort should

improve overall V&V activities, allow model-to-model comparisons and simplify eventual accreditation for various applications.

JCATS, JWARS and JSIMS are the future joint models for constructive and virtual combat simulation for training and analysis applications. Plans to incorporate CB defense effects into these models were initiated in FY98. VLSTRACK has been loosely coupled to JCATS to demonstrate the ability to add high resolution CW effects. The JSIG will be funding the continuation of this effort in FY99 and beyond. A contractor has been tasked by the JWARS program office to develop a plan for incorporating CB effects into JWARS.

The JSMG is sponsoring a program to develop models to evaluate effects of CB defense at APODS and SPODS.

Training.

5.7.2 Army

In an effort to refine doctrine and training, the Army is quantifying the impact of NBC environments on combat operations. Two programs have been executed to achieve this goal: (1) Combined Arms in a Nuclear/Chemical Environment (CANE), and (2) Physiological and Psychological Effects of the NBC Environment and Sustained Operations on Systems in Combat (P2NBC2). These Force Development Testing and Experimentation (FDTE) evalu ations have improved our understanding of individual and unit operations and performance degradation while in MOPP. The CANE FDTE evaluations quantified field data that commanders can use for planning, training, and decision making to respond to the threat.

The Army, as proponent for CANE tests, has completed five field evaluations (mech an-ized infantry squad/platoon in 1983, tank company team in 1985, armor heavy battalion task force in 1988, light infantry forces in 1992, and air defense artillery in 1993). The Army has established the Chemical Vision Implementation Plan (CVIP) a systematic review process to ensure identified deficiencies are addressed and corrected. The Commandant of the Army' s Chemical School reviews the CVIP annually. Army field manuals are then revised to address deficiencies identified in CANE tests.

Before CANE FDTEs were conducted, commanders' training in a simulated NBC environment had an indication of the degradation that MOPP places on their operations. They were aware that training could maximize proficiency, but they lacked the feedback to direct that training. Consequently, training was often sporadic and incomplete.

The Army is now implementing several training guidance improvements by:

- Providing heightened command emphasis to unit commanders on NBC threat with attention to Third World countries;
- Simulating NBC environments in training;
- Continuing emphasis and effort to integrate safe, realistic NBC defense in all training.

5.7.3 Air Force

The Air Force currently has three training and readiness initiatives underway and continues to improve its professional training.

The Civil Engineer Readiness Technical School implemented an advanced scenario-driven exercise in the CDTF revolving around a terrorism incident involving chemical muni tions. This training is provided to advanced students and differs from the lock step training provided to Apprentice-level students. The scenario will be reviewed/revised annually during the respective course reviews. Air Force instructors are qualified to conduct joint classes at the CDTF and are fully integrated into CDTF operations. Readiness instructors lead Air Force students from five of six residence courses through the training and also assist the other ser vices with their training requirements. Additionally, they provide an orientation of NBC defense concepts and live-agent training in the CDTF for key Air Force personnel during the semi-annual Joint Senior Leaders Course.

The school revised its courses of instruction effective October 97 to comply with changes to the Specialty Training Standard (STS) resulting from the Readiness Utilization and Training Workshop held in October 1996. The new STS requires Readiness students and personnel be highly qualified in chemical-biological warfare operations, including conducting and advising leaders on hazards analysis and the use of emerging detection and plotting technologies.

Air Force Readiness personnel enrolled in correspondence courses for upgrade training to the five skill level will soon be able to complete the course on interactive CD-ROM including full motion-video and sound. The course is presently available only in a paperback version, which will continue to remain available for a limited period after the CD-ROM release. Interactive courseware development began in FY97 and is expected to be completed by FY00.

The Air Force NBC Ability to Survive and Operate (ATSO) Working Group (WG) (IPT) is a cross-functional forum that identifies and tracks AF NBC defense action items. Current NBC defense training initiatives tracked by the WG include the following:

- Implement a chem-bio protective mask quantitative fit training (QNFT) program to maximize protection by ensuring personnel attain the best fit possible
- Enhance Civil Engineer Squadron Commanders Course to put more emphasis on NBC defensive operations; provide an overview of Air Force Manual (AFMAN) 32-4019, *Chemical-Biological Warfare Commander' s Guide* to include the Vulnerability Assessment Tool; and new consequence management (CM) requirements
- Enhance Air Force Group Commanders Course to include new CM requirements
- Enhance On-Scene Commanders Course to include new CM requirements
- Develop a multimedia training format for AFMAN 32-4019
- Develop AFMAN 32-4019 training for Readiness personnel
- Incorporate AFMAN 32-4019 training in Air Force SILVER FLAG training site curriculum

- Incorporate depleted uranium training in initial and refresher NBC defense training; NBC readiness training plans (RTPs) have been revised and depleted uranium awareness is beginning to be taught at AF installations
- Provide robust DU training to personnel who have a greater risk of exposure to DU on the battlefield; AF special operations personnel are reviewing functional pipeline courses and evaluating new DU training requirements in the NBC RTPs
- Enhance AF NBC defense unit training to allow for increased emphasis on NBC defensive posture during unit training.

Additionally, the AF Medical Service has developed, or is in the process of developing, NBC Defense Training contract SOWs for eleven initiatives. Paragraph 5.3.2 lists all eleven. All are being managed by HQ AETC/SGP and HQ USAF/SGX.

5.7.4 Navy

The Navy' s main initiative is the integration of CBR-D requirements in the tactical training strategy. These requirements are executed via the interdeployment training cycle' s aggressive training and material readiness program. Additionally, the supplemental funds made available from the FY96 National Defense Authorization bill have been utilized to upgrade existing training aids and delivery of training support equipment to all units.

Additionally, the Navy' s basic NBC defense course has been incorporated in both officer and enlisted accession training curriculums. In conjunction with this initiative, the same course taught at the fleet training centers has been restructured to improve throughput. The Navy Environmental Health Center, Norfolk, Virginia, is in the process of implementing a training and consultation team at the Navy Environmental and Preventive Medicine Unit (NEPMU) #2 in Norfolk, Virginia and NEPMU#5 in San Diego, California. These teams will provide Navy Medical Department personnel with the training and consultation necessary to ensure effective medical management of casualties caused by chemical, biological, radiological, and environmental (CBRE) exposures.

The Navy is also working to improve Joint CBR Defense Doctrine. The Navy is actively supporting a Joint Service Integration Group (JSIG) and Air Land Sea Application Center (ALSA) initiative to streamline the development of multi-service CBR-Defense tactical publications. The implementation of the JSIG/ALSA process in FY99 will provide a method for implementing service specific CBR-D requirements into Tactical Training Publications used by all services.

5.7.5 Marine Corps

During FY98 the Marine Corps Chemical Biological Incident Response Force (CBIRF) continued to refine its tactics, techniques, and procedures to respond to the growing biological and chemical terrorist threat. The CBIRF was activated April 1, 1996 and has deployed to the Olympics in Atlanta, the Presidential Inauguration, the Summit of Eight Conference in Denver, Colorado, two State of the Union Addresses, the Papal Visit to St. Louis, and numerous other

exercises to include Agile Lion, Bold Endeavor, and Ill Wind. A CBIRF detachment was deployed in support of Operation DESERT THUNDER. The CBIRF was a primary participant in both the BIO-911 Advanced Concept Technology Demonstration (ACTD) and the Port and Airfield ACTD.

National Asset Activated 1 April 1996

-- Provides an operational force to rapidly respond to WMD incidents
-- Tests New Equipment, Procedures, and Techniques
-- Provides Consequence Management training to Marine Forces through Mobile Training Teams
-- Assists Unit/Facility Vulnerabilities to Enhance Force Protection Planning
-- Works with other Emergency Response Agencies

FORCE MULTIPLIER FOR THE MAGTF.

Figure 5-7. Chemical/Biological Incident Response Force (CBIRF) Role in Training

The CBIRF focuses on consequence management to terrorist-initiated NBC incidents. The CBIRF is a national asset, to be globally sourced to Marine Force Commanders and National Command Authority for duties as the President may direct. The CBIRF consists of 360 skilled and trained Navy and Marine personnel, organized into five elements: Headquarters (including a Reach-Back Advisory Group), Security, Search and Rescue, Service Support, Force Protection (Reconnaissance/Decontamination) and Medical. The CBIRF has state-of-the-art detection, monitoring, medical and decontamination equipment and is prepared for operations in a wide range of military-civilian contingencies. In addition to the CBIRF' s capabilities to respond to chem/bio incidents it serves as a training asset to the operational forces. The CBIRF will provide mobile training teams to various units to provide advanced consequence management. This will provide operational forces with the most up-to-date techniques, tactics, and procedures developed by the CBIRF. CBIRF also assists in Unit/Facilities Vulnerability Assessments to enhance force protection. The bottom line is that the CBIRF serves as a force multiplier to the MAGTF.

Marine Corps FY98 Accomplishments:

- Revised Marine Corps NBC Specialist Individual Training Standards (ITS), (MCO 1510.71) on 5 August 98.
- Conducted a Marine Corps-wide Table of Equipment and Table of Organization Review.
- Participated in Joint Marine Corps and Navy shipboard decontamination exercises with 7th Fleet.
- Developed an Enhanced NBC Capability Set for MEUs.
- Developed and initiated CBIRF training packages for MEUs.

- Published MCWP 3-37, *MAGTF NBC Defense*, September 1998.
- Conducted and managed the Joint Service Mask Surveillance and Testing Program.

Marine Corps FY99 Initiatives:

- Integration of NBC defense procedures in Mission Oriented Tasks (Garrison and Field).
- Conduct USMC NBC Defense Course Content Reviews based on revised ITSs and emerging NBC equipment requirements.
- Continue development of USMC NBC Staff Planning follow-on course, a training course to prepare NBC defense officers and NCOs to assist in the staff planning process.
- Establishment of combat training package for ISMs for reserve forces and follow-on forces in the event of hostilities involving an NBC threat.
- Continued Annual Joint Marine Corps and Navy shipboard decontamination exercises with 7th Fleet.
- Continue participation in a bilateral exchange program with the Republic of Korea (ROK) Chemical Corps.
- Conduct Front End Analysis for an NBC SNCO Advanced Course.
- Continue development of an "Enhanced NBC" capability for MEUs.

5.7.6 Emergency Response: Army Medical Response

The AMEDD continues to be involved in supporting DoD and federal counter terrorism initiatives and contingency operations related to NBC threat agents, mainly with elements of the Medical Research and Materiel Command (MRMC). The following offices and agencies have required AMEDD assistance: DoD SO/LIC, J4 Medical Readiness, U.S. Army Technical Escort Unit, US Department of State, Federal Bureau of Investigation, Department of Health and Human Services, Office of Emergency Preparedness, and the U.S. Marine Corps CBIRF.

The U.S. Army has recently published AR 525-13, Antiterrorism Force Protection (AT/FP): Security of Personnel, Information, and Critical Resources from Asymmetric Attacks, dated 10 September 1998. From this regulation it is assumed that U.S. Army medical treatment facilities and clinics will be called upon to provide assistant to civilian first responders if a WMD terrorist act occurs and to provide emergency room and inpatient treatment for both eligible DoD beneficiaries and civilian casualties. This regulation specifically states that the Surgeon General (TSG) will:

a) Establish policy and guidance on the management and treatment of conventional and nuclear, biological, and chemical (NBC) casualties.
b) Coordinate emergency medical NBC response capabilities worldwide with other DoD, Joint, Federal, state, local and HN agencies.
c) Maintain medical NBC response teams to address nuclear, biological/emerging infection, chemical accidents/incidents worldwide
d) Provide chemical and biological analysis of biomedical samples from patients/decease to assist in the identification of agent(s) used against U.S. personnel.
e) Provide guidance on the vaccination and prophylaxis against biological warfare agents.

The Office of the Surgeon General is currently updating Army Regulation 40-13, Nuclear/Chemical Accident Incident Response, to include all medical teams which could potentially be available to support civil authorities in the event of a terrorist attack with Weapons of Mass Destruction (WMD). The regulation will also include the Army policy for fixed facility medical treatment facilities in support of local domestic first responders.

The AMEDD has formed Specialty Response Teams (SRTs). These teams provide a rapidly available asset to complement the need to cover the full spectrum of military medical response–locally, nationally, and internationally. These teams are organized by USAMEDCOM subordinate commands; they are not intended to supplant TOE units assigned to Forces Command or other major commands. The regional medical commands (RMCs), the United States Army Center for Health Promotion and Preventive Medicine (USACHPPM), and the US Army Medical Research and Materiel Command (USAMRMC) commanders organize SRTs using their table of distribution and allowances (TDA) assets. These teams enable the commander to field standardized modules in each of the SRT areas to meet the requirements of the mission. Members of the US Army Reserve (USAR) may be relied upon to provide a variety of functions in support of the various SRT missions. All SRTs will be capable of deploying within 18 to 24 hours of notification. The two SRTs that can support NBC are the Special Medical Augmentation Response Team – Preventive Medicine (SMART-PM) and the Special Medical Augmentation Response Team – Chemical/Biological (SMART-CB).

The mission of the SMART-PM is to provide initial disease and environmental health threat assessments. This is accomplished prior to or in the initial stages of a contingency operation, or during the early or continuing assistance stages of a disaster. The SMART-PM can:

- Perform on-site initial health threat assessments, limited and rapid hazard sampling, monitoring, and analysis, health risk characterization, and needs assessment for follow-on PVNTMED specialty support in the AO.
- Prepare PVNTMED estimates.
- Perform analysis of, but not limited to--
  - Endemic and epidemic disease indicators within the AO.
  - Environmental toxins related to laboratories, production and manufacturing facilities, nuclear reactors, or other industrial operations.
  - Potential NBC hazards.
- Provide medical threat information and characterize the health risk to deployed forces or civilian populations.
- Provide guidance to local health authorities on surveying, monitoring, evaluating, and controlling health hazards relative to naturally occurring and man-made disasters.
- Assist local health authorities in surveying, monitoring, evaluating, and controlling health hazards relative to naturally occurring and man-made disasters.

In general, the SMART-PM team provides augmentation and public health and environmental engineering expertise in the following areas:

(1) ISO 9000 Accredited Laboratories
(2) Environmental Health
(3) Epidemiology & Disease Surveillance
(4) Toxicology
(5) Entomology
(6) Health Physics (Nuclear/Radiological)
(7) Industrial Hygiene
(8) Water Quality
(9) Clinical Preventive Medicine
(10) Sanitation
(11) Solid & Hazardous Waste Management
(12) Food Service Sanitation

The Special Medical Augmentation Response Team – Chemical/Biological (SMART-CB) includes the following USAMEDCOM staffed assets: the National Medical Chem-Bio Advisory Team (MCBAT) at the USAMRMC, and the RMC Chemical/Biological SRTs. The National MCBAT is comprised of USAMRMC elements from the US Army Medical Research Institute of Infectious Diseases (USAMRIID) and the US Army Medical Research Institute of Chemical Defense (USAMRICD). These assets are Tier 1 elements of the DoD Chemical Biological Rapid Response Team (C/B-RRT) and are ready to deploy worldwide within 4 hours after receiving their orders. The RMC Chemical/Biological SRTs are trained medical teams located at the RMCs that can deploy in response to a chemical, biological, or radiological incident. Examples of incidents that may require a rapid response include:

- An accident involving the transport or storage of NBC weapons,
- The release of CW or BW agents or radiological material,
- A leak of an industrial chemical, infectious material, or radioactive material.

The National Chem-Bio Advisory Team is the principal DoD medical advisor to the Commander, C/B-RRT and the Interagency Response Task Force. Both the National MCBAT and regional Chemical/Biological SRT can provide medical advice and consultation to commanders or local medical and political authorities for preparation of a response to a threat or actual incident. They can also provide medical advice to commanders or local authorities on protection of first responders and other health care personnel, casualty decontamination procedures, first aid (for non-medical personnel) and initial medical treatment, and casualty handling. The initial advice includes identifying signs and symptoms of NBC exposure, first aid (self-aid, buddy aid, combat lifesaver aid for military personnel), and initial treatment when an incident has occurred. The NCBAT also assists in facilitating the procurement of needed resources.

The RMC Chemical/Biological SRT will conduct the initial response, and upon arriving at the incident site will determine the types and numbers of other responders required. The RMC Chemical/Biological SRT may, after initial assessment of the situation, elect to use telemedicine reach back or to call in domestic or foreign response assets organized at the national level. These response assets include the National MCBAT and the Aeromedical Isolation Team (AIT) from USAMRIID. The AIT is a highly specialized medical evacuation asset for the evacuation of limited numbers of contagious casualties, with lethal infectious diseases, or for consultation on appropriate management of such casualties in the event of a mass casualty situation.

The US Army Medical Research Ins titute of Chemical Defense (USAMRICD) has developed a Chemical Casualty Site Team (CSST) with the capability of rapid deployment in

support of DoD, the Foreign Emergency Response Team (FEST), or the Domestic Emergency Response Team (DEST). The team is tasked to support each specific mission. Personnel available for deployment consist of physicians, a nurse, toxicologists, veterinarians, and laboratory specialists. These personnel, when coupled with their supporting capabilities, are knowledgeable in the medical effects of a specific chemical warfare agent, identification of chemical agents or their metabolites in biological samples, determination of blood cholinesterase levels, technical and biomedical expertise required to enable protection of personnel responding to chemical incidents or to guide decontamination of personnel and causalities, and technical expertise to accomplish mission planning.

The AMEDD also provides assets to support the Chemical Biological Augmentation Team (CBAT), a 5-person chem/bio plug-in to the FEST or the DEST. We also provide two medical advisors as part of the SBCCOM Tier I CB Rapid Response Team (C/B-RRT) package. The AMEDD provides advisors to the CBRIF Reachback Scientific Advisory Group.

The US Army Medical Research Institute of Infectious Diseases (USAMRIID) has developed the capability to deploy an AIT consisting of physicians, nurses, medical assistants, and laboratory technicians who are specially trained to provide care to and transport patients with disease caused by biological warfare agents or by infectious diseases requiring high containment. USAMRIID' s teams are deployable worldwide on a 12-hour notice using USAF transportation assets. The AIT uses specialized isolation units that maintain a contained environment under negative pressure to safely transport such patients and to provide medical care to them while in transit. Quarterly training missions are flown with the West Virginia Air National Guard.

As a supporting capability, USAMRIID has a 16-bed ward with the capability of isolating (up to Biosafety Level 3) patients with infectious diseases in a contingency situation. USAMRIID also has a special Biosafety Level 4 (highest level of containment) patient care area designed for a maximum of 4 patients requiring this level of containment. These patient care areas are capable of providing intensive care for critically ill patients with specialized personnel and equipment augmentation from Walter Reed Army Medical Center. An additional supporting capability at USAMRIID is its capacity for medical diagnostic assays for recognized biological agents.

5.8 READINESS REPORTING SYSTEM

CJCSI 3401.02, the policy document for the Status of Resources and Training System (SORTS) requires units from all Services to independently assess their equipment on hand and training status for operations in a chemical and biological environment. This is a change to previous SORTS reporting requirements and provides more visibility to NBC defense related issues.

The Services individually monitor their SORTS data to determine the type of equipment and training needing attention. Units routinely report their equipment on hand and training status for operations in a chemical or biological environment. Commanders combine this information

with other factors, including wartime mission, to provide an overall assessment of a unit' s readiness to go to war.

Additionally, the Commanders-in-Chief (CINCs) of the Unified Commands submit readiness assessments at each Joint Monthly Readiness Review (JMRR). In the JMRR, CINCs assess the readiness and capabilities of their command to integrate and synchronize forces in executing assigned missions. As needed, CINCs address NBC defense readiness and deficiencies as part of the JMRR.

5.9 NBC DEFENSE TRAINING AND READINESS ASSESSMENT

ISSUE: **DoD lacks a mechanism to provide adequate information on the current status of training, equipment, and readiness. It needs adequate information to assess operational force capabilities from the Department and the warfighting CINCs' perspectives.**

SOLUTION: Assign consistent and higher priority to NBC defense, especially by the Joint Chiefs of Staff and the warfighting CINCs, in order to maintain an adequate state of readiness and to ensure NBC defense reporting information is accomplished in a timely and adequate manner. Adequately resource CJCS J-7 and CINC ACOM to ensure that WMD and NBC defense issues are integrated into all joint training exercises and that integration and training assessments are conducted by subject matters experts. Existing reporting systems may provide an adequate mechanism for assessing readiness if the assessments are formally performed by WMD/NBC defense subject matter experts.

ISSUE: **Joint NBC defense doctrine needs to be continually developed and include joint tactics, techniques, and procedures.**

SOLUTION: Initiatives began in 1987 to develop joint NBC defense doctrine which resulted in Joint Pub 3-11, *Joint Doctrine for Nuclear, Biological, and Chemical (NBC) Defense*. In FY95, efforts were initiated to update this document. The Joint Service Integration Group is responsible for assisting the U.S. Army in the development of this doctrine under sponsorship of the Joint Staff. Current initiatives with the Air, Land, Sea Application Center (ALSA) to revise and update NBC doctrinal publications is underway. Continued Service interaction and cooperation facilitated by these organizations will produce the next generation of Joint NBC Defense Doctrine.

ISSUE: **There are limited chemical and biological features in wargaming and planning models.**

SOLUTION: Funding to add chemical and biological warfare defense to joint simulations has been allocated by the JSIG M&S Commodity Area for FY99 and beyond. The program will focus on incorporating chemical effects into JCATS and JSIMS in FY99-00 and BW effects in FY00-01. To add CB defense capabilities to

OneSAF, the possibility of incorporating the CB- ModSAF model developed by SBCCOM will be considered.

Chapter 6

Status of DoD Efforts to Implement the Chemical Weapons Convention (CWC)

6.1 INTRODUCTION

The Chemical Weapons Convention (CWC) was opened for signature on January 13, 1993. The Convention entered into force on April 29, 1997. As of 12 November 1998, 121 countries, including the United States, had signed and ratified the CWC. Another 48 countries have signed but not ratified.

6.2 DEPARTMENT OF DEFENSE IMPLEMENTATION OF THE CWC

Since the CWC entered into force, DoD has hosted more than 40 visits and inspections at chemical weapons storage, former production, and destruction facilities. The Army, (the Service most directly impacted by CWC implementation activities), and OSIA (now part of DoD's Defense Threat Reduction Agency (DTRA)) continue to host and escort Organisation for the Prohibition of Chemical Weapons (OPCW) Technical Secretariat inspectors who conduct both continuous monitoring at DoD CW destruction facilities and systematic inspections at DoD CW storage and former production facilities.

The Department of Defense conducts a Chemical Weapons Agreements Implementation Working Group (CWIWG) to implement the Chemical Weapons Convention (CWC). Through regularly recurring meetings, representatives of the Office of the Secretary of Defense (OSD), the Joint Staff, the Military Departments, the Military Services, and DoD agencies and activities coordinate planning efforts to ensure proper implementation of the CWC. Formal meetings of the CWIWG are scheduled approximately monthly and small group meetings are held as needed to address specific requirements in support of the CWIWG. A Compliance Review Group (CRG) was established within DoD to meet as needed to address CWC compliance concerns, should they arise.

OSD, the Joint Staff, the Military Services, and DTRA provide technical experts to support activity at the U.S. Delegation to the OPCW in The Hague, The Netherlands. The OPCW is charged with overseeing worldwide implementation of the CWC.

The Army was tasked to destroy all chemical warfare materiel under the Program Manager for Chemical Demilitarization (PMCD). PMCD includes programs for unitary stockpile destruction, destruction of bulk agent by alternative technologies (non-incineration), and destruction of other chemical warfare materiel and former CW production facilities. There is a separate non-PMCD program to demonstrate alternative technologies to destroy assembled

CW munitions. DoD and the Army coordinate closely to ensure that these programs are compliant with CWC provisions.

6.3 SAFETY ORIENTATION FOR INSPECTORS

OPCW inspectors who conduct continuous monitoring at U.S. chemical weapons demilitarization facilities have attended a 32-hour safety orientation which is broken down into two sections. One section is a 24-hour hazardous waste operations and emergency response (HAZWOPR) course which is a U.S. Government requirement of all personnel who must be present on a more than short-term basis at U.S. chemical demilitarization facilities. The second section is an 8-hour demilitarization protective ensemble (DPE) procedures course required only for those inspectors designated by the OPCW Technical Secretariat, whose responsibilities would include the use of such protective equipment. Approximately 200 inspectors have attended HAZWOPR training; some 50 of the 200 inspectors have taken the 8-hour DPE class. The orientation is conducted at the Chemical Demilitarization Training Facility in Edgewood, MD. Annual 8-hour HAZWOPR refresher classes are also required, and are being accomplished.

6.4 PREPARATION OF DEFENSE INSTALLATIONS

The Military Services and DTRA have developed individual implementation and compliance plans to provide guidance for their commands and activities under the CWC.

The Military Services have individually established implementation support offices which participate actively at the DoD CWIWG, provide Service policy direction, and conduct ongoing liaison with their major commands to ensure that all military elements are fully prepared for inspections under the CWC.

The Military Services continue to coordinate actively with DTRA to prepare DoD installations for inspections under the CWC. All defense installations which are subject to declarations under the requirements of the CWC, and many which are subject to challenge inspections even though not declared, have been visited by Military Service representatives and DTRA technical experts. DTRA will continue to support site assistance visits and Army treaty compliance implementation meetings.

All of the Military Services have held exercises to test their preparedness for short-notice CWC challenge inspections. Such exercises involve the active participation of Service, DTRA, and other DoD representatives in the roles they would assume during a real challenge inspection. DoD and the Services have exercised written DoD guidance and procedures to test the operational readiness of personnel and facilities. Commonly, the lead Service responsible for developing an exercise also produces comprehensive lessons-learned to further ensure DoD readiness for challenge inspections. The Services have initiated efforts to ensure that in the case of a challenge inspection affected commands take timely and appropriate measures, based on lessons-learned, to demonstrate compliance while protecting security concerns.

6.5 DEFENSE TREATY INSPECTION READINESS PROGRAM

The Defense Treaty Inspection Readiness Program (DTIRP), for which DTRA is the executive agent, has implemented an extensive outreach program to provide information about the CWC, security countermeasures, facility preparation, to both government and DoD industry. DTIRP provides training and awareness services through such fora as industry seminars, mock inspections, mobile training teams, industry associations, national conventions and symposia. DTIRP speakers participated in more than 70 outreach events during the last fiscal year. DTIRP also publishes various educational products (printed and video) and administers electronic bulletin boards to provide information concerning the CWC to government and industry. DTIRP, in close coordination with the Naval Surface Warfare Center at Indian Head, MD, has also produced and conducted the first Chemical Technology Security Course, to be given annually.

6.6 ARTICLE X ASSISTANCE AND OTHER ASSISTANCE

Under Article X of the CWC, a State Party to the treaty may make an appeal for assistance to the Director-General of the OPCW. In accordance with a condition of U.S. Senate ratification of the CWC, the United States will provide "no assistance..other than medical antidotes and treatment," which the U.S. Government deems are necessary, to those CWC States Parties that have requested assistance under Article X of the CWC.

Under the CWC, DoD has not provided any chemical weapons detection equipment, or assistance in the safe transportation, storage, and destruction of chemical weapons to other signatory nations. Such assistance, however, is being provided to Russia under DoD' s Cooperative Threat Reduction (CTR) program.

6.7 VERIFICATION TECHNOLOGY

DTRA conducts RDT&E to support U.S. roles in global chemical arms control initiatives by developing technologies and procedures for DoD identified implementation, verification, monitoring and inspection needs as required by chemical weapons arms control agreements. The arms control technology program is directed towards protecting national security interests, improving the effectiveness of verification efforts, assisting the United States to meet legal obligations imposed by treaty provisions, supporting development of U.S. policy, minimizing inspection and implementation costs, and enhancing the safety of treaty inspections.

The current DTRA arms control technology program continues to support DoD' s efforts to implement the CWC by focusing on the following: compliance support/data management; off-site monitoring; non-destructive evaluation; and on-site analysis.

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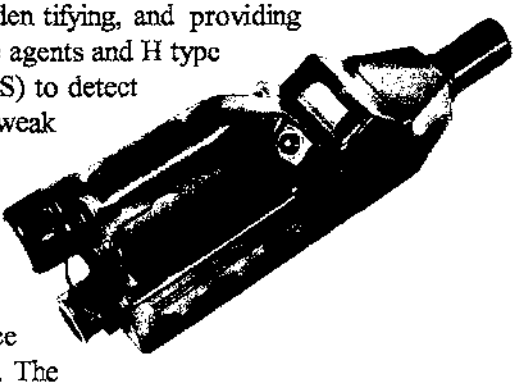
Annex A

Contamination Avoidance Programs

SECTION 1: FIELDED AND PRODUCTION ITEMS

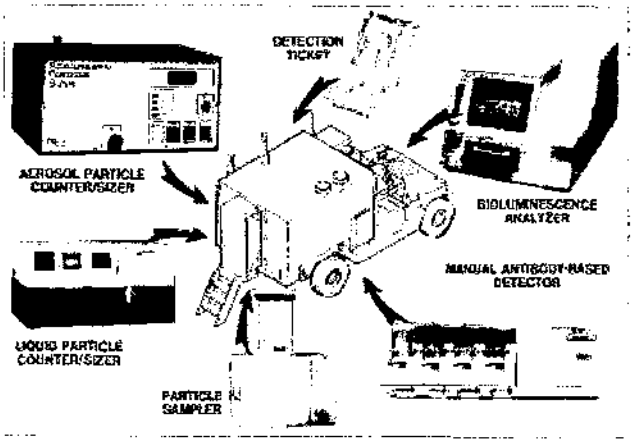
DETECTORS AND MONITORS

Chemical Agent Monitor (CAM) and Improved Chemical Agent Monitor (ICAM)



The CAM is a hand held instrument capable of detecting, iden tifying, and providing relative vapor concentration readouts for G and V type nerve agents and H type blister agents. The CAM uses ion mobility spectrometry (IMS) to detect and identify agents within one minute of agent exposure. A weak radioactive source ionizes air drawn into the system, and the CAM then measures the speed of the ions' movement. Agent identification is based on charac teristic ion mobility and relative con centrations based on the number of ions detected. The four pound, 15" long CAM can bc powered either by an internal battery or by an external source through the CAM' s combination power/fault diagnosis plug. The CAM may be used for a variety of missions, to include area reconnaissance and area surveillance, and monitoring of decontamination operations. The improved ICAM significantly reduces the level and frequency of maintenance without affecting performance. The ICAM sieve pack has double the capacity of the two CAM sieve packs, which results in twice the operational life of the ICAM over the CAM. This fielding will significantly reduce operating and sustainment costs associated with the CAM.

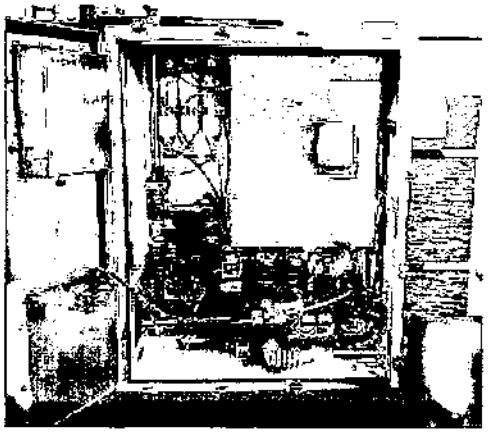
M31 Biological Integrated Detection System (BIDS) NDI



BIDS uses a multiple technology ap proach, both developmental and off-the-shelf materiel, to detect biological agents with maximum accuracy. BIDS is a vehicle-mounted, fully in tegrated biological detection system. The system, which is a collectively-protected, HMMWV-mounted S788 shelter, is modular to allow component replacement and exploitation of "leap ahead" technologies. The system is capable of detecting and presumptively identifying four BW agents simultaneously in less than 45 minutes. Thirty-eight BIDS (NDI versions) were

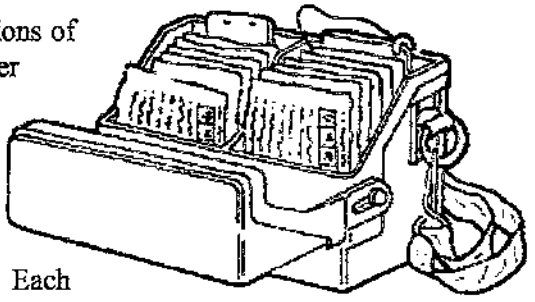
fielded to the 310th Chemical Company (U.S. Reserve) during FY96. This gives the Depart ment of Defense its first credible, rapidly deployable biological detection capability. The BIDS is a Corps level asset. The BIDS program includes a P^3I development effort which will increase automation and integrate the CB Mass Spectrometer (CBMS) with the Biological Detector as sub-components. Each sub-component may also be used as stand-alone systems to meet other service needs.

Interim Biological Agent Detector (IBAD) -Rapid Prototype



IBAD provides a near term solution to a deficiency in shipboard detection of biological war fare agents. IBAD consists of a particle sizer/counter, wet wall cyclone particle sampler, and hand held colorimetric, immunochemical assay tic kets for identification of suspect aerosol particles (through hand-held assay). IBAD is capable of detecting an increase in the par ticulate background, which may indicate a man-made biological attack is underway, and sampling the air for identification analysis. IBAD can de tect a change in background within 15 minutes, and can identify biological agents within an ad ditional 30 minutes. It is a rapid prototype system that started service with the fleet in FY96. Twenty IBAD systems are currently fielded. These systems will be among ship platforms as dictated by fleet priorities.

M256A1 Chemical Agent Detector Kit



The M256A1 kit can detect and identify field con centrations of nerve agents (sarin, tabun, soman, GF, and VX), blister agents (mustard, phosgene oxime, mustard-lewisite, and lewisite), and blood agents (hydrogen cyanide and cyanogen chloride) in about 15–20 minutes. The kit consists of a carrying case containing twelve indi vidually wrapped detector tickets, a book of M8 chemical agent detector paper, and a set of instructions. Each detector ticket has pretreated test spots and glass ampoules containing chemical re agents. In use, the glass ampoules are crushed to release a reagent, which runs down pre-formed channels to the appropriate test spots. The presence or absence of chemical agents is indicated through specific color changes on the test spots. The kit may be used to determine when it is safe to unmask, to locate and identify chemical hazards (reconnaissance), and to monitor decontamination effectiveness.

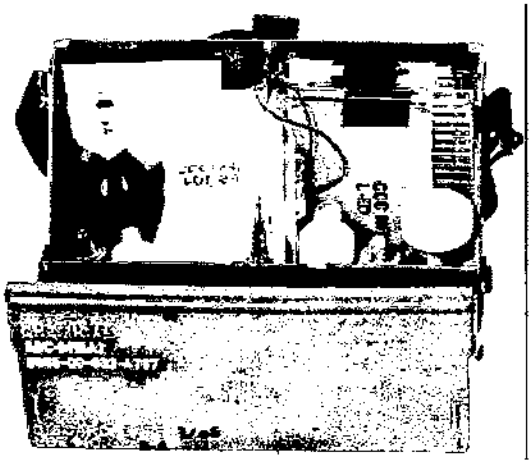
ABC-M8 VGH, and M9 Chemical Agent Detector Paper

M8 Paper

M8 and M9 paper are dye impregnated papers that change color when exposed to liquid chemical agent. These papers cannot detect chemical agents in vapor form. M8 paper comes in 4" by 2 $^{1}/_{2}$" booklets. Each booklet contains 25 sheets of detector paper that are capable of detecting G series nerve agents (sarin, tabun, soman, and GF), V type nerve agents, and H (mustard) type blister agents. M8 paper can identify agents through distinctive color changes from its original off-white: yellow-orange for G, blue-green for V, and red for H. M8 paper is typically used to identify unknown liquid droplets during chemical reconnaissance/ surveillance missions. M9 paper is issued as a 33 foot long, adhesive backed strip that is rolled into a 3" x 2-$^{1}/_{3}$" roll. M9 paper can detect G and V nerve agents, and H blister agents. It cannot distinguish the identity of agents. It turns red, red-purple, or red-brown when in contact with liquid chemical nerve and blister agents. M9 paper is typically placed on the BDO, equipment, and vehicle exteriors to warn personnel of the presence of a liquid chemical agent.

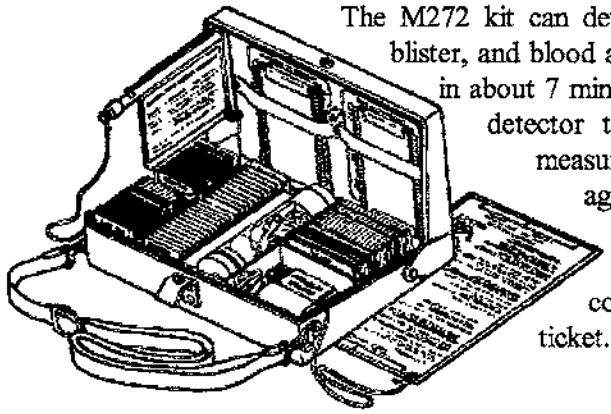

M9 Paper

M18A2 Chemical Agent Detector Kit



The M18A2 can detect and identify dangerous concentrations of nerve agents (sarin, tabun, soman, GF, and VX), blister agents (mustards, phosgene oxime, mustard-lewisite mixture, phenyl dichlorarsine (PD), ethyl dichlorarsine (ED), and methyl dichlorarsine (MD)), blood agents (hydrogen cyanide and cyanogen chloride), and choking agents (phosgene) in about 1–4 minutes. The kit is also used to confirm results of the M256A1 kit. The M18A2 kit contains a squeeze bulb and enough detector tubes, detector tickets, and chemical reagents needed to conduct 25 tests for each agent vapor. The kit also contains a booklet of M8 chemical agent detector paper to detect liquid agents. Agent vapor detection is indicated by the production of a specific color change in the detector tubes. The M18A2 kit was fielded in 1982 and only used by special teams such as surety teams or technical escort personnel.

M272 Water Test Kit

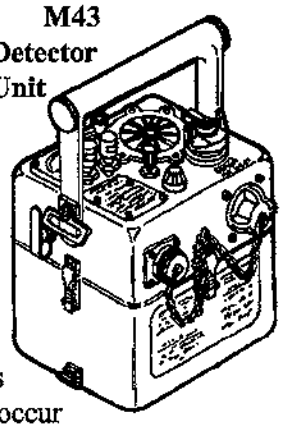


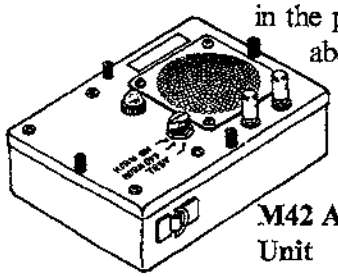
The M272 kit can detect and identify hazardous levels of nerve, blister, and blood agents in treated or untreated water resources in about 7 minutes. The kit contains enough detector tubes, detector tickets, a test bottle, and pre-packed, pre-measured test reagents to conduct 25 tests for each agent. The kit also contains simulants used for training. Agent detection in water is indicated by the production of a specific color change in the detector tubes or in the ticket. The M272 was fielded in 1984.

M8A1 Automatic Chemical Agent Alarm (ACAA)

The M8A1 ACAA is a system that continuously samples the air to detect the presence of dangerous concentrations of G and V type nerve agent vapors. The M8A1 ACAA may be employed in a number of configurations, but all configurations are built around the M43A1 detector unit and the M42 alarm unit. The configurations differ primarily in their mountings and power supplies: ground mounted and battery operated, or mounted on a vehicle and powered by the vehicle's electrical system. The M43A1 detector unit measures 6 1/2" x 5 1/2" x 11" with the battery used in ground mounted operations adding another 7 3/4" in height. The M43A1 detector unit uses a radio-isotope to ionize molecules in the air that is pumped through the system, then detects electrical current changes that occur in the presence of nerve agents. The M43A1 detector unit will alarm within about 1-2 minutes from exposure to agent. The M42 alarm unit is a remote visual and audible alarm that measures 7" x 4" x 2 1/3". The M42 alarm unit may be placed up to 400 meters from the M43A1 detector unit to give users warning of an approaching agent cloud.

M43 Detector Unit

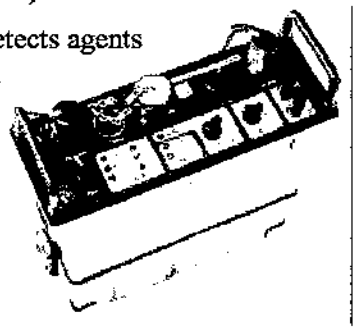




M42 Alarm Unit

M-90 Automatic Agent Detector (AMAD)

The AMAD is an automatic nerve and mustard agent detector that detects agents in vapor form. This system is currently in use by the Air Force. It transmits an alarm by radio to a central alarm unit.

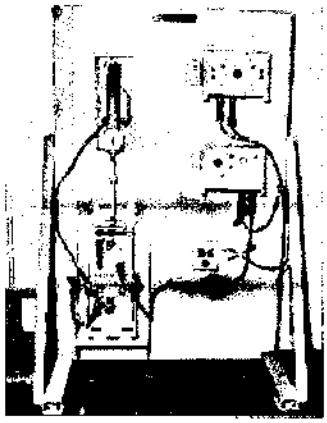


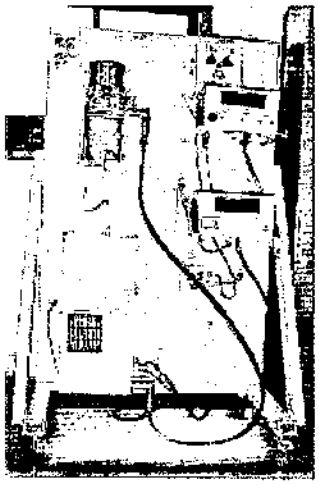
Automatic Liquid Agent Detector (ALAD)

The ALAD is a liquid agent detector that can detect droplets of GD, VX, HD, and L as well as thickened agents. It transmits its alarm by field wire to a central alarm unit. Although the remote transmission is useful, the device only detects droplets of liquid agents. It must be used in conjunction with other point or standoff vapor agent detectors to afford a complete detection capability.

Chemical Agent Point Detection System (CAPDS), MK21, MOD1

This is a fixed system capable of detecting nerve agents in vapor form, using a simple baffle tube ionization spectrometer. Installed in a ship' s upper superstructure level, CAPDS obtains a sample of external air, ionizes airborne vapor molecules, and collects them on a charged plate after eliminating lighter molecules via the baffle structure. When a sufficient mass of ions is collected, a pre-set potential is achieved, and an alarm signal is generated and sent to both Damage Control Central and the bridge. The system has been installed on essentially all surface ships.



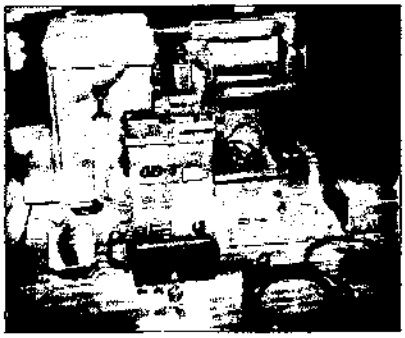


Improved (Chemical Agent) Point Detection System (IPDS) - Production

The IPDS is a new shipboard point detector and alarm that replaces the existing shipboard CAPDS. IPDS uses special elongated ion mobility cells to achieve the resolution necessary to counter false alarms caused by interferent vapors. IPDS can detect nerve and blister agent vapors at low levels, and automatically provide an alarm to the ship. The unit is built to survive the harsh sea environment and the extreme electromagnetic effects found on Navy ships.

M22 Automatic Chemical Agent Detection Alarm (ACADA)

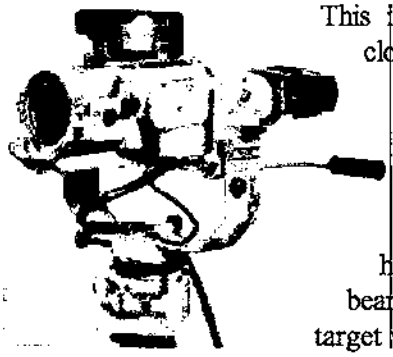
ACADA is a man-portable, point sampling alarm system that provides significant improvement over cur rent capabilities; it detects and identifies all nerve agents, mustard, and lewisite, by class. ACADA provides concurrent nerve and blister agent detection, improved sensitivity and response time, agent identification capability, improved inter ference rejection, extensive built-in test, a data communications interface, and the capability to be programmed for new threat agents. It replaces



the M8A1 Alarm as an automatic point detector and augments the CAM as a survey instrument. The ACADA consists of an off-the-shelf non-developmental item (NDI)—the GID-3 chemical agent alarm. A shipboard version of the ACADA is being built to address the unique interferents found aboard Navy ships that cause false alarms on the NDI ACADA. The shipboard version of ACADA will serve to cover the Navy' s emergency requirements until the Joint Chemical Agent Detector can be fielded.

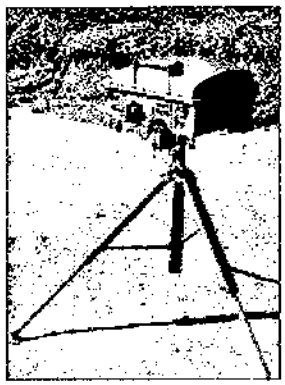
STAND-OFF DETECTION AND REMOTE/EARLY WARNING

AN/KAS-1/1A Chemical Warfare Directional Detector (CWDD)



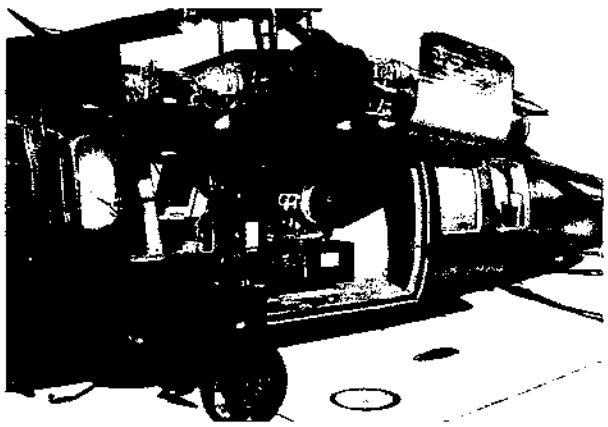
This is a semi-portable system designed to detect nerve agent vapor clouds at ranges up to five kilometers. The AN/KAS-1/1A must be removed from its stowage case and set up on a pre-installed pedestal for operation. A trained, diligent operator must manually aim the detector at the suspect cloud and interpret its infrared images to determine whether or not the cloud contains nerve agent vapors. The AN/KAS-1A provides a remote video display, an enhanced capability for vapor cloud analysis, and a remote relative bearing indicator useful for avoiding the agent cloud or other surface target with a thermal signature.

M21 Remote Sensing Chemical Agent Alarm (RSCAAL)



The M21 RSCAAL is an automatic scanning, passive infrared sensor that detects nerve (GA, GB, and GD) and blister (H and L) agent vapor clouds based on changes on the infrared spectrum caused by the agent cloud. It is effective at line-of-sight distances of up to five kilometers. The alarm is used for surveillance and reconnaissance missions in both vehicle-mounted and tripod-mounted modes.

Long Range Biological Stand-off Detector System (LRBSDS) - NDI



LRBSDS utilizes elastic backscatter and infrared light detection and ranging (IR-LIDAR) technology to detect, range, and track particulate clouds that are indicative of a BW attack; the LR-BSDS cannot discriminate biological from non-biological clouds. The system, which is approximately 1,240 pounds and 2.3 cubic meters, has three major components: a pulsed laser transmitter operating at IR wavelengths; a receiver and telescope; and an information processor and display. The system is mounted on a UH 60 Blackhawk

helicopter for operations. This program has been designed in two phases; an NDI phase designed to rapidly field an interim capability and a pre-planned product improvement (P3I) phase. The three NDI LR-BSDSs have been fielded to the 310th Chemical Company (USAR). The NDI system is able to detect and track man-made aerosols out to 30 km, but is non-eyesafe out to about 2.5 km. The P3I will provide an eye safe laser system at all ranges, an automated cloud detection and tracking capability, and an increased detection range (50 km).

NBC RECONNAISSANCE

M93 NBC Reconnaissance System (NBCRS)

The M93 NBC Reconnaissance System, known as the FOX, is a high mobility armored vehicle capable of performing NBC reconnaissance on primary, secondary, and cross country routes throughout the battlefield. The NBCRS was procured as a Non-Developmental Item and is capable of detection, warning and sampling the effects of NBC weapons and is used as a reconnaissance vehicle to locate, identify and mark chemical and nuclear contamination on the battlefield. The M93 FOX usually accompanies the scouts or motorized reconnaissance forces when performing its NBC mission. The NBCRS has an overpressure filtration system that permits the crew to operate the system in a shirt sleeve environment which is fully protected from the effects of NBC agents and contamination. It utilizes a secure communications system to warn follow-on forces. Samples gathered are forwarded to the Theatre Area Medical Laboratory for further analysis and verification. The mobility platform is a six wheeled all wheel drive, armored combat vehicle capable of cross-country operation at speeds up to 65 MPH. The Fox System is fully amphibious and is capable of swimming speeds up to 6 MPH. The M93 NBCRS has been fielded worldwide to the Army and Marine Corps forces.

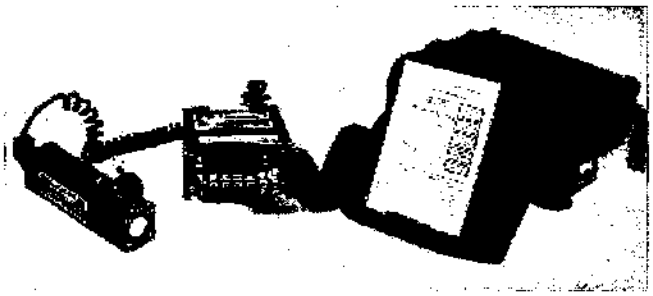
M93A1 – FOX System

The Block I Modification-M93A1 NBCRS contains an enhanced and fully integrated NBC sensor suite consisting of the M21 RSCAAL, MM1 Mobile Mass Spectrometer, CAM/ICAM, AN/VDR-2, and M22 ACADA. The NBC sensor suite has been digitally linked together with the communications and navigation subsystems by a dual-purpose central processor system known as the MICAD. The MICAD processor fully automates NBC Warning and Reporting functions and provides the crew commander full situational awareness of the Fox's NBC sensors, navigation, and communications systems. The M93A1 FOX is also equipped with an advanced position navigation system (GPS & ANAV) that enables the system to accurately locate and report agent contamination. The NDI mobility

platform is a six wheeled, all wheel drive armored vehicle capable of cross-country operation at speeds up to 65 MPH. The Fox System is also fully amphibious and is capable of swimming at speeds up to 6 MPH. It is used as a reconnaissance vehicle to locate, identify, and mark chemical and biological agents on the battlefield. The FOX usually accompanies the scouts or motorized reconnaissance forces when performing its NBC mission.

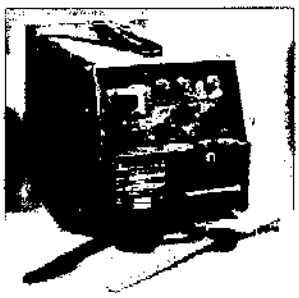
RADIACS

AN/VDR-2



The AN/VDR-2 measures gamma dose rates from 0.01 μGy/hr (micro-Grays per hour) to 100 Gy/hr and beta dose rates from 0.01 μGy/hr to 5 cGy/hr. The unit functions simultaneously as a dose rate meter and dose meter with independent adjustable alarms that can be set at any level over the entire range. Dosage data is independently stored in non-destructive memory for display on command and may be retained when the unit is turned off. The unit is powered by three 9 volt batteries.

AN/PDR-75 Radiac Set



The AN/PDR-75 measures dose from 0 to 999 cGy (centi-Gray). The Radiac Set consists of a dosimeter and a reader. It provides the capability to monitor and record the exposure of individual personnel to gamma and neutron radiation. Each individual will be issued a DT-236/PDR-75 dosimeter. This device, worn on the wrist, contains a neutron diode and a phosphate glass gamma detector. When a determination of exposure is required, the dosimeter is inserted into a CP-696/PDR-75 reader, which then displays the cumulative neutron and gamma dose. The reader is issued at the company level and the dosimeters are issued to all combat, combat support, and combat service support personnel. The reader can be powered by a BA-5590 lithium battery, vehicle battery, or external power supply via adapter cables provided.

AN/PDR-77 Radiac Set

The AN/PDR-77 Radiac Set is a set of portable radiation detection equipment for detecting alpha, beta, gamma, and x-ray radiation. The set consists of a radiacmeter to which one of three radiation probes can be attached for measuring particular types of radiation. The probes are part of the set. The set includes accessories and basic test and repair parts for unit maintenance including a carrying pouch with shoul der straps capable of holding the radiacmeter, alpha probe, and beta/gamma probe for field use. The entire set is contained in a carrying case (large brief case) for easy portability and storage.

AN/UDR-13 Pocket RADIAC (Platoon Radiac) - Production (FUE FY98)

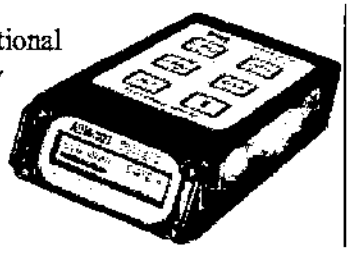
The AN/UDR-13 Pocket RADIAC is a compact, hand-held, tactical device capable of measuring the gamma dose-rate and gamma and neutron cumulative dose in a battlefield environment. Its pocket size permits convenient use by troops on foot. Alarm pre-sets are provided for both the dose-rate and total dose modes. A push-button pad enables mode selection and functional control. Data readout is by liquid crystal display. It will replace the obsolete IM-93 quartz fiber dosimeter.

Multi-Function Radiation (MFR) Detector -Production

This program will develop improved radiation detection equipment to replace the current suite of logistically unsupportable assets. Present detectors (PAC-1S, AN/PDR-43 and AN/PDR-56F) have exceeded maintainability standards. Original manufacturers have either discontinued production or are no longer in business. An improved capability is required to support both wartime and peacetime nuclear accident response operations. A production contract was awarded in March 1995. First deliveries were made in 1997.

ADM-300A Multifunction Survey Meter

The ADM300A is a battery-operated, self-diagnostic, multiple functional instrument. It is used alone to locate and measure low and high intensity radioactivity in the form of gamma rays or beta particles. It is used with external probes to locate and measure alpha, beta, gamma, and x-rays, and neutron radiation.



SECTION 2. RDTE ITEMS

AUTOMATIC DETECTORS AND MONITORS

Agent Water Monitors

The Joint Service Chemical Biological Agent Water Monitor is a cooperative RDTE effort, chartered to develop a detection system which will detect chemical and biological agents in water. The detector will feature multi-agent capabilities, and operate automatically, improving both ease and response time of existing system. The project will accommodate the four services' requirements for the following:

In-line CB Detector (IL CBDWS)
Chemical Agent Water Monitor (CAWM)
CB Agent Water Monitor (CBAWM)

Rationale:

- Joint Army, Air Force, and Marine Corps requirement
- Navy interest

Key Requirements:

- Detect and identify chemical agents and agents of biological origin in water
- Perform monitoring automatically with continuous and batch sampling capabilities
- Easy to operate and support in forward areas, austere environments, and limited lighting

Description:

The Agent Water system will improve current water monitoring and purifying capa bilities. It will automatically detect CB agents at or below harmful levels in water and not false alarm to common interferents. The system will be compact, man-portable and easy to use, and be decontaminated to a negligible risk level.

Joint Chemical Agent Detector (JCAD)

The JCAD is a fully cooperative RDTE effort, chartered to develop a chemical agent detector for a variety of mission requirements and service platforms. The detector will provide warfighters near-real time information on the presence of chemical agents so that miosis or more severe effects can be avoided and not subvert the mission. The project will accommodate the four services' requirements for the following:

Individual Soldier Detector (ISD)
Special Operation Force Chemical Agent Detector (SOFCAS)
Individual Vapor Detector (IVD)
Aircraft Interior Detector (AIDET)
Shipboard Chemical Agent Monitor Portable (SCAMP)
CW Interior Compartment System (CWICS)
Improved Chemical Detection System (ICDS)

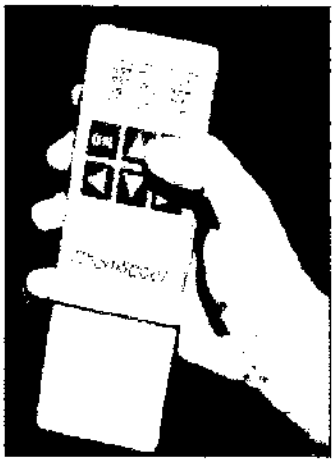
Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Small, lightweight detector capable of detecting presence of chemical agent vapors
- Capable of de-warning, allowing for rapid reduction of protective postures
- Detect, identify, quantify, and warn of presence of even low levels of nerve, blister, and blood agents in vapor form in aircraft and shipboard interiors
- Operated/maintained by ship' s force; operate in a shipboard environment

Description:



JCAD will provide a detector or a network of detectors capable of automatically detecting, identifying, and quantifying chemical agents (nerve, blister, and blood) inside aircraft and shipboard interiors. The device must be sufficiently sensitive to warn aircrews before accumulation, over the entire mission, of levels of agent that may cause miosis or more severe effects. JCAD will also provide hand-held monitoring capabilities, protecting the individual soldier, sailor, airman, and marine through the use of pocket-sized detection and alarm.

Shipboard Automatic Liquid Agent Detector (SALAD)

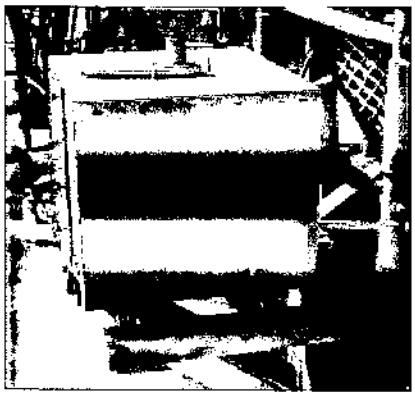
Rationale:

- Navy service-unique requirement

Key Requirements:

- Automatic detection of liquid chemical agents
- Operated/maintained by ship' s force
- Operate in a shipboard environment and detect while the ship is underway

Description:



SALAD is an exterior, liquid agent point detection and monitoring system that will detect and alarm in the presence of liquid nerve and blister agents. The SALAD EDM consists of a detector unit that uses chemically treated paper, optical scanners, a central processing unit, and alarms (visual and audible) on the bridge and Damage Control Central. Production units will be contracted for based on a performance specification. These units may use detection technologies other than that selected for the EDM.

BIOLOGICAL LONG LINE SOURCE RELEASE AND POINT DETECTION

Biological Point Detection is a fully cooperative acquisition effort chartered to develop new biological point detectors and detection systems for quad-services. The BIDS P3I effort will encompass development of an integrated system as well as several stand-alone biological detectors. In addition, a Joint Biological Point Detection System (JBPDS) is under development. JBPDS will be a system that can stand alone, or be used in a suite of systems.

Biological Integrated Detection System (BIDS) -P3I

Rationale:

- Army service-unique requirement
- Navy, Air Force, and Marine Corps interest in BIDS' sub-components

Key Requirements:

- Detect and identify 5 to 25 agent-containing particles/liter of air (ACPLA) in the 2–10 micron range in 15–30 minutes
- Provide agent detection and simultaneous identification of 8 agents
- Provide collective protection with environmental controls
- Knowledge-based system to process detector information
- FM/HF radios to communicate
- Automatically identify biological pathogens and toxins
- Reject common battlefield interferents and be re-programmable to detect new agents

- Be data-linked with a centralized hazard information data collection center
- Respond to agent vapors or aerosols
- Possess modules to accommodate future advances in technology and CB threat

Description:

BIDS uses a multiple technology approach, both developmental and off-the-shelf materiel, to detect and presumptively identify biological agents with maximum accuracy. The BIDS P^3I system will integrate the CB Mass Spectrometer (CBMS) and the Biological Detector (BD) as sub-components.

The Biological Detector is an antibody-based device capable of identifying specific biological agents. It consists of electronics processing equipment, fluid processing modules, reservoirs for antibody reagents, and a light addressable potentiometric sensor to provide biological agent identification. The total processing time, from insertion of sample to data readout, will be approximately 15 minutes at threshold concentrations. The biodetector includes an operator display which will provide identification and relative concentration of the biological agent detected. Built-in tests will also be provided to identify system malfunctions.

CBMS detects and characterizes all known chemical and biological threat agents. It continuously and automatically detects threat agents via a mass analyzer chassis, a bio logical aerosol sampling probe, a surface sampling probe and sample identification device. The mass analyzer chassis houses the mass analyzer, pumps, control electronics, and com puters. With the aerosol probe attached, the CBMS detects biological agent aerosols and chemical agents as aero sols and/or vapors in the air. With the ground probe attached, the CBMS detects chemical agents whether they exist as airborne vapors or aerosols, or as liquid droplets on surfaces. The CBMS will replace the MM1 and be mounted within the NBC Recon System to search for areas of CB agent contamination.

Air Base/Port Biological Detection (Portal Shield)
Advanced Concept Technology Demonstration (ACTD)

Rationale:

- Requirements identified by the Commander-in-Chief Central Command (CINCCENT) and Commander-in-Chief Pacific Command (CINCPAC)

Key Requirements:

- Field interim systems to sponsoring CINCs that provides rapid, automated biological attack detection, identification and warning (in less than 20 minutes) to high value fixed sites (*e.g.*, ports and airfields)
- Automated "smart" sensor network
- Chemical sensor interfaces for automated biological and chemical network warning and reporting
- In addition to the biological detection system itself, provide the following "leave-behinds" or "residuals" to the fixed sites: an integrated command and control system

to assist base personnel in rapid assessment, warning and dissemination of attack data; unmasking procedures; contamination detection sampling kits, tested tactics, techniques and procedures.

- Demonstrate the military utility of a smart sensor network and exercise operational concepts that may both fill the CINCs immediate needs, and provide valuable "lessons learned" for future systems

Description:

While the BIDS and Long Range Biological Detection Sys tem (LR-BSDS) programs have made significant ad vances towards mitigating the effects of the worst case biological attack scenario (long line source releases—*e.g.*, an aircraft spraying agent along a course tens of kilometers long), we still have potential vulnerabilities in pro tecting those high value fixed sites that will play critical roles in force projection op erations. Ports and air-bases, by nature of their commonly known locations and high den sity of personnel, make lucrative targets for point source releases (*e.g.*, theater ballistic mis siles, covert spraying by land and sea vehicles, or even man-portable disseminators). JPO-BD proposed taking available technologies and, through an ACTD, provide a limited number of biological detection systems to warfighting CINCs. The concept has been to build an intelligent network of sensors based on the Navy' s IBAD components, but add to each sensor an automated immunoassay ticket reader for near real time identification of BW agents, location and meteorology modules and "smart" network algorithms to reduce use of consumables and lower false positive rates. The detector net work is able to detect significant changes in background aerosol con centrations in near real time, and can also (15-25 minutes) provide the operator located in the central command post a presumptive identification of the BW agent. Site personnel are then able to retrieve samples of the aerosol from the sensors for confirmatory identification of the BW agent. The ACTD will not only provide detection and identification hardware and procedures, it will also provide leave-behinds for post attack actions, such as: contamination detection sampling kits that can provide BW identification of contaminated surfaces such as missile fragments, in 15 minutes; and Enzyme Linked ImmunoSorbent Assay (ELISA) kits for a "gold standard' identification capa bility. User acceptance testing was completed in September 1997. The prototype Mark II network was successfully deployed to Kuwait in support of Operation Desert Thunder in February 1998. Full scale deployment of the ACTD to CENTCOM and PACOM will begin in 2QFY99. The Joint Chiefs of Staff (JCS) directed the production of additional Portal Shield networks starting in FY99 and funded their fabrication and support through FY02.

Joint Biological Point Detection System (JBPDS)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Automatically detect, identify and warn of the presence of aerosolized biological warfare agents at levels of sensitivity, speed and reliability equal to or better than currently fielded detection systems
- Provide a common suite of biological detection equipment that can be applied to all four services' designated platforms
- Provide a man-portable version (Air Force and Marine Corps)
- Be operable while on the move (Army and Navy)

Description:

JBPDS is the joint biological point detection system. This developmental system will replace all existing biological detection systems (BIDS, IBAD and Air Base/Port ACTD), and provide biological detection capabilities throughout the services and throughout the battlespace. The common biological detection suite will consist of four functionalities: *trigger* (detects a significant change in the ambient aerosol in real time), *collector* (collects samples of the suspect aerosol for analysis by the JBPDS, and for confirmatory analysis by supporting laboratories in the Communications Zone (COMMZ) and CONUS), *detector* (able to broadly categorize the contents of the aerosol and lend confidence to the detection process; *e.g.*, biological material in the aerosol or not, bacteriological, spore, protein, *etc.*), and *identification* (provides presumptive identification of the suspect BW agent and increases confidence in the detection process). These four functionalities will be integrated to allow fully automatic operation, and warning of a positive BW detection. The JBPDS program consists of two phases (Block I and Block II) to allow the fastest possible fielding of a joint biological detection system, while at the same time preparing to take advantage of the rapid advances taking place in the biological detection/identification, information processing and engineering sciences. JPO-BD awarded an Engineering and Manufacturing Development (EMD) contract in FY97 for the development of Block I JBPDS prototypes for all four services. Production is anticipated to start in 4QFY00, with first unit equipped in March 2002. This joint acquisition strategy will allow for significant economies throughout the RDA process by eliminating duplicative efforts among the services, and greater logistic supportability in joint operations as each service will be able to support the other services' JBPDSs.

Critical Reagents Program (CRP)

Rationale:

- Supports all Services biological detection programs

Key Requirements:

- Provide Total Life Cycle Management for the critical reagents (antibodies, and gene probes and primers) that are necessary to the operation of nearly all DoD biological detection systems.
- Ensure best quality reagents are available in time and in adequate quantities.
- Ensure adequate security and surge capability of critical reagents.
- Put in place a production program for the Handheld Immunochromatographic Assays (HHAs) that are critical to several bio detection programs.

Description:

The Critical Reagents Program will ensure the quality and availability of reagents that are critical to the successful development, test and operation of biological warfare detection systems and medical biological products managed by JPO-BD. The program will main tain an R&D effort to ensure the best possible reagents are available for use against both current and future threats. The program will institute a program wide quality assurance program and address relevant security issues. During the first four years of the program, the CRP will require the greatest level of effort and funding to ensure required reagents are available to support fielded systems (BIDS NDI, P3I and IBAD), and developmental systems (JBPDS Block I and Portal Shield ACTD). The next three years require the development of 12 additional reagents to support the development and fielding of the JBPDS Block II. Outlying years will focus on the development of reagents to detect new and emerging threats and procurement of more effective reagents to replace older stocks.

STAND-OFF DETECTION AND REMOTE/EARLY WARNING

Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD)

The JSLSCAD is a fully coordinated joint service RDTE program, chartered to develop a lightweight standoff chemical detector for the quad-services. The JSLSCAD will utilize a passive infrared sensor with 360° scanning to satisfy requirements for:

Lightweight Standoff Chemical Agent Detector (LSCAD)
M21 Moving Background
Chemical Agent Remote Detection System (CARDS)
Stand-off Detector for Armored System Modernization (SD/ASM)

Rationale:

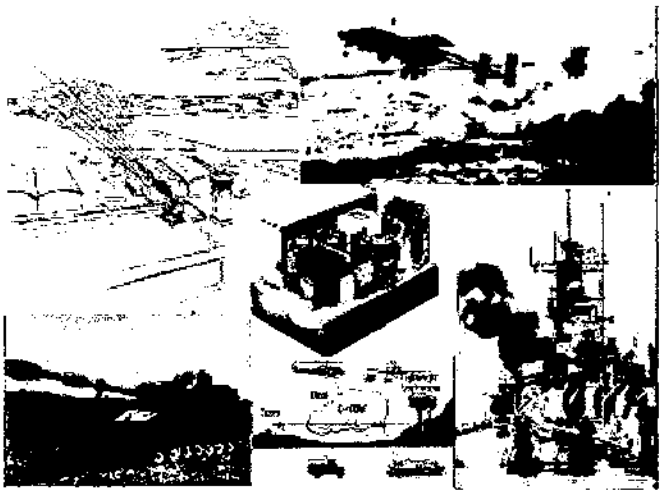
- Joint Army, Navy, Air Force, and Marine Corps requirement. (Army is lead Service)

Key Requirements:

- Automatically detect nerve, blister, and blood agents at a distance up to 5 km
- Lightweight and employed from manned and unmanned systems

- Capable of being data-linked with centralized hazard information data collection center
- Capable of remote operations; aerial and on-the-move operation

Description:



JSLSCAD will be capable of scanning 360° x 60°, and automatically detecting nerve or blister agents at a distance up to 5 km. The system will be light, compact and operate from a stationary position or on-the-move. The JSLSCAD Michelson interferometer employs a passive infrared system that will detect presence of chemical agents by completing a spectral analy sis of target vapor agent chemical clouds. JSLSCAD is envisioned for employment on various platforms and in various roles, including fixed site defense, unmanned aerial vehicles, tanks and other vehicles, and on board ships.

Joint Service Warning and Identification LIDAR Detector (JSWILD)

JSWILD is a joint effort chartered to develop a chemical warning and identification system for the quad-services. JSWILD will utilize an active LIDAR sensor to perform rapid agent identification and ranging to satisfy requirement for:

Laser Stand-Off Chemical Detector (LSCD)
Area Detection System (ADS)
Stand-off Detector (SD)
CB Stand-off Detector (CBSD)

Rationale:

- Army and Air Force interest

Key Requirements:

- Automatically detect, range, and map CW agents at distances of up to 20 km
- Scan atmosphere and terrain to detect chemical vapors and airborne liquids and particles
- Provide stand-off capability for both fixed site and reconnaissance
- Provide rapid agent concentration mapping

Description:

JSWILD will be a lightweight, vehicle-mountable, contamination monitoring sys tem, which detects and quantifies all types of chemical agent contamination (including agent rain, vapors, and aerosols) in a stand-off mode from a distance of 20 kilometers (km). In addition, JSWILD will provide similar but shorter range (1–5 km) capabilities in biological standoff detection as the Long Range Biological Standoff Detection System. The JSWILD

will operate from fixed sites and ground vehicles. The system has dis tance-ranging and contamination-mapping capabilities and transmits this information to a battlefield information network.

Biological Remote/Early Warning

The Army' s Long Range Biological Standoff Detection System (LR-BSDS) is a legacy system that is being incorporated into what is envisioned to be a family of early warning systems

The Joint Biological Remote Early Warning System (JBREWS) program is intended to give the warfighting commander a significantly shortened decision cycle regarding biological attacks; that is, the commander will see and be able to react to a biological attack much faster, thereby allowing many more personnel to take protective measures before they become exposed to the biological warfare agents. This means that fewer people will become casualties, and fewer people will have to take post-attack medical treatments.

Long Range Biological Standoff Detection System (LR-BSDS) P3I

Rationale:

- Army requirement
- Navy and Air Force interest

Key Requirements:

- Stand-off detection of aerosol clouds out to a range of at least 50 km
- Provides relative concentration, range, location, and tracking of suspect aerosol clouds
- Automated cloud discrimination
- Operating crew reduced to one operator
- UH-60 helicopter-mounted

Description:

LRBSDS uses infrared light detection and ranging (IR-LIDAR) technology to detect, range and track aerosol clouds that are indicative of a BW attack; the LR-BSDS cannot discriminate biological from non-biological clouds. The system, which is approximately 1,240 pounds and 2.3 cubic meters, has three major components: a diode pulsed IR laser transmitter operating at IR wavelengths; a receiver and telescope; and an informati on processor and display. This program, like BIDS, has been designed in two phases; an NDI phase designed to rapidly field an interim capability, and a pre-planned product improvement (P3I) phase. Three NDI LR-BSDSs have already been fielded to the 310th Chemical Company (USAR). A total of 10 LR-BSDS P3I systems will be procured from FY00 to FY02 (3 per company with 1 training system). The NDI system is able to detect and track man-made aerosols out to 30 km, but is non-eyesafe out to about 2.5 km. The P3I LR-BSDS will be eyesafe, will have a longer operating range (50 km), and will be easier to operate. The first P3I LR-BSDSs will be fielded to the 7th Chemical Company (Biological Detection) in 1QFY01.

The Joint Program Office for Biological Defense is leveraging the benefits of the ACTD program to greatly accelerate the development of the next generation of remote/early warning systems (i.e., systems other than the LR-BSDS). This new generation of detectors is referred to as the Joint Biological Remote/Early Warning System (JBREWS). JPO-BD is managing a JBREWS ACTD that will address selected CINCs' needs, and will better refine our requirements and concepts regarding remote/early warning systems.

Joint Biological Remote Early Warning System (JBREWS)

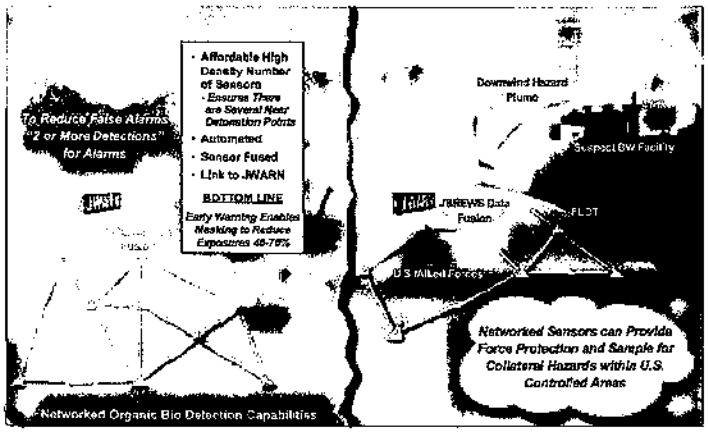
Rationale:

- CENTCOM and EUCOM requirement (ACTD)
- All services interest (ACTD and objective system)

Key Requirements:

- JPO-BD is sponsoring a series of concept studies, including a Study Advi sory Group (SAG) composed of CINC, Service, and Joint NBC Defense Board representatives. This cooperative effort will define the requirements for the JBREWS ACTD
- The ACTD formally started in FY98, with fielding of ACTD systems to selected CINCs around FY01
- Lessons learned from the JBREWS ACTD will assist the SAG in developing/refining its requirements document for the JBREWS objective system
- JBREWS objective system is expected to start fielding around FY03

Description:



JBREWS is planned to become a "system of systems." That is, it may have legacy systems—BIDS, JBPDS, and standoff LIDAR systems such as the LR-BSDS—integrated with short range biological standoff detection systems (SR-BSDS) and dense arrays of miniaturized, rugged point detectors into a distributed network of sensors. The miniature sensors will possess only one or two of the functionalities that the much more robust JBPDS will have. The point detectors may be employed in a variety of ways: carried on vehicles, emplaced by hand around unit/site perimeters, remotely emplaced by aircraft, or possibly even delivered by artillery or rocket systems to project the sensors into contested or enemy controlled areas. The systems need to be networked to provide the greatest confidence of accurate detection and rapid warning. They will need to be deployed and distributed widely and in high numbers to ensure point releases are not missed.

NBC RECONNAISSANCE

Joint Service NBC Reconnaissance System (JSNBCRS)

The Joint Service NBC Reconnaissance program is a coordinated Army and Marine Corps effort which will yield improved reconnaissance capabilities for both heavy and lightweight vehicle platforms. It will satisfy requirements for:

M93A1 NBC Reconnaissance System (NBCRS) Production
M93A1 P3I Block II
Light NBC Reconnaissance System (LNBCRS)
Lightweight Reconnaissance System (LWRS)

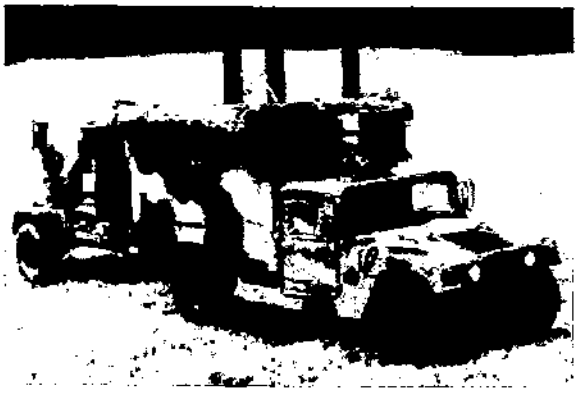
Rationale:

- Joint Army, Air Force, and Marine Corps Requirement

Key Requirements:

- Armored vehicle with over-pressure collective protection and macro cooling
- Chemical agent stand-off and point detectors and monitors
- Radiation detector and monitor
- Integrate central data processor with all detectors and monitors; navigation and communications system; jam resistant communications system; and meteorological sensing system
- Integration of advanced NBC detection and analysis equipment suited for Marine Air-Ground Task Force (MAGTF) operations (LNBCRS)
- Standard Marine Corps host vehicle, transportable by C-130, CH-53E, and LCAV-30 (LNBCRS)

Description:



The LNBCRS (shown) will provide a premiere vehicle for accurate, rapid NBC combat hazard information by verifying the absence of, finding, mapping, and marking radiological, biological, and chemical hazards. The LNBCRS will be an integration of advanced NBC detection and analysis equipment suited for Marine Air-Ground Team Force expeditionary operations and Army rapid deployment/light operations.

WARNING AND REPORTING

Joint Service Warning and Reporting Network (JWARN) (FUE FY 99)

Rationale:

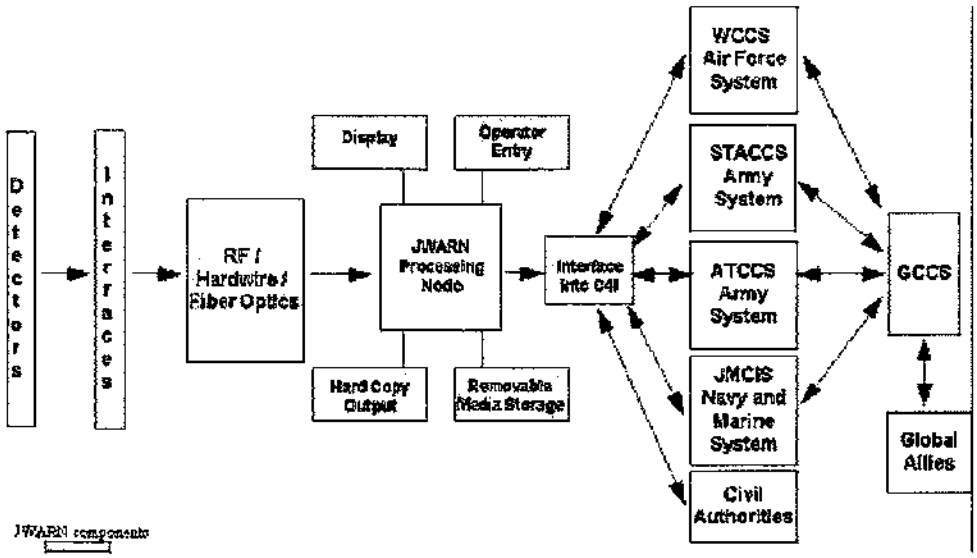
- Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Capable of interfacing with all NBC detectors and sensors
- Capable of interoperability with all service command and control systems
- Capable of generating NBC reports
- Capable of automatic transmission of NBC alarm and data
- Capable of vehicle operation

Description:

JWARN will provide the Joint Force a comprehensive analysis and response capability to minimize the effects of hostile NBC attacks or accidents/incidents. It will provide the operational capability to employ NBC warning technology that will collect, analyze, identify, locate, report and disseminate NBC threat and hazard information. JWARN will be compatible and inte grated with Joint Service C^4I systems. JWARN will be located in command and control centers at the appropriate level defined in Service-specific annexes and employed by NBC defense specialists and other designated personnel. It will transfer data automatically from and to the actual detector/sensor and provide commanders with analyzed data for decisions for disseminating warnings to the lowest echelons on the battlefield. It will provide additional data processing, production of plans and reports, and access to specific NBC information to improve the efficiency of NBC personnel assets.



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Annex B

Non-Medical Protection Programs

SECTION 1: FIELDED AND PRODUCTION ITEMS

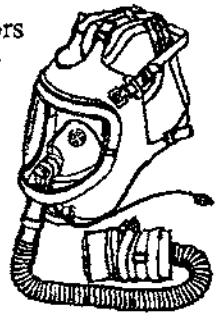
RESPIRATORY

M17A2 Protective Mask

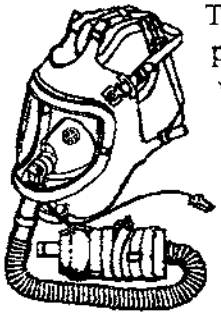
The M17A2 Protective Mask consists of a natural blend rubber face piece; two activated charcoal filters mounted within cheek pouches; a voicemitter to facilitate communications, a drinking tube; eyelens outserts to protect the mask' s integral eyelens and reduce cold weather fogging; an impermeable hood; and a carrier for the mask, its components, and medical items (such as the Nerve Agent Antidote Kit). The Army and Marine Corps are replacing this mask with the M40 series protective mask. The Navy has replaced the M17A2 protective mask with the MCU-2/P. The Air Force replaced it with the MCU-2A/P, but retained limited quantities of extra small M17A2s for those situations where the MCU-2A/P short is too large.

ABC-M24 Aircraft Protective Mask

This protective mask provides the wearer protection from NBC aerosols/vapors both in aircraft, and on the ground. The mask consists of: wide view, clear plastic lens embedded in a butyl rubber face blank; an integral microphone; eyelens outserts; carrying case; anti-fog kit; and a hose-mounted filter canister. The mask has a microphone connection to fit the aircraft communications systems. The M24 has an adapter that allows coupling to the aircraft' s oxygen supply system. The M24 is being replaced by the M45 and M49 masks.



M25A1 Tank Protective Mask



This protective mask provides the wearer protection from NBC aerosols and vapors both in the vehicle/aircraft, and on the ground. The mask consists of: wide view, clear plastic lens embedded in a butyl rubber face blank; an integral microphone; eyelens outserts; carrying case; anti-fog kit; and a hose mounted filter canister. The mask has a micro phone connection to fit the armored vehicle commu nications systems. The M25A1 has an adapter that allows it to be coupled to the tank' s filtered and temperature controlled Gas Particulate Filtration Unit (GPFU). The M25A1 is being replaced by the M42/M42A1/M42A2 protective mask.

MCU-2A/P Protective Mask

The MCU-2A/P provides eye and respiratory protection from all chemical and biological agents as well as radioactive particulate material. The mask uses a replaceable, standard NATO filter canister which is mounted on either side of a wide-view optical quality visor. The mask provides improved fit, comfort, and visibility relative to earlier masks, and includes a drinking tube for attachment to the standard canteen, and electronic voicemitter connections for improved communications.

M40/42 Series Protective Mask

The M40/42 series protective masks provide eye-respiratory face protection from tactical concentrations of CB warfare agents, toxins and radioactive fallout particles. Each mask consists of a silicone rubber face piece with an in-turned peripheral face seal and binocular rigid lens system. The facepiece is covered with a chlorobutyl/EPDM second skin to provide optimum liquid agent protection for the masks. It accommodates NATO standard canisters, which can be worn on either cheek of the mask. The M40 series is designed for the individual dismounted ground warrior, while the M42 series is designed for combat vehicle crewmen. Recent improvements include a universal second skin, making th e mask compatible with JSLIST and Saratoga overgarments, and ballistic/laser protective eye lens outserts. The mask facepiece has been made a spare part, which has resulted in a significant operation and support cost savings. Use of modular parts permits the M40 series to be used in both the M40 and M42 configuration. This has resulted in significant operational and support cost savings.

M43 Protective Mask

The M43 Aviator Mask consists of a form-fitting face piece with lenses mounted close to the eyes; an integral CB hood and skull-type suspension system; an inhalation air distribu tion assembly for air flow regulation, lenses and hood; and a portable motor/blower filter assem bly that operates on either battery or aircraft power. The M43 Type I was developed for the AH-64 aviator and is compatible with the AH-64 Integrated Helmet and Display Sight System and the Optical Relay Tube. The M43 Type II is intended for the general aviator.

M45 Aircrew Protective Mask (ACPM) (FUE FY98)

The M45 Air Crew Protective Mask is specially designed to meet the requirements of helicopter and special crews. It does not require power or forced air to provide CB protection; it provides compatibility with helicopter optical systems, aircraft displays and night vision devices; and has reduced weight, cost and logistical burden when compared to the M48/M49 series of mask. The ACPM has close fitting eyelenses mounted in a silicone rubber facepiece with an in-turned peripheral seal, a detachable hood system, and utilizes the standard NATO canister.

M48/49 Protective Masks - Production

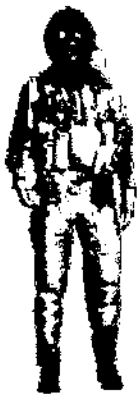
M48 Mask

The M48/M49 are third generation M43 series masks. The M48 mask replaces the M43 Type I mask and will be the only mask for the Apache aviator for the foreseeable future. The M49 mask, along with the M45 mask will replace the M24 and M43 Type II masks. The M48 and M49 masks consist of a lightweight motor blower, a new hose assembly, a web belt, the mask carrier, facepiece carrier, eyelens cushions, and the facepiece of the M43A1. The M49 mask will only be issued to the General Aviation population in Korea.

M49 Mask

Aircrew Eye/Respiratory Protection (AERP)

The AERP (replaces the MBU-13/P system for aircrews) is a protective mask which enables aircrews to conduct mission operations in a chemical-biological environment. The AERP system includes a protective hood assembly with a standard MBU-12/P mask, an intercom for ground communication, and a blower assembly that provides de-misting. The blower is stowed during flight operations on a bracket that is mounted inside the aircraft.

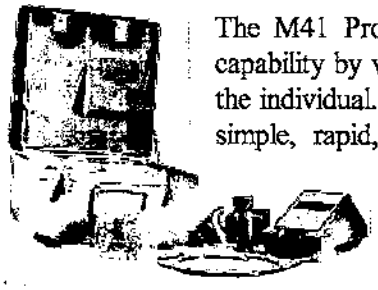


CB Respiratory System (A/P22P-14(V) 1, 2, 3, & 4) NDI

The CB Respiratory System is a self-contained protective ensemble designed for all forward deployed rotary wing (Version 1 for USN) and fixed wing (Version 2–4 for USN and USMC) aircrew. The design incorporates a CB filter, dual air/oxygen supply and a cross-over manifold with ground flight selector switch to provide filtered air for hood ventilation, and filtered air for oxygen for breathing. The system provides enhanced protection and offer anti-drown features.

ANCILLARY MASK EQUIPMENT

M41 Protection Assessment Test System

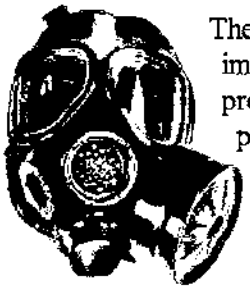


The M41 Protection Assessment Test System (PATS) enhances operational capability by validating proper fit of the mask to the face of the individual. The PATS is a new capability that provides a simple, rapid, and accurate means of validating the face piece fit and function of protective masks.

Voice Communication Adapter

The Voice Communication Adapter (VCA) is a low risk program providing additional capability to the M40/42 mask. The VCA is a joint program between the USMC and US Army.

Universal Second Skin



The Universal Second Skin is one of the components of a pre-planned product improvement (P3I) in the M40/M42 series mask. The Universal second skin provides liquid agent protection for the mask faceblank material. This program is a Joint U.S. Army/U.S. Marine Corps effort. Both Services developed prototype designs and, after field user and human engineer testing, the Marine Corps design was selected. The Air Force is developing a second skin for the MCU-2A/P.

BATTLEFIELD PROTECTIVE SUITS

Battle Dress Overgarment (BDO)

The BDO is a camouflage patterned (desert or woodland), two piece, air permeable overgarment typically worn over the duty uniform. The overgarment material consists of an outer layer of nylon cotton, and an inner layer of activated charcoal impregnated polyurethane foam. The BDO provides protection against chemical agent vapors and liquid droplets, biological agents (to include toxins), and radioactive alpha and beta particles. The BDO is issued in a sealed vapor-barrier bag that protects the garment from rain, moisture and sunlight. The BDO provides 24 hours of chemical agent protection once contaminated and has a field durability of 22 days (extendable to 30 days at the discretion of Field Commanders).

JSLIST Overgarment

The JSLIST Overgarment will provide 24 hour protection after 45 days of wear and 6 launderings. The liner currently is based upon activated carbon bead technology, replacing the bulky activated carbon foam technology in previous garments. The JSLIST Overgarment is a two-piece jacket and trouser design with an integrated hood compatible with respective Service masks and second skins. It will be worn as an overgarment for the duty uniform or as a primary garment over underwear depending upon the environment and mission.

Chemical Protective (CP) Suit, OG MK-III (Navy Suit)

The Chemical Protective Overgarment (CPO) protects the wearer against all known chemical and biological agents which present a percutaneous hazard. The suit consists of a smock and separate pair of trousers, and is sized to accommodate the 5 percentile female through the 95 percent male ratio. This garment will be replaced Navy-wide by a superior suit developed under the auspices of the Joint Service Lightweight Integrated Suit Technology (JSLIST) program. The Mark III chemical, biological, radiological (CBR) suit protects against chemical agent vapors, aerosols, droplets of liquid, and biological agents.

CP Suit, Saratoga (USMC)

Like the BDO, the SARATOGA CP Suit is an air permeable, camouflage patterned overgarment. Instead of carbon impregnated foam, SARATOGA uses spherical, activated carbon adsorbers immobilized in the liner fabric. This system allows for a lighter, cooler garment, which is launderable. The Saratoga provides a 24 hour protection period and has a durability of 30 days continuous wear.

CWU-66/P Aircrew Ensemble - Production (FUE FY96)

The CWU-66/P, a one-piece flightsuit configuration, provides 24-hour pro tection against standard NATO threats. It is made with Von Blucher carbon spheres, and is less bulky than prior ensembles. It offers a reduced thermal load burden and is compatible with aircrew life support equipment.

Chemical Protective Undergarment (CPU)

The CPU is a two-piece lightweight undergarment made of a non-woven fabric containing activated charcoal. When worn under the combat vehicle crewmen (CVC) coverall or battle dress uniform (BDU), the CPU provides 12 hours of protection and is durable for 15 days.

SPECIALTY SUITS

Joint Firefighter Integrated Response Ensemble (JFIRE)

JFIRE is a joint effort between the Air Force (lead agency) and the Army. The JFIRE Program has developed an ensemble that will protect the military firefighters IAW National Fire Protection Associated (NFPA) standards and provide CB protection during firefighting operations in a CB environment. JFIRE leverages the JSLIST overgarment for chemical protection, to be worn under aluminized proximity firefighting outergear and with a switchable filtered/supplied air mask with chemical warfare (CW) kit. A Commercial Off-the-Shelf (COTS) glove that can be used for both fire and CB protection will replace the need for CB gloves to be worn under standard proximity gloves. JFIRE meets several key requirements, including (1) providing 24 hours of CB agent protection against 10 g/m^2 liquid agent, (2) providing firefighters CB protection in both structural and crash fire fighting/rescue operation, (3) allowing firefighters to use mission essential tools and equipment in a CB environment, (4) providing resistance to water and all standard fire fighting chemicals (foam, CO_2, aircraft POL), and (5) is capable of being donned in 8 minutes.

Suit Contamination Avoidance Liquid Protection (SCALP)

The SCALP is worn over the BDO to provide 1 hour of protection from gross liquid contamination. The SCALP, which consists of a jacket with hood, trouser and booties, is made from a polyethylene-coated Tyvek™material.

Interim-Self Contained Toxic Environment Protective Outfit (STEPO-I)

Approved as an interim system for 2-hour depot operations in Immediate Danger to Life and Health (IDLH) environments. It consists of encapsulating suit made of butyl rubber-coated nylon with a polycarbonate visor. Respiratory protection is provided by one of two options—tethered clean air supply or a self-contained rebreather worn as a back-pack. Cooling is provided by an ice vest worn underneath the suit.

Self-Contained Toxic Environment Protective Outfit (STEPO)

STEPO provides OSHA level A protection for Army Chemical Activity/Depot (CA/D), Explosive Ordnance Disposal (EOD) and Technical Escort Unit (TEU) personnel. The STEPO is a totally encapsulating protective ensemble for protection against chemical and biological agents, missile/rocket fuels, POL, and industrial chemicals for periods up to four hours. The ensemble incorporates two types of NIOSH approved self-contained breathing systems (one hour and four hour configurations) and a tether/emergency breathing apparatus option, a battery powered Personal Ice Cooling System (PICS), a hands-free communications system, and standard Toxico logical Agent Protective (TAP) boots and gloves. The suit is capable of being decontaminated for reuse up to 5 times after chemical vapor exposures. STEPO shares common, modular components with the ITAP and JFIRE ensembles simplifying logistics and reducing costs.

PROTECTIVE ACCESSORIES

Green/Black Vinyl Overboots (GVO/BVO)

The GVO/BVO are fitted vinyl overshoes that are worn over the combat boots to provide chemical agent or moisture vapor protection during wet weather. The impermeable GVO/BVO provide protection against chemical agents for 12 hours and are durable for up to 14 days.

Multipurpose Overboot (MULO)
(JSLIST Boots)

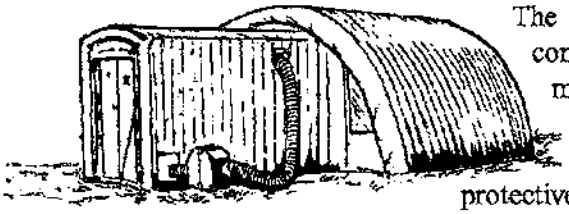
The MULO is a joint service program under the auspices of the JSLIST program and will replace the GVO/BVO. It is made of an elastomer blend and will be pro duced by injection molding. It is designed for wear over the combat boot, jungle boot, and intermediate cold/wet boot. The MULO provides more durability, improved traction, resistance to POLs and flame, and better donning and doffing characteristics over standard footwear.

Chemical Protective (CP) Gloves

The CP glove set consists of a butyl-rubber outer glove for protection from chemical agents, and a cotton inner glove for perspiration absorption. CP outer gloves come in three thicknesses: 7, 14, and 25 mil. The 7 mil glove is used by personnel who require a high degree of tac tility, such as medical and personnel engaged in electronic equipment repair. The 14 mil glove is used by personnel like aviators and mechanics, in cases when good tactil ity is necessary and stress to the glove is not too harsh. The 25 mil glove is used by personnel who require a durable glove to perform close combat tasks and heavy labor. The 14 and 25 mil glove sets will provide protection for at least 24 hours. The 7 mil glove set should be replaced within 6 hours of exposure to a chemical agent.

COLLECTIVE PROTECTION EQUIPMENT

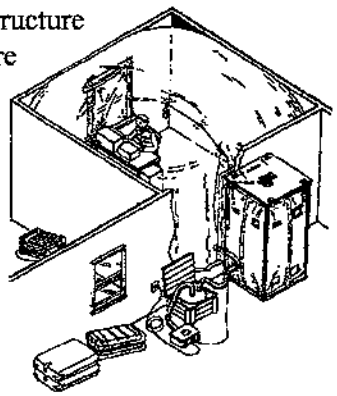
M51 Protective Shelter, CB



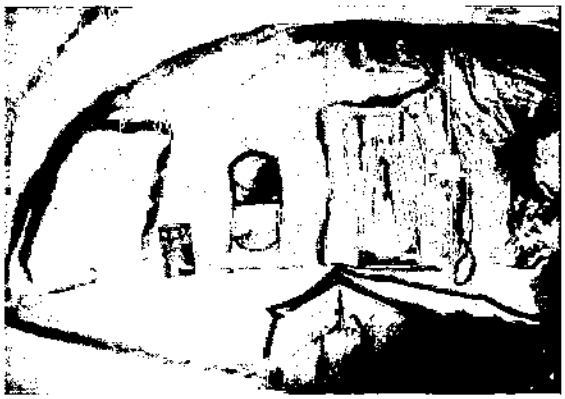
The M51 shelter is a trailer-mounted system that consists of the following major components: a 10-man shelter, a protective entrance, and a support system. The shelter and protective entrance support themselves through air filled ribs. The protective entrance minimizes carry-over of vapor contamination from outside to inside the shelter, and paces entries to the shelter to prevent loss of shelter over-pressure. The air handling system is permanently mounted in the trailer, and provides forced, filtered, and environmentally con ditioned air to the shelter. The M51 is mostly used by battalion aid stations and other medical units. It can also be used as a temporary rest and relief shelter. The M51 utilizes outdated technologies and is being replaced with CBPS. Very few M51s remain serviceable and logistically supportable. This system can be erected and employed by 4–6 personnel in approximately one hour. This system provides heat stress relief from the effects of MOPP for 12–14 personnel.

M20 Simplified Collective Protective Equipment

The M20 SCPE is used to convert an interior room of an existing structure into a positive overpressure, NBC collective protection shelter where individuals can perform assigned missions without wearing the protective mask and overgarment. The system consists of a liner, protective entrance, filter canister, and support kit.



M20A1/M28 Simplified CPE (SCPE)

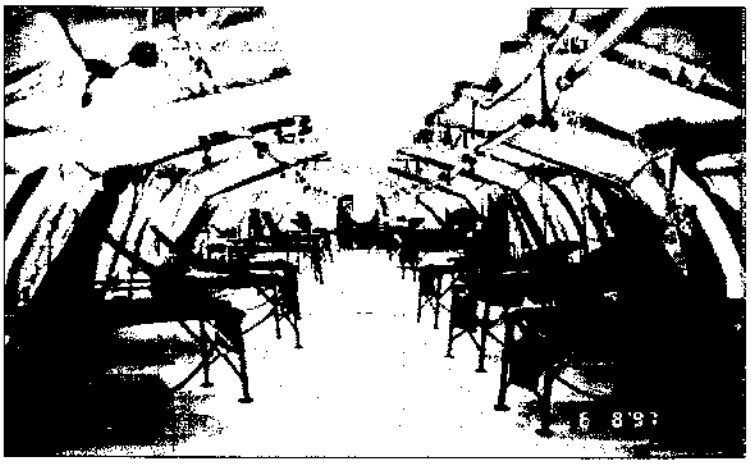


The SCPE is a low cost method of transforming a room of an existing structure into an NBC collective protection shelter for command, control and communication (C^3), medical treatment, and soldier relief functions. M20A1 is a room liner for existing shelters; M28 is a liner for the TEMPER tent. Components include a CB vapor resistant polyethylene liner that provides a protected area in an existing structure; a collapsible, protective entrance that allows entry to/exit from the protected area; a hermetically sealed filter canister, which provides filtered air to both the liner and the protective entrance; and a support kit, which contains ducting, lighting, sealing and repair material and an electronically powered blower. A preplanned product improvement (P^3I) program to the SCPE (M20A1/M28) provides liquid agent resistant liners, protective liners for tents, interconnectors, and an interface with environmental control units. The improved SCPE also allows more people to enter at one time, and protects hospitals under tents.

Chemically Protected Deployable Medical System (CP DEPMEDS) - Development/Production

The Army's CP DEPMEDS program is a joint effort with the Air Force to provide environmentally controlled collective protection into field hospitals. The requirement is to be able to sustain medical operation for 72 hours in a chemical contaminated environment. Environmentally-controlled collective protection is provided through the integration of M28 SCPE, chemically protected air conditioners, heaters, water distribution and latrines, and alarms systems. M28 SCPE provides protection to existing TEMPER Tents and passageways within the hospital. DEPMEDS ISO shelters are protected through the replacement of existing shelter seals with those that are CB protected. The Field Deployable Environmental Control Unit provides air conditioning and the Army Space Heater provides heating. Both environmental control units are chemically protected through the addition of a CB kit. To sustain approximately 500 patients and staff, chemically protected latrines and water distribution systems have been developed.

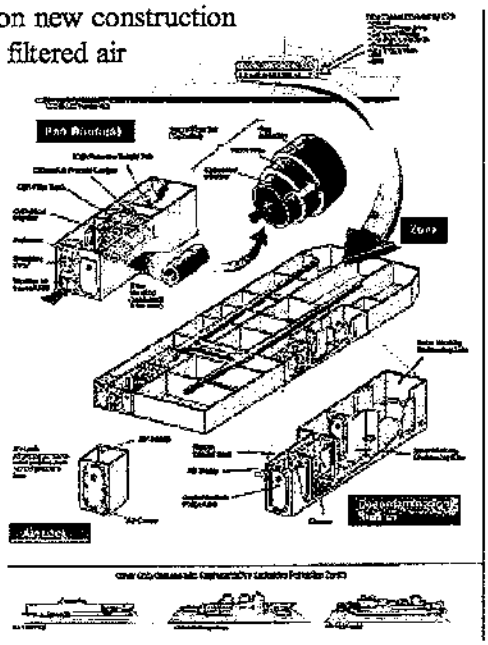
Chemically/Biologically Hardened Air Transportable Hospital (CHATH) – Production



The Air Force' s CHATH program is a joint effort with the Army to enable medical personnel to deploy and setup in chemical and biological threat areas and operate in chemically and biologically ac tive environments. CHATH allows personnel to perform their hospital duties in a Toxic Free Area. CHATH upgrades the present Air Transportable Hospitals (ATHs) retaining the same medical equipment and personnel. CHATH uses existing and modified U.S. Army equipment to line the current ATH tents providing an airtight shelter. The Human Systems Program Office (HSC/YA) developed a Chemically/biologically Hardened Air Management Plant (CHAMP). The CHAMP filters chemically and biologically contaminated air, and recirculates and filters interior air to maintain a clean hospital standard, provides heating, cooling, and overpressurization to the hospital. The CHAMP can be operated from standard electrical sources or from its own internal generator. The CHAMP comes equipped with an Automatic Transfer Switch (ATS) to maintain power after Base power is shut off. The ATS starts the Diesel generator after three seconds of power interruption. The CHAMP allows the CHATH to be staged near warfighters in the field in a bare base environment. The CHATH can be deployed in increments of 10, 25, and 50 beds. This flexibility of the CHATH system helps ensure the best medical care as near the crisis area as possible.

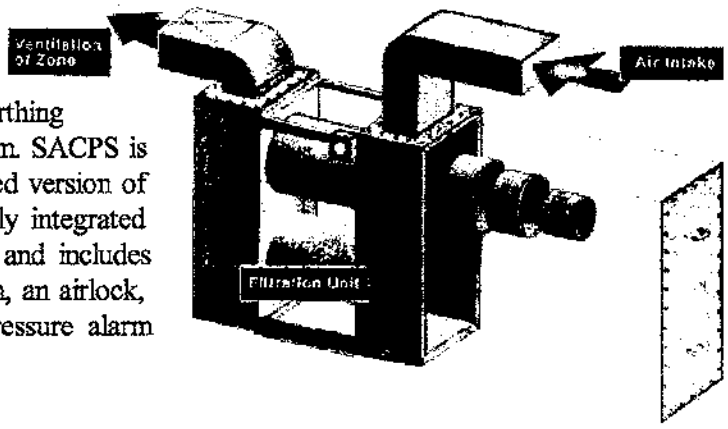
Shipboard Collective Protection System - Production

Shipboard CPS is an integral part of the HVAC systems on new construction ships. CPS provides each protected zone on the ship with filtered air at an overpressure of 2.0 inches water gage. CPS is modular and is based on a Navy-improved version of the 200 cfm M56 filter. CPS includes filters, filter housings, high pressure fans, airlocks, pressure control valves, low pressure alarm system, and personnel decontamination stations.

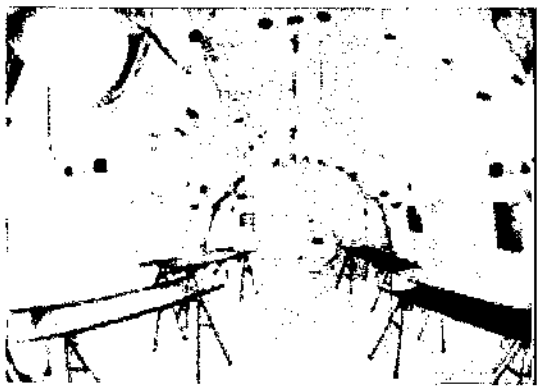


Selected Area Collective Protection System - Production

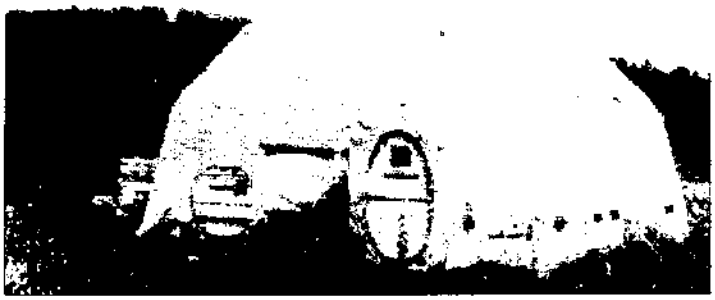
Selected Area CPS (SACPS) is designed to be easily adaptable to current ships to provide selected spaces (*i.e.*, command and control, berthing areas, *etc.*) with an affordable CPS system. SACPS is modular and is based on a Navy-improved version of the 200 cfm M56 filter. SACPS is easily integrated into the ship's existing HVAC system, and includes filters, filter housings, a high pressure fan, an airlock, a pressure control valve, and a low pressure alarm system.



CB Protected Shelter (CBPS) - Production



CBPS is a highly mobile, rapidly deployable shelter system designed to be used for Echelon I and II forward area medical treatment facilities as a replacement for the M51. The system is self-contained and self-sustaining. The CBPS consists of a dedicated M1113 Expanded Capacity Vehicle (ECV), a Lightweight Multipurpose Shelter (LMS) mounted onto the vehicle, a 300 square foot airbeam support CB protected shelter, and a High Mobility Trailer with a 10kW tactical Quiet Generator Set. The ECV and LMS transports a crew of four and their gear. All medical equipment required for the shelter is transported in the LMS or on the trailer. The CB shelter is rolled and carried on the rear of the LMS during transport. The CBPS is operational within 20 minutes with a crew of four. All power required to support operations is provided by the ECV engine or with the 10kW generator for limited power. The system is environmentally conditioned by a hydraulically powered environmental support system, which provides filtered air, heating, air conditioning, and electrical power. The system is presently in limited production with fielding scheduled to initiate in 4QFY99.



Portable Collective Protection System

The transportability and ease of use of the Portable Collective Protection System (PCPS) permit mobility and flexibility in chemically or bio logically contaminated areas. PCPS can be erected by four Marines within 30 minutes wearing MOPP 4 gear. The protective shelter is divided into a main area and two smaller compartments; the entry area, and the storage area. When overpressure is applied, the protective shelter provides protection from liquid and vapor chemical and bio logical agent. An airlock (protective entrance) allows purging of possible chemical agent vapors and additional decontamination of personnel entering the main area.

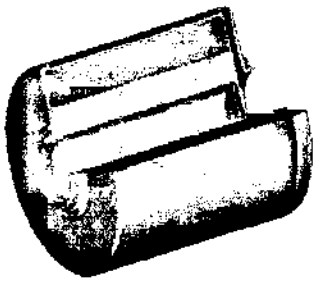
GENERIC NBC FILTERS AND COLLECTIVE PROTECTION FILTRATION SYSTEMS

Generic, high volume air flow NBC filters, and CP filtration systems exist that are currently installed on a wide variety of applications. These CP systems are modular and have been applied to numerous vehicles, vans, mobile shelters, and fixed sites.

GENERIC NBC FILTERS

NBC filters are used to remove Nuclear and Biological particulates and Chemical aerosols and vapors from the air supplied to collective protection systems.

M48/M48A1



The 100 cubic foot per minute (cfm) filter is used in the M1A1/A2 Abrams tank, M93 Modular Collective Protection Equipment (MCPE), CB Protected Shelter, and Paladin Self Propelled Howitzer.

M56

The 200 cfm filter is used as the basic filter set in the MCPE and in Naval applications. It can be stacked to obtain filtration of higher air flow rates.

600 cfm and 1200 cfm Stainless Steel Fixed Installation Gas Filters

These filters are used in fixed site applications where high volumes of air flow are required. They can be stacked to provide higher NBC filtered air flow rates. Particulate filter would be procured separately.

GENERIC NBC CP FILTRATION SYSTEMS

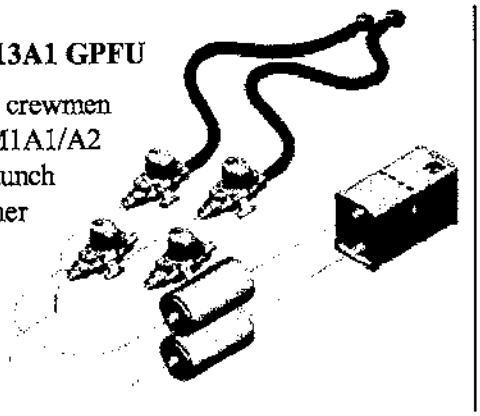
The following are modular NBC CP filtration systems which are applied to a wide variety of applications. They consist of an NBC filter, motor/blower unit, housings, and integration housings/ductwork. Some can be integrated into environmental control equipment.

M8A3 Gas Particulate Filter Unit (GPFU)

The 12 cfm system provides air to armored vehicle crewman ventilated facemasks, *i.e.*, M42A1/A2. Used in M113 Armored Personnel Carrier variants and USMC AAVP7A1 amphibious vehicle.

M13A1 GPFU

The 20 cfm system provides air to armored vehicle crewmen ventilated facemasks, *i.e.*, M42A1/A2. Used on the M1A1/A2 Abrams tanks, Bradley Fighting Vehicles, Multiple Launch Rocket System (MLRS), tank transporter, and other vehicles.



Modular Collective Protection Equipment (100, 200, 400, 600 cfm Systems)

Modular Collective Protection Equipment (MCPE) consists of a family of related end items from which modules can be chosen and combined to meet the unique demands of individual systems. These end items employ common parts and mountings and interchangeable connections and accessories to the greatest extent possible. MCPE provides collective overpressure to a wide variety of mobile shelters and vans. It uses the M48 NBC filter in the 100 cfm system and the M56 NBC filter in the others.

SECTION 2: RDTE ITEMS

INTEGRATED

Force XXI Land Warrior

Rationale:

- Army requirement
- Navy, Air Force, and Marine Corps interest

Key Requirements:

- Protection from all threats for the individual, to include NBC threats
- Integrated vision, communication, and locator systems and enhanced equipment interface

Description:

The Force XXI Land Warrior is an integrated soldier defense system that will improve the warfighter's combat system interface and ability to detect, recognize, and destroy enemy soldiers and equipment. Monitor and protection systems are integrated into a full body ensemble along with advanced locations, communications, microcomputer, and vision systems to maximize the warfighter's battlefield awareness, survivability, and lethality.

RESPIRATORY

Joint Service General Purpose Mask (JSGPM)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- 24-hour CB protection
- Lower breathing resistance
- Reduced weight and bulk

Description:

The JSGPM will be a lightweight protective mask system—consisting of mask, carrier, and accessories—incorporating state-of-the-art technology to protect U.S. forces from all future threats. The mask components will be designed to minimize it impact on the wearer's performance and to maximize its ability to interface with future Service equipment and protective clothing.

Joint Service Aviation Mask (JSAM)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Continuous CB protection
- Improved anti-G features
- Hypoxia protection up to 60,000 feet

Description:

JSAM will be a lightweight CB protective mask that can be worn as CB protection for all aircrew. With the addition of anti-G features, it can be worn as combined CB and anti-G protection for aircrews in high performance aircraft. It will be compatible with existing CB ensembles, provide flame and thermal protection, reduce heat stress imposed by current CB protective masks, and the CB portion will be capable of being donned in flight. JSAM will also be compatible with existing aircrew life support equipment.

BATTLEFIELD PROTECTIVE SUITS

Joint Service Lightweight Integrated Suit Technology (JSLIST)

The JSLIST program is a fully cooperative Joint Service RDTE effort chartered to develop new CB protective clothing for all Services. The program will yield a family of garments and ensembles, developed for Joint Service mission needs and tested to Joint Service standards. The JSLIST will provide enhanced CB protective ensembles with reduced physiological heat burden and will be generally lightweight and launderable. JSLIST is the first of a 3 phase program and supports a variety of Service suit and accessories. Previous chemical protective requirements from all Services are incorporated within the Joint ORD for JSLIST. There are five JSLIST clothing item requirements: 1) overgarment, 2) undergarment, 3) duty uniform, 4) boots and 5) gloves. Each of the Services' requirements are incorporated by these five JSLIST requirements.

In April 1997, the JSLIST program type classified the JSLIST Overgarment and Multi-purpose Overboot (MULO). The remaining items are being addressed in the JSLIST Pre-Planned Product Improvement (P3I) program, currently underway, with completion scheduled for late 1999. P3I is seeking new and advanced material candidates only. The garment design will be the JSLIST design with only minor design modifications allowed under a P3I.

Lightweight Chemical/Biological Protective Garment (LCBPG) JSLIST P3I

Rationale:

- Army and SOF requirement

Key Requirements:

- Provide 6 hours protection against 10 g/m^2 liquid; 5000 CT vapor/aerosols
- Provide 7 days field wear (minimum) in all geographical areas (launderability not required)
- Weigh no more than 4 pounds (3 pounds desired)
- Have package volume for size medium no more than 500 in ^{3} (300 desired)
- Reduce the physiological heat burden by at least 20% (30% desired) over that experienced when wearing the BDO.

Description:

The LCBPG is required to provide 6 hours of protection against all CB agents after moderate periods of wear. The requirement has a trade-off of wear-time and protection-time in order to achieve a lightweight, low-bulk garment for short-term, high-risk missions. The LCBPG will be a two-piece suit designed with an integrated hood compatible with the M40 mask with second skin. It will be worn as an overgarment for the duty uniform or as primary garment over underwear depending upon the environment or mission.

60-Day Overgarment JSLIST P3I

Rationale:

- Joint Army, Navy, Air Force, Marine Corps, and SOF requirement

Key Requirements:

- Provide 24 hours of protection against 10g/m^2 liquid agent, 5000 CT vapor/aerosols
- Provide 60 days field wear in all geographical areas
- Retain chemical protection after 8 launderings
- Weigh less than 4 lbs for a size medium-regular, packed garment
- Reduce physiological heat burden currently imposed by BDO

Description:

The 60-day Overgarment JSLIST P3I will provide 24 hours protection after extended wear and laundering. Liner candidates are based upon activated carbon technology (carbon beads, thin carbon foam, and others). The 60-Day Overgarment JSLIST P3I will be a two-piece design with an integrated hood compatible with the M40 mask and second skin. The 60-Day Overgarment JSLIST P3I will be worn as an overgarment for the Battle Dress Uniform (BDU), or as a primary garment over personal underwear depending upon the environment and mission.

30-Day Overgarment JSLIST P3I

Rationale:

- Air Force requirement

Key Requirements:

- Provide 24 hours protection against 10 g/m^2 liquid agent; 5000 CT vapor/aerosols
- Provide 30 days field wear (minimum) in all geographical areas
- Retain chemical protection after 4 launderings
- Weigh less than 4 lbs for a size medium-regular, packed garment
- Reduce physiological heat burden currently imposed by BDO
- Provide less than 20 percent 2nd degree burns at 2-2.5 gcal/cm^2/sec for two seconds

Description:

The 30-Day Overgarment JSLIST P3I will provide 24 hour protection after 30 days wear time and 4 launderings. Liners currently are based upon various activated carbon technologies (carbon beads, thin carbon foam and others). It will be a two-piece suit with an integrated hood compatible with the MCU-2/P mask with second skin. The 30-Day Overgarment JSLIST P3I will be worn as an overgarment for the duty uniform or as a primary garment over underwear depending upon the environment and mission.

Vapor Protective Undergarment (VPU) JSLIST P3I

Rationale:

- SOF requirement
- Army, Air Force, and Marine Corps interest

Key Requirements:

- Provide 12 hours protection (24 desired) against 10 g/m^2 liquid; 10,000 CT vapor/ aerosols
- Provide 30 days field wear (minimum) in all geographical areas
- Retain chemical protection after 4 launderings (10 desired)
- Weigh less than 3 pounds
- Reduce the physiological heat burden imposed by the CPU

Description:

The VPU will provide 12 hour protection after extended wear and laundering. It will also offer a reduction for the heat stress burden when compared to the CPU. The VPU will be a one or two-piece undergarment with an integral hood compatible with the M42 series mask.

Duty Uniform (JSLIST P3I)

Rationale:

- Marine Corps requirement
- Army, Air Force, and SOF interest

Key Requirements.

- Enhance existing capability with lighter, less thermal burdening ensemble

Description:

The Duty Uniform will be the primary NBC garment. It will be worn by all Marines, except those aircrew with special environmental or equipment interface requirements and those Marines who must deal with large volumes of liquid contamination. It will provide the wearer with protection from liquid, vapor, and aerosol hazards while reducing physiological stress.

Joint Service Aircrew Protective Ensemble (JPACE)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps Requirement (Navy lead)

Key Requirements:

- Provides Below-the-Neck (BTN) protection for rotary and fixed wing aircrew
- 30 day wear time
- Launderable
- Includes hand and foot protection
- Compatible with aircrew mounted aviation life support systems
- Ejection safe and water survivable

Description:

JPACE will be a chemical biological (CB) protective ensemble (including gloves and footwear) for all services' aviation communities. It will be a replacement for the Navy/Marine Corps MK-1 undergarment, Army ABDU-BDO system and AF CWU-66/P overgarment. Due to mission constraints and threat analysis, a separate garment may be considered for fixed wing versus rotary wing aircrew. JPACE started as a spin-off from JSLIST to address aviation specific CB requirements. Therefore, JSLIST and JSLIST P3I materials, designs, and documentation will be used to the maximum extent possible. This ensemble will be jointly tested and fielded with JSAM (Joint Service Aviation Mask) and will be used as a technical insertion to the Army Air Warrior program. JPACE will provide the fixed and rotary wing aviator with BTN protection against CB threats.

Multipurpose Protective Sock (MPS)
(JSLIST P3I)

Rationale:

- SOF requirement
- Army, Air Force, and Marine Corps interest

Key Requirements:

- Provide 12 hours of protection against $10 g/m^2$ liquid agent, (5000 $mg\text{-}min/m^3$ vapor/aerosols if boot is made of permeable material)
- Provide 30 days field wear
- Must be comfortable, fit well and be compatible with all SOF footwear; *i.e.*, desert, jungle, assault boots, *etc.*
- Retain chemical Protection after 4 launderings

Description:

The MPS will provide 12 hours protection after extended wear and laundering when worn over the issue wool sock and under SOF footwear. The MPS must provide comfort, fit and compatibility when worn over the wool sock and under the various types of SOF footwear. The boots' composition and design will determine whether both liquid and vapor protection must be integrated into the sock material.

Improved CB Protective Glove
(JSLIST P3I)

Rationale:

- Joint Army, Air Force, and Marine Corps requirement

Key Requirements:

- Provide 24 hours protection against 10 g/m^2 liquid agent
- Provide protection against POL and standard decontaminants
- Provide self-extinguishing flame resistance
- Provide 30 days wear durability in all environments without degradation of protection
- Provide dexterity equal to or better than the standard 14 and 25 mil butyl gloves

Description:

Two candidates are being evaluated in the JSLIST P3I glove program. One is a general purpose glove for durability and the other is a high tactile glove for improved dexterity.

SPECIALTY SUITS

Improved Toxicological Agent Protective (ITAP)

Rationale:

- Program is a Joint Service Program

Key Requirements:

- Provide splash and vapor protection against a potential exposure to liquid agent when worn as a system–requirements: 10g/m ^{2} HD, VX, GB, L agent challenge for 2 hours.
- Provide an optional Personal Ice Cooling System (PICS).
- Be functional as a system where temperatures range from 0 ° to 100°F when used with a cooling system.
- The suit and overhood are capable of being decontaminated for a minimum of 5 reuses, 2 hours per use (1 hour at IDLH), after vapor and particulate contamination. After liquid contamination ITAP suit will be decontaminated and held for disposal.
- Must have a minimum shelf life of 5 years.
- It is required that the fabric be self-extinguishing meeting NFPA 1991.

- It is required that the fabric be static dissipative and not hold a charge sufficient to set off munitions and explosives in accordance with current Explosive Safety Board requirements.
- The fabric should be light in color to reduce operator solar heat load. Capable of being stored within the temperature range of 0° to 120°F.

Description:

ITAP will replace the M3 TAP ensemble. ITAP will en hance existing capabilities by increasing personal protection and reducing the thermal bur den on the wearer. ITAP will provide skin and respiratory protection both during peacetime and wartime for short term operations in Immediately Dangerous to Life and Health (IDLH) toxic chem ical environments (up to 1 hr), emergency life saving response, routine Chem ical Activity operations and initial entry and monitoring. ITAP shares common, modular components with the STEPO and JFIRE ensembles, simplifying logistics and reducing costs.

COLLECTIVE PROTECTION EQUIPMENT

Advanced Integrated Collective Protection System (AICPS) for Vehicles, Vans and Shelters (VVS)

Rationale:

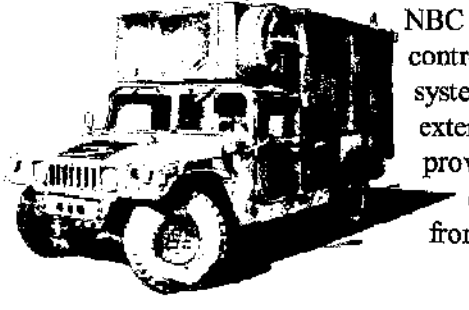
- Army requirement
- Marine Corps interest

Key Requirements:

- Integral NBC filtration power and environmental control for vehicles, vans and shelters
- Minimize filter changes and overall system logistics burden
- Reduced size, weight and energy requirements

Description:

The AICPS (shown mounted to an S788 Shelter on an M1097 HMMWV) is an NBC filtration system integrated with an environmental control unit and auxiliary power unit for combat systems. It uses a deep-bed carbon vapor filter for extended gas filter life. The combined components provide overall size, weight and energy reduction, and eliminate the need for additional electrical power from the host system.



Shipboard Collective Protection Equipment

Rationale:

- Navy Service-Unique requirement

Key Requirements:

- Provide protection against chemical and biological threat agents
- Provide a minimum of three year continuous operational life
- Provide more efficient, long life filters
- Provide quieter, more efficient supply fans
- Develop methods to counter new and novel threat agents

Description:

Shipboard Collective Protection Equipment (CPE) provides a contamination-free environment within specified zone boundaries such that mission essential operations and life sustaining functions can be performed during or after a CB attack. The objective of this program is to provide Pre-Planned Product Improvements (P3I) to the current Shipboard CPS to decrease logistic costs by extending particulate filter life, reducing shipboard maintenance requirements, and providing energy-efficient fans. The program develops improvements to existing shipboard HEPA and gas adsorber filters, supports long term shipboard testing of filter improvements to develop filter life database, and provides plans for backfitting existing non-CPS ships. Shipboard CPE is being installed on selected new construction ships.

Collective Protection System (CPS) Backfit

Rationale:

- Navy Service-Unique requirement

Key Requirements:

- Provides protection to forces operating ships within a chemical/biological threat environment
- Provides plans for backfitting existing non-CPS ships

Description:

Collective protection systems use filtered air to pressurize ship zones such that specified contamination-free spaces can remain functional for mission critical and sustaining operations within a chemical/biological threat or contaminated area. CPS backfit provides a means for retrofitting existing ships with required collective protection. Only ships with significant operational life beyond the FY05 through FY10 time frame will be considered for CPS Backfit.

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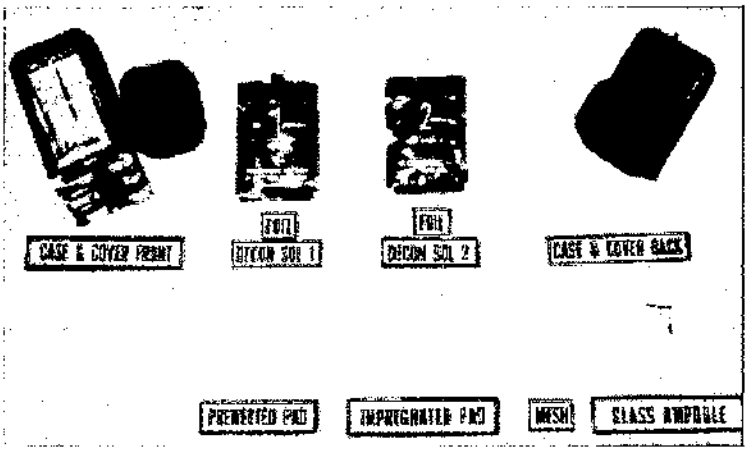
Annex C

Decontamination Programs

SECTION 1: FIELDED AND PRODUCTION ITEMS

PERSONNEL

M258A1 Skin Decontamination Kit (SDK)

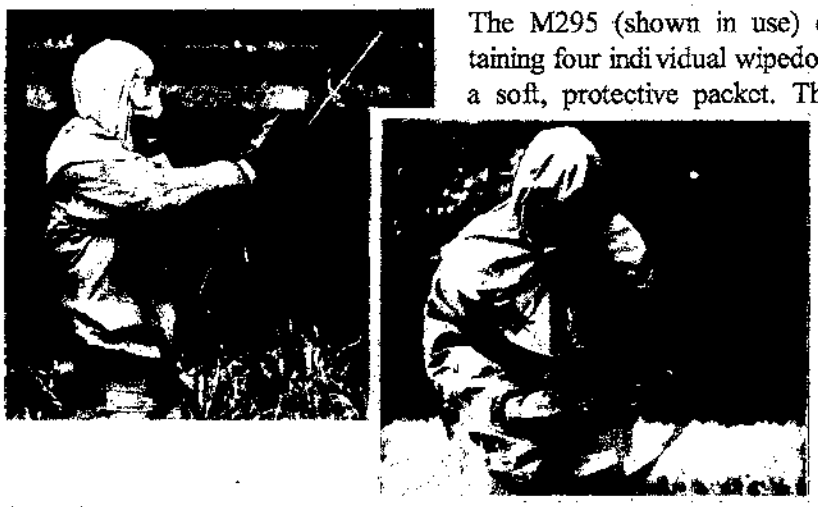


The M258A1 consists of a pocket-sized plastic case containing three sets of foil-packaged decontaminating wipes. The decontaminating sets consist of PACKET 1 containing an aqueous decon solution soaked gauze pad, and PACKET 2 containing a decon solution filled glass ampoule within a gauze pad. Personnel use the two wipes successively to remove and neutralize liquid chemical agents from their skin, clothing, personal equipment and weapons. The M258A1 is being replaced by the M291 decon kit.

M291 Skin Decontamination Kit

The M291 (shown in use) consists of a wallet-like flexible carrying pouch containing individually packaged hermetically sealed foil packets. Each packet contains a folded nonwoven fiber applicator pad with an attached strap handle on one side. The pad contains a reactive and sorptive resin polymer mixture. The kit enables warfighters to remove, neutralize, and destroy chemical and biological warfare agents on contaminated skin. The kit is carried in a pocket of the Battle Dress Overgarment (BDO).

M295 Equipment Decontamination Kit



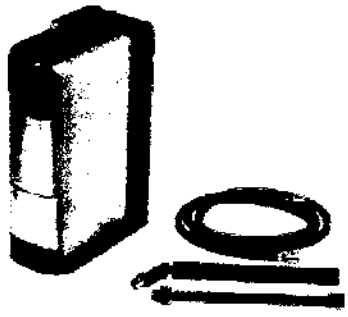
The M295 (shown in use) consists of a pouch containing four individual wipedown mitts, each enclosed in a soft, protective packet. The pouch assembly is designed to fit comfortably within the pocket of a BDO. Each individual wipedown mitt in the kit is comprised of adsorbent resin contained within a nonwoven polyester material and a polyethylene film backing. In use, resin from the mitt is allowed to flow freely through the non-woven polyester pad material. Decontamination is accomplished through sorption of contamination by both the non-woven polyester pad and by the resin. The M295 enables the warfighter to perform basic decontamination to remove, neutralize, or destroy CB warfare agents and toxins on contaminated personal and load bearing equipment.

COMBAT EQUIPMENT, VEHICLES, AND AIRCRAFT

ABC-M11 Portable Decontaminating Apparatus

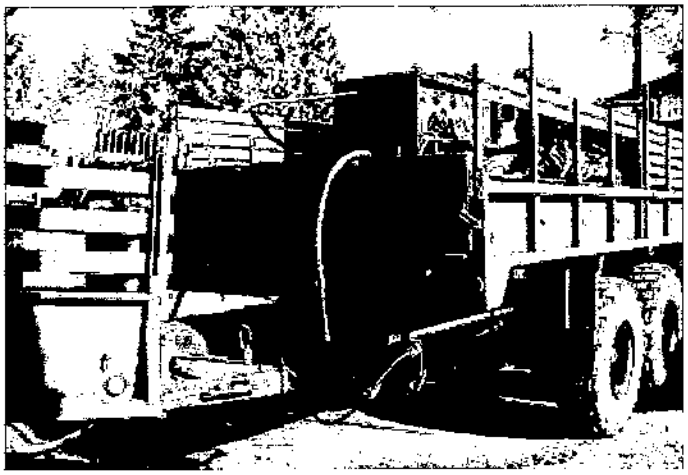
The 1-1/3 quart capacity M11 is used to spray DS2 decontaminating solution onto critical areas (*i.e.*, frequently used parts) of vehicles and crew served weapons. The M11 consists of a steel cylinder, a spray head assembly, and a small nitrogen cylinder (about 3" long). The refillable M11 can produce a spray 6 to 8 feet long, and cover an area of about 135 square feet. The M11 is currently used on tanks and other systems where the larger M13 Decontaminating Apparatus, Portable (DAP) cannot be effectively stowed.

M13 Decontaminating Apparatus, Portable (DAP)



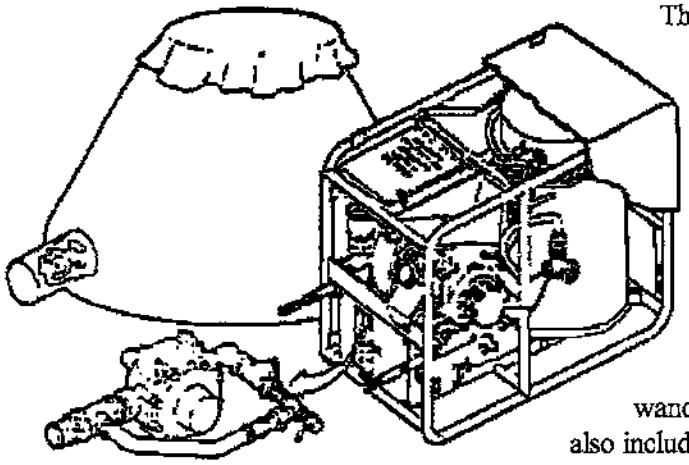
The man portable M13 consists of a vehicle mounting bracket, a pre-filled fluid container containing 14 liters of DS2 decontaminating solution, and a brush-tipped pumping handle con nected to the fluid container by a hose. The fluid container and brush head are both disposable. The M13 can decontaminate 1,200 square feet per fluid container. The combination of spray pump and brush allows personnel to decontaminate hard to reach surfaces, and remove thickened agent, mud, grease and other material.

ABC-M12A1 Power Driven Decontamination Apparatus (PDDA); Skid-Mounted



The M12A1 consists of three main components: a pump unit, a 500 gallon tank unit, and a 600 gallon per hour liquid fuel water heater. The M12A1 is a flexible system that can be used for purposes such as de-icing, fire fighting with water or foam, water pumping/transport, and personnel showering in addition to equipment and area decontamination. The M12A1 can pump 50 gallons of decontaminating solution per minute through both of its two hoses. The integral shower assembly provides 25 shower heads. The M12A1 is typically mounted on a 5 ton truck for tactical mobility, but can be dismounted to facilitate air transport. The Marine Corps has replaced the M12A1 PDDA with the M17 series Lightweight Decontamination Apparatus.

M17 Series Lightweight Decontamination Apparatus



The M17 series Lightweight Decontamination System is a portable, lightweight, compact engine driven pump and water heating system. The system is used during decontamination operations. The LDS is capable of drawing water from any source and delivering it at moderate pressure and controlled temperatures. The system has an accessory kit with hoses, spray wands, and personnel shower hardware. It also includes a collapsible water bladder.

SECTION 2: RDTE ITEMS

COMBAT EQUIPMENT, VEHICLES, AND AIRCRAFT

Sensitive Equipment Decontamination System

Rationale:

- Joint Service requirement

Key Requirements:

- Non-aqueous based decontamination systems for sensitive equipment
- Capable of being used in both mobile and fixed-sites

Description:

Provide a first ever capability to decontaminate chemical and biological warfare agents and toxins from sensitive electronic, avionics, electro-optic equipment, and vehicle interiors. Its use must be compatible with and not degrade sensitive materials or equipment. It must be operator safe and offer protection from off-gassing and direct liquid exposure during decontamination.

Sorbent Decontamination System

Rationale:

- Army and Marine Corps requirement
- Navy and Air Force interest

Key Requirements:

- Effectively decontaminates all CB warfare agents from contaminated surfaces
- Easy-to use and possess no hazard to users
- Non-damaging and non-corrosive to military equipment
- Environmentally safe to store

Description:

The reactive sorbent decontamination system provides a simple, rapid, and efficient system to decontaminate small and individual issue items of equipment. It is effective in all environments, is less corrosive, and presents a lowered logistics burden through improved shelf life and reduced special handling and storage needs. The system uses a catalytic component that reacts with the chemical agents being sorbed; this eliminates the potential hazard created by the off-gassing of agents from used sorbents.

M21/M22 Modular Decontamination System (MDS)

Rationale:

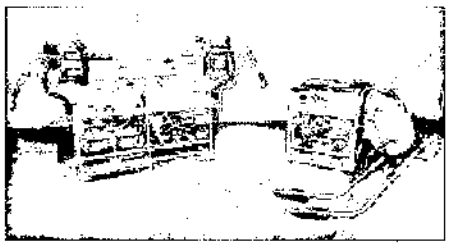
- Army requirement
- Navy, Air Force, and Marine Corps interest - no imminent requirement

Key Requirements:

- Provide high pressure water for the primary wash process
- Mechanically dispense and scrub decontaminant
- Fit within the payload limits of a 3/4 ton trailer and a 1-1/2 ton trailer
- Use existing equipment to supplement the deliberate decontamination process
- Provide adapters to draw water from fire hydrants

Description:

The MDS will provide the soldier an improved capability to perform detailed equipment decontamination on the battlefield. The system will replace current methods of decontamination application (*i.e.*, mops and brooms or with the portable M13 Decontamination Apparatus) which are both time consuming and labor intensive. The MDS improves effectiveness, reduces water usage, equipment processing time, and labor intensiveness. The MDS consists of a M21 decontaminant Pumper/Scrubber module, and M22 High Pressure/Hot Water module. The M22 delivers DS2 or liquid field expedient decon taminants and is capable of drawing the decontaminant directly from a container on the ground while mounted on a trailer. The M22 provides hot water up to 3000 psi at a rate of 5 gpm with the capability of high volume cold water and detergent injector. It will also be capable of drawing water from natural and urban water sources and delivering it at variable adjustable pressures, temperatures and flow rates. Each module (M21 or M22) may be transported or operated from a 3/4-ton trailer towed by a M1037 High Mobility Multipurpose Wheeled Vehicle.



M17 Diesel Lightweight Decontamination System (LDS)

Rationale:

- Navy and Marine Corps requirement
- Air Force interest - no imminent requirement)

Key Requirements:

- Be capable of operation using Military Standard (MIL STD) fuels
- Have no component which cannot be moved by a four man crew
- Be capable of decontaminating both sides of a vehicle or aircraft simultaneously
- Generate no new manpower requirements
- Decontaminate personnel, equipment and other material without an external power source and in coordination with a water tank or natural water resource.

Description:

The Diesel LDS is a portable, lightweight, compact, engine-driven pump and multifuel-fired water heating system. The system will be capable of performing the same hasty and deliberate decontamination procedures as required of the M17 series LDS.

Joint Service Fixed Site Decontamination System

Rationale:

- Army, Air Force, and Marine Corps requirement; Navy to be determined

Key Requirements:

- Provide restoration capability at fixed site locations
- Provide improved/state-of-the-art NBC decontamination equipment
- Provide non-hazardous and environmentally safe NBC decontaminates

Description:

The Joint Service Fixed Site Decontamination program is a joint effort for the four Services. The system will provide a family of decontamination equipment to provide the capability to decontaminate ports, airfield, and rear-area supply depots.

Annex D

Joint Medical Chemical, Biological, and Nuclear Defense Research Programs

The joint medical chemical, biological, and nuclear (radiological) defense research programs are each addressed in the next three sections.

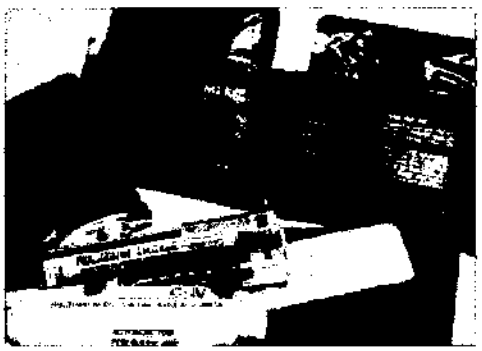
D.1 MEDICAL CHEMICAL DEFENSE RESEARCH PROGRAM

D.1.1 Fielded Products

Advances in medical research and development (R&D) significantly improve the warfighting mission by sustaining unit effectiveness through conserving the fighting strength of our forces and supporting the nation' s global military strategy, which requires the ability to effectively deploy and operate. Medical R&D products (materiel and non-materiel solutions) provide the foundation that ensures the fielding of a flexible, sustainable, modernized force across the spectrum of conflict and in the full breadth and depth of the battlefield. Overcoming medical threats and extending human performance have provided a significant increase in military effectiveness in the past and present the potential for future enhancement of military operational effectiveness. Some fielded medical chemical defense R&D materiel and non-materiel solutions are:

Pharmaceuticals:

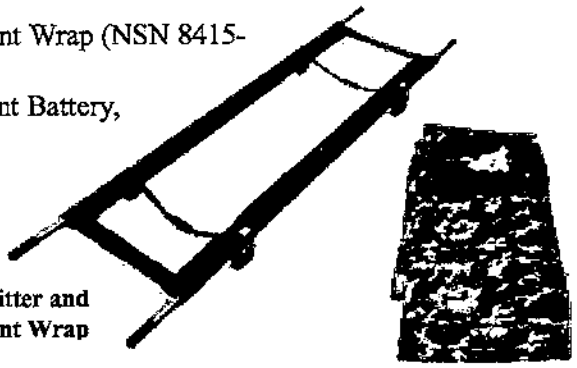
- Nerve Agent Antidote Kit (Mark I), 1983
- Skin Decontamination Kit (M291), 1990
- Nerve Agent Pretreatment (Pyridostigmine), 1985
- Convulsant Antidote for Nerve Agent (CANA), 1991
- Medical Aerosolized Nerve Agent Antidote (MANAA), 1994



MARK I, M291, Nerve Agent Pretreatment, and CANA

Materiel:

- Test Mate® ChE (Cholinesterase) Kit, 1997 (*shown*)
- Resuscitation Device, Individual, Chemical, 1990
- Decontaminable Patient Litter (NSN 6530-01-380-7309), 1991
- Chemical Warfare (CW) Protective Patient Wrap (NSN 8415-01-311-7711), 1991
- Computer-Based Performance Assessment Battery, 1993
- M40 Protective Mask Vision Correction (optical inserts)



Decontaminable Patient Litter and CW Protective Patient Wrap

Technical Information and Guidance:

- Taxonomic Work Station, 1985
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) Technical Memoranda on Chemical Casualty Care, 1990
- Field Manual (FM) 8-285, "Treatment of Chemical Agent Casualties and Conventional Military Chemical Injuries," 1990
- Handbook, "Medical Management of Chemical Casualties," 1995
- Field Management Handbook, "Medical Management of Chemical Casualties," 1996
- Technical Bulletin (TB) Medical (MED) 296, 1996
- Compact Disk - Read-Only Memory (CD-ROM) on "Management of Chemical Warfare Injuries," 1996

D.1.2 Medical Chemical Defense R&D Accomplishments

The medical chemical defense R&D technical barriers and accomplishments during FY98 are grouped by medical chemical defense strategies, which include the following:

- Prophylaxes
- Pretreatment
- Therapeutics
- Diagnostics

Today' s chemical threat, however, is not restricted to commonly accepted classical agents, such as vesicants [sulfur mustard (HD)], nerve agents (soman, sarin, tabun, and VX), respiratory agents (phosgene), or blood agents (cyanide). Potential adversaries may develop novel threat agents. The ability to provide timely and effective medical countermeasures to new threats depends upon maintaining a high level of technological capability.

Countermeasure strategies to the classic and novel threats include pharmaceuticals, medical equipment, specialized materiel or medical procedures, and concepts for training,

doctrine, and organization. Medical countermeasures are designed not only to prevent lethality but also to preserve and sustain combat effectiveness in the face of combined threats from chemical and conventional munitions on the integrated battlefield by:

- Prevention of the effects of chemical agents (*e.g.*, prophylaxes or pretreatment).
- Far-forward treatment upon exposure to chemical warfare threats (*e.g.*, antidotes).
- Chemical casualty care (*e.g.*, therapy and management).
- Rapid diagnosis of chemical agent exposure.

Research Category: Prophylaxes/Pretreatments

The countermeasures, technical barriers, and accomplishments in the medical chemical defense research category of prophylaxes/pretreatments are outlined below.

Countermeasures:

- Reactive topical skin protectant (rTSP) for chemical agents.
- Pretreatment regimen that protects against rapid action and incapacitating effect of chemical threat category of nerve agents and novel threat agents.
- Pharmaceutical/biological pretreatments, treatments, antidotes or decontaminants/protectants.

Technical Barriers:

- Lack of appropriate model systems for testing treatment efficacy and safety in humans.
- Lack of pretreatments/antidotes that are quick acting, long lasting, easy to carry and use on the battlefield.
- Lack of appropriate experimental model systems to predict pretreatment or treatment efficacy and safety in humans.
- Lack of detailed molecular model of novel threat agents to understand the origin of their unique chemical properties.
- Potential performance decrement with pretreatment under investigation unless effects are closely monitored during administration.

Accomplishments:

- Observed that neonatal mice fail to develop HD lesions comparable to those seen in weanling mice.
- Identified a prototype formulation for rTSP that dramatically increases protection against HD vapor.
- Developed a method for preparing crystals of *T. californica* acetylcholinesterase (AChE) inhibited with sarin, soman or diisopropylfluorophosphate. Refinement of three-dimensional structure is almost complete (collaboration with the Weizmann Institute, Israel).
- Examined inhibition rates of butyrylcholinesterase (BuChE) mutants having organophosphorus (OP) anhydrolase activity by carbamates and determined that slow reactivity of BuChE mutants with OP probably results from interference of transition state stabilization by the bulky histidine sidechain that was introduced.

- Elucidated control mechanism of *in vitro* secretion of carboxylesterase (CaE) by mutagenesis of C-terminal of CaE.
- Expressed human CaE for use as an exogenous scavenger for OP agents.
- Made four double mutants of CaE each with altered C terminal residues; of these, two had a histidine introduced near the active site and two had a glutamine introduced near the active site.
- Observed that cholinesterase (ChE) attached to a solid support has enhanced stability over soluble forms of the enzyme.
- Found that differences in terminal elimination rates of soman in guinea pig and marmoset *vs.* rat correlated with differences in the levels of soman binding sites in liver of these species.
- Found that tissue/plasma partition coefficients of soman in rat, guinea pig, and marmoset were essentially equal suggesting that the pharmacokinetic distribution of soman in these species should be quite similar (collaboration with Prins Maurits Laboratory, TNO).
- Standardized the Chinese hamster ovary expression system for BuChE and CaE expression.
- Developed a more sensitive and safe method to determine partition coefficients of nerve agents.
- Found differences in the oligosaccharides of native and recombinant CaEs with regard to the total carbohydrate content and charge- and size-based oligosaccharide profiles.
- Determined that neither the carbohydrate composition nor the oligosaccharide profile could be completely correlated with the pharmacokinetic parameters of these enzymes.
- Explored synthesis of a monoclonal anti-soman antibody for further development as a ' dip-stick' diagnostic product (collaboration with Army Research Laboratory).
- Created a database for physiologically based pharmacokinetic (PB/PK) parameters for rat, guinea pig, monkey, and human; these parameters are being evaluated for allometric consistency to develop a simplified PB/PK model that can predict nerve agent toxicokinetics regardless of species (collaboration with Prins Maurits, TNO).
- Developed a PB/PK computer model for inhalation exposure to soman (collaboration with Prins Maurits, TNO).
- Determined percutaneous median lethal doses of five novel threat agents in guinea pigs.
- Measured the rates of absorption of three novel threat agents administered by subcutaneous and percutaneous routes in guinea pigs.
- Evaluated the distribution of three novel threat agents in rodents after subcutaneous administration.
- Measured the physiological effects of five novel threat agents on electrocorticographic, respiratory, electromyographic, and cardiovascular parameters in guinea pigs.
- Demonstrated that the mechanism of toxicity of novel threat agents was due to their inhibition of AChE and the resulting elevation of acetylcholine (ACh) levels in the nervous system.
- Physicochemical measurements revealed that novel threat agents were not ionized under physiological conditions and were hydrolyzed at a slower rate than conventional nerve agents.
- Demonstrated that carbamate pretreatment was required for significant protection by current medical countermeasures against three of the novel threat agents.

- Elucidated the structural/functional relationship between the glycosylation and the pharmacokinetic behavior of ChEs. Successful application of native and recombinant ChEs as detoxifying drugs largely depends on their ability to remain at therapeutic plasma levels for prolonged periods. Variations in ChE charge, structure, and oligosaccharide content are factors in establishing ChE mean residence time *in vivo*.
- Demonstrated that serum- and tissue-derived AChEs are more effective bioscavangers than recombinant DNA-derived AChEs as potential candidates for pre- or postexposure treatment for OP toxicity.
- Demonstrated that reinhibition of organophosphate-inhibited AChE by phosphoryl oxime depends on the structure of the oxime reactivator and the organophosphate used.
- Established that in simultaneous acute exposure to DEET, permethrin, and pyridostigmine, there was no synergistic inhibition of binding to muscarinic or nicotinic receptors or inhibition of cholinestrase activity.
- Demonstrated differences in the active-site gorge dimensions of AChEs and BuChEs using data gathered from inhibition studies with BuChE.
- Elucidated the complete amino acid sequence of equine serum BuChE, a protein of 574 amino acids.
- Showed that monoclonal antibodies that inhibit catalytic activity of AChE do so, in part, by allosterically affecting the orientation of tryptophane 86, located at the base of the active-site gorge.

Research Category: Therapeutics/Diagnostics

The countermeasures, technical barriers, and accomplishments in the medical chemical defense research category of therapeutics/diagnostics are outlined below.

Countermeasures:

- Products that prevent or moderate vesicant injury.
- Medical countermeasures to minimize lethality, morbidity, and incapacitation of these agents.
- Specific casualty management techniques to improve survival and minimize lost duty time.
- Pharmaceutical/biological pretreatments, treatments, antidotes, or decontaminants/ protectants.

Technical Barriers:

- Need for quick-acting and long-lasting antidotes that are deployable.
- Lack of appropriate experimental model systems for treatment efficacy and safety in humans.
- Need for detailed molecular model of novel threat agents to understand the origin of their unique chemical properties.

Accomplishments:

- Determined that the cytokines IL-1b, IL-6, TNF-alpha, and MIP-1a mRNA levels are dramatically increased following cutaneous HD exposure in the mouse ear.

- Showed that two precursor enzymes for substance P are elevated following cutaneous HD exposure in the mouse ear.
- Found a weak but positive signal for the presence of NFkB, an inflammatory response regulator, in lung tissue within 6 hours after HD exposure.
- Observed that inhalation exposure to HD in rats results in a significant leukocyte suppression at 24 hours after the exposure.
- Developed a mathematical model of anaerobic glycolysis that was used to test the hypothesis that HD-induced inhibition of glycolysis is mediated by NAD+ depletion.
- Using a monoclonal antibody against DNA ligase I, affinity column chromatography confirmed that activation of DNA ligase following HD exposure is through phosphorylation.
- Showed upregulation of 100 gene transcripts including multiple inflammatory protein transcripts such as intracellular adhesion to molecule-1 and interleukin-8 following HD exposure.
- Modified the single cell comet assay for DNA strand breakage for detection of the effects of HD crosslinking on the demonstration of strand breaks caused by H_2O_2.
- Demonstrated that exposure of keratinocytes to HD leads to cytotoxicity involving terminal differentiation and apoptosis via a calcium-calmodulin and caspase-dependent pathway.
- Assessed the toxicokinetics of HD in the hairless guinea pig following IV admini stration of 0.3 LD_{50} using gas chromatography coupled with PFPD and showed that the half-lives of distribution and elimination were 0.7 and 152 minutes, respectively.
- Found 17 candidate medical countermeasures that provide significant reduction in HD-induced edema, histopathology, or both in the mouse ear assay.
- Determined that 6 of the compounds showing a statistical reduction of injury in the mouse ear assay produced greater than 50% reduction of edema or histopathology.
- Measured the ability of oximes to reactivate enzymes inhibited by novel threat agents and correlated the refractoriness of novel threat agents to medical countermeasures with the inability of oximes to reactivate novel agent-inhibited AChE.
- Established nonhuman primate electroencephalographic (EEG) recording model to assess anticonvulsant action of current treatment (diazepam) *vs.* proposed new anticonvulsant therapies for nerve agent-induced seizures.
- Determined that the benzodiazepine, midazolam, provides more rapid and more potent anticonvulsant action against nerve agent-induced seizures than the current therapy diazepam.
- Established that certain anticholinergic drugs in combination with benzodiazepines provide more potent anticonvulsant action against nerve agent seizures than either class of drug by itself.
- Determined that two neuroactive steroids with purported anticonvulsant activity could neither prevent nor stop nerve agent seizures.
- Demonstrated that the anticholinergic drug biperiden provides potent anticonvulsant activity against all nerve agents to include the novel threat compounds.
- Established that the drug baclofen, a compound that acts preferentially at GABA-B receptor sites, is not effective as an anticonvulsant against nerve agent-induced seizures.
- Identified compounds that can act as neuroprotectant agents against brain damage pro-

duced by nerve agent seizures. These compounds may act by preventing destabilization of calcium homeostasis, or as free radical scavengers, or both. Some are able to prevent the seizure-induced damage without influencing the severity or duration of seizure activity. Such compounds could be used in addition to traditional anticonvulsant drugs to protect severely poisoned casualties against the neurotoxic effects of nerve agent exposure.

- Determined that calcium channel blockers such as nifedipine do not increase survival rates of mice exposed to phosgene.
- Developed a mouse model that allows for the determination of arterial blood gas and electrolyte status over 24 hours in mice after exposure to phosgene.
- Determined that there are increases in blood potassium, hematocrit, hemoglobin, ionized calcium, and sodium in mice exposed to phosgene.
- Developed a porcine model to investigate the use of positive end expiratory pressure in the treatment of phosgene exposure.
- Found that 6 hours after exposure of lung tissue to HD, there was a dose-response change in the concentration of protein, an early marker of acute lung injury in the bronchoalveolar lavage.
- An antisense oligodeoxynucleotide construct based on amino acid sequence of HD-stimulated protease prevents protease mRNA expression induced by HD.
- Performed rat EEG studies and determined that the muscular tremor and high-dose lethal effects of huperzine, a potential nerve agent antidote and anticonvulsant, are not associated with cortical brain seizure activity.
- Evaluated the possible utility of kainic acid-induced sustained cortical EEG seizures and status epilepticus as a preclinical rat model mimicking agent-like, antiepileptic drug-resistant brain seizures.
- A study was undertaken to determine if abnormally low blood ChE activity, abnormal red blood cell acetylcholinesterase (RBC-AChE), PB inhibition kinetics, and/or unusu ally high frequencies of the atypical phenotype of plasma BuChE could explain some of the symptoms exhibited by Gulf War veterans or represent a risk factor for adverse effects after PB exposure. Sampling of Gulf War veterans showed no evi dence of unusually low ChE activity or altered RBC-AChE kinetics, as evaluated by determination of spontaneous reactivation time after PB inhibition.
- Developed a prototype, noninvasive finger-cuff optical probe to simultaneously monitor continuous measurements of oxyhemoglobin, deoxyhemoglobin, methemoglobin and carboxyhemoglobin for use in cyanide exposure.
- Demonstrated that ChE ' sponges' could neutralize nerve agents and then be reused up to five times after oxime regeneration with only a 30% loss of initial activity.
- Established a laboratory for 24-hour EEG monitoring for cholinergically induced seizures in freely moving rats, to permit high-throughput screening for novel anticonvulsants.
- Developed noninvasive technique (Dynamic Area Telethermometry) to evaluate mustard and other exposures (*i.e.*, nerve gas) to the skin.
- Conducted experiments to calibrate and verify noninvasive optical probe monitor used to monitor pretreatment decrements. Preliminary analysis showed efficacy to be comparable to the oximeter instrument (OSM3) currently employed.

- Showed that postexposure therapy with bioscavenger ChE was effective against residual anticholinesterase activity produced by chlorpyrifos exposure as much as four hours earlier.
- Developed a product composed of ChEs, oxime, and polyurethane foam for removal and decontamination of OP compounds from biological surfaces such as skin that also can be used to develop methods for safe disposal of stored OP nerve agents.
- Characterized the interaction of anti-Alzheimer drugs, huperzine A and E2020 (Aricept®), with ChEs, showing that both inhibitors display a high level of selectivity for AChE over BuChE and that major interactions are with aromatic residue Tyrosine 337 in the active-site gorge of AChE.
- Concluded that huperzine A may interfere with and be beneficial for excitatory amino acid overstimulation, which has been postulated to cause neuronal cell death.
- Showed that stable complexes formed by AChE and amyloid-β-Peptide may increase the neurotoxicity of Aβ fibrils and thus may determine the selective neuronal loss observed in Alzheimer' s brain.
- Found that a monoclonal antibody directed against fetal bovine serum AChE inhibited promotion of Alzheimer amyloid fibril formation triggered by AChE (collaboration with Pontificia Universidad Católica de Chile).

D.1.3 Advanced Development Products

In advanced development, the goal is proof-of-principle and conducting all studies necessary to obtain FDA approval/licensure of drugs, vaccines, and devices. The medical R&D process links the materiel developer (U.S. Army Medical Research and Materiel Command [USAMRMC]) with the combat and training developer (Army Medical Department Center and School [AMEDD C&S]) and the logistician in addressing the threat and Department of Defense (DoD) requirements. Medical chemical defense products now in the advanced development phase are the following:

Product: Topical Skin Protectant (TSP)

Concept:

- Use perfluorinated formulations.
- Form nontoxic, nonirritating barrier film layer on skin.
- Augments Mission Oriented Protective Posture (MOPP).
- Protection against vesicant and nerve agents.

Status:

- Two candidates transitioned to demonstration/validation phase.
- Candidates demonstrated efficacy against broad spectrum of threat agents; down-selected to one candidate.
- Investigational New Drug (IND) application submitted to the FDA.
- Demonstrated the human safety and technical performance of the TSP.
- Demonstrated extended stability of the TSP.
- Validated production/manufacturing capability for the TSP.

- Awarded a manufacturing development contract.
- NDA is under preparation.

Product: Multichambered Autoinjector

Concept:

- Speed administration of life-saving antidotes against nerve agents.
- Replace two-Injector Mark I Nerve Agent Antidote Kit with single autoinjector.

Status:

- Engineering contract awarded in September 1993.
- Fielding will require full FDA approval.
- Demonstrated the human safety of the multi-chambered autoinjector.
- Engineering and development of final prototype completed.

Product: Cyanide Pretreatment

Concept:

- Provide protection against incapacitation and lethality without performance degradation.
- Enhance soldier protection and sustainment.

Status:

- Completed preclinical toxicology and drug distribution studies.
- Developed dose parameters and performance assessments.
- Concluded animal toxicology studies for cyanide pretreatment.
- Completed preparation of IND application.
- Initial efforts to conduct first human safety tests.
- Draft Engineering and Manufacturing Development Request for Proposals undergoing staffing.

D.2 MEDICAL BIOLOGICAL DEFENSE RESEARCH PROGRAM

D.2.1 Biological Defense Products

Advances in DoD medic al R&D significantly impact the warfighting mission by sustaining unit effectiveness through conserving the fighting strength of our soldiers and support ing the nation' s global military strategy, which requires the ability to effectively deploy and operate. Medical R&D products (materiel and non-materiel solutions) provide the founda tion that ensures the fielding of a flexible, sustainable, modernized force across the spectrum of conflict and in the full breadth and depth of the battlefield. Overcoming medical threats and extending human performance have provided a significant increase in military effectiveness in the past and present the potential for future enhancement of military operational effectiveness. Some of the materiel and non-materiel solutions developed for use in medical biological defense R&D include the following:

Vaccines and Antisera:

- Anthrax Vaccine (licensed)
- Plague Vaccine (licensed)*
- Smallpox Vaccine (licensed)
- Botulinum Toxoid Vaccine, Pentavalent (IND #3723)
- Botulinum Type F Toxoid Vaccine (IND #5077)
- Botulinum Antitoxin, Heptavalent Equine (Types A, B, C, D, E, F, and G) (IND #3703)
- Botulism Immune Globulin, Human (IND #1332)
- Botulism, Antitoxin, Heptavalent Equine, Types A, B, C, D, E, F, and G (IND #5077)
- Q Fever Vaccine, Purified Whole Cell, CM Residue, Formalin Inactivated, Gamma Irradiated (IND #3516)
- Tularemia Vaccine (IND #157)
- Vaccinia Virus Vaccine, Cell Cultured (IND #4984)
- Venezuelan Equine Encephalitis Virus Vaccine, TC-83 (IND #142)
- Eastern Equine Encephalitis Virus Vaccine (IND #266)
- Western Equine Encephalitis Virus Vaccine (IND #2013)

**Plague vaccine is licensed against bubonic plague but is probably not effective against aerosolized* Yersinia pestis *(Plague)*

Technical Information and Guidance:

- Handbook "Medical Management of Biological Casualties," 1998.
- In FY98, U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), in collaboration with the Centers for Disease Control and Prevention, broadcast a live, interactive satellite distance learning course entitled "Medical Response to Biological Warfare and Terrorism" to 17,319 military and civilian health professionals and first responders at 500 sites across the United States. This 3-day course proved to be very cost-effective, as the cost was $69 per student trained; whereas, it costs an estimated $1,000 to train a health care provider at USAMRIID' s resident in-house course, which is

given four times yearly to 76 students per course. This satellite distance learning course represented a new era in cooperation with a civilian government agency to provide important information to all who may confront threats from biological agents.

- CD-ROM on "Management of Biological Warfare Casualties" late fall 1999.

D.2.2 Biological Defense Research and Development Accomplishments

The biological defense research and development technical barriers and accomplish ments during FY98 are grouped by biological threat category, which include the following:

- Bacterial (and rickettsial) agents.
- Protein toxins.
- Viral agents.

In addition, research and development accomplishments in the area of confirmatory diagnostic assays for biological warfare threat agents are presented at the end. The objective of this effort is to sustain and enhance the capability to confirm in biological samples the initial field diagnosis/identity of a biological warfare threat agent indicated by initial field screening.

Several projects and technologies are shared with other agencies, including the Department of Energy (DOE) and the Defense Advanced Research Projects Agency (DARPA). The DOE projects tie into the strengths of the DOE laboratories in developing advanced technol ogies in order to enable rapid detection of and response to a chemical or biological agent incid ent. DOE is not involved directly in protection and treatment of personnel, but actively assists DoD with drug/chemical database searches, DNA sequencing, advanced protein chemistry and modeling/simulation projects. Successful sequencing of plasmids found in the causative agents of plague and anthrax helped create the "lab on a chip" that is a hand-held chromatography laboratory. The extensive knowledge and databases available to DOE allow application of computational tools to predict sites of intervention by novel therapies against threat agents.

DARPA is pursuing multi-agent and broad-spectrum approaches, both to defend against current known threats and to anticipate potential future threats. Accomplishments of DARPA programs for FY98 include the following:

Medical Countermeasures Research and Development by DARPA:

- Demonstrated the feasibility of modified red blood cells to eliminate a model pathogen (bacteriophage) from the circulation. In an animal model, more than 99.9% clearance of circulating virus was achieved in less than 1 hour.
- Demonstrated feasibility of genetically engineering stem cells in vitro to express new gene products in order to develop modified stem cells to produce therapeutic products or provide automatic "booster" immunizations.
- Identified a synthetic SEB peptide capable of blocking binding of SEB to human MHC class II antigen.
- Demonstrated that monoclonal antibodies to TNF alpha and interferon gamma protect mice from lethal SEB challenge.

- Evaluated the role of antibodies in mice in mediating alphavirus vaccine interference. Found that non-neutralizing antibodies may act at the surface of infected cells to reduce the hose response to live alphavirus vaccines.
- Concluded a study on the efficacy in guinea pigs of anthrax vaccine against a trans of *B. anthracis* from numerous geographic areas.

Advanced Medical Diagnostics:

- Began studies to determine the feasibility of using exhaled nitric oxide (NO) as an early marker of infection of BW exposure.
- Developed an integrated sample preparation cartridge (to extract DNA from a biological sample) for connection to a miniature automated PCR apparatus.

Consequence Management Tools:

- ENCOMPASS (Enhanced Consequence Management Planning and Support System), an integrated set of consequence management tools, was developed and demonstrated with CBIRF (Marine Corps Chemical and Biological Incident Response Force). ENCOMPASS was used in Denver by CBIRF during the Summit of the Eight (June 1997) to provide plans, situational awareness and patient management in the event of a chemical or biological incident.

The following are accomplishments of medical biological defense research conducted by USAMRMC laboratories and/or their contractors.

Bacterial Agents

The countermeasures, technical barriers, and accomplishments in the bio logical threat category of bacterial agents are outlined below.

Countermeasures:

- Vaccines for immunity against threat agents.
- Antimicrobials for treatment of bacterial diseases.
- Forward deployed diagnostic systems.

Technical Barriers:

- Incomplete genetic information for all the threat agents.
- Lack of appropriate animal model systems for investigation of some bacterial threats and countermeasures.
- Limited capability to produce large bulk Good Manufacturing Practice (GMP) lots of vaccine candidates.
- Lack of suitable epidemiological situations in which to perform human clinical trials to evaluate efficacy of vaccines.
- Difficulty in field testing rapid identification kits under natural conditions.
- Difficulty in defining surrogate markers of protection.

Accomplishments:

- Found that all *B. mallei*/glanders strains were closely related antigenically.
- Determined antibiotic susceptibilities of *Burkholderia* (glanders) in mice and found that tetracycline was the most effective antibiotic, followed by ciprofloxacin and tobramycin.
- Demonstrated that killed *B. mallei* partially protected hamsters challenged with virulent organisms.
- Demonstrated two anti-spore activities of anti-PA antibodies-enhancement of phagocytosis by macrophages and inhibition of spore germination.
- Determined that serologic data suggest that endpoint ELISA titers do not correlate with predicting immunity to lethal plague challenge, but that other, more specific antibody subtypes may be useful as surrogate markers.
- Demonstrated that the assay for neutralization of anthrax toxin was useful in predicting the probability of survival in rabbits immunized with anthrax vaccine and challenged by the aerosol route.
- Completed sequencing of the GroES protein of *Rickettsia typhi*.
- Patent awarded for gene and protein applicable to the preparation of vaccines for *Rickettsia prowazekii* and *Rickettsia typhi* and the detection of both.
- Developed a nonhuman primate model for aerosolized Brucella, demonstrated that Rhesus monkeys develop bloodstream infection after aerosol challenge with as few as 100 colony forming units of *B. melitensis*.
- Improved a candidate Brucella vaccine strain of *purE*201 by eliminating its antibiotic resistance using gene replacement.
- Established an oral immunization regimen in mice using rough mutants of *B. melitensis*.
- Demonstrated that candidate vaccine strain, a mutant *purE*201, is cleared slowly from profoundly immunodeficient Rag-1 mice, indicating a role for nonspecific host defense in protection against this attenuated strain.
- Determined the DNA sequence of the *Yersinia enterocolitica* large virulence plasmid for comparison with similar plasmid found in *Y. pestis*. Determined that ribotyping is the best method for comparing strains.
- Initiated effort to isolate, characterize and detect ciprofloxacin-resistant *Y. pestis* mutants. Determined the wild-type sequence for genes known to be involved in resistance and characterized 20 resistant mutants.
- Evaluated numerous approaches to identify the enzymatic activities and targets of putative immunosuppressive effects of plague infection *in vivo*.
- Characterized inhibition of neutrophil migration as a potential biological activity of the V antigen of *Y. pestis*.
- Concluded a study on the efficacy in guinea pigs of anthrax vaccine against strains of *B. anthracis* from numerous geographical areas.

Protein Toxins

The countermeasures, technical barriers, and accomplishments in the biological threat category of toxins are outlined below.

Countermeasures:

- Antibodies (antitoxins) directed against common antigens of protein toxin molecules.
- Vaccines for immunity against protein toxin threat agents.
- Confirmatory assays to identify protein toxins specifically or classes of protein toxins.
- Drugs for supportive therapy of agent intoxication.
- Pharmaceuticals to delay or antagonize toxin effects.

Technical Barriers:

- Limited capability to produce large bulk GMP pilot lots of vaccine candidates.
- Lack of suitable epidemiological situations to perform human clinical trials to prove efficacy of vaccines and antitoxins.
- Difficulty in field testing diagnostic assays for toxins under natural conditions.
- Difficulty in producing polyvalent toxoid vaccines effective against classes of toxins.
- Lack of appropriate animal model systems for investigation of some protein toxin threats and countermeasures, or for testing treatment efficacy and safety in humans.
- Difficulty in defining surrogate markers of protection.

Accomplishments:

- Developed first pilot lot for expressing in yeast the C-fragment of BoNT/B made in compliance with the cGMP FDA regulations. This and other C-fragment candidates will be transitioned as potential vaccines.
- Completed the lot release and preclinical testing of the rBoNT/B(Hc) vaccine.
- Developed the fermentation and purification processes for the production of the rBoNT/A(Hc) vaccine.
- Obtained the first x-ray crystal structures for type A BoNT and for the C-fragment of tetanus toxin, a closely related clostridial neurotoxin.
- Determined spectroscopically that the secondary structure of BoNT/A & /B C-fragments in aqueous solution is predominantly composed of negative-strand elements, a result that is consistent with the x-ray diffraction data and with molecular modeling predictions. This information will be useful in the structural characterization of these candidate vaccine products.
- Developed and successfully tested a proof-of-concept DNA vaccine candidate for BoNT/A
- Modeled the secondary structural elements for BoNT/A-G.
- Successfully applied secondary structure and solvent accessibility predictive algorithms to the design of peptides for BoNT/A antibody response.
- Developed in-house the first sets of monoclonal antibodies that neutralize either BoNT/A or BoNT/B.
- Synthesized a potent polypeptide inhibitor for BoNT/A that will be used as a lead compound in future combinatorial chemistry syntheses.
- Screened a variety of thermolysin (the prototypic metalloprotease) inhibitors; effective concentration for the best compound was 20 μm against BoNT/B. This may become another lead inhibitory compound.
- Developed a novel *in vitro* system using biological membranes to examine the physiological activity of BoNT-induced ionic channels and their potential role as a target for chemotherapies to counteract the internalization of the toxin.

- Developed cell-free *in vitro* assays to study the actions of candidate metalloprotease inhibitors on the catalytic activity of botulinum toxin light chain. These systems monitor the rate of cleavage of the substrates synaptobrevin (serotype B) and SNAP-25 (serotype A) by capillary electrophoresis. Emphasis will be placed on greater assay automation and on faster separation of cleavage products.
- A primary mouse spinal cord culture system was examined for its suitability as a cellular model for botulinum toxin research. The cultures were found to be highly sensitive to serotypes A and B but relatively insensitive to serotype E, can be used to study the mechanisms of action of botulinum toxin, and to test therapeutic agents.
- Tested extensively the isolated mouse phrenic nerve hemidiaphragm preparation and found it to be highly suitable for evaluating botulinum toxin antagonists.
- Developed a synthetic approach and began the synthesis of a potential botulinum antidote.
- Maintained Chemical Repository so that putative drugs could be sent for testing against threats, *i.e.*, selected and sent 50 putative antibotulinum toxin agents to USAMRICD, for testing.
- Work on mechanisms of botulinum toxin A and on protectants performed completely *in vitro*, thereby generating scientific progress without performing animal experiments.
- Described the use of a natural peptide, Buforin 1, to inhibit the toxic enzymatic activity of botulinum toxin B, making it a potential drug for counteracting botulinum toxicity.
- The SEB toxoid proteosome vaccine was found to be effective in protecting monkeys from SEB aerosol challenges (10-18 LD_{50}). A comparison study was conducted recently in monkeys for the efficacy of the new soluble SEB toxoid, the SEB toxoid-containing microspheres, and the SEB toxoid formulated with proteosomes.
- Chemically modified histidines of the SEB molecule and studied its biological activities. Used methods of genetic engineering to change the histidine codons of SEB genes by site-directed mutagenesis and cloned the mutated genes in *E. coli*. These SEB mutant proteins are under investigation for use as intranasal vaccines and as therapeutics.
- Completed ultrastructural studies to assess the effect of an incapacitating dose of SEB on Rhesus monkeys following an aerosol exposure. Demonstrated that the chosen SEB dose induced blastogenesis in 52%-57% of lymphocytes indicating high superantigenic activity of the toxin.
- Developed a primate test battery to assess behavioral incapacitation induced by nonlethal exposure to SEB as part of a collaborative effort with Division of Pathology [Walter Reed Army Institute of Research (WRAIR)] and Division of Toxinology (USAMRIID). This accomplishment earned 1998 Army Research and Development Awards for the two WRAIR scientists who directed this project.
- Extended the primate test battery to a touchscreen platform that greatly increases the flexibility and utility of the behavioral assessment capability.
- Demonstrated effectiveness of a newly developed, multi-channel telemetry device that assesses physiological parameters associated with SEB toxicity.
- Established a sublethal SEB exposure time course for dose-dependent production of eicosanoids, neuropeptides and cytokines.
- Identified three potential therapeutic agents against the toxic effects of SEB.
- Began cGMP vaccine recombinant SEB (rSEB) pilot lot, including seed stock,

fermentation, purification, formulation/ vialing, QC testing and documentation, identity and rSEB/cGMP vaccine stability, safety, and reactogenicity.

- Standardized a potency assay for rSEB vaccine.
- Developed surrogate endpoint in animal models that will be used to evaluate the immune response in humans following vaccination for protection against the BW threat.
- Produced a lot of GMP SEB toxin to be used as a reference standard (Battelle/Centre for Applied Microbiology and Research, U.K.).
- Successfully completed bivalent (SEA/SEB) recombinant vaccine 12-month immunogenicity study in nonhuman primates.
- Initiated studies evaluating the effectiveness of SEB vaccines (both toxoid and rSEB) against lethality and incapacitation: nonhuman primate study of toxoid and rSEB vaccines.
- Correlated the structural features of SEB with its functional properties by designing and synthesizing 26 site-specific mutant proteins, sets of synthetic peptide fragments and truncated proteins.
- Identified several peptide fragments of the SEB molecule which in turn were developed into vaccine candidates that elicited neutralizing antisera production without associated effects of SEB toxicity.
- Initiated development of a transgenic mouse model of SE intoxication/incapacitation based on expression of higher affinity human receptor molecules.
- Developed a new and powerful computational method for the rapid prediction and assessment of protein-protein binding modes and their affinities for the genetically engineered mutants of the SEs.
- Predicted the binding characteristics of the rSEB and rSEA proteins with MHC class II molecules, and their oligomerization with T-cell receptors.
- Identified a synthetic SEB peptide capable of blocking binding of SEB to human MHC class II antigen.
- Demonstrated that monoclonal antibodies to TNF alpha and interferon gamma protect mice from a lethal SEB challenge.
- Demonstrated that chlorpromazine, an FDA-approved tranquilizer, protects mice from a lethal SEB challenge, and that pentoxifylline diminished the lethal effects of SE in mice.
- Demonstrated that SEB-induced production of mediators were centrally controlled by a battery of selected protein kinases and inhibitors of several kinase pathways blocked SEB' s biological effects and abrogated SEB-induced lethality in a mouse model.
- Developed a potency assay for deglycosylated A-chain ricin vaccine and submitted a validation plan for this assay for approval.
- Determined that lyophilized deglycosylated A-chain ricin vaccine is chemically stable and maintains its potency for at least 18 months. (PerImmune, Inc.).
- Determined optimum vaccine schedule protecting mice and rats in a lethal aerosol challenge model for ricin.
- Conducted successful general and acute GLP safety testing on deglycosylated A-chain ricin vaccine (PerImmune Inc.).
- Produced a pilot lot of deglycosylated A-chain ricin vaccine in collaboration with an industrial partner (IntraCel).
- Determined high-dose and longevity safety parameters in a mouse model for the

deglycosylated A-chain ricin vaccine.
- Identified surrogate markers for immunological protection against aerosolized ricin.
- Determined the sequence-specific interactions of the ricin-rRNA binding determinant critical for the design of selective N- glycosidase inhibitors.
- Modeled *de novo* designed ricin inhibitors based on substrate analogs.
- Developed a synthetic method and commenced the synthesis of the ricin inhibitor.
- Tested *C. perfringens* iota toxin (a binary, lethal enterotoxin) and found that it does not elicit proinflammatory cytokines from human peripheral blood lymphocytes *in vitro*, unlike other bacterial enterotoxins (*i.e.*, staphylococcal enterotoxins [SE]) that represent BW threats and are very active at inducing a lethal cytokine cascade.
- Began receptor binding studies for iota toxin on various tissue culture cell lines and additional studies are ongoing to characterize the surface receptor on susceptible African green monkey kidney cells.
- Conducted aerosol challenge in rats using spores of *C. perfringens* and determined that this animal species is not susceptible to infection/ intoxination by this route.

Viral Agents

The countermeasures, technical barriers, and accomplishments in the biological threat category of viral agents are outlined below.

Countermeasures:
- Vaccines for immunity against viral threat agents.
- Antibodies and antiviral drugs for treatment of viral disease.
- Devices and technologies for diagnosis of viral disease.

Technical Barriers:
- Lack of appropriate animal model systems for investigation of viral threats and countermeasures.
- Limited capability to produce large bulk GMP pilot lots of vaccine candidates
- Lack of suitable epidemiological situations in which to perform human clinical trials to evaluate efficacy of vaccines.
- Need for production of multivalent vaccines against heterologous viral agents.
- Difficulty in optimizing and comparing different expression vectors for recombinant products (vaccines and antibodies).
- Need for rapid virus identification technology.
- Difficulty in defining of surrogate markers of protection.

Accomplishments:
- Demonstrated that fibroblastic reticulum cells of lymphoid tissue are the early target cells of Ebola virus.
- Discovered that nonlethal infection of Ebola virus confers protective immunity to intraperitoneal (IP) challenge by a subsequent lethal dose of virus.
- Identified a reverse genetic system for Ebola virus in which virus is rescued from a clone copy of the viral genome. This allows manipulation of the genome to create attenuated

viruses for purposes of vaccination.

- Protected a mouse model against filovirus challenge using replicon Ebola virus RNA expressed in the VEE replicon system.
- Demonstrated protection against Marburg virus challenge in guinea pigs immunized using Marburg DNA cloned into a plasmid and delivered using a "gene gun".
- Demonstrated the first successful protection of non-human primates from lethal Marburg virus challenge after immunization with a genetically constructed replicon Marburg virus vaccine.
- Refined animal models of filovirus infection using conjunctival, oral, and aerosol routes of challenge.
- Discovered that a key pathogenic event in Ebola virus infection is destruction of mononuclear phagocytes.
- Discovered that serum from mice immunized against an adapted Ebola virus passively protects naïve mice from lethal disease.
- Identified candidate prophylactic agents for filoviruses, a group of hydrolase inhibitors, to be evaluated in a nonhuman primate challenge model.
- Designed and characterized novel monoclonal antibody complexes, targeting bound Marburg virus, for hepatic immune system clearance.
- Initiated development of an *in vitro* model system of Ebola virus replication that can be used to better understand early stages of virus infection as well as to investigate potential therapeutic compounds.
- Synthesized the enantiomers of 9-(trans-2′,trans-3′-dihydrocyclopent-4-yl)-3-deazadenine for evaluation as potential chemotherapeutic agents against Ebola and Marburg viruses.
- Established purity, stability, and reversion database for the deletion-mutant VEE vaccine candidate, V3526.
- Evaluated three VEE virus vaccines in laboratory mice. Three candidates, formalin-inactivated C-84, live-attenuated TC-83, and deletion-mutant V3526, were evaluated for efficacy and onset and duration of immunity. The V3526 was shown to be more attenuated and more immunogenic in protecting nonhuman primates than TC-83.
- Completed histopathological evaluation of CNS tissue of VEE exposed, susceptible and immunized mice. CNS invasion by VEE challenge is prevented in mice vaccinated with TC-83 or V3526. The deletion mutant V3526 showed significantly less neurovirulence in mice than the TC-83 preparation.
- Demonstrated inability of deletion-mutant V3526 to revert to wild-type VEE in the natural mosquito vector.
- Applied deletion-mutant technology to formulate WEE and EEE vaccine candidates. For WEE the best candidate, WE2102, elicited high serum neutralizing antibody titers in mice, reduced mortality, but did not affect morbidity.
- Generated a live-attenuated molecular clone of VEE subtype IE that appeared to be nonvirulent, immunogenic, and protective in animal models. It may serve as the basis for further development of a vaccine candidate.
- Evaluated the role of antibodies in mice in mediating alphavirus vaccine interference. Found that non-neutralizing antibodies may act at the surface of infected cells to reduce the host response to live alphavirus vaccines.

- Determined in animal models that deletion-mutant V3526 VEE vaccine candidate was less susceptible to interference by pre-existing alphavirus antibodies than the existing TC-83 vaccine.
- Developed a monkeypox model using nonhuman primates to evaluate efficacy of both the licensed and cell-culture-derived replacement vaccines against variola. Both vaccines showed protection against high dose aerosol challenge of monkeypox.
- Demonstrated ability to clone vaccinia glycoprotein genes into an alphavirus (VEE) replicon vector to assess this approach to a genetically engineered smallpox vaccinia.
- Mice immunized with L1R immunogen derived from vaccinia virus and delivered using a "gene gun" were completely protected against a lethal dose challenge of vaccinia.
- Demonstrated efficacy of DNA-polymerase inhibitors against variola virus.
- Demonstrated that monoclonal antibodies specific to L1R of vaccinia virus neutralized the virus in cell culture.
- Conducted histopathologic examination of monkeypox aerosol-challenged nonhuman primates, documenting fibrinonecrotic bronchopneumonia and diffuse dispersal of antigen in airway epithelium and surrounding interstitium.

Diagnostic Assays for Biological Warfare Threat Agents

The accomplishments in the diagnostic assays for biological warfare threat agents are outlined below. The objective of this effort is to develop the capability to confirm in biological samples the initial field diagnosis of a biological warfare threat agent.

Technical Barriers:

- Difficulty in field testing rapid identification kits under natural conditions.
- Lack of rapid confirmatory assays with "gold standard" sensitivity and specificity.
- Limited rapid deployable identification technology.

Accomplishments:

- Evaluated two molecular diagnostic approaches to identify pathogenic orthopoxviruses. These two assays will allow delineation between strains of orthopoxviruses including those that may have been genetically manipulated.
- Developed a specific and sensitive ELISA for *C. perfringens* alpha toxin, a lethal protein produced by all *C. perfringens* strains and intimately linked to the pathogenesis of this microorganism.
- Designed primers for cloning putative genes involved in regulation of iron binding proteins (*tonB*), murein biosynthesis (*murE*), methionine biosynthesis (*metL*, *thrA*), the chaperonins involved in protein translocation to the periplasm (*secE*), and transcription termination (*nusG*).
- Developed strategies and techniques to analyze lymphoid cells exposed (*in vitro* or *in vivo*) to biological or chemical threat agents to catalogue unique patterns of alterations in gene expression to use as surrogate markers of exposure to specific BW agents and predict patterns of impending illness.
- Developed monoclonal antibodies specific for Q fever (phases 1 and 2) to replace existing polyclonal antibodies in existing antigen capture ELISA.

- Developed improved monoclonal antibodies to VC 01 serotypes and developed antigen capture ELISA with improved sensitivity and specificity.
- Developed a monoclonal antibody to *Burkholderia mallei* to replace existing polyclonal antibodies in antigen capture ELISA.
- Developed methods for subtyping *Bacillus anthracis*.
- Developed and optimized methods for the isolation of viral RNA from environmental and clinical specimens.
- Developed an antigen capture ELISA for poxviruses.
- Developed a monoclonal antibody specific for botulinum toxin B to be used in the development of an antigen capture ELISA.
- Developed rapid PCR system for the detection of BW agents to be incorporated into a field deployable laboratory. Successfully field-tested this system for the detection of bacterial agents in aerosol collections.
- Transferred immunochromatographic hand-held assay technology to a selected commercial company for production quantity in service of the Joint Program Office for Biological Defense. Developed a prototype hand-held assay housing for its portability.
- Developed SEB, Ricin, *B. anthracis*, botulinum toxins A and B, and *F. tularensis* detection assays using the Bidiffractive Gating Biosensor.
- Constructed database of known DNA sequences relating to organisms of biological warfare concern. Currently includes over 4,800 genes. Continuing to add new DNA sequences and other capabilities to the database.
- Developed rapid, sensitive and specific immunochromatographic hand-held assays for SEA, SEC, Q fever, and *Y. pestis* non-F1.
- Developed rapid, single step PCR assays for the following agents: *B. anthracis*, *Y. pestis*, *Vibrio cholerae*, *Clostridium botulinum* A, *Clostridium botulinum* B, orthopox virus, and Venezuelan equine encephalitis (VEE) virus. These rapid PCR assays use fluorescent biosensor detectors capable of detection of BW agents in less than 25 minutes.
- Identified in collaboration with Lawrence Berkeley National Laboratory a new, chromosomal DNA marker for the identification of *B. anthracis* and developed PCR assays using that marker.
- Developed rapid, sensitive and specific immunochromatographic hand-held assays for VEE, pox, and Ebola viruses.
- Developed recombinant antibodies to ricin and botulinum toxin E that are being incorporated into diagnostic assays.

D.2.3 Advanced Development Accomplishments

The Joint Program Office for Biological Defense (JPO-BD) is a DoD chartered agency to provide intensive centralized management of medical and non-medical programs to expedite materiel solutions for validated biological defense deficiencies. Vaccine products will be further developed by the Joint Vaccine Acquisition Program (JVAP) under the auspices of the JPO-BD. Medical devices, diagnostics, and therapeutics will continue to be developed by USAMMDA. Vaccines directed against high threat agents will be produced and stockpiled to fulfill a 1.2 million Troop Equivalent Doses (TEDs) requirement [TED = the amount of vaccine required to

immunize a service member to protect against a biological warfare agent] . Vaccines against low threat agents will be produced to fulfill a 300,000 TEDs requirement.

The following products have transitioned from Tech base R&D to advanced development and are managed and funded by JPO-BD.

D.2.3.1 Botulism Immune Globulin (Human), Pentavalent (IND #1332)

- The IND remains open to accommodate emergency treatment requirements for exposure or possible exposure to botulinum toxin types A, B, C, D, or E.

D.2.3.2 Botulinum Type F Toxoid Vaccine (IND #5077)

- Completed the Phase 2 Safety and Immunogenicity clinical study of Botulinum Type F Toxoid Vaccine. The purpose of this study is to identify a vaccination schedule and route of vaccination that is safe and maximally immunogenic.
- The 12-month serology after the primary three-inoculation series of vaccinations has was drawn from the last cohort in the Phase 2 study and demonstrated that the immunogenicity of the purified Botulinum Type F Toxoid.
- The 1-year booster phase of the Phase 2 study is complete and 142 sera were above 0.25 IU/ml of antibody demonstrating the effectiveness of this vaccine.
- Provided product for a laboratory comparison of F toxoid with recombinant Fc product in animal efficacy experiments.

D.2.3.3 Anthrax Vaccine Human Adsorbed

- The sale of Michigan Biologic Products Institute (MBPI) by the state of Michigan was finalized. MBPI was purchased by BioPort that consists of the management team from MBPI and outside capital; it is a private sector entity without state of Michigan affiliation.
- Managed and funded efforts leading to the submission of a PLA amendment to the FDA for Anthrax Vaccine Adsorbed. The data was submitted to reduce the current schedule of six doses to a five-dose schedule that will provide protection against aerosol exposure to anthrax.
- Managed the anthrax vaccine production and stockpile to ensure sufficient vaccine is available to support the Secretary of Defense' s anthrax immunization efforts.
- DoD continued to provide technical assistance to MBPI/BioPort to identify and correct FDA compliance deviations.
- Funded and provided oversight of production facility upgrades and ancillary support function renovation at BioPort that are critical to maintaining anthrax vaccine availability

D.2.3.4 Botulinum (Pentavalent) Toxoid Adsorbed (ABCDE) (IND#3703)

- Indemnification was granted for the conduct of the pivotal clinical trial for product approval.

- Protocol written and approved for pivotal clinical study. This protocol was briefed to the FDA April 1998 and accepted after coordination.
- Animal studies were completed demonstrating the equivalence of intramuscular (IM) and IP administration of toxin challenge doses. This study validated the use of the IP route of administration.
- Final reports were submitted to the FDA documenting (1) the validation of assays and the passive transfer of human antibody to an animal model (*i.e.*, guinea pig) in support of the Pentavalent Botulinum Toxoid vaccine licensure.
- A study demonstrating the effectiveness of human toxin neutralizing antibodies as a surrogate correlate of efficacy/protection against aerosol challenge with botulinum toxin was successfully completed.
- A botulism IM challenge study demonstrating the protective efficacy of human neut ral-izing antibodies transferred to guinea pigs was completed. This study will provide the data for the protective geometric mean titers for each of the botulinum serotypes.

D.2.3.5 Botulism Immune Globulin $F(ab')_2$, Heptavalent, Equine, Types A, B, C, D, E, F, & G IND (#7451)

- Contracted for continued stability testing of the product.
- Filed IND with the FDA.
- Initiated Phase 1 Safety and Pharmacokinetics clinical study.
- Provided Botulinum Antitoxin Standards to Battelle Medical Research and Evaluation Facility used for the development of the Pentavalent Botulinum Toxoid (ABCDE).
- Manufactured 4,913 doses of cGMP Botulism Immune Globulin.

D.2.3.6 Botulism Immune Globulin (Human), Pentavalent (IND #1332)

- Conducted storage stability testing on this IND product.
- The IND remains open to accommodate emergency treatment requirements for exposure or possible exposure to botulinum toxin types A, B, C, D, or E.

D.2.3.7 Botulinum Type F Toxoid Vaccine (IND #5077)

- Completed the Phase 2 Safety and Immunogenicity clinical study of Botulinum Type F Toxoid Vaccine. The purpose of this study is to identify a vaccination schedule for the vaccine that is safe and maximally immunogenic.
- Provided product for a laboratory comparison of the F toxoid with a recombinant Fc product in animal efficacy experiments.

D.2.4 Joint Vaccine Acquisition Program (JVAP) Accomplishments

D.2.4.1 Prime Systems Contract

- The JVAP was initiated to consolidate all required manu facturing, testing, human clinical trial, logistical and regulatory expertise necessary to develop and license vaccines to protect against validated biological warfare agent threats.
- The JVAP prime system contract was awarded to DynPort Limited Liability Corpor ation (LLC) on 7-Nov-97. The basic contract consists of the storage, distribution and testing of the DoD contingency stockpile of Biological Defense (BD) vaccines and the development and licensure of 3 BD vaccines: Q-fever vaccine, Tularemia vaccine, and Vaccinia Virus vaccine. The contract has options for the development and licensure of an additional 15 BD vaccines. These options will be exercised as promising vaccine candidates transition into advanced development.
- Began work 2-Mar-98 after GAO resolution of contract award protest.
- Continued advanced development of these BD vaccine candidates through DynPort' s use of government laboratories and facilities as DynPort' s application for indemnification of unusually hazardous risks was being processed.
- DynPort is participating with government tech-base to help vaccine candidates transition into advanced development faster with reduced risk.
- Coordinated and conducted a meeting with the FDA to update Center for Biologics Evaluation and Review staff on the JVAP, to introduce the JVAP-Project Management Office and their Prime Systems Contractor (DynPort) and to describe the current vaccines included in the program.

D.2.4.2 Contingency Stockpile of Biological Defense (BD) Vaccines

- Transfer of the contingency stockpile of Biological Defense vaccines from the Salk Institute Biologics Development Center to McKesson BioServices was completed. McKesson BioServices is the DynPort sub-contractor for vaccine storage and distribution. McKesson BioServices has a state of the art facility dedicated to the storage of the BD investigational new drug (IND) contingency stockpile. The facility features redundant security systems, fully automated temperature monitoring, back up power system that ensures fully automatic transfer to a natural gas generator, and the capacity to meet the current and projected stockpile storage requirements.

D.2.4.3 Advanced Development of the Tularemia Vaccine

- Reviewed historical records and identified technical and regulatory issues to form the basis for a scientifically sound, feasible plan for the advanced development of a live attenuated tularemia vaccine.
- Selected a National Drug Company vaccine candidate as parent seed for development of the new vaccine for tularemia.
- Initiated process definition studies at the Life Science Division, Dugway Proving Ground to characterize large scale manufacturing procedures for the new tularemia vaccine.

D.2.4.4 Advanced Development of the Q-fever Vaccine

- Reviewed historical records and identified technical and regulatory issues to form the basis for a scientifically sound, feasible plan for the advanced development of a Q-fever vaccine.
- Met with a potential manufacturing subcontractor to discuss how their product meets our user' s requirement.
- JVAP has received concurrence from our user about the suitability of this vaccine candidate.

D.2.4.5 Advanced Development of the Smallpox Virus Vaccine (Vaccinia Virus)

- Reviewed historical records and identified technical and regulatory issues to form the basis for a scientifically sound, feasible plan for the advanced development of a cell culture vaccinia vaccine for smallpox.
- Prepared a clinical protocol to evaluate the candidate vaccines administered by scarification.
- Guided protocol through all internal review boards and FDA review.
- Initiated process definition studies to evaluate large-scale production methods.
- Began discussions with the Department of Health and Human Services about the feasibility of scale-up production for the DoD vaccine to obtain for a civilian stockpile.
- Clinical protocol has stalled due to regulatory concerns about Vaccinia Immune Globulin, which is required before immunizations can take place.
- Baxter, current license holder for VIG, no longer plans to manufacture this product. JVAP market survey information from potential manufactures is being forwarded to DynPort to manage a new manufacturing and licensure effort for this product.

D.2.4.6 International Cooperative Research and Development

- The JVAP-Project Management Office conducted technical discussions with representatives of the United Kingdom and Canada about cooperative research and development agreements for Biological Defense vaccine products. A conceptual approach to tri-national cooperative research and development has been developed and is under review by the JPO-BD.
- Proposed recombinant plague vaccine candidates from the U.S. and United Kingdom recently underwent a pre-IND review at the FDA. This collaborative approach between the two countries leverages tech-base and advanced development efforts to provide a safe and effective vaccine protecting against aerosol exposure to *Yersinia pestis*.

D.3 MEDICAL NUCLEAR (RADIOLOGICAL) DEFENSE RESEARCH PROGRAM

D.3.1 Fielded Products

Advances in medical R&D significantly impact the warfighting mission by sustaining unit effectiveness through conserving the fighting strength of our service members. The indiv idual service member whose performance is decremented by illness is significantly more likely to become a traumatic casualty. In this era of small, but highly lethal forces, loss of only a few team members can dramatically diminish a unit' s capability. Medical R&D products (materiel and non-materiel solutions) provide the foundation that ensures the fielding of a flexible, sustainable, modernized force across the spectrum of conflict and in the full breadth and depth of the battlefield. Overcoming medical threats and extending human performance have provided a significant increase in military effectiveness in the past and present the potential for future enhancement on military operational effectiveness. Some of the fielded materiel and non-materiel solutions by medical radiological defense R&D are:

- Cytokine-based therapeutic applications to prevent the two major fatal syndromes—sepsis and uncontrolled bleeding —following acute radiation injury.
- Cytogenetic biodosimetry service operating to measure individual radiation exposure using blood samples.
- NATO Handbook on the Medical Aspects of NBC Defensive Operations, Volume 1-Nuclear (AMedP-6).
- Medical Effects of Ionizing Radiation (MEIR) Course—Training for approximately 660 Medical Department personnel in FY98.
- Videotapes and CD-ROM of MEIR course lectures produced for distribution to military medical units.

D.3.2 Nuclear Defense Research and Development Accomplishments

The nuclear (or radiological) defense research and development technical barriers and accomplishments during FY98 are grouped in the following threat categories:

- Prompt high-dose radiation.
- Protracted low-dose radiation.
- Combined radiation and chemical or biological agents.
- Embedded Depleted Uranium.

"*Prompt high-dose radiation*" refers to the deposition of high-energy radiation in biological tissues in very short periods of time. Sources of high-energy radiation include emissions within the first 60 seconds of a nuclear weapon detonation and "criticality events" that occur when a nuclear reactor achieves peak energy output either accidentally or through an intentional act. The high linear-energy-transfer imparted by the neutrons of these sources causes significant

tissue injury within seconds of exposure, resulting in both short- and long-term health consequences.

"*Protracted low-dose radiation*" refers to the deposition of low-energy radiation in biological tissues over extended periods of time. Sources of low-energy radiation include fallout from nuclear weapon detonations, radiological dissemination devices, and any other source of environmental radiation contamination. Health consequences are generally intermediate- to long-term and result from cumulative tissue injury accruing over time due to chronic exposure. Health consequences can be exacerbated further when radionuclides are deposited internally by ingestion, inhalation or through open wounds in the external integument.

"*Combined radiation and chemical or biological agents*" refers to the amplified health consequences when chemical or biological insults are incurred in conjunction with radiological injury. Both clinical and subclinical exposures to ionizing radiation compromise host defenses against a variety other stressors, including infectious agents and chemical toxicants. Exposures to doses of radiation and infectious or chemical agents that are by themselves sublethal can produce mortality rates of nearly 100% when combined.

"*Embedded Depleted Uranium*" refers to the metal used in penetration munitions and armor and the resultant radiological and toxicological consequences to personnel injured by embedded fragments of these munitions. Because of the unique and poorly understood radiological and toxicological properties of embedded depleted uranium, knowledge of the immediate and long-term risks is limited. Current treatment strategies are not well developed for personnel with tissue embedded depleted uranium and conventional diagnostic capabilities make it difficult to ascertain that personnel are injured with embedded depleted uranium.

The Medical Radiological Defense Research Program focuses on developing medical countermeasures to the health consequences of both prompt high-dose and protracted low-dose exposures to ionizing radiation. It also develops experimental data detailing combined NBC medical effects needed by computer modeling programs for casualty prediction. Specific research on medical countermeasures includes work on prophylactic and therapeutic drugs, drug delivery devices to enhance efficacy and simplify administration under field conditions, and combined prophylactic/therapeutic protocols to further enhance efficacy. Work also focuses on developing novel biological dosimetry techniques to measure individual absorbed doses. Knowledge of the dose of radiation absorbed helps guide medical treatment decisions and saves lives. It also provides field commanders with an assessment of the radiological health of deployed forces and leads to better-informed operational decision making.

Threat Category: Prompt High Dose Radiation

The countermeasures, technical barriers, and accomplishments in the threat area of prompt high dose radiation are outlined below.

Countermeasures:

- Advanced medical treatment strategies for radiation injuries.

- Drugs designed to increase resistance of soldiers to radiation and protect the soldier against radiation injury without compromising performance.
- Drugs designed to prevent the onset of radiation-induced performance decrements such as fatigue, nausea and vomiting.
- Biological dosimetry techniques for rapid injury assessment needed to guide medical treatment decisions and assessment of radiological health of combat units.

Technical Barriers:

- Need for reduction of the performance-degrading toxicity of prophylactic drugs that otherwise have good efficacy for the prevention of radiological injury.
- Need to advance knowledge of cellular, sub-cellular and molecular mechanisms of radiological injury to improve rational development of prophylactic and therapeutic drugs.
- Need for extending the stability of a prophylactic drug to allow its use in a slow-release delivery device for extended bioavailability and enhanced efficacy.
- Difficulty in identifying and calibrating biological markers that can both indicate the amount of absorbed radiation dose and differentiate whole-body from partial-body exposure.
- Inability to automate sample preparation and reducing sample preparation times of cytogenetic biodosimetry tests.

Accomplishments:

- Completed pilot demonstration of improved clinical support protocol (modified antibiotic and platelet transfusion regimens) for acute, potentially fatal radiation injury.
- Continued assessment and optimization of a combined radioprotectant, cytokine, and clinical support treatment modalities for enhancing survival following acute, lethal irradiation.
- Developed new prophylactic strategy for reducing acute radiation injury based on (a) apoptotic and reproductive mechanisms-based tissue injury and pathology, (b) low-toxicity drug selection, (c) pharmacologic quenching to further reduce toxic side effects, and (d) new drug delivery alternatives.
- Simplified sample preparation procedure used in cytogenetic assays to assess biologically absorbed radiation dose.
- Completed initial studies extending the application of radiation dose measuring protocols to exposure scenarios involving incremental doses of gamma and fission neutrons.

Threat Category: Protracted Low Dose Radiation

The countermeasures, technical barriers, and accomplishments in the threat area of protracted low dose radiation from nuclear fallout, radiological explosive devices, etc ., are outlined below.

Countermeasures:

- Advanced medical treatment strategies for protracted radiation to mitigate injuries from both external and internal sources of radioactivity.

- Drugs designed to protect personnel from the early and late effects of ionizing radiation without compromising performance pharmacologic intervention strategies that protect against both early and late health effects arising from cellular and molecular damage caused by ionizing radiation.
- Improved techniques to detect and remove internally deposited sources of radioactivity
- Improved drug delivery systems that provide non-encumbering protection during the entire period of radiation exposure.
- Enhanced biodosimetry technique that can differentiate prior from recent exposures to radiation.

Technical Barriers:

- Lack of suitable radiation sources to study the effects of chronic exposure at relevant doses.
- Difficulty in manipulating cellular repair mechanisms.
- Toxicity of chelating agents used to remove sources of radioactivity.
- Brief periods in which traditional radioprotective drugs are active.
- Toxicity of radioprotective drugs used over protracted periods of time. Limited knowledge of DNA damage surveillance and repair mechanisms under protracted exposure conditions hinders development of pharmacologic agents to prevent late-arising cancers.
- Need to reduce the toxicity of heavy metal chelating agents while maintaining their efficacy.
- Need to extend bioavailability of prophylactic drugs to achieve maximum long-term protection.
- Potential cumulative toxicity of prophylactic drugs (antimutagenic and anticarcinogenic agents) when used for extended periods.
- Lack of a sustained drug delivery system of radioprotectants.
- Microbial resistance to antibiotics.

Accomplishments:

- Developed new prophylactic strategy for reducing chronic radiation injury based on (a) improved understanding of tissue damage and repair and subsequent late-arising disease, (b) selection of low-toxicity drugs that enhance tissue repair and minimize gene mutations, and (c) new slow release drug delivery systems that extend the radioprotective window.
- Established therapeutic drug assay to monitor blood levels of prophylactic drugs in support of studies to develop sustained drug delivery systems.
- Demonstrated use of implanted capsules as possible approach to provide sustained efficacious delivery of prophylactic drugs.
- Developed novel protocols using a fluorometric PCR for precise quantifiable measurements of molecular responses to radiation (oncogene expression, mitochondria DNA deletions) that can provide advanced biological markers for radiation dose assessments.
- Observed that ionizing radiation induces a specific deletion in mitochondrial DNA and alterations in oncogene mRNA expression, both of which appear to occur in dose-

dependent fashions.

Threat Category: Combined Radiation and Chemical or Biological Agents

The countermeasures, technical barriers, and accomplishments in the threat area of combined effects of nuclear ionizing radiation with trauma, burns, infection, or chemical toxicants radiation and trauma, burns, and infection are outlined below.

Countermeasures:

- Radiotherapeutic agents designed to decrease morbidity and mortality from multi-organ system failure due to the combined effects of radiation, trauma, burns, and infection or chemical toxicants.
- Radioprotective drugs designed to harden the soldier against the effects of radiation in combination with trauma, burns, infection, or chemical toxicants.
- Combined therapeutic agents designed to decrease morbidity and mortality from combined exposures and to enhance innate immune responses.
- Computer models for predicting casualties following combined exposure to low levels of ionizing radiation and biological warfare/chemical warfare agent aerosols.

Technical Barriers:

- No surrogate models for extrapolating data to humans.
- Limited animal models that are optimum for both radiation and a biological warfare or chemical warfare agent.
- Need to gain access to radiation sources and biological containment facilities in order to complete full range of experiments on combined effects of radiation and BW agents.
- Growing number of microbial organisms resistant to antibiotics.
- Accounting for variability in sensitivities of biological systems to different radiation qualities (*e.g.*, neutron *vs.* gamma radiation).
- Mechanism of action of cell-growth factors is not well understood.
- Sensitivity of bone marrow progenitor cells to low doses of ionizing radiation.

Accomplishments:

- Quantified increased mortality rates in irradiated mice infected via pulmonary route with *Bacillus anthracis* (Sterne) spores.
- Initiated studies to assess effects of radiation on immune status after vaccination with anthrax vaccine.
- Established in vitro and in vivo model systems to assess radiation/viral interactions.
- Established capability to integrate health consequences of radiation/biological warfare agent interactions, extrapolated from animal model studies, into the Consequence Assessment Tool Set (CATS).
- Identified synergistic consequence of combined exposure to sublethal radiation and therapeutic levels of PB resulting in redistribution of blood flow.
- Developed enhanced treatments for radiation-associated infections using immune system stimulators.

Threat Category: Embedded Depleted Uranium

The countermeasures, technical barriers, and accomplishments in the threat area of embedded depleted uranium are outlined below.

Countermeasures:

- Rapid assessment clinical analyses to identify personnel wounded with embedded depleted uranium.
- Safe and effective treatment strategies to minimize long-term health risks.

Technical Barriers:

- Determining the redistribution and toxicological consequences of exposure to embedded fragments of depleted uranium.
- Developing the reagents needed to improve sensitivity of tests to detect uranium.
- Developing or modifying pharmacological treatments to increase efficacy and reduce toxicity.

Accomplishments:

- Determined from studies designed to simulate embedded depleted uranium that depleted uranium from embedded fragments distributes to tissues far from the site of implantation.
- Described preliminary findings of carcinogenicity, neurotoxicity, and immunotoxicity of embedded depleted uranium fragments.
- Developed a new method for the colorimetric measurement of urinary uranium concentration.
- Developed a new method for the identification of uranium fragments in wounds.

D.3.3 Predevelopment Products

Technical developments in predevelopment products for medical radiological defense include the following:

- *Iloprost/Misoprostol/3D-MPL/WR-3689*
- "Slow release" radioprotectant for longer protection time for individuals at risk of high, potentially lethal levels of ionizing radiation.
- Nontoxic immune system stimulator for protection against radiation-induced immunosuppression and associated infection.
- CATS model enhancements to incorporate radiation/BW interactions.
- Product improvement of the cytogenetic biodosimetry system by automation of satellite scoring subsystem to increase sample throughput.
- Rapid and sensitive method to measure urinary uranium concentration.

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Annex E

Joint Nuclear, Biological, and Chemical, Defense Program Funding Summary

In accordance with 50 USC 1522, *Department of Defense Chemical and Biological Defense Program*, RDT&E for all DoD chemical and biological defense programs (with the exception of those conducted by the Defense Advanced Research Projects Agency, DARPA) are consolidated into six defense-wide program element (PE) funding lines plus procurement funds are consolidated. Detailed funding information previously contained in this annex is provided annually to Congress in the Joint Service Chemical and Biological Defense Program, President' s Budget Submit, Descriptive Summaries of Research, Development, Test and Evaluation, and in the Department of Defense Extract found in the Budget of the United States. These budget submissions provide a detailed account of prior year accomplishments and planned activities for the budget request period. Table E-1 (and Figure E-1) provides a summary of appropriated and requested funding from FY96–FY03. FY96 was the first year in which all Service and Defense Agency CB defense programs were consolidated into defense-wide funding lines. Prior to FY96, funding was included in several separate Service and Defense Agency funding lines. Also, during FY96 approximately $30 million was transferred to the CB Defense Program procurement line from Army operations and maintenance accounts for biodefense vaccine acquisition. Much of the growth in the program between FY96 and FY97 resulted from the transfer of funds between existing accounts rather than real growth in the overall CB Defense Program.

Table E-2 provides a summary of expenditures by the DoD Chemical and Biological Defense Program. Expenditures represent the amount of checks issued or other payments made (including advances to others), net of refunds and reimbursements. The term is frequently used interchangeably with the term "outlays," which are the measure of government spending (*i.e.*, payments to liquidate obligations (other than the repayment of debt), net of refunds and offsetting collections. It is important to note that funds appropriated for a given year may be expended incrementally over a period of years. Thus, expenditures shown in Table E-2 will be updated in following years to show total expenditures of appropriated funds.

Table E-1. Chemical and Biological Defense Program Appropriations Summary

Program Element (PE) ($ millions)	FY96‡	FY97‡	FY98‡	FY99‡	FY00*	FY01*	FY02**	FY03**	FY04**	FY05**
0601384BP - Basic Research	26.492	28.372	25.263	29.500	31.386	31.332	29.705	30.245	31.256	32.286
0602384BP - Applied Research	68.571	70.823	69.329	63.992	64.780	68.024	81.787	83.159	74.556	77.226
0603384BP - Advanced Tech. Dev.	33.727	41.693	43.517	52.212	40.910	44.881	52.169	61.227	81.949	79.738
0603884BP - Demonstration/Validation	29.184	44.747	51.886	60.227	62.033	89.510	65.830	73.463	72.073	47.004
0604384BP - EMD	87.229	97.468	120.624	110.943	116.365	100.296	165.639	172.041	110.967	79.050
0605384BP - Management Support	6.954	17.936	21.441	24.849	24.043	24.054	24.692	25.211	24.892	25.637
0605502BP - Management Support/Small Business Innovative Research (SBIR)	0.000	0.000	5.612	0.000	0.000	0.000	0.000	0.000	0.000	0.000
RDT&E Subtotal	**252.157**	**301.039**	**337.672**	**341.723**	**339.517**	**358.097**	**419.822**	**445.346**	**395.693**	**340.941**
Procurement	135.647	232.952	233.943	303.656	377.396	399.673	417.170	426.827	484.852	524.167
CB Defense Program Total	**387.804**	**533.991**	**571.615**	**645.379**	**716.913**	**757.770**	**836.992**	**872.173**	**880.545**	**865.108**

‡ Total Obligation Authority (TOA)
* President' s Budget Request
** Estimated [from President' s Budget]

Table E-2. Chemical and Biological Defense Program Expenditures Summary

Program Element (PE) ($ millions)	FY96†	FY97†	FY98†
0601384BP - Basic Research	25.353	24.939	18.153
0602384BP - Applied Research	63.411	59.150	36.582
0603384BP - Advanced Technology Development	31.131	39.250	17.603
0603884BP - Demonstration/Validation	28.549	22.673	25.614
0604884BP - Engineering & Manufacturing Development	77.581	68.413	48.940
0605384BP - Management Support	5.236	16.657	13.819
0605502BP - Management Support/SBIR	0.000	0.000	0.437
RDT&E Subtotal	**231.261**	**231.082**	**161.148**
Procurement	109.080	130.508	36.261
CB Defense Program Total	**340.341**	**361.590**	**197.409**

† Expenditures as of September 30, 1998.

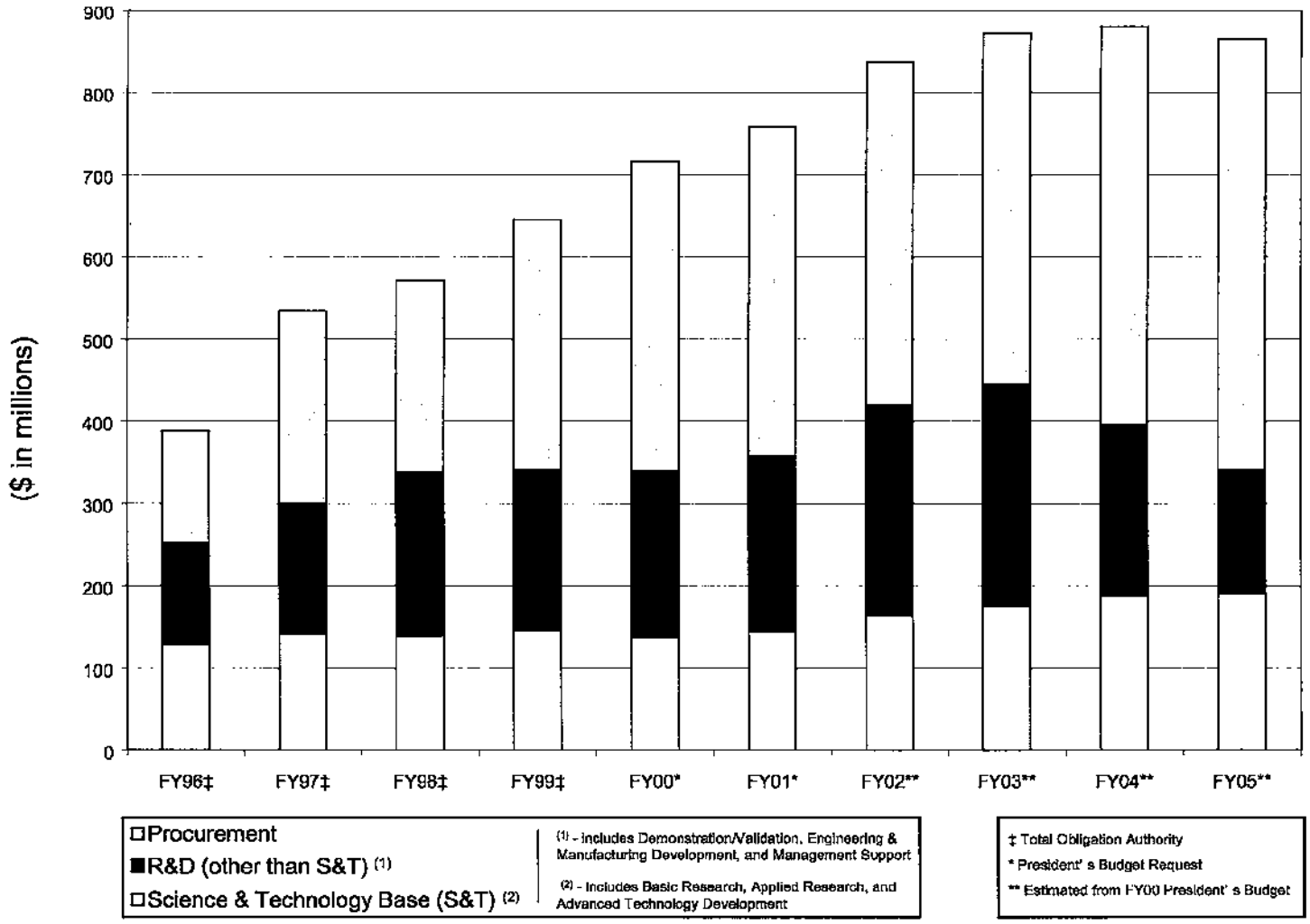

Figure E-1. Chemical and Biological Defense Program Appropriations Summary

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Annex F

Nuclear, Biological, and Chemical Defense Internet Sites

Following is a list of selected locations on the internet that nay provide information about nuclear, biological, and chemical defenses. This list is not intended to be exhaustive, but rather to aid those in the research and analysis of NBC defense issues. Identification of a site here does not represent an endorsement by the Department of Defense nor any of its subordinate organizations, nor any responsibility for the content or accuracy of information provided at each site. Site locations (URLs) may change or be deleted, but were accurate as of January 1, 1999.

DefenseLink
http://www.defenselink.mil/
The official home page of the Department of Defense. Includes numerous reports and links to DoD organizations.

Defense Threat Reduction Agency
http://www.dtra.mil
Home page of the Defense Threat Reduction Agency). Includes information on each of the major mission areas and Directorates at DTRA.

CBIAC (Chemical Warfare/Chemical Biological Defense (CW/CBD) Information Analysis Center)
http://www.cbiac.apgea.army.mil/
CBIAC serves as the DoD focal point for CW/CBD technology. The CBIAC serves to collect, review, analyze, synthesize, appraise and summarize information pertaining to CW/CBD. It provides a searchable database for authorized users and links to many other CW/CBD related sites.

The NBC Medical Defense Information Server
http://www.nbc-med.org/
The Nuclear Biological and Chemical Medical (Med-NBC) web page contains extensive medical documentation, training material, audio-video clips, a powerful search engine, and links to other related internet sites.

The Army Medical Department Center and School
http://www.armymedicine.army.mil/armymed/
Provides extensive information about the Army' s Medical Department. Includes information on doctrine development and the use of medical NBC defense products.

U.S. Army Soldier and Biological Chemical Command Information Server
http://www.sbccom.apgea.army.mil/
Home page of the U.S. Army Soldier and Biological Chemical Command.

Edgewood Research, Development and Engineering Center (ERDEC) Home Page
http://www.sbccom.apgea.army.mil/RDA/erdec/
ERDEC is the Army's principal R&D center for chemical and biological defense technology, engineering, and service. Provides technical and other information on ERDEC's products and services.

Joint Service Chemical Biological Information System (JSCBIS)
http://www.sarda.army.mil/jscbis/jscbis.htm
Provides financial and programmatic information for DoD' s Chemical and Biological Defense Program. Requires user identification and password, which can be applied for through the home page.

Dugway Proving Ground Home Page
http://www.atc.army.mil/~dugway/
Home page of the U.S. Dugway Proving Ground, location of much of the field tests of chemical and biological defense equipment and repository of historical chemical and biological warfare information.

Chemical and Biological Weapons Nonproliferation Project
http://www.stimson.org/cwc/
This project serves as a problem-solver and an information clearinghouse in the general subject areas of CB treaties, chemical demilitarization (especially in Russia), CB terrorism, and related areas. Sponsored by The Stimson Center.

The PTS-OPCW-PrepCom Home Page
http://www.opcw.nl/
The home page of the Provisional Technical Secretariat, the Organization for the Prohibition of Chemical Weapons, and the Preparatory Commission of the Chemical Weapons Convention (CWC). Provides detailed information about the CWC, its implementation, and technical and background information on chemical weapons, chemical defenses, and related subjects.

United States Army Chemical School
http://www.mcclellan.army.mil/
Home Page for Fort McClellan, Alabama. Provides information on the U.S. Army Chemical School located at Fort McClellan, Alabama which is one of the most advanced and sophisticated training centers for chemical and biological defense. Also provides information on the Chemical Corps Museum.

Harvard Sussex Program on CBW Armament and Arms Limitation
http://fas-www.harvard.edu/~hsp/
Provides files that promote the global elimination of chemical and biological weapons and to strengthen the constraints against hostile uses of biomedical technologies.

Medical Chemical and Biological Defense
http://mrmc-www.army.mil/
Provides information on Medical Chemical Defense Overview, Nerve, Agents, Cyanide, Skin Decontamination and Protection, Performance Effects of Protectant Drugs, and Chemical Casualty Management. Linked to the Medical Research and Materiel Command Home Page and the U.S. Army Medical Research Institute for Chemical Defense Home Page (http://chemdef.apgea.army.mil). Also provides information on Medical Biological Defense Overview, Diagnostic Assays, Viruses, Bacteria, and Toxins, Drugs, Vaccines, and Biological Casualty Management.

United States Army Medical Research Institute of Infectious Diseases
http://www.usamriid.army.mil
Home Page of the U.S. Army Medical Research Institute of Infectious Diseases, location of much of the science and technology research efforts for medical biological defense.

Armed Forces Radiobiological Research Institute (Medical Radiological Defense)
http://www.afrri.usuhs.mil/
Provides information on Medical Radiobiological research and education activities of the triservice Armed Forces Radiobiological Research Institute. The site includes information on the latest developments, products, resources, research approach, strategy, research teams/staff, outreach training, professional meetings, and links to related sites.

Defense Advanced Research Projects Agency (DARPA)
http://www.darpa.mil/
Home Page of DARPA describes basic and applied research and development projects being performed for DoD. Link to the Defense Sciences Office (DSO) provides a link to the Biological Warfare Defense (BWD) Program (http://www.bwd.org/).

Joint Service Tech Base Planning for CB Defense
http://www.techbase.tasc.com/techbase/
This site is the Internet Center for all FY98 CB Tech Base Planning. It provides technology roadmaps and information about the Joint Service tech base business areas, solicitations, and points of contact. Also links to the Joint Science and Technology Panel for Chemical/Biological Defense (JSTPCBD).

Program Manager for Chemical Demilitarization
http://www-pmcd.apgea.army.mil/
Provides information on the Chemical Stockpile Disposal Program, the Non-Stockpile Chemical Materiel Program, the Alternative Technologies Program, the Chemical Stockpile Emergency Preparedness Program, and the Cooperative Threat Reduction Office.

ACDA Home Page
http://www.acda.gov/
Home page of the Arms Control and Disarmament Agency. Provides information on nuclear, biological, and chemical weapons and how their delivery systems pose a major threat to our security and that of our allies.

Cal Poly CBW Page
http://www.calpoly.edu/~drjones/chemwarf.html
This page was developed by the students in Chem 450 at Cal Poly, SLO, during Spring, 1996. The goal is to provide an overview of chemical and biological warfare, weapons, and efforts to outlaw them. This site provides a comprehensive overview of numerous aspects of chemical and biological warfare and defenses.

Joint Vaccine Acquisition Program
http://www.Armymedicine.army.mil/jvap
Home page of the Joint Vaccine Acquisition Program Office, provides program history, programmatic information concerning the DoD efforts to produce vaccines against biological warfare agents

NBC Industry Group
http://www.erols.com/nbcgroup/
Home page of the NBC Industry Group, an association of organizations supporting NBC defense, domestic preparedness, and the Chemical Weapons Convention.

Joint Program Office for Biological Defense
http://www.jpobd.net
Home page of the Joint Program Office for Biological Defense. The site is currently being developed and will include information concerning the DoD biological defense acquisition programs managed by the Joint Program Manager for Biological Defense to include enhanced detection systems, Hand Held Immunochromatographic Assays (HHAs), the Joint Field Trials (JFTs), medical products and vaccines.

Annex G

Statement Regarding Chemical and Biological Defense Programs Involving Human Subjects

The reporting requirement (50 USC 1523) for the annual report to Congress on the DoD Chemical and Biological Defense Program was modified by Section 1086 of the FY98 National Defense Authorization Act. The amendment requires the following information:

> A description of any program involving the testing of biological or chemical agents on human subjects that was carried out by the Department of Defense during the period covered by the report, together with a detailed justification for the testing, a detailed explanation of the purposes of the testing, the chemical or biological agents tested, and the Secretary's certification that informed consent to the testing was obtained from each human subject in advance of the testing on that subject.

Table F-1 provides a summary of prior and planned tests conducted by the Department of Defense, both directly or under contract, which involve the use of human subjects for the testing of chemical or biological agents. In summary, there has been no such testing since 1969 with biological agents, since 1975 for chemical agents, and no testing is planned.

Table F-1. Summary of Experiments and Studies with Human Subjects Involving the Use of Chemical or Biological Agents

November 25, 1969	–	Human biological agent testing ended
July 28, 1975	–	Human chemical agent testing ended
Since 1969/1975	–	No activities with human subjects involving exposure to biological agents (since 1969) nor chemical agents (since 1975) have occurred since testing ended

The Department is in full compliance with the requirements of all laws regarding the use of human subjects involving chemical or biological agents. DoD is involved in no experimentation or any other efforts which involve the exposure of human subjects to chemical or biological agents.

As part of the DoD Chemical and Biological Defense Program, DoD requires the use of small quantities of chemical and biological agents in the research, development, test and evaluation (RDT&E) of detection, protection, and decontamination equipment and systems. Chemical and biological agents are also used in small quantities in training U.S. forces to operate in protective equipment and to operate detection and decontamination systems in a

chemical or biological environment. However, no RDT&E nor training involves the exposure of human subjects to chemical or biological agents.

Medical chemical and biological defense programs involve the use of human subjects in controlled clinical trials to test and evaluate the safety, immunogenicity, and other effects of medical products (drugs, vaccines, therapies, *etc.*) to protect against chemical and biological agents. The use of human subjects in these trials involves volunteers who have provided informed consent. All use of human subjects in these trials is in full compliance with the "Common Rule," Federal Policy for the Protection of Human Subjects, Food and Drug Administration (FDA) regulations, Federal Acquisition Regulations (FAR), DoD Directives and Instructions, and *all* other applicable laws, regulations, issuances, and requirements. No medical chemical or biological defense programs involving human subjects involves the exposure of these subjects to chemical or biological agents.

While DoD conducted tests involving the exposure of human subjects to chemical and biological agents in the past, all such tests and programs have been halted and disbanded. The United States formally renounced the "use of lethal biological agents and weapons, and all other methods of biological warfare" in National Security Decision 35, November 25, 1969. Human testing with lethal biological warfare agents was never done and testing with incapacitating biological warfare agents was ceased in 1969. The last human testing of chemical warfare agents occurred on July 25, 1975. Acting Secretary of Army Norman Augustine suspended testing of chemical compounds on human volunteers on July 28, 1975.

Tests involving the exposure of human subjects to chemical agents began in the 1940s and continued following World War II through the Cold War until the early 1970s. Such testing has been documented and reported to Congress. See for example, Department of Army, Inspector General Report, DAIG-IN 21-75, *Use of Volunteers in Chemical Agent Research*, March 1976. In addition, there was extensive Congressional testimony on this subject during 1975 and 1976. DoD has not conducted any experimentation since that time involving the exposure of human subjects to chemical warfare agents.

Annex H

Congressional Reporting Requirement: 50 USC 1523

Text of Public Law Mandating Report on The Department of Defense Chemical and Biological Defense Program

Title 50 of the U.S. Code, Sec. 1523. Annual report on chemical and biological warfare defense
Implemented by Public Law 103-160, The FY94 National Defense Authorization Act

(a) Report required

The Secretary of Defense shall include in the annual report of the Secretary under section 113(c) of title 10, a report on chemical and biological warfare defense. The report shall assess--

(1) the overall readiness of the Armed Forces to fight in a chemical-biological warfare environment and shall describe steps taken and planned to be taken to improve such readiness; and

(2) requirements for the chemical and biological warfare defense program, including requirements for training, detection, and protective equipment, for medical prophylaxis, and for treatment of casualties resulting from use of chemical or biological weapons.

(b) Matters to be included

The report shall include information on the following:

(1) The quantities, characteristics, and capabilities of fielded chemical and biological defense equipment to meet wartime and peacetime requirements for support of the Armed Forces, including individual protective items.

(2) The status of research and development programs, and acquisition programs, for required improvements in chemical and biological defense equipment and medical treatment, including an assessment of the ability of the Department of Defense and the industrial base to meet those requirements.

(3) Measures taken to ensure the integration of requirements for chemical and biological defense equipment and material among the Armed Forces.

(4) The status of nuclear, biological, and chemical (NBC) warfare defense training and readiness among the Armed Forces and measures being taken to include realistic nuclear, biological, and chemical warfare simulations in war games, battle simulations, and training exercises.

(5) Measures taken to improve overall management and coordination of the chemical and biological defense program.

(6) Problems encountered in the chemical and biological warfare defense program during the past year and recommended solutions to those problems for which additional resources or actions by the Congress are required.

(7) A description of the chemical warfare defense preparations that have been and are being undertaken by the Department of Defense to address needs which may arise under article X of the Chemical Weapons Convention.

(8) A summary of other preparations undertaken by the Department of Defense and the On-Site Inspection Agency to prepare for and to assist in the implementation of the convention, including activities such as training for inspectors, preparation of defense installations for inspections under the convention using the Defense Treaty Inspection

Readiness Program, provision of chemical weapons detection equipment, and assistance in the safe transportation, storage, and destruction of chemical weapons in other signatory nations to the convention.

(9) A description of any program involving the testing of biological or chemical agents on human subjects that was carried out by the Department of Defense during the period covered by the report, together with a detailed justification for the testing, a detailed explanation of the purposes of the testing, the chemical or biological agents tested, and the Secretary's certification that informed consent to the testing was obtained from each human subject in advance of the testing on that subject.

In addition the House National Security Committee added the following reporting requirements for this report(HNSC H. Rpt. 105-532, H.R. 3616; p. 209):

Stated that the budget request for CBDP also included $88.0M in PE 62383E for DARPA's component of the bio warfare defense program. The committee has repeatedly expressed its concerns about the need for a strong CBDP to meet the potential threat posed by the proliferation of CBW in the post-Cold War world. The committee has strongly supported and insisted upon a coordinated and integrated CBDP and the need for joint coordination and oversight of the program. The committee notes ongoing R&D activities by the DoE national laboratories that are addressed elsewhere in this report, including $17.0M for the DoE Deterrence and Detection Technologies Program and $56.5M for the DoE Proliferation Detection Program. The committee believes that increased and continuing emphasis should be given to the development of advanced stand-off detectors that employ a range of potential sensing technologies capable of detecting NCB weapon proliferation effluents and agents. The committee also believes that the CBDP must incorporate the best efforts of the military services' R&D establishment, defense agencies, national laboratories, federally funded R&D centers, and industry. The committee directs that the SecDef address this issue, including plans for developing a more fully integrated program with the DoE, as a specific item of interest in the next annual report to Congress on DoD's NCB Defense Program.

Annex I

Acronyms and Abbreviations

–A–

AAAV – Advanced Amphibious Assault Vehicle
AAR – after action report
ACAA – Automatic Chemical Agent Alarm
ACADA - Automatic Chemical Agent Detector
ACC – Air Combat Command
ACES – Air Force Command Exercise System
Ach - acetylcholine
ACOM – Atlantic Command
ACPLA - agent containing particle per liter of air
ACPM - Aircrew Protective Mask
ACTD - Advanced Concept Technology Demonstration
ADS - Area Detection System
AERP - Aircrew Eye/Respiratory Protection
AFMAN – Air Force Manuel
AFMS – Air Force Medical Service
AFRRI - Armed Forces Radiobiology Research Institute
AG - Australia Group
AICPS - Advanced Integrated Collective Protective System
AIDET - Aircraft Interior Detector
AIT – Aeromedical Isolation Team
ALAD – Automatic Liquid Agent Detector
ALSA – Air Land Sea Application Center
AMAD - Automatic Mustard Agent Detector
AMC - U.S. Army Materiel Command
AMEDDC&S - Army Medical Department Center and School
ANCOC – Advanced NCO Course
AN/VDR-2 - Portable dose-rate gamma/beta radiation meter
AN/VDR-13 - Compact, digital whole body radiation meter
APODS – Aerial Port of Debarkation
ARTEP – Army Training and Exercise Plan
ASA(RDA) - Assistant Secretary of the Army for Research, Development and Acquisition
ASBREM - Armed Services Biomedical Research Evaluation and Management
ASCC – Air Standardization Coordinating Committee
ASD(HA) - Assistant Secretary of Defense for Health Affairs
ATD - Advanced Technology Demonstration
AT/FP – Antiterrorism Force Protection
ATG – Airfloat Training Group
ATH – Air Transportable Hospital
ATP - Adenosine Triphosphate
ATSD(NCB) - Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs
ATSO – Ability to Survive and Operate

–B–

B. anthracis - Bacillus anthracis
BCTP – Battle Command Training Center
BD - biological detector (also, biological defense)
BDO – Battledress Overgarment
BDU – Battledress Uniform
BES - Budget Estimate Submission
BIDS - Biological Integrated Detection System
BNCOC - Basic Non-Commissioned Officer Course
BOG - Board of Governors
BoNT - Botulinum Neurotoxin
BoNT/A - Botulinum Neurotoxin A
BoNT/B - Botulinum Neurotoxin B
BRP – Basic Research Plan
BTN – below the neck
BuChE - butyrylcholinesterase
BVO/GVO – black vinyl overboot/green vinyl overboot
BW - biological warfare
BWC - Biological Weapons Convention

–C–

C^4I – command, control, communication, computer, and intelligence
CA – Commodity Area
CAA – Center for Army Analysis
CA/D – Chemical Activity/Depot
CaE - carboxylesterase
CAM – Chemical Agent Monitor
CANA - Convulsant Antidote, Nerve Agent autoinjector

CANE - Combined Arms in a Nuclear/Chemical Environment
CAPDS – Chemical Agent Point Detection System
CARDS- Chemical Agent Remote Detection System
CASTFOREM – Combined Arms and Support Task Force Evaluation Model
CatOx – catalytic oxidation
CAWM - Chemical Agent Water Monitor
CB - chemical and biological (also C/B)
CBAT – Chemical Biological Augmentation Team
CBAWM - CB Agent Water Monitor
CBD - chemical and biological defense
CBDCOM - Chemical Biological Defense Command (U.S. Army)
CBDP – Chemical/Biological Defense Program
CBIRF – Chemical Biological Incident Response Force
CBM&S – Chemical/Biological Modeling & Simulation
CBMS - CB mass spectrometer
CBPS- CB Protective Shelter
CBR - chemical, biological, and radiological
CBR-D - chemical, biological, radiological defense
C/B-RRT – Chemical Biological Rapid Response Team
CBSD - Chemical Biological Stand-off Detector
CBW - chemical and biological warfare
CCD – Camouflage, Concealment, and Deception
CDC - Centers for Disease Control and Prevention
CD-ROM - Compact Disk - Read Only Memory
CDTF - Chemical Defense Training Facility (at the U.S. Army Chemical School)
CEM – Concept Evaluation Model
CENTCOM – Central Command
CFM - cubic feet per minute
CFR – Code of Federal Regulations
CHAMP – Chemically/biologically Hardened Air Management Plant
CHATH - Chemically/Biologically Hardened Air Transportable Hospital
ChE - cholinesterase
CINC – Commander – in – Chief
CINCCENT – Commander-in-Chief Central Command
CINCPAC – Commander-in-Chief Pacific Command
CJCS – Chairman of the Joint Chief of Staff
CM - Chloroform-Methanol (also, consequence management)
CMR - Chloroform-Methanol Residue
CMTC – Combat Mancuver Training Center
CNS - Central Nervous System
COBC – Chemical Officer Basic Course
COMMZ – Communications Zone
COMPTUEX – Composite Training Unit Exercise
CONOPS – Concept of Operations
CONUS – continental Untied States
COTS – Commercial Off-the-Shelf
CP - chemical protective (also, collective protection, or counterproliferation)
CPE - Collective Protection Equipment
CPO – Chemical Protective Overgarment
CPRC – Counterproliferation Review Council
CPS - Collective Protection System
CPU - Chemical Protective Undergarment
CRG – Compliance Review Group
CSST – Chemical Casualty Site Team
CTC – Combat Training Center
CTR - Cooperative Threat Reduction
CVC – Combat Vehicle Crewmen
CVIP – Chemical Vision Implementation Plan
CW - Chemical Warfare
CWC - Chemical Weapons Convention
CWCIWG - Chemical Weapons Convention Implementation Working Group
CWDD - Chemical Warfare Directional Detector (AN/KAS-1A)
CWICS - Chemical Weapons Interior Compartment System

–D–

DAB - Defense Acquisition Board
DAP - Decontaminating Apparatus Portable
DARPA - Defense Advanced Research Projects Agency
DATSD (CP/CBD) - Deputy Assistant to the Secretary of Defense for Counterproliferation and Chemical/Biological Defense
DCSOPS - U.S. Army Deputy Chief of Staff for Operations
DDR&E - Director, Defense Research and Engineering
DEPMEDS - CB Protected Deployable Medical Systems
DEST – Domestic Emergency Response Team
DLA - Defense Logistics Agency
DNA - Deoxyribonucleic Acid
DoD - Department of Defense
DoE – Department of Energy
DPE – Demilitarization Protective Ensemble
DPG - Defense Planning Guidance; Also Dugway Proving Grounds
DRB - Defense Review Board (also, Defense Resources Board, or Division Ready Brigade)
DRI – Defense Reform Initiative
DS2 - Decontamination Solution 2
DSCP – Defense Supply Center Philadelphia

DSO – Defense Sciences Office
DTAP – Defense Technology Area Plan
DTIRP - Defense Technical Inspection Readiness Program
DTLOM – Doctrine, Training, Leader-Development, Organization, and Material Requirements
DTO - Defense Technology Objective
DT/OT – developmental/operational testing
DTRA - Defense Threat Reduction Agency
DTRA(CB) - Defense Threat Reduction Agency' s Chemical and Biological Defense Directorate

–E–

E. coli - Escherichia coli
ECV – Expanded Capacity Vehicle
ED – ethyl dichlorarsine
EEE - Eastern Equine Encephalomyelitis
EEG – electroencephalographic
ELISA - Enzyme-Linked Immunosorbent Assay
EMD – Engineering and Manufacturing Development
ENCOMPASS – Enhanced Consequence Management Planning and Support System
EOD - Explosive Ordnance Disposal
ERDEC - Edgewood Research, Development, and Engineering Center (U.S. Army)
EUCOM – European Command

–F–

F1 - Fraction 1
F1-V - Fraction 1 - "V" Antigen
Fab - Fragment Antigen Binding
FAR – Federal Acquisition Regulations
Fc - Fragment Crystallizable
FCBC – Field Management of Chemical and Biological Casualties Course
FDA - Food and Drug Administration
FDTE – Force Development Testing and Experimentation
FEST – Foreign Emergency Response Team
FLEETEX – Fleet Exercise
FM - Field Manual
FORCEM – Force Evaluation Model
FR – flame resistance
FUE - First Unit Equipped
FY - fiscal year
FY99 - Fiscal Year 1999
FYDP - Future Years Defense Plan

–G–

GA – tabun, a nerve agent
GAO – General Accounting Office
GB - sarin , a nerve agent
GD - soman, a nerve agent
GF – a nerve agent
GMP - Good Manufacturing Practice
GPFU - Gas Particulate Filter Unit

–H–

HAZWARN – NBC Hazardous Warning System
HAZWOPR – Hazardous Waste Operations and Emergency Response
hBuChE - Human Butrylcholinesterase
hCaE - Human Carboxylesterase
HD - sulfur mustard, a blister agent
HEPA – high efficiency particulate
HHA – Hand Held Immunochromatographic Assays
HMMWV - High Mobility Multipurpose Wheeled Vehicle
HN – Host Nation
HSC/YA – Human Systems Program Office
HTA – high threat area

–I–

IBAD - Interim Biological Agent Detector
IBMC - Industrial Base Maintenance Contract
ICAD – Individual Chemical Agent Detector
ICAM - Improved Chemical Agent Detector
ICDS - Improved Chemical Detection System
IDLH - Immediate Danger to Life and Health
IEG – Information Exchange Group
IL CBDWS - In-Line Chemical Biological Defense Water System
IM - intramuscular
IND - Investigational New Drug
IP – intraperitoneal
IPDS - Improved (chemical) Point Detection System
IPE - Individual Protective Equipment
IPT – Integrated Product Team
IR&D – Independent Research & Development
IR-LIDAR – Infrared Light Detection and Ranging
IS – Instrumentation System
ISD - Individual Soldier Detector
ITAP - Improved Toxicological Agent Protective Ensemble
ITS – Individual Training Standard
IVD - Individual Vapor Detector

–J–

JBPDS - Joint Biological Point Detection System
JBREWS - Joint Biological Remote Early Warning System
JBSDS – Joint Biological Standoff Detection System
JBUD - Joint Biological Universal Detector

JCAD – Joint Chemical Agent Detector
JCBAWM – Joint Chemical Biological Agent Water Monitor
JCBUD – Joint Chemical and Biological Universal Detector
JCHEMRATES - Joint Chemical Defense Equipment Consumption Rates
JCPE – Joint Collective Protection Equipment
JCS - Joint Chiefs of Staff
JFIRE - Joint CB Protective Firefighter Suit
JFOC - Joint Future Operational Capabilities
JFT – Joint Field Trail
JLAS – Joint Land, Aerospace, and Sea Simulation
JMAR – Joint Medical Asset Repository
JMNS - Joint Mission Need Statement
JMRR – Joint Monthly Readiness Review
JNBCDB - Joint NBC Defense Board
JORD - Joint Operational Requirements Document
JPACE - Joint Protective Aircrew Ensemble
JPO-BD - Joint Program Office for Biological Defense
JRTC – Joint Readiness Training Center
JSA - Joint Service Agreement
JSAM - Joint Service Aviation Mask
JSCBIS - Joint Service Chemical Biological Information System
JSGPM - Joint Service General Purpose Mask
JSIG - Joint Service Integration Group
JSIMS – Joint Simulation System
JSLIST - Joint Service Lightweight Integrated Technology (individual protection)
JSLNBCRS – Joint Service Light NBC Reconnaissance System
JSLSCAD – Joint Service Lightweight Stand-off Chemical Agent Detector
JSMG - Joint Service Materiel Group
JSNBCRS – Joint Service NBC Reconnaissance System
JSTPCBD - Joint Science and Technology Panel for Chemical/Biological Defense
JSWILD - Joint Service Warning and Identification LIDAR Detector
JTASC – Joint Training and Analysis Center
JTC - Joint Training Council
JTCG - Joint Technology Coordinating Group
JTCOPS – Joint Transportable CP System
JTF – Joint Task Force
JTPCBD – Joint Technology Panel for Chemical and Biological Defense
JVAP – Joint Vaccine Acquisition Program
JWARN - Joint Warning and Reporting Network
JWFC – Joint Warfighting Center
JWSTP – Joint Warfighting S & T Plan

–L–

L - lewisite, a vesicant agent
LAM - Louisiana Maneuvers
LCBPG - Lightweight CB Protective Garment
LD_{50} - Median Lethal Dose
LDS - Lightweight Decontamination System
LHA – general purpose amphibious assault ship
LHD – general purpose amphibious assault ship (with internal dock)
LIDAR - LIght Detection And Ranging
LLC – limited liability corporation
LMS – Lightweight Multipurpose Shelter
LNBCRS – Light NBC Reconnaissance System
LRBSDS - Long-Range Biological Stand-off Detection System
LSCAD - Lightweight Stand-off Chemical Agent Detector
LSCD - Laser Stand-off Chemical Detector
LSD – landing ship, dock
LSP - Logistics Support Plan
LWRS - Lightweight Reconnaissance System

–M–

M&S - Modeling and Simulation

M&S CA – Modeling and Simulation Commodity Area

M&S R&D – Modeling and Simulation Research and Development
MAGTF – Marine Air Ground Task Force
MAJCOM - Major Command
MANAA - Medical Aerosolized Nerve Agent Antidote
MANSCEN – Maneuver Support Center
MBDRP - Medical Biological Defense Research Program
MBPI - Michigan Biologic Products Institute
MCBAT – National Medical Chem-Bio Advisory Team
MCBC – Management of Chemical and Biological Casualties Course
MCBDRP - Medical Chemical and Biological Defense Research Program
MCDRP - Medical Chemical Defense Research Program
MCPE – Modular Collective Protection System
MCU-2A/P - a chemical protective mask
MCWP – Marine Corps Warfighting Publication
MD – methyl dichlorarsine
MDS - Modular Decontamination System
MED – Medical
MEIR – Medical Effects of Ionizing Radiation
METL - Mission Essential Task List

metL, thrA - methionine biosynthesis
MEU – Marine Expeditionary Unit
MFR - Multi-Function Radiac Set
MICAD - Multipurpose Integrated Chemical Agent Detector
MIL STD – Military Standard
MLRS – Multiple Launch Rocket System
MNDRP - Medical Nuclear Defense Research Program
MNS - Mission Needs Statement
MOP - Memorandum of Policy
MOPP - Mission Oriented Protective Posture
MOS - Military Occupational Specialist
MPH – miles per hour
MPS – Mission Performance Standard (also, Multipurpose Protective Sock)
MPSP - Medical Program Sub-Panel
MRMC – Medical Research and Materiel Command
MTW – Major Theater War
MULO - Multi-purpose Overboot
murE – murein biosynthesis

–N–

NAADS – Nerve Agent Antidote Delivery System
NAAG – NATO Army Armaments Group
NAAK – Nerve Agent Antidote Kit
NAAS - Nerve Agent Antidote System
NAPP - Nerve Agent Pyridostigmine Pretreatment
NATO - North Atlantic Treaty Organization
NBC - Nuclear, Biological, and Chemical
NBCDT – NBC Defense Training
NBC-E – nuclear, biological, and chemical-environment
NBCRS - NBC Reconnaissance System (Fox Vehicle)
NBCWP – NBC Defense Interservice Working Party
NCO - Non-Commissioned Officer
NDA - New Drug Application
NDI - Non-Developmental Item
NEPMU – Navy Environmental and Preventative Medicine Unit
NFPA – National Fire Protection Agency
NICP - National Inventory Control Points
NIEX - No-Notice Interoperability Exercise
NIH – National Institute of Health
NO – nitric oxide
NSN - National Stock Number
NTC – National Training Center

–O–

OAC – Officer Advance Course
OBC – Officer Basic Course
OG - Overgarment
O&M - Operations & Maintenance
OPCW - Organization for the Prohibition of Chemical Weapons (in The Hague)
OPR - Office of Primary Responsibility
ORD - Operational Requirements Document
OSD - Office of the Secretary of Defense

–P–

P3I - Pre-Planned Program Improvement
PACAF – Pacific Command
PACOM – Pacific Command
PAM – Preventative and Aerospace Medicine
PATS - Protective Assessment Test System
PB - President' s Budget
PCPS – Portable Collective Protection System
PCR - polymerase chain reaction
PD – phenyl dichlorarsine
PDDA - Power Driven Decontamination Apparatus
PDM – Program Decision Memorandum
PDRR - Program Definition and Risk Reduction
PE – Program Element
PF - Positive Force Exercise
PfP – Partnership for Peace
PICS - Personal Ice Cooling System
PL 130-160 - Public Law 103-160, The National Defense Authorization Act of FY94
PMCD - Program Manager for Chemical Demilitarization
POL – petroleum, oil, and lubricant
POM - Program Objectives Memorandum
PQS – Personnel Qualification
PR - Positive Response Exercise
PRG – Program Review Group
PROFIS – Medical NBC Professional Filler Course
PSA – Pressure Swing Adsorption

–Q–

QDR - Quadrennial Review
QNFT – quantitative fit testing
QRR - Qualitative Research Requirements
OSM3 – oximeter instrument
QSTAG - Quadripartite Standardization Agreement
QWG – Quadripartite Working Group

–R–

RBC-AchE – red blood cell acetylcholinesterase
R&D – Research and Development
RDA - Research, Development, and Acquisition
RDTE (Also, RDT&E) - Research, Development, Test and Evaluation
RMC - Regional Medical Commands

RSCAAL - Remote Sensing Chemical Agent Alarm
RTP – Readiness Training Plan
rTSP - Reactive Topical Skin Protectant
RW – radiological/nuclear warfare

–S–

SACPS - Selected Area Collective Protection System
SAG – Study Advisory Group
SALAD - Shipboard Automatic Liquid Agent Detector
Saratoga - a CB protective overgarment
SAT – Systems Approach to Training
SAW - Surface Acoustic Wave
SBCCOM- Solider, Biological and Chemical Command (U.S. Army)
SCALP - Suit Contamination Avoidance Liquid Protection
SCAMP - Shipboard Chemical Agent Monitor Portable
SCPE – Simplified Collective Protective Equipment
SCUD – surface – to –surface missile system
SD - Stand-off Detector
SD/ASM - Stand-off Detector for Armor System Modernization
SDK – Skin Decontamination Kit
SE – staphylococcal enterotoxins
SEA - Staphylococcal Enterotoxin A
SEB - Staphylococcal Enterotoxin B
SMART-CB – Special Medical Augmentation Response Team-Chemical./Biological
SMART-PM – Special Medical Augmentation Response Team-Preventative Medicine
SNCO – Staff-Noncommissioned Officer
SOF - Special Operations Forces
SOFCAS - Special Operation Forces Chemical Agent Detector
SOI – School of Infantry
SO/LIC – Special Operations and Low Intensity Conflict
SORTS - Joint Status of Resources and Training System
SPOD – Seaport of Debarkation
SRT - Specialty Response Team
S&T – Science & Technology
STANAG – standard agreement
STB - Supertropical Bleach
STEPO - Self-Contained Toxic Environment Protective Outfit
STEPO-I - Interim Self-Contained Toxic Environment Protective Outfit
STO – Science Technology Objective
STRAC – Standards in Training Commission
STS – Specialty Training Standard

–T–

TAA – Total Army Analysis
TACWAR – Tactical Warfare
TAP – Toxicological Agent Protective boots and gloves
TAV - Total Asset Visibility
TB - Technical Bulletin
TBM – Transportation of Biomedical Materials
TDA – table of distribution and allowances
TED – Troop Equivalent Doses
TEU – Technical Escort Unit
TIM – toxic industrial material
TSG – The Surgeon General
TSP - Topical Skin Protectant

–U–

UAV – Unmanned Aerial Vehicle
UDP – Unit Deployment Program
UN – United Nations
UNSCOM – United Nations Special Commission
USA – United States Army
USACHPPM – United States Army Medical Research and Materiel Command
USACMLS – US Army Chemical School
USAF – United States Air Force
USAMEDDC&S – U.S. Army Medical Department Center and School
USAMMA – U.S. Army Medical Materiel Agency
USAMMDA – U.S. Army Medical Materiel Development Activity
USAMRICD - U.S. Army Medical Research Institute of Chemical Defense
USAMRIID - U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC - U.S. Army Medical Research and Materiel Command
USANCA - United States Army Nuclear and Chemical Agency
USAR – US Army Reserve
USC – United States code
USD(A&T) - Undersecretary of Defense (Acquisition and Technology)
USG – United States Government
USMC - United States Marines Corps
USN – United States Navy
USUHS - Uniformed Services University of the Health Sciences
UTC – Unit Type Code

–V–

VCA - Voice Communication Adapter
VEE - Venezuelan equine encephalomyelitis
VIC – Vector – In –Command
VLSTRACK – Vapor, Liquid, and Solid Tracking Model
VPU - Vapor Protective Undergarment
VTC – Video Teleconference
V&V – verification and validation
VVS – Vehicles, Vans and Shelters
VX - a nerve agent

–W–

WCF - Working Capital Fund
WEE - Western Equine Encephalomyelitis
WG – Working Group
WMD - weapons of mass destruction
WRAIR - Walter Reed Army Institute of Research
WRM – war reserve materiel
WRSI - War Reserves Secondary Items

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ASSISTANT TO THE SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

NUCLEAR AND CHEMICAL
AND BIOLOGICAL DEFENSE
PROGRAMS

DEC 12 2002

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

SUBJECT: Trip Report from Visit to the Centers for Disease Control and Prevention (CDC) – 28 October 2002

I have reviewed your Trip Report to the CDC and have the following comments.

1 Establishing standards for unknown sample analysis across federal agencies (p.3)

It is important that standardization for reagents and standard operating procedures exist for unknown sample analysis. I recommend convening a group of appropriate DoD and civilian agency representatives to develop proposed guidelines for White House or Homeland Security approval. Agree

2. Vaccine Safety and Monitoring Review Board (p 4)

The "Vaccine Adverse Events Reporting System" (VAERS) is the currently accepted method for reporting vaccine adverse events to the Food and Drug Administration (FDA) This system is currently used by DoD and the civilian health care system for keeping the FDA aware of adverse vaccine events. I feel a new board should review VAERS reports to keep abreast of adverse events but not create a new reporting system. Both the Army PEO-CBD and the Joint Vaccine Acquisition Program Office should be included in such a review process

3 Anthrax Vaccine Adsorbed (AVA) studies (p.8)

Under the auspices of my office, I hold a bi-monthly "Next Generation Anthrax Vaccine" meeting attended by various Pentagon offices to discuss DoD and DHHS efforts toward production of a second generation anthrax vaccine. Health Affairs is represented at this meeting and regularly presents on the ongoing CDC studies to assess route change and dose reduction for AVA. Good. OK

Anna Johnson-Winegar

Anna Johnson-Winegar, Ph.D.
Deputy for Chemical/Biological Defense

November 11, 2002 3 00 PM

INFORMATION PAPER

SUBJECT Trip Report for Visit to Centers for Disease Control and Prevention, October 28, 2002

I Purpose To inform the USD(P&R) on significant issues identified during a visit to the Centers for Disease Control and Prevention (CDC)

II Summary On October 28, the ASD(HA) met with Dr Julie Gerberding, the Director of the CDC, several other program office directors, and other senior members of her staff The objectives of this visit were to

A Establish a better understanding of CDC's mission, its organizational structure and components, and how the events of the past year have impacted upon their near-term and strategic objectives;
B Establish an agenda of how the CDC and the Defense Department can promote enhanced collaboration and communication on activities and programs for which we either share responsibility or have a common vision and purpose, and
C Review the entire inventory of joint efforts/activities we are currently engaged in and determine how we can proceed in the coming year

III Issues

A Terrorism Preparedness and Response Overview

1 Mr Joe Henderson, Associate Director for Terrorism, Preparedness and Response, provided a presentation on CDC's "All Hazards (biological, chemical and radiological) Approach" to terrorism preparedness and response

2 CDC has oversight for 62 programs in 50 states using the State Health Departments as their focus Approximately $150M is allocated for planning purposes

3 Congress appropriated $2 3 billion as a supplemental emergency appropriation in FY02—$918M was allocated for state and local health agencies, $512M for smallpox vaccine production, $645M for the National Pharmaceutical Stockpile, and approximately $183M for improving capacity enhancements, hardening of facilities, and improving security FY03 appropriation will provide essentially the same budget, with approximately $15M increase

4 Major Program Components of the this Office include

a Preparedness and Response Planning

b Public Health Interventions—include the National Pharmaceutical Stockpile (NPS) and provisions for quarantine and isolation

(1) NPS is deployed in 10 strategic sites around the US, and can provide 50 tons of material within 12 hours of an event Stockpile includes vaccines, antivirals, antibiotics, ventilators, burn treatment material, pain management treatment and other trauma items

c Disease Detection and Investigation—surveillance and epidemiological efforts at state and local levels can rapidly scaleup a consequence management response

d Biological and Chemical Laboratories

e Information Systems and Technology—one-third of CDC funds are invested in supporting a public health information network

f Public and Media Risk Communications—improve ability of public health leadership to communicate with the general public using websites, hotlines and other venues

g Training—sharing and disseminating information on biological and chemical health threats, preparedness and response

h Worker Safety

i Environmental Monitoring

j Select Agent Program—may become the responsibility of the Office of Homeland Security, in the mid-90s this was a program which required laboratories and other organizations in possession of biologicals/toxic agents that could affect public health to notify and register

k Research

5 Mr Henderson identified the following as critical next steps to support the Public Health System of Response

a Office of Terrorism Preparedness and Response established—would provide oversight in support of activities to improve state and local programs, operate the NPS, and operate in conjunction with the Office of Emergency Response (OER) OER reports through the Assistant Secretary of Public Health and Emergency Preparedness

b Priorities

(1) Focus on critical bio/chem agents (i e , smallpox, VX)

(2) Drive to exercise national, state and local capacities to demonstrate response proficiency,

(3) Establish a Public Health Information Network,

(4) Research new ways to detect and diagnose disease presence, and develop new vaccines and therapeutics to treat,

(5) Train

6 In discussion following the presentation, Mr Henderson appealed for establishing a single standard for accepting an unknown sample for analysis This standard must be implemented across all federal agencies that may be involved in this activity (USDA, FBI, HHS, SBCCOM, AFIP, federal research laboratories, etc) Standards need to be established for transport of samples, accepting samples and chain of custody, processing standards, managing mixed samples, and numerous other issues

ACTION: DASD (FHP&R). Need to begin dialogue with Mr. Henderson to link relevant DoD organizations with other agencies responsible for specimen transport and sample analysis.

B Discussion with CDC Director on Opportunities for Collaboration Dr Winkenwerder then met with Dr Gerberding, Director of the CDC, to discuss opportunities for collaboration

1 Local linkages between military installations and public health agencies Dr Winkenwerder discussed DoD's completion of a smallpox response plan that provides a comprehensive guide for commanders in the event of a smallpox bioterrorism attack Dr Gerberding requested a copy

ACTION: DASD, FHP&R. Provide CDC a copy of the Smallpox Response Plan CD.

a Dr Winkenwerder and Dr Gerberding agreed that there was a need to establish stronger dialogue and coordination between military installations and public health departments Because of their essential roles in consequence management, pre-event planning and exercises of their response plans is critical

b Dr Gerberding also requested the assistance of DoD in preparing an "interagency" response for "non-domestic" events that could affect civilians residing abroad Response may include assistance with quarantine and isolation, response teams for vaccination, use of overseas laboratory capability, evacuation using military airlift of infected US citizens, and use of military aircraft for transport of specimens Dr Winkenwerder and she discussed the need for a broad Memorandum of Understanding that would delineate all responsibilities for both CDC and DoD for this purpose Further, they determined that a tabletop exercise with CDC and DoD participation, perhaps with representation from other critical agencies in the Federal Response Plan, would be enormously useful for identifying the substance of this MOU

ACTION: DASD (FHP&R). Coordinate with CDC to determine how we might plan and schedule a tabletop exercise that includes Service and Joint Staff representation, as well as other critical federal agencies. Goal should be to use this exercise as a means to improve the DoD smallpox response plan, provide recommendations for revising the Federal Response Plan, and identify responsibilities that should be delineated in an interagency MOU.

2 National Pharmaceutical Stockpile Dr Gerberding mentioned that DoD's capability to transport logistics quickly may be of enormous assistance to them in moving items from strategic supply points in the NPS

3 Civil Support Teams

(a) In discussion of the Public Health System of Response, Mr Henderson asked how the Defense Department viewed the role of the Civil Support Teams, and how they should incorporate them into their infrastructure

(b) Dr Winkenwerder responded that these teams are an asset that is more under the control of the states than DoD for purposes of domestic consequence management It is, however, an issue that we need to review and incorporate into an overall response plan that includes the roles of NORTHCOM, HHS, Office Homeland Security, and other agencies involved in medical consequence management

ACTION: DASD, FHP&R. Review this issue with OASD(RA) and provide an information paper to CDC that describes how the CSTs are employed following an event; who has authority to activate, under whose authority they operate, and their primary functions. Include in the forthcoming work with the DoD Homeland Security Task Force and NORTHCOM specific assessment on how CSTs fit in the response model if federalized.

4 Research (i e , vaccines, anti-virals, etc)

(a) Dr Winkenwerder related to Dr Gerberding a recent conversation he had with Dr Joshua Lederberg on establishing a Vaccine Safety and Monitoring Review Board to study and follow initial smallpox vaccine recipients This DoD-CDC cooperative effort could provide a single, consistent manner for profiling vaccinees and reviewing adverse events associated with smallpox vaccination, as well as offer empirical information to drive vaccination protocols

ACTION: DASD (C&PP) in coordination with DASD (FHP&R). Coordinate with the Service Surgeons General, and specifically with MILVAX in Army OTSG, to identify appropriate clinical researchers for this board. Coordinate with Dr. Joshua Lederberg to identify study questions and research design that should be undertaken. Contact the CDC POC, Dr. Dave Fleming, Deputy Director for Science and Public Health, to coordinate CDC's participants on this board.

5 Laboratory Response Network—Enhanced collaboration with USAMRIID and the Naval Medical Research Institute's Biomedical Defense Directorate

6 National Disease Surveillance Systems

(a) The Health Alert Network (HAN) is another major initiative undertaken by CDC Ideally, the HAN provides a state-of-the-art information and communications system to rapidly identify and respond to a bioterrorist attack, chronic disease epidemics, emerging infectious disease, or environmental health danger

(b) The current construct for this initiative is to integrate the HAN in all 50 states, Guam and 7 major cities There are several functional components.

(1) The National Evaluation Data Service (NEDS) is currently being deployed and provides a list of "notifiable diseases" that must be reported by health facilities to the state health departments Subsequently, these reports are forwarded to the CDC where they can compile thousands of microbiological reports into a single

nationalized "electronic laboratory database" system that can analyze trends and provide feedback to the public health system Expect this to be fielded in 22 states by the end of 2002 Another 16 states are considering this opportunity

(2) The second component will be Emergency Room and ADT (admissions, discharges and transfer) reports that will be compiled in a single database CDC is undertaking this effort in cooperation with the American Association of Health Plans.

(3) The Laboratory Response Network (LRN) is another component that would create an integrated network of public health and clinical laboratories that would provide laboratory diagnostics and disseminated testing capability to support public health preparedness and response to an act of bioterrorism The LRN would promulgate and support a common specimen management and reporting protocol, and provide an aggregated database for pathogen/agent identification and response

(4) An "Alert" function in the HAN would provide real-time information to health care providers and systems on health threats and appropriate response

(5) Finally, a secure component is necessary for communicating sensitive events in progress with public health leadership

ACTION: PDASD(HA). Include this as an agenda item for a CDC-DoD meeting to determine how our MTFs, registered laboratories in the LRN and other relevant facilities can tie into their IT infrastructure.

8 Training CDC is interested in establishing distance learning training centers to reach a broader audience of care providers to keep them readily informed on issues relating to vaccine protocols, management of adverse events, response to bioterrorism attacks, and numerous other issues. They inquired as to whether DoD could assist in expanding their infrastructure for accomplishing this task by using their facilities

ACTION: HA CIO. Provide an analysis of how DoD may be able to provide assistance with distance learning training centers—review possibility of using DoD satellites, installations, and all available options. Provide cost analysis and recommendation on reimbursement. Please include USUHS in your consideration of options and their center of excellence in distance learning.

9 Biosurveillance and Detection Dr Winkenwerder discussed briefly with Dr. Gerberding some of the current efforts on biosurveillance and detection in metropolitan areas that DoD has worked collaboratively with other federal agencies, including CDC DoD anticipates HHS will take the lead on this effort

10 Public and Media Risk Communication Dr Gerberding expressed a strong interest in working collectively on Public Affairs messages to ensure consistency between DoD, HHS, the White House and others CDC is very focused on risk

pre- and post-exposure Aventis product, pre- and post-exposure for Acambis, BioThrax post-exposure, as well as INDs for different dilution factors

a CDC suggested that DoD may be pursuing INDs for vaccination that are not for "research" purposes—which is the primary reason for developing these protocols Instead, they suggested that it may be possible for us to develop protocols for "emergent circumstances"

ACTION: HA General Counsel. Contact (b)(6) **Legal Advisor to CDC, to determine how they assess it is possible to use unlicensed vaccines in "emergent circumstances" without an IND and provide a summary for ASD(HA). Investigate the possibility of identifying all combat contingencies as "emergent circumstances", and whether we might include other biomedical therapeutics under this type of protocol. Additionally, please advise ASD(HA) if is it possible for us to "adopt" CDC's IND protocols for vaccinations.**

D Tours of CDC Biological Laboratories

1 Dr Winkenwerder visited briefly with the Rapid Response and Advanced Technology Laboratory staff, and received a short presentation on the LRN

2 The LRN upper tier of facilities are capable of presumptive and confirmatory tests for all of the primary bioterrorist threat agents—anthrax, variola (smallpox), plague, tularemia, brucellosis, botulism, alphaviruses, Q-fever, glanders, ricin toxin, staphylococcus enterotoxin B, varicella, vaccinia (cowpox), and others pathogens

3 More than 110 of these upper tier facilities currently exist with capability in all 50 states Approximately 22 DoD facilities are partners in the LRN The CDC acts as the national public health reference laboratory for major threat agents

4 CDC would like to expand their upper tier to approximately 250 registered facilities They continue to develop collection and laboratory processing protocols for existing and emerging biological threat agents, as well as evaluate rapid screening assays to determine effectiveness and how they may be incorporated into their testing algorithm Of primary concern is ensuring state-of-the-art biodetection and diagnostic capabilities as well as surge capacity for all member laboratories Other near-term priorities include training of initial tier (clinical and academic) laboratories for "rule-out" and referral steps, and establishing a secure website and electronic communications capability between laboratories

E Smallpox and Anthrax Vaccine Policies

1 Dr Fleming summarized, specifically, the IND protocols for smallpox vaccine In this discussion, he elaborated more upon the current status of the 85 million doses of Aventis stock These doses are separated into 12 separate lots with varying numbers of doses remaining in each. Recent testing indicates that some of the lots may not have

sufficient titres to allow for dilution, or may not be available at all The Aventis product has been considered for dilution at 1 5 and 1 10 (providing yields estimated at 425M and 850M, respectively) This discovery decreases the available doses of Aventis—although CDC is not yet certain to what degree

ACTION: DASD (FHP&R) in cooperation with MILVAX. Contact Dr. Dave Fleming or Mr. Joe Henderson at CDC to ascertain the latest status on the Aventis stockpile.

2 CDC has developed a number of risk communication materials including videos, written materials, a website and MMWR messages. Educational materials for informed consent have been developed as well

ACTION: DASD(C&PP). Contact MILVAX to determine DoD's present status with regard to appropriate training, educational, and risk communications materials. Confer with CDC to acquire materials they have already developed.

ACTION: PDASD(HA) and DASD(HPA). Need to establish a plan to use our managed care support contractors to communicate smallpox educational and training material with community providers and healthcare facilities.

3 Anthrax vaccine research on BioThrax to assess route change and dose reduction continues

a To date, 5 sites have enrolled 36-percent of the 1560 personnel necessary for clinical trials Interim analysis will be presented to FDA by September 04—goal is to drop dose 2 and change to IM route of administration. Dr Winkenwerder explained that dropping only dose 2 would not greatly relieve the administrative and logistical burdens under the current protocol Ideally, would like to reduce to no less than a 3-4 dose protocol

ACTION: DASD(FHP&R) in cooperation with MILVAX. Confer with CDC to assess whether these trials could include a reduction in the dosing to 3 or 4 versus the current 6 dose protocol.

b Non-human primate studies commenced in March 02 to determine efficacy against inhalational exposure with reduced dosing Final data is expected in FY05

c Development of an Anthrax Immune Globulin (AIG) is underway for treatment of persons ill with anthrax who are failing antibiotic therapy Anthrax hyperimmune plasma is currently kept in the NPS to be used under an IND for emergency response An October 02 contract with Cangene to manufacture AIG is co-funded with DoD through an interagency agreement

d Studies are also planned to support licensing of BioThrax for post-exposure Additionally, a pediatric post-exposure study will also assess safety and efficacy

e CDC is also working to develop surveys to capture knowledge, attitudes and beliefs regarding anthrax This survey should provide considerable information to assist in developing appropriate educational tools A survey is also being developed to improve provider's use of the VAERS form

ACTION: DASD(C&PP) in coordination with PDASD(HA) and OTSG MILVAX. Confer with CDC on these survey tools to determine applicability for DoD and to assess results for developing educational tools.

F National Center for Infectious Disease (NCID) Dr Jim Hughes and Dr Steve Ostroff, the NCID Director and Deputy Director, respectively, led a presentation on their strategic priorities These priorities include international outbreak assistance, a "global" approach to disease surveillance, applied research on diseases of global importance, global initiatives for disease control—e g , reducing the prevalence and mortalities associated with HIV/AIDS, tuberculosis and malaria, expanding public health training and capacity through the establishment of International Emerging Infectious Programs in developing countries

ACTION: DASD(FHP&R) in cooperation with MILVAX. Determine if NCID is chartered as the lead federal agency on response to smallpox or other contagious outbreaks outside the US. Determine what role do they assume in positioning of smallpox and other vaccine supplies

G National Center for Injury Prevention and Control Dr Sue Binder, the Director for the National Center for Injury Prevention and Control, led a presentation on CDC's current collaborative efforts within DoD

1 CDC is providing consultation for the US Army FORSCOM for enhancing safety and prevention efforts CDC is using existing data to address hypotheses for role of deployment and related factors in fatal and traumatic injury, evaluating existing programs to improve safety and prevent injury, and evaluate surveillance systems designed to monitor fatal and traumatic injuries

2 FORSCOM is also requesting assistance in epidemiological assessment on contributing factors to violence-related and unintentional injuries

3 CDC also participated in an epidemiological consultation (EPICON) with the Army Office of the Surgeon General to assess and provide recommendation on the recent cluster of homicide/suicide cases at Fort Bragg, NC They assess that the EPICON at Fort Bragg further illustrated the need for a direct and systematic comparison of civilian and military domestic violence CDC is participating with DoD (largely with the Army) to design survey tools to conduct this comparative analysis

H National Center for Chronic Disease Prevention and Health Promotion Dr Janet Collins, the Deputy Director for the National Center for Chronic Disease Prevention and Health Promotion, provided a presentation on their current efforts to assess chronic diseases and related risk factors—and how to inform, educate and promote healthier behaviors

1. They are currently funded and engaged in 20 states to implement coordinated school health programs to reduce chronic disease and obesity Dr Winkenwerder agreed that obesity, and particularly obesity in youth, has become a national epidemic By extension, it has become a national security issue CDC efforts in addressing risk factors (physical activity, good nutrition, smoking cessation, and obesity), monitoring problems and progress through disease registries, and analyzing surveys to guide their outreach activities could be an enormous asset to DoD

ACTION: DASD (C&PP) and PDASD(HA). There is enormous potential for improved processes, programs, and ultimately health outcomes, within DoD through collaboration with CDC on infectious disease, chronic disease prevention, safety and injury prevention. Need to include these Centers in the development of formal agenda items that can be managed in direct cooperation with CDC.

Prepared by Lieutenant Colonel (b)(6), OASD(HA), (b)(6)

Approved by _____
William Winkenwerder, Jr , MD

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

INFO MEMO

HEALTH AFFAIRS

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: Recommendations on Vaccine Safety Monitoring Board and Establishing Standards for Unknown Sample Analysis

- Per your request, I have reviewed the comments on the CDC trip report, dated December 12, 2002 (TAB B). My recommendations are at TAB A.

COORDINATION: TAB C.

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD, (b)(6), PCDOCS# 43968, 44759

SUBJECT: Recommendations on Vaccine Safety Monitoring Board and Establishing Standards for Unknown Sample Analysis

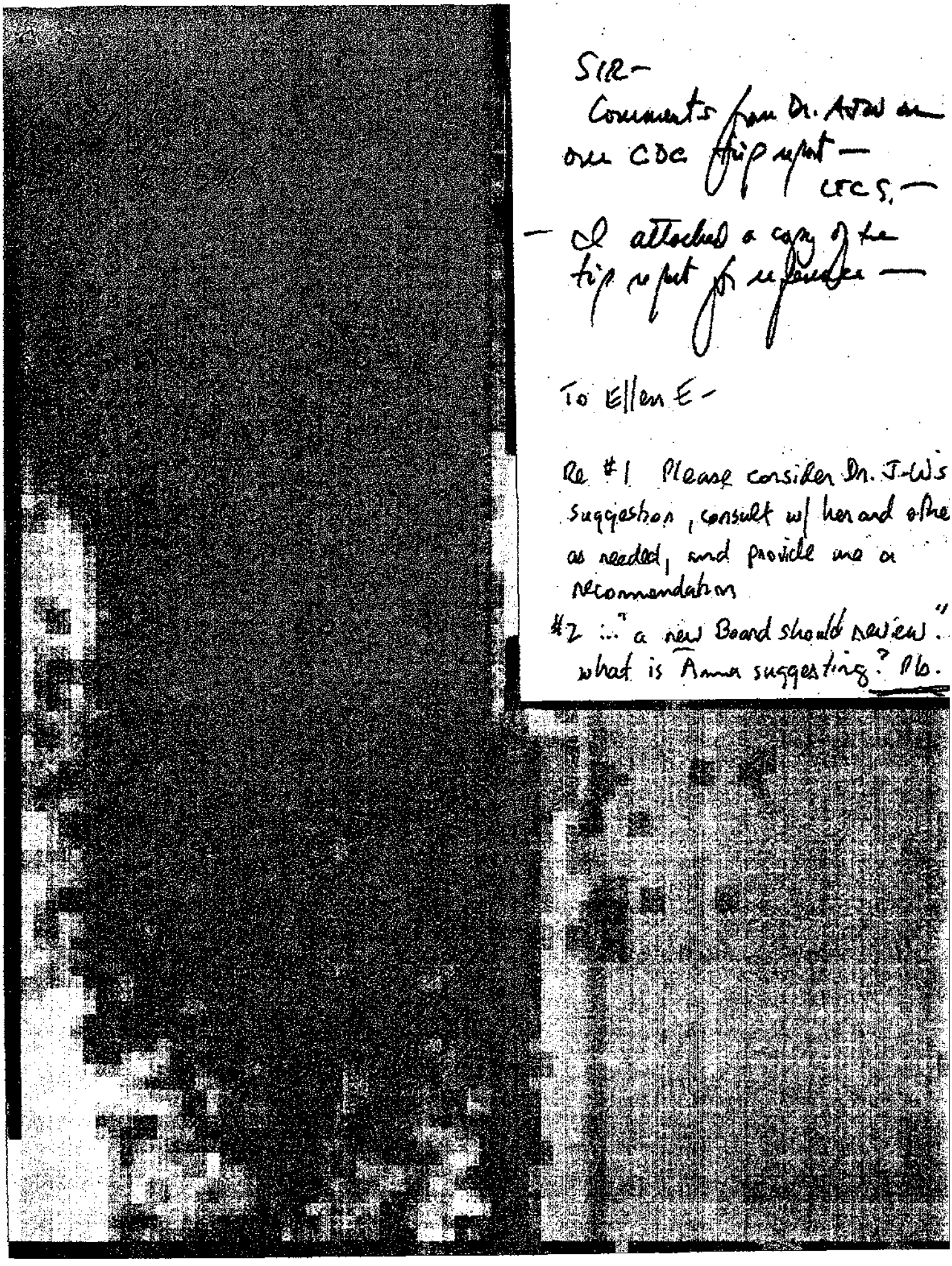
Vaccine Safety and Monitoring Review Board

- DoD shall use the Joint Working Group of the Armed Forces Epidemiological Board (AFEB) and the Advisory Committee on Immunization Practices (ACIP) to assess safety of smallpox and other military vaccinations. The process and procedures have been established and agreed upon.
- The National Academy of Sciences' Institute of Medicine discourages attribution of causality, particularly important given the potential for misclassification of reported vaccine adverse events. The MILVAX office and the AFEB's Joint Working Group concur with this assessment. The Joint Working Group's review process for smallpox vaccinations will use a mutually supporting set of human studies.
- These studies will include descriptions of exempted DoD personnel, descriptions of acute responses (for smallpox: take rates), symptoms, sick-call visits, outpatient visits, surveillance for sentinel events, and most importantly, comparisons of vaccinated and unvaccinated populations.
- This approach has the scientific merit of combining an interlocking set of research designs, as well as bolstering public confidence by establishing a forum for independent review of the study results.

Establishing Standards for Unknown Sample Analysis

- Recommend that CDC's Laboratory Response Network (LRN), in conjunction with DoD, form a working group to discuss and develop standard guidelines for all federal agencies that may have to deal with the analysis of an unknown laboratory sample.
- Recommend the CDC's LRN be the responsible agency for given the fact they are the experts on procedures for standardization of reagents and the shipping of sample probes used in the quality assurance testing of all laboratories.
- Representatives should include the Armed Forces Institute of Pathology's Center for Clinical Laboratory Medicine, ASD(HA)-Clinical Programs and Policy, the Program Executive Office for ChemBio Defense, Chief of Microbiology at Brooke Army Medical Center, representative of the Theater Army Medical Laboratory, Service's Microbiology representatives, and others as appropriate.

Recognizing the importance of standardizing procedures for unknown sample analysis, several organizations have been working parallel efforts towards standardization. Recommend all stakeholders in this matter be invited to participate in the discussions.



SIR—
Comments from Dr. Adler on our CDC trip report—
CFCs—
— I attached a copy of the trip report for reference—

To Ellen E—

Re #1 Please consider Dr. J-W's suggestion, consult w/ her and others as needed, and provide me a recommendation

#2 :.. "a new Board should review". what is Anna suggesting? Pls.

Consult. w/ her, and also provide me a recommendation on this suggestion

Thanks,
Bill

SUBJECT: Recommendations on Vaccine Safety Monitoring Board and Establishing Standards for Unknown Sample Analysis

COORDINATIONS

MILVAX	(b)(6)	Concur 12/20/02
AVEC		Concur 12/23/02
Armed Forces Institute of Pathology		Concur 01/07/03
Army Consultant for Laboratory		Concur 01/07/03
Chief of Microbiology Brooke Army Medical Center		Concur 01/07/03
Deputy Director, DHSD		Concur 12/31/02
PM Preventive Medicine, FHP/R		Concur 12/20/02
CoS (HA)		_____
PDASD (HA)		_____
DASD(CPP)		_____

CMAT Control #
2003030-0000002

(263)

ASSISTANT TO ME SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

NUCLEAR AND CHEMICAL AND BIOLOGICAL DEFENSE PROGRAMS

JAN 24 2003

MEMORANDUM FOR UNDER SECRETARY OF DEFENSE(COMPTROLLER)
DEPUTY UNDER SECRETARY OF DEFENSE {INDUSTRIAL POLICY)
ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS) 3E1682
ASSISTANT SECRETARY OF DEFENSE (LEGISLATIVE AFFAIRS)
DEPARTMENT OF DEFENSE GENERAL COUNSEL
DIRECTOR. ACQUISITION RESOURCES AND ANALYSIS
DIRECTOR, DEFENSE PROCUREMENT
JOINT REQUIREMENTS OFFICE (CBRN DEFENSE)

SUBJECT: Report to Congress on Anthrax Vaccine Supply Preparedness as Required by the FY03 Appropriation Report, Public Law **107-732**

Request coordination **NLT** COB Monday, **January** 27, on the attached draft Action Memo and Report to Congress from Dr. **Winegar** to Mr. Aldridge. The report addresses "anthrax vaccine supply preparedness" as required by **FY** 03 Appropriations Report, Public Law 107-732. The Report is being re-staffed since it has been significantly shortened and therefore represents a major revision to the original staffed version.

If you have questions regarding this matter, please contact (b)(6) or LTC (b)(6) at (b)(6) **Please** fax or send an Adobe pdf file attachment to e-mail for your coordination (TAB E). The fax number is (b)(6) and the e-mail address is (b)(6) **@osd.mil.**

Steve C. Lawrence LTC USA
for **Anna Johnson-Winegar, Ph.D.**
Deputy for Chemical/Biological Defense

Attachments:
As Stated

ASSISTANT TO THE SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON. DC 20301-3050

NUCLEAR AND CHEMICAL
AND BIOLOGICAL DEFENSE
PROGRAMS

ACTION MEMO

January **23, 2002, 9:30** AM

FOR: UNDER SECRETARY OF DEFENSE (ACQUISITION, TECHNOLOGY, AND LOGISTICS) **ATSD(NCB)** Action _____

FROM: Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense

SUBJECT: Report to Congress on Anthrax Vaccine Supply Preparedness as Required by the FY03 Appropriation Report, Public Law **107-732**

- Sign the letters at TAB A and forward the Report at TAB B.
- The **FY03** Appropriations Act, Public Law 107-732 (TAB C), requires a report to Congress by January **23, 2003.**
- The Report to Congress on Anthrax Vaccine Supply Preparedness (TAB B).
- The Secretary of Defense has delegated authority to Under Secretaries **(DoD** Directive 5545.2) to submit reports to Congress in a memo dated July **26, 2002** (TAB **D).**
- Specific report requirements are:

  (1) Assess the immediate and short-term preparedness and potential future total biowarfare defense need for the FDA-licensed anthrax vaccine.
  (2) Assess the potential capacity to meet that need, and the need for a separate production capacity to mitigate risks of an event which could halt current vaccine production.

- None of the options discussed in the draft Report are funded in the POM, or officially submitted as an unfunded requirement.

RECOMMENDATION: Sign the letters (TAB A).

COORDINATIONS: ODoD(GC), ASD(HA), ASD(LA), DIR(ARA), USD(C), DIR(DP), DUSD(IP), JRO(CBRN) (TAB E **)**

Attachments:
As stated

Cc: **PDUSD(AT&L)**
Prepared by: LTC (b)(6), ODATSD(CBD), Medical Advisor, (b)(6)

LT JAN

Ms. Embrey -

Coordination action
for Dr. J-W

Report to Congress -
Anthrax Vaccine Supply
Preparedness as required by
the FY03 Appropriations Report,
PL 107-732

Report at Tab B

Coordination at Tab E.

30 JAN

(b)(6)

- No recommended changes from MILVAX office.
- Per (b)(6) Ms Embrey concurs
- Provided info to (b)(6) last night. Voice Mail mess.

HA/TMA Document Profile

45201, 45358

Subject	Coordination-RTC on Anthrax Vaccine Supply Preparedness as Required by the FY03 Appropriation, P		
Author:		Congressional Name:	
Date of Document:	1/24/2003	Input By:	GSHAPIRO
OSD#:		Profilers Directorate:	
PR #:		Response Signed By:	
Organization:		Dt Response Signed:	
Department:		Doc Type:	103-04
Assigned To:	FHP&R	Application:	DOCSIMAGE
Prepared For:		Previous Documents:	
Suspense Date:	1/27/2003	Related Documents:	
Coord Office(s):	[redacted]		

Notes: On 1/27/03 DMD/PNT scanned in to PCDOCS and assigned to FHP&R.(gjs) —

extension to 1/29/03. ELN per (b)(6)

Beneficiary Info

Beneficiary Name:	
Address 1:	
Apartment #	
Phone #	
Email Address:	
City:	
State:	Zip:

History

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Edited: 1/27/2003 HA Red Tag
Status: Available

Retention Schedule

Type: Keep

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EXTension

The Honorable John W. Warner
Chairman
Committee on Armed Services
United States Senate
Washington, DC 205104050

Dear Mr. Chairman:

The House Conference Report 107-732, accompanying the Department of Defense Appropriations Act for 2003, Public Law 107-248, requested that the enclosed report be submitted to the congressional defense committees on the Department of Defense's Anthrax Vaccine Supply Preparedness. A similar letter has been provided to the other congressional defense committees.

Sincerely,

E. C. Aldridge. Jr.

Enclosures:
As Stated

cc: The Honorable Carl Levin
Ranking Member

The Honorable Duncan Hunter
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 205 15-6035

Dear Mr. Chairman:

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Sincerely,

E. C. Aldridge, Jr.

Enclosures:
As Stated

cc: The Honorable Ike Skelton
Ranking Member

The Honorable Ted Stevens
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 205 1 O-6028

Dear Mr. Chairman:

The House Conference Report 107-732, accompanying the Department of Defense Appropriations Act for 2003, Public Law 107-248, requested that the enclosed report be submitted to the congressional defense committees on the Department of Defense's Anthrax Vaccine Supply Preparedness. A similar letter has been provided to the other congressional defense committees.

Sincerely,

E. C. Aldridge, Jr.

Enclosures:
As Stated

cc: The Honorable Daniel K. Inouye
Ranking Member

The **Honorable** Jerry Lewis
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC **20515-6018**

Dear Mr. Chairman:

The House Conference Report 107-732, accompanying the Department of Defense Appropriations Act for 2003, Public Law 107-248, requested that the enclosed report be submitted to the congressional defense committees on the Department of Defense's Anthrax Vaccine Supply Preparedness. A similar **letter** has been provided to the other congressional defense committees.

Sincerely,

E. C. Aldridge. Jr.

Enclosures:
As stated

cc: The Honorable John P. Murtha
Ranking Member

Report on Preparedness of the Anthrax Vaccine Supply

This report is in response to a requirement from the House of Representatives October 9.2002, Conference Report 107-732 for the FY03 Department of Defense (DoD) Appropriations Act.

"The conferees are concerned about the adequacy of the supply and production capacity for the only FDA-licensed anthrax vaccine currently available in the U.S. to protect our military and civilian defense personnel from the demonstrated and potential future threat of anthrax. The Secretary of Defense is directed to provide a report which assesses the immediate and short-term preparedness and potential future total biowarfare defense need for the FDA-licensed anthrax vaccine. the potential need for expanded production capacity to meet that need, and the need for a separate production capacity to mitigate risks of an event which could result in a halt to current vaccine production. The Secretary shall submit this report to the congressional defense committees within 90 days after enactment of this act?'

Assessment of the immediate and short-term preparedness and potential future total biowarfare defense need for the FDA-licensed anthrax vaccine, and the potential need for expanded production capacity to meet that need:

The DoD has conducted an evaluation of projected Anthrax Vaccine Adsorbed (AVA) requirements and the industrial base. It concludes that the capacity at the BioPort facility in Lansing, Michigan, given present capabilities and absent major manufacturing interruptions, is adequate to meet currently projected DoD immunization requirements and other validated federal agency requirements through September 2006, However, the Department has received additional requests for AVA from other domestic and foreign sources that are not addressed in this analysis because they have not yet been validated as requirements. If these additional requests increase the requirement the current capacity at the Lansing facility would not be sufficient.

Assessment of the need for a separate production capacity to mitigate risks of an event that could result in a halt to current vaccine production:

The DoD is reviewing all options associated with this issue. Efforts are currently underway to establish redundancy that will mitigate risks to a halt in vaccine production. An alternative site for potency testing is in the final stages of qualification for submission to the FDA. A secondary vaccine filling facility is currently being sought. New vaccine storage and animal testing facilities areunder construction. Critical utilities for production are being expanded. A fourth production train is being validated and is expected to come on line during FY03. By employing these risk mitigation strategies, and in the absence of any unforeseen surge requirement for AVA, BioPort Corporation will meet DoD and other federal agency needs for AVA for the foreseeable future.

CHEMICAL AND BIOLOGICAL DEFENSE

The conferees agree to establish a "Chem-bio Defense Initiatives Fund" within the Department of Defense's Chemical and Biological Defense program, and provide an increase of $25,000,000 for this purpose. The Secretary of Defense is directed to allocate these funds among the program proposals listed below in a manner which yields the greatest gain in our chem-bio defensive posture. The program proposals to be considered are:

The National Center for Biodefense;
Chem-bio Threat Mitigation technologies;
Global Pathogen Sensing Portal;
Advanced Sensors for Chem-bio Agents;
Rapid Sensitive Biowarfare Protection;
Diagnostic Tool for Biowarfare;
Ultra-High Field Instrumentation;
Urban Security Initiative;
Chemical Imaging Biothreat Detection;
Biological Agent Sensor/Detection System;
Chem-bio Air Filtration System;
Food Safety and Security Sensors;
Bioinformatics;
Phylogenetic- and PCR-based Detector System
Field Portable Nucleic Acid Bioterrorism Detection;
LISA-Inspector Transportable Chem-bio Detection System;
Distributed Chemical Agent Sensing and Transmission;
Wide-Area Standoff Chem-bio Agent Detection System;
Air Purification for Protection System,
Rapid Antibody-based Countermeasures;
Oral Anthrax Antibiotic;
Plant Vaccine Development;
Rapid Response Sensor Networking for Multiple Applications; and
Chemical Biological Incident Response Force (CBIRF).

ANTHRAX VACCINE SUPPLY PREPAREDNESS

The conferees are concerned about the adequacy of the supply and production capacity for the only FDA-licensed anthrax vaccine currently available in the U.S. to protect our military and civilian defense personnel from the demonstrated and potential future threat of anthrax. The Secretary of Defense is directed to provide a report which assesses the immediate and short-term preparedness and potential future total biowarfare defense need for the FDA-licensed anthrax vaccine, the potential need for expanded production capacity to meet that need, and the need for a separate production capacity to mitigate risks of an event which could result in a halt to current vaccine production. The Secretary shall submit this report to the congressional defense committees within 90 days after enactment of this Act.

CHRONIC MULTI-SYMPTOM ILLNESSES

The conferees have provided $5,200,000 to extend research on chronic multi-symptom illnesses with a special focus on the relationship between Gulf War Illnesses and other diseases.

THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON DC 20301-1000

July 26, 2002

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
UNDER SECRETARIES OF DEFENSE
DIRECTOR, DEFENSE RESEARCH AND ENGINEERING
ASSISTANT SECRETARIES OF DEFENSE
GENERAL COUNSEL OF THE DEPARTMENT OF DEFENSE
INSPECTOR GENERAL OF THE DEPARTMENT OF DEFENSE
DIRECTOR, OPERATIONAL TEST AND EVALUATION
ASSISTANTS TO THE SECRETARY OF DEFENSE
DIRECTOR, ADMINISTRATION AND MANAGEMENT
DIRECTOR, PROGRAM ANALYSIS AND EVALUATION
DIRECTOR, FORCE TRANSFORMATION
DIRECTORS OF THE DEFENSE AGENCIES
DIRECTORS OF THE DOD FIELD ACTIVITIES

SUBJECT: Expeditious Submission of Reports to Congress and Congressional Committees

In order to expedite the submission of required reports to the Congress, officials assigned responsibility by the Under Secretary of Defense (Comptroller) under DoD Directive 5545.2, "DoD Policy for Congressional Authorization and Appropriations Reporting Requirements," for preparing Secretarial Reports are delegated the authority to submit reports directly to the Congress or its Committees. This delegation of authority may be redelegated in writing to the Heads of DoD Components and to other civilian officials of the Department of Defense appointed by the President with the advice and consent of the Senate.

Notwithstanding the foregoing, when deemed appropriate, a report may be forwarded to the Secretary or Deputy Secretary of Defense for review and submission to the Congress or its Committees. Such reports shall be forwarded in sufficient time to permit review and submission before the report due date.

All Secretarial Reports required by law shall be coordinated with the Under Secretary of Defense (Comptroller), the Assistant Secretary of Defense (Legislative Affairs), the DoD General Counsel and, as appropriate, other DoD officials having collateral or related responsibilities.

U11837-02

(b)(6)

Forwarded this to COL
Powell —
(b)(6) —

FOUL, FOUL, FOUL on this action... I don't want to hear (b)(6) complaints on short suspense anymore - this is dated 24 JAN (just received) for a 27 JAN suspense ??!
You may want to call and request extension —

(b)(6)

Anthrax Vaccine Supply Preparedness - Report to Congress

Coordination*

	Concur	Non-concur	Concur with Comments
USD(C)			
DUSD(IP)			
ODoD(GC)			
ASD(HA)	X Embargo		
ASD(LA)			
DIR(ARA)			
DIR(DP)			
JRO(CBRN)			

* Please print the name of the principal responding on this action.

CMAT Control #
2002046-0000001

(264)

ASSISTANT TO THE SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

NUCLEAR AND CHEMICAL
AND BIOLOGICAL DEFENSE
PROGRAMS

13 FEB 2002

MEMORANDUM FOR DISTRIBUTION

SUBJECT: FINAL DRAFT DoD Chemical and Biological Defense Program Annual Report to Congress

As directed by public law (Section 1523 of Title 50 of the U.S. Code (50 USC 1523)), the Department has prepared a report to Congress detailing information on the Chemical and Biological Defense Program. This report includes information on existing capabilities; research, development, and acquisition programs; requirements; status of training and readiness; and measures to improve management and coordination.

This final draft is being issued for coordination and concurrence. A coordination sheet is attached for your convenience. Signature by a principal representative within each organization is requested (Organization Director, Flag Officer, or civilian equivalent.) Comments and concurrence are due by **Tuesday, 5 March 2002**. Concurrence will be assumed if there is no response by this date. My contractor point of contact for coordination of the report is Mr. David W. Evans (phone: 703-416-3040, e-mail: david.evans@anser.org).

Also on **13 March 2002**, a final review of the pre-publication draft of the report will be held at the ANSER conference facility in Arlington, Virginia. (See attachment for directions.) You or a representative from your office are invited to attend this open session from 0800-1600 to review the final pre-publication version of the report, which will incorporate all final changes (to include the final budget figures, layout and design of the final report, and final editorial changes.) Thank you for your support in this effort.

<<SIGNED>>

Anna Johnson-Winegar, Ph.D.
Deputy for Chemical and Biological Defense

Attachment
1. Coordination Sheet
2. Directions to Pre-Publication Review
3. Final Draft DoD CBDP Annual Report

DISTRIBUTION:

Under Secretary for Defense for Acquisition, Technology, and Logistics

Under Secretary for Defense for Policy

Under Secretary for Defense for Personnel and Readiness

OSD Comptroller (Attn: David Decker)

Director, Joint Chiefs of Staff

Secretaries of the Military Departments

- Secretary of the Army
- Secretary of the Air Force
- Secretary of the Navy
- Commandant of the Marines Corps

Director, For Strategic Plans and Policy (J-5)

Assistant Secretary of Defense for Health Affairs

Assistant Secretary of Defense Special Operations/Low Intensity Conflict (Attn: Mr. John Reingruber)

Assistant Secretary of Defense (Strategy & Threat Reduction)

Assistant Secretary of Defense (Legislative Affairs)

Assistant Secretary of Defense (Public Affairs)

Deputy Assistant Secretary of Defense for Counterproliferation Policy

Special Assistant to the Secretary of Defense for Gulf War Illness (Attn: Director, Lessons Learned Implementation)

Director, ARA (Attn: Ms. Dianne Carroll)

Director, Defense Research and Engineering

Defense Intelligence Agency (TWP-4 and TWP-5)

Director, Defense Threat Reduction Agency (DTRA)

- Director, DTRA Chemical/Biological Directorate

Director, Defense Advanced Research Projects Agency

Joint Nuclear, Biological, and Chemical Defense Board Secretariat (Attn: Col Brown, DAMO-FDB)

Joint Service Material Group

Joint Service Integration Group

Joint Program Office for Biological Defense

Department of Defense Chemical and Biological Defense Program

Annual Report to Congress and Performance Plan

Coordination Sheet

My organization has reviewed the final draft of the Annual CB Defense Report and Performance Plan, which has been prepared in accordance with 50 USC 1523.

[ ] **Concur**, without change to final draft.

[ ] **Concur**, with recommended changes.

[ ] **Non-concur**. Concur with incorporation of attached recommended substantive changes.

Organization: _____

Phone: _____

Name (printed): _____

Signature: _____

Coordination sheets should be provided to:

COL Karl Semancik
DATSD(CBD)
Room 3C257
3050 Defense
The Pentagon
Washington, D.C. 20301-3050

Fax: (b)(6)
Phone:
e-mail

Alternate fax: (b)(6)
Phone: (b)(6) :

Attachment 2

Directions to Pre-Publication Review
Directions to ANSER

FROM THE SOUTH: From I-95 north, take I-395 north toward Washington. Take exit number 6, toward Shirlington. Keep left at the fork in the ramp, and left at the next fork in the ramp. Then keep right and turn left onto South Quincy Street.

FROM THE NORTH-WEST: Take I-270 east to I-495 south (toward Richmond). Take the VA-193 exit, number 14-13, toward George Washington Memorial Parkway/Georgetown Pike. Keep right at the fork in the ramp. Merge onto George Washington Memorial Parkway south. Take the exit toward I-395 south. Keep right at the fork in the ramp. Merge onto Washington Boulevard. Take the I-395 south ramp toward Ridge Road/Richmond. Keep left at the fork in the ramp. Merge onto I-395 south. Take the VA-120/Glebe Road exit, number 7, toward Shirlington. Keep left at the fork in the ramp. Keep right at the next fork in the ramp. Turn left onto South Shirlington Road. Take the I-395 ramp. Keep right at the fork in the ramp. Turn left onto South Quincy Street.

FROM SOUTH-EAST (MD): Take the I-495 south ramp toward Alexandria/Richmond. Merge onto the Capital Beltway. Take the US-1 south/US-1 north exit, number 1, toward Mount Vernon Highway. Keep left at the fork in the ramp. Merge onto US-1 north/South Patrick Street. Turn left onto King Street/VA-7. Turn right onto North Quaker Lane/VA-402 north. Take the I-395 ramp. Keep left at the fork in the ramp. Then keep right and turn left onto South Quincy Street.

FROM NORTH-EAST (MD): Take I-95, exit 22 to get onto I-295; follow I-295 south to the South-East South-West Exit (I-395). Follow I-395 south to VA-120/Glebe Road exit, number 7, toward Shirlington. Keep left at the fork in the ramp. Keep right at the next fork in the ramp. Turn left onto South Shirlington Road. Take the I-395 ramp. Turn left onto South Quincy Street.

FROM METRO (Subway): Take the Yellow Line or Blue Line to the Pentagon stop. An ANSER Shuttle bus will take you from the Metro to Quincy Tower in Shirlington.

FROM THE AIRPORTS:

Baltimore-Washington International Airport

By car: Start out going Southeast on Friendship Road toward hourly parking by turning right. Follow the sign for Departures. Turn slightly right and follow the Airport Exit sign. Take I-195 west. Take the MD-295 south/Baltimore-Washington Parkway exit, number 2B, toward Washington. Merge onto MD-295 south. Take the exit toward Washington. Merge onto US-50 west. Take I-395 south. Take the VA-120/Glebe Rd exit, number 7, toward Shirlington. Keep left at the fork in the ramp. Keep right at the next fork in the

ramp. Turn left onto South Shirlington Road. Take the I-395 ramp. Keep right at the fork in the ramp. Turn left onto South Quincy Street.

By Public Transit: Take the free shuttle bus to the BWI rail station. Take a MARC or Amtrak train (both run approximately hourly) to Union Station in Washington (the end of the line for all MARC and most Amtrak trains). Take the Red Line Metro going toward Shady Grove for two stops, to Gallery Place. Get on the Yellow Line going toward Huntington, and ride to the Pentagon. At the bus stop above the station, take the ANSER shuttle bus to Quincy Tower.

Ronald Reagan Washington National Airport

By Car: Start out going Northeast by following signs for B C Arrivals/Ticketing toward B C Ticketing/Check In. Turn slight left, follow signs for B C Arrivals/Bag Claim. Stay straight to go onto Airport Exit. Take the ramp toward George Washington Parkway north. Merge onto George Washington Parkway north. Take the exit for I-395 south/US-1 south toward I-66 west/Richmond. Merge onto I-395 south. Take the VA-120/Glebe Road exit, exit 7, toward Shirlington. Keep left at the fork in the ramp. Keep right at the next fork in the ramp. Turn left onto South Shirlington Road. Take the I-395 ramp. Keep right at the fork in the ramp. Turn left onto South Quincy Street.

By Public Transit: Take the Metro Blue Line going toward Addison Road or the Yellow Line toward Mount Vernon Square (both lines depart on the same track). Ride three stops to the Pentagon; take the ANSER shuttle bus to Quincy Tower.

Washington-Dulles International Airport

By Car: Start out going West on Dulles Airport Access Road toward Saarinen Circle by turning left. Turn slightly right onto Saarinen Circle. Stay straight to go onto Dulles Airport Access Road which becomes VA-267 east. Take I-66 east. Take the Fairfax Drive exit, number 71, toward VA-120/VA-237/Glebe Rd. Stay straight to go onto exit 71. Stay straight to go onto North Fairfax Drive. Turn right onto North Glebe Rd/VA-120 south. Turn slightly right onto South Shirlington Road. Take the I-395 ramp. Keep right at the fork in the ramp. Turn left onto South Quincy Street.

By Public Transit: Take the Washington Flyer bus to the West Falls Church Metro stop. Take the Metro toward New Carrollton. Get off at the Rosslyn stop. Take the Blue Line going toward Franconia-Springfield. Ride two stops to the Pentagon; take the ANSER shuttle but to Quincy Tower.

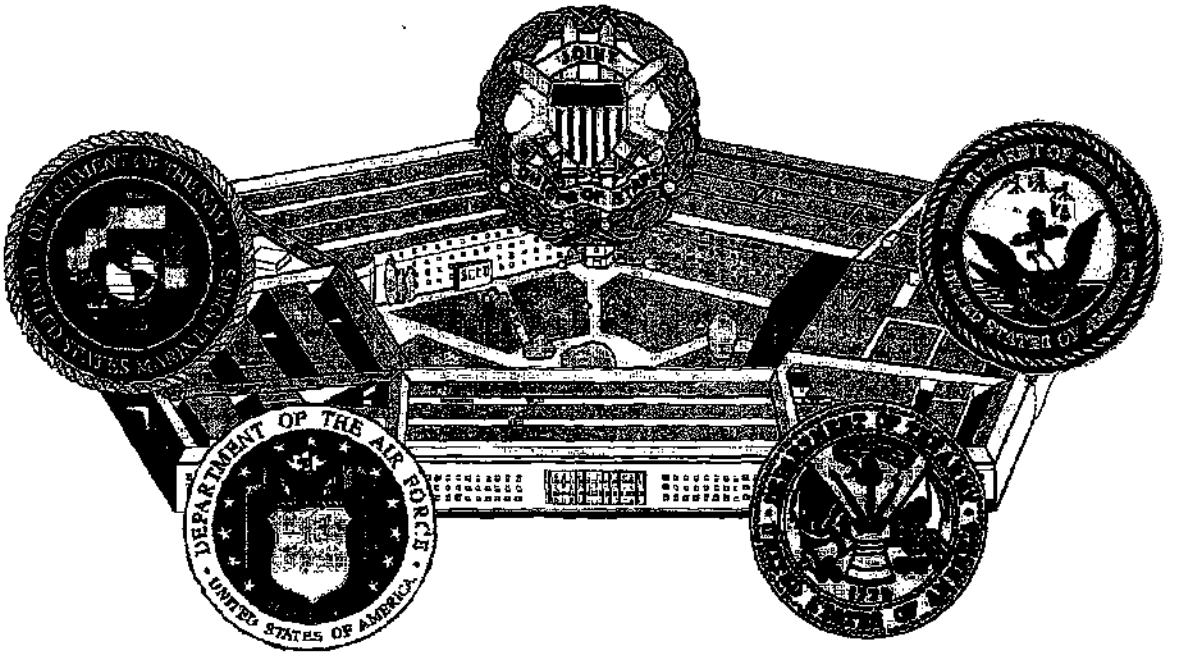
Public Transportation

Check the ANSER website at www.anser.org, "ANSER is Moving," for Public Transportation options and metro bus schedules.

If you need assistance, call 416-2000 (ANSER operator).

DRAFT

Department of Defense Chemical and Biological Defense Program



Volume I: Annual Report to Congress

Volume II: FY2001-2003 Performance Plan

See inside cover for coordination information.

MARCH 2002

COORDINATION INFORMATION:

Coordination Sheets should be completed and returned not later than Tuesday, March 5, 2002.

Return coordination sheets:

By mail or delivery:

DATSD(CBD)
Attn: COL Karl Semancik
Room 3C257
3050 Defense
Then Pentagon
Washington, D.C. 20301-3050

Or by e-mail: (b)(6) **@osd.mil**

cc: (b)(6) **@anser.org**

Or by Fax: (b)(6)

Executive Summary (DRAFT)

In accordance with 50 USC 1523 (Section 1703, Public Law No. 103-160) the Secretary of Defense is required to submit an annual report to Congress on chemical and biological (CB) defense. This report is intended to assess:

(1) the overall readiness of the Armed Forces to fight in a chemical-biological warfare environment and shall describe steps taken and planned to be taken to improve such readiness; and

(2) requirements for the chemical and biological warfare defense program, including requirements for training, detection, and protective equipment, for medical prophylaxis, and for treatment of casualties resulting from use of chemical and biological weapons.

The vision of the DoD Chemical and Biological Defense Program (CBDP) is to ensure U.S. military personnel are the best equipped and best prepared force in the world for operating in future battlespaces that may feature chemically and biologically contaminated environments. To fulfill this vision, the CBDP has established a mission to provide world-class chemical and biological defense capabilities to allow the military forces of the United States to survive and successfully complete their operational missions—from peacetime contingency missions through two nearly simultaneous major theater wars across the entire spectrum of conflict—in battlespace environments contaminated with chemical or biological warfare agents. The probability of U.S. forces encountering CB agents during worldwide conflicts remains high. An effective defense reduces the probability of a CB attack, and if an attack occurs, it enables U.S. forces to survive, continue operations, and win. The unique physical, toxicological, destructive, and other properties of each threat requires that operational and technological responses be tailored to the threat. Scientific, technological, and resource limitations remain in preventing U.S. forces from having complete full dimensional protection or in meeting all requirements for two nearly simultaneous Major Theater Wars. Nevertheless, significant progress has been made in overcoming many of these limitations since the establishment of the DoD CBDP. *U.S. forces remain the best protected forces in the world for surviving and conducting operations in chemically or biologically contaminated environments.*

During the past year, ...[*summary of accomplishments, highlights pending*]

Numerous rapidly changing factors continually influence the program and its management. These factors include limited DoD resources, planning for warfighting support to numerous regional threat contingencies, the evolving geopolitical environment resulting from the breakup of the Soviet Union, the entry into force of the Chemical Weapons Convention, and continuing proliferation of chemical and biological weapons.

Chemical and biological defense programs are managed jointly by the Services under the oversight of the OSD CB Defense Steering Committee. The Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense, DATSD(CBD), exercises day-to-day oversight of the DoD CBDP and serves as executive secretary for the Committee. The DoD CBDP coordinates its programs with other DoD components (including the Defense Advanced Research Projects Agency), international partners, and other federal agencies, whose primary focus is on the development of capabilities to protect the civilian population from exposure to chemical or biological agents.

The DoD CBDP invests in technologies to provide improved capabilities that have minimal adverse impact on warfighting potential. Chemical and biological defenses are conducted within the framework of four operational concepts: contamination avoidance, CB battle management, protection, and decontamination. Contamination avoidance consists of capabilities and procedures to detect, identify, and conduct reconnaissance of the battlespace for CB warfare threats. The information from contamination avoidance systems provide input to CB battle management systems to provide commanders with a view of the battlespace to enable them to determine the appropriate protective posture and plan operational responses. When contamination cannot be avoided, protection provides capabilities to survive, fight, and win in a CB contaminated environment. Protection consists of individual protection, collective protection, and medical systems. Finally, decontamination provides critical capabilities to allow the sustainment of operations in a contaminated environment.

Several capabilities have been fielded that address shortcomings in CB defense capabilities that were identified to have existed during the Persian Gulf War (Operation Desert Storm.) These systems are in addition to the continued sustainment of legacy systems and the development of new capabilities within the research and science and technology base programs. Selected examples of capabilities fielded since the establishment of the DoD CBDP include:

- Automatic Chemical Agent Detector Alarm (M22 ACADA),
- Biological Integrated Detection System (M31 BIDS),
- Biological Warfare Sampling Kit,
- Chemically and Biologically Protected Shelter (CBPS),
- Improved (Chemical Agent) Point Detection System,
- M291 Personal Decontamination Kit,
- M295 Equipment Decontamination Kit,
- M41 Protective Assessment Test System,
- M99 Portal Shield Network Sensor System,
- M93A1 NBC Reconnaissance System (NBCRS), and
- Modular Decontamination System.

All CB defense capabilities are integrated into a system-of-systems to provide the most effective approach to avoid contamination and sustain operational tempo on an asymmetric battlefield. Moreover, sound joint doctrine and realistic training remain fundamental to the defense against CB weapons. Descriptions of CB defense capabilities are detailed in this report.

In summary, the DoD CBDP continues to focus on a jointly integrated research, development, and acquisition approach—balancing short-term procurement and long-term science and technology efforts—to obtain needed CB defense capabilities for U.S. forces.

OVERVIEW OF REPORT

The ***INTRODUCTION*** provides a background of the rationale and purpose of the DoD Chemical and Biological Defense Program (CBDP). This section summarizes the key counterproliferation priorities and the current CB warfare threats to U.S. forces. Intelligence documents tailored to the threat are essential for developing and updating requirements for CB defense programs. Each CB defense research, development, and acquisition effort funded within the program responds to a defined or validated threat. Variations among chemical and biological agents and each agent's unique physical, toxicological, destructive, and other properties such as means of delivery require that operational and technological responses be tailored to the threat. Intelligence efforts continue to emphasize collection and analysis of nations' "dual-use" chemical and biological industrial capabilities and develop the indications and warning of adversarial use or diversion of dual-use capabilities to weapons programs.

CHAPTER 1 describes the accomplishments, processes, and issues related to DoD CBDP management and oversight. Since the program's inception, DoD has made significant progress in improving the overall joint management and coordination of the NBC defense program, including integration of medical and non-medical chemical and biological defense programs. *50 USC 1522 has been a critical tool for ensuring the elimination of redundant programs, focusing funds on program priorities, and enhancing readiness.* This chapter outlines the changes within the oversight and management structure that have occurred as a result of the Defense Reform Initiative and the establishment of the Defense Threat Reduction Agency.

CHAPTER 2 provides information on medical and non-medical NBC defense requirements and research, development, and acquisition programs. Requirements and the status of research and development assessments are described within the framework of the functional areas of NBC defense. This chapter outlines plans and strategies for the development and acquisition of capabilities in each of the program commodity areas, including contamination avoidance, individual protection, collective protection, modeling and simulation, medical chemical defense, and medical biological defense. In addition, this chapter includes a "Special Report on Anthrax Vaccine Costs, Acquisition Strategy, and Related Issues," in section 2.8 in accordance with the request for information as stated in the National Defense Authorization Act for Fiscal Year 2001 - Authorization Conference Report (106-945, Section 217, Joint Biological Defense Program, p. 719).

CHAPTER 3 provides an analysis of NBC defense logistics posture. The analysis reviews the status of quantities, characteristics, and capabilities and limitations of all fielded NBC defense equipment, industrial base requirements, procurement schedules, and problems encountered. Much of the information is based on the model of Joint Chemical Defense Equipment Consumption Rates (JCHEMRATES IV). Additional information is derived from the Joint NBC Defense Logistics Support Plan.

CHAPTER 4 assesses the status of NBC defense training and readiness conducted by the Services. Each of the Services' training standards and programs is reviewed. In accordance with Section 1702 of P.L. 103-160 (50 USC 1522) all chemical and biological warfare defense training activities of the Department of Defense have been consolidated at the United States Army Chemical School. This chapter also provides information on the move of the Chemical School from Fort McClellan, Alabama to Fort Leonard Wood, Missouri.

CHAPTER 5 provides information on the status of DoD efforts to implement the Chemical Weapons Convention (CWC), which was ratified by the United States and entered into force during 1997. This chapter also includes a summary of plans and activities to provide assistance to other countries in response to an appeal by another State Party to the CWC, pursuant to Article X of the CWC.

Finally, there are several ***ANNEXES*** to this report. ***Annexes A through E*** provide detailed information on Joint and Service-unique NBC defense equipment, including contamination avoidance, protection, decontamination, and medical programs. Detailed descriptions are provided for systems and equipment that have been fielded, are in production, or under development. ***Annex G*** provides NBC defense logistics readiness data and a breakout of service war requirements, stocks on-hand, and planned acquisitions. This information supplements information in Chapter 3. ***Annex G*** provides a summary of funds appropriated, budgeted, and expended by the DoD CBDP. One of the successes of the DoD NBC Defense Program has been the consolidation of all DoD NBC Defense research, development, test, and evaluation (RDT&E) and procurement program funds under defense-wide program elements, rather than throughout numerous Service accounts. ***Annex H*** provides a statement regarding chemical and biological defense programs involving human subjects as required by 50 USC 1523. As detailed in the annex, no such testing has been conducted in over two decades and none is planned. ***Annex I*** provides the text of the congressional language requiring this report. ***Annex J*** provides a list of the many acronyms and abbreviations that are used throughout this report.

Table of Contents

Volume I: Annual Report to Congress

ANNEXES **Page**

TABLES AND FIGURES

TABLES **Page**

FIGURES

Introduction

I. PURPOSE OF REPORT

In accordance with 50 USC 1523, this report provides Congress with an assessment of the overall readiness of the Armed Forces to fight in a chemical and biological warfare environment. This is the eighth report submitted under 50 USC 1523.*

II. GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

The Department of Defense (DoD) Chemical and Biological Defense Program (CBDP) has prepared a performance plan (included as Volume II of this report) to align itself more closely with the tenets of the GPRA. This performance plan demonstrates full compliance with the requirements of the GPRA, which requires agencies to submit an annual performance plan to Congress. This establishes a *process* by which the CBDP can measure the effectiveness of the various projects under the CBDP and assess their contributions to the operational goals and the mission of the program. This process provides a tool for identifying strengths and weaknesses in the development and execution of programs. This plan will act as a reference document for the effective oversight and management of the program. The Office of the Secretary of Defense (OSD) Chemical and Biological Defense Steering Committee prepared this performance plan in order to provide targets—both planned and actual—for the current assessed year (FY2001) and the next two planning years (FY2002 & 2003). Specifically, the plan:

- Establishes explicit and outcome-oriented goals linked to warfighters' ability to survive, fight, and win in a CB environment,
- Identifies quantitative and/or qualitative performance measures that can be used to assess progress towards goal achievement,
- Describes how performance data is validated,
- Describes how RDT&E activities of participating DoD and non-DoD organizations are coordinated to achieve program goals, and
- Identifies human capital, financial, and resource challenges or external factors that limit the ability of the program to achieve its goals.

The performance plan draws on information and consolidates data from reports and plans already being prepared within the CBDP, including (1) the Modernization Plan, (2) the Research, Development, and Acquisition (RDA) Plan, (3) the Logistics Support Plan, (4) the Joint Warfighting Science and Technology Plan, (5) the Defense Technology Area Plan, (6) Joint Service Chemical/Biological Information System (JSCBIS) materiel fact sheets, and (7) the Annual Report to Congress. In addition, the performance plan draws on current data contained in documents prepared

* The text of 50 USC 1523, *Annual report on chemical and biological warfare defense*, (implemented as part of Public Law 103-160, the FY94 National Defense Authorization Act) is included at Annex I.

in support of the Planning, Programming, and Budgeting System (PPBS), including Defense Planning Guidance, the CBDP Program Strategy Guidance, the Program Objectives Memorandum, the President's Budget and supporting detailed information in the RDT&E and Procurement Congressional Exhibits Forms.

CBDP Vision, Mission, and Goals

DoD has developed a vision statement, mission statement, and corporate-level goals that reflect critical steps in the execution of the National Security Strategy. To support and relate to the DoD plan, the CBDP has developed supporting mission, vision and corporate goals.

DoD Vision:

- Fields the best trained, best equipped, best-prepared fighting force in the world.
- Supports alliances and security relationships that protect and advance U.S. security interests.
- Advances national interests by working effectively with other federal agencies, congress, and the private sector.
- Serves as a model of effective, efficient, innovative management and leadership.

Chemical and Biological Defense Program Vision

Ensure U.S. military personnel are the best equipped and best prepared force in the world for operating in future battlespaces that may feature chemically and biologically contaminated environments.

DoD Mission:

Support and defend the Constitution of the United States; to provide for the common defense of the United States, its citizens, and its allies; and to protect and advance U.S. interests around the world.

Chemical and Biological Defense Program Mission

Provide world-class chemical and biological defense capabilities to allow the military forces of the United States to survive and successfully complete their operational missions—from peacetime contingency missions through two nearly simultaneous major theater wars across the entire spectrum of conflict—in battlespace environments contaminated with chemical or biological warfare agents.

DoD Corporate-Level Goals:

- Shape the international environment and respond to the full spectrum of crises by providing appropriately sized positioned and mobile forces.
- Prepare now for an uncertain future by pursuing a focused modernization effort that maintains U.S. qualitative superiority in key warfighting capabilities. Transform the force by exploiting the Revolution in Military Affairs, and reengineer the Department to achieve a 21st century infrastructure.

Chemical and Biological Defense Program Corporate-Level Goals

Develop, acquire and field NBC defense equipment that meets warfighter requirements while reducing acquisition costs and time of development. Equipment will be developed that permits the warfighters to:

- *View NBC Warfare Agents within the Theater Area of Operations.*
- *Dominate the Battlespace through Reconnaissance, Surveillance, and Target Acquisition.*
- *Enhance the Situational Awareness of Unit Battlespace.*
- *Provide Real-Time Hazard Information to Influence Current Operations.*
- *Enhance Personnel and Equipment Survivability.*
- *Maintain Ground, Air and Maritime Operational Tempo.*
- *Sustain Operations, Recovery and Reconstitution Efforts.*

All of the capabilities integrated together as a system-of-systems are essential to avoid contamination and to sustain operational tempo on an asymmetric battlefield. Sound Joint doctrine and realistic training remain fundamental to defense against NBC weapons.

On February 13, 2001, at Norfolk Naval Air Station, President Bush stated, "we must prepare our nations against the dangers of a new era. The grave threat from nuclear, biological and chemical weapons has not gone away with the Cold War. It has evolved into many separate threats, some of them harder to see and harder to answer. And the adversaries seeking these tools of terror are less predictable, more diverse." U.S. forces must have numerous capabilities in order to respond and deploy quickly to various worldwide needs. Counterproliferation capabilities are required by forces to meet worldwide needs, and NBC defense is integral to counterproliferation capabilities. In a February 2001 Joint Warfighting Capabilities Assessment (JWCA) study approved by the Joint Requirements Oversight Council, the Commanders-in-Chief identified their priorities for counterproliferation capabilities. These priorities are shown in Table I-1. Capabilities that are supported by the CB defense program are highlighted in **bold**. As currently identified, CB defense capabilities are listed in four of the top ten CINC priorities. *Individual protection* includes physical protection devices, medical countermeasures (vaccines, prophylaxes, pre-treatments, antibiotics, antidotes, and post-exposure treatments), and CB mass casualty medical treatment. *Detect and Monitor Use of WMD* includes establishing and maintaining the necessary capabilities to detect CB use, including medical diagnostics. *Communicate the Ability and Will to Employ Defensive Capabilities* includes demonstrating the capacity to employ defensive capabilities to reduce an enemy's perceived utility in developing, producing, and threatening to use or actually using CB weapons. *Collective protection* provides relief from sustained operations in full individual CB protective equipment, shelters for sensitive equipment not easily decontaminated, and clean environments for operations that cannot be performed under CB contaminated conditions. *Establish/Maintain Ability to Restore from WMD* use includes establishing and maintaining the necessary capabilities to restore operations after the employment of CB contamination. Restoration activities may include decontamination operations.

Table I-1. Finalized Geographic CINC Prioritized Counterproliferation Requirements

Rank	CP Requirement
1	**Provide individual protection to forces and assist allies/coalition partners with relief from the effects of NBC**
2	**Detect and Monitor Development, Production, Deployment, Employment* and Transfer of WMD and Determine Vulnerabilities**
3	Communicate the Ability / Will to Employ Interdiction / Response Capabilities
4	**Intercept the Conventional Delivery of WMD with Minimal Collateral Effects**
5	**Detect and Monitor Use of WMD**
6	**Conduct Off-Site Attack to Destroy, Disable, and Deny WMD Targets**
7	**Communicate the Ability and Will to Employ Defensive Capabilities**
8	**Establish and Maintain Relations with Allies, and Potential Adversaries to Discourage Development, Production, and Use of WMD**
9	**Provide Collective Protection to Forces and Assist Allies / Coalition with Relief from the Effects of NBC**
10	**Seize, Destroy, Disable, and Deny Transport of WMD**
11	Conduct Information Warfare to Destroy, Disable, and Deny WMD Development, Production, Deployment, and Employment
12	**Determine vulnerabilities in decision-making process related to WMD**
13	Conduct On-Site Attack to Seize, Destroy, Disable, and Deny WMD Targets
14	**Provide Alternatives to the Pursuit of WMD**
15	Support treaties, export controls, and political/diplomatic efforts
16	**Destroy, Disable, and Deny Actor's Non-WMD Resources and Capabilities**
17	**Establish / Maintain Ability to Restore from WMD use**
18	**Provide personnel, training, materiel, equipment, to support security assistance**
19	Provide intelligence collection capabilities in support of USG NP efforts

* Detecting "employment" refers to the capability to detect prior to actual use.

The response to the threat of CB weapons must be based on the nature of this threat, not just where the threat occurs. A key part of DoD's strategy is to stem the proliferation of such weapons and to develop an effective capability to deal with these threats. To focus the response to the threat, DoD and the intelligence community have completed several classified reports providing threat assessments on chemical and biological threats to U.S. forces. To minimize the effect of these threats to U.S. forces, DoD continues to improve defensive capabilities. These continuing improvements also contribute to our overall deterrence by demonstrating to an adversary that use of CB agents or weapons provides little or no military advantage. The DoD CB Defense Program continues to work towards increasing the capabilities of Joint Forces to survive and continue their mission during conflicts that may involve the use of CB agents or weapons.

Those countries which persist in offensive chemical weapons programs are adding agents and more sophisticated delivery systems. Similarly, the sophistication of CB weapons capabilities is increasing. Proliferation of weapons technology, precision navigation technology, nuclear technologies (medical, power, and industrial applications), and advanced chemical and biological technologies to developing nations presents the United States with a complicated national security challenge. Intelligence efforts include collection and analysis of nations' "dual-use" nuclear, chemical, and biological industrial capabilities, and development of the indications and warning of diversion of dual-use

capabilities to weapons programs. Tailored intelligence documents are essential for assessing, developing and updating requirements for CB defense programs. Numerous threat documents tailored to the CB threat have been produced and are updated periodically. The Intelligence Community continues to review U.S. chemical and biological warfare intelligence requirements and assess the adequacy of intelligence assets to execute the required intelligence program.

III. THE CURRENT CHEMICAL AND BIOLOGICAL WARFARE THREAT

Northeast Asia

North Korea has been pursuing research and development related to biological warfare since the 1960s. Pyongyang's resources presently include a rudimentary (by Western standards) biotechnology infrastructure that is sufficient to support the production of limited quantities of toxins, as well as viral and bacterial biological warfare agents. In the early 1990s, an open press release by a foreign government referred to applied military biotechnology work at numerous North Korean medical institutes and universities dealing with the anthrax, cholera, plague and smallpox pathogens. North Korea possesses a sufficient munitions-production infrastructure to accomplish weaponization of BW agents. North Korea does possess a sufficient munitions production infrastructure to accomplish weaponization of BW agents.

By comparison, North Korea's chemical warfare program is believed to be mature and includes the capability, since 1989, to indigenously produce bulk quantities of nerve, blister, choking and blood chemical agents as well as a variety of filled munitions systems. North Korea is believed to possess a sizable stockpile of chemical weapons, which could be employed in offensive military operations against the South. In fact, the United States believes that North Korea has some long-range artillery deployed along the demilitarized zone (DMZ) and ballistic missiles, some of which could deliver chemical warfare agents against forward-based U.S. and allied forces, as well as against rear-area targets.

North Korea has also devoted considerable scarce resources to defensive measures aimed at protecting its civilian population and military forces from the effects of chemical weapons. Such measures include extensive training in the use of protective masks, suits, detectors, and decontamination systems. Though these measures are ostensibly focused on a perceived threat from U.S. and South Korean forces, they could also support the offensive use of chemical weapons by the North during combat. North Korea has yet to sign the Chemical Weapons Convention (CWC) and is not expected to do so in the near-term, due to intrusive inspection and verification requirements mandated by the agreement.

China possesses an advanced biotechnology infrastructure as well as the requisite munitions production capabilities necessary to develop, produce and weaponize biological agents. China has consistently claimed that it never researched, produced, or possessed any biological weapons and would never do so. Nevertheless, China's declarations under the voluntary BWC declarations for confidence building purposes are believed to be inaccurate and incomplete, and there are some reports that China may retain elements of its biological warfare program.

China is believed to have an advanced chemical warfare program that includes research and development, production and weaponization capabilities. While China claims it possesses no chemical agent inventory, it is believed to possess a moderate inventory of chemical agents. It has a wide variety of potential delivery systems for chemical agents, including cannon artillery, multiple rocket launchers, mortars, land mines, aerial bombs, SRBMs, and MRBMs. Chinese military forces most likely have a good understanding of chemical warfare doctrine, and its forces routinely conduct defensive chemical warfare training. Even though China has ratified the CWC, made its declaration, and subjected its declared chemical weapons facilities to inspections, DoD believes that Beijing has not acknowledged the full extent of its chemical weapons program.

South Asia

India has many well-qualified scientists, numerous biological and pharmaceutical production facilities, and biocontainment facilities suitable for research and development of dangerous pathogens. At least some of these facilities are being used to support research and development for biological warfare defense work. India has ratified the BWC.

India is an original signatory of the CWC. In June 1997, it acknowledged that it had a dedicated chemical warfare production program. This was the first time India had publicly admitted that it had a chemical warfare effort. India also stated that all related facilities would be open for inspection, as called for in the CWC, and subsequently, it has hosted all required CWC inspections. While India has made a commitment to destroy its chemical weapons, its extensive and well-developed chemical industry will continue to be capable of producing a wide variety of chemical agent precursors should the government change its policy.

Pakistan is believed to have the resources and capabilities to support a limited biological warfare research and development effort. Pakistan may continue to seek foreign equipment and technology to expand its biotechnology infrastructure. Pakistan has ratified the BWC and actively participates in compliance protocol negotiations for the treaty.

Pakistan ratified the CWC in October 1997 and did not declare any chemical agent production or development. Pakistan has imported a number of dual-use chemicals that can be used to make chemical agents. These chemicals also have commercial uses and Pakistan is working towards establishing a viable commercial industry capable of producing a variety of chemicals, some of which could be used to make chemical agents. Chemical agent delivery methods available to Pakistan include missiles, artillery, and aerial bombs.

The Middle East and North Africa

Iran has a growing biotechnology industry, significant pharmaceutical experience and the overall infrastructure to support its biological warfare program. Tehran has expanded its efforts to seek considerable dual-use biotechnology materials and expertise from entities in Russia and elsewhere, ostensibly for civilian reasons. Iran's biological warfare program began during the Iran-Iraq War. Iran is believed to be pursuing offensive biological warfare capabilities and its effort may have evolved beyond agent research and development to the capability to produce small quantities of agent. Iran has ratified the BWC.

Iran ratified the chemical Weapons Convention (CWC), and in a May 1998 session of the CWC Conference of the States Parties, Tehran, for the first time, acknowledged the existence of a past chemical weapons program. Iran admitted developing a chemical warfare program during the latter stages of the Iran-Iraq war as "deterrent" against Iraq's use if chemical agents against Iran. Moreover, Tehran claimed that after the 1988 cease-fire, it "terminated" its program.

Nevertheless, Iran has continued its efforts to seek production technology, expertise and precursor chemicals from entities in Russia and China that could be used to create a more advanced and self-sufficient chemical warfare infrastructure. In the past, Tehran has manufacture and stockpiled blister, blood and choking chemical agents, and weaponized some of these into artillery shells, mortars, rockets, and aerial bombs. It also is believe to be conducting research on nerve agents. Iran could employ these agents during a future conflict in the region.

Prior to the Gulf War, *Iraq* developed the largest and most advanced biological warfare program in the Middle East. Though a variety of agents were studied, the Iraqis declared anthrax, botulinum toxin, and aflatoxin to have completed the weaponization cycle. Iraq also admitted that during the Persian Gulf War it had deployed biological agent-filled munitions to airfields and that these weapons were intended for use against Israel and coalition forces in Saudi Arabia. Iraq stated that it destroyed all of these agents and munitions in 1991, but it has provided insufficient credible evidence to support this claim.

The UN believes that Baghdad has the ability to reconstitute its biological warfare capabilities within a few weeks or months, and in the absence of UNSCOM or other international inspections and monitoring during 1999 and 2000, DoD is concerned that Baghdad again may have produced some biological warfare agents.

Since the Gulf War, Baghdad has rebuilt key portions of its industrial and chemical production infrastructure; it has not become a state party to the CWC. Some of Iraq's facilities could be converted fairly quickly to production of chemical warfare agents. Following OPERATION DESERT FOX, Baghdad again instituted a rapid reconstruction effort on those facilities to include former dual-use chemical warfare-associated production facilities, destroyed by U.S. bombing. In 1999, Iraq may have begun installing or repairing dual-use equipment at these or other chemical warfare –related facilities. Previously, Iraq was known to have produced and stockpiled mustard, tabun, sarin, and VX, some of which likely remain hidden. It is likely that an additional quantity of various precursor chemicals also remain hidden.

In late 1998, UNSCOM reported to the UN Security Council that Iraq continued to withhold information related to its chemical program. UNSCOM inspectors, which indicated that Iraq had not consumed as many chemicals munitions during the Iran-Iraq War as had been declared previously by Baghdad. This document suggests that Iraq may have an additional 6,000 chemical munitions hidden. Similarly, UNSCOM's discovery in 1998 of evidence of VX in Iraqi missile warheads showed that Iraq had lied to the international community for seven years when it repeatedly said that it had never weaponized VX.

Syria has a limited biotechnology infrastructure but could support a limited biological warfare effort. Though Syria is believed to be pursuing the development of biological weapons, it is not

believed to have progressed much beyond the research and development phase and may have produced only pilot quantities of usable agent. Syria is a signatory to, but has not ratified, the BWC.

Syria is not a state party to the CWC and has had a chemical warfare program for many years, although it has never used chemical agents in a conflict. Damascus already has a stockpile of the nerve agent sarin that can be delivered by aircraft or ballistic missiles. Additionally, Syria is trying to develop the more toxic and persistent nerve agent VX. In the future, Syria can be expected to continue to improve its chemical agent production and storage infrastructure.

Libya has ratified the BWC, but has continued a biological warfare program. This program has not advanced beyond the research and development stage, although it may be capable of producing small quantities of biological agent. Libya's program has been hindered by the country's poor scientific and technological base, equipment shortages, and a lack of skilled personnel, as well as by UN sanctions in place from 1992 to 1999.

Following the suspension of UN sanctions in April 1999, Libya wasted no time in reestablishing contacts with foreign sources of expertise, parts and precursor chemicals for its program. Clearly, Tripoli has not given up its goal of reestablishing its offensive chemical warfare ability and continues to pursue an indigenous chemical warfare production capability.

Prior to 1990, Libya produced about 100 tons of chemical agents—mustard and some nerve agent—at a chemical facility at Rabta. However, it ceased production there in 1990 due to intense international media attention and the possibility of military intervention, and fabricated a fire to make the Rabta facility appear to have been seriously damaged. Libya maintains that the facility is a pharmaceutical production plant and announced in September 1995 that it was reopening the Rabta pharmaceutical facility. After 1990, the Libyans shifted their efforts to trying build a large underground chemical production facility at Tarhunah. However, the pace of activity there has slowed, probably due to increases international attention.

Russia

The FSU offensive biological warfare program was the world's largest and consisted of both military facilities and civilian research and development institutes. According to Ken Alibek, the former Deputy Director of BIOPRPARAT, the principal Soviet government agency for biological weapons research and development, by the early 1970s, the Soviet Union had developed a biological warfare employment doctrine, where biological weapons were categorized as strategic or operational.

The Russian government has publicly committed to ending the former Soviet biological weapons program and claims to have ended the program in 1992. Nevertheless, serious concerns remain about Russia's offensive biological warfare capabilities and the status of some elements of the offensive biological warfare capability inherited form the FSU.

Since the breakup of the Soviet Union, more extensive downsizing and restructuring of the program have taken place. Many of the key research and production facilities have taken severe cuts in funding and personnel. However, some key components of the former Soviet program may remain largely intact and may support a possible future mobilization capability for the production of biological agents and delivery systems. Despite Russian ratification of the BWC, work outside the scope of legitimate biological defense may be occurring now that selected facilities within Russia, and the United

States continues to receive unconfirmed reports of some ongoing offensive biological warfare activities.

Moscow has acknowledged the world's largest stockpile of chemical agents of 40,000 metric tons of agent. The Russian chemical warfare agent inventory consists of a comprehensive array of blister, choking, and nerve agents in weapons and stored in bulk. These agents can be employed by tube and rocket artillery, bombs, spray tanks, and SRBM warheads. In addition, since 1992, Russian scientists familiar with Moscow's chemical warfare development program have been publicizing information on a new generation of agents, sometimes referred to as "Novichoks." These scientists report that these compounds, some of which are binaries, were designed to circumvent the CWC and to defeat Western detection and protection measures.

As a state party to the CWC, Russia is obligated to declared and destroy its chemical weapons stockpile and to forego the development, production, and possession of chemical weapons. However, DoD believes that the Russians probably have not divulged the full extent of their chemical agent and weapon inventory.

Australia Group

The proliferation of chemical and biological warfare related technology remains a critical threat to peace and stability throughout the world. One mechanism through which industrialized countries have agreed to control the proliferation of key chemical and biological warfare related technologies is the Australia Group. The Australia Group (AG) is a consortium of countries organized to slow the proliferation of chemical and biological warfare programs by harmonizing national export controls and sharing information on trends in proliferation, entities of concern, chemical and biological warfare (CBW) terrorism, and licensing and enforcement experiences. The AG is not a treaty, and hence has no formal guidelines, charter, or constitution. Initial efforts of this group began in June 1985 and focused on precursor chemicals used in the manufacture of chemical agents. However, convinced of the threat posed from biological weapons, AG countries subsequently agreed, in December 1992, to also control the sale of items that most likely could be used to develop biological agents and weaponry. The AG developed control lists of dual-use chemical- and biological-related materials that are particularly suited for use in CBW. These lists currently contain 54 chemical precursors (34 of these chemicals are on the Chemical Weapons Convention (CWC) Schedules); 93 human, animal, and plant biological pathogens and toxins; and dual-use chemical- and biological-related production equipment. The listed items include animal and plant pathogen that could be used for anti-crop and anti-animal biological warfare.

PROLIFERATION

The United States faces a number of regional proliferation challenges. Many of these are detailed in the January 2001 report published by the Office of the Secretary of Defense, *Proliferation: Threat and Response*. In the Middle East, Iran continues with a concerted effort to acquire an independent production capability for all aspects of its chemical weapons program and has reduced dependency on foreign assistance. Nevertheless, Iran has continued its efforts to seek production technology, expertise and precursor chemicals from entities in Russia and China that could be used to create a more advanced and self-sufficient chemical warfare infrastructure. Iran is also pursuing a program to purchase dual-use biotech equipment from other countries, ostensibly for civilian uses. Russia is a key source of biotechnology for Iran. Russian entities have been key sources of biotechnology and chemicals for Iran. Russia's world-leading expertise in biological and chemical weapons makes it an attractive source for Iranians seeking technical information and training on biological

and chemical warfare agent production processes.

Proliferation of chemical and biological warfare technology in South Asia also raises several important issues. In the past, India has exported a wide array of chemical products, including Australia Group-controlled items, to numerous countries of proliferation concern in the Middle East. The controlled items include specific chemical agent precursors, pathogens with biological warfare applications, and dual-use equipment which can be used in both chemical and biological warfare programs. Pakistan, on the other hand, may continue to seek foreign equipment and technology to expand its biotechnology infrastructure. In addition, Pakistan has imported a number of dual-use chemicals that can be used to make chemical agents.

In North Africa, following the suspension of UN sanctions in April 1999, Libya wasted no time in reestablishing contacts with foreign sources of expertise, parts, and precursor chemicals for its program. Clearly, Tripoli has not given up its goal of reestablishing its offensive chemical warfare ability and continues to pursue an indigenous chemical warfare production capability. In addition, with suspension of UN sanctions, Libya's ability to acquire biological-related equipment and expertise will increase.

OUTLOOK

In the next 10 years, the threat from the proliferation of CBW weapons will certainly increase. This will result from the development of chemical and biological agents that are more difficult to detect and from the adoption of more capable delivery systems.* DoD expects that more states with existing programs will master the production processes for complete weapons and will be less dependent on outside suppliers. States will be more proficient at incorporating chemical or biological agents into delivery systems and will be focusing on battlefield training as well as employment strategy and doctrine. Therefore, the threshold of some states to consider using these capabilities may be lowered.

DoD does not expect significant increases in the number of government-sponsored offensive CBW programs. Nevertheless, the United States and its allies must be alert to this possibility as well as to the apparent growing interest in CBW on the part of sub-national groups such as terrorist organizations. Any nation with the political will and a minimal industrial base could produce CBW agents suitable for use in warfare. Efficient weaponization of these agents, however, does require design and production skills usually found in countries that possess a munitions development infrastructure or access to such skills from cooperative sources. On the other hand, crude agent dispersal devices could be fabricated by almost any nation or group. Such weapons might be capable of inflicting only limited numbers of casualties; nevertheless, they could have significant operational repercussions due to the psychological impact created by fears of CBW agent exposure.

* An assessment of potential new biological agents that may challenge U.S. forces is in a DoD report to Congress entitled *Advances in Biotechnology and Genetic Engineering: Implications for the Development of New Biological Warfare Agents*, June 1996.

Chapter 1

DoD Chemical and Biological Defense Program Management and Oversight

1.1 INTRODUCTION

In compliance with public law, chemical and biological defense programs within the Department are overseen by a single office within the Office of the Secretary of Defense. The vision and mission of the Department's Chemical and Biological Defense Program (CBDP) are outlined in the introduction of this report. A key value in support of the program vision is to emphasize a Joint Service approach to chemical and biological defense research, development, and acquisition. This value provides a process that eliminates unnecessary redundancies among the Services, leverages common technologies and requirements, provides capabilities for Service-unique missions, and coordinates among U.S. government agencies and U.S. allies to field the best available chemical and biological defense capabilities. This chapter provides an overview of the processes involved in the oversight, management, and execution of the CBDP.

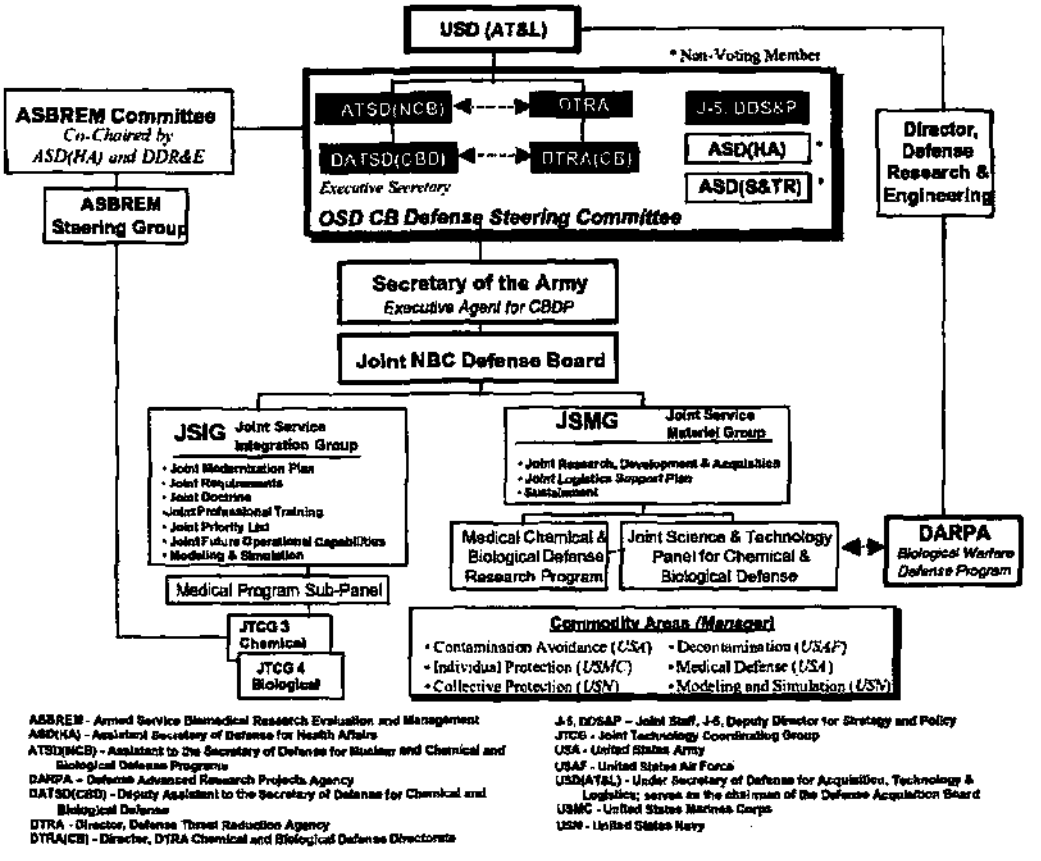
1.2 MANAGEMENT IMPLEMENTATION EFFORTS

The Department of Defense (DoD) implemented a process to consolidate, coordinate, and integrate the chemical and biological (CB) defense requirements of all Services into a single DoD CB defense program. Additionally, DoD continues to refine organizations and processes to ensure close and continuous coordination between the Chemical and Biological Warfare Defense program and the Medical Chemical Biological Defense program.

Through the Joint Service Agreement on NBC Defense, the Military Services have established a program management structure to ensure that Service operational needs are fully integrated and coordinated from their inception and that duplication of effort is eliminated from NBC defense research, development, and acquisition. The series of reviews conducted by the Joint Service Integration Group (JSIG) and the Joint Service Materiel Group (JSMG), both separately and together, have served as an appropriate organizational method to accomplish the coordinating and integrating function. Section 1.3 details organizational relationships within the CBDP. Section 1.4 highlights organizational relationships between the CBDP and related organizations within the Department of Defense, with other U.S. Government organizations, and international efforts with U.S. allies. As discussed in Section 1.7 at the end of this chapter, the organization structure is under review, and a new structure will be proposed to be implemented during FY2002 that will improve acquisition management and improve the integration of requirements generation.

1.3 ORGANIZATIONAL RELATIONSHIPS

The CB Defense Program management structure, portrayed in Figure 1-1, represents organizational relationships in place through FY2001. This management and oversight structure was developed in late 1996 to provide integration of formerly separate service programs and of medical and non-medical CB defense efforts at the Service level. The organization represents all key stakeholders within the Department and provides a balance between operational requirements and research, development, and acquisition (RDA) programs.



ASBREM - Armed Service Biomedical Research Evaluation and Management
ASD(HA) - Assistant Secretary of Defense for Health Affairs
ATSD(NCB) - Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs
DARPA - Defense Advanced Research Projects Agency
DATSD(CBD) - Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense
DTRA - Director, Defense Threat Reduction Agency
DTRA(CB) - Director, DTRA Chemical and Biological Defense Directorate
J-5, DDS&P – Joint Staff, J-5, Deputy Director for Strategy and Policy
JTCG - Joint Technology Coordinating Group
USA - United States Army
USAF - United States Air Force
USD(AT&L) - Under Secretary of Defense for Acquisition, Technology & Logistics; serves as the chairman of the Defense Acquisition Board
USMC - United States Marines Corps
USN - United States Navy

Figure 1-1 CBDP Management & Oversight (FY2001)

The Office of the Secretary of Defense (OSD) CB Defense Steering Committee provides direct oversight of the DoD Chemical and Biological Defense Program. The OSD CB Defense Steering Committee is composed of the following voting members:

- Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense, ATSD(NCB),
- Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense, DATSD(CBD),

- Director, Defense Threat Reduction Agency (DTRA),
- Director, Chemical Biological Defense Directorate, DTRA, (DTRA(CB)),
- Deputy Director for Strategy and Policy, Joint Staff, J-5 (DDS&P, J-5)

Additionally, the Assistant Secretary of Defense for Health Affairs, ASD(HA), and the Assistant Secretary of Defense for Strategy and Threat Reduction, ASD(S&TR), participate as non-voting members on the steering committee.

The Steering Committee provides the fiscal and programming guidance to the Joint NBC Defense Board (JNBCDB) to develop the Program Objectives Memorandum (POM). The JNBCDB issues POM Preparation Instructions to the subordinate groups and builds the POM strategy in accordance with guidance. The OSD CB Defense Steering Committee is overseen by the Under Secretary of Defense for Acquisition, Technology, and Logistics, USD(AT&L), who approves the POM for the CBDP.

The DATSD(CBD) serves as the Executive Secretary of the OSD CB Defense Steering Committee. The DATSD(CBD) is the single office within OSD responsible for oversight of the DoD CB Defense Program. As Executive Secretary, DATSD(CBD) is responsible for ensuring coordination between the medical programs and the non-medical CB defense efforts, and management oversight of the DoD CBDP in accordance with 50 USC 1522. The DATSD(CBD) is responsible for the overall coordination and integration of all CB defense RDA and military construction efforts. DATSD(CBD) provides the overall guidance for planning, programming, budgeting, and executing the CB defense program. The Services retain responsibility for operations and maintenance (O&M) support for chemical and biological defense.

The Secretary of the Army is the Executive Agent for the CBDP and is responsible to coordinate, integrate, and review all Services' CB defense requirements and programs. The Secretary has delegated this responsibility to the chairperson of the Joint NBC Defense Board. The military departments' acquisition organizations execute the individual CB defense programs according to Service and DoD directives.

The CBDP is divided into six commodity areas, with each commodity area being managed by one of the Services in accordance with the Joint Service Agreement, as follows:

Commodity Area	**Commodity Area Manager**
Contamination avoidance	Army
Individual protection	Marines Corps
Collective protection	Navy
Decontamination	Air Force
Medical systems	Army
Modeling & simulation	Navy

The commodity areas correspond to the projects under the budget program elements, which includes a program budget element to support program management and oversight, user testing (*i.e.*, Dugway Proving Grounds), and doctrine development in accordance with the Joint Service Agreement. The JSIG is the principal steering group that oversees the coordination and integration of Service and CINC requirements and priorities for RDT&E and initial procurement. The JSMG is the

principal steering group that manages the execution of RDT&E materiel development efforts to ensure that program risk is mitigated across commodity areas, and the ongoing efforts are complementary but not duplicative.

The Medical Program Sub-Panel (MPSP) continues to be an integral part of the JSIG. The purpose of the MPSP is to identify medical program needs and requirements as developed by the Service users. The MPSP has the primary responsibility for prioritizing medical CB defense requirements; however, medical radiological and nuclear defense requirement development also play an important role. The MPSP uses technical expertise from a variety of sources including Service medical CB Defense Agencies/Activities, the Joint Staff, the Armed Service Biomedical Research Evaluation and Management (ASBREM), the Service schools, Service environmental, reference, and clinical laboratories as well as Service-unique centers of excellence. The users and JTCG 3 (Medical Chemical Defense Research Program), JTCG 4 (Medical Biological Defense Research Program), and JTCG 7 (Medical Nuclear Defense Research Program) review medical NBC defense capabilities and provide input/review of medical needs that the Combat Developers form into Medical Requirements (as well as medical applications of non-medical requirements) to the MPSP. The MPSP coordinates, integrates, and prioritizes all of the user requirements input. It provides the consolidated, integrated, and prioritized list of medical CB defense requirements to the JSIG. The priority listing process has become fully integrated. Medical requirements and programs are prioritized together with the non-medical requirements and programs with an integrated priority list provided to the JNBCDB for approval. The JNBCDB and the OSD CB Defense Steering Committee may make changes to the Integrated NBC Defense Priority List.

The U.S. Army is the Executive Agent for the Joint Medical Chemical and Biological Defense Research Program (JMCBRP) as prescribed in DoD Directive 5160.5 and, as such, is the lead requirements coordinator. The JMCBRP integrates DoD in-house and external efforts. JTCG 3 and JTCG 4 of the ASBREM Committee are responsible for the programs' joint consolidation, coordination, and integration. The ASBREM Committee maximizes efficiency among the Services by coordinated planning, and minimizes unnecessary program overlaps and costly materiel retrofits. The *CB Defense Technology Area Plan* and *The Joint Nuclear Biological Chemical Defense Research, Development, and Acquisition Plan* are the primary program drivers for joint CB research programs. The science and technology base is managed through the development and execution of Defense Technology Objectives (DTOs).

Science and technology encompasses a progression through Concept and Technology Development (basic and applied research and concept exploration phases) directed toward the development of medical countermeasures for chemical and biological threat agents. Early in Concept and Technology Development, basic principles are observed and reported. This is accomplished through the identification of threat agents, developing an understanding the disease process (pathophysiology), and developing hypotheses/concepts. Activities later in the process include development of animal models that are predictive of the human response, development of and assays and reagents to characterize concepts/technologies, and preliminary evaluation of hypotheses and concepts/technologies to determine their potential as new medical countermeasures (pre-treatments, vaccines, therapeutics/treatments, and diagnostics technologies). As the concepts/technologies mature through these phases, they may be formulated as Defense Technology Objectives (DTOs), which are

essentially strategic plans for specific concept development efforts. The Joint Medical Chemical and Biological Defense Research Program (JMCBRP) executes its DTOs through the U.S. Army Medical Research and Materiel Command (USAMRMC) lead laboratories for medical chemical defense (U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)) and biological defense (U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)) with scientific input from researchers at other Army laboratories (Walter Reed Army Institute of Research (WRAIR, U.S. Army Research Institute of Environmental Medicine (USARIEM)) and from Navy and Air Force laboratories. Private sector laboratories and universities also participate and contribute to these research efforts through extramural contracting arrangements and Collaborative Research and Development Agreements (CRADAs).

Successful completion of key DTO milestones/metrics events will lead to a *Milestone A* review that will then initiate the analytical and experimental critical function and characteristic proof of concept for the medical concept/technology. Following a Milestone A decision, model vaccines, pre-treatments, therapeutics, and diagnostic capabilities are further developed and characterized. Safety and efficacy trials for potential vaccines, pre-treatments, and therapeutics are performed in various animal models and diagnostic capabilities are evaluated with rigid laboratory test protocols. Following this, a Component Advanced Development In Process Review (IPR) is conducted and the technologies may transition to advanced development. The advanced development program for medical biological defense products is directed by the Joint Program Office for Biological Defense (JPO-BD). The Joint Vaccine Acquisition Program (JVAP) is an Acquisition Category II (ACAT II) program under the JPO-BD whose mission is to develop and produce FDA licensed medical products (vaccines) to protect the warfighter in a biological warfare environment. The USAMRMC U.S. Army Medical Materiel Development Activity (USAMMDA) directs advanced development for medical chemical defense products.

1.4 COORDINATION WITH RELATED PROGRAMS AND INITIATIVES

The DoD Chemical and Biological Defense Program coordinates efforts with other U.S. government agency and with other countries to achieve the vision of equipping U.S. forces with the best available chemical and biological defense equipment. This section provides an overview of some key cooperative efforts.

1.4.1 Other U.S. Government Agencies.

There are several organizations within the U.S. government developing chemical and biological defense technologies. Three organizations with which the CBDP currently has formal coordination efforts include: (1) the Defense Advanced Research Projects Agency (DARPA), (2) the Technical Support Working Group (TSWG), and (3) the Department of Energy (DOE) Chemical and Biological Nonproliferation Program (CBNP). An overview of these programs is provided below. There also are other governmental agencies with chemical and biological defense related programs with which the CBDP maintains various levels of coordination and cooperation. These include the Office of Homeland Security, the National Security Council, Department of Health and Human Services (including the Food and Drug Administration, and the Centers for Disease Control and Prevention), U.S. Department of Agriculture, and the Department of Justice, among others.

1.4.1.1 DARPA Biological Warfare Defense Program. DARPA is charged with seeking breakthrough concepts and technologies that will impact our national security. DARPA's Biological Warfare (BW) Defense Program is intended to complement the DoD CB Defense Program by anticipating threats and developing novel defenses against them. The DARPA program is unique in that its focus is on the development of technologies with *broad applicability* against *classes* of threats. DARPA invests primarily in the early technology development phases of programs, with rapidly decreasing involvement in the succeeding stages that lead to system development and deployment.

The FY98 National Defense Authorization Act directed the Secretary of Defense to ensure that the DARPA biological warfare defense program is coordinated and integrated under the program management and oversight of the DoD CBDP. The DARPA BW Defense Program coordinates its efforts with a large number of organizations, including the DATSD(CBD) through regular briefings to both DATSD(CBD) and DTRA(CB) and by participation in the Technology Area Review and Assessment (TARA) process. The Advanced Diagnostics portion of the DARPA BW Defense Program is closely coordinated with the U.S. Army Medical Research and Materiel Command (MRMC) and is represented on the recently formed Common Medical Diagnostic Systems Executive Committee. A panel of chemical and biological defense experts is routinely consulted by DARPA to evaluate programs and to ensure that National Institutes of Health (NIH) efforts are not being duplicated. DARPA representatives actively serve in a non-voting capacity on the Joint Science and Technology Panel for Chemical and Biological Defense (JSTPCBD) and attend CBDP committee meetings, such as ASBREM sub-committee meetings. DARPA also participates in the BW Seniors Group, which provides Government coordination outside of DoD and works closely with the military Services to ensure that technologies are effectively transitioned into the hands of the user community.

1.4.1.2 Technical Support Working Group. The TSWG is an interagency forum that identifies, prioritizes, and coordinates interagency and international research and development (R&D) requirements for combating terrorism. Policy oversight is provided by the Department of State and execution oversight is provided by the Department of Defense, specifically the Assistant Secretary of Defense for Special Operations and Low Intensity Conflict, ASD (SO/LIC). The TSWG rapidly develops technology and equipment to meet the high-priority needs of the combating terrorism community, and addresses joint international operational requirements through cooperative R&D with the United Kingdom, Canada, and Israel. The TSWG also has an effective outreach program so that state and local agencies can benefit from new technology developments.

TSWG membership includes representatives from nearly eighty organizations across the Federal Government. These representatives work together by participating in one or more of TSWG's eight subgroups. One of the subgroups is the Chemical, Biological, Radiological, and Nuclear Countermeasures (CBRNC) subgroup, which is co-chaired by the Federal Bureau of Investigation (FBI) and the Central Intelligence Agency (CIA). The CBRNC subgroup identifies and prioritizes interagency chemical, biological, radiological, and nuclear combating terrorism requirements, and identifies solutions for detection, protection, decontamination, containment, mitigation, and disposal.

The DoD CBDP and TSWG coordinate requirements and projects to maximize leveraging opportunities. However, the scope and mission of the combating terrorism community often requires different technologies to satisfy user requirements.

1.4.1.3 DOE Chemical and Biological Nonproliferation Program (CBNP). The CBNP was established in 1997 in response to the *Defense Against Weapons of Mass Destruction Act* ("Nunn-Lugar-Domenici") passed by Congress in 1996. The CBNP was established to ensure the full engagement of the DOE National Laboratories in responding to the threat posed by chemical and biological weapons to U.S. civilians. The strategy of the CBNP relies on close linkages between technology development and systems analysis and integration to systematically and comprehensively address the domestic chemical and biological terrorism threat. The CBNP is comprised of three key components:

- Definition of operational needs to guide the development and implementation of enhanced preparedness and response systems.
- Use of accelerated system demonstrations to enable rapid fielding of the best available systems and technologies to meet critical needs.
- Development of individual technologies to enhance capabilities across the full spectrum of chemical and biological threats.

Many technologies under development may support both CBNP and CBDP missions. There are formal agreements between the CBNP and CBDP to ensure that efforts are coordinated and duplication is avoided. Some cooperative efforts include DOE representation on the Joint NBC Defense Board as a non-voting member, DOE participation in the Technology Area Review and Assessment (TARA) of science and technology base programs, and DoD participation in the annual CBNP program review.

1.4.1.4 Other Interagency Coordination. The CBDP participates in efforts to coordinate research, development, and other efforts related to chemical and biological defense with other organizations throughout the federal government. Following are some highlights of these coordination efforts:

- *The InterAgency Board for Equipment Standardization and Interoperability* (known as the IAB), is a partnership with federal, state, and local agencies focused on the capabilities necessary for fire, medical, and law enforcement responses to WMD terrorism.
- Interagency Agreements with departments of Justice's Office Domestic Preparedness to purchase equipment in support of Justice's grant program.
- The White House Office of Science and Technology Policy chaired Weapons of Mass Destruction Program, Research and Development Subgroup.

1.4.2 Chemical and Biological Defense Research, Development and Acquisition (CBD RDA) Focus Group.

The CBD RDA Focus Group was established in 1999 under the auspices of the Counter-proliferation Program Review Committee (CPRC) to review and coordinate DoD and DOE R&D technologies and identify future capabilities needed to provide for a more cohesive, integrated effort to

broadly address CB proliferation. The primary goal of this group is to avoid duplication of development efforts between military and domestic defense programs while minimizing investment costs. Membership in the Focus Group is currently limited to the representatives from the CBDP, DARPA, and the DOE Chemical and Biological Nonproliferation Program (CBNP). The Focus Group submitted its first report to Congress in April 2000. This report provided an overview of the roles and responsibilities of DoD and DOE and discussed interagency coordination.

In an effort to supplement the original report and formally integrate programs, the Focus Group is currently developing a detailed, integrated plan including an interagency roadmap for the Biological Point Detection focus area. This integrated plan will discuss the process for developing and annually reviewing DOD and DOE interagency R&D roadmaps, CB technologies related to biological point detection, and findings resulting from an analysis conducted among technology approaches within the biological point detection thrust area. The plan will also contain an integrated roadmap that will illustrate how biological point detection technologies will feed into testing activities or transition into ACTDs, DoD acquisition programs and/or DOE demonstrations. The integration process and roadmap developed during this effort will be used as a template for developing detailed integration plans for other technology areas such as chemical point detection, wide area detection, decontamination, and modeling and simulation.

The integration plan development effort will facilitate interagency awareness, coordination and cooperation between DoD and DOE at all levels. The biological point detection integrated plan will be submitted to Congress as a part of the 2001 CPRC Annual Report to Congress. A goal of the group is broaden its representation to include other DOD and DOE programs and users.

1.4.3 International Cooperation.

The CBDP participates in numerous international cooperative and collaborative efforts to leverage technology development and to achieve commonality, interoperability, and systems integration among U.S. allies and coalition partners. (In addition, there are numerous cooperative efforts in doctrine and training, which are described in Section 4.2 of this report.) In order to exchange information or conduct government to government cooperation, an appropriate agreement must be in place. Types of agreements include (1) Data Exchange Agreements (DEAs), (2) Foreign Military Sales, (3) Engineer and Scientist Exchange Programs, (4) Foreign Comparative Testing, (5) Technology Development Project Agreements, and (6) Research, Development and Acquisition Memoranda of Understanding (MOU). Table 1-1 list examples of international cooperative efforts in FY01.

Table 1-1. International Cooperative Efforts in Chemical and Biological Defense.

• Smallpox Vaccine Development and Acquisition. • Next Generation Urban Dispersion Model. • Next Generation Biological Detection Technologies. • Non-incineration Technology for CW Agent Destruction. • New Technologies for CB Agent Monitoring in Aqueous Environments. • Testing of CB Protective Clothing in a Hot and Humid Environment.	• Ecotoxicology due to CW Agents and Remediation of Soil and Water. • Medical Countermeasures to CB Agents. • Anthrax Letter Tests. • Toxic Industrial Chemicals. • CB Events in Operations Other Than War. • Collective Protection. • Effects of Wearing Individual Protective Equipment (IPE) in a Hot/Dry Environment. • Fate and Effect of Chemical Agents. • Next Generation Plague Vaccine.

During FY01, the United States participated in numerous international cooperative research and development efforts. Highlights of these efforts include (1) 50 DEAs with 15 countries, (2) seven Technology Development Project Agreements in place or in development, (3) two MOUs, and (4) one Engineer and Scientist Exchange Program in CB. In addition to these efforts, in FY00, there are (1) two new DEAs in development in biological defense, (2) three Technology Development Project Agreements in development addressing chemical detection, protection, and fundamental toxicology, and (3) two Engineer and Scientist Exchange Programs.

All cooperative agreements yield benefits to all participants in the agreement. In addition, there have been numerous CB defense capability gains from FY98 and through FY01 as a result of international cooperation. During FY01 under the Foreign Comparative Testing (FCT) program, the Graseby modified Lightweight Chemical Agent Detector (LCAD) and the Environics Oy M100 were tested as a possible alternative to the Joint Chemical Agent Detector (JCAD). The FCT is the same program that saw successful procurement of the NBC Reconnaissance System (Fox Vehicle), Improved Chemical Agent Monitor (ICAM), the Automatic Chemical Agent Detector and Alarm (ACADA) and components of the Biological Integrated Detection System (BIDS).

1.5 TECHNOLOGY BASE REVIEW AND ASSESSMENT

The DATSD(CBD) is responsible for chemical and biological defense programs science and technology base programs. The DATSD(CBD) provides technical oversight of all Service and Defense Agency chemical and biological defense science and technology base (S&T) programs and reviews these programs. The Joint Science and Technology Panel for Chemical and Biological Defense (JSTPCBD) coordinates all Service science and technology base activities for the JSMG. The JSTPCBD prepares the relevant chemical and biological defense portions of the Defense Technology Area Plan (DTAP), and provides input to the Joint Warfighting S&T Plan (JWSTP). The DTAP and JWSTP are submitted to Congress separately in accordance with public law.

Science and technology programs are reviewed annually through the Technology Area Review and Assessment (TARA). The TARA includes a review of S&T programs by an independent panel of experts from academia, national laboratories, and other organizations. This panel provides assessments of key projects, overall areas within the program, and identifies any major findings or issues

related to CB defense science and technology. A summary of the FY2001 TARA results is provided in Section 3 of the CBDP Performance Plan included as Volume II of this report.

1.6 FUNDS MANAGEMENT

Figure 1-2 illustrates the funds management and execution process for the CB defense program and the coordination between funding and executing organizations. The key organizations in this process are: DATSD(CBD) as the OSD focal point; the JNBCDB Secretariat representing the Executive Agent; the Defense Threat Reduction Agency (DTRA) is the funds manager); the JSMG as coordinator and interface between the participating organizations; and the operating agencies and performers which execute the programs. For budget distribution, the JNBCDB Secretariat provides funds distribution information to DATSD(CBD) based on the appropriated budget. The DATSD(CBD) prepares funds suballocation instructions (with support provided by DTRA(CB)) and submits them to the DTRA Comptroller for distribution to the operating agencies.

The lead components or operating agencies provide notification of all funding adjustments to the JSMG Executive Office. The JSMG Executive Office, in turn notifies other components and agencies and the JNBCDB Secretariat. The JSMG Executive Office forwards reprogramming requests with recommendations and any concerns raised by the other components and operating agencies to the JNBCDB Secretariat. The JNBCDB Secretariat reviews the reprogramming actions and forwards recommendations to DTRA(CB) for DATSD(CBD) approval. Once approved, DATSD(CBD) authorizes the JNBCDB Secretariat to update the database, and the DTRA Comptroller to execute the reprogramming. For medical programs, the Headquarters, U.S. Army Medical Research and Materiel Command, staffs all actions resulting from the requirement to reallocate funds between the Services.

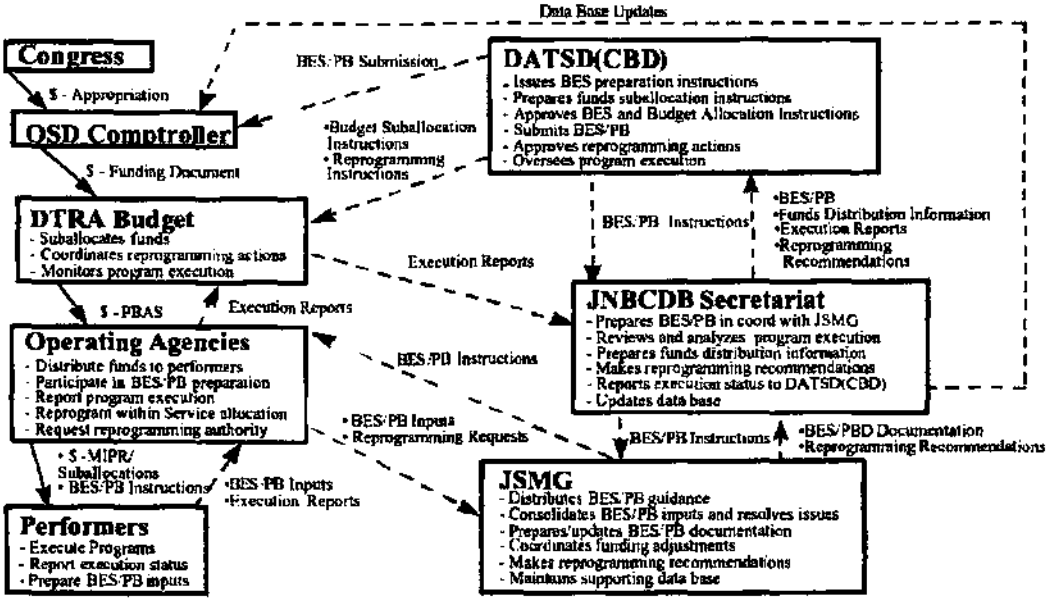


Figure 1-2. Chemical and Biological Defense Funds Management Process

DATSD(CBD), with the support of DTRA(CB), instructs the DTRA Comptroller to issue execution and program status reporting instructions to the operating agencies. The operating agencies report execution status to the DTRA Comptroller on a monthly basis. The DTRA Comptroller forwards all program funds execution reports to the JNBCDB Secretariat and DTRA(CB) for program and budget database update and analysis, respectively. DTRA(CB) reports execution status to DATSD(CBD) on a quarterly basis. DTRA(CB) is responsible to notify the DATSD(CBD) when programs deviate from or are in danger of not meeting OSD obligation and execution goals.

The DTRA Comptroller serves as the funds manager for the CB defense program. This office issues funding documents, per DATSD(CBD) direction, and performs all required accounting functions, with the assistance of the Army staff which represents the Executive Agent. The JNBCDB Secretariat updates the OSD comptroller program and budget databases as necessary after the POM, Budget Estimate Submission (BES), and President's Budget (PB). DATSD(CBD), with support provided by DTRA(CB), ensures that the JNBCDB Secretariat is kept informed of all OSD comptroller guidance, directives, and schedules.

1.7 CB DEFENSE PROGRAM MANAGEMENT ASSESSMENT

ISSUE: **In a memorandum issued on 19 October 2001, the Under Secretary of Defense for Acquisition, Technology, and Logistics, USD(AT&L) reviewed the current management structure of the CBDP and a number of alternatives, and concluded that establishing a single Milestone Decision Authority (MDA) would be of great benefit to the process. The USD(AT&L) directed the DATSD(CBD) to establish a task force, comprising representatives from Service Acquisition Executives, the Joint Staff, and appropriate OSD principals, to develop an implementation plan for a Joint Program Element Office for Chemical and Biological Defense (JPEO-CBD). The task force also will develop any legislative proposal that may be required to conform section 1522 of title 50, United States Code, to the proposed, revised management structure.**

SOLUTION: The task force will develop a plan and appropriate recommendations during 2nd Quarter FY 2002 regarding implementation of a management structure that features a single MDA and a JPEO-CBD.

***ISSUE*: In a memorandum issued on 23 November 2001, the USD(AT&L) requested the Director of the Joint Staff to form a task force to assess how to best structure the joint requirements generation process for CB defense, and to consider not only the requirements within traditional MTW scenarios but also force protection, homeland defense, and consequence management. This task force, composed of representatives from the four Services and Joint Staff, developed recommendations on a Joint Requirements Organization for NBC Defense, for JROC approval and forwarding to USD(AT&L).**

SOLUTION: The task force's recommendations, once approved by the JROC, will be integrated into the JPEO-CBD implementation plan.

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Chapter 2

Nuclear, Biological, and Chemical (NBC) Defense Requirements and Research, Development, and Acquisition Program Status

2.1 INTRODUCTION

This chapter describes the consolidation of Joint Service non-medical and medical NBC defense requirements and assesses how these programs meet the needs of U.S. forces. The discussion of requirements and the status of research and development assessments are conducted within the framework of the six operationally oriented commodity areas:

- Contamination Avoidance
- Modeling and Simulation
- Decontamination
- Individual Protection
- Collective Protection
- Medical Systems

There are three principles of NBC defense as defined in Joint Publication 3-11, *Joint Doctrine for Operations in Nuclear, Biological, and Chemical (NBC) Environments.* The first principle, contamination avoidance, includes the Contamination Avoidance Commodity Area, which comprises detection and avoidance (bypassing contaminated areas). Individual Protection, Collective Protection, and Medical Systems make up the second principle—Protection. Decontamination, the third principle of NBC defense, restores combat power and is essential for sustaining operations in a contaminated environment. The commodity area of Modeling and Simulation has application in the other five commodity areas and spans the three principles.

The threat from the continued proliferation of NBC weapons creates a continuous need to ensure that U.S. forces can survive, fight, and win in an NBC threat environment. The increasing danger from these weapons demands that we look for every opportunity to avoid technological surprises. Evolving operational requirements demand that the joint program progressively capture and leverage advances in technology to provide the best in NBC defense equipment for the forces.

The non-medical research, development, and acquisition (RDA) goal is to equip the joint warfighting forces with sufficient quantities of the best available equipment and in the shortest time possible to win decisively, quickly, and with minimal casualties. The goal of the medical RDA is to provide the warfighter with medical protection to prevent, or reduce the effects of exposure to chemical or biological warfare agents. Products intended for medical protection (vaccines, pre-treatment drugs, post-exposure treatments, diagnostics capabilities) require approval by the Food and Drug Administration (FDA) before they enter the distribution chain. If an item is not approved by the FDA but is considered a necessary medical countermeasure, it will be distributed in accordance with regulations

as an Investigational New Drug (IND) product. As authorized under the Joint Service Agreement and in cooperation with the Armed Services Biomedical Research, Evaluation, and Management (ASBREM) Committee for medical programs, the Army as executive agent coordinates, integrates, and reviews the DoD CB Defense Program. The results of these reviews, conducted with all Services participating, are documented in the Joint Service Modernization and Joint Service RDA Plans. These documents form the basis for the consolidated CB Defense Program Objectives Memorandum (POM).

In coordination with the Commanders-in-Chief (CINCs), the Services decide if a materiel solution is needed to satisfy a requirement for a warfighting capability. They first examine doctrinal, training, or organizational solutions (non-materiel solutions), and when these cannot fulfill the need, they seek equipment or materiel solutions through the materiel acquisition cycle. If a valid need exists, then the research and development modernization process will identify technological approaches that may provide a new system or medical product or upgrade an existing system or medical product.

During FY00 the Joint Service Integration Group documented the Joint Future Operational Capabilities (JFOCs) in an integrated format merging the medical and non-medical needs. The purpose of the JFOCs is to identify and prioritize Joint User (Services and CINCs) far-term future operational capabilities as expressed in the emerging Joint NBC Defense Concept. Priorities of the JFOCs were not changed in FY01. The overall intent is to provide enhanced user guidance to the Joint NBC defense science and technology (S&T) community to assist in S&T program planning and execution. JFOCs will also support the development of new NBC Defense Joint Mission Needs Statements (JMNSs) and future Joint Operational Requirement Documents (JORDs). The prioritized list of JFOCs establishes a clear link between near and long-term Joint NBC defense research and development efforts and user needs. Table 2-1 provides a synopsis of the current (FY01) JFOC priorities, descriptions, and objectives. JFOCs have become an integral part of the Joint Service NBC Defense Modernization Plan and related S&T plans, specifically the Joint Warfighting Science and Technology Plan (JWSTP) and the Defense Technology Area Plan (DTAP).

In accordance with the national strategy of achieving and applying technological superiority, several underlying concepts form the foundation of acquisition modernization. The first is the need to reduce cycle time in the acquisition of new systems or medical products or the integration of emerging technologies into existing systems. The use of Advanced Concept Technology Demonstrations (ACTDs), open systems and architectures, along with the new emphasis on commercial standards and practices, allow us to shorten the acquisition cycle time. The program acquisition process reduces lifecycle costs through practices such as design-to-cost and concurrent engineering to ensure that equipment is easy to maintain and repair even with the inherent complexity in most new systems.

Table 2-1. Prioritized NBC Defense Joint Future Operational Capabilities

1: NBC Battle Management—Capability to access, assimilate and disseminate NBC information from throughout the battlespace via standard, joint service and automatic information/ data transmission systems. Enhance warfighter protection by providing the critical link between detection and protection. Commanders at all levels will be provided sufficient, timely information through early and direct warning. Commanders will be able to quickly and effectively quantify the risk associated with various courses of action and provide real-time display with local 3-D digital terrain graphics to portray the current status of the NBC battlespace.
2: Contamination Avoidance—An enhanced capability to detect, locate, identify, and confirm the presence or absence of any standard or non-standard NBC hazard. Significantly improve tactical, operational, and strategic NBC situational awareness by rapidly detecting, locating, identifying, confirming and disseminating NBC and toxic industrial material (TIM) detection information to the joint force.
3: Individual Protection—To protect individual members of the joint force, allowing it to operate safely, at near-normal levels of effectiveness, while under NBC threat, or in NBC, TIM or other environmental hazards area.
4: Restoration Capability—Enhanced capability to provide rapid, effective, and safe removal/ neutralization of hazards resulting from NBC or TIM contamination to enable restoration of unit operational capabilities. Protect and sustain the Joint force by rapidly returning equipment and personnel to normal operating modes/efficiencies after exposure to an NBC or TIM contaminated environment.
5: Collective Protection—To protect the joint force collectively, allowing it to operate safely, at near-normal levels of effectiveness, while under NBC threat, or in NBC, TIM or other environmental hazards area. Enhance filter systems on existing vehicles, aircraft, shipboard, communications vans and other static/mobile structures.

2.2 NBC DEFENSE MISSION AREA REQUIREMENTS AND RDA SUMMARY

As noted previously, NBC defense programs are categorized broadly under three operational principles: contamination avoidance, protection, and decontamination. The Services have been working closely together to increase jointness in ongoing programs for each of these areas. This report highlights improvements during FY01 and discusses cooperative efforts for further Joint development of requirements. This section summarizes the requirements in each of the mission commodity areas. This chapter provides a focus on research, development, and acquisition efforts. Fielded items are discussed separately in Chapter 3. Detailed descriptions of non-medical developmental and fielded equipment can be found in Annexes A, C, and D; medical accomplishments are listed in Annex E, and modeling and simulation efforts are described in Annex B of this report.

The following sections (2.3 though 2.7) provide an overview of the goals and timeframes, potential payoffs, and major technical challenges for specific commodity area science and technology (S&T) efforts. A detailed account of S&T efforts for all commodity areas is provided in two separate reports: (1) the *Joint Warfighting Science and Technology Plan*, especially Chapter XII, "Counterproliferation of Weapons of Mass Destruction," and (2) the *Defense Technology Area Plan*, especially Chapter II, "Chemical and Biological Defense." The *Basic Research Plan*, also provides descriptions of various supporting sciences—including chemistry, biological sciences, materials science, and others—that support CB defense S&T activities. Within the *Joint Warfighting Science and Technology Plan* and the *Defense Technology Area Plan*, key projects are defined as

Defense Technology Objectives (DTOs). A DTO states specific technology advancements to be developed or demonstrated, the schedule, costs, specific warfighter payoffs (stated quantitatively against two or more metrics), and the customers for whom the technology is being developed (*e.g.*, a specific Commander in Chief). DTOs represent only a portion of science and technology base funding, yet represent high priority projects, consistent with strategy and guidance. DTOs provide a key means for S&T planning and programming and for fulfilling GPRA requirements. DTOs are proposed or updated annually.

In addition to technology base thrusts supporting materiel development, the CB defense technology base program incorporates basic and applied research, including CB threat agents and chemical toxicology, which support development across multiple commodity areas. Understanding both established and emerging CB threats drive the overall CB defense program. Toxicological determination of operationally significant dosages of threat agents is fundamental to developing target requirements for materiel solutions across all commodity areas.

Investments are being made in the establishment of a comprehensive threat agent infrastructure, to acquire threat agents (both recognized and emerging), using chemical synthesis, biological manipulation, and procurement. Emphasis is placed on the characterization of the properties of threat agents needed by Joint Service materiel and medical developers. Emphasis is also placed on developing appropriate simulants for use in the RDT&E process. Execution and funding of the work are integrated among DoD and DOE performers and coordinated with the Intelligence Community. Deliverables from this program are threat agents, technical data on threat agents, and simulants for developmental and operational testing.

CW toxicology data support all commodity areas, at all levels, including protection, decontamination, and detection. Primary data gaps include the lack of complete agent dose-response curves and probit slopes. Secondary data gaps include the toxicology of mixtures found in munitions and of by-products resulting from agent degradation or decontamination.

A multi-year program involving both the non-medical and medical communities is currently underway to address the medical and operational issues of low level exposures to chemical agents. The issues of prevention, diagnosis, and treatment of persistent health effects are central aspects of the medical program. The toxicological emphasis is airborne exposure to low concentrations of agent for exposure durations extending out to several hours, determination of the lowest chemical concentrations that are operationally significant, and characterization of the concentration-time response curve. Medical emphasis is on the determination of exposure thresholds for effects from chemical warfare agents. The order in which the agents will be addressed is responsive to user input and requirements.

2.3 CONTAMINATION AVOIDANCE (Detection, Identification and Warning)

The operational concept of contamination avoidance includes NBC reconnaissance, detection, identification, warning and reporting. Earliest possible warning is the key to avoiding NBC contamination. For fixed sites where contamination cannot readily be avoided and for missions requiring operations in a contaminated environment, detection, identification, and warning are equally critical to ensure that forces can (1) assume the optimal protective posture so that they can continue to sustain operations and (2) rapidly identify and decontaminate affected areas, equipment, and personnel.

Sensors for the individual warfighter and systems capable of detecting multiple agents and characterizing new agents are being developed. Advances in technology are being pursued in chemical and biological standoff, early warning detection, miniaturization, interconnectivity, improved detection sensitivity, improved interference rejection, improved logistics supportability, and affordability. The following sections detail contamination avoidance science and technology efforts, modernization strategy, and Joint Service programs.

2.3.1 Contamination Avoidance Science and Technology Efforts

2.3.1.1 Goals and Timeframes. The goal of contamination avoidance is to provide real-time capability to detect, identify, characterize, locate, and warn against all known or validated CB warfare agent threats below threshold effects levels (see Table 2-2). To meet near term needs a number of sensor technologies are being optimized while alternative detection technologies mature. Mid-term technologies focus on developments to improve tactical detection and identification capabilities for both chemical and biological warfare agents. Far-term science and technology efforts focus on multi-agent sensors for CB agent detection and remote/early warning CB detection. These far-term objective technologies seek to integrate chemical and biological point and remote/early warning detection modules into a single system. Research and Development (R&D) efforts seek to optimize and balance system sensitivity, size/weight, cost, power consumption, signature and false alarm rate. Ultimately the goal is direct integration of CB detectors as a single system into various platforms, and command, control, communication, computer, and intelligence (C^4I) networks.

As identified in the *Defense Technology Area Plan* and the *Joint Warfighting Science and Technology Plan,* the following are Defense Technology Objectives (DTOs) focused on near and mid-term science and technology goals.

Ongoing DTOs:*

- Laser Standoff Chemical Detection Technology
- Chemical Imaging Sensor
- Biological Sample Preparation System for Biological Identification
- Stand-off Biological Aerosol Detection
- Joint CB Agent Water Monitor
- Biological Warfare Defense Sensor Program
- Activity-Based Detection and Diagnostics
- Force Medical Protection/Dosimeter ACTD
- Terrorist Chemical/Biological Countermeasures

Completed DTOs (in ACTD Sustainment Phase):

- Chemical Add-On to Airbase/Port Biological Detection ACTD

2.3.1.2 Potential Payoffs and Transition Opportunities. Future CB detection systems will provide the capability to detect, identify in real time, map, quantify, and track all known CB contamination in a theater of operations. This will enable commanders to avoid CB contamination, determine the need for

* Complete DTO descriptions are provided in Volume II, *CBDP Performance Plan.*

and verification of effective reconstitution procedures, and assume the appropriate protection required to continue fighting and sustain their mission with minimal performance degradation and casualties. CB detection technologies have dual use potential in monitoring air pollution, noxious fumes inside enclosed areas, and municipal water supplies.

Table 2-2. Contamination Avoidance Science and Technology Strategy

By 2002	By 2007	By 2012
• Complete installation of the Joint Portal Shield biological detection network sensor systems at CINC fixed site locations and transition to full production status • Complete demonstration of integrated point biodetection capability (Advanced Technology Demonstration) • Demonstrate lightweight (30% weight reduction) chemical point detector in the laboratory with a capability to detect and identify a wide range of chemical threat agents and high-threat toxic industrial chemicals. Demonstrate enhanced aerogel-based biological agent sample collection capability. • Initiate development of the Joint Biological Standoff Detection System (JBSDS) Block I	• Demonstrate Chemical Imaging Sensor for wide area detection • Complete development of Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD) • Complete development of Joint Service Warning and Identification LIDAR Detection (JSWILD/Artemis) • Complete development of Joint Chemical Agent Detector (JCAD) • Complete development of Block II Joint Biological Point Detection System (JBPDS) • Complete fielding of JBSDS Block I • Complete development of the JBSDS Block II • Complete fielding of Portal Shield production systems to 21 critical sites	• Demonstrate integration of chemical and biological agent detection modules into a single sensor suite • Complete fielding of the Block II JBPDS • Complete development of CB water monitor • Initiate development of the Joint Modular Chem/Bio Detection System (JMCBDS)

2.3.1.3 Major Technical Challenges. The major technical challenges are in the areas of biological collection, detection and identification, including remote/early warning sensing, improved agent discrimination and quantification, sample processing, interferent (*i.e.*, false positive and negative alarms) and ambient biological background rejection, and genetic probe development. Size, weight, and power reduction of detectors, power generation and consumption, development of integrated biological and chemical detection systems, and the fusion of sensor data with mapping, imagery, and other data for near real-time display of events are other areas of challenge.

There are two critical needs focused on biological agent detection. Current technologies require a *high level of logistical support* and *lack discrimination in biological standoff detection*. The challenge in reducing logistical support stems from the dependence on reagents and size, weight, and power requirements of the systems. Several efforts are aimed at providing minimum reagent requirements with higher sensitivity, better stability, and fewer supporting reagents, and scientific and engineering strategies to reduce size, weight, and power requirements, especially in the sample collections components. There are several factors directly limiting the ability to discriminate biological agents using standoff detection technologies. Key factors include: (1) a lack of fundamental data in understanding the spectral properties of biological warfare agents, (2) range limitations due to atmospheric absorption, and (3) natural background interference. Over the last two years, a number of strategies and concepts have been developed to improve the discrimination capability of standoff detection for biological materials. Further efforts in FY02 and FY03 will begin to validate the feasibility of providing an enhanced level of discrimination of biological material using standoff detection.

2.3.2 Contamination Avoidance Modernization Strategy

The increased lethality and heightened operational tempo of the future battlefield demand responsive NBC detection and warning capabilities in order to reduce force degradation caused by contamination. These capabilities—which also encompass NBC reconnaissance, detection, identification, and reporting—are critical for force readiness and will continue to be emphasized by the DoD community in the near and distant future. Table 2-3 shows the roadmap of DoD requirements for contamination avoidance. While requirements identified in the near-term meet service-specific needs, those in the mid to far-terms demonstrate the increase in joint development and modernization since the founding of the CBDP.

Table 2-3. Contamination Avoidance Modernization Strategy

	NEAR (FY02-03)	MID (FY04-09)	FAR (FY10-19)
Chemical Point Detection	• Surface off-gas sampling capability (ICAM) • Automatic point detection of nerve and blister agents (ACADA) • Navy-*Ship based improved automatic point detection of nerve/blister (IPDS)*	• Improved, all-agent programmable automatic point detection; portable monitor, miniature detectors for aircraft interiors; interior ship spaces; wheeled and tracked vehicles; and individual soldiers (JCAD)	• Improved surface contamination monitor • Detection of CB contamination in water (Joint Chemical Biological Agent Water Monitor, JCBAWM)
Biological Point Detection	• Detection System, Biological Agent: Joint Portal Shield provides an automated network biological detection capability to protect high value fixed sites. • Automatic long line source and point/mobile biodetection to detect and identify bio-agents; programmable (JBPDS Block I) • Navy-*Ship based Interim Biological Agent Detector (IBAD)* • Army-*Biological Integrated Detection System (BIDS)*	• Complete development of Block II JBPDS – increase number of agents detected and identified with increased sensitivity, lower false positive rates; smaller and lighter with increased reliability.	• Automatic point biodetection, to detect and identify; programmable (JBPDS Block II) • Automated, integrated detection of both biological and chemical agents in a single sensor package (Joint Modular Chemical/Biological Detector System, JMCBDS) • JCBAWM (See above)
NBC Reconnaissance and CB Remote and Stand-off Detection	• Improved NBC Reconnaissance Vehicle with remote/early warning and data fusion capabilities (M93A1) • Limited long range particulate cloud detection and tracking (LR-BSDS NDI)	• Lightweight passive stand-off detection for chemical agent vapors (JSLSCAD) • Add biological detection and identification capabilities (JSNBCRS P3I) • Light reconnaissance vehicle (JSLNBCRS) • Integrated NBC detection (point/standoff)/identification/ sampling (Army-NBCRV Block II/IAV-NBCRV) • Automated biological remote detection and early warning capabilities (JBSDS Block I)	• Automated biological remote detection and early warning capabilities (JBSDS Block II) • Stand-off detection, ranging, and mapping of chemical vapors and aerosols (JSWILD/Artemis) • Wide area detection • Single, fully-integrated multifunctional NBC Recon platform with NBC Unmanned Ground Vehicle System (UGVS) capability (IAV-NBCRV)
Battle Management Systems	• Automated warning and reporting (JWARN Phase I)	• Automatic NBC warning and reporting interoperable with all Services (JWARN Phase II)	• Integrated and automatic warning and reporting (JWARN Phase III)

	NEAR (FY02-03)	MID (FY04-09)	FAR (FY10-19)
Radiation Detection	• Army-*Compact, digital whole body radiation measurement (AN/UDR-13)*		• Stand-off radiation detection and measurement • Portable radiation meter

1. All programs shown are joint or multi-service, unless indicated as a Service-unique effort (italicized text).
2. Where applicable, systems which meet requirements are listed following the entry.

Early detection and warning is the key to avoiding NBC contamination. As a result, DoD is concentrating RDA efforts on providing its warfighters real-time capabilities to detect, identify, quantify, and warn against all CB warfare threats below threshold effects levels. Real time detection of biological agents below threshold effects levels is unlikely in the near to mid-term. Current emphasis is on developing lightweight, automated CB sensors capable of providing enhanced detection and early warning of all biological and chemical threat agents. To meet the needs in the near to mid term, several stand-alone detectors and sensors are being developed. Developmental efforts are focusing on system miniaturization, improved sensitivity and specificity, agent characterization and range, decreased false alarm rate, and decreased operation and support costs. This focus will facilitate the integration of chemical detectors into personal warfighter gear, chemical and biological detectors onto various air, sea, and ground platforms, and integration of detectors into automated warning and reporting networks. Table A-1 in Annex A provides an overview of RDA efforts and Service involvement.

The management challenge involves the coordination and consolidation of numerous detection and warning RDA efforts across the Services. This strategy, led by the JSMG through the Contamination Avoidance Commodity Area Manager, resulted in the initiation of RDA efforts which shared common technical goals, but were constrained to Service unique requirements. Management organizations and initiatives, such as the Joint Program Office for Biological Defense (JPO-BD) and the Joint NBC Defense Board are building Joint Service coordination across the mission area.

Since the establishment of the Joint CB Defense Program, the JSMG and JSIG, through the Contamination Avoidance Commodity Area Manager, and with assistance from JPO-BD, transformed and consolidated 44 separate contamination avoidance developmental efforts into eleven fully coordinated joint projects. The Joint Programs are:

- Automatic Chemical Agent Detection Alarm (ACADA).
- Joint Chemical Agent Detector (JCAD).
- Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD).
- Joint Service Warning and Identification LIDAR Detector (JSWILD/Artemis).
- Joint Biological Point Detection System (JBPDS).
- Joint Biological Standoff Detection System (JBSDS).
- Joint Service Light NBC Reconnaissance System (JSLNBCRS).
- Joint Warning and Reporting Network (JWARN).
- Joint Chemical Biological Agent Water Monitor (JCBAWM).
- Joint Portal Shield (JPS).
- Critical Reagents Program.

2.3.3 Joint Service Contamination Avoidance Programs

Consolidation of Joint Service contamination avoidance programs has been completed. All detection programs have been restructured to meet current multi-Service needs. Table 2-3 highlights Joint programs; Service-unique programs are italicized. Detailed descriptions of Joint contamination avoidance programs are provided in Annex A.

Chemical Warfare Agent Contamination Avoidance. An ACADA non-developmental item (NDI) is being procured for point detection of chemical (nerve and mustard) agent vapors. ACADA is suitable for many vehicle-mounted and man-portable applications. A shipboard version of ACADA, which addresses unique shipboard interferents, is being built to provide the Navy with an interim monitoring capability until JCAD is fielded. The Improved Chemical Agent Monitor (ICAM) is being procured and fielded for post attack monitoring of chemical agent vapors. The ICAM is three times more reliable than its predecessor and much simpler and cheaper to repair. Both the ACADA and ICAM will be replaced by the JCAD.

JCAD provides point chemical vapor detection and is in Phase II (Engineering and Manufacturing Development, EMD) of the acquisition cycle. JCAD will function as a chemical point detection system in order to accomplish a variety of mission requirements on multiple service platforms. The requirements are for the detector to be considerably smaller (within 40 cubic inches) and lighter (2 lbs. or less) than the ACADA and to be configurable for a variety of applications, such as individual soldier detectors, post-attack monitoring, shipboard chemical agent monitoring, special operations forces applications, and aircraft interior detection. JSLSCAD provides passive standoff, on-the-move detection of chemical agent vapor and is in Phase II (EMD) of the acquisition cycle. The JSLSCAD program is a joint program with a Joint Operational Requirements Document (ORD) approved by all Services. The basic JSLSCAD system (Operator display unit, scanner and sensor/electronics module) will weigh approximately 50 pounds and occupy approximately one cubic foot. The system may be modified to accommodate a variety of requirements, including a 360° x 60° scanner for Armored Systems Modernization applications (tracked and wheeled vehicles), a 60° forward looking scanner for Marine Corps helicopters and a gimbal mount for unmanned aerial vehicle (UAV) contamination avoidance roles. The Air Force's primary use for this system will be in air base defense. The Navy will install JSLSCAD on shipboard and airborne platforms and at high priority oversea installations. This system will be fully evaluated by all the Services during EMD.

In the near-term, the Army, Air Force, and Marine Corps have agreed to focus on the development of a Joint Service Light NBC Reconnaissance System (JSLNBCRS). The proposed system will consist of a suite of detectors required for a specific mission that could be easily integrated into the platform of choice. Currently two configurations are proposed: a light and a medium version, to fulfill expeditionary and armored mission profiles, respectively. The M93A1 NBCRS fulfills heavy requirements. The M93A1 NBCRS is being upgraded to include a chemical standoff detection capability and other electronic improvements including data fusion.

In the far-term, the Army, Air Force, and Marines have agreed to a Joint Chemical Biological Agent Water Monitor (JCBAWM). JCBAWM is a system that will detect the presence of contaminants in potable water. A requirement for an agent water monitor has been identified by the Army, Air Force, and Marines and a technology base program is underway. The operational scenarios defined in

the JCBAWM ORD include source water, water distributions systems, and verification of water treatment. The Army and Air Force have identified a need for an early warning and identification detector. The Joint Service Warning and Identification LIDAR Detector (JSWILD/Artemis) is a technology base effort to address this problem. JSWILD/ Artemis is a laser-based standoff detection system being developed to meet the need for the detection of chemical liquids, aerosols, and vapors. Although this system is much heavier than its passive counterpart (JSLSCAD), it provides the ability to detect chemical agents in all forms—liquids, vapors, aerosols—as well as mapping and ranging information. The integrated multifunctional platform technologies developed for the Interim Armored Vehicle—NBC Reconnaissance Vehicle (IAV-NBCRV) will be leveraged to develop the NBC Unmanned Ground Vehicle (NBC-UGV).

Biological Warfare Agent Contamination Avoidance. Currently, the Joint Program Office for Biological Defense (JPO-BD) manages the following biological detection efforts:

(1) Joint Biological Point Detection System (JBPDS), Block I and II.
(2) Joint Biological Standoff Detection System (JBSDS).
(3) Joint Portal Shield (JPS).
(4) Critical Reagents Program.
(5) Technology Transfer Program.
(6) Biological Integrated Detection Systems (BIDS NDI and P3I).
(7) Interim Biological Agent Detector (IBAD).

Currently fielded systems include the Navy's rapid prototype shipboard detection system (IBAD), the Joint Portal Shield that provides an automated networked biological detection system, and the Army's land-based system (BIDS-NDI and P3I). The Army's LR-BSDS NDI is a helicopter mounted infrared LIDAR system for the detection, ranging and tracking of aerosol clouds that may indicate a biological warfare (BW) attack. A reevaluation of the user's requirements has led to the termination of the follow-on effort, a P3I version called the Counterproliferation (CP) LR-BSDS..

The Air Base/Port Biological Detection (Portal Shield) ACTD was developed and has demonstrated the capability of an automated network of biological detection systems to protect high value fixed sites against BW attacks. The system consists of a variable number of biological sensors forming a network under the command and control of a centralized command post computer (CPC). The CPC communicates with and monitors the operation of each sensor. The sensor can detect and presumptively identify up to 8 biological warfare agents simultaneously in less than 25 minutes. The system network increases the probability of detection while decreasing false alarms and consumables. The Joint Portal Shield (JPS) has been deployed to a total of nine sites in Southwest Asia (SWA) and Northeast Asia (NEA). Twelve additional sites will be fielded with Portal Shield production systems by 2QFY02. JBPDS will be produced to meet each of the four Services' needs for an integrated biological point detector. This program is developing a standard biological detection suite that will be integrated on Service designated platforms. Fielding of the JBPDS Block I is scheduled for 3QFY03. In response to the national emergency, PM-JBPDS has deployed a network of 8 Block I JBPDS systems in the National Capital Region. These LRIP Phase I systems were deployed in a commercial trailer configuration that was jointly developed and produced by the PM-JBPDS and the Edgewood Chemical/ Biological Center (ECBC) of the Soldier, Biological, Chemical Command (SBCCOM).

These systems, referred to as the Homeland Defense Trailer (HDTR), were deployed November 28, 2001 and were fully operational on December 3, 2001. This deployment may serve as a method to collect additional effectiveness and suitability data to support the acceleration of an Army-only operational test and evaluation in June-July 2002 (IOT&E for the other Services will take place on or about October–November 2002).

In addition, the Critical Reagents Program (CRP) supports all services within DoD to include DoD first responders and NATO countries. The CRP consolidates all DoD antibody, antigen and gene probe/primer developments and requirements. The CRP is tasked with ensuring the availability of reagents critical to the development, test and operation of biological defense systems; supporting research, development and acquisition efforts to ensure the best possible reagents are available against current and emerging threat agents and producing Hand Held immunochromatographic Assays (HHAs) and DoD Biological Sampling Kits. The CRP also maintains a rigorous quality assurance and quality control program and ensures the security of the aforementioned CRP products.

The Critical Reagents Program (CRP) ensures the quality, availability, and security of BW reagents, Hand Held Assays (HHAs) and DoD Biological Sampling Kits, which are critical to the successful development, test, and operation of DoD biological warfare detection systems and medical biological products. The program maintains an R&D effort to ensure the best possible reagents are available for use against both current and emerging threats and to include analysis of commercially available reagents and technologies. The CRP has instituted a program-wide quality assurance program and addresses relevant security issues. The CRP consolidates all DoD antibody, antigen, gene probe/primer, HHA, and DoD Biological Sampling Kit developments and requirements. The CRP currently has reagents and HHAs to detect 10 BW threat agents from the ITF-6A threat list. The CRP provides required reagents and HHAs to support fielded DoD BW detection systems (BIDS NDI and P3I, XM-99 Joint Portal Shield, IBAD, and DoD Biological Sampling Kits) and developmental systems (JBPDS), as well as the detection needs of other Federal Agencies and NATO allies. The next three years requires the development of 12 additional reagents to support the development and fielding of JBPDS Block II and the development of environmental and diagnostic molecular reagents for the JBAIDS. Outlying years will focus on the development of reagents to identify new and emerging threats and on the procurement of improved reagents to replace older stocks.

From 5–29 September 2000, the JPO-BD, in conjunction with the United States European Command (USEUCOM), conducted a technical and operational assessment of the Joint Biological Remote Early Warning System (JBREWS) ACTD. The JBREWS ACTD was comprised of an integrated suite of components, organic to a tactical unit, designed to detect, identify, and warn of on/off target point biological attacks (*e.g.*, Scud missiles). The principle finding from the assessment was that JBREWS was not successful in demonstrating the required capabilities with sufficient functionality, reliability and maturity to warrant consideration as a residual within the operational units under USEUCOM. The JBREWS ACTD was completed in January 2001 with no residual equipment fielded.

In the mid-term the JPO-BD will develop the JBPDS Block II. This operational level biological detection system will provide significant enhancements in number of agents detected and

identified with increased sensitivity and lower false positive rates. The system will be smaller and lighter with increased reliability. The JPO-BD will also begin development of the next generation biological standoff detection system. The Joint Biological Standoff Detection System (JBSDS) will be the first joint biological standoff detection program. JBSDS will be capable of providing near real time detection of biological attacks/incidents and standoff early detection/warning of BW agents at fixed sites or when mounted on multiple platforms, including NBC reconnaissance platforms. It will be capable of providing standoff detection, ranging, tracking, discrimination (bio *vs.* non-bio) of BW aerosol clouds for advanced warning, reporting and protection. JBSDS will augment and integrate with existing biological detection systems to provide a biological detection network capable of near real time detection and warning, theater-wide, to limit the effects of biological agent hazards against U.S. forces at the tactical and operational level of war. The JPO-BD will use an evolutionary acquisition strategy for the JBSDS program with block developments. JBSDS Block I will provide an initial operationally useful and supportable capability in as short a time as possible. JBSDS Block II will operate on the move, increase range and sensitivity while decreasing weight, power, and size over the JBSDS Block I.

In the far-term, chemical and biological detection will be integrated into a single system. The Joint Modular Chemical and Biological Detection System (JMCBDS) is envisioned to be modular, miniaturized, multi-technology, automated system capable of detecting all CW/BW agents. The JMCBDS is envisioned to integrate advanced chemical detection with miniaturized biological point detection capabilities into a single system. It will automatically warn troops and provide fused sensor data to JWARN.

2.3.4 CB Battle Management

The Battle Management area seeks to develop the capability to use automatic collection and fusion of medical and non-medical information from all CB defense assets throughout the battlespace and integrate that with other relevant battlespace information and C^4I systems. It will integrate threat information, CB sensor and reconnaissance data, protective posture, enviromental conditions, and other data pertaining to the CB conditions in the battlespace. The end result of this capability is the rapid dissemination and display of operationally meaningful information to commanders and units at all levels to support decision making related to joint force protection, restoration of operational tempo, and casualty care treatment.

Warning and reporting is a critical component of this capability. It provides the critical link between CB detection and CB protection and provides situational awareness to the commander. Warning and reporting provides the hardware and software to connect detection systems into the overall command and control architecture. Additionally, it provides modeling and simulation capabilities to enhance hazard forecasting and assessment. The goal of warning and reporting is to provide sufficient, accurate, and timely information to commanders at all levels through early and direct warning capabilities so they assume appropriate protective postures and develop options to continue mission-essential operations.

The Services have agreed to expedite development of this capability by integrating ongoing hardware and software into a Joint Warning and Reporting Network (JWARN). This network will be

compatible with, but not duplicate, all C4I equipment, both current and developmental. The JWARN Phase I effort began fielding the first version of software in FY98. The JWARN Phase II EMD effort commenced in FY01. This will address hardware and software integration onto Service designated platforms and installation at fixed sites.

An integrated warning and reporting network will enhance the overall approach used in the chemical biological defense strategy. The enhancements will come from a warning and reporting network that is linked to numerous point detectors, such as JCAD, which can identify and quantify chemical threats, and which are cued by early warning systems, such as JSLSCAD and JSWILD/Artemis. The information from all the sensor systems in the operational theater becomes available to various command levels with appropriate levels of resolution determined by the command decision needs. For example, a fixed facility commander can determine the appropriate level of protective posture by monitoring the direction of an ongoing attack or the effects of weather in moving contamination in a post attack situation.

2.3.5 Other Contamination Avoidance Programs

Various detection and warning requirements have unique mission profiles and technical specifications. While in some instances the development effort may leverage the technical achievements of a closely related detection and warning project, the application beyond its intended mission is limited and accordingly supports only one or a few a specific requirements. The Navy awarded a production contract in FY97 for the Improved (chemical agent) Point Detection System (IPDS), and began installation in FY99. IPDS is used to automatically detect and alarm in the presence of chemical agents in vapor form and will provide continuous detection and alarm capability in the harsh shipboard environment. The IPDS replaces the existing shipboard Chemical Agent Point Detection System (CAPDS), improving detection thresholds, response time, rejection of shipboard interferents, and adding the capability to detect mustard agents.

The Marine Corps is conducting a Force Medical Protection/Dosimeter ACTD, the goal of which is to develop an individually worn sampler that can measure and archive exposure levels of chemical and biological agents. The objectives of the system are to warn the wearer, provide real-time analysis of chemical agents, and trap biological agents for later analysis.

2.3.6 Defense Advanced Research Projects Agency (DARPA) Programs

There are four related programs currently ongoing within DARPA that contribute to the development of advanced sensor technology: BW defense environmental sensors, tissue-based biosensors, microfluidic molecular systems, and pathogen genome sequencing.

DARPA BW Defense Environmental Sensors Program. DARPA is developing technologies to enable bioagent detection and identification. Technologies using universal polymerase chain reaction (PCR) probes are being developed to permit the detection and identification of known threats as well as to provide significant potential for identifying engineered agents. Enhanced multiplexing is being developed to reveal BW agent family, genus, and species on a single chip. The chip is structured to take advantage of the environmental hierarchical phylogenetic classification of microorganisms. A mass spectrometer is being miniaturized for potential use in identifying BW agents and contaminants without

the use of liquids. A desktop mass spectrometer using an infrared (IR) laser analysis of the biological sample has been developed and commercialized by DARPA for analysis of biological agents. These systems will be automated for unattended operations. Detection technologies that provide information on BW agent pathogenicity, anti-biotic resistance and viability are also being developed under the DARPA biological detection program.

DARPA Activity Detection Technologies Program. DARPA is exploring the development of activity detection systems which report on functional consequences of exposure (mechanism and activity) to a wide spectrum of chemical or biological toxins, whether they are living or dead, or whether they have been bioengineered and are currently undetectable by other means (antibodies, nucleic acid sequencing). These systems incorporate enzyme based, cellular or tissue based assays, and a number of technical issues are being addressed in the program including (1) the fabrication of biocompatible matrices and interfaces for the long-term retention of cell and tissue function, (2) pattern recognition from critical pathways responsible for the processing of toxins, (3) sampling strategies to accurately extract and present the toxin from air, liquid, or solid samples, and (4) systems integration into a functional device. One current focus of the program is the use of neuronal and immunological cells and tissues as detectors for such devices. Engineering of cells and tissues of these origins, including stem cells, is proceeding in order to optimize sensor performance requirements and fabricate prototype devices for testing and evaluation.

DARPA Microfluidic Molecular Systems Program. Micro total analysis systems are being developed through focused research on microfluidic, chip-scale technologies. Automated sample collection and sample preparation are key front-end processes for early biological agent detection, whether it is by immunoassays, DNA assays, or tissue-based assays. To scale down these processes into miniaturized, multiplexed detection systems, microfluidic chip-scale components need to be developed. Microfluidic components/devices currently being developed by DARPA include chip-scale micropumps/valves, particle separation filters, fluidic interconnects, fluidic manipulation of hybridized microbeads, controlled mixing/dosing, *etc.* Several demonstrable handheld prototypes, such as a programmable microfluidic system for remote sensors, are currently being tested.

DARPA Pathogen Genome Sequencing Program. DARPA is sequencing the genomes of high threat BW agents. This effort, undertaken with broad community interaction, will support DARPA BW Defense research activities and is intended to satisfy the needs of DoD components, the Intelligence Community, and other governmental organizations. Interest is focused on BW pathogens, and selected non-pathogenic near neighbors thought to be important to establish a basis for low false alarm detection and identification. The work also contributes to the development of advanced unconventional pathogen countermeasures.

2.4 MODELING AND SIMULATION (M&S)

Chemical and Biological Defense (CBD) Modeling and Simulation provides tools for the Warfighter to fundamentally understand a specific challenge and evaluate proposed solutions. It is intended to provide the warfighter with a full spectrum of capabilities to perform hazard analyses, operational effects analyses, simulation based acquisition, and accurate training when the use of live chemical or biological agents is not available due to legal, ethical, financial, or other constraints.

Modeling and simulation is used to provide situational awareness, to provide hazard warning and prediction, and for planning or modification of operations. In the future, modeling and simulation will be used to provide warfighters and decision makers at every level of command with the ability to analyze courses of action immediately prior to or in concert with combat need. In addition, modeling and simulation information systems aid in the assessment of Joint Service doctrine, training, materiel development, and equipment design (*i.e.*, Simulation Based Acquisition). They are also used in warfighter training and the training of battle staffs using larger conflict simulations. In the latter aspect, they are used to perform and support analyses of CBD operations within the context of larger military operations. Models are also critical components of sensor systems, such as the Joint Warning and Reporting Network and Command and Control (C2) systems that function by taking sensor output signals and processing them into meaningful command information. It also supports simulation based acquisition in the development of critical NBC defense capabilities. Modeling and simulation is essential to reduce costs, shorten development schedules, and improve system performance. Thus, models and simulations can be either stand-alone systems or imbedded within other software and hardware systems.

The following sections provide a summary of modeling and simulation science and technology efforts, modernization strategy, and Joint Service Programs.

2.4.1 M&S Science and Technology Efforts

M&S technology base efforts are provided by a refocused business area—Information Systems Technology. This business area includes four sub-areas to fully meet the JFOCs required by the CINCs. The JFOCs focus on capabilities to provide improved battle management, characterization of the CB environment, information systems, and simulation based acquisition. To provide improved characterization of the CB environment, efforts are continuing to provide advanced hazard assessment methodologies, address specific environmental flow regime issues (such as high altitude and urban transport and diffusion (T&D) methodologies) and support first principles physics, chemistry, and meteorology efforts. Battle Management information systems technologies are addressing operational effects and processes for fixed site simulations, as well as, advances in conflict simulation methodologies and distributed information systems. The technology base efforts also collaborate with the weapons effects, medical and larger DoD Modeling and Simulation communities to address source term and toxicology, interoperability and architectural issues. [NOTE: Dispersion is the combination of T&D. T&D only refers to the airborne behavior of a contaminant. The DoE uses transport and fate to address additional physical processes. Hazard assessment includes all of these factors, plus the inclusion of source characterization and toxicity.]

2.4.1.1 Goals and Timeframes.

The goals of CBD M&S science and technology efforts are as follows:

- support the warfighter directly through existing C^4I networks and information systems,
- support the operational and national command authority with CBD environment decision systems,
- support DoD level theater and warfare simulation efforts, and

- support materiel acquisition programs with Simulation Based Acquisition (SBA) tools and architectures.

Table 2-4 shows specific efforts supporting theses goals. Current modeling capabilities are designed to support warfighter efforts to conduct scenario simulations prior to engagements and to train in a realistic manner. Recent advances allow CBD planning to be folded into larger conflict simulation and consequence management tools. SBA tools will be used for detectors in conjunction with other CBD environment models to assess acquisition strategies for several Service/Joint detector and platform acquisition programs. The next generation T&D methodologies will provide a multi-fidelity capability, which will allow the warfighter increased flexibility and more responsiveness to threat and hazard predictions. The far-term capabilities will include a near-real-time operational hazard prediction capability. An ongoing effort in modeling is the incorporation of specific advances in the characteristics of contamination avoidance, decontamination, medical and protection systems into models so that warfighters are able to evaluate and plan for advances. Integrated conflict simulation capabilities are also envisioned to meet theater and strategic simulation requirements.

Table 2-4. Modeling & Simulation Science and Technology Strategy

By 2002	By 2007	By 2012
• Demo improved VLSTRACK Version 3.1 • Continue efforts with MESO and CBW-CFX technologies • Demo-Fixed Site (STAFFS) capability • Demo multi-fidelity M&S capability • Initiate JEM acquisition program • Provide VLSTRACK, HPAC and D2PC methodologies to JEM	• Demonstrate and transition MESO and CBW-CFX methodologies to JEM • Demo and transition STAFFS and NCBR Simulator to JOEF • Demo and transition JMNBCDST to JOEF • Detection SBA application transitioned to VPS • Collective Protection SBA application to VPS • VERTS transitioned to TSC Block I • Demo emerging advanced info system technologies	• Demonstrate advanced system architectures for JEM and JOEF • Demo real-time, course-of-action decision making options technology • Demo Micro scale weather forecast hazard prediction capability • Demo mobile forces CBD ops effects capability • Demo emerging advanced info systems technologies • Decontamination SBA applications transitioned to VPS

Defense Technology Objectives (DTOs) with an M&S focus include DTO CB.43, Chemical and Biological Warfare Effects on Operations, and DTO BE.10, High-Resolution Meteorological Nowcasting for Chemical/Biological Hazard Prediction. This objective is to develop a general-purpose model of the operations of large fixed-site facilities [air bases, aerial ports of debarkation (APODs) and seaports of debarkation (SPODs)], with the capability to represent chemical and biological warfare (CBW) attacks and their operational impacts.

2.4.1.2 Potential Payoffs and Transition Opportunities. Future CB M&S systems will complement C4ISR systems with a level of situational awareness unknown at this time: accurate information, knowledge, and predictions of threats, the environment, operational alternatives and effects in real time, accelerated time, or as required. This will enable commanders to control the battle, analyze the need for CBD actions, verify effective deployment of CBD assets and reconstitution procedures, and assume the appropriate protection required to continue operations and sustain their

mission with minimal performance degradation and casualties. CB M&S technologies have dual use potential predicting and responding to civil support events such as terrorist activities, air pollution, Toxic Industrial Chemical and Toxic Industrial Material (TIC and TIM) releases both outside and inside enclosed areas, and municipal water supplies. The key payoffs of M&S include: (1) commanders and battle staffs better trained and able to analyze alternate courses of action with advanced simulations, (2) less confusion and more consistent decision making via use of a federation of analytical and real time CBD environment M&S tools, (3) CBD systems and operational concepts that match requirements more closely because warfighter feed back is captured earlier in the development cycle under the tenets of SBA, and (4) advanced hazard prediction and human effects modeling that has dual use potential in aiding civilian responders or planners to prepare for or respond to terrorist attacks and industrial accidents.

2.4.1.3 Major Technical Challenges. The major technical challenges for M&S include the following: (1) modeling and validating the effects of complex and urban terrain on CB hazards, (2) modeling and validating high altitude threat intercept effects, (3) modeling and validating human effects and small unit behaviors in a CB environment, (4) modeling and validating effects of low level and long term exposures, (5) effectively quantifying the effects that CBW has on complex fixed site operations, (6) integrating CB effects and operations with C4I systems for training and operations, (7) interjecting CB effects into combat and materiel evaluation simulations with adequate fidelity without bringing the simulations to a standstill, and (8) developing engineering level models of CBD equipment that can participate in distributed simulations to support SBA from inception to system retirement.

2.4.2 Modeling and Simulation Modernization Strategy

During FY2001, the JSMG and the JSIG prepared a Draft *Modeling and Simulation Master Plan* that details the modernization strategy and RDA efforts for M&S within the CBDP. The Master Plan will also highlights coordination efforts with other organizations throughout the Department. As a result of the oversight responsibilities being assigned to the DATSD(CBD) in November 2000 for all DoD CBD M&S efforts, there were several key changes to the CBD M&S program over the past year. The CBD M&S program includes efforts from basic research through full scale engineering and manufacturing development. This is in contrast to past efforts that were limited to technology development and the fielding and support of technology products by the scientists who created them. Guidance provided by the DATSD(CBD) in January of 2001 directed the initiation of the first M&S acquisition program, the Joint Effects Model (JEM). This program is based upon the proven technologies of existing agent hazard assessment models and the emerging operational requirements document, which articulates the Joint Service needs. The JEM program achieved Milestone A in May 2001. With the start up of this initial M&S acquisition program, the Services and CINCs will receive a system that not only meets their needs, but that will also receive training support in the future. It also creates the transition program for emerging technologies and capabilities to assure the warfighter that they receive the best capability, for the best value, at the earliest time.

This year also saw the introduction of the Joint Operational Effects Federation (JOEF) program into the POM process. This is a milestone in that JOEF will be the acquisition program to

address the entity-based operational analysis requirements. JOEF will initiate and coordinate all efforts associated with providing the warfighter with the information system required to predict the operational consequences of a given CB hazard event. JOEF will use JEM to predict or analyze the nature of the hazard area, but will take that information and use a federation of other models and simulations to meet a specific operational commander's or other authority's needs. The combination of JEM and JOEF will meet the entire spectrum of the users needs for analytical M&S systems.

Table 2-5. Modeling and Simulation Modernization Strategy

	NEAR (FY02-03)	MID (FY04-09)	FAR (FY10-19)
Hazards Analysis	• Counterforce hazard prediction (HPAC 4.0) • Passive defense hazard analysis (VLSTRACK 3.1) • High altitude intercept analysis (PEGEM) • Urban environment analysis (MIDAS-AT) • CONUS facilities analysis (D2PC)	• Integrated VLSTRACK, HPAC, and D2PC hazard prediction and effects capability (JEM Block 1) • Increase capability to analyze high altitude intercepts and urban environments (JEM Block 2)	• Multi-fidelity hazard prediction, to move at will from global, to theater, to battle, to building, to individual scale analyses (JEM Block 3) • Micro-scale event analysis (JEM Block 4)
Operational Effects Analysis	• Fixed site analysis (STAFFS) • Medical resources analysis (CREST) • Mobile forces analysis (NCBR Simulator)	• Integrated fixed site and medical simulations with JWARS and JSIMS (JOEF Block 1)	• Mobile forces simulations incorporated into the federation (JOEF Block 2) • Automated C4I system integration (JOEF Block 3)
Simulation Based Acquisition Systems	• Navy-Ship based analysis (CWNavSim) • Point and stand-off detector systems (NCBR Simulator)	• Detection (VPS Block 1) • Biological detection and identification capabilities (VPS Block 2)	• Protection and decontamination (VPS Block 3&4)
Training Simulation Systems	• Virtual Emergency Response Training System capability (VERTS TSC)	• VERTS Capability (TSC Blocks 1 and 2) • Individual and crew training systems (TSC Block 2)	• Integrated training systems for battle staffs and commanders (TSC Block 3)

Analysis and training are the keys to being prepared for and responding to a CB event. As a result, DoD is concentrating RDA efforts on providing its warfighters and decision makers with analytical systems to predict or forensically analyze events and courses of action for the full spectrum of CB threats. In the near term, efforts are focused on taking advantage of our decade of technology development in hazard assessment methodologies to provide interim accreditation for a number of analysis regimes. In addition, efforts in operational effects and SBA will be prepared to transition to full scale development programs. In the mid-term, first priority has been given to transitioning the most mature technologies to the new start JEM and JOEF programs. These will provide accredited, common use hazard information systems by the years 2005 and 2007 respectively. Largely due to the maturity of the technologies, requirements and the vision for them, the SBA and Training Systems Capability (TSC) will be addressed behind those for analysis. However, both SBA and TSC are also functionally and structurally dependent upon the analytical systems so a delay in their start is appropriate. Table B-1 in Annex B provides an overview of RDA efforts and Service involvement.

The management challenge involves the coordination and consolidation of numerous previously uncoordinated RDA efforts across the Services and Agencies. This strategy, led by the JSMG through the M&S CAM, established in April 2000, has already resulted in the initiation of the above mentioned Joint Service RDA efforts.

2.4.3 Defense Advanced Research Projects Agency (DARPA) Programs

DARPA Sensor Integration and Modeling for Biological Agent Detection (SIMBAD). This is a combined program of hardware and software. DARPA is investigating various biodetection technologies and is developing the simulation tools to be able to evaluate conceptual systems against postulated reasonable attacks. The goal of the program is to develop well characterized, optimized, fully integrated BW and CW agent sensor systems by maturing current and emerging sensor technologies, and developing new technologies as required. BW agent sensor systems are the primary goal, with CW agent sensor systems a secondary goal. The ultimate product of SIMBAD is one or more fully integrated and well-characterized sensor systems capable of responding to the threats defined during the duration of the SIMBAD program.

As part of achieving this goal, several other supporting goals must be achieved. These are (1) to develop engineering models for the widest possible array of current and emerging CW and BW agent sensor systems at a level of detail that permits both component-level and system-level optimization and performance prediction, and (2) to develop protocols for validation of both the component-level and system-level sensors and sensor models. This validation must include models, experimental model validation, and direct experimental validation of sensor performance. Innovative methodologies for characterizing sensor performance against live agents and real clutter, interference and backgrounds are an important element of the SIMBAD program.

Finally, sensors can only be developed, optimized and evaluated in the context of specific threats to which they are designed to respond. Therefore, several other supporting goals of the program are (3) to develop a sufficiently detailed engineering description of the threat—corresponding to several realistic scenarios—to support both measurements and prediction of sensor component and sensor system response to this threat, and (4) to evaluate (using measurements and predictions) both sensor component and sensor system response to the threat under conditions corresponding to several realistic scenarios.

2.5 DECONTAMINATION

When contamination cannot be avoided, personnel and equipment must be decontaminated to reduce or eliminate hazards after NBC weapons employment. Decontamination systems provide a force restoration capability for units that become contaminated. Modular decontamination systems are being produced to provide decontamination units with the capability to tailor their equipment to specific missions. Technology advances in sorbents, coatings, catalysis, and physical removal will reduce logistics burden, manpower requirements, and lost operational capability associated with decontamination operations. The following sections detail CB decontamination science and technology efforts, modernization strategy, and Joint Service programs.

2.5.1 Decontamination Science and Technology Efforts

2.5.1.1 Goals and Timeframes. The goal of decontamination science and technology is to develop technologies that support two key Joint Future Operational Capabilities (JFOCs): (1) the RC-EL (Restore - Equipment/Facilities/Large Areas) JFOC, and (2) the RC-LG (Restore - Logistics) JFOCS. These capabilities will eliminate toxic materials or their effects without performance degradation to the contaminated object, are non-corrosive, environmentally safe, and lightweight (see Table 2-6). This area includes decontamination of personnel, individual equipment, tactical combat vehicles, aircraft, facilities, and fixed sites. Decontamination technologies currently being pursued include enzymes, non-chlorine based oxidants, catalysts that improve reactivity, decontaminants that are effective in both fresh and brackish water, improved reactive sorbents, and nanoparticle technology. Supercritical fluid technology, non-ozone depleting fluorocarbons, and solvent wash technologies are being investigated for sensitive equipment decontamination, while thermal approaches, solvent wash technologies, and plasma are among the candidates being evaluated as a decontaminant for interior spaces of vehicles such as aircraft. Enzyme-based decontaminants that are nontoxic, non-corrosive, and environmentally safe are being pursued through DTO CB.09, Enzymatic Decontamination. New oxidative decon formulations that are effective against both chemical and biological agents are being developed through DTO CB.44, Oxidative Formulations. These potential decontaminants will also be nontoxic, non-corrosive, and environmentally safe.

Contamination control involves investigating procedures that minimize the extent of contamination pickup and transfer, and maximize the ability to eliminate the contamination pickup on-the-move as well as during decontamination operations. During the last year, increased emphasis has been placed on aircraft decontamination, especially analyzing material compatibility concerns, as part of the Joint Service Sensitive Equipment Decontamination program, the RestOps ACTD, and other DoD sponsored studies.

Table 2-6. Decontamination Science and Technology Strategy

By 2002	By 2007	By 2012
• Demo improved sorbent delivery systems • Aircraft Interior Decon procedures • Demonstrate Fixed Site decontaminants	• Sensitive Equipment Decon Systems • Demonstrate concentrated enzymatic and oxidative decontaminants • Fixed Site applicators • Demonstrate the next generation of reactive sorbent powders	• New self-decontaminating materials • Improved thorough decon materials • Aircraft and other vehicle interior decontamination

2.5.1.2 Potential Payoffs and Transition Opportunities. The payoff from enhanced decontaminants and decontamination systems will be new non-corrosive, non-toxic, non-flammable, and environmentally safe decontamination systems suitable for a timely elimination of CB agents from all materials and surfaces. This ability will allow forces to reconstitute personnel and equipment more quickly to increase combat efficiency and lessen the logistic burdens. In the future, reactive coatings may allow the continuation of combat operations without the need to disengage for decontamination.

Dual use potential for chemical agent stockpile as well as environmental remediation, especially those dealing with pesticide and toxic industrial chemical contamination, is being exploited.

2.5.1.3 Major Technical Challenges. There are two principal technical difficulties associated with this effort. The first is the development of decontaminants that are reactive, non-aqueous, non-corrosive, safe for use on sensitive equipment, able to decontaminate a broad spectrum of chemical and biological agents, environmentally safe, and pose no unacceptable health hazards. The second technical difficulty is the development of decontamination systems that effectively clean all surfaces and materials, while at the same time reduce the manpower and logistics burden.

2.5.2 Decontamination Modernization Strategy

Decontamination systems provide a force restoration capability for contaminated units. Existing capabilities rely upon the physical application and rinse down of decontaminants on contaminated surfaces. Existing systems are effective against a wide variety of threat agents, yet are slow and labor intensive and present logistical, environmental, material, and safety burdens. In addition, existing systems are inadequate for electronic equipment decontamination, deficient for large area, port, and airfield decontamination, and rely on Decontamination Solution 2 (DS2) and water. To improve capabilities in this functional area, the Joint Services have placed emphasis upon new decontaminating technologies that reduce existing manpower and logistics requirements. These technologies are safer on the environment, the warfighter, and equipment. Table 2-5 shows the roadmap for modernizing decontamination systems in DoD.

The goal of the NBC decontamination program area is to provide technology to remove and detoxify contaminated material without damaging combat equipment, personnel, or the environment. In FY99 the RDA community worked with the Joint Staff and Services' operations community and completed a Decontamination Master Plan that provide a roadmap that integrates RDA efforts with non-RDA efforts, including policy, doctrine, standards, and revised tactics, techniques & procedures. Research and development of non-corrosive, all-agent multipurpose decontaminants and decontaminating systems for combat equipment, aircraft, and personal gear remains a priority. Alternative technologies, such as sensitive equipment decontamination methods and large-scale decontamination systems attract interest across the Services. Table D-1 in Annex D provides an overview of Joint Service RDA efforts and Service involvement.

Table 2-7. Decontamination Modernization Strategy

	NEAR (FY02-03)	MID (FY04-09)	FAR (FY10-19)
Personal Equipment Decontaminants	• More reactive, high capacity adsorbent (M291/M295) • Army-*Higher efficiency decon methods (Sorbent Decon)*	• Non-caustic, non-corrosive decontaminant for personnel and equipment	
Bulk Decontaminants	• Non-caustic, non-corrosive, easy to store and manufacture multipurpose decontaminants	• Decontaminants for fixed sites • Navy -*Less caustic capability*	• Mission tailored decontaminants • Navy -*Contamination resistant shipboard materials* • Army -*Environmentally acceptable replacement for DS2* • Army -*Enzymes for chemical agent decontamination*
Expedient Delivery Systems		• Auto-releasing coatings; reduces skin contact hazard & labor requirements	• Self-decontaminating, auto-releasing coatings; reduces man-power and logistic requirements eliminates skin contact hazard
Deliberate Delivery Systems	• High pressure water wash; mechanical scrubber; improved decontaminant dispenser (increased vehicle throughput) • Army -*High pressure hot water washing and decontaminate scrubber capability; reduced water, labor, and logistic burden (M21/M22 Modular Decon System)*	• Rapid large scale decon capability for fixed sites; reduced manpower and logistic burden • Non-aqueous capability for electronics, avionics and other sensitive equipment	• Vehicle interior decon capability • Supercritical fluid decontamination apparatus • Army -*Waterless decon capability for electronics and avionics* • Air Force - *Sensitive equipment decontamination system for aircraft interiors*

1. All programs shown are joint or multi-service, unless indicated as a Service-unique effort (*italicized text*).
2. Where applicable, systems which meet requirements are listed following the entry.

In order to improve interagency coordination with decontamination S&T efforts, the RDA community worked with the Defense Threat Reduction Agency (DTRA), the Defense Advanced Research Projects Agency (DARPA), and the Department of Energy to develop an integrated decontamination RDA plan. This plan allows agency leaders and researchers to have visibility across current and planned RDA efforts to avoid duplication of effort, identify relevant research performed by other agencies, and establish meaningful collaborative efforts.

2.5.3 Joint Service Decontamination Programs

The Army has developed the M291 skin decontamination kit as a replacement for the M258A1 decontamination kit for all Services, and has introduced the M295 for improved personal equipment decontamination. The M295 provides the warfighter a fast and non-caustic decontamination system for personal gear. A new adsorbent which is more reactive and has higher capacity of absorbing contamination was developed and completed to improve the performance of the M295 kit. The M295 kit filled with the new sorbent became available for requisition in January 2000.

In the near- and mid- term, DoD continues to research new multi-purpose decontaminants as a replacement for bulk caustic Decontamination Solution 2 (DS2) and for corrosive High Test Hypochlorite and Super Tropical Bleach. New technologies, such as reactive decontaminating systems, enzyme-based formulations, and enhanced sorbents are being explored and may offer operational,

logistical, cost, safety, and environmental advantages over current decontaminants. Present shipboard chlorine-based decontaminant solutions pose an unacceptable corrosion risk to Naval aircraft. Current procedures require the use of fresh water and normal aircraft detergent solutions.

Ideally, new decontaminant formulations must be extremely reactive with dwell times of under 15 minutes and be effective at a pH below 10.5 in order to eliminate the corrosion risk. Potential new solutions-based approaches consist of organic, aqueous and mixed organic-aqueous systems, which use catalytic and oxidative chemistries. Some promising decontaminants under consideration are organized assemblies incorporating monoethanolamine-type moieties, non-chlorine containing oxidants, such as stabilized peroxides, peroxycarboxylic acids and dioxiranes, and liquid slurries or suspensions of nanoparticles in organic solvents.

In the far-term, the Services are seeking non-aqueous decontamination systems to provide for sensitive equipment decontamination at mobile and fixed sites. Advancements during the last 18 months in plasma-based systems appear promising for these types of applications. Additionally, there is interest and exploratory research in coatings which can reduce or eliminate the necessity of manual decontamination. The ultimate goal of this coatings effort is to develop a chemically or possibly electrically reactive coating to apply on equipment when operating under high CB threat conditions. This coating would then provide immediate decontamination on contact with CB agents, thus reducing the hazard without any actions required at that time by the warfighter. A detailed description of the decontamination projects is provided in Annex D.

2.5.4 Other Decontamination Programs

In the near-term, the Army is producing the Modular Decontamination System (MDS) to enhance vehicle decontamination. The MDS will support thorough decontamination for ground forces and possess mechanical scrubbing and improved decontaminant dispensing capabilities. It will also offer a reduction in size, weight, logistics burden, and workload requirements over existing decontamination systems. Similarly, the Marine Corps has procured and is fielding an M17 Lightweight Decontamination System (LDS) that can be operated with Military Standard fuels. The M100 Sorbent Decon System is scheduled for fielding in February 2002. This decontamination system replaces the M11/M13 DAP and associated DS2 used in immediate decon. This system consists of a non-toxic and non-corrosive, powder-based system that provides greater coverage than the M11 at 33% less weight.

2.6 PROTECTION

When early warning is not possible or units are required to occupy or traverse contaminated environments, protection provides life sustainment and continued operational capability in the NBC contaminated environment. The two types of non-medical protection are individual and collective.

- ***Individual protective equipment*** includes protective masks and clothing. Protective masks that reduce respiratory stress on the user while improving compatibility with weapon sighting systems and reduce weight and cost are being developed. Technology advances are being pursued to produce mask systems that provide fully compatible vision capabilities, laser/ ballistic protection, and further reduction in logistics and physiological burden. Protective clothing and integrated suit

ensembles are being developed that will improve protection, reduce the physiological and psychological burden, have extended durability, and have less weight and heat stress burden than present equipment.

- ***Collective protection equipment*** consists of various types of NBC protective filters, entry/exit, and air movement devices that provide filtered air to a wide range of applications, transportable shelter systems equipped with NBC filtration systems and, in selected cases, environmental control. Collective protection in the form of overpressure can be applied to mobile and fixed command posts, medical facilities, rest and relief shelters, buildings/fixed sites, vehicles, aircraft, and ships. Lightweight shelters integrated with NBC filtration, environmental control and power generation facilities for medical treatment facilities have been developed and are in production. Technology improvements are being pursued to reduce power requirements and improve filtration capacity against current and future NBC agents. Technologies that reduce weight, volume, cost, and improve the deployability of shelters and filtration systems are also being pursued.

2.6.1 Protection Science and Technology Efforts

2.6.1.1 Individual Protection Goals and Timeframes. The goal of the individual protection area is to reduce the physiological burden associated with wearing protective equipment while maintaining, and potentially improving, the already high level of protection against CB warfare agents and radiological particles (see Table 2-8). Individual protection equipment must also provide protection against emerging threats, such as novel agents or toxic industrial materials (TIMs). To achieve these goals, key physiological performance requirements to the design and evaluation of clothing and respirators are being established. New barrier and filtration materials and selectively permeable materials are being developed and evaluated to accommodate these performance requirements. Maximizing the protection afforded by mask filters is being addressed by Defense Technology Objective Universal End-of-Service-Life Indicator for NBC Mask Filters. The technology is expected to have applications for collective protection also.

Table 2-8. Protection Science and Technology Strategy

By 2002	By 2007	By 2012
• Demonstrate semi-permeable membranes as a viable alternative to adsorbent lined permeable materials for clothing • Demonstrate improved filtration media and advanced filter bed configurations for protective mask and collective protection applications • Demonstrate lightweight, low cost materials and advanced closures for shelters	• Investigate reactive materials as a means of self-detoxifying clothing and shelters • Investigate residual life indicators for mask filters, collective protection filters, and clothing • Investigate advanced adsorbents and filter bed configurations to provide protection against a wider spectrum of threats (NBC & TIM)	• Investigate membrane/ adsorbent composites for clothing • Investigate nontraditional filtration (non-adsorbent based and/or non-single pass) for collective protection applications • Investigate protective shelter materials to replace general purpose (non-protective) shelter materials

2.6.1.2 Collective Protection (CP) Goals and Timeframes. The goals of the collective protection area are to (1) reduce the weight, size and power requirements of CP systems, (2) reduce the logistical burdens associated with the maintenance of CP filters, (3) improve protection capabilities against current and emerging threat agents, including TIMs, and (4) improve the deployability of trans-

portable shelter systems (see Table 2-8). To achieve these goals, improvements to system components (including transportable shelters) are being investigated along with improvements to the current vapor and particulate filtration media. Regenerative vapor and particulate filtration materials processes are being investigated to eliminate the need for filter change and improve the capability against any battlespace NBC threats. The primary effort for investigating adsorbents for both single-pass and regenerative filtration applications is articulated in the Defense Technology Objective Advanced Adsorbents for Protection Applications.

2.6.1.3 Potential Payoffs and Transition Opportunities. Individual protection investments will result in improved respiratory and percutaneous (skin) protection with reduced physiological and psychological burden to the individual warfighter. Improved air filtration systems or technologies for collective protection applications will allow for extended operation in an NBC contaminated environment, reduce the logistics burden associated with filter replacement, reduce weight, volume and power requirements, and improve the capability against current and emerging threats. Filtration technology has commercial application to the chemical industry and automotive applications.

2.6.1.4 Major Technical Challenges. Integrating CB protection into future weapon systems necessitates tradeoffs between performance requirements and limitations of materials and designs. Integral respiratory protection requires tradeoffs between physiological performance parameters such as pulmonary function, field of view, speech intelligibility and anthropometric sizing against constraints such as cost, size/weight, protection time, and interfacing with other equipment. CB protective clothing development requires balancing the physiological and psychological burden imposed upon the warfighter with maximum obtainable CB agent protection. Significant advancements have been made in improving the weight/bulk and power requirements of personal cooling systems, but further work in this area is needed. Air purification systems require tradeoffs with respect to performance, user requirements, size, weight and power constraints, as well as longer life. Addition of threats such as TICs/TIMs increases the need for additional protection and makes the challenge of reducing physiological performance and size/weight constraints more difficult, requiring threat versus design tradeoffs essential and tailoring of equipment to meet the threat.

2.6.2 Protection Modernization Strategy

Forces cannot always avoid NBC hazards, therefore, individual warfighting units must be provided materiel to protect them from the effects of these lethal agents. Protection must be effective against all known threats with minimal degradation to the performance of personnel, weapons, or equipment. Protective measures allow our forces to maintain combat superiority in NBC contaminated environments. A summary of protection modernization requirements is provided in Table 2-9.

The goal of the protection RDA area is to provide equipment that allows U.S. forces to operate in a NBC contaminated environment with minimal degradation of the warfighters' performance. Near-, mid-, and far-term objectives are to reduce physiological and logistical burdens while maintaining current protection levels.

Protective masks will be improved to reduce fatigue, thus enhancing ability to perform mission tasks. Mask systems will require increased NBC survivability and compatibility with combat or

personal equipment. Future respiratory systems, such as the Joint Service Aircrew Mask (JSAM) and Joint Service General Purpose Mask (JSGPM) will require enhanced compatibility with life support equipment and tactical systems, and JSAM with fixed and rotary wing aircraft. They will also require the capability to remove TICs/TIMs as well as traditional CB agents. In the future, the focus will be on integrated respiratory protective ensembles, which offer optimal compatibility with personal, tactical, and crew support systems. Key technologies for future mask systems include mask service life indicator, advanced materials, improved adsorbents, and improved models and test technologies for protection assessment.

Future protective clothing ensembles for U.S. forces will require reductions in bulk and weight without any loss of protection or durability. To satisfy these needs, the Services have consolidated their mission specific requirements into the first truly joint program for the next generation chemical garments—the Joint Service Lightweight Integrated Suit Technology (JSLIST) program. The JSLIST program developed and is fielding the JSLIST Overgarment and is manufacturing Multi-purpose Overboots (MULO). The JSLIST Block 1 Glove Upgrade (JB1GU) Program is seeking an interim glove to replace the current butyl rubber glove. The follow on to the JB1GU will be the JB2GU program that will be produce gloves for both ground and aviation units. The Joint Protective Aircrew Ensemble (JPACE) will be developed to provide aviators with the same advantages and improved protection as JSLIST provides to other warfighters. Similarly, clothing systems for Explosive Ordnance Disposal (EOD) personnel and firefighters are required to enhance existing chemical protection systems without undue physiological burdens.

Table 2-9. Protection Modernization Strategy

	NEAR (FY02-03)	MID (FY04-09)	FAR (FY10-19)
Individual Eye/ Respiratory	• Voice amplification; laser/ballistic eye protection; improved decontaminability, better comfort (M40A1/M42A2) • Army - *Aircrew mask compatible with Apache helicopter systems with a significantly lighter motor/blower unit (M48)* • Army -*Improved compatibility with aviation sighting/night vision systems; reduced logistics burden using non-blower systems, selected for Land Warrior (M45)*	• Reduced physiological and psychological burden, improved comfort, enhanced optical and communications, improved compatibility • New mask systems for general purpose and aviation masks (JSGPM, JSAM) • Lightweight CB mask for low threat environments (JSCESM) • Navy -*Improved complete protection for all aircrews (CB Respiratory System)* • Improved mask leakage tester (JSMLT)	• Advanced Integrated Individual Soldier Protection system (Future Soldier System) • Improved multiple agent protection
Individual Clothing	• Advanced protective suit technology; lighter, improved agent protection; reduced heat stress integrated with all respiratory systems. - Improved foot protection (MULO) Improved hand protection	• Improved cutaneous protection • Improved protection for aviators (JPACE) • Service Life Indicator • Army -*Improved protection for short term use for special purposes (ITAP)*	• Integrated multiple threat modular protection (chemical, biological, environmental, and flame) • Self-detoxifying clothing

Collective Protection	• Chemically Protected Deployable Medical Systems (CP DEPMEDS) • Chemically Hardened Air Transportable Hospital (CHATH) • Rapid insertion of technology improvements into existing equipment (JCPE) • Marine Corps -*Protection for all combat vehicles and unit shelters* • Army -*NBC protection for tactical Medical units (CB Protective Shelter, CBPS).* *- Apply regenerable vapor filter to Comanche.* *- Apply collective protection to advanced vehicle concepts.* • Air Force - *Upgrade/install collective protection into existing rest/relief shelters.* • Navy - *Backfit ships with contamination free protected zones - (Collective Protection System Backfit)*	• Improved filters to extend filter life, reduce maintenance and reduce logistical burden • Reduced logistics burden, improved protection against current and future threats • Improved current collective protection filters and equipment (JCPE) • Support medical treatment in a CB environment for Airborne, Air Assault, and Heavy Divisions (CBPS)	• Family of advanced collective protective systems for vehicles, shelters, ships, and light forces • Regenerable/advanced protective filtration for vehicles/vans/shelters

1. All programs shown are joint or multi-service, unless indicated as a Service-unique effort (italicized text).
2. Where applicable, systems which meet requirements are listed following the entry.

Collective protection equipment (CPE) development efforts are focused on NBC protection systems at the crew, unit, and platform level. New CPE systems will be smaller, lighter, less costly, and more easily supported logistically. New systems are required to provide clean environments for critical operations (*i.e.*, where individual protective equipment (IPE) otherwise places an unacceptable burden upon the warfighter in performing duties) and for essential rest and relief. Modernization efforts will concentrate on: (1) improvements to current vapor and particulate filtration media to extend filter life and to offer improved performance against current and/or emerging threats, (2) advanced air filtration (vapor and particulate) technologies, integrated with environmental control, to greatly reduce the logistical burden and offer greatly improved performance against current and postulated threats, (3) increased application of collective protection systems onto vehicles, vans, shelters, fixed sites, and ships, within the Joint Services, (4) improved transportable shelter system with integrated power/environmental control/filtration, (5) improvements to current collective protection systems to reduce weight, volume, and power requirements, and (6) standardization of filters within the joint services to address storage and procurement concerns. Efforts are in place to support major weapons systems developments, such as the U.S. Army's Comanche, Crusader, Bradley, Breacher, Heavy Assault Bridge, Future Scout and Cavalry System, the USMC Advanced Amphibious Assault Vehicle (AAAV), and other advanced weapons platforms.

2.6.3 Joint Service Protection Programs

Joint programs are shown in Table 2-9; Service-unique programs are italicized. A detailed description of Joint IPE and CPE programs is provided in Annex B.

Individual Protection

Eye/Respiratory. The M40 and M42 series masks (for individuals and armored vehicle crewmen, respectively) are undergoing the final stages of fielding to replace their M17, M9 and M25 series counterparts. The new masks offer increased protection, improved fit and comfort, ease of filter change, better compatibility with weapon sights, and a second skin, which is compatible with Army and Marine Corps protective ensembles. The second skin design also is being reviewed by the Navy and Air Force for potential adoption. The Army, Marines, and Air Force are also fielding the Protection Assessment Test Systems (PATS) to provide users of the M40, M42, and MCU-2/P series masks with a rapid and simple means for validating the fit and function of the mask to ensure readiness. The Navy is evaluating the use of PATS with its MCU-2/P series mask.

The Navy, in coordination with the Marine Corps, is leading an effort to equip all forward deployed fixed and rotary wing aircrew with improved chemical, biological, and radiological (CBR) protection. The CBR ensembles will feature off-the-shelf items, such as the CB Respiratory System. The Army, in cooperation with the Marine Corps, recently completed a product improvement program for the M40 series mask that allows ground crew to aircrew communication. The Air Force continues to field Aircrew Eye-Respiratory Protection (AERP) systems to protect aircrews from CB hazards. This system complements the recently fielded lighter weight aircrew ensemble. Efforts are planned in the near- to mid-term to develop a Joint Service Mask Leakage Test System as a supplement and/or replacement for the M41 PATS, depending on service specific maintenance concepts.

Mid- and far-term research is focused on improved vapor and particulate filtration technology, as well as improved masks for light and special operations forces (SOF). Development will be completed in the mid-term for the Joint Service Aircrew Mask and Joint Service General Purpose Mask, which will provide improved eye, respiratory, and face protection against current and future agents. It will maximize compatibility with future weapon systems, be lightweight, and offer modular facepieces to accommodate a variety of mission profiles. A mid-term Joint Service Chemical Environment Survivability Mask (JSCESM) will provide a mask capable of being stowed easily in packs or pocket as an expedient means of CB protection in low threat and special operation situations. Future protective mask efforts will focus on integrated mask-helmet systems supporting specific needs of the Joint Services and integrated warrior programs (Land Warrior, Air Warrior, Mounted Warrior, and Force XXI).

Clothing. In the area of full body protection, the JSLIST program coordinated the selection of advanced technology chemical protective materials and prototype materials. The JSLIST Overgarment and the Multipurpose Overboot (MULO) were adopted by all four services. The JSLIST Overgarment is a 45 day garment (*i.e.*, it may be worn for 45 days over a maximum of 120 days after the suit has been opened) that provides 24 hours of chemical protection. It is launderable and lighter weight than the Battle Dress Overgarment (BDO). The MULO will replace the black vinyl overboot/ green vinyl overboot (BVO/GVO). The MULO is a 60 day boot that provides 24 hours of chemical protection. The boot has increased traction, improved durability, petroleum, oil, and lubricant (POL) and flame resistance.

The JSLIST Pre-Planned Product Improvement (P3I) addressed requirements not met through the baseline JSLIST program. This program sought new JSLIST material technologies, but no candidate materials were found to meet the requirements under this program. Subsequently, the JSLIST Additional Source Qualification (JASQ) was initiated to qualify additional sources of JSLIST materials and to conduct field wear tests and laboratory chemical tests on commercial JSLIST suit candidates. Government and industry are partnering to plan the testing approach. The JASQ candidates that perform as well as, or better than the current JSLIST garment will be considered for placement on a JSLIST qualified products list and may be authorized as additional JSLIST material sources. In addition, the Air Force and Army leveraged technology from the JSLIST program in the development of a chemical protective firefighter's ensemble.

In the far-term, efforts will focus on integrated protection. Next generation technology will be directed toward integrating CB protection into a system that will also provide environmental, ballistic, directed energy, and flame protection, as well as reduced physiological and psychological burdens. A strong emphasis on supporting technologies must continue. Materials that detoxify a broad range of chemical and biological agents on contact, which can be incorporated into fibers, nanofibers, fabrics, and selectively permeable membranes, are being developed using biotechnology, electrospinning, and more conventional approaches.

Collective Protection (CP)

The Services currently use the M20A1 Simplified CPE and the M28 shelter liners to provide CP collective protection to existing structures. Environmental control is also being added to selected applications. The M20A1 CPE provides resistance to liquid agent and allows expansion of protection area and has been fielded. The M28 Simplified CPE has been integrated into CP DEPMEDS and CHATH field hospitals.

CHATH and CP DEPMEDS are joint programs to integrate environmentally controlled collective protection into already fielded Army and Air Force field hospitals in order to sustain medical operations in a CB contaminated environment for 72 hours. Chemical protection is integrated into existing Tent Extendable Modular Personnel (TEMPER)-based medical tents and shelters and the Modular, General Purpose, Tent, Extendable System (MGPTS) through addition of M28 Simplified CPE, chemically protected heaters and air conditioners, and alarms. CP DEPMEDS also includes CB protective water distribution and latrine systems.

The Chemically and Biologically Protected Shelter (CBPS) is a highly mobile, rapidly deployable shelter system designed to be used for Level I and II divisional and non-divisional forward area medical treatment facilities. The system is self contained/self-sustaining. It is permanently integrated with a M1113 Expanded Capacity Vehicle (ECV) with a Lightweight Multipurpose Shelter. The vehicle tows a trailer and generator set. The vehicle transports a CB protected airbeam supported soft shelter, self-contained environmental support and power generation system, a crew of four and gear, and medical equipment. The CBPS presently is in limited production to meet an urgency of need requirement. Operational Testing was conducted July through November 2000 to verify operational suitability and effectiveness for use in treatment squads to support type classification in April 2001.

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companies and Forward surgical Teams. Mid-term objectives are to initiate development of CBPS to support medical treatment for Airborne, Air Assault and Heavy Divisions.

Other near to mid-term collective protection efforts, such as the Joint Collective Protection Equipment (JCPE) will use the latest technologies in filtration, environmental controls, and power generation to improve and/or standardize current collective protection equipment so that it is lighter, more efficient, more affordable and less logistically burdensome. The Joint Transportable Collective Protection System (JTCOPS) will be the next generation lightweight, modular, easily transportable, self-supporting collective protection shelter that will provide relief from psychological and physiological stresses during sustained operations in a contaminated environment. Redesign and concept tradeoff assistance regarding advanced filtration technologies, such as Pressure Swing Adsorption (PSA) and Catalytic Oxidation (CatOx) has been provided to the Comanche, Crusader, USMC AAAV, and U.S. Army advanced vehicle efforts. The USAF is currently undergoing a major upgrade to their mobile and fixed site collective protection capabilities.

2.6.4 Defense Advanced Research Projects Agency (DARPA) Protection Programs

This thrust focuses on destroying or neutralizing pathogens and toxins before they enter the body. For example, both personal and collective protection air purification systems under development will have significantly enhanced performance relative to the conventional carbon/ HEPA-filtered gas masks and currently used catalytic oxidizer-based systems in use today. These existing systems suffer from a number of drawbacks including poor selectivity, slow adsorption kinetics, the need for expensive containment techniques, relatively low capacity, and high pressure drops. DARPA is developing air purification systems that (1) provide filtration media with lower pressure drops, greater capacity, improved retention, and possible neutralization of the pathogens using designer carrier systems—such as microfibrous materials—and designer sorbent materials (tailored pore size and pore chemistry for personal protection), (2) destroy and neutralize chemical and/or biological agents using a small catalytic oxidation reactor, and (3) for personal protection, the paper-making technique, prepared and mirofibrous sorbent based, highly advanced felt-like filters are designed and packaged for the next generation of a joint service mask. These filters also lend themselves to fabricating low-cost, foldable/ portable emergency smoke hoods with extended gas sorption capabilities and regenerable, biological pathogen-destroying and gas-sorbing aircraft cabin and collective protection filters. The small thermocatalytic air purifier intended for collective protection shelters has been recently selected by the Joint Service CB Defense science and technology program for technology transition funding.

DARPA is also developing a number of innovative approaches to disinfect and purify water in the field from any source. These approaches include the use of mixed oxidants combined with novel and improved filtration methods. A pen-sized or cap-sized mixed chemical oxidant unit kills or inactivates microbial pathogens, prevents re-growth of microbial contaminants for days after initial treatment, and provides an order of magnitude improvement in disinfection effectiveness against spores compared with chlorine or iodine. The mixed oxidant solution can also disinfect equipment, utensils, and possibly wounds inflicted on an individual. During 2001–2002, the mixed oxidant water disinfection pens are being field tested by the Marines in Afghanistan. In the near-term, the USAF and other Special Operations plan to evaluate the device for Escape and Evasion kits. The same mixed

oxidants are dispensed into a backpack worn on-the-move, new generation hydration system compatible with the current fighting load carrier and body armor. The oxidants deactivate biological pathogens; a thick film adsorbent removes volatile organics and a direct (forward) osmosis membrane filters undesirable mineral content, pesticides and spore forming bacteria to cover all CB requirements. Recently, a larger scale prototype of the same mixed oxidant technology successfully demonstrated the ability to purify water on board the USS Empire. For improved filtration, newly discovered methods to fabricate and treat the surface of carbon are exploited to create far superior performance (lower pressure drops, contact efficiency, improved viral absorption rates) than existing activated carbon granules.

Projects in the area of decontamination and neutralization are developing methods for destroying agents in a non-corrosive manner without using extremely high power or harmful chemicals. Current decontamination methods either employ concentrated bleach that can be corrosive to materials, people, and electronics or else methods that use extremely high power lasers, lamps, or discharges. One approach in the DARPA program is the development of BCTP—an emulsion made from water, soybean oil, Triton X 100 detergent, and the solvent tri-n-butyl phosphate—that is benign to humans, plants, animals, and electronics but quickly kills bacteria, spores, and most viruses. Stable, highly effective biological enzyme/polyurethane foam mixtures are also being explored for their ability to neutralize both biological and chemical threat agents and for the decontamination of exposed personnel and materiel.

2.6.5 Other Protection Programs

Programs supporting requirements of a single service are shown in Table 2-7 as italicized entries. A detailed description of IPE and CPE projects is presented in Annex C.

Individual Protection

Eye/Respiratory. The Army is developing the M48 protective mask to replace the M43 series masks. The M48 will be for Apache pilots. It will provide a lightweight motor blower unit, use a standard battery, and will provide increased protective capability.

In the near-term, the Army will replace the M43 mask for the general aviator (non-Apache applications) with the Aircrew Protective Mask, M45. The M45 is lighter and less expensive than the M43 and features CB protection without the aid of force ventilated air.

Clothing. The Army has approved fielding of the Self-Contained Toxic Environment Protective Outfit (STEPO). STEPO provides OSHA level A protection for Army Chemical Activity/Depot (CA/D), Explosive Ordnance Disposal (EOD), and Technical Escort Unit (TEU) personnel. The Army has also developed an Improved Toxicological Agent Protective (ITAP) ensemble for short term operations in Immediately Dangerous to Life and Health (IDLH) toxic chemical environments (up to one hour), emergency life saving response functions, routine Chemical Activity operations, and initial entry and monitoring activities. The ITAP ensemble incorporates improvements in material and design. It includes a one-hour supplied air bottle system, which can be switched to a filtered air respirator

when operators exit the area of high contamination. A Personal Ice Cooling System (PICS) has been developed for use with both the ITAP and STEPO.

Collective Protection

The Navy now includes the Collective Protection System (CPS) on selected spaces on new construction ships. Currently the DDG-51, LHD-1, AOE-6, and LSD-41 ship classes are being built with CPS. The Navy also has the capability to backfit CPS on ships already in Service. The Selected Area Collective Protective System (SACPS) has been installed on selected LHA-1 class ships. The Ship CPS Backfit program continues to backfit selected spaces critical to amphibious ships with CPS. These spaces include hospital areas, command and control areas, and rest and relief areas. The Navy Shipboard Collective Protection Equipment (CPE) effort will increase the shipboard particulate filter life (from the current one or two years) to at least a three year service life, through the use of new particulate pre-filter materials and the use of new high efficiency particulate (HEPA) filter media. The Shipboard CPE will thus provide millions of dollars of savings in life cycle costs by reducing shipboard maintenance requirements and providing energy efficient fans. The Shipboard CPE will transition to the JCPE in FY03.

2.7 MEDICAL SYSTEMS

2.7.1 Introduction

Many countries and terrorist groups have acquired the means to produce and deliver chemical, biological, and radiological weapons. NBC proliferation increases the threat to deployed U.S. forces. Chemical warfare (CW) agents are available worldwide and include vesicants (blister agents), nerve, blood, and respiratory agents. Biological warfare (BW) agents include bacteria, viruses, rickettsiae, and toxins, many of which can be produced by any group with some basic knowledge of microbiology and access to a scientific laboratory or a pharmaceutical facility. The primary radiological/nuclear warfare (RW) threat is the use of conventional explosives to spread nuclear contamination over a limited area or strategic terrain (including use against reactors or industrial radiation sources) and potentially the use of a single or a small number of crude nuclear weapons. Exposure to multiple threats may result in synergistic effects.

Under the CDPD, and overseen by the Medical Systems Commodity Area Manager, the Medical Chemical and Biological Defense Research Program (MCBDRP) is charted as the joint focal point for medical research efforts to counter CW and BW threats. Separate from the CBDP, the focal point for medical radiological defense research at the Armed Forces Radiobiology Research Institute (AFRRI). Taken together, these programs for a virtual Joint Medical Chemical, Biological, and Radiological Defense Research Program (JMCBRDRP). The JMCBRDRP mission is to preserve combat effectiveness by timely provision of medical countermeasures. Countermeasures are developed in accordance with joint service mission needs and requirements in response to threats of chemical, biological, or radiological contamination.

Along with individual and collective protection, medical systems forms a third area associated with the NBC defense principle of protection. *Medical Systems* include all pharmaceuticals, biologics,

and devices that preserve combat effectiveness by timely identification, diagnosis, and provision of medical countermeasures in response to Joint Service chemical, biological, or radiological warfare defense requirements. Technology advances are being pursued in the creation and manufacturing of vaccines and pharmaceuticals that prevent the lethal and/or incapacitating effects of biological, chemical, or radiological warfare agents. Therapies that improve survival and lessen time for return to duty have been developed. Also being developed are rapid portable diagnostics that will facilitate a quick medical response for exposed warfighters

The JMCBRDRP has the following goals:

(1) Provide individual level medical protection and prevention to preserve fighting strength.
(2) Maintain technological capabilities to meet present requirements and counter future threats.
(3) Provide medical management of CW, BW, and RW casualties to enhance survivability, and expedite and maximize return to duty.
(4) Sustain basic research that provides the knowledge upon which innovative diagnostics, prophylaxes, and therapies are developed.

The DoD medical NBC defense research and development programs have provided numerous products to protect and treat service members. Assessment methodologies enable threat evaluation and injury prediction. Medical prophylaxis and treatment strategies reduce the performance decrement, injury, and death of military personnel in the field, thereby enabling them to accomplish their missions, reducing the need for medical resources, and decreasing the probability of long-term health effects.

Specific initiatives programmed to improve NBC defense medical readiness include:

- Continued emphasis on NBC medical countermeasures research.
- Development and implementation of a biological defense immunization policy for U.S. forces and other-than-U.S. forces.
- Cooperative initiative with the U.S. Food and Drug Administration (FDA) for acceptance of efficacy data derived from animal studies as surrogates for large-scale human efficacy trials to license drugs and biological products that cannot be ethically tested for efficacy in humans.
- A prime systems contractor to the Joint Vaccine Acquisition Program (JVAP) continues its effort to develop, license, produce, and store biological defense vaccines.
- Enhanced medical diagnostic capability for diseases/injuries caused by all agents.
- Studies to elucidate the toxicity and mechanism of action of Fourth Generation Agents, and to determine the effectiveness of current medical countermeasures.
- Studies to evaluate the effects of exposure to low levels of chemical warfare agents (CWAs).
- Training of health care professionals for the medical management of chemical, biological, and radiological casualties.
- Identification and testing of medications and therapeutic regimens that reduce the effect of radiation on both bone marrow and the intestinal tract.
- Consequence assessment of sub-lethal radiation exposure combined with susceptibility to biological and chemical agents.

2.7.2 Challenges in Medical NBC Warfare Defense Programs

Medical prophylaxes, pretreatments, and therapies are necessary to protect personnel from the toxic or lethal effects of exposure to all validated threat agents, as well as other anticipated threats. DoD has fielded a number of medical countermeasures that greatly improve individual medical protection, treatment, and diagnostic capabilities.

Executive Order 13139 of September 30, 1999 makes it the policy of the United States Government to provide military personnel with safe and effective vaccines, antidotes, and treatments that will negate or minimize the effects of exposure to a range of CBR weapons as well as diseases endemic to an area of operations. This executive order establishes the procedures for the administration of investigational new drugs to members of the Armed Forces to include informed consent requirements and waiver provisions. DoD Directive 6200.2, *Use of Investigative New Drugs for Force Health Protection*, August 1, 2000, establishes policy for the use of investigational new drugs for force health protection, incorporating the requirements of 10 U.S.C. 1107, the Executive Order 13139, and the FDA interim final rule.

The acquisition life cycle of medical products developed by DoD is normally managed in accordance with the guidelines found in DoD Regulation 5000.2-R. DoD also must comply with the requirements of Title 21, Food & Drugs, Code of Federal Regulations (CFR), for the manufacture, testing, and licensing of medical products.

The DoD is working closely with the FDA to amend the Code of Federal Regulations (CFR) for New Drug and Biological Products that cannot meet the efficacy studies required by the FDA for product licensure because they are either not feasible and/or cannot ethically be conducted under the FDA's regulations for adequate and well controlled studies in humans. (See 21 CFR Sec. 312.21(2)(b).) DoD presented a proposal to the FDA's Vaccines and Related Biological Products Advisory Committee to use animal efficacy data as evidence demonstrating the efficacy of the Pentavalent Botulinum Toxoid (ABCDE). The Advisory Committee recommended that the FDA accept DoD's proposed animal model for efficacy data for licensure of the Pentavalent Botulinum Toxoid (ABCDE). The FDA has proposed a rule that allows the use of animal efficacy data for those products that either cannot be tested ethically in humans or it is unfeasible to test. This proposed rule has been published in the Federal Register [Federal Register: October 5, 1999 (Volume 64, Number 192)].* As of the second quarter FY02, the proposed rule has not been finalized.

Medical NBC defense products are thoroughly tested and evaluated for their safety in accordance with FDA guidelines before administration to *any* personnel. All medical products must be safe to use and not degrade operational performance. In cases where adverse effects are known or possible, a decision must be made—and a risk accepted—of the potential effects of a medical product versus the catastrophic effects of NBC weapons. Even in those cases where efficacy could not be studied in human clinical trials, the safety profiles of the products are well delineated. In many cases, the safety is well understood because the medical products have been widely used to treat other medical conditions.

* Available at http://www.fda.gov/cber/rules.htm

Medical NBC defense research programs discussed in this section are divided into chemical, biological, and nuclear areas of research. Table 2-8 provides a summary of the programs and the planned modernization strategy over the next sixteen years.

2.7.3 Reducing Reliance on the Use of Animals as Subjects of Research

In accordance with the FY95 National Defense Authorization Act, which directed DoD to establish aggressive programs to reduce, refine, or replace the use of animals in research, the JMCBRDRP utilizes and develops technologies that will reduce reliance on animal research. When possible, the research programs employ computerized molecular modeling, computer predictions, *in vitro* cell cultures, a cell-free reaction system, an *in vitro* model of human skin, and a lipid bilayer system to replace the use of animals. Statisticians evaluate all research proposals that use animals to ensure that the minimum number of animals required to obtain scientific validity are used. Animals lower on the phylogenetic scale (or the least sentient species) are used if the selection will permit attainment of the scientific objective. Additionally, a veterinarian with expertise in laboratory animal medicine reviews all procedures that might cause pain or distress in laboratory animals to determine the procedural modifications, analgesics and/or anesthetic regimens that could be incorporated to minimize pain or distress. Detailed protocols are comprehensively reviewed and approved by an Institutional Animal Care and Use Committee before experiments are initiated; the small percentage of protocols which specify the use of non-human primates undergo further scrutiny by the U.S. Army Medical Research and Materiel Command (USAMRMC) Animal Use Review Office. Policies and procedures of the Association for the Assessment and Accreditation of Laboratory Animal Care – International are rigorously enforced and followed. DoD policy states that animal use will be conducted in full compliance with the Animal Welfare Act and that animals are to be used in research only when scientifically acceptable alternatives are not available.

Table 2-10. Medical NBC Defense Programs and Modernization Strategy

	NEAR (FY02-03)	MID (FY04-09)	FAR (FY10-19)
Medical Chemical Defense	Licensed SERPACWA (Skin Exposure Reduction Paste against Chemical Warfare Agents) Licensed multichambered autoinjector	Licensed pyridostigmine Bromide Licensed ophthalmic ointment for vesicant ocular injury Licensed advanced anticonvulsant	Licensed active topical skin protectant Licensed advanced prophylaxis for chemical warfare nerve agents Licensed specific protection and treatment for blister agents (vesicant agent countermeasures) Licensed therapeutic lotion for burns caused by vesicant agents Licensed vesicant agent prophylaxis
Medical Biological Defense	Anthrax vaccine amendment for new dosing schedule Joint Biological Agent Identification and Diagnostic System (JBAIDS) Block I	Licensed smallpox (vaccinia virus, cell culture-derived) vaccine JBAIDS (Block II) - FDA approval for use as a diagnostic system FDA-approval to add indications to licensed therapeutics for exposure to plague, anthrax and smallpox Licensed broad spectrum immunomodulator for biodefense against multiple threat agents including anthrax, plague and tularemia	Licensed Next Generation Anthrax vaccine Licensed recombinant Plague vaccine Licensed multivalent Venezuelan equine encephalitis (VEE) vaccine Multiagent vaccine delivery capability JBAIDS Block III Licensed Recombinant Multivalent (A,B) Botulinum vaccine Licensed Ricin vaccine Licensed Tularemia vaccine Licensed recombinant Staphylococcal Enterotoxin (A, B) vaccine Licensed broad spectrum antibiotics and antivirals Licensed therapeutics for toxin exposure Alternative delivery methods for vaccines and immunogens

	NEAR (FY02-03)	MID (FY04-09)	FAR (FY10-19)
Medical Nuclear Defense	Broad spectrum, nontoxic androstene steroid protectant validated in small/large preclinical models Combination cytokine therapy for blood-forming tissue injury; safety and efficacy testing in small/large animal model Improved cytogenetic markers with automated sample processing and image analysis; reduced analysis time and increased throughput Complete assessment of prophylactic efficacy of anthrax vaccine for animals exposed to combined *B. anthracis* spores and ionizing radiation	Sustained, slow-release radioprotective drug delivery for extended-exposure protection New-generation neutraceutical and recombined biologics for prophylaxis and therapy of multiorgan radiation injuries; safety and efficacy testing in large animal model Multiplexed cytogenetic biodosimetry with better accuracy and precision; improved diagnostic predictive capability Molecular biomarker-based biodosimetry for field applications; dose/response correlation for selected expression molecular biomarkers Module for casualty prediction models (CATS/HPAC); mortality prediction from combined *B. anthracis* and radiation exposure Evaluation of therapeutic approach (genistein and *Lactobacillus reuteri*) for shigellosis and radiation exposure	Licensed products to reduce/prevent radiation-induced short- and long-term (cancer) injuries Licensed products for treating severe radiation injuries Cytogenetic-based biodosimetry system; employment in field hospitals Molecular biomarker-based biodosimetry system validation complete; small, transportable system for field environments Approved standards for medical management of combined radiation/*B. anthracis* exposure Licensed products to reduce/prevent injury and disease from combined radiation/human pathogen exposure Field-capable suite of clinical biological dosimetry tests for rapid assessment of exposure.

2.7.4 Joint Medical Chemical Defense Research Program

The mission of the Joint Medical Chemical Defense Research Program (JMCDRP) is preserve the health, safety, and combat effectiveness of warfighters by timely provision of medical countermeasures in response to joint service chemical warfare defense requirements.

2.7.4.1 Goals. The goals of the JMCDRP are the following:

- Maintain technological capability to meet present requirements and counter future threats:
  - Determine sites, mechanisms of action and effects of exposure to CWAs.
  - Exploit neuroscience technology and dermal pathophysiology to identify mechanism of action of CWAs.
  - Identify sites and biochemical mechanisms of action of medical countermeasures.
  - Exploit molecular biology and biotechnology to develop new approaches for medical countermeasures.
  - Exploit molecular modeling and quantitative structure-activity relationships supporting drug discovery and design.
- Provide individual-level prevention and protection to preserve fighting strength:
  - Develop improved prophylaxes, pretreatments, antidotes, and therapeutic countermeasures.
  - Develop skin protectants and decontaminants.
  - Identify factors that influence safety and efficacy properties of candidate countermeasures.
  - Develop and maintain preformulation, formulation, and radiolabeling capabilities.
- Provide medical management of chemical casualties to enhance survival and expedite and maximize return to duty:
  - Develop concepts and recommend therapeutic regimens and procedures for the management of chemical casualties.
  - Develop diagnostic and prognostic indicators for chemical casualties.
  - Develop safe and effective wound decontamination formulations and procedures.
  - Provide education on medical management of chemical casualties.

2.7.4.2 Objectives. The objectives of the JMCDRP differ with the varying threats:

- For vesicant (or blister) agents, the objective is to develop a pathophysiological database on vesicant chemical agents and a working hypothesis on how damage occurs at the cellular level. Used with associated technologies, this approach will enable the formulation of definitive pretreatment and treatment strategies, and is expected to produce a realistic concept for medical prophylaxis, immediate post-exposure therapy, and topical protection. Alternatively, in dealing with liquid agent threat, active topical skin protectants (aTSPs) can be developed that will improve protection by enhancing barrier properties and will detoxify any CW agent that penetrates the protective barrier.

- For nerve agents, one objective is the fielding of a safe and effective improved anticonvulsant. The advanced anticonvulsant will be more water soluble, will terminate seizures more quickly, will reduce the likelihood of seizure recurrence, and will prevent seizure-induced brain damage and subsequent behavioral incapacitation. Another objective is to field an advanced pretreatment effective against all nerve agents based on physiological scavengers such as the human enzymes butyrylcholinesterase (BuChE) or carboxylesterase (CaE). Ideally the prophylaxis would not require any follow-on treatment, and would have no adverse side effects. These naturally occurring enzymes, as well as acetylcholinesterase, are targets for nerve agents. Through bioengineering efforts, human BuChE and CaE have been mutated to forms that are not only less susceptible to inhibition by the nerve agents, but have the added capability to catalyze nerve agent breakdown. Another potential chemical warfare agent scavenger is human paraoxonase. This enzyme also is being bioengineered to make it more effective and decrease the time it takes to destroy nerve agent.
- For blood agents, the objective is to identify safe and effective pretreatments for protection from cyanide exposure.
- For respiratory agents, the objective is to develop prophylaxes and therapies by understanding pathophysiological changes after agent exposure.

2.7.4.3 Threats, Countermeasures, Technical Barriers, and Accomplishments

The chemical warfare threats and countermeasures, as well as chemical defense research and development technical barriers and accomplishments, are outlined in Annex E (Section E.1). Countermeasures and diagnostic techniques for chemical weapons are shown in Table 2-11. Critical issues of medical chemical defense include the ability to protect U.S. warfighters from the very rapidly acting nerve agents and persistent vesicating agents as well as choking agents and respiratory agents. New threats are also emerging. The effectiveness of current countermeasures against Fourth Generation Agents is currently being investigated.

Table 2-11. Medical Chemical Defense Countermeasures and Diagnostic Techniques

- ***Chemical Warfare Agent (CWA) Scavengers*** – Human enzymes that have been engineered to destroy nerve agents are being developed as nerve agent scavengers.
- ***Advanced Anticonvulsant*** – Benzodiazepines that are water soluble and long acting are being evaluated for control of nerve agent-induced seizure activity.
- ***Active Topical Skin Protectant – Development of topical creams that contain reactive moieties that can neutralize CWA as well as act as barriers to skin contact with CWA.***
- ***Antivesicants*** – Countermeasures that provide reduction in mustard-induced blister formation, corneal opacity, dermal histopathology; and systemic effects are being evaluated.
- ***Laser debridement of vesicant burn injuries*** - Techniques and methodologies using laser technology to accelerate recovery from sulfur mustard injury are being developed.
- ***Effects of exposure to non-lethal levels of CWA*** – The probability and severity of medical effects of single and multiple low-level exposures to CWA are being evaluated.
- ***Fourth Generation Agents*** – Current medical regimens used for protection against the conventional nerve agents are being evaluated as countermeasures for Fourth Generation Agents.
- ***Cyanide Countermeasures*** – Potential pretreatment compounds (*e.g.*, methemoglobin formers and sulfide donors) and regimen are being evaluated for safety and efficacy as pretreatments.
- *Nerve agent antidotes* – New nerve agent antidote compounds that are water soluble, have a broader spectrum of efficacy, and are more effective than current antidote compounds.
- ***Chemical Casualty Management*** - Technologies to assist in the diagnosis, prognosis, and management of chemical casualties are being developed.
- ***Respiratory Agent Injury*** – Mechanisms of respiratory agent injury are being determined and medical countermeasures for respiratory agent casualties are being developed.

2.7.5 Joint Medical Biological Defense Research Program

The mission of the Joint Medical Biological Defense Research Program (JMBDRP) is to develop medical countermeasures to protect U.S. forces and thereby deter, constrain, and defeat the use of biological agents against them (DoD Directive 5160.5, May 1985). The program is directed against agents of biological origin that are validated military threats. The primary concern is the development of vaccines, therapeutic drugs and treatment regimens, and diagnostic tools, and other medical products that are effective against agents of biological origin.

2.7.5.1 Goals. Goals of the JMBDRP include the following:

- Protecting U.S. forces warfighting capability during a biological attack.
- Reducing vulnerability to validated and emerging threats by maintaining a strong technology base.
- Providing consultation medical management of BW casualties.

2.7.5.2 Objectives. In accomplishing the goals of the JMBDRP, efforts are focused on three objectives:

- Maintaining technological capability to meet present requirements and counter future threats:

- Determine sites, mechanisms of action, and effects of exposure to biological warfare agents with emphasis on exploitation of molecular science.
- Identify sites and biochemical mechanisms of action of medical countermeasures.
- Exploit genomics, proteomics, and bioinformatics to greatly expand the knowledge base necessary for advancing research leading to next generation medical countermeasures against "traditional" biological threats and genetically modified threats
- Exploit molecular biology and biotechnology to develop new approaches for medical countermeasures.
- Exploit molecular modeling and quantitative structure-activity relationships supporting drug and vaccine discovery and design.

- Providing individual-level prevention and protection to preserve fighting strength:
  - Develop improved vaccines, pretreatments, antidotes, and therapeutic countermeasures.
  - Identify factors that influence safety and efficacy properties of candidate countermeasures.
- Providing training in medical management of biological casualties to enhance survival and expedite and maximize return to duty:
  - Develop concepts and recommend therapeutic regimens and procedures for the management of biological casualties.
  - Provide education on medical management of biological warfare casualties.

One of the key efforts to achieve the goals and objectives of the medical biological defense program has been the protection of U.S. forces against anthrax — a deadly biological warfare agent. This is being accomplished through total force vaccination against anthrax, as described in Table 2-12.

The JMBDRP responds to requirements from the DoD as identified in the Joint Service Agreement on Biological Defense, the Joint Warfighting Science and Technology Plan, the Defense Technology Area Plan, the Defense S&T Strategy, and DoD Directive 6205.3, "Biological Defense Immunization Program."

Highly sophisticated technology base efforts for medical biological defense hold the promise of yielding important new products and technologies to protect our troops against a wide range of biological threat agents. These products include multi-agent vaccine delivery capabilities/systems that will reduce costs of vaccine production and simplify immunization schedules, and a common diagnostic system that can be deployed at forward sites to rapidly analyze clinical samples for the presence of biological warfare agents as well as infectious diseases of military importance. The development of these products, as well as the complementary technology-based research and development to enhance and expand these capabilities and to identify and develop new capabilities, is also being supported by collaboration with other agencies, including the Defense Advanced Research Projects Agency (DARPA) and the Department of Energy (DOE).

Projects and technologies shared with the DOE are related to the strengths of DOE laboratories in developing advanced technologies in order to enable rapid detection of and response to a chemical or biological incident. While DOE focuses internal technology development efforts on the domestic threat, they actively support the DoD. The work spans DNA sequencing and biodetection to modeling and simulation, collaborating on projects such as x-ray crystallography and nuclear magnetic resonance imaging of BW agent antigens. The DNA sequencing efforts have led to advances in developing "lab on a chip" diagnostic technology for several BW threat agents. DOE is not involved in protection and treatment of personnel, but they are assisting DoD with drug/chemical database searches with the intent of identifying novel inhibitors of pathogens.

Table 2-12. Anthrax Vaccine Immunization Program (AVIP)

Detailed information on the AVIP may be found on the internet at http://www.anthrax.mil/. The AVIP web site provides a detailed account on the nature of the threat from anthrax (*Bacillus anthracis*), description of the vaccine, explanation of U.S. DoD policies regarding biological defense vaccines, U.S. DoD policies regarding the anthrax vaccine, immunization schedule, information on adverse event reporting, and other information related to the AVIP.

As of October 29, 2001, 2,100,381 doses of the vaccine have been administered to 522,980 persons. Also as of this date, 74,670 service members have completed the 6-shot series.

In December of 1997, the Secretary of Defense announced plans to begin vaccinating Service personnel deployed in high-threat areas (HTAs) against the BW agent anthrax. Vaccinations for troops in Southwest Asia began in March 1998. The Secretary of Defense approved the Anthrax Vaccine Immunization Program for the Total Force in May 1998. Vaccinations for troops in Korea began in August 1998. The AVIP Agency was established in September 1998 to implement and monitor the DoD policy and Services' plans. The Services' AVIP plans call for eventual vaccination of the Total Force (active and reserve components) and emergency-essential DoD civilians and contractors. The AVIP plan included three phases. Forces at highest risk are immunized first.

Phase I began in Mar 1998, vaccinating personnel assigned or deploying to high threat areas (HTAs) of Southwest Asia. Due to an unanticipated delay in release of FDA-approved vaccine, DoD slowed its implementation of the AVIP incrementally between July 2000 and June 2001. DoD is currently executing a modified Phase I, vaccinating only designated special mission units and personnel involved in vaccine research. Phase II will vaccinate the early deploying forces projected to deploy in support of contingency plans into the HTAs. Phase III will vaccinate the remainder of the Total Force.

After FDA approval of BioPort's newly renovated anthrax vaccine production facility and vaccine supply is restored, DoD will resume its phased execution program; catching up with those people who were asked to defer doses and continuing to ensure that individuals deploying to high threat areas receive the vaccine. People who deferred doses during the slow down period will resume their vaccination series where they left off; next doses are then counted from that point.

BioPort has recently submitted their Biologics License Application supplement to the FDA and it has received FDA approval on December 27, 2001. DoD is working with BioPort to examine increased production alternatives.

The DARPA BW defense program includes collaborating with USAMRMC on new platforms to enhance delivery and effectiveness of multi-agent vaccines (for example, stem cells genetically programmed to express antigens sequentially in order to provide automatic boosters in the body).

Multi-agent vaccines are similar to the measles-mumps-rubella vaccine administered to children except that the technologies being explored for producing these new vaccines are more advanced, relying on bioengineering technologies such as naked DNA and the replicon-based delivery systems. Research within USAMRMC in both the naked DNA and replicon approaches is advancing rapidly with demonstration of proof-of-principle in a higher animal model of a multi-agent vaccine planned for FY03.

Bioengineering techniques are also being used to prepare a variety of recombinant vaccines against single threat agents that will be produced without the need to grow the actual threat agent during the vaccine production process. Several recombinant vaccines are scheduled for transition out of the technical base to advanced development and ultimately FDA licensure over the next ten years.

Development of a common diagnostic system is proceeding with the adoption of rapid nucleic acid analysis methods. In FY01, the research focused on three configurations of portable instruments using common polymerase chain reaction (PCR) chemistries. These have demonstrated the capability for rapidly identifying panels of biological warfare agents and naturally occurring infectious diseases. The Common Diagnostic Systems Defense Technology Objective (DTO) obtained a Milestone A decision at the beginning of FY02 and transitioned to Concept Exploration. With these tools, laboratory-based identification of infections will be made much faster (less than 30 minutes) and farther forward than is now possible.

The JMBDRP includes the following areas of research:

Pre-exposure Countermeasures: This area involves prophylactic measures undertaken to prevent illness and injury associated with exposure to bacterial, viral, and toxin threat agents. The primary focus of pre-exposure therapy is the production of effective vaccines. The roles of various factors in stimulating cellular and humoral immunity are determined through study of specific genes or properties of threat agents. This knowledge provides tools for development of second-generation recombinant or multi-agent vaccine candidates as well as pretreatment therapies, such as the use of immunomodulators, to intervene in the pathogenic effects of threat agents.

Post-exposure Countermeasures: Research efforts in this area are focused on developing safe, effective treatments to alleviate disease or injury associated with exposure to bacterial, viral, or toxin threat agents. Therapeutic measures may involve administration of antimicrobials, antivirals, antitoxins or generic compounds formulated to intervene at the pathogen's site of action. The knowledge necessary to develop such products requires in-depth research in the basic pathogenesis and physiology of the BW agents. These analyses will afford researchers tools to create a universal approach in treating post-exposure casualties of a BW attack.

Diagnostics: Diagnostics research involves the investigation and evaluation of sensitive and specific methods for detection of infectious organisms, toxins, antigens and antibodies in biological materials to include the application of nucleic acid probes or synthetic antigens. Rapid identification tests and diagnostic methods for the assay of bacteria, viruses, toxins, metabolites, and analogs in clinical specimens are major goals of this program area. Research is also being directed toward an understanding of gene expression patterns and changes in the patterns shortly after exposure to

biological agents that may provide very early markers of exposure before the sign and symptoms of infection are evident.

2.7.5.3 **Threats, Countermeasures, Technical Barriers, and Accomplishments**. A biological threat agent is defined as an intentionally disseminated living microorganism or toxin that can cause disease or death in humans, animals, or plants. Threat agents include a broad range of microorganisms (bacteria, rickettsiae, and viruses) and toxins of biological origin. Biological weapons are easy to make, difficult to detect, and can be very effective. Defense against this class of weapon is difficult, particularly when biological agents can produce casualties over an area of thousands of square kilometers. Biological agents could also be used with devastating effect in combination with nuclear, chemical, or conventional weapons.

Countermeasures and diagnostic techniques for biological weapons are shown in Table 2-13. Critical elements of medical biological defense include the ability to protect U.S. forces from BW agents, to rapidly diagnose (in clinical specimens) infection or intoxication from agents, and to treat casualties. Currently, the most effective countermeasure is pre-deployment active immunization. Future threats, however, may involve genetically engineered biological weapons that may be easily produced, highly lethal, difficult to detect, and resistant to conventional therapies. An enemy's ability to produce genetically engineered threats on demand also exacerbates the long-lead time between research for a medical solution and obtaining FDA licensure for the medical product.

The current JMBDRP includes the following research areas for the development of medical countermeasures:

- Characterize the biochemistry, molecular biology, physiology, and morphology of BW threat agents.
- Investigate the pathogenesis and immunology of the disease.
- Determine the mechanism of action of the threat agent in animal model systems.
- Select antigen(s) for candidate vaccines.
- Develop and compare potential vaccine candidates and characterize their effects in animal models.
- Develop surrogate markers of efficacy.
- Establish safety and efficacy data for candidate vaccines.
- Develop medical diagnostics to include far forward, confirmatory, and reference labs.
- Develop chemo/immunotherapeutic agents and preparations.

Technical shortcomings in the private sector include (1) the lack of high-level biological containment (BL-3 and BL-4) laboratory facilities to support biological defense research, (2) lack of widespread scientific expertise in biological defense, and (3) a continuing and growing lack of availability of Indian Rhesus macaques, frequently use d and the animal model of choice in definitive efficacy studies of vaccines and therapeutics. These factors restrict the depth of expertise, facilities, and support available. A recent redress of funds and authorizations over a six year period (FY02–07) will be used for DoD facility upgrades and to maintain scientific and technological expertise.

Details of the biological warfare threats and countermeasures, as well as biological defense research and development technical barriers and accomplishments, are presented in Annex E (Section E.2).

Table 2-13. Medical Biological Defense Countermeasures and Diagnostic Techniques

VACCINES

- *Killed* – killed or inactivated microorganism that is incapable of replicating but stimulates immunity.
- *Live, attenuated* – live organism, selected not to cause disease but able to stimulate immunity.
- *Toxoid* – toxin protein treated to inactivate its toxicity but retains its ability to stimulate immunity.
- *Recombinant* – gene coding for a protein that stimulates specific immunity to a BW agent is inserted into biological vector for production. Protein may be produced in high yields through bioengineering.
- *Deoxyribonucleic Acid (DNA)* – section of DNA that codes for protein that stimulates specific immunity to a BW agent. DNA produces the desired protein in recipient that stimulates immunity.
- *Polyvalent/Multivalent/Multiagent* – mixture of antigens or vaccine constructs that protect against a number of different BW agents.
- *Vectored* – carrier organism bioengineered to confer immunity against an unrelated BW agent or multiple agents.

ANTIBODY (ANTISERUM, ANTITOXIN)

- *Heterologous* – antibodies collected from animals (*i.e.*, different species than the recipient) repeatedly immunized against the BW threat. These antibodies must be treated to reduce the human immune response to them (serum sickness).
- *Homologous* – antibodies of human origin (*i.e.*, same species as the recipient) that provide protective immunity against the BW threat. These antibodies are not prone to stimulating serum sickness.
- *Monoclonal* – a cell culture technique for producing highly specific antibodies against a disease agent.
- *Bioengineered* – antigen binding site on the variable portion of an antibody elicited in a nonhuman system is combined with the nonvariable portion of a human antibody to produce a "humanized" antibody.

DRUGS

- *Antibiotics* – very effective against bacteria, but are ineffective against viruses and toxins.
- *Antiviral compounds* – promising drugs in development by the pharmaceutical industry are being evaluated against biological threat viruses
- *Others* – compounds that offer new possibilities for protecting against and treating exposure to BW agents (such as drugs to treat toxins or nonspecific treatments such as immunomodulators.)

DIAGNOSTIC TECHNOLOGIES

- *Immunological technologies* – These tests rely on antibodies for detecting the presence of proteins associated with the BW agent. They are easy to use, compact, rapid (minutes), and require little logistic support. This technology is currently used in out-patient clinics and doctor's offices.
- *Nucleic acid technologies* – nucleic acid tests, specifically the polymerase chain reaction (PCR), rely on segments of genes unique to BW agents to detect the presence of those agents. These tests are extremely sensitive and specific, but currently require more support to perform.
- *DNA Microarray technologies* – Often referred to as "gene chips", this technology assesses the status of thousands of genes simultaneously for changes in level of gene expression. Events that occur immediately after exposure to a biological agent may be related to changes in gene expression.

2.7.5.4 Defense Advanced Research Projects Agency (DARPA) Programs. As one of its major program areas, DARPA is pursuing the demonstration and development of new biological warfare defense capabilities. Major thrusts include real-time (environmental) sensing; medical countermeasures (developing barriers to prevent entry of pathogens into the human body and developing pathogen countermeasures to block pathogen virulence and to modulate host immune

response); Advanced Medical Diagnostics for the most virulent pathogens and their molecular mechanisms; and Consequence Management Tools.

Medical countermeasures research includes: (1) broad spectrum therapeutics against known, biological warfare pathogens, (2) therapeutics against virulence pathways (mechanisms of disease) shared by broad classes of pathogens and (3) stimulators of innate immunity. Specific approaches include modified red blood cells to sequester and destroy pathogens, development of broad spectrum vaccines, engineering of plants to produce human vaccines and other products, identification of virulence mechanisms shared by pathogens, development of novel therapeutics targeting these mechanisms, and efficacy testing in cell cultures and animals.

Early diagnosis is key to providing effective therapy against BW agents since many of these agents cause early nonspecific flu-like symptoms. The goal of the DARPA Advanced Medical Diagnostics thrust is to develop the capability to detect the presence of infection by biological threat agents, differentiate from other significant pathogens, and identify the pathogen, even in the absence of recognizable signs and symptoms (when the pathogen numbers are low). Specific accomplishments are listed in Annex E.

Mission effectiveness requires rapid, correct medical responses to biological threats. The objective of the Consequence Management thrust is to provide comprehensive protocols to protect or treat combatants by using current and emerging biological countermeasures. It will provide accelerated situational awareness for biological agents events by detecting exposure to agents through an analysis of casualty electronic theater medical records, and will locate and determine the most effective logistical support for providing appropriate treatment and pathogen-specific resources required to mitigate effects of the attack.

2.7.6 Medical Nuclear (Radiological) Defense Research Program

The mission of the Medical Nuclear Defense Research Program (MNDRP) is to conduct research in the field of radiobiology and related matters essential to the support of DoD and the Military Services. The sole repository of defense radiobiology expertise is the Armed Forces Radiobiological Research Institute (AFRRI).

2.7.6.1 Goals. The goals of the MNDRP are the following:

- Understand the pathological consequences of radiation injury in order to guide development of pharmacological agents for mitigating injury.
- Develop medical countermeasures for acute, delayed, and chronic radiation injury.
- Develop and test prophylactic drugs to reduce the adverse health consequences of sublethal radiation exposures.
- Identify biological markers and develop rapid assay systems to assess radiation injury under field environments and enhance medical management of radiological casualties.
- Quantify and build into casualty prediction models the morbidity and mortality due to combined exposure to ionizing radiation and infectious disease or chemical agents.

- Sustain combat capability, increase survival, and minimize short- and long-term problems associated with ionizing radiation when combined with other mass casualty weapons or battlefield stressors such as traumatic injury and endemic disease.

2.7.6.2 Objectives. The primary objective of this research group is to address the major aspects of military operational requirements for dealing with radiation injuries. A nuclear threat agent is any weapon that causes detrimental medical effects by either direct external irradiation or by internal contamination with radioactive material. These agents include radiation dispersal weapons, which scatter radioactive material with conventional explosives; deliberate area contamination; destruction of a nuclear power plant; improvised nuclear devices; and traditional nuclear weapons. Operational requirements include programs in casualty management, medical radioprotectants to diminish radiation injury, medical therapeutic regimens, biodosimetry, combined NBC injury effects and its mitigation, maintenance of performance, and radiation hazards assessment.

2.7.6.3 Threats, Countermeasures, Technical Barriers, and Accomplishments. If counterproliferation and intelligence efforts fail to deter the use of nuclear weapons, medical remediation of casualties must be available to treat the effects of weapons use. Such a device would most likely be utilized against military, economic, or a political targets (*e.g.*, an airbase, the seat of government, large population center, or commercial port city). In such scenarios, citizens outside the immediate lethal area would be exposed to the prompt radiation of the initial explosion as well as to chronic exposures resulting from the residual radioactive fallout.

If an adversary employs a nuclear weapon, the concomitant use of biological or chemical weapons should be anticipated. Radiation dispersal events could include the destruction of a nuclear reactor, intentional contamination of a battlefield with nuclear waste, or dispersal of radiological materials in a terrorist car bomb attack involving conventional explosives. Most casualties in these scenarios would suffer non-lethal doses of external irradiation. This would complicate the management of their conventional injuries and could cause internal contamination with radionucleides. Prompt effects of moderate- to high-dose radiation injury diminish the soldier's ability to fight and survive. Effective radiation countermeasures must protect the warfighter from performance decrement and simultaneously diminish lethality and the long-term health effects of radiation injury. Prophylactic and therapeutic applications of novel pharmacological agents will increase survival and diminish morbidity of individual soldiers wounded by radiation. A research program to understand molecular and cellular damage induced by radiation is needed to determine the best medical countermeasures for the newly arising radiological threats on the modern battlefield. Table 2-14 presents an overview of countermeasures to radiological exposure and research accomplishments during FY01.

Significant progress has been made in prophylactic and therapeutic measures that will reduce mortality and morbidity in high-dose radiation environments. During the Cold War, the number of casualties resulting from the large-scale deployment of nuclear weapons would have easily overwhelmed the medical assets of NATO forces. In the current threat environment, adequate planning for medical response to a very limited nuclear attack is mandatory. While casualty numbers from a nuclear detonation will still be large, countermeasures have been developed that will significantly limit the morbidity and the secondary mortality. These modalities will be particularly important in the likely

scenario of terrorist use of radiation weapons. If the attack is limited to one or, at worst, a small number of events, the ability to provide intensive, sophisticated medical and other support is highly credible because of the availability of uncompromised treatment/research centers and medical evacuation capabilities.

Details of the radiological threats and countermeasures, as well as nuclear defense research and development technical barriers and accomplishments, are presented in Annex D (Section E.3).

Table 2-14. Medical Nuclear Defense Countermeasures

PRETREATMENTS
Single agents: Injections and/or oral administration of androstene steroid, vitamin E, genistein and/or amifostine (Ethyol®) enhance survival of acutely irradiated laboratory animals.
Multidrug combinations: Enhanced survival in animal models is possible using a two-pronged strategy of pretreatments (*e.g.*, androstene steroids, amifostine, *etc.*) followed by postexposure cytokine therapy.
MEDICAL THERAPIES
Blood Forming Cell Stimulants: Granulocyte colony stimulating factor (G-CSF, Neupogen®) granulocyte-macrophage colony stimulating factor (GM-CSF, Leukine®) have been demonstrated to be highly effective in restoring the immune competence of the bone marrow and allowing survival from radiation injuries previously considered lethal. The cytokine thrombopoietin has been developed as a therapeutic agent and is undergoing further trials as a platelet-formation stimulant. Interleukin 11 (IL-11, Neumega®) has moderate thrombopoietic activity, as well as epithelial tissue repair capacity, and is currently available for human use. Keratinocyte growth factor is a promising new recombinant cytokine for treating radiation-damaged barrier epithelium, and preliminary experiments have shown its efficacy in preventing translocation of intestinal microflora in irradiated animals.
Broad Range Cellular Recovery Stimulants: Research continues into biologically stable compounds that stimulate recovery of multiple hematopoietic cell lineages.
Susceptibility to Infectious Agents and Efficacious Therapy: Research continues into assessing susceptibility and resistance to infectious agents in individuals exposed to prompt and chronic sublethal radiation doses, and developing combined-modality therapies that attack microorganisms while enhancing innate immunity. A significant reduction in mortality was shown in animal models using a clinical support protocol based on antibiotic and platelet transfusion regimens.
DIAGNOSTIC TECHNIQUES
Biodosimetry and Dose Assessment: No dose-assessment method other than individual physical dosimeters is currently available to deployed soldiers. A novel automated chromosome aberration analytical procedure based on premature chromosome condensation was developed and could be made deployable to the Echelon-3 level of medical care. Novel analytical methods and newly identified biological markers that leverage nucleic acid amplifying technologies are being developed. These will lead to a new-generation suite of biodosimetry assays that are rapid and deployable for field use point-of-care testing and provide greater diagnostic value for medical treatment decisions.
CHEMICAL AND BIOLOGICAL WARFARE CONSEQUENCES WITH RADIATION
Increased lethality of biological weapons after low level irradiation: Ongoing studies indicate even low sublethal levels of radiation will markedly increase susceptibility to infection by agents of biological warfare. Existing data suggest synergistic consequences of mustard and nerve agents under combined exposure with ionizing radiation.

2.8 JOINT BIOLOGICAL DEFENSE PROGRAM – SPECIAL REPORT ON ANTHRAX VACCINE COSTS, ACQUISITION STRATEGY, AND RELATED ISSUES

2.8.1 Introduction

As part of the National Defense Authorization Act for Fiscal Year 2001 - Authorization Conference Report (106-945, Section 217, Joint Biological Defense Program, page 719), Congress directed the Department to submit a special report along with the Annual Report to Congress on the Chemical and Biological Defense Program. (Related activities of the overall Joint Medical Biological Defense Research Program are described in Section 2.7.5 of this chapter and Annex E of this report.) The conferees directed the Department to provide information on the costs incurred by, and payments made to, each contractor or other entity engaged in the production, storage, distribution, or marketing of the anthrax vaccine administered by the Department of Defense. Additionally, Congress directed that in the report to be submitted in calendar year 2001, the following information should be included:

(1) an estimate and update of the life cycle costs of the anthrax vaccination program;
(2) a description of the anthrax vaccine acquisition strategy;
(3) an assessment of government requirements (defense and non-defense) for the anthrax vaccine;
(4) an assessment of the financial and manufacturing ability of the manufacturer of the anthrax vaccine to meet government requirements; and
(5) a description of any activity related to any anthrax vaccine license with significant implications for the Department of Defense.

2.8.2 Costs Incurred by, and Payments Made to, Each Contractor or Other Entity Engaged in the Production, Storage, Distribution, or Marketing of the Anthrax Vaccine.

Table 2-15 provides a list of all obligations associated with the manufacture of the Anthrax Vaccine Adsorbed (AVA) as of November 15, 2001. Storage costs outside of BioPort, distribution, and marketing are funded by the Anthrax Vaccine Immunization Program (AVIP) Agency (Table 2-16).

Table 2-15. Obligation of Funds for Anthrax Vaccine Adsorbed ($000)

System Cost Element	FY 00 & Prior	FY 01
Vaccine Program		
BioPort K DAMD17-98-C-8052	54,881	0
Redundancy		
BioPort K DAMD17-98-C-8052	4,361	0
Process Validation/BLA Supplement Approval		
BioPort K DAMD17-91-C-1139	28,836	39,300
Testing, Labeling, Shipping, & Security		
BioPort K DAMD17-97-D-0003	6,799	1,858
Facility Renovation		
BioPort K DAMD17-91-C-1139	390	
BioPort K DAMD17-98-C-8052	303	
MBPI K DAMD17-91-C-1139	2,641	
Washington Group International	84	
Facility Renovation Subtotal	3,418	0
Oversight		
Camber	868	913
Quantic	1,886	4,317
Don Hill Associates	142	344
Quintiles	2	
Mitretek		32
Program Management Support	213	608
AVA Consultant	100	
SAIC	1,290	
Oversight Subtotal	4,501	6,214
Second Source		
Center for Applied Microbiology & Research	50	
CanGene	50	
Second Source Subtotal	100	0
Total	100,986	47,372

Table 2-16. Storage and Marketing Costs for Anthrax Vaccine Adsorbed ($000)

AVIP Costs	FY99	FY00	FY01
Contract Personnel/ Support	3,509	3,214	3,264
Vaccine Distribution	327	348	360
Education	946	1,724	1,149
Program Research and Evaluation	–	2,602	2,618
VA-DoD Force Health Protection Initiative	628	517	521
Total	5,410	8,405	7,912

2.8.3 An Estimate and Update of the Life Cycle Costs of the Anthrax Vaccination Program.

Table 2-17 provides an estimate of the procurement program costs for the anthrax vaccination program. Table 2-18 provides life cycle costs for the Anthrax Vaccine Immunization Program (AVIP). Future costs beyond FY2005 to complete the program are to be determined.

Table 2-17. Estimated Anthrax Vaccine Adsorbed Procurement Program Costs ($000)

FY 00 & Prior	FY 01	FY 02	FY03	FY04
100,896	47,372	56,074	43,935	58,056

Table 2-18. Estimated Anthrax Vaccine Immunization Program (AVIP) Costs ($000)

AVIP Costs	FY02	FY03	FY04	FY05
Contract Personnel/ Support	3,259	3,575	3,562	3,898
Vaccine Distribution	373	386	400	172
Education	1,244	1,276	1,309	1,343
Program Research and Evaluation	2,733	2,857	2,987	2,824
VA-DoD Force Health Protection Initiative	3,758	4,970	5,457	5,457
Total	**11,367**	**13,064**	**13,716**	**13,694**

2.8.4 Anthrax Vaccine Acquisition Strategy.

BioPort Corporation is the only Food and Drug Administration (FDA)-licensed manufacturer of the AVA. DoD personnel have worked with BioPort in Lansing, Michigan, to complete the essential tasks for achieving FDA approval of the renovated facility, restoration of assured vaccine production, and to enable resumption of the immunization program mandated by the Secretary of Defense. FDA approved BioPort's Biologics License Application supplement on December 27, 2001.

DoD conducted an evaluation of the advantages and disadvantages of converting the BioPort facility to a Government-Owned, Contractor-Operated (GOCO) facility. The evaluation concluded that converting BioPort to a GOCO facility would not result in vaccine being delivered any faster than under the current strategy.

Risk mitigation measures are also being pursued for a second source, and, in the long term, for a GOCO Vaccine Production Facility. A GOCO Vaccine Production Facility is being evaluated as a long-term strategy for Biological Defense (BD) vaccine production. This facility would provide the capability to manufacture AVA along with smallpox, botulinum toxins, tularemia, plague, and other required BD vaccines.

2.8.5 An assessment of government requirements (defense and non-defense) for the anthrax vaccine.

Defense

In December 1997, the Secretary of Defense (SECDEF) ordered the immunization of all U.S. forces by 2005. This required over 14 million doses of AVA (2.6 million doses annually based on AVIP estimates). Phase I vaccination of forces assigned or rotating to the highest threat areas was started in FY98. Phase II vaccination will begin after the FDA approves BioPort's renovated production facility and BioPort can supply AVA on a scheduled basis. Phase III involves vaccination of the remaining forces and sustainment vaccination.

Non-Defense

Identification of domestic requirements will continue to be met through efforts of a BioDefense Vaccine Production Facility Advisory Group. Members of this group represent various agencies such as the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Security Council (NSC), and the Department of Health and Human Services (DHHS). The bioterrorism events following 11 September 2001 have increased both civilian and medical community interest in biodefense vaccines to include the anthrax vaccine. While no specific civilian requirements have been set, CDC has worked with DoD to purchase, label, and position reserved quantities of AVA that could be used under informed consent in an emergency situation.

2.8.6 An Assessment of the Financial and Manufacturing Ability of the Manufacturer of the Anthrax Vaccine to Meet Government Requirements.

BioPort is, at present, not generating revenue, because dose release cannot resume until FDA approves the renovated facility. Therefore, DoD is funding all activities related to obtaining FDA approval for AVA. DoD is providing extensive assistance and oversight, including pharmaceutical and regulatory experts, to ensure that the supplier is capable of manufacturing vaccine in accordance with all Federal regulations. Progress is being made toward achieving FDA approval to produce vaccine. The two key elements to successful Biologics License Application (BLA) supplement approval are 1) process validation and submission of the documentation, and 2) approval of the potency test supplement. FDA approved the Relative Potency test supplement retrospectively in November 2001. Upon FDA's complete approval of BioPort's renovations and approval of its contract filler, BioPort will have the capacity to manufacture enough vaccine to resume the SECDEF-mandated immunization program.

2.8.7 A Description of Any Activity Related to Any Anthrax Vaccine License with Significant Implications for the Department of Defense.

There is only one FDA license for the manufacture of anthrax vaccine. BioPort Corporation, the manufacturer of AVA, holds this license. Last year, DoD reported on several activities that were relevant to the anthrax vaccine license. These activities and the current status are:

- Submission of the potency supplement—FDA approved November 2001.
- Submission of the BLA supplement—BioPort's BLA supplement was submitted to the FDA in October 2001 for approval of their renovated production facility. BioPort completed a successful Pre-Approval Inspection (PAI) by the FDA, December 19, 2001. The FDA reviewed and approved the BLA supplement, December 27, 2002.
- Award of subcontract for the filling & packaging operation—BioPort awarded a contract to Hollister-Steir for filling and packaging of the vaccine. Filling and packaging was outsourced because BioPort's filling and packaging suite does not meet current Good Manufacturing Practices (cGMP). BioPort submitted its supplement for Hollister-Stier to the FDA. An FDA PAI is anticipated in January 2002.

- Potential Second Source award—not funded. In order to reduce the risk associated with a sole source for the anthrax vaccine, DoD sought industry interest in developing a second source for anthrax vaccine. Five companies responded and submitted program plans. If DoD had awarded a contract for a second source, BioPort could have shared the existing license with the selected company, or the selected company could have requested a new license from the FDA. DoD Program Budget Decision 741 redirected funding for this effort in FY01.

2.9 OPERATIONAL TESTING - PROJECT O49

Increased awareness of the chemical and biological (CB) threat has resulted in increased requirements for CB defense information and operationally oriented data and analysis from the Services and the Commanders in Chiefs (CINCs) of the Unified Combatant Commands. One of DoD's most valuable assets for meeting these requirements is the *Joint/CINC Operational Testing* (Project O49) program, based at the West Desert Test Center at U.S. Army Dugway Proving Ground (WDTC at DPG), Utah. Project O49 is a joint service program funded through the CB Defense Program. Objectives are to: (1) plan, conduct, evaluate and report on laboratory analyses, field tests and technical assessments in response to user requirements; (2) serve as the DoD's Joint Contact Point for CB defense test and technical data; and (3) publish and maintain the many volumes of the CB Technical Data Source Book. Project O49 recently has upgraded the West Desert Technical Information Center (WDTIC) and coordinated with the Chemical-Biological Information Analysis Center (CBIAC) to vastly improve literature search and analysis capabilities.

Following are summaries of current Project O49 operational tests:

- *Persistent Chemical Agents and Their Reactions with Surfaces* will be conducted during 2002 at the WDTC at DPG for the U.S. Air Force (USAF). The objectives of this test are to 1) determine the evaporation rate of five different CW agents, neat and thickened, from several warfighting surfaces, 2) determine the transfer hazard of the same CW agents and mixtures from the same surfaces at various times, 3) determine a methodology for extraction of CW agent from concrete and identify various reactions of CW agents in absorbed on or into concrete, 4) determine levels of contamination of CW agents on various surfaces that will result in a contact hazard to personnel, and 5) fully characterize the soil samples used in the previous objectives as to type and world wide incidence.
- *Processing Cargo and Troops Through an Exchange Zone* will be conducted during 2002 for the Air Mobility Command. The objective of this test is to determine if clean cargo and troops can be processed through an exchange zone without hindering transload operations. Evaluations will consist of attempting to move cargo and troops through several zones without cross contamination.
- *Large Frame Aircraft Decontamination* will be conducted during June 2002. The objective of this test is to examine decontamination technologies and tactics, techniques, and procedures (TTP) to determine the most appropriate means to decontaminate large frame aircraft.

- *Operation Southern Breeze Field Test (MTMC-Cargo)* was conducted during May 2001 at Charleston Naval Weapons Station, South Carolina for the US Transportation Command, in conjunction the Military Traffic Management Command (MTMC). The test objective was to determine how covering versus not covering cargo from a Large Medium Speed Roll On, Roll Off (LMSR) Ship affected the level of contamination and the amount of time needed to decontaminate the items.
- *Operation Southern Breeze Field Test (MSC-Ship)* will be conducted during June 2002 at Charleston Naval Weapons Station, South Carolina, for the Military Sealift Command (MSC). Test objectives are to (1) evaluate the extent of internal contamination allowed by the ventilation system of an LMSR Ship when contaminated with a simulated chemical agent, (2) evaluate the effectiveness of current decontamination procedures and the use of portable collective protection systems (M20A1s) inside crew quarters, and (3) evaluate the feasibility of wrapping equipment/cargo in a protective cover as a means of contamination avoidance and expediting port throughput.

2.10 CB DEFENSE RDA PROGRAMS REQUIREMENTS ASSESSMENT

***ISSUE:* DoD does not have a current approved mechanism for licensure of chemical and biological defense medical products (*i.e.*, drugs and vaccines) because legal and ethical constraints prevent adequate full testing in humans.**

SOLUTION: The FDA and DoD are working together to amend the Code of Federal Regulations to allow animal efficacy data to be used in lieu of large-scale human clinical efficacy trials. FDA's Center for Biologics Evaluation and Research (CBER) proposed a rule on October 5, 1999 entitled, "New Drug and Biological Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted," and is available at www.fda.gov/cber/rules.htm. This rule is expected to be finalized in 2002. This mechanism of licensure is vital to provide military service personnel with licensed products. This rule will also establish requirements for licensure and allow the DoD to plan and conduct the appropriate studies to obtain approval for the products planned for production and licensing. Requests for approval of each medical product will be reviewed on an individual basis. In some cases, human efficacy may be determined to some degree (*e.g.*, the Topical Skin Protectant was tested against poison ivy extract in humans.) In other cases, human efficacy data will not be available.

***ISSUE:* DoD lacks FDA-licensed vaccines against some BW threat agents.**

SOLUTION: DoD currently has only one licensed vaccine for biological defense protection, the Anthrax Vaccine Adsorbed. For other biological defense vaccines, DoD awarded a prime systems contract to DynPort LLC, now called Dynport Vaccine Company (DVC). This contract establishes a single integrator to develop, license, produce, and maintain a stockpile of BD vaccines for protection against BW agents. DVC is required to obtain and maintain FDA licensure for all the vaccine products developed under this contract.

The contract was awarded in November 1997 and began with the development and licensure of three vaccines: Q fever, Tularemia, and Smallpox, and the storage of the current unlicensed BD vaccine stockpile (IND products). There are options for the development and licensure of ten other BD vaccines, which are programmed for development and licensure.

In July 2001, DoD submitted to "Report on Biological Warfare Defense Vaccine Research & Development Programs." This report this report addresses: 1) the implications of relying on the commercial sector to meet the DoD's biological defense vaccine requirements; 2) a design for a government-owned, contractor-operated (GOCO) vaccine production facility; 3) preliminary cost estimates and schedule for the facility; 4) consultation with the Surgeon General on the utility of such a facility for the production of vaccines for the civilian sector and the impact of civilian production on meeting Armed Forces needs and facility operating costs; and 5) the impact of international vaccine requirements and the production of vaccines to meet those requirements on meeting Armed Forces needs and facility operating costs.

As part of the DoD's vaccine initiative, DoD selected an independent panel of experts to assess the DoD acquisition of vaccine production programs and report their recommendations for improvement to the Deputy Secretary of Defense. The panel prepared a report to reflect its independent opinions for consideration by DoD. This report discusses vaccine industry constraints and concludes that the size and scope of the DoD program is too large for either DoD or industry alone. It recommends the application of a combined, integrated approach by DoD and industry, coupled with better alignment with industry best practices. DoD is working with the Department of Health and Human Services and other federal agencies to develop the requirements and plans for constructing a national biological defense vaccine production facility.

ISSUE: **Anthrax vaccination currently requires a primary series, six dose regimen spaced out over the course of 18 months, with an annual booster to maintain immunity. This protocol makes it difficult to complete before deployment of forces or to ensure that mobile forces, once deployed, are administered the proper regimen.**

SOLUTION: DoD conducted a successful pilot study evaluating a dosage regime using fewer doses of Anthrax Vaccine Adsorbed. The results of this study were presented to the Food and Drug Administration (FDA) in FY99. The results have been accepted for publication in the peer-reviewed journal "Vaccine," and will appear in an early 2002 issue. Congress funded the Department of Health and Human Services effort for expanded, pivotal studies. These studies will take place at five research centers, with enrollment of volunteers expected to begin in February 2002.

ISSUE: **There is no currently licensed manufacturer for the smallpox vaccine.**

SOLUTION: The currently licensed smallpox vaccine, made by outdated methods and last produced over 20 years ago, is in limited supply. A more modern replacement is needed. The U.S. Army has developed a candidate vaccine. Human trials of the Army vaccine are very promising. The final report from a clinical trial of the candidate vaccine administered by

scarification indicates that the candidate is safe and immunogenically similar to the licensed vaccine. The candidate vaccine continues to be developed for FDA licensure. The subcontractor selected by the JVAP prime systems contractor to manufacture the new smallpox vaccine completed process definition studies, manufactured a GMP pilot lot suitable for a phase 1 clinical trial, and validated a vaccine potency assay in FY01. A phase 1 trial of the newly manufactured GMP pilot lot is planned for start up in February 2002. FDA licensure is expected in 2004. An immune globulin product (Vaccinia Immune Globulin or VIG) is required to treat adverse reactions to vaccination with the smallpox vaccine. To ensure continued availability of previously manufactured VIG, an IND was obtained for this material, thus allowing planned clinical trials to proceed. The JVAP prime systems contractor also filed the first annual report for the IND (#9141) obtained for a new VIG product for intravenous administration. The selected subcontractor has manufactured three lots of the new VIG product. A clinical trial using this material is currently undergoing data analysis and two more lots are in the process of being manufactured. This product is in clinical testing, with licensure expected in 2004. The JVAP Program Management Office is in close coordination with the Centers for Disease Control and Prevention that has contracts for the development of a separate smallpox vaccine candidate for homeland defense. Parallel development of these vaccines is judicious risk reduction since both must undergo extensive human testing. Down selections to a single vaccine is desirable.

ISSUE: **The effects on humans resulting from the exposure to low doses of chemical agents, particularly organophosphate (nerve) agents, are not clearly understood.**

SOLUTION: Beginning in FY96, DoD, in association with the Research Working Group of the Interagency Persian Gulf Veterans' Coordinating Board, dedicated $5 million to evaluate the chronic effects of low-dose level exposure to chemical agents. Studies have been underway since 1QFY97 to develop highly specific and sensitive assays, preferably forward-deployable, to detect and potentially quantify low-level exposure to chemical agents. These ongoing studies may also identify any long-lasting and toxic metabolites of chemical agents that could account for delayed and long-term health consequences. In addition, studies to look at the impact of possible genetic polymorphisms of cholinesterase enzymes upon individual response to nerve agents are underway. Additional funds have been committed and contracts are being awarded to evaluate potential chronic health complaints resulting from exposure to nerve agents. These contracts were begun 1QFY98. In May 1999, the Department of Defense submitted a report to Congress entitled *DoD Strategy to Address Low-Level Exposures to Chemical Warfare Agents (CWAs)*. This report provided a review of the policies and doctrines of the Department of Defense on chemical warfare defense. Based on this review, DoD recommended no modifications to policies and doctrine, and stated that existing efforts were well designed to address the need, based on current scientific information.

During FY00, DoD established the Low Level Chemical Warfare Agent Working Group, which was chartered to provide advice on the research programs to understand the health effects of exposure to low-level chemical warfare agents, to prevent unnecessary duplication of research efforts, and to focus and direct scientific investigations to address operational issues. In FY01,

research efforts to understand the effects of low level chemical toxicity on the human body and to develop medical countermeasures to minimize effects of low level chemical exposure the were underway at or were sponsored by USAMRMC's U.S. Army Medical Research Institute for Chemical Defense. Accomplishments are found in Annex E.

ISSUE: **The toxic characteristics of the Fourth Generation Agents (FGAs) may be similar to the conventional nerve agents. Therefore, FGAs are recognized as a potential threat to the safety of our warfighters. Current medical countermeasures may not provide the same level of protection against the FGAs as they do against the conventional nerve agents.**

SOLUTION: Develop prophylactics, pretreatment, or therapeutics for the FGAs to reduce the likelihood that our adversaries will employ these agents. Basic pharmacokinetic characteristics such as absorption, distribution, metabolism, and excretion of these agents are necessary to determine the differences in the mechanism of action of the novel agents and the conventional nerve agents in order to develop effective countermeasures.

The Chemical and Biological Agents Action Group (CBAAG) was established to address the FGA threat. This group—composed of senior representatives from the intelligence, requirements, materiel development, and medical research and development communities—has reviewed applicable intelligence sources, requirements documents, and materiel development programs to assess the impact of the FGA threat to defense requirements and defensive systems development. Joint Service Integration Group and Joint Service Materiel Group representatives are working with representatives of the intelligence community to assess the FGA threat effect on current, developmental, and future defense systems. The CBAAG findings and recommendations were published in an initial report and action plan in 2002.

As part of the effort develop a more responsive process to coordinate and integrate activities among the intelligence, requirements, and R&D communities to react to emerging threats for the CB Defense Program, the Chemical and Biological Threat Agent Program (CBTAP) has been established. The objectives of the CBTAP are to promote continuing communication among these communities, to facilitate technical documentation, and to provide an information reach-back capability.

In FY01, research efforts to understand the mechanism(s) of new nerve agent threats and to develop improved pre- and post-exposure products and treatments against new nerve agents were underway at or were sponsored by USAMRMC's U.S. Army Medical Research Institute for Chemical Defense. Accomplishments in the FGA research area are found in Annex E.

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Chapter 3

Nuclear, Biological, and Chemical (NBC) Defense Logistics Status

3.1 INTRODUCTION

The overall logistical readiness of the Department of Defense's NBC defense equipment continues to improve. The Services have increased stock of most NBC defense equipment, and the overall Service requirements have decreased as a result of a smaller force. Both factors have improved the overall DoD readiness and sustainment status. Asset visibility initiatives continue to increase the ability to manage what is becoming an increasingly joint collection of NBC defense end items and consumables. A number of items continue to pose a moderate to high risk challenge due to low inventories and continued modernization efforts.

The DoD Chemical and Biological Defense Program jointly manages the research, development, and procurement of major end items of NBC defense equipment. These items are funded through defense-wide funding accounts. Consumable NBC defense items are managed by the Services and the Defense Logistics Agency (DLA) in accordance with Title X responsibilities of the Services and their desires to manage their own operations and maintenance funds. Under the provisions of Title X of the FY95 Defense Authorization Act, Service Secretaries are responsible for, and have the authority to conduct, all affairs of their respective departments including supplying, researching, developing, maintaining equipment, and training. The existence of defense-wide (rather than Service-specific) research, development, and acquisition funding accounts has ensured the joint integration of NBC defense programs. However, no defense-wide (that is, joint) operations and maintenance funding mechanism exists for the sustainment of NBC defense items, including consumables. Because of this, the *joint* NBC defense community is limited to tracking the status of the DoD NBC defense logistics readiness and sustainment program and making recommendations to correct funding shortfalls.

The Joint Service Materiel Group (JSMG) coordinates NBC defense logistics issues. The JSMG, established by the Joint Service Agreement (JSA), works to ensure a smooth transition through the phases of NBC defense equipment life cycles. It is also charged with developing and maintaining an annual Joint Service NBC Defense Logistics Support Plan (LSP). This LSP forms the basis for the analysis found later in this chapter.

During the past year, increased focus by all Services and DLA on NBC defense logistics has visibly improved the overall program. Readiness shortfalls have been identified and addressed to the degree that full sustainment through a one Major Theater War (MTW) scenario is reasonably assured. The ability to sustain a second nearly simultaneous MTW scenario is in question, due to current and potential critical shortfalls of specific program areas. Contingent upon implementation of the recommendations contained in the Secretary of Defense's Quadrennial Defense Review, the Services have programmed funds to specifically address these problem areas. Additionally, the services are

formulating doctrine, tactics, techniques, and procedures for domestic response to terrorist incidents involving weapons of mass destruction.

The Joint Chemical Defense Equipment Consumption Rates (JCHEMRATES) IV study was completed in November 1998. This study was sponsored by the Joint Services Coordination Committee and executed through the U.S. Army Center for Army Analyses. The goal of the JCHEMRATES study was to define parameters of future chemical warfare scenarios and determine the consumption rates for consumable chemical defense equipment. Using the current Defense Planning Guidance, the JCHEMRATES study developed consumption rates for the two MTW scenarios. Consumption rates include both medical and non-medical chemical defense items for each Service and overall DoD roll-ups for both scenarios. They include both initial issue of chemical defense equipment and sustainment through the 120-day period. These rates form an important basis for determining future Service purchases and their readiness to go to war. The final report on the JCHEMRATES IV study was published in April 1999.

The JCHEMRATES IV study's two MTW requirement is not and should not be considered a procurement target. This study did not fully consider certain factors such as air transport into theaters of conflict or Navy fleet requirements for ships at sea but not in the theater of operations. Thus, while the Services agree with the methodology and intent of the study, the Navy and Air Force disagree with some of the findings. Future iterations of this study will require further refinement prior to becoming a fully accepted planning tool. The JCHEMRATES MTW requirement does not consider peacetime training requirements, sizing requirements, full procurement to the entire active and Reserve forces, or the increasing number of peacekeeping missions in recent years. An increasing emphasis on counterterrorism, and humanitarian and peacekeeping missions worldwide is an additional drain on NBC defense supplies and has added to planning factors since these missions exceed the requirements planning figures (that is, 2 MTWs) used for acquisition planning. Therefore, the MTW requirement denotes a ***minimum planning number***, which if the total DoD inventory drops below, may represent a critical shortfall for that particular item which should be immediately addressed to avoid diminishing the force's NBC defense capability. Because of this limitation in the study, the Services have identified their total Service requirements as their procurement targets, while acknowledging JCHEMRATES as a necessary step in joint service management of the NBC defense program.

To address the shortcomings of the JCHEMRATES studies and to include biological defense, the Joint NBC Defense Board is sponsoring a follow-on study, the Joint Chemical Biological—Quantitative Requirements and Equipment Consumption (JCB-QREC) study. This study began in the fourth quarter of FY01 with an identification of user needs and concerns while developing the study scenarios.

The Services continue to have issues regarding the accountability and management of NBC defense item inventories. Limited asset visibility of consumable NBC defense items below the wholesale level remains a problem due to the lack of automated tracking systems at that level (the exceptions being the Air Force and a recent Marine Corps initiative). This has the full attention of the senior NBC defense managers. The Joint Total Asset Visibility (JTAV) project is progressing toward addressing these problems in the long term, but is initially hampered by the uneven quality of inventory reporting.

The Services still procure consumable NBC defense items through multiple, separate, and distinct funding authorizations, as discussed in Section 3.6 of this chapter. Each Service is addressing secondary item procurement policies independently. However, there continue to be shortfalls of specific NBC defense items when measured against DoD requirements of a two MTW scenario.

The process by which the Services and DLA fund and store war reserve materiel has been hampered by differing definitions, different deployment strategies, and a lack of validated requirements for jointly managed items. The Joint Service Integration Group (JSIG) was tasked in calendar year 2000 to study Service concerns with JCHEMRATES IV. Initiation of a follow-on study, the Joint Chemical Biological—Quantitative Requirements and Equipment Consumption (JCB-QREC) study is underway and is being tailored to address these concerns and thus will create a solid foundation for providing a basis for the common planning of future requirements.

The JSMG initiated its sixth Joint Service NBC Defense Logistics Support Plan (LSP) in August 2001. This report focuses on identifying the current on-hand stores of the Services' and DLA's NBC defense equipment, and matching these numbers against the requirements generated from the final JCHEMRATES IV study. The LSP's aim is to identify the Services' readiness and sustainment capability, maintenance requirements, and industrial base issues in the area of NBC defense. The data call conducted for the FY02 LSP was used to develop the findings in this chapter.

3.2 NBC DEFENSE LOGISTICS MANAGEMENT

NBC defense logistics management remains in transition. The Joint NBC Defense Board has begun to exercise full authority in this area, and the JSMG, which reports to the Joint NBC Defense Board, has been charged with coordinating and integrating logistics readiness. The Joint NBC Defense Board has identified the need to standardize the MTW equipment requirements among the Services. They initiated a process to collect data and define requirements to ensure consistency across all planning efforts. The JSMG's role is to identify current readiness and sustainment quantities in the logistics area, with respect to the two MTW scenario outlined in the Defense Planning Guidance. Developmental NBC defense programs that will be fielded within the POM time period are addressed to identify modernization efforts that are underway.

As currently envisioned, all Services retain "starter stocks" of NBC defense equipment that will support immediate deployments and initial operations. The length of time that these stocks will last each unit depends on the respective parent Service. Air Force units deploy with 30 days of NBC defense consumables. Army divisions use a planning figure of 45 days, while Marine Corps forces and Navy shore units use 60 days as the basis for their plans. As a matter of policy, Navy ships stock 45 days or 90 days of consumable materiel based on the units mission. However, Navy ship values are notional in that they are based on peacetime demand and/or projections of wartime demand as contained in pertinent allowance documentation. For NBC defensive materiel, and particularly in the case of individual protective equipment (IPE), the days of supply represent a minimum stockage position based on current investment guidelines for such materiel. In most cases, the Services will first redistribute any available uncommitted assets to provide sustainment before sourcing elsewhere. Once these starter stocks are depleted, the military force turns to the DoD NBC defense item managers for "swing stocks," also known as "sustainment stocks."

DLA and the Army Materiel Command (AMC) are the item managers, or National Inventory Control Points (NICP), for the vast majority of NBC defense items in all four Services. They are responsible for industrial base development, acquisition, and storage of wholesale peacetime and sustainment wartime stocks. They buy (process procurement actions) and, if requested, store NBC defense materiel (swing stocks) for the Services. However, the Services must provide funding to DLA and AMC for the procurements.

Primarily Army owned sustainment stocks are stored in DLA and AMC depots although USAF, USMC, and USN may provide funds to DLA and AMC to store their sustainment stocks. All Services are responsible for individually programming and funding sustainment stocks to provide the required support to their supporting force structure. Because of a lack of visibility of NBC defense items, unclear wartime requirements (given the post-Cold War environment), scarce Operations and Maintenance funds, and low priorities given to NBC defense stocks, the current quantity of DLA and AMC NBC defense war reserves have been reduced and will not support sustainment requirements for the entire DoD force during a full two MTW scenario. These numbers are reflected in the tables of Annex F.

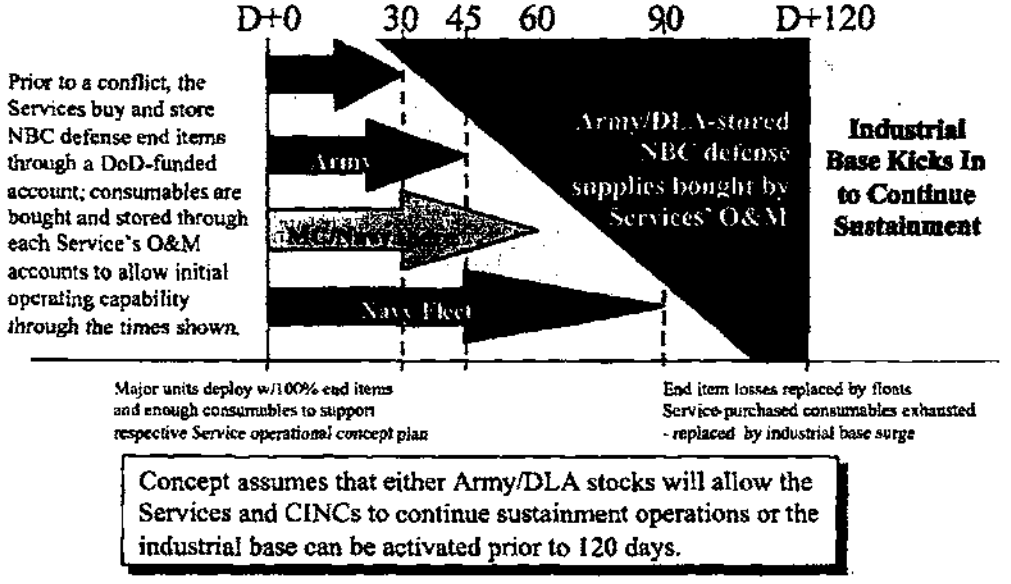

Figure 3-1. War Reserve Requirements and Planning

Service inventories of NBC defense items maintained at unit level use either manual records or a semi-automated tracking system. Stocks held at wholesale level are maintained using a separate automated system. Currently, there is little connectivity between the two systems. As a result, there is limited Service level asset visibility for NBC defense items. The Services are addressing this deficiency under the auspices of Total Asset Visibility (TAV), a long-term initiative that will link existing DoD logistics automated systems.

The Army has improved its visibility through an initiative to standardize individual issue of eleven critical NBC defense items across all major commands. Unit Status Reporting was implemented for units to report on-hand stocks *vs.* requirements on a monthly basis. In addition, plans are in place for consumable chemical defense equipment for all forces other than Force Package I and other early deploying units to be consolidated and centrally stored at Bluegrass Army Depot. This seven-year execution plan is managed by HQ AMC and will enable better visibility and rotation of NBC defense consumable items. The Air Force has a similar program that consolidates stocks of NBC defense items for deployment in support of contingency operations. These initiatives have also reduced surveillance costs and improved overall management of NBC defense stocks. The Marine Corps has been leading a joint surveillance Technical Working Group, whose initiatives have been increasing cooperative efforts in surveillance and shelf life programs. The Marine Corps has also begun an NBC stocks consolidation program and is developing an NBC Defense Equipment Management Program (DEMP) database to track the inventory, shelf life, and maintenance histories of NBC defense items.

Both DLA and AMC will remain key players in the future NBC defense logistics management system. The Joint NBC Defense Board, through the JSMG, provides coordination and integration based upon the input of all Services and Commanders-in-Chief (CINCs). DLA and AMC will continue to provide services such as raw data collection, inventory control, and a distribution infrastructure. With the results of JCHEMRATES IV, the Services and DLA can immediately begin plans to improve their readiness and sustainment status based on a common understanding of modern conflict scenario requirements.

3.3 QUANTITIES, CHARACTERISTICS, AND CAPABILITIES

The results of the data collection efforts are compiled in Tables F-1 through F-5 in Annex F, NBC Defense Logistics Readiness Data. A table is included for each of the four Services and DLA.

The items listed under "Nomenclature" in Tables F-1 through F-5 of Annex F are 129 NBC defense items that are currently fielded in the Services. "Total Service Requirements" include the quantity required for the entire Service (to include active and reserve forces), and includes peacetime replacements (wear and tear) and training requirements. Previously, the two MTW requirement quantities were based on the larger of (1) the initial issue for two MTW, or (2) the two MTW consumption, as computed by the JCHEMRATES IV study (March 1999 data). Those quantities represented the minimum requirements for full sustainment through two conflicts. Recognizing that potentially our forces would be left depleted of resources after the conflicts, the LSP Integrated Product Team (IPT) voted last year to add initial issue quantities to consumption in calculating the two MTW requirement for consumable items. The consumption that is used to compute the two MTW requirement provided in Tables F-1 through F-5 is based on the final JCHEMRATES IV calculations, dated March 1999. The Services and the JNBCDB have the option of providing different requirements if they determine the JCHEMRATES calculations to be inaccurate or outdated.

Note that materiel requirements for training, sizing variations and peacetime replacements are *not* included in the wartime requirements calculated by JCHEMRATES. This number represents an average expenditure calculated among four scenarios: chemical defense equipment expenditures under

low chemical weapons use during favorable and marginal weather conditions; and of chemical defense equipment expenditures against high chemical weapons use during favorable and marginal weather conditions. All sets of conditions were run for the North-East Asia and South-West Asia scenarios.

The "Stocks On-Hand" represents the total of all serviceable NBC defense materiel available in each of the Services (stocks positioned with troops, stocks in the supply system and stocks stored in depots/facilities, both peacetime stores and war reserve). This number represents only those items physically "on-hand". Quantities for which a Service or agency has submitted a funded requisition or purchase order in FY01, but has not received the requisitioned items are included in FY02. Finally, the quantities depicted as "Projected Due-Ins" are quantities the Services plan to buy to replace peacetime consumption of NBC defense assets (to include training use and shelf-life expiration), and to buy wartime sustainment stocks. It must be emphasized that these numbers are based on major command estimates of requirements. Actual procurements will be based on available funding.

3.4 LOGISTICS STATUS

During collection of FY01 data, information on the inventory status of 129 fielded NBC defense equipment items was compiled. While radiacs were not traditionally a part of this chapter, they have been retained in an effort towards continuity with other chapters and annexes of this report. NBC defense items such as spare parts and sub-components were considered a subset of the primary item for risk assessments, and were not reviewed separately. Batteries for critical systems are listed for informational purposes. Inventory tracking for batteries is difficult because of a lack of visibility and because they typically have other applications. Trainers were not included in the assessment process, since they do not reflect wartime service requirements. Quantities required for wartime needs were then compared to quantities currently on-hand. Characteristics and capabilities of selected fielded NBC defense items are discussed in detail in Annexes A-E of this report.

Among medical consumables, sodium nitrite and sodium thiosulfate are now combined in a single Cyanide Antidote Treatment Kit. The requirements for Pyridostigmine Bromide tablets were adjusted to reflect FDA guidelines, which allows them to be administered for only 14 days, rather than 30 days. The Chemical Agent Patient Treatment Medical Equipment Set and Medical Aerosolized Nerve Agent Antidote (MANAA) Atropine Sulfate Inhalation Aerosol were added.

Beginning with the 2000 report, the two MTW requirement for consumables was adjusted to include the initial issue along with the consumption provided by JCHEMRATES. This decision was made to provide for some inventory to remain after 120 days, thus enhancing our readiness if another conflict ensues. This more closely aligns the requirements calculations with those of other commodities such as ammunition.

Two MTW Requirement for Consumables
Previous definition: equal to the **greater** of JCHEMRATES Initial Issue **or** Consumption
⇒ No inventory remains after 120 days

New definition: equal to JCHEMRATES Initial Issue **plus** Consumption
⇒ Some inventory remains after 120 days
Readiness for the next conflict is enhanced

Of the 129 items extensively reviewed, DoD developed risk assessments for 50 items based on data gathered as of 30 September 2001 (see Table 3-1). These items were singled out because of their critical role or their ability to represent the general state of their respective commodity area. While

some of the items assessed changed from the previous year's report due to obsolescence, the balance of assessed items among the commodity areas remained as constant as possible to provide for continuity. These items were rated as being in a low, moderate, or high risk category. "Risk" is based on the currently available percent fill of the two MTW requirements; the lower this fill the greater the likelihood that such shortages may significantly reduce DoD's ability to respond to a contingency. Shortages for FY01 were calculated by comparing the two MTW requirements, as defined for this year, to on-hand quantities, as shown in Annex F, Tables F-1 through F-5.

RISK ASSESSMENT

Low –	Services have at least 85 percent of wartime requirement on-hand to support two nearly simultaneous major theater wars
Moderate –	Services have between 70 to 84 percent of wartime requirement on-hand to support two nearly simultaneous major theater wars
High –	Services have less than 70 percent of wartime requirement on-hand to support two nearly simultaneous major theater wars

Table 3-1 provides the results of the assessment. Programs rated as high or moderate risk are discussed in greater detail in Annex F. A seven-year comparison of data assessments is shown in Figure 3-2. In comparison to FY00 report data, the percentage of the FY01 report's items in the low risk category remained constant at 66 percent. The percentage of items in moderate rose from 14 percent to 18 percent, while the percentage of items in the high risk category dropped from 20 percent to 16 percent.

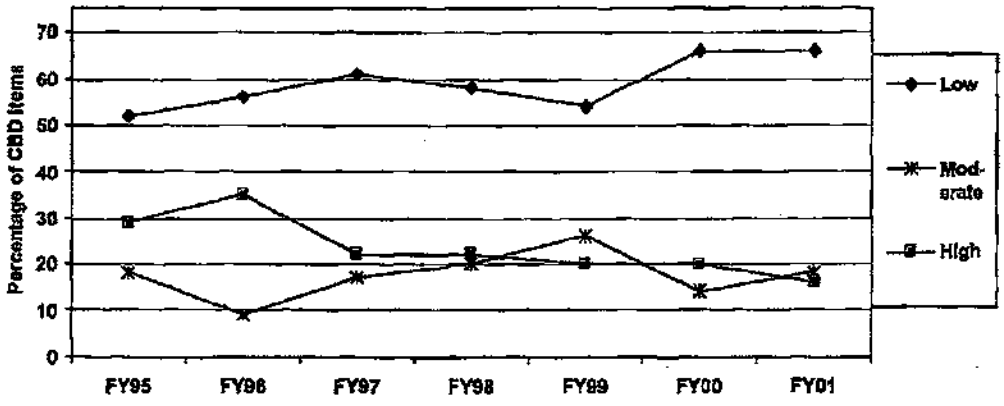

Figure 3-2. Logistic Risk Assessments: 50 NBC Defense Items

The redefinition of the two MTW requirement did not significantly affect most of the items that were assessed. Several items remain in the high to moderate risk categories while they are being fielded. These items will be monitored as continued procurement ameliorates their risk. The following items are highlighted:

- The status of M8A1 chemical agent detectors improved due to repairs while its replacement, the M22 ACADA, is being fielded.

- Collectively, 60% of the Marine Corps inventory of CAM 1.5 and CAM 2.0 have been refurbished and are currently being shipped to Marine Corps users. Funding for the remaining CAMs has been received and refurbishment action should be completed during FY02.
- Quantities of BDOs are not adequate to fill the Air Force requirement. The Air Force developed a mitigation plan in concert with procurement of the JSLIST ensembles to minimize risk. The recent plus-up of procurement funds for protective suits has aided in plans to transition to the JSLIST program. Despite the removal of quantities of BDOs from inventory because of defects the overall level of DoD War Reserve Materiel (WRM) stockage of BDOs remains high, thus the immediate risk is assessed as low. Also, DLA is providing an offset to the Services, based on the value of the defective BDOs, that is being applied toward purchase of additional JSLIST suits. Other BDOs will remain in inventory until they reach maximum shelf life.
- The Air Force is relying on the CWU 66/77P to provide a protective air crew ensemble. It will replace the now obsolete Chemical Protective Undercoverall, and is assessed at moderate risk. Continued planned procurements should correct this assessment in the short term. The Joint Protective Aircrew Ensemble (JPACE), being procured in FY04, will replace this suit.
- The collective protection area continues to be assessed as high risk, in part due to the continued emphasis on contamination avoidance and individual protection, which overshadows this area. As the procurement cycle in these two latter areas matures, the risk assessment of collective protection systems will lessen slightly.
- DS2 requirements, as determined by JCHEMRATES IV, indicated a significant increase in DS2 requirements compared to JCHEMRATES III and current on-hand stocks. Because of the magnitude of this change, DS2 is omitted from the risk assessments while the LSP Integrated Product Team considers the validity of the JCHEMRATES III requirement vice the JCHEMRATES IV calculation.
- With the expiration of M258A1 decontamination kits in FY99, the status of M291 kits becomes more critical. Present inventory and planned procurements should keep this risk low. Production of M295 kits has improved since last year to lessen their risk.
- Medical chemical defense materiel remains generally in low risk. The shortage of 2-PAM autoinjectors can be supplemented with existing supplies of atropine and Nerve Agent Antidote Kits (NAAK), reducing its risk from moderate to low. These items are gradually being replaced by the Antidote Treatment Nerve Agent Autoinjector.
- To meet JVAP requirements, the prime systems contractor (DynPort Vaccine Company) and its subcontractors have retrieved data, files, microbial stocks, and experimental lots of biological defense vaccines produced over the last 10–30 years from government laboratories and contractors in order to conduct an assessment of the suitability of these products for contingency/emergency use. A thorough and ongoing review of this information in the light of current FDA requirements for use under a contingency/ emergency use scenario has been completed. Recommended expanded testing and maintenance requirements are now being evaluated for implementation in order to make these products available for contingency/emergency use to reduce the risk of not meeting wartime requirements. This risk

of not meeting wartime requirements is still high but with expanded testing and maintenance over the next year could be reduced to a low to moderate risk.

Table 3-1. Logistic Risk Assessments: 50 NBC Defense Items

Items	Risk Assessment	Remarks
CONTAMINATION AVOIDANCE/DETECTION EQUIPMENT		
Radiological		
AN/VDR-2 Radiac Set	Low	
AN/PDR-75 Radiac Set	Low	
AN/UDR-13 Pocket Radiac	High	Low inventory, still fielding
Biological		
Biological Integrated Detection System (BIDS)	Low	
Chemical		
M256A1 Chemical Agent Detector Kit	Low	Shelf life expiration may reduce stocks in future, but has been extended from five to six years
M8 Detection Paper	Moderate	
M8A1 Automatic Chemical Agent Alarm	Low	Being replaced by M22 ACADA
M1 Chemical Agent Monitor (CAM)/Improved CAM	High	USMC fielding in progress; 40% of USMC stock awaiting repair
Chemical Agent Point Detection System (CAPDS)	Low	
AN/KAS-1 Chemical Warfare Directional Detector	Low	
M21 Remote Sensing Chemical Agent Alarm (RSCAAL)	Low	
M22 Automatic Chemical Agent Detector/Alarm	High	Low inventory; still fielding
M93A1 NBC Reconnaissance System "Fox"	Low	
M272A1 Water Testing Kit	Low	
M274 NBC Marking Set	Low	
INDIVIDUAL PROTECTION		
Masks		
MCU-2/P-series Mask	Moderate	USAF/USN mask
M40-series General Purpose Mask	Low	USA/USMC mask
M42-series Tank Mask	Low	
M48 Apache Mask	Low	Replaces M43-series mask
MBU-19/9 Aircrew Eye/Resp. Protection (AERP)	Low	Replaces MBU-13/P; still fielding
Suits		
JSLIST protective suits	Moderate	In process of fielding to all Services
Battle Dress Overgarment (BDO)	Low	No further production – being replaced by JSLIST
Saratoga Suit	Low	No further production – being replaced by JSLIST
CWU 66/77P	Moderate	Low inventory
Chemical Protective Undercoverall	Low	No further production - replaced by CWU 66/77P
Mark III Suit, Chemical Protection Overgarment	Moderate	No further production – being replaced by JSLIST
Aircrewman Cape	Low	
Gloves/Overboots		
Chemical Protective Gloves (7/14/25-mil)	Low	Near term DLA emergency buys lower risk
Green/Black Vinyl Overshoes (GVO/BVO)	Low	Risk low due to CPFC stocks
Chemical Protective Footwear Covers (CPFC)	Moderate	
Disposable Chemical Protective Footwear Covers	Low	Replaced by GVO/BVO

Note - Only selected Low Risk programs are displayed for information purposes.

Table 3-1. Logistic Risk Assessments: 50 NBC Defense Items (*continued*)

Items	Risk Assessment	Remarks
COLLECTIVE PROTECTION		
Chemical and Biological Protective Shelter (CBPS)	High	Limited fielding in FY02
M20A1 Simplified Collective Protective Equipment (SCPE)	High	Low inventory, not in production
M28 CPE HUB	High	Low inventory, still in production
M48A1 General Purpose Filter	Moderate	Low inventory
Filter For (M59, M56, Shipboard) (200 CFM)	High	Low inventory
DECONTAMINATION EQUIPMENT		
M291 Skin Decontaminating Kit	Low	Quantities cover loss of M258A1
M295 Individual Equipment Decontamination Kit	Low	
DS2, M13 Can	High	Low inventory
M11 Decontaminating Apparatus	Low	
M13 Decontaminating Apparatus, Portable	Low	
M17-series Lightweight Decontamination System (LDS) (to include the A/E32U-8 Decontamination System)	Low	
M12A1 Power Driven Decontamination Apparatus (PDDA)	Low	
MEDICAL DEFENSE		
Mark 1 Nerve Agent Antidote Kit (NAAK)	Low	Risk lowered based on autoinjector stocks
Atropine Autoinjector	Low	
2-PAM Chloride Autoinjector	Low	
Nerve Agent Preventative Pyridostigmine (NAPP) Tablet	Low	
Convulsant Antidote Nerve Agent (CANA) Autoinjector	Low	
Biological Defense Vaccines	Moderate	Prime contract awarded for development, production, FDA licensure, and storage
Biological Warfare Agent Diagnostics	Moderate	First DoD biological diagnostic effort

Note - Only selected Low Risk programs are displayed for information purposes.

Recognizing that the risk to individual protection of the warfighter is contingent on the availability of a complete protective ensemble, an alternative risk calculation is provided in Table 3-2. The risk is presented for each component of a protective ensemble. The quantity of each component is an aggregate of all available fielded items that fulfill that protective function. The requirement is the sum of the 2 MTW requirements for those items as determined by the JCHEMRATES IV study or those provided by the Services. The overall risk is then determined by the component in shortest supply.

Based on the average two MTW requirements identified in the JCHEMRATES IV study as of March 1999, the Services continue to exhibit shortages in certain critical areas. Shortages of chemical and biological agent detection systems, collective protection shelters and their respective filters, and biological warfare vaccines may have a serious impact on the joint force's ability to survive and sustain combat operations under NBC warfare conditions in two nearly simultaneous MTWs. The extent of the operational impact of NBC defense equipment shortages is under review in several classified studies.

Table 3-2. Protective Ensemble Risk Assessment

Combined Services			
Component	**2 MTW Requirement**	**FY01 On-Hand**	**Risk Assessment**
Suits	6,407,606	4,240,620	66% High [1]
Masks	1,804,715	1,694,712	94% Low
Filters	4,033,912	3,707,468	92% Low
Gloves	9,059,376	6,154,411	68% High [2]
Boots	5,803,579	3,890,726	67% High
Hoods	3,183,883	3,199,595	101% Low
			Overall risk is High
Army			
Component	**2 MTW Requirement**	**FY01 On-Hand**	**Risk Assessment**
Suits	2,900,000	2,766,222	95% Low
Masks	704,377	1,011,735	144% Low
Filters	1,367,626	1,642,900	120% Low
Gloves	4,634,380	3,900,227	84% Moderate
Boots	2,899,864	2,128,750	73% Moderate
Hoods	1,703,570	1,852,551	109% Low
			Overall risk is Moderate
Air Force			
Component	**2 MTW Requirement**	**FY01 On-Hand**	**Risk Assessment**
Suits	1,584,000	654,596	41% High
Masks	525,021	342,557	65% High
Filters	1,070,356	1,345,524	126% Low
Gloves	2,338,682	1,247,828	53% High
Boots	714,651	1,101,586	154% Low
Hoods	1,134,467	1,341,635	118% Low
			Overall risk is High
Navy			
Component	**2 MTW Requirement**	**FY01 On-Hand**	**Risk Assessment**
Suits	1,236,000	231,808	19% High
Masks	425,000	125,985	30% High
Filters	1,236,000	369,071	30% High
Gloves	1,294,160	254,357	20% High
Boots	1,537,918	235,978	15% High
Hoods	2,517	372	15% [3]
			Overall risk is High
Marine Corps			
Component	**2 MTW Requirements**	**FY01 On-Hand**	**Risk Assessment**
Suits	687,606	565,434	82% Moderate
Masks	150,000	214,435	143% Low
Filters	359,930	349,973	97% Low
Gloves	792,154	430,136	54% High
Boots	651,146	424,412	65% High
Hoods	343,869	5,147	2% [3]
			Overall risk is High

[1] DLA buys in FY02 reduce risk to moderate

[2] DLA buys in FY02 reduce risk to low

[3] risk is low when suits with integrated hoods are counted

3.5 PEACETIME REQUIREMENTS

In peacetime, quantities of NBC defense equipment are necessary to train personnel in NBC defense and to build confidence among our warfighters that NBC equipment will provide the necessary protection when used correctly. The two most critical areas of peacetime stocks are individual protective equipment and medical chemical defense materiel. The Services have indicated that adequate NBC defense equipment is on-hand to conduct training.

Generally, items used in peacetime for training are drawn from wholesale stocks, requiring units to maintain both training and contingency stocks. For selected items, such as protective clothing, contingency utility is lost when the item is used (or consumed) for training. Because peacetime training requirements are met in this manner, major commands do not track training equipment in their estimates of on-hand requirements.

3.6 FUNDING

In accordance with the NBC defense management initiatives outlined in Chapter 1, funding of RDT&E and procurement was centralized in a DoD defense-wide account beginning in FY96. Operations and maintenance (O&M) funding for NBC defense materiel is not consolidated at the DoD level. Therefore, for non-major (secondary) end items (*e.g.*, consumables such as decontamination kits, detection kits, and filters), each Service continues to separately fund replenishment and sustainment of NBC defense equipment. Depot maintenance and contractor logistics support for some low density major items are also O&M funded. These appropriations are not included in the joint NBC defense program. Additionally, the Army is the only Service that currently fences funds solely for the purchase of NBC defense medical consumable items.

Funding of NBC defense items classified as war reserves secondary items (WRSI) remains a significant issue. The Services are responsible for developing the requirements and funding items in war reserve stocks. Funding of WRSI comes from Congressional appropriations made into the Working Capital Fund from the transfer of Services' O&M funds. For example, replenishment of NBC defense items in Army war reserves will require substantial funding through 2006 as some items reach their maximum extended shelf lives and require replacement. The recent plus-up of funds for protective suits is assisting in building an initial stockage and minimum sustainment (war reserve) stock to meet the current defense planning guidance.

Under current acquisition procedures and DoD guidance to minimize wholesale stockpiles, procurements are based only on funded Service requisitions. The Services remain responsible for program funding to replace NBC defense equipment wartime stocks. Procurement is usually based on economic buy quantities (a consolidation of all Service requisitions) to provide the best value to the government. Some procurements, however, suffer significant delays in delivery because of the time required to accumulate sufficient requisitions to produce economic buy quantities. This situation occurs when item managers try to plan purchases of consumable items that have a low peacetime consumption but high wartime consumption (such as decontamination kits, large collective protection filters and M256A1 detector kits). The result is a low purchasing history with a small industry

production capability, which in turn causes a very low war reserve status with minimal industry surge capability. The JCHEMRATES IV study was intended to provide more accurate requirements on which the Services could base their planning.

3.7 INDUSTRIAL BASE

Since the end of the Cold War, and with a smaller DoD force, the industrial base has seen mergers and acquisitions, which have reduced the number of firms participating in defense production. The decreased number of firms has reduced competition in the sector, but the remaining firms appear to have stabilized. While the sector is stable, vulnerabilities still exist. Collective protection systems (filters in particular) continue to be the most critical subsector in the NBC defense area. Additionally, protective clothing procurement continues to receive intense scrutiny due to the possibility of industrial base shortfalls in satisfying requirements during a contingency. The limited pharmaceutical industrial base to support DoD CB defense medical programs, coupled with a lack of government vaccine production, represents a serious medical industrial base shortcoming.

Recent assessments indicate that the NBC defense industrial base sector is evolving to include firms ranging from small to large with some dedicated to producing military unique products, while others have significant commercial markets. With the growing awareness of terrorist threats, the commercial market is growing. Other companies are still dependent on Service demands and sales for their financial survival. Selected NBC defense items (JSLIST, chemical gloves, and nerve agent autoinjectors) have been designated as critical to combat operations because of low peacetime demand, high wartime use, and the fragile supporting industrial base. As a result, DLA established, with OSD approval, a "War Stopper" program to sustain key industrial base capabilities, utilizing industrial preparedness funding under PE 07080110.

Included in the mission of the Joint Service Integrated Product Team (IPT) for the Logistic Support Plan is an assessment of the Industrial Base. This assessment is designed to assist the Services in identifying problems and issues related to production capabilities of consumable and end item Chemical and Biological Defense Equipment (CBDE). It identifies CBDE not able to fully support 2 MTW requirements due to asset shortfalls, and documents maximum production capabilities, warm and cold base, for each item. These assessments provide DoD decision-makers with accurate industrial base information and analysis.

The IPT is addressing issues from across the Services for more than 128 items/systems and spare parts critical to readiness. The IPT is conducting analyses to include industrial and technology capabilities, alternative sources of supply, and a financial and economic analysis. These analyses will provide the NBC management structure with alternatives and recommendations within the sub-sectors of NBC defense. To date, all systems were evaluated with 41 systems given in-depth analysis. Industrial preparedness measures were recommended for some of those items with others identified as having a need for re-programming to fund buy-outs that would make up the shortfalls.

3.8 NBC DEFENSE LOGISTICS SUPPORT ASSESSMENT

ISSUE: **The Department of Defense CB Defense Program has a full capability to support and sustain the first of two MTWs. Readiness shortfalls that would preclude full support of a second MTW have been identified and were addressed in the POM (FY02-07). The Services' modernization efforts and common war reserve requirements will lessen the overall risk over the near term.**

SOLUTION: The Services continue to increase their readiness and sustainment status by consolidating common stocks and increasing visibility of their wholesale stocks. In most cases, accelerated procurement of critical items into war reserves will increase readiness against the potential use of weapons of mass destruction.

During 1998, all four Services participated in the development of the JCHEMRATES IV study, which was finalized in 1999. JCHEMRATES IV provided a more accurate prediction of the initial issue and sustainment quantities required for each Service. A follow-on study, the Joint Chemical Biological – Quantitative Requirements and Equipment Consumption (JCB-QREC) is being conducted in FY02 under the auspices of the Joint NBC Defense Board. The use of this common methodology will allow the presentation of joint service requirements in future reports and facilitate improved joint logistics management.

ISSUE: **DoD continues to lack a joint, integrated system to maintain asset visibility of NBC defense equipment below wholesale level, and lacks a standardized war reserve program for NBC defense equipment. Resourcing the procurement and sustainment of wartime stocks of consumables such as individual protective equipment, decontamination kits, and detector kits remains the responsibility of the Services.**

SOLUTION: DoD established the requirement for asset visibility and reviewed existing systems and procedures, both for peacetime reporting and war time reporting. The Services and DLA are addressing the NBC defense asset visibility deficiency under the auspices of the Joint Total Asset Visibility initiative. Additionally, DLA is actively involved in a Business System Modernization (BSM) Program to replace the current legacy inventory management system by FY05. The resulting fully integrated system will interface with the individual Services. The Marine Corps have continued to improve and implement the automated NBC Defense Equipment Management Program (DEMP) which standardizes accountability by tracking inventory by NSNs, contract numbers, lot numbers, shelf lives, and related personnel data (issues, sizes, *etc.*)

ISSUE: **NBC defense industries have a limited ability to augment specific shortfalls during any future contingency, in part due to lowered DoD procurements and the inability to retain warm production lines in critical areas. Without the introduction of significant plus ups or the use of innovative business practices (such as the use of performance specifications), many of the small firms that make up this sector may choose to re-focus on the commercial market place.**

SOLUTION: DoD continues to pursue innovative strategies to maintain a responsive industrial base, especially those strategies that decrease industry reliance on DoD procurement for industrial base survival. Strategies may include tapping into independent research and development (IR&D) conducted by universities and corporations, increasing reliance on dual-use technologies, and pursuing strategies that will encourage companies to decrease dependency on DoD requirements for their survival.

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Chapter 4

Nuclear, Biological, and Chemical (NBC) Defense Readiness and Training

4.1 INTRODUCTION

The Joint NBC Defense Program builds on the successes of each Service to develop a viable Joint orientation to NBC defense capabilities, which includes Joint requirements documents; Joint doctrine and tactics, techniques, and procedures; Joint modeling, simulation, and wargaming; and Joint professional training.

4.2 NBC DEFENSE DOCTRINE

Joint Doctrine. Joint Publication 3-11, *Joint Doctrine for Operations in Nuclear, Biological, and Chemical (NBC) Environments*, 11 July 2000, provides guidelines for the planning and execution of NBC defensive operations. Its focus is on the NBC threat, national policy, and considerations peculiar to the preparation and conduct of NBC defense. These considerations include principles of theater NBC defense, logistics support, medical support, training, and readiness.

Multi-service Doctrine. The Joint Service Integration Group (JSIG) is working with the Air Land Sea Application (ALSA) Center, U.S. Army Chemical School (USACMLS), and the Joint Warfighting Center to lead the effort in the development of multi-service NBC defense doctrine. The JSIG is sponsoring the revision/development of a core list of multi-service NBC Defense Doctrine publications selected by the Services. This core list will provide a logical framework for NBCD multi-service tactics, techniques, and procedures (MTTP) that will integrate service's TTPs where possible and provide service unique TTPs when different. Using the ALSA process, and with the U.S. Army Chemical School selected as the lead service for doctrine development, two NBCD Doctrinal publications will be revised each year over a five year period. The selected core Multi-service NBCD Doctrinal list is shown below:

- MTTP for NBC Defense of Theater Fixed Sites, Ports and Airfields.
- NBC Contamination Avoidance.
- NBC Aspects of Consequence Management.
- NBC Defense Operations.
- NBC Decontamination (Restoration) MTTP.
- NBC Protection MTTP.
- Field Behavior of NBC Agents.
- Potential Military Chemical/Biological Agents and Compounds
- NBC Vulnerability Analysis.
- MTTP for NBC Reconnaissance and Surveillance.

The FY01 effort consisted of JSIG sponsored initiatives to continue the development of NBC multi-service Doctrine. The multi-service doctrine manuals currently being revised under FY01 efforts include *NBC Protection* and *NBC Reconnaissance and Surveillance*. Multi-service doctrine manuals scheduled for revision in FY02 are *NBC Vulnerability Analysis and Potential Military Chemical/Biological Agents and Compounds.*

Multi-National Doctrine. The U.S. Army Nuclear and Chemical Agency (USANCA) has been delegated the lead DoD representative for international standardization of NBC operational matters. USANCA participates in the following North Atlantic Treaty Organization (NATO) groups:

- NBC Defense Interservice Working Party (NBCWP) under the Military Agency for Standardization,
- Land Group 7 (LG. 7)—NBC Equipment, under the NATO Army Armaments Group (NAAG),
- Working Group 2 (LG. 7)—Low Level Radiation in Military Environments,
- Challenge Subgroup (LG. 7)—Chemical/Biological Toxicity Challenge Levels,
- Technical Subgroup (LG. 7)—Nuclear Weapons Defense, and
- ATP 45 (NBCWP) NBC Warning/Reporting.
- ATP 59 (B) Doctrine for the NBC Defense of NATO Forces

USANCA also has been delegated as the representative in the American, British, Canada, Australia (ABCA) Quadripartite Alliance in the Quadripartite Working Group (QWG) for NBC Defense. In that group, USANCA also participates in the RADIAC Information Exchange Group (IEG). The USACMLS participates with USANCA to incorporate NBC group agreements in revising existing manuals.

The USACMLS has been delegated as the representative at the NATO Training Group (Joint Services Subgroup) in addition to providing representation and subject matter expertise to support USANCA at NATO/QWG meetings as required. This includes consultation to coordinate the official US position on NBC defense issues prior to international meetings.

4.2.1 Joint NBC Defense Doctrine Program Management

The NBC defense program management strategy described in Chapter 1 provides the mechanism to assist the Joint Staff in the further development of the Joint NBC defense doctrine program. The JSIG coordinates with the Services to ensure the program is realistic and meets the needs of the Joint community.

4.2.2 Joint NBC Defense Doctrine Development Program

The JSIG has implemented a program to ensure NBC/WMD is appropriately addressed in Joint doctrinal materials. Through this process, selected joint publications, either in development or in revision, are reviewed and NBC/WMD related recommendations are provided to the developers.

The U.S. Army Medical Department Center and School (USAMEDDC&S) is the lead agency for the revision of Joint Publication 4-02, *Doctrine for Health Service in Joint Operations*.

The publication was approved 30 July 2001. The revision contains additional information on the medical aspects of NBC defense.

4.2.3 Army Medical Doctrine Development Program

Multi-Service Doctrine. The FY01 effort consisted of initiatives to develop new Army Medical Department (AMEDD) NBC defense doctrine products, provide AMEDD input to other service NBC doctrine publications, and provide input to multinational medical NBC procedures. FM 4-02.283 (NTRP 4-02.21; AFMAN 44-161(I); MCRP 4-11.1B) *Treatment of Nuclear Warfare Casualties and Low-Level Radiation Exposure* was printed and distributed in Dec 00 as a multi-service publication. FM 4-02.7 (FM 8-10-7), *Health Service Support in a Nuclear, Biological, and Chemical Environment* is being revised and developed as a multi-service publication. Doctrine for medical aspect of toxic industrial material (radiological biological, and chemical) will be developed and incorporated into current and new manuals as the technology allows. Available material on medical aspects of toxic industrial material will be included in the revision of FM 4-02.7.

Multi-National Doctrine. The Office of The Surgeon General, Department of the Army – Health Care Operations (OTSG, DASG-HCO) has been designated the head of Delegation for the NBC Medical Working Group for standardization of NBC medical operational matters. OTSG, DASG-HCO participates in or coordinates with the following NATO groups:

- NBC Defense Working Group
- NBC Medical Working Group—Head of Delegation
- Land Group 7 (LG.7)—Joint NBC Defense
- Working Group 2 (LG.7)—Low Level Radiation in Military Environments
- Challenge Subgroup (LG.7)—Chemical/Biological Toxicity Challenge Levels
- General Medical Working Party, Aeromedical Working Group
- Research Technology Area/Human Factors Medical Panel NBC Medical Subgroups.

The AMEDD participated in numerous NATO medical NBC procedural product reviews, resulting in several NATO Standardization Agreements (STANAGs) being updated. Further, the AMEDD participated in a QWG to develop and update additional Quadripartite Standardization Agreements (QSTAGs), which are medical NBC procedural products. STANAGs and QSTAGs are reviewed for integration of these agreements into Army-specific doctrine literature products as well as multi-service medical doctrine products for which the AMEDD is the proponent.

The USAMEDDC&S has been designated as the lead agency to revise the "NATO Emergency War Surgery Handbook". The initial draft for the revision is currently being developed. This draft is projected for completion during FY01.

4.2.4 Air Force Doctrine Program

HQ USAF/XONP and the Air Force Doctrine Center have filled a void in Air Force doctrine by developing an overarching Counter-NBC Operations Doctrine for the USAF. The new document brings the Air Force into compliance with DoD Directive 2060.2, which requires each Service to develop a counter-NBC doctrine, and outlines integration with Joint and Multi-Service doctrine.

USAF guidance historically has focused piecemeal on updating USAF doctrine by incorporating counter-NBC concepts, whereas the new document integrates all the essential areas—proliferation prevention, counterforce, active defense, passive defense, counter NBC terrorism and command, control, communications and computers, intelligence, surveillance, and reconnaissance (C4ISR).

The Air Force Surgeon General (HQ USAF/SGXR) has been participating with the Army in development of joint and multi-service medical doctrine and guidance (see paragraph 4.2.3 above). Medical NBC doctrine was included in AFDD 2-1.8, *Counter-Nuclear, Biological and Chemical Operations*.

4.2.5. Navy Doctrine

The Navy actively participated in all phases of Joint, Multi-service and Service-unique Chemical Biological Defense. The Navy Warfare Development Command (NWDC) serves as the lead Navy organization participating in efforts to revise and update multi-service Chemical-Biological Defense publications. Publications under current revision include NWP 3-11 *Multiservice NBC Operations*, NTTP 3-11.24 *Multiservice Tactics Techniques and Procedures for NBC Aspects of Consequence Management* and NTTP 3-11.25 *NBC Contamination Avoidance*. Updates are planned for the Navy publications NWP 3-20.31 *Surface Ship Survivability* and NSTM 470 *Shipboard BW/CW Defense and Countermeasures* to improve interoperability with the USMC during amphibious operations and to revise biological defense procedures.

The Navy Warfare Development Command participates in the following North Atlantic Treaty Organization (NATO) Groups:

- NBC Defense Interservice Working Party (NBCWP) under the Military Agency for Standardization,
- Land Group 7 (LG. 7)—NBC Equipment, under the NATO Army Armaments Group (NAAG),
- Working Group 2 (LG. 7)—Low Level Radiation in Military Environments,
- ATP 45 Panel (NBCWP) NBC Warning/Reporting.
- ATP 59 (B) Doctrine for the NBC Defense of NATO Forces

The Surgeon General of the Navy (OPNAV 093) represents the Navy at the NATO Medical NBC-D Working Group and related medical working groups on behave of NWDC.

4.2.6 Marine Corps Doctrine

The Marine Corps is fully participating in all joint doctrine working groups to produce and update jointly funded multi-service NBC defense doctrinal publications. The NBC Operational Advisory Group met for one week to assess the Marine Corps' capstone doctrinal manual for NBC Defense, Marine Corps Warfighting Publication (MCWP) 3-37, Marine Air Ground Task Force NBC Defense Operations. The MCWP will be revised and updated during FY02. This revision and update will better address NBC defense tactics, techniques and procedures in amphibious operations.

In November 1998, the Deputy Secretary of Defense directed the Navy and Marine Corps to assess its ability to conduct amphibious assaults in a chemical and biological environment. The studies

that were conducted resulted in the identification of several doctrinal deficiencies in this area. During November 2001, Navy and Marine Corps representatives met in Quantico to discuss current doctrinal deficiencies with respect to chemical biological defense during amphibious operations. Two Naval publications were considered for possible modification to correct these deficiencies—NWP 3-20.1, "Surface Ship Survivability," and NSTM 470, "Shipboard BW/CW Defense and Countermeasures." Any changes to current Marine Corps Doctrine will also be addressed or annotated in the revised/updated MCWP 3-37, MAGTF NBC Defense Operations.

4.2.7 United States Special Operations Command Doctrine

The United States Special Operations Command (USSOCOM) – Center for Operations, Plans and Policy (SOOP) with its components developed USSOCOM Pub 3-11, "Multi-service Techniques, and Procedures for Special Operations Forces in Nuclear, Biological, and Chemical Environments," dated 6 April 2001. This publication is multi-service designated (Army FM 3-05.105, Navy NTTP 3-11.30, Air Force AFTTP(I) 3-2.35.

This publication was prepared at the direction of the Commander in Chief, United States Special Operations Command who recognized the need to share the TTPs developed by individual components within the Special Operations Forces (SOF) community. This publication compiles existing Joint Doctrine, principles, and known Multi-Service/component TTPs for NBC defense preparedness. It establishes a single "How To" guide for use by individual SOF personnel and SOF components supporting Joint Task Force/Joint Special Operations Task Force (JTF/JSOTF) operations. It is a guide intended to enhance SOF force protection, survivability, and readiness in NBC environments. USSOCOM Pub 3-11 is for "Official Use Only."

USSOCOM is a participating member in joint doctrine working groups to produce and update multi-service NBC defense doctrinal publications.

4.3 STANDARDS OF PROFICIENCY AND CURRENCY

Each service establishes standards of proficiency and currency for NBC defense training. The following sections describe each Service's activities for NBC defense training.

4.3.1 Army

Army Regulation 350-41, *Training in Units*, establishes Army standards for proficiency for NBC defense training. NBC defense training is conducted at schools and in units. The USACMLS is responsible to train and sustain Chemical Corps soldiers and leaders and provide task/condition/standard limits, suggested training products, and oversight in the areas of NBC matters. Although the USACMLS is neither designated nor resourced to be the DoD Executive Agent for joint NBC defense training, it is pursuing the following initiatives to the extent available resources allow:

(1) assisting CINCs, Major Commands, and their staffs in assessing and providing reference materials regarding the NBC threat and recommending actions to reduce the NBC threat in their areas of operations;

(2) providing broad-based joint NBC defense doctrine and joint doctrine development support;
(3) introducing and upgrading instructional aids and training support material for War Colleges and Command and Staff Colleges for all Services;
(4) developing, evaluating, and fielding advanced instructional capabilities for both resident and nonresident instruction; and
(5) conducting the Joint Senior Leader Training Course – A Focus on Weapons of Mass Destruction, intended to provide leaders from all Services with an understanding of joint NBC defense operations, training, readiness, threat, doctrine, and capabilities.

Individual Training.

- At the initial training level, NBC defense tasks are taught to students wearing Mission Oriented Protective Posture (MOPP) during Basic Soldier Training and Warrant Officer Candidate Training to satisfy Initial Entry Training Requirements.
- Common core qualification is achieved from NBC tasks training during Officer (basic and career) and Warrant Officer (basic) training.
- NCOs train on leader NBC skills during their NCO development courses.
- Other Officer and NCO courses require training in NBC as a condition that effects the performance of branch specific tasks.
- At the company level most units have an NBC NCO specialist, and at the battalion or higher level most units have an NBC Officer and Senior NCO.

Unit Training.

- The Army is constantly challenged to improve its training of NBC battlefield hazards by integrating such training into unit mission training as well as individual and leader training.
- NBC Defense emphasis in the FY01 Common Task Test . The Army has taken steps to address this issue by making the task: "Maintain Your Assigned Protective Mask" an element of the Common Task Test for FY01. Soldiers will practice this task until they can meet the test standards.
- NBC collective tasks are published in Army Training Evaluation Program (ARTEP) Mission Training Plans. The highest level of NBC training recognizes NBC as a battlefield condition and units train to execute their Mission Essential Task List (METL) while under NBC conditions.

Medical Training. The Army funds medical NBC training oriented towards patient care, leader development and medical force health protection. Patient care training provides medical professionals with the clinical skills necessary to diagnose and treat individuals exposed to NBC agents. Leader development prepares Army medical unit leaders to manage NBC casualties on the battlefield. Medical force health protection training provides preventive medicine personnel with the skills

necessary to support Force Health Protection Programs across the full spectrum of military operations.

Army funded medical NBC training is conducted at the U.S. Army Medical Department Center and School (AMEDDC&S), the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the Armed Forces Radiobiology Research Institute (AFRRI) and the US Army Center for Health Promotion and Preventive Medicine (USACHPPM). Training modalities include training presented at the training commands (In-House training), training conducted at the requesting unit's site (On-Site training), and training achieved via the different types of distance learning programs (Distance Learning training).

Each training modality offers unique advantages. In-house training enables students to use laboratory and field training facilities while maximizing student-instructor interactions. On-site training, *i.e.*, courses taken "on the road" and presented at military installations worldwide, minimizes student travel costs while preserving direct student-instructor interactions. Distance learning programs minimize training costs and support increased audience sizes, but at the cost of direct student-instructor interactions. A summary of Army sponsored medical NBC training is provided in Table 4-1 below.

Table 4-1. Summary of Army Medical NBC Training (FY2001)

Training Command	Type of Training	Training Method	Number of Students
AMEDDC&S	Leader Development	In House	2686
	Leader-Development	Distance Learning	388
	Force Health Protection	In House	71
USAMRICD	Patient Care	In House	361
	Patient Care	Distance Learning	4477
	Patient Care	On-Site	520
	Leader-Development	In House	331
USAMRIID	Patient Care	In House	361
	Patient Care	Distance Learning	500
	Patient Care	On-Site	520
	Leader-Development	In House	323
AFRRI	Patient Care	In House	81
	Patient Care	On-Site	408

The AMEDDC&S trains all U.S. Army Medical Department (AMEDD) personnel and selected personnel from all three armed services, including the active, reserve and National Guard components. The primary focus of the AMEDDC&S's medical NBC training has historically been basic soldier skills, leader development, and training to preparing AMEDD leaders to meet the challenges of supporting Medical Force Health Protection Programs in the face of NBC threats.

AMEDDC&S medical NBC leader development training begins when new AMEDD officers receive 39 hours of NBC classroom instruction and 12 hours of NBC field training during their Officer Basic Course (OBC). The OBC teaches new AMEDD officers basic soldier skills and the fundamental knowledge necessary to conduct medical operations in NBC environments, control NBC contamination in medical units, and understand the medical implication of NBC exposures. In FY01, 1649 students completed OBC.

The Army Medical Department (AMEDD) Officer Advanced Course (OAC) includes 10 hours of medical NBC correspondence courses. The foreign officers from Allied armies attending the AMEDD OAC received an additional 40 hours of Medical NBC training. In FY01, 388 students completed OAC.

Prior to promotion to the rank of staff sergeant, Army combat medics attend the AMEDDC&S Basic NCO Course (BNCOC). BNCOC incorporates classes and practical exercises in battlefield medical operations in an NBC environment, decontaminating, managing and treating contaminated casualties, and training non-medical soldiers in casualty decontamination procedures. In FY01, 578 NCOs completed the BNCOC.

USAMRICD's "Field Management of Chemical and Biological Casualties Course" (FCBC) provides detailed training in the first echelon management of chemical and biological agent casualties. This leadership development course, presented as a five-day in-house course at Aberdeen Proving Grounds, is also offered as a three-day on-site course. The FCBC's classroom discussions include: the current global threat of chemical and biological agent use, the characteristics and effects of threat agents, recognition and emergency treatment of agent exposure, principles of triage and decontamination of chemical and biological agent casualties. During FY01, USAMRICD presented the FCBC to 331 AMEDD officers and NCOs in the in-house courses.

The Principles of Preventive Medicine Course prepare future preventive medicine officers to support medical force health protection programs in NBC environments. In FY01, 71 students completed the Principles of Military Preventive Medicine Course. The Preventive Medicine Specialist Course was revised to incorporate Low Level Radiological (LLR) training. LLR training has been expanded in the Health Physics Specialists course and in training provided Army Nuclear Medical Science Officers (NMSOs) during attendance of the OBC, OAC and Principles of Preventive Medicine Courses. LLR training enables NMSOs and Health Physics Specialists, with the support of Preventive Medicine Specialists, to provide medical force health protection to deploy forces supporting incidents involving potential radiation exposures, including Radiological Dispersal Device (RDDs) attacks or releases of radioactive materials from nuclear facilities.

Patient care training of physicians, physician assistants, and nurses is primarily accomplished by the specialized Army and DoD research laboratories. The laboratories' courses, taught by physicians and scientists from all three armed services, are presented to the medical professionals of all armed services. The courses are also generally available to non-DoD agencies and have made significant contribution to Homeland Security initiatives.

USAMRICD and USAMRIID trained 331 medical professionals with the in-house version of the "Medical Management of Chemical and Biological Casualties Course" (MCBC). Sponsored by the AMEDDC&S, the students attending the in-house MCBC divide their time between USAMRIID at Ft. Detrick, Maryland and USAMRICD at Aberdeen Proving Grounds, Maryland. The MCBC provides DoD personnel, primarily physicians, physician assistants, and nurses, with a working knowledge of the potential threat of chemical and biological weapons and the status and scope of medical defense strategies. It combines classroom instruction and field experience to establish essential skills, instill confidence, and define limitations in therapeutic modalities with each type of medical setting. The course also provides instruction on the use of specialized equipment and skills required for

safe, long distance evacuation. First-hand experience in triage, decontamination, and medical operations on the integrated battlefield is stressed.

AFRRI, a DoD agency, trained 489 DoD and non-DoD students with the "Medical Effects of Ionizing Radiation" (MEIR) Course. The MEIR course, funded by the Army Office of the Surgeon General, provides up-to-date information concerning the biomedical consequences of radiation exposure, how the effects can be reduced, and the medical management of radiological casualties. The MEIR course, sponsored by the AMEDDC&S, is presented in-house at Bethesda, Maryland, on-site at US military installations worldwide, and via videotape as a distance-learning course. The course has been expanded to include non-nuclear weapon radiological hazards, such as LLR hazards, which could be encountered on the battlefield or during non-combat military operations.

The Army Office of the Surgeon General (OTSG) continued funding for USAMRIID and USAMRICD initiatives to exploit the potential of medical NBC distance learning courses. Distance learning courses, using VTC, satellite broadcasting, videotape series and computer based training programs, offers an alternative for those otherwise unable to attend training. The convenience of distance learning also enables large numbers of medical professionals to attend training.

In FY01, USAMRICD presented the interactive satellite distance learning course "Medical Response to Chemical Warfare and Terrorism". This course trained military and civilian health care professionals in the proper medical response in the event of an intentional or accidental chemical agent exposure. World-renowned experts from the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) and the Chemical Casualty Care Division (CCCD) presented this program at no charge to 4,137 participants. The program was taped and is now offered as a video tape program.

The Army Office of the Surgeon General sponsored a 5-day Medical NBC Readiness workshop at the AMEDDC&S for 32 AMEDD leaders with operational medical planning responsibilities. The workshop increased the participants understanding of the impact of NBC threats on military operations and enabled participants to conduct Medical NBC exercises. Attendees learned to design and conduct Medical NBC exercises using the NBC Casualty Training System (NBC CTS).

The Army Office of the Surgeon General maintains the Medical NBC Online Information Server, an Internet web site at: http://www.nbc-med.org/. This searchable web site, visited over 400 times per day, presents medical NBC related news articles, case studies, congressional testimony, information papers, medical NBC references, training materials, and the schedule for related conferences and courses. Links are provided to AMEDDC&S, USAMRICD, USAMRIID, AFRRI, and other NBC related Internet sites offering training documents and software packages. Many references and documents can be downloaded directly from the OTSG site, including the Medical Management of Biological Casualties Handbook and Medical Management of Chemical Casualties Handbook

The Field Preventive Medicine and Training Divisions of USACHPPM are currently working with U.S. Army Forces Command to assist field preventive medicine units in assessment of their existing environmental sampling and analysis capabilities and provide technical training on toxic industrial material risk assessment and radiological hazard risk assessment. This training includes

orientation and training on existing Table of Organization and Equipment as well as USACHPPM provided equipment and support.

The AMEDD and OTSG since 1996 have conducted a series of medical Chemical Biological Awareness Training (CBAT) seminar wargames for U.S. Pacific Command, U.S. European Command, and U.S. Central Command and two for U.S. Forces Korea. These seminars, for senior and executive level officials, were highly successful and have led to an increase in demand for this type of training. The CBAT games were a predecessor to the current series of Command and Staff Awareness Training (CSAT) seminar games programmed for FY 2000 through 2004. The purpose of these games is to provide an open forum for commanders and staffs to increase their awareness and explore contemporary issues, concepts, doctrine and policies relating to the medical aspects of chemical and biological defense. Most recent exercises include "Crimson Cross" CSAT for Third Medical Command and "Orbit Comet '00" CSAT for XVIII Airborne Corps & Fort Bragg. "Orbit Comet" involved Pope Air Force Base as well as the communities of Spring Lake and Fayetteville, NC. This seminar wargame considered the operational and medical implications of a terrorist WMD attack on Fort Bragg and the impact on the XVIII Airborne Corps to sustain force projection operations during the response. Subsequent CSAT seminars are currently scheduled for I Corps and III Corps.

The AMEDD and OTSG since 1996 have conducted a series of medical chemical biological exercises including Chemical Biological Awareness Training (CBAT) seminar war games for U.S. Forces in Korea, USPACOM, USEUCOM and USCENTCOM. These seminars, for senior and executive level officials, were highly successful and have led to an increase in demand for this type of training. The CBAT games were a predecessor to the current series of Command and Staff Awareness Training (CSAT) seminar games. The purpose of these games is to provide an open forum for commanders and staffs to increase their awareness and explore contemporary issues, concepts, doctrine and policies relating to the medical aspects of chemical and biological defense. The AMEDD, besides sponsoring the exercises listed below, has participated in numerous other WMD/NBC exercises.

- "Exercise Terminal Breeze 96" - Provided an opportunity for law enforcement, health and medical, fire, environmental and emergency management agencies of Virginia, Maryland, and Washington, D.C. to work with the military community in examining plans, policies and procedures for crisis and consequence management in response to a WMD terrorist attack.
- "Chem Bio Awareness Training (CBAT) PACOM Aug 96" - U.S. assesses readiness of current forces to engage in CBD operations against North Korea and formulate reinforcement package options to enhance capabilities of in-theater forces to survive in a CB environment.
- "Exercise Coral Breeze" CBAT-Korea, Mar 97 - Assessment of impact of North Korean use of CB weapons on Us forces during deployments and Reception, Staging, Onward Movement and Integration (RSOI), conduct of non-combat evacuation operations and warfighting.
- "Exercise Azure Haze" CBAT EUCOM, Nov 97 - Provided awareness training to EUCOM, USAREUR & 7th Army, community and appropriate agencies on consequence management responses to a casualty-producing chemical substance incident on a US installation

- "Exercise Crimson Shield" Joint Medical Planners Workshop, Korea, Feb 98 - Assessed salient issues and identified actions that US and ROK commands need to consider when faced with NBC attacks during the conduct of a Major Theater War in Korea. Allowed development of action plans to improve theater medical readiness, capabilities and mitigate risks. Provided data and a conceptual framework for modifications to existing doctrine, policies, programs and OPLANs. Identify intersections between combatant commanders' and medical operations and commanders' needs and identified medical considerations for NEO in WMD environment.
- "Exercise CBAT-CENTCOM", Feb 99 - Seminar game that corresponds to OPLAN 1003-96. The scenario was a major contingency in Gulf in 99–00 requiring US and coalition deployments and health service support operations under CB conditions. Provided commanders and staffs a conceptual baseline for framing options to CB threats and attacks. Enhanced planning for operations in a CB environment and identified areas requiring further coordinated research, analysis & program development.
- "Exercise Crimson Cross", Command and Staff Awareness Training (CSAT), 3rd MEDCOM, Sep 00 - Identify HSS vertical integration problems in a theater land component with respect to: C4I; logistics; preventive medicine; patient movement and regulation; Joint connectivity and integration during a WMD event. Capture insights for Army efforts such as: continued evolution of medical organizations; doctrinal development and harmonization; and medical elements of the Army Transformation Strategy.
- "Exercise Orbit Comet", CSAT XVIII ABN Corps, Oct 00 - Exercise considered the operational and medical implications of a mass casualty incident resulting from a terrorist attack involving a chemical agent on Ft Bragg and the impact of the terrorist attack on XVIII ABN Corps' ability to sustain force projection operations during the response. The exercise also involved the local communities and the USAF. It involved WMD consequence management operations including medical and mass casualty management, antiterrorism and force protection and maintaining the capability to deploy forces as directed by appropriate authority, during and immediately following a natural or manmade catastrophic event on Ft Bragg.
- "Exercise Urgent Response" CSAT I Corps - Medical NBC AC/RC Conference, Apr 01 - Provided the forum to improve the NBC awareness of attendees and their organizations. The exercise centered around the deployment of an I Corps Joint Task Force for Consequence Management (JTF-CM), including 2d Medical Brigade and subordinate units, deploying to Thailand to provide medical assistance in response to the use of a biological weapon (smallpox).

4.3.2 Air Force

Air Force policy is to provide initial and annual refresher training to military personnel and emergency essential civilians in or deployable to chemical-biological threat areas, especially personnel in NBC medium and high threat areas (HTAs). The Air Force standards of proficiency are based on two international standardization agreements: NATO Standardization Agreement 2150 (NATO Standards of Proficiency for NBC Defense) and Air Standardization Coordinating Committee

(ASCC) Air Standard 84/8 (Initial, Continuation and Unit NBC Standards). Both agreements are currently implemented through Air Force Instruction 32-4001, *Disaster Preparedness Planning and Operations and will move to AFI 10-2501, Full Spectrum Threat Response Planning and Operations in March 2002.* The Air Force ensures proficiencies and currency of NBC warfare defense training through classroom training, unit level training, and exercises. NBC Defense Training (NBCDT) is required only for military personnel and emergency essential civilians in or deployable to NBC threat areas. Major Commands (MAJCOMs), the Air Reserve Component, and Direct Reporting Units may tailor their NBCDT programs to meet their specific mission requirements. The subjects presented in the classroom follow the three principles of NBC defense (avoidance, protection, and decontamination) as identified in Joint Pub 3-11. Unit level training follows the classroom training on wartime mission critical tasks. Supervisors train personnel to complete mission critical tasks while the workers are wearing their full complement of individual protective equipment. Exercises are used for training and evaluation purposes. NBC Defense training instructors at base level receive their professional training through Air Force Apprentice and Advanced courses at Fort Leonard Wood, Missouri.

Individual Training. There are two types of individual training. The first is general equipment and procedures training that enables personnel to recognize and protect themselves and others from NBC hazards. The second is individual proficiency training that enables personnel to perform their wartime tasks in an NBC-contaminated environment. Detailed training comes with assignment to a threat area or to a deployable unit. NBC Defense training is required for military personnel and emergency essential civilians who are in or identified as "tasked to deploy" or "identified to deploy" to a medium or high threat area, as well as any conventional threat areas. Individuals graduating from Air Force Basic Military Training will receive credit for NBC Defense Initial training. Personnel receive NBC defense training courses, as shown in Table 4-2. (Requirement changes per draft AFI 10-2501 are included in parenthesis)

Table 4-2. Air Force NBC Defense Individual Training

AUDIENCE[1]	TYPICAL INITIAL INSTRUCTION TIME	INITIAL (FREQUENCY)	REFRESHER (FREQUENCY)	REMARKS
Low threat	6 hours (8 hours)	Within 90 days of assignment to mobility positions or 90 days prior to permanent change of station (PCS) to a CB high threat area. (Within 60 days of arrival to the installation)	Annual show of competency or as directed by MAJCOM. (Within 15 months thereafter) (4 hours)	Allow extra time for quantitative fit testing (QNFT)/ confidence exercise and CCA training.
Medium threat	6 hours (8 hours)	Within 90 days of arrival (Within 30 days of arrival)	Within 90 days of arrival (Within 15 months thereafter) (4 hours)	See Note 2
High threat	6 hours (8 hours)	Within 90 days prior to PCS to high threat area. (Within 60 days prior to arrival)	Within 30 days of arrival - topics should only include theater specific procedures and QNFT. (Same as above) (Annually Thereafter)	See Note 2

1. NBC Defense Training is required for military personnel and emergency essential civilians in or deployable to chemical-biological medium and high threat areas.

2. Initial training is required if there has been a break of 36 months or more in NBC defense training.

NBC refresher training is at the discretion of the MAJCOMs, with the majority opting for annual refresher training through classroom training and exercise participation. Individual NBC proficiency training occurs through on-the-job-training and exercise participation. In addition, aircrews are required to conduct a one-time flight while wearing chemical defensive equipment.

Air Force major commands have reported significant increases over the last three years in the number of people receiving equipment and procedures training as well as the number of hours spent for that training.

Unit Training. Units in or deployable to NBC threat areas must conduct the following training:

Table 4-3. Air Force NBC Defense Unit Training

CB Threat Area	Minimum Exercise Requirements
Low	**Annually** - Conduct attack response exercise implementing the base OPlan 32-1 and other contingency plans (*i.e.*, NBC, terrorist, or conventional attack). - Conduct an attack response exercise for units' mobility commitments based upon the threat at deployment locations.
Medium	**Semiannually** - Conduct attack response exercise implementing the base OPlan 32-1, BSP, and other contingency plans (*i.e.*, NBC, terrorist, or conventional attack). One exercise may be satisfied by a tabletop exercise. - Conduct attack response exercise for unit mobility commitments based on the threat at deployment locations. One exercise can be satisfied by a tabletop exercise.
High	**Semiannually** - Conduct attack response exercises implementing the base OPlan 32-1, BSP, and other contingency plans.

Medical Training Initiatives. Following the Air Force Medical Service (AFMS) NBC Warfare Defense Training Workshop in 1998, eleven training initiatives were prepared to meet gaps in Air Force chemical and biological medical defense training. Training tools for the AFMS re-engineered unit type codes, such as: (1) Patient Decontamination Teams, (2) Chemically Hardened Air Transportable Hospital, (3) Preventive and Aerospace Medicine (PAM) team training, (4) Bioenvironmental Engineering NBC team training, (5) PACAF AFMEDPAC 2000, (6) Continuing Medical Readiness NBC training, (7) NBC CD-ROM Toolboxes, (8) ACC/ Force Protection Battle Lab Initiative – Bio Agent detection training, and (9) NBC Defense Leadership Skills training were identified for contractor development. The Army (funded by the AF) is the office of primary responsibility for the final initiatives: (10) Medical Management of Chemical Casualties,(11) Medical Management of Biological Casualties, and (12) NBC CD-ROMs. The AFMS is participating in satellite provided Medical Management of Chemical Casualties hosted by USAMRICD/USAMRIID respectively. Additionally, the NBC CD-ROMs were distributed to every AFMS medical treatment facility in FY00. The AF IERA trained four students per AEF rotation cycle on PCR based clinical pathogen diagnosis supporting the Biological Augmentation Team UTC. Care providers who have not been afforded the opportunity to attend the Army MCBC Course will receive an instructor-based course on medical management of chemical and biological casualties training at their units. Overseas locations have priority over CONUS bases for this initiative. In addition, identified medical UTC

teams will receive medical reference materials developed by the US Army and civilian contractors for training.

4.3.3 Navy

Navy Chemical, Biological and Radiological Defense (CBR-D) training is conducted in two phases: individual and unit training. Individual training consists of attendance at formal school courses and completion of Basic and Advanced CBR Defense Personnel Qualification Standard (PQS) training. Navy personnel also conduct periodic unit CBR Defense training and pre-deployment unit training exercises.

Individual Training. The Navy provides initial entry-level CBR defense training to all officers and enlisted personnel in the accession programs. Enlisted personnel receive three hours of training (two hours in the classroom; one hour in the lab) focused on the use of personal protection equipment and survival skills, including a CBR-D "confidence" chamber exposure. Officers receive two hours of class time focused on personal protection equipment and survival skills.

Officer and Enlisted Personnel assigned to ship and shore billets requiring CBR-D expertise receive additional CBR-D related courses. These courses include the Disaster Preparedness Specialist Course and the CBR-D Operations and Training Specialist Course conducted at the U.S. Army Chemical School. Additional CBR-D training is covered in the Repair Party Leader Courses conducted at various Fleet Training Centers. Officers receive additional CBR-D related training at the Damage Control Assistant Course, the Shipboard Department Head Course, the Prospective Executive Officer Course, and the Prospective Commanding Officer Course held at the Surface Warfare Officer School, Newport, RI.

Navy medical providers attend the Management of Chemical and Biological Casualties Course at the U.S. Army Medical Research Institute for Chemical Defense and the U.S. Army Medical Research Institute of Infectious Diseases. The Navy Environmental Health Center (NEHC) sponsors a three-day course for providers, and a one-day familiarization/awareness course. Additionally, NEHC is actively developing a "distance-learning", CNET web-based, provider course expected to be on-line by June 2002.

After reporting to designated units, Navy personnel are required to complete basic and advanced CBR-D Personnel Qualification Standards (PQS) training. PQS is a compilation of the minimum knowledge and skills that an individual must demonstrate in order to qualify to stand watches or perform other specific duties necessary for the safety, security or proper operation of a ship, aircraft or support system. The objective of PQS is to standardize and facilitate these qualifications. Basic and Advanced level Chemical, Biological, Radiological (CBR) Defense PQS are contained in NAVEDTRA 43119-H. Basic level CBR PQS, which is required for all personnel assigned to a command, and consists of "CBRD Fundamentals-Watchstation 106" and "Basic CBR Defense-Watchstation 306." (See Table 4-4) Advanced level CBR PQS is required for personnel assigned to CBR teams, including Detection Teams, Decon Station Teams, Internal/External Monitoring Teams, Decontamination Teams and Team Leaders. Advanced level PQS consists of "CBR Detection Equipment Systems-Watchstation 215" and "Advanced CBR Defense Person- Watchstation 309."

Table 4-4. Navy Basic CBR Defense Standards

• Complete Chemical, Biological, Radiological Defense (CBRD) Fundamentals PQS
• Locate and transit Decontamination station/ CCA stations
• Locate Casualty Collection stations and Deep Shelter Stations
• Don and doff Chemical Protective Ensemble
• Change protective mask canister
• Use the M-291 skin decon kit
• Demonstrate self and buddy aid for nerve agent exposure
• Identify CBR markers
• Use M8 and M9 paper
• Pass through CPS air lock/pressure lock
• Decontaminate internal and external areas
• Satisfactorily perform or simulate immediate actions for the following emergencies: nuclear attack, chemical attack, biological attack, nuclear radiation exposure, chemical agent exposure, and biological agent exposure.

Unit Training. Proficiency training is conducted at the unit level by Navy instructors, who are graduates of the CBR-D Operations and Training Specialist Course conducted at the U.S. Army Chemical School. Navy units conduct Basic, Intermediate, and Advanced training exercises as part of the Inter-Deployment Training Cycle . During the Basic training phase, CBR-D training exercises may involve additional unit training by CBR-D specialists from an Afloat Training Group (ATG).

Early in the Basic training phase, a ship is required to conduct a Command Assessment of Readiness and Training (CART) which is a performance based assessment of a unit's readiness in each mission area. CART assesses material, administrative, and training proficiency. By the end of the Basic Training Phase, ships are required to be proficient in all missions areas and have demonstrated the ability to sustain readiness through their internal training team organization. Internal CBR training is conducted by the ship's Damage Control Training Team (DCTT).

A Final Evaluated Problem (FEP) is the culmination of the Basic training phase and demonstrates the ship's ability to conduct multiple simultaneous combat missions and support functions and to survive complex casualty control situations under stressful conditions. The conduct of the FEP is dependent upon the ship's previously demonstrated proficiency and may require the ship to progress through all mission oriented protective postures (MOPP) levels as part of a chemical defense exercise. After completion of the Basic training phase, the completion of a Chemical Defense Drill is a repetitive requirement, conducted every six months.

The Intermediate and Advanced training phases consist of multi-ship and battle group training directed by a numbered fleet commander. Emphasis is placed on integrated watch section training in a fully coordinated multi-threat environment. During the intermediate and advanced phases of the training cycle, combat readiness is reinforced through Composite Training Unit Exercises (COMPTUEXs) and Fleet Exercises (FLEETEXs).

4.3.4 Marine Corps

The Marine Corps' NBC training focuses on the ability to conduct operations throughout the battlespace with particular emphasis on amphibious deployment, littoral, and air/ground operations. The Marine Corps views NBC as an environment, similar to daylight/darkness and cold/heat, yet with its own unique challenges.

Training requirements are derived from the Force Commander's Mission Essential Task Lists, Joint Universal Lessons Learned, Marine Corps Lessons Learned, Mission Need Statements, and Universal Needs Statements. Once validated, the training requirements are introduced into the Systems Approach to Training (SAT) Process. One of the results of the SAT process is the development of training tasks and standards that will fulfill the training requirements. These task lists and standards are incorporated into Individual Training Standards (ITSs) for individual Marines and Mission Performance Standards (MPS) for Marine units. These ITSs and MPSs are published as Marine Corps Orders for standardization and compliance throughout the Marine Corps. During FY02, ITSs and MPSs related to NBC defense training will be updated and begin transition to a newer, more effective Training & Readiness (T&R) Manual format. The T&R Manuals provides greater specificity in standards and will enhance commanders' abilities to determine readiness based on training accomplishments.

The Marine Corps conducts training in two categories: Individual Training based on ITSs and Collective (unit) Training based on MPSs. Figure 4-1 shows the individual NBC training provided to all Marines.

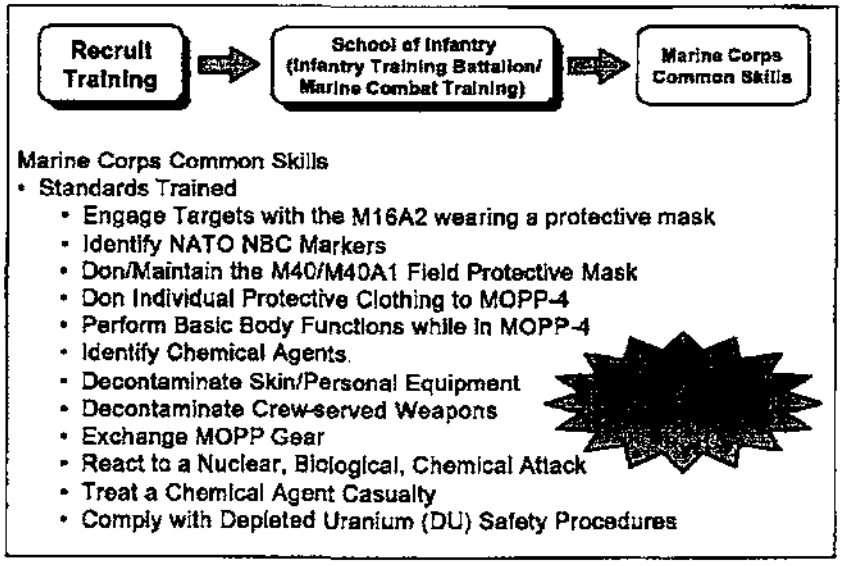


Figure 4-1. USMC Individual NBC Training

Individual Training. Marine entry-level training begins at recruit training or at Officers Candidate School (OCS) where Marines are introduced to the field protective mask and the CS chamber exercise. All enlisted Marines then proceed either to Marine Combat Training (MCT) or the School of Infantry (SOI) and, upon completion of OCS, all Officers proceed to The Basic School (TBS). The NBC portion of this training focus is surviving and functioning in an NBC environment. Training transitions from a classroom/academic environment to practical application/field environment in order to provide students more hands-on experience.

Once Marines reach their units they begin the Marine Corps Common Skills (MCCS) and Marine Battle Skills Training (MBST) program. MCCS and MBST tasks are individual training standards that all Marines are required to be proficient in and are evaluated on annually. Marine Battle Skills NBC training focuses on providing Marines with the capability to survive as well as function in an NBC environment. Senior Field grade and General Grade Officers attend the "United States Army Chemical School Joint Senior Leaders Course". These courses will round out the phases that the Marine Corps go through in the development of our Marines and Leaders to operate in an NBC environment

Unit Training. Unit level (or collective) training includes classroom and field training identified in unit training exercises and plans. (See figure 4-2.) Many units are also required to meet specific training standards. These requirements take the form of Mission Performance Standards (MPSs) for specific types of units such as infantry, artillery or tank units. These MPSs are published in the 3500 Series of Marine Corps Orders.

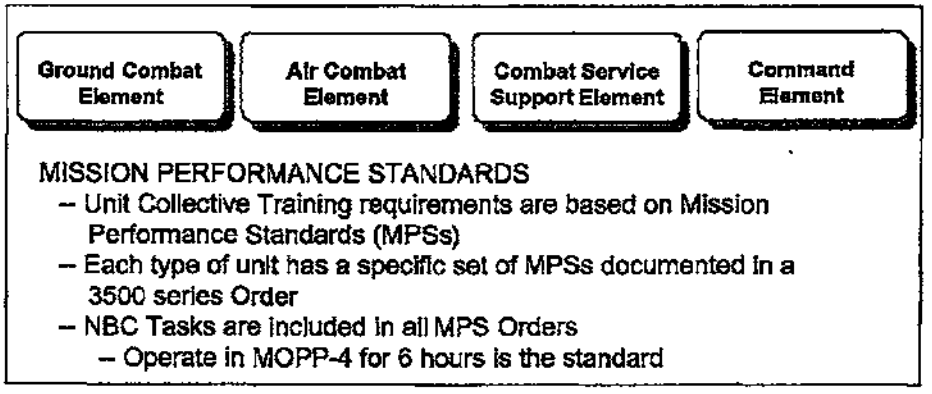


Figure 4-2. USMC Collective Training, NBC Requirements

Each MPS Order includes NBC Tasks that the unit must accomplish. However, each set of requirements varies from unit to unit. For example, a Tank Battalion must be able to utilize the vehicle's NBC filtration system, decontaminate tanks, and operate tanks under NBC conditions. An Infantry Battalion on the other hand has no requirement to decontaminate tanks, but does have to decontaminate crew served weapons. NBC training is validated through the Marine Corps' inspection program. Those units that are part of the Marine Corps' Unit Deployment Program (UDP) and designated Marine Expeditionary Units (MEUs) are required to undergo an NBC evaluation prior to

deployment. Units that do not have specific NBC defense MPSs are evaluated in NBC defense as part of routine Commanding Generals' Inspection Programs, normally conducted at least biennially.

4.4 NBC DEFENSE PROFESSIONAL TRAINING

Public Law 103-160 requires all Services to conduct NBC defense professional training at the same location. Currently, all Service training, except for medical NBC courses (as described in sections 4.3.1 and 4.3.2 above), is co-located at the United States Army Chemical School. Each Service conducts their training with their own Service instructors. The experts who graduate from the Service's technical training and the Army's Chemical Defense Training Facility become instructors for their Service's unit training. The Defense Nuclear Weapons School (DNWS), as part of the Defense Threat Reduction Agency (DTRA) Albuquerque Operations Office at Kirtland AFB, New Mexico, conducts a Radiological Emergency Team Operations Course; Radiological Emergency Medical Response Course; Radiological Accident Command, Control and Coordination Course; and Weapons of Mass Destruction Command, Control, and Coordination Course.

4.4.1 Joint NBC Defense Professional Training

The JSIG has established a Joint Training Sub-panel (JTSP) comprised of designated Service training representatives to:

- Promote Joint NBC Defense training.
- Monitor Joint NBC Defense training.
- Assess Joint NBC Defense training.
- Report on assessments and recommend solutions.
- Develop Joint Training Road Map.
- Produce a Joint NBC Defense Training Development guide.
- Enhance Joint War Fighting Operations.

Information exchanges between the Services were facilitated by the JSIG and plans put in place to review future doctrine and new equipment training plans.

Joint Professional Military Education, Phases I and II, currently contains a limited degree of NBC defense considerations and requirements. It is essential that officers of all Services assigned to joint staffs understand the NBC threat, are familiar with U.S. capabilities to detect and mitigate the threat, and comprehend their staff roles and responsibilities in dealing with NBC issues. Section 4.7.1 details an ongoing JSIG initiative that addresses these shortfalls. The JSIG also sponsors the Joint Senior Leaders Course at the USACMLS. This course is targeted at leaders from all services with the intent of increasing their awareness and understanding regarding NBC defense issues.

Within the joint medical arena, the U.S. Army Medical Department sponsors the Medical Management of Chemical and Biological Casualties (MCBC) course, which provides training to DoD personnel.

All Medical Nuclear Casualty Training has been consolidated under the Armed Forces Radiobiology Research Institute in Bethesda, Maryland, where radiobiology education is made available in a Tri-Service format.

4.4.2 Army NBC Defense Professional Training

- U.S. Army NBC Defense Professional Training presently takes place at Fort Leonard Wood, Missouri.
- Training consists of three enlisted/non-commissioned officer courses and two officer courses.
- At initial entry One Station Unit Training, enlisted soldiers receive training in chemical and biological agent characteristics and hazards, smoke and decontamination operations, chemical and radiological survey procedures, and individual protective clothing and equipment. This program provides 19 weeks of intensive training, culminating in live/toxic agent training in the Chemical Defense Training Facility. Toxic agent training is an integral, mandatory component of all Chemical Corps initial entry and professional courses.

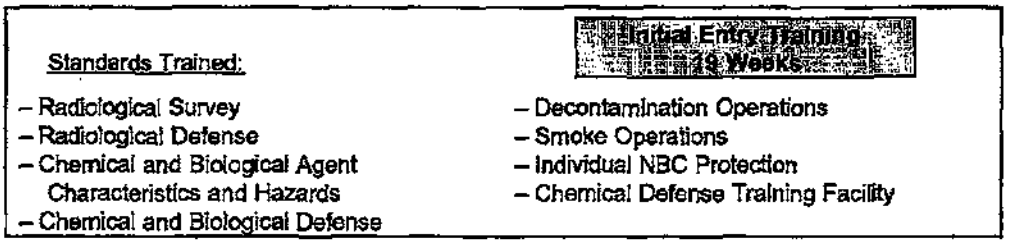


Figure 4-3. U.S. Army Initial Entry Training

- Chemical Corps sergeants attend the 9 week, 3 day Chemical Basic Non-commissioned Officer Course (BNCOC), where they are trained to be an NBC company squad leader and a non-chemical company or battalion NBC NCO.
- Chemical BNCOC provides the NCO with the technical and tactical skills needed to advise company/battalion commanders in NBC operations and procedures:
    - to train non-chemical soldiers in NBC avoidance
    - decontamination
    - protective measures
    - lead smoke/decontamination squads.
- Chemical Corps staff sergeants and sergeants first class attend the 7 week, 2 day Chemical Advanced NCO Course (ANCOC), where they are trained to be an NBC platoon sergeant, an NBC NCO at brigade level, and an NBC NCO in a division or Corps level NBC element.
    - advanced technical operations
    - hazard estimates
    - logistics and maintenance management
    - combined arms operations
    - smoke and flame support
    - training management.
- Chemical Corps lieutenants attend a 19-week officer basic course, 10-weeks during mobilization. Reserve Component officers must attend the resident course.

- The Maneuver Support Center (MANSCEN), instructs the 3-weeks of common lieutenant training from the Chemical, Engineer, and Military Police schools. The Chemical Officer Basic Course (COBC) prepares lieutenants to serve as a Chemical Corps platoon leader or as a non-chemical battalion chemical staff officer/assistant operations officer. This course provides them with a fundamental knowledge of:
    - NBC agent characteristics and hazards
    - NBC recon (non-FOX), decon, and smoke operations
    - NBC staff functions
    - NBC defensive planning
    - individual and unit tactical operations
    - biological detection operations
    - Completion of live/toxic agent training is a prerequisite for graduation.
- Chemical Corps captains attend the Captain's Career Course, an 18-week officer advanced course. Extensive use is made of computer simulations to reinforce the application of NBC assets in support of tactical operations. In the MANSCEN configuration, the Chemical Officer shares training with Military Police and Engineer Officers in Common Training, Shared Tactical Training, and Brigade Battle Simulation Exercise (BBS), in which they are trained:
    - to serve as the commander of a Chemical Company
    - serve as NBC staff officers at the brigade and division level.
- Instruction focuses on:
    - leadership
    - Army operations
    - smoke and flame operations in support of maneuver units
    - biological detection operations
    - NBC defensive planning to include: hazard prediction, NBC reconnaissance and decontamination operations
    - nuclear, biological and chemical vulnerability analysis
    - operational radiological safety
    - environmental management

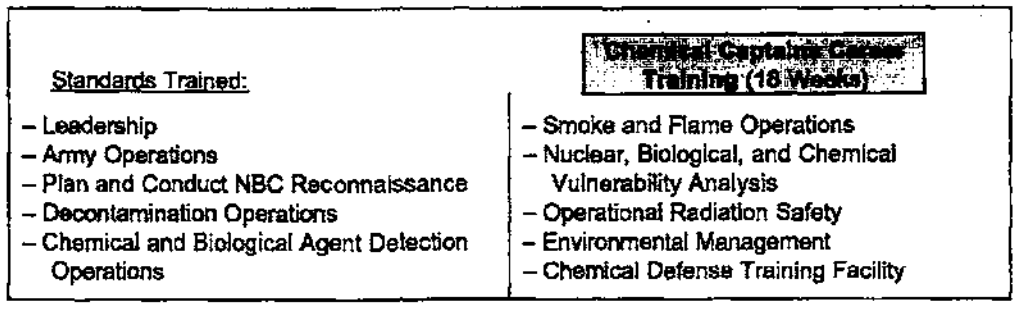


Figure 4-4. U.S. Army Captain's Career Course Officer Advanced Training

Specialized professional training is conducted in stand-alone courses attended by DoD, Allied, and international students. These courses include:

NBC Reconnaissance Operations (FOX)	(5 weeks)
Radiological Safety (Installation level)	(3 weeks)
Operational Radiation Safety	(1 week)
Decon Procedures (Non-US) (GE, UK, NE)	(1 week)
RADIAC Calibrator Custodian	(1 week)
Biological Detection Specialist (BIDS)	(5 weeks)
Master Fox Scout	(2 weeks)
Installation Emergency Responders Course	(1 week)

4.4.3 Air Force NBC Defense Professional Training

The Air Force training detachment at Fort Leonard Wood, Missouri offers five separate in-residence courses designed to enhance the NBC proficiency of primary-duty AF Civil Engineer Readiness Flight personnel. These courses fulfill the differing needs of the total force, including Active Duty, Air National Guard, and Air Force Reserve. Further, the Air Force administers a career development correspondence course and two mobile courses in airbase operability and NBC cell operations. The AF courses range from 53 days for the Apprentice course; 10 days for the Craftsman and Readiness Flight Officer Courses; Five days for the NBC Cell Advanced and Mobile Air Base Operations and Advanced Readiness courses. The Air Force also offers computer based Qualification Training Packages (QTPs) that have been developed for most NBC Defense Equipment items, and are included as part of professional upgrade training.

Each course contains a wide range of materials covering critical aspects of Readiness Flight operations in situations ranging from peacetime, military operations other than war, through wartime. The following is a synopsis of the NBC aspects of these courses.

Training for personnel being assigned primary readiness duties includes comprehensive coverage of agent characteristics and hazards (to include determination of incapacitation/ lethality levels); nuclear weapons effects and other specific hazards associated with ionizing radiation; NBC detection and contamination control and contamination avoidance techniques; plotting and reporting procedures; detailed NBC persistency and duration of hazard calculations to provide advice on MOPP variations; the inter-relationship between NBC defense and other passive defense activities (*e.g.*, camouflage, concealment, and deception, (CCD), dispersal, and hardening, *etc.*); and systematic analysis procedures for assessing hazards identification, vulnerability assessment, and risk assessment and providing credible mission continuation (sortie generation) and force survivability advice to commanders.

Air Force learning theory emphasizes hands-on training, and the school makes extensive use of available training ranges and equipment. The school includes Chemical Defense Training Facility (CDTF) toxic agent training in four of five in-residence courses. Training is provided on every major piece of NBC detection and decontamination equipment available in the field today, including state-of-the-art items currently being fielded.

The Civil Engineer (CE) Readiness Flight Officer and 7-level Craftsman courses provide flight leaders and mid-level NCOs with the background and technical information that is necessary for effective management of the CE Readiness Flight and contingency response operations.

Readiness is the key to successful Air Force operations. Consequently, the various aspects of CE Readiness Flight operations, including NBC defense, are also topics of instruction at briefings for Air War College, Air Force Institute of Technology, and the Joint Senior Leaders Course. Readiness personnel receive additional training on wartime and contingency aspects of NBC defense at one of three Silver Flag Exercise sites. These sites are located at Tyndall AFB, FL, Kadena AB, Japan, and Ramstein AB, Germany. Personnel deploy with their complete complement of personal NBC protective equipment and receive comprehensive training that builds upon their baseline knowledge in the areas of NBC detection, NBC reconnaissance, decontamination, warning and reporting and equipment use and inspection. Silver Flag also trains Readiness personnel on newly fielded equipment items, new techniques and procedures, and equipment that is not available at all installations.

The School of Aerospace Medicine at Brooks AFB trains over 7,000 students per year in a variety of AFMS readiness specialties. These courses are tailored to the approved and registered medical deployable NBC related unit type code assemblies. Bioenvironmental Engineering NBC Operations provide specialized medical detection, surveillance, and risk assessment training to 88 officers and 7-level NCOs per year. Critical Care Air Transport Team training includes movement of CB casualties at 250 students per year. Contingency Public Health Operations focuses on early recognition, evaluation and control of disease (including CB casualties) through expeditionary preventive medicine. Other specialty courses include NBC Battlefield Nursing, Preventive and Aerospace Medicine contingency training, Global Medicine, Military Tropical medicine and Medical Survival training. The AF Institute for Environment, Safety, and Occupational Health Risk Analysis, also at Brooks AFB, teaches PCR-based biological agent clinical diagnosis for members of the AF biological augmentation team.

4.4.4 Navy CBR Defense Professional Training

The Navy Construction Training Center Detachment at the U.S. Army Chemical School, Fort Leonard Wood, Missouri, offers two courses of instruction for Navy CBR-D specialists. The courses are open to Navy, Coast Guard, Military Sealift Command, and select foreign military personnel, E-5 and above. Courses are designed to provide both afloat and ashore commands with individuals who can successfully perform their requisite duties in a CBR contaminated environment. In addition, the training enables CBR-D specialists to act as the primary CBR-D trainers for their respective commands.

The training, conducted at Fort Leonard Wood, capitalizes on the unique capabilities of the Army Chemical School and makes extensive use of the Chemical Defense Training Facility (CDTF). Approximately 200 students graduate annually from the Detachment's courses. In addition to being fully qualified to conduct training using the Army's facilities, the Navy Detachment actively participates as part of the JAWG.

In addition to CBR-D Specialist courses conducted at the US Army Chemical School, the Navy has incorporated CBR-D readiness training into courses that are attended by personnel at all levels of professional development.

Course Name	Course Location
Recruit Training CBR-D	Naval Training Center Great Lakes, IL
Damage Control "A" School	
Senior Enlisted Damage Control	Fleet Training Center San Diego, CA
Hospital Corpsman "A" School	Naval Training Center Great Lakes, IL
Independent Duty Corpsman	Naval School of Health Sciences San Diego, CA and Naval School of Health Sciences Portsmouth, VA
Management of Chemical Casualties	U.S. Army Medical Research Institute for Chemical Defense, Aberdeen Proving Ground, MD
Medical Affects of Ionizing Radiation	Armed Forces Radiobiology Research Institute Bethesda, MD
Radiation Health Indoctrination	Naval Undersea Medical Institute Groton, CT
Radiation Health Officer	
CBR-D Command Center	Naval Construction Training Center Gulfport, MS
CBR-D Personnel Protection	
CBR-D Team Training	Naval Construction Training Center Gulfport, MS and Naval Construction Training Center Port Hueneme, CA
MSC CBR-D Course	Military Sealift Command Training Center Earle, NJ
Repair Party Leader	Fleet Training Center San Diego, CA Norfolk, VA; Mayport, FL Ingleside, TX Pearl Harbor HI; Yokosuka, Japan
Repair Party Officer Short Course	Surface Warfare Officers School Newport, RI
Division Officer	
Damage Control Assistant	
Department Head	
Executive Officer	
Commanding Officer	

4.4.5 Marine Corps NBC Defense Professional Training

The Marine Corps NBC Defense School at Fort Leonard Wood consists of an Enlisted Basic NBC Defense Course, and an Officer Basic NBC Defense Course. In addition to the courses conducted by the Marine Corps NBC Defense School, Marines attend four other functional courses (Chemical Captain's Career Course, Radiological Safety Officer Course, NBC Reconnaissance Course, and the Master FOX Scout) conducted by the U.S. Army Chemical School at Fort Leonard Wood

The USMC Enlisted Basic NBC Defense Course trains approximately 220 NBC Defense Specialists in a comprehensive 10-week program covering all the ITSs specified in MCO 1510.71. The course not only trains Marines to perform their wartime duties but also provides them with the tools they will need on a daily basis to perform their primary peacetime mission of conducting NBC Defense training for their assigned units. The course is divided into eight blocks of instruction as shown in Figure 4-5.

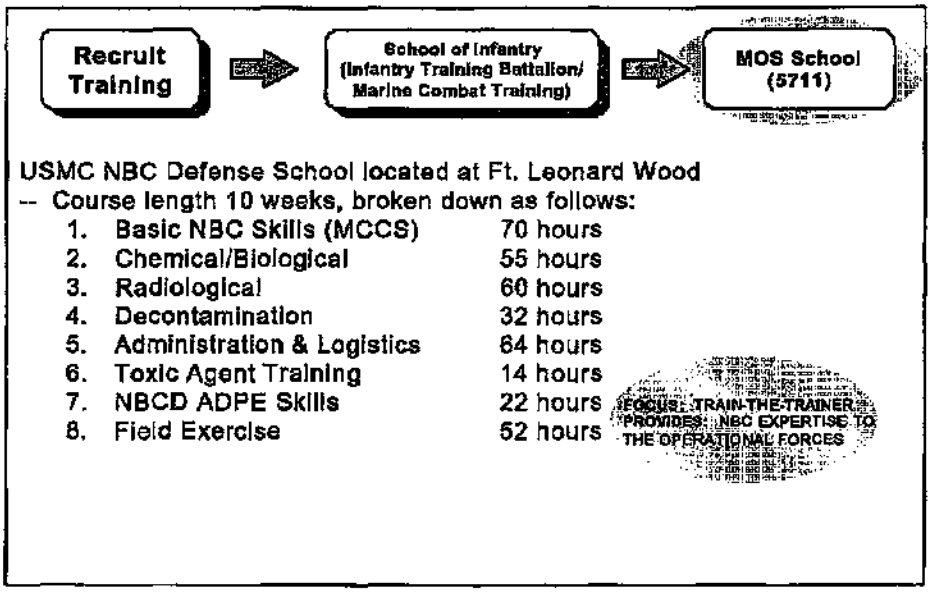


Figure 4-5. USMC Individual Training (Enlisted NBC Specialists)

All Marine NBC Officers are Warrant Officers. As Warrant Officers, they focus entirely on technical expertise, NBC defense operations, training, and supervision of enlisted NBC defense specialists. Many of the Marine Corps' NBC Defense Officers also attend the U.S. Army's Chemical Captains Career Course and other Joint NBC courses as part of advanced Military Occupational Specialist (MOS) training. The NBC Warrant Officer's course is divided into eight blocks as outlined in Figure 4-6.

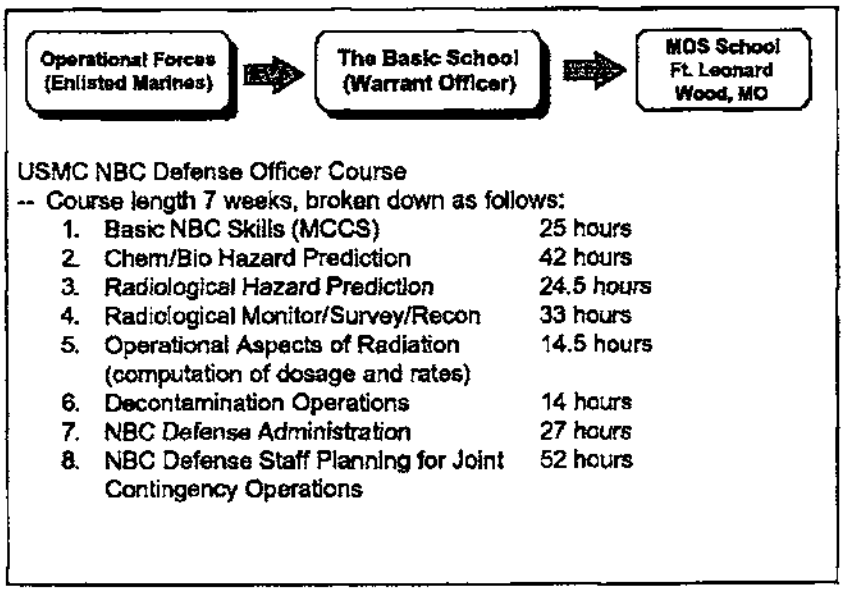


Figure 4-6. USMC Individual Training (Training for NBC Officers)

4.5 TRAINING IN A TOXIC CHEMICAL ENVIRONMENT

In 1987 the Army established the Chemical Defense Training Facility (CDTF) at Fort McClellan, Alabama. In October 1999, the Chemical School started training students at its new facility at Fort Leonard Wood, Missouri. The CDTF trains military and civilian personnel in a toxic chemical environment. Since its opening, the Army has used this valuable resource to train over 58,000 U.S. and Allied military personnel as well as selected DoD civilians. The CDTF promotes readiness by providing realistic training in the areas of detection, identification, and decontamination of chemical agents. The training develops confidence in chemical defense tactics, techniques, procedures, and chemical defense equipment. Instructors ensure that trainees can adequately perform selected tasks on a chemically contaminated battlefield. To date, the CDTF has maintained a perfect safety and environmental record.

Enrollment at the Joint Senior Leaders Course and the Toxic Agent Leader Training Course at Ft. Leonard Wood, Missouri continues to be in demand. Over 2,000 active and reserve commanders, service leaders, and toxic agent handlers from each of the services have attended. These personnel become very familiar with NBC considerations. Additionally, toxic chemical environment training provides senior officers, commanders, and future NBC defense specialists confidence in their doctrine, warfighting techniques, and the equipment they fight with in the face of challenges presented by NBC contamination.

The Weapons of Mass Destruction Civil Support Teams (WMD-CST) are trained at the Fort Leonard Wood facility. The facility has the flexibility to design toxic chemical agent training to prepare the WMD-CST for this unique mission — assisting civil authorities facing the threat of domestic terrorism involving weapons of mass destruction.

There is continued international interest in CDTF training. Germany and the Netherlands use the CDTF, Denmark and the United Kingdom have expressed interest.

Finally, Federal and state law enforcement agencies and other first responder-type agencies have also participated in the training. The Chemical School continues to support requests from civil authorities for toxic chemical agent training.

4.6 INTEGRATION OF REALISM/WARFIGHTEREXERCISES

4.6.1 Simulations and Warfighter Exercises

There are three types of simulations: live, constructive and virtual. Simulations may also be sub-grouped as training or analytic simulations.

Live simulations involve real people operating real systems. Such simulations are also known as exercises and are discussed further in the next section.

Constructive simulations allow battles to be waged on a synthetic battlefield. They are designed to give commanders and their staffs the opportunity to make decisions during a course of a battle, adjust plans to react to enemy movements, synchronize all available assets and learn, through the After Action Review (AAR) process.

Virtual simulations are designed for training and analysis primarily at the tactical level of war. These simulations are "mock-ups" of actual vehicles and give units an opportunity to train on necessary individual, crew and collective tasks without having to maneuver actual equipment in the field. While the crews maneuver their equipment around the battlefield, the rest of the environment is generated through the use of Semi-Automated Forces (SAF). SAF are computer representations of adjacent elements, the enemy, and the environments upon which the battle is waged. SAF elements not only look like other units they can be programmed to perform tasks/missions autonomously, thus adding to the realism of the training.

There are over 750 virtual and constructive models and simulations in the Army community alone. Table 4-5 lists the primary battle command simulations in current use throughout the Army and their baseline ability to use NBC events in their scenarios. However, characterization of NBC effects in these models and simulations is limited. Very few combat simulations incorporate the effects of NBC, and none incorporate all aspects.

Table 4-5. Nuclear (N), Biological (B), Chemical (C), or Radiological (R) Capability In Current Constructive Simulations

NAME	USE	FIDELITY	N	B	C	R
Corps Battle Simulation (CBS)	Training	Operational	X		X	X
SPECTRUM	Training	Operational				
Brigade Battle Simulation (BBS)	Training	Tactical	X		X	X
Conflict Evaluation Model (CEM)	Analytic	Joint/Strategic	X	X	X	
TACWAR	Analytic	Joint/Strategic	X	X	X	
Vector In Command (VIC)	Analytic	Operational			X	
Computer Assisted Map Exercise (CAMEX)	Analytic	Operational				
EAGLE	Training	Operational				

Combined Arms and Support Task Force Evaluation Model (CASTFOREM)	Analytic	Tactical	X		X	
JANUS	Training/Analytic	Tactical			X	

Current training exercise warfighting simulations have not received sufficient priority and/or funding to adequately portray NBC effects and challenge commanders and staffs to apply NBC defense doctrine and leader-development training strategies to prepare their forces to maintain operational continuity and achieve mission success in an NBC environment. To be an effective training mechanism, these simulations must challenge training audiences to understand adversaries' NBC intent and capabilities. Simulations must also allow players to visualize how NBC capabilities affect the battle space, friendly courses of action, tactics, techniques and procedures, and operation plans to allow players to apply NBC defense principles and capabilities to set conditions for mission success against NBC threats. Warfighting simulations—Joint Warfare System (JWARS), Joint Simulation (JSIMS), and Joint Conflict and Tactical Simulation (JCATS)—are in development to accurately replicate the NBC hazards of future battlefields and their effects on friendly systems. These warfighting simulations will enable commanders staffs, and soldiers, airmen, and sailors to train and develop required high-order battlefield cognitive skills that will allow for full integration of enemy intent and capabilities, NBC environment effects, and friendly force capabilities while planning and executing operations.

There is currently no standardized Instrumentation System that can realistically portray all facets of NBC effects during field training. The U.S. Army Chemical School has developed NBC Recon training interface devices allowing Multi Integrated Chemical Agent Detector (MICADS) to link the FOX Reconnaissance Vehicle into the Combat Training Center (CTC) instrumentation for the detection and tracking of simulated NBC contamination at CTCs and home station training areas. Resourcing will be pursued to upgrade the fielded training device interfaces at CTCs and other locations. The upgraded MICADS interface to the Instrumentation System will retrieve, process, and calculate digital contamination data for maneuver units and will also include AAR feedback in the areas of NBC casualties, change of custody, and reaction procedures during NBC attacks and operations. This Instrumentation System will provide a realistic replication of NBC contamination as portrayed on the battlefield.

The requirement to establish a baseline capability within the emerging OneSAF Test Bed version B simulation was completed. This baseline capability is interoperable with high level architecture and works as an NBC environment and effects model in both constructive and virtual simulations. Further development of the capability awaits funding.

The virtual simulation for the M93A1 NBC Reconnaissance System is operational at Fort Leonard Wood, Missouri. Future systems are planned for Fort Hood, Texas (installed in FY 02) and Fort Polk, Louisiana (installed in FY 03).

A virtual simulation for the P3I BIDS system has been installed at Fort Leonard Wood, Missouri. A portable unit has been installed with the 7th Chemical Company, stationed at Fort Polk, Louisiana. The Fort Polk system will be tested in FY 02.

4.6.2 Joint NBC Training/Joint and Combined Exercises

Chairman of the Joint Chiefs of Staff (CJCS) Exercise Program. Joint Vision 2020 provides the operational based templates for the evolution of our Armed Forces to meet challenges posed by an adversary's use of weapons of mass destruction. JV 2020 serves as the Doctrine, Training, Leader-development, Organization, and Material (DTLOM) requirements benchmark for Service and Unified Command visions. The NBC defense cornerstone resource for this vision of future warfighting embodies three required operational imperatives:

First, and most importantly, CJCS and Service leaders should recognize that NBC strategic and operational level of war expertise is an essential resource requirement in the Joint Warfighter Center (JWFC) and USJFCOM Joint Training and Analysis Center (JTASC). Success for Joint Vision 2020, a strategy centered on capabilities-based forces, requires these organizations to successfully accomplish their respective joint NBC defense doctrine, training, and leader development roles, and for USJFCOM to accomplish its NBC defense mission as force provider, force trainer, and force integrator. NBC expertise at all levels and from all Services is paramount.

Second, Unified Commands should staff their organization appropriately with the right expertise to meet current and future requirements to shape and respond to NBC challenges.

Third, doctrine, training, and leader-development training strategies should facilitate sophisticated battlefield visualization and situational awareness proficiency, allowing commanders and staffs to conduct service, joint, and combined operations in an NBC environment.

The Chairman of Joint Chiefs of Staff published Master Plan Exercise Guidance in May 1998. This guidance provides exercise objectives to the CINCs. This guidance provided specific counterproliferation objectives. NBC Defense and Force Protection were identified as the Chairman's top training issues. This guidance will influence and guide development of CINC exercises and training, which will be conducted in Fiscal Year 2001.

As examples of Joint training and exercises, U.S. Pacific Command (USPACOM) training includes the following Joint Mission Essential Tasks (JMETs):

- Strategic Theatre (ST) 6.2 - Provide Protection for Theater Strategic Forces and Means - safeguarding friendly strategic and operational centers of gravity and force potential by reducing or avoiding the effects of enemy and unintentional friendly actions.
- Operational (OP) 6.2.8 - Establish CBW Protection in Theater of Operations/Joint Operating Area (JOA) - ensure we can detect, warn and report CBW events and protect against CBW threats in the operational area.
- Lessons learned from exercises on operational concepts, doctrine and readiness, have resulted in innovation and adaptation for USPACOM counter-CBW operations. Areas of innovation include contaminated aircraft Concept of Operations (CONOPS), decontamination standards, and in-theater capabilities for detection and testing for Bio hazards/agents.

USPACOM has made training and exercising for warfare in a CBW environment more routine, by executing a logical and progressive Consequence Management (CoM) program. The program has

evolved through workshops, exercises, and seminars. USPACOM's Joint Task Force (JTF) for CoM will exercise a foreign CoM Command Post Exercise during TEMPO BRAVE 01.

Army. The Army emphasizes integration of NBC defense training in unit rotations at the Combat Training Centers (CTCs). These centers include the National Training Center (NTC), Joint Readiness Training Center (JRTC), the Combat Maneuver Training Center (CMTC), and the Battle Command Training Program (BCTP).

At the CTCs, the Army continues to see units at the company, battalion, and brigade levels unable to perform all NBC tasks to standard. Less than satisfactory performance at the CTCs is directly attributable to lack of homestation NBC training. These results clearly indicate a need for increased emphasis in educating senior leaders on how to leverage homestation training. Units that (1) have the necessary command support and equipment, (2) balance NBC within their overall training requirements, and (3) execute according to approved training plans, are able to survive and continuously operate in a simulated NBC environment. However, increasingly constrained training resources limit NBC training to fundamentals. This often means training consists only of NBC survival and not training for continuous operations in an NBC environment.

Air Force. NBC warfare defense preparedness is an integral part of periodic Operational Readiness Inspections conducted by MAJCOM Inspectors General. Realism is injected into these scenarios using a simulated wartime environment including the use of bomb simulators, smoke, and attacking aircraft. Personnel are tasked to perform war skills while in their full complement of protective equipment. Additionally, Air Force units participate in major joint and combined exercises that incorporate realistic NBC situations. Following are examples that describe exercises incorporating NBC situations:

- ULCHI FOCUS LENS - PACAF Joint/combined command and control exercise conducted in conjunction with the Republic of Korea's national mobilization exercise "ULCHI."
- FOAL EAGLE - PACAF Joint/combined rear area battle and special operations field training exercise.

Navy. Due to the unique nature of Naval force deployments, CBR defense training may be conducted whether platforms are operating independently or in a group. During scheduled CBR defense training periods, realism is stressed and CBR defense equipment is used extensively.

Naval units conduct basic, intermediate, and advanced training CBR-D exercises prior to deployment. During the basic training phase, CBR-D training exercises may involve additional unit training by CBR-D specialists from Afloat Training Groups (ATG).

The exercises conducted by deploying Battle Groups and Amphibious Ready Groups during pre-deployment Composite Training Unit Exercises and Fleet Exercises are designed to meet CINC training requirements for forces in the deployment area of responsibility.

These CINC requirements are also tested during exercises with deployed forces. Chemical – Biological Defense scenarios have been incorporated into major Joint/Combined Exercises and Fleet Exercises for deployed units. Some of these exercises and experiments include:

- Exercise NEON FALCON.

- Exercise DESERT SAILOR.
- Ulchi FOCUS LENS.
- Fleet Battle Experiments.

Marine Corps. The Marine Corps provides the opportunity for units to incorporate NBC training into combined arms exercises (CAX) at the Marine Corps Air Ground Combat Center in Twenty Nine Palms, California. Battalion level unit exercises are also conducted during Korea and Thailand Incremental Training Programs where units deploy and exercise various tasks. Like the Air Force and Army, the Marine Corps also participated in major joint/combined exercises. The mission, threat, and task organization determines the level of training allowed. During FY01, the Marine Corps incorporated NBC defense training into the following exercises:

- JTF Exercise United Endeavor
- Ulchi Focus Lens
- Foal Eagle
- IMEFEX
- Keystone
- Desert Knight
- Azure Haze
- Urban Warrior
- ChemWar 2000
- Brave Knight
- Agile Lion
- Restoration of Operations (RESTOPS)

All Marine Corps units conduct annual NBC evaluations. Evaluations include operational, administrative, and logistical functional areas. These evaluations incorporate realistic NBC defense training into an operational scenario that supports the units combat mission.

4.7 INITIATIVES

This section provides details on a variety of joint and Service-unique initiative in support of defense readiness and training.

4.7.1 Joint

Doctrine/Training. The JSIG has continued a multi-year strategy to address WMD/NBC in Joint Doctrine and education at Mid/Senior-level, Joint and Service Colleges as recommended in the 1999 JSIG NBC Defense Training and Doctrine assessment. This effort is designed to improve awareness across the entire spectrum of WMD/NBC defense; including doctrine, training, war-games, exercises, and studies. It provides resources to assist in the Joint Doctrinal review process by providing WMD/NBC input where appropriate. It also provides resources to assist Mid/Senior-level, Joint and Service Colleges in reviewing their curriculum for the purpose of incorporating WMD/NBC defense material and providing WMD/NBC expert guest speakers.

During the year the JSIG provided assistance to four Service mid and senior level colleges with curriculum reviews and recommended NBC/WMD enhancements. The JSIG conducted a workshop with the colleges to facilitate the coordination of NBC/WMD education across the PME system. The JSIG provided assistance at two service colleges with wargame enhancements and also at the Joint Land, Aerospace, and Sea Simulation (JLASS) exercise. The JSIG is nearing completion of

a one day exportable NBC/WMD awareness course targeted at O4-O5 level CINC Staff Officers. This course is planned for piloting by Mobile Training Team (MTT) during 3QFY02 and will later be converted into a form of Distance Learning.

The Chairman, Joint Chiefs of Staff designated WMD/NBC Defense his top priority in his Joint Training Master Plan 2002 Chairman's Commended Training Issues (CCTI) for immediate action. CCTIs are special interest items developed from all-source lessons learned, readiness reports and operational assessments. These issues are incorporated into the Chairman's Master Training Plan to ensure appropriate visibility by the combatant commands, combat support agencies and the Services in developing their Joint Training Plans. Commands are instructed to assess prescribed CCTIs in relation to their theater conditions as a key joint training readiness indicator.

USJFCOM is currently reviewing the Universal Joint Task List (UJTL) version 4.0 for adequacy in addressing CBD-related tasks, and has requested input from the CINCs and Combat Support Agencies. USJFCOM is partnering with DTRA in the preparation of lists associated with CBD-related tasks. Additionally, USJFCOMs Joint Training System Support Teams will offer to the combatant commands, during their assistance visits to the CINCs in FY 01-02, to assist with the preparation/validation of CINC JMETLs associated with CBD. Measures of performance associated with CBD-related tasks will be addressed with the development of UJTL version 5.0, during FY 02-03, with the assistance of the Defense Data Manpower Center.

Under the 1999 Unified Command Plan, the Secretary of Defense directed the formation of the Joint Task Force for Civil Support (JTF-CS) within JFCOM to act as the military command and control unit to coordinate the military response in support of the Lead Federal Agency for Domestic CBRNE consequence management response.

Modeling. On 1 Nov 00 the DepSecDef signed a memo that delegated authority for accrediting all common use chemical and biological modeling and simulations with the Department to USD(AT&L), who in turn has delegated this responsibility to DATSD(CBD).

JCATS, JWARS and JSIMS are the future joint models for constructive and virtual combat simulation for training and analysis applications. Plans to incorporate CB defense effects into these models were initiated in FY98. VLSTRACK has been loosely coupled to JCATS to demonstrate the ability to add high resolution CW effects. JWARS will incorporate a chemical defense capability in release 1.1.

Training.

4.7.2 Army

Over the past several years, the Army has developed domestic response capabilities within the Chemical Biological – Rapid Response Team (CB-RRT) and the Weapons of Mass Destruction Civil Support Teams (WMD CSTs).

The CB-RRT provides a technical support package specifically tailored for response requirements and is composed of a variety of existing DoD elements. Upon arrival at an incident site, the CB-RRT command element quickly established initial coordination with the Lead Federal Agency

(LFA), and prepares to deploy an advisory team to the federal, state, and local command and control organizations as required or directed by the designated operational commander. It also coordinates and plans assistance to local authorities and first responders for consequence management operations. The CB-RRT organizes, based on the situation, to provide the appropriate level of graduated response and technical expertise necessary to assist in mitigating a chemical or biological incident.

The WMD CSTs are Army National Guard teams of 22 persons, organized and held on active duty to respond to a validated request for military support from the civil authority, and rapidly deploy in support of the Incident Commander to assess the type of chemical, biological, or radiological contamination that may be present, advise on how to handle the effects, and facilitate State and Federal military support.

4.7.3 Air Force

The Air Force currently has three training and readiness initiatives underway and continues to improve its professional training.

The Civil Engineer (CE) Readiness Technical School implemented an advanced scenario-driven exercise in the CDTF revolving around a terrorism incident involving chemical munitions. This training is provided to advanced students and differs from the lock step training provided to Apprentice-level students. The scenario will be reviewed/revised annually during the respective course reviews. Air Force instructors are qualified to conduct joint classes at the CDTF and are fully integrated into CDTF operations. Readiness instructors lead Air Force students in four of five resident courses through the training and also assist the other services with their training requirements. Additionally, they provide an orientation of NBC defense concepts and toxic-agent training in the CDTF for key Air Force personnel during the semi-annual Joint Senior Leaders Course. The CE Readiness Career Field Education and Training Plan's Specialty Training Standard requires readiness students and personnel to be highly qualified in chemical biological defense operations, including conducting and advising leaders on hazards analysis and the use of emerging detection and plotting technologies.

Air Force Readiness personnel enrolled in correspondence courses for upgrade training to the five skill level will eventually be able to complete a hybrid course, which includes both paper-based and interactive CD-ROM containing full motion-video and sound. The course is presently available only in a paperback version, which will continue to remain available. Interactive courseware development began in FY97 with the goal of developing the entire course on CD-ROM. This initiative was revised in FY00 in favor of the hybrid course. A CE Correspondence course writer at Sheppard AFB, Texas will begin CD-ROM development in FY01. This product will set the standard for all other CE specialties.

The Air Force has established the Counter Proliferation Integrated Process Team (CP IPT) as the Air Staff focal point for counter-proliferation issues. The CP IPT will also commission working groups as necessary, including a Passive Defense Working Group. The Passive Defense Working Group will:

- Define the end state for future AF NBC operations.

- Focus on near, mid, and far term actions.
- Transform force while maintaining ability to go to war.
- Identify existing CONOPS for sustaining mission essential tasks under biological and chemical warfare conditions.
- Identify gaps in existing chemical-biological defense (CBD) CONOPS.
- Recommend steps for developing comprehensive and effective CBD CONOPS.
- Identify specific issues and recommend corrective actions.
- Identify doctrinal voids for subsequent proposal, preparation and submission to May 02 Joint Doctrine Working Party.

Additionally, the AF Medical Service has developed, or is in the process of developing, NBC Defense Training contract statements of work for eleven initiatives, which are listed in section 4.3.2. All are being managed by HQ AETC/SGP and HQ USAF/SGX.

4.7.4 Navy

Navy initiatives focused on improving CB Defense Readiness, Training, Doctrine and Readiness Reporting across the fleet and also improving coordination of defense actions with other services and agencies. In addition the Navy has focused on the long term integration of CBR Defense, Afloat Anti-terrorism Force Protection, and Homeland Defense initiatives. As a result of an internal re-organization, Navy requirements in these areas are now managed by a single Chief Of Naval Operations office.

The Navy maintains a response capability at the Naval Medical Research Center (NMRC). NMRC is primarily a research institute, however, its Biological Defense Research Directorate has developed a capability that consists of a transportable biological field laboratory, expressly for the identification of biological warfare agents. This capability has been utilized extensively by DOD and other government agencies to provide a rapid analysis of biological samples.

To improve Navy readiness to respond to Chemical, Biological, and Radiological events the Navy has conducted an extensive series of CBRD studies. These studies includes:

- "The NBC Warfight" which analyzes operational decision-making within the concept of the a Joint CBR Battle Management Cell.
- "Biological Attack on a Pier" which analyzes the consequence management and interagency response to a biological attack on a pier adjacent to a naval base.
- "Shipboard Biological Hoax" which examines the tactical and operational implications of an internal contamination event on a ship.
- "Preparing a Fixed Site for CBR Defense" which analyzes basic naval base CBR defensive responses and command and control systems.

- "A Framework for Navy Forward Fixed Site CBR Defense Requirements" which examines CBR defense requirements for small, remote facilities, large fixed sites and large fixed administrative sites in peacetime and wartime.

- "Improving CB Defense for Domestic Naval Bases" which focuses on preparedness, point detection requirements, and medical responses to a biological attack at a US Navy base.

To improve Fleet participation in the Joint NBC Defense Program a successful series of Type Commander (TYCOM) CBRD Conferences have recently been convened. These recurring conferences have allowed personnel from the Naval Surface Force, Aviation Force, and Submarine Force Commanders and also personnel from operational units throughout the fleet to actively participate in improving Navy CBRD readiness. The results of these meetings have been used to shape CBRD equipment, doctrine, and training requirements.

To support warfighting and force protection missions, the Navy is assisting the United States Coast Guard (USCG) in evaluating requirements and improving capabilities for CBR Defense. The ultimate goal is the integration of the USCG into the Joint Service Chemical and Biological Defense Program to ensure full interoperability with the DoD services. The Coast Guard is in the process of upgrading their Naval Operational Capabilities and raising Survivability Standards to include enhanced CBR defense capability for future "Deepwater" assets (new ships and aircraft) and also improving the readiness of current USCG assets.

To improve unit CBRD readiness reporting the Navy has instituted changes to the Status of Resources and Training System (SORTS) reporting process. These changes will improve unit CBR equipment readiness and training readiness reporting procedures. These changes are designed to improve the visibility of CBR readiness issues throughout a naval units entire chain of command.

4.7.5 Marine Corps

During FY01 the Marine Corps Chemical Biological Incident Response Force (CBIRF) continued to refine its tactics, techniques, and procedures to respond to the growing biological and chemical terrorist threat.

National Asset Activated 1 April 1996

- Provides an operational force to rapidly respond to WMD incidents
- Tests New Equipment, Procedures, and Techniques required to support their mission
- Provides Consequence Management training to Marine Forces through Mobile Training Teams
- Assists in the assessment of Unit/Facility Vulnerabilities to Enhance Force Protection Planning
- Works with other Emergency Response Agencies

Figure 4-7. Chemical/Biological Incident Response Force (CBIRF) Role in Training

The CBIRF's mission focuses on consequence management to terrorist-initiated NBC incidents. The CBIRF is a national asset, to be globally sourced to CINCs and the National Command Authority for duties as the President may direct. The CBIRF consists of 360 highly skilled and trained Navy and Marine Corps personnel, organized into three elements: Command Element, Headquarters & Service Company and a Reaction Force Company with three Reaction Platoons. The CBIRF has state-of-the-art detection, monitoring, medical and decontamination equipment and is prepared for operations in a wide range of military-civilian contingencies. In addition to the CBIRF's capabilities to respond to CB incidents, it also serves as a training asset to the operational forces. The CBIRF can provide mobile training teams to various units to provide advanced consequence management training. This can provide operational forces with the most up-to-date techniques, tactics, and procedures developed by the CBIRF. CBIRF also assists in Unit/Facilities Vulnerability Assessments to enhance force protection. The bottom line is that the CBIRF serves as a force multiplier to the MAGTF.

Marine Corps FY01 Accomplishments:

- The Marine Corps NBC Defense School provided exercise and training support for the staff of Commander, United States Naval Forces Central Command and Commander, United States Fifth Fleet in support of Joint/Combined Exercise Neon Falcon 01.
- Began fielding, training and deployment of the "Enhanced NBC" Force Protection sets for the Marine Expeditionary Units (MEUs) that are forward deployed with the Navy.
- The Marine Corps participated in the Operational Testing (OT) for the Sorbent Decontamination System, which will help continue the process of replacing DS-2 with a waterless decontaminant.
- Participated in the Portable Biological Agent Sampler test demonstration conducted by the U.S. Army Chemical School at Fort Leonard Wood, MO during June 2001.
- The Marine Corps participated in the decontamination performance demonstration exercise conducted by the U.S. Army chemical School at Fort Leonard wood, MO during July 2001.
- Conducted the Annual NBC Conference in Dumfries, Virginia on 17–21 September 2001. The Marine Corps Conference gathered Marine Corps NBC Subject Matter Experts for the purpose of refining and defining doctrine, reviewing current NBC Requirements, and distributing information on programs currently in material development.
- Participated in CINCCENT's Desert Breeze and CINCUNC/CFC's Coral Breeze WMD Wargame Seminars. The primary purpose of these seminars was to educate the CINC and Component commanders and staffs on implications of the current and emerging WMD threat (MARFORPAC).
- Conducted a comprehensive assessment of USMC vulnerability to WMD within the context of major OPLANs that included gauging adequacy of individual and unit level training (MARFORPAC).
- Provided forces and equipment in support of the Restoration of Operations (RESTOPS) Advanced Concept Technology Demonstration (ACTD). These forces performed various missions, including training and evaluation, toward ACTD objectives (MARFORPAC).

- Marine Forces Reserve (MarForRes) NBC Defense Single Site Storage Facility (SSSF) became fully operational. This site is located on the Fort Worth Federal Center, Fort Worth, Texas. The SSSF is designed to house, inspect, and maintain all NBC equipment for MarForRes except for the field protective mask.

Marine Corps FY01 Initiatives:

- Continued development of a joint Navy/Marine Corps web-based distance learning-course for NBC Defense Individual Survival Measures co-sponsored by the Marine Corps Institute and the Marine Corps NBC Defense School for use by all Marines, throughout the Marine Corps.
- The Marine Corps NBC Defense School is actively involved in the JSIG Joint Training Sub-Panel activities regarding assistance with identification of training requirements for all joint NBC defense equipment development programs.
- The Marine Corps Combat Development Command (MCCDC) formed the USMC NBC Defense Operational Advisory Group (OAG) that is comprised of representation from all Marine Component Commands and their Major Subordinate Commands (MSC). Per the OAG's charter, the purpose of the OAG is to provide a USMC NBCD decision making and guidance forum among the USMC NBCD Specialist Community. The first OAG meeting was conducted between 10-14 Sep 01 with subsequent meetings scheduled biannually thereafter.
- Marine Forces Pacific is actively involved in a Plan of Action and Milestones (POA&M) for internal improvements and for engaging external agencies more effectively to reach long-term improvement. CG, I MEF held the initial POA&M working group on 10-13 Oct 2000. Sixty-five military and civilians attended. Attendees represented a cross-section of intelligence analysts, operators, planners, logisticians, and NBC Defense subject matter experts. The working group was organized into five mission analysis teams: Standards & Peacetime Requirements, Contamination Avoidance, Protection, Restoration, and Battle Management. Each mission analysis team identified NBC Defense requirements and deficiencies based on a Korean theater scenario using the Doctrine, Organization, Training, Equipment, and Support/ Sustainment (DOTES) model as an analytical methodology. Three major OPLAN operational scenarios were used to generate requirements: Maritime Prepositioned Force operations, amphibious assault, and subsequent combat operations ashore. The current NBC threat and ongoing Marine Corps/Department of Defense (DoD) NBC Defense programs were considered in the analysis. The working group validated the vulnerabilities revealed during MARFORPAC's NBC Defense readiness assessment. It identified internal and external deficiencies across a wide-ranging spectrum: standards, doctrine, training, evaluations, readiness assessment and reporting, and resources (both personnel and equipment). Working group recommendations for improvement were then developed into a draft POA&M per guidance from the Commander of Marine Force Pacific. The POA&M was approved in Dec 2000 and contains 138 complex tasks, phased over a three-year period, similar to a campaign plan.
- In a support role, Marine Force Pacific continues its participation in RestOps. The RestOps Advanced Concept Technology Demonstration (ACTD) is a USCINCPAC-USCINCCENT

co-sponsored experiment designed to improve the before, during and after attack actions to protect against and immediately react to the consequences of a chem-bio attack. These actions aim to restore operating tempo (OPTEMPO) in wartime mission execution and the movement of individuals and materiel to support combat operations at a fixed site. The ACTD will: identify effective means of pre-attack protection of personnel and critical equipment while maintaining operational agility; identify chem-bio collection, detection, identification and warning that is achievable to reduce vulnerabilities; identify expedient methods of post-attack decontamination of personnel and personal equipment; provide for enhanced decontamination of critical equipment and facilities necessary to restore and sustain operations; provide enhanced ability to determine the extent and location of contamination; and provide for improved post-attack medical treatment to exposed personnel. MARFORPAC participates in this ACTD as a component of both sponsoring CINCs and sits on two of its oversight committees. Also MARFORPAC provides forces and equipment for operational tests and evaluations conducted in support of ACTD objectives. The primary ACTD demonstration site is Osan Air Base, Republic of Korea. Locations for testing and evaluating specific technologies, tactics, techniques, and procedures include the West Desert Test Center, Dugway, Utah, Marine Corps Base Kaneohe Bay, Hawaii, Brooks Air Force Base, Texas, Nellis Air Force Base, Nevada, and Kirtland Air Force Base, New Mexico.MARFORPAC sponsored a force protection initiative funded by DTRA. DTRA will conduct an independent assessment of USMC operations in a Weapons of Mass Destruction (WMD) environment which encompasses chemical/biological/nuclear attacks.

4.7.6 Emergency Response: Army Medical Response

The AMEDD continues to be involved in supporting DoD and federal counterterrorism initiatives and contingency operations related to NBC threat agents, mainly with elements of the Medical Research and Materiel Command (MRMC). The following offices and agencies have required AMEDD assistance: DoD SO/LIC, J4 Medical Readiness, U.S. Army Technical Escort Unit, US Department of State, Federal Bureau of Investigation, Department of Health and Human Services, Office of Emergency Preparedness, and the U.S. Marine Corps CBIRF.

The U.S. Army published AR 525-13, *Antiterrorism Force Protection (AT/FP): Security of Personnel, Information, and Critical Resources from Asymmetric Attacks*, dated 10 September 1998. From this regulation it is assumed that U.S. Army medical treatment facilities and clinics will be called upon to provide assistant to civilian first responders if a WMD terrorist act occurs and to provide emergency room and inpatient treatment for both eligible DoD beneficiaries and civilian casualties. This regulation specifically states that the Surgeon General will:

- Establish policy and guidance on the management and treatment of conventional and nuclear, biological, and chemical (NBC) casualties.
- Coordinate emergency medical NBC response capabilities worldwide with other DoD, Joint, Federal, state, local and HN agencies.
- Maintain medical NBC response teams to address nuclear, biological/emerging infection, chemical accidents/incidents worldwide.

- Provide chemical and biological analysis of biomedical samples from patients/decease to assist in the identification of agent(s) used against U.S. personnel.
- Provide guidance on the vaccination and prophylaxis against biological warfare agents.

During 2002, MEDCOM will publish Regulation 525-xx, *Medical Emergency Management Planning* , which includes all medical teams and systems that could potentially be available to support civil authorities in the event of a Chemical, Nuclear, Biological, Radiological-Explosive (CNBR-E) event or a terrorist attack with Weapons of Mass Destruction. The regulation also includes the Army policy for fixed facility medical treatment facilities in support of local domestic First Responders.

The AMEDD has formed Specialty Response Teams (SRTs), which in some instances may be designated Special Medical Augmentation Response Teams (SMART). These teams provide a rapidly available asset to complement the need to cover the full spectrum of military medical response—locally, nationally, and internationally. These teams are organized by the U.S. Army Medical Command (USAMEDCOM) subordinate commands; they are not intended to supplant TOE units assigned to Forces Command or other major commands. The regional medical commands (RMCs), the United States Army Center for Health Promotion and Preventive Medicine (USACHPPM), and the US Army Medical Research and Materiel Command (USAMRMC) commanders organize SRTs using their table of distribution and allowances (TDA) assets. These teams enable the commander to field standardized modules in each of the SRT areas to meet the requirements of the mission. Members of the US Army Reserve (USAR) may be relied upon to provide a variety of functions in support of the various SRT missions. The two SRTs that can most likely to support NBC are the Special Medical Augmentation Response Team – Preventive Medicine (SMART-PM) and the Special Medical Augmentation Response Team – Nuclear/Biological/Chemical (SMART-NBC). The following paragraphs describe activities/programs within the Army Medical Command (MEDCOM) that support civil authorities, consequence management, and domestic preparedness.

Medical Capabilities. The U.S. Army Medical Command (MEDCOM) has organized, trained and equipped Special Medical Augmentation Response Teams. Designated MEDCOM Subordinate Commands will deploy SMART's in CONUS or OCONUS to provide short duration, medical augmentation to Local, State, Federal and Defense Agencies or Medical Teams responding to disasters, civil-military cooperative actions, humanitarian assistance, Weapons of Mass Destruction and emergencies within 12 hours of notification. Reaction time to and length of OCONUS missions will vary based on the situation.

SMART Areas. There are a total of 43 SMART's in ten functional areas that are capable of responding.

(1) Trauma/Critical Care (SMART-TCC).
(2) Nuclear/Biological/Chemical (SMART-NBC).
(3) Stress Management (SMART-SM).
(4) Medical Command, Control, Communications, Tele-medicine (SMART-MC3T).
(5) Pastoral Care (clinical) (SMART-PC).
(6) Preventive Medicine (SMART-PM).
(7) Burn (SMART-B).

(8) Veterinary (SMART-V).
(9) Two Health Systems Assessment and Assistance (SMART-HS).
(10) Aero-Medical Isolation (SMART-AIT)

SMART Composition. The teams are composed of military officers, warrant officers, enlisted soldiers, civilian employees and appropriate contractors of the Department of Defense assigned to MEDCOM by name and capable of deploying to augment local, state and federal response assets in domestic support, civil-military cooperative assistance, disaster relief and humanitarian assistance operations in CONUS. There are approximately 287 MEDCOM Personnel designated to respond as SMART members. These teams are trained and equipped and can be alerted and sent out within 12 hours of notification.

The National Medical Chemical and Biological Advisory Team (MCBAT) is comprised of USAMRMC elements from USAMRIID and USAMRICD. These assets are Tier 1 elements of the DoD Chemical Biological Rapid Response Team (C/B-RRT) and are ready to deploy worldwide within 4 hours after receiving their orders. The RMC Chemical/Biological SMARTs are trained medical teams located at the RMCs that can deploy in response to a chemical, biological, or radiological incident. Examples of incidents that may require a rapid response include:

- An accident involving the transport or storage of NBC weapons,
- The release of CW or BW agents or radiological material,
- A leak of an industrial chemical, infectious material, or radioactive material.

The MCBAT is the principal DoD medical advisor to the Commander, C/B-RRT and the Interagency Response Task Force. Both the MCBAT and regional Chemical/Biological SMARTs can provide medical advice and consultation to commanders or local medical and political authorities for preparation of a response to a threat or actual incident. They can also provide medical advice to commanders or local authorities on protection of first responders and other health care personnel, casualty decontamination procedures, first aid (for non-medical personnel) and initial medical treatment, and casualty handling. The initial advice includes identifying signs and symptoms of NBC exposure, first aid (self-aid, buddy aid, and combat lifesaver aid for military personnel), and initial treatment when an incident has occurred. The MCBAT also assists in facilitating the procurement of needed resources. The RMC Chemical/ Biological SMART may, after initial assessment of the situation, elect to use telemedicine reach back.

USAMRICD has developed a Chemical Casualty Site Team (CSST) with the capability of rapid deployment in support of DoD or the MCBAT as part of the Foreign Emergency Response Team (FEST), or the Domestic Emergency Response Team (DEST). The team is tasked to support each specific mission. Personnel available for deployment consist of physicians, a nurse, toxicologists, veterinarians, and laboratory specialists. These personnel, when coupled with their supporting capabilities, are knowledgeable in the medical effects of a specific chemical warfare agent, identification of chemical agents or their metabolites in biological samples, determination of blood cholinesterase levels, technical and biomedical expertise required to enable protection of personnel responding to chemical incidents or to guide decontamination of personnel and causalities, and technical expertise to accomplish mission planning.

USAMRIID has developed the capability to deploy an Aeromedical Isolation Team (AIT) consisting of physicians, nurses, medical assistants, and laboratory technicians who are specially trained to provide care to and transport patients with disease caused by biological warfare agents or by infectious diseases requiring high containment. The AIT is a highly specialized medical evacuation asset for the evacuation of limited numbers of contagious casualties, with lethal infectious diseases, or for consultation on appropriate management of such casualties in the event of a mass casualty situation. USAMRIID's teams are deployable worldwide on a 12-hour notice using USAF transportation assets.

Another asset that USAMRIID has is the Biological Threat Response Cell (BTRC). The BTRC is designed to respond to any CONUS or OCONUS biological warfare or biological terrorist event. The cell is composed of the Deputy Commander as OIC/POC, the Operational Medicine physicians and the AIT, selected scientists and clinicians, a Biological Safety Officer, a logistician and an engineer. USAMRIID also provides consultants to the Chem-Bio Rapid Response Team as members of the MCBAT.

As a supporting capability, USAMRIID has a 16-bed ward with the capability of isolating (up to Biosafety Level 3) patients with infectious diseases in a contingency situation. USAMRIID also has a special Biosafety Level 4 (highest level of containment) patient care area designed for a maximum of 4 patients requiring this level of containment. These patient care areas are capable of providing intensive care for critically ill patients with specialized personnel and equipment augmentation from Walter Reed Army Medical Center. An additional supporting capability at USAMRIID is its capacity for medical diagnostic assays for recognized biological agents.

MEDCOM has also taken the initiative to provide a standardized decontamination equipment, documentation, and personnel training package for the command's fixed medical treatment facilities. This equipment and training will provide a decontamination capability at all Army fixed medical treatment facilities for a CBRNE event. The intent is to standardize a minimum level of decontamination capability by providing the same decontamination equipment and training to each medical treatment facility. The execution phase began with the first shipment of equipment in December 2000 and will end with the final equipment delivery and personnel training on 30 April 2001.

4.7.7 Medical Countermeasures and Surveillance against NBC and other Battlefield Toxicants and Occupational Health Hazards

Historically, most veterans' health and benefit issues are related to service in combat operations. U.S. forces are now more likely to deploy into non-combat environments such as peace-keeping, peacemaking, humanitarian assistance, or training. Presidential Review Directive (PRD)/National Science and Technology Council (NSTC)-5 directs DoD, the Department of Veterans Affairs, and the Department of Health and Human Services to review policies and programs and develop a plan that may be implemented by the Federal government to better safeguard those individuals who may risk their lives to defend our Nation's interests. An NSTC Interagency Working Group oversaw the work of four task forces that focused on (1) deployment health, (2) record keeping, (3) research, and (4) health risk communication.

DoD policy that requires pre- and post-deployment health assessments, screenings, and briefings shall be performed active and reserve component personnel deployed as a resulting of a Joint Chiefs of Staff/Unified Command deployment order for 30 continuous days or greater to a land-based location outside of the United States that does not have a permanent U.S. military treatment facility. Routine shipboard operations that do not involve field operations ashore for over 30 days are exempt from this policy. The details for completing these assessments are found in JCS Policy Memorandum MCM-251-98, 4 December 1998, subject: Deployment Health Surveillance and Readiness; ASD(HA) Policy Memorandum, 6 October 1999, subject: Policy for Pre- and Post-Deployment Health Assessment and Blood Samples; and DoD Instruction 6490.3, "Implementation and Application of Joint Medical Surveillance for Deployments," August 7, 1997.

Deployment can encompass a wide range of missions in which additional operations in NBC environments may expose a Joint Task Force to other toxic chemicals, radiological contamination, and environmental contamination from industrial operations within the host nation. Standard U.S. occupational health and environmental standards are not enforceable in a host nation scenario. As a result, the JFC has been confronted with toxic industrial chemicals, radiological hazards, and long-term environmental contamination from industrial operations within the host nation. The Joint Force Commander must utilize organic NBC reconnaissance and preventive medicine medical surveillance assets to identify host nation occupational and environmental hazards and to determine troop deployment locations that will minimize the short- and long-term health risk during occupation by U.S. forces. This type of information, if not provided by the host nation, is available from the Armed Forces Medical Intelligence Center (AFMIC) and the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM). Joint medical surveillance within the theater of operations can identify NBC related occupation, industrial, and environmental health hazards. Factors to be considered will include the type of contamination and the prevailing wind direction. Proposed planning factors for downwind hazard distances for some commonly known industrial chemicals are provided in the USACHPPM Technical Guide 230A, "Short-Term Chemical Exposure Guidelines for Deployed Military Personnel". The technical guide is to be used as a tool to assess potential adverse health impacts resulting from exposure to harmful chemicals as a result of uncontrolled industrial release, sabotage, or from the intentional or unintentional actions of enemy or friendly forces. Preventive medicine assets within the theater can be employed to conduct joint medical surveillance and to provide recommendations to the Joint Force Commander for risk communication to minimize the short-term and long-term health effects of toxic exposures to deployed military personnel. DoD Directives (6055.1 and 6490.2) and Instruction (6490.3) apply to joint medical surveillance and safety and occupational health in an NBC or otherwise contaminated environment.

The Joint Publication 3-11, *Doctrine for Nuclear, Biological, and Chemical Defense Operations* sets forth principles to assist commanders and staffs to plan for and conduct joint, multinational and interagency operations in which their forces may encounter the employment or threat of NBC weapons and other toxic materials. It has taken into account new DoD and JCS policies, directives, and instructions for joint medical surveillance and risk communication. New DoD standards and guidelines are being developed for accurate risk communication. The Assistant Secretary of the Army for Installations and Environment, ASA(I&E), is the DoD Executive Agent for developing these new DoD nuclear, biological, chemical, and environmental (NBC-E) force protection policies.

ASA(I&E) is staffing a new Army policy entitled "Medical Force Protection: Environmental and Occupational Health Threats Policy." The need for this new policy was identified during the 1999 Medical Functional Area Assessment and was validated by the Deputy Chief of Staff for Operations, Headquarters, Department of the Army, in a 23 July 1999 memo to the ASA(I&E). This new policy for force health protection is urgently needed to permit the development of appropriate U.S. Army doctrine, detection standards, and risk communication guidelines for use by commanders to protect soldiers from battlefield toxicants and occupational health hazards during deployments.

4.7.8 Air Force Medical NBC Teams

The Air Force Medical Readiness Re-engineering efforts have created eight specialty teams for NBC Medical Defense. These teams include (1) Theater Epidemiology Team, (2) Radiological Assessment Team, (3) Wartime Patient Decon Team, (4) Bioenvironmental Engineering NBC Team, (5) Infectious Diseases Team, (6) Preventative Aerospace Medicine Team, (7) Biological Augmentation Team, and (8) In-place Patient Decon Team (USAFE). Following is a brief description of the capabilities provided by these teams.

The *Theater Epidemiology Team* (TET) provides (1) theater medical and environmental threat assessments, (2) theater disease surveillance and disease outbreak investigation, and (3) baseline environmental monitoring. The TET is a theater-level medical asset.

The *Radiological Assessment Team* (AFRAT) is composed of two Nuclear Incident Response Force (NIRF) Teams and one Radio analytical Augmentation Team. The NIRF Teams include health physicists, industrial hygienists, equipment technicians, and bioenvironmental technicians. The AFRAT provides comprehensive radiological monitoring, hazard evaluation, and health physics support in a radiological response operation. The AFRAT is a service-level asset.

The *Wartime Patient Decon Team* (WMDT) is deployed in direct support of medical treatment facilities operating in NBC threat environments. They construct and operate decontamination sites and facilities in the vicinity of the supported medical treatment facilities. The WMDT is deployed at the unit level to support a medical treatment facility. Currently, there are 33 complete teams (2 personnel packages and 1 equipment package each) in the Air Force inventory.

The *Bioenvironmental Engineering NBC Team* provides the following capabilities in support of CE Readiness NBC personnel: (1) NBC agent surveillance, detection and abatement, (2) reconnaissance teams for NBC agent detection, (3) advice on health effects and human performance due to extended wear of the ground crew ensemble, and (4) information on other NBC related health risks to deployed forces.

The *Infectious Diseases Team* provides personnel that augment the capability to identify, control, report, and provide treatment for infectious diseases and biological warfare agents in the deployed theater. The Team is designed to be deployed to facilities with greater than 100 beds where a significant threat for biological warfare casualties or infectious disease exists.

The *Preventative Aerospace Medicine Team*: (PAM) (1) identifies, monitors and prevents disease and non-battle injury (DNBI), (2) performs health threat and risk assessment, such as communicable disease tracking, (3) performs health hazard surveillance, (4) controls health hazards

through food, water and field sanitation inspections, and, (5) mitigates the effects and prevents DNBI. PAM teams are an integral to all deployed AIR Force medical treatment facilities. There presently are 35 teams in the inventory, and can deploy in increments of 2 to 9 personnel. PAM teams operate at the unit level, while the TET serves as a theater medical asset.

The *Biological Augmentation Team* (BAT) is a three to two-person team of skilled medical laboratory officer and enlisted personnel that provides rapid pathogen identification using nucleic acid-based identification diagnostic capability. The team is modular so that it may augment other teams, capabilities, and facilities. The BAT Team can analyze clinical samples

Such as food and water for pathogens of operational concern. There are currently 8 complete BAT teams in the Air Force, and more are planned.

The *In-place Patient Decon Team* supports five U.S. Air Forces in Europe (USAFE) medical treatment facilities (MTF).

4.8 READINESS REPORTING SYSTEM

CJCSI 3401.02, the policy document for the Status of Resources and Training System (SORTS) requires units from all Services to independently assess their equipment on hand and training status for operations in a chemical and biological environment. This is a change to previous SORTS reporting requirements and provides more visibility to NBC defense related issues.

The Services individually monitor their SORTS data to determine the type of equipment and training needing attention. Units routinely report their equipment on hand and training status for operations in a chemical or biological environment. Commanders combine this information with other factors, including wartime mission, to provide an overall assessment of a unit's readiness to go to war.

Additionally, the Commanders-in-Chief (CINCs) of the Unified Commands submit readiness assessments at each Joint Monthly Readiness Review (JMRR). In the JMRR, CINCs assess the readiness and capabilities of their command to integrate and synchronize forces in executing assigned missions. As needed, CINCs address NBC defense readiness and deficiencies as part of the JMRR.

USMC CBD Readiness Reporting. The Marine Corps has developed the Chemical and Biological Defense (CBD) Calculator (automated program) that can be used by Commanders to assist in assessing their unit's CBD readiness. The CBD Calculator provides a measurable standard that commanders can use to base their assessment on. Unit NBC personnel enter training and equipment data into the calculator and automatically generate a recommended CBD readiness status formatted for input to the SORTS report. The Marine Corps SORTS order is being revised to recommend that all Commanders use the CBD Calculator when determining their CBD status for SORTS reporting.

Chapter 5

Status of DoD Efforts to Implement the Chemical Weapons Convention (CWC)

5.1 INTRODUCTION

The CWC was opened for signature on January 13, 1993. The Convention entered into force on April 29, 1997. As of January 1, 2002, 145 countries, including the United States, had signed and ratified or acceded to the CWC. Another 29 countries have signed but not ratified.

5.2 DEPARTMENT OF DEFENSE IMPLEMENTATION OF THE CWC

Since the CWC entered into force, DoD has hosted more than 340 visits and inspections at chemical weapons (CW) storage, former production, and destruction facilities. The Army (the Service most directly impacted by CWC implementation activities) and DoD's Defense Threat Reduction Agency (DTRA) continue to host and escort inspectors from the Organisation for the Prohibition of Chemical Weapons (OPCW) Technical Secretariat (TS). The OPCW is charged with overseeing worldwide implementation of the CWC. TS inspectors conduct both continuous and non-continuous monitoring at DoD CW destruction facilities and systematic inspections at DoD CW storage, former production and schedule 1 facilities. DTRA provides CWC Orientation Training to United States Government (USG) national escorts and other treaty compliance personnel and to date has provided training to over 700 USG personnel.

In addition to supporting inspections at DoD facilities, DTRA assists the Department of Commerce (DOC) with CWC inspections at U.S. chemical industry sites pursuant to a Memorandum of Agreement. The DOC is the lead agency for chemical industry inspections. DTRA supports DOC with training, escort, and logistic support on a non-interference, cost reimbursable basis. U.S. chemical industry inspections began in May 2000 and, as of January 1, 2002, the OPCW had conducted 28 inspections.

The Department of Defense conducts a Chemical Weapons Agreements Implementation Working Group (CWIWG) to implement the CWC. Through regularly recurring meetings, representatives of the Office of the Secretary of Defense (OSD), the Joint Staff, the Military Departments, the Military Services, and DoD agencies and activities coordinate planning efforts to ensure proper implementation of the CWC. Formal meetings of the CWIWG are scheduled approximately monthly and small group meetings are held as needed to address specific requirements in support of the CWIWG. A Compliance Review Group (CRG) was established within DoD to meet, as needed, to address CWC compliance concerns, should they arise. OSD, the Joint Staff, the Military Services, and DTRA provide technical experts to support activity at the U.S. Delegation to the OPCW in The Hague, The Netherlands.

The Army was tasked to destroy all chemical warfare materiel under the Program Manager for Chemical Demilitarization (PMCD). PMCD includes programs for unitary stockpile destruction, destruction of bulk agent by alternative technologies (non-incineration), destruction of other chemical warfare materiel and the destruction of former CW production

facilities. There is a separate Army program to demonstrate alternative technologies to destroy assembled CW munitions. The Army coordinates closely with the OSD to ensure that these programs are compliant with CWC provisions.

5.3 SAFETY ORIENTATION FOR INSPECTORS

All OPCW inspectors, who conduct continuous monitoring at U.S. chemical weapons demilitarization facilities, are required to attend a 32-hour safety orientation presented by the Army that is broken down into two sections. One section is a 24-hour hazardous waste operations and emergency response (HAZWOPER) course which is a USG requirement of all personnel who must be present on a more than short-term basis at U.S. chemical demilitarization facilities. The second section is an 8-hour Ammunition Safety Course. A 48-hour demilitarization protective ensemble (DPE) procedures course is required only for those inspectors designated by the OPCW TS, whose responsibilities would include the use of such protective equipment. Approximately 211 currently assigned OPCW TS inspectors have attended HAZWOPER training; 90 of the 211 inspectors have taken the 48-hour DPE class. The orientation is conducted at the Chemical Demilitarization Training Facility in Edgewood, Maryland. Annual 8-hour HAZWOPER refresher classes are also required, and are being accomplished by the Army in The Hague. DTRA provides USG national escorts for OPCW inspectors while attending required training at US facilities. DTRA insures that all inspectors and escorts receive required training.

5.4 PREPARATION OF DEFENSE INSTALLATIONS

The Military Services and DTRA have developed individual implementation and compliance plans to provide guidance for their commands and activities under the CWC.

The Military Services have individually established implementation support offices which participate actively at the DoD CWIWG, provide Service policy direction, and conduct ongoing liaison with their major commands to ensure that all military elements are fully prepared for inspections under the CWC.

The Military Services continue to coordinate actively with DTRA to prepare DoD installations for inspections under the CWC. All defense installations which are subject to declarations under the requirements of the CWC, and many which are subject to challenge inspections even though not declared, have been visited by Military Service representatives and DTRA technical experts. DTRA will continue to support site assistance visits and Army treaty compliance implementation meetings.

All of the Military Services have held exercises to test their preparedness for short-notice CWC challenge inspections. Such exercises involve the active participation of Service, DTRA, and other DoD representatives in the roles they would assume during a challenge inspection. DoD and the Services have exercised written DoD guidance and procedures to test the operational readiness of personnel and facilities. Commonly, the lead Service responsible for developing an exercise also produces comprehensive lessons-learned to further ensure DoD readiness for challenge inspections. The Services have initiated efforts to ensure that in the case of a challenge inspection affected commands take timely and appropriate measures, based on lessons-learned, to demonstrate compliance while protecting security concerns.

DoD organized both a tabletop and a mock challenge inspection exercise in 2001 at a DoD facility and the TS participated by providing an inspection team. DoD's objective in including the TS was to better understand the challenges DoD would face in demonstrating compliance and protecting national security and gauge TS readiness to conduct a challenge inspection. DoD is organizing a challenge inspection exercise to be conducted in 2002, utilizing the lessons learned from the mock challenge inspection exercises conducted in 2001. The 2002 exercise will only be attended by USG agencies.

5.5 DEFENSE TREATY INSPECTION READINESS PROGRAM

The Defense Treaty Inspection Readiness Program (DTIRP), for which DTRA is the executive agent, has implemented an extensive outreach program to provide information about the CWC, security countermeasures, and facility preparation, to both government and DoD industry. DTIRP provides training and awareness services through such fora as seminars, site assistance visits, mock inspections, mobile training teams, industry associations, national conventions and symposia. DTIRP also publishes various educational products (electronic media and print) and administers electronic bulletin boards to provide information concerning the CWC to government and industry. DTIRP, in close coordination with the Naval Surface Warfare Center at Indian Head, MD, has produced and conducted the Chemical Technology Security Course, to train USG personnel from the departments of Defense, Commerce, and Justice.

The DTIRP has provided, and will continue to provide, arms control vulnerability assessment teams in support of any requirement to assess risks to national security and United States industry and research institutions such as those required under Public Law 106-113, §1124.

In October 2001, Joint Staff and DTIRP co-sponsored a seminar to provide the CINC CWC Supervisors a seminar formatted program updating them on DoD plans for executing Challenge Inspections if one should occur in the CINC Area of Responsibility.

5.6 TECHNICAL EQUIPMENT INSPECTION PROGRAM

The Technical Equipment Inspection (TEI) Program ensures OPCW TS verification equipment meets U.S safety, environmental and security requirements through a familiarization process authorized by Conference of States Parties Decision 71. The familiarization results are documented in the "Certification Report of Chemical Weapons Convention Organisation for the Prohibition of Chemical Weapons Technical Secretariat Equipment." In addition, TEI performs chemical agent monitoring of inbound equipment at the Point of Entry to protect U.S. personnel and to prevent inaccurate findings as a result of pre-existing contaminants on the verification equipment.

5.7 ARTICLE X ASSISTANCE AND OTHER ASSISTANCE

Under Article X of the CWC, a State Party to the treaty may make an appeal for assistance through the Director-General of the TS. In accordance with a condition established in the U.S. Senate's Advise and Consent to the Ratification of the CWC, the United States will provide "no assistance...other than medical antidotes and treatment," which the USG deems

are necessary, to those CWC States Parties that have requested assistance under Article X of the CWC.

Under the CWC, DoD has not provided any chemical weapons detection equipment or assistance in the safe transportation, storage, and destruction of chemical weapons to other signatory nations. Such assistance, however, is being provided to Russia under DoD's Cooperative Threat Reduction (CTR) program.

5.8 ARMS CONTROL TECHNOLOGY

DTRA conducts research, development, test and evaluation (RDT&E) to support U.S. roles in global CW arms control and nonproliferation initiatives. The primary goal of the program is to protect DoD equities and minimize the threat to national security interests posed by U.S. involvement in CW arms control activities. Related objectives are to assist the U.S. in meeting legal obligations imposed by treaty provisions, support development of U.S. policy, minimize implementation costs, enhance the safety of inspections and conduct research and development (R&D) on enabling technologies for future treaties or nonproliferation initiatives. Current emphasis is on technologies and procedures for on-site analysis under the CWC, development of advanced non-destructive evaluation, and environmental characterization of the emerging CW threat.

DTRA developments to date include analytical software for use in chemical analysis by gas chromatography/mass spectrometry (GC-MS). This software satisfied a critical requirement to prevent the release of potential sensitive or confidential business data during CWC inspections. Additionally DTRA has developed and fielded non-destructive analysis technologies that have been employed as confidence building measures under the CWC. These technologies have also demonstrated their multi-functional role in other nonproliferation related efforts such as United Nations Special Commission (UNSCOM) inspections in Iraq and more recently, support to law enforcement agencies at events such as the Democratic National Convention and the Olympics in Atlanta. DTRA, in cooperation with Finland, also continues to develop and validate procedures for GC-MS sample preparation and is currently finalizing Version 3.0 of these procedures in support of Senate ratification condition 18 of the CWC. Finally, DTRA is cooperating with the intelligence community in the evaluation of new threat agents and their degradation pathways.

Annex A

Contamination Avoidance Programs

Table A-1. Contamination Avoidance RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
Automatic Detectors and Monitors	- M22 Automatic Chem Agent Detection Alarm (ACADA)	Production	Joint	Joint	Joint	Rqmt
	- Improved Point Detection System (IPDS)	Production				Rqmt
	- Improved CAM (ICAM)	Production	Rqmt	Interest	Rqmt	Rqmt
	- Joint Chemical Biological Agent Water Monitor (JCBAWM)	RDTE	Joint*	Joint*	Joint*	Interest
	- Joint Chemical Agent Detector (JCAD)	RDTE	Joint*	Joint*	Joint*	Joint*
	- Biological Point Detection	Fielded				*Rqmt*
	--Interim Biological Agent Detector (IBAD)	Fielded	*Rqmt*			
	--Biological Integrated Detection System (BIDS NDI)	Fielded	*Rqmt*			
	--BIDS P3I	Fielded	Joint	Joint	Joint	Joint
	--DOD Biological Sampling Kit	Production	Joint	Joint		Joint
	- Detection System, Biological Agent: Joint Portal Shield	RDTE	Joint	Joint	Joint	
	- Joint Bio Point Detection System (JBPDS), Block I					
Remote/ Early Warning	- Joint Service Lightweight Stand-off Chemical Agent Detector (JSLSCAD)	RDTE	Joint	Joint	Joint	Joint
	- Joint Service Warning and Identification LIDAR Detector (JSWILD/Artemis)	RDTE	Interest	Interest	Interest	Interest
	- Biological Stand-off					
	--Long Range Bio Stand-off Detection System-NDI (LRBSDS-NDI)	Fielded	*Rqmt*	*Interest*		
	--Joint Bio Stand-off Detection System (JBSDS)	RDTE	Joint	Joint	Joint	Joint
NBC Recon	- Joint Service NBC Reconnaissance System (JSNBCRS)	RDTE				
	--NBCRS/CB Mass spectrometer	*	*Rqmt*		*Rqmt*	
	--Joint Service Light NBCRS/Lightweight Recon System (JSLNBCRS)	*	Joint	Joint	Joint	*Interest*
	- Interim Armored Vehicle-NBC Recon Vehicle (NBCRV Block II)	RDTE	Joint			
Warning and Reporting	- Joint Warning and Reporting Network (JWARN)	RDTE/Prod	Joint	Joint	Joint	Joint
	— Multipurpose Integrated Chemical Agent Detector (MICAD)	*	*Rqmt*		*Rqmt*	
Radiation Detection	- AN/UDR-13 Pocket Radiac	Production	Rqmt	Interest		

Joint= Joint Service requirement
Rqmt= Service requirement
Rqmt, Interest= sub-product requirement or interest
LRIP= Low Rate Initial Production
Joint*=Draft Joint Service requirement
Int-NIR= Service interest, no imminent requirement
*= Sub-product(s) of a Joint project

DETECTORS AND MONITORS

FIELDED AND PRODUCTION ITEMS

Chemical Agent Monitor (CAM) and Improved Chemical Agent Monitor (ICAM)

The CAM is a hand held instrument capable of detecting, identifying, and providing relative vapor hazard readouts for G and V type nerve agents and H type blister agents. The CAM uses ion mobility

spectrometry (IMS) to detect and identify agents within one minute of agent exposure. A weak radioactive source ionizes air drawn into the system, and the CAM then measures the speed of the ions' movement. Agent identification is based on characteristic ion mobility and relative concentrations based on the number of ions detected. The ICAM has the same chemical agent detection capability as the CAM; improvements are that it is 300% more reliable, starts up 10 times faster, and the modular design is much less expensive to repair. The ICAM has the additional features of an RS-232 data communications interface, and the ability to be programmed for new/different threat agents. The four pound, 15" long ICAM can be powered either by an internal battery or by an external source through the ICAM's combination power/fault diagnosis/RS-232 plug. The ICAM may be used for a variety of missions, to include area reconnaissance and area surveillance, monitoring of decontamination operations, and medical triage operations. The ICAM significantly reduces the level and frequency of maintenance *vs.* CAM without affecting performance. The ICAM sieve pack has double the capacity of the two CAM sieve packs, which results in twice the operational life of the ICAM over the CAM. When fielded, the ICAM will significantly reduce operating and sustainment costs associated with the CAM by $135 million over its life cycle in present day dollars. This savings is based on the total planned procurement of the ICAM, and would be greater if all CAMs were replaced by ICAMs.

M31 Biological Integrated Detection System (BIDS) Non-Developmental Item (NDI) & Pre-Planned Product Improvement (P3I)

BIDS uses a multiple technology approach, both developmental and off-the-shelf materiel, to detect biological agents with maximum accuracy. BIDS is a vehicle-mounted, fully integrated biological detection system. The system, which is a collectively-protected, HMMWV-mounted S788 shelter, is modular to allow component replacement and exploitation of "leap ahead" technologies. The NDI variant is capable of detecting and presumptively identifying four BW agents simultaneously in less than 45 minutes. Thirty-eight BIDS NDI (version, shown) were fielded to the 310th Chemical Company (U.S. Reserve) during FY96. This gave DoD its first credible, rapidly deployable biological detection capability. The BIDS is a Corps level asset. The P3I BIDS is capable of detecting and presumptively identifying 8 BW agents simultaneously in 30 minutes. The suite is semi-automated and contains next generation technologies such as the Ultraviolet Aerosol Particle Sizer (UVAPS), Chemical Biological Mass Spectrometer (CBMS), Mini-Flow Cytometer, and the Biological Detector (BD). Fielding of 38 systems to the 7th Chemical Company was completed in October 1999. In 4QFY03, the third BIDS company, 13th Chemical (P3I), will be fielded at Ft. Hood, Texas.

Interim Biological Agent Detector (IBAD)

IBAD provides shipboard detection of biological warfare agents. IBAD consists of a particle sizer/counter, wet wall cyclone particle sampler, and hand held assays (HHAs) for the presumptive identification of suspect aerosol particles. IBAD is capable of detecting an increase in the particulate background, which may indicate a man-made biological attack is underway, and sampling the air for identification analysis. IBAD can detect a change in background within 15 minutes and can identify biological agents within an additional 30 minutes, utilizing the HHAs. It is an interim rapid prototype

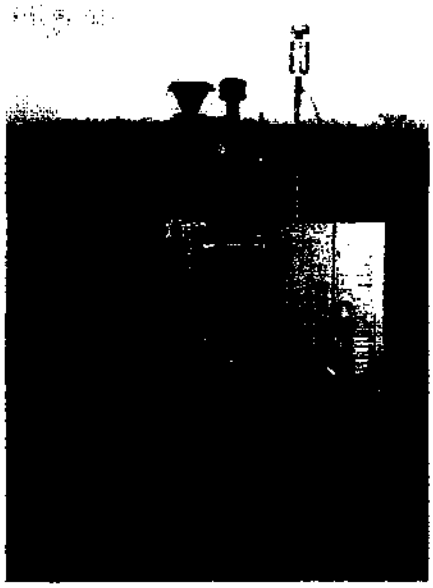
system that started service with the fleet in FY96. Twenty IBAD systems have been fielded. These systems will be among ship platforms as dictated by fleet priorities.

Detection System, Biological Agent: Joint Portal Shield

Portal Shield is a biological detection capability at high value fixed sites. Portal Shield has transitioned from an ACTD to a formal production program in 1999. The system uses an innovative network of sensors to increase the probability of detecting a BW attack while decreasing false alarms and consumables. The Portal Shield system consists of a variable number of biological sensors placed around the perimeter of a fixed site forming a network under the command and control of a centralized command post computer (CPC). The CPC communicates with and monitors the operation of each sensor. The sensor is modular in design and can detect and presumptively identify up to eight BW agents simultaneously in less than 25 minutes. The Portal Shield was successfully deployed overseas in support of Operation Desert Thunder, and was also successfully operated during the NATO 50th anniversary. First Unit Equipped was in March 1999. Nine overseas sites are currently fielded and outfitted with Portal Shield networks. An additional 12 sites are scheduled and funded for fielding in FY01-02. Portal Shield also provides a chemical sensor interface (M22 ACADA, M21 RSCAAL, M90 AMAD) for an integrated chemical and biological sensor network capability.

Joint Biological Point Detection System (JBPDS)

JBPDS provides point biological detection capabilities for all four services and throughout the battlespace. The system, which complements Joint Portal Shield and P3I BIDS and replaces the NDI-BIDS and IBAD, is both more reliable and sensitive than all predecessor systems. The sensor's highly maintainable and modular design detects and presumptively identifies ten BW agents simultaneously in less than 20 minutes. Its detection suite is common across multiple configurations (*i.e.*, the XM96 Man Portable, the XM97 Shelter, the XM98 Shipboard, and the XM102 Trailer Mounted for airbase, vehicle, surface combatant and marine expeditionary applications). The system may be operated locally or remotely, and fully automates the functions of: *collection* (capturing samples of the suspect aerosol for systems and confirmatory analysis), *detection* (interrogating and broadly categorizing the contents of the aerosol), *identification* (providing presumptive identification of the suspect BW agent), and *warning* (providing visual and audible alert to local and remote control units). This acquisition strategy allows for significant economies throughout the RDA process, eliminating duplicative efforts among the services, and greater logistic supportability in joint operations. The current strategy also offers the fastest possible fielding of these urgently required systems, as well as the flexibility needed to continuously improve the system (by virtue of a parallel Block II Spiral Development effort) with the latest advances in the biological detection/identification, information processing and engineering sciences.



Hand Held immunochromatographic Assay (HHA)

The HHA is a simple, antibody-based test used as a quick screen to presumptively identify BW agents from environmental samples. HHAs are inexpensive easy to use, very reliable, and provide presumptive identification in 15 minutes. HHAs are designed to presumptively identify one agent per HHA and can currently identify 10 different BW threat and 4 simulant agents. Training HHAs are also available. HHAs are read at 15 minutes and can either be read by eye or incorporated into automated detection device (*e.g.*, XM-99 Joint Portal Shield, Joint Biological Point Detection System (JBPDS), *etc.*). HHAs should not be used for the analysis of soil samples and are not for diagnostic use. HHAs must be stored at 4°C, but cannot be frozen. Shelf life at refrigeration temperatures (4°C) is 2 years. The HHA has a one-time use only capability, cannot be reused once fluid is applied, and must be disposed of as medical waste. All HHA results must be confirmed by a "Gold Standard" laboratory.

DoD Biological Sampling Kit

The DoD Biological Sampling Kit, with its associated HHAs, provides a presumptive identification capability for BW agents in environmental samples and are employed for: field screening suspect

munitions or munitions fragments for presence of biological warfare (BW) agents; screening envelopes or packages that display suspicious liquids, powders or suspensions; screening suspect terrorist laboratory or weapons materials that might be associated with the manufacture or delivery of BW agents; or as a contamination identification kit for indoor areas where it is suspected a BW agent has been released in fairly high concentrations. The DoD Biological Sampling Kit contains a panel of 8 HHAs, a blue-capped tube containing a bottle of buffer solution and cotton tipped swabs, and a basic instruction card. Training DOD Biological Sampling Kits are also available as well as an interactive, multimedia training CD-ROM. The DoD Biological Sampling Kit must be stored at 4°C, has a one-time use only capability, and is not for diagnostic use. All components of the DoD Biological Sampling Kit must be disposed of as medical waste. All HHA results must be confirmed by a "Gold Standard" laboratory.

M256A1 Chemical Agent Detector Kit

The M256A1 kit can detect and identify field concentrations of nerve agents (sarin, tabun, soman, GF, and VX), blister agents (mustard, phosgene oxime, mustard-lewisite, and lewisite), and blood agents (hydrogen cyanide and cyanogen chloride) in both vapor and liquid form in about 15–20 minutes. The kit consists of a carrying case containing twelve chemistry sets individually sealed in a plastic laminated foil envelope, a book of M8 chemical agent detector paper, and a set of instructions. Each detector ticket has pretreated test spots and glass ampoules containing chemical reagents. In use, the glass ampoules are crushed to release a reagent, which runs down pre-formed channels to the appropriate test spots. The presence or absence of chemical agents is indicated through specific color changes on the test spots. The kit may be used to determine when it is safe to unmask, to locate and identify chemical hazards (reconnaissance), and to monitor decontamination effectiveness.

ABC-M8 VGH, and M9 Chemical Agent Detector Paper

M8 and M9 paper are dye impregnated papers that change color when exposed to liquid chemical agents or aerosols. These papers cannot detect chemical agents in vapor form. M8 paper comes in 4" by 2 ½" booklets. Each booklet contains 25 sheets of detector paper that are capable of detecting G series nerve agents (sarin, tabun, soman, and GF), V type nerve agents, and H (mustard) type blister agents. M8 paper can identify agents through distinctive color changes from its original off-white: yellow-orange for G, blue-green for V, and red for H. M8 paper is typically used to identify unknown liquid droplets during chemical reconnaissance/surveillance missions. M9 (SR119) detector paper is rolled into 2-inch wide by 30-feet long rolls on a 1.25-inch diameter core. M9 paper can detect G and V nerve agents, H agents, and L agents but it cannot distinguish the identity of agents. It turns pink or a shade of red when in contact with liquid chemical nerve and blister agents. M9 paper is typically placed on the BDO, equipment, and vehicle exteriors to warn personnel of the presence of a liquid chemical agent.

M18A3 Chemical Agent Detector Kit

The M18A3 can detect and identify dangerous concentrations of nerve agents (sarin, tabun, soman, GF, and VX), blister agents (mustards, phosgene oxime, mustard-lewisite mixture, phenyl dichloroarsine

(PD), ethyl dichloroarsine (ED), and methyl dichloroarsine (MD)), blood agents (hydrogen cyanide and cyanogen chloride), and choking agents (phosgene) in about 1–4 minutes. The kit is also used to confirm results of the M256A1 kit. The M18A3 kit contains a squeeze bulb and enough detector tubes, detector tickets, and chemical reagents needed to conduct 25 tests for each agent vapor. The kit also contains a booklet of M8 chemical agent detector paper to detect liquid agents. Agent vapor detection is indicated by the production of a specific color change in the detector tubes. The M18A3 kit is only used by special teams such as surety teams or technical escort personnel.

M272 Water Test Kit

The M272 kit can detect and identify hazardous levels of nerve, blister, and blood agents in treated or untreated water resources in about 20 minutes. The kit contains enough detector tubes, detector tickets, a test bottle, and pre-packed, pre-measured test reagents to conduct 25 tests for each agent. The kit also contains simulants used for training. Agent detection in water is indicated by the production of a specific color change in the detector tubes or in the ticket. The M272 was fielded in 1984 and does not meet current lower level detection requirements.

M8A1 Automatic Chemical Agent Alarm (ACAA)

The M8A1 ACAA is a system that continuously samples the air to detect the presence of dangerous concentrations of G and V type nerve agent vapors. This system is currently being replaced by the ACADA in many Army units. Displaced M8A1 systems are being cascaded to lower priority units throughout the Army. The M8A1 ACAA may be employed in a number of configurations, but all configurations are built around the M43A1 detector unit and the M42 alarm unit. The configurations differ primarily in their mountings and power supplies: ground mounted and battery operated, or mounted on a vehicle and powered by the vehicle's electrical system. The M43A1 detector unit measures 7 1/2" x 5 1/2" x 11". Using the battery in ground mounted operations adds another 7 3/4" to the height. The M43A1 detector unit uses a radio-isotope to ionize molecules in the air that is pumped through the system, then detects electrical current changes that occur in the presence of nerve agents. The M43A1 detector unit will alarm within about 1-2 minutes from exposure to agent. The M42 alarm unit is a remote visual and audible alarm that measures 7" x 4" x 2 1/3". The M42 alarm unit may be placed up to 400 meters from the M43A1 detector unit to give users warning of an approaching agent cloud.

M90 Automatic Agent Detector (AMAD)

The AMAD is an automatic nerve and mustard agent detector that detects agents in vapor form. This system is currently in use by the Air Force. It transmits an alarm by radio to a central alarm unit.

Automatic Liquid Agent Detector (ALAD)

The ALAD is a liquid agent detector that can detect droplets of GD, VX, HD, and L as well as thickened agents. It transmits its alarm by field wire to a central alarm unit. Although the remote transmission is useful, the device only detects droplets of liquid agents. It must be used in conjunction with other point or standoff vapor agent detectors to afford a complete detection capability.

Chemical Agent Point Detection System (CAPDS), MK21, MOD1

CAPDS is a fixed system capable of detecting nerve agents in vapor form, using a simple baffle tube ionization spectrometer. Installed in a ship's upper superstructure level, CAPDS obtains a sample of external air, ionizes airborne vapor molecules, and collects them on a charged plate after eliminating lighter molecules via the baffle structure. When a sufficient mass of ions is collected, a pre-set potential is achieved, and an alarm signal is generated and sent to both Damage Control Central and the bridge. The system has been installed on almost all surface ships.

Improved (Chemical Agent) Point Detection System (IPDS)

The IPDS is a new shipboard point detector and alarm that replaces the existing shipboard CAPDS. IPDS uses special elongated ion mobility cells to achieve the resolution necessary to counter false alarms caused by interferent vapors. IPDS can detect nerve and blister agent vapors at low levels, and automatically provide an alarm to the ship. The unit is built to survive the harsh sea environment and the extreme electromagnetic effects found on Navy ships.

M22 Automatic Chemical Agent Detection Alarm (ACADA)

ACADA is a man-portable, point sampling alarm system that provides significant improvement over current capabilities; it detects and identifies all nerve agents, mustard, and lewisite, by class. ACADA provides concurrent nerve and blister agent detection, improved sensitivity and response time, agent identification capability, improved interference rejection, extensive built-in test, a data communications interface, and the capability to be programmed for new threat agents. It replaces the M8A1 Alarm as an automatic point detector and augments the CAM as a survey instrument. The ACADA consists of an off-the-shelf non-developmental item (NDI)—the GID-3 chemical agent alarm. A shipboard version of the ACADA is being built to address the unique interferents found aboard Navy ships that cause false alarms on the NDI ACADA. The shipboard version of ACADA will serve to cover the Navy's emergency requirements until the Joint Chemical Agent Detector can be fielded.

DETECTORS AND MONITORS

RDTE ITEMS

Agent Water Monitors

The Joint Service Chemical Biological Agent Water Monitor is a cooperative RDTE effort, chartered to develop a detection system which will detect chemical and biological agents in water. The detector will feature multi-agent capabilities, and operate automatically, improving both ease and response time of existing system. The project will accommodate the four services' requirements.

Rationale:

- Joint Army, Air Force, and Marine Corps requirement
- Navy interest

Key Requirements:

- Detect and identify chemical agents and agents of biological origin in water
- Perform monitoring automatically with continuous and batch sampling capabilities
- Easy to operate and support in forward areas, austere environments, and limited lighting

Description:

The Agent Water system will improve current water monitoring and purifying capabilities. It will automatically detect CB agents at or below harmful levels in water and not false alarm to common interferents. The system will be compact, man-portable and easy to use, and be decontaminated to a negligible risk level.

Joint Chemical Agent Detector (JCAD)

The JCAD is a fully cooperative RDTE effort, chartered to develop a chemical agent detector for a variety of mission requirements and service platforms. The detector will provide warfighters near-real time information on the presence of chemical agents so that miosis or more severe effects can be avoided and not subvert the mission. The project will accommodate the four services' requirements.

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Small, lightweight detector capable of detecting presence of chemical agent vapors
- Capable of de-warning, allowing for rapid reduction of protective postures
- Detect, identify, quantify, and warn of
  presence of even low levels of nerve, blister,
  and blood agents in vapor form in aircraft and shipboard interiors
- Operated/maintained by ship's force;
  operate in a shipboard environment

Description:

JCAD will provide a detector or a network of detectors capable of automatically detecting, identifying, and quantifying chemical agents (nerve, blister, and blood) inside aircraft and shipboard interiors. The device must be sufficiently sensitive to warn aircrews before accumulation, over the entire mission, of levels of agent that may cause miosis or more severe effects. JCAD will also provide hand-held monitoring capabilities, protecting the individual soldier, sailor, airman, and marine through the use of pocket-sized detection and alarm.

Force Medical Protection/Dosimeter ACTD

Rationale:

- Supports Joint Forces Command (JFCOM)

Key Requirements:

- Develop an individually worn sampler that can continuously measure and archive exposure levels of chemical and biological warfare agents using passive sampling methodology (Phase I)
- Include real-time analysis, an alarm to warn the wearer of an immediate chemical hazard, and a trap for biological agents for later analysis (Phase II)
- Develop extensive concepts of operations (CONOPS) encompassing diverse operational forces and scenarios

Description:

The Force Medical Protection Dosimeter ACTD seeks to develop an individually worn sampler that can continuously measure and archive exposure levels of chemical and biological warfare agents. The Phase I of the development will emphasize collection and archiving of exposure to chemical agents using passive sampling methodology. Phase II will include real-time analysis, an alarm to warn the wearer of an immediate chemical hazard, and will trap biological pathogens for later analysis.

Improved detection and identification capabilities will provide greater awareness of immediate chemical exposure risk, more precise identification of exposure, and amount of individual or multiple doses, which will result in improved situational awareness, treatment, and record keeping. Additional payoffs will include the ability to perform real-time analysis of agents, communication of exposure information to command centers, and increased battlefield awareness and intelligence.

Specific challenges include developing technologies to collect, analyze, and differentiate between agents, interferents, and naturally occurring compounds; improving selectivity and sensitivity to agents. Providing communications capabilities and real-time alarm while reducing size and weight will require advances in sampling methods, chemical analysis techniques, and electronics. Developing CONOPS for use of a sampler will require modeling, experimentation, field testing to improve capabilities and increase utility, and analysis to determine value of information of exposure data collected, especially if exposure levels are below threshold clinical effects levels.

BIOLOGICAL LONG LINE SOURCE RELEASE AND POINT DETECTION

RDTE ITEMS

Biological Point Detection is a fully cooperative acquisition effort chartered to develop new biological point detectors and detection systems for the four services. The BIDS effort encompasses development of an integrated system as well as several stand-alone biological detectors. In addition, a Joint Biological Point Detection System (JBPDS) is under development. JBPDS will be a system that can stand alone, or be used in a suite of systems.

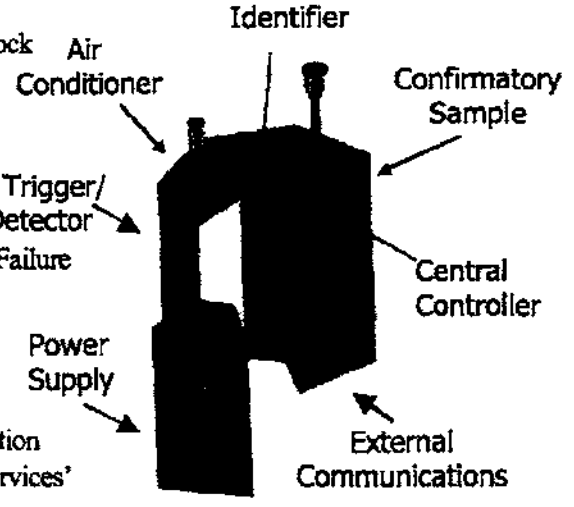
Joint Biological Point Detection System (JBPDS) Block II

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Automatically detect, identify and warn of the presence of biological warfare and produce a sample for transport to and further analysis by designated laboratories.
- Simultaneously identify eight to ten agents with and interchangeable library of assays for all ITF-6 agents.
- Detect cloud concentrations better than Block I and/or militarily significant levels of BW agents at a detection probability of 90% in less than five minutes.
- Reliability of 0.92.
- Availability of 0.90.
- Mean Time Between Operational Mission Failure of 288 hours
- Mean Corrective Maintenance Time for Operational Mission Failure Repair of 5 hours or less.
- Provide a common suite of biological detection equipment that can be applied to all four services' designated platforms



Potential JBPDS Block II Configuration

Description:

This developmental system will replace all existing biological detection systems (BIDS, IBAD and the Joint Portal Shield Network System), and complement the JBPDS Block I in the field. It will provide biological detection capabilities for all four services and throughout the

battlespace. The Block II JBPDS program will undertake a spiral development process to exploit rapid advances taking place in the biological detection/identification, information processing and engineering sciences. The Block II Development effort will yield technology advancements and insertions into the Block I Production effort and provide for the fastest possible fielding and upgrade of joint biological detection capabilities. The PM, JBPDS plans to award a Development contract in FY03 for the design, integration and fabrication of Block II JBPDS. Block II Low Rate Initial Production is anticipated to start in FY06, with first unit equipped in 3QFY07.

Critical Reagents Program (CRP)

Rationale:

- Supports all Services, DoD first responders, Federal Agency's, and NATO countries' biological detection programs

Key Requirements:

- Provide Total Life Cycle Management for the critical reagents (antibodies, antigens, and gene probes and primers), Hand Held Assays (HHAs), and DoD Biological Sampling Kits necessary to the operation of all DoD biological detection systems.
- Ensure best quality reagents and HHAs are available in time and in adequate quantities.
- Ensure adequate security and surge capability of critical reagents and HHAs.
- Produce Hand Held Assays (HHAs) and DoD Biological Sampling Kits that are critical to all DoD biological detection programs.

Description:

The Critical Reagents Program (CRP) ensures the quality, availability, and security of BW reagents, Hand Held Assays (HHAs) and DoD Biological Sampling Kits, which are critical to the successful development, test, and operation of DoD biological warfare detection systems and medical biological products. The program maintains an R&D effort to ensure the best possible reagents are available for use against both current and emerging threats and to include analysis of commercially available reagents and technologies. The CRP has instituted a program-wide quality assurance program and addresses relevant security issues. The CRP consolidates all DoD antibody, antigen, gene probe/primer, HHA, and DoD Biological Sampling Kit developments and requirements. The CRP currently has reagents and HHAs to detect 10 BW threat agents from the ITF-6A threat list. The CRP provides required reagents and HHAs to support fielded DoD BW detection systems (BIDS NDI and P3I, XM-99 Joint Portal Shield, IBAD, and DoD Biological Sampling Kits) and developmental systems (JBPDS), as well as other Federal Agencies and NATO allies. The near future requires the development of 12 additional reagents to support the development and fielding of JBPDS Block II and the development of environmental and diagnostic molecular reagents for the JBAIDS. Outlying years will focus on the development of reagents to identify new and emerging threats and the procurement of improved reagents to replace older stocks.

STAND-OFF DETECTION AND REMOTE/EARLY WARNING

FIELDED AND PRODUCTION ITEMS

AN/KAS-1/1A Chemical Warfare Directional Detector (CWDD)

This is a semi-portable system designed to detect nerve agent vapor clouds at ranges up to five kilometers. The AN/KAS-1/1A must be removed from its stowage case and set up on a pre-installed pedestal for operation. A trained, diligent operator must manually aim the detector at the suspect cloud and interpret its infrared images to determine whether or not the cloud contains nerve agent vapors. The AN/KAS-1A provides a remote video display, an enhanced capability for vapor cloud analysis, and a remote relative bearing indicator useful for avoiding the agent cloud or other surface target with a thermal signature.

M21 Remote Sensing Chemical Agent Alarm (RSCAAL)

The M21 RSCAAL is an automatic scanning, passive infrared sensor that detects nerve (GA, GB, and GD) and blister (H and L) agent vapor clouds based on changes on the infrared spectrum caused by the agent cloud. It is effective at line-of-sight distances of up to five kilometers. The alarm is used for surveillance and reconnaissance missions in both vehicle-mounted and tripod-mounted modes.

Long Range Biological Stand-off Detector System (LRBSDS) - NDI

LRBSDS utilizes elastic backscatter and infrared light detection and ranging (IR-LIDAR) technology to detect, range, and track particulate clouds that are indicative of a BW attack. It is able to detect and track aerosols out to 30 km, but it cannot discriminate biological from non-biological particulates. The system, which is approximately 1,240 pounds and 2.3 cubic meters, has three major components: a pulsed laser transmitter operating at IR wavelengths; a receiver and telescope; and an information processor and display. The system is mounted on a UH 60 Blackhawk helicopter for operations. The three NDI LR-BSDSs have been fielded to the 310th Chemical Company (US Army Reserves).

STAND-OFF DETECTION AND REMOTE/EARLY WARNING

RDTE ITEMS

Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD)

The JSLSCAD is a fully coordinated joint service RDTE program, chartered to develop a lightweight standoff chemical detector for the four services. The JSLSCAD will utilize a passive infrared sensor with 360° scanning to satisfy requirements for all four services.

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement. (Army is lead Service)

Key Requirements:

- Automatically detect nerve, blister, and blood agents at a distance up to 5 km
- Lightweight and employed from manned and unmanned systems
- Capable of being data-linked with centralized hazard information data collection center
- Capable of remote operations; aerial and on-the-move operation

Description:

JSLSCAD will be capable of scanning 360° x 60°, and automatically detecting nerve or blister agents at a distance up to 5 km. The system will be light, compact and operate from a stationary position or on-the-move. The JSLSCAD Michelson interferometer employs a passive infrared system that will detect presence of chemical agents by completing a spectral analysis of target vapor agent chemical clouds. JSLSCAD is envisioned for employment on various platforms and in various roles, including fixed site defense, unmanned aerial vehicles, tanks and other vehicles, and on board ships. Among the vehicle platforms will be the JSLNBCRS (both HMMWV and LAV variants).

Joint Service Warning and Identification LIDAR Detector (JSWILD/Artemis)

JSWILD is a joint effort chartered to develop a chemical warning and identification system for the quad-services. JSWILD will utilize an active LIDAR sensor to perform rapid agent identification and ranging to satisfy requirement for all four services.

Rationale:

- Army, Navy, and Air Force interest

Key Requirements:

- Automatically detect, range, and map CW agents at distances of up to 20 km
- Scan atmosphere and terrain to detect chemical vapors and airborne liquids and particles
- Provide stand-off capability for both fixed site and reconnaissance
- Provide rapid agent concentration mapping

Description:

JSWILD/Artemis will be a vehicle-mountable, contamination monitoring system, which detects and quantifies all types of chemical agent contamination (including agent rain, vapors, and aerosols) in a stand-off mode from a distance of 20 kilometers (km). The JSWILD/Artemis will operate from fixed sites ground vehicles, or shipboard. The system has distance-ranging and contamination-mapping capabilities and transmits this information to a battlefield information network.

Biological Remote/Early Warning

The Joint Biological Remote Standoff Detection System (JBSDS) program is intended to give the warfighting commander a significantly shortened decision cycle regarding biological attacks; that is, the commander will see and be able to react to a biological attack much faster, thereby allowing many more personnel to take protective measures before they become exposed to the biological warfare agents. This means that fewer people will become casualties, and fewer people will have to take post-attack medical treatments.

Joint Biological Standoff Detection System (JBSDS)

Rationale:

- Joint Requirement

Key Requirements:

- Detect and track aerosol clouds out to 15 km
- Discriminate biological particles from non-biological particles in aerosol clouds out to 3 km
- Operate at fixed site or in stationary mode from mobile platform
- Operate in conjunction with bio point detectors
- Operationally skin and eye safe

Description:

The JBSDS will be a standoff early warning biological detection system. The system will be capable of providing near real time, on-the-move detection of biological attacks/ incidents and standoff early detection/warning of BW agents at fixed sites or when mounted on multiple platforms, including NBC reconnaissance platforms. JBSDS will be employed to provide detection of biological hazards employed by various means and will provide early warning via the Joint Warning and Reporting System

IR LIDAR Cloud Detection & Tracking (15 km)
UV LIDAR Generic Discrimination (Bio vs. Non-Bio) (3 km)
Early Warning Communications
Command & Control Nodes

(JWARN). JBSDS will augment and integrate with existing biological detection systems to provide a biological detection network capable of near real time detection and warning theater-wide to limit the effects of biological agent hazards against U.S. forces at the tactical and operational level of war. JBSDS will have the flexibility to warn automatically or to allow for human intervention in the detection-to-alarm process. JBSDS will be employed in support of various areas of interest (*e.g.*, fixed sites, air/sea ports of debarkation, amphibious landing sites, *etc.*), remotely, in unattended configurations, or on platforms to include vehicles, aircraft, and ships. JBSDS will pass detection information and warnings through existing and planned communications networks (*e.g.*, JWARN). Commanders may integrate JBSDS outputs with information from intelligence, meteorological and oceanographic, radar, medical surveillance, local area operations, and other available assets to increase force protection, mitigate the consequence of biological hazards, and maximize combat effectiveness.

NBC RECONNAISSANCE

FIELDED AND PRODUCTION ITEMS

M93 NBC Reconnaissance System (NBCRS)

The M93 NBC Reconnaissance System, known as the FOX, is a high mobility armored vehicle capable of performing NBC reconnaissance on primary, secondary, and cross country routes throughout the battlefield. The NBCRS was procured as a Non-Developmental Item and is capable of detection, warning and sampling the effects of NBC weapons and is used as a reconnaissance vehicle to locate, identify and mark chemical and nuclear contamination on the battlefield. The M93 FOX usually accompanies the scouts or motorized reconnaissance forces when performing its NBC mission. The NBCRS has an overpressure filtration system that permits the crew to operate the system in a shirt sleeve environment which is fully protected from the effects of NBC agents and contamination. It utilizes a secure communications system to warn follow-on forces. Samples gathered are forwarded to the Theater Area Medical Laboratory for further analysis and verification. The mobility platform is a six wheeled all wheel drive, armored combat vehicle capable of cross-country operation at speeds up to 65 MPH. The Fox System is fully amphibious and is capable of swimming speeds up to 6 MPH. The M93 NBCRS has been fielded worldwide to the Army and Marine Corps forces.

M93A1 – FOX NBC Reconnaissance System (NBCRS)

The Block I Modification-M93A1 NBCRS contains an enhanced and fully integrated NBC sensor suite consisting of the M21 RSCAAL, MM1 Mobile Mass Spectrometer, CAM/ICAM, AN/VDR-2, and M22 ACADA. The NBC sensor suite has been digitally linked together with the communications and navigation subsystems by a dual-purpose central processor system known as MICAD. The MICAD processor fully automates NBC Warning and Reporting functions and provides the crew commander full situational awareness of the Fox's NBC sensors, navigation, and communications systems. The M93A1 FOX is also equipped with an advanced position navigation system (GPS & ANAV) that

enables the system to accurately locate and report agent contamination. The NDI mobility platform is a six wheeled, all wheel drive armored vehicle capable of cross-country operation at speeds up to 65 MPH. The Fox System is also fully amphibious and is capable of swimming at speeds up to 6 MPH. It is used as a reconnaissance vehicle to locate, identify, and mark chemical and biological agents on the battlefield. The FOX usually accompanies the scouts or motorized reconnaissance forces when performing its NBC mission.

NBC RECONNAISSANCE

RDTE ITEMS

NBC Reconnaissance System (NBCRS) Block II

Rationale:

- U.S. Army and U.S. Marine Corps Requirements

Description:

The Block II modification will incorporate enhanced chemical and biological detectors that will allow on-the-move standoff chemical agent vapor detection. Biological agent detection capability is added for the first time through the Chemical Biological Mass Spectrometer (CBMS). The CBMS (shown) also improves the detection and identification of liquid agents. Integration of common NBC technical architecture will facilitate low-cost expansion/upgrading of on-board computers. The NBCRS Block II Program will provide CB Sensor Suites to the Army's Nuclear, Biological and Chemical Reconnaissance Vehicle (NBCRV) Program, which will be used to equip the Army's future Brigade Combat Teams.

Joint Service Light NBC Reconnaissance System (JSLNBCRS)

Rationale:

- Joint U.S. Army, U.S. Air Force, and Marine Corps Requirements

Key Requirements:

- Stand-off and point detection from vehicle mounted or dismounted operations
- Chemical standoff detection
- Detection while on-the-move capability from speeds of 0–45 kph
- Biological point detection and identification
- A dismountable, handheld, self-contained chemical point detection capability
- Radiological detection capability (vehicle mounted or dismounted operations)
- Collective protection
- Environmental Conditioning Unit capable of providing climate conditioning for the crew and equipment
- Overpressure protection from all known agents

Description:

The JSLNBCRS (*HMMWV variant shown*) will provide a premiere vehicle for accurate, rapid NBC combat hazard information by verifying the absence of, finding, mapping, and marking radiological, biological, and chemical hazards. The JSLNBCRS will be an integration of advanced NBC detection and analysis equipment suited for Marine Air-Ground Task Forces (MAGTFs), U.S. Air Force tactical forces, and U.S. Army Light Contingency Forces. Two variants, the High Mobility Multipurpose Wheeled Vehicle (HMMWV) and the Light Armored Vehicle (LAV) are planned and will house the same equipment.

WARNING AND REPORTING

FIELDED AND PRODUCTION ITEMS

Joint Service Warning and Reporting Network (JWARN) (FUE FY 99)

Rationale:

- Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Capable of interfacing with all NBC detectors and sensors
- Capable of interoperability with all service command and control systems
- Capable of generating NBC reports
- Capable of automatic transmission of NBC alarm and data
- Capable of vehicle operation

Description:

The Joint Warning and Reporting Network (JWARN) is an automated Nuclear, Biological, and Chemical (NBC) Information System. The JWARN will be essential for integrating the data from NBC detectors and sensors into the Joint Service Command, Control, Communication, Computers, Information and Intelligence (C^4I^2) systems and networks in the digitized battlefield. JWARN will provide the Joint Force a comprehensive analysis and response capability to minimize the effects of hostile NBC attacks or accidents/incidents. JWARN will also provide the Joint Forces with the operational capability to employ NBC warning technology that will collect, analyze, identify, locate, report and disseminate NBC threat and hazard information. JWARN will be located in command and control centers at the appropriate level defined in Service-specific annexes and employed by NBC defense specialists and other designated personnel. It will transfer data automatically from and to the actual detector/sensor/network node and provide commanders with analyzed data for decisions for disseminating warnings to the lowest echelons on the battlefield. It will provide additional data processing, production of plans and reports, and access to specific NBC information to improve the efficiency of NBC personnel assets. A Block I upgrade is planned to automate NBC warning and reporting tools and to standardize NBC warning and reporting requirements across the Service boundaries.

RADIACS

FIELDED AND PRODUCTION ITEMS

AN/VDR-2

The AN/VDR-2 measures gamma dose rates from 0.01 μGy/hr (micro-Grays per hour) to 100 Gy/hr and beta dose rates from 0.01 μGy/hr to 5 cGy/hr. The unit functions simultaneously as a dose rate meter and dose meter with independent adjustable alarms that can be set at any level over the entire range. Dosage data is independently stored in non-destructive memory for display on command and may be retained when the unit is turned off. The unit is powered by three 9 volt batteries.

AN/PDR-75 Radiac Set

The AN/PDR-75 measures dose from 0 to 999 cGy (centi-Gray). The Radiac Set consists of a dosimeter and a reader. It provides the capability to monitor and record the exposure of individual personnel to gamma and neutron radiation. Each individual will be issued a DT-236/PDR-75 dosimeter. This device, worn on the wrist, contains a neutron diode and a phosphate glass gamma detector. When a determination of exposure is required, the dosimeter is inserted into a CP-696/PDR-75 reader, which then displays the cumulative neutron and gamma dose. The reader is issued at the company level and the dosimeters are issued to all combat, combat support, and combat service support personnel. The reader can be powered by a BA-5590 lithium battery, vehicle battery, or external power supply via adapter cables provided.

AN/PDR-77 Radiac Set

The AN/PDR-77 Radiac Set is a set of portable radiation detection equipment for detecting alpha, beta, gamma, and x-ray radiation. The set consists of a radiacmeter to which one of three radiation probes can be attached for measuring particular types of radiation. The probes are part of the set. The set includes accessories and basic test and repair parts for unit maintenance including a carrying pouch with shoulder straps capable of holding the radiacmeter, alpha probe, and beta/gamma probe for field use. The entire set is contained in a carrying case (large briefcase) for easy portability and storage.

AN/UDR-13 Pocket RADIAC - Production (FUE FY99)

The AN/UDR-13 Pocket RADIAC is a compact, hand-held, tactical device capable of measuring the gamma dose-rate and gamma and neutron cumulative dose in a battlefield environment. Its pocket size permits convenient use by troops on foot. Alarm pre-sets are provided for both the dose-rate and total dose modes. A push-button pad enables mode selection and functional control. Data readout is by liquid crystal display. It will replace the obsolete IM-93 quartz fiber dosimeter and the PP-1578 Dosimeter Charger.

Multi-Function Radiation (MFR) Detector -Production

This program improves radiation detection equipment by replacing the current suite of logistically unsupportable assets. Present detectors (PAC-1S, AN/PDR-43 and AN/PDR-56F) have exceeded maintainability standards. Original manufacturers have either discontinued production or are no longer in business. An improved capability is required to support both wartime and peacetime nuclear accident response operations. A production contract was awarded in March 1995. First deliveries were made in 1997.

ADM-300A Multifunction Survey Meter

The ADM-300A is a battery-operated, self-diagnostic, multiple functional instrument. It is used alone to locate and measure low and high intensity radioactivity in the form of gamma rays or beta particles. It is used with external probes to locate and measure alpha, beta, gamma, and x-rays, and neutron radiation.

DARPA Programs

Tissue-Based Biosensors Program

Accomplishments:

- B-cell sensor prototype system fabricated and tested. Simulant detection down to 200 particles in solution reported.
- Engineered liver and vascular endothelial cells into chip format. Genetically induced fluorescent reporter elements for cell stress into liver cells for detector system.
- Used green fluorescent protein to optically tag transcriptional upregulation cellular events (NFkB) for FLUORO-tox prototype high throughput cell sensor system
- Initiated fluorotox database for data mining cell responses to unknown pathogens.
- Demonstrated 4 order magnitude increase in cell survival by introducing extremophile genes into labile cells.
- Defined mechanism of action of operational neurotoxicants from engine lubricant in neuronal based hand held biosensors.

Description:

DARPA is exploring the use of biological cells and tissues as detector components for sensor devices that will report on chemical and biological toxins. Cells and tissues can be used to report on the functional consequences of exposure (mechanism and activity) to a wide spectrum of chemical and or biological toxins, whether they are living or dead, or whether they have been bioengineered and are currently undetectable by other means (antibodies, nucleic acid sequencing). Technical issues that are being addressed in the program include, (1) the fabrication of biocompatible matrices and interfaces for the long-term retention of cell and tissue function, (2) pattern recognition from critical pathways responsible for the interfaces for the long-term retention of cell and tissue function, (2) pattern recognition from critical pathways

responsible for the processing of toxins, (3) sampling strategies to accurately extract and present the toxin from air, liquid, or solid samples, and (4) systems integration into a functional device. The current focus of the program is on the use of neuronal and immunological cells and tissues as detectors for such devices. Engineering of cells and tissues of these origins, including stem cells, is proceeding in order to optimize sensor performance requirements and fabricate prototype devices for testing evaluation.

Microfluidic Molecular Systems Program

Accomplishments:

- Demonstrated discrimination of 0.4% differences in cell impedance using micromachined dielectrophoreses system.
- Demonstrated on-chip circulation—controlled transport of target liquids through combination of integrated fluidic channels and reaction components.
- Demonstrated microscale enabled immunoassay with enzyme labelers to replace conventional optical label.
- Demonstrated microfan and filter system to capture airborne particulates into liquid for input to detection system.
- Demonstrated efficient transport of DNA over cm distances using electrophoretic confinement and transport through electrophoretic vias.
- Demonstrated a multi-channel device that is able to carry out six independent assays simultaneously using a single point detector.

Description:

Micro total analysis systems are being developed through focused research on microfluidic, chip-scale technologies. Automated sample collection and sample preparation are key front-end processes for early biological agent detection, whether it is by immunoassays, DNA assays, or tissue-based assays. To scale down these processes into miniaturized, multiplexed detection systems, microfluidic chip-scale components need to be developed. Microfluidic components/devices currently being developed by DARPA include chip-scale micropumps/valves, particle separation filters, fluidic interconnects, fluidic manipulation of hybridized microbeads, controlled mixing/dosing, etc. Several demonstrable handheld prototypes, such as a programmable microfluidic system for remote sensors, are currently being tested.

Pathogen Genome Sequencing Program

Accomplishments:

- Sequencing and analysis of the pathogenic bacteria *Brucella suis*, *Coxiella burnetti*, *Burkholderia mallei*, *Rickettsia typhi*, and several orthopoxvirus variants is nearing completion.
- Random phase sequencing via low-level coverage of Ochrobactrum anthrop, a near neighbor of *Brucella suis* was completed.
- Random phase sequencing with high level coverage of *Bacillus cereus* and *Bacillus thuringiensis*, near neighbors of *Bacillus anthracis* was completed.

- Re-initiated sequencing of *Franciscella tularensis* in FY01 with completion anticipated in 3Q FY02. Sequence information is available via National Library of Medicine for all but *O. anthropi* (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=Genome).

Description:

DARPA has made a commitment to sequencing the genomes of one representative strain for each of the high threat biowarfare agents identified by the Chairman of the Joint Chief of Staff threat list. This effort, undertaken with broad community interaction, supports Biological Warfare Defense research activities sponsored by DARPA and is intended to satisfy the needs of Department of Defense components, the Intelligence Community, and other governmental organizations. Interest is focused on BWD pathogens, and non-pathogenic near neighbors thought to be important to establish a basis for low false alarm detection and identification via genotype analysis. The work also contributes to the development of advanced unconventional pathogen countermeasures.

Protection Program

Accomplishments:

- Built first prototype of water disinfection pen (size of a thick fountain pen) based on an eletrochemical cell. The pen was able to create a mixed oxidant solution that is more potent than tablets used nowadays by the forces: the mixed oxidant pen was able to destroy many waterborne pathogens to at least 3 to 4 log removal.
- Demonstrated that harmonic pulsing of a reverse osmosis membrane increases water flux through the membrane and decreases the total dissolved solids.
- Built first prototype water distillation unit the size of a coffee mug that distills water. The distillation unit was able to desalt seawater without clogging. Tests on waterborne bugs show at least a 4 log removal. The water generation rate was measured to be approximately 0.3 liters in 5 minutes.
- Built first generation air purification unit to destroy airborne pathogens by thermocatalytic destruction. The destruction efficiencies for various air pathogens and simulants in the high 90% range. The goal is to get towards at least 99.999% removal rates.
- Began work on advanced carbon surface treatments to improve adsorption capacity and kinetics.

Description:

There are two related programs currently ongoing within DARPA that further enable the individual warfighter by providing significantly more mobile and flexible water purification and desalinization systems and better air filtration media. The intent is to demonstrate highly efficient, smaller, lighter, high water through-put technologies for water purification and desalinization, and to explore pioneering air filtration schemes that have an acutely high utility for the DoD enabling new mission scenarios that are critical to the changing battlefield environment. The water desalinization and purification systems would meet Army Operational Requirements (*i.e.*, effectively treat salt/brackish water and nuclear, biological and chemical contaminated water, purify 0.2 liter water per minute, weigh less than 2 lbs., *etc.*) The proposed man-portable water units will be multifunctional in that they can be used for several functions, such as water purifi-

cation, power generation and camp stoves. Work in air purification develops simple air filtration and purification systems for the individual that provide significant improvements over the current charcoal filter gas mask technology (which have remained virtually unchanged for over 20 years). The intention is to develop air purification systems for collective protection that will require much less maintenance and greater personal safety than current based-carbon recirculating filters.

Annex B

Modeling and Simulation Programs

Table B-1. Modeling and Simulation RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
Hazards Analysis Systems	- VLSTRACK	RDTE/Fielded	Joint*	Joint*	Joint*	Joint* Rqmt
	- CWNAVSIM					
	- MESO	RDTE	Joint*	Joint*	Joint*	Joint*
	- CBW-CFX	RDTE	Joint*	Joint*	Joint*	Joint*
	- HPAC	RDTE	Joint*	Joint*	Joint*	Joint*
	- D2PC/D2Puff	Fielded	Joint*	Joint*	Joint*	Joint*
	- JEM	Fielded RDTE	Joint*	Joint*	Joint*	Joint*
Operational Effects Analysis Systems	- STAFFS	RDTE	Joint*	*Rqmt*	Joint*	Joint*
	- JOEF	RDTE	Joint*	Joint*	Joint*	Joint*
	- JMNBCDST	RDTE	Joint*	Joint*	Joint*	Joint*
Simulation Based Acquisition Systems	- NCBR Simulator	RDTE	Joint*	Joint*	Joint*	Joint*
	- VPS	RDTE	Joint*	Joint*	Joint*	Joint*
Training Simulation Systems	- VERTS	RDTE	Joint*	Joint*	Joint*	Joint*
	- TSC	RDTE	Joint*	Joint*	Joint*	Joint*

Joint= Joint Service requirement
Joint*=Draft Joint Service requirement
Rqmt= Service requirement
Rqmt = sub-product requirement or interest

HAZARDS ANALYSIS

FIELDED AND PRODUCTION

Vapor, Liquid and Solid Tracking (VLSTRACK)

VLSTRACK is a chemical and biological agent hazard assessment model *that predicts the behavior of agents and the resulting hazards from a chemical or biological weapons attack.* This model has been specifically verified and validated against all known data concerning passive defense against biological and chemical weapons and is the only model accredited by the Department of Defense for this purpose. As such, it supports operational decisions, operational contingency planning, threat assessment doctrine, acquisition program studies, and requirements generation. VLSTRACK Version 3.1 is currently available and fielded directly from the science and technology program. Limited training is also available from the developer.

Hazard Prediction and Assessment Capability (HPAC)

HPAC is a nuclear, chemical and biological hazard prediction system *that predicts hazards resulting from the use of our forces on opposition facilities or assets.* It is the only model accredited by the Department of Defense for this purpose. HPAC Version 4.0 is a modular system of capabilities using a Gaussian puff methodology Transport and Dispersion engine called SCIPUFF to drive specific nuclear, biological or chemical event applications. It has a broad data base system and is able to use various weather data inputs. HPAC supports operational decisions, operational contingency planning, threat assessment doctrine, acquisition program studies, and requirements generation. HPAC Version 4.0 is currently available and fielded directly from the Technology development program conducted by the Defense Threat Reduction Agency (DTRA). Training is also available from the developer.

D2PC

D2PC is a Gaussian plume transport and diffusion model that predicts potential hazards involving accidental releases of chemical warfare agents in the U.S. Army's stockpile and non-stockpile programs. The model is used in the planning and response phases of potential accidents. D2 is used to support funding decisions by the Army and Federal Emergency Management Agency (FEMA) to enhance safety in the local civilian communities, including location of planning zones, sirens, tone alert radios, and collective protection facilities. Automated links allow direct input of on-site meteorological data, continuous updating of projected hazard areas, and rapid communication of model results to County and State Emergency Management Agencies. D2 is currently being phased-out and replaced with the D2-Puff model. D2-Puff version 4.0 is a kinematic gaussian puff model that accounts for spatial and temporal variability in a wind field over complex terrain. D2-Puff is currently installed at five stockpile sites and is scheduled for installation at the three remaining sites in CY02. The U.S. Army Safety Office has accredited the D2 model for all applications; D2-Puff has full accreditation at three sites and partial accreditation at two other sites. An Independent Verification & Validation was performed on both models in 1999. Training is provided on-site periodically. Model development is funded by the U.S. Army SBCCOM Program Manager for the Chemical Stockpile Emergency Preparedness Program.

HAZARDS ANALYSIS

RDTE ITEMS

CWNAVSIM

Rationale:

- Navy requirement

Key Requirements:

- Predict ship system degradation resulting from a chemical attack.
- Predict Mission Oriented Protective Posture (MOPP) requirements resulting from a chemical attack.
- Predict shipboard chemical agent detection system effectiveness.

Description:

CWNAVSIM was developed to address specific Naval acquisition program decisions regarding Chemical weapons defensive systems, specifically, the needed Tactics, Techniques and Procedures (TTPs) needed to defend the ship and the need for and placement of detection devices. CWNAVSIM makes use of VLSTRACK, two ship-specific models (VENM and NURA), gridded ship representations and other ship specific databases to predict hazard levels throughout the ship as well as shipboard casualties and mission degradation. It has been accredited by specific Chief of Naval Operation offices to support acquisition program decisions. CWNAVSIM is only available from the CBD science and technology program. Training is not available.

MESO

Rationale:

- Joint requirement

Key Requirements:

- Advance the state-of-the-art in use of Lagrangian particle transport and diffusion (T&D)
- Advance the state-of-the-art in characterization of the planetary boundary layer
- Address physical processes and hazard assessment capabilities of current standard models for CBD

Description:

MESO is developed by ITT to provide a T&D capability which is more accurate and theoretically sound than Gaussian puff methodology but does not require the time and computer resources of a full Navier-Stokes Computational Fluid Dynamics (CFD) code. The development effort for the Department of Defense is also intended to provide advances in modeling important physical processes relevant to hazard assessment. MESO is currently not in distribution.

Computational Fluid Dynamics for Chemical and Biological Defense (CBW-CFX)

Rationale:

- Joint requirement

Key Requirements:

- Track threat from vapor, liquid, and solid CB agents around or within complex structures, *e.g.*, ships and buildings

Description:

Interface with other models as needed, *e.g.*, VLSTRACK and VENM. CBW-CFX uses CFD code to model the transport, diffusion, deposition, and surface evaporation of chemical and biological agents in and around 3-D structures. CFX is a commercial code developed by AEA Technologies which allows licensed users to develop subroutines which can be used within the code. CBW-CFX adds methodology for physical processes unique to chemical and biological agents. CBW-CFX is intended for use by the developers.

Joint Effects Model (JEM)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Predict hazard areas and contamination effects from nuclear, chemical or biological attack
- Predict hazard areas and contamination effects from nuclear, chemical or biological agent releases and releases of toxic industrial materials

Description:

JEM is the acquisition program of record that will transition the Science and Technology capabilities of VLSTRACK, HPAC, and D2PC. Once fielded, JEM will be the standard DoD Nuclear, Biological and Chemical (NBC) hazard prediction model. JEM will be capable of modeling hazards in a variety of scenarios including: counterforce, passive defense, accident and/or incidents, high altitude releases, urban NBC environments, building interiors, and human performance degradation; some of these capabilities will be included following release of Block 1. JEM will support defense against NBC and Toxic Industrial Chemical (TIC)/Toxic Industrial Material (TIM) weapons, devices, and incidents. JEM will be verified, validated, and accredited (VV&A) according to an approved process that adheres to the DoD VV&A directives. When used operationally, JEM will reside on and interface with command, control, communications, computers, and intelligence (C4I) systems. Warning systems on those C4I systems will use JEM to predict hazard areas and provide warning to U.S. forces within those areas. When used analytically, JEM will assist DoD components to train jointly, develop doctrine and tactics, and assess warfighting, technology, and materiel development proposals, and force structuring. JEM (unclassified version) will also support homeland defense through use by Civil Authorities and Allies.

OPERATIONAL EFFECTS ANALYSIS

RDTE ITEMS

Simulation Training and Analysis For Fixed Sites (STAFFS)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Determines operational effects of CB warfare environment on military fixed site operations
- Interfaces with key NBC models, simulations, and data bases

Description:

STAFFS is a general-purpose simulation model which represents the operations of large fixed-site facilities such as air bases, aerial ports of debarkation (APODs) and seaports of

debarkation (SPODs), with the capability to represent chemical and biological warfare (CBW) attacks and their effects on operations. No other capability currently exists within DoD to assess the operational impact of CBW attacks on critical fixed-site targets. Due to their fixed location and essential combat support roles to forces in the theater of operation, these rear-area facilities can be expected to be high priority targets to aggressor forces and thus one of the most likely targets to encounter CB weapons and their effects. These sites may be particularly susceptible to repeated CBW attacks, which could significantly degrade logistical throughput and hamper combat operations. STAFFS is currently in use and being further developed in two major functional areas: 1) support of wargaming and operational exercises including distributed interactive environments, and, 2) support of operational and requirements analysis. Wargame applications run interactively with STAFFS accepting input and providing output to other model applications running as a system. Man-in-the-loop games and simulations may be performed. Analysis applications typically involve the examination of many different simulation/analysis cases (a case matrix) often involving parametric representation of unknown system data. Different user interfaces are provided specific to the application. STAFFS wargaming applications utilize an interactive graphic user/system interface while analysis applications typically utilize file base batch processing.

STAFFS utilizes spatial and temporal CB challenge data calculated by other standard CB hazard assessment models including VLSTRACK and HPAC. CB equipment and agent effects represented in high resolution include detectors, protective gear, decontamination, toxic and infective agent effects, collective protection, medical treatment, equipment induced thermal effects, equipment induced encumbrance, and doctrinal procedures such as work-rest cycles. These effects are represented by engineering level sub-models which can be easily changed to represent different equipment capabilities and levels of availability. Basic operational tasks are modeled using a task-network approach that is adaptable to any desired level of resolution. STAFFS is developed by AFRL. Limited training is available.

Joint Operational Effects Federation (JOEF)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Analyzes operational issues and doctrine through the interrelation and effects of various elements within the overall system.
- Evaluates the performance of particular equipment based on material characteristics.
- Assesses individual Warfighter ability to perform mission essential tasks.
- Integrates existing transport/diffusion models for CB agent hazards.

Description:

The JOEF will provide the operational community with the federated models and simulations specific to their operational environment required to predict or immediately respond to the need for operational effects information relative to any nuclear, radiological, chemical, or

biological event. JOEF will include both fixed site and mobile forces simulation capabilities that, when married to specific data bases, will completely simulate all nuclear, radiological, chemical and biological defense processes, forces, and battlespace environments. In addition, the Federation will address both personnel degradation and medical processes and resources. JOEF will be used by both the operational commander and operational analyst to make rapid course of action analysis effects- based operational decisions, logistics decisions, CBD asset location decisions, and develop TTPs for CBD operations. The JOEF will be utilized by: 1) operational planners and decision makers in support of course of action assessment and plan evaluation; 2) the analysis community in support of high level concept assessments and system effectiveness studies and 3) Joint exercises and experiments in support of planning, execution, and analysis. The JOEF vision is of a set of validated low-to-medium fidelity warfare entity models, certified data, appropriate simulation services, and related user support tools in a framework suitable for modeling multi-warfare scenarios.

Joint Medical NBC Decision Support Tool (JMNBCDST)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Provide the capability to support deliberate planning, crisis action planning, exercises/training, and execution of operational missions, both on the battlefield and in urban environments.
- Interface with current and co-developmental medical planning tools such as the Medical Analysis Tool (MAT), Command and Control systems, medical informatics including the Defense Medical Surveillance System (DMSS) database, and Joint Warning and Reporting Network (JWARN) for discretionary transmission of data.

Description:

The Joint Medical NBC Decision Support Tool will enable the Service/medical planner/operator to model and analyze the NBC battlefield both to identify Service/Joint Force agent exposures on military and civilian populations and to estimate NBC casualties. It will also relate treatment protocols (time, task, treater files) to these casualties to determine: medical materiel requirements, medical personnel requirements, medical evacuation requirements and for hospital bed requirements at Level 3-5. As such, it supports operational decisions, operational contingency planning, threat assessment doctrine, acquisition program studies, and requirements generation.

SIMULATION BASED ACQUISITION SYSTEMS

RDTE ITEMS

Nuclear, Chemical, Biological and Radiological (NCBR) Simulator

Rationale:

- Army requirement, and Navy, Air Force and Marine Corps interest.

Key Requirements:

- Simulation of fielded and developmental CB defense systems to evaluate performance in operational situations.
- Integration of a CB environment into a distributed simulation environment involving mobile forces.

Description:

The NCBR Simulator provides the capability to utilize existing hazard transport and dispersion codes within the context of detailed materiel evaluations. NCBR enables high fidelity simulations of CB defense equipment (CBDE) such as detectors and protective gear to "see" and react to CB hazards within a detailed synthetic environment. In real time, the NCBR calculates a high fidelity, three-dimensional (3D) hazard environment as a function of hazard delivery system (source term), meteorological conditions and complex (3D) terrain. The DTRA SCIPUFF and the Naval Surface Warfare Center's VLSTRACK Gaussian puff models provide the means for the NCBR to calculate CBR hazard environments. The NCBR makes the data available to other simulations via full 3D representations of the environments (instantaneous air concentration), 2D grids (dose, deposition, and air concentration contours), and at a point via a subscription process. SBCCOM serves as the proponent for configuration control and release of the NCBR, and DTRA WMD Analysis and Assessment Center supported the migration of the tool to the DoD's High Level Architecture (HLA) standard for distributed simulation. NCBR is a key enabling technology for the more inclusive Virtual Prototyping System and will provide the mobile forces capability to JOEF.

To address nuclear environments, the NCBR uses DTRA's External Blast (XBLAST) and Version 6 of Atmospheric Transport of Radiation (ATRv6) as the means for calculating the blast and prompt radiation environments resulting from tactical nuclear warheads. The NCBR publishes axis-symmetric 2D grids and 1D (line) arrays that the receiving simulation rotates about the origin of symmetry to obtain a full 2D or 3D environment.

Virtual Prototyping System (VPS)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Represent standoff and point detection systems on stationary and mobile platforms in urban, rural, and littoral terrains.
- Detector representations will be reconfigurable and responsive to design and operations changes.
- Immersive simulation capability will allow evaluation of operator interfaces.
- Represent individual and collective protection systems in operational environments.

Description:

The VPS will provide the immersive capability to evaluate how the operating characteristics of proposed or developmental CBDE will affect the performance of the overall system. VPS will enable materiel developers to assess how proposed CB defense systems will provide increased capabilities. At a more detailed level it will allow system designers to assess the impact that design changes have on the overall system performance. The virtual immersive capability will enable human factors evaluations of operator interfaces long before the first prototype units of the developmental CBDE are built in hardware. All of these capabilities address the basic SBA tenet of enabling early and sustained user feedback throughout the system design process.

Performance assessments and evaluation will be enabled at the engagement and engineering levels of simulations. The trade space for evaluating technical options for system and component alternatives will be expanded. That evaluation will take place in a realistic synthetic or virtual operating environment. Human and live system in-the-loop capability will exist. Development will be based on current proof-of-concepts simulation used to support developmental, analysis, training and testing efforts. The envisioned simulation system will be able to operate at specific sites for focused evaluations or distributed to many sites for robust Joint Task Force (JTF) engagement assessments of engineering alternatives.

TRAINING SIMULATION SYSTEMS

RDTE ITEMS

Virtual Emergency Response Training System (VERTS)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement.

Key Requirements:

- Visually immersive training environment for specialized missions of the US Army National Guard Weapons of Mass Destruction Civil Support Teams- (WMD CST).
- Must represent not only the deploying military units' personnel and equipment, but also the civil first responders and their equipment with which the CSTs will work..
- Detailed visual and structural databases required for each city/site.

Description:

The VERTS is being developed to enhance the training of WMD CSTs. WMD response requires significant training demands for individual and collective tasks. Soldiers and airmen must be proficient on a wide array of government and commercial equipment for NBC protection, detection and medical response. The WMD CSTs, in particular, are required to master a variety of equipment and procedures. The VERTS is required to support both individual and collective training. VERTS supports training in all tasks for the CST. It allows training on procedures for response to dangerous NBC agents, procedures that are difficult if not impossible to recreate in a live training environment. VERTS also allows mission rehearsals in actual and realistic urban settings. Training in the virtual cities of VERTS allows these teams to learn to navigate in actual cities, in actual buildings and to do so without the threat of being observed by adversaries, criminals and terrorists. VERTS, by being distributable over a network, allows teams to train together without having to travel long distances. Once validated for CSTs, VERTS offers the promise to train other DoD response elements and first responders as well.

The simulation system will consist of a network of PC-based modules that will serve as Survey Team Stations (Desk-Top), a Chief Trainer/Battlemaster Station, Immersive Station, Medical Station, Network Server Station, AAR Station, and Data Logger Station.

Training Simulation Capability (TSC)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Integration with and have access to current and planned individual service C^4I^2RS systems

- Provide ability to gather and store lessons learned and identified failure/error incidents in order to provide after action review
- Provide capability to use NBC effects models and mission data to perform mission rehearsals using a simulation federation.

Description:

The TSC will provide the ability to simulate NBC attacks using NBC defense assets and Command, Control, Communications, Computers, Intelligence, Information, Reconnaissance, and Surveillance (C^4I^2RS) systems for training and exercises. It will allow for exercise planning, execution, and capturing lessons learned for after action review (AAR). It will provide the capability to use or simulate the use of NBC sensors, Tactical Engagement Simulation (TES) gear, and simulators for training and exercises. The TSC will provide the capability to simulate NBC environments and effects under live, virtual, and constructive simulations. It will provide the capability to use training and simulations in both Command Post Exercise (CPX) and Field Training Exercise (FTX) environments. It will operate in conjunction with the Joint Warning and Reporting Network (JWARN), future Joint NBC Battle Management systems, and the other Model and Simulation capabilities developed to support NBC defense requirements.

The TSC will be used at all levels of NBC defense decision-making to train for and simulate NBC attacks against friendly forces. It will provide for the training and use of simulation capability by all NBC defense personnel and commanders related to NBC threats and scenarios. When fully fielded the TSC will run the gamut from individual/team trainers up through large unit battle staff training capabilities.

Annex C

Non-Medical Protection Programs

Table C-1. Protection RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
	INDIVIDUAL PROTECTION:					
Eye/	- MBU-19/P Aircrew Eye/Respiratory Protection (AERP)	Production	Interest	Rqmt	Interest	
Respiratory	- M48 Aircraft Mask	Production	Rqmt			
Protective Masks	- CB Respiratory System (A/P22P-14(V))	Production			Rqmt	Rqmt
	- M45 Aircrew Protective Mask (ACPM)	Production	Rqmt		Interest	
	- M40A1/M42A2	Fielded	Rqmt		Rqmt	Rqmt
	- MCU-2A/P	Production		Rqmt		Rqmt
	- Joint Service Aircrew Mask (JSAM)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
	- Joint Service General Purpose Mask (JSGPM)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
Ancillary	- Protection Assessment Test System (PATS)	Production	Rqmt	Rqmt	Rqmt	Interest
Equipment	- Voice Communication Adapter	Production	Rqmt	Rqmt	Rqmt	Rqmt
	- Joint Service Mask Leakage Tester	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
Battlefield	- CB Protective Overgarment Saratoga	Fielded	Interest		Rqmt	Interest
Protective	- Chemical Protective Undergarment (CPU)	Fielded	Rqmt		Int-NIR	
Suits	- Modified CPU (mCPU)	RDTE	Rqmt			
	- Joint Service Lightweight Integrated Suit Technology, Additional Source Qualification (JASQ)					
	-- Overgarment	Prod.*	Rqmt	Rqmt	Rqmt	Rqmt
	-- Boots (MULO)	MS III*	Rqmt	Rqmt	Rqmt	
	-Battledress Overgarment (BDO)	Fielded	Rqmt	Rqmt		
Specialty	- STEPO	Fielding	Rqmt			
Suits	- EOD Ensemble	Production		Rqmt		
	- Improved Toxicological Agent Protective (ITAP)	MS III	Rqmt		Interest	Interest
	- Joint Firefighter Integrated Response Ensemble (JFIRE)	Production	Rqmt	Rqmt		
	- Suit Contamination Avoidance Liquid Protective (SCALP)	Fielded	Rqmt			
	COLLECTIVE PROTECTION:					
Tentage and	- M20A1/M28 Simplified CP Equipment (CPE)	Fielded	Rqmt	Rqmt		Rqmt
Shelter Systems	- CB Protective Shelter (CBPS) (Medical)	Production	Rqmt		Interest	Interest
	- CP Deployable Medical System -Chemically/ Biologically Hardened Air Transportable Hospital (DEPMEDS/CHATH)	Production	Rqmt	Rqmt		
	- Joint Transportable CP System (JTCOPS)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
Collective	- Shipboard Collective Protection System (CPS)	Production	Interest	Interest		Rqmt
Protection (CP)	- Modular Collective Protection System (MCPE)	Fielded	Rqmt	Interest		Interest
Systems	- M8A3 GPFU	Fielded	Rqmt			
	- M13A1 GPFU	Fielded	Rqmt	Rqmt		Rqmt
	Joint Collective Protection Equipment (JCPE)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
Generic Filters	- M48/M48A1 (100 cfm)	Fielded	Rqmt		Rqmt	Rqmt
	- M56 (200 cfm)	Fielded	Rqmt	Rqmt	Interest	Rqmt
	- Fixed Installation Filters	Fielded	Rqmt	Rqmt		

Rqmt = Product requirement
Interest = Product Interest
Int-NIR = Product Interest, No Imminent Requirement

* - Sub-Product(s) of a Consolidated Joint Service Project
Rqmt, Interest = Sub-Product requirement or Interest

INDIVIDUAL PROTECTION EQUIPMENT

RESPIRATORY

FIELDED AND PRODUCTION ITEMS

M17A2 Protective Mask

The M17A2 Protective Mask consists of a natural blend rubber face piece; two activated charcoal filters mounted within cheek pouches; a voicemitter to facilitate communications, a drinking tube; eyelens outserts to protect the mask's integral eyelens and reduce cold weather fogging; an impermeable hood; and a carrier for the mask, its components, and medical items (such as the Nerve Agent Antidote Kit). The Army and Marine Corps are replacing this mask with the M40 series protective masks. The Navy has replaced the M17A2 protective mask with the MCU-2/P. The Air Force replaced it with the MCU-2A/P, but retained limited quantities of extra small M17A2s for those situations where the MCU-2A/P small size is too large.

ABC-M24 Aircraft Protective Mask

This protective mask provides the wearer protection from NBC aerosols/vapors both in aircraft, and on the ground. The mask consists of: wide view, clear plastic lens embedded in a butyl rubber face blank; an integral microphone; eyelens outserts; carrying case; anti-fog kit; and a hose-mounted filter canister. The mask has a microphone connection to fit the aircraft communications systems. The M24 has an adapter that allows coupling to the aircraft's oxygen supply system. The M24 is being replaced by the M45 mask.

M25A1 Tank Protective Mask

This protective mask provides the wearer protection from NBC aerosols and vapors both in the vehicle/aircraft, and on the ground. The mask consists of: wide view, clear plastic lens embedded in a butyl rubber face blank; an integral microphone; eyelens outserts; carrying case; anti-fog kit; and a hose mounted filter canister. The mask has a microphone connection to fit the armored vehicle communications systems. The M25A1 has an adapter that allows i to be coupled to the tank's filtered and temperature controlled Gas Particulate Filtration Unit (GPFU). The M25A1 is being replaced by the M42A2 protective mask.

MCU-2A/P Protective Mask

The MCU-2A/P provides eye and respiratory protection from all chemical and biological agents as well as radioactive particulate material. The mask uses a replaceable, standard NATO filter canister which is mounted on either side of a wide-view optical quality visor. The mask provides improved fit, comfort, and visibility relative to earlier masks, and includes a drinking tube for attachment to the standard canteen, and electronic voicemitter connections for improved communications.

M40/42 Series Protective Mask

The M40/42 series protective masks provide eye-respiratory face protection from tactical concentrations of CB warfare agents, toxins and radioactive fallout particles. Each mask consists of a silicone rubber face piece with an in-turned peripheral face seal and binocular rigid lens system. The facepiece is covered with a chlorobutyl/EPDM second skin to provide optimum liquid agent protection for the masks. It accommodates NATO standard canisters, which can be worn on either cheek of the mask. The M40 series is designed for the individual dismounted ground warrior, while the M42 series is designed for combat vehicle crewmen. Recent improvements include a universal second skin, making the mask compatible with JSLIST and Saratoga overgarments, and ballistic/laser protective eye lens outserts. The mask facepiece has been made a spare part, which has resulted in a significant operation and support cost savings. Use of modular parts permits the M40 series facepiece to be used in both the M40 and M42 configuration. This has resulted in significant operational and support cost savings.

M43 Protective Mask

The M43 Aviator Mask consists of a form-fitting face piece with lenses mounted close to the eyes; an integral CB hood and skull-type suspension system; an inhalation air distribution assembly for air flow regulation, lenses and hood; and a portable motor/blower filter assembly that operates on either battery or aircraft power. The M43 Type I was developed for the AH-64 aviator and is compatible with the AH-64 Integrated Helmet and Display Sight System and the Optical Relay Tube. The M43 Type II is intended for the general aviator. The M43 Type I (Apache version) will be replaced by the M48. The M43 Type II general aviation version is being replaced by the M45.

M45 Aircrew Protective Mask (ACPM) (FUE FY98)

The M45 Air Crew Protective Mask is specially designed to meet the requirements of Army helicopter pilots and crews (except for the Apache helicopter). It does not require power or forced air to provide CB protection; it provides compatibility with helicopter optical systems, aircraft displays and night vision devices; and has reduced weight, cost and logistical burden when compared to the M43 series of mask. The ACPM has close fitting eyelenses mounted in a silicone rubber facepiece with an in-turned peripheral seal, a detachable hood system, and utilizes the standard NATO canister. The M45 will replace the M43 (Type II) and the M24 aviators mask. The M45 is also being used as a mask for personnel who do not get an adequate face seal in the M40 or MCU-2A/P masks. The M45 comes in four sizes, versus the three sizes for the M40 and MCU-2A/P, and fits a higher percentage of the extra small and extra large population. It will be used to phase out the extra small M17 masks currently being used for some of these hard-to-fit personnel.

M48 Protective Mask - Production

The M48 is the third generation M43 series masks. The M48 mask replaces the M43 Type I mask and will be the only mask for the Apache aviator for the foreseeable future. The M48 mask consist of a lightweight motor blower, a new hose assembly, a web belt, the mask carrier, facepiece carrier, eyelens

cushions, and facepiece. The motor blower is aircraft mounted with a quick disconnect bracket on the pilot's seat during flight operations.

Aircrew Eye/Respiratory Protection (AERP)

The AERP (replaces the MBU-13/P system for aircrews) is a protective mask which enables aircrews to conduct mission operations in a chemical-biological environment. The AERP system includes a protective hood assembly with a standard MBU-12/P mask, an intercom for ground communication, and a blower assembly that provides de-misting. The blower is stowed during flight operations on a bracket that is mounted inside the aircraft.

CB Respiratory System (A/P22P-14(V) 1, 2, 3, & 4) NDI

The CB Respiratory System is a self-contained protective ensemble designed for all forward deployed rotary wing (Version 1 for USN) and fixed wing (Version 2–4 for USN and USMC) aircrew. The design incorporates a CB filter, dual air/oxygen supply and a cross-over manifold with ground flight selector switch to provide filtered air for hood ventilation, and filtered air for oxygen for breathing. The system provides enhanced protection and offer anti-drown features.

RESPIRATORY

RDTE ITEMS

Joint Service General Purpose Mask (JSGPM)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- 24-hour CB protection
- Lower breathing resistance
- Reduced weight and bulk

Description:

The JSGPM will be a lightweight protective mask system—consisting of mask, carrier, and accessories—incorporating state-of-the-art technology to protect U.S. forces from all future threats. The mask components will be designed to minimize the impact on the wearer's performance and to maximize the ability to interface with future Service equipment and protective clothing.

Joint Service Aircrew Mask (JSAM)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Continuous CB protection
- Improved anti-G protection

Description:

JSAM will be a lightweight CB protective mask that can be worn as CB protection for all aircrew. With the addition of anti-G features, it can be worn as combined CB and anti-G protection for aircrews in high performance aircraft. It will be compatible with existing CB ensembles, provide flame and thermal protection, provide hypoxia protection to 60,000 feet, and the CB portion will be capable of being donned in flight. JSAM will also be compatible with existing aircrew life support equipment.

Joint Service Chemical Environment Survivability Mask (JSCESM)

Rationale:

- Joint Army (SOCOM), Air Force, Marine Corps, Navy (potential) requirement

Key Requirements:

- One size fits all
- For low threat area usage
- Limited protection (6 hours, limited agent concentrations)
- Small, lightweight
- Drinking capability

Description:

The JSCESM is intended to be a lightweight complement to the JSGPM. It will provide commanders at all levels with greater options for protection, especially in Operations Other Than War (OOTW). The JSCESM will provide an inexpensive/disposable, emergency mask for use in NBC situations confronting the Services operating in low NBC threat conditions and military medical care providers and patients in certain instances when using the standard service mask is not practical. Warfighters in special operations or other combat/non-combat roles will carry JSCESM (in the uniform cargo pocket) or while in civilian clothing (concealable) during deployment when an NBC threat is possible, but unlikely. Additionally, other missions exist for the JSCESM such as use in collective protection shelters (CPS) if the shelter filtration system fails or emergency evacuation of a shelter is required when contamination is present.

ANCILLARY MASK EQUIPMENT

FIELDED AND PRODUCTION ITEMS

M41 Protection Assessment Test System

The M41 Protection Assessment Test System (PATS) enhances operational capability by validating proper fit of the mask to the face of the individual. PATS provides a simple, rapid, and accurate means of validating the face piece fit and function of protective masks.

Voice Communication Adapter

The Voice Communication Adapter (VCA) is a low risk program providing additional capability to the M40/42 mask. The VCA is a joint program between the USMC and US Army.

Universal Second Skin

The Universal Second Skin is one of the components of a pre-planned product improvement (P3I) in the M40/M42 series mask. The Universal second skin provides liquid agent protection for the mask faceblank material. This program is a Joint U.S. Army/U.S. Marine Corps effort. Both Services developed prototype designs and, after field user and human engineer testing, the Marine Corps design was selected. The Air Force is developing a second skin for the MCU-2A/P.

ANCILLARY MASK EQUIPMENT

RDTE ITEMS

Joint Service Mask Leakage Tester

The Joint Service Mask Leakage Tester (JSMLT) will b a man portable test system capable of checking the serviceability of a protective mask in the field. It will have expanded capability compared to the M41 PATS by allowing component level testing of the mask as well as system level testing with added components. It will provide a capability for an overall mask serviceability and fit factor validation of protective masks in the field.

BATTLEFIELD PROTECTIVE SUITS

FIELDED AND PRODUCTION ITEMS

Battle Dress Overgarment (BDO)

The BDO is a camouflage patterned (desert or woodland), two piece, air permeable overgarment typically worn over the duty uniform. The overgarment material consists of an outer layer of nylon cotton, and an inner layer of activated charcoal impregnated polyurethane foam. The BDO provides protection against chemical agent vapors and liquid droplets, biological agents (to include toxins), and radioactive alpha and beta particles. The BDO is issued in a sealed vapor-barrier bag that protects the garment from rain, moisture and sunlight. The BDO provides 24 hours of chemical agent protection once contaminated and has a field durability of 22 days (extendable to 30 days at the discretion of Field Commanders).

Joint Service Lightweight Integrated Suit Technology (JSLIST) Overgarment

The JSLIST Overgarment will provide 24 hour protection after 45 days of wear and 6 launderings. The liner currently is based upon activated carbon bead technology, replacing the bulky activated carbon foam technology in previous garments. The JSLIST Overgarment is a two-piece jacket and trouser design with an integrated hood compatible with respective Service masks and second skins. It will be worn as an overgarment for the duty uniform or as a primary garment over underwear depending upon the environment and mission.

Chemical Protective Suit, OG MK-III
(Navy Suit)

The Chemical Protective Overgarment (CPO) protects the wearer against all known chemical and biological agents which present a percutaneous hazard. The suit consists of a smock and separate pair of trousers, and is sized to accommodate the 5 percentile female through the 95 percent male ratio. This garment will be replaced Navy-wide by a superior suit developed under the auspices of the JSLISTprogram. The Mark III suit protects against chemical agent vapors, aerosols, droplets of liquid, and biological agents.

CP Suit, Saratoga (USMC)

Like the BDO, the SARATOGA CP Suit is an air permeable, camouflage patterned overgarment. Instead of carbon impregnated foam, SARATOGA uses spherical, activated carbon adsorbers immobilized in the liner fabric. This system allows for a lighter, cooler garment, which is launderable. The Saratoga provides a 24 hour protection period and has a durability of 30 days continuous wear.

CWU-66/P Aircrew Ensemble - Production (FUE FY96)

The CWU-66/P, a one-piece flightsuit configuration, provides 24-hour protection against standard NATO threats. It is made with Von Blucher carbon spheres, and is less bulky than prior ensembles. It offers a reduced thermal load burden and is compatible with aircrew life support equipment.

Chemical Protective Undergarment (CPU)

The CPU is a one-time launderable two-piece lightweight undergarment made of a non-woven fabric containing activated charcoal. When worn under a new combat vehicle crewman (CVC) coverall, battle dress uniform (BDU), or aviation battle dress uniform (ABDU), the CPU provides 12 hours of both vapor and liquid protection and is durable for 15 days.

BATTLEFIELD PROTECTIVE SUITS

RDTE ITEMS

Joint Service Lightweight Integrated Suit Technology (JSLIST)

The JSLIST program is a fully cooperative Joint Service RDTE effort chartered to develop new CB protective clothing for all Services. The program will yield a family of garments and ensembles, developed for Joint Service mission needs and tested to Joint Service standards. The JSLIST will provide enhanced CB protective ensembles with reduced physiological heat burden and will be generally lightweight and launderable. JSLIST is the first of a 3 phase program and supports a variety of Service suit and accessories. Previous chemical protective requirements from all Services are incorporated within the Joint ORD for JSLIST. There are five JSLIST clothing item requirements: 1) overgarment, 2) undergarment, 3) duty uniform, 4) boots and 5) gloves. Each of the Services' requirements are incorporated by these five JSLIST requirements.

In April 1997, the JSLIST program type classified the JSLIST Overgarment and Multi-purpose Overboot (MULO).

The JSLIST Additional Source Qualification (JASQ) was initiated to qualify additional sources of JSLIST materials and to conduct field wear tests and laboratory chemical tests on commercial JSLIST suit candidates. The JASQ candidates that perform as well as, or better than the current JSLIST garment will be considered for placement on a JSLIST qualified products list and may be authorized as additional JSLIST material sources.

Joint Protective Aircrew Ensemble (JPACE)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps Requirement (Navy lead)

Key Requirements:

- Provides Below-the-Neck (BTN) protection for rotary and fixed wing aircrew
- 30 day wear time
- Launderable
- Compatible with aircrew mounted aviation life support systems
- Ejection safe and water survivable

Description:

JPACE will be a chemical biological (CB) protective ensemble for all services' aviation communities. It will be a replacement for the Navy/Marine Corps MK-1 undergarment, Army ABDU-BDO and/or CPU system and AF CWU-66/P overgarment. Due to mission constraints and threat analysis, a separate garment may be considered for fixed wing versus rotary wing aircrew. JPACE started as a spin-off from JSLIST to address aviation specific CB requirements. Therefore, JSLIST and JSLIST P3I materials, designs, and documentation will be used to the maximum extent possible. This ensemble will be jointly tested and fielded with JSAM (Joint Service Aircrew Mask) and will be used as a technical insertion to the Army Air Warrior program. JPACE will provide the fixed and rotary wing aviator with BTN protection against CB threats.

Modified Chemical Protective Undergarment (mCPU)

A modified CPU (mCPU) is being developed to include a pass-through for microclimate cooling unit tubing. The mCPU worn with the Aviation Battledress Uniform will be used as interim chemical protection for Army aviators until the development and fielding of the Joint Protective Aircrew Ensemble (JPACE).

PROTECTIVE ACCESSORIES

FIELDED AND PRODUCTION ITEMS

Chemical Protective Footwear Covers

The CPFC are unsupported, impermeable, butyl rubber overshoes that can be stored flat. They are a loose fitting butyl rubber upper vulcanized to a non-slip molded butyl rubber sole with five holes to allow lacing around the foot. They are worn over the combat boot. They have the ability to resist acid, jet fuel, oil and fire. They were manufactured in two sizes, small and large, but are no longer being procured.

Chemical Protective Sock

This sock is the first generation Air Crew Chemical Defense Equipment. It is plastic and disposable. The sock comes in one size as 500 ea per roll, 21 inch long, 4 mils thick and 8 in wide flat extruded tubing with 1/8 in wide heat-seal closure. This sock is to be worn over regular sock.

Disposable Footwear Cover

Plastic over-boots are worn over the flyer's boot. They protect the user from chemical contamination en-route from the shelter and the aircraft. They come in one size and are removed before entering the aircraft or shelter.

Green Vinyl Overboots /Black Vinyl Overboots (GVO/BVO)

The GVO/BVO are fitted vinyl overshoes that are worn over the combat boots to provide chemical agent protection and/or moisture vapor protection during wet weather. The impermeable GVO/BVO provide protection against chemical agents for 24 hours and are durable for up to 60 days.

Multipurpose Overboot (MULO) *(JSLIST Boots)*

The MULO is a joint service program under the auspices of the JSLIST program and will replace the GVO/BVO. It is made of an elastomer blend and will be produced by injection molding. It is designed for wear over the combat boot, jungle boot, and intermediate cold/wet boot, and provides 24 hours of protection chemical agents with a wear life of 60 days. The MULO provides more durability, improved traction, resistance to POLs and flame, and better donning and doffing characteristics over standard footwear.

Chemical Protective (CP) Gloves

The CP glove set consists of a butyl-rubber outer glove for protection from chemical agents, and a cotton inner glove (25 mil glove only) for perspiration absorption. CP outer gloves come in three thicknesses: 7, 14, and 25 mil. The 7 mil glove is used by personnel who require a high degree of tactility, such as medical and personnel engaged in electronic equipment repair. The 14 mil glove is used by personnel like aviators and mechanics, in cases when good tactility is necessary and stress to the glove is not too harsh. The 25 mil glove is used by personnel who require a durable glove to perform close combat tasks and heavy labor. The 14 and 25 mil glove sets provide protection for at least 24 hours. The 7 mil glove set should be replaced within 6 hours of exposure to a chemical agent.

Glove Inserts

These gauntlet cotton inserts are worn under the chemical protective (CP) butyl rubber gloves. They provide perspiration absorption. They can be worn in either hand and are available in three sizes (small, medium and large).

Chemical Protective Helmet Cover

The Chemical Protective Helmet Cover is intended to provide any standard helmet with protection from chemical and biological contamination. It is a one-piece configuration made of butyl coated nylon cloth and gathered at the opening by an elastic webbing enclosed in the hem. The covers come in one size and are of olive green color.

Aircrewman Cape

This disposable cape is a one size fits all plastic bag (74 in x 23 in) worn over the entire body to provide additional protection against liquid contamination. The over-cape should be worn if aircrews have to walk around liquid contaminated areas and if aircraft are not sheltered. If worn, the over-cape is removed before entering the aircraft.

SPECIALTY SUITS

FIELDED AND PRODUCTION ITEMS

Joint Firefighter Integrated Response Ensemble (JFIRE)

JFIRE is a joint effort between the Air Force (lead agency) and the Army. The JFIRE Program has developed an ensemble that will protect the military firefighters IAW National Fire Protection Association (NFPA) standards and provide CB protection during firefighting operations in a CB environment. JFIRE leverages the JSLIST overgarment for chemical protection, to be worn under aluminized proximity firefighting outergear and with a switchable filtered/supplied air mask with chemical warfare (CW) kit. A Commercial Off-the-Shelf (COTS) glove that can be used for both fire and CB protection has replaced the need for CB gloves to be worn under standard proximity gloves. JFIRE meets several key requirements, including (1) providing 24 hours of CB agent protection against 10 g/m^2 liquid agent, (2) providing firefighters CB protection in both structural and crash fire fighting/rescue operation, (3) allowing firefighters to use mission essential tools and equipment in a CB environment, (4) providing resistance to water and all standard fire fighting chemicals (foam, CO_2, aircraft POL), and (5) is capable of being donned in 8 minutes.

Suit Contamination Avoidance Liquid Protection (SCALP)

The SCALP can be worn over standard chemical protective garments to provide 1 hour of protection from gross liquid contamination. The SCALP, which consists of a jacket with hood, trouser and booties, is made from a polyethylene-coated Tyvek™ impermeable material.

Self-Contained Toxic Environment Protective Outfit (STEPO)

STEPO provides OSHA level A protection for Army Chemical Activity/Depot (CA/D), Explosive Ordnance Disposal (EOD) and Technical Escort Unit (TEU) personnel. The STEPO is currently being fielded to CA/D, TEU and EOD. The STEPO is a totally encapsulating protective ensemble for protection against CB agents, missile/rocket fuels, POL, and industrial chemicals for periods up to four hours. The ensemble incorporates two types of NIOSH approved self-contained breathing systems (one hour and four hour configurations) and a tether/emergency breathing apparatus option, a battery powered Personal Ice Cooling System (PICS), a hands-free communications system, and standard M3 Toxicological Agent Protective (TAP) boots and gloves. The suit is capable of being decontaminated for reuse up to 5 times after chemical vapor exposures. STEPO shares common, modular components with the ITAP and JFIRE ensembles simplifying logistics and reducing costs.

EOD M3 Toxicological Agents Protective (TAP) Ensemble

One-piece coverall for the protection of personnel engaged in extreme hazardous decontamination work or other special operations involving danger from spillage or splashing of chemical agents including toxic industrial material. The coverall is constructed from butyl rubber coated plain weave nylon cloth and comes in four sizes (small, medium, large and extra large). The design consists of snap-type button front and protective flap. This is a special purpose Life Support Clothing and Equipment (LSC&E) item.

Improved Toxicological Agent Protective (ITAP)

ITAP replaces the M3 TAP ensemble. ITAP enhances existing capabilities by increasing personal protection and reducing the thermal burden on the wearer. ITAP also provides skin and respiratory protection both during peacetime and wartime for short term operations in Immediately Dangerous to Life and Health (IDLH) toxic chemical environments (up to 1 hour), emergency life saving response, routine Chemical Activity operations and initial entry and monitoring. ITAP shares common, modular components with the STEPO and JFIRE ensembles, simplifying logistics and reducing costs.

ITAP provides splash and vapor protection against potential exposure to liquid agent when worn as a system—requirements: 10g/m^2 HD, VX, GB, L agent challenge for 1 hour. It provides an optional Personal Ice Cooling System (PICS), and is functional as a system where temperatures range from 0° to 100°F when used with the cooling system. The ITAP suit and overhood are capable of being decontaminated for a minimum of 5 reuses, 2hours per use (1 hour at IDLH), after vapor and particulate contamination. After liquid contamination ITAP suit will be decontaminated and held for disposal.

The ITAP fabric is self-extinguishing meeting NFPA 1991. The fabric is also static dissipative and does not hold a charge sufficient to set off munitions and explosives in accordance with current Explosive Safety Board requirements. The fabric is light in color to reduce operator solar heat load, and is capable of being stored within the temperature range of 0° to 120°F. ITAP has a minimum shelf life of 5 years.

COLLECTIVE PROTECTION EQUIPMENT

TENTAGE AND SHELTERS

FIELDED AND PRODUCTION ITEMS

M20/ M20A1 Simplified Collective Protective Equipment

The M20/M20A1 SCPE is used to convert an interior room of an existing structure into a positive overpressure, NBC collective protection shelter where individuals can perform assigned missions without wearing the protective mask and overgarment. The system consists of a liner, protective entrance, filter canister, and support kit. The SCPE is a low cost method of transforming a room in an existing structure into an NBC collective protection shelter for command, control and communication (C^3), medical treatment, and soldier relief functions. M20A1 is a room liner for existing shelters. Components include a CB vapor resistant polyethylene liner that provides a protected area in an existing structure; a collapsible, protective entrance that allows entry to/exit from the protected area; a hermetically sealed filter canister, which provides filtered air to both the liner and the protective entrance; and a support kit, which contains ducting, lighting, sealing and repair material and an electronically powered blower.

M28 Simplified CPE (SCPE)

The M28 SCPE is a low cost method of transforming a room of an existing structure into an NBC collective protection shelter for command, control and communication (C^3), medical treatment, and soldier relief functions. M28 is a liner for the TEMPER tent. Components include a CB vapor resistant polyethylene liner that provides a protected area in an existing structure; a collapsible, protective entrance that allows entry to/exit from the protected area; a hermetically sealed filter canister, which provides filtered air to both the liner and the protective entrance; and a support kit, which contains ducting, lighting, sealing and repair material and an electronically powered blower. A pre-planned product improvement (P^3I) program to the M28 SCPE provides liquid agent resistant liners, protective liners for tents, interconnectors, and an interface with environmental control units. The improved SCPE also allows more people to enter at one time, and protects hospitals under tents.

Chemically Protected Deployable Medical System (CP DEPMEDS) - Development/Production

The Army's CP DEPMEDS program is a joint effort with the Air Force to insert environmentally controlled collective protection into currently fielded hospital shelters. The requirement is to be able to sustain medical operation for 72 hours in a chemical contaminated environment. Environmentally-controlled collective protection is provided through the integration of M28 CPE, chemically protected air conditioners, heaters, water distribution and latrines, and alarms systems. M28 CPE provides protection to existing TEMPER Tents and passageways within the hospital. DEPMEDS ISO shelters are protected through the replacement of existing shelter seals with those that are CB protected. The Field Deployable Environmental Control Unit provides CB protective air conditioning and the Army Space Heater provides CB protective heating. Both environmental control units are chemically protected through the addition of a CB kit. To sustain approximately 500 patients and staff, chemically protected latrines and water distribution systems have been developed.

Chemically/Biologically Hardened Air Transportable Hospital (CHATH) – Production

The Air Force's CHATH program is a joint effort with the Army to enable medical personnel to deploy and setup in chemical and biological threat areas and operate in chemically and biologically active environments. CHATH allows personnel to perform their hospital duties in a Toxic Free Area. CHATH upgrades TEMPER-based Air Transportable Hospitals (ATHs) retaining the same medical equipment and personnel. CHATH uses existing and modified U.S. Army equipment to line the current ATH tents providing an airtight shelter. The Human Systems Program Office (HSC/YA) developed a Chemically/biologically Hardened Air Management Plant (CHAMP). The CHAMP filters chemically and biologically contaminated air, and recirculates and filters interior air to maintain a clean hospital standard, provides heating, cooling, and over-pressurization to the hospital. The CHAMP can be operated from standard electrical sources or from its own internal generator. The CHAMP comes equipped with an Automatic Transfer Switch (ATS) to maintain power after Base power is shut off. The ATS starts the Diesel generator after three seconds of power interruption. The CHAMP allows the CHATH to be staged near warfighters in the field in a bare base environment. The CHATH can be deployed in increments of 10, 25, and 50 beds. This flexibility of the CHATH system helps ensure the best medical care is as near to the crisis area as possible.

CB Protected Shelter (CBPS)

CBPS is a highly mobile, rapidly deployable shelter system designed to be used for Level I and II forward area medical treatment facilities and forward surgical teams. CBPS also replaces the M51. The system is self-contained and self-sustaining. The CBPS consists of a dedicated M1113 Expanded Capacity Vehicle (ECV), a Lightweight Multipurpose Shelter (LMS) mounted onto the vehicle, a 300 square foot airbeam supported CB protected shelter, and a High Mobility Trailer with a towed 10kw tactical Quiet Generator Set. The ECV and LMS transports a crew of four and their gear. All medical equipment required for the shelter is transported in the LMS or on the trailer. The CB shelter is rolled and carried on the rear of the LMS during transport. The CBPS is operational within 20 minutes with a crew of four. All power required to support operations is provided by the ECV engine or with the 10kw generator for limited power. The system is environmentally conditioned by a hydraulically powered environmental support system, which provides filtered air, heating, air conditioning, and electrical power. The system is presently in limited production.

COLLECTIVE PROTECTION SYSTEMS

FIELDED AND PRODUCTION ITEMS

Shipboard Collective Protection System

Shipboard CPS is an integral part of the HVAC systems on new construction ships. CPS provides each protected zone on the ship with filtered air at an overpressure of 2.0 inches water gage. CPS is modular and is based on a Navy-improved version of the 200 cfm M56 filter. CPS includes filters, filter housings, high pressure fans, airlocks, pressure control valves, low pressure alarm system, and

personnel decontamination stations. These systems are being installed through both new ship construction and the CPS Backfit program.

COLLECTIVE PROTECTION SYSTEMS

RDTE ITEMS

Shipboard Collective Protection Equipment

Rationale:

- Navy Service-Unique requirement

Key Requirements:

- Provide protection against chemical and biological threat agents
- Provide a minimum of three year continuous operational life
- Provide more efficient, long life filters
- Provide quieter, more efficient supply fans
- Develop methods to counter new and novel threat agents

Description:

Shipboard Collective Protection Equipment (CPE) provides a contamination-free environment within specified zone boundaries such that mission essential operations and life sustaining functions can be performed during or after a CB attack. The objective of this program is to provide Pre-Planned Product Improvements (P3I) to the current Shipboard CPS to decrease logistic costs by extending particulate filter life, reducing shipboard maintenance requirements, and providing energy-efficient fans. The program develops improvements to existing shipboard HEPA and gas adsorber filters, supports long term shipboard testing of filter improvements to develop filter life database, and provides plans for backfitting existing non-CPS ships. Shipboard CPE is being installed on selected new construction ships. The Shipboard CPE program will transition to the JCPE program in FY03.

Joint Collective Protection Equipment (JCPE)

Rationale:

- Joint Service requirement

Key Requirements:

- Rapid insertion of technology improvements to existing equipment
- Increased number of shelters for command/control, medical, and rest/relief areas
- Improved shipboard systems
- Standardization of equipment

Description:

JCPE provides needed improvements and cost saving standardization to currently fielded collective protection systems by using the latest technologies in filtration, shelter materials, and environmental controls to provide affordable, lightweight, easy to operate and maintain equipment. Inserting improved technology into currently fielded systems will result in improved performance with reduced operating costs. Standardization of individual system components across Joint Service mission areas will reduce logistics burden while maintaining the industrial base. Taken both individually and collectively, these tasks will improve NBC defense readiness for Joint Services by providing state-of-the-art, off-the-shelf solutions for currently fielded equipment deficiencies.

Joint Transportable Collective Protection System (JTCOPS)

Rationale:

- Joint Service requirement

Key Requirements:

- Protection against chemical and biological agents, toxic industrial materials, and radiological particulate matter
- Use as a stand-alone structure or within existing structures
- Ability to process personnel through a contamination control area to a contamination-free area

Description:

The JTCOPS program is a new start program that will use new technology to provide relief from psychological and physiological stresses during sustained operations in a contaminated environment due to wearing full Individual Protection Equipment. JTCOPS will be a modular shelter system that will provide the ability to process contaminated personnel through a Contamination Control Area into a Toxic Free Area, and will be expandable to meet changing mission needs. It will allow collective protected vehicles/vans to be connected for safe personnel ingress/egress. The system will include air filtration, environmental control, and power generation elements. JTCOPS will be used for a variety of mission scenarios to include command and control, rest and relief, billeting and medical treatment.

GENERIC NBC FILTERS AND COLLECTIVE PROTECTION FILTRATION SYSTEMS

FIELDED AND PRODUCTION ITEMS

Generic, high volume air flow NBC filters, and CP filtration systems exist that are currently installed on a wide variety of applications. These CP systems are modular and have been applied to numerous vehicles, vans, mobile shelters, and fixed sites.

GENERIC NBC FILTERS

NBC filters are used to remove Nuclear and Biological particulates and Chemical aerosols and vapors from the air supplied to collective protection systems.

M48/M48A1

The 100 cubic foot per minute (cfm) filter is used in the M1A1/A2 Abrams tank, M93 Modular Collective Protection Equipment (MCPE), CB Protected Shelter, and Paladin Self Propelled Howitzer.

M56

The 200 cfm filter is used as the basic filter set in the MCPE and in Naval applications. It can be stacked to obtain filtration of higher air flow rates.

600 cfm and 1200 cfm Stainless Steel Fixed Installation Gas Filters

These filters are used in fixed site applications where high volumes of air flow are required. They can be stacked to provide higher NBC filtered air flow rates. Particulate filter would be procured separately.

GENERIC NBC CP FILTRATION SYSTEMS

The following are modular NBC CP filtration systems which are applied to a wide variety of applications. They consist of an NBC filter, motor/blower unit, housings, and integration housings/ductwork. Some can be integrated into environmental control equipment.

M8A3 Gas Particulate Filter Unit (GPFU)

The 12 cfm system provides air to armored vehicle crewman ventilated facemasks, *i.e.*, M42A1/A2. Used in M113 Armored Personnel Carrier variants and USMC AAVP7A1 amphibious vehicle.

M13A1 GPFU

The 20 cfm system provides air to armored vehicle crewmen ventilated facemasks, *i.e.*, M42A1/A2. Used on the M1A1/A2 Abrams tanks, Bradley Fighting Vehicles, Multiple Launch Rocket System (MLRS), tank transporter, and other vehicles.

Modular Collective Protection Equipment (100, 200, 400, 600 cfm Systems)

Modular Collective Protection Equipment (MCPE) consists of a family of related end items from which modules can be chosen and combined to meet the unique demands of individual systems. These end items employ common parts and mountings and interchangeable connections and accessories to the greatest extent possible. MCPE provides collective overpressure to a wide variety of mobile shelters and vans. It uses the M48 NBC filter in the 100 cfm system and the M56 NBC filter in the others.

Annex D

Decontamination Programs

Table D-1. Decontamination RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
Personnel	- M295 Individual Equipment Decontaminating Kit	Production	Rqmt	Rqmt	Interest	Rqmt
	- M291 Skin Decontaminating Kit	Production		Rqmt	Rqmt	Rqmt
Combat Equipment, Vehicles, and Aircraft	- M17A2/A3 Lightweight Decontamination System	Production	Rqmt	Rqmt	Rqmt	Rqmt
	- M17 MCHF Lightweight Decontamination System	Production		Int-NIR	Rqmt	Rqmt
	- M21/M22 Modular Decontamination System (MDS)	Production	Rqmt	Int-NIR	Int-NIR	Int-NIR
	- Joint Service Sensitive Equipment Decon	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
	- Joint Service Fixed Site Decon	RDTE		Rqmt	Rqmt	
Decontaminant Solutions and Coatings	- M100 Sorbent Decontamination System and Solution Decontaminants	Production	Rqmt	Interest	Rqmt	Interest

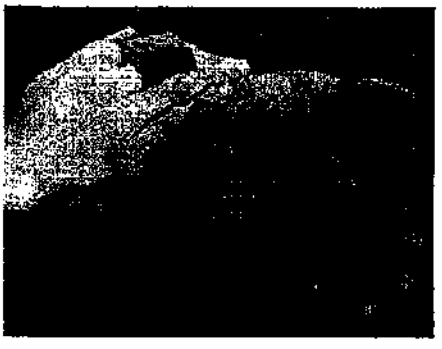
Rqmt = Product Requirement
Interest = Product Interest
Int-NIR = Product Interest, No Imminent Requirement

* = sub-Product(s) of a Consolidated Joint Service Project
Rqmt, Interest = Sub-Product Requirement or Interest

PERSONNEL

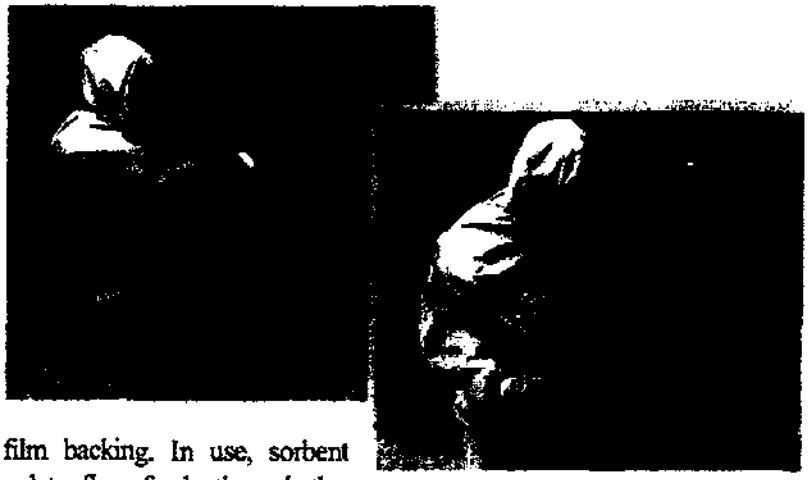
FIELDED AND PRODUCTION ITEMS

M291 Skin Decontamination Kit



The M291 (shown in use) consists of a wallet-like flexible carrying pouch containing six individually sealed foil packets. Each packet contains a folded non-woven fiber applicator pad with an attached strap handle on one side. The pad contains a reactive and sorptive resin polymer mixture. The kit enables warfighters to remove, neutralize, and destroy chemical and biological warfare agents on contaminated skin. The kit is carried in a pocket of the Battle Dress Overgarment (BDO).

M295 Equipment Decontamination Kit



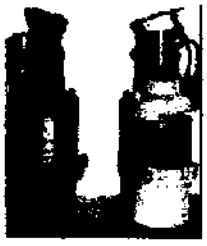
The M295 (shown in use) consists of four individual wipedown mitts, each enclosed in a soft, protective packet. The packet assembly is designed to fit comfortably within the pocket of a BDO. Each wipedown mitt in the kit is comprised of a decontaminating sorbent powder contained within a non-woven polyester material and a polyethylene film backing. In use, sorbent powder from the mitt is allowed to flow freely through the non-woven polyester pad material. Decontamination is accomplished through sorption of contamination by both the non-woven polyester pad and by the decontaminating sorbent powder. The M295 enables the warfighter to perform basic decontamination to remove, neutralize, or destroy CB warfare agents and toxins on contaminated personal and load bearing equipment.

COMBAT EQUIPMENT, VEHICLES, AND AIRCRAFT

FIELDED AND PRODUCTION ITEMS

M100 Sorbent Decontamination System

The reactive sorbent decontamination system provides a simple, rapid, and efficient system to decontaminate small and individual issue items of equipment. It is effective in all environments, is less corrosive, and presents a lowered logistics burden through improved shelf life and reduced special handling and storage needs. The M100 system uses a catalytic component that reacts with the chemical agents being adsorbed; this eliminates the potential hazard created by the off-gassing of agents from used adsorbents.



ABC-M11 Portable Decontaminating Apparatus

The 1-1/3 quart capacity M11 is used to spray DS2 decontaminating solution onto critical areas (*i.e.*, frequently used parts) of vehicles and crew served weapons. The M11 consists of a steel cylinder, a spray head assembly, and a small nitrogen cylinder (about 3" long). The refillable M11 can produce a spray 6 to 8 feet long,

and cover an area of about 135 square feet. The M11 is currently used on tanks and other systems where the larger M13 Decontaminating Apparatus, Portable (DAP) cannot be effectively stowed.

M13 Decontaminating Apparatus, Portable (DAP)

The man portable M13 consists of a vehicle mounting bracket, a pre-filled fluid container containing 14 liters of DS2 decontaminating solution, and a brush-tipped pumping handle connected to the fluid container by a hose. The fluid container and brush head are both disposable. The M13 can decontaminate 1,200 square feet per fluid container. The combination of spray pump and brush allows personnel to decontaminate hard to reach surfaces, and remove thickened agent, mud, grease and other material.

ABC-M12A1 Power Driven Decontamination Apparatus (PDDA); Skid-Mounted

The M12A1 consists of three main components: a pump unit, a 500 gallon tank unit, and a 600 gallon per hour liquid fuel water heater. The M12A1 is a flexible system that can be used for purposes such as de-icing, fire fighting with water or foam, water pumping and transport, and personnel showering in addition to equipment and area decontamination. The M12A1 can pump 50 gallons of decontaminating solution per minute through both of its hoses. The integral shower assembly provides 25 shower heads. The M12A1 is typically mounted on a 5 ton truck for tactical mobility, but can be dismounted to facilitate air transport. The USMC has replaced the M12A1 PDDA with the M17 series Lightweight Decontamination Apparatus.

M17 Series Lightweight Decontamination System

The M17 series Lightweight Decontamination System (LDS) is a portable, lightweight, compact engine driven pump and water heating system. The system is used during decontamination operations. The LDS is capable of drawing water from any source and delivering it at moderate pressure and controlled temperatures. The system has an accessory kit with hoses, spray wands, and personnel shower hardware. It also includes a collapsible water bladder.

M17 MCHF Lightweight Decontamination System (LDS)

The M17 Marine Corps Heavy Fuel (MCHF) LDS is a portable, lightweight, compact, engine-driven pump and multifuel-fired water heating system. The system is capable of performing the same hasty and deliberate decontamination procedures as required of the M17 series LDS. All components can be moved by a four-man crew, and can be operated using Military Standard Fuels (diesel fuel, JP-8, *etc.*) It can decontaminate both sides of a vehicle or aircraft simultaneously, and can decontaminate personnel, equipment, and other materiel without an external power source and in coordination with a watertank or natural water resource.

M21/M22 Modular Decontamination System (MDS)

The MDS provides the warfighter an improved capability to perform detailed equipment decontamination on the battlefield. The system replaces current methods of decontamination application (*i.e.*, mops and brooms or with the portable M13 Decontamination Apparatus), which are time consuming

and labor intensive. The MDS improves effectiveness, reduces water usage, reduces equipment processing time, and is less labor intensive. The MDS consists of an M21 decontaminant Pumper/Scrubber module, and M22 High Pressure/Hot Water module. The M22 delivers DS2 or liquid field expedient decontaminants and is capable of drawing the decontaminant directly from a container on the ground while mounted on a trailer. The M22 provides hot water up to 3000 psi at a rate of 5 gpm with the capability of high volume cold water and detergent injector. It is also capable of drawing water from natural and urban water sources (such as fire hydrants) and delivering it at variable and adjustable pressures, temperatures, and flow rates. Each module (M21 or M22) may be transported or operated from a 3/4-ton trailer towed by a M1037 High Mobility Multipurpose Wheeled Vehicle (HMMWV).

COMBAT EQUIPMENT, VEHICLES, AND AIRCRAFT

RDTE ITEMS

Joint Service Sensitive Equipment Decontamination (JSSED)

Rationale:

- Joint Service requirement

Key Requirements:

- Non-aqueous based decontamination systems for sensitive equipment and vehicle interiors
- Capable of being used in both mobile and fixed-sites

Description:

Provide a first ever capability to decontaminate chemical and biological warfare agents and toxins from sensitive electronic, avionics, electro-optic equipment, and vehicle interiors. Its use must be compatible with and not degrade sensitive materials or equipment. It must be operator safe and offer protection from off-gassing and direct liquid exposure during decontamination.

Joint Service Fixed Site Decontamination System

Rationale:

- Army, Air Force, and Marine Corps requirement

Key Requirements:

- Provide restoration capability at fixed site locations
- Provide improved/state-of-the-art NBC decontamination equipment
- Provide non-hazardous and environmentally safe NBC decontaminants

Description:

The Joint Service Fixed Site Decontamination program is a joint effort. The system will provide a family of decontaminants and applicators to provide the capability to decontaminate ports, airfield, and rear-area supply depots, and includes personnel and casualties with open

wounds. In FY02 the program name will officially change to the Joint Service Family of Decontamination Systems (JSFDS) to better reflect the approach to meeting the program requirements.

Annex E

Joint Medical Chemical, Biological, and Radiological Defense Research Programs

The Joint Medical Chemical, Biological, and Radiological Defense Research Programs are addressed in three sections of this annex. Section E.1 addresses medical chemical defense research, section E.2 addresses medical biological defense research, and section E.3 addresses medical radiological defense research.

Table E-1. Medical Chemical and Biological Defense RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
Medical Chemical Defense	- Antidote Treatment – Nerve Agent Autoinjector	Fielded	Joint	Joint	Joint	Joint
	- Convulsant Antidote for Nerve Agents	Fielded	Joint	Joint	Joint	Joint
	- Skin Advanced Anticonvulsant System	RDTE	Joint	Joint	Joint	Joint
	- Cyanide Pretreatment	RDTE	Joint	Joint	Joint	Joint
	- Medical Aerosolized Nerve Agent Antidote	Fielded	Joint	Joint	Joint	Joint
	- Nerve Agent Pretreatment, Pyridostigmine	Fielded	Joint	Joint	Joint	Joint
	- Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA)	Production	Joint	Joint	Joint	Joint
	- Active Topical Skin Protectant	RDTE	Joint*	Joint*	Joint*	Joint*
	- Chemical Agent Prophylaxes	RDTE	Joint*	Joint*	Joint*	Joint*
Medical Biological Defense	- Anthrax Vaccine Adsorbed	Production	Joint	Joint	Joint	Joint
	- Clostridium Botulinum Toxins Medical Defense System	RDTE	Joint*	Joint*	Joint*	Joint*
	- Next Generation Anthrax Vaccine	RDTE	Joint*	Joint*	Joint*	Joint*
	- Improved Plague vaccine	RDTE	Joint*	Joint*	Joint*	Joint*
	- Ricin Vaccine	RDTE	Joint	Joint	Joint	Joint
	- Smallpox Vaccine (cell cultured derived)	RDTE	Joint*	Joint*	Joint*	Joint*
	- Staphylococcus Enterotoxin Vaccine	RDTE	Joint	Joint	Joint	Joint
	- Tularemia Live Vaccine	RDTE	Joint	Joint	Joint	Joint
	- Venezuelan Equine Encephalitis Vaccine	RDTE	Joint*	Joint*	Joint*	Joint*
	- Joint Biological Agent Identification and Diagnostic System	RDTE	Joint	Joint	Joint	Joint

Joint= Joint Service requirement Joint*=Draft Joint Service requirement

E.1 MEDICAL CHEMICAL DEFENSE RESEARCH PROGRAM

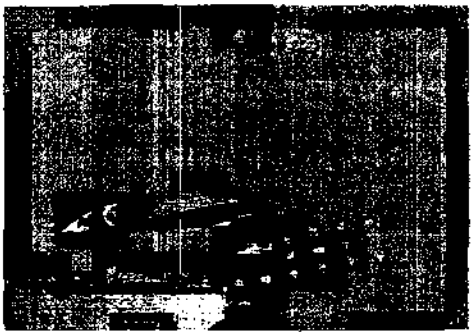
E.1.1 Fielded Products

Advances in medical research and development (R&D) significantly improve the warfighting mission by sustaining unit effectiveness through conserving the fighting strength of our forces and supporting the nation's global military strategy, which requires the ability to effectively deploy and operate. Medical R&D products (materiel and non-materiel solutions) provide the foundation that ensures the fielding of a flexible, sustainable, modernized force across the spectrum of conflict and in the full breadth and depth of the battlefield. Overcoming medical threats and extending human performance have provided a significant increase in military effectiveness in the past and present the

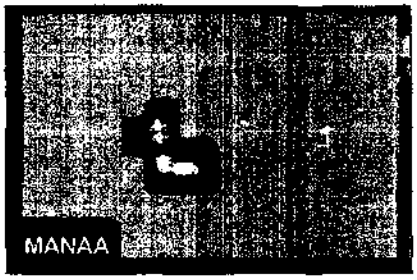
potential for future enhancement of military operational effectiveness. Following are fielded medical chemical defense items, including pharmaceuticals, materiel, and technical information and guidance (with initial fielding date shown.)

Pharmaceuticals:

- Nerve Agent Antidote Kit (Mark I), 1983
- Skin Decontamination Kit (M291), 1990
- Nerve Agent Pretreatment (Pyridostigmine), 1987
- Convulsant Antidote for Nerve Agent (CANA), 1991
- Medical Aerosolized Nerve Agent Antidote (MANAA), 1994

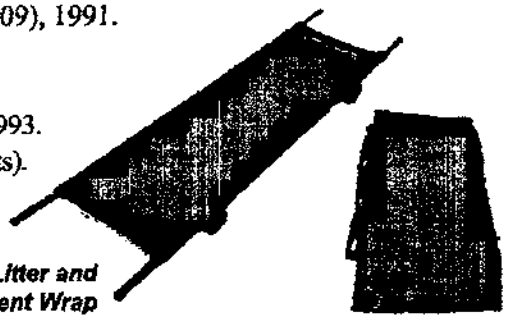


MARK I, M291, Nerve Agent Pretreatment, and CANA



Materiel:

- Test Mate® ChE (Cholinesterase) Kit, 1997 (*shown*).
- Resuscitation Device, Individual, Chemical, 1990.
- Decontaminable Patient Litter (NSN 6530-01-380-7309), 1991.
- Chemical Warfare (CW) Protective Patient Wrap (NSN 8415-01-311-7711), 1991.
- Computer-Based Performance Assessment Battery, 1993.
- M40 Protective Mask Vision Correction (optical inserts).



Decontaminable Patient Litter and CW Protective Patient Wrap

Technical Information and Guidance:

- Taxonomic Work Station, 1985.
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) Technical Memoranda on Chemical Casualty Care, 1990.
- Field Manual (FM) 8-285, *Treatment of Chemical Agent Casualties and Conventional Military Chemical Injuries*, 1995.
- *Field Management of Chemical Casualties Handbook*, Second Edition, July 2000
- Technical Bulletin (TB) Medical (MED) 296, 1996: *Assay Techniques for Detection of Exposure to Sulfur Mustard, Cholinesterase Inhibitors, Sarin, Soman, GF, and Cyanide.*
- Compact Disk - Read-Only Memory (CD-ROM) on "Management of Chemical Warfare Injuries," 1996.

- *Medical Management of Chemical Casualties Handbook*, Third Edition, July 2000.

E.1.2 Medical Chemical Defense R&D Accomplishments

The medical chemical defense R&D technical barriers and accomplishments during FY01 are grouped by medical chemical defense strategies, which include:

- *Pretreatments.*
- *Therapeutics.*
- *Diagnostics.*

Today's chemical threat, however, is not restricted to commonly accepted classical agents, such as vesicants [sulfur mustard (HD)], nerve agents (soman, sarin, tabun, and VX), respiratory agents (phosgene), or blood agents (cyanide). Potential adversaries may develop novel threat agents. Additionally, the potential for transient or sustained systemic toxicity from low dose exposure(s) to chemical warfare agents must be thoroughly investigated to determine the potential effect on Service members. The ability to provide timely and effective medical countermeasures to new threats depends upon maintaining a high level of technological capability. Sustaining and enhancing this technological capability is dependent upon the continued support of a robust program investigating basic pathophysiological mechanisms which, in turn, contributes to the knowledge and database upon which new, innovative, and improved diagnostics, pretreatments, and therapies are based.

Countermeasure strategies to the classic and novel threats include pharmaceuticals, medical equipment, specialized materiel or medical procedures, and concepts for training, doctrine, and organization. Medical countermeasures are designed not only to prevent lethality but also to preserve and sustain combat effectiveness in the face of combined threats from chemical and conventional munitions on the integrated battlefield by:

- Rapid diagnosis of chemical agent exposure.
- Prevention of the effects of chemical agents (*e.g.*, prophylaxes or pretreatment).
- Far-forward treatment upon exposure to chemical warfare threats (*e.g.*, antidotes).
- Chemical casualty care (*e.g.*, therapy and management).

Medical chemical defense research directly conducted or sponsored by the United States Army Medical Research and Materiel Command (USAMRMC) laboratories yielded the following accomplishments in FY01:

Research Category: Pretreatments/Prophylaxes

The countermeasures, technical barriers, and accomplishments in the medical chemical defense research category of pretreatments are outlined below.

Countermeasures:

- Improved Skin Exposure Reduction Paste against Chemical Warfare Agents (SERPACWA) by incorporation of active moieties that detoxify the chemical agents.
- Pretreatment regimen that protects against rapid action and incapacitating effect of chemical threat category of nerve agents and fourth generation nerve agents.

- Pharmaceutical and biological pretreatments, treatments, antidotes, decontaminants and protectants.

Technical Barriers:

- Lack of pretreatments and/or antidotes that are quick acting, long lasting, easy to carry and use on the battlefield.
- Lack of appropriate experimental model systems to predict pretreatment or treatment efficacy and safety in humans.
- Lack of detailed molecular model of Fourth Generation Agents to understand the mechanism of their unique chemical properties and their effects.
- Potential performance decrement with pretreatment is being investigated.
- Lack of a capability to provide forensic diagnostics for chemical threats.

Accomplishments:

The detailed accomplishments that follow are drawn from the basic research, applied research, and concept exploration related to the development of pretreatments.

- Modified several modules in the active Topical Skin Protectant (aTSP) Decision Tree Network (DTN) to allow more effective efficacy evaluation comparisons with SERPACWA.
- Investigated 158 candidate active moieties in over 350 formulations as part of the aTSP effort.
- Demonstrated significantly improved efficacy over SERPACWA by 17 active moieties against sulfur mustard (HD) and 15 active moieties against soman.
- Identified a formulation containing a polyamine as the lead aTSP candidate with demonstrated efficacy against sulfur mustard and soman in both *in vitro* and *in vivo* models.
- Filed 9 patents describing aTSP development.
- Identified several candidate active moieties that would be useful in a multiple layer protective system as part of the aTSP research effort.
- Determined that Oltrapraz, a stimulator of glutathione-S-transferase, had no protective effect against HD cytotoxicity in human epidermal keratinocyte (HEK) cells.
- Demonstrated protective efficacy of heparin management test (HMT), mesna and olvanil against HD-induced biochemical changes in lung lavage fluids
- Initiated studies of liposome encapsulated drug delivery.
- Identified Cohn Fraction IV from blood as a good source for obtaining large quantities of purified human butyrylcholinesterase (huBuChE) suitable for use as a bioscavenger for organophosphate (OP) poisoning.
- Inititiated the purification of huBuChE from 100 Kg of Cohn fraction IV paste containing ~12-15 g of enzyme, resulting in 5 g of purified enzyme.
- Five hundred milligrams of purified huBuChE was provided to the Netherlands Organization (TNO) labs for toxicokinetic and toxicodynamic studies. Of this, 200 mg was committed for neutron scattering studies and approximately 300 mg will be used for testing safety, toxicity, and efficacy as a bioscavenger in mice and non-human primates.
- Determined the effectiveness of huBuChE as a single pretreatment drug against OP nerve agents in non-human primates and observed no performance decrement. Continued to develop joint program comprising WRAIR, USAMRICD, MedImmune Inc., and the National

Institute for Drug Abuse (NIDA) to prepare ~1000 doses of huBuChE from Cohn Fraction IV in compliance with current Good Manufacturing Practices (cGMP).

- Investigated the role of amino acid residues in the reactivation of DEPQ- and MEPQ-inhibited mouse acetylcholinesterase (AchE) and huBuChE by TMB_4, Toxogonin, 2-PAM, and HI-6.
- Demonstrated that phosphoryl oxime inhibition occurs during reactivation of DEPQ- and MEPQ-inhibited AChE by TMB_4 and Toxogonin, but not HI-6. Reactivation of both DEPQ- and MEPQ-inhibited AChE was accelerated in the presence of organophosphorus hydrolase (OPH) and the AchE was able to hydrolyze phosphoryl oximes formed during reactivation.
- A full-length cDNA clone for the mature tetrameric subunit of bovine brain AChE was expressed in Chinese Hamster ovary cells (CHO) as well as HEK 293 cells to generate the tetrameric form of bovine brain AChE.
- Truncated the full-length cDNA clone for the mature tetrameric subunit of bovine brain AChE at the C-terminus to obtain a 1745 base pair cDNA clone for the monomeric subunit of bovine brain AChE.
- Determined carbohydrate structures of eight of nine site-specific glycopeptides derived from human butyrylcholinesterase; three of four site-specific carbohydrate structures of bovine serum AChE; and three of eight site-specific carbohydrate structures of equine BuChE. This is an important step to elucidating the requirements for prolonged circulatory time of cholinesterases.
- Initiated investigations on the use of a liposome-mediated delivery system for the transfection of huBuChE gene into lungs.
- Developed High Performance Liquid Chromatography (HPLC) techniques to purify the custom peptides designed for targeting and aiding penetration of liposomes with BuChE gene to mouse lung cells.
- Elucidated the amino acid residues that control the binding of anti-Alzheimer's drug, galanthamine to cholinesterases (ChEs) and demonstrated that galanthamine interacts with the active site of ChEs.
- Synthesized and evaluated eight tacrine-related hetero- and homo-bivalent ligands as candidate pretreatment drugs for protection against OP toxicity (in collaboration with Sienna University, Italy).
- Synthesized and evaluated the anti-cholinesterase properties of the hybrid analog of AChE inhibitors, huperzine A and huperzine B (in collaboration with Georgetown University, Washington, DC).
- Demonstrated that huperzine A provides neuroprotection against oxidative stress in rodent cerebella and forebrain neurons.
- Determined that Sodium channel blockers and huperzine A provide differential neuroprotection against hypoxia or glutamate mediated neurotoxicity in primary cultures of rat cerebella neurons.
- Showed that huperzine A modulated and decreased the neurotoxicity induced by b-amyloid in primary neurons.
- Initiated telemetry study of animals to evaluate neuroprotective compound efficacy by measuring EEG, ECQ, heart rates, blood pressure and respiratory rates.

- Quantified and correlated huperzine A effects on cholinesterase levels in brain, blood and other tissues in rats after low, medium and near lethal doses of huperzine A.
- Determined that huperzine A protects against NMDA-induced lethality in rats.
- Determined pharmacokinetic parameters for (-) huperzine A in rat serum. Isolated and structurally characterized the major huperzine A metabolite from rat liver and serum.
- Developed isolation methods and sensitive HPLC-based assay for pyridostigmine bromide measurements from human plasma in support of the Pyridostigmine Bromide Integrated Project Team FDA submission effort.
- Designed and synthesized a new series of compounds named pyridophens to achieve binary prodrugs to preferentially inhibit AChE over BuChE, while still retaining the muscarinic receptor antagonism of aprophen.
- Developed the use of a viability assay (ProCheck™; Intergen, Inc.), containing no hazardous components that can detect 2-chloroethyl ethyl sulfide (CEES; half mustard) - induced viability changes in as few as 1000-3000 leukocytes/ml.
- Determined that human whole blood exposure to CEES vapor (1.5 mg/L/min) for only 15 minutes (total CEES dose of 22.5 mg) significantly decreased total leukocyte viability compared to controls.
- Demonstrated human whole blood exposure to CEES vapor (1.5 mg/L/min) from 15-60 minutes (total CEES dose of 22.5-90 mg) resulted in similar total leukocyte cell counts relative to controls, even when viability was significantly reduced.
- Identified reductions in the number of human whole blood lymphocytes with cell surface markers CD3, CD5 or CD45 as an indicator of CEES (30 min; 1.5 mg/L/min; total CEES dose of 45 mg)-induced damage.
- Established a cooperative research and development agreement with Emory University to test the leukocyte-protective effect of polyoxometalates in the presence or absence of other potential vesicant antidotes following exposure of human whole blood to CEES.
- Initiated a non-human primate (Rhesus monkey) model study to assess the effects of huBuChE on complex cognitive tasks (Serial probe recognition and targeting) as part of the OP prophylactic countermeasure research effort. As part of this same effort, developed a mouse behavioral and reflex assay to evaluate novel esterase compounds in normal and genetically modified (knockout and transgenic) animals.
- Developed a rodent model to assess the effects of low dose (sub-clinical) exposure to OP nerve agents that evaluates general behavioral performance and cognitive ability with emphasis on acquisition of new tasks.
- Determined in rats that AChE inhibition following repeated low-dose VX exposure was highly correlated between different brain regions but less so between brain and RBC. Found that measures indicative of general CNS energy systems (*e.g.*, cortical Na, K-ATPase) were not significantly affected.

Research Category: Therapeutics/Diagnostics

The countermeasures, technical barriers, and accomplishments in the medical chemical defense research category of therapeutics/diagnostics are outlined below.

Countermeasures:

- Products that moderate or improve healing of vesicant injury.
- Medical countermeasures to minimize lethality, morbidity, and incapacitation caused by chemical warfare agents (CWAs).
- Specific casualty management techniques to improve survival and minimize lost duty time.
- Pharmaceutical/biological antidotes, or decontaminants/protectants.
- Diagnostics for the effects of exposure to rapidly acting nerve agents, vesicants, cyanide, and Fourth Generation Agents.

Technical Barriers:

- Need for quick-acting and long-lasting antidotes that are deployable.
- Lack of appropriate experimental model systems for treatment efficacy and safety in humans.
- Need for detailed molecular model of Fourth Generation Agents to understand the origin of their unique chemical properties.
- Lack of simple and sensitive field-portable diagnostic assays for CWA exposure.

Accomplishments:

- Evaluated the release of lung immune products in response to *in vivo* mustard exposure to better define lung injury and the potential for therapeutic agents to prevent cellular damage. Observed that, for peroxidase reactions, reduced glutathione (GSH) demonstrated a greater response. Regarding cytokines, the inflammatory mediator MIP2 was released more than interleukins 4 and 6.
- Completed testing of colony stimulating factor (CSF) in African Green Monkeys and showed efficacy by CSF against HD-induced leukopenia.
- Studies were conducted on IL-6 expression and secretion and structural changes following HD exposure of HEK. While ELISA data show an HD-induced increased secretion over 24 h, mRNA data present wave –like patterns. NMR data clearly show the unfolding of the IL-6 glycoprotein. This is related to disappearance of one of the two disulfide bonds in IL-6.
- Modified the mouse ear drug screen model by lowering the dose of HD to produce a model with increased sensitivity.
- Several procedures for inhibiting apoptosis resulted in reduction of cytotoxicity following HD exposure of cells in culture. These include the calmodulin antagonist W&, an antibody against the Fas receptor (CD95) and a general caspase inhibitor Z-VAD.
- Identified treatments (2-deoxyglucose, fructose +/- CysA, and elevated glucose) that can increase mitochondrial metabolism but not necessarily prevent loss of viable cells caused by HD exposure.
- Demonstrated concentration dependent inhibition of a1-antitrypsin, the primary protease inhibitor at the epidermal-dermal junction.Demonstrated, using inhibitors and antisense RNA, no involvement of PLA2 in HD-induced amino acid release. PLD does seem to be involved.
- Demonstrated increased expression of caspase 3, CD95 (Fas receptor), and intracellular IL-8 in HEK following HD exposure.
- Suppressed (dose dependent) HD-induced IL-8 and improved cellular morphology in HEK using the synthetic analogue of tetrahydocannabinol (THC), CT3.

- Identified several apoptosis inhibitors (dithiocarbamates, aurintricarboxylic acid and caspase inhibitors) that protect against HD cytotoxicity in HEK with best protection applied 3h post-HD exposure, using combinations. The 48 and 96 hour toxicities were identified as more significant than at 24 hours.
- Demonstrated various micro-pathological changes resulting from exposure to HD.
- Identified in HEK that a substantial reorganization and 25% decrease in a6b4 and laminin-5 at 1 hour post exposure to 400uM HD.
- Demonstrated that HD and nitrogen mustard (HN2) degrades laminin-5 in HEK.
- Identified alterations in actin, tubulin, and keratin and high molecular weight aggregates involving k-14 as a result of HD exposure.
- Identified SAPK/JNK, p38, and NF-kB 3 to be important signaling pathways and that pharmacological inhibition of p38 or NF-kB pathways significantly reduced the HD-induced cytokine response.
- Demonstrated that HD-induced cell death may occur through down-regulation of a specific regulatory pathway controlled by the gene Akt or PDK1, its upstream effector.
- Developed a method for removal of GD (soman) from blood in order to quantify the pyridostigmine-spared cholinesterases.
- Developed methods to determine coefficients of distribution of acetyl and butyryl cholinesterases in guinea pigs, mice, and other species of animals in blood, brain, and other tissues.
- Demonstrated that pyridostigmine inhibited binding to the muscle ACh receptor (mAChR) but not to the nerve ACh receptor (nAChR). Also showed that DEET, an insecticide, did not affect mAChR binding but that it did non-competitively inhibit nerve AChR binding. Co-exposure of mAChR and nAChR to the compounds yielded no enhancement of inhibition.
- Demonstrated that pyridostigmine inhibited purified acetylcholinesterase (AChE) more potently than butyrylcholinesterase, while DEET partially blocked the inhibition of both enzymes by pyridostigmine. Permethrin (an insecticide) emulsion did not perturb binding at either receptors nor inhibit ChEs. Therefore, it appears that there should be no correlation between cholinergic functions and the exposure to DEET, permethrin, and pyridostigmine bromide.
- Demonstrated a protective ratio of 15.7 for polyurethane sponges (combination of HI-6 and extracting additives) to decontaminate soma-exposed guinea pigs (LD_{50}, 155 mg/kg). A protective ratio of almost 25 was obtained in VX contaminated guinea pigs (LD_{50}, 3.37 mg/kg).
- Initiated the development of enzyme-coupled assays to rapidly detect mustargen (generic name mechlorethamine, MSD, mustine, or nitrogen mustard) and HD using a visible or fluorescent indicator. The enzymes, choline oxidase and horseradish peroxidase, have been successfully immobilized on polyurethane prepolymers, making the reaction suitable for long-term monitoring of this CWA.
- Demonstrated a dose-dependent reversible coupling of soluble AChE to the macroaffinity sponge polymer for purification of the AchE using a new scheme to synthesize a spacer-ligand.

- Determined the enzymatic rate constants (kcat and K_M) for soluble OPH and OPH immobilized on polyallylamine cotton for both paraoxon and demeton-S. This represents a more stable form of cotton (SBIR, Phase II).
- Demonstrated the ability of polyurethane immobilized OPH and OPH-AE, a modified OPH, to detoxify a wide variety of pesticides (OP surrogates). (SBIR, Phase II).
- Determined that magnesium sulfate and the nitrone PBN (N-tert-Butyl-alpha-phenylnitrone) were ineffective in reducing neuronal damage subsequent to soman-induced status epilepticus.
- Initiated a modified model study for investigating less severe neuronal damage that may be more amenable to neuroprotectant drug treatment while increasing survivability and reducing morbidity of animals.
- Determined that the scavenger dihydrolipoic acid protects cultured neurons from oxidative stress *in vitro*, but the addition of the nitrone free radical spin trap PBN (N-tert-butyl-α-phenylnitrone) substantially enhanced neuroprotection.
- Determined that increasing endogenous stores of naturally occurring lipoates followed by supplementing with spin trapping nitrones may constitute an effective neuroprotective strategy based upon *in vitro* and *in vivo* studies.
- Initiated pilot studies in rats to determine whether the neuroprotection offered by dexanabinol (HU-211) will reduce behavioral deficits reducing from soman-induced status epilepticus as measured using the active avoidance paradigm.
- Determined that HU-211 protects against soman-induced excitotoxicity but appears to have no effect on the vasogenic-related damage seen in the thalamus.
- Determined a relationship between lesion volume and certain frequency bands of the electroencephalographic recording device at specific time intervals that can confidently predict impending brain damage following soman-induced seizure activity.
- Developed a one-compartment mathematical model to describe the level of protection provided by stoichiometric scavengers against nerve agents.
- Identified a new oxime that produced better survival than 2-PAM or HI-6 against fourth generation agents (FGAs) in guinea pigs.
- Identified a new oxime that provides better reactivation of FGA-inhibited AChE than 2-PAM.
- Initiated studies of the relationship between the occurrence of coma and neuropathology in guinea pigs exposed to FGAs.
- Identified four anticonvulsants that terminated seizures induced by FGAs at doses 2-10 fold less than diazepam.
- Identified three anticonvulsants that terminated seizures induced by FGAs at times 4-5 fold earlier than diazepam.
- Initiated studies of the effects of FGAs on respiratory dynamics and lung biochemistry of guinea pigs.
- Developed a new *in vitro* model to screen for better oximes using human AChE.
  Determined that steroidal eye drops (prednisolone acetate) applied for up to 2 hours to sulfur mustard exposed eyes, followed by subtenon injection of triamcinolone/cefazolin combination significantly reduced ocular damage in the rabbit. In addition, determined that matrix metalloproteases inhibitor (Ilomastat) droplets applied to sulfur mustard exposed eyes showed promising therapeutic results.

- Determined maximum doses of the nerve agents sarin (GB), cyclosarin (GF), soman (GD), VX, and VR that can be absorbed daily in male and female guinea pigs without lethal effects or clinical signs of toxicity, thus establishing an upper limit for chronic low-dose chemical nerve agent studies.
- Identified an enhanced sensitivity to low-dose nerve agents in animals on food-restricted diets, suggesting an interaction between food intake and maximum tolerated dose.
- Determined the doses of sarin (GB), soman (GD) and VX that abnormally enhance startle responses in animals exposed to low-level chemical warfare nerve agents.
- Identified specific gene products that are either enhanced or depressed in the brain following low-level chemical warfare nerve agent exposures to GB and GD.
- Observed changes in brain electrical activity (EEG) suggesting cumulative and slowly reversing sleep disruption with low-dose sarin (GB) exposures.
- Measured cumulative and regionally selective inhibition of brain acetylcholinesterase activity with low-dose VX exposure.
- Developed a computer model of electrical flow in the heart to predict nerve agent induced cardiac arrhythmias.
- Verified that sarin (GB), soman (GD) and VX have no direct effect on electrical excitability and resting membrane potentials in single neurons at low-doses.
- Identified functional changes in synaptic connections between brain neurons following acute exposure to low-dose VX and sarin (GB) and investigated allosteric drugs such as galanthamine as a method to reverse these synaptic changes.
- Observed a loss of electrical excitability resulting from direct interaction between sulfur mustard (HD) and neuron membranes in cell culture.
- Continued developing a swine model to test treatment of sulfur mustard induced dermal injury similar to third degree burns.
- Determined in the swine model that full thickness laser debridement or surgical excision followed by skin grafting significantly improved wound healing. Initiated development of the model to mimic superficial and second degree burns.
- Continued to develop a mouse inhalation model to test phosgene injury.
- Found that bronchoalveolar lavage fluid in these animals had greater amounts of total Ca++ and K+ than non-phosgene exposed animals, as early as one hour after exposure. This model may be an early indicator of phosgene exposure, providing the medical staff with ample time to properly treat for injury. We have also used this model to determine that N-acetylcysteine given intraperitoneally increased survival rates in mice.
- Developed a fixed site cholinesterase assay to analyze cholinesterase activity in whole blood, red blood cells and tissue as an indicator of nerve agent poisoning. This assay is automated, uses small sample size (10 microliters), and is very accurate.
- Developed polyurethane sponges for skin and wound decontamination of chemical warfare agents. The wetting solution of oxime (HI-6) and tetraglyme provides greater than ten-fold and one hundred-fold increase in survival when used to decontaminate soman and VX, respectively, applied to the guinea pig skin.

Research Category: Reducing Reliance on the use of Animals as Subjects of Research

- Initiated development of an *in vitro* human whole blood model to rapidly screen for potential antidote combinations that effectively protect cells from the damage associated with vesicant exposure.

E.1.3 Advanced Development Products

In advanced development, the goals are proof-of-principle and the conduct of studies necessary to obtain FDA approval/licensure of drugs, vaccines, and devices. The medical R&D process links the materiel developer (U.S. Army Medical Research and Materiel Command, USAMRMC) with the combat and training developer (U.S. Army Medical Department Center and School, AMEDD C&S) and the logistician (U.S. Army Medical Materiel Agency, USAMMA) in addressing the threat and JMCDRP requirements. Medical chemical defense products now in the advanced development phase are the following:

Product: Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA) [formerly Topical Skin Protectant (TSP)]

Concept:

- Use perfluorinated formulations.
- Form non-toxic, nonirritating barrier film layer on skin.
- Augments Mission Oriented Protective Posture (MOPP).
- Protection against vesicant and nerve agents.

Accomplishments:

- FDA required Phase IV studies are completed or ongoing

Product: Antidote Treatment, Nerve Agent, Autoinjector (Formerly Multi-chambered Autoinjector)

Concept:

- Speed administration of life-saving antidotes against nerve agents.
- Replace two-Injector Mark I Nerve Agent Antidote Kit with single autoinjector.

Accomplishments:

- Production line upgrade underway with a custom-built high- speed autoinjector filling machine to increase capacity
- The FDA issued an approval letter for the New Drug Application (NDA) on 17 January 2002.
- A Transition Planning and Tracking Group formed

Product: Advanced Anticonvulsant System

Concept:

- A buddy-aid administered anticonvulsant to protect against convulsions after CWA exposure.

- Replace the currently fielded Convulsant Antidote Nerve Agent (CANA) with a faster acting and more effective anticonvulsant.

Accomplishments:

- Laboratory efforts to develop information required to down select one candidate for human trials continued.

E.2 MEDICAL BIOLOGICAL DEFENSE RESEARCH PROGRAM

E.2.1 Biological Defense Products

Advances in DoD medical R&D significantly impact the warfighting mission by sustaining unit effectiveness through conserving the fighting strength of our forces and supporting the nation's global military strategy, which requires the ability to effectively deploy and operate in all environments. Medical R&D products (materiel and non-materiel solutions) provide the foundation that ensures the fielding of a flexible, sustainable, modernized force across the spectrum of conflict and in the full breadth and depth of the battlefield. Overcoming medical threats and extending human performance have provided a significant increase in military effectiveness in the past and present the potential for future enhancement of military operational effectiveness. Only one medical materiel solution (Anthrax Vaccine Adsorbed) is fully licensed by the Food and Drug Administration (FDA) and available for use. Currently, however, access to the vaccine is limited until the FDA approves the manufacturer's Biologics License Application. Others are in investigational new drug (IND) status, which may only be used consistent with Executive Order 13139. A Prime Systems Contract, which supports the Joint Vaccine Acquisition Program (JVAP), is responsible for moving mature solutions from the technology base through advanced development to FDA licensure and procurement of baseline stockpiles. Currently licensed and IND solutions for use in medical biological defense R&D include the following:

Vaccines and Antisera:

- Anthrax Vaccine Adsorbed (licensed)
- Smallpox Vaccine (limited stockpile of licensed vaccine)
- Botulinum Toxoid, Absorbed
- Botulinum Pentavalent Vaccine (IND #3723)
- Botulinum Type F Toxoid Vaccine (IND #5077)
- Equine Heptavalent F(ab')2 Botulinum Antitoxin (Types A, B, C, D, E, F, and G) (IND #3703)
- Botulism Immune Globulin, Human (IND #1332)
- Botulism Antitoxin Heptavalent Equine, Types A, B, C, D, E, F, and G (IND #7451)
- Q Fever Vaccine, Formalin inactivated, CM Extract, Gamma Irradiated (Henzerling Strain) (IND #3516)
- Tularemia Vaccine (IND #157)
- New smallpox vaccine (Vaccinia Virus, Cell Culture-derived) (IND #4984)
- Venezuelan Equine Encephalitis Virus Vaccine (attenuated), TC-83 (IND #142)
- Venezuelan Equine Encephalitis Virus Vaccine (inactivated), C-84 (IND #914)
- Eastern Equine Encephalitis Virus Vaccine (IND #266)
- Western Equine Encephalitis Virus Vaccine (IND #2013)

The status of medical materiel solutions being managed by the Joint Program Office for Biological Defense (JPO-BD) and JVAP are reported in Section E.2.3.

Technical Information and Guidance:

- *Medical Management of Biological Casualties Handbook*, fourth edition, February 2001.
- CD-ROM on "Management of Biological Warfare Casualties," 1999.
- NATO Handbook "Medical Aspects of NBC Defensive Operations, AMedP-6(B), Part II (Biological)," 1998.

E.2.2 Biological Defense Research and Development Accomplishments

The biological defense research and development technical barriers and accomplishments during FY01 are grouped by the following medical defense strategies against biological threats (bacteria, viruses, and toxins):

- Vaccines against bacterial agents.
- Therapeutics for bacterial agents.
- Vaccines against viral agents.
- Therapeutics for viral agents.
- Vaccines against toxin agents.
- Therapeutics for toxin agents.
- Diagnostics.

Several projects and technologies are shared with other agencies, including the Department of Energy (DOE) and the Defense Advanced Research Projects Agency (DARPA). The DOE projects tie into the strengths of the DOE laboratories in developing advanced technologies in order to enable rapid detection of and response to a chemical or biological agent incident. DOE is not involved directly in protection and treatment of personnel, but actively assists DoD with drug/chemical database searches, DNA sequencing, advanced protein chemistry, and modeling/simulation projects. Successful sequencing of plasmids found in the causative agents of plague and anthrax helped create the "lab on a chip". The extensive knowledge and databases available to DOE allow application of computational tools to predict sites of intervention by novel therapies against threat agents.

Medical biological defense research conducted or sponsored by the United States Army Medical Research and Materiel Command (USAMRMC) laboratories yielded the following accomplishments in FY01:

Bacterial Agents

The countermeasures, technical barriers, and accomplishments in the biological threat category of bacterial agents are outlined below.

Countermeasures:

- Vaccines for immunity against bacterial threat agents.
- Therapeutics for treatment of bacterial diseases.

Technical Barriers:

- Incomplete genetic information for all of the bacterial threat agents.
- Lack of appropriate animal model systems for investigation of some bacterial threats and countermeasures.
- Lack of suitable epidemiological situations in which to perform human clinical trials to evaluate efficacy of vaccines.
- Difficulty in field testing rapid identification kits under natural conditions.

- Difficulty in defining surrogate markers of protection.
- Necessity to enhance the otherwise limited data on which to base rational drug and antibody therapies for bacterial agents of interest.
- Necessity to establish and maintain capabilities to assess threats and provide countermeasures for new, emerging, and genetically engineered bacterial threats.

Vaccines Accomplishments:

- Completed a dose-seeking experiment in mice (two vaccine doses) challenged parenterally with *Yersinia pestis* and generated data for calculating the effective dose required to protect mice against a parenteral challenge (*i.e.*, ED50 0.6 μg/dose or ED95 10 μg/dose).
- Performed a single-vaccine dose experiment in mice challenged by aerosol with *Y. pestis* and This experiment established the optimal effective single vaccine dose (10 μg) in the mouse for aerosolized plague..
- Performed a preliminary experiment comparing immunogenicity and efficacy versus route of administration (subcutaneous (sc) and intramuscular (im)) of a single dose of the F1-V fusion antigen recombinant plague vaccine candidate and found a dose dependent advantage in F1-V-dependent antibody production the sc route. This was less apparent at higher vaccine doses and, in the mouse, did not appear to have a significant effect on vaccine efficacy.
- Completed two anti-F1-V passive transfer experiments in mice challenged by aerosols of *Y. pestis* and found that mice can be protected from challenge with aerosolized plague with passively transferred antibody. Establishing that protection from plague can be mediated by antibody has important implications in that antibody levels may be used as a surrogate marker of immunity and antibody therapy may be useful for plague prophylaxis and or treatment.
- Compared a nose-only versus whole-body exposure to determine the lethal aerosol dose of *Y. pestis* in mice. and found that F1-V induced statistically significant protection from aerosolized plague challenge in NHPs.
- Conducted an immunogenicity/efficacy study in non-human primates challenged with capsulated and non-encapsulated *Y. pestis*.
- Completed a preclinical plague vaccine (F1-V fusion antigen) stability and formulation study.
- Completed an independent contractor study for F1-V vaccine safety.
- Defined the research base process for purifying the F1-V antigen, making it amenable to scale-up production in compliance with current Good Manufacturing Processes (cGMP) and transferred the technology package to the JVAP.
- Showed that five research-grade lots of F1-V candidate vaccine were nearly identical in composition and purity through a combination of novel applications of light-scattering methods and traditional protein assays.
- Determined the long-term stability and efficacy of F1-V bulk protein and Alhydrogel-formulated vaccine. Protein retained biophysical integrity for 1 month at 4°C and the vaccine retained its immunogenicity for up to 9 months at 4°C.
- Compiled all research data into a "Technical Data Packet for Milestone 0 Exit" in preparation for a Component Advanced Development decision review.
- Devised a research project management approach to answer issues and difficulties specific to F1-V.

- Conducted a study to determine the effectiveness of the plague vaccine candidate in non-human primates. Twenty African green monkeys were immunized via intramuscularly with the recombinant F1-V candidate vaccine formulated with Alhydrogel. Results indicated that 30 % of the animals were protected against an aerosol challenge as compared to 0 % protection with the previously licensed plague vaccine.
- Created and screened anti-V monoclonal antibodies in passive protection studies against parenteral plague challenge.
- Established a cooperative research agreement with the National Institutes of Health to evaluate the F1-V vaccine candidate in the flea-bite model of plague infection
- Performed preliminary experiments on the protective efficacy of alternative recombinant proteins (YopD combined with V antigen) in mice challenged with aerosolized plague and in macrophages to determine the ability of antibody to YopD to block cytotoxicity and apoptosis.
- Established a contract for a scaled-up production and purification of recombinant YopD protein for use in follow up studies.
- Recloned important plague virulence genes SycD, YopB, YopD, YscC and TyeA for testing as alternative plague vaccines.
- Screened 300 genetic mutants of *Y. pestis* to identify essential virulence genes. Two possible essential genes were identified for additional study.
- Found that extracellular *Y. pestis* (KIM5) bacteria expressing certain virulence factors (Yops) can significantly inhibit the host cellular immune response.
- Determined that the DNA sequences of *Y. pestis* strains Angola, Pestoides A and Pestoides F *usd* and *galE* genes have single nucleotide polymorphisms. Using pulse field gel electrophoresis, genetically typed 47 different strains of *Y. pestis*.
- Defined genetic mutations in *Y. pestis* were created through a cooperative research agreement. The pools of mutants (96 mutants/pool) will be studied to identify genes that are turned on inside the infected host.
- Established that *Y. pestis* grown at 37°C had decreased aerosol virulence.
- Constructed a panel of insertion mutations in the *Y. pestis* virulence plasmid (pFra). This plasmid contains genes for known virulence factors such as the bacterial capsule and other gene sequences of undefined function that may be important in pathogenesis.
- Established an effective dose (ED50) for rabbit polyclonal anti-F1 antibody in the mouse.
- Constructed V-antigen alleles to study virulence regulation and cross-protective immunity among *Yersinia sp.*
- Characterized a new phage-resistant mutant strain of the plague bacteria.
- Constructed *Y. pestis* strains that express a bioluminescent operon for use in pulmonary deposition and pathogenesis studies.
- Through a collaborative study, established the ability of multi-locus variable tandem repeat analysis to define genetic relatedness among strains of *Y. pestis*. Also, through two other collaborative studies, established the genetic relatedness of *Y. pestis* strains using insertion sequences and subtractive hybridization techniques.
- Discovered a novel virulence plasmid (pJars), which confers resistance to arsenic.
- Identified putative host protein targets of the *Y. pestis* V antigen.

- Tested the safety and efficacy of attenuated *Y. pestis* live vaccine candidates in higher animal species (non-human primates/NHP).
- Tested the efficacy of DNA-based F1, V, and F1-V candidate vaccines in the mouse and found that F1-V provided protection against both parenteral and aerosol plague challenges, that V alone is less effective than F1-V, and that F1 alone does not appear to confer significant protection.
- Identified several possible adherence factors within the genome of *Bacillus anthracis*.
- Discovered that anthrax spores adhere to lung cells *in vitro*.
- Tested 24 different anthrax strains in vaccinated guinea pigs. Nine strains were identified as equally virulent, compared to the Ames strain.
- Purified virulent and avirulent anthrax spores to be used to vaccinate and challenge rabbits.
- Developed procedures to produce highly purified anthrax capsule protein to be evaluated as a vaccine candidate.
- Identified 19 novel virulence genes from the available *B. anthracis* preliminary DNA sequence database.
- Developed protocols to mutate the *B. anthracis* Ames strain to a non-lethal form to identify the role of certain virulence genes in the disease.
- Determined that *B. anthracis* produces an enterotoxin component of *B. cereus*, a gastrointestinal pathogen.
- Determined lethal dose-50% values for challenge and attenuated vaccine strains of *B. anthracis* in outbred mice.
- Inactivated the hemolysin gene in two attenuated strains of *B. anthracis*. These strains retained some hemolytic capability, suggesting that other factors are involved in this property of the pathogen.
- Evaluated the recombinant PA (rPA) component of a next-generation anthrax vaccine with and without formaldehyde added as a stabilizer in the rabbit model.
- Prepared a large volume of high-titer immune ascites fluid in mice injected with rPA in Freund's adjuvant or rPA in Alhydrogel. The anti-rPA immune globulin G (IgG) was used to develop a quantitative mouse anti-PA antibody assay.
- Utilized the quantitative anti-PA antibody assay to analyze serum samples on a routine basis.
- Completed experiments testing various amounts of rPA in a single dose vaccine in rabbits.
- Conducted preliminary passive transfer studies in rabbits using either rabbit anti-AVA or rabbit anti-rPA sera.
- Developed a quantitative anti-PA IgG immune assay for guinea pig and mouse sera.
- Devised an isolation methodology for isolating rPA pools enriched for either of two biochemical variants of the protein.
- Demonstrated that *B. anthracis* lethal toxin inhibits the activation of specific biochemical pathways in immune cells.
- Demonstrated effects of anthrax lethal toxin on cytokine expression *in vitro*.
- Found that antitoxin antibodies contributed significantly to antiserum-associated stimulation of anthrax spore uptake by immune cells *in vitro*.
- Detected anti-PA-reactive antigen on anthrax spores by immunoelectron microscopy

- Demonstrated that exposing immune cells to inhibitors of phagosomal acidification reduced the efficiency of killing and allowed outgrowth and replication of the *B. anthracis* organism.
- Developed improved methods to characterize the effects of antitoxin antibodies on the extracellular germination of anthrax spores.
- Established *in vitro* assays of immune function in a new BSL-3 laboratory at the new WRAIR facility. Found that serum from monkeys infected with Brucella has opsonic activity for ingestion of Brucellae by human mononuclear phagocytes. This activity correlates with anti-lipopolysaccharide ELISA titers.
- Found that mice immunized with two new live attenuated Brucella vaccine candidates make anti-lipopolysaccharide antibody and that immune cells from these mice make IL-2 and interferon-gamma in response to specific antigen.
- Developed an improved Brucella antigen preparation that is essentially free of endotoxin contamination for use in cell stimulation assays and diagnostic assays.
- Using real-time PCR technology, confirmed gene array studies that mRNA for at least 10 unexpected proteins is significantly increased in cells from immune animals stimulated with Brucella antigen. This finding should allow more extensive characterization of the scope of immune responses elicited by vaccination.
- Found that immunodeficient Rag-1 mice can eventually clear a live, attenuated vaccine strain of Brucella from their tissues. Found that passive transfer of anti-Brucella antibody into these severely immunodeficient animals leads to changes in tissue distribution of injected attenuated and virulent Brucellae, but does not ultimately lead to enhanced clearance of virulent organisms. These studies further emphasize the safety of the first live, attenuated Brucella vaccine candidate and demonstrate a requirement for cellular immune function in defense against virulent organisms.
- Found that a double deletion mutant Brucella vaccine candidate described last year was protective against intranasal challenge in mice.
- Constructed a new double deletion mutant vaccine candidate and found that it is attenuated and immunogenic after oral administration to mice.
- Found that conjunctival inoculation of virulent *Brucella melitensis* into Rhesus macaques leads to bacteremic, febrile illness, suggesting that this mucosal challenge route will be useful for testing of vaccine efficacy.
- Found that IL-12 was inferior to meningococcal outer membrane protein as an adjuvant for induction of anti-Brucella lipopolysaccharide antibody responses in mice.
- Developed IgG1 anti-Brucella lipopolysaccharide monoclonal antibody for use as a potential diagnostic reagent.
- Prepared protocol for a comparative analysis of Canadian O-polysaccharide and U.S. live, attenuated vaccine candidate against 3 species of Brucella.
- Established fermentation conditions for a live, attenuated Brucella vaccine candidate.
- Found that Brucella lipopolysaccharide-induced secretion of alpha interferon by murine macrophage cell lines, suggesting that modulation of this process might be used to enhance protective immune responses to Brucella infection.
- Constructed model plasmid expressing both green fluorescent protein and non-antibiotic selectable marker in candidate Brucella vaccine strain for plasmid maintenance.

- Cloned reporter genes and tetanus toxin C fragment under the control of a Brucella promoter for use in heterologous antigen expression for multiagent vaccine development.
- Found that monocyte and monocyte-derived macrophages use toll-like receptor 4 to produce TNF alpha in response to both *E. coli* and Brucella lipopolysaccharide.
- Found that uptake of rough and smooth *B. melitensis* by macrophages and dendritic cells is greatly increased by addition of human serum. Smooth *B. melitensis* inhibits apoptosis of infected monocyte while rough Brucella accelerates this process. These data support observations that smooth strains survive longer in macrophages *in vivo* and provide more prolonged stimulation of immune response.
- Found that transfection of human monocyte-derived macrophages with a gene for human heat shock protein-70 inhibited *B. melitensis* lipopolysaccharide-induced production of TNFα, IL-1α, IL-10 and IL-12 but not IL-6 and protected macrophages from killing by lipopolysaccharide. These studies suggest that strategies to increase intracellular heat shock protein-70 may be useful for modulating host defense against Brucella.
- Evaluated a heat-killed, irradiation-inactivated, capsule negative mutant of Burkholderia mallei, the causative agent of glanders, as a potential candidate vaccine.
- Determined that certain killed *B. mallei* cell preparations were not able to protect mice when challenged with *B. mallei*.
- Determined that vaccinated mice challenged with a low dose of B. *mallei* had greatly enlarged, still-infected spleens, demonstrating in the laboratory a chronic state of the disease.
- Found that administration of CpG oligodeoxynucleotides just before respiratory challenge of mice with virulent B. mallei improved survival and delayed death.

Therapeutics Accomplishments:

- Determined the minimum inhibitory concentration levels (MIC) for 45 antibiotics against 16 different strains of *B. anthracis*.
- Developed a screening system for polyamide inhibition of *B. anthracis*.
- Test 20 polyamides in *B. anthracis* for activity and identified several promising compounds.
- Completed the determination of LD_{50} for anthrax (Ames strain) by aerosol in a mouse model for lethal inhalation anthrax.
- Tested doxycycline, ceftazadime, imipenem, ciprofloxacin, azithromycin, and tobramycin for efficacy in the mouse model for glanders.
- Explored methods for direct assay of adenosine triphosphate (ATP) levels in bacterial cells to assess feasibility as a rapid and accurate bioenergetic metric for *in vitro* antibiotic activity.
- Evaluated antibiotics to identify candidates for laboratory prophylaxis (pre-treatment protection) of plague and found that ciprofloxacin and levofloxacin provided the lowest minimum inhibitory concentrations (MIC).
- Experimentally demonstrated that kanamycin resistance in Y. pestis does not cross protect the bacteria from gentamicin and streptomycin, thereby reducing potential concerns over the use of the kanamycin resistance marker in making laboratory manipulations in the plague bacterial genome.

Toxin Agents

The countermeasures, technical barriers, and accomplishments in the biological threat category of toxins are outlined below.

Countermeasures:

- Vaccines that produce long-term protective immunity against toxin agents.
- Drugs that can be administered prior to toxin exposure to protect against toxic effects of the agent.
- Therapeutics for treatment of diseases/symptoms caused by toxin agents.

Technical Barriers:

- Develop appropriate model systems that emulate human aerosol exposure and intoxication.
- Methods for induction of respiratory and mucosal immune responses that produce long term protective immunity at the agent's port of entry.
- Development of markers of pulmonary inflammation in animal models.
- Identification and development of appropriate animal models for investigation of surrogate endpoints of human clinical efficacy.
- Retention of toxin antigenicity without toxic properties for vaccine candidate.
- Insertion of stable genetic alteration of toxin biological targets to produce toxin-resistant biological targets.
- Generic protection from families of toxins with subtle alterations in toxic modes of action.
- Necessity to enhance the otherwise limited data on which to base rational drug and antibody therapies for toxin agents of interest.
- Necessity to establish and maintain capabilities to assess threats and provides countermeasures for new and emerging toxin threats.

Vaccine Accomplishments:

- Provided technical assistance to Joint Vaccine Acquisition Program in support of the botulinum neurotoxin serotypes A, B, C, and F vaccine candidates that previously transitioned to advanced development.
- Demonstrated that mice inoculated with botulinum B and F recombinant vaccine candidates were completely protected from lethal challenge with botulinum neurotoxin type F at a concentration of 10^5 median LD_{50}.
- Demonstrated that mice vaccinated with the recombinant botulinum toxin type E heavy chain [rBoNTE(H_c)] were protected from lethal challenge with botulinum neurotoxin type E.
- Redesigned and created a recombinant botulinum type A heavy chain [rBoNTA(H_c)] clone by site-directed mutagenesis, during which three amino acid residues downstream from the initiation codon were removed.
- Expressed and purified rBoNTE(H_c) from the *Pichia pastoris yeast expression system.*
- Established assays for analyzing the stability of clinical grade recombinant staphylococcal enterotoxin B (rSEB) vaccine candidate under various storage times. Stability data has been collected for 12 months to date.
- Established SEB toxicity assays based on non-potentiated lethality and cytokine-release from inhalation challenge.

- Completed vialing of the cGMP lot of the rSEB vaccine candidate.
- Completed assays to generate a Certificate of Analysis (CoA) for the cGMP lot of the rSEB vaccine candidate.
- Reviewed and revised documentation package prepared for the cGMP lot of the rSEB vaccine candidate.
- Initiated a contract for preclinical purification of the recombinant staphylococcal enterotoxin A (rSEA) vaccine standard.
- Established the aerosol LD_{50} of SEB and protective efficacy of the rSEB vaccine candidate in HLA transgenic mice.
- Determined immunological, toxicological, and histopathological parameters in BALB/c and transgenic mouse strains.
- Established safety and efficacy of the novel mucosal adjuvant, CpG oligodeoxynucleotides, in mice.
- Evaluated the efficacy of inhaled rSEB vaccine candidate in transgenic and BALB/c mice.
- Inserted and tested a new promoter gene from lactobacilli to improve expression of SEB mutant genes.
- Expressed (using an *E. coli* expression system), purified, and partly characterized four novel mutants of the ricin toxin A chain as potential vaccine candidates to replace the chemically-derived deglycosylated ricin A chain candidate, which had manufacturing and other issues of concern regarding transition to advanced development.
- Demonstrated that two of the novel mutant ricin vaccine candidates were not toxic *in vitro* since they did not inhibit protein synthesis in a cell-free assay system.
- Demonstrated that two of the novel mutant ricin vaccine candidates with increased protein stability also could elicit significant protective immunity in mice challenged by intraperitoneal and aerosol administration of ricin toxin.
- Developed a liposomal ricin A subunit vaccine that could be administered by an intramuscular or intranasal route. The vaccine protected 100% of the mice from an intranasal ricin challenge with $5LD_{99}$ dose of ricin toxin.
- Demonstrated that immunization with *Ricinus communis* agglutinin protected 100% of mice from an intranasal ricin challenge of $5LD_{99}$ doses.
- Demonstrated that skin patch immunization of mice with a sulfhydryl-blocked ricin A subunit induced antibodies to ricin.
- Initiated project to develop a skin patch vaccine that protects against anthrax

Therapeutics Accomplishments:

- Generated an oligoclonal antibody composed of two human and one chimeric monoclonal antibody, and demonstrated that it is capable of neutralizing over 800,000 Median LD_{50} of botulinum neurotoxin type A/mg antibody.
- Developed the first practical high performance liquid chromatography (HPLC)-based activity assays for botulinum neurotoxins types D and F, enabling the first thorough characterization of these two toxins.
- Developed high-throughput (96 well microtiter plate) assays for four of the seven botulinum neurotoxin serotypes and filed a patent application for the assay.

- Evaluated several hundred pseudo-tripeptides as inhibitors of botulinum neurotoxin type A using non-toxic recombinant light chain and a high-throughput activity assay.
- Identified two structurally analogous isocoumarin compounds with substitutions in the 7-N position of the isocoumarin ring as inhibitors of botulinum neurotoxin.
- Characterized buforin II and various analogs as inhibitors of botulinum neurotoxin type B and produced novel buforin II mutants for use in ongoing structural studies.
- Synthesized fluorescent derivatives of buforin compounds for site-specific studies on botulinum B light chain.
- Completed synthesis of botulinum neurotoxin light chain genes types A, B, C, E, F, and G and expressed recombinant light chain A, B, and E.
- Purified recombinant light chain for botulinum types A, B, and E and demonstrated that these are proteolytic. The light chains are being produced for *in vitro* assays to screen compounds for their ability to inhibit the activity of the toxin.
- Cloned and expressed genes in *E. coli* encoding botulinum toxin substrates (SNAP-25, VAMP, and syntaxin) for use in inhibitor screening assays.
- Used X-ray crystallography to determine the structure of the catalytic domain of botulinum neurotoxin type B in a state where it was free from the holotoxin
- Used X-ray crystallography to determine the structure of a complex of an inhibitor (BABIM) bound to the active site of botulinum type B.
- Crystallized botulinum neurotoxin type E with gangliosides and their bound fragments and collected complete X-ray diffraction datasets.
- Use X-ray crystallography to determine the structure of the tetanus toxin C fragment with the drug doxorubicin bound to the putative ganglioside binding site.
- Demonstrated proof-of-concept for use of the heavy chain of botulinum type A as a delivery vehicle in primary spinal cord cells.
- Produced a non-toxic, proteolytically-inactive, triple mutant of botulinum toxin light chain for use in transporting therapeutic drugs into cholinergic nerve cells.
- Expressed the non-cleavable SNAP-25 mutant as a GST fusion protein in BL21(DE3)pLysS bacteria.
- Found that over-expression of RhoB, a signal transduction protein involved in modulation of the actin cytoskeleton, prevents the inhibitory effects of botulinum toxin on actin reorganization and LPA/KCl-stimulated Acetylcholine release.
- Initiated dose efficacy testing of pentoxyfylline in non-human primates to aid in determining its potential as a possible therapeutic for SEB intoxication.
- Identified two additional drugs, baicalin and chlorogenic acid, which blocked SEB-induced cytokine proliferation.
- Demonstrated that the drug candidates D609 and baicalin inhibited SEB-induced cytokines and chemokines at the transcriptional level.
- Found that D609, a phospholipase C (PLC) inhibitor, showed promising results in human MHC II transgenic mice.
- Created new clones of a single-chain T-cell receptor protein for use in a cell-free bioassay and expressed large quantities of T cell receptor protein is support of the SEB therapeutics research effort.

- Developed a novel cell-based, high-throughput assay to evaluate therapeutics against SEA and SEB toxins.
- Obtained several diversity sets from the National Cancer Institute's Natural Products Repository and tested 2,238 of them for activity on SEB binding to MHC Class II molecules.
- Found several compounds from NCI diversity sets that inhibited SEB interaction with the receptors.
- Found that aerosolized SEB was lethal to all HLA transgenic mice, showing the potential utility of this "human-like" animal model.
- Determined that aerosolized SEB could induce high levels of inflammatory cytokines in the lungs and spleens of HLA transgenic mice.
- Found that aerosolized SEB could induce lung lesions in the HLA transgenic mice, similar to SEB lesions induced in non-human primates.
- Found that humanized transgenic mice succumbed to lethal shock induced by injection of superantigens without potentiation.
- Further characterized lethal shock induced by SEB or SEA in piglets, observing histological lesions, loss of regulation of vascular tone (Doppler/laser blood pressure device) and pulmonary distress (blood gases). Also identified regulators of vascular tone that were disrupted upon challenge of piglets with SEB or SEA. Reversal of SEB-induced blood pressure plummeting was accomplished by intervening with the identified regulators of vascular tone.
- Characterized in a piglet model, SEA or SEB-induced incapacitation (vomiting, diarrhea, prostration) that can lead to dehydration and the requirement for intensive medical intervention.
- Identified a family of drugs that rescued SEA or SEB-induced incapacitation even after onset of initial symptoms. Diarrhea and vomiting stopped immediately upon drug administration; untreated SEB-challenged animals remained prostrate for ~5h while drug-treated SEB-challenged animals showed immediate recovery.
- Established cDNA array technology to analyze differential gene profiles following aerosol exposure to ricin for the identification of secondary therapeutic targets
- Established a novel fluorescent detection assay for ricin in cell-free media and used it to test candidate inhibitor compounds.

Viral Agents

The countermeasures, technical barriers, and accomplishments in the biological threat category of viral agents are outlined below.

Countermeasures:

- Vaccines for immunity against viral threat agents.
- Antibodies and antiviral drugs for treatment of viral disease.

Technical Barriers:

- Logistical difficulties from the necessity to work with live agents in high-containment (BL3 and BL4) laboratories.

- Difficulty in optimizing and comparing different expression vectors for recombinant products (vaccines and antibodies).
- Need for rapid virus identification technology.
- Insufficient or incompletely understood animal model systems for investigation of viral threats and countermeasures.
- Necessity to develop and fully characterize animal models for eventual FDA licensure of vaccines for which efficacy data from human clinical trials is impossible to obtain.
- Need for multivalent vaccines and compatible vaccine platforms to protect against an array of unrelated viral agents.
- Difficulty in defining surrogate markers of protection.
- Necessity to enhance the otherwise limited data on which to base rational drug and antibody therapies for viral agents of interest.
- Necessity to establish and maintain capabilities to assess threats and provide countermeasures for new, emerging, and genetically engineered hazardous viruses.

Vaccine Accomplishments:

- For the Venezuelan equine encephalitis (VEE) IE cleavage site deletion mutant vaccine construct (IE115A), a vaccine dose-escalation study was completed in mice, an onset/duration of immunity study was initiated, and safety and efficacy studies were begun in non-human primates.
- Demonstrated that IE1150 replicated inefficiently in mosquitoes and did not revert to virulence after passage through mosquitoes.
- Assessed the duration of immunity elicited by candidate VEE subtype IE vaccine (IE1150) for nine months. Protection determined to be sufficient for greater than 90% protection for the nine month test period. Additional testing to extend the time frame will continue.
- Demonstrated that the western equine encephalitis (WEE) cleavage site deletion mutants, W2102 and W2130, replicated inefficiently in mosquitoes and did not revert to virulence after mosquito passage.
- Demonstrated that WEE mutants W2102 and W2103 failed to provide 80% protection in mice.
- Initiated a vaccine dose-escalation study in mice using WEE candidate W2130.
- Constructed cleavage site deletion mutants of the VEE IIIA virus for evaluation as potential vaccine candidates for IIIA strains of the virus. Two vaccine candidates have been identified and attenuation has been demonstrated by challenge in mice.
- Determined by the aerosol route in two strains of mice, the lethal dose of wild-type eastern equine encephalitis (EEE) virus strain FLA and VEE virus IIIA strain Mucambo.
- Evaluated four monoclonal antibodies specific for WEE virus were evaluated for protective efficacy. Two failed to exhibit protective ability against a subcutaneous lethal challenge and two protected 70-100% of the challenged mice.
- Determined the nucleotide sequences of the complete genomes of a guinea pig-lethal Marburg virus (MBGV) Musoke, guinea pig attenuated MBGV Musoke, and MBGV Ci67.
- In a study in which macaques were vaccinated with DNA encoding MBGV glycoprotein (GP), baculovirus-derived MBGV GP, or a combination of the two, it was demonstrated that

DNA alone offered protective immunity and that baculovirus-derived GP was not protective when administered with RIBI adjuvant or when used as a boost to DNA priming vaccination.

- Demonstrated that DNA-based vaccine for Marburg virus showed promising protection in the majority of non-human primates tested, raising the possibility of further improvement to match efficacy seen against this agent with replicon-based vaccines.
- Completed a guinea pig vaccination study with chimeric GPs (constructed by swapping GP1 and GP2 subunits between MBGV and Ebola viruses/EBOV). Results indicated that the smallest subunit, GP2, was sufficient for protecting the animals from challenge with the homologous virus.
- Demonstrated that immunization of guinea pigs with EBOV GP DNA was not enhanced with boosts of baculovirus-derived EBOV GP (with or without a transmembrane anchor).
- Demonstrated that adding subcellular targeting signals to EBOV GP or NP DNA constructs did not increase the protective efficacy afforded by the DNA/gene gun approach.
- Created a replicon construct to express EBOV secretory GP.
- Completed analysis of the vaccination results of guinea pigs inoculated with the bivalent VEE replicon expressing Lassa virus GP and EBOV GP genes. Results revealed the animals were protected against both Lassa and EBOV challenge.
- Concluded that VEE 26S DNA vaccine elicits strong antibody responses and confers protection in guinea pigs in the absence of neutralizing antibodies.
- Evaluated multiple-agent DNA vaccines (EBOV, MBGV, VEE, and anthrax) in guinea pigs and concluded there were no measurable differences between immunogenicity and protective efficacy of single agent and multiagent vaccines.
- Cloned and sequenced the hemagglutinin gene (A56R) from the DoD smallpox vaccine candidate TSI/Connaught as a precedent to mapping monoclonal antibodies reactive with that protein.
- Completed the evaluation of immunogenicity and protective efficacy of vaccinia LIR, A33R, B5R, and A27L genes in mice using DNA vaccine technology.
- Performed passive transfer experiments and demonstrated that LIR-specific monoclonal antibodies protects adult mice from a lethal vaccinia challenge.
- Demonstrated that DNA vaccination of rhesus monkeys elicited antibody responses against A27L, B5R, and A33R gene products.
- Cloned and sequenced six additional vaccinia virus genes.
- Evaluated human antibody response to vaccination with the current smallpox vaccine using naked DNA reagents expressing individual poxvirus genes.
- Compared the nucleotide sequence of vaccinia virus genes with those of variola and monkeypox homologues.

Therapeutics Accomplishments:

- Completed the large-scale production and purification of three EBOV GP-specific monoclonal antibodies for testing in the form of a cocktail as a possible prophylactic for Ebola virus.
- Purified and initiated characterization of additional monoclonal antibodies to the GP of EBOV to identify additional protective epitopes.

- Sequenced the genome of the mouse-adapted virus to identify mutations from the Mayinga strain of Ebola Zaire.
- Defined the role of EBOV VP40 in virus egress and it's role in causing cytopathic effects at the cellular level.
- Expressed and purified EBOV NP and established that it has preferential affinity for sequences at the 5'-end of the virus genome.
- Expressed EBOV NP, VP30, VP35 in E. coli and determined conditions for purification
- Completed evaluation of the pathology of EBOV infection in mice
- Showed that resistance to filovirus infection in mice is controlled by the type I interferon response.
- Discovered that an S-adenosylhomocysteine hydrolase inhibitor protects EBOV-infected mice by inducing massive interferon-alpha production.
- Determined that the antiviral compound cyanovirin has anti-EBOV activity.
- Comparatively sequenced selected fragments of variola and other orthopox viruses in collaboration with the Centers for Disease Control and Prevention (CDC).
- Developed a real-time assay for rapid and specific identification of variola virus based on Taqman® chemistry with the orthopoxvirus hemagglutinin gene used as the target sequence.
- Evaluated the assay in a blind study at CDC using 164 samples, including genomic DNA from 40 different isolates of variola and 8 different isolates from camelpox, cowpox, monkeypox and vaccinia viruses. The assay was shown to be 100% specific for variola virus.
- Using genomic DNA purified from variola Bangladesh 1975, determined that the detection limit of the Taqman® assay was approximately 483 copies.
- Collaborated with the CDC to complete the sequence of the variola viral DNA polymerase E9L from 31 variola strains.
- Tested 124 possible therapeutic compounds against five viruses (two variola, one monkeypox, one cowpox, and one vaccinia strains) in two cell lines. Determined that cowpox is the best choice for a surrogate virus for initial testing of therapeutic compounds.
- Identified the drug cidofovir (HPMPC, Vistide™; a viral DNA polymerase inhibitor) as an effective inhibitor of variola, monkeypox, cowpox and vaccinia.
- Using the cowpox mouse model, established that cidofovir treatment during vaccinia vaccination did not interfere with vaccine protection.
- Determined that cidofovir treatment initiated on the day of infection completely protected all three non-human primates infected with a small-particle aerosol of monkeypox.
- Characterized the inhibition of 32 variola strains in two cell lines by cidofovir. Results were sufficient to support the preclinical section of an IND for intravenous cidofovir for treating smallpox.
- Found that variola strain India 7124 was inhibited at the same concentrations of cidofovir as were the other strains.
- Determined that aerosol delivery of cidofovir was effective at a much lower concentration than intraperitoneal-delivered drug.
- Evaluated an approach to orally available therapy *in vitro* against a series of analogs based on cidofovir prodrugs and found that these prodrugs can inhibit poxvirus at 1,000-fold lower concentrations than the parent drug.

- Determined that intravenous administration of variola virus to cynomolgous monkeys resulted in development of smallpox-like lesions and lethal disease.

Diagnostic Assays for Biological Warfare Threat Agents

Countermeasures:

- Portable common diagnostic systems for a broad range of biological threats.
- Field laboratory capability to identify biological threat agents.
- Reference laboratory for confirmatory identification of biological threat agents.

Technical Barriers:

- Development of identification technologies and reagents of sufficient sensitivity and specificity to support early disease diagnosis.
- Development of rapid processing methods that can be used with a broad array of possible clinical specimens, including whole blood, sputum, swabs, feces, and tissues.
- Reduction of laboratory methods to portable devices.
- Lack of available data on genetic variability pertaining to markers used for diagnostic development.
- Inability to type organisms specifically and determine geographic origin.

Accomplishments:

- Completed design and sub-system prototype construction of a four-cartridge system with integrated specimen processing and gene amplification.
- Selected and optimized reagent sets to be incorporated into disposable cartridges for the rapid identification of *B. anthracis, Y. pestis, Francisella tularensis, and Clostridium botulinum* neurotoxin genes.
- Completed the production of purified nucleic acids under strict quality control for 77 bacterial agents for use as reference evaluation standards of emerging diagnostic technologies.
- Established an RNA virus reference panel of over 30 viral strains (including prototype alphaviruses and related viruses), completed purification of 25 strains, and prepared RNA master stocks of seven preparations.
- Demonstrated that two proposed rapid nucleic acid analysis systems had identical sensitivity and specificity and comparable limits of identification for identifying *B. anthracis*.
- Found that VEE could be detected by isolation and plaque assay of samples from pharyngeal swabs up to 6 days post-exposure in animal models.
- Demonstrated that VEE could be detected in buccal and nasal swabs 1 to 2 days post-exposure in high-dose animal models by standard culture methods and PCR.
- Developed an *in vitro* culture system of NHP alveolar macrophages to study host response and to identify potential diagnostic markers for EBOV.
- Characterized EBOV virus replication in alveolar macrophages by plaque assay, immunohistochemistry, and in situ hybridization.
- Designed fluorogenic 5'nuclease assays specific for non-human primate proinflammatory cytokines and chemokines and used them to evaluate mRNA transcription in macrophages infected with EBOV.

- Developed and evaluated one-tube reverse transcription PCR assays to detect Ebola-Zaire, Ebola Sudan and Marburg viruses by the ABI PRISM™ 7700 Sequence Detection System.
- Determined that the a newly designed primer/probe set (MBGGP3) was equivalent to or tenfold more sensitive for the identification of MBGV than previously designed primer sets.
- Found that the Marburg GP3 assay was able to detect specifically all MGBV strains, but was negative for other hemorrhagic fever and related viruses.
- Optimized and established the specificity of rapid gene amplification assays for nine bacterial agents against a panel of 65 related organisms and human DNA.
- Synthesized and optimized gene amplification primers for the rapid identificaiton of EEE virus.
- Demonstrated a host RNA transcription pattern of approximately 250 genes that were never expressed above baseline under normal conditions, yet showed some increased expression upon exposure to one or more of the nine different BW or infectious agents.
- Demonstrated the kinetics of host gene expression after exposing peripheral blood monocytes to botulinum neurotoxin A by using a custom microarray and a 3,900 gene microarray.
- Evaluated the single-site Autolyzer® (Model 303) spun fleece columns for their ability to bind, elute and purify biological agent nucleic acids from the binding matrix.
- Demonstrated the sensitivity (100 to 100 colony forming units per sample) of the Igene® Cartridge system for extracting DNA from *B. anthracis* spores and vegetative cells.
- Determined that the quartz fleece disks and suspended silica slurry were equivalent for rapid purification of biological agent nucleic acids, while spun fleece was less efficient.
- Demonstrated the Cepheid Microsonicator module enhanced rapid sample preparation by 10 to 1000 fold.
- Designed and tested two Taqman® assays for detecting *Brucella melitensis, B suis,* and *B. abortus*. The assay was successful for all samples tested.
- Found that the Taqman® Omp25 assay is capable of detecting *B, melitensis, B. suis,* and *B. abortus* genes.
- Tested and optimized Taqman® primers and probe for *Francisella tularensis* Tul4gene and FopA genes. The Tul4 gene assay was able to detect all seven *F. tularensis* isolates in the reference library.
- Designed and tested one set of fluorescence resonance transfer probes for *Brucella* Omp2b amplicons that will improve identification methods
- Determined the limit of detection (10 femtograms) of orthopoxvirus primers in the LightCycler® and the R.A.P.I.D.® gene amplification systems.
- Developed a Taqman® assay capable of distinguishing the SaspB gene of *B. anthracis* from the SaspB gene of other species of *Bacillus*.
- Developed rapid gene amplification assays for tetracycline resistance classes A, B, and C in *Y.pestis*.
- Identified an improved system for stabilization of enzyme linked immunosorbent assay reagents for biological threat agents.
- Optimized nine pre-coated and fieldable enzyme-linked immunosorbent assays for the identification of biological threat agents.
- Vaccinated mice with *B. anthracis* spore and capsule preparations, *Y.pestis*, botulinum pentavalent toxoid, ricin, and VEE virus to obtain omniclones.

- Cloned Ebola genes NP, GP, and sGP into a commercial vector (pUniV 5his TOPO) to obtain expression in the ECHO expression system to improve the production of critical diagnostic reagents.
- Cloned the heavy and light chain genes of a botulinum A/B reactive antibody into mammalian heavy and light chain expression vectors to improve production of critical reagents.
- Demonstrated the superiority of electrochemiluminescence assays as compared to time resolved fluorescence and Luminex technologies with multiple detection assays.
- Developed improved probe hydrolysis assays for *B. anthracis, Y. pestis, F. tularensis Brucellae sp, Burkholderia sp, C. burnetii* and Orthopoxviruses.
- Demonstrated the limits sensitivity and specificity of existing hand-held assays specific for the detection of *B. anthracis* in oral and nasal swabs.
- Evaluated samples from a population of animals from two naturally occurring outbreaks of anthrax in wildlife in Etosha National Park, Namibia, by using hand-held specific assays. Results indicated the assay was 100% accurate in determining which animals had died of anthrax and was able to detect protective antigen up to 24 hr after death.
- Developed eight enzyme-linked immunosorbent assays for detecting biological warfare agents using time-resolved fluorescence technology.
- Demonstrated the use of HPLC and DNA sequencing to identify a single point mutation difference between *B. mallei* and *B. pseudomallei*.
- Optimized fluorogenic 5'nuclease assays for *B. anthracis* protective antigen (pX01), capsule B (pX02), 23sRNA gene targets on the SmartCycler® and R.A.P.I.D.® nucleic acid analysis systems.
- Determined the DNA sequences of five of seven *F. tularensis* isolates and demonstrated single nucleotide polymorphisms that are type-specific.
- Developed and optimized a real-time PCR assay that specifically and consistently detected *Rickettsia prowazekii*.
- Demonstrated the successful performance of candidate rapid nucleic acid analysis systems in extreme conditions, including a temperature of 115°F and humidity of 100%.
- Demonstrated sensitive detection of *B. anthracis* in post-mortem biomedical specimens and selected environmental samples at remote field sites by using rapid nucleic acid analysis systems.
- Demonstrated the rapid and sensitive detection of *Y. pestis* in fleas but not soils by using rapid nucleic acid analysis systems at a remote field site.
- Established that specimen processing methods compatible with field laboratories were required to sensitively identify biological agents in mock clinical specimens and environmental samples. Selected processing methods improved the sensitivity of gene detection by any platform by 10- to 1,000-fold, depending on the specimen matrix.
- Demonstrated the user friendliness and compatibility with the unit CONOPS for portable rapid nucleic acid analysis systems. R.A.P.I.D.® systems had better soldier interface that similar SmartCycler® XC systems.
- Evaluated assay result acceptance criteria for the SmartCycler® XC.
- Demonstrated that rapid nucleic acid analysis devices were 300% faster than standard PCR.

- Developed laboratory training packages to enhance transition of agent identification technologies to the Theater Army Medical Laboratory.
- Established patterns of gene expression responses in peripheral blood mononuclear cells (PBMC) upon exposure to *B. anthracis*, *Y. pestis*, *B. melitensis*, SEB toxin, VEE virus, cholera toxin, and other agents. The ability to identify early host responses will permit rapid detection of overt exposure. This will also allow differentiation of exposure to selected biological threat agents upon onset of early flu-like symptoms. In addition, naturally or deliberately mutated pathogens unidentifiable by structural-based probes can be categorized as to type of illness based on gene patterns.

Unconventional Pathogen Countermeasures Program

The focus of this thrust is the development of revolutionary, broad-spectrum medical countermeasures against pathogenic microorganisms and/or their pathogenic products. By identifying those features of biological threat agents that are essential for their ability to cause disease and then undermining these disease-causing mechanisms, the medical countermeasures under development will be versatile enough to eliminate biological threats, whether from natural sources or modified through bioengineering or other manipulation. They will also have the potential to provide protection both within the body and at the most common portals of entry (*e.g.*, inhalation, ingestion, and transcutaneous). Strategies include:

- Defeat of a pathogen's ability to enter the body, traverse the bloodstream or lymphatics, and enter target tissues;
- Identification of novel pathogen vulnerabilities based on fundamental, critical molecular mechanisms of survival or pathogenesis (*e.g.*, Type III secretion, cellular energetics, virulence modulation);
- Construction of unique, robust vehicles for the delivery of countermeasures into or within the body;
- Development of effective treatments for late stage injections; and
- Modulation of the advantageous and/or deleterious aspects of the immune response to significantly neutralize pathogenic microorganisms and/or their pathogenic products in the body.

The work is divided into three main thrust areas: antiviral/immunizations, anti-bacterials/anti-toxins and multipurpose agents. Specific approaches currently under development include the identification of critical cellular pathways necessary for the proliferation of pathogens in the host, development of broad-spectrum vaccination schemes, development of broad-spectrum antibiotics with reduced chance of resistance development, enhancement of innate immunity, plant-based vaccine production and other protein production, and development of novel decontamination approaches for bio-threat agents.

E.2.3 Advanced Development Accomplishments

The Joint Program Office for Biological Defense (JPO-BD) is a DoD agency chartered to provide intensive centralized management of medical and non-medical programs to expedite materiel

solutions for validated biological defense deficiencies. Vaccine products will be further developed by the Joint Vaccine Acquisition Program (JVAP), an ACAT II program under JPO-BD. Vaccines directed against high threat agents will be produced and stockpiled to fulfill a 1.2 million Troop Equivalent Doses (TEDs) requirement (Note: TED = total amount of vaccine required to immunize a service member to protect against a biological warfare agent.) Vaccines against low threat agents will be produced to fulfill a 300,000 TEDs requirement.

E.2.3.1 Botulism Immune Globulin (Human), Pentavalent (IND #1332)

- The IND remains open to accommodate emergency treatment requirements for exposure or possible exposure to botulinum toxin types A, B, C, D, or E.

E.2.3.2 Botulinum Type F Toxoid Vaccine (IND #5077)

- Completed the Phase 2 Safety and Immunogenicity clinical study of Botulinum Type F Toxoid Vaccine. The purpose of this study was to identify a vaccination schedule and route of vaccination that is safe and maximally immunogenic.
- A final report for the Phase 2 safety and immunogenicity clinical study was completed.
- Work has been stopped on the development of this product because it did not meet user requirements.

E.2.3.3 Anthrax Vaccine Adsorbed (AVA) (Human)

- BioPort, the sole manufacturer of AVA, obtained FDA approval for their renovated facility on December 27, 2001. There have been a series of issues that have delayed efforts to resume full production. Regulatory reform initiatives implemented in the mid-1990s led to changes in FDA regulation of biologics. More stringent Good Manufacturing Practices to validate production have extended this process at BioPort. However, since March 2001, BioPort has submitted 18 regulatory submissions to the FDA including its final supplement for its renovated facility and the supplement for their contract filler. On January 31, 2002, the FDA announced that it approved license supplements for anthrax vaccine, allowing lots from the renovated facility to be released and distributed.

E.2.3.4 Botulinum (Pentavalent) Toxoid Adsorbed (ABCDE) Vaccine (IND#3723)

- Clinical trial data showed that the vaccination schedule does not stimulate sufficient protective immunity against all serotypes (A, B, C, D, and E) to meet pre-set battlefield protection level requirements. However, preliminary data show that an additional booster vaccination may stimulate the desired level of immunity.
- Based upon the marginal performance of the vaccine, difficulties in producing new batches of vaccine, and progress being made in a new recombinant product, the JVAP PMO is reassessing efforts to license this product.

E.2.3.5 Botulism Immune Globulin F(ab')$_2$, Heptavalent, Equine, Types A, B, C, D, E, F, & G IND (#7451)

- This product does not meet the Combat Developer's requirements as an effective battlefield countermeasure. Further efforts to develop and license this product have been stopped.

E.2.4 Joint Vaccine Acquisition Program (JVAP) Accomplishments

E.2.4.1 Prime Systems Contract

- DynPort Vaccine Company continued to expand their operations, finding a variety of commercial subcontractors to engage in the advanced development of BD vaccines (Smallpox vaccine, Tularemia vaccine, Botulinum vaccines, Next Generation Anthrax Vaccine, and a recombinant plague, Venezuelan equine encephalitis vaccine) and Vaccinia Immune Globulin.

E.2.4.2 Contingency Stockpile of Biological Defense (BD) Vaccines

- Southern Research Institute (SRI), Frederick, Maryland, a subcontractor to DynPort Vaccine Company, continues the stability testing on all IND lots of Tularemia, Q fever, VEE, EEE, and WEE vaccines.
- An assessment is being conducted to determine the FDA requirements for additional testing that would make this inventory ready for immediate use under a Presidential Executive Order.

E.2.4.3 Advanced Development of the Tularemia Vaccine

- Under the JVAP Prime Systems Contract, BioScience of Baltimore, Maryland was selected as the subcontractor for manufacture and stockpiling of Tularemia vaccine.
- Defined optimum culture and harvesting criteria needed for manufacturing process for the proposed vaccine.
- Work continued on animal models for safety and lot consistency evaluations at Defense Evaluation Research Agency (UK).

E.2.4.4 Advanced Development of the Smallpox Vaccine

- Under the JVAP Prime Systems Contract, BioReliance Corporation of Rockville, Maryland was selected as the manufacturer of the new Smallpox vaccine. BioReliance continued manufacturing efforts by completing process definition studies, manufacturing a GMP pilot lot suitable for a phase 1 clinical trial, and validating a plaque reduction assay to demonstrate product potency. The plaque reduction assay is antibody levels, and the FDA, for product licensure, requires a validated assay.
- The final report from a clinical trial to evaluate the candidate vaccine administered by scarification, indicates that the candidate is safe and immunogenic similar to the old licensed product, Dryvax. A phase 1 trial for the newly manufactured product is planned for execution in February 2002.

- Filed an annual report with the FDA under IND #8429 to insure continued availability of previously manufactured Vaccine Immune Globulin (VIG), which allows clinical trial to proceed.
- DynPort Vaccine Company filed the first annual report for IND (#9141) for a new VIG product for intravenous administration. Three lots have been manufactured by Massachusetts Biologics Laboratory, Boston, Massachusetts. A clinical trial using this material is currently in data analysis, and two more lots are being manufactured.
- A plaque neutralization assay necessary for lot release testing of the VIG product and to evaluate clinical specimens from both VIG and smallpox vaccine trials has been developed and is being validated by BioReliance Corporation, Rockville, Maryland. Clinical specimens from the aforementioned VIG trial will be assayed once this method is validated.

E.2.4.5 Venezuelan Equine Encephalitis Vaccine

- Pilot lot in production with delivery of bulk product anticipated in 2QFY02.

E.2.4.6 Recombinant Botulinum Toxin Vaccine

- Selected Covance, Cary, North Carolina, as the subcontractor for manufacture of a multivalent (serotypes A and B) recombinant botulinum toxin vaccine.
- Began manufacturing process development for production of a multivalent recombinant botulinum vaccine.

E.2.4.7 International Cooperative Research and Development

- The new Chemical Biological and Radiological Memorandum of Understanding (CBR MOU) between the U.S., the UK, and Canada (CANUKUS) was signed and implemented on 1 June 2000. The new CANUKUS CBR MOU permits full cooperative research and development of vaccines. Negotiations are underway to develop a Project Arrangement for cooperative research and development of a smallpox vaccine.
- In addition to the Vaccinia Virus Vaccine Project Arrangement development, the JVAP is exploring opportunities for CANUKUS development of new vaccines against anthrax, plague, and brucellosis.

E.2.4.8 Joint Biological Agent Identification and Diagnostic System (JBAIDS)

The JBAIDS program is designed to fill a medical mission critical need to rapidly confirm and identify Biological Warfare (BW) and Infectious Disease (ID) agents in both environmental and clinical specimens. JBAIDS will provide medical personnel with the capability to identify the biological agents within one hour of specimen analysis. This system will provide this capability at a lower system cost, reduced logistical burden and with greater reliability than currently available commercial laboratory methods.

JBAIDS will utilize commercial and developmental identification technologies, components and military hardware into a single integrated platform. The design will stress modularity and capability for future technology insertion.

The Joint Program Manager for Biological Defense has structured the JBAIDS program in a block development format in order to expedite procurement and fielding while reducing technical risk. Block I is focused on quickly transitioning mature technology from the Common Diagnostics Systems Defense Technology Objective (DTO) to a fielded system; mature commercial off-the-shelf technology will also be evaluated for fielding. Block II will focus on meeting the Joint Operational Requirements Document (JORD) objectives of integrating a biological toxin identification capability. Block III will fully integrate sample preparation, bacterial, viral and toxin identification capability into a single, small, lightweight, completely automated unit.

- Transition from DTO CB.26 to Advanced Development the current R&D effort for JBAIDS Block I.
- Begin Food and Drug Administration (FDA) approval process for JBAIDS Block I.
- Continue development of JBAIDS Block II toxin identification device via the DTO process.
- Incorporate the developments generated from DTO CB.20 into JBAIDS for the automated sample preparation device.

E.2.4.9 Integrated Digital Environment (IDE)

In order to meet the Under Secretary of Defense for Acquisition, Technology & Logistics mandate to transition acquisition activities to an IDE by 2002, and to achieve the streamlining and savings associated with the mandate the JVAP PMO continued efforts to establish a BD vaccine enterprise-wide IDE in collaboration with DynPort. An automated program assessment tool tailored to vaccine development has been developed and implemented at the PMO. DynPort, LLC has established a web-based, shared data base system. A detailed IDE system requirements analysis was completed in early 2000 and included implementation of an IDE test bed. In 2001, an IPT of government and contractor personnel completed an analysis of Electronic Data Management Systems and recommended Livelink for the JVAP IDE. Livelink licenses have been purchased and full-scale implementation was initiated late CY 2001. Implementation of Livelink has also expanded to include the Biological Defense Research Laboratory - United States Army Medical Institute of Infectious Diseases (USAMRIID). Implementation of common IDEs in both Tech Base and Advanced Development activities will provide significant streamlining opportunities.

E-3 MEDICAL RADIOLOGICAL DEFENSE RESEARCH PROGRAM

E.3.1 Fielded Products

Appropriately applied, advances in medical science and biotechnology can significantly effect the warfighting mission by sustaining unit effectiveness and conserving the fighting strength of our service members. The individual service member whose performance is decremented by injury or illness is significantly more likely to become a traumatic casualty. In this era of small, but highly lethal forces, loss of only a few team members can dramatically diminish a unit's capability. Medical R&D products (materiel and non-materiel solutions) provide the foundation that ensures fielding of a flexible, sustainable, modernized force across the spectrum of conflict and in the full breadth and depth of the battlefield. Overcoming medical threats and extending human performance have provided significant improvements in military effectiveness in the past and new developments promise even greater improvements in the future. Some of the materiel and non-materiel solutions developed for medical radiological defense are:

- Cytokine-based therapeutic applications to prevent two major fatal syndromes—sepsis and uncontrolled bleeding—of acute radiation injury.
- Cytogenetic biodosimetry analytical systems that accurately measure radiation exposure levels from blood samples.
- NATO Handbook on the Medical Aspects of NBC Defensive Operations, Volume 1-Nuclear (AMedP-6).
- Medical Effects of Ionizing Radiation (MEIR) Course—Training for approximately 350 Medical Department personnel in FY00.
- Videotapes and CD-ROM of MEIR course lectures produced for distribution to military medical units.

E.3.2 Nuclear Defense Research and Development Accomplishments

Technical barriers and accomplishments within the Medical Radiological Defense Research Program are grouped in the following threat categories:

- Prompt high-dose radiation.
- Protracted low-dose radiation.
- Combined radiation and chemical or biological agents.

"*Prompt high-dose radiation*" refers to the deposition of high levels of ionizing radiation energy in biological tissues in very short periods of time. Sources of high-energy radiation include emissions within the first 60 seconds of a nuclear weapon detonation and "criticality events" that occur when a nuclear reactor achieves peak energy output either accidentally or through an intentional act. The high linear-energy-transfer radiation imparted by the neutrons from these sources causes significant tissue injury within seconds of exposure, resulting in both short- and long-term health consequences.

"*Protracted low-dose radiation*" refers to the deposition of low-energy radiation energy in biological tissues over extended periods of time. Sources of low-energy radiation include fallout from nuclear weapon detonations, radiological dissemination devices, and any other source of environmental radiation contamination. Health consequences are generally intermediate to long-term and result from cumulative tissue injury accruing over time due to chronic exposure. Health consequences can be exacerbated further when radionuclides are deposited internally by ingestion, inhalation or through open wounds in the external integument.

"*Combined ionizing radiation and either chemical or biological agents*" refers to the amplified health consequences when chemical or biological insults occur in conjunction with radiological injury. Exposures to ionizing radiation compromise host defenses against a variety of stressors, including infectious agents and chemical toxicants. Doses of radiation and infectious or chemical agents that are by themselves sub-lethal can produce mortality rates of nearly 100% when combined.

The Medical Radiological Defense Research Program focuses on developing medical countermeasures against the health consequences of both prompt high-dose and protracted low-dose exposures to ionizing radiation. The program also develops experimental data that quantifies lethality from combined exposure to NBC agents and is used in computer modeling for casualty prediction and operational planning. Specific research on medical countermeasures includes work on prophylactic and therapeutic drugs, drug delivery devices to enhance efficacy and simplify administration under field conditions, and combined prophylactic/therapeutic protocols to further enhance efficacy. Work also focuses on developing novel biological dosimetry techniques to measure individual absorbed doses. Knowledge of absorbed radiation dose helps guide medical treatment decisions and saves lives. It also provides field commanders with an assessment of the radiological health of deployed forces and leads to better-informed operational decision-making.

Threat Category: Prompt High-Dose Radiation

The countermeasures, technical barriers, and accomplishments in the threat area of prompt high-dose radiation are outlined below.

Countermeasures:

- Advanced medical treatment strategies for radiation injuries.
- Drugs designed to increase resistance of soldiers to radiation and protect the Service member against radiation injury without compromising performance.
- Drugs designed to prevent the onset of radiation-induced performance decrements such as fatigue, nausea and vomiting.
- Biological dosimetry techniques for rapid injury assessment needed to guide medical treatment decisions and assess radiological health of combat units.

Technical Barriers:

- Minimizing the performance-degrading effects of prophylactic drugs that otherwise have good efficacy for the prevention of radiological injury.
- Advancing knowledge of cellular, sub-cellular, and molecular mechanisms of radiological injury to improve rational development of prophylactic and therapeutic drugs.

- Increasing prophylactic drug stability in order to improve bioavailability and enhance drug efficacy.
- Increasing prophylactic drug stability for use in slow-release delivery devices that extend bioavailability and enhanced efficacy.
- Difficulty in identifying and calibrating biological markers that can both indicate the amount of absorbed radiation dose and differentiate between whole-body from partial-body exposures.
- Difficulty in automating sample preparation and reducing sample preparation times for cytogenetic-based biodosimetry tests.

Accomplishments:

- Demonstrated efficacy of orally administered 5-androstenediol (5-AED), a non-androgenic steroid with newly identified broad-spectrum radioprotective attributes (*i.e.*, protection against simple acute radiation injury, acute radiation injury complicated by infectious challenge, and chronic, late-arising radiation injury).
- Determined blood pharmacologic profile of injectable 5-AED in a large animal model. Verified non-androgenicity of 5-AED by demonstrating absence of testosterone-elevating effect following treatment.
- Continued assessment and optimization of a therapeutic regimen combining cytokine and clinical support modalities for enhancing survival following acute, lethal irradiation.
- Demonstrated in a pre-clinical model that 5-AED pretreatment enhances therapeutic efficacy of combined cytokine therapy (IL-11 and G-CSF) for acute, potentially lethal radiation injury.
- Verified initial experimental evidence of therapeutic efficacy of an epithelial tissue repair cytokine, keratinocyte growth factor, used to manage acute radiation-induced gastrointestinal injury and associated septicemia resulting from translocation of intestinal microflora.
- Continued exploring potential new prophylactic strategies for reducing acute radiation injury through (a) systematic screening of nutritional supplements and promising new pharmaceutical agents, (b) pharmacologic quenching of the toxic side effects of existing efficacious drugs, and (c) testing of new drug delivery systems.

Threat Category: Protracted Low-Dose Radiation

The countermeasures, technical barriers, and accomplishments in the threat area of protracted low-dose radiation from nuclear fallout, radiological explosive devices, *etc.* are outlined below.

Countermeasures:

- Advanced medical treatment strategies to mitigate injuries induced by protracted exposure to radiation from both external and internal sources.
- Drugs that protect against early and late effects of ionizing radiation and do not compromise performance.
- Improved techniques to detect and remove internally deposited sources of radioactivity.
- Improved drug delivery systems that provide non-encumbering protection during the entire period of radiation exposure.
- Persistent biological markers of radiation exposure that can be easily measured in deployed field laboratories and that give useful diagnostic information for triage and medical treatment decisions.

Technical Barriers:

- Difficulty in manipulating cellular repair mechanisms.
- Toxicity of chelating agents used to remove internally deposited radioisotopes.
- Short-lived activity of conventional radioprotective drugs.
- Toxicity of radioprotective drugs used over protracted periods of time.
- Limited knowledge of DNA damage surveillance and repair mechanisms under protracted exposure conditions hinders development of pharmacologic agents to prevent late-arising cancers.
- Microbial resistance to antibiotics.
- Difficulty in identifying a persistent biological marker to accurately measure low-dose radiation exposures.

Accomplishments:

- Determined that the radioprotectant 5-androstenediol inhibits low-level radiation-induced growth and development of cancer cells *in vitro*.
- Demonstrated therapeutic advantage of combined cytokine treatment (IL-11 plus G-CSF) in managing protracted radiation injury of the blood-forming and gastrointestinal tissues.
- Established ultra-sensitive and reliable assay to monitor blood and tissue levels of aminothiol-type radioprotectants following various dosing regimens and routes of administration.
- Demonstrated therapeutic efficacy of keratinocyte growth factor in managing protracted radiation injury of gastrointestinal tissues.
- Demonstrated dose-dependent increases in expression levels of specific oncogene m-RNA and protein species in an *in vivo* irradiated mouse model system that may provide the basis for important new biological markers of radiation exposure.
- Completed initial-phase optimization of PCR-based assays that quantify gene expression levels of single-target molecular biomarkers and that can be incorporated into existing field-deployable analytical platform.

Threat Category: Combined Ionizing Radiation and Either Chemical or Biological Agents

The countermeasures, technical barriers, and accomplishments in the threat area of combined effects of ionizing radiation and trauma, burns, infection, or chemical toxicants are outlined below.

Countermeasures:

- Therapeutic agents designed to decrease morbidity and mortality from multi-organ system failure due to the combined effects of radiation and trauma, burns, infections or chemical toxicants.
- Radioprotective drugs designed to harden the Service members against the effects of radiation in combination with trauma, burns, infection, or chemical toxicants.
- Combined preventive and therapeutic regimens that reduce morbidity and mortality from combined exposures.
- Computer models for predicting casualties from combined exposure to low levels of ionizing radiation and biological warfare/chemical warfare agent aerosols.

Technical Barriers:

- Limited surrogate models to improve extrapolation of data to human responses.
- Non-availability of radiation sources and biological containment capabilities within the same research facility that would allow full range of experiments on combined effects of radiation and BW agents.
- Growing number of microbial organisms resistant to antibiotics.
- Variability in biological responses to different radiation qualities (*e.g.*, neutron *vs.* gamma radiation).
- Identifying the best surrogate model system for studying the combined effects of radiation and other toxicants; *e.g.*, the best radiation model may not be well suited for a particular infectious agent.

Accomplishments:

- Demonstrated in an irradiated animal model that standard antimicrobial therapy for anthrax, penicillin G, increases survival by only 5% upon challenge with *Bacillus anthracis* (Sterne) spores and that therapy needs to be initiated within 24 hours of challenge to have any effect.
- Discovered disseminated mixed bacterial infections from translocation of normal intestinal microflora in 40% of sub-lethally irradiated animals upon challenge with *B. anthracis* Sterne spores, implying the need for alternative antimicrobial therapy in cases of combined exposure.
- Determined in animal model that *B. anthracis* Sterne spore challenge followed by sub-lethal irradiation results in 50% mortality.
- Demonstrated a maximum 80% efficacy for the human anthrax-vaccine-absorbed (AVA) vaccine in sub-lethally gamma-irradiated animals challenged with *B. anthracis* Sterne spores, whereas non-irradiated animals are 100% protected.
- Continued incorporation of data from combined NBC effects animal studies into the Consequence Assessment Tool Set (CATS) and other casualty prediction model programs under development by the Defense Threat Reduction Agency.

E.3.3 Predevelopment Products

Technical developments in predevelopment products for medical radiological defense include the following:

- Androstene steroids as broad spectrum, nontoxic radioprotectants.
- "Slow release" radioprotectant for extended periods of protection.
- Cytokine therapeutic for the effective treatment of acute radiation injury of the gastrointestinal system.
- Therapeutic regimen for bacterial infections following sub-lethal irradiations and BW agent challenge.
- CATS model enhancements to incorporate radiation/BW interactions.
- Product improvement of the cytogenetic biodosimetry system by automation of satellite scoring subsystem to increase sample throughput.
- Rapid and sensitive method to measure urinary uranium concentration.

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Annex F

NBC Defense Logistics Readiness Data

F.1 BREAKOUT OF SERVICE WAR REQUIREMENTS, STOCKS ON-HAND, AND PLANNED ACQUISITIONS

The following tables display NBC defense equipment total Service requirements, their wartime requirements, FY01 stocks on-hand quantities, and FY02–03 planned procurements for each of the four Services and Defense Logistics Agency. As described in Chapter 3, the two MTW requirements for consumables are based on the sum of the initial issue and the average consumption developed under the JCHEMRATES IV study, updated as of March 1999.

It should be emphasized that the JCHEMRATES IV study's two MTW requirement is not and should not be considered a procurement target. This study did not fully consider air transport into theaters of conflict or Navy fleet requirements for ships at sea. While the Services in general agree with the methodology and intent of the study, it may require further refinement prior to becoming a fully accepted planning tool. The MTW requirement does not consider peacetime training requirements, sizing requirements, or full procurement for the entire active and Reserve forces and critical operational personnel. The MTW requirement does denote a minimum planning number, which if the total DoD inventory drops below, may represent a critical shortfall for that particular item, which should be immediately addressed to avoid diminishing the force's NBC defense capability.

The JCHEMRATES IV study also did not consider the requirements of units specific identified to provide domestic CBRNE consequence management support. Units such as the Army CB-RRT, SMART and WMD CSTs, the Navy NMRC, the Marines Corps CBIRF, and the Air Force Medical NBC Teams will require individual and collective protection, detection, and decontamination equipment. Since domestic CBRNE consequence management response is not regarded as a mission of the two MTW scenario, these requirements are not included in the following tables.

Because of the limitations in the study, the Services have identified their total Service requirements as their procurement targets, while acknowledging JCHEMRATES as a necessary step in joint service management of the NBC defense program. The Services continually update these data call sheets on a frequent basis and consider these working papers rather than a static set of figures. The Services and DLA are working through the FY02 Joint Service NBC Defense Logistics Support Plan to update all figures and to provide 100% of the information required for logistics readiness and sustainment assessments.

Table F-1a. Army Logistics Readiness Data – Nonconsumables

NOMENCLATURE	NSN	TOTAL SERVICE ROUNDS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN					
					FY02	FY03	FY04	FY05	FY06	FY07
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, CB, M17A2	4240-[illegible]-43-3013-30	0	0	28,234	[illegible]	3	2	0	0	0
MASK, CB, M40/M42A1	4240-01-258-2061-03	957,624	610,516	500,518	2,660	0	2	0	0	0
MASK, M24, AVIATOR	4240-01-276-4384	0	0	3,413	3	3	2	0	0	0
MASK, M25A1, TANK	4240-01-394-8702-02	0	0	3,183	31	3	2	0	0	0
MASK, M42, TANK	4240-01-258-0064-66	88,722	59,015	100,590	44	2	2	0	0	0
MASK, M40, APACHE	4240-01-208-6995-99	0	0	2,781	28	0	0	0	0	0
MASK, M45, AVIATOR	4240-01-414-0034-35[illegible]-02	31,156	1,509	15,353	27	0	0	0	0	0
MASK, M48, APACHE	4240-01-286-0196-[illegible]-0017	825	1,609	2,259	0	0	0	0	0	0
MISC PROTECTION										
SUITS, M51	8340-01-395-4241	2,957	2,765	5,122	35	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
NUCLEAR DETECTION EQUIPMENT										
AN-PDR-75	6665-01-[illegible]-4217	2,445	5,425	4,021	122	0	0	0	3	3
AN/PDR-77	6665-01-[illegible]-00	332	332	1,209	67	0	0	1	1	1
AN/VDR-2	6665-01-[illegible]-7337	5,[illegible]1	26,32	18,790	4,[illegible]2	0	0	2	2	2
AN/VDR-2	6665-01-225-2435	33,651	33,431	28,548	230	0	0	2	2	2
BIOLOGICAL DETECTION EQUIPMENT										
BIDS, M31	6665-01-342-[illegible]91	76	76	74	3	42	0	3	2	0
CHEMICAL DETECTION EQUIPMENT										
ACADA, M22	6665-01-426-6965	7,830	5,926	6,194	463	3	2	2	0	0
ALARM, CAA, M43A1	6665-01-265-5623	20,000	20,000	22,218	5	2	2	0	0	0
CAM/ICAM	6665-01-337-1502	13,592	19,592	11,589	321	2	2	2	0	0
M21 RSCAAL	6665-01-[illegible]-6637	191	191	379	2	0	0	0	0	0
NBC RECON SYS, M93A1	6665-01-[illegible]-1503	1,0	1,0	127	3	2	0	0	0	0
DECONTAMINATION COMMODITY AREA										
DECON APPAR, M13	4230-01-[illegible]-1616	40,998	45,221	31,503	2,090	2	0	0	0	0
DECON APPAR, M15	4230-01-[illegible]-4124	113,913	112,000	122,269	3,372	2	0	0	0	0
DECON APPAR, PDDA, M 22A1	4230-01-[illegible]-9488	129	129	68	55	0	0	0	0	0
LWT DEC SYS, M17A1	4230-01-[illegible]-5239	2,516	2,516	2,527	49	2	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
CP DEPHEDS [HUS, CP, M28]	4240-01-[illegible]-5179	23	23							
SHELTER, C3 PROTECT	5410-01-[illegible]-3354	279	279							
SHELTER, CP, MED, MEDAC	6530-01-[illegible]-2254	1,747	1,747							
SHELTER, M51	5340-01-[illegible]-44	3	3							
MEDICAL COMMODITY AREA										
LITTER, DECONTAMINABLE, S	6530-01-383-[illegible]29	5,221	5,148	2,125	0	0	0	0	0	0

Table F-1b. Army Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE ROCTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	PROJECTED DUE IN FY03
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
CHEM PROT UNDERGARMENT TOP	8415-01-353-6683-20		0	3,592	529	0
CPU DRAWERS	8415-01-353-6683-01	421,564	431,564	2,463	536	0
[illegible]	SEE NSNs IN TABLE 2-5	1,360,000	2,501,000	134,232	6,353	0
SCALP (TAN AND GREEN)	8415-01-331-0387-00		0	983	0	0
	8415-01-554-2225-02	51,450	151,385	457		0
SUIT, CP CAMO (BDO)	8415-01-131-2702-02	1	0	2,571,932	41,954	0
OVERBOOTS/GLOVES						
[illegible] MULTI	8430-01-464-9453-02					
BLK/GRN VINYL OVERBOOTS	8430-01-512-3774-05		0	1,911,353	6,501	0
	8430-01-049-0378-07	2,353,854	2,859,666	122,153	384	0
CPU FOOT COVERS	8430-01-302-3678	71	0	75,501		0
CP GLOVES, XS	8415-01-158-2937-06	154,612	54,672	55,141	997	0
CP GLOVES, MED	8415-01-158-2937-08	613,448	836,448	173,589	1,209	0
CP GLOVES, LRG	8415-01-053-3577-10	1,357,527	3,361,720	1,628,593	31,277	0
MISC PROTECTION						
[illegible] SKIN, XXS-MED	8415-01-413-1543-03	691,042	691,240	503,134	3,169	0
BATTERY, BA-5590 (PSC MASK)	6135-00-760-0982	61,032	61,032	53,031	593	0
CP HELMET COVER	8415-01-[illegible]-9023	1,005,279	1,685,215	5,142,525	15,164	0
FILTER CAN, C2A1	4240-01-361-1319	1,567,629	1,767,629	1,193,672	11,256	0
FILTER CAN, M13A1	4240-01-[illegible]-7186	0	0	75,166	0	0
FILTER ELEMENT, M28A2	4240-01-165-2026	0	31	277,162	488	0
HOOD, M20	4240-01-176-3126	1,703,500	1,791,537	1,460,556	21,252	0
HOOD, M9 FOR M25A1	4240-01-160-1965	0	3	92,811	10	0
HOOD, M9A2 (FSRM FT)	4240-01-559-0450	0	1	260,884	4	0
HOOD, M9 (FOR M28)	4240-01-021-1602	0	0	29,025	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
BATTERY, ACCESS BA-5590	6135-01-526-2466	110,600	115,002	25,343	1,134	0
BATTERY, BA-3517	6135-00-450-3521	52,545	52,645	18,572	652	0
BATTERY, CAR BA-5803	6665-99-785-5742	52,645	52,645			0
BATTERY, M43 BA5061	6135-01-505-3191	320,100	441,001			
DET KIT, M256A1	6665-01-133-4564	48,027	43,027	65,725	1,255	0
DET PAPER, M8	6665-00-035-3535	2,169,231	2,169,231	1,470,345	10,150	0
DET PAPER, M9	6665-01-225-5385	2,221,571	2,025,873	1,251,113	2,332	0
[illegible] M295/M256	5[illegible]-01-559-5405		0	45,691	552	0
	5[illegible]-01-103-1725	41,391	40,306	6,277	405	0
NBC MARK SET, M274	5905-12-124-5595	9,906	9,956	1,020	377	0
WATER TEST KIT, M272A1	6665-01-154-0382	9,580	9,590	10,158	291	0
DECONTAMINATION COMMODITY AREA						
DECON KIT, M291 (Box of 20)	4925-01-275-1925	133,552	165,262	339,238	2,719	0
DECON KIT, M295 (Box of 20)	4925-01-330-8455	145,892	166,892	215,898	10,395	0
DS2, 1 1/2 QT	4925-[illegible]-755-4327	192,381	152,315	252,167	350	0
DS2, 5 GAL	4925-00-755-4325	226,140	226,182	251,579	323	0

Table F-1b. Army Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	PROJECTED DUE IN FY03
DS2, M13 CAN	6850-01-136-8888	369,535	369,535	98,627	1,954	0
NITROGEN CYLINDERS	4230-00-775-7541	1,319,022	1,319,022	12,476		0
STB, 50 LB	6850-00-297-6653	10,628	10,628	49,580	140	0
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP, M12A2 (M14 GPFU)	4240-01-365-0981	12,816	12,816	4,433		0
FILTER, CP, M13 SERIES (M14 GPFU)	4240-00-368-6291	12,816	12,816	4,399		0
FILTER, CP, M18A1	4240-01-365-0982	60,580	60,580	19,417	1	0
FILTER, CP, M19	4240-00-866-1825	44,971	44,971	11,391	1	0
FILTER, GP, M48A1	4240-01-363-1311	15,930	15,930	12,696	1	0
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533	1,167	1,167	3,706	7	0
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	1,349,637	1,349,637	873,314		
ATROPINE AUTOINJ	6505-00-926-9083	1,874,828	1,874,828	142,173		
CANA AUTOINJ	6505-01-274-0951	1,554,920	1,554,920	471,548	92,579	92,579
NAAK, MKI	6705-01-174-9919	2,281,312	2,281,312	459,439		
PYRIDOSTIGIMINE TAB	6505-01-178-7903	1,317,309	1,317,309	88,749	14,813	14,813
PATIENT WRAPS	6530-01-383-6260	18,900	18,900	0	1,329	1,329
MED AEROS NERVE AG ANT (MANAA)	6505-01-332-1281	2,238		3,885		
OTHER TREATMENTS						
CIPROFLOXACIN (500 mg 50s)	6505-01-272-2385		0	13,786	24,688	24,688
(500 mg 100s)	6505-01-273-8650		0	45,703		
(500 mg 100s)	6505-01-333-4154	1,881,870	1,881,870	59		
DOXYCYCLINE CAPS	6505-01-153-4335		0	37,036	18,518	18,518
ANTIDOTE TREATMENT KIT, CYANIDE	6505-01-143-4641	67,140	67,140	616		
	6505-01-457-8901	22,380	22,380	0		

Table F-2a. Air Force Logistics Readiness Data - Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	FY03	FY04	FY05	FY06	FY07
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, A/P22P2	NOT ASSIGNED		14,810	10	0	0	0	0	0	0
MASK, AERP	8475-01-339-9782(S)	32,864	29,879	26,449	0	0	0	0	0	0
MASK, CB, M17A2	4240-01-143-2017-20	5,132	5,132	5,129	0	0	0	0	0	0
MASK, MCU-2/P,	4240-01-415-4239-41	445,112		225,298	0	0	0	0	0	0
MASK, MCU-2A/P	4240-01-284-3615-17	0	475,200	65,588	0	0	0	0	0	0
MASK, MCU-2A/P (WR) USAF	4240-01-327-3299-01	39,978		20,083	0	0	0	0	0	0
MISC PROTECTION										
PATS, M41	4240-01-365-8241	1,500	1,208	281	0	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
NUCLEAR DETECTION EQUIPMENT										
ADM 300 - A KIT	6665-01-363-6213NW	300		163	0	0	0	0	0	0
- B KIT	6665-01-342-7747NW	800	1,800	685	0	0	0	0	0	0
- C KIT	6665-01-320-4712NW	750		740	0	0	0	0	0	0
- E KIT	6665-01-426-5071NW	250		189	0	0	0	0	0	0
CHEMICAL DETECTION EQUIPMENT										
ACADA, M22	6665-01-438-6963	3,521	3,521	235	0	0	0	0	0	0
ALARM, CAA, M8A1	6665-01-105-5623	423	331	225	0	0	0	0	0	0
CAM/ICAM	6665-01-357-8502	0	0	662	0	0	0	0	0	0
	6665-01-199-4153	1,960	1,960	259	0	0	0	0	0	0
M90 CHEM WARFARE ALARM	6665-01-408-5108	65	58	140	0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA										
A/E32U-8 DECON SYS	4230-01-153-8660	175	0		0	0	0	0	0	0
L/WT DEC SYS, M17	4230-01-251-8702	299	0		0	0	0	0	0	0
L/WT DEC SYS, M17A1	4230-01-303-5225	50	0		0	0	0	0	0	0
L/WT DEC SYS, M17A2	4230-01-349-1778	324	324		0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
CHATH (HUB, CPE, M28)	NOT ASSIGNED	*21	20		0	0	0	0	0	0
MEDICAL COMMODITY AREA										
LITTER, DECONTAMINABLE	6530-01-380-7309	26,770	26,770		0	0	0	0	0	0

* CHATH fielding currently being reevaluated by Air Force Medical Service

Table F-2b. Air Force Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	PROJECTED DUE IN FY03
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
AIRCREWMAN CAPE	8415-01-040-9018	290,014	283,502	257,319	0	0
CLOTHING TEST KIT	6630-00-783-8192	200	167	0	0	0
CP UNDERCOVERALL	8415-01-040-3136-44	75,000	67,376	12,484	0	0
EOD HGU-65P HOOD	4240-01-338-1646	225	192	1,293	0	0
EOD M-3 TAP	8415-00-099-6962/68/70	312	176	9	0	0
	8415-01-105-2535		0	9	0	0
EOD TAP BOOTCOVER	8430-00-820-6295-6306	275	199	1,168	0	0
EOD TAP GLOVES	8415-00-753-6550-54	500	375	1,442	0	0
IMPREG UNDERGARMENT	8415-00-782-3242-5	5,000	5,000	2,028	0	0
JSLIST (ABDO) 45 DAYS	SEE NSNs IN TABLE E-5	1,584,000	1,584,000	109,358	63,000	63,000
M-2 APRON	8415-00-281-7813-16	225	198	50	0	0
M3 COOLING HOOD	8415-00-261-6443	350	308	9	0	0
M3 COOLING SUIT	8415-00-264-2929	200	170	9	0	0
SUIT, AIRCREW, CWU-66/77P	8475-01-328-3434-57	150,000	126,000	73,948	0	0
SUIT, CP CAMO (BDO)	8415-01-137-1700-07	1,175,090	528,880	429,244	0	0
SUIT, CP CAMO-DESERT 3 clr	8415-00-327-5347-53	13,878	13,878	39,236	0	0
SUIT, CP CAMO-DESERT 6 clr	8415-01-324-3084-91	23,656	23,656	2,810	0	0
OVERBOOTS/GLOVES						
JLIST MULO	8430-01-464-9453-84			141,824		
BLK/GRN VINYL O/BOOTS BVO	8430-01-317-3374-85		0	308,066	0	0
GVO	8430-01-049-0878-87	1,175,090	528,880	218,892	0	0
CP FOOTWEAR COVERS	8430-01-118-8172		0	12,583	0	0
	8430-01-021-5978	154,802	0	69,162	0	0
CP GLOVES 7 MIL	8415-01-138-2501-04	2,350,181	1,057,760	397,338	0	0
CP GLOVES 14 MIL	8415-01-138-2497-00		1,257,871	834,485	0	0
CP GLOVES 25 MIL	8415-01-033-3517-20		23,051	16,005	0	0
CP SOCKS	8415-01-040-3169	200,056	170,768	150,358	0	0
DISP FOOTWEAR COVER	8430-00-580-1205-06	201,980	185,771	351,059	0	0
GLOVE INSERTS	8415-00-782-2809 (S)	2,350,181	1,057,760	1,008,160	0	0
MISC PROTECTION				0	0	0
FILTER CAN, C2/C2A1	4240-01-119-2315	2,350,181	1,057,760	1,281,412	0	0
FILTER, GP	4240-01-161-3110	2,090	1,750	33,075	0	0
FILTER ELEMENT, M13A2	4240-00-165-5026	12,596	12,596	64,112	0	0
HOOD, M6A2 (FOR M17)	4240-00-999-0420	95,093	76,707	324,566	0	0
HOOD, MCU-2/P	4240-01-189-9423	2,350,181	1,057,760	1,017,069	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
BATTERY, ACADA BA-5590	6135-01-036-3495	46,331	46,331	506	0	0
BATTERY, BA-3517	6135-00-450-3528	880	0	727	0	0
BATTERY, ICAM BA-5800	6665-99-760-9742	67,295	67,295	1,178	0	0
DET KIT, M18A2	6665-00-903-4767	100	0	21,031	0	0

Table F-2b. Air Force Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	PROJECTED DUE IN FY03
DET KIT, M256A1	6665-01-133-4964	50,123	1,292	150,019	0	0
DET PAPER, M8	6665-00-050-8529	293,773	132,220	623,087	0	0
DET PAPER, M9	6665-01-049-8982		0	87,487	0	0
	6665-01-226-5589	293,773	132,220	227,337	0	0
MAINTENANCE KIT, M293	5180-01-379-6409	90	0	7,172	0	0
NBC MARK SET, M274	9905-12-124-5955	725	517	8,635	0	0
WATER TEST KIT, M272A1	6665-01-134-0885	100	764	45	0	0
DECONTAMINATION COMMODITY AREA						
CALCIUM HYPOCHLORITE (6 oz)	6810-00-255-0471	625	625	421	0	0
CALCIUM HYPOCHLORITE (100 lb)	6810-12-132-2439			57,190		
DECON KIT, M291	6850-01-276-1905	58,755	26,444	26,292	0	0
DECON KIT, M295	6850-01-357-8456	29,378	13,222	14,262	0	0
DRY SORBENT POWDER	6850-01-262-0484	1,150	100	26,234	0	0
SODIUM HYPOCHLORITE	6810-00-598-7316	100	0	29,238	0	0
STB, 50 LB	6850-00-297-6653	517	517	2,411	0	0
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP M13 SERIES (M14 GPFU)	4240-00-368-6291	0	0	450	0	0
FILTER, GP M48A1	4240-01-363-1311	8	8	0	0	0
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533	0	0	252	0	0
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	354,796	354,796	804,703		
	6505-01-080-1986		0	89,256		
ATROPINE AUTOINJ	6505-00-926-9083	354,796	354,796	754,285		
	6505-00-299-9673		0	23,635		
CANA AUTOINJ	6505-01-274-0951	113,323	113,323	291,324		
NAAK, MKI	6705-01-174-9919	2,947	0	1,913	0	0
PYRIDOSTIGIMINE TAB	6505-01-178-7903	26,731	23,460	151,437	0	0
TETRACYCLINE	6505-00-655-8355	0	0	14,752	0	0
PATIENT WRAPS	6530-01-383-6260	0	0	0	0	0
OTHER TREATMENTS						
DOXYCYCLINE CAPS, 100s	6505-00-009-5060		0	1,789	0	0
500s	6505-00-009-5063		0	209	0	0
CIPROFLOXACIN	6505-01-273-8650		0	70,175	0	0
	6505-01-333-4154	33,515	33,515	15,278	0	0

Table F-2b. Air Force Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	PROJECTED DUE IN FY03
DET KIT, M256A1	6665-01-133-4964	50,123	1,292	150,019	0	0
DET PAPER, M8	6665-00-050-8529	293,773	132,220	623,087	0	0
DET PAPER, M9	6665-01-049-8982		0	87,487	0	0
	6665-01-226-5589	293,773	132,220	227,337	0	0
MAINTENANCE KIT, M293	5180-01-379-6409	90	0	7,172	0	0
NBC MARK SET, M274	9905-12-124-5955	725	517	8,635	0	0
WATER TEST KIT, M272A1	6665-01-134-0885	100	764	45	0	0
DECONTAMINATION COMMODITY AREA						
CALCIUM HYPOCHLORITE (6 oz)	6810-00-255-0471	625	625	421	0	0
CALCIUM HYPOCHLORITE (100 lb)	6810-12-132-2439			57,190		
DECON KIT, M291	6850-01-276-1905	58,755	26,444	26,292	0	0
DECON KIT, M295	6850-01-357-8456	29,378	13,222	14,262	0	0
DRY SORBENT POWDER	6850-01-262-0484	1,150	100	26,234	0	0
SODIUM HYPOCHLORITE	6810-00-598-7316	100	0	29,238	0	0
STB, 50 LB	6850-00-297-6653	517	517	2,411	0	0
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP M13 SERIES (M14 GPFU)	4240-00-368-6291	0	0	450	0	0
FILTER, GP M48A1	4240-01-363-1311	8	8	0	0	0
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533	0	0	252	0	0
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	354,796	354,796	804,703		
	6505-01-080-1986		0	89,256		
ATROPINE AUTOINJ	6505-00-926-9083	354,796	354,796	754,285		
	6505-00-299-9673		0	23,635		
CANA AUTOINJ	6505-01-274-0951	113,323	113,323	291,324		
NAAK, MKI	6705-01-174-9919	2,947	0	1,913	0	0
PYRIDOSTIGIMINE TAB	6505-01-178-7903	26,731	23,460	151,437	0	0
TETRACYCLINE	6505-00-655-8355	0	0	14,752	0	0
PATIENT WRAPS	6530-01-383-6260	0	0	0	0	0
OTHER TREATMENTS						
DOXYCYCLINE CAPS, 100s	6505-00-009-5060		0	1,789	0	0
500s	6505-00-009-5063		0	209	0	0
CIPROFLOXACIN	6505-01-273-8650		0	70,175	0	0
	6505-01-333-4154	33,515	33,515	15,278	0	0

Table F-2b. Air Force Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	PROJECTED DUE IN FY03
DET KIT, M256A1	6665-01-133-4964	50,123	1,292	150,019	0	0
DET PAPER, M8	6665-00-050-8529	293,773	132,220	623,087	0	0
DET PAPER, M9	6665-01-049-8982		0	87,487	0	0
	6665-01-226-5589	293,773	132,220	227,337	0	0
MAINTENANCE KIT, M293	5180-01-379-6409	90	0	7,172	0	0
NBC MARK SET, M274	9905-12-124-5955	725	517	8,635	0	0
WATER TEST KIT, M272A1	6665-01-134-0885	100	764	45	0	0
DECONTAMINATION COMMODITY AREA						
CALCIUM HYPOCHLORITE (6 oz)	6810-00-255-0471	625	625	421	0	0
CALCIUM HYPOCHLORITE (100 lb)	6810-12-132-2439			57,190		
DECON KIT, M291	6850-01-276-1905	58,755	26,444	26,292	0	0
DECON KIT, M295	6850-01-357-8456	29,378	13,222	14,262	0	0
DRY SORBENT POWDER	6850-01-262-0484	1,150	100	26,234	0	0
SODIUM HYPOCHLORITE	6810-00-598-7316	100	0	29,238	0	0
STB, 50 LB	6850-00-297-6653	517	517	2,411	0	0
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP M13 SERIES (M14 GPFU)	4240-00-368-6291	0	0	450	0	0
FILTER, GP M48A1	4240-01-363-1311	8	8	0	0	0
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533	0	0	252	0	0
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	354,796	354,796	804,703		
	6505-01-080-1986		0	89,256		
ATROPINE AUTOINJ	6505-00-926-9083	354,796	354,796	754,285		
	6505-00-299-9673		0	23,635		
CANA AUTOINJ	6505-01-274-0951	113,323	113,323	291,324		
NAAK, MKI	6705-01-174-9919	2,947	0	1,913	0	0
PYRIDOSTIGIMINE TAB	6505-01-178-7903	26,731	23,460	151,437	0	0
TETRACYCLINE	6505-00-655-8355	0	0	14,752	0	0
PATIENT WRAPS	6530-01-383-6260	0	0	0	0	0
OTHER TREATMENTS						
DOXYCYCLINE CAPS, 100s	6505-00-009-5060		0	1,789	0	0
500s	6505-00-009-5063		0	209	0	0
CIPROFLOXACIN	6505-01-273-8650		0	70,175	0	0
	6505-01-333-4154	33,515	33,515	15,278	0	0

Table F-3a. Navy Logistics Readiness Data – Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN					
					FY02	FY03	FY04	FY05	FY06	FY07
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, A/P22P2	NOT ASSIGNED									
MASK, CB, M40/M40A1	4240-01-258-0061-63			315						
MASK, M45, AVIATOR	4240-01-414-4034-35A 4051-52		2,000	2,002						
MASK, MCU-2/P	4240-01-173-3443	50,000	50,000	74,288	0	0	0	0	0	0
MASK, MCU-2A/P	4240-01-284-3615/17	370,000	373,000	49,695	0	0	0	0	0	0
MASK, MCU-2A/P (WR) USN	4240-00-327-4148-50				0	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
NUCLEAR DETECTION EQUIPMENT										
AN/PDR-27	6665-00-543-1435	3,824	3,824	1,252	0	0	0	0	0	0
AN/PDR-43	6665-00-580-9646	2,544	2,544	1,081	0	0	0	0	0	0
AN/PDR-56	6665-00-086-8060	1,280	1,280	47	0	0	0	0	0	0
AN/PDR-65	6665-01-279-7516	382	382	234	0	0	0	0	0	0
CP-95	6665-00-526-8645	1,216	1,216	450	0	0	0	0	0	0
PP-4276	6665-00-489-3106	2,912	2,912	599	0	0	0	0	0	0
IM-143	6665-00-764-6395	10,800	10,800	5,937	0	0	0	0	0	0
DT-60	6665-00-978-9637	145,300	145,300	121,922	0	0	0	0	0	0
BIOLOGICAL DETECTION EQUIPMENT										
IBAD	NOT ASSIGNED	0	0	6	0	0	0	0	0	0
CHEMICAL DETECTION EQUIPMENT										
ACADA, M22	6665-01-438-6963	444	444	378	0	0	0	0	0	0
ALARM, CAA, M8A1	6665-01-105-5623	98	98	50	0	0	0	0	0	0
CAPDS	6665-01-294-2556	145	145	79	0	0	0	0	0	0
CHEM AGENT MONITOR/ICAM	6665-01-199-4153	1,008	1,008	606	0	0	0	0	0	0
CWDD, AN/KAS-1	5855-01-147-4362	401	401	630	0	0	0	0	0	0
IMP POINT DETECTION SYSTEM	6665-LL-HAL-5532	254	254		28	45	43	40	38	0
M21 RSCAAL	6665-01-382-1968	0	0		0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA										
DECON APPAR, M11	4230-00-720-1618	144	144	183	0	0	0	0	0	0
L/WT DEC SYS M17A3 DIESEL	4230-01-346-3122	412	412	6	0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
SHELTER, CP, M20/M20A1	4240-01-166-2254	7,311	7,311	516	0	0	0	0	0	0
MEDICAL COMMODITY AREA										
LITTER, DECONTAMINABLE	6530-01-380-7309	1,200	1,200	90						

Table F-3a. Navy Logistics Readiness Data – Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	FY03	FY04	FY05	FY06	FY07
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, A/P22P2	NOT ASSIGNED									
MASK, CB, M40/M40A1	4240-01-258-0061-63			315						
MASK, M45, AVIATOR	4240-01-414-4034-35/ 4051-52		2,000	2,002						
MASK, MCU-2/P	4240-01-173-3443	50,000	50,000	74,288	0	0	0	0	0	0
MASK, MCU-2A/P	4240-01-284-3615/17	370,000	373,000	49,695	0	0	0	0	0	0
MASK, MCU-2A/P (WR) USN	4240-00-327-4148-50				0	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
NUCLEAR DETECTION EQUIPMENT										
AN/PDR-27	6665-00-543-1435	3,824	3,824	1,252	0	0	0	0	0	0
AN/PDR-43	6665-00-580-9646	2,544	2,544	1,081	0	0	0	0	0	0
AN/PDR-56	6665-00-086-8060	1,280	1,280	47	0	0	0	0	0	0
AN/PDR-65	6665-01-279-7516	382	382	234	0	0	0	0	0	0
CP-95	6665-00-526-8645	1,216	1,216	450	0	0	0	0	0	0
PP-4276	6665-00-489-3106	2,912	2,912	599	0	0	0	0	0	0
IM-143	6665-00-764-6395	10,800	10,800	5,937	0	0	0	0	0	0
DT-60	6665-00-978-9637	145,300	145,300	121,922	0	0	0	0	0	0
BIOLOGICAL DETECTION EQUIPMENT										
IBAD	NOT ASSIGNED	0	0	6	0	0	0	0	0	0
CHEMICAL DETECTION EQUIPMENT										
ACADA, M22	6665-01-438-6963	444	444	378	0	0	0	0	0	0
ALARM, CAA, M8A1	6665-01-105-5623	98	98	50	0	0	0	0	0	0
CAPDS	6665-01-294-2556	145	145	79	0	0	0	0	0	0
CHEM AGENT MONITOR/ICAM	6665-01-199-4153	1,008	1,008	606	0	0	0	0	0	0
CWDD, AN/KAS-1	5855-01-147-4362	401	401	630	0	0	0	0	0	0
IMP POINT DETECTION SYSTEM	6665-LI-HAL-5532	254	254		28	45	43	40	38	0
M21 RSCAAL	6665-01-382-1968	0	0		0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA										
DECON APPAR, M11	4230-00-720-1618	144	144	183	0	0	0	0	0	0
L/WT DEC SYS M17A3 DIESEL	4230-01-346-3122	412	412	6	0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
SHELTER, CP, M20/M20A1	4240-01-166-2254	7,311	7,311	516	0	0	0	0	0	0
MEDICAL COMMODITY AREA										
LITTER, DECONTAMINABLE	6530-01-380-7309	1,200	1,200	90						

Table F-3a. Navy Logistics Readiness Data – Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN					
					FY02	FY03	FY04	FY05	FY06	FY07
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, A/P22P2	NOT ASSIGNED									
MASK, CB, M40/M40A1	4240-01-258-0061-63			315						
MASK, M45, AVIATOR	4240-01-414-4034-35/4051-52		2,000	2,002						
MASK, MCU-2/P	4240-01-173-3443	50,000	50,000	74,288	0	0	0	0	0	0
MASK, MCU-2A/P	4240-01-284-3615/17	370,000	373,000	49,695	0	0	0	0	0	0
MASK, MCU-2A/P (WR) USN	4240-00-327-4148-50				0	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMO DITY AREA										
NUCLEAR DETECTION EQUIPMENT										
AN/PDR-27	6665-00-543-1435	3,824	3,824	1,252	0	0	0	0	0	0
AN/PDR-43	6665-00-580-9646	2,544	2,544	1,081	0	0	0	0	0	0
AN/PDR-56	6665-00-086-8060	1,280	1,280	47	0	0	0	0	0	0
AN/PDR-65	6665-01-279-7516	382	382	234	0	0	0	0	0	0
CP-95	6665-00-526-8645	1,216	1,216	450	0	0	0	0	0	0
PP-4276	6665-00-489-3106	2,912	2,912	599	0	0	0	0	0	0
IM-143	6665-00-764-6395	10,800	10,800	5,937	0	0	0	0	0	0
DT-60	6665-00-978-9637	145,300	145,300	121,922	0	0	0	0	0	0
BIOLOGICAL DETECTION EQUIPMENT										
IBAD	NOT ASSIGNED	0	0	6	0	0	0	0	0	0
CHEMICAL DETECTION EQUIPMENT										
ACADA, M22	6665-01-438-6963	444	444	378	0	0	0	0	0	0
ALARM, CAA, M8A1	6665-01-105-5623	98	98	50	0	0	0	0	0	0
CAPDS	6665-01-294-2556	145	145	79	0	0	0	0	0	0
CHEM AGENT MONITOR/ICAM	6665-01-199-4153	1,008	1,008	606	0	0	0	0	0	0
CWDD, AN/KAS-1	5855-01-147-4362	401	401	630	0	0	0	0	0	0
IMP POINT DETECTION SYSTEM	6665-LL-HAL-5532	254	254		28	45	43	40	38	0
M21 RSCAAL	6665-01-382-1968	0	0		0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA										
DECON APPAR, M11	4230-00-720-1618	144	144	183	0	0	0	0	0	0
L/WT DEC SYS M17A3 DIESEL	4230-01-346-3122	412	412	6	0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
SHELTER, CP, M20/M20A1	4240-01-166-2254	7,311	7,311	516	0	0	0	0	0	0
MEDICAL COMMODITY AREA										
LITTER, DECONTAMINABLE	6530-01-380-7309	1,200	1,200	90						

Table F-3b. Navy Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	PROJECTED DUE IN FY03
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
APRON,TAP	8415-00-281-7813-16	72	72	164	0	0
IMPREG UNDERGARMENT	8415-00-782-3242-5	240	240		0	0
JSLIST (ABDO) 45 DAYS	SEE NSNs IN TABLE E-5	1,755,600	1,236,000	140,742		
SUIT, CP CAMO (BDO)	8415-01-137-1700-07	0	0		0	0
SUIT, TAP3	8415-00-099-6962/68/70	471	471	1,336	0	0
	8415-01-105-2535		0			
SUIT, CP, OG MK3 *	8415-01-214-8289-92	0	0	46,904	0	0
SUIT, CP, SARATOGA	8415-01-333-7573-76			44,122		
SUIT, CP SARATOGA-DESERT	8415-01-333-7577-80			40		
OVERBOOTS/GLOVES						
JLIST MULO	8430-01-464-9453-84					
BLK/GRN VINYL O/BOOTS BVO	8430-01-317-3374-85	97,094	97,094	76,549		
GVO	8430-01-049-0878-87		0		0	0
CP FOOTWEAR COVERS	8430-01-118-8172		0		0	0
	8430-01-021-5978	1,500,000	1,236,000	160,429	0	0
CP GLOVES 14 MIL	8415-01-138-2497-00	58,160	58,160	57,190	0	0
CP GLOVES 25 MIL	8415-01-033-3517-20	1,755,460	1,236,000	197,167	0	0
CP SOCKS	8415-01-040-3169	204,824	204,824		0	0
DISP FOOTWEAR COVER	8430-00-580-1205-06	204,824	204,824		0	0
GLOVE INSERTS	8415-00-782-2809	1,755,600	1,236,000	132,209	0	0
MISC PROTECTION						
CP HELMET COVER	8415-01-111-9028	450	450	200	0	0
FILTER CAN, C2/C2A1	4240-01-119-2315	1,500,000	1,236,000	369,071	0	0
HOOD, MCU-2/P	4240-01-189-9423	2,517	2,517	372	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
DET KIT, M256A1	6665-01-133-4964	11,400	11,400	5,471	0	0
DET PAPER, M8	6665-00-050-8529	111,707	111,707	37,921	0	0
DET PAPER, M9	6665-01-226-5589	50,803	50,803	20,131	0	0
NBC MARK SET, M274	9905-12-124-5955	1,859	1,859	198	0	0
TUBE PHOSGENE	6665-01-010-7965	1,280	1,280	574	0	0
WATER TEST KIT, M272A1	6665-01-134-0885	142	142	243	0	0
DECONTAMINATION COMMODITY AREA						
CALCIUM HYPOCHLORITE (6 oz)	6810-00-255-0471	10,626	10,626	12,637	0	0
CALCIUM HYPOCHLORITE (100 lb)	6810-12-132-2439			0		
DECON KIT, M291	6850-01-276-1905	34,500	30,000	20,770	0	0
DECON KIT, M295	6850-01-357-8456	9,049	9,049	4,322	0	0
DS2, 5 GAL	6850-00-753-4870	42	42	62	0	0
SODIUM HYPOCHLORITE	6810-00-598-7316	12	12	380	0	0
STB, 50 LB	6850-00-297-6653	1,718	1,718	21	0	0

Table F-3b. Navy Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	PROJECTED DUE IN FY03
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, GP, M48A1	4240-01-363-1311	450	450		0	0
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533	6,800	6,800	114	0	0
PRE-FILTER, SHIPBOARD CPE	4240-01-348-8785	7,481	7,481	462	0	0
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	1,500,000	1,236,000	221,365		
ATROPINE AUTOINJ	6505-00-926-9083	1,500,000	1,236,000	200,402		
CANA AUTOINJ	6505-01-274-0951	500,000	436,000	7,515		
NAAK, MKI	6705-01-174-9919	113,051	113,051			
PYRIDOSTIGIMINE TAB	6505-01-178-7903	500,000	436,000	79,672		
TETRACYCLINE	6505-00-655-8355	1,212,205	1,212,205			
PATIENT WRAPS	6530-01-383-6260	0	0			
OTHER TREATMENTS						
CIPROFLOXACIN	6505-01-273-8650		0			
	6505-01-333-4154	100,472	100,472			
DOXYCYCLINE CAPS, 100s	6505-00-009-5060		0			
500s	6505-00-009-5063		0			

* Allowance is included in JSLIST total, which is the allowance for all protective suits

Table F-4a. Marine Corps Logistics Readiness Data - Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	FY03	FY04	FY05	FY06	FY07
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, A/P22P2	NOT ASSIGNED			0	0	0	0	0	0	0
MASK, CB, M40/M40A1	4240-01-258-0061-63	227,069	150,000	208,346	6,184	9,222	4,611	0	0	0
MASK, CB, M17A2	4240-01-143-2017-20	0	0	2,522	0	0	0	0	0	0
MASK, M24, AVIATOR	4240-00-776-4384	0	0	123	0	0	0	0	0	0
MASK, M25A1, TANK	4240-00-994-8750-52	0	0	0	0	0	0	0	0	0
MASK, M42, TANK	4240-01-258-0064-66	0	0	3,142	0	0	0	0	0	0
MASK, MCU-2/P, -2A/P	4240-01-284-3615-17	0	0	302	0	0	0	0	0	0
MISC PROTECTION										
MASK COMM ADAPTOR	5996-01-381-9012	50,000	50,000	16,517	0	0	0	0	0	0
PATS, M41	4240-01-365-8241	469	469	430	0	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
NUCLEAR DETECTION EQUIPMENT										
AN/PDR-75	6665-01-211-4217	1,203	1,203	1,156		0	0	0	0	0
AN/VDR-2	6665-01-222-1425	1,182	1,182	2,275	67	0	0	0	0	0
CHEMICAL DETECTION EQUIPMENT										
ACADA, M22	6665-01-438-6963	762	762	728	0	0	0	0	0	0
ALARM, CAA, M8A1	6665-01-105-5623	28	28	22	0	0	0	0	0	0
CAM 1.5	6665-01-359-9006	1,854	1,565	278	0	0	0	0	0	0
CAM 2.0	6665-99-725-9996	1,528	875	2,469	0	0	0	0	0	0
M21 RSCAAL	6665-01-382-1968	151	151	131	0	0	0	0	0	0
NBC RECON SYS, M93	6665-01-372-1303	10	10	10	0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA										
DECON APPAR, M11	4230-00-720-1618	21,050	7,235	46,728	0	0	0	0	0	0
DECON APPAR, M13	4230-01-133-4124	16,913	16,913	7,506	0	0	0	0	0	0
DECON APPAR, PDDA, M12A1	4230-00-926-9488	0	0	0	0	0	0	0	0	0
L/WT DEC SYS, M17A1	4230-01-303-5225	344	0	366	0	0	0	0	0	0
HEAVY FUEL DECON	4230-01-470-5288			17						
L/WT DEC SYS, M17A3	4230-01-346-3122	1,570	1,570	660	0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
** SHELTER, CP, PORTABLE	4240-01-346-2564			16	0	0	0	0	0	0
MEDICAL COMMODITY AREA										
LITTER, DECONTAMINABLE	6530-01-380-7309	0	0	0	0	0	0	0	0	0

* 40% of CAMs remain unserviceable, but refurbishment action should be completed during FY02

** - Note: The Marine Corps is using the Portable Collective Protection System for training purposes.

Table F-4b. Marine Corps Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	PROJECTED DUE IN FY03
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
JSLIST (ABDO) 45 DAYS	SEE NSNs IN TABLE E-5	853,176	687,606	28,754	35,136	35,145
SUIT, CP CAMO (BDO)	8415-01-137-1700-07	0	0	1,405	0	0
SUIT, CP, SARATOGA	8415-01-333-7573-76	596,131	596,131	519,111	0	0
SUIT, CP SARATOGA-DESERT	8415-01-333-7577-80	50,000	50,000	16,164	0	0
OVERBOOTS/GLOVES						
JLIST MULO	8430-01-464-9453-84					
BLK/GRN VINYL O/BOOTS BVO	8430-01-317-3374-85		0	224,297		
GVO	8430-01-049-0878-87	654,000	651,146	24,144	0	0
CP FOOT COVERS	8430-01-021-5978		0	175,971	0	0
CP GLOVES 25 MIL	8415-01-033-3517-28	792,154	792,154	430,136	0	0
MISC PROTECTION						
2D SKIN, M40 SERIES	4240-01-413-1540-43	277,069	183,684	257,055	0	0
CP HELMET COVER	8415-01-111-9028	0	0	0	0	0
FILTER CAN, C2/C2A1	4240-01-119-2315		0	271,134		
	4240-01-361-1319	554,246	359,930	38,256	0	0
FILER CAN, M10A1	4240-00-127-7186	2,468	0	26	0	0
FILTER ELEMENT, M13A2	4240-00-165-5026	27,766	0	40,557	0	0
HOOD, M40	4240-01-376-3152	343,869	343,869	2,799	0	0
HOOD, M5 FOR M25A1	4240-00-860-8987	867	0	0	0	0
HOOD, M6A2 FOR M17	4240-00-999-0420	25,973	0	2,348	0	0
HOOD, M7 (FOR M24)	4240-01-021-8695	323	0	0	0	0
HOOD, MCU-2/P	4240-01-189-9423		0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
BATTERY, BA-3517	6135-00-450-3528		0	0	0	0
BATTERY, ICAM BA-5800	6665-99-760-9742	27,136	27,136	35	0	0
BATTERY, ACADA BA-5590	6135-01-036-3495	20,706	20,706	855	0	0
DET KIT, M256A1	6665-01-133-4964	30,547	30,547	4,996	0	0
DET PAPER, M8	6665-00-050-8529	272,770	272,770	36,398	0	0
DET PAPER, M9	6665-01-049-8982		0	6,629		
	6665-01-226-5589	380,949	380,949	56,079	0	0
MAINT KITS, M273/M293	5180-01-379-6409		0	0	0	0
NBC MARK SET, M274	9905-12-346-4716	2,286	2,262	28	0	0
WATER TEST KIT, M272A1	6665-01-134-0885	3,159	1,115	375	0	0
DECONTAMINATION COMMODITY AREA						
DECON KIT, M291	6850-01-276-1905	408,220	33,067	116,635	0	0
DECON KIT, M295	6850-01-357-8456	29,244	29,244	0	0	0
DS2, 1 1/3 QT	6850-00-753-4827	1,006,813	1,006,813	9,503	0	0
DS2, 5 GAL	6850-00-753-4870	253,837	2,919	7,376	0	0
DS2, M13 CAN	6850-01-136-8888	32,451	0	0	0	0
NITROGEN CYLINDERS	4230-00-775-7541	27,993	27,993	12,296	0	0
STB, 50 LB	6850-00-297-6653	7,410	1,264	4,397	0	0

Table F-4b. Marine Corps Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	PROJECTED DUE IN FY03
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP, M12A2 (M14 GPFU)	4240-01-365-0981	1,108	1,108	0	0	0
FILTER, CP, M13 SERIES (M14 GPFU)	4240-00-368-6291	1,122	1,122	166	0	0
FILTER, CP, M18A1	4240-01-365-0982	3,236	3,236	2	0	0
FILTER, CP, M19	4240-00-866-1825	1,674	1,674	233	0	0
FILTER, GP, M48A1	4240-01-363-1311	644	644	50	0	0
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533		0	0	0	0
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	500,505	500,505	104,605		
ATROPINE AUTOINJ	6505-00-926-9083	500,505	500,505	29,440		
	6505-00-299-9673			493		
CANA AUTOINJ	6505-01-274-0951	142,481	142,481	0		
NAAK, MKI	6705-01-174-9919	405,446	405,446	0		
PYRIDOSTIGIMINE TAB	6505-01-178-7903	289,075	289,075	1,308,767		
OTHER TREATMENTS						
DOXYCYCLINE CAPS, 500s	6505-00-009-5063			14		

Table F-5. Defense Logistics Agency Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	PROJECTED DUE IN FY03
INDIVIDUAL PROTECTION COMMODITY AREA				
OVERGARMENTS				
CAPE, AIRCREWMAN	8415-01-040-9018	0	60,000	44,000
CP UNDERCOVERALL	8415-01-040-3141	0	54,000	20,000
CHEM PROT UNDERGARMENT TOP	8415-01-363-8692-00	0		
CPU DRAWERS	8415-01-363-8683-91	5,645	24,000	8,000
EOD M-3 TAP	8415-00-099-6962/68/70			
	8415-01-105-2535	317	634	311
EOD TAP BOOTCOVER	8430-00-820-6295-6306	312	634	311
EOD TAP GLOVES	8415-00-753-6550-54	101	634	311
IMPREG UNDERGARMENT	8415-00-782-3243	93	634	311
JSLIST SUITS *				
Wood - Coat	8415-01-444-1163/1169/1200/38/49/65/70	22,598	519,082	233,250
Wood Trousers	8415-01-444-1435/39/1613-/2308/10/25/38	19,220	519,082	233,250
Desert Coat	8415-01-444-5902/05/13/26/6116/31/38	377	202,110	77,500
Desert Trousers	8415-01-444-5417/5504/06/5892/93/98/5900	384	202,110	77,500
SCALP (TAN AND GREEN)	8415-01-333-0987	0	0	0
	8415-01-364-3320	0	0	0
SUIT, AIRCREW, CWU-66/77P	8475-01-328-3454(S)	22,600	15,000	15,000
SUIT, CP CAMO (BDO)	8415-01-137-1700-07	0	0	0
SUIT, CP CAMO-DESERT - 3 color	8415-00-327-5347-53	0	0	0
SUIT, CP CAMO-DESERT - 6 color	8415-01-324-3084-91	0	0	0
SUIT, CP, OG MK3	8415-00-214-8289-92	0	0	0
SUIT, CP, SARATOGA	8415-01-333-7573-76	0	0	0
OVERBOOTS/GLOVES				
JLIST MULO	8430-01-464-9453-84	0	0	0
BLK/GRN VINYL O/BOOTS	8430-01-317-3374-85	0	0	0
CPO FOOT COVERS	8430-01-021-5978	0	0	0
CP GLOVES 7 MIL	8415-01-138-2501-04	53,634	95,000	90,000
CP GLOVES 14 MIL	8415-01-138-2497-00	220,397	635,000	571,000
CP GLOVES 25 MIL	8415-01-033-3517-20	101,466	1,237,000	1,235,500
CP SOCKS	8415-01-040-3169	0	0	0
DISP FOOTWEAR COVER	8430-00-580-1205-06	0	0	0
MISC PROTECTION				
HOOD, MCU-2A/P	4240-01-189-9423	0	0	0
CP HELMET COVER	8415-01-111-9028	238	396,000	365,750
CONTAMINATION AVOIDANCE COMMODITY AREA				
CHEMICAL DETECTION EQUIPMENT				
BATTERY, BA3517	6135-00-450-3528	3,769	144	
MAINT KITS, M273/M293	5180-01-108-1729			
	5180-01-379-6409			
TUBE, DET, PHOSGENE GAS	6665-01-010-7965	9	64	
DECONTAMINATION COMMODITY AREA				

Table F-5. Defense Logistics Agency Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	FY01 STOCKS ON HAND	PROJECTED DUE IN FY02	PROJECTED DUE IN FY03
CALCIUM HYPOCHLORITE (6 oz)	6810-00-255-0471	33,679	30,374	
CALCIUM HYPOCHLORITE (100 lb)	6810-12-132-2439			
DRY SORBENT POWDER	6850-01-262-0484	30	0	
STB, 50 LB	6850-00-297-6653	0	1,200	
COLLECTIVE PROTECTION COMMODITY AREA				
PRE-FILTER, SHIPBOARD CPE	4240-01-348-8785	0	0	0
MEDICAL COMMODITY AREA				
2-PAM CHLORIDE, AUTOINJ	6505-01-125-3248	88,298	0	0
ATROPINE AUTOINJ	6505-00-926-9083	3,220,000	0	0
CANA AUTOINJ	6505-01-274-0951	2,107,000	60,000	0
NAAK, MKI	6705-01-174-9919	2,914,000	0	0
PYRIDOSTIGIMINE TABLETS	6505-01-178-7903	113,806	0	0
LITTER, DECONTAMINABLE	6530-01-380-7309	8,868	0	0
ATROPINE SULFATE AEROSOL	6545-01-332-1281	0	0	0
OTHER TREATMENTS				
CIPROFLOXACIN, 500 MG	6505-01-272-2385	0	0	0
	6505-01-274-0951	0	0	0
	6505-01-333-4154	23,000	0	0
DOXYCYCLINE CAPS	6505-01-153-4335	0	0	0
100's	6505-00-009-5060	12	0	0
500's	6505-00-009-5063	0	300	0
ANTIDOTE TREAT KIT, CYANIDE	6505-01-143-4641	0	0	0
	6505-01-457-8901	0	0	0

* DLA purchases JSLIST suits for the Services. These suits are allocated to the Services in the following manner: 50% to the Army, 20% each to the Air Force and Navy, and 10% to the Marine Corps. However, this allocation of suits to the Services has been suspended pending a review of the requirements.

F.2 FIELDED NBC DEFENSE ITEMS - ISSUES AND CONCERNS

NBC defense items are generally used in combination to form a system or subsystem for a particular function. Therefore, this report will address items used as a system. These systems are categorized into five functional areas: (1) Contamination Avoidance, (2) Individual Protection, (3) Collective Protection, (4) Decontamination, and (5) Medical.

F.2.1 CONTAMINATION AVOIDANCE

Contamination avoidance programs generally include equipment that is used to conduct NBC agent reconnaissance, detection, and identification. This area represents approximately half of the annual DoD NBC defense RDT&E budget. Due to recent type-classification of several programs that are intended to modernize contamination avoidance programs, this area has an unusually high number of developmental programs, as compared to other commodity areas. Many programs will complete their fielding beyond FY05. Thus several systems appear in the moderate and high risk categories, but their risk will improve with continued procurement in coming years.

Current numbers of biological detection devices, to include the Biological Integrated Detection System (BIDS), Interim Biological Agent Detector (IBAD), and Joint Portal Shield are insufficient as measured against the MTW requirements. Automatic biological agent point detectors and stand-off detectors are currently in development, and will not be deployed in significant numbers prior to FY02. The USAF is fielding an off-the-shelf capability called the Ruggedized Advanced Pathogen Identification Device (RAPID). RAPID is a medical tool used for clinical identification of pathogenic agents within 25 minutes. It is capable of processing up to 32 samples simultaneously. Also, the USAF has limited quantities of the Joint Portal Shield biological networked Sensor Systems. Until fielding of the Joint Biological Point Detection System, Marine Corps will not have that capability either.

The combined total of chemical agent detection systems remains at moderate risk, but will improve slowly as the M22 Automatic Chemical Agent/Detector (ACADA) supplements the M8A1 Automatic Chemical Agent Alarm. An Army initiative to inspect and repair M8A1 alarms at Anniston Army Depot has resulted in the quick assessment and return of 1,600 units to the field. Another 1,500 alarms were coded as requiring depot maintenance and are undergoing repairs. As a result of this program, the Army has no shortage of alarms for training purposes and there is no longer an acquisition gap between the combined acquisition of M8A1 and M22 alarms.

Although the combined number of CAM/ICAMs reported by the Services places them in the high risk category, the actual number available for use by the Marine Corps is currently much lower but will improve in the near term. Collectively, 60% of the Marine Corps inventory of CAM 1.5 and CAM 2.0 have been refurbished and are currently being shipped to Marine Corps users. Funding for the remaining CAMs has been received and refurbishment action should be completed during FY02.

The M21 Remote Sensing Chemical Agent Alarm (RSCAAL) is at low risk with present quantities exceeding the two MTW requirement. The M93A1 NBCRS is currently fielded at less than half of its projected requirements. This system adds improved mass spectrometer sampling system along with stand-off chemical vapor detection. Several units continue to

use trained reconnaissance personnel in HMMWVs and APCs, thus moderating this risk as continued fielding and developmental systems enter the inventory. Also, the M93 NBC Recon System completes the fill in the interim when added to the on-hand quantity of M93A1 systems.

Traditional consumables in this commodity area (M8 and M9 detection paper, M256A1 kits and M272A1 water test kits) are available in sufficient quantities to meet wartime requirements. Some shortages exist in individual Services, but overall there is little risk. Shelf life concerns may change this projection; this area remains under review.

The Army and Air Force radiac programs are expected to just meet the two MTW scenario average requirements. The Army National Guard still has a large number of obsolete radiacs. These will be replaced in the near future by the AN/VDR-2 which is available in sufficient quantities through the depot system. The Navy has small quantities of older radiacs still in the inventory, which will be replaced through a modernization program currently underway. The Marine Corps has most of the required AN/VDR-2s and about three-quarters of its AN/PDR-75s as compared to the MTW requirements, putting it in a moderate risk category. While Army stores or industry could compensate for this shortfall, it represents a potential risk, especially at the onset of any contingency.

F.2.2 INDIVIDUAL PROTECTION

Currently fielded protective suits and masks are designed to protect against all known CB threat agents. Past Service-unique requirements led to Service-specific procurements and some duplication in capability resulting in the procurement of six different chemical protective suits and six different masks. This has caused difficulties in meeting current needs and exacerbated logistics planning. Fielding of the M40/42 protective masks, JSLIST protective suits and the MULO boot has begun to resolve many of these former challenges.

F.2.2.1 Protective Ensembles

The Services are continuing acquisition of the Joint Services Lightweight Integrated Suit Technology (JSLIST) suits as a replacement for the BDO and other chemical protective suits. As such, the protective suits should be viewed as a system with the older suits providing readiness stocks until the end of their service life. The initial JSLIST contracts did not include surge option clauses. Defense Supply Center Philadelphia (DSCP), whose solicitations include the surge option as a requirement, took management of JSLIST in FY98. By examining the year-by-year status of protective suits, a number of older suits still within service life were added to the number of JSLIST suits purchased by that year and matched the total against the requirements. In FY01, the total Services' inventory of protective suits are at high risk of not meeting projected average two MTW requirements. Additionally, available inventory will continue to drop as the service life of older protective suits, such as BDOs, expires in large quantities. Near term buys will moderate that risk, however. Also, DLA is taking steps to identify alternative sources for JSLIST suits which will add to the overall production capacity.

The Battle Dress Overgarment (BDO) is reaching its maximum extended shelf life limit (14 years), and the Services have no plans for new production. There are no companies currently manufacturing the BDO. The Army and Air Force have sufficient suits on hand in war reserves to sustain its requirements for the near term. The Saratoga suit, purchased by DSCP for the

Marine Corps, is also out of production, but current stocks will sustain the Marine Corps until the JSLIST is available in adequate numbers. The Navy is relying on existing stocks of their Mark III chemical protective suit (also out of production) as stocks of JSLIST are being procured.

Armor crews and aircrews require special protective ensembles to integrate with their weapon systems. Services have sufficient numbers of aircrew suits to meet requirements, given the smaller total requirements for aircrews (relative to ground troops). An exception is the Chemical Protective Undercoverall, which is now obsolete. It is replaced by the CWU-66/77 which remains low in inventory resulting in a moderate risk rating. To protect armor crewmen when they exit their vehicles, the Services have developed the Suit Contamination Avoidance Liquid Protection (SCALP), which is available in sufficient quantities to meet MTW requirements.

The Services have adequate stocks of 7 and 25-mil chemical protective gloves on-hand for contingency use. Currently, DLA and the Marine Corps do not have adequate stocks of 14 mil chemical protective gloves on-hand for contingency use. DLA currently has an emergency buy for 14 mil gloves with a February 2002 estimated delivery date. An additional buy will be made shortly thereafter and at that time DLA will have adequate stock on hand. Recent DoD surveillance tests have validated the protective qualities of the existing butyl rubber glove stocks. The status of the Services on-hand inventories has allowed DLA to pursue an Industrial Base Maintenance Contract (IBMC) with both current manufacturers (Siebe North, Inc., Charleston, SC, and Guardian Corp., Willard, Ohio) to sustain the industrial base with "War Stopper" funding. The IBMC is to maintain the equipment only.

Chemical Protective Footwear Covers, also known as the "fishtail" boot, have been out of production for several years. Their shortages are supplemented by the Black/Green Vinyl Overboot (BVO/GVO), which is the interim chemical protective footwear until the JSLIST MULO boots have been fielded. Because the GVO's primary purpose is not chemical protection, current contracts do not include surge option clauses. Again, one should view protective footwear as a system with older GVOs providing readiness stocks until the MULO is fielded in sufficient quantities. Currently, the total DoD inventory shows adequate quantities of protective footwear, resulting in low risk assessment. The USMC is the only service reporting a shortage of footwear, but DLA can fill their shortfall.

F.2.2.2 Eye/Respiratory Protection

The Services continue modernizing their chemical protective mask inventories. Different versions of the protective mask were developed to meet the requirements of different military occupational specialties (*e.g.*, air crew, tank crew, *etc.*). For the Army and Marine Corps, the M40 (for generic use) and M42 (for armor crew members) series masks are replacing the M17 and M25-series masks, respectively. Some Army aviation units are still equipped with the old M24 mask, which will be replaced by the M45 mask. The M43-series mask, designed to be used by Apache equipped units, was in fact issued to all types of aviation units. It is being replaced by the M48 (Apache) series mask. The M45 will replace the M49 as the general aviation mask. This modernization effort is still ongoing; not all units have replaced their M43-series masks. All of these masks are at low risk, as the combined numbers of all aviator masks on hand exceeds the requirement. These newer masks provide increased protection, improved fit and comfort, and compatibility with most Services' weapons systems' optics and sights.

The Marine corps is performing a product improvement program (PIP) to modify the existing M40/M42 series mask. The PIP will be completed in Fiscal Year 2004. PIP actions include installation of a new nose cup, polycarbonate eye lenses, drink tube coupling, and drink tube quick disconnect: banding of the outlet valve housing: and laser etching serial numbers on the mask. The new components and banding procedure will improve the mask's durability and protective capability requirements established by the Marine Corps and eliminate inadvertent damage to the mask by the unit (*i.e.*, painting a number on the head harness, engraving in the eyelens-retaining ring). The cost to perform the PIP is estimated at $12M with the Marine Corps saving approximately $10M by performing the rebuild vice buying new modified masks.

The MCU-2A/P mask is designed to meet the needs of the Air Force ground crews, Navy shipboard and shore-based support missions, and Marine Corps rotary wing forces. The number of these masks on hand generally exceeds the requirement. The USAF has some shortages in masks and does not have second skins to provide complete personal protection. It will continue to be the mainstay of these units until the Joint Service General Purpose Mask is fielded, which will also replace the M40/42 masks. The Aircrew Eye/Respiratory Protection (AERP) mask is specially designed to enable pilots of high performance aircraft to conduct missions in a contaminated environment. Quantities of this mask are currently below the MTW requirement, making this a moderate risk.

In order to provide complete protection to our forces on the contaminated battlefield, particularly from liquid chemical agents, protective hoods and helmet covers are required as part of the individual protective ensemble. The protective hood for the M40 is rated as low risk. It is being replaced by the second skin for the M40 series mask, which is a high risk program with only 65 percent of requirements on hand in FY02. The MCU-2P hood is at low risk with an abundant inventory. Protective hoods for the M17-series, M24, and M25A1 masks are also in good supply, and thus are not a readiness issue. These masks are leaving the inventory, however. The Chemical Protective Helmet Cover is also available in sufficient quantities.

Filters and canisters provide the active ingredients that absorb the chemical and biological agents and provide the essential protection required. The C2/C2A1 canister is used with the M40, M42, M43, M45, M48, and MCU-2/P masks. The number on hand falls short of the MTW requirements as a moderate risk. The M13A2 filter element exceeds requirements, but will be leaving the inventory with the retirement of the M17-series mask. The M10A1 filter canister used on the M24/25 is short of the requirement, but these masks will also leave the inventory and will not be a readiness problem.

F.2.3 COLLECTIVE PROTECTION

There are two general categories of collective protection: stand-alone shelters and integrated systems. Integrated collective protection equipment is component equipment designed to provide protection against CB agents through the use of filtered air under positive pressure to a variety of facilities, vans, vehicles, aircraft and ships. Filters for these integrated collective protection systems (CPS) are in short supply due to low peacetime demand and low production quantities. The increased emphasis on procuring individual protection and contamination avoidance equipment has resulted in a corresponding decrease in procurements of shelters and large collective protection filters.

The Air Force has expressed interest in a greater collective protective shelter capability. The Air Force fielded through FY 00 the Pacific Air Force Interim Transportable Collective Protection System (PITCOPS). PITCOPS is an above ground NBC shelter that provides NBC filtration integrated with an environmental control unit and auxiliary power unit. Beginning in FY 05 the Air Force plans to field the Joint Transportable Collective Protection System (JTCOPS). Combined with the Navy's increasing shipboard collective protection filter requirements and the Army and Marine Corps traditional integrated vehicular systems and tactical shelter requirements, the near-term MTW requirements for large carbon-based filters have outpaced current inventories even aided by industrial surge capability. As a result, much of this sector is assessed as high risk, though the risk is primarily due to the level of funding rather than technical shortfalls. Most of the filter manufacturers retain the industrial capability to produce them.

In the near term, the M51 shelter is replaced by the new Chemical and Biological Protective Shelter (CBPS). All Army M51 shelters have been coded as unserviceable. The CBPS is presently in limited production with only limited fielding during 3QFY02. Both Army and Air Force field hospitals are being integrated with environmentally controlled collective protection. The Army's Chemically Protected Deployable Medical Systems (CP DEPMEDS) and the Air Force's Chemically Hardened Air Transportable Hospital (CHATH) achieve collective protection through the integration of the M28 Simplified CPE, chemically protected air conditioner, heaters, water distribution and latrine and alarm systems. The M28 Simplified CPE is in production and chemically protected heaters and air conditioners initiated production in FY99. Procurement and production of CP DEPMEDS components has initiated. All components will be assembled into CP DEPMEDS sets at depot. The FY02-07 POM fully supports the production of 14 of the required 17 CP DEPMEDS. In FY00, production initiated for remaining M28 CPE, CB protected water distribution and latrine systems, CB ISO Shelter Seals and Low Pressure Alarms.

The M20-series Simplified CPEs are used to provide a contamination-free, environmentally controlled work space for Echelon I and II forward area medical treatment facilities. Current funding levels, however, only will meet Force Package I requirements. There are some Force Package II units designated for deployments into high threat regions that will not be equipped with M20 shelters. This leads to an assessment as high risk. Current policy is that the M20/M20A1 Simplified CPE is a free issue item with no requirement to stock other than spares replenishment. The Marine Corps has Portable Collective Protection Shelters (PCPS) but does not plan to field them. The Marine Corps is instead using them for training purposes. The M20A1 SCPE is by default the only modern collective protection stand-alone shelter outside of the medical community in the inventory.

The Services have continued to improve integrated collective protection systems in armored vehicles and vans. All modern armored vehicles and armored vehicles in development have either filtered air systems, hybrid collective protection or full collective protection systems designed into their chaises. Notable progress has been made in providing shipboard collective protection. By the year 2000, most Naval ships that have close-in support roles (including amphibious ships, gunfire support combatants, and new logistics support ships) will contain significant CPS capabilities.

Collective protection filters for integrated systems (such as armored vehicles, ships and planes) continue to suffer from low stocks. While the Services have been proactive in selecting more capable industrial sources, actual procurement and storage of these filters to MTW

requirements has not been initiated for all filters. As a result, stocks of some filters remain at a low level. However, the filters associated with the 200 CFM Particulate Filter Set for Shipboard Collective Protection Systems are being procured in sufficient quantities. Continued difficulties in obtaining a strong industrial base in this field compounds the issue of fielding and sustaining these items.

F.2.4 DECONTAMINATION

Current decontaminants are highly effective against all CB agents, but most present environmental hazards and are manpower intensive. The services are attempting to find environmentally safe decontaminants that are less labor intensive.

Basic soldier skills for decontamination of vehicle and crew-served weapons rely on the M11 Decontamination Apparatus, Portable (DAP) and M13 DAP. While the M11 is assessed as posing low risk, there are insufficient quantities of the M13 DAP as measured against the MTW requirements. The 1-1/3 quart M11 can be used in place of the 14-liter M13 DAP, but they do not fulfill the same exact capability (in part due to the volume of DS-2).

The M17-series Lightweight Decontamination System (LDS) is used to provide operational equipment decontamination in many battalion-level units and dual-purpose (smoke/decontamination) chemical companies. The Air Force employs the M17 at the squadron level for operational equipment decontamination. The M17 is assessed as a moderate risk, due in part to a delay in rebuilding several hundred systems caused by a lack of funding since 1990. There is still a large mix of different models in the inventory, forcing the Services to retain a large number of differing spare parts to maintain the different models. Based on projected inventory, should spare parts become difficult to obtain for the different models, the risk may become high. Overall, this risk should drop as more systems are produced and the older models are upgraded or replaced. The Marine Corps is upgrading all of their LDS to the diesel engine. The Air Force is deleting stocks of A/E32-U systems by attrition, modifying existing M17s to M17A2s, and procuring additional M17A3s to satisfy shortages.

In the Army, the M12A1 Power-Driven Decontamination Apparatus (PDDA) and the M17A3 LDS are the primary pieces of equipment used to decontaminate vehicles, crew-served equipment and large areas of terrain. The M12A1 is assessed as low risk. Although there are sufficient quantities on-hand of the M12A1, the maintenance requirements, due to the age of this item, limit its full utilization and may increase its risk. The M21/M22 Modular Decontamination System will displace 200 M12A1 PDDAs over the POM period, resulting in a high-low mix of technology. By FY02, the on-hand quantities of the M21/M22 MDS alone should satisfy the two MTW requirement. Additionally, the Marine Corps is replacing their M12A1 PDDAs with the M17-series LDS.

The Army and Marine Corps plans for stocking containers of DS-2 (5-GAL and M13 Can) are below the MTW requirements expected for decontamination operations. The situation is compounded by a decreasing availability of DS-2. Bulk DS-2 stored at Seneca Army Depot underwent lot testing to ascertain how much has deteriorated and is unusable. As a result, stocks of DS-2 are being released for contingency use only. While less hazardous replacement decontaminants, such as sorbent decon are being developed, the quantities and packaging of current decontaminants present potential risk. The projected stockage of STB meets average MTW requirements, but has been considered a high-risk category in the past. Slight shortages

in calcium hypochlorite and sodium hypochlorite can be made up by the industrial base, using commercially available alternatives. These increased requirements come as a result of increased attention to the need for decontamination capabilities in the 2 MTW scenario, and will be further refined. Continued monitoring is recommended.

The shelf life of the M258A1 Skin Decontamination Kit expired on 30 July 1999. Its replacement, the M291 Skin Decontaminating Kit, became the primary item used in personnel decontamination. Although M258A1 stocks are no longer available to supplement inventory of the M291, the risk assessment is low. Projected buys are expected to meet the 2 MTW requirements, but may need to be augmented to meet the total service requirements. Rohm & Haas, Co., the sole supplier of the resin, sold the mixing and packaging equipment they used to manufacture the M291 Decontaminating Kit. Pine Bluff Arsenal, Arkansas, set up a production line and began to manufacture the M291 Decontaminating Kit in October 1996. Rohm & Haas continues to provide some of the XE-555 resin components. Quantities of the proprietary resin component are being purchased by the item manager and provided to Pine Bluff for production of additional M291 Kits. Alternatives to producing a kit that does not use the XE-555 resin are being studied, including novel sorbent decontaminants.

The projected stockage of the M295 Individual Equipment Decontamination Kit puts it in a low risk category when compared with 2 MTW requirements. The M295 Decontamination Kit uses the same resin mix as the M291 Decontaminating Kit, and began delivery in December 1997. True Tech Inc. has been producing this item. Increased funding for its procurement would maintain the low risk.

F.2.5 MEDICAL

Medical NBC defense items are used to counteract the effects of exposure to chemical, biological, or nuclear agents through pre-treatment, vaccines, or post-treatment. Current projections for medical chemical defense material indicates that sufficient quantities should be on hand through the POM years and present overall low risk. Quantities of Nerve Agent Antidote Kits (NAAK), and Atropine and 2-PAM Chloride Autoinjectors now support two MTW requirements. Convulsant Antidote Nerve Agent (CANA), and Nerve Agent Pyridostigmine Pretreatment (NAPP) Tablets (also known as PB Tablets) are now at low risk because of continued purchases. This report includes medical treatments for biological warfare agents and cyanide exposure along with the addition of new chemical treatments.

NAPP is still an Investigational New Drug (IND) for the use as a nerve agent pre-treatment. The U.S. Army Medical Materiel Development Activity (USAMMDA) has continued to work with the FDA for approval. Defense Supply Center – Philadelphia (DSCP) is working with ICN Pharmaceuticals to establish a requirements contract for the manufacture of NAPP.

The sole supplier to DoD for NAAK, atropine autoinjectors, pralidoxime autoinjectors and CANA is Meridian Medical Technologies, St Louis, Missouri. The medical chemical defense production line is being maintained with an IBMC. Meridian is an U.S. company but it obtains its atropine for the autoinjectors from a German supplier. Currently there is no domestic source for this drug. Pralidoxime and diazepam (CANA) for the autoinjectors is available from U.S. sources. The replacement for NAAK is the Antidote Treatment, Nerve Agent, Autoinjector (ATNAA), which is a multi-chambered injector that will begin procurement in FY01.

Patient Chemical Wraps have not been procured since 1991 and are made of the BDO materiel. USAMMA and the AMEDDC&S are currently assessing several versions of the patient wrap before initiating new procurement of this item. All services are procuring the new decontaminable litter, but in limited quantities, for first line units. There is a very large stockpile of canvas litters that can be used once in an NBC environment and then destroyed. As the canvas litters are depleted, they will be replaced with the new nylon decontaminable litter.

The Office of the Surgeon General has centrally programmed and funded the Army's Medical Chemical Defense Materiel since 1994. USAMMA has procured, stored and maintained this materiel for the Army in strategic locations for early deployers and forward deployed forces as Division Ready Brigades (DRB) sets, which support 5,000 personnel each. The Marine Corps has consolidated its medical defense materiel into five centralized locations. The materiel is issued from one of the centralized locations whenever a Marine Corps element deploys, and is returned to the centralized program upon redeployment. The Air Force and Navy maintain their medical CB materiel in decentralized unit locations. Visibility of on-hand assets has been improved with the release of the Joint Medical Asset Repository, which is the Class VIII (medical) portion of JTAV.

Currently, the U.S. total force (active and reserve forces) is being vaccinated against anthrax, which is considered the primary high-threat BW agent. The anthrax vaccination program is a three-phase program, starting with the troops serving in—or identified to deploy to—the two high-threat areas where hostile anthrax-use poses the greatest potential danger. That status and schedule of the anthrax vaccination program is provided in Table 2-10 in Chapter 2 of this report.

JPO-BD continues to support the sole domestic supplier of anthrax vaccine to achieve FDA approval of their contract filler. In the area of medical therapeutics, the Department is maintaining a stockpile of antibiotics (*e.g.*, ciprofloxacin, doxycycline) sufficient to address the treatment needs of potential BW exposures, where such treatment is medically indicated.

The DoD/FDA Shelf Life Program was developed by OSD Health Affairs and the Military Medical Departments in response to Congressional concern over the conservation of military medical resources. The program's focus is to save replacement cost of date sensitive medical materiel especially medical materiel in War Reserve Stocks, Medical Biological Defense Materiel Programs and Medical Chemical Defense Materiel Programs. The Joint Readiness Clinical Advisory Board (JRCAB) manages the shelf-life extension program for the Services and interfaces with the FDA. The FDA requests samples from the JRCAB and the Services. The samples have an initial potency test performed, followed by a 90-day stress test, and then a final potency test. The potency results are compared against a degradation curve, and a new potency period is assigned. The FDA sends the information to the JRCAB and Services who disseminate instructions to extend and re-mark or destroy the materiel to activities and units worldwide. The same lots are subjected to yearly retest and subsequent extensions until the materiel fails or is removed for lack of sufficient on-hand quantities required for testing. The Army maintains its extended materiel at Meridian Medical Technologies for use by Force Package 3 and 4 units. The Air Force maintains its materiel at its local medical logistics activities that re-mark the materiel and maintains it for the deploying units. The Navy remarks the materiel and maintains it with the unit. The Marines remark the materiel at its centralized storage locations. It is currently looking at other alternatives, similar to the Army's, the replace pen and ink changes. The DoD/FDA Shelf Life Program has saved an average of $118.50 of

medical chemical defense materiel from having to be destroyed and repurchased for every $1.00 it has cost the Services to get materiel tested and extended by the FDA.

Annex G

DoD Joint Service Chemical and Biological Defense Program Funding Summary

In accordance with 50 USC 1522, *Department of Defense Chemical and Biological Defense Program*, research, development, test and evaluation (RDT&E) and procurement for all DoD chemical and biological (CB) defense programs (with the exception of those biological warfare defense RDT&E programs conducted by the Defense Advanced Research Projects Agency, DARPA) are consolidated into defense-wide program element (PE) funding lines. The detailed funding information in this annex is provided annually to Congress in the DoD Joint Service Chemical and Biological Defense Program, President's Budget Submission, Research, RDT&E, Defense-Wide and Procurement, Defense-Wide budget exhibits, and in the Department of Defense Extract found in the Budget of the United States. These budget submissions provide a detailed account of prior year accomplishments and planned activities for the budget request period. Table G-1 (and Figure G-1) provides a summary of appropriated and requested funding from FY 1996 – FY 2007. Detailed funding request for FY 2003-2007 are provided separately in the President's FY2003 Budget Submission. Fiscal year 1996 was the first year in which all Service and Defense Agency CB defense programs were consolidated into defense-wide funding lines. Prior to FY 1996, funding was included in several separate Service and Defense Agency funding lines. Also, during FY 1996 approximately $30 million was transferred to the CB Defense Program procurement line from the Army's operations and maintenance (O&M) accounts for bio-defense vaccine acquisition. Much of the growth in program funding between FY 1996 and FY 1997 resulted from the transfer of funds between existing accounts rather than real growth in the overall DoD CB Defense Program.

Table G-2 (and Figure G-2) provides a summary of expenditures by the DoD Chemical and Biological Defense Program. Expenditures represent the amount of checks issued or other payments made (including advances to others), net of refunds and reimbursements. The term is frequently used interchangeably with the term "outlays," which are the measure of government spending (*i.e.*, payments to liquidate obligations (other than the repayment of debt), net of refunds and offsetting collections.) It is important to note that funds appropriated for a given year may be expended incrementally over a period of years. Thus, expenditures shown in Table G-2 will be updated in following years to show total expenditures of appropriated funds.

Table G-1. Chemical and Biological Defense Program Appropriations Summary

Program Element (PE) ($ in millions)	FY96‡	FY97‡	FY98‡	FY99‡	FY00‡	FY01‡	FY02*	FY03**	FY04**	FY05**	FY06**	FY07**
0601384BP - Basic Research	25.492	28.372	25.255	26.526	44.041	26.369	39.061	64.115	35.454	37.542	38.538	42.192
0602384BP - Applied Research	68.271	70.823	69.522	82.351	47.436	95.172	123.481	266.177	65.342	94.494	92.528	91.171
0603384BP - Advanced Tech. Dev.	31.727	41.653	43.517	29.896	56.915	38.241	59.249	249.642	105.503	103.522	87.259	82.236
Science & Technology Base Subtotal	128.790	140.848	138.432	149.992	148.351	159.783	221.796	519.136	206.679	235.956	218.774	215.598
0603884BP - Demonstration/Validation	29.184	44.742	45.465	61.408	68.502	82.215	82.626	144.730	102.535	59.659	47.954	45.976
0604384BP - EMD	87.229	95.463	123.245	106.229	78.458	98.538	159.943	159.018	126.678	105.478	117.043	98.463
0605384BP - Management Support	6.954	17.936	21.137	23.069	24.253	27.226	51.275	42.955	36.523	34.495	39.523	42.555
0605502BP - Small Business Innovative Research (SBIR)	0.010	0.010	5.512	5.834	0.020	5.833	0.010	0.000	0.010	0.000	0.000	0.000
RDT&E Subtotal	252.157	301.059	337.671	348.293	409.164	404.700	509.561	936.905	473.387	435.518	423.330	408.118
0208384BP - Procurement) Subtotal	835.647	232.953	233.943	295.193	381.156	469.753	346.709	435.731	397.816	479.532	550.219	539.031
Military Construction (MILCON)												
CB Defense Program Total	287.804	533.991	571.614	640.486	731.020	874.453	856.179	1372.636	868.413	915.060	973.549	943.149

‡ Total Obligation Authority (TOA)
* FY02 President's Budget Request
** Estimated [From FY03 President's Budget]

Table G-2. Chemical and Biological Defense Programs Expenditures Summary

Program Element (PE) ($ in Millions)	FY96†	FY97†	FY98†	FY99†	FY00†	FY01†
RDT&E, Defense-Wide	241.096	366.429	239.879	168.227	322.286	287.413
Procurement, Defense-Wide	125.803	199.476	152.202	72.275	284.518	153.205
CB Defense Program Total	366.899	465.905	462.081	240.597	410.804	331.418

† Expenditures as of September 30 2001.

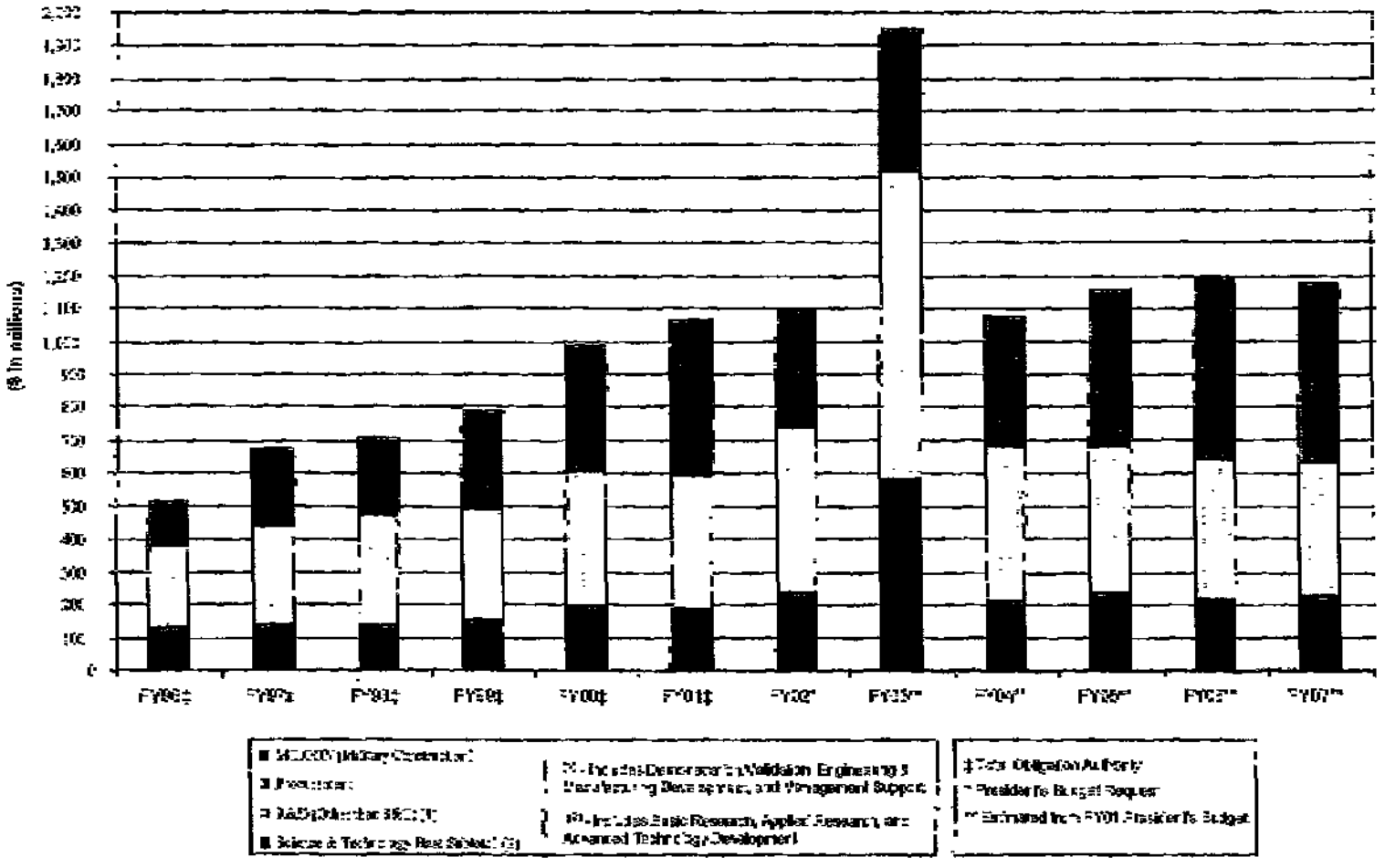

Figure G-1. Chemical and Biological Defense Program Appropriations Summary

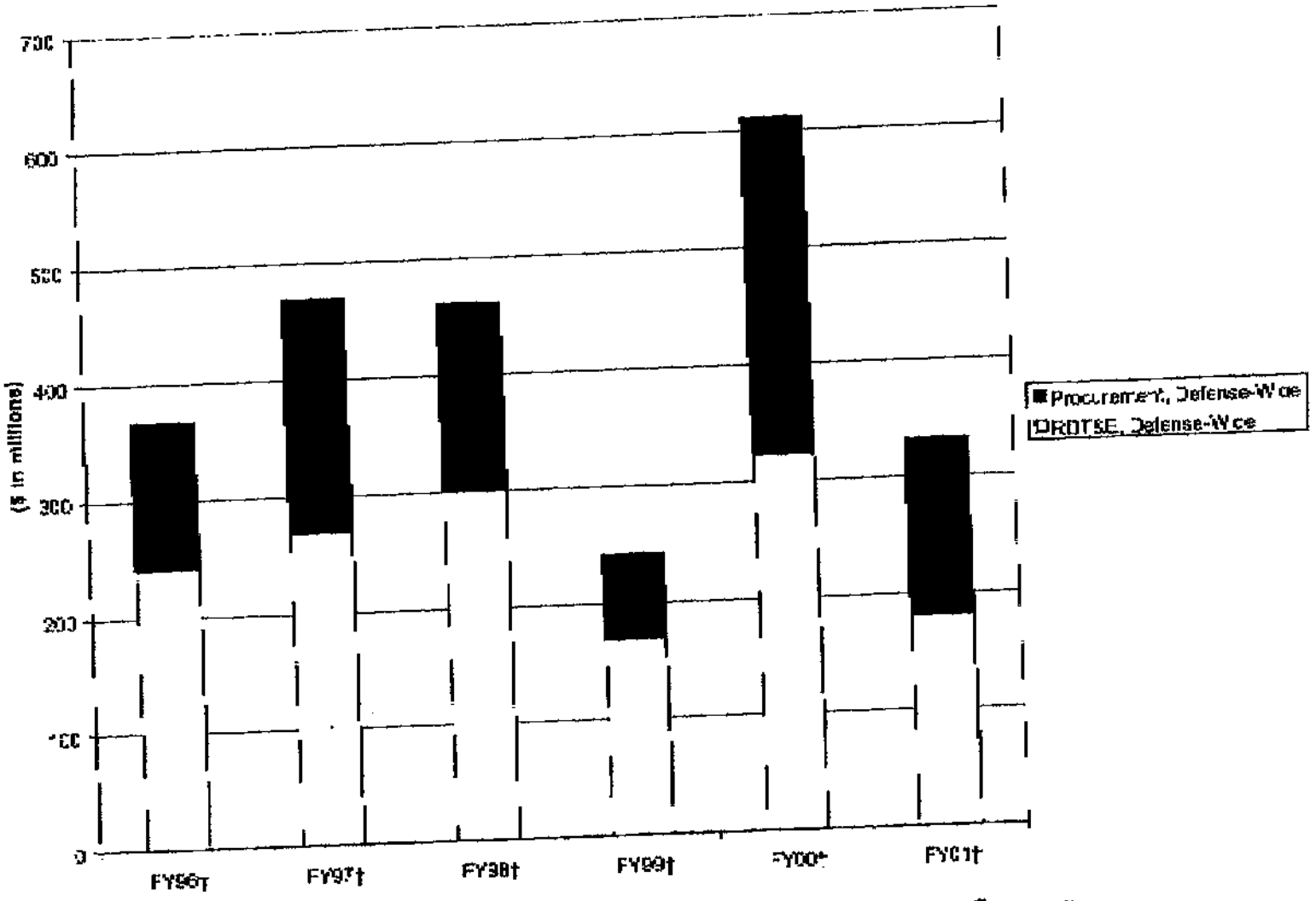

Figure G-2. Chemical and Biological Defense Program Expenditures Summary

Annex H

Statement Regarding Chemical and Biological Defense Programs Involving Human Subjects

The reporting requirement (50 USC 1523) for the annual report to Congress on the DoD Chemical and Biological Defense Program was modified by Section 1086 of the FY98 National Defense Authorization Act. The amendment requires the following information:

> A description of any program involving the testing of biological or chemical agents on human subjects that was carried out by the Department of Defense during the period covered by the report, together with a detailed justification for the testing, a detailed explanation of the purposes of the testing, the chemical or biological agents tested, and the Secretary's certification that informed consent to the testing was obtained from each human subject in advance of the testing on that subject.

Table H-1 provides a summary of prior and planned tests conducted by the Department of Defense, both directly or under contract, which involve the use of human subjects for the testing of chemical or biological agents. In summary, there has been no such testing since 1969 with biological agents, since 1975 for chemical agents, and no testing is planned.

Table H-1. Summary of Experiments and Studies with Human Subjects Involving the Use of Chemical or Biological Agents

November 25, 1969	–	Human biological agent testing ended
July 28, 1975	–	Human chemical agent testing ended
Since 1969/1975	–	No activities with human subjects involving exposure to biological agents nor chemical agents have occurred since testing ended

The Department is in full compliance with the requirements of all laws regarding the use of human subjects involving chemical or biological agents. DoD is involved in no experimentation or any other efforts which involve the exposure of human subjects to chemical or biological agents.

As part of the DoD Chemical and Biological Defense Program, DoD requires the use of small quantities of chemical and biological agents in the research, development, test and evaluation of detection, protection, and decontamination equipment and systems. Chemical and biological agents are also used in small quantities in training U.S. forces to operate in protective equipment and to operate detection and decontamination systems in a chemical or biological environment. However, no

research, development, test or evaluation involves the exposure of human subjects to chemical or biological agents.

Medical chemical and biological defense programs involve the use of human subjects in controlled clinical trials to test and evaluate the safety, immunogenicity, and other effects of medical products (drugs, vaccines, therapies, *etc.*) to protect against chemical and biological agents. The use of human subjects in these trials involves volunteers who have provided informed consent. All use of human subjects in these trials is in full compliance with the "Common Rule," Federal Policy for the Protection of Human Subjects, Food and Drug Administration (FDA) regulations, Federal Acquisition Regulations (FAR), DoD Directives and Instructions, and *all* other applicable laws, regulations, issuances, and requirements. The FDA has a proposed rule "New Drug and Biological Drug Products; Evidence needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Human Ethically Cannot be Conducted" October 5, 1999. No medical chemical or biological defense programs involving human subjects involves the exposure of these subjects to chemical or biological agents.

While DoD conducted tests involving the exposure of human subjects to chemical and biological agents in the past, all such tests and programs have been halted and disbanded. The United States formally renounced the "use of lethal biological agents and weapons, and all other methods of biological warfare" in National Security Decision 35, November 25, 1969. Human testing with lethal biological warfare agents was never done and testing with incapacitating biological warfare agents was ceased in 1969. The last human testing of chemical warfare agents occurred on July 25, 1975. Acting Secretary of Army Norman Augustine suspended testing of chemical compounds on human volunteers on July 28, 1975.

Tests involving the exposure of human subjects to chemical agents began in the 1940s and continued following World War II through the Cold War until the early 1970s. Such testing has been documented and reported to Congress. See for example, Department of Army, Inspector General Report, DAIG-IN 21-75, *Use of Volunteers in Chemical Agent Research*, March 1976. In addition, there was extensive congressional testimony on this subject during 1975 and 1976. DoD has not conducted any experimentation since that time involving the exposure of human subjects to chemical warfare agents.

Annex I

Congressional Reporting Requirement: 50 USC 1523

Text of Public Law Mandating Report on
The Department of Defense Chemical and Biological Defense Program

Title 50 of the U.S. Code, Sec. 1523. Annual report on chemical and biological warfare defense
Implemented by Public Law 103-160, The FY94 National Defense Authorization Act

(a) Report required

The Secretary of Defense shall include in the annual report of the Secretary under section 113(c) of title 10, a report on chemical and biological warfare defense. The report shall assess--

(1) the overall readiness of the Armed Forces to fight in a chemical-biological warfare environment and shall describe steps taken and planned to be taken to improve such readiness; and

(2) requirements for the chemical and biological warfare defense program, including requirements for training, detection, and protective equipment, for medical prophylaxis, and for treatment of casualties resulting from use of chemical or biological weapons.

(b) Matters to be included

The report shall include information on the following:

(1) The quantities, characteristics, and capabilities of fielded chemical and biological defense equipment to meet wartime and peacetime requirements for support of the Armed Forces, including individual protective items.

(2) The status of research and development programs, and acquisition programs, for required improvements in chemical and biological defense equipment and medical treatment, including an assessment of the ability of the Department of Defense and the industrial base to meet those requirements.

(3) Measures taken to ensure the integration of requirements for chemical and biological defense equipment and material among the Armed Forces.

(4) The status of nuclear, biological, and chemical (NBC) warfare defense training and readiness among the Armed Forces and measures being taken to include realistic nuclear, biological, and chemical warfare simulations in war games, battle simulations, and training exercises.

(5) Measures taken to improve overall management and coordination of the chemical and biological defense program.

(6) Problems encountered in the chemical and biological warfare defense program during the past year and recommended solutions to those problems for which additional resources or actions by the Congress are required.

(7) A description of the chemical warfare defense preparations that have been and are being undertaken by the Department of Defense to

address needs which may arise under article X of the Chemical Weapons Convention.

(8) A summary of other preparations undertaken by the Department of Defense and the On-Site Inspection Agency to prepare for and to assist in the implementation of the convention, including activities such as training for inspectors, preparation of defense installations for inspections under the convention using the Defense Treaty Inspection Readiness Program, provision of chemical weapons detection equipment, and assistance in the safe transportation, storage, and destruction of chemical weapons in other signatory nations to the convention.

(9) A description of any program involving the testing of biological or chemical agents on human subjects that was carried out by the Department of Defense during the period covered by the report, together with a detailed justification for the testing, a detailed explanation of the purposes of the testing, the chemical or biological agents tested, and the Secretary's certification that informed consent to the testing was obtained from each human subject in advance of the testing on that subject.

Annex J

Acronyms and Abbreviations

Note: The acronyms and abbreviations in this annex reflect an extensive, though not exhaustive, list of terms related to the various and diverse CB defense activities. The acronyms may have different meanings in other contexts.

–A–

AAAV – Advanced Amphibious Assault Vehicle
AAR – after action report
AARS – Advanced Airborne Radiac System
AB – Air Base
ABDU – Aviation Battle Dress Utilities
ABO – Agent of Biological Origin
AC – Active Component
ACAA – Automatic Chemical Agent Alarm
ACADA – Automatic Chemical Agent Detector
ACAT – Acquisition Category
ACC – Air Combat Command
ACES – Air Force Command Exercise System
Ach – acetylcholine
ACOM – Atlantic Command
ACPLA – agent containing particle per liter of air
ACPM – Aircrew Protective Mask
ACTD – Advanced Concept Technology Demonstration
ADS – Area Detection System
AERP – Aircrew Eye/Respiratory Protection
AFB – Air Force Base
AFI – Air Force Instruction
AFIP – Armed Forces Institute of Pathology
AFMAN – Air Force Manual
AFMS – Air Force Medical Service
AFRRI – Armed Forces Radiobiology Research Institute
AG – Australia Group
AICPS – Advanced Integrated Collective Protective System
AIDET – Aircraft Interior Detector
AIT – Aeromedical Isolation Team
ALAD – Automatic Liquid Agent Detector
ALSA – Air Land Sea Application
AMAD – Automatic Mustard Agent Detector
AMC – U.S. Army Materiel Command
AMEDDC&S – Army Medical Department Center and School
ANCOC – Advanced NCO Course
ANG – Air National Guard
AN/VDR-2 – Portable dose-rate gamma/beta radiation meter
AN/VDR-13 – Compact, digital whole body radiation meter
APC – Armored Personnel Carrier
APODS – Aerial Port of Debarkation
ARNG – Army National Guard
ARTEP – Army Training and Exercise Plan
ASA(ALT) – Assistant Secretary of the Army for Acquisition, Logistics & Technology
ASBREM – Armed Services Biomedical Research Evaluation and Management
ASCC – Air Standardization Coordinating Committee
ASD(HA) – Assistant Secretary of Defense for Health Affairs
ASD(S&TR) – Assistant Secretary of Defense for Strategy and Threat Reduction
ASD(SO/LIC) – Assistant Secretary of Defense for Special Operations and Low-Intensity Conflict
ATD – Advanced Technology Demonstration
AT/FP – Antiterrorism Force Protection
ATG – Afloat Training Group
ATH – Air Transportable Hospital
ATNA – Antidote Treatment Nerve Agent Autoinjector
ATP – Adenosine Triphosphate or Allied Tactical Publication
ATS – Automatic Transfer Switch
ATSD(NCB) – Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs
ATSO – Ability to Survive and Operate
aTSP – active Topical Skin Protectant
AVA – Anthrax Vaccine Adsorbed
AVIB – Aircrew Uniform Integrated Battlefield
AVIP – Anthrax Vaccine Immunization Program

–B–

B. anthracis – *Bacillus anthracis* (anthrax)
B. mallei– *Burkholderia mallei* (glanders)
BBS – Brigade Battle Simulation
BCTP – Battle Command Training Center
BD – biological detector (also, biological defense)
BDO – Battledress Overgarment
BDU – Battledress Uniform

BES – Budget Estimate Submission
BG – *Bacillus Globigii*
BIDS – Biological Integrated Detection System
BIODET – biological detection
BL – Biosafety Level
BLA – Biologics Licensing Application
BNCOC – Basic Non-Commissioned Officer Course
BOG – Board of Governors
BoNT – Botulinum Neurotoxin
BoNT/A – Botulinum Neurotoxin A
BoNT/B – Botulinum Neurotoxin B
BRP – Basic Research Plan
BSPS – Biological Sample Preparation System
BTN – below the neck
BTRC – Biological Threat Response Cell
BuChE – butyrylcholinesterase
BVO/GVO – black vinyl overboot/green vinyl overboot
BW – biological warfare
BWC – Biological Weapons Convention
BWD – Biological Warfare Defense

–C–

C4I – command, control, communication, computer, and intelligence
C4ISR – command, control, communication, computer, intelligence, surveillance, and reconnaissance
C. burnetii – *Coxiella burnetii* (Q fever)
CA – Commodity Area
CAA – Center for Army Analysis
CA/D – Chemical Activity/Depot
CaE – carboxylesterase
CAM – Chemical Agent Monitor (also, Commodity Area Manager)
CAMEX – Computer Assisted Map Exercise
CANA – Convulsant Antidote, Nerve Agent autoinjector
CANE – Combined Arms in a Nuclear/Chemical Environment
CAPDS – Chemical Agent Point Detection System
CARDS – Chemical Agent Remote Detection System
CASTFOREM – Combined Arms and Support Task Force Evaluation Model
CatOx – catalytic oxidation
CATS – Consequence Assessment Tool Set
CAWM – Chemical Agent Water Monitor
CAX – Combined Arms Exercise
CB – chemical and biological (also C/B)
CBAAG – Chemical and Biological Agent Advisory Group
CBAT – Chemical Biological Augmentation Team
CBAWM – Chemical Biological Agent Water Monitor
CBD – chemical and biological defense
CBDP – Chemical/Biological Defense Program
CBIAC – Chemical and Biological Information Analysis Center
CBIRF – Chemical Biological Incident Response Force
CBIS – CB Individual Sampler
CBM&S – Chemical/Biological Modeling & Simulation
CBMS – chemical biological mass spectrometer
CBNP – Chemical Biological Nonproliferation Program
CBPS – Chemical Biological Protective Shelter
CBR – Chemical, Biological, and Radiological
CBR-D – Chemical, Biological, Radiological Defense
CBRNE – Chemical , Biological, Radiological, Nuclear, and High-Yield Explosives
CBRNC – Chemical, Biological, Radiological & Nuclear Countermeasures
C/B-RRT – Chemical Biological Rapid Response Team
CBS – Corps Battle Simulation
CBSD – Chemical Biological Stand-off Detector
CBTAP – Chemical and Biological Threat Agent Program
CBW – chemical and biological warfare
CCD – Camouflage, Concealment, and Deception
CCTI – Chairman's Commended Training Issues
CDC – Centers for Disease Control and Prevention
CD-ROM – Compact Disk - Read Only Memory
CDTF – Chemical Defense Training Facility (at the U.S. Army Chemical School)
CE – Civil Engineering
CEES – half mustard (2-chloroethyl ethylsulfide)
CEM – Concept Evaluation Model
CENTCOM – Central Command
CESM – Chemical Environment Survivability Mask
CESS – Chemical Environment Survivability Suit
CFD – Computational Fluid Dynamics
CFM – cubic feet per minute
CFR – Code of Federal Regulations
CFX – computational fluid effects
cGMP – current Good Manufacturing Practices
CHAMP – Chemically/biologically Hardened Air Management Plant
CHATH – Chemically/Biologically Hardened Air Transportable Hospital
ChE – Cholinesterase
CIA – Central Intelligence Agency
CINC – Commander-in-Chief
CINCCENT – Commander-in-Chief Central Command

CINCPAC – Commander-in-Chief Pacific Command
CJCS – Chairman of the Joint Chief of Staff
CM – Chloroform-Methanol
(also, consequence management, crisis management, or countermeasures)
CMO – Central MASINT Office
CMR – Chloroform-Methanol Residue
CMTC – Combat Maneuver Training Center
CMX – Crisis Management Exercise
CNS – Central Nervous System
COBC – Chemical Officer Basic Course
CoM – Consequence Management
COMMZ – Communications Zone
COMPTUEX – Composite Training Unit Exercise
CONOPS – Concept of Operations
CONUS – continental United States
COTS – Commercial Off-the-Shelf
CP – chemical protective (also, collective protection, command post, or counterproliferation)
CP/CBD – Counterproliferation/Chemical and Biological Defense
CPE – Collective Protection Equipment
CPO – Chemical Protective Overgarment
CPRC – Counterproliferation Review Council
CPS – Collective Protection System
CPU – Chemical Protective Undergarment
CRDA – Cooperative Research & Development Agreement
CRG – Compliance Review Group
CRP – Critical Reagents Program
CS – tear gas
CSAT – Command and Staff Awareness Training
CSST – Chemical Casualty Site Team
CT – Concentration over time
CTC – Combat Training Center
CTR – Cooperative Threat Reduction
CTS – Casualty Training System
CVC – Combat Vehicle Crewmen
CVIP – Chemical Vision Implementation Plan
CW – Chemical Warfare
CWA – Chemical Warfare Agent
CWC – Chemical Weapons Convention
CWCIWG – Chemical Weapons Convention Implementation Working Group
CWDD – Chemical Warfare Directional Detector (AN/KAS-1A)
CWICS – Chemical Weapons Interior Compartment System
CWNAVSIM – Chemical Warfare Naval Simulation

–D–

DAB – Defense Acquisition Board
DAIG – Department of the Army Inspector General
DAP – Decontaminating Apparatus Portable
DARPA – Defense Advanced Research Projects Agency
DASG-HCO – Department of the Army Surgeon General-Health Care Office
DATSD (CBD) – Deputy Assistant to the Secretary of Defense for Chemical/Biological Defense
DCSOPS – U.S. Army Deputy Chief of Staff for Operations
DDR&E – Director, Defense Research and Engineering
DEA – Data Exchange Agreement
DEPMEDS – Deployable Medical Systems
DEST – Domestic Emergency Response Team
DHHS – Department of Health and Human Services
DLA – Defense Logistics Agency
DMMP – Dimethyl Methyl Phosphonate
DNA – Deoxyribonucleic Acid
DNBI – Disease and Non-Battle Injury
DNWS – Defense Nuclear Weapons School
DoD – Department of Defense
DoE – Department of Energy
DPE – Demilitarization Protective Ensemble
DPG – Defense Planning Guidance; Also Dugway Proving Grounds
DRB – Defense Review Board (also, Defense Resources Board, or Division Ready Brigade)
DRI – Defense Reform Initiative
DS2 – Decontamination Solution 2
DSCP – Defense Supply Center Philadelphia
DSO – Defense Sciences Office
DSTAG – Defense Science and Technology Advisory Group
DTO – Defense Technology Objective
DTAP – Defense Technology Area Plan
DTIRP – Defense Technical Inspection Readiness Program
DTLOMS – Doctrine, Training, Leader Development, Organization, Material, and Soldier/Personnel
DTN – Decision Tree Network
DTO – Defense Technology Objective
DT/OT – developmental/operational testing
DTRA – Defense Threat Reduction Agency
DTRA(CB) – Defense Threat Reduction Agency's Chemical and Biological Defense Directorate

–E–

E. coli – *Escherichia coli*
EBO – ebola virus
ECBC – Edgewood Chemical & Biological Center
ECU – Environmental Control Unit
ECV – Expanded Capacity Vehicle
ED – ethyl dichlorarsine
EEE – Eastern Equine Encephalomyelitis

EEG – electroencephalographic
ELISA – Enzyme-Linked Immunosorbent Assay
EMD – Engineering and Manufacturing Development
ENCOMPASS – Enhanced Consequence Management Planning and Support System
EOD – Explosive Ordnance Disposal
ESS – Environmental Support System
EUCOM – European Command

–F–

F1 – Fraction 1
F1-V – Fraction 1 - "V" Antigen
Fab – Fragment Antigen Binding
FABS – Force Amplified Biosensor
FAR – Federal Acquisition Regulations
FBI – Federal Bureau of Investigations
Fc – Fragment Crystallizable
FCBC – Field Management of Chemical and Biological Casualties Course
FDA – Food and Drug Administration
FDTE – Force Development Testing and Experimentation
FEST – Foreign Emergency Response Team
FGA – Fourth Generation Agents
FLEETEX – Fleet Exercise
FM – Field Manual
FORCEM – Force Evaluation Model
FORSCOM – Forces Command
FR – flame resistance
FUE – First Unit Equipped
FY – fiscal year
FY99 – Fiscal Year 1999
FYDP – Future Years Defense Plan

–G–

G-CSF – Gramucolyte Colony Stimulating Factor
GA – tabun, a nerve agent
GAO – General Accounting Office
GAS – Group A *Streptococcus*
GB – sarin , a nerve agent
GC – gas chromatography
GD – soman, a nerve agent
GEMS – Global Expeditionary Medical System
GF – a nerve agent
GMP – Good Manufacturing Practice
GOCO – Government-Owned/Contractor-Operated
GP – glycoprotein
GPFU – Gas Particulate Filter Unit
GPRA – Government Performance and Results Act

–H–

HAZWARN – NBC Hazardous Warning System
HAZWOPER – Hazardous Waste Operations and Emergency Response
hBuChE – Human Butrylcholinesterase
hCaE – Human Carboxylesterase
HD – sulfur mustard, a blister agent
HEPA – high efficiency particulate
HHA – Hand Held Immunochromatographic Assay
HLA – high level architecture
HMMWV – High Mobility Multipurpose Wheeled Vehicle
HN – Host Nation
HPAC – Hazard Prediction Assessment Capability
HQ – headquarters
HSC/YA – Human Systems Program Office
HTA – high threat area
HTH – High Test Hypochlorite
HVAC – heating, ventilation, and air conditioning

–I–

IBAD – Interim Biological Agent Detector
IBMC – Industrial Base Maintenance Contract
ICAD – Individual Chemical Agent Detector
ICAM – Improved Chemical Agent Monitor
ICDS – Improved Chemical Detection System
ID – infantry division
IDE – integrated digital environment
IDLH – Immediate Danger to Life and Health
IEG – Information Exchange Group
IET – Initial Entry Training
IL – Interleukin
IL CBDWS – In-Line Chemical Biological Defense Water System
IM – intramuscular
IMS – Ion Mobility Spectroscopy
IND – Investigational New Drug
IOT&E – Initial Operational Testing & Evaluation
IP – intraperitoneal
IPDS – Improved (chemical) Point Detection System
IPE – Individual Protective Equipment
IPR – In-Process Review
IPT – Integrated Product Team
IR&D – Independent Research & Development
IR-LIDAR – Infrared Light Detection and Ranging
IS – Instrumentation System
ISD – Individual Soldier Detector
ISO – International Standards Organization
ITAP – Improved Toxicological Agent Protective Ensemble
ITS – Individual Training Standard
IVD – Individual Vapor Detector

–J–

JAGG – Joint Air and Ground Glove
JAWG – Joint Assessment Working Group

JB1GU – JSLIST Block 1 Glove Upgrade
JB2GU – JSLIST Block 2 Glove Uprgrade
JBAIDS – Joint Biological Agent Identification and Diagnostic System
JBPDS – Joint Biological Point Detection System
JBREWS – Joint Biological Remote Early Warning System
JBSDS – Joint Biological Standoff Detection System
JBUD – Joint Biological Universal Detector
JCAD – Joint Chemical Agent Detector
JCATS – Joint Conflict and Tactical Simulation
JCBAWM – Joint Chemical Biological Agent Water Monitor
JCBUD – Joint Chemical and Biological Universal Detector
JCHEMRATES – Joint Chemical Defense Equipment Consumption Rates
JCPE – Joint Collective Protection Equipment
JCRS – Joint Canteen Refill System
JCS – Joint Chiefs of Staff
JFCOM – Joint Forces Command
JFIRE – Joint CB Protective Firefighter Suit
JFOC – Joint Future Operational Capabilities
JFT – Joint Field Trail
JGEM – Joint Ground Effects Model
JLAS – Joint Land, Aerospace, and Sea Simulation
JMANS – Joint Multimission Advanced NBC System
JMAR – Joint Medical Asset Repository
JMCBDRP – Joint Medical Chemical and Biological Defense Research Program
JMCBRDRP – Joint Medical Chemical, Biological, and Radiological Defense Research Program
JMCBDS – Joint Modular Chemical and Biological Detection System
JMCDRP – Joint Medical Chemical Defense Research Program
JMNS – Joint Mission Need Statement
JMRR – Joint Monthly Readiness Review
JNBCDB – Joint NBC Defense Board
JOA – Joint Operations Area
JORD – Joint Operational Requirements Document
JPACE – Joint Protective Aircrew Ensemble
JPO-BD – Joint Program Office for Biological Defense
JRCAB – Joint Readiness Clinical Advisory Board
JRTC – Joint Readiness Training Center
JSA – Joint Service Agreement
JSAF – Joint Simulated Automated Force
JSAM – Joint Service Aircrew Mask
JSCBIS – Joint Service Chemical Biological Information System
JSFXD – Joint Service Fixed Site Decon
JSGPM – Joint Service General Purpose Mask
JSIG – Joint Service Integration Group
JSIMS – Joint Simulation System
JSLIST – Joint Service Lightweight Integrated Technology (individual protection)
JSLNBCRS – Joint Service Light NBC Reconnaissance System
JSLSCAD – Joint Service Lightweight Stand-off Chemical Agent Detector
JSMG – Joint Service Materiel Group
JSMLT – Joint Service Mask Leakage Tester
JSNBCRS – Joint Service NBC Reconnaissance System
JSTPCBD – Joint Science and Technology Panel for Chemical/Biological Defense
JSWILD – Joint Service Warning and Identification LIDAR Detector
JTASC – Joint Training and Analysis Center
JTAV – Joint Total Asset Visibility
JTWAG – Joint Training Assessment Working Group
JTC – Joint Training Council
JTCG – Joint Technology Coordinating Group
JTCOPS – Joint Transportable Collective Protection System
JTF – Joint Task Force
JVAP – Joint Vaccine Acquisition Program
JWARN – Joint Warning and Reporting Network
JWARS – Joint Warfighting Simulator
JWFC – Joint Warfighting Center
JWSTP – Joint Warfighting S & T Plan

–L–

L – lewisite, a vesicant agent
LAM – Louisiana Maneuvers
LAV – Light Armored Vehicle
LCBPG – Lightweight CB Protective Garment
LD_{50} – Median Lethal Dose
LDS – Lightweight Decontamination System
LG7 – Land Group 7
LHA – general purpose amphibious assault ship
LHD – general purpose amphibious assault ship (with internal dock)
LIDAR – LIght Detection And Ranging
LLC – limited liability corporation
LLR – Low Level Radiological
LMS – Lightweight Multipurpose Shelter
LMSR – Large, Medium-speed Roll-on, Roll-off Ship
LNBCRS – Light NBC Reconnaissance System
LRBSDS – Long-Range Biological Stand-off Detection System
LSCAD – Lightweight Stand-off Chemical Agent Detector
LSCD – Laser Stand-off Chemical Detector
LSD – landing ship, dock

LSP – Logistics Support Plan
LWRS – Lightweight Reconnaissance System

–M–

M&S – Modeling and Simulation
M&S CA – Modeling and Simulation commodity Area
M&S R&D – Modeling and Simulation Research and Development
MAGTF – Marine Air Ground Task Force
MAJCOM – Major Command
MALDI – Matrix-Assisted Laser Desorption Ionization
MANAA – Medical Aerosolized Nerve Agent Antidote
MANSCEN – Maneuver Support Center
MANTECH – Manufacturing Technology
MASINT – Measures & Signatures Intelligence
MBDRP – Medical Biological Defense Research Program
MBGV – *marburg* virus
MCBAT – Medical Chem-Bio Advisory Team
MCBC – Management of Chemical and Biological Casualties Course
MCO – Marine Corps Order
MCPE – Modular Collective Protection System
MCU-2A/P – a chemical protective mask
MCWP – Marine Corps Warfighting Publication
MD – methyl dichlorarsine
MDS – Modular Decontamination System
MED – Medical
MEIR – Medical Effects of Ionizing Radiation
MEPS – Multiplex Electronic/Photonic Sensor
METL – Mission Essential Task List
metL, thrA – methionine biosynthesis
MEU – Marine Expeditionary Unit
MFR – Multi-Function Radiac Set
MHC – Major Histocompatibility Complex
MICAD – Multipurpose Integrated Chemical Agent Detector
MIL STD – Military Standard
MIPR – Military Interdepartmental Purchase Request
MLRS – Multiple Launch Rocket System
MNDRP – Medical Nuclear Defense Research Program
MNS – Mission Needs Statement
MOE– Measure of Effectiveness
MOP – Memorandum of Policy
MOPP – Mission Oriented Protective Posture
MOS – Military Occupational Specialist
MOU – Memorandum of Understanding
MPH – miles per hour
MPS – Mission Performance Standard (also, Multipurpose Protective Sock)
MPSP – Medical Program Sub-Panel
MRMC – Medical Research and Materiel Command
MS – Mass Spectrometry or Milestone
MSC – Military Sealift Command or Mesenchymal Stem Cells
MTF – Medical Treatment Facility
MTTP – Multiservice Tactics, Techniques, and Procedures
MTW – Major Theater War
MULO – Multi-purpose Overboot
murE – murein biosynthesis

–N–

NAADS – Nerve Agent Antidote Delivery System
NAAG – NATO Army Armaments Group
NAAK – Nerve Agent Antidote Kit
NAAS – Nerve Agent Antidote System
NAPP – Nerve Agent Pyridostigmine Pretreatment
NATO – North Atlantic Treaty Organization
NAVMED – Naval Medical
NBC – Nuclear, Biological, and Chemical
NBCD – NBC Defense
NBCDT – NBC Defense Training
NBC-E – nuclear, biological, and chemical-environment
NBC-R – nuclear, biological, chemical, and radiological
NBCRS – NBC Reconnaissance System (Fox Vehicle)
NBCWP – NBC Defense Interservice Working Party
NCO – Non-Commissioned Officer
NDA – New Drug Application
NDI – Non-Developmental Item
NEHC – Naval Environmental Health Center
NEPMU – Navy Environmental and Preventative Medicine Unit
NFPA – National Fire Protection Agency
NGIC – National Ground Intelligence Center
NICP – National Inventory Control Points
NIEX – No-Notice Interoperability Exercise
NIH – National Institute of Health
NIOSH – National Institute for Occupational Safety and Health
NIRF – Nuclear Incident Response Force
NMSO – Nuclear Medical Science Officer
NO – nitric oxide
NSC – National Security Council
NSN – National Stock Number
NSTC – National Science and Technology Council
NTA – Novel Threat Agent
NTC – National Training Center
NTTP – Naval Tactics, Techniques, and Procedures

NWDC – Naval Warfare Development Command
NWP – Naval Warfare Publication

–O–

O49 – Joint Contact Point and Test Project
OAC – Officer Advance Course
OBC – Officer Basic Course
OCONUS – Outside the continental United States
OG – Overgarment
O&M – Operations & Maintenance
OPCW – Organization for the Prohibition of Chemical Weapons (in The Hague)
OPLAN – Operational Plan
OPR – Office of Primary Responsibility
ORD – Operational Requirements Document
ORF – Open Reading Frames
OSD – Office of the Secretary of Defense
OSHA – Occupational Safety and Health Administration
OSM3 – oximeter instrument
OT – Operational Testing
OTSG – Office of the Surgeon General

–P–

P3I – Pre-Planned Program Improvement
PA – protective antigen
PACAF – Pacific Command
PACOM – Pacific Command
PAM – Preventative and Aerospace Medicine
PATS – Protective Assessment Test System
PB – President's Budget
PBAS – Program Budget Accounting System
PCPS – Portable Collective Protection System
PCR – polymerase chain reaction
PCS – Permanent Change of Station
PD – phenyl dichlorarsine
PDDA – Power Driven Decontamination Apparatus
PDM – Program Decision Memorandum
PDRR – Program Definition and Risk Reduction
PE – Program Element
PF – Positive Force Exercise
PICS – Personal Ice Cooling System
PIP – Product Improvement Program
PL 103-160 – Public Law 103-160, The National Defense Authorization Act of FY94
PMCD – Program Manager for Chemical Demilitarization
PMCS – Preventative Maintenance Checks and Services
PMO – Product Management Office
POL – petroleum, oil, and lubricant
POM – Program Objectives Memorandum
PPBS – Program Planning and Budgeting System
PQS – Personnel Qualification
PR – Positive Response Exercise
PRD – Presidential Review Directive
PRG – Program Review Group
PROFIS – Medical NBC Professional Filler Course
PSA – Pressure Swing Adsorption

–Q–

QDR – Quadrennial Review
QNFT – Quantitative fit testing
QRR – Qualitative Research Requirements
QSTAG – Quadripartite Standardization Agreement
QWG – Quadripartite Working Group

–R–

R&D – Research and Development
RADIAC – Radiation
RAPID – Ruggedized Advanced Pathogen Identification Device
RBC-AchE – red blood cell acetylcholinesterase
RC – Reserve Component
RDA – Research, Development, and Acquisition
RDD – Radiological Dispersal Device
RDTE (Also, RDT&E) – Research, Development, Test and Evaluation
RestOps – Restoration of Operations
RFP – Request for Proposal
RMC – Regional Medical Commands
rPA – recombinant protective antigen
RSCAAL – Remote Sensing Chemical Agent Alarm
RSTA – Reconnaissance, Surveillance, and Target Acquisition
RTP – Readiness Training Plan
rTSP – Reactive Topical Skin Protectant
RW – radiological/nuclear warfare

–S–

S&T – Science & Technology Base
SACPS – Selected Area Collective Protection System
SAF – Semi-Automated Forces
SAFEGUARD – Scanning Airborne Fourier Emission for Gaseous Ultraspectral Analysis and Radiometric Detection
SAG – Study Advisory Group
SALAD – Shipboard Automatic Liquid Agent Detector
Saratoga – a CB protective overgarment
SASO – Stability and Support Operations
SAT – Systems Approach to Training
SAW – Surface Acoustic Wave
SBA – Simulation Based Acquisition
SBCCOM – Solider, Biological and Chemical Command (U.S. Army)

SCALP – Suit Contamination Avoidance Liquid Protection
SCAMP – Shipboard Chemical Agent Monitor Portable
SCPE – Simplified Collective Protective Equipment
SCUD – surface-to-surface missile system
SD – Stand-off Detector
SD/ASM – Stand-off Detector for Armor System Modernization
SDK – Skin Decontamination Kit
SDS – Sorbent Decon System
SE – staphylococcal enterotoxins or status ellepticus
SEA – Staphylococcal Enterotoxin A
SEB – Staphylococcal Enterotoxin B
SECDEF – Secretary of Defense
SERPACWA – skin exposure reduction paste against chemical warfare agents
SFR – System Function Requirement
SGXA – Air Force Surgeon General
SIMBAD – Sensor Integrated Modeling for Biological Agent Detection
SMART-CB – Special Medical Augmentation Response Team-Chemical/Biological
SMART-PM – Special Medical Augmentation Response Team-Preventative Medicine
SNCO – Staff-Noncommissioned Officer
SOF – Special Operations Forces
SOFCAS – Special Operation Forces Chemical Agent Detector
SOI – School of Infantry
SO/LIC – Special Operations and Low Intensity Conflict
SOMCBD – Special Operations Modular CB Detector
SORTS – Status of Resources and Training System
SOW – Statement of Work
SPA – surface protein antigen
SPOD – Seaport of Debarkation
SRT – Specialty Response Team
STAFFS – Simulation Training and Analysis for Fixed Sites
STANAG – standard agreement
STB – Super Tropical Bleach
STEPO – Self-Contained Toxic Environment Protective Outfit
STEPO-I – Interim Self-Contained Toxic Environment Protective Outfit
STO – Science and Technology Objective
STRAC – Standards in Training Commission
STS – Specialty Training Standard
SUBD – Small Unit Biological Detector
SWA – Southwest Asia

–T–

T&D – Transport and Diffusion
TAA – Total Army Analysis
TACWAR – Tactical Warfare
TAP – Toxicological Agent Protective boots and gloves
TARA – Technology Area Review and Assessment
TAV – Total Asset Visibility
TB – Technical Bulletin
TBM – Transportation of Biomedical Materials or Tactical Ballistic Missiles
TDA – table of distribution and allowances
TED – Troop Equivalent Dose
TEI – Technical Equipment Inspection
TEMPER – Tent Extendable Modular Personnel
TEU – Technical Escort Unit
TIC – Toxic Industrial Chemical
TIM – toxic industrial material
TM – Transport Molecules
TOF – Time of Flight
TSA – Transition State Analogue
TSG – The Surgeon General
TSP – Topical Skin Protectant
TSWG – Technical Support Working Group
TTP – Tactics, Techniques, and Procedures

–U–

UAV – Unmanned Aerial Vehicle
UCP – Upconverting Phosphors or Unified Command Plan
UDP – Unit Deployment Program
UN – United Nations
UNSCOM – United Nations Special Commission
USA – United States Army
USACHPPM – United States Army Center for Health Promotion and Preventive Medicine
USACMLS – US Army Chemical School
USAF – United States Air Force
USAF(SGXR) – USAF Surgeon General
USAMEDDC&S – U.S. Army Medical Department Center and School
USAMMA – U.S. Army Medical Materiel Agency
USAMMDA – U.S. Army Medical Materiel Development Activity
USAMRICD – U.S. Army Medical Research Institute of Chemical Defense
USAMRIID – U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC – U.S. Army Medical Research and Materiel Command
USANCA – United States Army Nuclear and Chemical Agency
USAR – US Army Reserve

USARAK – US Army Alaska
USARJ – US Army Japan
USC – United States Code
USCENTCOM – US Central Command
USCINCEUR – US Command in Chief, Europe
USCINCPAC – US Commander in Chief, Pacific
USD(AT&L) – Undersecretary of Defense (Acquisition Technology and Logistics)
USEUCOM – US European Command
USFK – U. S. Forces, Korea
USG – United States Government
USJFCOM – US Joint Forces Command
USMC – United States Marines Corps
USN – United States Navy
USPACOM – US Pacific Command
USSTRATCOM – US Strategic Command
USTC – US Transportation Command
USUHS – Uniformed Services University of the Health Sciences
UTC – Unit Type Code
UV – ultra-violet

–V–

VCA – Voice Communication Adapter
VCSA – Vice Chief-of-Staff of the Army
VEE – Venezuelan equine encephalomyelitis
VIC – Vector-In-Command
VIG – Vaccinia Immune Globulin
VLP – virus-like particles
VLSTRACK – Vapor, Liquid, and Solid Tracking Model
VNTR – Variable Number Tandem Repeat
VPU – Vapor Protective Undergarment
VTC – Video Teleconference
VVA – verification, validation, and accredidation
VVS – Vehicles, Vans and Shelters
VX – a nerve agent

–W–

WCF – Working Capital Fund
WDTC – West Desert Test Center
WDTIC – West Desert Technical Information Center
WEE – Western Equine Encephalomyelitis
WG – Working Group
WMD – weapons of mass destruction
WMD-CST – Weapons of Mass Destruction Civil Support Teams
WRAIR – Walter Reed Army Institute of Research
WRM – war reserve materiel
WRSI – War Reserves Secondary Items

–Y–

Y. pestis – *Yersinia Pestis* (Plague)

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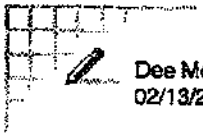

Dee Morris
02/13/2002 04:22 PM

To: Ed Rushin/OSAGWI@OSAGWI, Bonnie Whittier/OSAGWI@OSAGWI
cc:

Subject: 2002 CBDP Report -- Final Coordination

This is the final coordination, and the only one we have to formally comment on, of subject report. This was originally assigned CMAT 1285-020 when they started writing it and asked us to play.

---------- Forwarded by Dee Morris/OSAGWI on 02/13/2002 04:23 PM ----------

"Evans, David" <David.Evans@anser.org> on 02/13/2002 04:12:30 PM

To: "Parker, COL Chris" <christopher.parker@sbccom.apgea.army.mil>, "Danley, COL David" <david.danley@det.amedd.army.mil>, "PM-NBC COL Debra Dubois (E-mail)" <debra.dubois@sbccom.apgea.army.mil>, "Shandle, Donna" <donna.shandle@sbccom.apgea.army.mil>, "PM-NBC Robert Stern (E-mail)" <robert.stern@SBCCOM.APGEA.ARMY.MIL>, "Smith Markham DTRA" <Markham.Smith@DTRA.MIL>, "CBDP (JSMG) Pam Barrett (E-mail)" <pamela.barrett@sbccom.apgea.army.mil>, "Hubbard, Susan Mrs. PEOCBD" <Susan.Hubbard@peocbd.army.mil>, "Starks, Jennifer" <jennifer.starks@det.amedd.army.mil>, "Lachenmayer, Carl" <carl.lachenmayer@det.amedd.army.mil>, "Kay, Bruce" <bruce.kay@det.amedd.army.mil>, "Sheffer, Linda" <linda.sheffer@det.amedd.army.mil>, "Corriveau, Joseph, Dr, OSD/ATL" <Joseph.Corriveau@osd.mil>, "Al Mauroni (JS/J-5)" <albert.mauroni@js.pentagon.mil>, "Andy Beckey (AMEDD)" <Andrew.Beckey@CEN.AMEDD.ARMY.MIL>, "Andy Blankenbiller (JSMG)" <andrew.blankenbiller@sbccom.apgea.army.mil>, "Angela Batts" <Angela.Batts@DET.AMEDD.ARMY.MIL>, Anna.Johnson-Winegar@osd.mil, "Arleigh Rice (DTRA(OSAC))" <arleigh.rice@dtra.mil>, benneid@socom.mil, bogner.chuck@hq.navy.mil, "Bolluyt, Michael D., MAJ, J-5" <michael.bolluyt@js.pentagon.mil>, ccasteel@snap.org, "Channel, Stephen R Lt Col SBCCOM" <stephen.channel@SBCCOM.APGEA.ARMY.MIL>, "COL Al Hardy (Policy)" <hardya@mail.policy.osd.mil>, "COL Mike Brown" <brownmt@hqdaq.army.mil>, "Cole, Chris, Mr., AF/ILEXR" <Chris.Cole@pentagon.af.mil>, "Craig Walling (DTRA)" <Craig.Walling@DTRA.MIL>, "David Grenier (M&S CAM)" <grenierdb@nswc.navy.mil>, Dee Morris/OSAGWI@OSAGWI, "Doug Bryce" <Brycedw@mcsc.usmc.mil>, "Enatsky, Stan" <enatskysa@navsea.navy.mil>, "Ensor, John E MAJ ODCSLOG" <john.ensor@hqda.army.mil>, "George Kurpiel" <kurpiel.george@hq.navy.mil>, "Glasow, Jerry A LTC DUSA-OR" <Jerry.Glasow@HQDA.Army.Mil>, "Hudson Webb (DCSOPS)" <Webbhud@hqda.army.mil>, "Hunt, Sam, Mr. AF/ILEXR" <Sam.Hunt@pentagon.af.mil>, "Ishmael, Lauren (JPO-BD/CAMBER)" <ishmaell@jpobd.osd.mil>, "Jeff Macky (OPNAV N514)" <macky.jeffrey@cno.navy.mil>, Jerry.Threatt@dtra.mil, "Jim Zarzycki (SBCCOM)" <jim.zarzycki@emh1.apgea.army.mil>, "Joe Finerfrock (MARCORSYSCOM)" <finerfrockj@mcsc.usmc.mil>, "John Humpton (DAMO-SSD)" <john.humpton@hqda.army.mil>, "John Palman (JSMG - Logistics)" <john.palman@sbccom.apgea.army.mil>, "Jole Ritchie (DTRA)" <jole.ritchie@dtra.mil>, Karl.Semancik@osd.mil, "Kavanagh, M Ellen LTC" <Ellen.Kavanagh@CEN.AMEDD.ARMY.MIL>, "Kirk Phelps" <krphelps@sbccom.apgea.army.mil>, "Klenke, William J" <William.Klenke@CEN.AMEDD.ARMY.MIL>, "Kohout, Frank LTC (JSIG)" <KOHOUTF@wood.army.mil>, lepple.fred@hq.navy.mil, "Linden Carol D" <Carol.Linden@DET.AMEDD.ARMY.MIL>, "Lindstrom, Timothy E., CAPT, J-5" <timothy.lindstrom@js.pentagon.mil>, "LTC Debra Schnelle (OTSG)" <debra.schnelle@otsg.amedd.army.mil>, "Lynn Dievendorf (OTSG)" <lynn.dievendorf@otsg.amedd.army.mil>, "MAJ Jeff Stiefel (JPO-BD)" <stiefelj@jpobd.osd.mil>, "Matthew Eussen (ANSER)" <Eussenm@anser.org>, "Max Klein" <klein_max@bah.com>, "Maxey, John@AF" <john.maxey@pentagon.af.mil>, "McLane, Christopher, Major, AF/ILEXR" <Christopher.McLane@pentagon.af.mil>, "Merrick Harrison (AMEDDC&S)" <Merrick.Harrison@cen.amedd.army.mil>, MGOLDBLATT@DARPA.MIL, michael.lindauer@pentagon.af.mil, michael.wolozyn@hqda.army.mil, "Mike Grosser (MARCORSYSCOM)" <grosserjm@mcsc.usmc.mil>, "Millie Donlon" <mildonlon@darpa.mil>, "Morris, Jocelyn MRS" <MorrisJo@WOOD.ARMY.MIL>, "Perry Williams (J34)" <williapw@js.pentagon.mil>, "Pete Diegel (NAVFAC)" <diegelcp@navfac.navy.mil>, "Roger Blankenship (JSIG)" <blankenr@wood.army.mil>, Salvatore.Cirone@ha.osd.mil, "Saunders, Rich" <saunders@anser.org>, "Scott, Brian G LTC (AMEDD)" <Brian.Scott@CEN.AMEDD.ARMY.MIL>, sean.kirschner@js.pentagon.mil; "Siegel, Steve Mr. PEOCBD" <Steve.Siegel@peocbd.army.mil>, "Snyder, Michael LTC (OCAR-LOG)" <Michael.Snyder@ocar.army.pentagon.mil>, "Steve Sadler (DLA)" <steve_sadler@hq.dla.mil>, "Steve Tesko" <Steve.Tesko@anser.org>, "Steven Tesko" <steven.tesko@USAFSG.bolling.af.mil>, Thomas.Bibby@DET.AMEDD.ARMY.MIL, turviller@battelle.org, "Wheeler GySgt Darren S" <WheelerDS@MCCDC.USMC.MIL>

cc:

Subject: 2002 CBDP Report -- Final Coordination

<<2002 CBDP Report final draft.pdf>> <<CBDP Report final coordination.doc>>

For Distribution:

Attached is the final draft of the annual report to Congress.

Attached are pdf files with all the chapters and annexes. Microsoft Word versions of the individual chapters and annexes are posted on the report web site at http://www.acq.osd.mil. Please call me if you do not have the username and password to access this site.

This draft has incorporated the comments received to date.

Attached is a coordination sheet. The deadline for coordination is March 5, 2002.

On March 13, 2002, there will be a final pre-publication review of the report before it is published.

Please note that the final report will be published in two volumes. Volume I is the annual report and includes the information attached. Volume II is the Performance Plan. This will be available for distribution tomorrow.

Paper copies of the report will be formally distributed to the principals beginning tomorrow. The paper copies are identical to the pdf files attached.

Please call me or send me an e-mail with any questions or comments you may have on the report.

Thanks to all of you who have provided the substantial inputs to this year's edition of the report.

Respectfully,

David W. Evans
Principal Analyst
ANSER Inc.
Phone: 703-416-3040
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e-mail: david.evans@anser.org
web sites: www.anser.org, www.homelandsecurity.org

 - att1.htm

 - 2002 CBDP Report final draft.pdf

 - CBDP Report final coordination.doc

Dee Dodson Morris, JD
Deputy for Transformation Integration
Deployment Health Support Directorate
(703) 845-8339/fax (703) 578-8501

****
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5113 Leesburg Pike, Suite 901
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FACSIMILE TRANSMITTAL SHEET

TO: DAVID EVANS *FROM:* Ed Rushin

ORGANIZATION: ANSER

FAX NUMBER: 703 416 1393 *TOTAL NO. OF PAGES INCLUDING COVER:* 3

PHONE NUMBER: 703 693 9410 *SENDER'S PHONE NUMBER:* 703 575 2672

SUBJECT DoD Chem/Bio Def Program Annual Report

☐ URGENT ☐ FOR REVIEW ☐ PLEASE
☐ COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

DAVID,

Attached our DHSD comments that

****
*** TX REPORT ***
****

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ORGANIZATION:

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PHONE NUMBER: 703 697 1797 *SENDER'S PHONE NUMBER:* 703 575 2672

SUBJECT

☐ URGENT ☐ FOR REVIEW ☐ PLEASE
☐ COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Colonel,

A copy has been faxed to Dave

Department of Defense Chemical and Biological Defense Program

Annual Report to Congress and Performance Plan

Coordination Sheet

My organization has reviewed the final draft of the Annual CB Defense Report and Performance Plan, which has been prepared in accordance with 50 USC 1523.

[ ] **Concur**, without change to final draft.

[X] **Concur**, with recommended changes.

[ ] **Non-concur.** Concur with incorporation of attached recommended substantive changes.

Organization: Deployment Health Support Directorate

Phone: 703 - 845 - 8339

Name (printed): Ms. Dee Morris

Signature: Michael E. Kilpatrick

Michael E. Kilpatrick, MD, Director

Coordination sheets should be provided to:

COL Karl Semancik
DATSD(CBD)
Room 3C257
3050 Defense
The Pentagon
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Alternate fax: (703) 695-0476
Phone: (703) 416-3040 :

Deployment Health Support Directorate
Comments
Final Draft - DoD Chemical and Biological Defense Program
Annual Report to Congress

1. Page i, Executive Summary, large middle paragraph and page 2, box on Chemical and Biological Defense Program Mission. Spectrum of conflict is defined as extending to "two nearly simultaneous major theater wars." Recent policy announcements have indicated that DOD is no longer capable of waging the two theater war – to include it in this document goes against the Department's stated capabilities and makes the report appear dated.

2. Page 10, OUTLOOK. These two paragraphs do not include any reference to the significant budget plus-ups being made to the CBDP to respond to homeland defense issues. Since the war on terrorism is being fought on the home front as well as abroad, this omission understates the true impact of the CBDP and makes the report appear dated. While this is addressed in Chapter One under the discussions of the TSWG (page 16), the CBNP (page 17) and the CB Defense Program Management Assessment (page 21); it should be included in the Outlook to ensure those reading only the Executive Summary are aware of the entire range of effort.

3. Chapter Two. While the 'non-defense' needs for vaccines is briefly addressed (page 74) under medical aspect of the CBDP, there is no mention of ongoing homeland defense related initiatives in the areas of contamination avoidance, decontamination, and individual or collective protection. This omission makes the program appear one-dimensional (traditional war), when it is, in fact, far more multi-dimensional.

4. Chapter Three. Again the concept of two MTW is used to define logistical requirements. In addition, 'peacetime' requirements are represented only as training needs. I can find no mention of the need to determine any homeland defense stockage levels. There is an expectation that DOD is involved in this process and appropriate equipment and supplies will be available. This chapter needs to address DOD's responsibilities in this area as well as those planning and stockpiling responsibilities held by other governmental agencies.

5. FY 2001-2003 Performance Plan. The Performance Plan remains focused on battlefield CB defense. The CB aspects of homeland defense need to be specifically articulated in the Performance Plan. Otherwise it appears the CBDP does not address those issues. We know that there is quite a bit of ongoing work in the area that comes under the purview of the CBDP – we need to take the appropriate credit and outline our requirements.

6. A continuing comment from last year is that "[c]areful reading of the report and accompanying performance plan reveal a programmatic materiel research and development focus which fails to oversee the integration of the developed materiel into the force via policy, doctrine and training. A recurring lesson from well before the Gulf War is that proper fielding of new equipment requires clearly articulated policy and doctrine for the equipment's use as well as trained and experienced operators and leaders who understand what the equipment can, and cannot, do. The report must outline how the CBDP will oversee the effective integration of developed materiel into the force."

(265)

CMAT Control #
2000095-0000015

ASSISTANT TO THE SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

NUCLEAR AND CHEMICAL
AND BIOLOGICAL DEFENSE
PROGRAMS

April 3, 2000

MEMORANDUM FOR DEPUTY SPECIAL ASSISTANT FOR GULF WAR ILLNESSES
OSD

SUBJECT: Information Paper, "United States Armed Forces Vaccine Administration During the Gulf War Era"

In my role as a senior member of the Project Badger task force, I participated extensively in discussions relevant to use of anthrax vaccine and botulinum toxoid during the Gulf War. The discussions of our group were limited to acquisition and technology issues, and I feel that your information paper accurately summarizes the findings of Project Badger.

I have little additional information to add to your response, but continue to offer my assistance in answering specific questions on providing a personal perspective on the technological aspects of the vaccines or the problems identified in the manufacturing sector. After meeting with LCDR (b)(6) last week, I hope any open questions have been answered. If not, please feel free to contact me again. This is an extremely important issue with regard to chemical-biological defense, and I will continue to give it a high priority.

Anna Johnson-Winegar, Ph.D.
Deputy for Chemical/Biological Defense

IMAGE ONLY FILE. USE/VIEW DOCUMENT
FOR COMPLETE INFORMATION.

KEYWORDS

CMAT#: 1999242-0000002

WHAT EVERY SERVICE MEMBER NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE

Q: Is this vaccine safe?

A: Yes, this vaccine has been safely and routinely administered in the U.S. to veterinarians, laboratory workers, and livestock handlers since 1970. However, as with other vaccines, minor reactions and, to a lesser extent, more serious adverse reactions may occur in a small number of people.

Q: What if I am pregnant, planning on becoming pregnant, or breast feeding?

A: Anthrax vaccine, like other inactivated vaccines, is not expected to cause fetal harm. No evidence exists that indicates any other adverse reproductive effects including fertility. Prudent medical practice is to defer all immunizations during pregnancy unless clearly needed. Therefore, pregnant women should not receive the anthrax vaccine unless anthrax exposure occurs or is imminent. Service members who believe that they may be pregnant are instructed to inform their health care provider. Anthrax imunizations will be deferred until the pregnancy is complete. A woman does not need to delay becoming pregnant or stop breastfeeding after receiving a dose of anthrax vaccine.

Q: What other medical conditions should I inform the medical staff about?

A: If you have an active infection or are taking a prescription medicine, inform your health care provider before taking this shot.

Q: The anthrax vaccine was administered to personnel deployed in the Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?

A: No. Several national scientific groups, including the National Academy of Sciences, have addressed this issue and found no evidence to link anthrax vaccine with illnesses among Gulf War veterans.

Q: How many shots will I have to take?

A: Six shots, three given two weeks apart followed by three additional injections given at 6, 12 and 18 months. An annual booster shot is required to maintain ongoing immunity.

Q: What are the side effects?

A: The vaccine has been in use since 1970, and since that time there have been no long-term side effects identified or reported. However, as with other vaccinations or medications, pain may occur at the site of injection. Temporary side effects (sore arm, redness, and slight swelling) may occur. Small, non-tender nodules or knots under the skin at the site of injection occur in about 30% of vaccine recipients. These nodules usually disappear within a few weeks, but in some cases the process takes several months.

Q: Am I required to take the vaccine?

A: Yes. This program will be treated like any other vaccine that is required to prepare you for deployment. You will be required to take it unless medically deferred.

Q: How can I get more information about anthrax vaccine?

A: Your commanding officer or supporting medical facility. In addition, more information on the anthrax vaccine can be accessed at the website:

http://www.defenselink.mil/specials/Anthrax

WHAT EVERY SERVICE MEMBER NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE

Anthrax is a highly lethal biological weapon

"Vaccination against anthrax is a safe, prudent force protection measure."

William S. Cohen
Secretary of Defense

UPDATED 02 DECEMBER 1998

WHAT IS THE THREAT?

Biological weapons are maintained by several countries around the world. Use of these weapons could cause widespread illness among unprotected military forces. Anthrax is the biological weapon most likely to be encountered because it is:

- Highly lethal
- Easy to produce in large quantities
- Relatively easy to develop as a weapon
- Easily spread over a large area
- Easily stored and dangerous for a long time

WHAT IS ANTHRAX?

Anthrax is a disease normally associated with plant-eating animals (sheep, goats, cattle, and to a lesser degree swine). It is caused by the bacteria *Bacillus anthracis*. Once common where livestock were raised, it is now controlled through animal vaccination programs. Anthrax still occurs in countries where animals are not vaccinated, mainly in Africa and Asia. It does occur infrequently in many countries, including the United States. Human infection with anthrax usually results from direct contact with infected animals, or animal products such as wool, meat or hides. However, when anthrax is used as a biological weapon, people become infected by breathing anthrax that is released into the air. Inhalation anthrax is the disease that results from breathing anthrax. Under expected battlefield conditions, experts believe you can inhale enough anthrax spores to kill you in one deep breath. Symptoms of inhalation anthrax can begin as early as 24 hours after breathing the spores. Initial symptoms include: fever, cough, and weakness and usually progress to breathing problems, shock, and death.

WHY VACCINATE?

Vaccines prevent illness by stimulating the body's natural disease-fighting abilities. They are among the most powerful tools developed by modern medicine for keeping people healthy. Vaccines are routinely used in the United States to protect against diseases such as mumps, measles, whooping cough, and polio. As part of force protection, military personnel are given additional vaccines to protect against naturally occurring diseases encountered when deploying overseas, such as typhoid, hepatitis, and yellow fever. Vaccines also help protect against biological weapons.

The Department of Defense has established a vaccination program to protect military personnel against anthrax.

WHAT IS THE ANTHRAX VACCINE?

Anthrax vaccine is a sterile product made from filtrates of cultures of a strain of the anthrax organism that does not cause disease. The vaccine contains no living or dead anthrax organisms. The anthrax vaccine is not new. Human anthrax vaccines were developed in England and the U.S. in the 1950s and early 1960s. The anthrax vaccine you will receive was licensed by the FDA in 1970 and has been manufactured by the Michigan Biologic Products Institute (MBPI) under Establishment License No. 99. BioPort purchased MBPI in September of 1998 and will continue to manufacture the anthrax vaccine.

It has been safely and routinely administered in the United States to veterinarians, laboratory workers, and livestock handlers for more than twenty-five years.

FACTS ABOUT THE ANTHRAX VACCINE

- Vaccination is a critical part of protection against infection
- Manufactured in the United States
- Safely used for more than 25 years
- As with other vaccinations, pain may occur at the site of injection
- Temporary side effects (sore arm, redness, slight swelling, and a small nodule or knot under the skin) may occur.
- No known long term side effects
- Six shots are required over 18 months, followed by an annual booster

COMMONLY ASKED QUESTIONS & ANSWERS

Q: Why are we getting this vaccine?

A: Anthrax is a lethal weapon we may encounter. Vaccination before exposure is a critical part of our protection against this weapon.

Q: Is the vaccine all I need to protect against inhalation anthrax?

A: Vaccination is a vital component of Force Health Protection. Being fully vaccinated greatly increases the chances of surviving an exposure to anthrax. Force Health Protection is further enhanced through sophisticated early warning and detection systems, health surveillance measures, and the proper wear of the protective mask and overgarments.

Q: Is this an experimental vaccine?

A: No, Anthrax vaccine has been FDA approved since 1970.

IMAGE ONLY FILE. USE/VIEW DOCUMENT
FOR COMPLETE INFORMATION.

KEYWORDS

CMAT#: 1999242-0000003

WHAT EVERY PERSON NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE

Q: Is this vaccine safe?

A: Yes, this vaccine has been safely and routinely administered in the U.S. to veterinarians, laboratory workers, and livestock handlers since 1970. However, as with other vaccines, minor reactions and, to a lesser extent, more serious adverse reactions may occur in a small number of people.

Q: Is there anyone who should not receive the vaccine?

A: Anthrax vaccine should be administered only to healthy men and women from 18-65 years of age because investigations to date have been conducted exclusively in that population.

Q: What if I am pregnant, planning on becoming pregnant, or breast feeding?

A: Anthrax vaccine, like other inactivated vaccines, is not expected to cause fetal harm. No evidence exists that indicates any other adverse reproductive effects including fertility. Prudent medical practice is to defer all immunizations during pregnancy unless clearly needed. Therefore, pregnant women should not receive the anthrax vaccine unless anthrax exposure occurs or is imminent. Service members who believe that they may be pregnant are instructed to inform their health care provider. Anthrax imunizations will be deferred until the pregnancy is complete. A woman does not need to delay becoming pregnant or stop breastfeeding after receiving a dose of anthrax vaccine.

Q: What other medical conditions should I inform the medical staff about?

A: If you have an active infection or are taking a prescription medicine, inform your health care provider before taking this shot.

Q: The anthrax vaccine was administered to personnel deployed in the Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?

A: No. Several national scientific groups, including the National Academy of Sciences, have addressed this issue and have found no evidence to link anthrax vaccine with illnesses among Gulf War veterans.

Q: How many shots will I have to take?

A: Six shots, three given two weeks apart followed by three additional injections given at 6, 12 and 18 months. An annual booster shot is required to maintain ongoing immunity.

Q: What are the side effects?

A: The vaccine has been in use since 1970, and since that time there have been no long-term side effects identified or reported. However, as with other vaccinations or medications, pain may occur at the site of injection. Temporary side effects (sore arm, redness, and slight swelling) may occur. Small, non-tender nodules or knots under the skin at the site of injection occur in about 30% of vaccine recipients. These nodules usually disappear within a few weeks, but in some cases the process takes several months.

Q: How can I get more information about anthrax vaccine?

A: Your supervisor will have more information. In addition, more information on the anthrax vaccine can be accessed at the website:

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COMMONLY ASKED QUESTIONS & ANSWERS

Q: Why are we getting this vaccine?

A: Anthrax is a lethal weapon we may encounter. Vaccination before exposure is a critical part of our protection against this weapon.

Q: Is the vaccine all I need to protect against inhalation anthrax?

A: Vaccination is a vital component of Force Health Protection. Being fully vaccinated greatly increases the chances of surviving an exposure to anthrax. Force Health Protection is further enhanced through sophisticated early warning and detection systems, health surveillance measures, and the proper wear of the protective mask and overgarments.

Q: Is this an experimental vaccine?

A: No, Anthrax vaccine has been FDA approved since 1970.

IMAGE ONLY FILE. USE/VIEW DOCUMENT
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KEYWORDS

CMAT#: 1999242-0000004

WHAT EVERY FAMILY NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE

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Q: What other medical conditions could affect the use of this vaccine?

A: If a person has an active infection or is taking some prescription medications, a decision to give the vaccine will be made on a case by case basis.

Q: The anthrax vaccine was administered to personnel deployed in the Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?

A: No. Several national scientific groups, including the National Academy of Sciences, have addressed this issue and have found no evidence to link anthrax vaccine with illnesses among Gulf War veterans.

Q: How many shots will be given?

A: Six shots, three given two weeks apart followed by three additional injections given at 6, 12 and 18 months. An annual booster shot is required to maintain ongoing immunity.

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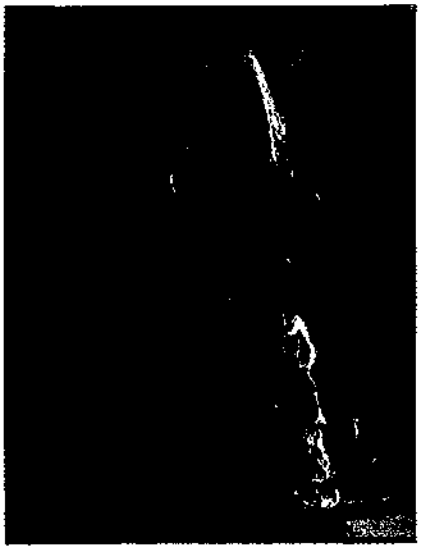
WHAT EVERY FAMILY MEMBER NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE



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COMMONLY ASKED QUESTIONS & ANSWERS

Q: Why are Service members getting this vaccine?

A: Anthrax is a lethal weapon that could be used against deployed personnel. Vaccination before exposure is a critical part of the protection against this weapon.

Q: Is the vaccine all that is needed to protect against inhalation anthrax?

A: Vaccination is a vital component of Force Health Protection. Being fully vaccinated greatly increases the chances of surviving an exposure to anthrax. Force Health Protection is further enhanced through sophisticated early warning and detection systems, health surveillance measures, and the proper wear of the protective mask and overgarments.

Q: Is this an experimental vaccine?

A: No, Anthrax vaccine has been FDA approved since 1970.

ANTHRAX VACCINE AND OTHER VACCINES

CURRENT ANTHRAX VACCINE PROGRAM:

- Anthrax: primary biological warfare threat faced by United States (US) forces.
- December 15, 1997: Secretary of Defense approved the plan to immunize the total force against anthrax.
- Vaccine was fully approved and licensed by the FDA in 1970.
- No evidence to link the vaccine to illnesses among Gulf War veterans. No long-term side effects reported.
- By 22 Sep 1999: 1,120,593 anthrax immunizations in 339,837 Service members. 193 written reports of adverse reactions (0.017 percent). 17 cases were hospitalized and 72 others missed 24 hours or more of duty.
- DoD policy: Personnel assigned or rotating to high threat areas, and those pre-designated for immediate contingency deployment to these areas, will be administered the anthrax immunization first. Eventually, the total force (including Reserve and National Guard) will be vaccinated as vaccine supplies permit.
- In response to expressed concerns, the Army conducted studies in 1999 that demonstrated: 1) anthrax vaccine contains no contaminating Mycoplasma fermentans bacteria; 2) vaccine and its preservatives will not permit the growth or survival of Mycoplasma deliberately put into vials of vaccine; 3) anthrax vaccine vials from 1991 and from the present do not contain the chemical squalene, as some have alleged.

COMPARISONS OF VACCINE PROGRAMS FOR GULF WAR: U.S. VS. UK:

	US Forces	UK Forces *
Anthrax	Some (~150,000)	Most (69 %) (Voluntary)
Botulinum Toxoid	Few (~8,000)	**NONE**
Cholera	Few	Some (31%)
Immune Globulin (for Hepatitis A)	Most	Few (8 %)
Influenza	Most	Few
Meningococcal	Most	Some
Pertussis	**NONE**	Some (36 %) (Voluntary) with Anthrax
Plague	**NONE**	Some (34 %)
Polio	Few	Few (16 %)
Tetanus	Some	Some (34 %)
Typhoid	Most	Some (25 %)
Yellow Fever	Some	Some (16 %)

* Specific percentages for UK Forces are derived from the published paper: Unwin, C. et al. Health of UK Servicemen Who Served in Persian Gulf War. Lancet (1999), 353: 169-178.

This paper surveyed UK Gulf War veterans and compared them with Bosnia veterans and non-deployed veterans of the Gulf era. Among the many findings were associations between increased risk of long term symptoms and: 1) vaccinations against BW agents (anthrax and plague);

2) receipt of many (7 or more) non-BW vaccinations; and,

3) recollections of vaccine side-effects at the time of receipt.

The authors could not explain these vaccine findings. Speculation about explanations includes:

1) effect of multiple vaccines on the immune system, (but no data confirm this);

2) an interaction between stress and the response to vaccination;

3) psychological mechanisms; and,

4) methodological limitations, including possible unreliable ascertainment of the exposures (recall of vaccines received) and the lack of a correction for the many statistical comparisons performed during analysis.

The authors have submitted a research protocol for funding to explore the explanation that the immune system may be affected by multiple vaccinations.

POINT PAPER (SEPTEMBER 1999)
THE USE OF PYRIDOSTIGMINE BROMIDE AS A PRETREATMENT FOR NERVE AGENT EXPOSURE

The purpose of this point paper is to briefly summarize four topics:

1. the DoD policy of using pyridostigmine bromide (PB) as a pretreatment for nerve agent exposure during the Gulf War;
2. the proposed DoD policy for using PB in future deployments, dated September 1999;
3. the main conclusions of the RAND report entitled *PB: A Review of the Literature as It Pertains to Gulf War Illnesses*, which will be published in October 1999; and
4. the potential impact that the RAND report could have on the scientific research being performed on PB and upon DoD policy on PB in future deployments.

DoD policy of using PB as a pretreatment for nerve agent exposure during the Gulf War

- During the Gulf War (GW), the US military and the UK military used PB as a pretreatment to protect personnel from death in the event of chemical warfare using the nerve agent soman. The number of US troops who took PB is estimated to be 250,000.

- PB is called a pretreatment because to be effective, it must be given before exposure to soman has occurred. PB is not effective alone. It confers benefit only if post-exposure treatments are given as well. Because soman exerts its lethal effects within two minutes of exposure, there is inadequate time for personnel to recognize the alarms of chemical agent detectors, to put on protective gear, and to inject the post-exposure treatments.

- PB was used as an "investigational new drug," (IND) during the GW, after the Food and Drug Administration (FDA) issued its Interim Final Rule in December 1990. This Rule permitted DoD to use two medical countermeasures that did not have full FDA approval, PB and the botulinum toxoid. This IND status is still in effect for PB, which means if DoD needs to use it in future deployments, FDA approval would be needed again. However, informed written consent for its use can be waived if the President exercises his authority under the 1998 Byrd Ammendment.

Proposed DoD policy for using PB in future deployments, dated September 1999

- DoD is seeking approval for an Action Memorandum, entitled "Policy on Use of PB as Pretreatment Adjunct for Soman or Tabun Nerve Agent Poisoning." This memo is currently being coordinated for concurrence and signatures.

- A specific DoD request to use PB must be approved by the Secretary of Defense, as long as it remains in IND status. This request must document a confirmed high threat of the use of soman or tabun by an enemy, consideration of the risks and benefits of potential PB use, and compliance with the requirements of the Action Memorandum.

- The use of PB, while in IND status, is subject to rigorous, special regulatory requirements of the FDA, concerning education and training, risk communication, logistical tracking,

extensive record keeping and reporting (e.g. on effectiveness and adverse effects), ethical review, and unless waived, informed consent of persons taking the drug.

- Informed consent for use of PB, while in IND status, may only be waived by the President, upon a request from the Secretary of Defense. PB use shall not be mandatory unless the President grants a waiver of the informed consent requirement. Such a waiver will require a demonstration of compelling need.

- In contrast to the American situation, PB was granted full approval for use as a nerve agent pretreatment in the UK in 1993. However, this approval will be considered for recertification in 1999, including evaluation of new data since 1993.

Main conclusions of the RAND report entitled *PB: A Review of the Literature as It Pertains to Gulf War Illnesses* (October 1999)

- The RAND report concludes that "PB cannot be ruled out as a possible contributor to the development of unexplained or undiagnosed illness in some GW veterans." The report points out that "data regarding chronic effects, particularly from low-dose exposures that do not produce acute symptoms, are meager and studies are frequently of poor quality."

- The RAND report also concludes that "uncertainties remain concerning the effectiveness of PB in protection of humans against nerve agents," but the "data regarding the efficacy of PB as a nerve agent pretreatment are not discussed in detail in this report."

Potential impact that the RAND PB report could have on scientific research and upon DoD policy in future deployments

- The RAND report lists six hypothetical mechanisms for the possible adverse effect of PB, which it concludes are valid candidates for PB research. (RAND concludes that a seventh hypothesis on bromism is highly unlikely.) Five of the six mechanisms are already the focus of funded GW-related research. DoD and VA have funded 22 studies (11 of which are completed) that focus specifically on the potential effects of PB, for a total of $12.4 million.

- The RAND report raises concern about the effectiveness of PB as a pretreatment. The RAND report states that "PB may reduce somewhat the effectiveness of post-exposure treatment for some non-soman nerve agents." One recommendation is: "Consistent strategies should be adopted for handling those who 'decline' to take PB when ordered."

- The RAND report does not include a comprehensive review of the abundant literature on the efficacy of PB as a pretreatment for soman exposure in non-human primates. The report also does not cite the data that PB doubles the efficacy of post-exposure treatments for tabun exposure.

- The RAND report raises concerns about the possible "detrimental" effects of PB when used before sarin or VX exposure. The US Army scientists who performed the sarin and VX studies concluded that the effects of PB could not be construed as detrimental,

because the differences in efficacy results of post-exposure treatments with and without PB were not medically significant.

DU TRAINING UPDATE PAPER (24 SEP 99)

The requirement for improved DU training has been recognized by DoD, the Services, and their respective medical, safety, operational, and training communities. Disparities in information and emphasis in pre-1998 DU training contained "mixed messages" about DU's hazard potential, detracting from the overarching objective of training servicemembers to respond safely and appropriately to battlefield DU contamination.

To address these issues, OSAGWI convened a Tri-Service DU Awareness Working Group that brought together Staff Representatives from each Service's and the Joint Staff's medical, safety, training, and operational communities. The group, which met in March and April, agreed that the new guidance and training had to:

a) characterize the DU "hazard" in clear, accurate terms
b) tell service members where and how they could encounter DU contamination
c) give service members the knowledge they needed to operate safely and effectively despite the presence of battlefield DU contamination

The Tri-Service DU Working Group agreed on the "essential elements of information" regarding DU, namely, that:

- The primary "hazard" from DU is its heavy metal toxicity, *not* its low level radioactivity
- In almost all cases, protective measures are not needed for depleted uranium contamination (or handling intact DU armor or unfired DU rounds)
- Standard field safety and basic field hygiene procedures will ensure soldier safety
- Protective measures may be required when:
  - In, on, or near (<50 meters) an armored vehicle when the vehicle is hit by DU munitions
  - Near (<50 meters) fires involving depleted uranium munitions explosions/fires (although standard guidance is to get at least 400 meters away from such fires)
  - Spending extended periods (hours daily for many days) entering and working inside DU damaged vehicles as part of your everyday duties

Using the best available dose assessment and health effects data, two additional points were added:

- Brief entries into DU-struck vehicles are safe
- Personnel wounded by DU *do not* pose a contamination hazard to first responders or treatment personnel, and first aid/medical treatment should *never* be delayed.

These primary, agreed-on points serve as a "corrected message" to be reflected in Tri-Service training and guidance.

The "DU Writer's Group" that developed the Army TSPs included representatives from the proponent branches (Chemical, Ordnance, etc.) as well as other stakeholder organizations. Technical writers and a trained risk communicator were retained, enabling precision in both language and concepts. Draft TSPs were staffed for formal review to the appropriate agencies and authorities, including the Undersecretary of the Army. As such, an unprecedented level of "buy-in" was obtained across the medical, safety, training, and operational spectrum.

TSP Tier I for general soldiers is being prepared for integration into the training syllabus at the appropriate training centers. An accompanying video, reflecting current information and guidance, is currently being fielded. Tiers II and III are currently being staffed.

The Tri-Service DU Awareness Working Group will reconvene in late Fall, 1999, to review training and implementation issues.

DEPLETED URANIUM INFORMATION PAPER

09/27/99

What is Uranium?

Uranium is a weakly radioactive element that occurs naturally in the environment. Each of us ingests and inhales natural uranium every day from the natural uranium in our air, water, and soil. The amount varies depending upon the natural levels found in the area you live and the levels found in the areas where the food you eat and the water you drink are produced. Consequently, each of us has some level of uranium in our body, which is eliminated in the urine. In areas where the natural uranium level in the soil or water is high, these levels can be substantially higher.

What is Depleted Uranium?

Depleted uranium (sometimes known as DU) is uranium that is 40% less radioactive than natural uranium, while retaining identical chemical properties. Depleted uranium is the most effective material for anti-armor penetrators because of its high density and the metallic properties that allow it to "self-sharpen" as it penetrates armor.

What are the health effects of Depleted Uranium?

The major health concerns about DU relate to its chemical properties as a heavy metal rather than to its radioactivity, which is very low. As with all chemicals, the hazard depends mainly upon the amount taken into the body. A recent RAND review of scientific literature reported, " Extensive information is available about the occupational exposure of workers in the uranium industry. No increase in overall deaths has been observed as a result of exposure to uranium in several epidemiological studies of workers exposed to uranium."

RAND also reported, "there are no peer-reviewed published reports of detectable increases of cancer or other negative health effects from radiation exposure to inhaled or ingested natural uranium at levels far exceeding those likely in the Gulf."

What DU follow-up program is available?

As part of follow-up efforts to ensure that Gulf War veterans who may have had the highest DU exposures receive appropriate evaluation and follow-up, DoD and VA have instituted a new program to identify, contact, and evaluate these individuals. This includes veterans who were riding in or on a vehicle that was struck by DU munitions or veterans who entered a struck vehicle immediately after it was hit by DU munitions. Also included are personnel who worked in or on US vehicles contaminated with DU. The follow-up protocol includes the standard Gulf War physical, an exposure questionnaire, and a 24-hour urine uranium test.

DEPLETED URANIUM INFORMATION PAPER

09/27/99

What is the status of DU follow-up efforts?

To date, 205 veterans have been referred to the VA and CCEP for DU follow-up, and an additional 168 have self referred, mostly to the VA. An estimated 100 additional veterans who meet the notification criteria are yet to be identified, located and notified.

As of the end of July, 1999, 141 urinalysis results had been reported; in all, eight are elevated. Five of the eight veterans with elevated results have been retested; and, of these, three have a second elevated result. Because of VA's confidentiality policy, only one of the three veterans with two elevated tests is known to OSAGWI. This veteran had embedded shrapnel from a DU friendly fire incident.

What are the UK's issues related to DU?

Due to the alarmingly high urine uranium levels reported in British veterans tested by Dr. Sharma of Canada, the UK is interested in participating in a quality assurance of the laboratories doing urine uranium evaluations. OSAGWI has taken some preliminary steps to set up such a program which would assess various methodologies for measuring total and isotopic urine uranium levels. Laboratories will be sent about 18 samples with known quantities of uranium in the range seen in Gulf War veterans. A qualified disinterested third party will tabulate the results and prepare a report assessing the merits of the various methodologies. A total of eight laboratories (including at least one in the UK) have agreed to participate in the program which would cost about $65K.

The UK is also interested in the GAO DU investigation. In August, 1999, the GAO met with the congressional staffs of all three GAO depleted uranium investigation requestors. As a result of these meetings, an agreement was reached on the methodology for answering each of the questions guiding the investigation. The GAO recently identified concerns calling into question the reliability of CHPPM's Level I dose assessment. Discussions are ongoing between CHPPM and a key research scientist at Picatinny Arsenal in an attempt to resolve differences in interpretation of research data bearing on this assessment. On another matter, the GAO is currently interviewing veterans who have been referred by OSAGWI for DU follow-up. They have identified about 17 veterans who indicated some problems with the follow-up procedure; about half having never been scheduled for an appointment. GAO's proposed timeline is to complete field work in December, submit a report to DoD in February and issue the report in March 2000.

KHAMISIYAH PIT DEMOLITION INCIDENT
(SA/DSA NOTES FOR MOD/GVIU MEETINGS)

Khamisiyah Pit Incident.

- A mixture of the chemical warfare nerve agents sarin (GB) and cyclosarin (GF) was released at 13:15 hours Greenwich Mean Time (16:15 local time), on March 10, 1991, as the result of the explosive demolition, by the 37th Engineer Battalion, of 122-millimeter rockets filled with the sarin/cyclosarin mixture and contained in stacked wooden crates at the open-air temporary munitions storage site, frequently referred to as the "pit", which is located outside of the actual Khamisiyah Ammunition Supply Point.

1997 Khamisiyah Modeling and Notification.

- In October 1996 the DoD was left with considerable uncertainty concerning the resultant fallout from the March 10, 1991 demolition in the Pit. DoD took a conservative position and announced that it would survey the estimated 20,000 veterans who were have thought to have been within 50 kilometers of Khamisiyah during the period of March1-15, 1991. Letters were sent to the 20,000 veterans urging them to call the Persian Gulf Incident Hotline with any additional information or report any illness they felt was attributable to their service in the Gulf War.
- DoD tasked the Institute of Defense Analysis (IDA) on November 2, 1996 to convene an independent panel of experts in meteorology, physics, chemistry and related disciplines. IDA reviewed the modeling done by the CIA and recommended using additional atmospheric models and data sources for modeling the Pit demolition.
- The DoD-CIA team used existing high quality models to develop the Khamisiyah-specific potential exposure areas. Different combinations of models were used to reduce model bias. The resultant hazard area was determined by presenting a composite (union) of the different modeling simulations-representing the overlay of the outermost perimeter of all models. Using the best unit locations data available then, DoD identified 98,910 troops who were within the combined area (the union) and were therefore possibly exposed during this period.
- The overall objective was to reasonably worst case the population for notification of potential low-level chemical warfare agent exposure to insure that the greatest number of veterans would be notified and given the opportunity to participate in the medical support programs established by both the DoD and the DVA.

Khamisiyah 1997 to 1999 Modeling Changes.

- Revised Source Term. The Intelligence Community has reduced the estimate of the total number of filled rockets destroyed at Khamisiyah by 55%, from 500 to 225. This decrement was validated against recently released UNSCOM data. All other values affecting the initial source term remain unchanged. Preliminary simulation runs indicate a reduction in the potential hazard area, as compared to that used for the 1997 notification effort.
- Toxicity of Agent Mixture. Cyclosarin is effectively two to three times as toxic as sarin. The 1997 effort assumed the mass of agent released to be all sarin, because there was 3 times more sarin than cyclosarin. The 1999 effort accounts for both the mixture of agents and their toxicity.

- General Population Limit. The 1997 outer contour of the notification hazard footprint was based on a calculation for a safe, low-level, sarin exposure over a persons lifetime, as extrapolated from a 72-hour air sample. The 1999 effort applies a more appropriate factor for a short-term one-time exposure, versus the inappropriate lifetime exposure calculation.
- Agent Degradation Factors. The 1997 input to the dispersion model simulations was not degraded by inclusion of particulate or gas deposition, nor by the atmospheric chemical reactions of hydroxylation and nitration. These effects are included in the 1999 runs, where appropriate.
- Contour Mapping Overlay. The 1999 hazard footprint will include the First Noticeable Effects (FNE) contour line to reflect the greater extending risk from the sarin/cyclosarin mixture. Also, the alarm threshold of the M8A1 Automatic Chemical Agent Alarm System will be reflected as an expanded view (zoom-in) along with the First Noticeable Effects (FNE) area.
- Unit Location Database. The U.S. Armed Services Center for Unit Records Research (USASCURR) compiled and continuously updates the locations and personnel databases. Current databases will be used to identify the units and associated personnel within the refined potential hazard area.

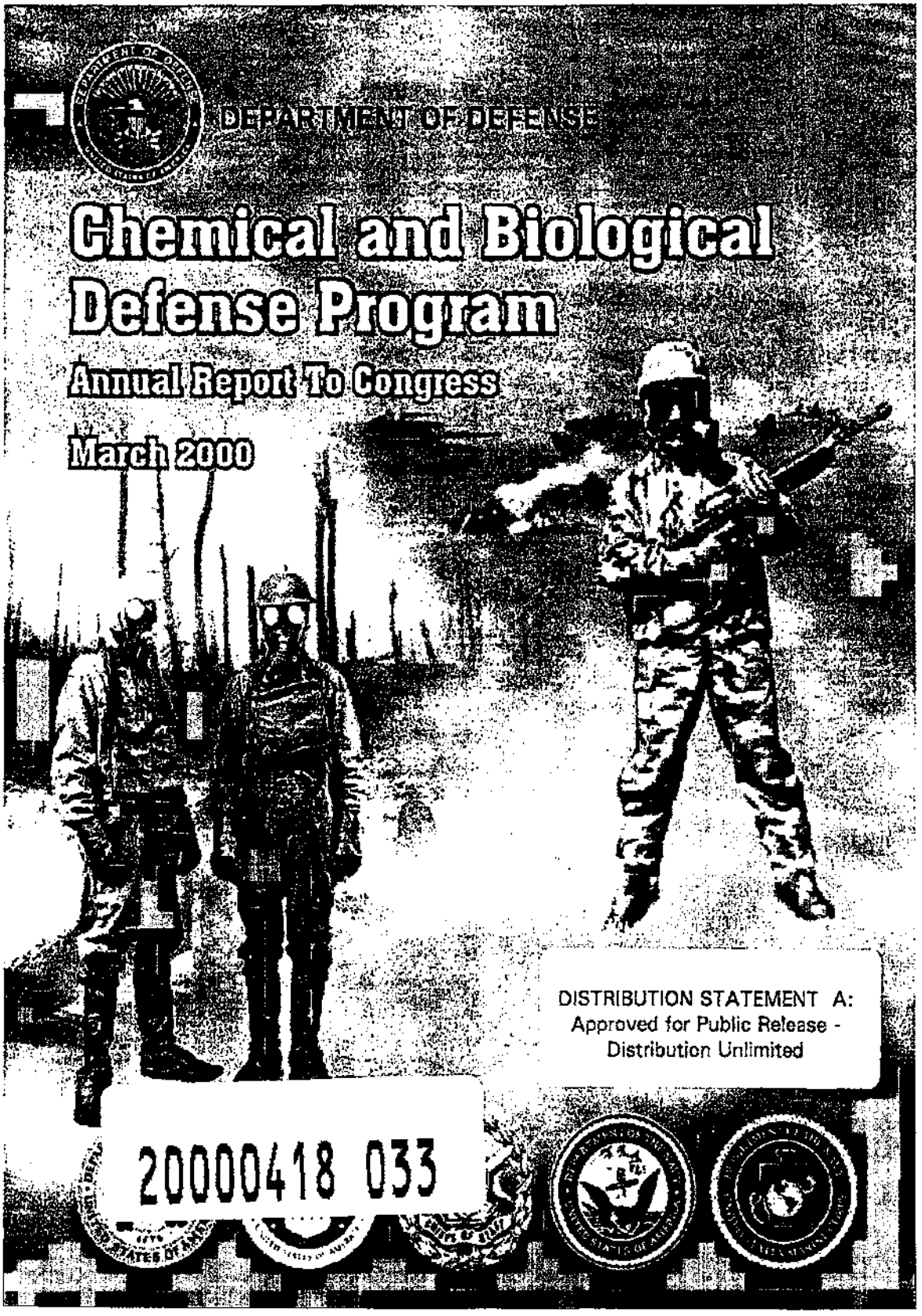
GVIU Khamisiyah Report.

- The GVIU is prepared to publish a report depicting UK unit locations under our 1997 hazard area and previously asked if they should delay the publication. They will ask this question again.
- We recommend they delay publication of their Khamisiyah report so it would reflect the results of our ongoing re-modeling. We should be able to provide to them the emerging results by October 15, 1999.
- If a delay in publication is untenable to them, we further recommended that their Khamisiyah report should reflect our 1997 modeling effort as a very conservative action to ensure notification of the largest number of military personnel potentially exposed.

Chemical and Biological Defense Program Annual Report to Congress

DEPARTMENT OF DEFENSE WASHINGTON DC

MAR 2000



Chemical and Biological Protection over the Century

The cover design illustrates chemical protective ensembles at the beginning of the century (World War I era chemical protective ensembles, shown on the left) and at the end of the century (the currently fielded Joint Service Lightweight Integrated Suit Technology ensemble with the M40 Protective Mask, shown on the right). The basic concept has changed little over a century (that is, prevent contact with the toxic agents). However, there have been significant improvements in the materials providing protective masks and ensembles that are more effective in protecting the individual, more durable, and less cumbersome for the wearer.

Executive Summary

The National Defense Authorization Act for Fiscal Year 1994, Public Law No. 103-160, Section 1703 (50 USC 1522), mandates the coordination and integration of all Department of Defense chemical and biological (CB) defense programs. As part of this coordination and integration, the Secretary of Defense is directed to submit an assessment and a description of plans to improve readiness to survive, fight and win in a nuclear, biological and chemical (NBC) contaminated environment. This report contains modernization plan summaries that highlight the Department's approach to improve current NBC defense equipment and resolve current shortcomings in the program. *50 USC 1522 has provided the essential authority to ensure the elimination of unnecessarily redundant programs, focusing funds on DoD and program priorities, and enhancing readiness.*

The objective of the Department of Defense (DoD) Chemical and Biological Defense Program (CBDP) is to enable our forces to survive, fight, and win in a chemically or biologically contaminated warfare environment. The DoD CBDP provides development and procurement of systems to enhance the ability of U.S. forces to deter and defend against CB agents during regional contingencies. The probability of U.S. forces encountering CB agents during worldwide conflicts remains high. An effective defense reduces the probability of a CB attack, and if an attack occurs, it enables U.S. forces to survive, continue operations, and win. Scientific, technological, and resource limitations remain in preventing U.S. forces from having complete full dimensional protection and meeting all requirements for two nearly simultaneous Major Theater Wars. The unique physical, toxicological, destructive, and other properties of each threat requires that operational and technological responses be tailored to the threat. Nevertheless, significant progress has been made in overcoming these limitations since the establishment of the DoD CBDP. Still, U.S. forces remain the best protected forces in the world for surviving and conducting operations in chemically or biologically contaminated environments.

During the past year, DoD took several steps to ensure the protection of U.S. forces against both immediate and future chemical and biological threats. This report details DoD's current and planned capabilities. Highlights from the past year include continuing immunization of all U.S. forces with the licensed anthrax vaccine, and continued enhancement of DoD CBDP funds to protect against validated and emerging threats through the far-term future.

Numerous rapidly changing factors continually influence the program and its management. These factors include declining DoD resources, planning for warfighting support to numerous regional threat contingencies, the evolving geopolitical environment resulting from the breakup of the Soviet Union, the entry into force of the Chemical Weapons Convention, and continuing proliferation of NBC weapons. To minimize the impact of use of NBC weapons on our forces, the DoD CBDP will continue to work towards increasing the defensive capabilities of Joint Forces to survive and continue the mission during conflicts that involve the use of NBC weapons. NBC defense programs are managed jointly under the oversight of a single office within DoD.

The program continues to implement congressional direction to improve jointness and reflects an integrated DoD developed program. This years program continues funding to support the highest priority counterproliferation initiatives. During the past year, the Department reviewed its capabilities to protect against the asymmetric threats from chemical and biological weapons. As a result of the review, funding was identified to enhance and accelerate high-payoff technologies and advanced CB defense systems. The FY0001 Presidents Budget Submission includes $380 million in increased research and development funding for biological warfare defense and vaccines over the FY 2000-05 Future Years Defense Program (FYDP), as well as additional FY 1999 Emergency Supplemental funding to procure CB defense equipment for the Guard and Reserves to support the Consequence Management mission. Moreover, the Department continues to procure new CB defense equipment for our forces, due in large measure to the May 1997 *Report of the Quadrennial Defense Review* (QDR) recommendation to increase planned spending on counterproliferation by $1 billion over the FY 19992003 program period, of which $732 million was allocated for chemical and biological defense efforts.

The DoD CBDP invests in technologies to provide improved capabilities that have minimal adverse impact on our warfighting potential. Joint and Service unique programs provide capabilities to support the framework of the three commodity areas of CB defense: Contamination Avoidance (detection, identification, warning/reporting, reconnaissance), Protection (individual, collective, medical support), and Decontamination. All of these capabilities integrated together as a system-of-systems are essential to avoid contamination and to sustain operational tempo on an asymmetric battlefield. Moreover, sound Joint doctrine and realistic training remain fundamental to our defense against chemical and biological weapons. In summary, the DoD CBDP is focusing on a jointly integrated, balanced approach to obtaining needed capabilities for our forces within affordability constraints.

OVERVIEW OF REPORT

The ***INTRODUCTION*** provides a background of the rationale and purpose of the DoD Chemical and Biological Defense Program (CBDP). This section summarizes the key counter-proliferation priorities and the current chemical and biological warfare threats to U.S. forces. Intelligence documents tailored to the threat are essential for developing and updating requirements for chemical and biological defense programs. Each chemical and biological defense research, development, and acquisition effort funded within the program responds to a defined or validated threat. Variations among chemical and biological agents and each agent's unique physical, toxicological, destructive, and other properties such as means of delivery require that operational and technological responses be tailored to the threat. Intelligence efforts continue to emphasize collection and analysis of nations' dual-use' chemical and biological industrial capabilities and develop the indications and warning of adversarial use of dual-use capabilities.

CHAPTER 1 describes the accomplishments, processes, and issues related to DoD CBDP management and oversight. Since the program's inception, DoD has made significant progress in improving the overall joint management and coordination of the NBC defense program, including integration of medical and non-medical chemical and biological defense programs. *50 USC 1522 has been a critical tool for ensuring the elimination of redundant programs, focusing funds on program priorities, and enhancing readiness.* This chapter outlines the changes within the oversight and management structure that have occurred as a result of the Defense Reform Initiative and the establishment of the Defense Threat Reduction Agency.

CHAPTER 2 provides information on non-medical NBC defense requirements and research and development programs. Requirements and the status of research and development assessments are described within the framework of the functional areas of NBC defense.

CHAPTER 3 provides information on medical NBC defense requirements and on research and development programs. Medical technologies are an integral part of providing individual protection both prior to, during and after a chemical or biological attack.

CHAPTER 4 provides an analysis of NBC defense logistics posture. The analysis reviews the status of quantities, characteristics, and capabilities and limitations of all fielded NBC defense equipment, industrial base requirements, procurement schedules, and problems encountered. Much of the information is based on the model of Joint Chemical Defense Equipment Consumption Rates (JCHEMRATES IV). Additional information is derived from the Joint NBC Defense Logistics Support Plan.

CHAPTER 5 assesses the status of NBC defense training and readiness conducted by the Services. Each of the Services' training standards and programs is reviewed. In accordance with Section 1702 of P.L. 103-160 (50 USC 1522) all chemical and biological warfare defense training activities of the Department of Defense have been consolidated at the United States Army Chemical School. This chapter also provides information on the move of the Chemical School from Fort McClellan, Alabama to Fort Leonard Wood, Missouri.

CHAPTER 6 provides information on the status of DoD efforts to implement the Chemical Weapons Convention (CWC), which was ratified by the United States and entered into force during 1997. This chapter also includes a summary of plans and activities to provide assistance to other countries in response to an appeal by another State Party to the CWC, pursuant to Article X of the CWC.

Finally, there are several ***ANNEXES*** to this report. ***Annexes A through D*** provide detailed information on Joint and Service-unique NBC defense equipment, including contamination avoidance, protection, decontamination, and medical programs. Detailed descriptions are provided for systems and equipment that have been fielded, are in production, or under development. ***Annex E*** provides a summary of funds appropriated, budgeted, and expended by the DoD CBDP. One of the successes of the DoD NBC Defense Program has been the consolidation of all DoD NBC Defense RDT&E and procurement program funds under defense-wide program elements, rather than throughout numerous Service accounts. ***Annex F*** provides a reference to NBC defense related sites on the internet. ***Annex G*** provides a statement regarding chemical and biological defense programs involving human subjects as required by 50 USC 1523. As detailed in the annex, no such testing has been conducted in over two decades and none is planned. ***Annex H*** provides the text of the congressional language requiring this report. ***Annex I*** provides a list of the many acronyms and abbreviations that are used throughout this report.

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Introduction

I. PURPOSE OF REPORT

In accordance with 50 USC 1523, this report provides Congress with an assessment of the overall readiness of the Armed Forces to fight in a chemical and biological warfare environment. This is the seventh report submitted under 50 USC 1523.*

II. GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

The following information outlines the vision, mission, values, and objectives of the DoD Chemical and Biological Defense Program in compliance with the GPRA.

Department of Defense Vision, Goals, and Objectives

The United States embraces several fundamental and enduring objectives: to maintain the sovereignty, political freedom, and independence of the United States with its values, institutions, and territory intact; to protect the lives and personal safety of Americans, both at home and abroad; and to provide for the well-being and prosperity of the nation and its people.

Achieving these basic objectives in an increasingly interdependent world requires fostering an international environment in which the spread of nuclear, biological, chemical, and other potentially destabilizing technologies is minimized. Key objectives that guide U.S. defense policy and planning include *shaping* the international environment through military engagement programs and activities, and *responding* to the full spectrum of crises with appropriately sized, positioned, and mobile forces. Of equal importance, the United Stated must prepare for an uncertain future by pursuing a focused modernization effort that maintains U.S. superiority in key warfighting capabilities.

It is the vision of the Department of Defense to:

- Field the best trained, best equipped, best prepared fighting force in the world.
- Support alliance and security relationships that protect and advance U.S. security interests.
- Advance national interests by working effectively with other federal agencies, Congress, and the private sector.
- Serve as a model of effective, efficient, innovative management and leadership.

* The text of 50 USC 1523, *Annual report on chemical and biological warfare defense*, (implemented as part of Public Law 103-160, the FY94 National Defense Authorization Act) is included at Annex H.

In support of this vision, the Department has established two corporate-level goals:

Goal 1. Shape the international environment and respond to the full spectrum of crises by providing appropriately sized, positioned, and mobile forces.

Goal 2. Prepare now for an uncertain future by pursuing a focused modernization effort that maintains U.S. qualitative superiority in key warfighting capabilities. Transform the force by exploiting the Revolution in Military Affairs, and reengineer the Department to achieve a 21st century infrastructure.

Chemical and Biological Defense Program Vision, Mission, Values, and Goals

The vision, mission, values, and goals of the DoD Chemical and Biological Defense Program (CBDP) support the Department of Defense vision and goals. The CBDP was established to coordinate and integrate the research, development, and acquisition (RDA) of chemical and biological defense materiel and systems to support the joint warfighting forces. The CBDP provides materiel and systems to support the activities of training, doctrine, and military operations. However, these activities are the responsibility of the Military Departments and the Commanders-in-Chief. The vision, mission, values, and goals of the CBDP are focused on RDA activities.

The DoD cannot strengthen its capabilities to survive, fight, and win in a CB contaminated environment simply by spending more money. DoD must use the limited resources to focus assets of the development and acquisition of materiel and systems to support the needs and prioritized requirements of the joint warfighting forces, and to defend against validated and credible threats to U.S. forces and assets.

Following is an overview of the direction of the CBDP. These ideas will be formalized in a performance plan that will be developed over the next year. This plan will provide guidance for the key planning documents of the CBDP, including the Modernization Plan, the Research, Development, and Acquisition Plan, the Logistics Support Plan, and other planning documents. These plans will incorporate specific program goals and performance measures, which will support the CBDP vision and increase the capabilities of the joint warfighting forces — not merely outline a spending plan.

CBDP Vision

Provide a jointly coordinated and integrated program within the Department of Defense for the research, development, and acquisition of capabilities to protect the joint warfighting forces and resources from the threat or use of chemical or biological warfare agents so that our personnel are the best equipped and best prepared fighting force in the world.

CBDP Mission

Provide chemical and biological defense capabilities to allow the military forces of the United States to survive and successfully complete their operational missions—from peacetime missions through two nearly simultaneous major theater wars—in battlespace environments contaminated with chemical or biological warfare agents.

CBDP Values

- **Deter the use of chemical and biological warfare agents.**
  – Deny the advantage of the potential effective use of any chemical or biological warfare agents through a system of capabilities to avoid, protect against, and sustain operations in a chemically or biologically contaminated environment — with only minimal performance degradation from either the effects of the agents or any protective equipment or medical countermeasures.
- **Ensure all capabilities provided respond to threats.**
  – Provide capabilities that address the highest priority chemical and biological agent threats, from immediate and validated threats through potential far term or emerging threats. Intelligence efforts must emphasize preparation of tailored intelligence documents that identify and assess threats from the the full spectrum of potential chemical and biological warfare agents, and include collection and analysis of nations' "dual-use" chemical and biological industrial capabilities and the indications and warning of adversarial use of dual-use capabilities. Tailored intelligence documents are essential for developing and updating requirements for CB defense programs.
- **Emphasize a Joint Service approach to chemical and biological defense research, development, and acquisition.**
  – Eliminate unnecessary redundancies among the Services and Defense Agencies, leverage common technologies and requirements, and provide capabilities for Service-unique missions. Ensure coordination among U.S. government agencies and among U.S. allies to field the best available chemical and biological defense capabilities.
- **Develop and acquire capabilities that are based on identified and prioritized requirements and mission needs.**
  – Ensure that acquisition planning is driven by operational requirements rather than by available funds or technology. However, cost, schedule, and performance should be optimized in all programs planning.
- **Maintain technological advantage over any potential adversaries and prevent technological surprise.**
  – Evaluate and leverage continuous improvements in the state-of-the-art in sciences and technology base.
- **Provide for a modernization strategy that minimizes CB casualties and provide capabilities to treat casualties and maximize return to duty.**

Chemical/Biological Defense Program Corporate-Level Goals

In order to pursue the mission of the CBDP, the following major goals have been established. Goals for specific technologies and systems will be developed during FY2000 and included in the CBDP Performance Plan. Following are key goals of the CBDP. (*Selected supporting capabilities are shown following each goal.*)

- View NBC warfare agents within the Theater Area of Operations – (*Early Warning and Stand-off Detection of NBC Agents*)
- Dominate the Battlespace through Reconnaissance, Surveillance, and Target Acquisition (RSTA) – (*NBC Reconnaissance Systems*)
- Enhance the situational awareness of Unit Battlespace – (*Automatic Point Detection of NBC Agents, and Modeling and Simulation*)
- Provide real-time hazard information to influence current operations – (*NBC Battle Management and Warning & Reporting*)
- Enhance personnel and equipment survivability – (*Individual Detection, Individual and Collective Protection, Medical defenses, Decontamination, and NBC contamination survivability*)
- Maintain ground, air and maritime Operational Tempo – (*Operational Decontamination and Collective Protection*)
- Sustain operations, recovery and reconstitution efforts – (*Training, Readiness, and Restoration Operations*)

All of the capabilities integrated together as a system-of-systems are essential to avoid contamination and to sustain operational tempo on an asymmetric battlefield. Sound Joint doctrine and realistic training remain fundamental to defense against NBC weapons.

The President's December 1999 report, *A National Security for a New Century*, emphasizes the three key elements of the executive branch's strategy as (1) to enhance our security with effective diplomacy and with military forces that are ready to fight and win; (2) to bolster America's economic prosperity; (3) to promote democracy abroad. U.S. forces must have numerous capabilities in order to respond and deploy quickly to various worldwide needs. Counterproliferation capabilities are required by forces to meet worldwide needs, and NBC defense is integral to counterproliferation capabilities. The Commanders-in-Chief have identified their priorities for counterproliferation capabilities. These priorities are shown in Table I-1. Capabilities which are supported by the NBC defense program are highlighted in **bold**. As currently identified, NBC defense capabilities are listed in four of the top five CINC priorities. *Individual protection* includes physical protection devices, medical immunization and prophylaxis, and NBC casualty medical treatment. *Collective protection* provides relief from sustained operations in full individual NBC protective equipment, shelters for sensitive equipment not easily decontaminated, and clean environments for operations that cannot be performed under NBC contaminated conditions. *Mitigating the effects of WMD use* includes capabilities for integrated NBC warning and reporting; thorough and rapid mobile intratheater decontamination; medical countermeasures (vaccines, antibiotics, antidotes, and pre-treatments); mobile and portable

detection and characterization devices (including stand-off); and mass casualty NBC treatment. *Detecting WMD* includes capabilities to locate and characterize the use of WMD.

Table I-1. Required CINC Counterproliferation Capabilities

1.	**Provide individual protection to forces and assist allies/coalition partners with relief from the effects of NBC**
2.	Intercept conventional delivery of WMD and control collateral effects
3.	**Provide collective protection to forces and assist allies/coalition partners with relief from the effects of NBC**
4.	**Mitigate the effects of WMD**
5.	**Detect** and monitor development, production, deployment, **employment of WMD**
6.	Communicate the ability/will to employ interdiction/response capabilities
7.	Determine vulnerabilities in WMD development, production, transfer, deployment, and employment
8.	Conduct off-site attack to destroy, disable, and deny WMD targets
9.	Establish and maintain relations with allies, and potential adversaries to discourage development, production, and use of WMD
10.	Seize, destroy, disable, and deny transport of WMD
11.	**Communicate the ability/will to employ defensive capabilities**
12.	Determine vulnerabilities in decision making process related to WMD
13.	Conduct information warfare to destroy, disable, and deny WMD
14.	Support treaties, export controls, and political/diplomatic efforts
15.	Provide alternatives to the pursuit of WMD
16.	Provide intelligence collection capabilities in support of USG non-proliferation efforts
17.	Conduct on-site attack to seize, destroy, disable, and deny WMD targets
18.	Provide personnel, training, materiel, and equipment to support security assistance
19.	Destroy, disable, and deny actor's non-WMD resources and capabilities

The response to the threat of NBC weapons must be based on the nature of this threat, not just where the threat occurs. A key part of DoD's strategy is to stem the proliferation of such weapons and to develop an effective capability to deal with these threats. To focus the response to the threat, DoD and the intelligence community have completed several classified reports providing threat assessments on chemical and biological threats to U.S. forces. To minimize the effect of these threats to U.S. forces, DoD continues to improve defensive capabilities. These continuing improvements also contribute to our overall deterrence by demonstrating to an adversary that use of NBC agents or weapons provides little or no military advantage. The DoD CB Defense Program continues to work towards increasing the capabilities of Joint Forces to survive and continue their mission during conflicts that may involve the use of NBC agents or weapons.

The number of nations with chemical and biological weapons (CBW) capabilities is not changing greatly, despite the implementation of the Chemical Weapons Convention. In addition, those countries with chemical weapons programs are adding agents and more sophisticated delivery systems. Similarly, the sophistication of CBW capabilities is increasing. Proliferation of weapons technology, precision navigation technology, nuclear (medical, power, and industrial applications), and CBW technology to developing nations presents the United States with a complicated national security challenge. Intelligence efforts include collection and analysis of nations' "dual-use" nuclear, chemical and biological industrial capabilities, and development of the indications and warning of adversarial use of dual-use capabilities. Tailored intelligence

documents are essential for developing and updating requirements for CB defense programs. Numerous threat documents tailored to the CB threat have been produced and are updated periodically. The Intelligence Community continues to review U.S. chemical and biological warfare intelligence requirements and assess the adequacy of intelligence assets to execute the required intelligence program.

III. THE CURRENT CHEMICAL AND BIOLOGICAL WARFARE THREAT

Northeast Asia

North Korea has been pursuing research and development related to biological warfare since the 1960s. Pyongyang's resources presently include a rudimentary (by Western standards) biotechnology infrastructure that is sufficient to support the production of limited quantities of toxins, as well as viral and bacterial biological warfare agents. In the early 1990s, an open press release by a foreign government referred to applied military biotechnology work at numerous North Korean medical institutes and universities dealing with pathogens such as anthrax, cholera, and plague. North Korea possesses a sufficient munitions-production infrastructure to accomplish weaponization of BW agents. North Korea acceded to the Biological Weapons Convention (BWC) in 1987.

By comparison, North Korea's chemical warfare program is believed to be mature and includes the capability, since 1989, to indigenously produce bulk quantities of nerve, blister, choking and blood chemical agents as well as a variety of different filled munitions systems. North Korea is believed to possess a sizable stockpile of chemical weapons, which could be employed in offensive military operations against the South. North Korea has also devoted considerable scarce resources to defensive measures aimed at protecting its civilian population and military forces from the effects of chemical weapons. Such measures include extensive training in the use of protective masks, suits, detectors, and decontamination systems. Though these measures are ostensibly focused on a perceived threat from U.S. and South Korean forces, they could also support the offensive use of chemical weapons by the North during combat. North Korea has yet to sign the Chemical Weapons Convention (CWC) and is not expected to do so in the near-term, due to intrusive inspection and verification requirements mandated by the agreement.

China possesses an advanced biotechnology infrastructure as well as the requisite munitions production capabilities necessary to develop, produce and weaponize biological agents. Although China has consistently claimed that it has never researched or produced biological weapons, it is nonetheless believed likely that it retains a biological warfare capability begun before acceding to the BWC.

China is believed to have an advanced chemical warfare program that includes research and development, production and weaponization capabilities. Its current inventory is believed to include the full range of traditional chemical agents. It also has a wide variety of delivery systems for chemical agents to include artillery rockets, aerial bombs, sprayers, and short-range ballistic missiles. Chinese forces, like those of North Korea, have conducted defensive CW

training and are prepared to operate in a contaminated environment. As China's program is further integrated into overall military operations, its doctrine, which is believed to be based in part on Soviet-era thinking, may reflect the incorporation of more advanced munitions for CW agent delivery. China has signed and ratified the CWC.

South Asia

India has a well-developed biotechnology infrastructure that includes numerous pharmaceutical production facilities bio-containment laboratories (including BL-3) for working with lethal pathogens. It also has qualified scientists with expertise in infectious diseases. Some of India's facilities are being used to support research and development for BW defense purposes. These facilities constitute a substantial capability for offensive purposes as well. India is a signatory to the BWC of 1972.

India also has an advanced commercial chemical industry, and produces the bulk of its own chemicals for domestic consumption. New Delhi ratified the CWC in 1996. In its required declarations, it acknowledged the existence of a chemical warfare program. New Delhi has pledged that all facilities related to its CW program would be open for inspection.

Pakistan has a capable but less well-developed biotechnology infrastructure than India. Its facilities, while fewer in number, could nonetheless support work on lethal biological pathogens. Moreover, Pakistan is believed to have the resources and capabilities necessary to support a limited offensive biological warfare research and development effort. Like India, Pakistan is a signatory to the BWC.

Pakistan has a less-well developed commercial chemical industry but is expected to eventually have the capability to produce all precursor chemicals needed to support a chemical weapons stockpile. Like India, Pakistan has numerous munitions systems which could be used to deliver CW agent, including artillery, aerial bombs, and missiles. Pakistan has ratified the CWC, but submitted a null declaration.

The Middle East and North Africa

Iran's biological warfare program, which began during the Iran-Iraq war, is now believed to generally be in the advanced research and development phase. Iran has qualified, highly trained scientists and considerable expertise with pharmaceuticals. It also possesses the commercial and military infrastructure needed to produce basic biological warfare agents and may have produced pilot quantities of usable agent. Iran is a signatory to the BWC of 1972.

Iran initiated a chemical weapons program in the early stages of the Iran-Iraq war after it was attacked with chemical weapons. The program has received heightened attention since the early 1990s with an expansion in both the chemical production infrastructure as well as its munitions arsenal. Iran currently possesses munitions containing blister, blood, and choking agents and may have nerve agents as well. It has the capability to deliver CW agents using artillery shells and aerial bombs. Iran has ratified the CWC, declared agents and chemical agent

production facilities, and is obligated to open suspected sites to international inspection and eliminate its CW program.

Prior to the Gulf War, *Iraq* developed the largest and most advanced biological warfare program in the Middle East. Though a variety of agents were studied, Iraq declared anthrax, botulinum toxin, and aflatoxin to have completed the weaponization cycle. During the Gulf War, coalition bombing destroyed or damaged many key facilities associated with BW activity. However, it is suspected that a key portion of Iraq's BW capability, in the form of agent-filled munitions, was hidden and may have subsequently escaped damage. Nonetheless, Iraq declared, after the war, that all BW agent stockpile and munitions were unilaterally destroyed. United Nations Special Commission (UNSCOM) activity has, however, revealed this assertion as well as many others related to BW activity, to be inaccurate and misleading. As with its chemical program, Iraq intends to re-establish its BW capabilities if afforded the opportunity by the relaxation or cessation of UNSCOM inspection activity.

Iraq had a mature chemical weapons program prior to the Gulf War that included a variety of nerve agents, such as tabun (GA), sarin (GB), and GF, as well as the blister agent mustard, available for offensive use. Iraq also undertook a program, begun in 1985 and continuing uninterrupted until December 1990, to produce the advanced nerve agent VX. Recent UNSCOM findings indicate that Iraq had weaponized VX in Al Hussein missile warheads. Although Iraq's chemical warfare program suffered extensive damage during the Gulf War and subsequently from UNSCOM activity, Iraq retains a limited capability to re-constitute key parts of its chemical warfare program. Moreover, UNSCOM, despite having destroyed over 700 metric tons of agent, is still unable to verify elements of Iraqi declarations such as the disposal of chemical precursors, as well as the destruction of all chemical munitions. The comprehensive nature of Iraq's previous chemical warfare activity and the consistent pattern of denial and deception employed by Iraqi authorities indicate a high-level intent to rebuild this capacity, should Iraq be given the opportunity.

Syria has a limited biotechnology infrastructure but could support a limited biological warfare effort. Though Syria is believed to be pursuing the development of biological weapons, it is not believed to have progressed much beyond the research and development phase and may have produced only pilot quantities of usable agent. Syria has signed, but not ratified, the BWC.

Syria has a mature chemical weapons program, begun in the 1970s, incorporating nerve agents, such as sarin, which have completed the weaponization cycle. Future activity will likely focus on CW infrastructure enhancements for agent production and storage, as well as possible research and development of advanced nerve agents. Munitions available for CW agent delivery likely include aerial bombs as well as SCUD missile warheads. Syria has not signed the CWC and is unlikely to do so in the near future.

Libya's biological warfare program is believed to remain in the early research and development phase. Progress has been slow due in part to an inadequate scientific and technical base. Though Libya may be able to produce small quantities of usable agent, it is unlikely to

transition from laboratory work to production of militarily significant quantities until well after the year 2000. Libya acceded to the BWC in 1982.

Libya has experienced major setbacks to its chemical warfare program, first as a result of intense public scrutiny focused on its Rabta facility in the late 1980s and more recently on its Tarhuna underground facility. Nevertheless, Libya retains a small inventory of chemical weapons, as well as a CW agent production capability. Prior to closing its Rabta plant in 1990, Libya succeeded in producing up to 100 tons of blister and nerve agent at the site. Although the site was re-opened in 1995, ostensibly as a pharmaceutical plant, the facility is still believed capable of producing CW agents. CW-related activities at the Tarhuna site are believed to be suspended. Libya has not ratified the CWC and is not likely to do so in the near future.

Independent States of the Former Soviet Union

The former Soviet offensive biological warfare program was the world's largest and consisted of both military facilities and nonmilitary research and development institutes. Nonmilitary activity was centrally coordinated and performed largely through a consortium of institutes known as Biopreparat. This network of facilities was created in 1973 as a cover for activity related to biological warfare. This huge organization at one time employed up to 25,000 people and involved nearly 20 research, development and production facilities. The Russian government has committed to ending the former Soviet BW program, although serious questions about offensive BW capabilities remain. Key components of the former program remain largely intact and may support a possible future mobilization capability for the production of biological warfare agents and delivery systems. Moreover, work outside the scope of legitimate biological defense activity may be occurring at selected facilities within Russia. Such activity, if offensive in nature, would contradict statements by top Russian political leaders that offensive activity has ceased.

While former Soviet biological warfare facilities existed in Ukraine, Kazakhstan, and Uzbekistan, none are currently active. Moreover, the governments in these new republics are not believed to have plans to establish any future BW capability. Also, Belarus has no program and no intention of establishing one. Ukraine, Belarus, and Uzbekistan have ratified the BWC, while Kazakhstan has not yet signed it.

Russia has acknowledged the world's largest stockpile of chemical agents, amounting to approximately 40,000 metric tons. This stockpile, consisting mostly of weaponized agent includes artillery, aerial bombs, rockets, and missile warheads. Actual agents include a variety of nerve and blister agents. Additionally, some Russian chemical weapons incorporate agent mixtures, while others have added thickening materials in order to increase agent persistence. Russian officials do not deny that CW research has continued but claim that it is for defensive purposes and therefore not proscribed by the CWC. Many of the components for new binary agents developed under the former-Soviet program have legitimate civilian applications and are not considered on the CWC's schedule of chemicals.

PROLIFERATION

The United States faces a number of regional proliferation challenges. Many of these are detailed in the November 1997 report published by the Office of the Secretary of Defense, *Proliferation: Threat and Response.* In the Middle East, Iran continues with a concerted effort to acquire an independent production capability for all aspects of its chemical weapons program and has reduced dependency on foreign assistance. China remains a key supplier of technologies and equipment for several Middle Eastern chemical warfare programs and may play a pivotal role in determining whether these countries attain their goals of independent production for these weapons. Iran is pursuing a program to purchase dual-use biotech equipment from other countries, ostensibly for civilian uses. Russia is a key source of biotechnology for Iran. Russia is an especially attractive target for Iranians seeking technical information on BW agent production processes.

Australia Group

The proliferation of chemical and biological warfare related technology remains a critical threat to peace and stability throughout the world. One mechanism through which industrialized countries have agreed to control the proliferation of key chemical and biological warfare-related technologies is the Australia Group. The Australia Group (AG) is a consortium of countries organized to slow the proliferation of chemical and biological warfare programs through the imposition of multilateral export controls. Initial efforts of this group began in June 1985 and focused on precursor chemicals used in the manufacture of chemical agents. However, convinced of the threat posed from biological weapons, AG countries subsequently agreed, in December 1992, to also control the sale of items that most likely could be used to develop biological agents and weaponry. The AG adopted a list of human pathogens consisting of 37 organisms, 10 toxins and associated genetically modified organisms, and a seven-item BW dual-use equipment list. In addition, the AG later adopted animal and plant pathogen lists in recognition of the threat posed from anti-crop and anti-animal biological warfare.

Proliferation of chemical and biological warfare technology in South Asia also raises several important issues. India has exported a wide array of chemical products, including Australia Group-controlled items, to numerous countries of proliferation concern in the Middle East. The controlled items include specific chemical agent precursors, pathogens with biological warfare applications, and dual-use equipment which can be used in both chemical and biological warfare programs. Pakistan, on the other hand, may be seeking to upgrade key parts of its biotechnology infrastructure with dual-use equipment and expertise. Such acquisition efforts would reflect Pakistan's less-well developed biotechnology infrastructure.

In North Africa, Libyan efforts to acquire foreign equipment and expertise related to biological warfare have been dealt a severe blow, largely because of UN sanctions. Due to the international community's encompassing restrictions on exports to Libya, efforts to proceed beyond laboratory-scale research and development related to biological warfare will be difficult.

OUTLOOK

In the next 10 years, the threat from the proliferation of CBW weapons will certainly increase. This will result from the development of chemical and biological agents that are more difficult to detect and from the adoption of more capable delivery systems.* DoD expects that more states with existing programs will master the production processes for complete weapons and will be less dependent on outside suppliers. States will be more proficient at incorporating chemical or biological agents into delivery systems and will be focusing on battlefield training as well as employment strategy and doctrine. Therefore, the threshold of some states to consider using these capabilities may be lowered.

DoD does not expect significant increases in the number of government-sponsored offensive CBW programs. Nevertheless, the United States and its allies must be alert to this possibility as well as to the apparent growing interest in CBW on the part of sub-national groups such as terrorist organizations. Any nation with the political will and a minimal industrial base could produce CBW agents suitable for use in warfare. Efficient weaponization of these agents, however, does require design and production skills usually found in countries that possess a munitions development infrastructure or access to such skills from cooperative sources. On the other hand, crude agent dispersal devices could be fabricated by almost any nation or group. Such weapons might be capable of inflicting only limited numbers of casualties; nevertheless, they could have significant operational repercussions due to the psychological impact created by fears of CBW agent exposure.

* An assessment of potentially new biological agents that may challenge U.S. forces is in a DoD report to Congress entitled *Advances in Biotechnology and Genetic Engineering: Implications for the Development of New Biological Warfare Agents*, June 1996.

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Chapter 1

DoD Chemical and Biological Defense Program Management and Oversight

1.1 INTRODUCTION

In compliance with public law, chemical and biological defense programs within the Department are overseen by a single office within the Office of the Secretary of Defense. The vision and mission of the Department's Chemical and Biological Defense Program are outlined in the introduction of this report. A key value in support of the program vision is to emphasize a Joint Service approach to chemical and biological defense research, development, and acquisition. This value provides a process that eliminates unnecessary redundancies among the Services, leverages common technologies and requirements, provides capabilities for Service-unique missions, and coordinates among U.S. government agencies and U.S. allies to field the best available chemical and biological defense capabilities. This chapter provides an overview of the processes involved in the oversight, management, and execution of the Chemical and Biological Defense Program.

1.2 MANAGEMENT IMPLEMENTATION EFFORTS

The Department of Defense (DoD) implemented a process to consolidate, coordinate, and integrate the chemical and biological (CB) defense requirements of all Services into a single DoD CB defense program. Additionally, DoD continues to refine organizations and processes to ensure close and continuous coordination between the Chemical Biological Warfare Defense program and the Medical Chemical Biological Defense program.

Through the Joint Service Agreement on NBC Defense, the Military Services have established a viable structure that ensures that Service operational needs are fully integrated and coordinated from their inception and that duplication of effort is eliminated from NBC defense research, development, and acquisition. The series of reviews conducted by the Joint Service Integration Group and the Joint Service Materiel Group, both separately and together, have proved to be an appropriate organizational method to accomplish the coordinating and integrating function. Section 1.3 details organizational relationships within the DoD CBDP. Section 1.4 highlights organizational relationships between the CBDP and related organizations within the Department of Defense, with other U.S. Government organizations, and international efforts with U.S. allies.

1.3 ORGANIZATIONAL RELATIONSHIPS

The CB Defense Program management structure, portrayed in Figure 1-1 represents the structure of the program coordination and integration. This management and oversight structure

was developed in late 1996 to provide integration of medical and non-medical CB defense efforts at the Service level. Integration of CB defense efforts continued in 1999.

The Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense, DATSD(CBD), as a deputy to the Director, Defense Research & Engineering (DDR&E), is responsible for the overall coordination and integration of all CB defense research, development, and acquisition (RDA) efforts. DATSD(CBD) provides the overall guidance for planning, programming, budgeting, and executing the CB defense program.

DATSD(CBD) remains the single office within OSD responsible for oversight of the DoD CB Defense Program. DATSD(CBD) retains approval authority for all planning, programming, and budgeting documents. DATSD(CBD) is responsible for ensuring coordination between the medical programs and the non-medical CB defense efforts, and management oversight of the DoD CBDP in accordance with 50 USC 1522.

The DATSD(CBD) is also the Executive Secretary of the OSD NBC Defense Steering Committee (see Figure 1-1.) The OSD NBC Defense Steering Committee provides direct oversight of the DoD Chemical and Biological Defense Program. The OSD NBC Defense Steering Committee is composed of the following members: (1) DDR&E, (2) Director, Defense Threat Reduction Agency (DTRA), (3) Director, Chemical Biological Defense Directorate, DTRA, (DTRA(CB)), and (4) DATSD(CBD). The OSD NBC Defense Steering Committee is overseen by the Under Secretary of Defense for Acquisition, Technology, and Logistics, USD(AT&L), who currently serves as the Acting ATSD(NCB). The Steering Committee provides the fiscal and programming guidance to the Joint NBC Defense Board (JNBCDB) to develop the POM. The JNBCDB issues POM Preparation Instructions to the subordinate groups, which review the validated requirements and build the POM strategy recommendations.

The CBDP is divided into six commodity areas, with each commodity area being managed by one of the Services in accordance with the Joint Service Agreement, as follows:

Commodity Area	Commodity Area Manager
Contamination avoidance	Army
Individual protection	Marines Corps
Collective protection	Navy
Decontamination	Air Force
Medical defense	Army
Modeling & simulation	Navy

The commodity areas correspond to the projects under the budget program elements. There is also a program budget element to support program management and oversight, user testing (*i.e.*, Dugway Proving Grounds), and doctrine development in accordance with the Joint Service Agreement. The JSIG is the principal steering group that oversees the coordination and integration of Service and CINC requirements and priorities for RDT&E and initial procurement. The JSMG is the principal steering group that manages the execution of RDT&E materiel

development efforts to ensure that program risk is mitigated across commodity areas, and the ongoing efforts are complementary but not duplicative.

The Secretary of the Army is the Executive Agent for the CBDP and is responsible to coordinate, integrate, and review all Services' CB defense requirements and programs. The Secretary has delegated this responsibility to the Assistant Secretary of the Army for Acquisition, Logistics, and Technology, ASA(ALT), who along with the Vice Chief of Staff of the Army, co-chairs the Joint NBC Defense Board. The military departments' acquisition organizations execute the individual CB defense programs according to Service and DoD directives.

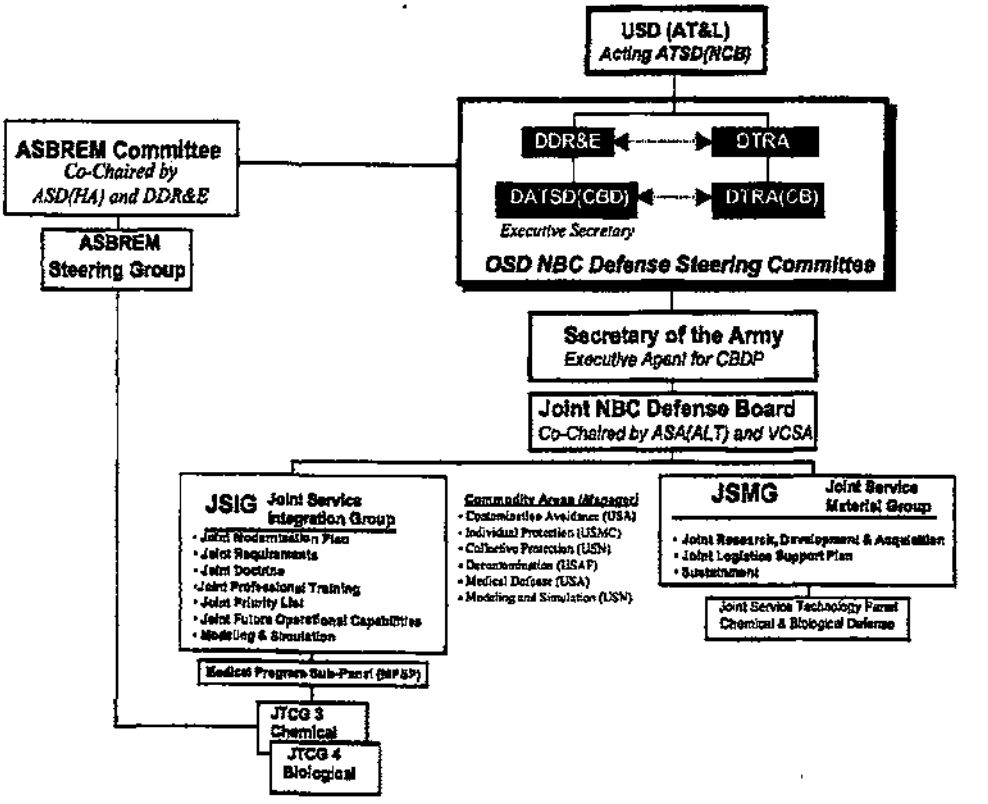

Figure 1-1 CBDP Management & Oversight

A Medical Program Sub-Panel (MPSP) has been implemented as part of the JSIG. The purpose of the MPSP is to identify medical program needs and requirements as developed by the CINCs, Services, Joint Staff, the ASBREM Committee, and other users. The Armed Service

Biomedical Research Evaluation and Management (ASBREM) Committee is co-chaired by the Assistant Secretary of Defense for Health Affairs (ASD(HA)) and the Director Defense Research and Engineering (DDR&E) and includes the Joint Technology Coordination Group (JTCG) 3 (Medical Chemical Defense Research Program) and JTCG 4 Medical Biological Defense Research Program). The MPSP has the primary responsibility for prioritizing medical NBC defense requirements. The users JTCG 3 (Medical Chemical Defense Research Program), JTCG 4 (Medical Biological Defense Research Program) and JTCG 7 (Nuclear) provide input of medical requirements (separate from non-medical requirements) to the MPSP. The MPSP coordinates, integrates, and prioritizes all of the user requirements input. It provides the consolidated, integrated, and prioritized list of medical NBC defense requirements to the JSIG. The first priority listing was submitted 14 May 1999 to the JSIG. The JSIG then submits both the medical and non-medical requirements to the JNBCDB. The JSIG provides comments but makes no changes to the list when submitting the medical requirements to the JNBCDB. The JNBDB and the OSD NBC Defense Steering Committee may make changes to the medical or the non-medical requirements and priorities lists.

1.4 COORDINATION WITH RELATED PROGRAMS AND INITIATIVES

The DoD Chemical and Biological Defense Program coordinates efforts with other U.S. government agency and with other countries to achieve the vision of equipping U.S. forces with the best available chemical and biological defense equipment. This section provides an overview of some key cooperative efforts.

1.4.1 Other U.S. Government Agencies

There are several organizations within the U.S. government developing chemical and biological defense technologies. Three organizations with which the CBDP currently has formal coordination efforts include: (1) the Defense Advanced Research Projects Agency (DARPA), (2) the Technical Support Working Group (TSWG), (3) the Department of Energy (DOE) Chemical and Biological Nonproliferation Program (CBNP). An overview of these programs is provided below. There also are other governmental agencies with chemical and biological defense related programs with which the CBDP maintains various levels of coordination and cooperation. These include the U.S. Department of Agriculture, the Center for Disease Control and Prevention, and the Department of Justice, among others.

1.4.1.1 DARPA Biological Warfare Defense Program. The Defense Advanced Research Projects Agency (DARPA) is charged with seeking breakthrough concepts and technologies that will impact our national security. DARPA's Biological Warfare (BW) Defense Program is intended to complement the DoD CB Defense Program by anticipating threats and developing novel defenses against them. The DARPA program is unique in that its focus is on the development of technologies with *broad applicability* against *classes* of threats. DARPA invests primarily in the early technology development phases of programs, with rapidly decreasing involvement in the succeeding stages that lead to system development and deployment.

The FY98 National Defense Authorization Act directed the Secretary of Defense to ensure that the DARPA biological warfare defense program is coordinated and integrated under the program management and oversight of the DoD CBDP. The DARPA BW Defense Program coordinates its efforts with a large number of organizations, including the DATSD(CBD) through regular briefings to both DATSD(CBD) and DTRA(CB) and by participation in the Technology Area Review and Assessment (TARA) process. The Advanced Diagnostics portion of the DARPA BW Defense Program is closely coordinated with the U.S. Army Medical Research and Materiel Command (MRMC) and maintains representation on the recently formed Common Medical Diagnostic Systems Executive Committee. A panel of chemical and biological defense experts is routinely consulted by DARPA to evaluate programs and to ensure that National Institutes of Health (NIH) efforts are not being duplicated. DARPA representatives actively serve on the Joint Service Technology Panel for Chemical and Biological Defense (JSTPCBD) and attend CBDP committee meetings, such as ASBREM sub-committee meetings. DARPA also participates in the BW Seniors Group, which provides Government coordination outside of DoD and works closely with the military Services to ensure that technologies are effectively transitioned into the hands of the user community.

1.4.1.2 Technical Support Working Group (TSWG). The mission of the TSWG is to conduct the national interagency research and development program for combating terrorism through rapid research, development and prototyping. TSWG objectives are: (1) to provide an interagency forum to coordinate R&D requirements for combating terrorism, (2) to sponsor research and development not addressed by individual agencies, and (3) to promote information transfer. The Department of State oversees the TSWG, and the Assistant Secretary of Defense for Special Operations and Low Intensity Conflict, ASD(SO/LIC), provides executive program direction. The Department of Defense provides program management for the TSWG. However, the TSWG coordinates with nearly all executive branch agencies, with state and local agencies, and with U.S. allies.

In support of its combating terrorism mission, the TSWG has established eight sub-groups, each of which is chaired (or co-chaired) by different federal agencies. One of the sub-groups — Chemical, Biological, Radiological, Nuclear Countermeasures (CBRNC) — is co-chaired by the Federal Bureau of Investigation (FBI) and the Central Intelligence Agency (CIA). The CBRNC sub-group is charted to (1) identify and prioritize interagency requirements related to chemical, biological, radiological, and nuclear terrorism, and (2) identify and recommend potential solutions to meet user requirements in detection, protection, decontamination, containment, mitigation, and disposal.

The DoD CBDP and TSWG coordinate requirements to maximize technology development cooperation, thus avoiding unnecessary redundancy. The scope and mission of the TSWG, however, often requires different technologies to satisfy user requirements. The TSWG CBRNC sub-group is funded annually at approximately one percent of the level of total CBDP funding.

1.4.1.3 DOE Chemical and Biological Nonproliferation Program (CBNP). The CBNP was established in 1997 in response to the *Defense Against Weapons of Mass Destruction Act* ("Nunn-Lugar-Domenici") passed by Congress in 1996. The CBNP was established to ensure the full engagement of the DOE National Laboratories in responding to the threat posed by chemical and biological weapons to U.S. civilians. The strategy of the CBNP relies on close linkages between technology development and systems analysis and integration to systematically and comprehensively address the domestic chemical and biological terrorism threat. The CBNP is comprised of three key components:

- Definition of operational needs to guide the development and implementation of enhanced preparedness and response systems.
- Use of accelerated system demonstrations to enable rapid fielding of the best available systems and technologies to meet critical needs.
- Development of individual technologies to enhance capabilities across the full spectrum of chemical and biological threats.

Many technologies under development may support both CBNP and CBDP missions. There are formal agreements between the CBNP and CBDP to ensure that efforts are coordinated and duplication is avoided. Some cooperative efforts include DOE representation on the Joint NBC Defense Board as a non-voting member, DOE participation in the Technology Area Review and Assessment (TARA) of science and technology base programs, and DoD participation in the annual CBNP program review.

1.4.2 International Cooperation

The CBDP participates in numerous international cooperative and collaborative efforts to leverage technology development and to achieve commonality, interoperability, and systems integration among U.S. allies and coalition partners. (In addition, there are numerous cooperative efforts in doctrine and training, which are described in Section 5.2 of this report.) In order to exchange information or conduct government to government cooperation, an appropriate agreement must be in place. Types of agreements include (1) Data Exchange Agreements (DEAs), (2) Foreign Military Sales, (3) Engineer and Scientist Exchange Programs, (4) Foreign Comparative Testing, (5) Technology Development Project Agreements, and (6) long-term Memoranda of Understanding (MOU).

During FY99, the United States participated in numerous international cooperative research and development efforts. Highlights of these efforts include (1) 50 DEAs with 15 countries, (2) two Technology Development Project Agreements, (3) one MOU, and (4) over 100 scientists and engineers participating in exchange programs. In addition, there are three Technology Development Project Agreements currently in discussion phase and an additional MOU in negotiation.

All cooperative agreements yield benefits to all participants in the agreement. Some key systems within the CBDP were procured through Foreign Military Sales, including the Improved Chemical Agent Monitor (ICAM), the NBC Reconnaissance System (Fox Vehicle), components

of the Biological Integrated Detection Systems, and the Automatic Chemical Agent Detector and Alarm (ACADA). In addition, there have been numerous CB defense capability gains during FY98 and FY99 as a result of international cooperation. Examples include:

- Ability to Detect and Identify Bacterial Spores
- Enhancement of Downwind Hazard Model
- First Generation Urban Dispersion Model
- Laser Standoff Chemical Detection Technology
- Next Generation Medical Countermeasures
- Encapsulated Antibiotics
- Multivalent Botulinum Toxin Vaccine
- Improved Plague Vaccine
- Report on Coalition CB Detection Capability to CENTCOM
- Current Detector/Monitor Technology
- CS Riot Control Capability on Light Vehicles
- Urban Field Trial
- Test and Procurement of Child/Infant CB System (USFK)
- Generic Individual Protection in Hot/Dry Environments
- Standardized Test for Individual Protection
- Standards for Measuring Biological Backgrounds
- Joint Medical Procedures in a BW Contaminated Environment

1.5 TECHNOLOGY BASE REVIEW AND ASSESSMENT

The DATSD(CBD) is the DDR&E office responsible for chemical and biological defense programs science and technology base programs. DATSD(CBD) provides technical oversight of all Service and Defense Agency chemical and biological defense science and technology base (S&T) programs and reviews these programs. The Joint Service Technology Panel for Chemical and Biological Defense (JSTPCBD), chaired by DTRA(CB), coordinates all Service science and technology base activities for the JSMG. DTRA(CB) prepares the relevant chemical and biological defense portions of two key documents detailing DoD S&T efforts — the Joint Warfighting S&T Plan (JWSTP) and the Defense Technology Area Plan (DTAP). These reports are submitted to Congress separately in accordance with public law.

1.6 FUNDS MANAGEMENT

Figure 1-2 describes the funds management and execution process for the CB defense program and the coordination between funding and executing organizations. The key organizations in this process are: DATSD(CBD) as the OSD focal point; the JNBCDB Secretariat representing the Executive Agent; the funds manager is the Defense Threat Reduction Agency (DTRA); the JSMG as coordinator and interface between the participating organizations; and the operating agencies and performers which execute the programs. For budget distribution, the JNBCDB Secretariat provides funds distribution information to DATSD(CBD) based on the appropriated budget. The DATSD(CBD) prepares funds suballocation instructions (with

support provided by DTRA(CB)) and submits them to the DTRA Comptroller for distribution to the operating agencies.

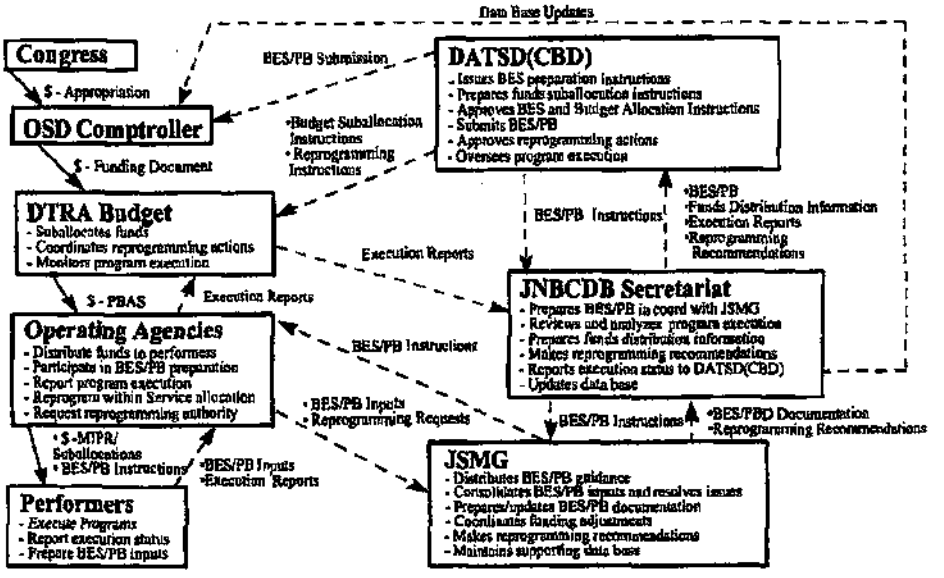

Figure 1-2. Chemical and Biological Defense Funds Management Process

The lead components or operating agencies provide notification of all funding adjustments to the JSMG Executive Office. The JSMG Executive Office, in turn notifies other components and agencies and the JNBCDB Secretariat. The JSMG Executive Office forwards to the JNBCDB Secretariat the reprogramming requests with recommendations and any concerns raised by the other components and operating agencies. The JNBCDB Secretariat reviews the reprogramming actions and forwards recommendations to DTRA(CB) for DATSD(CBD) approval. Once approved, DATSD(CBD) authorizes the JNBCDB Secretariat to update the database, and the DTRA Comptroller to execute the reprogramming. For medical programs, the Headquarters, U.S. Army Medical Research and Materiel Command staffs all actions resulting from the requirement to reallocate funds between the Services.

DATSD(CBD), with the support of DTRA(CB), instructs the DTRA Comptroller to issue execution and program status reporting instructions to the operating agencies. The operating agencies report execution status to the DTRA Comptroller on a monthly basis. The DTRA Comptroller forwards all program funds execution reports to the JNBCDB Secretariat and DTRA(CB) for program and budget database update and analysis, respectively. DTRA(CB) reports execution status to DATSD(CBD) on a quarterly basis. DTRA(CB) is responsible to notify the DATSD(CBD) when programs deviate from or are in danger of not meeting OSD obligation and execution goals.

The DTRA Comptroller serves as the funds manager for the CB defense program. This office issues funding documents, per DATSD(CBD) direction, and performs all required accounting functions, with the assistance of the Army staff which represents the Executive

Agent. The JNBCDB Secretariat updates the OSD comptroller program and budget databases as necessary after the POM, Budget Estimate Submission (BES), and President's Budget (PB). DATSD(CBD), with support provided by DTRA(CB), ensures that the JNBCDB Secretariat is kept informed of all OSD comptroller guidance, directives, and schedules.

1.7 CB DEFENSE PROGRAM MANAGEMENT ASSESSMENT

ISSUE: **Oversight and management of the DoD CB Defense Program continues to mature. It is imperative that the management system produces joint CB defense requirements and NBC defense equipment that can be used by all forces. Public Law 103-160 (50 USC 1522) has provided a key tool for ensuring a jointly focused CB Defense Program. The continued support of Congress and implementation of current plans will continue to improve jointness and readiness.**

SOLUTION: DoD has completed implementation of 50 USC 1522:

- DoD has developed an organizational structure ensuring close and continuous coordination of CB warfare defense and CB medical defense programs.
- The DoD CB Defense Program is fully integrated and coordinated and is based on validated Service requirements generated in response to defined threats. In addition, the Services now jointly prepare (i) Modernization Plans, (ii) Research, Development and Acquisition (RDA) Plans, and (iii) Joint Logistics Support Plans for NBC defense programs.
- Responsibility for the CB Defense Program is vested in a single office in OSD, DATSD(CBD), which provides the overall guidance for planning, programming, budgeting, and executing the CB Defense Program.
- The overall integrity of the CB Defense Program's organizational structure has been maintained throughout implementation of the Defense Reform Initiative (DRI) and establishment of the Defense Threat Reduction Agency through establishment of the OSD NBC Defense Steering Committee.

ISSUE: **In its August 1999 report (NSIAD 99-159, 16 Aug 99), the General Accounting Office (GAO) recommended that a performance plan for the CB Defense Program should be developed and based on the outcome-oriented management principles embodied in the Government Performance and Results Act (GPRA).**

SOLUTION: The introduction of this report outlines the broad mission, vision, values, and goals of the DoD CBDP. These statements provide linkage with the overall mission and vision of the Department of Defense and provide the framework for the development of a performance plan consistent with GPRA principles. To complete the performance plan, the CBDP is in the process of developing performance goals and performance measures. These goals and measures will be stated along with the development of the CBDP Program Strategy Guidance and incorporated into key planning, programming, and budgeting documents. A Performance Plan will be completed during calendar year 2000 and included in the next annual report to Congress.

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Chapter 2

Non-Medical Nuclear, Biological, and Chemical (NBC) Defense Requirements and Research, and Acquisition Program Status

2.1 INTRODUCTION

This chapter describes the consolidation of Joint Service non-medical NBC defense requirements and assesses how these programs meet the needs of U.S. forces. The discussion of requirements and the status of research and development assessments is conducted within the framework of the three principles of NBC defense doctrine for the mission area:

- Contamination avoidance
- Protection
- Decontamination

As defined in Joint Publication 3-11, *Joint Doctrine for Nuclear, Biological, and Chemical Defense,* contamination avoidance includes detecting, avoiding, and bypassing contaminated areas. Protection consists of individual and collective protection. Decontamination restores combat power and is essential for sustaining operations in a contaminated environment. Medical support is a critical mission area for operations in an NBC environment. Medical programs support these areas and are discussed in Chapter 3 and Chapter 5, especially Section 5.7.7.

The threat from the continued proliferation of NBC weapons creates a continuous need to ensure that U.S. forces can survive, fight, and win in an NBC threat environment. The increasing danger from these weapons demands that we look for every opportunity to avoid technological surprises. Evolving operational requirements demand that the joint program progressively capture and leverage advances in technology to provide the best in NBC defense equipment for the forces.

The research, development, and acquisition (RDA) goal is to equip the joint warfighting forces with sufficient quantities of the best available equipment and in the shortest time possible in order to win decisively, quickly, and with minimal casualties. As authorized under the Joint Service Agreement for non-medical programs and in cooperation with the Armed Services Biomedical Research, Evaluation and Management (ASBREM) Committee for medical programs, the Army as executive agent coordinates, integrates, and reviews the DoD CB Defense Program. The results of these reviews, conducted with all Services participating, are documented in the Joint Service Modernization and Joint Service RDA Plans. These documents form the basis for the consolidated CB Defense Program Objectives Memorandum (POM).

In coordination with the Commanders-in-Chief (CINCs), the Services decide if a material solution is needed to satisfy a requirement for a war fighting capability. They first look at doctrinal, training, or organizational solutions (non-material solutions), and when these cannot be found, they seek equipment solutions through the materiel acquisition cycle. If a valid need exists, then the research and development modernization process will identify technological approaches which may provide a new system or upgrade an existing system.

During FY99 the Joint Service Integration Group documented the Joint Future Operational Capabilities (JFOC). The purpose of the JFOC is to identify and prioritize Joint User (Services and CINCs) far-term future operational capabilities as expressed in the emerging Joint NBC Defense Concept. The overall intent is to provide enhanced user guidance to the Joint NBC Defense Science and Technology (S&T) community to assist in the NBC S&T program formulation and program execution process. The JFOC will also support the development of new NBC Defense Joint Mission Needs Statements (JMNSs) and future Joint Operational Requirement Documents (JORDs). The prioritized list of JFOCs establishes a clear link between near and long term Joint NBC Defense research and development efforts and user needs. Table 2-1 provides a synopsis of the current JFOC priorities, descriptions, and objectives. The JFOC has become an integral part of the Joint Service NBC Defense Modernization Plan and related science and technology plans, including the Joint Warfighting Science and Technology Plan (JWSTP) and the Defense Technology Area Plan (DTAP). Table 2-2 provides a prioritized list of non-medical NBC defense programs from 1999.

Table 2-1. Prioritized Joint Future Operational Capabilities

1: **Contamination Avoidance**—An enhanced capability to detect, locate, identify, and confirm the presence or absence of any standard or non-standard NBC hazard. Significantly improve tactical, operational, and strategic NBC situational awareness by rapidly detecting, locating, identifying, confirming and disseminating NBC and toxic industrial material (TIM) detection information to the joint force.
2: **NBC Battle Management**—Capability to access, assimilate and disseminate NBC information from throughout the battlespace via standard, joint service and automatic information/data transmission systems. Enhance warfighter protection by providing the critical link between detection and protection. Commanders at all levels will be provided sufficient, timely information through early and direct warning. Commanders will be able to quickly and effectively quantify the risk associated with various courses of action and provide real-time display with local 3-D digital terrain graphics to portray the current status of the NBC battlespace.
3: **Collective Protection**—To protect the joint force by allowing it to operate safely, at near-normal levels of effectiveness, while under NBC threat, or in NBC, TIM or other environmental hazards area. Enhance filter systems on existing vehicles, aircraft, shipboard, communications vans and other static/mobile structures.
4: **Restoration Capability**—Enhanced capability to provide rapid, effective, and safe removal/neutralization of hazards resulting from NBC or TIM contamination to enable restoration of unit operational capabilities. Protect and sustain the Joint force by rapidly returning equipment and personnel to normal operating modes/efficiencies after exposure to an NBC or TIM contaminated environment.
5: **Individual Protection**—To protect the joint force by allowing it to operate safely, at near-normal levels of effectiveness, while under NBC threat, or in NBC, TIM or other environmental hazards area.

Table 2-2. Prioritized Non-Medical NBC Defense Programs

JSIG Priority	Focus Area	Program	Acronym	Joint/ Service Unique
1	IP	Joint Service Lightweight Integrated Suit Technology	JSLIST	Joint
2	CA	Joint Biological Point Detection System	JBPDS	Joint
3	CA	Joint Biological Standoff Detection System	JBSDS	Joint
4	BM	Joint Warning and Reporting Network (includes MICAD)	JWARN	Joint
5	CA	Joint Chemical Agent Detector	JCAD	Joint
6	CA	Joint Service Lightweight Standoff Chem Agent Detector	JSLSCAD	Joint
7	CA	Joint Service Light NBC Recon System (includes CBMS)	JSLNBCRS	Joint
8	CA	Automatic Chemical Agent Detector and Alarm	ACADA	Joint
9	IP	Joint Service Aviation Mask	JSAM	Joint
10	IP	Aircrew Mask Programs - Current (XM 45, CB Helo, AERP)	AMP-C	Joint
11	IP	Joint Service General Purpose Mask	JSGPM	Joint
12	RES	Joint Service Sensitive Equipment Decon	JSSED	Joint
13	IP	Joint Protective Aircrew Chemical Ensemble	JPACE	Joint
14	CP	Joint Transportable Collective Protection System	JTCOPS	Joint
15	RES	Joint Service Fixed Site Decon (includes JADS & LWPDS)	JSFXD	Joint
16	RES	Sorbent Decontamination System	SDS	Joint
17	CA	NBC Recon System SIP	NBCRS-SIP	Army
18	CA	Biological Integrated Detection System	BIDS	Army
19	CP	Joint Collective Protection Equipment	JCPE	Joint
20	RES	Lightweight Decontamination System	LDS	Joint
21	CA	Long Range Biological Standoff Detection System	LRBSDS	Army
22	IP	Protection Assessment Test System	PATS	Joint
23	IP	Chemical Environment Survivability Mask	CESM	SOF
24	IP	M40A1 Series Mask	M40A1	Joint
25	IP	Chemical Environment Survivability Suit	CESS	SOF
26	CA	Joint Service Chemical Warning and Identification LIDAR Detection	JSWILD	Joint
27	CP	Shipboard Collective Protective Equipment	SHIP CPE	Navy
28	CA	Interim Biological Agent Detector	IBAD	Navy
29	CA	Joint Chemical/Biological Agent Water Monitor	JCBAWM	Joint
30	CA	Special Operations Modular Chem/Bio Detector	SOMCBD	SOF
31	RES	Modular Decontamination System	MDS	Joint
32	IP	Joint Service Mask Leakage Tester	JSMLT	Joint
33	CA	Improved Point Detection System	IPDS	Navy
34	CA	Improved Chemical Agent Monitor	ICAM	Army
35	IP	Joint Canteen Refilling System	JCRS	Joint
36	CA	Shipboard Automatic Liquid Agent Detector	SALAD	Navy
37	CA	Scanning Airborne Fourier Emission for Gaseous Ultraspectral Analysis and Radiometric Detection	SAFEGUARD	Joint
38	CA	Chemical/Biological Individual Sampler	CBIS	Joint
39	CA	Pocket RADIAC	AN/UDR-13	Army
40	CA	Chem/Bio Radiological Integrated Detection System	CBRIDS	Joint
41	CA	Stand-off Radiac	JS RADIAC	Army
42	CP	Advanced Integrated Collective Protection System	AICPS	Army
43	CA	Advanced Airborne RADIAC System	AARS	Army
44	CA	NBC Unmanned Ground Vehicle Sensor	NBC UGVS	Joint

Key: BM = Battle Management; CA = Contamination Avoidance; CP = Collective Protection; IP = Individual Protection; RES = Restoration of Operations; SOF = Special Operations Forces

In accordance with the national strategy of achieving and applying technological superiority, several underlying concepts form the foundation of acquisition modernization. The first is the need to reduce cycle time in the acquisition of new systems or the integration of emerging technologies into existing systems. The use of Advanced Concept Technology Demonstrations (ACTDs), open systems and architectures, along with the new emphasis on commercial standards and practices, allow us to shorten the acquisition cycle time. The program acquisition process reduces lifecycle costs through practices such as design-to-cost and concurrent engineering to ensure that equipment is easy to maintain and repair even with the inherent complexity in most new systems.

2.2 NBC DEFENSE MISSION AREA REQUIREMENTS AND RDA SUMMARY

NBC defense programs are categorized broadly under three operational principles: contamination avoidance, protection, and decontamination. Medical defense, a subset of protection, is addressed in the next chapter. The Services have been working closely together to increase jointness in ongoing programs for each of these areas. This report highlights improvements during FY99 and discusses cooperative efforts for further Joint development of requirements. This section summarizes the requirements in each of the mission commodity areas. Tables 2-3 through 2-11 display requirements and acquisition strategies. Since the focus of this chapter is on research and development efforts, fielded items are not included in these tables. Descriptions of developmental and fielded equipment can be found in Annexes A–C of this report.

The following is an overview of the goals and timeframes, potential payoffs, and major technical challenges for specific commodity area science and technology (S&T) efforts. A detailed account of S&T efforts for all commodity areas is provided in two separate reports: (1) the *Joint Warfighting Science and Technology Plan*, especially Chapter XII, "Chemical and Biological Defense and Protection and Counter Weapons of Mass Destruction," and (2) the *Defense Technology Area Plan*, especially Chapter II, "Chemical and Biological Defense." The *Basic Research Plan*, also provides descriptions of various supporting sciences—including chemistry, biological sciences, materials science, and others—that support CB defense S&T activities. Within the *Joint Warfighting Science and Technology Plan* and the *Defense Technology Area Plan*, key projects are defined as Defense Technology Objectives (DTOs). A DTO states specific technology advancements to be developed or demonstrated, the schedule, costs, specific warfighter payoffs (stated quantitatively against two or more metrics), and the customers for whom the technology is being developed (*e.g.*, a specific Commander in Chief). DTOs represent only a portion of science and technology base funding, yet represent high priority projects, consistent with strategy and guidance. DTOs provide a key means for S&T planning and programming and for fulfilling GPRA requirements. DTOs are proposed or updated annually.

2.3 CONTAMINATION AVOIDANCE (Detection, Identification and Warning)

The operational concept of contamination avoidance includes NBC reconnaissance, detection, identification, warning and reporting. Earliest possible warning is the key to avoiding NBC contamination. For fixed sites where contamination cannot readily be avoided and for

missions requiring operations in a contaminated environment, detection, identification, and warning are equally critical to ensure that forces can (1) assume the optimal protective posture so that they can continue to sustain operations and (2) rapidly identify and decontaminate affected areas, equipment, and personnel. Sensors for the individual warfighter and systems capable of detecting multiple agents and characterizing new agents are being developed. Advances in technology are being pursued in chemical and biological standoff, early warning detection, miniaturization, interconnectivity, improved detection sensitivity, improved logistics supportability, and affordability. The following sections detail contamination avoidance science and technology efforts, modernization strategy, and Joint Service programs.

2.3.1 Contamination Avoidance Science and Technology Efforts

2.3.1.1 Goals and Timeframes. The goal of contamination avoidance is to provide real-time capability to detect, identify, characterize, locate, and warn against all known or validated CB warfare agent threats below threshold effects levels (see Table 2-3). To meet near term needs a number of sensor technologies are being optimized while alternative detection technologies mature. Mid-term technologies focus on developments to improve tactical detection and identification capabilities for both chemical and biological warfare agents. Far-term science and technology efforts focus on multi-agent sensors for biological agent detection and remote/early warning CB detection. These far-term objective technologies seek to integrate chemical and biological point and remote/early warning detection modules into a single system. Research and Development (R&D) efforts seek to optimize and balance system sensitivity, size/weight, cost, power consumption, signature and false alarm rate. Ultimately the goal is direct integration of CB detectors as a single system into various platforms, and command, control, communication, computer, and intelligence (C^4I) networks.

As identified in the *Defense Technology Area Plan* and the *Joint Warfighting Science and Technology Plan*, following are Defense Technology Objectives (DTOs) focused on near and mid-term science and technology goals.

Ongoing DTOs:
- Laser Standoff Detection Technology
- Chemical Imaging Sensor
- Biological Sample Preparation System for Biological Identification
- Joint Biological Remote Early Warning System ACTD
- Force Medical Protection ACTD

Completed DTOs (in ACTD Sustainment Phase):
- Airbase/Port Biological Detection ACTD
- Chemical Add-On to Airbase/Port Biological Detection ACTD

DTOs Completed In FY99:
- Joint Warning and Reporting Network
- Integrated Biodetection Advanced Technology Demonstration.

Table 2-3. Contamination Avoidance Science and Technology Strategy

By 2000	By 2005	By 2010
• Complete installation of the Portal Shield ACTD biological and chemical detection network at CINC air bases and ports • Complete demonstration of integrated point biodetection capability (Advanced Technology Demonstration)	• Field upgrade (eye safe) Long Range Bio Stand-off Detector in FY00-02. • Joint Biological Remote Early Warning System (JBREWS) ACTD with fielding of ACTD systems to selected CINCs by FY01 • Complete development of Joint Service Light-weight Standoff Chemical Agent Detector (JSLSCAD) • Initiate development of Joint Service Warning and Identification LIDAR Detection (JSWILD) • Complete development of Joint Chemical Agent Detector (JCAD) • Complete development of Block II Joint Biological Point Detection System (JBPDS)	• Demonstrate integration of chemical and biological agent detection modules into a single sensor suite • Complete development of CB water monitor • Complete development of JSWILD

2.3.1.2 **Potential Payoffs and Transition Opportunities.** Future CB detection systems will provide the capability to detect, identify in real time, map, quantify, and track all known or validated CB contamination in a theater of operations. This will enable commanders to avoid CB contamination, determine the need for and verification of effective reconstitution procedures, and assume the appropriate protection required to continue fighting and sustain their mission with minimal performance degradation and casualties. CB detection technologies have dual use potential in monitoring air pollution, noxious fumes inside enclosed areas, and municipal water supplies.

2.3.1.3 **Major Technical Challenges.** The major technical challenges are in the areas of biological collection, detection and identification, including remote/early warning sensing, improved agent discrimination and quantification, sample processing, interferent (*i.e.*, false positive and negative alarms) and ambient biological background rejection, and genetic probe development. Size, weight, and power reduction of detectors, power generation and consumption, development of integrated biological and chemical detection systems, and the fusion of sensor data with mapping, imagery, and other data for near real-time display of events are other areas of challenge.

There are two critical needs focused on biological agent detection. Current technologies require a *high level of logistical support* and *lack discrimination in biological standoff detection*. The challenge in reducing logistical support stems from the dependence on reagents and size, weight, and power requirements of the systems. Several efforts are aimed at provide minimum reagent requirements with higher sensitivity, better stability, and fewer supporting reagents, and scientific/engineering strategies to reduce size, weight, and power requirements, especially in the sample collections components. There are several factors directly limiting the ability to discriminate biological agents using standoff (laser) detection technologies. Key factors include: (1) a lack of fundamental data in understanding the spectral properties of biological warfare agents, (2) range limitations of lasers due to atmospheric absorption, and (3) natural background interference. Over the last two years, a number of strategies and concepts have been developed to improve the discrimination capability of standoff detection for biological materials.

Preliminary data developed this past year has shown the potential feasibility of two of these concepts. Further efforts in FY02 and FY03 will begin to validate the feasibility of providing an enhanced level of discrimination of biological material using standoff detection.

2.3.2 Contamination Avoidance Modernization Strategy

The increased lethality and heightened operational tempo of the future battlefield demand responsive NBC detection and warning capabilities in order to reduce force degradation caused by contamination. These capabilities—which also encompass NBC reconnaissance, detection, identification, and reporting—are critical for force readiness and will continue to be emphasized by the DoD community in the near and distant future. Table 2-4 shows the roadmap of DoD requirements for contamination avoidance. While requirements identified in the near-term meet service-specific needs, those in the mid to far-terms demonstrate the increase in joint development and modernization since the founding of the CBDP.

Table 2-4. Contamination Avoidance Modernization Strategy

	NEAR (FY00-01)	MID (FY 02-05)	FAR (FY 06-15)
Chemical Point Detection	•Surface off-gas sampling capability (ICAM) •Automatic point detection of nerve and blister agents (ACADA) •Navy-*Ship based improved automatic point detection of nerve/blister (IPDS)* •Navy-*Automatically detect liquid agent shipboard (SALAD)*	•Improved, all-agent programmable automatic point detection; portable monitor, miniature detectors for aircraft interiors; interior ship spaces; wheeled and tracked vehicles; and individual soldiers (JCAD)	•Improved surface contamination monitor •Detection of CB contamination in water (Joint Chemical Biological Agent Water Monitor)
Biological Point Detection	•Fixed site defense biological detection Portal Shield network sensor system •Automatic long line source and point/mobile biodetection to detect and identify bio-agents; programmable (JBPDS Block I) •Navy-*Ship based Interim Biological Agent Detector (IBAD)* •Army-*Biological Integrated Detection System (BIDS)*	•Automatic point biodetection, to detect and identify; programmable (JBPDS Block II) •Joint Biological Remote Early Warning System (JBREWS) - A distributed network of fully automated lightweight sensors.	•Automated, integrated detection of both biological and chemical agents in a single sensor package (Joint Chemical and Biological Universal Detector, JCBUD)
NBC Recon-Naissance and CB Remote and Stand-off Detection	•Improved NBC Reconnaissance Vehicle with remote/early warning and data fusion capabilities (JSNBCRS) •Army - *Long Range Stand-off detection and mapping of aerosol clouds (LR-BSDS)*	•Biological remote detection and early warning capabilities (JBREWS) •Lightweight passive stand-off detection for chemical agent vapors (JSLSCAD) •Add biological detection and identification capabilities (JSNBCRS P3I) •Light reconnaissance vehicle (JSLNBCRS)	•Stand-off detection, ranging, and mapping of chemical vapors and aerosols (JSWILD) •Wide area detection •Automated standoff detection of biological agents (JBSDS)
Warning and Reporting	•Automated warning and reporting (JWARN Phase I)	•Automatic NBC warning and reporting interoperable with all Services (JWARN Phase II)	•Integrated and automatic warning and reporting (JWARN Phase III)
Radiation Detection	•Army-*Compact, digital whole body radiation measurement (AN/UDR-13)*		•Stand-off radiation detection and measurement •Portable radiation meter

1. All programs shown are joint or multi-service, unless indicated as a Service-unique effort (italicized text).
2. Where applicable, systems which meet requirements are listed following the entry.

Early detection and warning is the key to avoiding NBC contamination. As a result, DoD is concentrating RDA efforts on providing its warfighters real-time capabilities to detect, identify, quantify, and warn against all known or validated CB warfare threats below threshold effects levels. Real time detection of biological agents below threshold effects levels is unlikely in the near to mid-term. Current emphasis is on developing lightweight, automated CB sensors capable of providing enhanced detection and early warning, capable of detecting all known biological and chemical agents. To meet the needs in the near to mid term, several stand-alone detectors and sensors are being developed. Developmental efforts are focusing on system miniaturization, improved sensitivity and specificity, agent characterization and range, decreased false alarm rate, and decreased operation and support costs. This focus will facilitate the integration of chemical detectors into personal warfighter gear, chemical and biological detectors onto various air, sea, and ground platforms, and integration of detectors into automated warning and reporting networks. Table 2-5 provides an overview of RDA efforts and Service involvement.

Table 2-5. Contamination Avoidance RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
Automatic Detectors and Monitors	- M22 Automatic Chem Agent Detection Alarm (ACADA)	Production	Joint	Joint	Joint	Rqmt
	- Shipboard Automatic Liquid Agent Detector (SALAD)	LRIP				Rqmt
	- Improved Point Detection System (IPDS)	Production				Rqmt
	- Improved CAM (ICAM)	Production	Rqmt	Interest	Rqmt	Interest
	- Joint Chemical Biological Agent Water Monitor (JCBAWM)	RDTE	Joint*	Joint*	Joint*	Interest
	- Joint Chemical Agent Detector (JCAD)	RDTE	Joint*	Joint*	Joint*	Joint*
	- Biological Point Detection					
	--Interim Biological Agent Detector (IBAD)	Fielded				*Rqmt*
	--Biological Integrated Detection System (BIDS NDI)	Fielded	*Rqmt*			
	--BIDS P3I	Production	*Rqmt*			
	- Portal Shield	Production	Joint	Joint	Joint	Joint
	- Joint Bio Point Detection System (JBPDS)	RDTE	Joint	Joint	Joint	Joint
Remote/ Early Warning	- Joint Service Lightweight Stand-off Chemical Agent Detector (JSLSCAD)	RDTE	Joint	Joint	Joint	Joint
	- Joint Service Warning and Identification LIDAR Detector (JSWILD)	RDTE	Interest	Interest		
	- Biological Stand-off					
	--Joint Remote Biological Early Warning System (JBREWS)	RDTE	Joint	Joint	Joint	Joint
	--Long Range Bio Stand-off Detection System-NDI (LRBSDS-NDI)	Fielded	*Rqmt*	*Interest*		*Interest*
	--LRBSDS	RDTE	*Rqmt*	*Interest*		*Interest*
NBC Recon	- Joint Service NBC Reconnaissance System (JSNBCRS)	RDTE				
	--M93A1 NBCRS/CB Mass spectrometer (See BIDS)	*	*Rqmt*		*Rqmt*	
	--Joint Service Light NBCRS/Lightweight Recon System (JSLNBCRS)	*	Joint	Joint	Joint	*Interest*
Warning and Reporting	- Joint Warning and Reporting Network (JWARN)	RDTE/Prod	Joint	Joint	Joint	Joint
	-- Multipurpose Integrated Chemical Agent Detector (MICAD)	*	*Rqmt*		*Rqmt*	
Radiation Detection	- AN/UDR-13 Pocket Radiac	Production	Rqmt	Interest		

Joint= Joint Service requirement
Joint*=Draft Joint Service requirement
Rqmt= Service requirement
Int-NIR= Service interest, no imminent requirement
Rqmt, Interest= sub-product requirement or interest *= Sub-product(s) of a Joint project
LRIP= Low Rate Initial Production

The management challenge involves the coordination and consolidation of numerous detection and warning RDA efforts across the Services. This strategy, led by the JSMG through the Contamination Avoidance Commodity Area Manager, resulted in the initiation of RDA efforts which shared common technical goals, but were constrained to Service unique requirements. Management organizations and initiatives, such as the Joint Program Office for

Biological Defense (JPO-BD) and the Joint NBC Defense Board are building Joint Service coordination across the mission area.

Over the past several years, the JSMG and JSIG, through the Contamination Avoidance Commodity Area Manager, with assistance from JPO-BD transformed and consolidated 44 separate contamination avoidance developmental efforts into ten fully coordinated joint projects. The Joint Programs are:

- Automatic Chemical Agent Detection Alarm (ACADA)
- Joint Chemical Agent Detector (JCAD)
- Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD)
- Joint Service Warning and Identification LIDAR Detector (JSWILD)
- Joint Biological Point Detection System (JBPDS)
- Joint Biological Remote Early Warning System (JBREWS)
- Joint Service Light NBC Reconnaissance System (JSLNBCRS)
- Joint Warning and Reporting Network (JWARN)
- Joint Chemical Biological Agent Water Monitor (JCBAWM)
- Portal Shield Network sensor system

2.3.3 Joint Service Contamination Avoidance Programs

Consolidation of Joint Service contamination avoidance programs has been completed. All detection programs have been restructured to meet current multi-Service needs. Bolded entries in Table 2-4 highlight Joint programs. Detailed descriptions of Joint contamination avoidance programs are provided in Annex A.

Chemical Warfare Agent Contamination Avoidance. An ACADA non-developmental item (NDI) is being procured for point detection of chemical (nerve and mustard) agent vapors. ACADA is suitable for many vehicle-mounted and man-portable applications. A shipboard version of ACADA, which addresses unique shipboard interferents, is being built to provide the Navy with an interim monitoring capability until JCAD is fielded. The Improved Chemical Agent Monitor (ICAM) is being procured and fielded for post attack monitoring of chemical agent vapors. The ICAM is three times more reliable than its predecessor and much simpler and cheaper to repair. Both the ACADA and ICAM will be replaced by the JCAD.

JCAD provides point chemical vapor detection and is in Phase II (Engineering and Manufacturing Development, EMD) of the acquisition cycle. JCAD will function as a chemical point detection system in order to accomplish a variety of mission requirements on multiple service platforms. The requirements are for the detector to be considerably smaller (within 40 cubic inches) and lighter (2 lbs. or less) than the ACADA and can be configured for a variety of applications, such as individual soldier detectors, post-attack monitoring, shipboard chemical agent monitoring, special operations forces applications, and aircraft interior detection. JSLSCAD provides passive standoff, on-the-move detection of chemical agent vapor and is in Phase II (EMD) of the acquisition cycle. The JSLSCAD program is a joint program with a Joint Operational Requirements Document (ORD) being approved by all Services. The basic

JSLSCAD system (detector, scanner and electronics module) will weigh less than 50 pounds and occupy approximately one cubic foot. The system may be modified to accommodate a variety of requirements, including the addition of a 360° x 60° scanner for Armored Systems Modernization applications (tracked and wheeled vehicles), and a gimbal mount for Marine Corps helicopters and unmanned aerial vehicle (UAV) contamination avoidance roles. The Air Force's primary use for this system will be in air base defense. The Navy will install JSLSCAD on shipboard and airborne platforms and at high priority oversea installations. This system will be fully evaluated by all the Services during EMD.

In the near-term, the Army, Air Force, and Marine Corps have agreed to focus on the development of a Joint Service Light NBC Reconnaissance System (JSLNBCRS). The proposed system will consist of a suite of detectors required for a specific mission that could be easily integrated into the platform of choice. Currently two configurations are proposed: a light and a medium version, to fulfill expeditionary and armored mission profiles, respectively. The FOX NBCRS fulfills heavy requirements. The FOX NBCRS is being upgraded to include a chemical standoff detection capability and other electronic improvements including data fusion.

In the far-term, the Army, Air Force, and Marines have agreed to a Joint Chemical Biological Agent Water Monitor (JCBAWM). JCBAWM is a system that will detect the presence of contaminants in potable water. A requirement for an agent water monitor has been identified by the Army, Air Force, and Marines and a technology base program is underway. The operational scenarios defined in the JCBAWM ORD include source water, water distributions systems, and verification of water treatment. The Army and Air Force have identified a need for a warning and identification detector. The Joint Service Warning and Identification LIDAR Detector (JSWILD) is a technology base effort to address this problem. JSWILD is a laser-based standoff detection system being developed to meet the need for the detection of chemical liquids, aerosols, and vapors. Although this system is much heavier than its passive counterpart (JSLSCAD), it provides the ability to detect chemical agents in all forms—liquids, vapors, aerosols—as well as mapping and ranging information. In addition, JSWILD will provide similar but shorter range (1–5 km) capabilities in biological standoff detection as those developed and fielded for the Long Range Biological Standoff Detection System.

Biological Warfare Agent Contamination Avoidance. Currently, the Joint Program Office for Biological Defense (JPO-BD) manages the following biological detection efforts:

(1) Interim Biological Agent Detector (IBAD);
(2) Joint Biological Point Detection System (JBPDS);
(3) Biological Integrated Detection System (BIDS);
(4) Long Range Biological Stand-off Detection System (LR-BSDS);
(5) Air Base/Port Biological Detection (Portal Shield) Advanced Concept Technology Demonstration (ACTD);
(6) Portal Shield Production;
(7) Joint Biological Remote Early Warning System (JBREWS) ACTD;
(8) Critical Reagents Program;
(9) Technology Transfer Program.

Currently fielded systems include the Navy's shipboard detection system (IBAD), Portal Shield networked systems, and the Army's land-based system (BIDS-NDI). The Army's LR-BSDS is a helicopter mounted infrared LIDAR system for the detection, ranging and tracking of aerosol clouds that may indicate a biological warfare (BW) attack.

In the near-term, the Air Base/Port Biological Detection (Portal Shield) ACTD has developed and demonstrated the capability of networked sensors to protect high value fixed sites against BW attacks. Portal Shield has transitioned into production to meet urgent CINC requirements. JBPDS will be produced to meet each of the four Services' needs for an integrated biological point detector. This program is developing a standard bio detection suite that will be integrated on Service designated platforms. Fielding of the BIDS P3I to the 7th Chemical Company began in 1QFY99 and was completed by 4QFY99. In addition, the Critical Reagents Program consolidates all DoD antibody, antigen and gene probe/primer developments and requirements. This program will ensure the quality and availability of reagents that are critical to successful development, test, and operation of biological warfare detection systems and medical biological products. The Technology Transfer program will ensure the successful and rapid transition of DARPA and other Service breakthrough biological detection technologies into DoD fielded systems.

In the mid-term, the JPO-BD will demonstrate the Joint Biological Remote Early Warning Advanced Concept Technology Demonstration (ACTD). This tactical distributed network system of lightweight, automated sensors will use data fusion to reduce false alarms. The ACTD demonstration test in FY00 will demonstrate enhanced capabilities in detection, identification, and advanced warning of BW attacks.

In the far-term, the concept for the ultimate, joint service chemical and biological detector is the Joint Chemical Biological Universal Detector (JCBUD). JCBUD is envisioned to be a miniaturized, multi-technology, automatic system that may be manned or unmanned, capable of detecting all CW/BW agents, and able to automatically warn troops and report pertinent data relative to a CW/BW attack.

2.3.4 Warning and Reporting

Warning and reporting is a critical component of contamination avoidance. It provides the critical link between CB detection and CB protection and provides situational awareness to the commander. Warning and reporting provides the hardware and software to connect point detection and early warning detection systems into the overall command and control architecture. Additionally, it provides modeling and simulation capabilities to enhance hazard forecasting and assessment. The goal of warning and reporting is to provide sufficient, accurate, and timely information to commanders at all levels through early and direct warning capabilities so they assume appropriate protective postures and develop options to continue mission-essential operations.

The Services have agreed to expedite development of this capability by integrating ongoing hardware and software into a Joint Warning and Reporting Network (JWARN). This

network will be compatible with, but not duplicate, all C^4I equipment, both current and developmental. The JWARN Phase I effort began fielding the first version of software in FY98. The JWARN Phase II effort was initiated in FY99 into EMD for hardware and software integration onto Service designated platforms and installation at fixed sites.

An integrated warning and reporting network will enhance the overall approach used in the chemical biological defense strategy. The enhancements will come from a warning and reporting network that is linked to numerous point detectors, such as JCAD, which can identify and quantify chemical threats and which are cued by early warning systems, such as JSLSCAD and JSWILD. The information from all the sensor systems in the operational theater becomes available to various command levels with appropriate levels of resolution determined by the command decision needs. For example, a fixed facility commander can determine the appropriate level of protective posture by monitoring the direction of an ongoing attack or how the weather is moving the contamination in a post attack situation.

2.3.5 Other Contamination Avoidance Programs

Various detection and warning requirements have unique mission profiles and technical specifications. While in some instances the development effort may leverage the technical achievements of a closely related detection and warning project, the application beyond its intended mission is limited and accordingly supports only one or a few a specific requirements. The Navy awarded a production contract in FY97 for the Improved (chemical agent) Point Detection System (IPDS), and began installation in FY99. IPDS is used to automatically detect and alarm in the presence of chemical agents in vapor form and will provide continuous detection and alarm capability in the harsh shipboard environment. The IPDS replaces the existing shipboard Chemical Agent Point Detection System (CAPDS) improving detection thresholds, response time, rejection of shipboard interferents, and adding the capability to detect mustard agents. The Navy is also planning on fielding the Shipboard Automatic Liquid Agent Detector (SALAD) in fiscal year 2001. This shipboard system will be used to automatically detect and alarm in the presence of liquid chemical agents. By detecting automatically, it will minimize the sailor's exposure to contamination. As with the IPDS, it will provide continuous detection and alarm capability in the harsh shipboard environment. A performance-based contract for the low rate initial production of SALAD will be awarded in FY00.

The Marine Corps are conducting a Force Medical Protection/Dosimeter ACTD, the goal of which is to develop an individually worn sampler that can measure and archive exposure levels of chemical and biological agents. The goal of the system is to warn the wearer, provide real-time analysis of chemical agents, and trap biological agents for later analysis. The Marine Corps are also developing a Small Unit Biodetector (SUBD), which will have capabilities similar to the JBPDS but will be tailored to the size, weight, and power requirements of the Chem/Bio Incident Response Force (CBIRF).

2.3.6 Defense Advanced Research Projects Agency (DARPA) Programs

There are four related programs currently ongoing within DARPA that contribute to the development of advanced sensor technology: BW defense environmental sensors, tissue-based biosensors, microfluidic molecular systems, and pathogen genome sequencing.

DARPA BW Defense Environmental Sensors Program. DARPA is developing technologies to enable a multiplexing capability for bioagent identification. Technologies using up-converting phosphors provide improved detection sensitivity. Enhanced multiplexing is being developed to reveal BW agent family, genus, and species on a single chip. A mass spectrometer is being miniaturized for potential use in identifying BW agents and contaminants without the use of liquids. These systems will be automated for unattended operations. Detection technologies that provide information on BW agent pathogenicity and viability are also being developed under the DARPA biological detection program.

DARPA Tissue-Based Biosensors Program. DARPA is exploring the use of biological cells and tissues as detector components for sensor devices to report on chemical and biological toxins. Cells and tissues can be used to report on the functional consequences of exposure (mechanism and activity) to a wide spectrum of chemical or biological toxins, whether they are living or dead, or whether they have been bioengineered and currently undetectable by other means (antibodies, nucleic acid sequencing). Technical issues that are being addressed in the program include, (1) the fabrication of biocompatible matrices and interfaces for the long-term retention of cell and tissue function, (2) pattern recognition from critical pathways responsible for the processing of toxins, (3) sampling strategies to accurately extract and present the toxin from air, liquid, or solid samples, and (4) systems integration into a functional device. The current focus of the program is on the use of neuronal and immunological cells and tissues as detectors for such devices. Engineering of cells and tissues of these origins, including stem cells, is proceeding in order to optimize sensor performance requirements and fabricate prototype devices for testing and evaluation.

DARPA Microfluidic Molecular Systems Program. Micro total analysis systems are being developed through focused research on microfluidic, chip-scale technologies. Automated sample collection and sample preparation are key front-end processes for early biological agent detection, whether it is by immunoassays, DNA assays, or tissue-based assays. To scale down these processes into miniaturized, multiplexed detection systems, microfluidic chip-scale components need to be developed. Microfluidic components/devices currently being developed by DARPA include chip-scale micropumps/valves, particle separation filters, fluidic interconnects, fluidic manipulation of hybridized microbeads, controlled mixing/dosing, *etc.* Several demonstrable handheld prototypes, such as a programmable microfluidic system for remote sensors, are currently being tested.

DARPA Pathogen Genome Sequencing Program. DARPA is sequencing the genomes of high threat BW agents. This effort, undertaken with broad community interaction, will support DARPA BW Defense research activities and is intended to satisfy the needs of DoD compo-

nents, the Intelligence Community, and other governmental organizations. Interest is focused on BWD pathogens, and non-pathogenic near neighbors thought to be important to establish a basis for low false alarm detection and identification. The work also contributes to the development of advanced unconventional pathogen countermeasures.

2.4 PROTECTION

When early warning is not possible or units are required to occupy or traverse contaminated environments, protection provides life sustainment and continued operational capability in the NBC contaminated environment. The two types of non-medical protection are individual and collective.

- ***Individual protective equipment*** includes protective masks and clothing. Protective masks that reduce respiratory stress on the user while improving compatibility with weapon sighting systems and reduce weight and cost are being developed. Technology advances are being pursued to produce mask systems that provide fully compatible vision capabilities, laser/ballistic protection, and further reduction in logistics and physiological burden. Protective clothing and integrated suit ensembles are being developed that will improve protection, reduce the physiological burden, have extended durability, and have less weight and heat stress burden than present equipment.
- ***Collective protection equipment*** consists of generic NBC protective filters and air movement devices that provide filtered air to a wide range of applications, transportable shelter systems equipped with NBC filtration systems and, in selected cases, environmental control. Collective protection in the form of overpressure, can be applied to mobile and fixed command posts, medical facilities, rest and relief shelters, buildings/fixed sites, vehicles, aircraft, and ships. Lightweight shelters integrated with NBC filtration, environmental control and power generation facilities for medical treatment facilities have been developed and are in production. Technology improvements are being pursued to reduce power requirements and improve filtration capacity against current and future NBC agents. Technologies that reduce weight, volume, cost, and improve the deployability of shelters and filtration systems are also being pursued.

2.4.1 Protection Science and Technology Efforts

2.4.1.1 Individual Protection Goals and Timeframes. The goal of the individual protection area is to reduce the physiological burden associated with wearing protective equipment while maintaining, and potentially improving, the already high level of protection against CB warfare agents and radiological particles (see Table 2-6). Individual protection equipment must also provide protection against emerging threats, such as novel agents or toxic industrial materials (TIMs). To achieve these goals, key physiological performance requirements to the design and evaluation of clothing and respirators are being established. New barrier and filtration materials and selectively permeable materials are being developed and evaluated to accommodate these performance requirements. The primary effort to develop and demonstrate materials for a new generation of lightweight CB protective clothing based on selectively permeable membrane technology is an identified Defense Technology Objective entitled Advanced Lightweight Chemical Protection.

2.4.1.2 Collective Protection (CP) Goals and Timeframes. The goals of the collective protection area are to (1) reduce the weight, size and power requirements of CP systems, (2) reduce

the logistical burdens associated with the maintenance of CP filters, (3) improve protection capabilities against current and emerging threat agents, including TIMs, and (4) improve the deployability of transportable shelter systems (see Table 2-6). To achieve these goals, improvements to system components (including transportable shelters) are being investigated along with improvements to the current vapor and particulate filtration media. Regenerative vapor and particulate filtration materials processes are being investigated to eliminate the need for filter change and improve the capability against any battlespace NBC threats. The primary effort for investigating adsorbents for both single-pass and regenerative filtration applications is articulated in the Defense Technology Objective Advanced Adsorbents for Protection Applications.

Table 2-6. Protection Science and Technology Strategy

By 2000	By 2005	By 2010
• Prototype mask with 50% reduced breathing resistance and 50% improved field of vision • Joint Service Lightweight Integrated Suit Technology (Overgarment and MULO), extended durability, reduced heat stress, increased protection • JSLIST P3I, Joint Chemical Ensemble, chemical protective garments, gloves and footwear that are lightweight, and have extended durability and reduced heat stress • Demonstrate a lightweight CB protective duty uniform utilizing selectively permeable membrane technology • Demonstrate regenerative filtration for collective protection applications • Complete evaluation of low cost and lightweight CB tentage materials	• Demonstrate advanced adsorbents to enhance or replace carbon • Demonstrate a duty uniform utilizing selectively permeable membrane/nanofibers that provides integrated environmental protection • Service life indicator • Demonstrate new collective protection shelters utilizing low cost and lightweight CB tentage materials and novel CB resistant tentage closures • Improvements to collective protection systems (JCPE)	• New transportable shelter system (JTCOPS) • Improvements to collective protection systems (JCPE) • Continuous operation filter technology • Demonstrate lightweight, self-detoxifying clothing

2.4.1.3 Potential Payoffs and Transition Opportunities. Individual protection investments will result in improved respiratory and percutaneous (skin) protection with reduced physiological and psychological burden to the individual warfighter. Improved air filtration systems or technologies for collective protection applications will allow for extended operation, in an NBC contaminated environment, reduce the logistics burden associated with filter replacement, reduce weight, volume and power requirements, and improve the capability against current and emerging threats. Filtration technology has commercial application to the chemical industry and automotive applications.

2.4.1.4 Major Technical Challenges. Integrating CB protection into future weapon systems necessitates tradeoffs between performance requirements and limitations of materials and designs. Integral respiratory protection requires tradeoffs between physiological performance parameters such as pulmonary function, field of view, speech intelligibility and anthropometric sizing against constraints such as cost, size/weight, protection time, and interfacing with other equipment. CB protective clothing development requires balancing the physiological burden imposed upon the warfighter with maximum obtainable CB agent protection. Significant

advancements have been made in improving the weight/bulk and power requirements of personal cooling systems, but further work in this area is needed. Air purification systems require tradeoffs with respect to performance, user requirements, size, weight and power constraints, as well as longer life.

2.4.2 Protection Modernization Strategy

Forces cannot always avoid NBC hazards, therefore, individual warfighting units must be provided materiel to protect them from the effects of these lethal agents. Protection must be effective against all known threats with minimal degradation to the performance of personnel, weapons, or equipment. Protective measures allow our forces to maintain combat superiority in NBC contaminated environments. A summary of protection modernization requirements is provided in Table 2-7.

The goal of the protection RDA area is to provide equipment that allows U.S. forces to operate in a NBC contaminated environment with minimal degradation of the warfighters' performance. Near-, mid-, and far-term objectives are to reduce physiological and logistical burdens while maintaining current protection levels. Table 2-8 provides an overview of individual and collective protection RDA efforts and Service involvement.

Protective masks will be improved to reduce fatigue, thus enhancing ability to perform mission tasking. Mask systems will require increased NBC survivability and compatibility with combat or personal equipment. Future respiratory systems, such as the Joint Service Aviation Mask (JSAM) and Joint Service General Purpose Mask (JSGPM) will require enhanced compatibility with life support equipment, tactical systems, and fixed and rotary wing aircraft. In the future, the focus will be on integrated respiratory protective ensembles which offer optimal compatibility with personal, tactical, and crew support systems. Key technologies for future mask systems include mask service life indicator, advanced materials, and improved models and test technologies for protection assessment.

Future protective clothing ensembles for U.S. forces will require reductions in bulk and weight without any loss of protection or durability. To satisfy these needs, the Services have consolidated their mission specific requirements into a first truly joint program for the next generation chemical garments—the Joint Service Lightweight Integrated Suit Technology (JSLIST) program. The JSLIST program developed and is fielding the JSLIST Overgarment and Multipurpose Overboots (MULO). The goal of the JSLIST Pre-Planned Product Improvement (P3I) is to develop improved chemical protective overgarments, duty uniforms, undergarments, gloves, and socks that will increase protection, reduce physiological burden, and have increased durability beyond those items fielded in the baseline JSLIST program. New accessories, such as gloves and footwear, are required to execute missions and tasks which require greater tactility and traction. The Joint Protective Aircrew Ensemble (JPACE) will be developed to provide aviators with the same advantages and improved protection as JSLIST provides to other warfighters. Similarly, clothing systems for Explosive Ordnance Disposal (EOD) personnel and firefighters are required to enhance existing chemical protection systems without undue physiological burdens.

Table 2-7. Protection Modernization Strategy

	NEAR (FY00-01)	MID (FY02-05)	FAR (FY06-15)
Individual Eye/ Respiratory	•Voice amplification; laser/ballistic eye protection; improved decontaminability, better comfort (M40A1/M42A2) •Army - *Aircrew mask compatible with Apache helicopter systems with a significantly lighter motor/blower unit (M48)* •Army -*Improved compatibility with aviation sighting/night vision systems; reduced logistics burden using non-blower systems, selected for Land Warrior (M45)*	•Reduced physiological burden, improved comfort, enhanced optical and communications, improved compatibility •New mask systems for general purpose and aviation masks (JSGPM, JSAM) •Navy -*Improved complete protection for all aircrews (CB Respiratory System)*	•Advanced Integrated Individual Soldier Protection system (Future Soldier System) •Improved multiple agent protection
Individual Clothing	•Advanced protective suit technology; lighter, improved agent protection; reduced heat stress integrated with all respiratory systems. - Improved foot protection (MULO) •Improved protection, less burdensome, protective suits; Improved foot protection/less burdensome; Flame protection (JSLIST P3I) •Army -*Improved protection for short term use for special purposes (ITAP)* •Army -*Improved protection with self contained breathing capability for special purposes (STEPO)*	•Improved protection (Joint Service Chemical Ensemble) •Improved protection for aviators (JPACE) •Service Life Indicator and CB duty uniform •Improved hand protection	•Integrated multiple threat modular protection (chemical, biological, environmental, ballistic direct energy and flame) •Self-detoxifying clothing
Collective Protection	•Chemically Protected Deployable Medical Systems (CP DEPMEDS) •Chemically Hardened Air Transportable Hospital (CHATH) •Marine Corps -*Protection for all combat vehicles and unit shelters* •Army -*NBC protection for tactical Medical units (CB Protective Shelter, CBPS).* *- Apply regenerable vapor filter to Comanche,* *- Apply collective protection to advanced vehicle concepts.* *-Modular, reduced size, weight and power for vehicle/ shelter collective protection - Advanced Integrated Collective Protection Shelter (AICPS)* •Air Force - *Upgrade/install collective protection into existing rest/relief shelters.*	•Improved filters to extend filter life, reduce maintenance and reduce logistical burden •Regenerable/advanced protective filtration for vehicles/vans/shelters; reduce logistics burden, improved protection against current and future threats •Lighter, more mobile, easier setup, more affordable shelters (JTCOPS) •Improved current collective protection filters and equipment (JCPE) •Support medical treatment in a CB environment for Airborne, Air Assault, and Heavy Divisions (CBPS) •Navy - *Backfit ships with contamination free protected zones - (Selected Area Collective Protection System, SACPS). Integrate collective protection system into V-22*	•Family of advanced protective filtration systems for vehicles, shelters, ships, and light forces

1. All programs shown are joint or multi-service, unless indicated as a Service-unique effort (italicized text).
2. Where applicable, systems which meet requirements are listed following the entry.

Table 2-8. Protection RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
	INDIVIDUAL PROTECTION:					
Integrated	- Force XXI Land Warrior	RDTE	Rqmt	Interest	Interest	Interest
Eye/ Respiratory Protective Masks	- MBU-19/P Aircrew Eye/Respiratory Protection (AERP)	Production	Interest	Fielded	Interest	
	- M48 Aircraft Mask	Production	Rqmt			
	- CB Respiratory System (A/P22P-14(V))	RDTE			Rqmt	Rqmt
	- M45 Aircrew Protective Mask (ACPM)	Production	Rqmt		Interest	
	- M40A1/M42A2	Fielded	Rqmt		Rqmt	Rqmt
	- MCU-2A/P	Production		Fielded		Rqmt
	- Joint Service Aviation Mask (JSAM)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
	- Joint Service General Purpose Mask (JSGPM)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
Ancillary Equipment	- Protection Assessment Test System (PATS)	Production	Rqmt	Fielding	Fielded	Interest
	- Voice Communication Adapter	Production	Rqmt	Rqmt	Fielded	Fielded
Battlefield Protective Suits	- CB Protective Overgarment Saratoga	Fielded	Interest		Fielded	Interest
	- Chemical Protective Undergarment (CPU)	Fielded	Rqmt		Int-NIR	
	- Joint Service Lightweight Integrated Suit Technology (JSLIST/ISLIST P3I)					
	-- Overgarment	Prod.*	Rqmt	Rqmt	Rqmt	Rqmt
	-- Undergarment (P3I)	RDTE	Interest	Interest	Interest	
	-- Duty Uniform (P3I)	RDTE	Interest	Interest	Rqmt	
	-- Boots (MULO)	MS III*	Rqmt	Rqmt	Rqmt	
	-- Gloves (P3I)	RDTE	Rqmt	Rqmt	Rqmt	
	-- Socks (P3I)	RDTE	Interest	Interest	Interest	
	-Battledress Overgarment (BDO)	Fielded				
Specialty Suits	-Self-Contained Toxic Environment Protective Outfit (STEPO-I) Interim	Fielded	Rqmt			
	- STEPO	Production	Rqmt			
	- EOD Ensemble	Production	Rqmt			
	- Improved Toxicological Agent Protective (ITAP)	MS II	Rqmt		Interest	Interest
	- Joint Firefighter Integrated Response Ensemble (JFIRE)	Production	Rqmt	Rqmt		
	COLLECTIVE PROTECTION:					
Tentage and Shelter Systems	- M20A1/M28 Simplified CP Equipment (CPE)	Fielded	Rqmt	Rqmt		Rqmt
	- CB Protective Shelter (CBPS) (Medical)	Production	Rqmt		Interest	Interest
	- Portable Collective Protection System (PCPS)	Fielded			Rqmt	
	- CP Deployable Medical SystemChemically/ Biologically Hardened Air Transportable Hospital (DEPMEDS/CHATH)	Production	Rqmt	Rqmt		
	- Joint Transportable CP System (JTCOPS)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
Collective Protection (CP) Systems	- Shipboard Collective Protection System (CPS)	Production	Interest	Interest		Rqmt
	- Shipboard CPE	RDTE	Interest	Interest		Rqmt
	- Modular Collective Protection System (MCPE)	Fielded	Rqmt	Interest		Interest
	- Advanced Integrated Collective Protection System (AICPS) for Vehicle, Vans, and Shelters	RDTE	Rqmt		Interest	
	- Selected Area Collective Protection System (SACPS)	Production			Interest	Rqmt
	- M8A3 GPFU	Fielded	Rqmt			
	- M13A1 GPPU	Fielded	Rqmt	Rqmt		Rqmt
	Joint Collective Protection Equipment (JCPE)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
Generic Filters	- M48/M48A1 (100 cfm)	Fielded	Rqmt		Rqmt	Rqmt
	- M56 (200 cfm)	Fielded	Rqmt	Rqmt	Interest	Rqmt
	- Fixed Installation Filters	Fielded	Rqmt	Rqmt		

Rqmt = Product requirement
Interest = Product Interest
Int-NIR = Product Interest, No Imminent Requirement

* - Sub-Product(s) of a Consolidated Joint Service Project
Rqmt, Interest = Sub-Product requirement or interest

Collective protection equipment (CPE) development efforts are focused on NBC protection systems at the crew, unit, and platform level. New CPE systems will be smaller, lighter, less costly, and more easily supported logistically. New systems are required to provide clean environments for critical operations (*i.e.*, where individual protective equipment (IPE) otherwise places an unacceptable burden upon the warfighter in performing duties) and for essential rest and relief. Modernization efforts will concentrate on: (1) improvements to current vapor and particulate filtration media to extend filter life and to offer improved performance against current and/or emerging threats, (2) advanced air filtration (vapor and particulate) technologies, integrated with environmental control, to greatly reduce the logistical burden and offer greatly improved performance against current and postulated threats, (3) increased application of collective protection systems onto vehicles, vans, shelters, fixed sites, and ships, within the Joint Services, (4) improved transportable shelter system with integrated power/environmental control/filtration, (5) improvements to current collective protection systems to reduce weight, volume, and power requirements, and (6) standardization of filters within the joint services to address storage and procurement concerns. Efforts are in place to support major weapons systems developments, such as the U.S. Navy V-22 Osprey, the U.S. Army's Comanche, Crusader, Bradley, Breacher, Heavy Assault Bridge, Future Scout and Cavalry System, the USMC Advanced Amphibious Assault Vehicle (AAAV), and other advanced weapons platforms.

2.4.3 Joint Service Protection Programs

Joint programs are shown in Table 2-7 as bolded entries. A detailed description of Joint IPE and CPE programs is provided in Annex B.

Individual Protection

Eye/Respiratory. The M40 and M42 series masks (for individuals and armored vehicle crewmen, respectively) are undergoing the final stages of fielding to replace their M17, M9 and M25 series counterparts. The new masks offer increased protection, improved fit and comfort, ease of filter change, better compatibility with weapon sights, and a second skin, which is compatible with Army and Marine Corps protective ensembles. The second skin design also is being reviewed by the Navy and Air Force for potential adoption. The Army, Marines, and Air Force are also fielding the Protection Assessment Test Systems (PATS) to provide users of the M40, M42, and MCU-2/P series masks with a rapid and simple means for validating the fit and function of the mask to ensure readiness. The Navy is evaluating the use of PATS with its MCU-2/P series mask.

The Navy, in coordination with the Marine Corps, is leading an effort to equip all forward deployed fixed and rotary wing aircrew with improved chemical, biological, and radiological (CBR) protection. The CBR ensembles will feature off-the-shelf items, such as the CB Respiratory System. The Army, in cooperation with the Marine Corps, recently completed a product improvement program for the M40 series mask that allows ground crew to aircrew communication. The Air Force continues to field Aircrew Eye-Respiratory Protection (AERP) systems to protect aircrews from CB hazards. This system complements the recently fielded, lighter weight aircrew ensemble.

Mid- and far-term research is focused on improved vapor and particulate filtration technology, as well as improved masks for light and special operations forces (SOF). Development will be completed in the mid-term for the Joint Service Aviation Mask and Joint Service General Purpose Mask, which will provide improved eye, respiratory, and face protection against current and future agents. It will maximize compatibility with future weapon systems, be lightweight, and offer modular facepieces to accommodate a variety of mission profiles. Protective mask efforts will focus on supporting specific needs of the Joint Services and integrated warrior programs (Land Warrior, Air Warrior, Mounted Warrior, and Force XXI).

Clothing. In the area of full body protection, the JSLIST program coordinated the selection of advanced technology chemical protective materials and prototype materials. The JSLIST Overgarment and the Multipurpose Overboot (MULO) were adopted by all four services. The JSLIST Overgarment is a 45 day garment (*i.e.*, it may be used for 45 days after the suit has been opened) that provides 24 hours of chemical protection. It is launderable and lighter weight than the Battle Dress Overgarment (BDO). The MULO will replace the black vinyl overboot/green vinyl overboot (BVO/GVO). The MULO is a 60 day boot that provides 24 hours of chemical protection. The boot has increased traction, improved durability, petroleum, oil, and lubricant (POL) and flame resistance, and better chemical protection than the BVO/GVO.

The JSLIST Pre-Planned Product Improvement (P3I) will address requirements not met through the baseline JSLIST program. This program will obtain new material technologies for overgarments and duty uniforms using the existing JSLIST design. Fabric technologies for a chemical protective undergarment and materials and designs for chemical protective socks will also be addressed. This program will develop a 60 day overgarment with desired flame resistance (FR), a 30 day overgarment with required FR, a 30 day duty uniform with desired FR, a 7 day overgarment with desired FR, a 7 day undergarment with desired FR, general purpose gloves, high tactile gloves, and socks. Materials that meet Service's requirements will be placed on a qualified materials list to encourage multi-source competition and to provide surge capability, although no candidate glove materials were found to meet the requirements under this program. In addition, the Air Force is leveraging technology from the JSLIST program in the development of a chemical protective firefighter's ensemble.

In the far-term, efforts will focus on integrated protection. Next generation technology will be directed toward integrating CB protection into a system that will also provide environmental, ballistic, directed energy, and flame protection, as well as reduced physiological burden. A strong emphasis on supporting technologies must continue. Materials that detoxify a broad range of chemical and biological agents on contact, which can be incorporated into fibers, nanofibers, fabrics, and selectively permeable membranes are being developed using biotechnology, electrospinning, and more conventional approaches.

Collective Protection (CP)

The Services currently use the M20A1 Simplified CPE and the M28 shelter liners to provide CP collective protection to existing structures. Environmental control is also being

added to selected applications. The M20A1 CPE provides resistance to liquid agent and allows expansion of protection area and has been fielded. The M28 Simplified CPE has been integrated into CP DEPMEDS and CHATH field hospitals.

CHATH and CP DEPMEDS are joint programs to integrate environmentally controlled collective protection into already fielded Army and Air Force field hospitals in order to sustain medical operations in a CB contaminated environment for 72 hours. Chemical protection is integrated into existing Tent Extendable Modular Personnel (TEMPER)-based medical tents and shelters through addition of M28 Simplified CPE, chemically protected heaters, air conditioners, and alarms. CP DEPMEDS also includes water distribution and latrine systems and alarms. CP DEPMEDS successfully completed an Operational Test 4QFY97, with type classification scheduled for 2QFY00 and fielding in FY01.

The Chemically and Biologically Protected Shelter (CBPS) is a highly mobile, rapidly deployable shelter system designed to be used for Echelon I and II forward area medical treatment facilities. The system is self contained/self-sustaining. It is permanently mounted onto a M1113 Expanded Capacity Vehicle (ECV) with a Lightweight Multipurpose Shelter. The vehicle tows a trailer and generator set. The vehicle transports a CB protected airbeam supported soft shelter, self-contained environmental support and power generation system, a crew of four and gear, and medical equipment. The CBPS presently is in limited production with initial fielding scheduled for 3QFY00 to meet an urgency of need requirement. Further Operational Tests will be performed in FY00 with full type classification following. A preliminary Operational Test was completed 3QFY98. Mid-term objectives are to initiate development of CBPS to support medical treatment for Airborne, Air Assault and Heavy Divisions.

Other near to mid-term collective protection efforts, such as the Advanced Integrated Collective Protection System (AICPS) will provide a compact, integrated package for power, filtration, and environmental control (heating/cooling). AICPS will provide transportability and maintainability enhancements and decrease system set-up times. Joint Collective Protection Equipment (JCPE) will use the latest technologies in filtration, environmental controls, and power generation to improve and/or standardize current collective protection equipment so that it is lighter, more efficient, more affordable and less logistically burdensome. The Joint Transportable Collective Protection System (JTCOPS) will be the next generation lightweight, modular, easily transportable, self-supporting collective protection shelter that will provide relief from psychological and physiological stresses during sustained operations in a contaminated environment. JCPE and JTCOPS will initiate engineering development in FY00. Redesign and concept tradeoff assistance regarding advanced filtration technologies, such as Pressure Swing Adsorption (PSA) and Catalytic Oxidation (CatOx) has been provided to the Comanche, Crusader, USMC AAAV, and U.S. Army advanced vehicle efforts. The USAF is currently undergoing a major upgrade to their mobile and fixed site collective protection capabilities.

2.4.4 Defense Advanced Research Projects Agency (DARPA) Protection Programs

There are two related programs currently ongoing within DARPA that further enable the individual warfighter by providing significantly more mobile and flexible water purification and

desalinization systems and better air filtration media. The intent is to demonstrate highly efficient, smaller, lighter, high water-throughput technologies for water purification and desalinization, and to explore pioneering air filtration schemes of high utility to enable new mission scenarios that are critical to the changing battlefield environment. The water desalinization and purification systems would meet Army Operational Requirements (*i.e.*, effectively treat salt and brackish water and NBC contaminated water, purify 0.2 liter water per minute, weigh less than 2 lbs., *etc.*). The proposed man-portable water units will be multifunctional in that they can be used for several functions, such as water purification, power generation and camp stoves. Work in air purification is being conducted to develop simple air filtration/purification systems for the individual that provide significant improvements over the current charcoal filter gas mask technology (which have remained virtually unchanged for over 20 years). The intention is to develop air purification systems for collective protection that will require much less maintenance and greater personal safety than current carbon-based recirculating filters

2.4.5 Other Protection Programs

Programs supporting requirements of a single service are shown in Table 2-7 as italicized entries. A detailed description of IPE and CPE projects is presented in Annex B.

Individual Protection

Eye/Respiratory. The Army is developing the M48 protective mask to replace the M43 series masks. The M48 will be for Apache pilots. It will be lighter and offer enhanced protection and compatibility with night vision and aircrew systems.

In the near-term, the Army will replace the M43 mask for the general aviator with the Aircrew Protective Mask, M45. The M45 is lighter and less expensive than the M43 and features CB protection without the aid of force ventilated air.

Clothing. The Army has approved fielding of the Self-Contained Toxic Environment Protective Outfit (STEPO). STEPO provides OSHA level A protection for Army Chemical Activity/Depot (CA/D), Explosive Ordnance Disposal (EOD), and Technical Escort Unit (TEU) personnel. The Army has also developed an Improved Toxicological Agent Protective (ITAP) ensemble for short term operations in Immediately Dangerous to Life and Health (IDLH) toxic chemical environments (up to one hour), emergency life saving response functions, routine Chemical Activity operations, and initial entry and monitoring activities. The ITAP ensemble incorporates improvements in material and design. It includes a one-hour supplied air bottle system, which can be switched to a filtered air respirator when operators exit the area of high contamination. A Personal Ice Cooling System (PICS) has been developed for use with both the ITAP and STEPO.

Collective Protection

The Navy now includes the Collective Protection System (CPS) on selected spaces of all new construction ships. Currently the DDG-51, LHD-1, AOE-6, and LSD-41 ship classes are

being built with CPS. The Navy also has the capability to backfit CPS on ships already in Service. The Selected Area Collective Protective System (SACPS) has been installed on selected LHA-1 class ships. The Ship CPS Backfit program will backfit selected spaces critical to amphibious ships with CPS starting in FY00. These spaces include hospital areas, command and control areas, and rest and relief areas. In the mid-term, the Navy is designing the V-22 Osprey to be the first Naval aircraft to incorporate CBR protection for both aircrew and passengers. The ability to provide a pressurized, contamination free environment is a design requirement. The Navy Shipboard Collective Protection Equipment (CPE) effort will increase the shipboard particulate filter life (from the current one or two years) to at least a three year service life, through the use of new particulate pre-filter materials and the use of new high efficiency particulate (HEPA) filter media. The Shipboard CPE will thus provide millions of dollars of savings in life cycle costs by reducing shipboard maintenance requirements and providing energy efficient fans.

2.5 DECONTAMINATION

When contamination cannot be avoided, personnel and equipment must be decontaminated to reduce or eliminate hazards after NBC weapons employment. Decontamination systems provide a force restoration capability for units that become contaminated. Modular decontamination systems are being produced to provide decontamination units with the capability to tailor their equipment to specific missions. Technology advances in sorbents, coatings, catalysis, and physical removal will reduce logistics burden, manpower requirements, and lost operational capability associated with decontamination operations. The following sections detail CB decontamination science and technology efforts, modernization strategy, and Joint Service programs.

2.5.1 Decontamination Science and Technology Efforts

2.5.1.1 Goals and Timeframes. The goal of decontamination science and technology is to develop technologies that will eliminate toxic materials without performance degradation to the contaminated object, are non-corrosive, environmentally safe, and lightweight (see Table 2-9). This area includes decontamination of personnel, individual equipment, tactical combat vehicles, aircraft, facilities, and fixed sites. Decontamination technologies currently being pursued include enzymes, catalysts that improve reactivity, decontaminants that are effective in both fresh and brackish water, and improved reactive sorbents. Supercritical fluid technology and non-ozone depleting fluorocarbons are being investigated for sensitive equipment decontamination, while reactive gases are among the technologies being evaluated as a reactive decontaminant for interior spaces of vehicles such as aircraft. Contamination control involves investigating procedures that minimize the extent of contamination pickup and transfer, and maximize the ability to eliminate the contamination pickup on-the-move as well as during decontamination operations. Enzyme-based decontaminants that are nontoxic, noncorrosive, and environmentally safe are being pursued through DTO Enzymatic Decontamination.

Table 2-9. Decontamination Science and Technology Strategy

By 2000	By 2005	By 2010
• Demo improved sorbent delivery systems • Aircraft Interior Decon procedures (non-system, Project O-49) • Demonstrate Fixed Site decontaminants	• Sensitive Equipment Decon Systems • Demonstrate enzymatic decon • Fixed Site applicators	• Demonstrate environmentally safe, sensitive equipment decon materials • New self-decontaminating materials • Improved decon material to replace DS2 • Aircraft and other vehicle interior decontamination

2.5.1.2 Potential Payoffs and Transition Opportunities. The payoff from enhanced decontaminants and decontamination systems will be new non-corrosive, non-toxic, non-flammable, and environmentally safe decontamination systems suitable for a timely elimination of CB agents from all materials and surfaces. This ability will allow the forces to reconstitute personnel and equipment more quickly to increase combat efficiency and lessen the logistic burdens. In the future, reactive coatings may allow the continuation of combat operations without the need to disengage for decontamination. Dual use potential for environmental remediation, especially those dealing with pesticide contamination, is being exploited.

2.5.1.3 Major Technical Challenges. There are two principle technical difficulties associated with this effort. The first is the development of decontaminants that are reactive, non-aqueous, non-corrosive, safe to use on sensitive equipment, decontaminate a broad spectrum of chemical and biological agents, and environmentally safe. The second technical difficulty is the development of decontamination systems that effectively clean all surfaces and materials, while at the same time reduce the manpower and logistics burden.

2.5.2 Decontamination Modernization Strategy

Decontamination systems provide a force restoration capability for units that become contaminated. Existing capabilities rely upon the physical application and rinse down of decontaminants on contaminated surfaces. Existing systems are effective against a wide variety of threat agents, yet are slow and labor intensive and present logistical, environmental, material, and safety burdens. In addition, existing systems are inadequate for electronic equipment decontamination, deficient for large area, port, and airfield decontamination, and rely on DS2 and water. To improve capabilities in this functional area, the Joint Services have placed emphasis upon new decontaminating technologies that reduce existing manpower and logistics requirements. These technologies are safer on the environment, the warfighter, and equipment. Table 2-10 shows the roadmap for modernizing decontamination systems in DoD.

Table 2-10. Decontamination Modernization Strategy

	NEAR (FY00-01)	MID (FY02-05)	FAR (FY06-15)
Personal Equipment Decontam-inants	•More reactive, high capacity adsorbent (M291/M295)	•Non-caustic, non-corrosive decontaminant for personnel and equipment •Army-*Higher efficiency decon methods (Sorbent Decon)*	
Bulk Decontam-inants	•Non-caustic, non-corrosive, easy to store and manufacture multipurpose decontaminants	•Decontaminants for fixed sites •Navy -*Less caustic capability*	•Mission tailored decontaminants •Navy -*Contamination resistant shipboard materials* •Army -*Environmentally acceptable replacement for DS-2* •Army -*Enzymes for chemical agent decontamination*
Expedient Delivery Systems		•Auto-releasing coatings; reduces skin contact hazard & labor requirements	•Self-decontaminating auto releasing coatings; reduces man-power and logistic requirements eliminates skin contact hazard
Deliberate Delivery Systems	•High pressure water wash; mechanical scrubber; improved decontaminant dispenser (increased vehicle throughput) •Army -*High pressure hot water washing and decontaminate scrubber capability; reduced water, labor, and logistic burden (M21/M22 Modular Decon System)*	•Rapid large scale decon capability for fixed sites; reduced manpower and logistic burden •Non-aqueous capability for electronics, avionics and other sensitive equipment	•Vehicle interior decon capability •Supercritical fluid decontamination apparatus •Army -*Waterless decon capability for electronics and avionics* •Air Force - *Sensitive equipment decontamination system for aircraft interiors*

1. All programs shown are joint or multi-service, unless indicated as a Service-unique effort (*italicized text*).
2. Where applicable, systems which meet requirements are listed following the entry.

The goal of the NBC decontamination program area is to provide technology to remove and detoxify contaminated material without damaging combat equipment, personnel, or the environment. In FY99 the RDA community worked with the Joint Staff and Services' operations community and prepared a roadmap that integrates RDA efforts with non-RDA efforts. Other efforts include policy, doctrine, standards, and revised tactics, techniques & procedures. Research and development of non-corrosive, all-agent multipurpose decontaminants and decontaminating systems for combat equipment, aircraft, and personal gear remains a priority. Alternative technologies, such as sensitive equipment decontamination methods and large scale decontamination systems attract interest across the four Services. Table 2-11 provides an overview of Joint Service RDA efforts and Service involvement.

2.5.3 Joint Service Decontamination Programs

The Army has developed the M291 skin decontamination kit as a replacement for the M258A1 decontamination kit for all Services, and has introduced the M295 for improved personal equipment decontamination. The M295 provides the warfighter a fast and non-caustic decontamination system for personal gear. A new adsorbent which is more reactive and has higher capacity of absorbing contamination was developed and completed to improve the performance of the M295 kit. The M295 kit filled with the new sorbent will be available for requisition in January 2000.

Table 2-11 Decontamination RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
Personnel	- M295 Individual Equipment Decontaminating Kit	Production	Fielded	Fielded	Interest	Interest
	- M291 Skin Decontaminating Kit	Production		Fielded	Fielded	
Combat Equipment, Vehicles, and Aircraft	- M17A2/A3 Lightweight Decontamination System	Production	Fielded	Rqmt	Fielded	Interest
	- M21/M22 Modular Decontamination System (MDS)	RDTE	Rqmt	Int-NIR	Int-NIR	Int-NIR
	- M17 Diesel Lightweight Decontamination System	RDTE		Int-NIR	Rqmt	Interest
	- Joint Service Sensitive Equipment Decon	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
	- Joint Service Fixed Site Decon	RDTE		Rqmt	Rqmt	
Decontaminant Solutions and Coatings	- Sorbent Decontamination System and Solution Decontaminants	RDTE	Rqmt	Interest	Rqmt	Interest

Rqmt = Product Requirement
Interest = Product Interest
Int-NIR = Product Interest, No Imminent Requirement

* = sub-Product(s) of a Consolidated Joint Service Project
Rqmt, Interest = Sub-Product Requirement or Interest

In the near- and mid- term, DoD continues to research new multi-purpose decontaminants as a replacement for bulk caustic Decontamination Solution 2 (DS2) and corrosive Super Tropical Bleach (STB). New technologies, such as sorbents, enzymatic foams, and reactive decontaminating systems are being explored and may offer operational, logistics, cost, safety, and environmental advantages over current decontaminants. It should be noted that present shipboard chlorine-based decontaminant solutions pose an unacceptable corrosion risk to Naval aircraft. Current procedures require the use of fresh water and normal aircraft detergent solutions.

In the far-term, the Services are seeking non-aqueous decontamination systems to provide for sensitive equipment decontamination at mobile and fixed sites. Additionally, there is interest and research in coatings which can reduce or eliminate the necessity of manual decontamination. A detailed description of the decontamination projects is provided in Annex C.

2.5.4 Other Decontamination Programs

In the near- and mid-term, the Army is producing the Modular Decontamination System (MDS) to enhance vehicle decontamination. The MDS will support thorough decontamination for ground forces and possess mechanical scrubbing and improved decontaminant dispensing capabilities. It will also offer a reduction in size, weight, logistics burden, and workload requirements over existing decontamination systems. Similarly, the Marine Corps has explored an alternative man-portable decontamination system and is in the process of procuring an M17 Lightweight Decontamination System (LDS) with a diesel engine. The Air Force is upgrading existing M17 LDS to M17A2 versions and expanding sorbent kit inventories to improve operational and personnel decontamination programs.

2.6 NON-MEDICAL CB DEFENSE REQUIREMENTS ASSESSMENT

ISSUE: **Advanced technologies and new methods are currently being examined for fixed site decontamination. Follow-up investigations are planned over the next year to determine the requirements necessary to perform decontamination of large areas, including cleaning area to sustain cargo handling operations. Over the past year, the Services have worked together to improve the Joint orientation of NBC defense requirements. The work being accomplished will improve the equipment fielded in the near future. More emphasis needs to be placed on the Warfighting CINCs' requirements as input for equipment research and development. This is necessary to ensure that future equipment meets the needs of the Joint battlespace environment.**

SOLUTION: Areas of concern which are addressed under the management improvement initiatives include the following:

- Identifying baseline capabilities as a measure for determining what tactics, techniques, and procedures may be required.
- Focusing and prioritizing chemical and biological detector programs to ensure that resources are leveraging the most promising technologies and are not diluted by excessive Service unique requirements.
- Developing advanced individual protection ensembles that minimally degrade an individual's performance for all tasks performed in contaminated environments.
- Identifying requirements for collective protection programs to ensure that enough assets are available to complete missions in a CB contaminated environment.
- Developing advanced detection capabilities for the purpose of directing decontamination efforts and monitoring the effectiveness of those efforts.
- Identifying an environmentally safe decontaminant and development of a capability to accomplish fixed site and sensitive equipment decontamination.

In FY99 a Science and Technology Decontamination Master Plan was developed that linked technologies with decontamination needs and programs, resulting in a ten year roadmap that illustrated how the science and technology base should transition to engineering development to meet those needs. The Master Plan was an outgrowth of a front end analysis that provided a systematic evaluation of technologies and their applicability to CB decontamination in the areas outlined above.

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Chapter 3

Joint Medical Nuclear, Biological, and Chemical (NBC) Defense Requirements, and Research and Development Program Status

3.1 REQUIREMENTS

3.1.1 Introduction

Many countries and terrorist groups have acquired the means to produce chemical, biological and radiological weapons and the means to deliver them. NBC proliferation increases the threat to deployed U.S. forces. In response, the U.S. joint medical chemical, biological, and radiological defense research programs' (JMCBRDRP) mission is to preserve combat effectiveness by timely provision of medical countermeasures. Countermeasures are developed in accordance with joint service mission needs and requirements in response to chemical warfare (CW) threats, biological warfare (BW) threats, and threats associated with radiological/nuclear warfare (RW) devices. The JMCBRDRP has the following goals:

(1) Provide individual level protection and prevention to preserve fighting strength.
(2) Maintain technological capabilities to meet present requirements and counter future threats.
(3) Provide medical management of CW, BW, and RW casualties to enhance survivability, and expedite and maximize return to duty.
(4) Sustain basic research that provides the knowledge upon which innovative diagnostics, prophylaxes, and therapies are developed.

CW agents are available worldwide and include vesicants (blister agents), nerve, blood, and respiratory agents. BW agents include bacteria, viruses, rickettsiae, and toxins that can be produced by any group with access to a scientific laboratory or a pharmaceutical facility. The primary RW threat is the use of conventional explosives to spread nuclear contamination over a limited area or strategic terrain (including use against reactors or industrial radiation sources) and potentially the use of a single or a small number of crude, Hiroshima-type nuclear weapons. Exposure to multiple threats may result in synergistic effects. Assessment methodologies enable threat evaluation and injury prediction. Medical prophylaxis and treatment strategies reduce the performance decrement, injury, and death of military personnel in the field, thereby enabling them to accomplish their missions, reducing the need for medical resources and decreasing the probability of long term health effects.

The DoD medical NBC defense research and development program has provided numerous products to protect and treat service members. The DoD program to stockpile biological defense products has been smaller than the chemical defense effort, but has received greater emphasis in recent years.

Specific initiatives programmed to improve NBC defense medical readiness include:

- Continued emphasis on NBC medical countermeasures research.
- Identification and testing of medications and therapeutic regimens that reduce the effect of radiation on both bone marrow and the intestinal tract.
- A biological defense immunization policy for U.S. forces and for other-than-U.S. forces.
- Cooperative initiative with the U.S. Food and Drug Administration (FDA) for acceptance of efficacy data derived from animal studies as surrogates for large-scale human efficacy trials to license drugs and biological products that cannot be ethically tested for efficacy in humans.
- A prime systems contractor initiated efforts to develop, license, produce, and store biological defense vaccines.
- Enhanced medical diagnostic capability for diseases/injuries caused by all agents.
- Consequence assessment of sublethal radiation exposure combined with susceptibility to biological and chemical agents.
- Studies to elucidate the toxicity and mechanism of action of novel threat agents, and to determine the effectiveness of current medical countermeasures.
- Studies to evaluate the effects of chronic exposure to low level chemical warfare agents (CWAs).
- Training of health care professionals for the medical management of chemical, biological, and radiological casualties.

3.1.2 Challenges in the Medical NBC Warfare Defense Programs

Medical prophylaxes, pretreatments, and therapies are necessary to protect personnel from the toxic or lethal effects of exposure to all validated threat agents, as well as other anticipated threats. DoD has fielded a number of medical countermeasures that greatly improve individual medical protection, treatment, and diagnoses.

Executive Order 13139 of September 30, 1999 makes it the policy of the United States Government to provide military personnel with safe and effective vaccines, antidotes, and treatments that will negate or minimize the effects of exposure to a range of chemical, biological, and radiological weapons as well as diseases endemic to an area of operations. This executive order establishes the procedures for the administration of investigational new drugs to members of the Armed Forces to include informed consent requirements and waiver provisions.

The DoD complies with the Food, Drug and Cosmetic Act for Drugs and Public Health Services Act Section 351 for biologics to ensure that drug products are safe and efficacious and biological products are safe, pure, and potent. DoD is working closely with the FDA to amend the Code of Federal Regulations (CFR) for New Drug and Biological Products that cannot meet the efficacy studies required by the FDA for product licensure because they are either not feasible and/or cannot ethically be conducted under the FDA's regulations for adequate and well controlled studies in humans. (See 21 CFR Sec. 312.21(2)(b).) DoD presented a proposal to the

FDA's Vaccines and Related Biological Products Advisory Committee to use animal efficacy data as evidence demonstrating the efficacy of the Pentavalent Botulinum Toxoid (ABCDE). The Advisory Committee recommended that the FDA accept DoD's proposed animal surrogate data for licensure of the Pentavalent Botulinum Toxoid (ABCDE). The FDA drafted a proposed rule that allows the use of animal efficacy data for those products that either cannot be tested ethically in humans or it is unfeasible to test. This proposed rule has been published in the Federal Register [Federal Register: October 5, 1999 (Volume 64, Number 192)].

Medical NBC defense products are thoroughly tested and evaluated for their safety in accordance with FDA guidelines before administration to *any* personnel. All medical products must be safe to use and not degrade operational performance. In cases where adverse effects are known or possible, a decision must be made—and a risk accepted—of the potential effects of a medical product versus the catastrophic effects of NBC weapons. Even in those cases where efficacy could not be studied in human clinical trials, the safety profiles of the products are well delineated In many cases, the safety is well understood because the medical products have been widely used to treat other medical conditions. (The anthrax vaccine has been licensed and used since the 1970s to vaccinate veterinarians, textile workers, and others. The Pentavalent Botulinum Toxoid (ABCDE) was administered safely over 10,000 times to laboratory workers prior to its use for military personnel during the Gulf War. Various anti-emetics reduce the effects of radiological exposure have been used to treat cancer patients undergoing radiation therapy.) Several studies performed at the U.S. Army Medical Research Institute of Infectious Diseases demonstrated the efficacy of the licensed anthrax vaccine against inhalation anthrax in the monkey model. Rhesus monkeys were vaccinated with one or two doses of the licensed anthrax vaccine and then challenged with highly lethal levels of spores from the Ames strain of anthrax, the most virulent strain tested. In all these studies, the anthrax vaccine protected 42 of 43 monkeys against inhalation anthrax while none of a total of 14 controls used in these experiments survived.

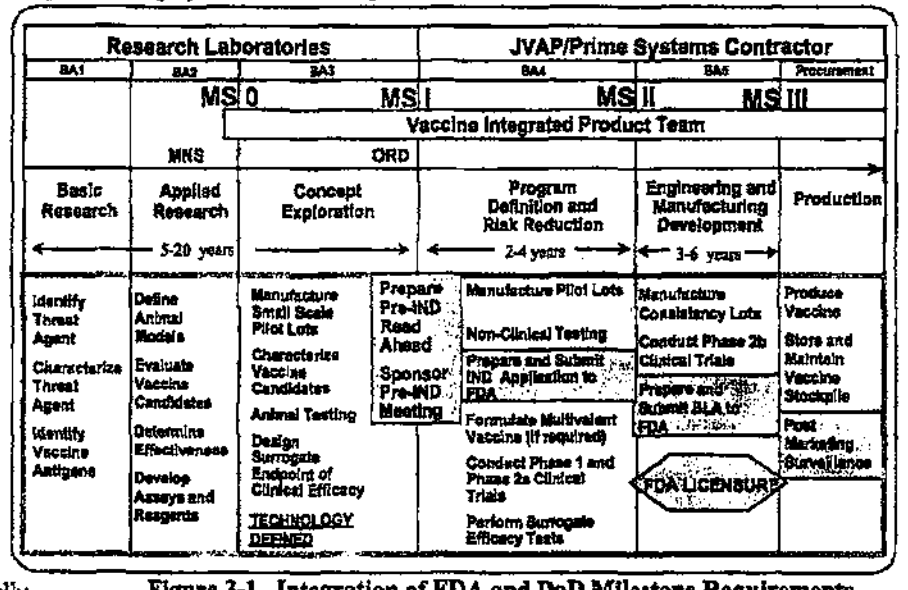

Figure 3-1. Integration of FDA and DoD Milestone Requirements

The acquisition life cycle of medical products developed by DoD is normally managed in accordance with the guidelines found in DoD Regulation DoD 5000.2-R. However, since DoD also complies with FDA requirements, it also must follow the requirements of Title

21, Food & Drugs, Code of Federal Regulations for the manufacture, testing, and licensing of medical products. Figure 3-1 illustrates the correlation of FDA requirements for vaccine development with the requirements of DoD 5000.2-R for the life cycle of product development in accordance with DoD acquisition policy.

The medical NBC defense research programs discussed in this section are divided into chemical, biological, and nuclear areas of research. Table 3-6 at the end of this chapter provides a summary of the medical NBC defense programs and the planned modernization strategy over the next fifteen years.

3.1.3 Medical CB Defense Requirements

The Medical Program Sub-Panel (MPSP) of the Joint Service Integration Group (JSIG) was formed in 1998 to prioritize and integrate the Services' medical NBC defense requirements. The Principals and Action Officers bring significant medical expertise to the panel and have access to the considerable medical expertise across each individual's Service. Working with the ASBREM helps to assure program consistency and proper application of biomedical research dollars. Table 3-1 below is the first prioritized medical requirements list produced by the MPSP in 1998/99; however, the list prepared for 1999/00 will include requirements to support the POM build.

A memorandum from the Principal Deputy Undersecretary of Defense for Acquisition, Technology, & Logistics asked the JSIG to have the MPSP perform an expeditious review and assessment of smallpox vaccine requirements. This review addressed "several threat scenarios including major theater war, a regional contingency, and CONUS and OCONUS terrorist attacks." This review resulted in a significant increase in the troop-equivalent dose requirement for the smallpox vaccine.

Table 3-1. CB Defense Prioritized Medical Requirements

Rank	Requirement
1	Diagnostic Kit for Biological Agents and Joint Biological Agent Identification and Diagnosis System (DKBWA/JBAID)
2	Nerve Agent Antidote Delivery System (NAADS), Multi-chambered Autoinjector
3	Smallpox Vaccine
4	Clostridium botulinum Toxin (CBT) Medical Defense System
5	Tularemia Vaccine
6	Venezuelan Equine Encephalomyelitis (VEE) vaccine
7	Topical Skin Protectant
8	Q-Fever vaccine
9	Chemical Biological Protective Shelter (CBPS) System
10	Cyanide Pretreatment
11	Botulism Immune (F(ab')2) Globulin Heptavalent, Equine
12	Pentavalent Botulism Toxoid
13	Type F Botulism Toxoid
14	Chemically Protected-Deployable Medical System/Chemically Hardened Air-transportable Hospital (CP-DEPMEDS/CHATH)

3.1.4 Reducing Reliance on Research Animals

In accordance with the FY95 National Defense Authorization Act, which directed DoD to establish aggressive programs to reduce, refine, or replace the use of research animals, the JMCBRDRP utilizes and develops technologies that will reduce reliance on animal research. In FY99, the JMCBRDRP employed computerized molecular modeling, computer predictions, *in vitro* cell cultures, a cell-free reaction system, an *in vitro* model of human skin, and a lipid bi-layer system to replace the use of animals when possible. All research proposals that use animals are evaluated by a statistician to ensure that the minimum number of animals required to obtain scientific validity are used. Animals lower on the phylogenetic scale (or the least sentient species) are used if the selection will permit attainment of the scientific objective. Additionally, all procedures that might cause pain or distress in laboratory animals are reviewed by a veterinarian with expertise in laboratory animal medicine to determine the procedural modifications, analgesics and/or anesthetic regimens to be incorporated to minimize pain or distress. Detailed protocols are comprehensively reviewed and approved by an Institute Animal Care and Use Committee before experiments are initiated; the small percentage of protocols which specify the use of primates undergoes further scrutiny at the USAMRMC Animal Use Review Office. Policies and procedures of the Association for the Assessment and Accreditation of Laboratory Animal Care – International are rigorously enforced and followed. DoD policy states that animal use will be conducted in full compliance with the Animal Welfare Act and that animals are to be used in research only when scientifically acceptable alternatives are not available.

3.1.5 Medical Program Organization

Chemical/Biological. The U.S. Army is the Executive Agent for the Joint Medical Chemical and Biological Defense Research Program (JMCBRP) as prescribed in DoD Directive 5160.5 and, as such, is the lead requirements coordinator. The JMCBRP integrates DoD in-house and external efforts. The Joint Technology Coordinating Group (JTCG) 3 (Medical CW Agent Defense) and JTCG 4 (Medical BW Agent Defense) of the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee are responsible for the programs' joint consolidation, coordination, and integration. The ASBREM Committee maximizes efficiency by coordinated planning, and minimizes unnecessary program overlaps and costly materiel retrofits. (The integration of program management and oversight of medical and non-medical NBC defense programs is described in Chapter 1.) The Army Science and Technology Base Master Plan, the Defense Technology Area Plan, the Joint Nuclear Biological Chemical Defense Research, Development, and Acquisition Plan, and the Medical Science and Technology Master Plan are the program drivers for the chemical and biological research programs. The Joint Service Integration Group (JSIG) established a Medical Program Sub-Panel (MPSP), which is the user representative from the medical community, to establish and direct joint service NBC medical defense program requirements. The science and technology base is managed through the development and execution of Defense Technology Objectives (DTOs). The predevelopment program (basic research, exploratory development, and concept exploration and definition) is directed by the U.S. Army Medical Research and Materiel Command (USAMRMC) through its lead laboratories for medical chemical defense, biological defense, and infectious disease research, U.S. Army Medical Research Institute of Chemical Defense

(USAMRICD), U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID), and Walter Reed Army Institute of Research (WRAIR), respectively. The advanced development program (Program Definition and Risk Reduction [PDRR]) and Engineering and Manufacturing Development (EMD) for medical *chemical* defense products is directed by the U.S. Army Medical Materiel Development Activity (a USAMRMC asset). The advanced development program (PDRR and EMD) for medical *biological* defense products is directed by the Joint Program Office for Biological Defense (JPO-BD). The Joint Vaccine Acquisition Program (JVAP) is an ACAT II program under JPO-BD to transition candidate biological defense vaccines from research laboratories to the Prime Systems Contractor for the development, testing, licensure, production, and storage of vaccine stockpiles.

Nuclear. The study of the medical and biological effects of ionizing radiation is performed by the tri-service Armed Forces Radiobiology Research Institute (AFRRI). AFRRI programs are integrated into other DoD in-house and external efforts under the coordination of the ASBREM. JTCG 7 (Medical Radiological Defense) of the ASBREM Committee is responsible for program consolidation, coordination, and integration. Specific requirements and program tasking for AFRRI research comes from the individual services, Joint Staff, and the Defense Technology Objectives (DTOs) through the authority of a Board of Governors (BOG) with funding from the Director, Defense Research and Engineering. AFRRI is under the administrative control of the Uniformed Services University of the Health Sciences. Members of the AFRRI BOG include representatives of Under Secretary of Defense for Acquisition, Technology, and Logistics, the Assistant Secretary of Defense for Health Affairs, the Surgeons General of the Army, Navy, and Air Force, and the Deputy Chiefs of Staff for Operations of the Army, Navy, and Air Force, or their designated representatives. Major inputs to AFRRI research requirements are driven by the biennial Army Specific Military Requirements compiled by the U.S. Army Nuclear and Chemical Agency.

3.2 JOINT MEDICAL CHEMICAL DEFENSE RESEARCH PROGRAM

The mission of the Joint Medical Chemical Defense Research Program (JMCDRP) is preserve the health, safety, and combat effectiveness of warfighters by timely provision of medical countermeasures in response to joint service chemical warfare defense requirements.

3.2.1 Goals

The goals of the JMCDRP are the following:

- Maintain technological capability to meet present requirements and counter future threats:
  - Determine sites, mechanisms of action and effects of exposure to CWAs.
  - Exploit neuroscience technology and dermal pathophysiology to identify mechanism of action of CWAs.
  - Identify sites and biochemical mechanisms of action of medical countermeasures.
  - Exploit molecular biology and biotechnology to develop new approaches for

medical countermeasures.
- Exploit molecular modeling and quantitative structure-activity relationships supporting drug discovery and design.

- Provide individual-level prevention and protection to preserve fighting strength:

  - Develop improved prophylaxes, pretreatments, antidotes, and therapeutic countermeasures.
  - Develop skin protectants and decontaminants.
  - Identify factors that influence safety and efficacy properties of candidate countermeasures.
  - Develop and maintain preformulation, formulation, and radiolabeling capabilities.

- Provide medical management of chemical casualties to enhance survival and expedite and maximize return to duty:

  - Develop concepts and recommend therapeutic regimens and procedures for the management of chemical casualties.
  - Develop diagnostic and prognostic indicators for chemical casualties.
  - Provide education on medical management of chemical casualties.

3.2.2 Objectives

The objectives of the JMCDRP differ with the varying threats:

- For vesicant (or blister) agents, the objective is to develop a pathophysiological database on vesicant chemical agents and a working hypothesis on how damage occurs at the cellular level. Used with associated technologies, this approach will enable the formulation of definitive pretreatment and treatment strategies, and is expected to produce a realistic concept for medical prophylaxis, immediate post-exposure therapy, and topical protection. Alternatively, in dealing with liquid agent threat, reactive topical skin protectants (rTSPs) can be developed that will protect the skin and simultaneously detoxify the agent.

- For nerve agents, an objective is to field a safe and effective advanced anticonvulsant nerve agent antidote superior to the currently fielded anticonvulsant (diazepam). The advanced anticonvulsant will be more water soluble, will terminate seizures more quickly, and will prevent seizure-induced brain damage and subsequent behavioral incapacitation. Another objective is to field an advanced pretreatment effective against all nerve agents based on physiological scavengers such as the human enzymes butyrylcholinesterase (BuChE) or carboxylesterase (CaE). Ideally the prophylactic would not require any follow-on treatment, and would have no adverse side effects. These naturally occurring enzymes, as well as acetylcholinesterase, are targets for nerve agents. Through bioengineering efforts, human BuChE and CaE have been mutated to forms that are not only less susceptible to inhibition by the nerve agents, but have the added capability to

catalyze nerve agent breakdown. Another potential chemical warfare agent scavenger is human paraoxonase. This enzyme also is being bioengineered to make it more effective and decrease the time it takes to destroy nerve agent.

- For blood agents, the objective is to examine the safety and efficacy of methemoglobin-formers or sulfide donors for cyanide pretreatment.

- For respiratory agents, the objective is to develop prophylaxes and therapies by understanding pathophysiological changes after agent exposure.

3.2.3 Threats, Countermeasures, Technical Barriers, and Accomplishments

The chemical warfare threats and countermeasures, as well as chemical defense research and development technical barriers and accomplishments, are outlined in Annex D (Section D.1). Countermeasures and diagnostic techniques for chemical weapons are shown in Table 3-2. Critical issues of medical chemical defense include the ability to protect U.S. warfighters from the very rapidly acting nerve agents and persistent vesicating agents as well as choking agents and respiratory agents. New threats are also emerging. The effectiveness of current therapeutics against novel threats is a current countermeasure under investigation.

Table 3-2. Medical Chemical Defense Countermeasures and Diagnostic Techniques

- ***Chemical Warfare Agent (CWA) Scavengers*** – Human enzymes that have been genetically engineered to destroy nerve agents are being developed as nerve agent scavengers.
- ***Advanced Anticonvulsant*** – Benzodiazepines that are water soluble and long acting are being evaluated for control of nerve agent-induced seizure activity.
- ***Reactive Topical Skin Protectant*** – Reactive barrier creams are being developed that can not only prevent penetration of CWA but will also destroy them.
- ***Antivesicants*** — Countermeasures that provide reduction in mustard-induced edema, corneal opacity, and dermal histopathology are being evaluated.
- ***Effects of exposure to non-lethal levels of CWA*** –The probability and severity of chronic medical effects of single and multiple low-level exposures to CWA are being evaluated.
- ***Novel Threat Agents*** –Current medical regimens used for protection against the conventional nerve agents are being evaluated as a countermeasure for novel threat agents.
- ***Cyanide Countermeasures*** – Methemoglobin formers and sulfide donors are being evaluated for safety and efficacy as pretreatments for cyanide intoxication. A non-invasive methemoglobin/cyanide monitor is being transitioned for development.
- ***Chemical Casualty Management*** - Technologies to assist in the diagnosis, prognosis, and management of chemical casualties are being developed.
- ***Respiratory Agent Injury*** –Mechanisms of respiratory agent injury are being determined and medical countermeasures for respiratory agent casualties are being developed.

3.3 JOINT MEDICAL BIOLOGICAL DEFENSE RESEARCH PROGRAM

The mission of the Joint Medical Biological Defense Research Program (JMBDRP) is to develop medical countermeasures to protect U.S. forces and thereby deter, constrain, and defeat the use of biological agents against them (DoD Directive 5160.5, May 1985). The program is directed against agents of biological origin that are validated military threats. A primary concern is the development of vaccines, drug therapies, and diagnostic tools, and other medical products that are effective against agents of biological origin.

3.3.1 Goals

Goals of the JMBDRP include the following:

- Protecting U.S. forces' warfighting capability during a biological attack.
- Reducing vulnerability to validated and emerging threats by maintaining a strong technology base.
- Providing education on medical management of BW casualties.

3.3.2 Objectives

In accomplishing the goals of the JMBDRP, efforts are focused on three objectives:

- Maintaining technological capability to meet present requirements and counter future threats:
  - Determine sites, mechanisms of action, and effects of exposure to biological warfare agents with emphasis on exploitation of molecular science.
  - Identify sites and biochemical mechanisms of action of medical countermeasures.
  - Exploit molecular biology and biotechnology to develop new approaches for medical countermeasures.
  - Exploit molecular modeling and quantitative structure-activity relationships supporting drug discovery and design.

- Providing individual-level prevention and protection to preserve fighting strength:
  - Develop improved vaccines, pretreatments, antidotes, and therapeutic countermeasures.
  - Identify factors that influence safety and efficacy properties of candidate countermeasures.

- Providing training in medical management of biological casualties to enhance survival and expedite and maximize return to duty:
  - Develop concepts and recommend therapeutic regimens and procedures for the management of biological casualties.
  - Provide education on medical management of biological warfare casualties.

One of the key efforts to achieve the goals and objectives of the medical biological

defense program has been the protection of U.S. forces against anthrax — a deadly biological warfare agent. This is being accomplished through total force vaccination against anthrax, as described in Table 3-3.

Table 3-3. Anthrax Vaccine Immunization Program (AVIP)

Detailed information on the AVIP may be found on the internet at http://www.anthrax.osd.mil/
This web site provides detailed account on the nature of threat from anthrax (*Bacillus anthracis*), description of the vaccine, explanation of U.S. policies regarding biological defense vaccines, U.S. policies regarding the anthrax vaccine, immunization schedule, information on adverse event reporting, and other information related to the AVIP.
As of January 27, 2000, approximately 399,542 members of the U.S. Armed Forces have received at least their initial vaccination and more than 17,066 have completed the 6-shot series. The total force is scheduled to have received the entire series of six shots by 2005.

The JMBDRP responds to requirements from the DoD as identified in the Joint Service Agreement on Biological Defense, the Joint Warfighting Science and Technology Plan, the Defense Technology Area Plan, the Defense S&T Strategy, and DoD Directive 6205.3, "Biological Defense Immunization Program".

Highly sophisticated technology base efforts for medical biological defense hold the promise of yielding important new products to protect our troops against a wide range of biological threat agents. These products include multi-agent vaccines that will reduce costs of vaccine production and simplify immunization schedules, and a common diagnostic system that can be deployed at forward sites to rapidly analyze clinical samples for the presence of biological warfare agents as well as infectious diseases of military importance. The development of these products, as well as the complementary technology-based research and development to enhance and expand these capabilities and to identify and develop new capabilities, is also being supported by collaboration with other agencies, including the Defense Advanced Research Projects Agency (DARPA) and the Department of Energy (DOE).

Projects and technologies shared with the DOE are related to the strengths of DOE laboratories in developing advanced technologies in order to enable rapid detection of and response to a chemical or biological incident. While DOE focuses internal technology development efforts on the domestic threat, they actively support the DoD. The work spans DNA sequencing and biodetection to modeling and simulation, collaborating on projects such as x-ray crystallography and nuclear magnetic resonance imaging of BW agent antigens. The DNA sequencing efforts have led to advances in developing "lab on a chip" diagnostic technology for several BW threat agents. DOE is not involved in protection and treatment of personnel, but they are assisting DoD with drug/chemical database searches with the intent of identifying novel inhibitors of pathogens.

The DARPA BW defense program includes collaborating with USAMRMC on new platforms to enhance delivery and effectiveness of multi-agent vaccines (for example, stem cells genetically programmed to express antigens sequentially in order to provide automatic boosters in the body). Multi-agent vaccines are similar to the measles-mumps-rubella vaccine administered

to children except that the technologies being explored for producing these new vaccines are more advanced, relying on bioengineering technologies such as naked DNA and the replicon-based delivery systems. Research within USAMRMC in both the naked DNA and replicon approaches is advancing rapidly with demonstration of a multi-agent vaccine planned for FY03.

Bioengineering techniques are also being used to prepare a variety of recombinant vaccines against single threat agents that will be produced without the need to grow the actual threat agent during the vaccine production process. Several recombinant vaccines are scheduled to be fielded over the next 10 years.

Development of a common diagnostic system is proceeding with the adoption of rapid nucleic acid analysis methods. Three configurations of portable instruments using common polymerase chain reaction (PCR) chemistries were demonstrated for the identification of biological warfare agents and naturally occurring infectious diseases. With these tools, laboratory-based identification of infections will be made much faster (less than 30 minutes) and farther forward than is now possible. The development of technologies for common diagnostic systems is jointly supported by DARPA.

The JMBDRP includes the following areas of research:

Pre-exposure Countermeasures: This area involves prophylactic measures undertaken to prevent illness and injury associated with exposure to bacterial, viral, and toxin threat agents. The primary focus of pre-exposure therapy is efforts to produce effective vaccines. The roles of various factors in stimulating cellular and humoral immunity are determined through study of specific genes or properties of threat agents. This knowledge provides tools for development of second-generation recombinant or multi-agent vaccine candidates as well as pretreatment therapies to intervene in the pathogenic effects of threat agents.

Post-exposure Countermeasures: Research efforts in this area are focused on developing safe, effective treatments to alleviate disease or injury associated with exposure to bacterial, viral, or toxin threat agents. Therapeutic measures may involve administration of antimicrobials, antitoxins or generic compounds formulated to intervene at the pathogen's site of action. The knowledge necessary to develop such products requires in-depth research in the basic pathogenesis and physiology of the BW agents. These analyses will afford researchers tools to create a universal approach in treating post-exposure casualties of a BW attack.

Diagnostics: Diagnostics research involves the investigation and evaluation of sensitive and specific methods for detection of infectious organisms, toxins, antigens and antibodies in biological materials to include the application of nucleic acid probes or synthetic antigens. Rapid identification tests and diagnostic methods for the assay of toxins, metabolites, and analogs in clinical specimens are major goals of this program area.

3.3.3 Threats, Countermeasures, Technical Barriers, and Accomplishments

A biological threat agent is defined as an intentionally disseminated living microorganism

or toxin that can cause disease or death in humans, animals, or plants. Threat agents include a broad range of microorganisms (bacteria, rickettsiae, and viruses) and toxins of biological origin. Biological weapons are easy to make, difficult to detect, and can be very effective. Defense against this class of weapon is difficult, particularly when biological agents can produce casualties over an area of thousands of square kilometers. Biological agents could also be used with devastating effect in combination with nuclear, chemical, or conventional weapons.

Countermeasures and diagnostic techniques for biological weapons are shown in Table 3-4. Critical elements of medical biological defense include the ability to protect U.S. forces from BW agents, to rapidly diagnose (in clinical specimens) infection or intoxication from agents, and to treat casualties. Currently, the most effective countermeasure is pre-deployment active immunization. Future threats, however, may involve genetically engineered biological weapons that may be easily produced, highly lethal, difficult to detect, and resistant to conventional therapies.

The current JMBDRP includes the following research areas for the development of medical countermeasures:

- Characterize the biochemistry, molecular biology, physiology, and morphology of BW threat agents.
- Investigate the pathogenesis and immunology of the disease.
- Determine the mechanism of action of the threat agent in an animal model system.
- Select antigen(s) for candidate vaccines.
- Develop and compare potential vaccine candidates and characterize their effects in animal models.
- Establish safety and efficacy data for candidate vaccines.
- Develop medical diagnostics to include far forward, confirmatory, and reference lab.
- Develop chemo/immunotherapeutic agents and preparations.

Technical shortcoming in the private sector include (1) the lack of high-level biological containment (BL-3 and BL-4) laboratory facilities to support biological defense research, and (2) scientific expertise in biological defense. These factors restrict the depth of expertise, facilities, and support available. A recent redress of funds and authorizations over a six year period (FY99-05) will be used for DoD facility upgrades and to maintain scientific and technological expertise.

Details of the biological warfare threats and countermeasures, as well as biological defense research and development technical barriers and accomplishments, are presented in Annex D (Section D.2).

Table 3-4. Medical Biological Defense Countermeasures and Diagnostic Techniques

VACCINES

- *Killed* – killed or inactivated microorganism that is incapable of replicating but stimulates immunity.
- *Live, attenuated* – live organism, genetically selected not to cause disease but able to stimulate immunity.
- *Toxoid* – toxin protein treated to inactivate its toxicity but retains its ability to stimulate immunity.
- *Recombinant* -gene coding for a protein that stimulates specific immunity to a BW agent is inserted into biological vector for production. Protein may be produced in high yields through bioengineering.
- *Deoxyribonucleic Acid (DNA)* –section of DNA that codes for protein that stimulates specific immunity to a BW agent. DNA produces the desired protein in recipient which stimulates immunity.
- *Polyvalent* – mixture of antigens that protects against a number of different BW agents.
- *Vectored* –carrier organism bioengineered to confer immunity against an unrelated BW agent or multiple agents.

ANTIBODY (ANTISERUM, ANTITOXIN)

- *Heterologous* -antibodies collected from animals (*i.e.*, different species than the recipient) repeatedly immunized against the BW threat. These antibodies must be treated to reduce the human immune response to them (serum sickness).
- *Homologous* – antibodies of human origin (*i.e.*, same species as the recipient) that provide protective immunity against the BW threat. These antibodies are not prone to stimulating serum sickness.
- *Monoclonal* – a cell culture technique for producing highly specific antibodies against a disease agent.
- *Bioengineered* – antigen binding site on the variable portion of an antibody elicited in a nonhuman system is combined with the nonvariable portion of a human antibody to produce a "humanized" antibody.

DRUGS

- *Antibiotics* – very effective against bacteria, but are ineffective against viruses and toxins.
- *Antiviral compounds* –Promising drugs in development by the pharmaceutical industry are being evaluated against biological threat viruses
- *Others* – compounds that offer new possibilities for protecting against and treating exposure to BW agents (such as drugs to treat toxins or nonspecific treatments such as immunomodulators.)

DIAGNOSTIC TECHNOLOGIES

- *Immunological technologies* – These tests rely on antibodies for detecting the presence of proteins associated with the BW agent. They are easy to use, compact, rapid (minutes), and require little logistic support. This technology is currently used in out-patient clinics and doctor's offices.
- *Nucleic acid technologies* – nucleic acid tests, specifically the polymerase chain reaction (PCR), rely on segments of genes unique to BW agents to detect the presence of those agents. These tests are extremely sensitive and specific, but currently require more support to perform.

3.3.4 Defense Advanced Research Projects Agency (DARPA) Programs

As one of the major program areas, DARPA is pursuing the demonstration and development of new biological warfare defense capabilities. Major thrusts include real-time (environmental) sensing (described in Chapter 2); medical countermeasures (developing barriers to prevent entry of pathogens into the human body and developing pathogen countermeasures to block pathogen virulence and to modulate host immune response); Advanced Medical Diagnostics for the most virulent pathogens and their molecular mechanisms; and Consequence Management Tools.

Medical countermeasures research includes: (1) multi-agent therapeutics against known, specific agents, and (2) therapeutics against virulence pathways (mechanisms of disease) shared by broad classes of pathogens. Specific approaches include modified red blood cells to sequester and destroy pathogens, modified stem cells to detect pathogens and to induce immunity or produce appropriate therapeutics within the body, identification of virulence mechanisms shared by pathogens, development of novel therapeutics targeting these mechanisms, and efficacy testing in cell cultures and animals.

Early diagnosis is key to providing effective therapy against BW agents since many of these agents cause early nonspecific flu-like symptoms. The goal of the DARPA Advanced Medical Diagnostics thrust is to develop the capability to detect the presence of infection by biological threat agents, differentiate from other significant pathogens, and identify the pathogen, even in the absence of recognizable signs and symptoms (when the pathogen numbers are low). Specific accomplishments are listed in Annex D.

Mission effectiveness requires rapid, correct medical responses to biological threats. The objective of the Consequence Management thrust is to provide comprehensive protocols to protect or treat combatants by using current and emerging biological countermeasures. It will provide accelerated situational awareness for biological agents events by detecting exposure to agents through an analysis of casualty electronic theater medical records, and will locate and determine the most effective logistical support for providing appropriate treatment and pathogen-specific resources required to mitigate effects of the attack.

3.4 MEDICAL NUCLEAR (RADIOLOGICAL) DEFENSE RESEARCH PROGRAM

The mission of the Medical Nuclear Defense Research Program (MNDRP) is to conduct research in the field of radiobiology and related matters essential to the support of DoD and the Military Services. The sole repository of defense radiobiology expertise is AFRRI.

3.4.1 Goals

The goals of the MNDRP are the following:

- Understand the pathological consequences of radiation injury in order to guide development of pharmacological agents for mitigating injury.
- Develop medical countermeasures for acute, delayed, and chronic radiation injury.
- Develop and test prophylactic drugs to reduce the adverse health consequences of sublethal radiation exposures.
- Identify biological markers and develop rapid assay systems to assess radiation injury under field environments and enhance medical management of radiological casualties.
- Quantify and build into casualty prediction models the morbidity and mortality due to combined exposure to ionizing radiation and infectious disease or chemical agents.
- Sustain combat capability, increase survival, and minimize short- and long-term problems associated with ionizing radiation when combined with other mass casualty weapons or battlefield stressors such as traumatic injury and endemic disease.

3.4.2 Objectives

The primary objective of this research group is to address the major aspects of military operational requirements for dealing with radiation injuries. A nuclear threat agent is any weapon that causes detrimental medical effects by either direct external irradiation or by internal contamination with radioactive material. These agents include radiation dispersal weapons, which scatter radioactive material with conventional explosives; deliberate area contamination; destruction of a nuclear power plant; improvised nuclear devices; and traditional nuclear weapons. Operational requirements include programs in casualty management, medical radioprotectants to diminish radiation injury, medical therapeutic regimens, biodosimetry, combined NBC injury effects and its mitigation, maintenance of performance, and radiation hazards assessment.

3.4.3 Threats, Countermeasures, Technical Barriers, and Accomplishments

The deployment of a relatively low-yield nuclear device is increasingly possible by a terrorist group or third-world country. If counterproliferation and intelligence efforts fail to deter deployment, medical remediation of casualties must be available. Such a device would most likely be utilized against either a military installation or a political target (*e.g.*, the seat of government, large population center, or commercial port city). In such a scenario, citizens outside the immediate lethal area would be exposed to the prompt radiation of the initial explosion as well as to chronic exposures resulting from the residual radioactive fallout.

The nuclear weapons inventory of current adversaries is thought to be small, but if a weapon is used for military advantage, concomitant use of biological or chemical weapons should be anticipated. Radiation dispersal events could include the destruction of a nuclear reactor, intentional contamination of a battlefield with nuclear waste, or dispersal of radiological materials in a terrorist car bomb attack involving conventional explosives. Most casualties in these scenarios would suffer non-lethal doses of external irradiation. This would complicate the management of their conventional injuries and could cause internal contamination with radionuclides. Prompt effects of moderate- to high-dose radiation injury diminish the soldier's ability to fight and survive. Effective radiation countermeasures must protect the soldier from performance decrement and simultaneously diminish lethality and the long-term health effects of radiation injury. Prophylactic and therapeutic applications of novel pharmacological agents will increase survival and diminish morbidity of individual soldiers wounded by radiation. A research program to understand molecular and cellular damage induced by radiation is needed to determine the best medical countermeasures for the newly arising radiological threats on the modern battlefield. Table 3-5 presents an overview of countermeasures to radiological exposure and research accomplishments during FY99.

Table 3-5. Medical Nuclear Defense Countermeasures

PRETREATMENTS
Single agents: Injections of androstene steroid, vitamin E and/or amifostine (Ethyol®) enhance survival of acutely irradiated laboratory animals.
Multidrug combinations: Enhanced survivability has been shown in animal models using pretreatments (*e.g.*, androstene steroids, amifostine, *etc.*) followed by postexposure cytokine treatments. Sustained and effective delivery of prophylactic drugs was demonstrated in animal models using implanted capsules. These are single agents used in consecutive manner.
MEDICAL THERAPIES
Blood Forming Cell Stimulants: Granulocyte colony stimulating factor (G-CSF, Neupogen®) granulocyte-macrophage colony stimulating factor (GM-CSF, Leukine®) have been demonstrated to be highly effective in restoring the immune competence of the bone marrow and allowing survival from radiation injuries previously considered lethal. The cytokine thrombopoietin has been developed as a therapeutic agent and is undergoing further trials as a platelet-formation stimulant. Interleukin 11 (IL-11, Neumega®) has moderate thrombopoietic activity and is currently available for human use.
Broad Range Cellular Recovery Stimulants: Research continues into biologically stable compounds that stimulate recovery of multiple hematopoietic cell lines.
Susceptibility to Infectious Agents and Efficacious Therapy: Research continues to assess susceptibility and resistance to infectious agents in conjunction with use of prompt and chronic sublethal irradiation, and to develop combined modality therapies that attack microorganisms and enhance innate immune response in irradiated personnel. A significant reduction in mortality was shown in animal models using a clinical support protocol based on antibiotic and platelet transfusion regimens.
DIAGNOSTIC TECHNIQUES
Biodosimetry and Dose Assessment: No dose-assessment method other than individual physical dosimeters is currently available to deployed soldiers. Automated chromosome dicentrometic analysis was developed and could be made deployable to the Echelon 3 medical care level. More rapid analytical methods and new biological markers are being evaluated.
CHEMICAL AND BIOLOGICAL WARFARE CONSEQUENCES WITH RADIATION
Increased lethality of biological weapons after low level irradiation: Ongoing studies indicate even low sublethal levels of radiation will markedly increase susceptibility to infection by agents of biological warfare. Existing data suggest synergistic consequences of mustard and nerve agents under combined exposure with ionizing radiation.

Significant progress has been made in prophylactic and therapeutic measures that will reduce mortality and morbidity in high-dose radiation environments. During the Cold War, the number of casualties resulting from the large-scale deployment of nuclear weapons would have easily overwhelmed the medical assets of NATO forces. In the current threat environment, adequate planning for medical response to a very limited nuclear attack is mandatory. While casualty numbers from a nuclear detonation will still be large, countermeasures have been developed that will significantly limit the morbidity and the secondary mortality. These modalities will be particularly important in the likely scenario of terrorist use of radiation weapons. If the attack is limited to one or, at worst, a small number of events, the ability to provide intensive, sophisticated medical and other support is highly credible because of the availability of uncompromised treatment/research centers and medical evacuation capabilities.

Details of the radiological threats and countermeasures, as well as nuclear defense research and development technical barriers and accomplishments, are presented in Annex D (Section D.3).

3.5 MEDICAL NBC RESEARCH PROJECTION

Table 3-6 presents a projection of the medical NBC defense programs and modernization strategy for the next 15 years.

Table 3-6. Medical NBC Defense Programs and Modernization Strategy

	NEAR (FY00-01)	MID (FY02-05)	FAR (FY06-16)
Medical Chemical Defense	Licensed topical skin protectant	Licensed advanced anticonvulsant Licensed multichambered autoinjector	Licensed reactive topical skin protectant Licensed advanced prophylaxis for chemical warfare agents Licensed specific protection and treatment for blister agents (vesicant agent countermeasures) Licensed ophthalmic ointment for vesicant injury Licensed therapeutic lotion for burns caused by vesicant agents Licensed vesicant agent prophylaxis
Medical Biological Defense	Anthrax vaccine amendment for new dosing schedule	Licensed Q fever vaccine Licensed smallpox (vaccinia virus, cell culture-derived) vaccine	Licensed Next Generation Anthrax vaccine Licensed new plague vaccine Licensed new Venezuelan Equine Encephalomyelitis (VEE) vaccine Licensed multivalent equine encephalitis (VEE/WEE/EEE) vaccine Multiagent vaccine delivery system Portable Common Diagnostic System Licensed multivalent (A,B,C,E, and F) Botulinum vaccine Licensed Ricin vaccine Licensed tularemia vaccine Licensed Brucellosis vaccine Licensed multivalent Staphylococcal enterotoxin vaccine
Medical Nuclear Defense	Broad spectrum, nontoxic androstene steroid protectant validated Combination cytokine therapy validated Risk assessment for low dose, low dose- rate radiation effect Biodosimetry assessment tool software program	Slow-release subcutaneous implants for sustained delivery of radioprotectants New-generation prophylactic and therapeutic immunomodulators for multiorgan injuries Computer models to understand effects resulting from combined NBC attacks Echelon 3 biodosimetry system	Licensed radiation-induced cancer/mutation preventive techniques Licensed countermeasure for chem-bio-radiation interaction Echelon 2 biodosimetry system

3.6 MEDICAL REQUIREMENTS ASSESSMENT

***ISSUE:* DoD does not have a current approved mechanism for licensure of chemical and biological defense medical products (*i.e.*, drugs and vaccines) because legal and ethical constraints prevent adequate full testing in humans.**

SOLUTION: The FDA and DoD are working together to amend the Code of Federal Regulations to allow animal efficacy data to be used in lieu of large-scale human clinical efficacy trials. This mechanism of licensure is vital to provide military service personnel with licensed products. This rule will also establish requirements for licensure and allow the DoD to plan and conduct the appropriate studies to obtain product approval for the products planned for production and licensing. Requests for approval of each medical product will be reviewed on an individual basis. In some cases, human efficacy may be determined to some degree (*e.g.*, the Topical Skin Protectant was tested against poison ivy extract in humans.) In other cases, human efficacy data will not be available. A proposal for the licensure of Botulinum Pentavalent Toxoid using the guinea pig as a surrogate model in lieu of human testing was accepted by a FDA Advisory Committee. The DoD is completing the clinical testing of Botulinum Pentavalent Toxoid for submission of this data to the FDA.

***ISSUE:* DoD lacks FDA-licensed vaccines against BW threat agents.**

SOLUTION: DoD awarded a prime systems contract to DynPort LLC. This contract establishes a single integrator to develop, license, produce, and maintain a stockpile of BD vaccines for protection against BW agents. DynPort LLC is required to obtain and maintain FDA licensure for all the vaccine products developed and produced under this contract by conducting clinical trials and establishing manufacturing procedures.

The contract was awarded in November 1997 and begins with the development and licensure of three vaccines: Q fever, Tularemia, and Vaccinia, and the storage of the current unlicensed BD vaccine stockpile (IND products). There are options for the development and licensure of ten other BD vaccines, which are programmed for development and licensure by FY10.

***ISSUE:* Anthrax vaccine issues. Anthrax vaccination currently requires a primary series, six dose regimen spaced out over the course of 18 months, with an annual booster to maintain immunity. The timetable for the vaccination series makes it difficult to complete before deployment of forces or to ensure that mobile forces, once deployed, are administered the proper regimen.**

SOLUTION: On 18 May 1998, DoD decided to systematically vaccinate all U.S. military personnel against anthrax. Current plans call for personnel serving in high threat regions to receive vaccinations, which began in summer 1998. As of December 1999, more than 383,000 military personnel have received shots of the anthrax vaccine. Total force vaccination is on schedule to be completed in 2005. This decision is crucial for

developing a strategy to maintain the industrial base capability for vaccine production.

A firm fixed price contract to purchase Anthrax Vaccine Adsorbed for the continued supply of anthrax vaccine was awarded, negotiated, and signed for a two-year period. DoD continues to work with BioPort to meet the more stringent requirements the FDA has imposed on all vaccine manufacturers. DoD has provided technical guidance on testing and evaluation and the auditing of quality systems. DoD conducted preliminary testing of a reduction of the dosage regime for Anthrax Vaccine Adsorbed from six vaccinations to five over an 18 month period. The results of this study will be presented to the FDA in FY2000. For more information on the DoD anthrax vaccine program, visit "Concerning the Anthrax Threat" on the Internet at http://www.anthrax.osd.mil/.

ISSUE: **There is no currently licensed manufacturer for the smallpox vaccine.**

SOLUTION: The United States retains approximately 10 million doses of the existing licensed vaccine. USAMRIID is conducting research for the development of antiviral drugs for the treatment of smallpox. Additionally, DoD has filed an investigational new drug (IND) application with the Food and Drug Administration to ensure continued availability of the Vaccinia Immune Globulin (VIG). This product is necessary for treatment of rare adverse events that may occur after smallpox immunization. Also, research is continuing on the development of DNA and replicon vaccines as well as therapeutics, such as monoclonal antibodies, to replace VIG.

ISSUE: **The effects on humans resulting from the exposure to low doses of chemical agents, particularly organophosphate (nerve) agents, are not clearly understood.**

SOLUTION: Beginning in FY96, DoD, in association with the Research Working Group of the Interagency Persian Gulf Veterans' Coordinating Board, dedicated $5 million to evaluate the chronic effects of low-dose level exposure to chemical agents. Studies are underway since 1QFY97 to develop highly specific and sensitive assays, preferably forward-deployable, to detect and potentially quantify low-level exposure to chemical agents. These ongoing studies may also identify any long-lasting and toxic metabolites of chemical agents that could account for delayed and long-term health consequences. In addition, studies to look at the impact of possible genetic polymorphisms of cholinesterase enzymes upon individual response to nerve agents are underway. Additional funds have been committed and contracts are being awarded to evaluate potential chronic health complaints resulting from exposure to nerve agents. These contracts were begun 1QFY98. In May 1999, the Department of Defense submitted a report to Congress entitled *DoD Strategy to Address Low-Level Exposures to Chemical Warfare Agents (CWAs)*. This report provided a review of the policies and doctrines of the Department of Defense on chemical warfare defense. Based on this review, DoD recommended no modifications to policies and doctrine, and that existing efforts were well designed to address the need, based on current scientific information.

ISSUE: **Radiation exposures below a level that cause acute effects predispose military personnel to injury from other battlefield agents. The magnitude of this interaction has not been fully evaluated.**

SOLUTION: Preliminary studies show that a sublethal dose of radiation causes 100% mortality when given to an animal exposed to a 40%-lethal dose of *B. anthracis* spores (anthrax). Furthermore, sublethal doses of radiation can abrogate by approximately 20% protective immunity against anthrax in vaccinated animals. Data is being developed in animal models across the spectrum of combined doses and *B. anthracis*, Venezuelan equine encephalitis virus or blistering agents that can be expected under operational scenarios. The data is subjected to standardized algorithmic analysis in order to extrapolate the consequences of combined exposures in humans and to build casualty prediction models.

ISSUE: **The toxic characteristics of the novel threat agents (NTAs) are similar to the conventional nerve agents, and therefore, these NTAs are recognized as a potential threat to the safety of our warfighters. However, current medical countermeasures do not provide the same high level of protection against the NTAs as they do against the conventional nerve agents.**

SOLUTION: Develop prophylactics, pretreatment, or therapeutics for the NTAs to reduce the likelihood that our adversaries will employ these agents. Basic pharmacokinetic characteristics such as absorption, distribution, metabolism, and excretion of these agents are necessary to determine the differences in the mechanism of action of the novel agents and the conventional nerve agents in order to develop effective countermeasures.

ISSUE: **Victims of a nerve agent attack may suffer silent seizures, *i.e.*, without behavioral manifestations. In a battlefield scenario a medic may not know whether an unconscious victim should be given an anticonvulsant. Left untreated, prolonged seizure activity can produce irreversible neuronal damage and death.**

SOLUTION: Develop a miniaturized hand held EEG system for use on the battlefield to detect seizure activity in unconscious victims.

ISSUE: **Nerve agents are a significant battlefield threat to the warfighter. Presently fielded antidotes are efficacious if administered promptly. However, some exposure victims may go into prolonged status epilepticus (SE) before being discovered and treated with antidotes. Prolonged untreated SE will lead to development of irreversible neuronal damage, severe incapacitation, and death.**

SOLUTION: Develop neuroprotective treatment that will prevent or significantly reduce seizure-induced neuronal damage when administered one or more hours after seizure onset.

Chapter 4

Nuclear, Biological, and Chemical (NBC) Defense Logistics Status

4.1 INTRODUCTION

The overall logistical readiness of the Department of Defense's NBC defense equipment continues to improve. The Services have increased stock of most NBC defense equipment, and the overall Service requirements have decreased as a result of a smaller force. Both factors have improved the overall DoD readiness and sustainment status. Asset visibility initiatives continue to increase the ability to manage what is becoming an increasingly joint collection of NBC defense end items and consumables. A number of items continue to pose a moderate to high risk challenge due to low inventories and continued modernization efforts.

The DoD Chemical and Biological Defense Program jointly manages the research, development, and procurement of major end items of NBC defense equipment. These items are funded through defense-wide funding accounts. Consumable NBC defense items are managed by the Services and the Defense Logistics Agency (DLA) in accordance with Title X responsibilities of the Services and their desires to manage their own operations and maintenance funds. Under the provisions of Title X of the FY95 Defense Authorization Act, Service Secretaries are responsible for, and have the authority to conduct, all affairs of their respective departments including supplying, researching, developing, training, and maintaining equipment. The existence of defense-wide (rather than Service-specific) funding accounts has ensured the joint integration of NBC defense programs. However, no defense-wide (that is, joint) funding mechanism exists for the NBC defense logistics area. Because of this, the *joint* NBC defense community is limited to tracking the status of the DoD NBC defense logistics readiness and sustainment program and making recommendations to correct funding shortfalls.

The Joint Service Materiel Group (JSMG) coordinates NBC defense logistics issues. The JSMG, established by the Joint Service Agreement (JSA), works to ensure a smooth transition through the phases of NBC defense equipment life cycles. It is also charged with developing and maintaining an annual Joint Service NBC Defense Logistics Support Plan (LSP). This LSP forms the basis for the analysis found later in this chapter.

During the past year, increased focus by all Services and DLA on NBC defense logistics has visibly improved the overall program. Estimates are that the risk posed by weapons of mass destruction to early deploying units and special operations forces has been considerably reduced. Readiness shortfalls have been identified and addressed to the degree that full sustainment through a one Major Theater War (MTW) scenario is reasonably assured. The ability to sustain a second nearly simultaneous MTW scenario is not fully assured, due to current and potential critical shortfalls of specific program areas. The Services are programming funds for the FY02-07 POM to specifically address these problem areas. Additionally, the services are formulating

doctrine, tactics, techniques, and procedures for domestic response to terrorist incidents involving weapons of mass destruction. An increasing emphasis on humanitarian and peacekeeping missions worldwide is an additional drain on NBC defense supplies and has added to planning factors.

The Joint Chemical Defense Equipment Consumption Rates (JCHEMRATES) IV study was completed in November 1998. It was staffed to the Services in January 1999 and was validated and approved by the Services in March 1999. This study was sponsored by the Joint Services Coordination Committee and executed through the U.S. Army Center for Army Analysis (CAA). The goal of the JCHEMRATES study is to define the parameters of future chemical warfare scenarios and determine the consumption rates for consumable DoD chemical defense equipment. Using the current Defense Planning Guidance and Quadrennial Defense Report, the JCHEMRATES study developed consumption rates for the two MTW scenarios. These consumption rates include both medical and non-medical chemical defense items for each Service and overall DoD roll-ups for both scenarios. They include both initial issue of chemical defense equipment and sustainment through the 120-day period. These rates form an important basis for determining future Service purchases and their readiness to go to war. The final report on the JCHEMRATES study was published in April 1999.

The JCHEMRATES IV study's two MTW requirement is not and should not be considered a procurement target. This study did not fully consider certain factors such as air transport into theaters of conflict or Navy fleet requirements for ships at sea. While the Services agree with the methodology and intent of the study, the study may require further refinement prior to becoming a fully accepted planning tool. The MTW requirement does not consider peacetime training requirements, sizing requirements, full procurement to the entire active and Reserve forces, or the increasing number of peacekeeping missions in recent years. Thus, the MTW requirement denotes a *minimum planning number*, which if the total DoD inventory drops below, may represent a critical shortfall for that particular item which should be immediately addressed to avoid diminishing the force's NBC defense capability. Because of this limitation in the study, the Services have identified their total Service requirements as their procurement targets, while acknowledging JCHEMRATES as a necessary step in joint service management of the NBC defense program.

The Services continue to have issues regarding the accountability and management of NBC defense item inventories. Limited asset visibility of consumable NBC defense items below the wholesale level remains a problem due to the lack of automated tracking systems at that level (the exceptions being the Air Force and a nascent Marine Corps initiative). This has the full attention of the senior NBC defense managers. The Total Asset Visibility (TAV) project is progressing toward addressing these problems in the long term, but is initially hampered by the uneven quality of inventory reporting.

The Services still procure consumable NBC defense items through multiple, separate, and distinct funding authorizations, as discussed in Section 4.6 of this chapter. Each Service is addressing secondary item procurement policies independently. However, there continue to be

shortfalls of specific NBC defense items when measured against DoD requirements of a two MTW scenario.

The process by which the Services and DLA fund and store war reserve materiel has been hampered by differing definitions, different deployment strategies, and a lack of validated requirements for jointly managed items. The Joint Service Integration Group (JSIG) may be tasked in calendar year 2000 to study Service concerns with JCHEMRATES IV. Once those concerns are addressed, JCHEMRATES will create a solid foundation for providing a basis for the common planning of future requirements.

The JSMG initiated its fourth Joint Service NBC Defense Logistics Support Plan (LSP) in August 1999. This report focuses on identifying the current on-hand stores of the Services' and DLA's NBC defense equipment, and matching these numbers against the requirements generated from the recently completed final JCHEMRATES IV study. The LSP's aim is to identify the Services' readiness and sustainment capability, maintenance requirements, and industrial base issues in the area of NBC defense. The data call conducted for the FY00 LSP was used to develop the findings in this chapter.

4.2 NBC DEFENSE LOGISTICS MANAGEMENT

NBC defense logistics management remains in transition. The Joint NBC Defense Board has begun to exercise full authority in this area, and the JSMG, which reports to the Joint NBC Defense Board, has been charged with coordinating and integrating logistics readiness. The JSMG's role is to identify current readiness and sustainment quantities in the DoD NBC logistics area, with respect to the two MTW scenario outlined in the Quadrennial Defense Review. Developmental NBC defense programs that will be fielded within the POM time period are addressed to identify modernization efforts that are underway.

As currently envisioned, all Services retain "starter stocks" of NBC defense equipment that will support immediate deployments and initial operations. The length of time that these stocks will last each unit depends on the respective parent Service. Air Force units deploy with 30 days of NBC defense consumables. Army divisions use a planning figure of 45 days, while Marine Corps forces and Navy shore units use 60 days as the basis for their plans. As a matter of policy, Navy ships stock 90 days of consumable materiel. However, these values are notional in that they are based on peacetime demand and/or projections of wartime demand as contained in pertinent allowance documentation. For NBC defensive materiel, and particularly in the case of individual protective equipment (IPE), the days of supply represent a minimum stockage position based on current investment guidelines for such materiel. In most cases, the Services will first redistribute any available uncommitted assets to provide sustainment before sourcing elsewhere. Once these starter stocks are depleted, the military force turns to the DoD NBC defense item managers for "swing stocks," also known as "sustainment stocks."

DLA and the Army Materiel Command (AMC) are the item managers, or National Inventory Control Points (NICP), for the vast majority of NBC defense items in all four Services. They are responsible for industrial base development, acquisition, and storage of

wholesale peacetime and sustainment wartime stocks. They buy (process procurement actions) and, if requested, store NBC defense materiel (swing stocks) for the Services. However, the Services must provide funding to DLA and AMC for the procurements.

Currently, only Army owned sustainment stocks are stored in DLA and AMC depots, providing limited back-up for deployed forces during a contingency. Because of a lack of visibility of NBC defense items, unclear wartime requirements (given the post-Cold War environment), scarce Operations and Maintenance funds, and low priorities given to NBC defense stocks, the current quantity of DLA and AMC NBC defense war reserves have been reduced and will not support sustainment requirements for the entire DoD force during a full two MTW scenario. These numbers are reflected in the tables of this chapter.

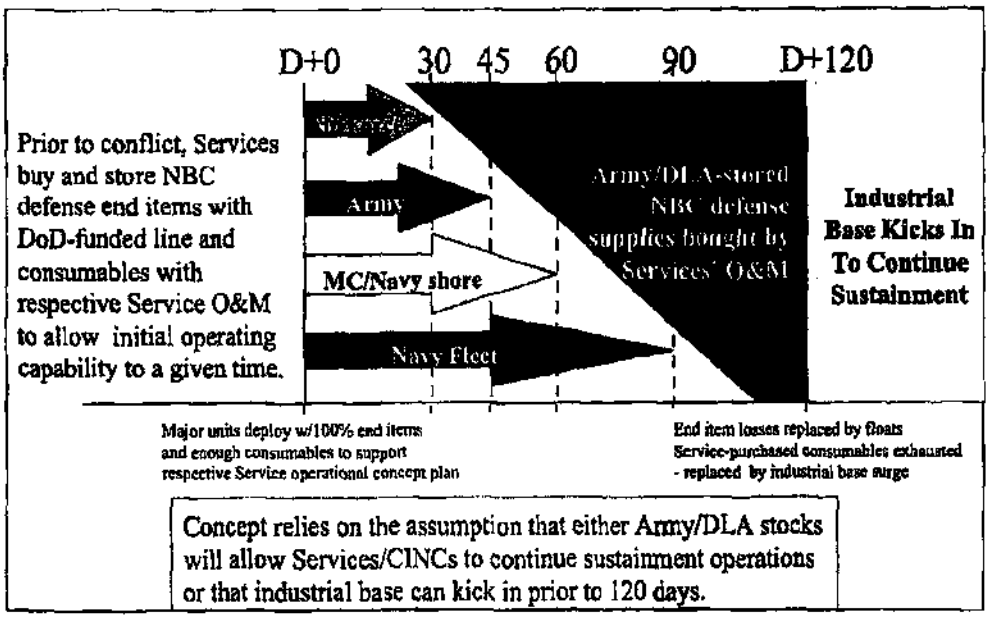

Figure 4-1. War Reserve Requirements and Planning

Service inventories of NBC defense items maintained at unit level use either manual records or a semi-automated tracking system. Stocks held at wholesale level are maintained using a separate automated system. Currently, there is little connectivity between the two systems. As a result, there is limited Service level asset visibility for NBC defense items. The Services are addressing this deficiency under the auspices of TAV, a long-term initiative that will link existing DoD logistics automated systems.

The Army has improved its visibility through an initiative to standardize individual issue of eleven critical NBC defense items across all major commands. Unit Status Reporting was implemented for units to report on-hand stocks *vs.* requirements on a monthly basis. In addition, plans are in place for consumable chemical defense equipment for all forces other than Force Package I and other early deploying units to be consolidated and centrally stored at Bluegrass

Army Depot. This seven-year execution plan is managed by HQ AMC and will enable better visibility and rotation of NBC defense consumable items. The Air Force has a similar program that consolidates stocks of NBC defense items for deployment in support of contingency operations. These initiatives have also reduced surveillance costs and improved overall management of NBC defense stocks. The Marine Corps has been leading a joint surveillance Technical Working Group, whose initiatives have been increasing cooperative efforts in surveillance and shelf life programs. The Marine Corps has also begun an NBC stocks consolidation program and is developing an NBC Defense Equipment Management Program (DEMP) database to track the inventory, shelf life, and maintenance histories of NBC defense items.

Both DLA and AMC will remain key players in the future NBC defense logistics management system. The Joint NBC Defense Board, through the JSMG, provides coordination and integration based upon the input of all Services and Commanders-in-Chief (CINCs). DLA and AMC will continue to provide services such as raw data collection, inventory control, and a distribution infrastructure. With the results of JCHEMRATES IV, the Services and DLA can immediately begin plans to improve their readiness and sustainment status based on a common understanding of post-Cold War requirements.

4.3 QUANTITIES, CHARACTERISTICS, AND CAPABILITIES

The results of the data collection efforts are compiled in Tables 4-2 through 4-5 in Appendix 1, Logistics Readiness NBC Report Data, located at the end of this chapter. A table is included for each of the four Services and DLA.

The items listed under "Nomenclature" in Tables 4-2 through 4-5 of Appendix 1 are 129 NBC defense items that are currently fielded in the Services. "Total Service Requirements" include the quantity required for the entire Service (to include active and reserve forces), and includes peacetime replacements (wear and tear) and training requirements. Last year, the two MTW requirement quantities were the larger of the initial issue for two MTW or the two MTW consumption computed by the JCHEMRATES IV study (November 1998 data). Those quantities represented the minimum requirements for full sustainment through two conflicts. Recognizing that potentially our forces would be left depleted of resources after the conflicts, the LSP Integrated Product Team (IPT) voted this year to add initial issue quantities to consumption in calculating the two MTW requirement for consumable items. The consumption that is used to compute two MTW requirement provided in Tables 4-2 through 4-5 is based on the final JCHEMRATES IV calculations, dated March 1999.

Note that materiel requirements for training, sizing variations and peacetime replacements are *not* included in the wartime requirements calculated by JCHEMRATES. This number represents an average expenditure calculated among four scenarios: chemical defense equipment expenditures under low chemical weapons use during favorable and marginal weather conditions; and of chemical defense equipment expenditures of high chemical weapons use during favorable and marginal weather conditions. All sets of conditions were run for the North-East Asia and South-West Asia scenarios.

The "Stocks On-Hand" represents the total of all serviceable NBC defense materiel available in each of the Services (stocks positioned with troops, stocks in the supply system and stocks stored in depots/facilities, both peacetime stores and war reserve). This number includes quantities for which a Service or agency has submitted a funded requisition or purchase order in FY99, but has not received the requisitioned items. Finally, the quantities depicted as "Projected Due-Ins 'are quantities the Services plan to buy to replace peacetime consumption of NBC defense assets (to include training use and shelf-life expiration), and to buy wartime sustainment stocks. It must be emphasized that these numbers are based on major command estimates of requirements. Actual procurements will be based on available funding.

4.4 LOGISTICS STATUS

During collection of FY99 data, information on the inventory status of 129 fielded NBC defense equipment items was compiled. While radiacs were not traditionally a part of this chapter, they have been retained as an effort towards continuity with other chapters and annexes of this report. NBC defense items such as spare parts and sub-components were considered a subset of the primary item for risk assessments, and were not reviewed separately. Batteries for critical systems are listed for informational purposes. Inventory tracking for batteries is difficult because of a lack of visibility and because they sometimes have other applications. Trainers were not included in the assessment process, since they do not reflect wartime service requirements. Quantities required for wartime needs were then compared to quantities currently on-hand. Characteristics and capabilities of selected fielded NBC defense items are discussed in detail in Annexes A-D of this report.

Although they were in use for part of the year, the M258A1 Decon Kit was dropped from the assessment since their shelf-lives expired during FY99. Among medical consumables, sodium nitrite and sodium thiosulfate are now combined in a single Cyanide Antidote Treatment Kit. The requirements for Pyridostigmine Bromide tablets were adjusted to reflect FDA guidelines which allow them to be administered for only 14 days, rather than 30 days. The Chemical Agent Patient Treatment Medical Equipment Set and Medical Aerosolized Nerve Agent Antidote (MANAA) Atropine Sulfate Inhalation Aerosol were added.

Starting with this report, the two MTW requirement for consumables was adjusted to include the initial issue along with the consumption provided by JCHEMRATES. This decision was made to provide for some inventory to remain after 120 days, thus enhancing our readiness if another conflict ensues. This more closely aligns the requirements calculations with those of other commodities such as ammunition.

Two MTW Requirement for Consumables
Previous definition: equal to the greater of
JCHEMRATES Initial Issue or Consumption
⇒ No inventory remains after 120 days

New definition: equal to JCHEMRATES Initial Issue **plus** Consumption
⇒ Some inventory remains after 120 days
Readiness for the next conflict is enhanced

Of the 129 items extensively reviewed, DoD developed risk assessments for 50 items based on data gathered as of 30 September 1999 (see Table 4-1). These items were singled out

because of their critical role or their ability to represent the general state of their respective commodity area. While some of the items assessed changed from the previous year's report due to obsolescence, the balance of assessed items among the commodity areas remained as constant as possible to provide for continuity. These items were rated as being in a low, moderate, or high risk category. "Risk" is based on the currently available percent fill of the two MTW requirements; the lower this fill the greater the likelihood that such shortages may significantly reduce DoD's ability to respond to a contingency. Shortages for FY99 were calculated by comparing the two MTW requirements, as defined for this year, to on-hand quantities, as shown in Tables 4-2 through 4-5.

RISK ASSESSMENT

Low –	Services have at least 85 percent of wartime requirement on-hand to support two nearly simultaneous major theater wars
Moderate –	Services have between 70 to 84 percent of wartime requirement on-hand to support two nearly simultaneous major theater wars
High –	Services have less than 70 percent of wartime requirement on-hand to support two nearly simultaneous major theater wars

Table 4-1 provides the results of the assessment. Programs rated as high or moderate risk are discussed in greater detail in Appendix 2. A five-year comparison of data assessments is shown in Figure 4-2. In comparison to FY98 report data, the percentage of the FY99 report's items in the low risk category dropped from 58 percent to 54 percent. The percentage of items in moderate rose from 20 percent to 26 percent, while the percentage of items in the high risk category dropped from 22 percent to 20 percent.

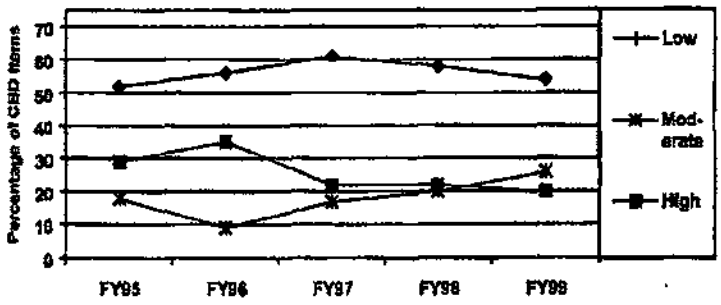

Figure 4-2. Logistic Risk Assessments: 50 NBC Defense Items

The redefinition of the two MTW requirement did not significantly affect most of the items that were assessed. The following items are highlighted:

- The status of M8A1 chemical agent detectors improved due to repairs while its replacement, the M22 ACADA, is being fielded. The Army's assessment and rebuild program returned 1,600 detectors to units, and another 1,500 are being repaired.

- Collectively, 59% of the Marine Corps inventory of CAM/ICAM 1.5 and CAM/ICAM 2.0 are at the Marine Corps Logistics Base needing repair. No funds are yet available for repair, thereby raising their risk.
- Limited quantities of M93A1 NBC Recon Systems continue to constrain early warning chemical reconnaissance and detection capabilities. Continued purchases through FY05 and acquisition of the JSLNBCRS will reduce this risk. Meanwhile, the collective stocks of M93 NBC Recon Systems and M93A1 NBC Recon Systems provide complete fill against the two MTW requirement, also mitigating the risk.
- Quantities of BDOs are not adequate to fill the Air Force requirement. The Air Force developed a mitigation plan in concert with procurement of the JSLIST ensembles to minimize risk. The recent plus-up of procurement funds for protective suits has aided in plans to transition to the JSLIST program. Due to the overall high level of DoD WRM stockage of BDOs, the immediate risk is assessed as low. The BDOs will remain in inventory until they reach maximum shelf life.
- The Air Force is relying on the CWU 66/77P to provide a protective air crew ensemble. It will replace the now obsolete Chemical Protective Undercoverall, and is assessed at moderate risk. Continued planned procurements should correct this assessment in the short term. The Joint Protective Aircrew Ensemble (JPACE), being procured in FY03, will replace this suit.
- The collective protection area continues to be assessed as high risk, in part due to the continued emphasis on contamination avoidance and individual protection, which overshadows this area. As the procurement cycle in these two latter areas matures, the risk assessment of collective protection systems will lessen slightly.
- DS-2 requirements, as determined by JCHEMRATES IV, indicate a significant increase in DS-2 requirements compared to JCHEMRATES III and current on-hand stocks. Because of the magnitude of this change, DS-2 is omitted from the risk assessments pending a detailed review of the JCHEMRATES IV methodology and results.
- With the expiration of M258A1 decontamination kits in FY99, the status of M291 kits becomes more critical. Present inventory and planned procurements should keep this risk low. Production of M295 kits has improved since last year to lessen their risk.
- Medical chemical defense materiel remains generally in low risk. The shortage of Nerve Agent Antidote Kits (NAAK) can be supplemented with existing supplies of atropine and 2-PAM autoinjectors, reducing its risk from moderate to low. These items will gradually be replaced by the Nerve Agent Antidote Treatment Kit beginning about FY04.
- Execution of the Joint Vaccine Acquisition Program (JVAP), combined with adequate stores of vaccine for the major BW threats, resulted in a lowering of the risk category from high to moderate risk. Continued oversight is needed to ensure that the prime systems contractor retains FDA-approved capabilities to develop, license, produce and store vaccines in quantities required to protect the force.

Table 4-1. Logistic Risk Assessments: 50 NBC Defense Items

CONTAMINATION AVOIDANCE/DETECTION EQUIPMENT

Items	Risk Assessment	Remarks
Radiological		
AN/VDR-2 Radiac Set	Low	USMC is short 22% of requirements
AN/PDR-75 Radiac Set	Moderate	USMC has less than half of requirements (in both above cases, USA quantities offset risk)
AN/UDR-13 Pocket Radiac	High	Low inventory, still fielding
Biological		
Biological Integrated Detection System (BIDS)	Moderate	Low inventory, still fielding
Chemical		
M256A1 Chemical Agent Detector Kit	Low	Shelf life expiration may reduce stocks in future, but has been extended from five to six years
M8 Detection Paper	Low	
M8A1 Automatic Chemical Agent Alarm	Low	Being replaced by M22 ACADA
M1 Chemical Agent Monitor (CAM)/Improved CAM	High	Low inventory; 59% USMC stock needs repair
Chemical Agent Point Detection System (CAPDS)	Low	
AN/KAS-1 Chemical Warfare Directional Detector	Low	
M21 Remote Sensing Chemical Agent Alarm (RSCAAL)	Low	
M22 Automatic Chemical Agent Detector/Alarm	High	Low inventory; still fielding
M93A1 NBC Reconnaissance System "Fox"	Moderate	Low inventory; still fielding; M93 available
Automatic Liquid Agent Detector (ALAD)	Moderate	Low inventory
M272A1 Water Testing Kit	Low	
M274 NBC Marking Set	Low	

INDIVIDUAL PROTECTION

Items	Risk Assessment	Remarks
Masks		
MCU-2/P-series Mask	Low	USAF/USN mask
M40-series General Purpose Mask	Low	USA/USMC mask
M42-series Tank Mask	Low	
M48 Apache Mask	High	Replaces M43-series mask
MBU-19/9 Aircrew Eye/Resp. Protection (AERP)	Moderate	Replaces MBU-13/P; still fielding
Suits		
JSLIST protective suits	Moderate	In process of fielding to all Services
Battle Dress Overgarment (BDO)	Low	No further production – being replaced by JSLIST
Saratoga Suit	Low	No further production – being replaced by JSLIST
CWU 66/77P	Moderate	Low inventory
Chemical Protective Undercoverall	Low	No further production - replaced by CWU 66/77P
Mark III Suit, Collective Protection, Overgarment	Moderate	No further production – being replaced by JSLIST
Aircrewman Cape	Moderate	
Gloves/Overboots		
Chemical Protective Gloves (7/14/25-mil)	Low	
Green/Black Vinyl Overshoes (GVO/BVO)	Low	Risk lowered due to chemical protective footwear
Chemical Protective Footwear Covers	Low	cover stocks
Disposable Chemical Protective Footwear Covers	Low	Replaced by GVO/BVO

Note - Only selected Low Risk programs are displayed for information purposes.

Table 4-1. Logistic Risk Assessments: 50 NBC Defense Items (continued)

COLLECTIVE PROTECTION

Items	Risk Assessment	Remarks
Chemical and Biological Protective Shelter (CBPS)	High	Low inventory, still fielding
M20A1 Simplified Collective Protective Equipment (SCPE)	High	Low inventory, not in production
M28 CPE HUB	High	Low inventory, still in production
M48A1 General Purpose Filter	Moderate	Low inventory
Filter For (M59, M56, Shipboard) (200 CFM)	Low	

DECONTAMINATION EQUIPMENT

Items	Risk Assessment	Remarks
M291 Skin Decontaminating Kit	Low	Quantities cover loss of M258A1
M295 Individual Equipment Decontamination Kit	Low	
DS-2, M13 Can	High	Low inventory
M11 Decontaminating Apparatus	Low	
M13 Decontaminating Apparatus, Portable	High	Low inventory
M17-series Lightweight Decontamination System (LDS) (to include the A/E32U-8 Decontamination System)	Moderate	Low inventory reported
M12A1 Power Driven Decontamination Apparatus (PDDA)	Low	

MEDICAL DEFENSE

Items	Risk Assessment	Remarks
Mark 1 Nerve Agent Antidote Kit (NAAK)	Low	Risk lowered based on autoinjector stocks
Atropine Autoinjector	Low	
2-PAM Chloride Autoinjector	Low	
Nerve Agent Preventative Pyridostigmine (NAPP) Tablet	High	Due to new 2 MTW requirement
Convulsant Antidote Nerve Agent (CANA) Autoinjector	Moderate	Due to new 2 MTW requirement
Biological Warfare Vaccines	Moderate	Prime contract awarded for development, production, FDA licensure, and storage

Note - Only selected Low Risk programs are displayed for information purposes.

Based on the average two MTW requirements identified in the JCHEMRATES IV study as of March 1999, the Services continue to exhibit shortages in certain critical areas. Shortages of chemical and biological agent detection systems, collective protection shelters and their respective filters, and biological warfare vaccines may have a serious impact on the joint force's ability to survive and sustain combat operations under NBC warfare conditions operating in two nearly simultaneous MTWs. The extent of the operational impact of NBC defense equipment shortages is under review in several classified studies.

4.5 PEACETIME REQUIREMENTS

In peacetime, quantities of NBC defense equipment are necessary to train personnel in NBC defense and to build confidence that NBC equipment will provide the necessary protection when used correctly. The two most critical areas of peacetime stocks are individual protective equipment and medical chemical defense materiel. The Services have indicated that adequate NBC defense equipment is on-hand to conduct training.

Generally, items used in peacetime for training are drawn from wholesale stocks, requiring units to maintain both training and contingency stocks. For selected items, such as

protective clothing, contingency utility is lost when the item is used (or consumed) for training. Because peacetime training requirements are met in this manner, major commands do not track training equipment in their estimates of on-hand requirements.

4.6 FUNDING

In accordance with the NBC defense management initiatives outlined in Chapter 1, funding of RDT&E and procurement was centralized in a DoD defense-wide account beginning in FY96. Operations and maintenance (O&M) funding for NBC defense materiel is not consolidated at the DoD level. Therefore, for non-major (secondary) end items (*e.g.*, consumables such as decontamination kits, detection kits, and filters), each Service continues to separately fund replenishment and sustainment of NBC defense equipment. Depot maintenance and contractor logistics support for some low density major items are also O&M funded. These appropriations are not included in the joint NBC defense program.

Funding of NBC defense items classified as war reserves secondary items (WRSI) remains a significant issue. The Services are responsible for developing the requirements and funding items in war reserve stocks. Funding of WRSI comes from Congressional appropriations made into the Working Capital Fund from the transfer of Services' O&M funds. For example, replenishment of NBC defense items in Army war reserves, such as the M258A1 kits and BDOs, will require substantial funding through 2006 as these items reach their maximum extended shelf lives. Funding will be required to replace the Army and Air Force's current inventories of BDOs with the Joint Service Lightweight Integrated Suit Technology (JSLIST). The Marine Corps, through its normal requirements generation and acquisition process, was able to obtain 100% war reserve of Saratogas for initial projected war reserves requirement (the Marine Corps no longer considers the BDO to be a viable asset). The recent plus-up of funds for protective suits is assisting in building an initial stockage and minimum sustainment (war reserve) stock to meet the current defense planning guidance.

Under current acquisition procedures and DoD guidance to minimize wholesale stockpiles, procurements are based only on funded Service requisitions. The Services remain responsible for program funding to replace NBC defense equipment wartime stocks. Procurement is usually based on economic buy quantities (a consolidation of all Service requisitions) to provide the best value to the government. Some procurements, however, suffer significant delays in delivery because of the time required to accumulate sufficient requisitions to produce economic buy quantities. This situation occurs when item managers try to plan purchases of consumable items that have a low peacetime consumption but high wartime consumption (such as decontamination kits, large collective protection filters and M256A1 detector kits). The result is a low purchasing history with a small industry production capability, which in turn causes a very low war reserve status with minimal industry surge capability. The JCHEMRATES IV study is intended to provide more accurate requirements on which the Services can base their planning.

4.7 INDUSTRIAL BASE

With the end of the Cold War, a smaller DoD force, and subsequently reduced requirements for NBC defense items, lowered purchases of NBC defense consumables continue to threaten the industrial viability of this sector. While the sector is improving, vulnerabilities still exist. Collective protection systems (filters in particular) continue to be the most critical subsector in the NBC defense area. Additionally, protective clothing procurement continues to receive intense scrutiny due to the possibility of industrial base shortfalls in satisfying requirements during a contingency. The reluctance of pharmaceutical industries to support DoD CB defense medical programs, coupled with a lack of government vaccine production, represents a serious medical industrial base shortcoming.

These assessments indicate that the NBC defense industrial base sector is primarily supported by small- to medium-sized highly specialized companies dedicated to producing military unique products with little or no commercial utility. These companies have become dependent on Service demands and sales for their financial survival. Selected NBC defense items (BDOs, chemical gloves, and nerve agent autoinjectors) have been designated as critical to combat operations because of low peacetime demand, high wartime use, and the fragile supporting industrial base. As a result, DLA established, with OSD approval, a "War Stopper" program to sustain key industrial base capabilities, utilizing industrial preparedness funding under PE 07080110.

The mission of the Joint Service Integrated Product Team (IPT) for Industrial Base Management and Planning is to assist the Services in identifying problems and issues associated with implementing and executing a Joint Service NBC Defense Industrial Base Management Plan. The IPT will be able to provide DoD decision makers with accurate industrial base information and analyses. It consists of representatives from the JSMG and JSIG, Joint Staff, Office of the Secretary of Defense, logistics representatives and Commodity Area Managers from the four Services and DLA.

The IPT is addressing issues from across the Services for more than 128 items/systems and spare parts critical to readiness. The IPT is conducting analyses to include industrial and technology capabilities, alternative sources of supply, and a financial and economic analysis. These analyses will provide the NBC management structure with alternatives and recommendations within the sub-sectors of NBC defense. To date, all systems were evaluated with 41 systems given in-depth analysis. Industrial preparedness measures were recommended for some of those items with others identified as having a need for re-programming to fund buy-outs that would make up the shortfalls.

4.8 NBC DEFENSE LOGISTICS SUPPORT ASSESSMENT

ISSUE: **The Department of Defense's NBC Defense Program has a full capability to support and sustain the first of two MTWs. Readiness shortfalls that would preclude full support of a second MTW have been identified and will be addressed in the next POM (FY02-07). The Services' modernization efforts and common war reserve requirements will lessen the overall risk over the near term.**

SOLUTION: The Services continue to increase their readiness and sustainment status by consolidating common stocks and increasing visibility of their wholesale stocks. In most cases, accelerated procurement of critical items into war reserves will increase readiness against the potential use of weapons of mass destruction.

During 1998, all four Services participated in the development of the JCHEMRATES IV study, which was finalized in 1999. JCHEMRATES IV provides a more accurate prediction of the initial issue and sustainment quantities required for each Service. The use of this common methodology will allow the presentation of joint service requirements in future reports and facilitate improved joint logistics management.

ISSUE: **DoD continues to lack a joint, integrated system to maintain asset visibility of NBC defense equipment below wholesale level, and lacks a standardized war reserve program for NBC defense equipment. Resourcing the procurement and sustainment of wartime stocks of individual protective equipment, decontamination kits, and detector kits remains the responsibility of the Services.**

SOLUTION: DoD established the requirement for asset visibility and reviewed existing systems and procedures, both for peacetime reporting and war time reporting. The Services and DLA are addressing the NBC defense asset visibility deficiency under the auspices of the Total Asset Visibility initiative.

ISSUE: **NBC defense industries have a limited ability to augment specific shortfalls during any future contingency, in part due to lowered DoD procurements and the inability to retain warm production lines in critical areas. Without the introduction of significant plus ups or the use of innovative business practices (such as the use of performance specifications), many of the small firms that make up this sector may choose to focus entirely on the commercial market place.**

SOLUTION: The Department of Defense continues to pursue innovative strategies to maintain a responsive industrial base, especially those strategies that decrease industry reliance on DoD procurement for industrial base survival. Strategies may include tapping into independent research and development (IR&D) conducted by universities and corporations, increasing reliance on dual-use technologies, and pursuing strategies that will encourage companies to decrease dependency on DoD requirements for their survival.

ISSUE: **Equipment assets needing repair reduce inventory. Mechanisms to track maintenance requirements and initiate repairs are needed to reduce this risk.**

SOLUTION: In 1984, with the assistance of the U. S. Army Defense Chemical Equipment (DCTE) Division, Pine Bluff Arsenal, the NBC Test and Evaluation Program was established to conduct surveillance testing and evaluation of all Individual Chemical Protective Equipment throughout the Marine Corps. The focus of the program was to ensure the combat readiness of NBC assets held at all levels of supply, from the depots to the using units, while maximizing the service life of assets. A surveillance unit was established at each of the Marine Corps Logistics Bases to perform both mobile and fixed site testing. Testing of overseas assets was accomplished utilizing a mail in program.

During Desert Shield, the two facilities conducted around the clock operations to ensure every Marine deploying to Southwest Asia had a serviceable Field Protective Mask and chemical ensemble. The two Test and Evaluation Units performed tests on over 94,000 masks from field units and warehouse stockpiles during this period.

The program was re-evaluated following Desert Shield/Desert Storm and reorganized to better support the Marine Forces. The Test and Evaluation Units were moved from the Logistics Bases to sites at Camp Lejeune, NC and Camp Pendleton, CA. A new test facility was stood up in Okinawa, Japan to support the high demand for overseas testing. Unmanned sites in Iwakuni, Japan (supported by the Okinawa unit) and Kaneohe Bay, Hawaii (supported by the Camp Pendleton unit) were also established,

In 1997, DoD encouraged the program to support NBC surveillance within all the branches of service. The program's name was changed to the Joint Service Equipment Surveillance Program and the Test and Evaluation Units were renamed as Equipment Surveillance Units.

The program provides surveillance, directed screening services, contracted toxic testing, repair, vacuum packaging, technical support, guidance and training to all services in support of NBC Individual Protective Equipment. Asset surveillance is utilized to detect degradation trends and promote unit readiness. Certified personnel and equipment are used to visually and mechanically test the assets.

The Equipment Surveillance Units perform intermediate level repairs of NBC assets to include M41 PATS and diagnostic checks on CAMs to correct defective assets. These repairs range from parts replacement, patching, eye lens crimping to packaging and repackaging. While on site, these teams provide training in the preventive maintenance and care of assets.

The DCTE Division at Pine Bluff Arsenal is the alternate source for NBC Individual Protective Equipment to support special surveillance efforts beyond the current program's capacity. Future plans are to expand the program to include Navy surveillance

personnel support and providing surveillance services in support of general clothing and equipment.

The program has a far-reaching impact upon NBC readiness throughout the services. It provides critical input into the research, development, testing and evaluation of new NBC equipment. The program is also a key player in the joint service's efforts to standardize NBC policy and procedures.

APPENDIX 1.
BREAKOUT OF SERVICE WAR REQUIREMENTS, STOCKS ON-HAND, AND PLANNED ACQUISITIONS

The following tables display NBC defense equipment total Service requirements, their wartime requirements, stocks on-hand quantities to include FY99 quantities on contract, and FY00–01 planned procurements for each of the four Services and Defense Logistics Agency. As mentioned earlier in this chapter, the two MTW requirements for consumables are based on the sum of the initial issue and the average consumption developed under the JCHEMRATES IV study, updated as of March 1999.

It should be emphasized that the JCHEMRATES IV study's two MTW requirement is not and should not be considered a procurement target. This study did not fully consider air transport into theaters of conflict or Navy fleet requirements for ships at sea. While the Services in general agree with the methodology and intent of the study, it may require further refinement prior to becoming a fully accepted planning tool. The MTW requirement does not consider peacetime training requirements, sizing requirements, or full procurement for the entire active and Reserve forces and critical operational personnel. The MTW requirement does denote a minimum planning number, which if the total DoD inventory drops below, may represent a critical shortfall for that particular item, which should be immediately addressed to avoid diminishing the force's NBC defense capability.

Because of this limitation in the study, the Services have identified their total Service requirements as their procurement targets, while acknowledging JCHEMRATES as a necessary step in joint service management of the NBC defense program. The Services continually update these data call sheets on a frequent basis and consider these working papers rather than a static set of figures. The Services and DLA are working through the FY00 Joint Service NBC Defense Logistics Support Plan to update all figures and to provide 100% of the information required for logistics readiness and sustainment assessments.

Table 4-2a. Army Logistics Readiness Data - Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE BUYOUT	NO. REQUIRED FOR 2 MTW	STOCKS ON HAND TO INCLUDE FY99 DCE IN	PROJECTED DCE IN					
					FY00	FY01	FY02	FY03	FY04	FY05
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, CB, M17A2	4240-01-345-2017-50	318,274	0	234,670	0	0	0	0	0	0
MASK, CB, M40/M42	4240-01-258-0061-63	508,818	347,158	505,398	125,370	25,530	0	0	0	0
MASK, M24, AVIATOR	4240-01-276-2586	46,591	0	8,660	0	0	0	0	0	0
MASK, M254, TANK	4240-00-99[illegible]-8130-52	17,642	0	8,277	0	0	0	0	0	0
MASK, M43, TANK	4240-01-258-0064-66	98,548	18,314	35,500	0	0	0	0	0	0
MASK, M45 APACHE	4240-01-208-6666-69	4,133	0	3,224	0	0	0	0	0	0
MASK, M48 AVIATOR	4240-01-414-4034-35[illegible]-4031-51	5,200	1,844	227	20,920	48	0	0	0	0
MASK, M48 APACHE	4240-01-586-0198-4630-[illegible]-4057	5,501	330	6	0	0	0	0	0	0
MASK, M49	4240-01-413-4555-59	12,544	1,844	0	0	0	0	0	0	0
NBC PROTECTION										
PATS, M41	4240-01-365-8341	3,334	3,334	3,234	752	589	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
NUCLEAR DETECTION EQUIPMENT										
ANPDR-75	6665-01-311-4217	5,035	2,448	3,603	3	0	1	3	0	0
ANPDR-77	6665-01-347-6388	485	556	246	3	0	1	3	0	0
ANVDR-3	6665-01-406-2377	28,581	26,901	258	3	0	1	3	0	0
ANVDR-2	6665-01-333-4255	35,578	27,405	29,693	3	0	1	3	0	0
BIOLOGICAL DETECTION EQUIPMENT										
BIDS, M2	6665-01-392-6191	124	124	78	0	0	1	0	3	0
LB-2258, M90	6665-01-422-8505	24	24	3	0	0	1	0	3	0
CHEMICAL DETECTION EQUIPMENT										
ACADA, M22	6665-01-418-9365	24,859	18,835	4,459	4,120	0	2	0	3	0
ALARM, CAA, M8A1	6665-01-165-5825	25,000	25,000	18,883	6000	800	1,200	800	960	520
CAM/CAM	6665-01-357-3502	18,817	9,817	6,552	0	0	1	0	3	0
M21 RSCAAL	6665-01-324-6417	135	133	136	0	0	0	0	3	0
NBC RECON SYS, M93A1	6665-01-392-1309	133	133	30	0	0	0	0	3	0
DECONTAMINATION COMMODITY AREA										
DECON APPAR, M13	4230-00-720-1618	34,286	33,589	25,928	0	0	0	0	0	0
DECON APPAR, M17	4230-01-133-4156	256,000	51,135	36,558	0	0	0	0	0	0
DECON APPAR, PODS, M28A1	4230-01-326-9485	486	328	439	0	0	0	0	0	0
LWT DEC SYS, M58A1	4230-01-305-4324	3,516	2,515	1,065	0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
CP SHELTER (HUB, CP, M28)	4240-01-395-2135	33	33	45	8	0	0	0	0	0
SHELTER, CB PROJECT	5410-01-461-6054	513	513	88	33	31	28	38	35	45
SHELTER, CP, MODULAR	4240-01-166-5254	2,019	1,342		0	0	0	0	0	0
SHELTER, M51	4240-00-824-4144	0	0		0	0	0	0	0	0
MEDICAL COMMODITY AREA										
LITTER, DECONTAMINABLE	6530-01-380-7125	5,148	5,148	5,026	1,552	0	0	0	0	0

Table 4-2b. Army Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE HQMTS	NO. REQUIRED FOR 2 MTFs	STOCKS ON HAND TO INCLUDE FY99 DUE IN	PROJECTED DUE IN FY00	PROJECTED DUE IN FY01
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
CHEM PROT UNDERGARMENT TOP	8415-01-263-9602-OL	728,718	0		0	0
CPU OVERALLS	8415-01-263-1685-91	728,718	457,564	155,891	0	0
ENSLST (ABOUT 45 DAYS	SEE NSNs IN TAB E-6	2,346,809	2,336,756	35,248	169,464	163,928
SCALP (TAN AND GREEN)	8415-01-332-8987-39		0		0	0
	8415-01-364-2229-35	151,475	151,475	236,568	0	0
SUIT, CPCOMBAT (BDO)	8415-01-130-1506-37	0	0	2,931,035	0	0
OVERBOOTS/GLOVES						
BLK/ORK VINYL OVERBOOTS	8430-01-317-3564-85		0	1,233,534	0	0
	8430-01-349-0838-87	7,412,667	5,899,864	103,228	0	0
CPO BOOT COVERS	8430-01-02[illegible]-5928	1,238,209	0	155,588	0	0
CP GLOVES 7 MIL	8415-01-131-2501-04	472,081	54,618	112,094	0	0
CP GLOVES 14 MIL	8415-01-131-2497-06	1,064,558	814,448	259,955	0	0
CP GLOVES 25 MIL	8415-01-003-8574-50	5,270,220	5,011,520	4,354,178	0	0
MASK PROTECTION						
ASSEMBLY, MASS/RIES	4240-01-412-1543-45	812,709	691,040	125,257	12,959	12,513
BATTERY, BA-5800 (FRC MASK)	6665-01-260-9742	61,152	61,152	266	0	0
CP HELMET COVER	8415-01-111-9058	1,605,275	1,605,275	1,083,423	0	0
FILTER CAN, 25AL	4240-01-331-1515	1,754,884	1,567,636	733,523	358,003	264,160
FILTER CAN, M9AL	4240-00-129-7158	35,468	0	32,219	0	0
FILTER ELEMENT, M/S42	4240-00-165-5026	584,311	0	260,879	0	0
HOOD, M40	4240-01-378-3752	3,534,465	1,901,570	1,165,841	534,503	201,000
HOOD, M3 (FOR M25A1)	4240-00-665-8987	46,316	0	26,388	0	0
HOOD, M42 (FOR M17)	4240-00-995-0420	133,910	0	50,824	0	0
HOOD, M7 (FOR M24)	4240-00-001-6695	44,722	0	219,221	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
BATTERY, ALKALINE BA-3590	6135-01-036-2455	55,068	110,292	221,199	0	0
BATTERY, BA-3517	6135-00-450-5558	151,147	52,645	18,992	0	0
BATTERY, ICAM BA-5800	6665-00-720-9742	52,645	52,645	5,948	0	0
Battery, M42 BA3030	6135-00-830-0950	220,000	440,000			
DET KIT, M18A1	6665-01-133-4964	138,290	48,037	65,135	0	0
DET PAPER, M8	6665-00-098-8529	2,369,551	2,165,251	959,967	98,334	0
DET PAPER, M9	6665-01-324-5389	2,021,375	2,021,875	320,132	0	0
MAINT KITS, M256/M278	5180-01-119-6409	80,225	0		0	0
	5180-01-104-5329	41,106	41,106	22,825	0	0
NBC MARK SET, M274	9905-12-124-5555	58,333	9,936	33,641	15,219	0
WATER TEST KIT, M272A1	6665-01-134-0085	9,583	9,580	3,068	2,069	0
DECONTAMINATION COMMODITY AREA						
DECON KIT, M258A1	4230-01-101-3984	854,253	1	212,466	0	0
DECON KIT, M295	6850-01-276-1905	1,142,688	136,383	119,455	5,452	0
DECON KIT, M295	6850-01-357-8458	732,255	136,852	30,355	0	0
DS, 1 US QT	6850-00-753-4827	332,244	220,244	136,355	77,499	0
DS, 5 GAL	6850-00-753-4830	4,865,259	4,865,259	248,288	0	0

Table 4-2b. Army Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	STOCKS ON HAND TO INCLUDE FY99 DUE IN	PROJECTED DUE IN FY00	PROJECTED DUE IN FY01
DS2, NEUT CAN	6850-01-136-6988	2,351,465	2,190,455	195,095	0	0
NITROGEN CYLINDERS	4220-00-775-[illegible]	1,069,082	1,319,022	59,121	0	0
STB SOLID	6850-00-297-6683	10,628	10,628	19,049	0	0
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP, M28A2 (M14 OPFL)	4240-01-365-0981	12,816	12,815	4,364	462	0
FILTER, CP, M13 SERIES (M14 OPFL)	4240-00-568-6257	12,816	12,815	3,335	3,126	0
FILTER, CP, M28A1	4240-01-365-0983	59,480	60,593	18,250	7,036	0
FILTER, CP, M29	4240-01-366-1824	44,971	44,971	10,002	370	0
FILTER, CP, 24484	4240-01-365-1211	15,930	15,930	11,284	8,562	0
FILTER SET FOR M99, M56, SHIPBOARD	4240-01-369-6831	1,167	1,167	4,775	6,336	4,314
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6850-01-129-3248	1,249,632	1,249,632	1,290,535	0	0
ATROPINE AUTOINJ	6525-00-526-5083	1,874,828	1,874,828	561,333	0	0
CANA AUTOINJ	6850-01-324-0025	1,554,930	1,554,930	559,010	185,180	185,180
MED AEROS NERVE AGENT, "MANAA"	6515-01-332-1281	2,330		3,587		
MASK, M50	8465-01-174-6919	2,281,312	2,281,312	925,412	222,185	0
PYRIDOSTIGMINE TAB	6525-01-178-1505	1,317,305	1,317,309	431,072	11,586	11,586
PATIENT WRAPS	6530-01-285-4301	18,900	18,900	9,179		
MES, CHEM AG PAT DECON	6545-01-176-4612	1,575	1,575	394	168	0
MES, CHEM AG PAT TREATMENT	6545-01-141-5459	2,231		468	315	0
OTHER TREATMENTS						
CIPROFLOXACIN	6505-01-272-2355		0	45,272	0	0
	6505-01-272-8650		0	37,822		
	6505-[illegible]-333-4[illegible]5	1,881,870	1,881,870	229	0	0
DOXYCYCLINE CAPS	6505-01-152-4035	0	0	133	0	0
ANTIDOTE TREATMENT KIT, CYANIDE	6505-01-342-4548	67,140	67,140	419	0	0
	6505-[illegible]-457-9931	22,380	22,380	1,295	985	0

Table 4-3a. Air Force Readiness Data – Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE ROLLUP	NO. REQUIRED FOR 2 MTW	STOCKS ON HAND TO INCLUDE FY99 DUE IN	PROJECTED DUE IN					
					FY00	FY01	FY02	FY03	FY04	FY05
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, ABC-M32	NOT ASSIGNED	16,810	16,810							
MASK, AERP	4240-01-236-0785/85J	24,855	24,855	4,538	0	350	350	12	10	13
MASK, CB, M17A2	4240-01-145-2017-20	5,152	5,152	1,577	10	2	0	0	0	0
MASK, MCU-2/P	4240-01-415-4239-41	65,328		65,328	225	2,500	787	225	120	130
MASK, MCU-2A/P	4240-01-228-3615-17	106,382	35,592	16,644	5,256	1,100	25	25	50	0
MASK, MCU-2A/P [WR] USAF	4240-01-527-5299-01	99,878		99,755	0	200	50	35	50	50
MISC PROTECTION										
PANTS, MAP	4240-01-355-8241	1,250	1,250	18	2	0	1	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
NUCLEAR DETECTION EQUIPMENT										
ADM-300 - A KIT	6665-01-291-9203/W	328	328	99	5	0	0	0	5	0
- B KIT	6665-01-342-3747/W	800	583	199	0	0	0	0	5	0
- C KIT	6665-01-326-4722/W	750	518	268	0	2	0	0	5	0
- E KIT	6665-01-426-5061/W	250	119	99	0	3	1	1	1	1
CHEMICAL DETECTION EQUIPMENT										
ACADA, M22	6665-01-438-6963	2,150	2,150	1,264	0	0	0	0	0	0
ALARM, CBA, M8A1	6665-01-135-5627	423	331	125	1	5	0	0	0	0
CAM/RDAM	6665-01-291-8500	125	108	54	0	14	0	0	0	0
	6665-01-199-4153	1,960	1,960	89	0	27	2	0	0	0
VHO CHEM WARFARE ALARM	6665-01-408-5109	65	58	15	0	10	1	0	0	0
DECONTAMINATION COMMODITY AREA										
AERIAL-8 DECON SYS	4220-01-133-6660	175	0	22	0	1	2	0	0	0
LWT DEC SYS, M17	4230-01-251-8702	299	0	72	0	3	2	1	0	0
LWT DEC SYS, M17A1	4230-01-303-5225	50	0	21	0	0	2	1	0	0
LWT DEC SYS, M17A2	4230-01-519-1779	137	152	25	0	0	1	1	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
SHELTER, COLLAPSIBLE, M20A1	4220-01-044-7639	25	16	1	0	0	0	1	0	0
SHELTER, CPE, M28B1	NOT ASSIGNED	*21	28	8	*12	0	0	1	0	0
MEDICAL COMMODITY AREA										
LITTER, DECONTAMINABLE	6530-01-580-7300	26,750	26,750	3,172	0	0	0	1	0	0

* CSHATH fielding currently being revalidated by Air Force Medical Service

Table 4-3b. Air Force Logistics Readiness Data - Consumables

NOMENCLATURE	SSN	TOTAL SERVICE BUYS	NO. REQUIRED FOR 2 YEARS	STOCKS ON HAND TO INCLUDE FY00 DUE IN	PROJECTED DUE IN	
					BY00	FY01
INDIVIDUAL PROTECTION COMMODITY AREA						
APPAREL/ITEMS						
AIRCREWMAN CAPE	8415-01-E4E-9018	291,014	285,912	101,257	432	1,212
CLOTHING TEST KIT	6630-CC-213-0153	200	167	370	0	252
CP UNDERCOVERALL	8415-01-545-2126-84	75,000	67,376	19,568	3,070	35
ECD HGU-25 HOOD	4240-CC-338-1548	225	192	604	0	35
ECD K-1 TAP	8415-CC-088-6762-8870	213	126	4	0	50
	8415-01-105-2535		0			
ECD TAP BOOT COVER	8430-00-323-5235-5536	275	199	28	0	50
ECD TAP GLOVES	84 5-00-759-6550-56	500	575	54	2	62
INSERD UNDERGARMENT	84 5-00-782-5942-5	5,287	5,000	1,428	2	78
ISSUE LABOR 45 DAYS	SEE PROGRAM SHEET	1,100,558	705,962	7,584	2	5,099
M-2 APRON	84 5-00-281-7813-16	225	198	34	2	1
M3 COOLING HOOD	84 5-00-261-6905	393	306	0	2	1
M3 COOLING SUIT	84 5-00-265-2929	200	170	0	2	1
SUIT, AIRCREW CWU-66/P	8415-01-338-2424-87	150,000	34,871	37,089	1,305	2,180
SUIT, CP CAMO (BDO)	8415-01-337-1700-05	122,162	121,167	526,997	1,595	12,509
SUIT, CP CAMO-DESERT Tan	8415-01-337-6348-92	13,878	13,878	38,634	43	645
SUIT, CP CAMO-DESERT Pair	8415-01-324-3084-97	23,656	23,656	1,934	0	30
OVERBOOTS/COVER						
BLK/GRN VINYL OVERBOOTS BVO	8430-00-337-3374-85	1,006,127	0	535,715	1,422	8,697
BVO	8430-01-349-3878-87	6,000	998,253	14,648	5,827	1,200
CP FOOTWEAR COVERS	8430-01-418-3172		0			
	8430-01-421-5978	154,806	0	32,236	0	0
CP GLOVES 7 MIL	8415-01-158-2501-04	466,534	466,534	90,535	0	2,718
CP GLOVES 14 MIL	8415-01-158-2502-00	1,834,566	1,287,572	1,177,596	5,168	14,336
CP GLOVES 25 MIL	8415-01-056-5517-20	90,520	25,051	25,035	20	1,428
CP SOCKS	8415-01-050-5169	300,458	170,368	62,301	2,652	2,244
DISP FOOTWEAR COVER	8430-00-580-1505-06	301,332	185,771	175,264	3,379	2,715
GLOVE INSERTS	8415-00-785-3609-85	2,245,875	1,688,235	656,543	11,615	5,357
MISC PROTECTION						
FILTER CAN, CC/CAT	4240-01-119-2215	1,598,925	555,551	589,585	17,052	25,723
FILTER, CF	4240-01-161-3110	2,090	1,250	952	0	100
FILTER ELEMENT, M25A2	4240-00-165-5006	21,595	21,596	14,593	12	280
HOOD, M6A2 (FOR K1T)	4240-00-995-0420	95,093	95,107	328,340	36	149
HOOD, NSU-3P	4240-01-115-9433	3,225,139	303,574	1,032,483	8,345	5,865
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
BATTERY, ACADA BA-5590	6135-01-035-3485	46,121	46,332	551	30	210
BATTERY, BA-3517	6135-01-450-3528	880	0	308	0	32
BATTERY, ICAM BA-5390	6665-99-700-9742	67,255	67,295	1,024	0	44
DET KIT, M18A2	6665-01-508-4267	250	0	15,525	317	0
DET KIT, M256A1	6665-01-123-4964	50,133	1,392	1,668	1,668	0
DET PAPER, M8	6665-00-050-8529	454,236	316,274	468,535	468,535	1,713

Table 4-3b. Air Force Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	STOCKS ON HAND TO INCLUDE FY99 DUE IN	PROJECTED DUE IN	
					FY00	FY01
DET PAPER, M9	6665-01-049-8982	50,606	0			
	6665-01-226-5589	355,994	355,994	470,099	13,774	11,948
MAINTENANCE KIT, M293	5180-01-379-6409	90	0	120	0	8
NBC MARK SET, M274	9905-12-124-5955	725	517	891	50	10
WATER TEST KIT, M272A1	6665-01-134-0885	764	764	188	25	1
DECONTAMINATION COMMODITY AREA						
CALCIUM HYPOCHLORITE	6810-00-255-0471	625	625	1	0	10
DECON KIT, M258A1	4230-01-101-3984	725,370	0	157,927	0	0
DECON KIT, M291	6850-01-276-1905	225,093	14,423	179,083	0	10,350
DECON KIT, M295	6850-01-357-8456	135,092	7,538	86,701	3,968	10,969
DRY SORBENT POWDER	6850-01-262-0484	1,150	100	1,891	4,542	5
SODIUM HYPOCHLORITE	6810-00-598-7316	100	0	51	0	10
STB, 50 LB	6850-00-297-6653	517	517	10	10	0
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP M13 SERIES (M14 GPFU)	4240-00-368-6291	0	0		0	0
FILTER, GP M48A1	4240-01-363-1311	0	8		0	0
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533	0	0		0	0
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	354,796	354,796	805,527	166,603	166,603
	6505-01-080-1986		0	19,676	4,747	4,747
ATROPINE AUTOINJ	6505-00-926-9083	354,796	354,796	822,695	167,682	167,682
	6505-00-299-9673		0	13,304	5,788	5,877
CANA AUTOINJ	6505-01-274-0951	113,323	113,323	286585	137,909	137,909
NAAK, MKI	6705-01-174-9919	2,947	0	155	16	16
PYRIDOSTIGIMINE TAB	6505-01-178-7903	26,731	23,460	35,712	0	9,926
TETRACYCLINE	6505-00-655-8355	0	0	54,682	11,351	11,351
PATIENT WRAPS	6530-01-383-6260	0	0			
OTHER TREATMENTS						
DOXYCYCLINE CAPS, 100s	6505-00-009-5060		0		0	0
500s	6505-00-009-5063		0	62	27	27
CIPROFLOXACIN	6505-01-273-8650		0	121,755	171,050	171,050
	6505-01-333-4154		33,515	12,215	13,559	13,559

Table 4-4a. Navy Logistics Readiness Data - Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE REQMTS	NOS REQUIRED FOR 2 MTFs	STOCKS ON HAND TO INCLUDE FY99 DUE IN	PROJECTED DUE IN					
					FY00	FY01	FY02	FY03	FY04	FY05
BIOMEDICAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, AP22P2	NOT ASSIGNED									
MASK, MCU-2/P	4240-01-151-2441	9,860		28,344	0	0	0	0	1	0
MASK, MCU-2A/P	4240-01-384-2619-C2	240,000	240,583		0	0	0	0	1	0
MASK, MCU-2A/P W/PC 358	4240-00-337-4148-52	184,564		174,554	0	0	0	0	1	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
NUCLEAR DETECTION EQUIPMENT										
AN/PDR-27	6665-00-910-5435	1,542	254	607	0	0	0	0	0	0
AN/PDR-43	6665-01-380-9646	3,780	930	25,958	0	0	0	0	0	0
AN/PDR-56	6665-01-386-9090	150	65	65	0	0	0	0	0	0
AN/PDR-77	6665-01-379-7516	530	258	388	0	0	0	0	0	0
CP-95	6665-01-526-8645	29,732	586	619	0	0	0	0	0	0
PP-4276	6665-00-499-3109	6,034	962	841	0	0	0	0	0	0
IM-143	6665-00-756-6595	10,756	10,243	9,933	0	0	0	0	0	0
DT-60	6665-00-978-9657	137,450	237,460	150,278	0	0	0	0	0	0
BIOLOGICAL DETECTION EQUIPMENT										
IBAD	NOT ASSIGNED	35	35		0	0	0	0	0	0
CHEMICAL DETECTION EQUIPMENT										
ACADA, M22	6665-01-418-6663	536	535	320	0	0	0	0	0	0
ALARM, CBA, M8A1	6665-01-105-5632	360	48	48	0	0	0	0	0	0
CAPDS	6665-01-394-2555	333	333	322	0	0	0	0	0	0
CHEM AGENT MONITOR/CAM	6665-01-155-4353	545	275	542	0	0	0	0	0	0
CW DD, ANVAS-1	5855-01-147-4152	386	338	375	0	0	0	0	0	0
DAP POINT DETECTION SYSTEM	6665-LL-ENC-5532	234	234		234	46	46	46	58	0
M21 RSCAAL	5965-01-324-6552	42	0	0	0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA										
DECON APPAS, M13	4235-01-323-5513	2,978	1,250	0	0	0	0	0	0	0
LWY DEC SYS M17A3 DIESEL	4230-01-346-3122	738	64	0	0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
SHELTER, CP, M20/M20A1	4960-01-166-2254	670	40	0	0	0	0	0	0	0
MEDICAL COMMODITY AREA										
LETTER, DECONTAMINABLE	8530-01-350-2209	* 1,684	* 1,684	2	2	0	0	0	0	0

* Includes Marine Corps requirement

Table 4-4b. Navy Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE EQUIPS	NO. REQUIRED FOR 2 MTW	STOCKS ON HAND TO INCLUDE FY99 DUE IN	PROJECTED DUE IN FY00	PROJECTED DUE IN FY01
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
APRON,TAP	8415-00-281-7033-16	0	0	0	0	0
IMPREG UNDERGARMENT	8415-00-782-3242-5	240	240		0	0
JSLIST CARDIC 45 DAYS	SEE NSNs IN TABLE 4-6	215,000	133,178	66,439	88,121	85,245
SUIT, CP CASIC (BDO)	8415-[illegible]-137-1709-57	0	0		0	0
SUIT, TAP 3	8415-01-299-6062-SET-70	240	240	4	0	1
	8415-01-105-2235		0	4		
SUIT, CP, CC MK3	8415-01-214-8289-52	285,666	285,666	165,351	0	0
OVERBOOTS/GLOVES						
BOOT,RBR VINYL OVERSHOE BVO 5VO	8430-01-317-2374-45		0	9,451		
	8430-[illegible]-249-0878-87	168,345	0		0	0
**CP FOOTWEAR COVERS	8430-01-[illegible]-8172	20	0		0	0
	8430-[illegible]-321-5978	339,000	339,000	285,710	0	0
CP GLOVES TMC	8415-[illegible]-158-2501-04	56,472	56,472		0	0
**CP GLOVES 25 MIL	8415-[illegible]-158-5519-20	431,317	431,317	215,658	0	0
CP SOCKS	8415-01-240-5169	204,824	204,824		0	0
DISP FOOTWEAR COVER	8430-00-582-2305-05	204,824	204,824	334,712	0	0
GLOVE INSERTS	8415-00-182-2933	478,000	478,000	744,000	0	0
MISC PROTECTION						
CP HELMET COVER	8415-01-[illegible]-9033	82,575	82,575	0	0	0
**FILTER,CAN,CB/GAS	4240-01-[illegible]-2915	494,329	494,329	403,446	0	0
HOOD,M9[illegible]-P	4240-01-[illegible]-9429	91,208	91,208		0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
DET KIT, AG36A1	6665-01-133-4964	10,235	259	1,905	0	0
DET PAPER, M8	6665-00-085-8528	81,267	80,524	4,109	0	0
DET PAPER, M9	6665-01-226-5582	82,353	82,353	7,765	0	0
SBC MARK SET, M272*	9905-12-134-9535	422	22	180	0	0
TUBE,THIOXENE	6665-01-016-1565	200	8	1,253	0	0
WATER TEST KIT, M272A1	6665-01-134-0935	424	122	2	0	0
DECONTAMINATION COMMODITY AREA						
CALCIUM HYPOCHLORITE	6810-00-525-0475	9,001	3,463	6,470	0	0
DECON KIT, M258A1	4230-01-101-3514	36,408	0	198	0	0
DECON KIT, M291	6850-01-276-1505	124,410	3,333	150,835	0	0
DECON KIT, M295	6850-01-337-8458	1,645	1,645	237	0	0
DS2, 5 GAL	6850-00-753-4872	32,562	12,262	0	0	0
SODIUM HYPOCHLORITE	6810-00-598-[illegible]	619	610	44	0	0
STB, 50 LB	6850-01-291-6651	4,525	4,525	203	0	0

Table 4-4b. Navy Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MEW	STOCKS ON HAND TO INCLUDE FYIII DUE IN	PROJECTED DUE IN	
					FYIII	FYIL
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, GP, M98A1	4240-01-360-1311	351	235		[illegible]	[illegible]
FILTER SET FOR 7919, M98 SHIPBOARD	4240-01-369-6555	2,336	1,235		[illegible]	[illegible]
PRE-FILTER, SEPBOARD CPE	4240-01-348-8782	25,855	233		1,428	420
MEDICAL COMMODITY AREA						
3-PAK CHLORIDE ALTEIN	6505-01-125-5248	144,818	146,818	257,067	0	0
ATROPINE AUTOINJ	6505-01-926-9085	144,818	146,818	914,197	0	0
CANA ALTOIN	6505-01-274-0951	42,106	42,106	15,551	0	0
SAAK, MK1	6505-01-174-9919	113,051	113,051	17,284	0	0
PROPOSTIGMINE TAB	6525-01-278-7913	78,551	78,551	287,950	0	0
TETRACYCLINE	6505-01-685-3535	1,212,205	1,212,205		0	0
PATIENT WRAPS	6530-01-355-6260	0	0		0	0
OTHER TREATMENTS*						
CIPROFLOXACIN	6505-01-225-3650		0	340	0	0
	6505-01-355-4154	230,472	230,472		0	0
DOXYCYCLINE CAPS, 100s	6505-01-439-9050		0		0	0
500s	6505-01-439-9053		0	50	0	0

Table 4-5a. Marine Corps Logistics Readiness Data – Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	NO. REQUIRED FOR 2 MTW	STOCKS ON HAND TO INCLUDE FY99 DUE IN	PROJECTED DUE IN					
					FY01	FY01	FY02	FY03	FY04	FY05
INDIVIDUAL PROTECTION COMMODITY AREA										
CB MASK										
MASK, APPEP	NOT ASSIGNED									
* MASK, CB, M40/M40A1	4240-01-286-0061-83	227,089	7,474	159,208	63,933	0	0	0	0	0
MASK, CB, M17A2	4240-01-142-2017-26	0	0	11,199	0	0	0	0	0	0
MASK, M24, AVIATOR	4240-01-276-4536	0	0	385	0	0	0	0	0	0
MASK, M9A1, TANK	4240-01-394-5290-55	0	0	2	0	0	0	0	0	0
* MASK, M9, TANK	4240-01-358-0054-66	5,088	5,088	4,525	0	0	0	0	0	0
MASK, ACU-2/P, SAP	4240-01-281-5015-17	0	0	162	0	0	0	0	0	0
NOSE PROTECTION										
NOSE, COMB. ADAPTER	5996-01-281-9312	50,000	20,000	2,048	0	0	0	0	0	0
PADS, M41	4240-01-285-8251	460	460	427	0	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA										
NUCLEAR DETECTION EQUIPMENT										
ANPDR-75	5865-01-[illegible]-4227	1,203	1,203	931	0	0	0	0	0	0
ANVDR-2	5865-01-322-1425	3,543	3,543	1,953	0	0	0	0	0	0
CHEMICAL DETECTION EQUIPMENT										
ACADA, M22	5865-01-[illegible]-6961	695	575	695	0	0	0	0	0	0
ALARM, GAS, M8A1	5865-01-105-9623	28	28	30	0	0	0	0	0	0
CAM, -5	5865-01-259-9006	1,359	1,359	1,529	0	0	0	0	0	0
CAM-10	5865-99-[illegible]-9006	875	875	1,529	0	0	0	0	0	0
M21 RSCAAL	5865-01-282-1968	151	151	151	0	0	0	0	0	0
NBC RECON SYS, M93	5865-01-[illegible]-1300	10	10	10	0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA										
DECON APPAR, M13	4230-01-220-1618	21,050	2,055	21,317	0	0	0	0	0	0
DECON APPAR, M13	4230-01-125-4154	16,864	16,864	11,995	0	0	0	0	0	0
DECON APPAR, RDEA, M13A1	4230-01-356-9488	0	0	0	0	0	0	0	0	0
LWT DEC SYS, M17A1	4230-01-306-5225	344	0	293	0	0	0	0	0	0
LWT DEC SYS, M17A2	4230-01-346-3122	1,250	1,250	648	0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA										
** SHELTER, CP, PORTABLE	4240-01-346-2564			22	0	0	0	0	0	0
MEDICAL COMMODITY AREA										
LITTER, DECONTAMINABLE	6530-01-380-7309	0	0	42	0	0	0	0	0	0

* 1,302 Mask 3440 and 838 Mask 3442 Code "H" (Unserviceable)

** - Note: The Marine Corps is using the Portable Collective Protection System for training purposes.

Table 4-5b. Marine Corps Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	QTY REQUIRED FOR 1 MTW	STOCKS ON HAND TO INCLUDE FY99 DUE IN	PROJECTED DUE IN	
					FY00	FY01
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
CSC, IST (ARCO) 45 DAYS	SEE NSNs IN TABLE 4-6	695,000	921,575	44,429	53,166	1,668
SUIT, G2 CARGO (BDC)	8415-01-327-1700-07	0	0	26,935	0	0
SUIT, G2, BARACODA	8415-01-333-2525-70	596,121	596,121	526,930	0	0
SUIT, G2 SARATOGA/DESERT	8415-01-333-3527-80	30,000	50,583	35,522	0	0
OVERBOOTS/GLOVES						
BOOT, CBR VINYL OVERBOOTS BVO (2/2)	8430-01-317-5530-85 8430-01-444-3923-37	654,000	551,142	264,284	0	0
CF FOOT COVERS	8430-01-402-3978		0	523,875	0	0
CF GLOVES 25 MIL	8415-01-403-8517-30	792,154	792,154	122,385	0	0
MISC PROTECTION						
20 SQ M, 6/40 SERIES	4240-01-413-1520-43	277,095	183,684	67,597	0	0
CF HELMET COVER	8415-01-411-9026	571,000	571,000	0	0	0
FILTER, CAN, C2/C2A1	4240-01-419-2515 4240-01-357-1519	554,246	569,535	383,427	0	0
FILTER, CAN, M-25A1	4240-00-422-2130	2,468	0	4,111	0	0
FILTER, ELEMENT, M13A2	4240-00-955-9026	22,166	0	22,150	0	0
HOOD, M9	4240-01-376-5156	345,865	345,865	7,036	0	0
HOOD, M9 FOR M25A1	4240-01-390-3965	887	0	280	0	0
HOOD, M9A2 FOR M17	4240-01-999-0430	24,870	0	12,663	0	0
HOOD, M9 (FOR M9A1)	4240-01-021-5695	320	0	1,006	0	0
HOOD, M9A1-P	4240-01-389-9425		0	648	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
BATTERY, BA-3517	6135-01-450-5828		0		0	0
BATTERY, ICAM 3A-3800	6665-01-390-9745	25,736	23,155	8,806	0	0
BATTERY, ACADA BA-5391	6135-01-036-1495	29,938	29,305		0	0
DET KIT, M256A1	6665-01-133-4664	29,547	29,547	4,954	0	0
DET PAPER, M8	6665-01-050-8539	272,778	272,778	28,545	0	0
DET PAPER, M9	6665-01-049-3985 6665-01-226-8586	280,949	280,949	91,522	0	0
MAINT KITS, M256/M256	6665-01-579-6406		0		0	0
NBC MARK SET, M274	6665-01-246-4716	2,286	1,262	236	0	0
WATER TEST KIT, M272A1	6665-01-134-0025	3,139	3,115	2911	0	0
DECONTAMINATION COMMODITY AREA						
DECON KIT, M258A1	4930-01-401-3984	201,558	0	38,065	0	0
DECON KIT, M291	6850-01-276-1505	406,239	27,067	162,856	0	0
DECON KIT, M295	6850-01-387-8456	28,244	28,244		0	0
DS2, 1 QT	6850-00-753-4825	21,231	21,251	9,272	0	0
DS2, 1 GAL	6850-00-753-4810	251,857	251,857	9,100	0	0
DS2, ICD CAN	6850-01-136-0816	32,651	32,651		0	0
NITROGEN CYLINDERS	4220-00-775-7547	27,995	27,995	13,043	0	0
STB, 50 LB	6850-00-299-6653	7,410	1,854	4,761	0	0

Table 4-5b. Marine Corps Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE ROUTES	NO. REQUIRED FOR 2 MTW	STOCKS ON HAND TO INCLUDE FY99 DELIV	PROJECTED DUE IN FY00	FY01
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP, M1262 (M14 GPU)	4240-01-565-0981	108	108		0	0
FILTER, CP, M20 SERIES (M14 GPU)	4240-01-358-6091	123	123		0	0
FILTER, CP, M98A1	4240-01-355-0962	1,256	1,256	478	0	0
FILTER, CP, M19	4340-00-166-1525	1,674	1,674	132	0	2
FILTER, SP, M98A1	4240-01-355-1511	644	644		0	0
FILTER SET CRIM99.8456 SERIES(M1)	4240-01-399-5553		0		0	3
MEDICAL COMMODITY AREA						
2-PAM CL/CRIDE AUTOINJ	6505-01-125-3284	500,505	500,505	58,455	0	2
ATROPINE AUTOINJ	6505-00-926-5283	500,505	500,505	51,342	0	0
CANA AUTOINJ	6505-01-274-5351	142,481	142,481	45,543	2	0
NAAK, MKI	6705-01-174-9319	405,445	405,445		0	0
* PYRIDOSTIGMINE TAB	6505-01-151-7393	369,775	369,775	3,295	3	0
PATIENT WEAPS	6550-01-283-6252				3	0

* 3,097 not received due to using repackaged vs comply with FDA requirements

Table 4-6. Defense Logistics Agency Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	STOCKS ON HAND TO INCLUDE FY99 DUE IN	PROJECTED DUE IN FY00	PROJECTED DUE IN FY01
INDIVIDUAL PROTECTION COMMODITY AREA				
OVERGARMENTS				
CAPE, AIRCREWMAN	8415-01-[illegible]	[illegible]	5,500	0
CP UNDERCOVERALL	[illegible]			
CHEM PROT UNDERGARMENT TOP	8415-01-363-[illegible]	40,675	,300	0
CPU DRAWERS	8415-01-363-[illegible]			
SOD CAP BOOT COVER	[illegible]	794	2,2[illegible]	0
IMPREG UNDERGARMENT	8415-01-[illegible]			
JSLIST SUITS		0	250,0[illegible]	150,0[illegible]
Wood - Coat	8415-01-444-[illegible]			
Wood Trousers	8415-01-444-[illegible]			
Desert Coat	8415-01-444-[illegible]			
Desert Trousers	8415-01-444-[illegible]			
SCALP (TAN AND GREEN)	8415-01-[illegible] 8415-01-[illegible]			
SUIT, AIRCREW, CWU-66/P	[illegible]		25,300	6,[illegible]
SUIT, CP CAMO (BDO)	8415-01-[illegible]		0	0
SUIT, CP CAMO-DESERT - 3 color	8415-00-[illegible]		0	0
SUIT, CP CAMO-DESERT - 5 color	8415-01-[illegible]		0	0
SUIT, CP, OG 106	8415-00-[illegible]		0	0
SUIT, CP, SARATOGA	8415-01-[illegible]		0	0
OVERBOOTS/GLOVES				
BLK-GRN VINYL OVERBOOTS	8430-01-[illegible]	[illegible]	[illegible]	0
CPO FOOT COVERS	8430-01-[illegible]		0	0
CP GLOVES 7 MIL	8415-01-[illegible]	[illegible]	[illegible]	[illegible]
CP GLOVES 14 MIL	8415-01-[illegible]	[illegible]	0	[illegible]
CP GLOVES 25 MIL	8415-01-[illegible]	[illegible]	150,[illegible]	0
CP SOCKS	8415-01-[illegible]	[illegible]	[illegible]	0
DISP FOOTWEAR COVER	8430-00-[illegible]	[illegible]	10,[illegible]	0
MISC PROTECTION				
HOOD, MCU-2A/P	4240-01-189-[illegible]		0	0
CP HELMET COVER	8415-01-111-[illegible]	132,[illegible]	345,000	0
CONTAMINATION AVOIDANCE COMMODITY AREA				
CHEMICAL DETECTION EQUIPMENT				
BATTERY, BA3517	6135-01-450-[illegible]	0	[illegible]	35,[illegible]
MAINT KITS, M256/M293	[illegible] [illegible]	2,0[illegible]	408	408
TUBE, DET, PHOSGENE GAS	6665-01-010-[illegible]	1[illegible]	306	306
DECONTAMINATION COMMODITY AREA				
CALCIUM HYPOCHLORITE	[illegible]	54,[illegible]	55,980	55,980
DRY SORBENT POWDER	[illegible]	[illegible]	190	0
STB, 50 LB	[illegible]	[illegible],000	84	84

Table 4-6. Defense Logistics Agency Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	STOCKS ON HAND TO EXCLUDE FY99 DUE IN	PROJECTED DUE IN FY00	PROJECTED DUE IN BYD1
COLLECTIVE PROTECTION COMMODITY AREA				
PRE-FILTER,SHIPBOARD CBR	4240-[illegible]-348-9385		588	588
MEDICAL COMMODITY AREA				
2-PAM CHLORIDE AUTOINJ	6505-01-125-3958	237,387	250,000	250,000
ATROPINE AUTOINJ	6505-00-926-9385	275,132	340,000	340,000
CANA AUTOINJ	6505-01-254-0951	287,054	300,000	300,000
KAAK, MKI	6505-01-134-2919	253,000	0	0
PERIDOSTIGMINE BASLETS	6505-01-318-7905	256,135	100,000	100,000
LITTER, DECONTAMINABLE	6530-00-990-7509	1,500	1,575	0
MES CREW ACT PROTCR	8465-01-[illegible]-3469	184	0	0
MES CREW AGENT DECON	8465-01-[illegible]-4512	184	0	0

APPENDIX 2
FIELDED NBC DEFENSE ITEMS - ISSUES AND CONCERNS

NBC defense items are generally used in combination to form a system or subsystem for a particular function. Therefore, this report will address items used as a system. These systems are categorized into five functional areas:

- Contamination Avoidance
- Individual Protection
- Collective Protection
- Decontamination
- Medical

1. CONTAMINATION AVOIDANCE

Contamination avoidance programs generally include equipment that is used to conduct NBC agent reconnaissance, detection, and identification. This area represents approximately half of the annual DoD NBC defense RDT&E budget. Due to recent type-classification of several programs that are intended to modernize contamination avoidance programs, this area has an unusually high number of developmental programs, as compared to other commodity areas. Many programs will complete their fielding beyond FY05.

Current numbers of biological detection devices, to include the Biological Integrated Detection System (BIDS) and Interim Biological Agent Detector (IBAD), are insufficient as measured against the MTW requirements. Automatic biological agent point detectors and stand-off detectors are currently in development, and will not be deployed in significant numbers prior to FY02. The USAF has no fielded biological agent detection capability other than the limited quantities of Portal Shield ACTD biological detectors.

The combined total of chemical agent detection systems remains at moderate risk, but will improve slowly as the M22 Automatic Chemical Agent/Detector (ACADA) supplements the M8A1 Automatic Chemical Agent Alarm. An Army initiative to inspect and repair M8A1 alarms at Anniston Army Depot has resulted in the quick assessment and return of 1,600 units to the field. Another 1,500 alarms were coded as requiring depot maintenance and are undergoing repairs. As a result of this program, the Army has no shortage of alarms for training purposes and there is no longer an acquisition gap between the combined acquisition of M8A1 and M22 alarms.

Although the combined number of CAM/ICAMs reported by the Services places them in the moderate risk category, the actual number available for use by the Marine Corps is much lower. Collectively, 59% of their total inventory of CAM/ICAM 1.5 and CAM/ICAM 2.0 is currently at the Marine Corps Logistics Base in Albany, GA awaiting repair. At present, the repairs are unfunded.

The M21 Remote Sensing Chemical Agent Alarm (RSCAAL) is at low risk with present quantities exceeding the two MTW requirement. The M93A1 NBCRS is currently fielded at less than half of its projected requirements. This system adds improved mass spectrometer sampling system along with stand-off chemical vapor detection. Several units continue to use trained reconnaissance personnel in HMMWVs and APCs, thus moderating this risk as continued fielding and developmental systems enter the inventory. Also, the M93 NBC Recon System completes the fill in the interim when added to the on-hand quantity of M93A1 systems.

Traditional consumables in this commodity area (M8 and M9 detection paper, M256A1 kits and M272A1 water test kits) are available in sufficient quantities to meet wartime requirements. Some shortages exist in individual Services, but overall there is little risk. Shelf life concerns may change this projection; this area remains under review.

The Army and Air Force radiac programs are expected to just meet the two MTW scenario average requirements. The Army National Guard still has a large number of obsolete radiacs. These will be replaced in the near future by the AN/VDR-2 which is available in sufficient quantities through the depot system. The Navy has small quantities of older radiacs still in the inventory, which will be replaced through a modernization program currently underway. The Marine Corps has most of the required AN/VDR-2s and about three-quarters of its AN/PDR-75s as compared to the MTW requirements, putting it in a moderate risk category. While Army stores or industry could compensate for this shortfall, it represents a potential risk, especially at the onset of any contingency.

2. INDIVIDUAL PROTECTION

Currently fielded protective suits and masks are designed to protect against all known CB threat agents. Past Service-unique requirements led to Service-specific procurements and some duplication in capability resulting in the procurement of six different chemical protective suits and six different masks. This has caused difficulties in meeting current needs and exacerbated logistics planning. Fielding of the M40/42 protective masks, JSLIST protective suits and the MULO boot has begun to resolve many of these former challenges.

2.1 Protective Ensembles

The Services are continuing acquisition of the Joint Services Lightweight Integrated Suit Technology (JSLIST) suits as a replacement for the BDO and other chemical protective suits. As such, the protective suits should be viewed as a system with the older suits providing readiness stocks until the end of their service life. The initial JSLIST contracts did not include surge option clauses. Defense Supply Center Philadelphia (DSCP), whose solicitations include the surge option as a requirement, took management of JSLIST in FY98. By examining the year-by-year status of protective suits, a number of older suits still within service life were added to the number of JSLIST suits purchased by that year and matched the total against the requirements. In FY03, the services have sufficient protective suits to meet requirements as projected for the average two MTW requirements. However, beginning in FY05, the number of suits on hand will fall below total Service requirements, as the service life of older protective suits, such as BDOs, expires in

large quantities. These calculations include the approximately $58 million Quadrennial Defense Review plus-up per year allocated to purchasing protective suits, which began in FY98.

The Battle Dress Overgarment (BDO) is reaching its maximum extended shelf life limit (14 years), and the Services have no plans for new production. There are no companies currently manufacturing the BDO. The Army and Air Force have sufficient suits on hand in war reserves to sustain its requirements for the near term. The Saratoga suit, purchased by DSCP for the Marine Corps, is also out of production, but current stocks will sustain the Marine Corps until the JSLIST is available in adequate numbers. The Navy is relying on existing stocks of their Mark III chemical protective suit (also out of production) as stocks of JSLIST are being procured.

Armor crews and aircrews require special protective ensembles to integrate with their weapon systems. Services have sufficient numbers of aircrew suits to meet requirements, given the smaller total requirements for aircrews (relative to ground troops). An exception is the Chemical Protective Undercoverall, which is now obsolete. It is replaced by the CWU-66/77 which remains low in inventory resulting in a moderate risk rating. To protect armor crewmen when they exit their vehicles, the Services have developed the Suit Contamination Avoidance Liquid Protection (SCALP), which is available in sufficient quantities to meet MTW requirements.

The Services have adequate stocks of 7, 14, and 25-mil chemical protective gloves on-hand for contingency use. Recent DoD surveillance tests have validated the protective qualities of the existing butyl rubber glove stocks. The results from calculating the number projected to be on hand for FY05 exceeds the projected average MTW requirement. The status of the Services on-hand inventories has allowed DLA to pursue an Industrial Base Maintenance Contract (IBMC) with both current manufacturers (Siebe North, Inc., Charleston, SC, and Guardian Corp., Willard, Ohio) to sustain the industrial base with "War Stopper" funding. The IBMC is to maintain the equipment only.

Chemical Protective Footwear Covers, also known as the "fishtail" boot, have been out of production for several years. Their shortages are supplemented by the Black/Green Vinyl Overboot (BVO/GVO), which is the interim chemical protective footwear until the JSLIST MULO boots have been fielded. Because the GVO's primary purpose is not chemical protection, current contracts do not include surge option clauses. Again, one should view protective footwear as a system with older GVOs providing readiness stocks until the MULO is fielded in sufficient quantities. Currently, the total DoD inventory shows adequate quantities of protective footwear, resulting in low risk assessment. The USMC is the only service reporting a shortage of footwear, but DLA can fill their shortfall.

2.2 Eye/Respiratory Protection

The Services continue modernizing their chemical protective mask inventories. Different versions of the protective mask were developed to meet the requirements of different military occupational specialties (*e.g.*, air crew, tank crew, *etc.*). For the Army and Marine Corps, the M40 (for generic use) and M42 (for armor crew members) series masks are replacing the M17

and M25-series masks, respectively. Some Army aviation units are still equipped with the old M24 mask, which will be replaced by the M45 mask. The M43-series mask, designed to be used by Apache equipped units, was in fact issued to all types of aviation units. It is being replaced by the M48 (Apache) and M49 (general aviation) series mask. The M45 will replace the M49 as the general aviation mask. This modernization effort is still ongoing; not all units have replaced their M43-series masks. All of these masks are at low risk, as the combined numbers of all aviator masks on hand exceeds the requirement. These newer masks provide increased protection, improved fit and comfort, and compatibility with most Services' weapons systems' optics and sights.

The Marine corps is performing a product improvement program (PIP) to modify the existing M40/M42 series mask. The PIP will be completed in Fiscal Year 2004. PIP actions include installation of a new nose cup, polycarbonate eye lenses, drink tube coupling, and drink tube quick disconnect: banding of the outlet valve housing: and laser etching serial numbers on the mask. The new components and banding procedure will improve the mask's durability and protective capability requirements established by the Marine Corps and eliminate inadvertent damage to the mask by the unit (*i.e.*, painting a number on the head harness, engraving in the eyelens-retaining ring). The cost to perform the PIP is estimated at $12M with the Marine Corps saving approximately $10M by performing the rebuild vice buying new modified masks.

The MCU-2A/P mask is designed to meet the needs of the Air Force ground crews, Navy shipboard and shore-based support missions, and Marine Corps rotary wing forces. The number of these masks on hand generally exceeds the requirement. The USAF has some shortages in masks and does not have second skins to provide complete personal protection. It will continue to be the mainstay of these units until the Joint Service General Purpose Mask is fielded, which will also replace the M40/42 masks. The Aircrew Eye/Respiratory Protection (AERP) mask is specially designed to enable pilots of high performance aircraft to conduct missions in a contaminated environment. Quantities of this mask are currently below the MTW requirement, making this a moderate risk.

In order to provide complete protection to our forces on the contaminated battlefield, particularly from liquid chemical agents, protective hoods and helmet covers are required as part of the individual protective ensemble. The protective hood for the M40 is rated as low risk. It is being replaced by the second skin for the M40 series mask, which is a high risk program with only 60 percent of requirements on hand by FY04. The MCU-2P hood is at low risk with an abundant inventory. Protective hoods for the M17-series, M24, and M25A1 masks are also in good supply, and thus are not a readiness issue. These masks are leaving the inventory, however. The Chemical Protective Helmet Cover is also available in sufficient quantities.

Filters and canisters provide the active ingredients that absorb the chemical and biological agents and provide the essential protection required. The C2/C2A1 canister is used with the M40, M42, M43, M45, M48, M49 and MCU-2/P masks. The number on hand falls short of the MTW requirements as a moderate risk. The M13A2 filter element exceeds requirements, but will be leaving the inventory with the retirement of the M17-series mask. The M10A1 filter

canister used on the M24/25 is short of the requirement, but these masks will also leave the inventory and will not be a readiness problem.

3. COLLECTIVE PROTECTION

There are two general categories of collective protection: stand-alone shelters and integrated systems. Integrated collective protection equipment is component equipment designed to provide protection against CB agents through the use of filtered air under positive pressure to a variety of facilities, vans, vehicles, aircraft and ships. Filters for these integrated collective protection systems (CPS) are in short supply due to low peacetime demand and low production quantities. The increased emphasis on procuring individual protection and contamination avoidance equipment has resulted in a corresponding decrease in procurements of shelters and large collective protection filters.

The Air Force has expressed interest in a greater collective protective shelter capability. Combined with the Navy's increasing shipboard collective protection filter requirements and the Army and Marine Corps traditional integrated vehicular systems and tactical shelter requirements, the near-term MTW requirements for large carbon-based filters have outpaced current inventories even aided by industrial surge capability. As a result, much of this sector is assessed as high risk, though the risk is primarily due to the level of funding rather than technical shortfalls. Most of the filter manufacturers retain the industrial capability to produce them.

In the near term, the M51 shelter will be replaced by the new Chemical and Biological Protective Shelter (CBPS). All Army M51 shelters have been coded as unserviceable. The CBPS is presently in production with fielding to initiate in 3Q00. Both Army and Air Force field hospitals are being integrated with environmentally controlled collective protection. The Army's Chemically Protected Deployable Medical Systems (CP DEPMEDS) achieves collective protection through the integration of the M28 Simplified CPE, chemically protected air conditioner, heaters, water distribution and latrine and alarm systems. The M28 Simplified CPE is in production and chemically protected heaters and air conditioners initiated production in FY99. The FY00-02 POM fully supports the production of the required 17 CP DEPMEDS. In FY00, production will initiate for remaining M28 CPE, CB protected water distribution and latrine systems, CB ISO Shelter Seals and Low Pressure Alarms.

The M20-series Simplified CPEs are used to provide a contamination-free, environmentally controlled work space for Echelon I and II forward area medical treatment facilities. Current funding levels, however, only will meet Force Package I requirements. There are some Force Package II units designated for deployments into high threat regions that will not be equipped with M20 shelters. This leads to an assessment as high risk. Current policy is that the M20/M20A1 Simplified CPE is a free issue item with no requirement to stock other than spares replenishment. The Marine Corps has Portable Collective Protection Shelters (PCPS) but does not plan to field them. The Marine Corps is instead using them for training purposes. The M20A1 SCPE is by default the only modern collective protection stand-alone shelter outside of the medical community in the inventory.

The Services have continued to improve integrated collective protection systems in armored vehicles and vans. All modern armored vehicles and armored vehicles in development have either filtered air systems, hybrid collective protection or full collective protection systems designed into their chaises. Notable progress has been made in providing shipboard collective protection. By the year 2000, most Naval ships that have close-in support roles (including amphibious ships, gunfire support combatants, and new logistics support ships) will contain significant CPS capabilities.

Collective protection filters for integrated systems (such as armored vehicles, ships and planes) continue to suffer from low stocks. While the Services have been proactive in selecting more capable industrial sources, actual procurement and storage of these filters to MTW requirements has not been initiated for all filters. As a result, stocks of some filters remain at a low level. However, the filters associated with the 200 CFM Particulate Filter Set for Shipboard Collective Protection Systems are being procured in sufficient quantities. Continued difficulties in obtaining a strong industrial base in this field compounds the issue of fielding and sustaining these items.

4. DECONTAMINATION

Current decontaminants are highly effective against all CB agents, but most present environmental hazards and are manpower intensive. The services are attempting to find environmentally safe decontaminants that are less labor intensive.

Basic soldier skills for decontamination of vehicle and crew-served weapons rely on the M11 Decontamination Apparatus, Portable (DAP) and M13 DAP. While the M11 is assessed as posing low risk, there are insufficient quantities of the M13 DAP as measured against the MTW requirements. The 1¼ quart M11 can be used in place of the 14-liter M13 DAP, but they do not fulfill the same exact capability (in part due to the volume of DS-2).

The M17-series Lightweight Decontamination System (LDS) is used to provide operational equipment decontamination in many battalion-level units and dual-purpose (smoke/decontamination) chemical companies. The Air Force employs the M17 at the squadron level for operational equipment decontamination. The M17 is assessed as a moderate risk, due in part to a delay in rebuilding several hundred systems caused by a lack of funding since 1990. There is still a large mix of different models in the inventory, forcing the Services to retain a large number of differing spare parts to maintain the different models. Based on projected inventory, should spare parts become difficult to obtain for the different models, the risk may become high. Overall, this risk should drop as more systems are produced and the older models are upgraded or replaced. The Marine Corps is upgrading all of their LDS to the diesel engine. The Air Force is deleting stocks of A/E32-U systems by attrition, modifying existing M17s to M17A2s, and procuring additional M17A3s to satisfy shortages.

In the Army, the M12A1 Power-Driven Decontamination Apparatus (PDDA) and the M17A3 LDS are the primary pieces of equipment used to decontaminate vehicles, crew-served equipment and large areas of terrain. The M12A1 is assessed as low risk. Although there are

sufficient quantities on-hand of the M12A1, the maintenance requirements, due to the age of this item, limit its full utilization and may increase its risk. The M21/M22 Modular Decontamination System will displace 200 M12A1 PDDAs over the POM period, resulting in a high-low mix of technology. By FY02, the on-hand quantities of the M21/M22 MDS alone should satisfy the two MTW requirement. Additionally, the Marine Corps is replacing their M12A1 PDDAs with the M17-series LDS.

The Army and Marine Corps plans for stocking containers of DS-2 (5-GAL and M13 Can) are below the MTW requirements expected for decontamination operations. The situation is compounded by a decreasing availability of DS-2. Bulk DS-2 stored at Seneca Army Depot is currently undergoing lot testing to ascertain how much has deteriorated and is unusable. As a result, stocks of DS-2 are being released for contingency use only. While less hazardous replacement decontaminants, such as sorbent decon are being developed, the quantities and packaging of current decontaminants present potential risk. The projected stockage of STB meets average MTW requirements, but has been considered a high-risk category in the past. Slight shortages in calcium hypochlorite and sodium hypochlorite can be made up by the industrial base, using commercially available alternatives. These increased requirements come as a result of increased attention to the need for decontamination capabilities in the 2 MTW scenario, and will be further refined. Continued monitoring is recommended.

The shelf life of the M258A1 Skin Decontamination Kit expired on 30 July 1999. Its replacement, the M291 Skin Decontaminating Kit, became the primary item used in personnel decontamination. Although M258A1 stocks are no longer available to supplement inventory of the M291, the risk assessment is low. Projected buys are expected to meet the 2 MTW requirements, but may need to be augmented to meet the total service requirements. Rohm & Haas, Co., the sole supplier of the resin, sold the mixing and packaging equipment they used to manufacture the M291 Decontaminating Kit. Pine Bluff Arsenal, Arkansas, set up a production line and began to manufacture the M291 Decontaminating Kit in October 1996. Rohm & Haas continues to provide the XE-555 resin components. True Tech Inc. is blending the components to make the XE-555 resin. Alternatives to producing a kit that does not use the XE-555 resin are being studied, including novel sorbent decontaminants. There are also a number of options being explored to retain this "at risk" technology.

The projected stockage of the M295 Individual Equipment Decontamination Kit puts it in a low risk category when compared with 2 MTW requirements. The M295 Decontamination Kit uses the same resin mix as the M291 Decontaminating Kit, and began delivery in December 1997. True Tech Inc. has been producing this item. Increased funding for its procurement would maintain the low risk.

5. MEDICAL

Medical NBC defense items are used to counteract the effects of exposure to chemical, biological, or nuclear agents through pre-treatment, vaccines, or post-treatment. Current projections for medical chemical defense material indicates that sufficient quantities should be on hand through the POM years and present overall low risk. Quantities of Nerve Agent Antidote Kits

(NAAK), and Atropine and 2-PAM Chloride Autoinjectors now support two MTW requirements. Convulsant Antidote Nerve Agent (CANA), and Nerve Agent Pyridostigmine Pretreatment (NAPP) Tablets (also known as PB Tablets) saw their risk increase because of the recalculated requirement for consumables. This report includes medical treatments for biological warfare agents and cyanide exposure along with the addition of new chemical treatments.

NAPP is still an Investigational New Drug (IND) for the use as a nerve agent pre-treatment. The U.S. Army Medical Materiel Development Activity (USAMMDA) has continued to work with the FDA for approval. Defense Supply Center – Philadelphia (DSCP) is working with ICN Pharmaceuticals to establish a requirements contract for the manufacture of NAPP.

The sole supplier to DoD for NAAK, atropine autoinjectors, pralidoxime autoinjectors and CANA is Meridian Medical Technologies, St Louis, Missouri. The medical chemical defense production line is being maintained with an IBMC. Meridian is an U.S. company but it obtains its atropine for the autoinjectors from a German supplier. Currently there is no domestic source for this drug. Pralidoxime and diazepam (CANA) for the autoinjectors is available from U.S. sources.

Patient Chemical Wraps have not been procured since 1991 and are made of the BDO materiel. USAMMA and the AMEDDC&S are currently assessing several versions of the patient wrap before initiating new procurement of this item. All services are procuring the new decontaminable litter, but in limited quantities, for first line units. There is a very large stockpile of canvas litters that can be used once in an NBC environment and then destroyed. As the canvas litters are depleted, they will be replaced with the new nylon decontaminable litter.

The Office of the Surgeon General has centrally programmed and funded the Army's Medical Chemical Defense Materiel since 1994. USAMMA has procured, stored and maintained this materiel for the Army in strategic locations for early deployers and forward deployed forces as Division Ready Brigades (DRB) sets, which support 5,000 personnel each. The Air Force, Navy and Marine Corps maintain their medical CB materiel in decentralized unit locations. Visibility of on-hand assets has been improved with the release of the Joint Medical Asset Repository, which is the Class VIII (medical) portion of JTAV.

Medical research programs continue to explore medical countermeasures to deter and defeat the use of biological warfare agents against U.S. forces. The Joint Program Office for Biological Defense (JPO-BD) has awarded a prime systems contract through the Joint Vaccine Acquisition Program (JVAP) for the development, FDA licensure, storage, and production of vaccines against DoD's identified potential biological warfare agents. Currently, the U.S. total force (active and reserve forces) is being vaccinated against anthrax, which is considered the primary high-threat BW agent. The anthrax vaccination program is a three-phase program, starting with the troops serving in-or identified to deploy to-the two high-threat areas where hostile anthrax-use poses the greatest potential danger. The overall vaccination program is on-schedule and will take between seven and eight years to complete for all service members (to include new personnel acquisitions as the program extends over the entire period).

JPO-BD assisted the sole domestic supplier of anthrax vaccine to maintain its FDA licensure and to transition the production facility to private ownership in FY98. A follow-on contract was also awarded in FY98 to ensure sufficient anthrax vaccine to meet the DoD vaccination program. Other vaccines (or combinations) are currently in various stages of development and testing to protect against other BW agents identified in the Chairman of the Joint Chiefs of Staff (CJCS) validated BW threat list. In the area of medical therapeutics, the Department is maintaining a stockpile of antibiotics (*e.g.*, ciprofloxacin, doxycycline, *etc.*) sufficient to address the treatment needs of potential BW exposures, where such treatment is medically indicated.

- The DoD/FDA Shelf Life Program was developed by the Department of Defense Health Affairs and the Military Medical Departments in response to Congressional concern over the conservation of military medical resources. The program's focus is to save replacement cost of date sensitive medical materiel especially medical materiel in War Reserve Stocks, Medical Biological Defense Materiel Programs and Medical Chemical Defense Materiel Programs. The Joint Readiness Clinical Advisory Board (JRCAB) coordinates with the FDA for items the Services wish to have tested. The FDA requests samples from the JRCAB and the Services. The samples have an initial potency test performed, followed by a 90-day stress test, and then a final potency test. The potency results are compared against a degradation curve, and a new potency period is assigned. The FDA sends the information to the JRCAB and Services who disseminate instructions to extend and re-mark or destroy the materiel to activities and units worldwide. The same lots are subjected to yearly retest and subsequent extensions until the materiel fails or is removed for lack of sufficient on-hand quantities required for testing. The Army maintains its extended materiel at Meridian Medical Technologies for use by Force Package 3 and 4 units. The Air Force maintains its materiel at its local medical logistics activities that re-mark the materiel and maintains it for the deploying units. The Navy and Marines re-mark the materiel and maintain it with the unit.

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Chapter 5

Nuclear, Biological, and Chemical (NBC) Defense Readiness and Training

5.1 INTRODUCTION

The Services' vision for Joint NBC Defense Management is: *America's Armed Forces trained and ready for the 21st Century, protecting our nation and its forces against nuclear, biological and chemical threats*. The Joint NBC Defense Program builds on the successes of each Service to develop a viable Joint orientation to NBC defense capabilities, which includes Joint requirements documents; Joint doctrine and tactics, techniques, and procedures; Joint modeling, simulation, and wargaming; and Joint professional training.

5.2 NBC DEFENSE DOCTRINE

Joint and Multi-Service Doctrine. Joint Publication 3-11, *Joint Doctrine for Nuclear, Biological, and Chemical (NBC) Defense Operations*, final draft 26 Nov 99 provides guidelines for the planning and execution of NBC defensive operations. Its focus is on the NBC threat, national policy, and considerations peculiar to the preparation and conduct of NBC defense. These considerations include principles of theater NBC defense, logistics support, medical support, training, and readiness.

The Joint Service Integration Group (JSIG) is working with the Air Land Sea Application (ALSA) Center, U.S. Army Chemical School (USACMLS), and the Joint Warfighting Center to lead the effort in the development of multi-service NBC defense doctrine. Currently ALSA is revising FM 3-4-1, *Multi-Service Procedures for NBC Defense of Fixed Sites, Ports, and Airfields*, in coordination with all the Services. Currently, the publication is in final review, incorporating Service-wide comments. Expected publication date is February 2000. Preliminary response to the publication has been favorable and the draft is being used as guidance in several locales.

Multi-National Doctrine. The U.S. Army Nuclear and Chemical Agency (USANCA) has been delegated the DoD representative for international standardization of NBC operational matters. USANCA participates in the following North Atlantic Treaty Organization (NATO) groups:

- NBC Defense Interservice Working Party (NBCWP) under the Military Agency for Standardization,
- Land Group 7 (LG. 7)—NBC Equipment—under the NATO Army Armaments Group (NAAG),

- Working Group 2 (LG. 7)—Low Level Radiation in Military Environments,
- Challenge Subgroup (LG. 7)—Chemical/Biological Toxicity Challenge Levels,
- Technical Subgroup (LG. 7)—Nuclear Weapons Defense, and
- ATP-45 (NBCWP) NBC Warning/Reporting.

USANCA also has been delegated as the representative in the ABCA Quadripartite Alliance (US, UK, Canada, Australia) in the Quadripartite Working Group (QWG) for NBC Defense. In that group, USANCA also participates in the RADIAC Information Exchange Group (IEG). The USACMLS participates with USANCA to incorporate NBC group agreements in revising existing manuals.

The USACMLS has been delegated as the representative at the NATO Training Group (Joint Services Subgroup) in addition to providing representation and subject matter expertise to support USANCA at NATO/QWG meetings as required. This includes consultation to coordinate the official US position on NBC defense issues prior to international meetings.

5.2.1 Joint NBC Defense Doctrine Program Management

The NBC defense program management strategy described in Chapter 1 provides the mechanism to assist the Joint Staff in the further development of the Joint NBC defense doctrine program. The JSIG coordinates with the Services to ensure the program is realistic and meets the needs of the Joint community.

5.2.2 Joint NBC Defense Doctrine Development Program

The USACMLS has been tasked by the Joint Staff to revise Joint Pub 3-11, *Joint Doctrine for Nuclear, Biological, and Chemical (NBC) Defense.* The title of the Joint Publication has been changed to *Operations in an NBC Environment.* This change reflects an increased emphasis on sustaining operations in a contaminated environment. Release of a final coordination draft of Joint Pub 3-11 to be distributed among the combatant Commands, Services, and the Joint Staff is planned for March 2000.

The USACMLS also provided exercise and training support to CINCs and various organizations throughout the year. Subject matter experts were provided to the Army War College for their "Strategic Crisis Exercise", Crisis Action Exercises, to the Atlantic Command (ACOM) for Joint Task Force (JTF) training, and to Exercise Silent Breeze II for briefing support.

The U.S. Army Medical Department Center and School (USAMEDDC&S) is the lead agency for the revision of Joint Publication 4-02, *Doctrine for Health Service in Joint Operations.* The preliminary coordinating draft was completed, staffed, and the Medical Doctrine Working Party reviewed and incorporated critical and major comments. A final draft is being prepared. The final draft will be forwarded to the Joint Staff for worldwide staffing. The revision contains additional information on the medical aspects of NBC defense.

USAMEDDC&S also is assisting USACMLS in revising the medical support aspects of Joint Pub 3-11.

5.2.3 Army Medical Doctrine Development Program

Multi-Service Doctrine. The FY99 effort consisted of initiatives to develop new Army Medical Department (AMEDD) NBC defense doctrine products, provide AMEDD input to other service NBC doctrine publications, and provide input to multinational medical NBC procedures. Field Manual (FM) 8-284/NAVMED P-5042/AFMAN (I) 44-156/MCRP 4-11.1C, *Treatment of Biological Warfare Agent Casualties* is complete. The FM will be printed and distributed in FY00. FM 8-283, *Treatment of Nuclear Warfare Casualities and Low-Level Radiation Exposure* is under development. This manual will be developed as a multi-service publication. FM 8-10-7, *Health Service Support in a Nuclear, Biological, and Chemical Environment* is being revised and developed as a multi-service publication. Doctrine for nuclear, biological, and chemical-environment (NBC-E) will be developed and incorporated into current and new manuals as the technology allows. The area of NBC-E includes the effects of long-term exposure to low-levels (sub-clinical levels) of NBC agents, industrial radiation, biological, and chemical hazards. Available material on NBC-E will be included in the revision of FM 8-10-7.

Multi-National Doctrine. The Office of The Surgeon General (OTSG, DASG-HCO) has been designated the head of Delegation for the NBC Medical Working Group for standardization of NBC medical operational matters. OTSG, DASG-HCO participates in or coordinates with the following NATO groups:

- NBC Defense Working Group
- NBC Medical Working Group—Head of Delegation
- Land Group 7 (LG.7)—Joint NBC Defense
- Working Group 2 (LG.7)—Low Level Radiation in Military Environments
- Challenge Subgroup (LG.7)—Chemical/Biological Toxicity Challenge Levels
- General Medical Working Party, Aeromedical Working Group
- Research Technology Area/Human Factors Medical Panel NBC Medical Subgroups.

The AMEDD participated in numerous NATO medical NBC procedural product reviews, resulting in several NATO Standardization Agreements (STANAGs) being updated. Further, the AMEDD participated in a Quadripartite Working Group to develop and update additional Quadripartite Standardization Agreements (QSTAGs), which are medical NBC procedural products. STANAGs and QSTAGs are reviewed for integration of these agreements into Army-specific doctrine literature products as well as multi-service medical doctrine products for which the AMEDD is the proponent.

5.2.4 Air Force Doctrine Program

HQ USAF/XONP has been working with the Air Force Doctrine Center to fill a void in Air Force Doctrine by developing an overarching Counter-NBC Operations Doctrine for the USAF. The new document will bring the Air Force into compliance with DoD Directive 2060.2,

which requires each Service to develop a counter-NBC doctrine, and will outline integration with Joint and Multi-Service doctrine. USAF guidance historically has focused on passive defense, whereas the new document will broaden the scope to include essential areas of counterforce, active defense, and command, control, communications and computers, intelligence, surveillance, and reconnaissance (C4ISR). The doctrine document is in final review and should be in formal coordination in the second quarter of FY00.

The Air Force Surgeon General (HQ USAF/SGXR) has been participating with the Army in development of a medical doctrine field manual, *Treatment of Biological Warfare Agent Casualties*. A Concept of Operations (CONOPS) was completed that standardized USAFE wartime medical contamination control operations. During FY99 SGXR has also participated in the review of numerous NATO Standardization Agreements that were updated during the year.

5.2.5. Navy Doctrine

The Navy has been actively participating in revisions to all phases of Joint, Multi-service and Service-unique Chemical Biological Defense Doctrine. Navy revisions have been incorporated into the latest version of Joint Pub 3-11, *Joint Doctrine for Nuclear, Biological, and Chemical (NBC) Defense Operations*. FM 3-4-1, *Multi-Service Procedures for NBC Defense of Fixed Sites, Ports, and Airfields*, has been revised in coordination with the other Services and has received a Naval Warfare Publication designation as NWP 3-11 23. The Navy unique publication NWP 3-20.31 *Surface Ship Survivability* also has undergone extensive revisions to update shipboard Chemical Biological Defense actions and provide better coordination with existing multi-service publications.

5.2.6 Marine Corps Doctrine

The Marine Corps continues to systematically review multi-service NBC doctrine. The Marine Corps has reviewed a number of NATO Standardization Agreements as well as multi-service doctrine with both the U.S. Army and the U.S. Navy. The Marine Corps has completed a new Marine Corps Warfighting Publication (MCWP) 3-37, *Marine Air Ground Task Force (MAGTF) NBC Defense.*

5.3 STANDARDS OF PROFICIENCY AND CURRENCY

Each service establishes standards of proficiency and currency for NBC defense training. The following sections describe of each Service's activities for NBC defense training.

5.3.1 Army

Army Regulation 350-41, *Training in Units*, establishes Army standards for proficiency for NBC defense training. NBC defense training is conducted at schools and in units. The USACMLS is responsible to train and sustain Chemical Corps soldiers and leaders and provide task/condition/standard limits, suggested training products, and oversight in the areas of NBC

matters. Although the USACMLS is neither designated nor resourced to be the DoD Executive Agent for joint NBC defense training, it is pursuing the following initiatives to the extent available resources allow:

(1) assisting CINCs, Major Commands, and their staffs in assessing and providing reference materials regarding the NBC threat and recommending actions to reduce the NBC threat in their areas of operations;
(2) providing broad-based joint NBC defense doctrine and joint doctrine development support;
(3) introducing and upgrading instructional aids and training support material for war colleges and command and staff colleges for all Services;
(4) developing, evaluating, and fielding advanced instructional capabilities for both resident and nonresident instruction; and
(5) conducting the Joint Senior Leader Training Course – A Focus on Weapons of Mass Destruction, intended to provide leaders from all Services with an understanding of joint NBC defense operations, training, readiness, threat, doctrine, and capabilities.

Individual Training. At the initial training level, NBC defense tasks are taught to students wearing Mission Oriented Protective Posture (MOPP) gear during Basic Soldier Training and Warrant Officer Candidate Training to satisfy Initial Entry Training Requirements. Common core qualification is achieved from NBC tasks training during Officer (basic and advanced) and Warrant Officer (basic) training. NCOs train on leader NBC skills during their NCO development courses. Other Officer and NCO courses require training in NBC as a condition that effects the performance of branch specific tasks. At the company level each unit has an NBC NCO specialist and at the battalion or higher level most units have an NBC Officer and Senior NCO.

Unit Training. The Army is constantly challenged to improve its training of NBC battlefield hazards by integrating such training into unit mission training as well as individual and leader training. It is required that the NBC protective mask be worn during weapons qualification training at least twice a year, depending on the unit category within the Standards in Training Commission (STRAC). Additionally, essential Army civilians are trained in NBC survival skills. Because of today's battlefield complexities, the Army takes a systems approach to its training. NBC tasks for individuals are published in Soldiers' Training Publications and trained in the Army School System. Sustainment training occurs in the unit. NBC collective tasks are published in Army Training and Exercise Plan (ARTEP) Mission Training Plans. The highest level of NBC training recognizes NBC as a battlefield condition and units train to execute their Mission-Essential Task List (METL) while under NBC conditions.

The Move of the U.S. Army Chemical School (USACMLS). The USACMLS moved to Fort Leonard Wood, Missouri, following closure of the base at Fort McClellan, Alabama, where it had been located previously. Construction was completed and was occupied by the Chemical School in accordance with the schedule shown:

Facility	Construction Completion	Available for Occupancy
CDTF* Admin Building	30 September 1998	15 November 1998
CDTF Training Building	7 January 1999	12 February 1999
Chemical Applied Training Facility	13 October 1998	8 January 1999
General Instruction Facility	17 May 1999	21 July 1999
Unaccompanied Enlisted Housing	17 May 1999	2 July 1999

*Chemical Defense Training Facility

In preparation for the move, the first individuals departed Fort McClellan in October 1998 and were assigned to the CDTF at Fort Leonard Wood. A second large group left during February through March 1999. These include the combat developers, the training developers, and portions of the Chemical Brigade staff. The training departments moved to Fort Leonard Wood during May to August 1999 upon completion of scheduled training at Fort McClellan.

The USACMLS activated the 3d Chemical Brigade at Fort Leonard Wood on 20 August 1999. This brigade is responsible for all training activities at the Chemical School. This brigade also will provide command and control for the 82d Chemical Battalion (OSUT), the 84th Chemical Battalion, and the 58th Transportation Battalion, the Chemical Defense Training Facility, and the International Student Detachment.

The 3rd Chemical Brigade began its first training of OSUT on 2 July 1999 and proceeds today. The first Professional Development course began on 16 August 1999. Although there have been many challenges, training the force to standard at the new installation continues. The Brigade executed the first Toxic Agent Training at the CDTF on 21 September 1999 with installation Senior Leadership. The first class of students trained in the CDTF beginning 4 October 1999. Smoke training for students will commence in accordance with the comprehensive plan that will ensure compliance with Federal and State environmental regulations pertaining to smoke training on Fort Leonard Wood.

Medical Training. The U.S. Army funded medical NBC defense training that was conducted by the U.S. Army Medical Department Center and School (AMEDDC&S), the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Armed Forces Radiobiology Research Institute (AFRRI). Courses were offered at the training center, at the requesting unit's site, and via distance education courses. In-house training, especially for the courses offered at USAMRIID and USAMRICD, enables students to use the extensive laboratory and field training facilities available at these commands. On-site training, *i.e.*, courses taken "on the road" and presented at military installations worldwide, minimizes student travel costs while preserving direct instructor-student interactions. Distance learning programs minimize training costs and increases the student audience size. During FY99, over 45,000 Army, Navy, Marine, Air Force, DoD civilian, non-DoD, and non-US personnel received some form of Medical NBC training via these courses.

The AMEDDC&S trains U.S. Army Medical Department (AMEDD) specialists and leaders with courses offered in-house at Fort Sam Houston, Texas. Initial Entry Training (IET) for AMEDD soldiers includes Medical NBC subjects appropriate for each specialty. This year,

over 3,000 combat medics received instruction in treating and decontaminating biological and chemical casualties and over 150 Food Inspection Technicians received training on food management in an NBC environment.

All new AMEDD officers received 39 hours of NBC classroom instruction and 12 hours of NBC field training during their Officer Basic Course (OBC). The OBC teaches the fundamental knowledge and skills necessary to conduct medical operations in an NBC environment, control NBC contamination in medical units, and understand the medical implication of NBC exposures, including battlefield Low-Level Radiological (LLR) hazards. In FY99, 8 OBC courses graduated 1,230 officers, including 457 USAR, 150 ARNG and 10 non-US officers.

Advanced officer training (OAC) includes 10 hours of medical NBC correspondence courses. For students who have not completed the "Medical Management of Chemical and Biological Casualties Course" (MCBC), the USAMRIID and USAMRICD presented the 3-day on-site version of the MCBC during the OACs at the AMEDDC&S. In FY99, 711 U.S. and 28 foreign officers attending the OAC. The foreign officers received an additional 40 hours of Medical NBC training. Sixteen U.S. Army officers received additional NBC instruction during the Brigade Surgeon Course.

In preparation for the rank of staff sergeant, Army combat medics attend the Basic NCO Course (BNCOC) of the AMEDDC&S. BNCOC includes classes and practical exercises in battlefield medical operations in an NBC environment, decontaminating, managing and treating contaminated casualties, and training non-medical soldiers in casualty decontamination procedures. In FY99, more than 1,267 NCOs attended BNOCC, including 7 USAR, 7 ARNG and 7 non-US students.

Low Level Radiological (LLR) training was presented by the AMEDDC&S during the Health Physics Specialists course, and to selected Army Nuclear Medical Science Officers (NMSOs). NMSOs fill field Medical NBC Defense Officer positions. LLR training enables NMSOs and health physics specialists to advise, and provide technical support, to units confronting Radiological Dispersal Devices (RDDs) or the accidental or malicious release of radioactive materials from nuclear facilities or storage sites. In FY99, 28 NCOs completed the 12-week Health Physics Specialists Course, and 4 NMSOs receive 40 hours of LLR training while attending other AMEDDC&S courses.

USAMRICD trained 187 Army, 20 Navy/Marine, 1 Air Force and 21 non-DoD personnel with the AMEDDC&S sponsored "Field Management of Chemical and Biological Casualties Course" (FCBC). The MCBC trains personnel in the first echelon management of chemical and biological agent casualties. Presented as a five-day in-house course at Aberdeen Proving Grounds, the FCBC is also offered as a three-day on-site course. The FCBC's classroom discussions include: the current global threat of chemical and biological agent use, the characteristics and effects of threat agents, recognition and emergency treatment of agent exposure, principles of triage and decontamination of chemical and biological agent casualties. During FY99, USAMRICD presented the FCBC five times in-house, once on-site, and once as a VTC course.

Thirty preventive medicine officers and other medical professionals assigned to deployable units, or directly responsible for NBC consequence management, attended the tri-Service "Medical NBC Readiness Workshop" of AMEDDC&S. Sponsored by the U.S. Army Office of the Surgeon General, this course provides instruction in the medical management the full spectrum of possible NBC threats, from battlefield NBC scenarios to the conduct of peacetime operations in areas deliberately contaminated with radioactive materials or industrial chemicals.

USAMRICD trained 1,574 Army, 242 Navy/Marine, 455 Air Force, 96 non-DoD and 8 non-US medical professionals with the "Medical Management of Chemical and Biological Casualties Course" (MCBC). Sponsored by the AMEDDC&S, the students attending the in-house MCBC divide their time between USAMRIID at Ft. Detrick, Maryland and USAMRICD at Aberdeen Proving Grounds, Maryland. The MCBC provides DoD personnel, primarily physicians, physician assistants, and nurses, with a working knowledge of the potential threat of chemical and biological weapons and the status and scope of medical defense strategies. It combines classroom instruction and field experience to establish essential skills, instill confidence, and define limitations in therapeutic modalities with each type of medical setting. The course also provides instruction on the use of specialized equipment and skills required for safe, long distance evacuation. First-hand experience in triage, decontamination, and medical operations on the integrated battlefield is stressed. The in-house MCBC course, which has doubled in size from 70 to 140 students per course, was offered four times this year. The off-site MCBC, presented 24 times during the fiscal year, is in the process of conversion into a distance learning course.

USAMRICD and the AMEDDC&S presented training to the 10 National Guard Weapons of Mass Destruction Civil Support Teams (WMD-CST) teams established this year. USAMRICD presented the MCBC course for WMD-CST members at Aberdeen Proving Grounds, Maryland. The AMEDDC&S presented a modified version of the two-week Medical NBC Readiness Workshop to the WMD-CST at the AMEDDC&S. The WMD-CST, which can be sent by the State or the Federal government to respond to a suspected or actual WMD attack, are tasked with initially assessing the situation and advising the local incident commander.

AFRRI trained 229 Army, 68 Navy/Marine, 34 Air Force, and 13 other personnel with the "Medical Effects of Ionizing Radiation" (MEIR) Course. The MEIR course, funded by the Army Office of the Surgeon General, provides up-to-date information concerning the biomedical consequences of radiation exposure, how the effects can be reduced, and the medical management of radiological casualties. The MEIR course, sponsored by the AMEDDC&S, is presented in-house at Bethesda, Maryland, and on-site at US military installations worldwide. The course has been expanded to include non-nuclear weapon radiological hazards, such as Low Level Radiological (LLR) hazards, which could be encountered on the battlefield or during non-combat military operations.

The Army Office of the Surgeon General funded USAMRIID and USAMRICD initiatives to exploit the potential of medical NBC distance learning courses. Distance learning courses, using VTC, satellite broadcasting, videotape series and computer based training pro-

grams, offers an alternative for those otherwise unable to attend training. The "Biological Warfare and Terrorism: the Military and Public Health Response" VTC course cost only $52.93 per student, a fraction of the estimated $1,000/student to present the course in-house. The convenience of distance learning also enables large numbers of medical professionals to attend training.

In FY98, U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), in collaboration with the Centers for Disease Control and Prevention, broadcast a live, interactive satellite distance learning course entitled "Medical Response to Biological Warfare and Terrorism" to 17,319 military and civilian health professionals and first responders at 500 sites across the United States. This 3-day course proved to be very cost-effective, as the cost was $69 per student trained; whereas, it costs an estimated $1,000 to train a health care provider at USAMRIID's resident in-house course, which is given four times yearly to 76 students per course. This satellite distance learning course represented a new era in cooperation with a civilian government agency to provide important information to all who may confront threats from biological agents.

USAMRIID trained 18,288 medical professionals, including 1,844 Army, 2,431 Air Force, 939 Navy/Marine, and 15,377 civilians with the "Biological Warfare and Terrorism: the Military and Public Health Response" distance learning course. This three-day course provided training in the diagnosis and treatment of biological casualties in both military warfare and civilian bioterrorism scenarios. Developed in collaboration with Centers for Disease Control and Prevention (CDC) and nationally known leaders in public health, this 12-hour, fully accredited, course was broadcast live to 721 downlink sites throughout the United States, Canada, Europe, the Middle East, Central America, and the Pacific Rim. A subsequent weekend re-broadcast of the taped course was targeted to U.S. Reserve and National Guard medical personnel.

USAMRICD provided the distance learning course "Medical Response to Chemical Warfare and Terrorism." This course provides training in the diagnosis and treatment of chemical casualties in both military warfare and civilian bioterrorism scenarios (see USAMRICD's Internet Web page at: http://ccc.apgea.army.mil). This 12-hour course is fully accredited and was developed and presented in collaboration with the Food and Drug Administration (FDA). It was broadcast live to approximately 800 down-link sites in all 50 States, Canada, Germany, Hong Kong, Iceland, Italy, Japan, Portugal, Republic of Singapore, South Korea, and Spain. The estimated viewing audience was 2.5 million people. A subsequent weekend re-broadcast of the taped course was targeted to U.S. Reserve and National Guard medical personnel.

The Army Office of the Surgeon General sponsors medical NBC training initiatives beyond specific training courses. These initiatives include the Nuclear, Biological, and Chemical Casualty Training System (NBC CTS) developed by the AMEDDC&S, and is scheduled for fielding during FY00. NBC CTS is a computer program to augment medical NBC training by providing a multi-player training of the medical consequences of an NBC attack. During the NBC scenarios, participants allocate limited personnel and logistical assets to evaluate, triage, and treat the casualties. NBC CTS allows participants to exercise decision-making and staff

coordination skills, and suffer the cascading effects of their decisions, while refining individual skills, evaluating contingency plans, and learning current NBC doctrine.

The Army Office of the Surgeon General maintains the Medical NBC Online Information Server, an Internet web site at: http://www.nbc-med.org/. This searchable web site, visited over 400 times per day, presents NBC related news articles, case studies, congressional testimony, information papers, medical NBC references, training materials, and the schedule for related conferences and courses. Links are provided to AMEDDC&S, USAMRICD, USAMRIID, AFRRI, and other NBC related internet sites offering training documents and software packages. Many references and documents can be downloaded directly from the OTSG site, including the Medical Management of Biological Casualties Handbook and Medical Management of Chemical Casualties Handbook

The Field Preventive Medicine and Training Divisions of USACHPPM are currently working with U.S. Army Forces Command to assist field preventive medicine units in assessment of their existing environmental sampling and analysis capabilities and provide technical training on toxic industrial material risk assessment and radiological hazard risk assessment. This training includes orientation and training on existing Table of Organization and Equipment as well as USACHPPM provided equipment and support. USACHPPM will complete the initial FORSCOM active component assistance visits by the end of FY2000 and reserve components in FY 2001-2002.

5.3.2 Air Force

Air Force policy is to provide initial and annual refresher training to personnel in or deployable to NBC high threat areas (HTAs). The Air Force standards of proficiency are based on two international standardization agreements: NATO Standardization Agreement 2150 (NATO Standards of Proficiency for NBC Defense) and Air Standardization Coordinating Committee (ASCC) Air Standard 84/8 (Initial, Continuation and Unit NBC Standards). Both agreements are implemented through Air Force Instruction 32-4001, *Disaster Preparedness Planning and Operations*. The Air Force ensures proficiencies and currency of NBC warfare defense training through classroom training, unit level training, and exercises. NBC Defense Training (NBCDT) is required only for military personnel and emergency essential civilians in or deployable to NBC threat areas. Major Commands (MAJCOMs), the Air Reserve Component, and Direct Reporting Units may tailor their NBCDT programs to meet their specific mission requirements. The subjects presented in the classroom follow the three principles of NBC defense (avoidance, protection, and decontamination) as identified in Joint Pub 3-11. Unit level training follows the classroom training on wartime mission critical tasks. Supervisors train personnel to complete mission critical tasks while the workers are wearing their full complement of individual protective equipment. Exercises are used for training and evaluation purposes. Instructors at base level receive their professional training through Air Force courses at Fort Leonard Wood, Missouri.

Individual Training. There are two types of individual training. The first is general equipment and procedures training that enables personnel to recognize and protect themselves and others from NBC hazards. The second is individual proficiency training that enables personnel to

perform their wartime tasks in a NBC-contaminated environment. Detailed training comes with assignment to a threat area or to a deployable unit. Personnel receive the following NBC defense training courses:

AUDIENCE[1,2]	TYPICAL INITIAL INSTRUCTION TIME	INITIAL (FREQUENCY)	REFRESHER (FREQUENCY)	REMARKS
Low threat	6 hours	Within 90 days of assignment to mobility positions or 90 days prior to permanent change of station (PCS) to a CB high threat area.	Annual show of competency or as directed by MAJCOM.	Allow extra time for quantitative fit testing (QNFT)/ confidence exercise and CCA training.
Medium threat	6 hours	Within 90 days of arrival	Within 90 days of arrival	See Note 2
High threat	6 hours	Within 90 days prior to PCS to high threat area.	Within 30 days of arrival - topics should only include theater specific procedures and QNFT.	See Note 2

1. NBC Defense Training is required for military personnel and emergency essential civilians in or deployable to chemical-biological medium and high threat areas.
2. Initial training is required if there has been a break of 36 months or more in NBC defense training.

NBC refresher training is at the discretion of the MAJCOMs, with the majority opting for annual refresher training through classroom training and exercise participation. Individual NBC proficiency training occurs through on-the-job-training and exercise participation. In addition, aircrews are required to conduct a one-time flight while wearing chemical defensive equipment.

Unit Training. Units in or deployable to NBC threat areas must conduct the following training:

CB Threat Area	MINIMUM EXERCISE REQUIREMENTS
Low	**Annually** - Conduct attack response exercise implementing the base OPlan 32-1 and other contingency plans (*i.e.*, NBC, terrorist, or conventional attack). - Conduct an attack response exercise for units' mobility commitments based upon the threat at deployment locations.
Medium	**Semiannually** - Conduct attack response exercise implementing the base OPlan 32-1, BSP, and other contingency plans (*i.e.*, NBC, terrorist, or conventional attack). One exercise may be satisfied by a tabletop exercise. - Conduct attack response exercise for unit mobility commitments based on the threat at deployment locations. One exercise can be satisfied by a tabletop exercise.
High	**Semiannually** - Conduct attack response exercises implementing the base OPlan 32-1, BSP, and other contingency plans.

Air Force major commands have reported significant increases over the last three years in the number of people receiving equipment and procedures training as well as the number of hours spent for that training.

Medical Training Initiatives. Following the Air Force Medical Service (AFMS) NBC Warfare Defense Training Workshop in 1998, eleven training initiatives were prepared to meet gaps in

Air Force chemical and biological medical defense training. Training tools for the AFMS re-engineered unit type codes, such as: (1) Patient Decontamination Teams, (2) Chemically Hardened Air Transportable Hospital, (3) Preventive and Aerospace Medicine (PAM) team training, (4) Bioenvironmental Engineering NBC team training, (5) PACAF AFMEDPAC 2000, (6) Continuing Medical Readiness NBC training, (7) NBC CD-ROM Toolboxes, (8) ACC/ Force Protection Battle Lab Initiative – Bio Agent detection training, and (9) NBC Defense Leadership Skills training were identified for contractor development. The Army (funded by the AF) is the office of primary responsibility for the final two initiatives: (10) Medical Management of Chemical Casualties, and (11) NBC CD-ROMs. Care providers who have not been afforded the opportunity to attend the Army MCBC Course will receive an instructor based course on medical management of chemical and biological casualties training at their units. Overseas locations have priority over CONUS bases for this initiative. In addition, identified medical UTC teams will receive medical reference materials developed by the US Army and civilian contractors for training.

5.3.3 Navy

Navy Chemical, Biological and Radiological Defense (CBR-D) training is conducted in two phases: individual and unit training. Individual training consists of attendance at formal school courses and completion of basic and advanced CBR Defense Personnel Qualification (PQS) training. Navy personnel also conduct periodic unit CBR Defense training and pre-deployment unit training exercises.

Individual Training. The Navy provides initial entry-level CBR defense training to all officers and enlisted personnel in the accession programs. Enlisted personnel receive three hours of training (two hours in the classroom; one hour in the lab) focused on the use of personal protection equipment and survival skills, including a CBR-D "confidence" chamber exposure. Officers receive two hours of class time focused on personal protection equipment and survival skills. After reporting to designated units, Navy personnel also are required to complete basic and advanced CBR-D PQS training.

Officer and Enlisted Personnel assigned to ship and shore billets requiring CBR-D expertise receive additional CBR-D related courses. These courses include the Disaster Preparedness Specialist Course and the CBR-D Operations and Training Specialist Course conducted at the U.S. Army Chemical School. Additional CBR-D training is covered in the Repair Party Leader Courses conducted at various Fleet Training Centers. Officers receive additional CBR-D related training at the Damage Control Assistant Course, the Shipboard Department Head Course, the Prospective Executive Officer Course, and the Prospective Commanding Officer Course held at the Surface Warfare Officer School, Newport, RI.

Navy medical providers attend the Management of Chemical and Biological Casualties Course at the U.S. Army Medical Research Institute for Chemical Defense, Aberdeen Proving Grounds, Maryland and the U.S. Army Medical Research Institute of Infectious Diseases, Ft. Detrick, Maryland.

Unit Training. Proficiency training is conducted at the unit level by Navy instructors who are graduates of the CBR-D Operations and Training Specialist Course conducted at the U.S. Army Chemical School. Navy units conduct basic, intermediate, and advanced training exercises as part of the Training and Readiness Cycle prior to deployment. During the basic training phase, CBR-D training exercises are overseen by the appropriate Type Commander and may involve additional unit training by CBR-D specialists from an Afloat Training Group (ATG). During the intermediate and advanced phases of the training cycle, combat readiness is reinforced through Composite Training Unit Exercises and Fleet Exercises.

5.3.4 Marine Corps

The Marine Corps' NBC training focuses on the ability to conduct operations throughout the battlespace with particular emphasis on amphibious deployment, littoral, and air/ground operations. The Marine Corps views NBC as an environment, similar to daylight/darkness and cold/heat, yet with its own unique challenges.

Training requirements are derived from the Force Commander's Mission Essential Task Lists, Joint Universal Lessons Learned, Marine Corps Lessons Learned, Mission Need Statements, and Fleet Operational Needs Statements. Once validated, the training requirements are introduced into the Systems Approach to Training (SAT) Process. One of the results of the SAT process is the development of training tasks and standards that will fulfill the training requirements. These task lists and standards are incorporated into Individual Training Standards (ITSs) for individual Marines and Mission Performance Standards (MPS) for Marine units. These ITSs and MPSs are published as Marine Corps Orders for standardization and compliance throughout the Marine Corps.

The Marine Corps conduct training in two categories: Individual Training based on ITSs and Collective (unit) Training based on MPSs. Figure 5-1 shows the individual NBC training provided to all Marines.

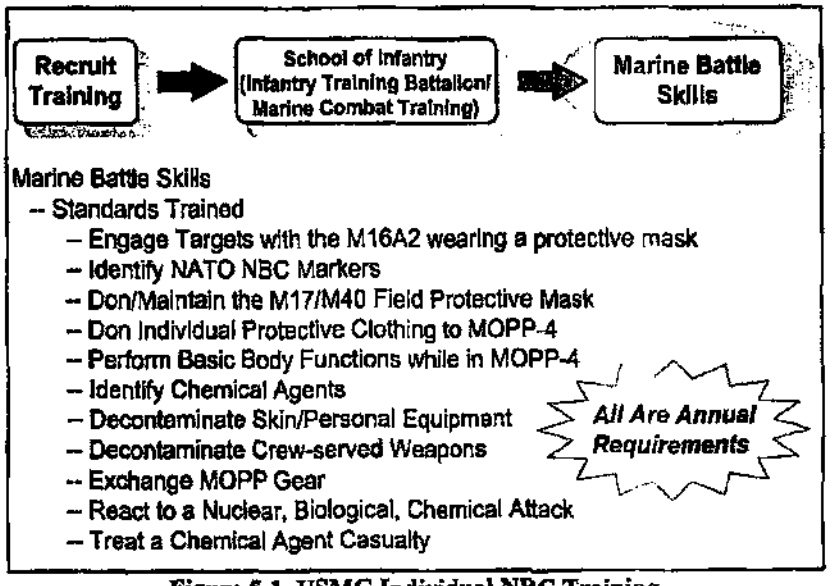

Figure 5-1. USMC Individual NBC Training

Individual Training. Enlisted Marine entry level training begins at recruit training or "Boot Camp" where Marines are introduced to the field protective mask and the gas chamber. All enlisted Marines then proceed to the School of Infantry (SOI). The training focus is surviving and functioning in an NBC environment. Training transitions from a classroom/academic environment to practical application/field environment to provide students more hands-on experience.

Once Marines reach their units they begin the Marine Battle Skills Training program. Marine Battle Skills is a set of tasks which all Marines are required to be proficient in and are evaluated annually. Marine Battle Skills NBC training focuses on providing Marines the capability to survive as well as function in an NBC environment.

Unit Training. Unit level (or collective) training includes classroom and field training and is included in unit training exercises and plans. (See figure 5-2.) Units are also required to meet very specific training standards. These requirements take the form of Mission Performance Standards (MPSs). Each type of unit in the Marine Corps has a set of MPSs assigned to it. These MPSs are published as 3500 Series Marine Corps Orders.

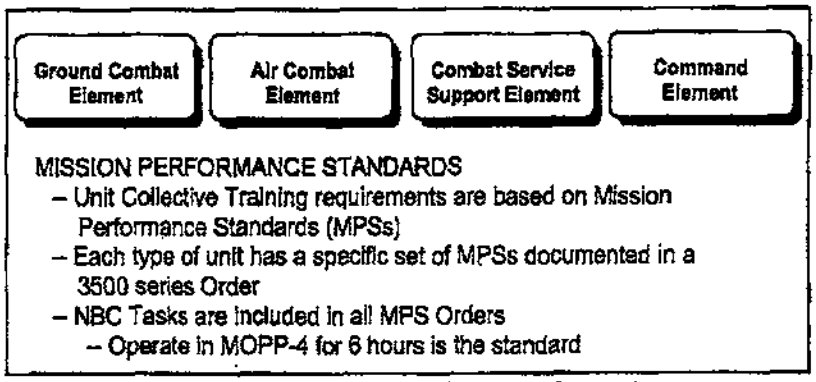

Figure 5-2. USMC Collective Training, NBC Requirements

Each MPS Order includes NBC Tasks which the unit must accomplish. However, each set of requirements varies from unit to unit. For example, a Tank Battalion must be able to utilize the vehicle's NBC filtration system, decontaminate tanks, and operate tanks under NBC conditions. An Infantry Battalion on the other hand has no requirement to decontaminate tanks, but does have to decontaminate crew served weapons. NBC evaluations are conducted annually for all Marine Corps units. Those units that are part of the Marine Corps' Unit Deployment Program (UDP) and designated Marine Expeditionary Units (MEUs) are required to undergo an NBC evaluation prior to deployment.

5.4 NBC DEFENSE PROFESSIONAL TRAINING

Public Law 103-160 requires all Services to conduct NBC defense professional training at the same location. Currently, all Service training is co-located at the United States Army Chemical School at Ft. Leonard Wood, Missouri. Each Service conducts their training with their own Service instructors. The experts who graduate from the Service's technical training and the Army's Chemical Defense Training Facility become instructors for their Service's unit training. The Defense Weapons School attached to the Field Command, Defense Threat Reduction Agency (DTRA) at Kirtland AFB, New Mexico, conducts a nuclear hazards training course: *e.g.*, Technical Escort Course and the Radiation Safety Officer Course.

5.4.1 Joint NBC Defense Professional Training

The JSIG has established Joint Assessment Working Group (JAWG) comprised of Service detachment representatives at the USACMLS to discuss issues pertaining to facilities and range scheduling and any other training issues that impact the ability of the Services to conduct effective professional training.

Information exchanges between the Services were facilitated by the JSIG and plans put in place to review future doctrine and new equipment training plans. Discussion concerning a Joint instructor pool was shelved due to unique training requirements each Service possesses. The Army plans to consolidate common and shared (Chemical, Military Police, and Engineer) training.

Joint Professional Military Education, Phases I and II, currently contains no NBC defense considerations or requirements. It is essential that officers of all Services assigned to joint staffs understand the NBC threat, are familiar with U.S. capabilities to detect and mitigate the threat, and comprehend their staff roles and responsibilities in dealing with NBC issues. The JSIG, along with the Services, Joint Staff, and CINCs will address these important shortfalls and requirements in the coming year.

Within the joint medical arena, the US Army Medical Department sponsors the Medical Management of Chemical and Biological Casualties (MCBC) course, which provides training to DoD personnel. Additional information on this course can be found in Section 5.3.1. Based on guidance contained in DoD Directive 6025.3, *Clinical Quality Management Program in the Military Health Services* (signed 20 July 1995), health care providers are directed to receive certification for assignments during military operations. This certification includes NBC defense training and provider courses where applicable. The medical commander will review certification annually. In addition, on 20 December 1995 the DoD completed DoD Instruction 1322.24, *Military Medical Readiness Skill Training*, which implements policy, assigns responsibility, and prescribes procedures for developing and sustaining comprehensive systems for providing, assessing, and monitoring military medical skills training essential for all military personnel, health care personnel, and medical units. NBC defense training, to include chemical and biological warfare defense measures and medical specialty training such as casualty management, are specifically articulated in the instruction.

All Medical Nuclear Casualty Training has been consolidated under the Armed Forces Radiobiology Research Institute in Bethesda, Maryland, where radiobiology education is made available in a Tri-Service format.

5.4.2 Army NBC Defense Professional Training

U.S. Army NBC Defense Professional Training presently takes place at Fort Leonard Wood, Missouri. Training consists of three enlisted/noncommisioned officer courses and two officer courses. At initial entry One Station Unit Training, enlisted soldiers receive training in chemical and biological agent characteristics and hazards, smoke and decontamination operations, chemical and radiological survey procedures, and individual protective clothing and equipment. This program provides 19 weeks of intensive training, culminating in live/toxic agent training in the Chemical Defense Training Facility. Toxic agent training is an integral, mandatory component of all Chemical Corps initial entry and professional courses.

Initial Entry Training
19 Weeks

Standards Trained:
- Radiological Survey
- Radiological Defense
- Chemical and Biological Agent Characteristics and Hazards
- Chemical and Biological Defense
- Decontamination Operations
- Smoke Operations
- Individual NBC Protection
- Chemical Defense Training Facility

Figure 5-3. U.S. Army Initial Entry Training

Chemical Corps sergeants attend the 15 week Chemical Basic Noncommissioned Officer Course (BNCOC) where they are trained to be an NBC company squad leader and a non-chemical company or battalion NBC NCO. Chemical BNCOC provides the NCO with the technical and tactical skills needed to advise company/battalion commanders in NBC operations and procedures, to train non-chemical soldiers in NBC avoidance, decontamination, and protective measures and to lead smoke/decontamination squads.

Chemical Corps staff sergeants and sergeants first class attend the 13 week Chemical Advanced NCO Course (ANCOC) where they are trained to be an NBC platoon sergeant, an NBC NCO at brigade level, and an NBC NCO in a division or Corps level NBC element. During training they receive advanced technical operations, hazard estimates, logistics and maintenance management, combined arms operations, smoke and flame support, and training management.

Chemical Corps lieutenants attend a 19-week officer basic course, 10-weeks during mobilization. Reserve Component officers must attend the resident course. The Maneuver Support Center (MANSCEN), will instruct the 3-weeks of common lieutenant training from the Chemical, Engineer, and Military Police schools. The Chemical Officer Basic Course (COBC) prepares lieutenants to serve as a Chemical Corps platoon leader or as a non-chemical battalion chemical staff officer/assistant operations officer. This course provides them with a fundamental knowledge of NBC agent characteristics and hazards, NBC recon (non-FOX), decon, and smoke operations, NBC staff functions and NBC defensive planning, individual and unit tactical operations, and biological detection operations. This course includes classroom instruction, hands-on equipment training, and field exercises. Completion of live/toxic agent training is a prerequisite for graduation.

Chemical Corps captains attend the Captain's Career Course, an 18-week officer advanced course, in which they are trained to serve as the commander of a Chemical Company and as NBC staff officers at the brigade and division level. Instruction focuses on leadership, Army operations, smoke and flame operations in support of maneuver units, biological detection operations and NBC defensive planning to include: hazard prediction, NBC reconnaissance and decontamination operations. Additionally, officers receive training in chemical and biological vulnerability analysis, nuclear target analysis/vulnerability analysis, operational radiological

safety, and environmental management. Extensive use is made of computer simulations to reinforce the application of NBC assets in support of tactical operations. In the MANSCEN configuration, the Chemical Officer shares training with Military Police and Engineer Officers in Common Training, Shared Tactical Training, and Brigade Battle Simulation Exercise (BBS).

Standards Trained:	**Officer Advanced Course Training 18 Weeks**
– Leadership	
– Army Operations	
– Plan and Conduct NBC Reconnaissance	
– Decontamination Operations	
– Chemical and Biological Agent Detection Operations	
– Smoke and Flame Operations	
– Nuclear, Biological, and Chemical Target Analysis/Vulnerability Analysis	
– Chemical Defense Training Facility	

Figure 5-4. U.S. Army Captain's Career Course Officer Advanced Training

Specialized professional training is conducted in stand-alone courses attended by DoD, Allied, and international students. These courses include:

NBC Reconnaissance Operations (FOX)	(5 weeks)
Radiological Safety (Installation level)	(3 weeks)
Operational Radiation Safety	(1 week)
Chemical Weapons Inspector/Escort (DTRA)	(1 week)
Chemical Weapons Convention Module II	(6 weeks)
Decon Procedures (Non-US) (GE, UK, NE)	(1 week)
RADIAC Calibrator Custodian	(1 week)
Biological Detection Specialist (BIDS)	(5 weeks)
Master Fox Scout	(2 weeks)
Long Range Biological Standoff Detection	(2 weeks)

5.4.3 Air Force NBC Defense Professional Training

The Air Force training detachment at Ft. McClellan offers six separate in-residence courses designed to enhance the NBC proficiency of primary-duty AF Civil Engineer Readiness Flight personnel. These courses fulfill the differing needs of the total force, including Active Duty, Air National Guard, and Air Force Reserve. Further, the Air Force administers a career development correspondence course and two mobile courses in airbase operability and NBC cell operations.

Each course contains a wide range of materials covering critical aspects of Readiness Flight operations in situations ranging from peacetime, military operations other than war, through wartime. The following is a synopsis of the NBC aspects of these courses.

Training for personnel being assigned primary readiness duties includes comprehensive coverage of agent characteristics and hazards (to include determination of incapacitation/ lethality levels); nuclear weapons effects and other specific hazards associated with ionizing radiation; NBC detection and decontamination; contamination control and avoidance techniques; plotting and reporting procedures; detailed NBC persistency and duration of hazard calculations; the inter-relationship between NBC defense and other passive defense activities (*e.g.*, camouflage, concealment, and deception, (CCD), dispersal, and hardening, *etc.*); and systematic analysis procedures for assessing the hazard and providing credible advice to commanders.

Air Force learning theory emphasizes hands-on training, and the school makes extensive use of available training ranges and equipment. The school includes Chemical Defense Training Facility (CDTF) live agent training in five of six in-residence courses. Training is provided on every major piece of equipment available in the field today, including state-of-the-art items currently being fielded.

The CE Readiness Flight Officer and 7-level Craftsman courses provide flight leaders and mid-level NCOs with the background and technical information that is necessary for effective management of the CE Readiness Flight and contingency response operations.

Readiness is the key to successful Air Force operations. Consequently, the various aspects of CE Readiness Flight operations, including NBC defense, are also topics of instruction at briefings for Air War College, Air Force Institute of Technology, or Joint Senior Leaders Course.

The School of Aerospace Medicine at Brooks AFB teaches a variety of readiness courses to medical personnel. Courses—such as Bioenvironmental Engineering, NBC Battlefield Nursing, Preventive and Aerospace Medicine contingency training, Global Medicine, Military Tropical medicine, Medical Survival training, plus many others—are provided at the San Antonio, TX base.

5.4.4 Navy CBR Defense Professional Training

The Navy Construction Training Center Detachment at the U.S. Army Chemical School offers two courses of instruction for Navy CBR-D specialists. The courses are open to Navy, Coast Guard, Military Sealift Command, and select foreign military personnel, E-5 and above. Courses are designed to provide both afloat and ashore commands with individuals who can successfully perform their requisite duties in a CBR contaminated environment. In addition, the training enables CBR-D specialists to act as the primary CBR-D trainers for their respective commands.

The training capitalizes on the unique capabilities of the Army Chemical School. Approximately 200 students graduate annually from the Detachment's courses. In addition to

being fully qualified to conduct training using the Army's facilities, the Navy Detachment actively participates as part of the JAWG.

In addition to CBR-D Specialist courses conducted at the US Army Chemical School, the Navy has incorporated CBR-D readiness training into courses that are attended by personnel at all levels of professional development.

Course Name	Course Location
Recruit Training CBR-D	Naval Training Center Great Lakes, IL
Damage Control "A" School	Naval Training Center Great Lakes, IL
Senior Enlisted Damage Control	Fleet Training Center San Diego, CA
Hospital Corpsman "A" School	Naval Training Center Great Lakes, IL
Independent Duty Corpsman	Naval School of Health Sciences San Diego, CA and Naval School of Health Sciences Portsmouth, VA
Management of Chemical Casualties	U.S. Army Medical Research Institute for Chemical Defense, Aberdeen Proving Ground, MD
Medical Affects of Ionizing Radiation	Armed Forces Radiobiology Research Institute Bethesda,MD
Radiation Health Indoctrination	Naval Undersea Medical Institute Groton, CT
Radiation Health Officer	Naval Undersea Medical Institute Groton, CT
CBR-D Command Center	Naval Construction Training Center Gulfport, MS
CBR-D Personnel Protection	Naval Construction Training Center Gulfport, MS
CBR-D Team Training	Naval Construction Training Center Gulfport, MS and Naval Construction Training Center Port Hueneme, CA
Repair Party Leader	Fleet Training Center San Diego, CA Norfolk, VA Mayport, FL Ingleside, TX Pearl Harbor HI Yokosuka, Japan
Repair Party Officer Short Course	Surface Warfare Officers School Newport, RI
Division Officer	Surface Warfare Officers School Newport, RI
Damage Control Assistant	Surface Warfare Officers School Newport, RI
Department Head	Surface Warfare Officers School Newport, RI
Executive Officer	Surface Warfare Officers School Newport, RI
Commanding Officer	Surface Warfare Officers School Newport, RI

5.4.5 Marine Corps NBC Defense Professional Training

The Marine Corps NBC Defense School at Ft. McClellan consists of an Enlisted Basic NBC Defense Course, and an Officer Basic NBC Defense Course. In addition to the courses conducted by the Marine Corps NBC Defense School, Marines attend three other functional courses (Chemical Officer Advanced Course, NBC Reconnaissance Course, and the Radiological Safety Officer Course) conducted by the Army Chemical School.

The USMC Enlisted Basic NBC Defense Course trains approximately 200 NBC specialists in a comprehensive 10 week program covering all the ITSs specified in MCO 1510.71. The curriculum includes 108 hours of instruction on how to conduct NBC training. This training provides Marines with the tools they will need on a daily basis as they perform their

primary peacetime mission of conducting NBC Defense training to their units. The course is divided into six blocks of instruction as shown in Figure 5-5.

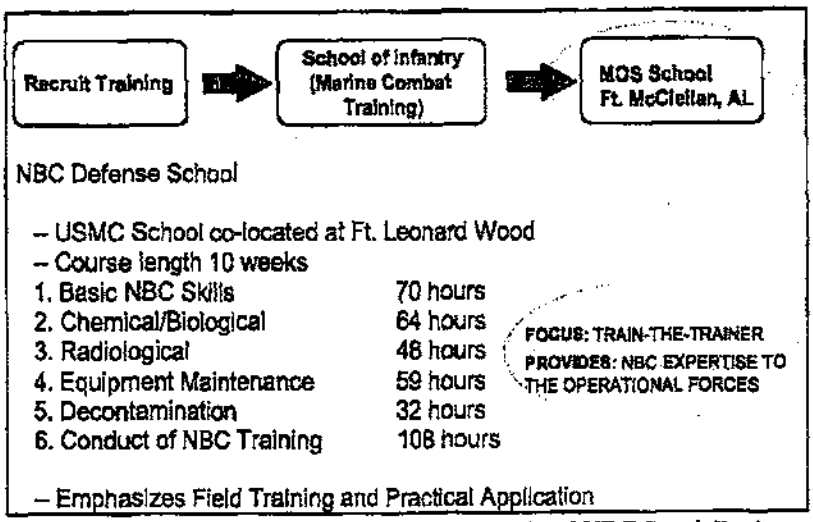

Figure 5-5. USMC Individual Training (Enlisted NBC Specialists)

Training For NBC Officers. Establishment of a Marine Corps Basic NBC Officer Course is complete. This course, shown in Figure 5-6, provides the requisite NBC skills to newly selected Marine Corps NBC Defense Officers. The first course began in June 1997. All Marine NBC Officers are Warrant Officers, usually selected from NBC Defense specialist enlisted ranks. As Warrant Officers, they focus entirely on technical expertise, NBC defense training, and supervision of enlisted NBC defense specialists. The NBC Defense Officers Course focuses on Warrant Officers and builds on previous training received. NBC Officers also attend the Army's Chemical Officer Advanced Course and Joint NBC courses as part of advanced Military Occupational Specialist (MOS) training.

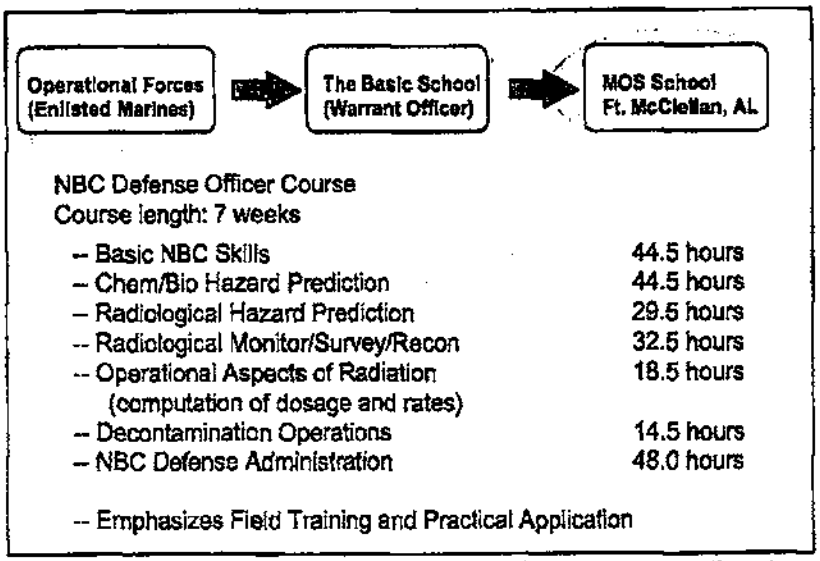

Figure 5-6. USMC Individual Training (Training for NBC Officers)

5.5 TRAINING IN A TOXIC CHEMICAL ENVIRONMENT

In 1987 the Army established the Chemical Defense Training Facility (CDTF) at Fort McClellan, Alabama. In October 1999, the Chemical School started training students at its new facility at Fort Leonard Wood, Missouri. The CDTF trains military and civilian personnel in a toxic chemical environment. Since its opening, the Army has used this valuable resource to train over 51,000 U.S. and Allied military personnel as well as selected DoD civilians. The CDTF promotes readiness by providing realistic training in the areas of detection, identification, and decontamination of chemical agents. The training develops confidence in chemical defense tactics, techniques, procedures, and chemical defense equipment. Instructors ensure that trainees can adequately perform selected tasks on a chemically contaminated battlefield. To date, the CDTF has maintained a perfect safety and environmental record.

Enrollment at the Joint Senior Leaders Course and the Toxic Agent Leader Training Course at Ft. Leonard Wood, Missouri continues to be in demand. Over 2,000 active and reserve commanders, service leaders, and toxic agent handlers from each of the services have attended. These personnel become very familiar with NBC considerations. Additionally, toxic chemical environment training provides senior officers, commanders, and future NBC defense specialists confidence in their doctrine, warfighting techniques, and the equipment they fight with in the face of challenges presented by NBC contamination.

The Weapons of Mass Destruction Civil Support Teams (WMD-CST) will begin training at the Fort Leonard Wood facility. The facility has the flexibility to design toxic chemical agent training to prepare the WMD-CST for this unique mission — assisting civil authorities facing the threat of domestic terrorism involving weapons of mass destruction.

There is growing international interest in CDTF training participation. Germany has been taking advantage of this training opportunity for about six years. The United Kingdom now uses this facility for training.

Finally, Federal and state law enforcement agencies and other first responder-type agencies have also participated in the training. The Chemical School continues to support requests from civil authorities for toxic chemical agent training.

5.6 INTEGRATION OF REALISM/WARGAMES/EXERCISES

5.6.1 Simulations and Wargames

There are three types of simulations: live, constructive and virtual. Simulations may also be sub-grouped as training or analytic simulations.

Live simulations involve real people operating real systems. Such simulations are also know as exercises and are discussed further in the next section.

Constructive simulations allow battles to be waged on a synthetic battlefield. They are designed to give commanders and their staffs the opportunity to make decisions during a course of a battle, adjust plans to react to enemy movements, synchronize all available assets and learn, through the After Action Review (AAR) process.

Virtual simulations are designed for training and analysis primarily at the tactical level of war. These simulations are "mock-ups" of actual vehicles and give units an opportunity to train on necessary individual, crew and collective tasks without having to maneuver actual equipment in the field. While the crews maneuver their equipment around the battlefield, the rest of the environment is generated through the use of Semi-Automated Forces (SAF). SAF are computer images which replicate adjacent elements, the enemy, and the environments upon which the battle is waged.

There are over 750 virtual and constructive models and simulations in the Army community alone. Table 5-1 lists the primary battle command simulations in current use throughout the Army and their baseline ability to use NBC events in their scenarios. However, characterization of NBC effects in these models and simulations is limited. Very few combat simulations incorporate the effects of NBC, and none incorporate all aspects.

Table 5-1. Nuclear (N), Biological (B), Chemical (C), or Radiological (R) Capability In Current Constructive Simulations

NAME	USE	FIDELITY	N	B	C	R
Corps Battle Simulation (CBS)	Training	Operational	X		X	X
SPECTRUM	Training	Operational				
Brigade Battle Simulation (BBS)	Training	Tactical	X		X	X
Conflict Evaluation Model (CEM)	Analytic	Joint/Strategic	X	X	X	
TACWAR	Analytic	Joint/Strategic	X	X	X	
Vector In Command (VIC)	Analytic	Operational			X	
Computer Assisted Map Exercise (CAMEX)	Analytic	Operational				
EAGLE	Training	Operational				
Combined Arms and Support Task Force Evaluation Model (CASTFOREM)	Analytic	Tactical	X		X	
JANUS	Training/Analytic	Tactical			X	

Current training exercise gaming simulations have not received sufficient priority and/or funding to adequately portray and challenge commanders and staffs to apply NBC defense doctrine and leader-development training strategies to prepare their forces to maintain operational continuity and achieve mission success in an NBC and smoke/obscurant environment. To be an effective training mechanism, these simulations must challenge training audiences to understand adversaries' NBC intent and capabilities. Simulations must also allow players to visualize how NBC capabilities affect the battlespace, friendly courses of action, and operation plans. Additionally, effective simulations must allow players to apply NBC defense principles and capabilities to set conditions for mission success against NBC capable threats. Gaming simulations (Joint Simulation, Warfighter Simulation 2000, and Combined Arms Tactical Trainer) are being developed that will accurately replicate the NBC hazards and smoke conditions of future battlefields and their effects on friendly systems. These gaming simulations will enable commanders and staffs to train and develop required high order battlefield cognitive skills that will allow for full integration of enemy intent and capabilities, NBC environment effects, and friendly force capabilities while planning and executing operations.

There is currently no standardized instrumentation system (IS) that can realistically portray all facets of NBC effects during field training. The U.S. Army Chemical School is developing NBC Recon training devices for the detection and tracking of simulated NBC contamination at Combat Training Centers (CTCs) and home station training areas. Proposed training IS will retrieve, process, and calculate digital contamination data for maneuver units and will also include AAR feedback in the areas of NBC casualties, change of custody, and reaction procedures during NBC attacks and operations. This IS would provide a realistic replication of NBC contamination as portrayed on the battlefield. Resourcing will be pursued to field proposed training devices at CTCs and other locations.

In December 1998 and January 1999, the NBC M&S domain leads within the Army, working with the Modeling and Simulation Commodity Area Manager for the Joint Service Integration Group (JSIG), developed a detailed Master Plan for requirements definition and

verification, validation, and accreditation (VV&A). This team also prepared a detailed NBC M&S Investment Strategy.

In April 1999, the Army, under agreement with the JSIG, began incorporating a baseline capability into the emerging OneSAF TestBed version B simulation. This baseline capability is interoperable with high level architecture and works as an NBC environment and effects model in both constructive and virtual simulations.

The Army completed development in July 1999 of an initial operating capability virtual simulation for the M93A1 NBC Reconnaissance System. This simulation permits NBC Reconnaissance specialists to learn to operate the M93A1 system as a member of a crew and section on a virtual battlespace. In August 1999, the system was disassembled for movement to Fort Leonard Wood, Missouri. Future systems are planned to be built at Fort Hood, Texas and Fort Polk, Louisiana.

In May 1999, the Army began work on virtual simulations for the P31 BIDS system, to be installed at Fort Leonard Wood, Missouri and a portable unit to go with the 7th Chemical Company, home stationed at Fort Polk, Louisiana.

5.6.2 Joint NBC Training/Joint and Combined Exercises

Chairman of the Joint Chiefs of Staff (CJCS) Exercise Program. Joint NBC defense training objectives must be incorporated into the CJCS Exercise Program. This program includes exercises sponsored by combatant commanders and the Chairman, JCS. Three different types of exercises are:

(1) **Positive Force** (PF) exercises are large scale Command Post Exercises that normally consider national level issues such as mobilization and deployment. During PF 98 (Mobilization) and PF 99 (Deployment), Joint Forces Command (JFCOM), in its role as the force provider, ensures that deploying units and personnel are certified as combat ready. Although an integral part of this certification procedure is determining unit, personnel, and equipment operational readiness under NBC conditions, JFCOM is not adequately staffed or organized to perform this certification.

(2) **Positive Response** (PR) exercises normally consider strategic level nuclear issues. In addition to considering command and control of nuclear forces, these exercises deploy and backup national command and control personnel and systems annually. Capabilities of these redundant systems are equally applicable during chemical and biological scenarios as they are during nuclear scenarios, but chemical and biological scenarios are not adequately exercised.

(3) The **No-Notice Interoperability Exercise (NIEX)** program continues to focus on our ability to interdict the proliferation of nuclear, chemical, and biological weapons. In 1995, the NIEX required the interagency process to respond to a foreign nation's request to interdict and recover three stolen nuclear weapons. National level forces were deployed in response to this crisis. The 1996 NIEX tested our nation's ability to respond to a crisis involving biological weapons. The Chairman of the Joint Chiefs' 1998

requirement for immediate action on WMD and NBC defense operations mandates integration of these topics into all futures NIEXs.

Joint Vision 2010 provides the operational based templates for the evolution of our Armed Forces to meet challenges posed by an adversary's use of weapons of mass destruction. JV 2010 serves as the Doctrine, Training, Leader-development, Organization, and Material requirements (*DTLOM*) benchmark for Service and Unified Command visions. The NBC defense cornerstone resource for this vision of future warfighting embodies three required operational imperatives:

First, and most importantly, CJCS and Service leaders should recognize that NBC strategic and operational level of war expertise is an essential resource requirement in the Joint Warfighter Center (JWFC) and USACOM Joint Training and Analysis Center (JTASC). Success for Joint Vision 2010, a strategy centered on capabilities-based forces, requires these organizations to successfully accomplish their respective joint NBC defense doctrine, training, and leader development roles, and for USACOM to accomplish its NBC defense mission as force provider, force trainer, and force integrator. NBC expertise at all levels and from all Services is paramount.

Second, Unified Commands should staff their organization appropriately with the right expertise to meet current and future requirements to shape and respond to NBC challenges.

Third, doctrine, training, and leader-development training strategies should facilitate sophisticated battlefield visualization and situational awareness proficiency, allowing commanders and staffs to conduct service, joint, and combined operations in an NBC environment.

The Chairman of Joint Staff published Master Plan Exercise Guidance in May 1998. This guidance provides exercise objectives to the CINCs. This guidance provided specific counterproliferation objectives. NBC Defense and Force Protection were identified as the Chairman's top training issues. This guidance will influence and guide development of CINC exercises and training, which will be conducted in Fiscal Year 2000.

Army. The Army emphasizes integration of NBC defense training in unit rotations at the Combat Training Centers (CTCs). These centers include the National Training Center (NTC), Joint Readiness Training Center (JRTC), the Combat Maneuver Training Center (CMTC), and the Battle Command Training Program (BCTP).

At the CTCs, the Army continues to see units at the company, battalion, and brigade levels unable to perform all NBC tasks to standard. Less than satisfactory performance at the CTCs is directly attributable to lack of homestation NBC training. These results clearly indicate a need for increased emphasis in educating senior leaders on how to leverage homestation training. Units that (1) have the necessary command support and equipment, (2) balance NBC within their overall training requirements, and (3) execute according to approved training plans, are able to survive and continuously operate in a simulated NBC environment. However,

increasingly constrained training resources limit NBC training to fundamentals. This often means training consists only of NBC survival and not training for continuous operations in an NBC environment.

Air Force. NBC warfare defense preparedness is an integral part of periodic Operational Readiness Inspections conducted by MAJCOM Inspectors General. Realism is injected into these scenarios using a simulated wartime environment including the use of bomb simulators, smoke, and attacking aircraft. Personnel are tasked to perform war skills while in their full complement of protective equipment. Additionally, Air Force units participate in major joint and combined exercises that incorporate realistic NBC situations. Following are examples that describe exercises incorporating NBC situations:

- ULCHI FOCUS LENS - PACAF Joint/combined command and control exercise conducted in conjunction with the Republic of Korea's national mobilization exercise
- FOAL EAGLE - PACAF Joint/combined rear area battle and special operations field training exercise.
- EFX – Air Combat Command sponsored expeditionary force projection exercise.

Navy. Due to the unique nature of Naval force deployments, CBR defense training is conducted whether platforms are operating independently or in a group. During scheduled CBR defense training periods, realism is stressed and CBR defense equipment is used extensively.

Naval units conduct basic, intermediate, and advanced training CBR-D exercises prior to deployment. During the basic training phase, CBR-D training exercises are overseen by the appropriate Type Commander and may involve additional unit training by CBR-D specialists from Afloat Training Groups (ATG). During the intermediate and advanced phases of the training cycle, combat readiness is reinforced through Composite Training Unit Exercises and Fleet Exercises.

The exercises conducted by deploying Battle Groups and Amphibious Ready Groups during pre-deployment Composite Training Unit Exercises and Fleet Exercises are designed to meet CINC training requirements for forces in the deployment area of responsibility.

These CINC requirements are also tested during exercises with deployed forces. Chemical – Biological Defense scenarios have been incorporated into major Joint/Combined Exercises and Fleet Exercises for deployed units. Some of these exercises include:

- Exercise Neon Falcon
- Exercise Desert Sailor
- Ulchi Focus lens
- Fleet Battle Experiment "Echo"
- Fleet Battle Experiment "Foxtrot"

Marine Corps. The Marine Corps incorporates NBC training into combined arms exercises at the Marine Corps Air Ground Combat Center in Twenty Nine Palms, California. Battalion level

unit exercises are also conducted during Korea and Thailand Incremental Training Programs where units deploy and exercise various tasks. Like the Air Force and Army, the Marine Corps also participated in major joint/combined exercises. Mission, threat, and task organization determine the level. During FY99, the Marine Corps incorporated NBC defense training into the following exercises:

- JTF Exercise United Endeavor
- Ulchi Focus Lens 99
- Foal Eagle
- IMEFEX
- Keystone 99
- Azure Haze
- Urban Warrior
- ChemWar 2000
- Brave Knight
- Agile Lion

It should be noted that all Marine Corps units must also conduct quarterly NBC exercises. Evaluations include operational, administrative, and logistical functional areas. These exercises incorporate realistic NBC defense training into the exercise scenario to enhance the value of the exercise.

5.7 INITIATIVES

This section provides details on a variety of joint and Service-unique initiative in support of defense readiness and training.

5.7.1 Joint

Doctrine. Initiatives in Joint NBC defense doctrine are detailed in section 5.2.

Modeling. At the request of the Deputy Assistant Secretary of Defense for Counterproliferation and Chemical and Biological Defense, DATSD(CBD), the JSIG has established a Commodity Area (CA) for CB Modeling and Simulation (M&S) and appointed the Navy to be the lead service. Unlike other commodity areas, which manage advanced development programs, the M&S CA will primarily develop joint requirements, identify funding requirements to improve training and doctrine development, and promote standardization.

To support the M&S CA, the JSIG is overseeing the development of a CB M&S Master Plan. When completed and approved, the plan will form the basis for future M&S research and development conducted by the JSIG and JSMG. Findings from the Master Plan will be used to refine the M&S portion of the Modernization Plan in FY2000.

The DATSD(CBD) initiated a study to evaluate the suitability of VLSTRACK and HPAC for operational analysis. A study advisory group has been formed to evaluate the study and recommend how to consolidate the capabilities of the two models into a single system and reduce future duplication of developmental effort.

The Counterproliferation Review Council Verification and Validation (V&V) Standards Working Group initiated a process in FY99 to standardize the V&V of CB models. This effort

should improve overall V&V activities, allow model-to-model comparisons and simplify eventual accreditation for various applications.

JCATS, JWARS and JSIMS are the future joint models for constructive and virtual combat simulation for training and analysis applications. Plans to incorporate CB defense effects into these models were initiated in FY98. VLSTRACK has been loosely coupled to JCATS to demonstrate the ability to add high resolution CW effects. The JSIG will be funding the continuation of this effort in FY99 and beyond. A contractor has been tasked by the JWARS program office to develop a plan for incorporating CB effects into JWARS.

The JSMG is sponsoring a program to develop models to evaluate effects of CB defense at APODS and SPODS.

Training.

5.7.2 Army

In an effort to refine doctrine and training, the Army is quantifying the impact of NBC environments on combat operations. Two programs have been executed to achieve this goal: (1) Combined Arms in a Nuclear/Chemical Environment (CANE), and (2) Physiological and Psychological Effects of the NBC Environment and Sustained Operations on Systems in Combat (P2NBC2). These Force Development Testing and Experimentation (FDTE) evaluations have improved our understanding of individual and unit operations and performance degradation while in MOPP. The CANE FDTE evaluations quantified field data that commanders can use for planning, training, and decision making to respond to the threat.

The Army, as proponent for CANE tests, has completed five field evaluations (mechanized infantry squad/platoon in 1983, tank company team in 1985, armor heavy battalion task force in 1988, light infantry forces in 1992, and air defense artillery in 1993). The Army has established the Chemical Vision Implementation Plan (CVIP) a systematic review process to ensure identified deficiencies are addressed and corrected. The Commandant of the Army's Chemical School reviews the CVIP annually. Army field manuals are then revised to address deficiencies identified in CANE tests.

Before CANE FDTEs were conducted, commanders' training in a simulated NBC environment had an indication of the degradation that MOPP places on their operations. They were aware that training could maximize proficiency, but they lacked the feedback to direct that training. Consequently, training was often sporadic and incomplete.

The Army is now implementing several training guidance improvements by:

- Providing heightened command emphasis to unit commanders on NBC threat with attention to Third World countries;
- Simulating NBC environments in training;
- Continuing emphasis and effort to integrate safe, realistic NBC defense in all types of training.

5.7.3 Air Force

The Air Force currently has three training and readiness initiatives underway and continues to improve its professional training.

The Civil Engineer Readiness Technical School implemented an advanced scenario-driven exercise in the CDTF revolving around a terrorism incident involving chemical munitions. This training is provided to advanced students and differs from the lock step training provided to Apprentice-level students. The scenario will be reviewed/revised annually during the respective course reviews. Air Force instructors are qualified to conduct joint classes at the CDTF and are fully integrated into CDTF operations. Readiness instructors lead Air Force students from five of six residence courses through the training and also assist the other services with their training requirements. Additionally, they provide an orientation of NBC defense concepts and live-agent training in the CDTF for key Air Force personnel during the semi-annual Joint Senior Leaders Course. The school's Specialty Training Standard requires readiness students and personnel to be highly qualified in chemical biological defense operations, including conducting and advising leaders on hazards analysis and the use of emerging detection and plotting technologies.

Air Force Readiness personnel enrolled in correspondence courses for upgrade training to the five skill level will soon be able to complete the course on interactive CD-ROM including full motion-video and sound. The course is presently available only in a paperback version, which will continue to remain available for a limited period after the CD-ROM release. Interactive courseware development began in FY97 and is expected to be completed by FY00.

The Air Force NBC Ability to Survive and Operate (ATSO) Working Group (WG) (IPT) is a cross-functional forum that identifies and tracks AF NBC defense action items. Current NBC defense training initiatives tracked by the WG include the following:

- Implement a chem-bio protective mask quantitative fit training (QNFT) program to maximize protection by ensuring personnel attain the best fit possible
- Enhance Civil Engineer Squadron Commanders Course to put more emphasis on NBC defensive operations; provide an overview of Air Force Manual (AFMAN) 32-4019, *Chemical-Biological Warfare Commander's Guide*, to include the Vulnerability Assessment Tool; and new consequence management (CM) requirements
- Enhance Air Force Group Commanders Course to include new CM requirements
- Enhance On-Scene Commanders Course to include new CM requirements
- Develop a multimedia training format for AFMAN 32-4019
- Develop AFMAN 32-4019 training for Readiness personnel
- Incorporate AFMAN 32-4019 training in Air Force SILVER FLAG training site curriculum
- Enhance AF NBC defense unit training to allow for increased emphasis on NBC defensive posture during unit training.

Additionally, the AF Medical Service has developed, or is in the process of developing, NBC Defense Training contract SOWs for eleven initiatives. Paragraph 5.3.2 lists all eleven. All are being managed by HQ AETC/SGP and HQ USAF/SGX.

5.7.4 Navy

Navy initiatives focused on improving both CB Defense Training and Doctrine across the fleet and also improving coordination of defense actions with the other services. To raise the level of CBR-D knowledge, CB Defense interactive CD-ROM trainers and videotapes were fielded to operational units.

Navy Environmental Health Units (NEHCs) in San Diego and Norfolk, VA initiated a course of instruction for the training of medical personnel in the medical management of casualties caused by chemical, biological, radiological, and environmental (CBRE) exposures.

Personnel from the Navy Warfare Development Command, Surface Warfare Officer School Command, and the Naval Construction Training Center assisted in revisions to CB Defense Doctrine, including NWP 3-20.31 *Surface Ship Survivability* and NWP 3-11.23 *Joint Doctrine for Nuclear, Biological, and Chemical (NBC) Defense Operations*. These doctrine changes were developed and tested during Joint/Combined training exercises.

The Naval Construction Training Center Detachment US Army Chemical School made a successful transition from Fort McClellan, Alabama to Fort Leonard Wood, Missouri. This transition was made without impacting Navy readiness.

5.7.5 Marine Corps

During FY99 the Marine Corps Chemical Biological Incident Response Force (CBIRF) continued to refine its tactics, techniques, and procedures to respond to the growing biological and chemical terrorist threat.

National Asset Activated 1 April 1996

-- Provides an operational force to rapidly respond to WMD incidents
-- Tests New Equipment, Procedures, and Techniques
-- Provides Consequence Management training to Marine Forces through Mobile Training Teams
-- Assists Unit/Facility Vulnerabilities to Enhance Force Protection Planning
-- Works with other Emergency Response Agencies

FORCE MULTIPLIER FOR THE MAGTF.

Figure 5-7. Chemical/Biological Incident Response Force (CBIRF) Role in Training

The CBIRF focuses on consequence management to terrorist-initiated NBC incidents. The CBIRF is a national asset, to be globally sourced to Marine Force Commanders and

National Command Authority for duties as the President may direct. The CBIRF consists of 360 skilled and trained Navy and Marine personnel, organized into five elements: Headquarters (including a Reach-Back Advisory Group), Security, Search and Rescue, Service Support, Force Protection (Reconnaissance/Decontamination) and Medical. The CBIRF has state-of-the-art detection, monitoring, medical and decontamination equipment and is prepared for operations in a wide range of military-civilian contingencies. In addition to the CBIRF's capabilities to respond to chem/bio incidents it serves as a training asset to the operational forces. The CBIRF will provide mobile training teams to various units to provide advanced consequence management. This will provide operational forces with the most up-to-date techniques, tactics, and procedures developed by the CBIRF. CBIRF also assists in Unit/Facilities Vulnerability Assessments to enhance force protection. The bottom line is that the CBIRF serves as a force multiplier to the MAGTF.

Marine Corps FY99 Accomplishments:

- Conducted a Marine Corps-wide Table of Equipment and Table of Organization Review.
- Participated in Joint Marine Corps and Navy shipboard decontamination exercises with 7th Fleet.
- Developed an Enhanced NBC Capability Set for MEUs.
- Developed and initiated CBIRF training packages for MEUs.
- Conducted and managed the Joint Service Mask Surveillance and Testing Program.
- Conducted USMC NBC Defense Conference during September 1999.

Marine Corps FY99 Initiatives:

- Integration of NBC defense procedures in Mission Oriented Tasks (Garrison and Field).
- Conduct USMC NBC Defense Course Content Reviews based on revised ITSs and emerging NBC equipment requirements.
- Continue development of USMC NBC Defense Staff Planning follow-on course, a training course to prepare NBC defense officers and NCOs to assist in the staff planning process.
- Establishment of combat training package for ISMs for reserve forces and follow-on forces in the event of hostilities involving an NBC threat.
- Continued Annual Joint Marine Corps and Navy shipboard decontamination exercises with 7th Fleet.
- Continue participation in a bilateral exchange program with the Republic of Korea (ROK) Chemical Corps.
- Conduct Front End Analysis for an NBC SNCO Advanced Course.
- Continue development of an "Enhanced NBC" capability for MEUs.

5.7.6 Emergency Response: Army Medical Response

The AMEDD continues to be involved in supporting DoD and federal counterterrorism initiatives and contingency operations related to NBC threat agents, mainly with elements of the Medical Research and Materiel Command (MRMC). The following offices and agencies have required AMEDD assistance: DoD SO/LIC, J4 Medical Readiness, U.S. Army Technical Escort

Unit, US Department of State, Federal Bureau of Investigation, Department of Health and Human Services, Office of Emergency Preparedness, and the U.S. Marine Corps CBIRF.

The U.S. Army published AR 525-13, *Antiterrorism Force Protection (AT/FP): Security of Personnel, Information, and Critical Resources from Asymmetric Attacks*, dated 10 September 1998. From this regulation it is assumed that U.S. Army medical treatment facilities and clinics will be called upon to provide assistant to civilian first responders if a WMD terrorist act occurs and to provide emergency room and inpatient treatment for both eligible DoD beneficiaries and civilian casualties. This regulation specifically states that the Surgeon General will:

a) Establish policy and guidance on the management and treatment of conventional and nuclear, biological, and chemical (NBC) casualties.
b) Coordinate emergency medical NBC response capabilities worldwide with other DoD, Joint, Federal, state, local and HN agencies.
c) Maintain medical NBC response teams to address nuclear, biological/emerging infection, chemical accidents/incidents worldwide
d) Provide chemical and biological analysis of biomedical samples from patients/decease to assist in the identification of agent(s) used against U.S. personnel.
e) Provide guidance on the vaccination and prophylaxis against biological warfare agents.

The Office of the Surgeon General is currently updating Army Regulation 40-13, *Nuclear/Chemical Accident Incident Response*, to include all medical teams which could potentially be available to support civil authorities in the event of a terrorist attack with WMD. The regulation will also include the Army policy for fixed facility medical treatment facilities in support of local domestic first responders.

The AMEDD has formed Specialty Response Teams (SRTs), which in some instances may be designated Special Medical Augmentation Response Teams (SMART). These teams provide a rapidly available asset to complement the need to cover the full spectrum of military medical response—locally, nationally, and internationally. These teams are organized by the U.S. Army Medical Command (USAMEDCOM) subordinate commands; they are not intended to supplant TOE units assigned to Forces Command or other major commands. The regional medical commands (RMCs), the United States Army Center for Health Promotion and Preventive Medicine (USACHPPM), and the US Army Medical Research and Materiel Command (USAMRMC) commanders organize SRTs using their table of distribution and allowances (TDA) assets. These teams enable the commander to field standardized modules in each of the SRT areas to meet the requirements of the mission. Members of the US Army Reserve (USAR) may be relied upon to provide a variety of functions in support of the various SRT missions. All SRTs will be capable of deploying within 18 to 24 hours of notification. The two SRTs that can support NBC are the Special Medical Augmentation Response Team – Preventive Medicine (SMART-PM) and the Special Medical Augmentation Response Team – Chemical/Biological (SMART-CB).

The mission of the SMART-PM is to provide short duration Expert Preventive Medicine Augmentation to DoD, other Federal, State and Local Agencies during regional and domestic emergencies, civil-military cooperative actions, weapons of mass destruction, humanitarian and disaster relief operations. The SMART-PM can:

- Conduct public health assessment and community characterization to help identify the population at risk.
- Conduct environmental health consultation to help identify possible hazards and threats that may be a target or result of industrial terrorism.
- Conduct health risk assessment to help determine the possible effects of toxic industrial material exposures and assist in development of educated casualty estimates and controls.
- Conduct hazard countermeasures planning to help protect DoD response assets and assist with planning for safe consequence restoration and recovery.
- Serve as DoD Public Health and Environment Technical Liaisons to other DoD assets and Federal
- Provided emergency support functions.

In general, SMART-PM can provide expert consultation for the re-entry and restoration portions of the consequence management phase of federal emergency response in the following areas:

- Health Physics (Nuclear/Radiological)
- Epidemiology & Disease Surveillance
- Medical Entomology
- Environmental Health Science
- Toxicology
- Industrial Hygiene
- Environmental Sampling and Analysis (Air, Water and Soil)
- Health Risk Assessment
- Sanitation and Hygiene
- Solid & Hazardous Waste Management
- Health Risk Communication

SMART-PM normally would work in support of SBCCOM's C/B-RRT during a WMD response mission.

The National Medical Chemical and Biological Advisory Team (MCBAT) is comprised of USAMRMC elements from the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD). These assets are Tier 1 elements of the DoD Chemical Biological Rapid Response Team (C/B-RRT) and are ready to deploy worldwide within 4 hours after receiving their orders. The RMC Chemical/Biological SMARTs are trained medical teams located at the RMCs that can deploy in response to a chemical, biological, or radiological incident. Examples of incidents that may require a rapid response include:

- An accident involving the transport or storage of NBC weapons,
- The release of CW or BW agents or radiological material,
- A leak of an industrial chemical, infectious material, or radioactive material.

The MCBAT is the principal DoD medical advisor to the Commander, C/B-RRT and the Interagency Response Task Force. Both the MCBAT and regional Chemical/Biological SMARTs can provide medical advice and consultation to commanders or local medical and political authorities for preparation of a response to a threat or actual incident. They can also provide medical advice to commanders or local authorities on protection of first responders and other health care personnel, casualty decontamination procedures, first aid (for non-medical personnel) and initial medical treatment, and casualty handling. The initial advice includes identifying signs and symptoms of NBC exposure, first aid (self-aid, buddy aid, combat lifesaver aid for military personnel), and initial treatment when an incident has occurred. The MCBAT also assists in facilitating the procurement of needed resources. The RMC Chemical/ Biological SMART may, after initial assessment of the situation, elect to use telemedicine reach back.

The US Army Medical Research Institute of Chemical Defense (USAMRICD) has developed a Chemical Casualty Site Team (CSST) with the capability of rapid deployment in support of DoD or the MCBAT as part of the Foreign Emergency Response Team (FEST), or the Domestic Emergency Response Team (DEST). The team is tasked to support each specific mission. Personnel available for deployment consist of physicians, a nurse, toxicologists, veterinarians, and laboratory specialists. These personnel, when coupled with their supporting capabilities, are knowledgeable in the medical effects of a specific chemical warfare agent, identification of chemical agents or their metabolites in biological samples, determination of blood cholinesterase levels, technical and biomedical expertise required to enable protection of personnel responding to chemical incidents or to guide decontamination of personnel and causalities, and technical expertise to accomplish mission planning.

The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) has developed the capability to deploy an Aeromedical Isolation Team (AIT) consisting of physicians, nurses, medical assistants, and laboratory technicians who are specially trained to provide care to and transport patients with disease caused by biological warfare agents or by infectious diseases requiring high containment. The AIT is a highly specialized medical evacuation asset for the evacuation of limited numbers of contagious casualties, with lethal infectious diseases, or for consultation on appropriate management of such casualties in the event of a mass casualty situation. USAMRIID's teams are deployable worldwide on a 12-hour notice using USAF transportation assets.

Another asset that USAMRIID has is the Biological Threat Response Cell (BTRC). The BTRC is designed to respond to any CONUS or OCONUS biological warfare or biological terrorist event. The cell is composed of the Deputy Commander as OIC/POC, the Operational Medicine physicians and the AIT, selected scientists and clinicians, a Biological Safety Officer, a logistician and an engineer. USAMRIID also provides consultants to the Chem-Bio Rapid Response Team as members of the MCBAT.

As a supporting capability, USAMRIID has a 16-bed ward with the capability of isolating (up to Biosafety Level 3) patients with infectious diseases in a contingency situation. USAMRIID also has a special Biosafety Level 4 (highest level of containment) patient care area designed for a maximum of 4 patients requiring this level of containment. These patient care

areas are capable of providing intensive care for critically ill patients with specialized personnel and equipment augmentation from Walter Reed Army Medical Center. An additional supporting capability at USAMRIID is its capacity for medical diagnostic assays for recognized biological agents.

5.7.7 Medical Countermeasures and Surveillance against NBC and other Battlefield Toxicants and Occupational Health Hazards

Presidential Review Directive (PRD)/National Science and Technology Council (NSTC)-5 directs DoD, the Department of Veterans Affairs, and the Department of Health and Human Services to review policies and programs and develop a plan that may be implemented by the Federal government to better safeguard those individuals who may risk their lives to defend our Nation's interests. An NSTC Interagency Working Group oversaw the work of four task forces that focused on (1) deployment health, (2) record keeping, (3) research, and (4) health risk communication.

Deployment can encompass a wide range of missions which in addition to operations in NBC environments may expose a Joint Task Force to other toxic chemicals, radiological contamination, and environmental contamination from industrial operations within the host nation. Historically, most veterans' health and benefit issues related to service in combat operations. Now, U.S. forces are more likely to deploy into non-combat environments such as peacekeeping, peacemaking, humanitarian assistance, or training. Pre-deployment medical screening of U.S. Forces prior to deployment is now a DoD requirement.

Joint Medical Surveillance within the Joint Operational Area should be initiated at the earliest opportunity to provide the Joint Force Commander with the information needed to position U.S. forces safely upon deployment. Medical surveillance information also is useful in identifying and applying pre-deployment medical countermeasures to protect the health of the force. More detailed information on PRD5 is available at "http://www.whitehouse.gov/WH/EOP/OSTP/NSTC/html/directive5.html."

It is DoD policy that pre- and post-deployment health assessments and blood sample collections shall be required for all troop movements of active and reserve component personnel resulting from a Joint Chiefs of Staff/Unified Command deployment order for 30 continuous days or greater to a land-based location outside of the United States that does not have a permanent U.S. military treatment facility. Routine shipboard operations that do not involve field operations ashore for over 30 days are exempt from this policy. The details for completing these assessments are found in JCS Policy Memorandum MCM-251-98, 4 December 1998, subject: Deployment Health Surveillance and Readiness; ASD(HA) Policy Memorandum, 6 October 1999, subject: Policy for Pre- and Post-Deployment Health Assessment and Blood Samples; and DoD Instruction 6490.3, "Implementation and Application of Joint Medical Surveillance for Deployments," August 7, 1997. All policy memorandums, instructions, and copies of blank DD forms can be found on the internet at http://www.cba.ha.osd.mil — select "Projects/Deployment

Recent deployments have confronted the JFC with toxic industrial chemicals, radiological hazards, and long term environmental contamination from industrial operations within the host nation. Standard U.S. occupational health and environmental standards are not effective for protecting the force during these deployments. The Joint Force Commander must utilize organic NBC reconnaissance and preventive medicine medical surveillance assets to identify host nation occupational and environmental hazards and to determine troop deployment locations that will minimize the short- and long-term health risk during occupation by U.S. forces. Prior identification of potentially hazardous industrial or medical sites and areas of known environmental contamination are essential to the risk management and risk communication process. This type of information if not provided by the host nation is available from the Armed Forces Medical Intelligence Center and the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM). Factors to be considered will include the type of contamination and the prevailing wind direction. Planning factors for downwind hazard distances for some commonly known industrial chemicals are provided USACHPPM Technical Guide 230A, "Short-Term Chemical Exposure Guidelines for Deployed Military Personnel". The "target population" consists of healthy deployed military personnel. The technical guide is to be used as a tool to assess potential adverse health impacts resulting from exposure to harmful chemicals as a result of uncontrolled industrial release, sabotage, of from the intentional or unintentional actions of enemy or friendly forces.

The Joint Publication 3-11, *Doctrine for Nuclear, Biological, and Chemical Defense Operations* is currently focused only on the use of NBC weapons in a global war. It is being updated to take into account new DoD and JCS policies, directives, and instructions for joint medical surveillance and risk communication. Current military deployments are Stability and Support Operations (SASO), peacekeeping, or humanitarian in nature. Commanders are being confronted with industrial hazards and environmental contamination within the host country which place the health of the force at risk. New DoD standards and guidelines are being developed for accurate risk communication. The Assistant Secretary of the Army for Installations, Logistics, and Environment, ASA(ILE), is the DoD Executive Agent for developing these new DoD nuclear, biological, chemical, and environmental (NBC-E) force protection policies.

Central to force protection is the integration into campaign and operational plans of medical force protection measures such as risk management and risk communication. Medical counter-measures include pre- and post- deployment medical screening, immunizations, medical pre-treatments, NBC casualty treatments, and medical record keeping. Functions being considered in medical readiness planning are area medical support, hospitalization, evacuation, preventive medicine, and laboratory. Joint medical surveillance within the theater of operations can identify NBC related occupation, industrial, and environmental health hazards. Preventive medicine assets within the theater can be employed to conduct joint medical surveillance and to provide recommendations to the Joint Force Commander for risk communication to minimize the short-term and long-term health effects of toxic exposures to deployed military personnel. DoD Directives (6055.1 and 6490.2) and Instruction (6490.3) as they apply to joint medical surveillance and safety and occupational health in an NBC or otherwise contaminated environment can be found at http://web7.whs.osd.mil.corres.htm.

5.7.8 Air Force Modular NBC Teams

The Air Force Medical Readiness Re-engineering efforts have created eight specialty teams for NBC Medical Defense. These teams include (1) Theater Epidemiology Team, (2) Radiological Assessment Team, (3) Wartime Patient Decon Team, (4) Bioenvironmental Engineering NBC Team, (5) Infectious Diseases Team, (6) Preventative Aerospace Medicine Team, (7) Biological Augmentation Team, and (8) In-place Patient Decon Team (USAFE). Following is a brief description of the capabilities provided by these teams.

The Theater Epidemiology Team provides (1) theater medical and environmental threat assessments, (2) theater disease surveillance and disease outbreak investigation, and (3) baseline environmental monitoring.

The *Radiological Assessment Team* is composed of two Nuclear Incident Response Force (NIRF) Teams and one Radioanalytical Augmentation Team. The NIRF Teams include health physicists, industrial hygienists, equipment technicians, and bioenvironmental technicians.

The *Wartime Patient Decon Team* is deployed in direct support medical treatment facilities operating in NBC threat environments. They construct decontamination sites and facilities in the vicinity of the medical treatment facilities.

The *Bioenvironmental Engineering NBC Team* provides the following capabilities: (1) NBC agent surveillance, detection and abatement, (2) reconnaissance teams for NBC agent detection, (3) advice on health effects and human performance due to extended wear of the ground crew ensemble, (4) information on other NBC related health risks to deployed forces.

The *Infectious Diseases Team* provides personnel that augment the capability to identify, control, report, and provide treatment for infectious diseases and biological warfare agents in the deployed theater. The Team is designed to be deployed to facilities with greater than 100 beds where a significant threat for biological warfare casualties or infectious disease exists.

The *Preventative Aerospace Medicine Team*: (1) identifies, monitors and prevents disease and non-battle injury (DNBI), (2) performs health threat and risk assessment, (3) performs health hazard surveillance, (4) controls health hazards, and (5) mitigates the effects and prevents DNBI.

The *Biological Augmentation Team* is a two-person team that provides rapid pathogen identification using DNA-based detection capability. The team is modular so that it may augment other teams, capabilities, and facilities.

The *In-place Patient Decon Team* supports five U.S. Air Forces in Europe (USAFE) medical treatment facilities (MTF).

5.8 READINESS REPORTING SYSTEM

CJCSI 3401.02, the policy document for the Status of Resources and Training System (SORTS) requires units from all Services to independently assess their equipment on hand and training status for operations in a chemical and biological environment. This is a change to previous SORTS reporting requirements and provides more visibility to NBC defense related issues.

The Services individually monitor their SORTS data to determine the type of equipment and training needing attention. Units routinely report their equipment on hand and training status for operations in a chemical or biological environment. Commanders combine this information with other factors, including wartime mission, to provide an overall assessment of a unit's readiness to go to war.

Additionally, the Commanders-in-Chief (CINCs) of the Unified Commands submit readiness assessments at each Joint Monthly Readiness Review (JMRR). In the JMRR, CINCs assess the readiness and capabilities of their command to integrate and synchronize forces in executing assigned missions. As needed, CINCs address NBC defense readiness and deficiencies as part of the JMRR.

5.9 NBC DEFENSE TRAINING AND READINESS ASSESSMENT

ISSUE: **There are limited chemical and biological features in wargaming and planning models.**

> ***SOLUTION:*** Funding to add chemical and biological warfare defense to joint simulations has been allocated by the JSIG M&S Commodity Area for FY99 and beyond. The program will focus on incorporating chemical effects into JCATS and JSIMS in FY99-00 and BW effects in FY00–01. To add CB defense capabilities to OneSAF, the possibility of incorporating the CB-ModSAF model developed by SBCCOM will be considered.

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Chapter 6

Status of DoD Efforts to Implement the Chemical Weapons Convention (CWC)

6.1 INTRODUCTION

The Chemical Weapons Convention (CWC) was opened for signature on January 13, 1993. The Convention entered into force on April 29, 1997. As of 23 December 1999, 129 countries, including the United States, had signed and ratified the CWC. Another 41 countries have signed but not ratified.

6.2 DEPARTMENT OF DEFENSE IMPLEMENTATION OF THE CWC

Since the CWC entered into force, DoD has hosted 117 visits and inspections at chemical weapons storage, former production, and destruction facilities. The Army, (the Service most directly impacted by CWC implementation activities), and the Defense Threat Reduction Agency's On-Site Directorate, DTRA(OS), continue to host and escort Organization for the Prohibition of Chemical Weapons (OPCW) Technical Secretariat inspectors, who conduct both continuous monitoring at DoD CW destruction facilities and systematic inspections at DoD CW storage and former production facilities.

The Department of Defense conducts a Chemical Weapons Agreements Implementation Working Group (CWIWG) to implement the CWC. Through regularly recurring meetings, representatives of the Office of the Secretary of Defense (OSD), the Joint Staff, the Military Departments, the Military Services, and DoD agencies and activities coordinate planning efforts to ensure proper implementation of the CWC. Formal meetings of the CWIWG are scheduled approximately monthly and small group meetings are held as needed to address specific requirements in support of the CWIWG. A Compliance Review Group (CRG) was established within DoD to meet as needed to address CWC compliance concerns, should they arise.

OSD, the Joint Staff, the Military Services, and DTRA provide technical experts to support activity at the U.S. Delegation to the OPCW in The Hague, The Netherlands. The OPCW is charged with overseeing worldwide implementation of the CWC.

The Army was tasked to destroy all chemical warfare materiel under the Program Manager for Chemical Demilitarization (PMCD). PMCD includes programs for unitary stockpile destruction, destruction of bulk agent by alternative technologies (non-incineration), and destruction of other chemical warfare materiel and former CW production facilities. There is a separate non-PMCD program to demonstrate alternative technologies to destroy assembled CW munitions. DoD and the Army coordinate closely to ensure that these programs are compliant with CWC provisions.

6.3 SAFETY ORIENTATION FOR INSPECTORS

OPCW inspectors who conduct continuous monitoring at U.S. chemical weapons demilitarization facilities have attended a 32-hour safety orientation which is broken down into two sections. One section is a 24-hour hazardous waste operations and emergency response (HAZWOPR) course which is a U.S. Government requirement of all personnel who must be present on a more than short-term basis at U.S. chemical demilitarization facilities. The second section is an 8-hour demilitarization protective ensemble (DPE) procedures course required only for those inspectors designated by the OPCW Technical Secretariat, whose responsibilities would include the use of such protective equipment. Approximately 450 inspectors have attended HAZWOPR training; some 110 of the 450 inspectors have taken the 48-hour DPE class. The orientation is conducted at the Chemical Demilitarization Training Facility in Edgewood, MD. Annual 8-hour HAZWOPR refresher classes are also required, and are being accomplished.

6.4 PREPARATION OF DEFENSE INSTALLATIONS

The Military Services and DTRA have developed individual implementation and compliance plans to provide guidance for their commands and activities under the CWC.

The Military Services have individually established implementation support offices which participate actively at the DoD CWIWG, provide Service policy direction, and conduct ongoing liaison with their major commands to ensure that all military elements are fully prepared for inspections under the CWC.

The Military Services and DTRA continue to prepare DoD installations for inspections under the CWC. All defense installations which are subject to declarations under the requirements of the CWC, and many which are subject to challenge inspections even though not declared, have been visited by Military Service representatives and DTRA technical experts. DTRA will continue to support site assistance visits and Army treaty compliance implementation meetings.

All of the Military Services have held exercises to test their preparedness for short-notice CWC challenge inspections. Such exercises involve the active participation of Service, DTRA, and other DoD representatives in the roles they would assume during a real challenge inspection. DoD and the Services have exercised written DoD guidance and procedures to test the operational readiness of personnel and facilities. Commonly, the lead Service responsible for developing an exercise also produces comprehensive lessons-learned to further ensure DoD readiness for challenge inspections. The Services have initiated efforts to ensure that in the case of a challenge inspection affected commands take timely and appropriate measures, based on lessons-learned, to demonstrate compliance while protecting security concerns.

6.5 DEFENSE TREATY INSPECTION READINESS PROGRAM

The Defense Treaty Inspection Readiness Program (DTIRP), for which DTRA is the executive agent, has implemented an extensive outreach program to provide information about the CWC, security countermeasures, facility preparation, to both government and DoD industry. DTIRP provides training and awareness services through such fora as industry seminars, mock inspections, mobile training teams, industry associations, national conventions and symposia. DTIRP speakers participated in more than 55 outreach events during the last fiscal year. DTIRP also publishes various educational products (printed and video) and administers electronic bulletin boards to provide information concerning the CWC to government and industry. DTIRP, in close coordination with the Naval Surface Warfare Center at Indian Head, MD, has also produced and conducted the first Chemical Technology Security Course, to be given annually.

6.6 ARTICLE X ASSISTANCE AND OTHER ASSISTANCE

Under Article X of the CWC, a State Party to the treaty may make an appeal for assistance to the Director-General of the OPCW. In accordance with a condition established in the U.S. Senate's advise and consent to the ratification of the CWC, the United States will provide no assistance other than medical antidotes and treatment, which the U.S. Government deems are necessary, to those CWC States Parties that have requested assistance under Article X of the CWC.

Under the CWC, DoD has not provided any chemical weapons detection equipment, or assistance in the safe transportation, storage, and destruction of chemical weapons to other signatory nations. Such assistance, however, is being provided to Russia under DoD's Cooperative Threat Reduction (CTR) program, a program not directly related to the CWC.

6.7 ARMS CONTROL TECHNOLOGY

DTRA conducts RDT&E to support U.S. roles in global chemical weapons (CW) control initiatives. The primary goal of the program is to protect DoD equities and minimize the threat to national security interests posed by U.S. involvement in CW arms control activities. A related objective is to assist the United States in meeting legal obligations imposed by treaty provisions, support development of U.S. policy, minimize implementation costs, and enhance the safety of inspections. Projects that support implementation and compliance requirements are approved by the CW Treaty Manager. Current emphasis is on technologies and procedures for on-site analysis under the CWC. Other key development areas include non-destructive evaluation and off-site monitoring.

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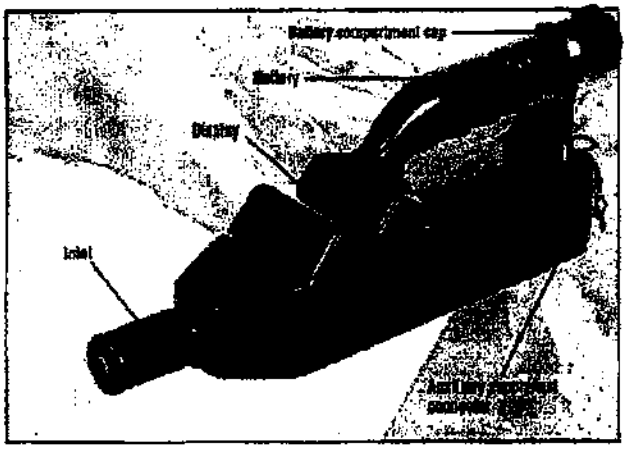
Annex A

Contamination Avoidance Programs

SECTION 1: FIELDED AND PRODUCTION ITEMS

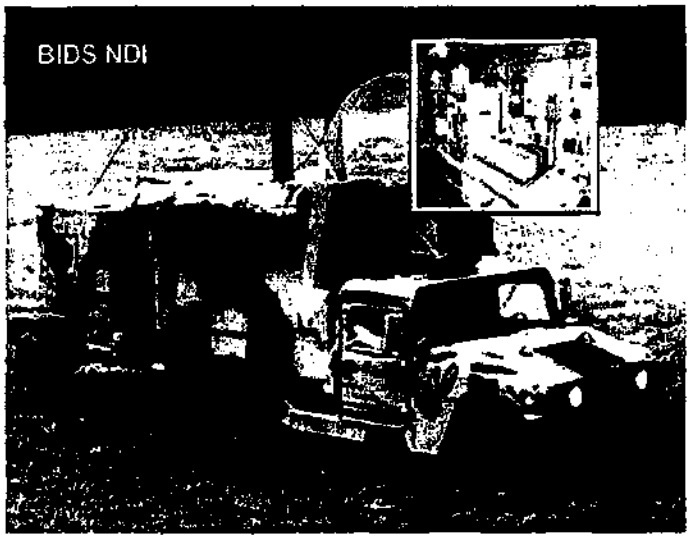
DETECTORS AND MONITORS

Chemical Agent Monitor (CAM) and Improved Chemical Agent Monitor (ICAM)



The CAM is a hand held instrument capable of detecting, identifying, and providing relative vapor hazard read-outs for G and V type nerve agents and H type blister agents. The CAM uses ion mobility spectrometry (IMS) to detect and identify agents within one minute of agent exposure. A weak radioactive source ionizes air drawn into the system, and the CAM then measures the speed of the ions' movement. Agent identification is based on characteristic ion mobility and relative concentrations based on the number of ions detected. The ICAM has the same chemical agent detection capability as the CAM; improvements are that it is 300% more reliable, starts up 10 times faster, and the modular design is much less expensive to repair. The ICAM has the additional features of an RS-232 data communications interface, and the ability to be programmed for new/different threat agents. The four pound, 15" long ICAM can be powered either by an internal battery or by an external source through the ICAM's combination power/fault diagnosis/RS-232 plug. The ICAM may be used for a variety of missions, to include area reconnaissance and area surveillance, monitoring of decontamination operations, and medical triage operations. The ICAM significantly reduces the level and frequency of maintenance *vs.* CAM without affecting performance. The ICAM sieve pack has double the capacity of the two CAM sieve packs, which results in twice the operational life of the ICAM over the CAM. When fielded, the ICAM will significantly reduce operating and sustainment costs associated with the CAM by $135 million over its life cycle in present day dollars. This savings is based on the total planned procurement of the ICAM, and would be greater if all CAMs were replaced by ICAMs.

M31 Biological Integrated Detection System (BIDS)
Non-Developmental Item (NDI) & Pre-Planned Product Improvement (P3I)



BIDS uses a multiple technology approach, both developmental and off-the-shelf *materiel*, to detect biological agents with maximum accuracy. BIDS is a vehicle-mounted, fully integrated biological detection system. The system, which is a collectively-protected, HMMWV-mounted S788 shelter, is modular to allow component replacement and exploitation of "leap ahead" technologies. The system is capable of detecting and presumptively identifying four BW agents simultaneously in less than 45 minutes. Thirty-eight BIDS (NDI versions, shown) were fielded to the 310th Chemical Company (U.S. Reserve) during FY96. This gave DoD its first credible, rapidly deployable biological detection capability. The BIDS is a Corps level asset. The P3I BIDS is capable of detecting and presumptively identifying 8 BW agents simultaneously in 30 minutes. The suite is semi-automated and contains next generation technologies such as the Ultraviolet Particle Sizer, Chemical Biological Mass Spectrometer, and the Biological Detector. 38 systems were recently fielded to the 7th Chemical Company.

The Biological Detector is an antibody-based device capable of identifying specific biological agents. It consists of electronics processing equipment, fluid processing modules, reservoirs for antibody reagents, and a light addressable potentiometric sensor to provide biological agent identification. The total processing time, from insertion of sample to data readout, will be approximately 15 minutes at threshold concentrations. The biodetector includes an operator display which will provide identification and relative concentration of the biological agent detected. Built-in tests will also be provided to identify system malfunctions.

CBMS detects and characterizes all known chemical and biological threat agents. It continuously and automatically detects threat agents via a mass analyzer chassis, a biological aerosol sampling probe, a surface sampling probe and sample identification device. The mass analyzer chassis houses the mass analyzer, pumps, control electronics, and computers. With the aerosol probe attached, the CBMS detects biological agent aerosols and chemical agents as aerosols and/or vapors in the air. With the ground probe attached, the CBMS detects chemical agents whether they exist as airborne vapors or aerosols, or as liquid droplets on surfaces. The CBMS will replace the MM1 and be mounted within the NBC Recon System to search for areas of CB agent contamination.

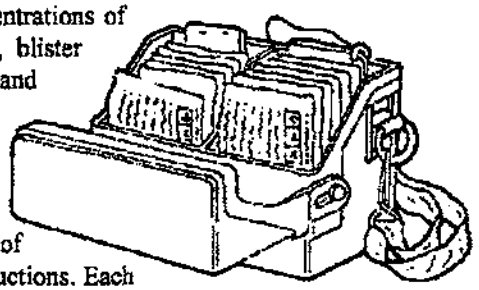
Interim Biological Agent Detector (IBAD)

IBAD provides shipboard detection of biological warfare agents. IBAD consists of a particle sizer/counter, wet wall cyclone particle sampler, and hand held colorimetric, immunochemical assay tickets for identification of suspect aerosol particles (through hand-held assay). IBAD is capable of detecting an increase in the particulate background, which may indicate a man-made biological attack is underway, and sampling the air for identification analysis. IBAD can detect a change in background within 15 minutes, and can identify biological agents within an additional 30 minutes. It is a rapid prototype system that started service with the fleet in FY96. Twenty IBAD systems are currently fielded. These systems will be among ship platforms as dictated by fleet priorities.

Portal Shield ACTD Residuals

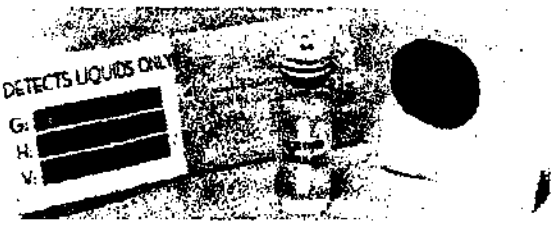
Portal Shield is an interim capability for biological detection at high value fixed overseas sites. The system uses an innovative network of sensors to increase probability of detecting a BW attack while decreasing false alarms and consumables. The Portal Shield system consists of a variable number of biological sensors forming a network under the command and control of a centralized command post (CP) computer. The CP communicates with and monitors the operation of each sensor. The Portal Shield system can detect and identify up to eight BW agents simultaneously in less than 25 minutes. The Portal Shield was successfully deployed overseas in support of Operation Desert Thunder, and was also successfully operated during the NATO 50th anniversary. Four overseas sites are currently fielded and outfitted with Portal Shield networks.

M256A1 Chemical Agent Detector Kit



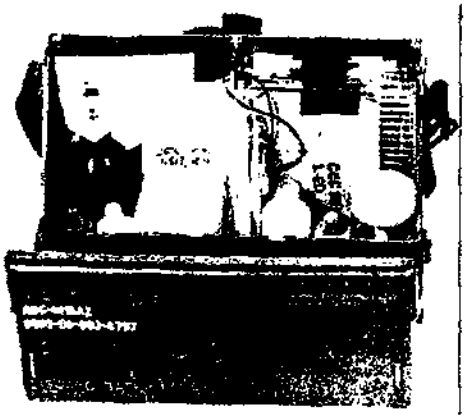
The M256A1 kit can detect and identify field concentrations of nerve agents (sarin, tabun, soman, GF, and VX), blister agents (mustard, phosgene oxime, mustard-lewisite, and lewisite), and blood agents (hydrogen cyanide and cyanogen chloride) in both vapor and liquid form in about 15–20 minutes. The kit consists of a carrying case containing twelve chemistry sets individually sealed in a plastic laminated foil envelope, a book of M8 chemical agent detector paper, and a set of instructions. Each detector ticket has pretreated test spots and glass ampoules containing chemical reagents. In use, the glass ampoules are crushed to release a reagent, which runs down pre-formed channels to the appropriate test spots. The presence or absence of chemical agents is indicated through specific color changes on the test spots. The kit may be used to determine when it is safe to unmask, to locate and identify chemical hazards (reconnaissance), and to monitor decontamination effectiveness.

ABC-M8 VGH, and M9 Chemical Agent Detector Paper



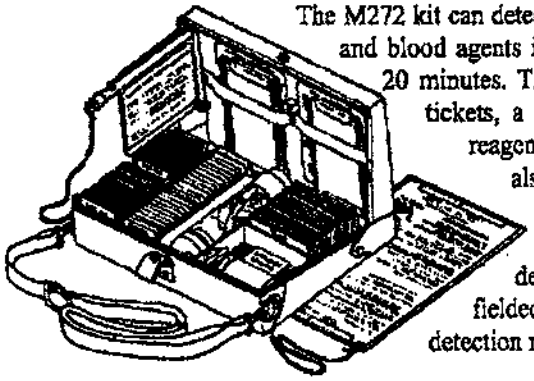
M8 and M9 paper are dye impregnated papers that change color when exposed to liquid chemical agents or aerosols. These papers cannot detect chemical agents in vapor form. M8 paper comes in 4" by 2 $^{1}/_{2}$" booklets. Each booklet contains 25 sheets of detector paper that are capable of detecting G series nerve agents (sarin, tabun, soman, and GF), V type nerve agents, and H (mustard) type blister agents. M8 paper can identify agents through distinctive color changes from its original off-white: yellow-orange for G, blue-green for V, and red for H. M8 paper is typically used to identify unknown liquid droplets during chemical reconnaissance/ surveillance missions. M9 (SR119) detector paper is rolled into 2-inch wide by 30-feet long rolls on a 1.25-inch diameter core. Although M9 paper cannot distinguish the identity of G and V nerve agents, H blister agents, and L agents, it does turn pink, red-brown, red-purple, or another shade of red when exposed to liquid or aerosol chemical nerve and blister agents. M9 paper is typically placed on the BDO, equipment, and vehicle exteriors to warn personnel of the presence of a liquid chemical agent.

M18A2 Chemical Agent Detector Kit



The M18A2 can detect and identify dangerous concentrations of nerve agents (sarin, tabun, soman, GF, and VX), blister agents (mustards, phosgene oxime, mustard-lewisite mixture, phenyl dichlorarsine (PD), ethyl dichlorarsine (ED), and methyl dichlorarsine (MD)), blood agents (hydrogen cyanide and cyanogen chloride), and choking agents (phosgene) in about 1–4 minutes. The kit is also used to confirm results of the M256A1 kit. The M18A2 kit contains a squeeze bulb and enough detector tubes, detector tickets, and chemical reagents needed to conduct 25 tests for each agent vapor. The kit also contains a booklet of M8 chemical agent detector paper to detect liquid agents. Agent vapor detection is indicated by the production of a specific color change in the detector tubes. The M18A2 kit was fielded in 1982 and only used by special teams such as surety teams or technical escort personnel.

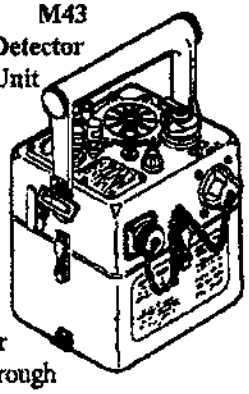
M272 Water Test Kit



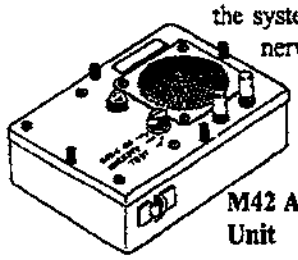
The M272 kit can detect and identify hazardous levels of nerve, blister, and blood agents in treated or untreated water resources in about 20 minutes. The kit contains enough detector tubes, detector tickets, a test bottle, and pre-packed, pre-measured test reagents to conduct 25 tests for each agent. The kit also contains simulants used for training. Agent detection in water is indicated by the production of a specific color change in the detector tubes or in the ticket. The M272 was fielded in 1984 and does not meet current lower level detection requirements.

M8A1 Automatic Chemical Agent Alarm (ACAA)

M43 Detector Unit



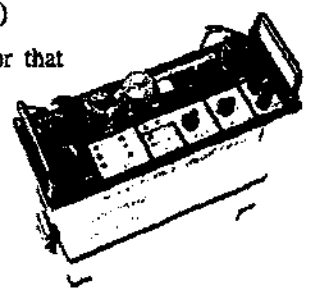
The M8A1 ACAA is a system that continuously samples the air to detect the presence of dangerous concentrations of G and V type nerve agent vapors. This system is being phased out of the inventory and will be replaced by the M22 ACADA. The M8A1 ACAA may be employed in a number of configurations, but all configurations are built around the M43A1 detector unit and the M42 alarm unit. The configurations differ primarily in their mountings and power supplies: ground mounted and battery operated, or mounted on a vehicle and powered by the vehicle's electrical system. The M43A1 detector unit measures 6 1/2" x 5 1/2" x 11" with the battery used in ground mounted operations adding another 7 3/4" in height. The M43A1 detector unit uses a radio-isotope to ionize molecules in the air that is pumped through the system, then detects electrical current changes that occur in the presence of nerve agents. The M43A1 detector unit will alarm within about 1-2 minutes from exposure to agent. The M42 alarm unit is a remote visual and audible alarm that measures 7" x 4" x 2 1/3". The M42 alarm unit may be placed up to 400 meters from the M43A1 detector unit to give users warning of an approaching agent cloud.



M42 Alarm Unit

M-90 Automatic Agent Detector (AMAD)

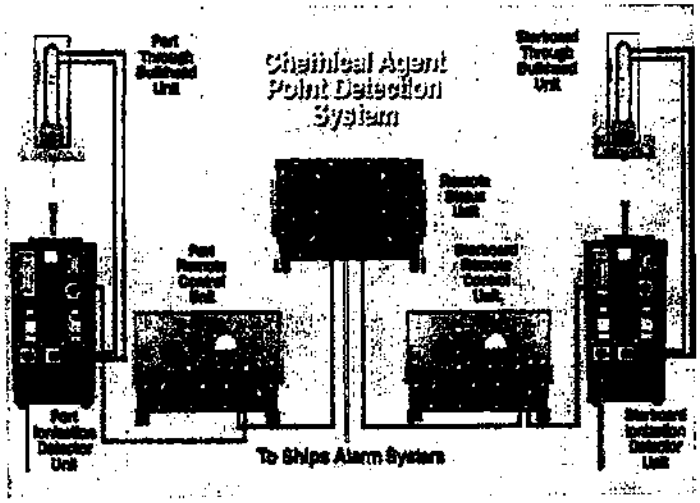
The AMAD is an automatic nerve and mustard agent detector that detects agents in vapor form. This system is currently in use by the Air Force. It transmits an alarm by radio to a central alarm unit.



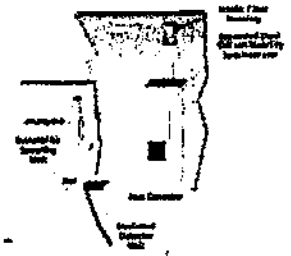
Automatic Liquid Agent Detector (ALAD)

The ALAD is a liquid agent detector that can detect droplets of GD, VX, HD, and L as well as thickened agents. It transmits its alarm by field wire to a central alarm unit. Although the remote transmission is useful, the device only detects droplets of liquid agents. It must be used in conjunction with other point or standoff vapor agent detectors to afford a complete detection capability.

Chemical Agent Point Detection System (CAPDS), MK21, MOD1

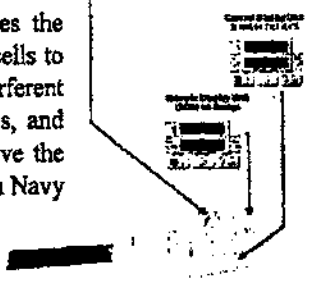


CAPDS is a fixed system capable of detecting nerve agents in vapor form, using a simple baffle tube ionization spectrometer. Installed in a ship's upper superstructure level, CAPDS obtains a sample of external air, ionizes airborne vapor molecules, and collects them on a charged plate after eliminating lighter molecules via the baffle structure. When a sufficient mass of ions is collected, a pre-set potential is achieved, and an alarm signal is generated and sent to both Damage Control Central and the bridge. The system has been installed on almost all surface ships.

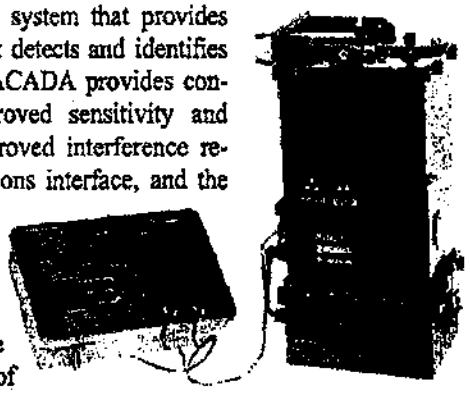


Improved (Chemical Agent) Point Detection System (IPDS) - Production

The IPDS is a new shipboard point detector and alarm that replaces the existing shipboard CAPDS. IPDS uses special elongated ion mobility cells to achieve the resolution necessary to counter false alarms caused by interferent vapors. IPDS can detect nerve and blister agent vapors at low levels, and automatically provide an alarm to the ship. The unit is built to survive the harsh sea environment and the extreme electromagnetic effects found on Navy ships.



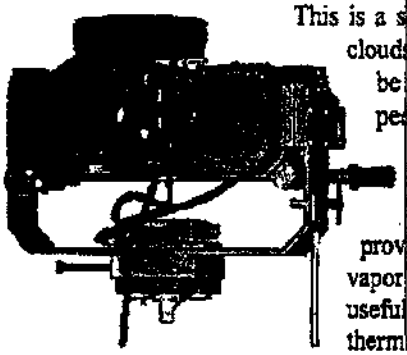
M22 Automatic Chemical Agent Detection Alarm (ACADA)



ACADA is a man-portable, point sampling alarm system that provides significant improvement over current capabilities; it detects and identifies all nerve agents, mustard, and lewisite, by class. ACADA provides concurrent nerve and blister agent detection, improved sensitivity and response time, agent identification capability, improved interference rejection, extensive built-in test, a data communications interface, and the capability to be programmed for new threat agents. It replaces the M8A1 Alarm as an automatic point detector and augments the CAM as a survey instrument. The ACADA consists of an off-the-shelf non-developmental item (NDI)—the GID-3 chemical agent alarm. A shipboard version of the ACADA is being built to address the unique interferents found aboard Navy ships that cause false alarms on the NDI ACADA. The shipboard version of ACADA will serve to cover the Navy's emergency requirements until the Joint Chemical Agent Detector can be fielded.

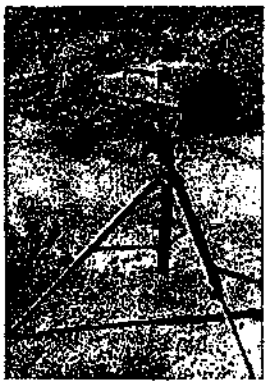
STAND-OFF DETECTION AND REMOTE/EARLY WARNING

AN/KAS-1/1A Chemical Warfare Directional Detector (CWDD)



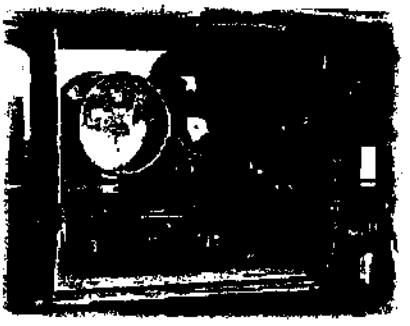
This is a semi-portable system designed to detect nerve agent vapor clouds at ranges up to five kilometers. The AN/KAS-1/1A must be removed from its stowage case and set up on a pre-installed pedestal for operation. A trained, diligent operator must manually aim the detector at the suspect cloud and interpret its infrared images to determine whether or not the cloud contains nerve agent vapors. The AN/KAS-1A provides a remote video display, an enhanced capability for vapor cloud analysis, and a remote relative bearing indicator useful for avoiding the agent cloud or other surface target with a thermal signature.

M21 Remote Sensing Chemical Agent Alarm (RSCAAL)



The M21 RSCAAL is an automatic scanning, passive infrared sensor that detects nerve (GA, GB, and GD) and blister (H and L) agent vapor clouds based on changes on the infrared spectrum caused by the agent cloud. It is effective at line-of-sight distances of up to five kilometers. The alarm is used for surveillance and reconnaissance missions in both vehicle-mounted and tripod-mounted modes.

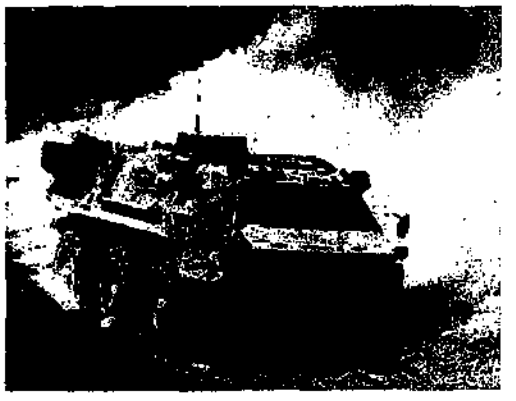
Long Range Biological Stand-off Detector System (LRBSDS) - NDI



LRBSDS utilizes elastic backscatter and infrared light detection and ranging (IR-LIDAR) technology to detect, range, and track particulate clouds that are indicative of a BW attack; the LR-BSDS cannot discriminate biological from non-biological clouds. The system, which is approximately 1,240 pounds and 2.3 cubic meters, has three major components: a pulsed laser transmitter operating at IR wavelengths; a receiver and telescope; and an information processor and display. The system is mounted on a UH 60 Blackhawk helicopter for operations. This program has been designed in two phases; an NDI phase designed to rapidly field an interim capability and a pre-planned product improvement (P3I) phase. The three NDI LR-BSDSs have been fielded to the 310th Chemical Company (USAR). The NDI system is able to detect and track man-made aerosols out to 30 km, but is non-eyesafe out to about 2.5 km. The P3I will provide an eye safe laser system at all ranges, an automated cloud detection and tracking capability, and an increased detection range (50 km). Fielding of the system is currently scheduled for FY01.

NBC RECONNAISSANCE

M93 NBC Reconnaissance System (NBCRS)



The M93 NBC Reconnaissance System, known as the FOX, is a high mobility armored vehicle capable of performing NBC reconnaissance on primary, secondary, and cross country routes throughout the battlefield. The NBCRS was procured as a Non-Developmental Item and is capable of detection, warning and sampling the effects of NBC weapons and is used as a reconnaissance vehicle to locate, identify and mark chemical and nuclear contamination on the battlefield. The M93 FOX usually accompanies the scouts or motorized reconnaissance forces when performing its NBC mission. The NBCRS has an overpressure filtration system that permits the crew to operate the system in a shirt sleeve environment which is fully protected from the effects of NBC agents and contamination. It utilizes a secure communications system to warn follow-on forces. Samples gathered are forwarded to the Theater Area Medical Laboratory for further analysis and verification. The mobility platform is a six wheeled all wheel drive, armored combat vehicle capable of cross-country operation at speeds up to 65 MPH. The Fox System is fully amphibious and is capable of swimming speeds up to 6 MPH. The M93 NBCRS has been fielded worldwide to the Army and Marine Corps forces.

M93A1 – FOX System

The Block I Modification—M93A1 NBCRS contains an enhanced and fully integrated NBC sensor suite consisting of the M21 RSCAAL, MM1 Mobile Mass Spectrometer, CAM/ICAM, AN/VDR-2, and M22 ACADA. The NBC sensor suite has been digitally linked together with the communications and navigation subsystems by a dual-purpose central processor system known as MICAD. The MICAD processor fully automates NBC Warning and Reporting functions and provides the crew commander full situational awareness of the Fox's NBC sensors, navigation, and communications systems. The M93A1 FOX is also equipped with an advanced position navigation system (GPS & ANAV) that enables the system to accurately locate and report agent contamination. The NDI mobility platform is a six wheeled, all wheel drive armored vehicle capable of cross-country operation at speeds up to 65 MPH. The Fox System is also fully amphibious and is capable of swimming at speeds up to 6 MPH. It is used as a reconnaissance vehicle to locate, identify, and mark chemical and biological agents on the battlefield. The FOX usually accompanies the scouts or motorized reconnaissance forces when performing its NBC mission.

RADIACS

AN/VDR-2

The AN/VDR-2 measures gamma dose rates from 0.01 μGy/hr (micro-Grays per hour) to 100 Gy/hr and beta dose rates from 0.01 μGy/hr to 5 cGy/hr. The unit functions simultaneously as a dose rate meter and dose meter with independent adjustable alarms that can be set at any level over the entire range. Dosage data is independently stored in non-destructive memory for display on command and may be retained when the unit is turned off. The unit is powered by three 9 volt batteries.

AN/PDR-75 Radiac Set

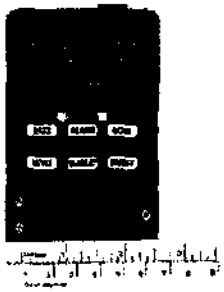
The AN/PDR-75 measures dose from 0 to 999 cGy (centi-Gray). The Radiac Set consists of a dosimeter and a reader. It provides the capability to monitor and record the exposure of individual personnel to gamma and neutron radiation. Each individual will be issued a DT-236/PDR-75 dosimeter. This device, worn on the wrist, contains a neutron diode and a phosphate glass gamma detector. When a determination of exposure is required, the dosimeter is inserted into a

CP-696/PDR-75 reader, which then displays the cumulative neutron and gamma dose. The reader is issued at the company level and the dosimeters are issued to all combat, combat support, and combat service support personnel. The reader can be powered by a BA-5590 lithium battery, vehicle battery, or external power supply via adapter cables provided.

AN/PDR-77 Radiac Set

The AN/PDR-77 Radiac Set is a set of portable radiation detection equipment for detecting alpha, beta, gamma, and x-ray radiation. The set consists of a radiacmeter to which one of three radiation probes can be attached for measuring particular types of radiation. The probes are part of the set. The set includes accessories and basic test and repair parts for unit maintenance including a carrying pouch with shoulder straps capable of holding the radiacmeter, alpha probe, and beta/gamma probe for field use. The entire set is contained in a carrying case (large briefcase) for easy portability and storage.

AN/UDR-13 Pocket RADIAC - Production (FUE FY99)

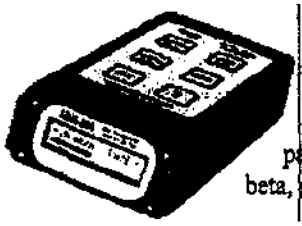


The AN/UDR-13 Pocket RADIAC is a compact, hand-held, tactical device capable of measuring the gamma dose-rate and gamma and neutron cumulative dose in a battlefield environment. Its pocket size permits convenient use by troops on foot. Alarm pre-sets are provided for both the dose-rate and total dose modes. A push-button pad enables mode selection and functional control. Data readout is by liquid crystal display. It will replace the obsolete IM-93 quartz fiber dosimeter and the PP-1578 Dosimeter Charger.

Multi-Function Radiation (MFR) Detector -Production

This program improves radiation detection equipment by replacing the current suite of logistically unsupportable assets. Present detectors (PAC-1S, AN/PDR-43 and AN/PDR-56F) have exceeded maintainability standards. Original manufacturers have either discontinued production or are no longer in business. An improved capability is required to support both wartime and peacetime nuclear accident response operations. A production contract was awarded in March 1995. First deliveries were made in 1997.

ADM-300A Multifunction Survey Meter



The ADM300A is a battery-operated, self-diagnostic, multiple functional instrument. It is used alone to locate and measure low and high intensity radioactivity in the form of gamma rays or beta particles. It is used with external probes to locate and measure alpha, beta, gamma, and x-rays, and neutron radiation.

SECTION 2. RDTE ITEMS

AUTOMATIC DETECTORS AND MONITORS

Agent Water Monitors

The Joint Service Chemical Biological Agent Water Monitor is a cooperative RDTE effort, chartered to develop a detection system which will detect chemical and biological agents in water. The detector will feature multi-agent capabilities, and operate automatically, improving both ease and response time of existing system. The project will accominodate the four services' requirements for the following:

In-line CB Detector (IL CBDWS)
Chemical Agent Water Monitor (CAWM)
CB Agent Water Monitor (CBAWM)

Rationale:

- Joint Army, Air Force, and Marine Corps requirement
- Navy interest

Key Requirements:

- Detect and identify chemical agents and agents of biological origin in water
- Perform monitoring automatically with continuous and batch sampling capabilities
- Easy to operate and support in forward areas, austere environments, and limited lighting

Description:

The Agent Water system will improve current water monitoring and purifying capabilities. It will automatically detect CB agents at or below harmful levels in water and not false alarm to common interferents. The system will be compact, man-portable and easy to use, and be decontaminated to a negligible risk level.

Joint Chemical Agent Detector (JCAD)

The JCAD is a fully cooperative RDTE effort, chartered to develop a chemical agent detector for a variety of mission requirements and service platforms. The detector will provide warfighters near-real time information on the presence of chemical agents so that miosis or more severe effects can be avoided and not subvert the mission. The project will accommodate the four services' requirements for the following:

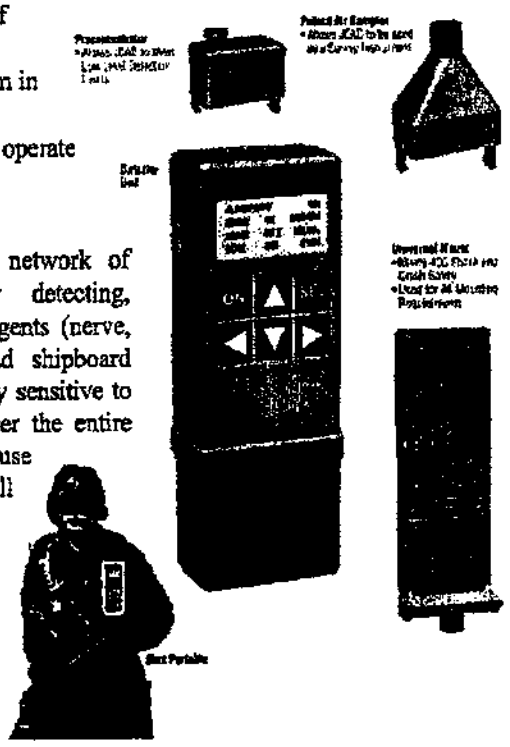
Individual Soldier Detector (ISD)
Special Operation Force Chemical Agent Detector (SOFCAS)
Individual Vapor Detector (IVD)
Aircraft Interior Detector (AIDET)
Shipboard Chemical Agent Monitor Portable (SCAMP)
CW Interior Compartment System (CWICS)
Improved Chemical Detection System (ICDS)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Small, lightweight detector capable of detecting presence of chemical agent vapors
- Capable of de-warning, allowing for rapid reduction of protective postures
- Detect, identify, quantify, and warn of presence of even low levels of nerve, blister, and blood agents in vapor form in aircraft and shipboard interiors
- Operated/maintained by ship's force; operate in a shipboard environment



Description:

JCAD will provide a detector or a network of detectors capable of automatically detecting, identifying, and quantifying chemical agents (nerve, blister, and blood) inside aircraft and shipboard interiors. The device must be sufficiently sensitive to warn aircrews before accumulation, over the entire mission, of levels of agent that may cause miosis or more severe effects. JCAD will also provide hand-held monitoring capabilities, protecting the individual soldier, sailor, airman, and marine through the use of pocket-sized detection and alarm.

Shipboard Automatic Liquid Agent Detector (SALAD)

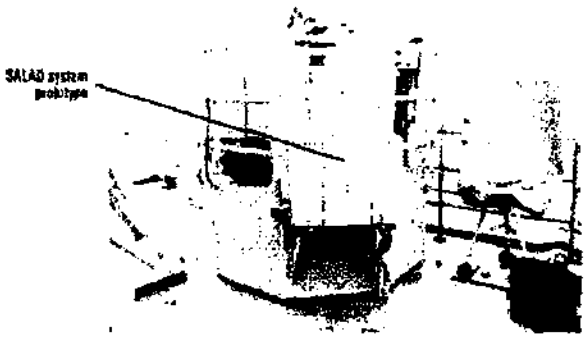
Rationale:

- Navy service-unique requirement

Key Requirements:

- Automatic detection of liquid chemical agents
- Operated/maintained by ship's force
- Operate in a shipboard environment and detect while the ship is underway

Description:



SALAD is an exterior, liquid agent point detection and monitoring system that will detect and alarm in the presence of liquid nerve and blister agents. It consists of a detector unit that uses chemically treated paper, optical scanners, a central processing unit, and alarms (visual and audible) on the bridge and Damage Control Central. Production units will be contracted for based on a performance specification.

Force Medical Protection/Dosimeter ACTD

Rationale:

- Supports Joint Forces Command (JFCOM)

Key Requirements:

- Develop an individually worn sampler that can continuously measure and archive exposure levels of chemical and biological warfare agents using passive sampling methodology (Phase I)
- Include real-time analysis, an alarm to warn the wearer of an immediate chemical hazard, and a trap for biological agents for later analysis (Phase II)

Description:

The Force Medical Protection Dosimeter will be an individually worn sampler that can continuously measure and archive exposure levels of chemical and biological warfare agents. The Phase I of the development will emphasize collection and archiving of exposure to chemical agents using passive sampling methodology. Phase II will include real-time analysis, an alarm to warn the wearer of an immediate chemical hazard, and will trap biological pathogens for later analysis.

Improved detection and identification capabilities will provide greater awareness of immediate chemical exposure risk, more precise identification of exposure, and amount of individual or multiple doses, which will result in improved situational awareness, treatment, and record keeping. Additional payoffs will include the ability to perform real-time analysis of agents, communication of exposure information to command centers, and increased battlefield awareness and intelligence.

Specific challenges include developing technologies to collect, analyze, and differentiate between agents, interferents, and naturally occurring compounds; improving selectivity and sensitivity to agents. Providing communications capabilities and real-time alarm while reducing size and weight will require advances in sampling methods, chemical analysis techniques, and electronics. Developing CONOPs for use of a sampler will require modeling, experimentation, field testing to improve capabilities and increase utility, and analysis to determine value of information of exposure data collected, especially if exposure levels are below threshold effects levels.

Key Milestones:

2000: Technical evaluations of Phase II candidate technologies and select technologies for integration into the Phase II sampler. Conduct laboratory testing of Phase I technologies. Begin demonstrations to assess sampler's ability to deal with operational issues identified by Joint Forces Command and other federal partners.

2001: Conduct laboratory testing of Phase II technologies. Continue demonstrations to assess sampler's ability to deal with operational issues identified by Joint Forces Command and other federal partners.

2002: Deliver residual capability to selected units for further user testing and development. Complete ACTD.

BIOLOGICAL LONG LINE SOURCE RELEASE AND POINT DETECTION

Biological Point Detection is a fully cooperative acquisition effort chartered to develop new biological point detectors and detection systems for the four services. The BIDS P3I effort encompasses development of an integrated system as well as several stand-alone biological detectors. In addition, a Joint Biological Point Detection System (JBPDS) is under development. JBPDS will be a system that can stand alone, or be used in a suite of systems.

Air Base/Port Biological Detection (Portal Shield) Advanced Concept Technology Demonstration (ACTD)

Rationale:

- Requirements identified by the Commander-in-Chief Central Command (CINCCENT) and Commander-in-Chief Pacific Command (CINCPAC)

Key Requirements:

- Field interim systems to sponsoring CINCs that provides rapid, automated biological attack detection, identification and warning (in less than 25 minutes) to high value fixed sites (*e.g.*, ports and airfields)
- Automated "smart" sensor network
- Chemical sensor interfaces for automated biological and chemical network warning and reporting
- In addition to the biological detection system itself, provide the following "leave-behinds" or "residuals" to the fixed sites: an integrated command and control system to assist base personnel in rapid assessment, warning and dissemination of attack data;

unmasking procedures; contamination detection sampling kits, tested tactics, techniques and procedures.

- Demonstrate the military utility of a smart sensor network and exercise operational concepts that may both fill the CINCs immediate needs, and provide valuable "lessons learned" for future systems

Description:

While the BIDS and Long Range Biological Detection System (LR-BSDS) programs have made significant advances towards mitigating the effects of the worst case biological attack scenario (long line source releases—*e.g.*, an aircraft spraying agent along a course tens of kilometers long), DoD still has potential vulnerabilities in protecting those high value fixed sites that will play critical roles in force projection operations. Ports and air-bases, by nature of their commonly known locations and high density of personnel, make lucrative targets for point source releases (*e.g.*, theater ballistic missiles, covert spraying by land and sea vehicles, or even man-portable disseminators). JPO-BD proposed taking available technologies and, through an ACTD, provide a limited number of biological detection systems to warfighting CINCs. The concept has been to build an intelligent network of sensors based on the Navy's IBAD components, but add to each sensor an automated immunoassay ticket reader for near real time identification of BW agents, location and meteorology modules and "smart" network algorithms to reduce use of consumables and lower false positive rates. The detector network is able to identify 8 biological warfare agents in less than 25 minutes. Site personnel are then able to retrieve samples of the aerosol from the sensors for confirmatory identification of the BW agent. The ACTD will not only provide detection and identification hardware and procedures, it will also provide leave-behinds for post attack actions, such as: contamination detection sampling kits that can provide BW identification of contaminated surfaces such as missile fragments, in 15 minutes; and Enzyme Linked ImmunoSorbent Assay (ELISA) kits for an additional complementary identification capability. User acceptance testing was completed in September 1997. The prototype Mark II network was successfully deployed to Kuwait in support of Operation Desert Thunder in February 1998. Full scale deployment of the ACTD to CENTCOM and PACOM began in 2QFY99. The Joint Chiefs of Staff (JCS) directed the production of five additional Portal Shield networks starting in FY99 and funded their fabrication and support through FY02. PDM1 provided funding for an additional 14 sites in FY01.

Joint Biological Point Detection System (JBPDS)

Rationale:

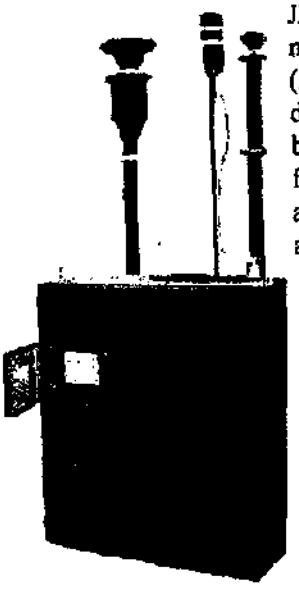
- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Automatically detect, identify and warn of the presence of aerosolized biological warfare agents at levels of sensitivity, speed and reliability equal to or better than currently fielded detection systems
- Provide a common suite of biological detection equipment that can be applied to all four services' designated platforms
- Provide a man-portable version (Air Force and Marine Corps)

- Be operable while on the move (Army and Navy)

Description:



JBPDS is a joint biological point detection system. This developmental system will replace all existing biological detection systems (BIDS, IBAD and Air Base/Port ACTD), and provide biological detection capabilities throughout the services and throughout the battlespace. The common biological detection suite will consist of four functions: *trigger* (detects a significant change in the ambient aerosol in real time), *collector* (collects samples of the suspect aerosol for analysis by the JBPDS, and for confirmatory analysis by supporting laboratories in the Communications Zone and CONUS), *detector* (able to broadly categorize the contents of the aerosol and lend confidence to the detection process; *e.g.*, biological material in the aerosol or not, bacteriological, spore, protein, *etc.*), and *identification* (provides presumptive identification of the suspect BW agent and increases confidence in the detection process). These four functions will be integrated to allow fully automatic operation, and warning of a positive BW detection. The JBPDS program consists of two phases (Block I and Block II) to allow the fastest possible fielding of a joint biological detection system, while at the same time preparing to take advantage of the rapid advances taking place in the biological detection/identification, information processing and engineering sciences. JPO-BD awarded an Engineering and Manufacturing Development (EMD) contract in FY97 for the development of Block I JBPDS prototypes for all four services. Production is anticipated to start in 4QFY00, with first unit equipped in March 2002. This joint acquisition strategy will allow for significant economies throughout the RDA process by eliminating duplicative efforts among the services, and greater logistic supportability in joint operations as each service will be able to support the other services' JBPDSs.

Critical Reagents Program (CRP)

Rationale:

- Supports all Services biological detection programs

Key Requirements:

- Provide Total Life Cycle Management for the critical reagents (antibodies, and gene probes and primers) that are necessary to the operation of nearly all DoD biological detection systems.
- Ensure best quality reagents are available in time and in adequate quantities.
- Ensure adequate security and surge capability of critical reagents.
- Put in place a production program for the Handheld Immunochromatographic Assays (HHAs) (*shown*) that are critical to several bio detection programs.

Description:

The Critical Reagents Program will ensure the quality and availability of reagents that are critical to the successful development, test and operation of biological warfare detection systems and medical biological products managed by JPO-BD. The program will maintain an R&D effort to ensure the best possible reagents are available for use against both current and future threats. The program will institute a program wide quality assurance program and address relevant security issues. During the first four years of the program, the CRP will require the greatest level of effort and funding to ensure required reagents are available to support fielded systems (BIDS NDI, P3I, Portal Shield and IBAD), and developmental systems (JBPDS Block I and JBREWS ACTD). The next three years require the development of 12 additional reagents to support the development and fielding of the JBPDS Block II. Outlying years will focus on the development of reagents to detect new and emerging threats and procurement of more effective reagents to replace older stocks.

Small Unit Biological Detector (SUBD)

Rationale:

- Marine Corps service-unique requirement

Key Requirements:

- Low power, portable biological detector tailored to the unique requirements of the Chem/Bio Incident Response Force (CBIRF)
- Include an aerosol collector and an identifier
- Weigh less than 80 lbs, occupy less than 2.5 cubic feet, and require less than 150 Watts of power
- Automatically identify 12 BW agents within 20 minutes and meet or exceed the detection sensitivity of JBPDS

Description:

SUBD will be a low power, portable biological detector to respond to the growing threat of military and terrorist biological attack. The development uses the JBPDS Performance Specification tailored to the unique requirements of the CBIRF. Other biodetection programs such as Portal Shield and JBPDS utilize mature, low risk identification technology, while SUBD is developing second generation technology that will be smaller with more reusable components. The SUBD technology will achieve the same sensitivities as JBPDS but in a smaller, lower power, truly man-portable package with fewer consumables. SUBD technologies may result in technology enhancements for the JBPDS Block II program.

Improved detection and identification capabilities will provide greater awareness of immediate biological agent exposure risk, more precise identification of exposure, and amount of individual or multiple doses which will result in improved situational awareness, treatment and record keeping. Additional payoffs will include the ability to perform real-time analysis of agents, communication of exposure information to command centers, and increased battlefield awareness and intelligence.

Specific challenges include developing technologies to collect and identify agents with an instrument that can be ruggedized for field-use and offer a short response time (<20

minutes). (Laboratory techniques exist but are not portable nor are they suitable for fielding.) Identifier and collector component development and system integration will take place in 2000. Prototype SUBD development will begin in 2001.

STAND-OFF DETECTION AND REMOTE/EARLY WARNING

Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD)

The JSLSCAD is a fully coordinated joint service RDTE program, chartered to develop a lightweight standoff chemical detector for the four services. The JSLSCAD will utilize a passive infrared sensor with 360° scanning to satisfy requirements for:

Lightweight Standoff Chemical Agent Detector (LSCAD)
M21 Moving Background
Chemical Agent Remote Detection System (CARDS)
Stand-off Detector for Armored System Modernization (SD/ASM)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement. (Army is lead Service)

Key Requirements:

- Automatically detect nerve, blister, and blood agents at a distance up to 5 km
- Lightweight and employed from manned and unmanned systems
- Capable of being data-linked with centralized hazard information data collection center
- Capable of remote operations; aerial and on-the-move operation

Description:

SCANNER

INTERFEROMETER

JSLSCAD will be capable of scanning 360° x 60°, and automatically detecting nerve or blister agents at a distance up to 5 km. The system will be light, compact and operate from a stationary position or on-the-move. The JSLSCAD Michelson interferometer employs a passive infrared system that will detect presence of chemical agents by completing a spectral analysis of target vapor agent chemical clouds. JSLSCAD is envisioned for employment on various platforms and in various roles, including fixed site defense, unmanned aerial vehicles, tanks and other vehicles, and on board ships.

Joint Service Warning and Identification LIDAR Detector (JSWILD)

JSWILD is a joint effort chartered to develop a chemical warning and identification system for the quad-services. JSWILD will utilize an active LIDAR sensor to perform rapid agent identification and ranging to satisfy requirement for:

Laser Stand-Off Chemical Detector (LSCD)
Area Detection System (ADS)
Stand-off Detector (SD)
CB Stand-off Detector (CBSD)

Rationale:

- Army and Air Force interest

Key Requirements:

- Automatically detect, range, and map CW agents at distances of up to 20 km
- Scan atmosphere and terrain to detect chemical vapors and airborne liquids and particles
- Provide stand-off capability for both fixed site and reconnaissance
- Provide rapid agent concentration mapping

Description:

JSWILD will be a lightweight, vehicle-mountable, contamination monitoring system, which detects and quantifies all types of chemical agent contamination (including agent rain, vapors, and aerosols) in a stand-off mode from a distance of 20 kilometers (km). The JSWILD will operate from fixed sites and ground vehicles. The system has distance-ranging and contamination-mapping capabilities and transmits this information to a battlefield information network.

Biological Remote/Early Warning

The Army's Long Range Biological Standoff Detection System (LR-BSDS) is a legacy system that is being incorporated into what is envisioned to be a family of early warning systems

The Joint Biological Remote Early Warning System (JBREWS) program is intended to give the warfighting commander a significantly shortened decision cycle regarding biological attacks; that is, the commander will see and be able to react to a biological attack much faster, thereby allowing many more personnel to take protective measures before they become exposed to the biological warfare agents. This means that fewer people will become casualties, and fewer people will have to take post-attack medical treatments.

Long Range Biological Standoff Detection System (LR-BSDS) P3I

Rationale:

- Army requirement
- Navy and Air Force interest

Key Requirements:

- Stand-off detection of aerosol clouds out to a range of at least 50 km
- Provides relative concentration, range, location, and tracking of aerosol clouds
- Automated cloud discrimination
- Operating crew reduced to one operator
- UH-60 helicopter-mounted

Description:

LRBSDS uses infrared light detection and ranging (IR-LIDAR) technology to detect, range and track aerosol clouds that are indicative of a BW attack; the LR-BSDS cannot discriminate biological from non-biological clouds. The system, which is approximately 1,240 pounds and 2.3 cubic meters, has three major components: a diode pulsed IR laser transmitter operating at IR wavelengths; a receiver and telescope; and an information processor and display. This program, like BIDS, has been designed in two phases; an NDI phase designed to rapidly field an interim capability, and a pre-planned product improvement (P3I) phase. Three NDI LR-BSDSs have already been fielded to the 310th Chemical Company (USAR). A total of 10 LR-BSDS P3I systems will be procured from FY00 to FY02 (3 per company with 1 training system). The NDI system is able to detect and track man-made aerosols out to 30 km, but is non-eyesafe out to about 2.5 km. The P3I LR-BSDS will be eyesafe, will have a longer operating range (50 km), and will be easier to operate. The first P3I LR-BSDSs will be fielded to the 7th Chemical Company (Biological Detection) in 1QFY01.

The Joint Program Office for Biological Defense is leveraging the benefits of the ACTD program to greatly accelerate the development of the next generation of remote/early warning systems (i.e., systems other than the LR-BSDS). This new generation of detectors is referred to as the Joint Biological Remote/Early Warning System (JBREWS). JPO-BD is managing a JBREWS ACTD that will address selected CINCs' needs, and will better refine our requirements and concepts regarding remote/early warning systems.

Joint Biological Remote Early Warning System (JBREWS)

Rationale:

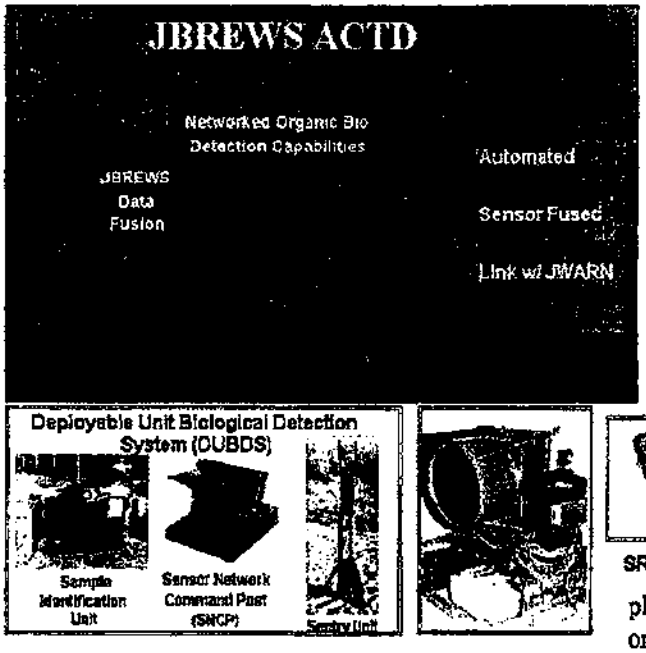
- EUCOM requirement (ACTD)
- All services interest (ACTD and objective system)

Key Requirements:

- JPO-BD is sponsoring a series of concept studies, including a Study Advisory Group (SAG) composed of CINC, Service, and Joint NBC Defense Board representatives. This cooperative effort will define the requirements for the JBREWS ACTD

- The ACTD formally started in FY98, with fielding of ACTD systems to the EUCOM CINC sponsor around FY01
- Lessons learned from the JBREWS ACTD will assist the SAG in developing/refining its requirements document for the JBREWS objective system
- JBREWS objective system is expected to start fielding around FY05

Description:



JBREWS is planned to become a "system of systems." That is, it may have legacy systems—BIDS, JBPDS, and standoff LIDAR systems such as the LR-BSDS—integrated with short range biological standoff detection systems (SR-BSDS) and dense arrays of miniaturized, rugged point detectors into a distributed network of sensors. The miniature sensors will possess only one or two of the functions that the much more robust JBPDS will have. The point detectors may be employed in a variety of ways: carried on vehicles, emplaced by hand around unit/site perimeters, remotely emplaced by aircraft, or possibly even delivered by artillery or rocket systems to project the sensors into contested or enemy controlled areas. The systems need to be networked to provide the greatest confidence of accurate detection and rapid warning. They will need to be deployed and distributed widely and in high numbers to ensure point releases are not missed.

NBC RECONNAISSANCE

Joint Service Light NBC Reconnaissance System (JSLNBCRS)

The Joint Service NBC Reconnaissance program is a coordinated U.S. Army, U.S. Air Force and Marine Corps effort which will yield improved reconnaissance capabilities for both heavy and lightweight vehicle platforms. It will satisfy requirements for:

M93A1 NBC Reconnaissance System (NBCRS) Production
M93A1 P3I Block II
Light NBC Reconnaissance System (LNBCRS)

Rationale:

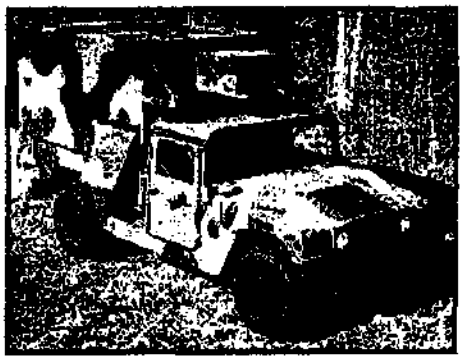
- Joint U.S. Army, U.S. Air Force, and Marine Corps Requirements

Key Requirements:

- Stand-off and point detection from vehicle mounted or dismounted operations
- Chemical standoff detection
- Detection while on-the-move capability from speeds of 0-45 kph
- Biological point detection and identification
- A dismountable, handheld, self-contained chemical point detection capability
- Radiological detection capability (vehicle mounted or dismounted operations)
- Collective protection
- Environmental Conditioning Unit capable of providing climate conditioning for the crew and equipment
- Overpressure protection from all known agents

Description:

The JSLNBCRS (*shown*) will provide a premiere vehicle for accurate, rapid NBC combat hazard information by verifying the absence of, finding, mapping, and marking radiological, biological, and chemical hazards. The JSLNBCRS will be an integration of advanced NBC detection and analysis equipment suited for Marine Air-Ground Task Forces (MAGTFs), U.S. Air Force tactical forces, and U.S. Army Light Contingency Forces.



WARNING AND REPORTING

Joint Service Warning and Reporting Network (JWARN) (FUE FY 99)

Rationale:

- Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Capable of interfacing with all NBC detectors and sensors
- Capable of interoperability with all service command and control systems
- Capable of generating NBC reports
- Capable of automatic transmission of NBC alarm and data
- Capable of vehicle operation

Description:

The Joint Warning and Reporting Network (JWARN) is an automated Nuclear, Biological, and Chemical (NBC) Information System. The JWARN will be essential for integrating the data from NBC detectors and sensors into the Joint Service Command, Control, Communication, Computers, Information and intelligence (C^4I^2) systems and

networks in the digitized battlefield. JWARN will provide the Joint Force a comprehensive analysis and response capability to minimize the effects of hostile NBC attacks or accidents/incidents. JWARN will also provide the Joint Forces with the operational capability to employ NBC warning technology that will collect, analyze, identify, locate, report and disseminate NBC threat and hazard information. JWARN will be located in command and control centers at the appropriate level defined in Service-specific annexes and employed by NBC defense specialists and other designated personnel. It will transfer data automatically from and to the actual detector/sensor/network node and provide commanders with analyzed data for decisions for disseminating warnings to the lowest echelons on the battlefield. It will provide additional data processing, production of plans and reports, and access to specific NBC information to improve the efficiency of NBC personnel assets.

DARPA Programs

Tissue-Based Biosensors Program

Accomplishments:

- B-cell sensor prototype system fabricated and tested. Simulant detection down to 200 particles in solution reported.
- Engineered liver and vascular endothelial cells into chip format. Genetically induced fluorescent reporter elements for cell stress into liver cells for detector system.
- Used green fluorescent protein to optically tag transcriptional upregulation cellular events (NFkB) for FLUORO-tox prototype high throughput cell sensor system
- Initiated fluorotox database for data mining cell responses to unknown pathogens.
- Demonstrated 4 order magnitude increase in cell survival by introducing extremophile genes into labile cells.
- Defined mechanism of action of operational neurotoxicants from engine lubricant in neuronal based hand held biosensors.

Description:

DARPA is exploring the use of biological cells and tissues as detector components for sensor devices that will rport on chemical and biological toxins. Cells and tissues can be used to report on the functional consequences of exposure (mechanism and activity) to a wide spectrum of chemical and or biological toxins, whether they are living or dead, or whether they have been bioengineered and are currently undetectable by other means (antibodies, nucleic acid sequencing). Technical issues that are being addressed in the program include, (1) the fabrication of biocompatible matrices and interfaces for the long-term retention of cell and tissue function, (2) pattern recognition from critical pathways responsible for the interfaces for the long-term retention of cell and tissue function, (2) pattern recognition from critical pathways responsible for the processing of toxins, (3) sampling strategies to accurately extract and present the toxin from air, liquid, or solid samples, and (4) systems integration into a functional device. The current focus of the program is on the use of neuronal and immunological cells and tissues as detectors for such devices. Engineering of cells and tissues of these origins, including stem cells, is

proceeding in order to optimize sensor performance requirements and fabricate prototype devices for testing evaluation.

Microfluidic Molecular Systems Program

Accomplishments:

- Demonstrated discrimination of 0.4% differences in cell impedance using micromachined dielectrophoreses system
- Demonstrated on-chip circulation—controlled transport of target liquids throught combination of integrated fluidic channels and reaction components
- Demonstrated microscale enabled immunoassay with enzyme labelers to replace conventional optical label
- Demonstrated microfan and filter system to capture airborne particulates into liquid for input to detection system
- Demonstrated efficient transport of DNA over cm distances using eletrophoretic confinement and transport through electrophoretic vias
- Demonstrated a multi-channel device that is able to carry out six independent assays simultaneously using a single point detector.

Description:

Micro total analysis systems are being developed through focused research on microfluidic, chip-scale technologies. Automated sample collection and sample preparation are key front-end processes for early biological agent detection, whether it is by immunoassays, DNA assays, or tissue-based assays. To scale down these processes into miniaturized, multiplexed detection systems, microfluidic chip-scale components need to be developed. Microfluidic components/devices currently being developed by DARPA include chip-scale micropumps/valves, particle separation filters, fluidic interconnects, fluidic manipulation of hybridized microbeads, controlled mixing/dosing etc.... Several demonstrable handheld prototypes, such as a programmable microfluidic system for remote sensors, are currently being tested.

Pathogen Genome Sequencing Program

Accomplishments:

- Initiated sequencing of the pathogenic bacteria *Brucella abortus, Brucella melitensis, Brucella suis* and their non-pathogenic near neighbor *Ochrobactrum anthrop*
- Initiated sequencing of the non-pathogen bacterium *Bacillus cereus*, the near neighbor of the pathogenic bacterium *Bacillus anthracis*
- Initiated sequencing of the non-pathogenic near-neighbor bacterium *Yersinia pseudotuberculosis*, the near neighbor of the pathogenic bacterium *Yersinia pestis*.

Description:

DARPA is committed to sequencing the genomes of high threat biowarfare agents. This effort, undertaken with broad community interaction, will support Biological Warfare Defense research activities sponsored by DARPA and is intended to satisfy the needs of Department of Defense components, the Intelligence Community, and other governmental organizations. Interest is focused on BWD pathogens, and non-pathogenic near neighbors

thought to be important to establish a basis for low false alarm detection and identification. The work also contributes to the development of advanced unconventional pathogen countermeasures.

Protection Program

Accomplishments:

- Built first prototype of water disinfection pen (size of a thick fountain pen) based on an eletrochemical cell. The pen was able to create a mixed oxidant solution that is more potent than tablets used nowadays by the forces: the mixed oxidant pen was able to destroy many waterborne pathogens to at least 3 to 4 log removal.
- Demonstrated that harmonic pulsing of a reverse osmosis membrane increases water flux through the membrane and decreases the total dissolved solids.
- Built first prototype water distillation unit the size of a coffee mug that distills water. The distillation unit was able to desalt seawater without clogging. Tests on waterborne bugs show at least a 4 log removal. The water generation rate was measured to be approximately 0.3 liters in 5 minutes.
- Built first generation air purification unit to destroy airborne pathogens by thermocatalytic destruction. The destruction efficiencies for various air pathogens and simulants in the high 90% range. The goal is to get towards at least 99.999% removal rates.
- Began work on advanced carbon surface treatments to improve adsorption capacity and kinetics.

Description:

There are two related programs currently ongoing within DARPA that further enable the individual warfighter by providing significantly more mobile and flexible water purification and desalinization systems and better air filtration media. The intent is to demonstrate highly efficient, smaller, lighter, high water through-put technologies for water purification and desalinization, and to explore pioneering air filtration schemes that have an acutely high utility for the DoD enabling new mission scenarios that are critical to the changing battlefield environment. The water desalinization and purification systems would meet Army Operational Requirements (i.e., effectively treat salt/brackish water and nuclear, biological and chemical contaminated water, purify 0.2 liter water per minute, weigh less than 2 lbs., etc.). The proposed man-portable water units will be multifunctional in that they can be used for several functions, such as water purification, power generation and camp stoves. Work in air purification develops simple air filtration and purification systems for the individual that provide significant improvements over the current charcoal filter gas mask technology (which have remained virtually unchanged for over 20 years). The intention is to develop air purification systems for collective protection that will require much less maintenance and greater personal safety than current based-carbon recirculating filters.

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Annex B

Non-Medical Protection Programs

SECTION 1: FIELDED AND PRODUCTION ITEMS

RESPIRATORY

M17A2 Protective Mask

The M17A2 Protective Mask consists of a natural blend rubber face piece; two activated charcoal filters mounted within cheek pouches; a voicemitter to facilitate communications, a drinking tube; eyelens outserts to protect the mask's integral eyelens and reduce cold weather fogging; an impermeable hood; and a carrier for the mask, its components, and medical items (such as the Nerve Agent Antidote Kit). The Army and Marine Corps are replacing this mask with the M40 series protective masks. The Navy has replaced the M17A2 protective mask with the MCU-2/P. The Air Force replaced it with the MCU-2A/P, but retained limited quantities of extra small M17A2s for those situations where the MCU-2A/P short is too large.

ABC-M24 Aircraft Protective Mask

This protective mask provides the wearer protection from NBC aerosols/vapors both in aircraft, and on the ground. The mask consists of: wide view, clear plastic lens embedded in a butyl rubber face blank; an integral microphone; eyelens outserts; carrying case; anti-fog kit; and a hose-mounted filter canister. The mask has a microphone connection to fit the aircraft communications systems. The M24 has an adapter that allows coupling to the aircraft's oxygen supply system. The M24 is being replaced by the M45 mask.

M25A1 Tank Protective Mask

This protective mask provides the wearer protection from NBC aerosols and vapors both in the vehicle/aircraft, and on the ground. The mask consists of: wide view, clear plastic lens embedded in a butyl rubber face blank; an integral microphone; eyelens outserts; carrying case; anti-fog kit; and a hose mounted filter canister. The mask has a microphone connection to fit the armored vehicle communications systems. The M25A1 has an adapter that allows it to be coupled to the tank's filtered and temperature controlled Gas Particulate Filtration Unit (GPFU). The M25A1 is being replaced by the M42/M42A1/M42A2 protective mask.

MCU-2A/P Protective Mask

The MCU-2A/P provides eye and respiratory protection from all chemical and biological agents as well as radioactive particulate material. The mask uses a replaceable, standard NATO filter canister which is mounted on either side of a wide-view optical quality visor. The mask provides improved fit, comfort, and visibility relative to earlier masks, and includes a drinking tube for attachment to the standard canteen, and electronic voicemitter connections for improved communications.

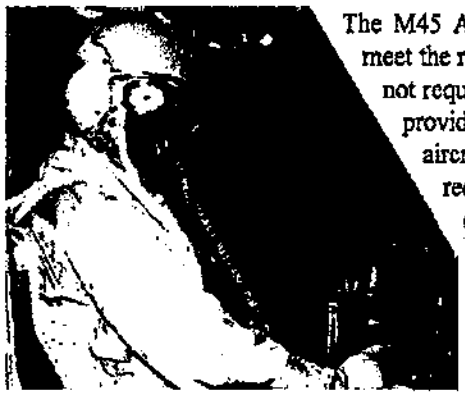
M40/42 Series Protective Mask

The M40/42 series protective masks provide eye-respiratory face protection from tactical concentrations of CB warfare agents, toxins and radioactive fallout particles. Each mask consists of a silicone rubber face piece with an in-turned peripheral face seal and binocular rigid lens system. The facepiece is covered with a chlorobutyl/EPDM second skin to provide optimum liquid agent protection for the masks. It accommodates NATO standard canisters, which can be worn on either cheek of the mask. The M40 series is designed for the individual dismounted ground warrior, while the M42 series is designed for combat vehicle crewmen. Recent improvements include a universal second skin, making the mask compatible with JSLIST and Saratoga overgarments, and ballistic/laser protective eye lens outserts. The mask facepiece has been made a spare part, which has resulted in a significant operation and support cost savings. Use of modular parts permits the M40 series to be used in both the M40 and M42 configuration. This has resulted in significant operational and support cost savings.

M43 Protective Mask

The M43 Aviator Mask consists of a form-fitting face piece with lenses mounted close to the eyes; an integral CB hood and skull-type suspension system; an inhalation air distribution assembly for air flow regulation, lenses and hood; and a portable motor/blower filter assembly that operates on either battery or aircraft power. The M43 Type I was developed for the AH-64 aviator and is compatible with the AH-64 Integrated Helmet and Display Sight System and the Optical Relay Tube. The M43 Type II is intended for the general aviator.

M45 Aircrew Protective Mask (ACPM) (FUE FY98)



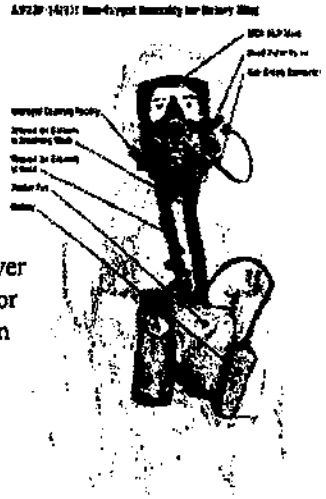
The M45 Air Crew Protective Mask is specially designed to meet the requirements of helicopter and special crews. It does not require power or forced air to provide CB protection; it provides compatibility with helicopter optical systems, aircraft displays and night vision devices; and has reduced weight, cost and logistical burden when compared to the M48 series of mask. The ACPM has close fitting eyelenses mounted in a silicone rubber facepiece with an in-turned peripheral seal, a detachable hood system, and utilizes the standard NATO canister. The M45 will replace the M43 (Type II) and the M24 aviators mask.

M48 Protective Mask - Production

The M48 is the third generation M43 series masks. The M48 mask replaces the M43 Type I mask and will be the only mask for the Apache aviator for the foreseeable future. The M48 mask consist of a lightweight motor blower, a new hose assembly, a web belt, the mask carrier, facepiece carrier, eyelens cushions, and the facepiece of the M43A1.

Aircrew Eye/Respiratory Protection (AERP)

The AERP (replaces the MBU-13/P system for aircrews) is a protective mask which enables aircrews to conduct mission operations in a chemical-biological environment. The AERP system includes a protective hood assembly with a standard MBU-12/P mask, an intercom for ground communication, and a blower assembly that provides de-misting. The blower is stowed during flight operations on a bracket that is mounted inside the aircraft.

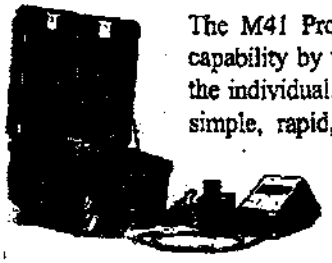


CB Respiratory System (A/P22P-14(V) 1, 2, 3, & 4) NDI

The CB Respiratory System is a self-contained protective ensemble designed for all forward deployed rotary wing (Version 1 for USN) and fixed wing (Version 2-4 for USN and USMC) aircrew. The design incorporates a CB filter, dual air/oxygen supply and a cross-over manifold with ground flight selector switch to provide filtered air for hood ventilation, and filtered air for oxygen for breathing. The system provides enhanced protection and offer anti-drown features.

ANCILLARY MASK EQUIPMENT

M41 Protection Assessment Test System



The M41 Protection Assessment Test System (PATS) enhances operational capability by validating proper fit of the mask to the face of the individual. The PATS is a new capability that provides a simple, rapid, and accurate means of validating the face piece fit and function of protective masks.

Voice Communication Adapter

The Voice Communication Adapter (VCA) is a low risk program providing additional capability to the M40/42 mask. The VCA is a joint program between the USMC and US Army.

Universal Second Skin

The Universal Second Skin is one of the components of a pre-planned product improvement (P3I) in the M40/M42 series mask. The Universal second skin provides liquid agent protection for the mask faceblank material. This program is a Joint U.S. Army/U.S. Marine Corps effort. Both Services developed prototype designs and, after field user and human engineer testing, the Marine Corps design was selected. The Air Force is developing a second skin for the MCU-2A/P.

BATTLEFIELD PROTECTIVE SUITS

Battle Dress Overgarment (BDO)

The BDO is a camouflage patterned (desert or woodland), two piece, air permeable overgarment typically worn over the duty uniform. The overgarment material consists of an outer layer of nylon cotton, and an inner layer of activated charcoal impregnated polyurethane foam. The BDO provides protection against chemical agent vapors and liquid droplets, biological agents (to include toxins), and radioactive alpha and beta particles. The BDO is issued in a sealed vapor-barrier bag that protects the garment from rain, moisture and sunlight. The BDO provides 24 hours of chemical agent protection once contaminated and has a field durability of 22 days (extendable to 30 days at the discretion of Field Commanders).

JSLIST Overgarment

The JSLIST Overgarment will provide 24 hour protection after 45 days of wear and 6 launderings. The liner currently is based upon activated carbon bead technology, replacing the bulky activated carbon foam technology in previous garments. The JSLIST Overgarment is a two-piece jacket and trouser design with an integrated hood compatible with respective Service masks and second skins. It will be worn as an overgarment for the duty uniform or as a primary garment over underwear depending upon the environment and mission.

Chemical Protective (CP) Suit, OG MK-III (Navy Suit)

The Chemical Protective Overgarment (CPO) protects the wearer against all known chemical and biological agents which present a percutaneous hazard. The suit consists of a smock and separate pair of trousers, and is sized to accommodate the 5 percentile female through the 95 percent male ratio. This garment will be replaced Navy-wide by a superior suit developed under the auspices of the Joint Service Lightweight Integrated Suit Technology (JSLIST) program. The Mark III chemical, biological, radiological (CBR) suit protects against chemical agent vapors, aerosols, droplets of liquid, and biological agents.

CP Suit, Saratoga (USMC)

Like the BDO, the SARATOGA CP Suit is an air permeable, camouflage patterned overgarment. Instead of carbon impregnated foam, SARATOGA uses spherical, activated carbon adsorbers immobilized in the liner fabric. This system allows for a lighter, cooler garment, which is launderable. The Saratoga provides a 24 hour protection period and has a durability of 30 days continuous wear.

CWU-66/P Aircrew Ensemble - Production (FUE FY96)

The CWU-66/P, a one-piece flightsuit configuration, provides 24-hour protection against standard NATO threats. It is made with Von Blucher carbon spheres, and is less bulky than prior ensembles. It offers a reduced thermal load burden and is compatible with aircrew life support equipment.

Chemical Protective Undergarment (CPU)

The CPU is a two-piece lightweight undergarment made of a non-woven fabric containing activated charcoal. When worn under the combat vehicle crewmen (CVC) coverall or battle dress uniform (BDU), the CPU provides 12 hours of protection and is durable for 15 days.

SPECIALTY SUITS

Joint Firefighter Integrated Response Ensemble (JFIRE)

JFIRE is a joint effort between the Air Force (lead agency) and the Army. The JFIRE Program has developed an ensemble that will protect the military firefighters IAW National Fire Protection Associated (NFPA) standards and provide CB protection during firefighting operations in a CB environment. JFIRE leverages the JSLIST overgarment for chemical protection, to be worn under aluminized proximity firefighting outergear and with a switchable filtered/supplied air mask with chemical warfare (CW) kit. A Commercial Off-the-Shelf (COTS) glove that can be used for both fire and CB protection will replace the need for CB gloves to be worn under standard proximity gloves. JFIRE meets several key requirements, including (1) providing 24 hours of CB agent protection against 10 g/m^2 liquid agent, (2) providing firefighters CB protection in both structural and crash fire fighting/rescue operation, (3) allowing firefighters to use mission essential tools and equipment in a CB environment, (4) providing resistance to water and all standard fire fighting chemicals (foam, CO_2, aircraft POL), and (5) is capable of being donned in 8 minutes.

Suit Contamination Avoidance Liquid Protection (SCALP)

The SCALP can be worn over standard chemical protective garments to provide 1 hour of protection from gross liquid contamination. The SCALP, which consists of a jacket with hood, trouser and booties, is made from a polyethylene-coated Tyvek™ material.

Interim-Self Contained Toxic Environment Protective Outfit (STEPO-I)

Approved as an interim system for 2-hour depot operations in Immediate Danger to Life and Health (IDLH) environments. It consists of encapsulating suit made of butyl rubber-coated nylon with a polycarbonate visor. Respiratory protection is provided by one of two options—tethered clean air supply or a self-contained rebreather worn as a back-pack. Cooling is provided by an ice vest worn underneath the suit.

Self-Contained Toxic Environment Protective Outfit (STEPO)

STEPO provides OSHA level A protection for Army Chemical Activity/Depot (CA/D), Explosive Ordnance Disposal (EOD) and Technical Escort Unit (TEU) personnel. The STEPO is a totally encapsulating protective ensemble for protection against chemical and biological agents, missile/rocket fuels, POL, and industrial chemicals for periods up to four hours. The ensemble incorporates two types of NIOSH approved self-contained breathing systems (one hour and four hour configurations) and a tether/emergency breathing apparatus option, a battery powered Personal Ice Cooling System (PICS), a hands-free communications system, and standard Toxicological Agent Protective (TAP) boots and gloves. The suit is capable of being decontaminated for reuse up to 5 times after chemical vapor exposures. STEPO shares common, modular components with the ITAP and JFIRE ensembles simplifying logistics and reducing costs.

Improved Toxicological Agent Protective (ITAP)

ITAP replaces the M3 TAP ensemble. ITAP enhances existing capabilities by increasing personal protection and reducing the thermal burden on the wearer. ITAP also provides skin and respiratory protection both during peacetime and wartime for short term operations in Immediately Dangerous to Life and Health (IDLH) toxic chemical environments (up to 1 hr), emergency life saving response, routine Chemical Activity operations and initial entry and monitoring. ITAP shares common, modular components with the STEPO and JFIRE ensembles, simplifying logistics and reducing costs.

ITAP provides splash and vapor protection against potential exposure to liquid agent when worn as a system—requirements: 10g/m^2 HD, VX, GB, L agent challenge for 1 hours. It provides an optional Personal Ice Cooling System (PICS), and is functional as a system where temperatures range from 0° to 100°F when used with the cooling system.

The ITAP suit and overhood are capable of being decontaminated for a minimum of 5 reuses, 2 hours per use (1 hour at IDLH), after vapor and particulate contamination. After liquid contamination ITAP suit will be decontaminated and held for disposal.

The ITAP fabric is self-extinguishing meeting NFPA 1991. The fabric is also static dissipative and does not hold a charge sufficient to set off munitions and explosives in accordance with current Explosive Safety Board requirements. The fabric is light in color to reduce operator solar heat load, and is capable of being stored within the temperature range of 0° to 120°F. ITAP has a minimum shelf life of 5 years.

PROTECTIVE ACCESSORIES

Green Vinyl Overboots /Black Vinyl Overboots (GVO/BVO)

The GVO/BVO are fitted vinyl overshoes that are worn over the combat boots to provide chemical agent protection and/or moisture vapor protection during wet weather. The impermeable GVO/BVO provide protection against chemical agents for 12 hours and are durable for up to 14 days.

Multipurpose Overboot (MULO) *(JSLIST Boots)*

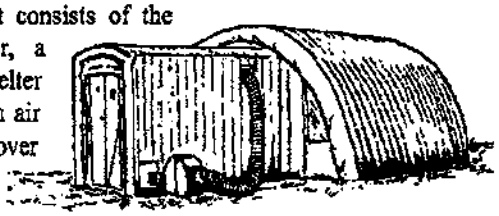
The MULO is a joint service program under the auspices of the JSLIST program and will replace the GVO/BVO. It is made of an elastomer blend and will be produced by injection molding. It is designed for wear over the combat boot, jungle boot, and intermediate cold/wet boot. The MULO provides more durability, improved traction, resistance to POLs and flame, and better donning and doffing characteristics over standard footwear.

Chemical Protective (CP) Gloves

The CP glove set consists of a butyl-rubber outer glove for protection from chemical agents, and a cotton inner glove for perspiration absorption. CP outer gloves come in three thicknesses: 7, 14, and 25 mil. The 7 mil glove is used by personnel who require a high degree of tactility, such as medical and personnel engaged in electronic equipment repair. The 14 mil glove is used by personnel like aviators and mechanics, in cases when good tactility is necessary and stress to the glove is not too harsh. The 25 mil glove is used by personnel who require a durable glove to perform close combat tasks and heavy labor. The 14 and 25 mil glove sets provide protection for at least 24 hours. The 7 mil glove set should be replaced within 6 hours of exposure to a chemical agent.

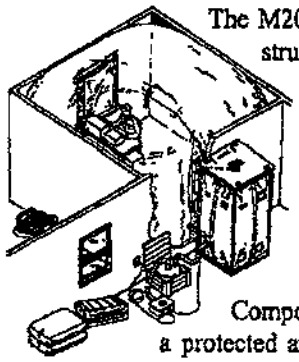
COLLECTIVE PROTECTION EQUIPMENT

M51 Protective Shelter, CB



The M51 shelter is a trailer-mounted system that consists of the following major components: a 10-man shelter, a protective entrance, and a support system. The shelter and protective entrance support themselves through air filled ribs. The protective entrance minimizes carry-over of vapor contamination from outside to inside the shelter, and paces entries to the shelter to prevent loss of shelter over-pressure. The air handling system is permanently mounted in the trailer, and provides forced, filtered, and environmentally conditioned air to the shelter. The M51 is mostly used by battalion aid stations and other medical units. It can also be used as a temporary rest and relief shelter. The M51 utilizes outdated technologies and is being replaced with CBPS. Very few M51s remain serviceable and logistically supportable. This system can be erected and employed by 4–6 personnel in approximately one hour. This system provides heat stress relief from the effects of MOPP for 12–14 personnel.

M20/ M20A1 Simplified Collective Protective Equipment



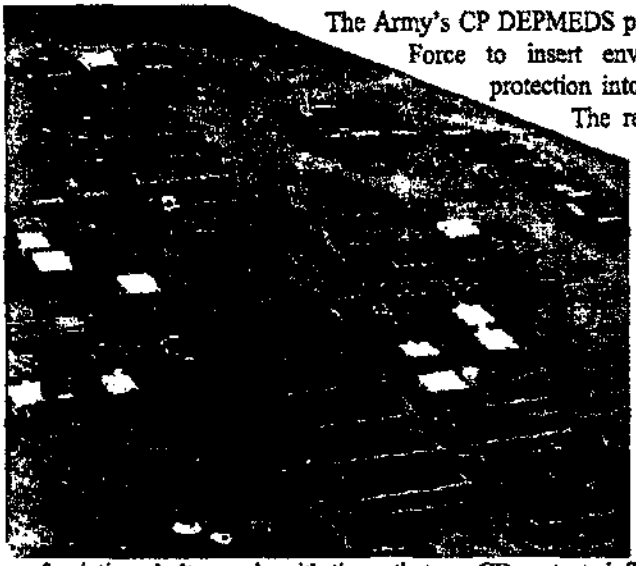
The M20/M20A1 SCPE is used to convert an interior room of an existing structure into a positive overpressure, NBC collective protection shelter where individuals can perform assigned missions without wearing the protective mask and overgarment. The system consists of a liner, protective entrance, filter canister, and support kit. The SCPE is a low cost method of transforming a room in an existing structure into an NBC collective protection shelter for command, control and communication (C^3), medical treatment, and soldier relief functions. M20A1 is a room liner for existing shelters. Components include a CB vapor resistant polyethylene liner that provides a protected area in an existing structure; a collapsible, protective entrance that allows entry to/exit from the protected area; a hermetically sealed filter canister, which provides filtered air to both the liner and the protective entrance; and a support kit, which contains ducting, lighting, sealing and repair material and an electronically powered blower.

M28 Simplified CPE (SCPE)

The M28 SCPE is a low cost method of transforming a room of an existing structure into an NBC collective protection shelter for command, control and communication (C^3), medical treatment, and soldier relief functions. M28 is a liner for the TEMPER tent. Components include a CB vapor resistant polyethylene liner that provides a protected area in an existing structure; a collapsible, protective entrance that allows entry to/exit from the protected area; a hermetically sealed filter canister, which provides filtered air to both the

liner and the protective entrance; and a support kit, which contains ducting, lighting, sealing and repair material and an electronically powered blower. A pre-planned product improvement (P^3I) program to the M28 SCPE provides liquid agent resistant liners, protective liners for tents, interconnectors, and an interface with environmental control units. The improved SCPE also allows more people to enter at one time, and protects hospitals under tents.

Chemically Protected Deployable Medical System (CP DEPMEDS) - Development/Production



The Army's CP DEPMEDS program is a joint effort with the Air Force to insert environmentally controlled collective protection into currently fielded hospital shelters. The requirement is to be able to sustain medical operation for 72 hours in a chemical contaminated environment. Environmentally-controlled collective protection is provided through the integration of M28 SCPE, chemically protected air conditioners, heaters, water distribution and latrines, and alarms systems. M28 SCPE provides protection to existing TEMPER Tents and passageways within the hospital. DEPMEDS ISO shelters are protected through the replacement of existing shelter seals with those that are CB protected. The Field Deployable Environmental Control Unit provides air conditioning and the Army Space Heater provides heating. Both environmental control units are chemically protected through the addition of a CB kit. To sustain approximately 500 patients and staff, chemically protected latrines and water distribution systems have been developed.

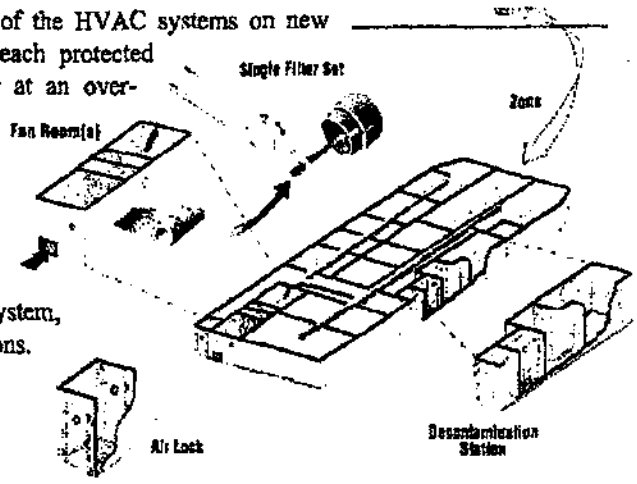
Chemically/Biologically Hardened Air Transportable Hospital (CHATH) - Production

The Air Force's CHATH program is a joint effort with the Army to enable medical personnel to deploy and setup in chemical and biological threat areas and operate in chemically and biologically active environments. CHATH allows personnel to perform their hospital duties in a Toxic Free Area. CHATH upgrades TEMPER-based Air Transportable Hospitals (ATHs) retaining the same medical equipment and personnel. CHATH uses existing and modified U.S. Army equipment to line the current ATH tents providing an airtight shelter. The Human Systems Program Office (HSC/YA) developed a Chemically/biologically Hardened Air Management Plant (CHAMP).

The CHAMP filters chemically and biologically contaminated air, and recirculates and filters interior air to maintain a clean hospital standard, provides heating, cooling, and over-pressurization to the hospital. The CHAMP can be operated from standard electrical sources or from its own internal generator. The CHAMP comes equipped with an Automatic Transfer Switch (ATS) to maintain power after Base power is shut off. The ATS starts the Diesel generator after three seconds of power interruption. The CHAMP allows the CHATH to be staged near warfighters in the field in a bare base environment. The CHATH can be deployed in increments of 10, 25, and 50 beds. This flexibility of the CHATH system helps ensure the best medical care as near the crisis area as possible. Implementation of the Aerospace Expeditionary Force concept and resulting changes in Air Force Medical Service support concept of operations during FY99 has altered plans to field CHATH systems during FY99-FY00.

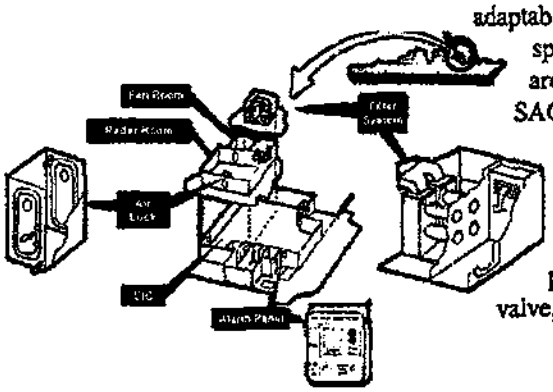
Shipboard Collective Protection System - Production

Shipboard CPS is an integral part of the HVAC systems on new construction ships. CPS provides each protected zone on the ship with filtered air at an over-pressure of 2.0 inches water gage. CPS is modular and is based on a Navy-improved version of the 200 cfm M56 filter. CPS includes filters, filter housings, high pressure fans, airlocks, pressure control valves, low pressure alarm system, and personnel decontamination stations.



Selected Area Collective Protection System - Production

Selected Area CPS (SACPS) is designed to be easily adaptable to current ships to provide selected spaces (*i.e.*, command and control, berthing areas, *etc.*) with an affordable CPS system. SACPS is modular and is based on a Navy-improved version of the 200 cfm M56 filter. SACPS is easily integrated into the ship's existing HVAC system, and includes filters, filter housings, a high pressure fan; an airlock, a pressure control valve, and a low pressure alarm system.



CB Protected Shelter (CBPS) - Production

CBPS is a highly mobile, rapidly deployable shelter system designed to be used for Echelon I and II forward area medical treatment facilities as a replacement for the M51. The system is self-contained and self-sustaining. The CBPS consists of a dedicated M1113 Expanded Capacity Vehicle (ECV), a Lightweight Multipurpose Shelter (LMS) mounted onto the vehicle, a 300 square foot airbeam supported CB protected shelter, and a High Mobility Trailer with a 10kW tactical Quiet Generator Set. The ECV and LMS transports a crew of four and their gear. All medical equipment required for the shelter is transported in the LMS or on the trailer. The CB shelter is rolled and carried on the rear of the LMS during transport. The CBPS is operational within 20 minutes with a crew of four. All power required to support operations is provided by the ECV engine or with the 10kW generator for limited power. The system is environmentally conditioned by a hydraulically powered environmental support system, which provides filtered air, heating, air conditioning, and electrical power. The system is presently in limited production with fielding scheduled to initiate in 3QFY00.

Portable Collective Protection System

The transportability and ease of use of the Portable Collective Protection System (PCPS) permit mobility and flexibility in chemically or biologically contaminated areas. PCPS can be erected by four Marines within 30 minutes wearing MOPP 4 gear. The protective shelter is divided into a main area and two smaller compartments; the entry area, and the storage area. When overpressure is applied, the protective shelter provides protection from liquid and vapor chemical and biological agent. An airlock (protective entrance) allows purging of possible chemical agent vapors and additional decontamination of personnel entering the main area.

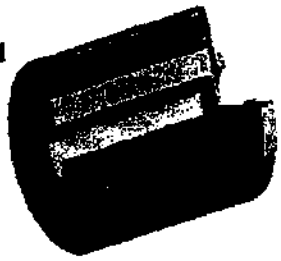
GENERIC NBC FILTERS AND COLLECTIVE PROTECTION FILTRATION SYSTEMS

Generic, high volume air flow NBC filters, and CP filtration systems exist that are currently installed on a wide variety of applications. These CP systems are modular and have been applied to numerous vehicles, vans, mobile shelters, and fixed sites.

GENERIC NBC FILTERS

NBC filters are used to remove Nuclear and Biological particulates and Chemical aerosols and vapors from the air supplied to collective protection systems.

M48/M48A1



The 100 cubic foot per minute (cfm) filter is used in the M1A1/A2 Abrams tank, M93 Modular Collective Protection Equipment (MCPE), CB Protected Shelter, and Paladin Self Propelled Howitzer.

M56

The 200 cfm filter is used as the basic filter set in the MCPE and in Naval applications. It can be stacked to obtain filtration of higher air flow rates.

600 cfm and 1200 cfm Stainless Steel Fixed Installation Gas Filters

These filters are used in fixed site applications where high volumes of air flow are required. They can be stacked to provide higher NBC filtered air flow rates. Particulate filter would be procured separately.

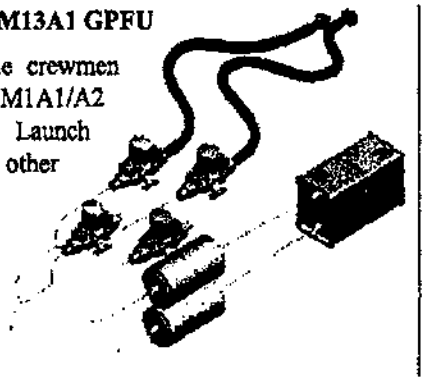
GENERIC NBC CP FILTRATION SYSTEMS

The following are modular NBC CP filtration systems which are applied to a wide variety of applications. They consist of an NBC filter, motor/blower unit, housings, and integration housings/ductwork. Some can be integrated into environmental control equipment.

M8A3 Gas Particulate Filter Unit (GPFU)

The 12 cfm system provides air to armored vehicle crewman ventilated facemasks, *i.e.*, M42A1/A2. Used in M113 Armored Personnel Carrier variants and USMC AAVP7A1 amphibious vehicle.

M13A1 GPFU



The 20 cfm system provides air to armored vehicle crewmen ventilated facemasks, *i.e.*, M42A1/A2. Used on the M1A1/A2 Abrams tanks, Bradley Fighting Vehicles, Multiple Launch Rocket System (MLRS), tank transporter, and other vehicles.

Modular Collective Protection Equipment (100, 200, 400, 600 cfm Systems)

Modular Collective Protection Equipment (MCPE) consists of a family of related end items from which modules can be chosen and combined to meet the unique demands of individual systems. These end items employ common parts and mountings and interchangeable connections and accessories to the greatest extent possible. MCPE provides collective overpressure to a wide variety of mobile shelters and vans. It uses the M48 NBC filter in the 100 cfm system and the M56 NBC filter in the others.

SECTION 2: RDTE ITEMS

INTEGRATED

Force XXI Land Warrior

Rationale:

- Army requirement
- Navy, Air Force, and Marine Corps interest

Key Requirements:

- Protection from all threats for the individual, to include NBC threats
- Integrated vision, communication, and locator systems and enhanced equipment interface

Description:

The Force XXI Land Warrior is an integrated soldier defense system that will improve the warfighter's combat system interface and ability to detect, recognize, and destroy enemy soldiers and equipment. Monitor and protection systems are integrated into a full body ensemble along with advanced locations, communications, microcomputer, and vision systems to maximize the warfighter's battlefield awareness, survivability, and lethality.

RESPIRATORY

Joint Service General Purpose Mask (JSGPM)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- 24-hour CB protection
- Lower breathing resistance
- Reduced weight and bulk

Description:

The JSGPM will be a lightweight protective mask system—consisting of mask, carrier, and accessories—incorporating state-of-the-art technology to protect U.S. forces from all future threats. The mask components will be designed to minimize it impact on the wearer's performance and to maximize its ability to interface with future Service equipment and protective clothing.

Joint Service Aviation Mask (JSAM)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Continuous CB protection
- Improved anti-G features
- Hypoxia protection up to 60,000 feet

Description:

JSAM will be a lightweight CB protective mask that can be worn as CB protection for all aircrew. With the addition of anti-G features, it can be worn as combined CB and anti-G protection for aircrews in high performance aircraft. It will be compatible with existing CB ensembles, provide flame and thermal protection, reduce heat stress imposed by current CB protective masks, and the CB portion will be capable of being donned in flight. JSAM will also be compatible with existing aircrew life support equipment.

BATTLEFIELD PROTECTIVE SUITS

Joint Service Lightweight Integrated Suit Technology (JSLIST)

The JSLIST program is a fully cooperative Joint Service RDTE effort chartered to develop new CB protective clothing for all Services. The program will yield a family of garments and ensembles, developed for Joint Service mission needs and tested to Joint Service standards. The JSLIST will provide enhanced CB protective ensembles with reduced physiological heat burden and will be generally lightweight and launderable. JSLIST is the first of a 3 phase program and supports a variety of Service suit and accessories. Previous chemical protective requirements from all Services are incorporated within the Joint ORD for JSLIST. There are five JSLIST clothing item requirements: 1) overgarment, 2) undergarment, 3) duty uniform, 4) boots and 5) gloves. Each of the Services' requirements are incorporated by these five JSLIST requirements.

In April 1997, the JSLIST program type classified the JSLIST Overgarment and Multi-purpose Overboot (MULO). The remaining items are being addressed in the JSLIST Pre-Planned Product Improvement (P3I) program, currently underway, with completion scheduled for late 1999. P3I is seeking new and advanced material candidates only. The garment design will be the JSLIST design with only minor design modifications allowed under a P3I.

Lightweight Chemical/Biological Protective Garment (LCBPG) JSLIST P3I

Rationale:

- Army and SOF requirement

Key Requirements:

- Provide 6 hours protection against 10 g/m^2 liquid; 5000 CT vapor/aerosols
- Provide 7 days field wear (minimum) in all geographical areas (launderability not required)
- Weigh no more than 4 pounds (3 pounds desired)
- Have package volume for size medium no more than 500 in^3 (300 desired)
- Reduce the physiological heat burden by at least 20% (30% desired) over that experienced when wearing the BDO.

Description:

The LCBPG is required to provide 6 hours of protection against all CB agents after moderate periods of wear. The requirement has a trade-off of wear-time and protection-time in order to achieve a lightweight, low-bulk garment for short-term, high-risk missions. The LCBPG will be a two-piece suit designed with an integrated hood compatible with the M40 mask with second skin. It will be worn as an overgarment for the duty uniform or as primary garment over underwear depending upon the environment or mission.

60-Day Overgarment JSLIST P3I

Rationale:

- Joint Army, Navy, Air Force, Marine Corps, and SOF requirement

Key Requirements:

- Provide 24 hours of protection against 10g/m^2 liquid agent, 5000 CT vapor/aerosols
- Provide 60 days field wear in all geographical areas
- Retain chemical protection after 8 launderings
- Weigh less than 4 lbs for a size medium-regular, packed garment
- Reduce physiological heat burden currently imposed by BDO

Description:

The 60-day Overgarment JSLIST P3I will provide 24 hours protection after extended wear and laundering. Liner candidates are based upon activated carbon technology (carbon beads, thin carbon foam, and others). The 60-Day Overgarment JSLIST P3I will be a two-piece design with an integrated hood compatible with the M40 mask and second skin. The 60-Day Overgarment JSLIST P3I will be worn as an overgarment for the Battle Dress Uniform (BDU), or as a primary garment over personal underwear depending upon the environment and mission.

30-Day Overgarment JSLIST P3I

Rationale:

- Air Force requirement

Key Requirements:

- Provide 24 hours protection against 10 g/m^2 liquid agent; 5000 CT vapor/aerosols
- Provide 30 days field wear (minimum) in all geographical areas
- Retain chemical protection after 4 launderings
- Weigh less than 4 lbs for a size medium-regular, packed garment
- Reduce physiological heat burden currently imposed by BDO
- Provide less than 20 percent 2nd degree burns at 2-2.5 kcal/cm^2/sec for two seconds

Description:

The 30-Day Overgarment JSLIST P3I will provide 24 hour protection after 30 days wear time and 4 launderings. Liners currently are based upon various activated carbon technologies (carbon beads, thin carbon foam and others). It will be a two-piece suit with an integrated hood compatible with the MCU-2/P mask with second skin. The 30-Day Overgarment JSLIST P3I will be worn as an overgarment for the duty uniform or as a primary garment over underwear depending upon the environment and mission.

Vapor Protective Undergarment (VPU) JSLIST P3I

Rationale:

- SOF requirement
- Army, Air Force, and Marine Corps interest

Key Requirements:

- Provide 12 hours protection (24 desired) against 10 g/m^2 liquid; 10,000 CT vapor/ aerosols
- Provide 30 days field wear (minimum) in all geographical areas
- Retain chemical protection after 4 launderings (10 desired)
- Weigh less than 3 pounds
- Reduce the physiological heat burden imposed by the CPU

Description:

The VPU will provide 12 hour protection after extended wear and laundering. It will also offer a reduction for the heat stress burden when compared to the CPU. The VPU will be a one or two-piece undergarment with an integral hood compatible with the M42 series mask.

Duty Uniform (JSLIST P3I)

Rationale:

- Marine Corps requirement
- Army, Air Force, and SOF interest

Key Requirements.

- Enhance existing capability with lighter, less thermal burdening ensemble

Description:

The Duty Uniform will be the primary NBC garment. It will be worn by all Marines, except those aircrew with special environmental or equipment interface requirements and those Marines who must deal with large volumes of liquid contamination. It will provide the wearer with protection from liquid, vapor, and aerosol hazards while reducing physiological stress.

Joint Protective Aircrew Ensemble (JPACE)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps Requirement (Navy lead)

Key Requirements:

- Provides Below-the-Neck (BTN) protection for rotary and fixed wing aircrew
- 30 day wear time
- Launderable
- Includes hand and foot protection
- Compatible with aircrew mounted aviation life support systems
- Ejection safe and water survivable

Description:

JPACE will be a chemical biological (CB) protective ensemble (including gloves and footwear) for all services' aviation communities. It will be a replacement for the Navy/Marine Corps MK-1 undergarment, Army ABDU-BDO and/or CPU system and AF CWU-66/P overgarment. Due to mission constraints and threat analysis, a separate garment may be considered for fixed wing versus rotary wing aircrew. JPACE started as a spin-off from JSLIST to address aviation specific CB requirements. Therefore, JSLIST and JSLIST P3I materials, designs, and documentation will be used to the maximum extent possible. This ensemble will be jointly tested and fielded with JSAM (Joint Service Aviation Mask) and will be used as a technical insertion to the Army Air Warrior program. JPACE will provide the fixed and rotary wing aviator with BTN protection against CB threats.

Multipurpose Protective Sock (MPS)
(JSLIST P3I)

Rationale:

- SOF requirement
- Army, Air Force, and Marine Corps interest

Key Requirements:

- Provide 12 hours of protection against $10g/m^2$ liquid agent, (5000 mg-min/m^3 vapor/aerosols if boot is made of permeable material)
- Provide 30 days field wear
- Must be comfortable, fit well and be compatible with all SOF footwear; *i.e.*, desert, jungle, assault boots, *etc.*
- Retain chemical Protection after 4 launderings

Description:

The MPS will provide 12 hours protection after extended wear and laundering when worn over the issue wool sock and under SOF footwear. The MPS must provide comfort, fit and compatibility when worn over the wool sock and under the various types of SOF footwear. The boots' composition and design will determine whether both liquid and vapor protection must be integrated into the sock material.

Improved CB Protective Glove
(JSLIST P3I)

Rationale:

- Joint Army, Air Force, and Marine Corps requirement

Key Requirements:

- Provide 24 hours protection against 10 g/m^2 liquid agent
- Provide protection against POL and standard decontaminants
- Provide self-extinguishing flame resistance
- Provide 30 days wear durability in all environments without degradation of protection
- Provide dexterity equal to or better than the standard 14 and 25 mil butyl gloves

Description:

Two candidates are being evaluated in the JSLIST P3I glove program. One is a general purpose glove for durability and the other is a high tactile glove for improved dexterity.

COLLECTIVE PROTECTION EQUIPMENT

Advanced Integrated Collective Protection System (AICPS)
for Vehicles, Vans and Shelters (VVS)

Rationale:

- Army requirement
- Marine Corps interest

Key Requirements:

- Integral NBC filtration power and environmental control for vehicles, vans and shelters
- Minimize filter changes and overall system logistics burden
- Reduced size, weight and energy requirements

Description:

The AICPS (shown mounted to an S788 Shelter on an M1097 HMMWV) is an NBC filtration system integrated with an environmental control unit and auxiliary power unit

for combat systems. It uses a deep-bed carbon vapor filter for extended gas filter life. The combined components provide overall size, weight and energy reduction, and eliminate the need for additional electrical power from the host system.

Shipboard Collective Protection Equipment

Rationale:

- Navy Service-Unique requirement

Key Requirements:

- Provide protection against chemical and biological threat agents
- Provide a minimum of three year continuous operational life
- Provide more efficient, long life filters
- Provide quieter, more efficient supply fans
- Develop methods to counter new and novel threat agents

Description:

Shipboard Collective Protection Equipment (CPE) provides a contamination-free environment within specified zone boundaries such that mission essential operations and life sustaining functions can be performed during or after a CB attack. The objective of this program is to provide Pre-Planned Product Improvements (P3I) to the current Shipboard CPS to decrease logistic costs by extending particulate filter life, reducing shipboard maintenance requirements, and providing energy-efficient fans. The program develops improvements to existing shipboard HEPA and gas adsorber filters, supports long term shipboard testing of filter improvements to develop filter life database, and provides plans for backfitting existing non-CPS ships. Shipboard CPE is being installed on selected new construction ships.

Collective Protection System (CPS) Backfit

Rationale:

- Navy Service-Unique requirement

Key Requirements:

- Provides protection to forces operating ships within a chemical/biological threat environment
- Provides plans for backfitting existing non-CPS ships

Description:

Collective protection systems use filtered air to pressurize ship zones such that specified contamination-free spaces can remain functional for mission critical and sustaining operations within a chemical/biological threat or contaminated area. CPS backfit provides a means for retrofitting existing ships with required collective protection. Only ships with significant operational life beyond the FY05 through FY10 time frame will be considered for CPS Backfit.

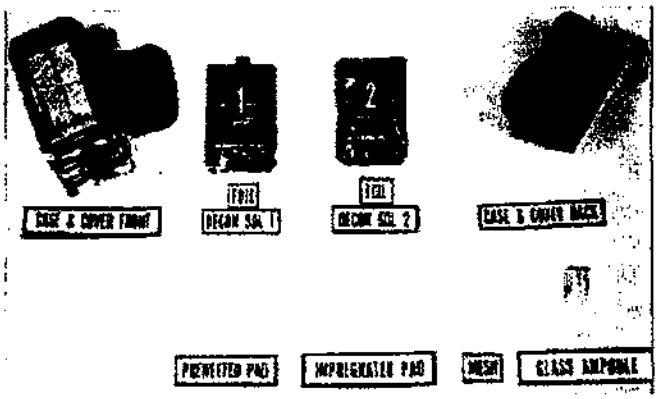
Annex C

Decontamination Programs

SECTION 1: FIELDED AND PRODUCTION ITEMS

PERSONNEL

M258A1 Skin Decontamination Kit (SDK)

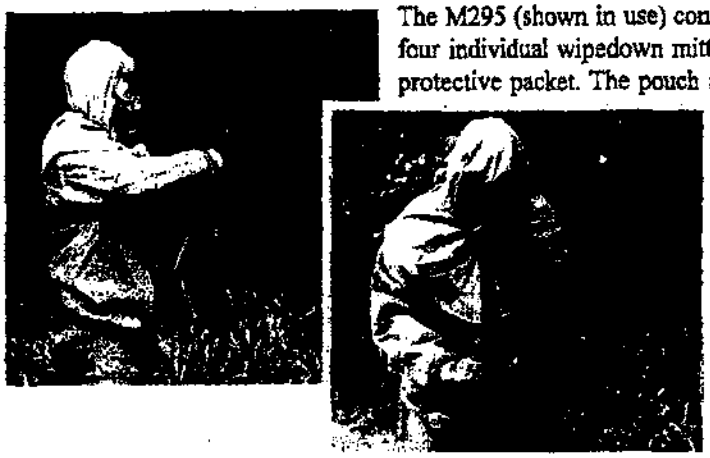


The M258A1 consists of a pocket-sized plastic case containing three sets of foil-packaged decontaminating wipes. The decontaminating sets consist of PACKET 1 containing an aqueous decon solution soaked gauze pad, and PACKET 2 containing a decon solution filled glass ampoule within a gauze pad. Personnel use the two wipes successively to remove and neutralize liquid chemical agents from their skin, clothing, personal equipment and weapons. The shelf life of the M258A1 expired in July 1999 and is replaced by the M291 skin decon kit.

M291 Skin Decontamination Kit

The M291 (shown in use) consists of a wallet-like flexible carrying pouch containing six individually sealed foil packets. Each packet contains a folded non-woven fiber applicator pad with an attached strap handle on one side. The pad contains a reactive and sorptive resin polymer mixture. The kit enables warfighters to remove, neutralize, and destroy chemical and biological warfare agents on contaminated skin. The kit is carried in a pocket of the Battle Dress Overgarment (BDO).

M295 Equipment Decontamination Kit



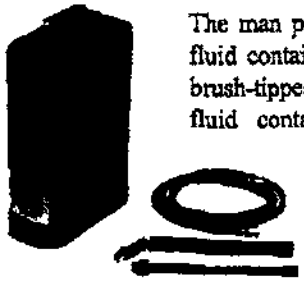
The M295 (shown in use) consists of a pouch containing four individual wipedown mitts, each enclosed in a soft, protective packet. The pouch assembly is designed to fit comfortably within the pocket of a BDO. Each wipedown mitt in the kit is comprised of adsorbent resin contained within a non-woven polyester material and a polyethylene film backing. In use, resin from the mitt is allowed to flow freely through the non-woven polyester pad material. Decontamination is accomplished through sorption of contamination by both the non-woven polyester pad and by the resin. The M295 enables the warfighter to perform basic decontamination to remove, neutralize, or destroy CB warfare agents and toxins on contaminated personal and load bearing equipment.

COMBAT EQUIPMENT, VEHICLES, AND AIRCRAFT

ABC-M11 Portable Decontaminating Apparatus

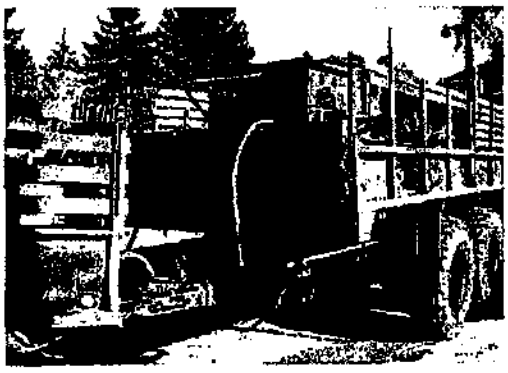
The 1-1/3 quart capacity M11 is used to spray DS2 decontaminating solution onto critical areas (*i.e.*, frequently used parts) of vehicles and crew served weapons. The M11 consists of a steel cylinder, a spray head assembly, and a small nitrogen cylinder (about 3" long). The refillable M11 can produce a spray 6 to 8 feet long, and cover an area of about 135 square feet. The M11 is currently used on tanks and other systems where the larger M13 Decontaminating Apparatus, Portable (DAP) cannot be effectively stowed.

M13 Decontaminating Apparatus, Portable (DAP)



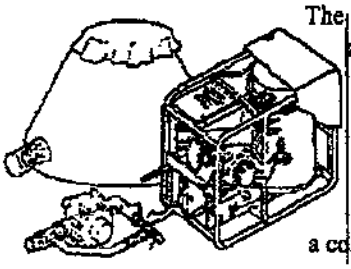
The man portable M13 consists of a vehicle mounting bracket, a pre-filled fluid container containing 14 liters of DS2 decontaminating solution, and a brush-tipped pumping handle connected to the fluid container by a hose. The fluid container and brush head are both disposable. The M13 can decontaminate 1,200 square feet per fluid container. The combination of spray pump and brush allows personnel to decontaminate hard to reach surfaces, and remove thickened agent, mud, grease and other material.

ABC-M12A1 Power Driven Decontamination Apparatus (PDDA); Skid-Mounted



The M12A1 consists of three main components: a pump unit, a 500 gallon tank unit, and a 600 gallon per hour liquid fuel water heater. The M12A1 is a flexible system that can be used for purposes such as de-icing, fire fighting with water or foam, water pumping and transport, and personnel showering in addition to equipment and area decontamination. The M12A1 can pump 50 gallons of decontaminating solution per minute through both of its hoses. The integral shower assembly provides 25 shower heads. The M12A1 is typically mounted on a 5 ton truck for tactical mobility, but can be dismounted to facilitate air transport. The USMC has replaced the M12A1 PDDA with the M17 series Lightweight Decontamination Apparatus.

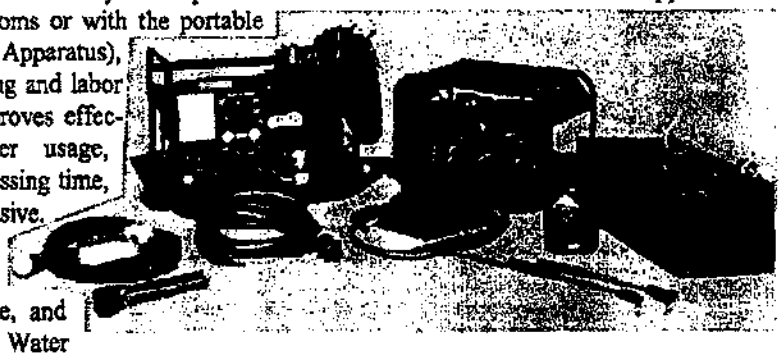
M17 Series Lightweight Decontamination Apparatus



The M17 series Lightweight Decontamination System is a portable, lightweight, compact engine driven pump and water heating system. The system is used during decontamination operations. The LDS is capable of drawing water from any source and delivering it at moderate pressure and controlled temperatures. The system has an accessory kit with hoses, spray wands, and personnel shower hardware. It also includes a collapsible water bladder.

M21/M22 Modular Decontamination System (MDS)

The MDS provides the warfighter an improved capability to perform detailed equipment decontamination on the battlefield. The system replaces current methods of decontamination application (*i.e.*, mops and brooms or with the portable M13 Decontamination Apparatus), which are time consuming and labor intensive. The MDS improves effectiveness, reduces water usage, reduces equipment processing time, and is less labor intensive. The MDS consists of an M21 decontaminant Pumper/Scrubber module, and M22 High Pressure/Hot Water module. The M22 delivers DS2 or liquid field expedient decontaminants and is capable of drawing the decontaminant directly from a container on the ground while mounted on a trailer. The M22 provides hot water up to 3000 psi at a rate of 5 gpm with the capability of high volume cold water and detergent injector. It is also capable of drawing water from natural and



urban water sources (such as fire hydrants) and delivering it at variable and adjustable pressures, temperatures and flow rates. Each module (M21 or M22) may be transported or operated from a 3/4-ton trailer towed by a M1037 High Mobility Multipurpose Wheeled Vehicle (HMMWV).

SECTION 2: RDTE ITEMS

COMBAT EQUIPMENT, VEHICLES, AND AIRCRAFT

Joint Service Sensitive Equipment Decontamination (JSSED)

Rationale:

- Joint Service requirement

Key Requirements:

- Non-aqueous based decontamination systems for sensitive equipment and vehicle interiors
- Capable of being used in both mobile and fixed-sites

Description:

Provide a first ever capability to decontaminate chemical and biological warfare agents and toxins from sensitive electronic, avionics, electro-optic equipment, and vehicle interiors. Its use must be compatible with and not degrade sensitive materials or equipment. It must be operator safe and offer protection from off-gassing and direct liquid exposure during decontamination.

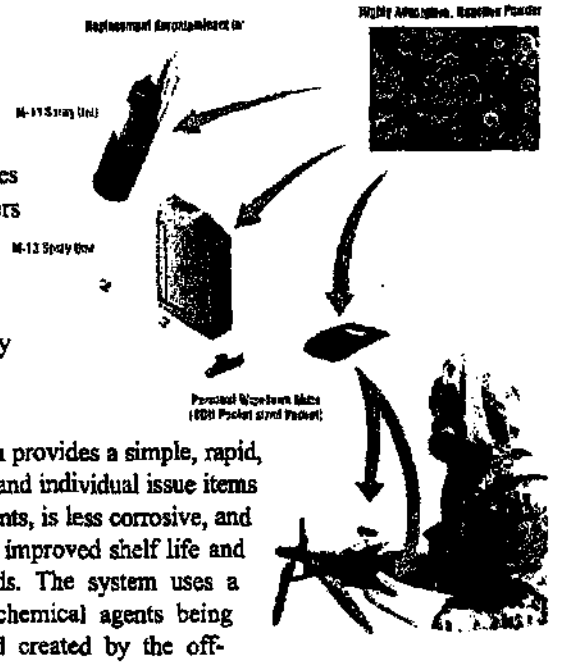
Sorbent Decontamination System

Rationale:

- Army and Marine Corps requirement

Key Requirements:

- Effectively decontaminates all CB warfare agents from contaminated surfaces
- Easy-to use and possess no hazard to users
- Non-damaging and non-corrosive to military equipment
- Environmentally safe to store
- More compatible with MOPP and military equipment than the currently used DS2



Description:

The reactive sorbent decontamination system provides a simple, rapid, and efficient system to decontaminate small and individual issue items of equipment. It is effective in all environments, is less corrosive, and presents a lowered logistics burden through improved shelf life and reduced special handling and storage needs. The system uses a catalytic component that reacts with the chemical agents being sorbed; this eliminates the potential hazard created by the off-

gassing of agents from used sorbents.

M17 Diesel Lightweight Decontamination System (LDS)

Rationale:

- Navy and Marine Corps requirement

Key Requirements:

- Be capable of operation using Military Standard (MIL STD) fuels
- Have no component which cannot be moved by a four man crew
- Be capable of decontaminating both sides of a vehicle or aircraft simultaneously
- Generate no new manpower requirements
- Decontaminate personnel, equipment, and other material without an external power source and in coordination with a water tank or natural water resource.

Description:

The Diesel LDS is a portable, lightweight, compact, engine-driven pump and multifuel-fired water heating system. The system will be capable of performing the same hasty and deliberate decontamination procedures as required of the M17 series LDS.

Joint Service Fixed Site Decontamination System

Rationale:

- Army, Air Force, and Marine Corps requirement

Key Requirements:

- Provide restoration capability at fixed site locations
- Provide improved/state-of-the-art NBC decontamination equipment
- Provide non-hazardous and environmentally safe NBC decontaminates

Description:

The Joint Service Fixed Site Decontamination program is a joint effort. The system will provide a family of decontaminants and applicators to provide the capability to decontaminate ports, airfield, and rear-area supply depots.

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Annex D

Joint Medical Chemical, Biological, and Nuclear Defense Research Programs

The joint medical chemical, biological, and nuclear (radiological) defense research programs are each addressed in the next three sections.

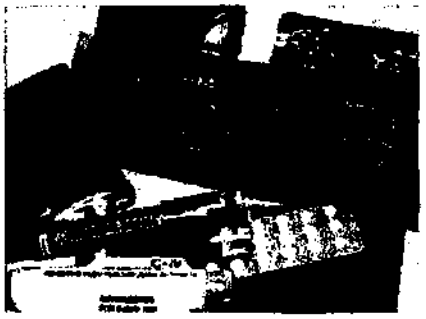
D.1 MEDICAL CHEMICAL DEFENSE RESEARCH PROGRAM

D.1.1 Fielded Products

Advances in medical research and development (R&D) significantly improve the war-fighting mission by sustaining unit effectiveness through conserving the fighting strength of our forces and supporting the nation's global military strategy, which requires the ability to effectively deploy and operate. Medical R&D products (materiel and non-materiel solutions) provide the foundation that ensures the fielding of a flexible, sustainable, modernized force across the spectrum of conflict and in the full breadth and depth of the battlefield. Overcoming medical threats and extending human performance have provided a significant increase in military effectiveness in the past and present the potential for future enhancement of military operational effectiveness. Following are fielded medical chemical defense items, including pharmaceuticals, materiel, and technical information and guidance (with initial fielding date shown.)

Pharmaceuticals:

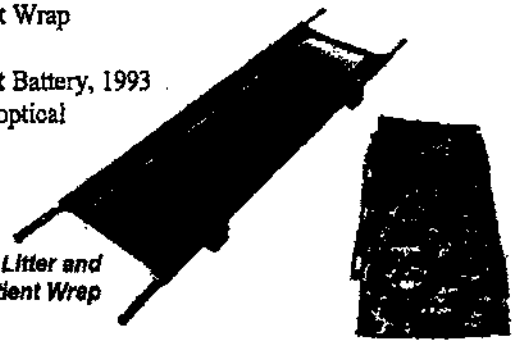
- Nerve Agent Antidote Kit (Mark I), 1983
- Skin Decontamination Kit (M291), 1990
- Nerve Agent Pretreatment (Pyridostigmine), 1987
- Convulsant Antidote for Nerve Agent (CANA), 1991
- Medical Aerosolized Nerve Agent Antidote (MANAA), 1994



MARK I, M291, Nerve Agent Pretreatment, and CANA

Materiel:

- Test Mate® ChE (Cholinesterase) Kit, 1997 (*shown*)
- Resuscitation Device, Individual, Chemical, 1990
- Decontaminable Patient Litter (NSN 6530-01-380-7309), 1991
- Chemical Warfare (CW) Protective Patient Wrap (NSN 8415-01-311-7711), 1991
- Computer-Based Performance Assessment Battery, 1993
- M40 Protective Mask Vision Correction (optical inserts)



Decontaminable Patient Litter and CW Protective Patient Wrap

Technical Information and Guidance:

- Taxonomic Work Station, 1985
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) Technical Memoranda on Chemical Casualty Care, 1990
- Field Manual (FM) 8-285, *Treatment of Chemical Agent Casualties and Conventional Military Chemical Injuries*, 1995
- Handbook, "Medical Management of Chemical Casualties," 1995
- Field Management Handbook, "Medical Management of Chemical Casualties," 1996
- Technical Bulletin (TB) Medical (MED) 296, 1996: *Assay Techniques for Detection of Exposure to Sulfur Mustard, Cholinesterase Inhibitors, Sarin, Soman, GF, and Cyanide*.
- Compact Disk - Read-Only Memory (CD-ROM) on "Management of Chemical Warfare
- *Medical Management of Chemical Casualties Handbook*, Third Edition, August 1999.

D.1.2 Medical Chemical Defense R&D Accomplishments

The medical chemical defense R&D technical barriers and accomplishments during FY98 are grouped by medical chemical defense strategies, which include the following:

- *Pretreatment*
- *Therapeutics*
- *Diagnostics*

Today's chemical threat, however, is not restricted to commonly accepted classical agents, such as vesicants [sulfur mustard (HD)], nerve agents (soman, sarin, tabun, and VX), respiratory agents (phosgene), or blood agents (cyanide). Potential adversaries may develop novel threat agents. The ability to provide timely and effective medical countermeasures to new threats depends upon maintaining a high level of technological capability. Sustaining and enhancing this technological capability is dependent upon the continued support of a robust

program investigating basic pathophysiological mechanisms which, in turn, contributes to the knowledge and database upon which new, innovative, and improved diagnostics, pretreatments, and therapies are based.

Countermeasure strategies to the classic and novel threats include pharmaceuticals, medical equipment, specialized materiel or medical procedures, and concepts for training, doctrine, and organization. Medical countermeasures are designed not only to prevent lethality but also to preserve and sustain combat effectiveness in the face of combined threats from chemical and conventional munitions on the integrated battlefield by:

- Rapid diagnosis of chemical agent exposure.
- Prevention of the effects of chemical agents (*e.g.*, prophylaxes or pretreatment).
- Far-forward treatment upon exposure to chemical warfare threats (*e.g.*, antidotes).
- Chemical casualty care (*e.g.*, therapy and management).

Research Category: Pretreatments

The countermeasures, technical barriers, and accomplishments in the medical chemical defense research category of pretreatments are outlined below.

Countermeasures:

- Reactive topical skin protectant (rTSP) for chemical agents.
- Pretreatment regimen that protects against rapid action and incapacitating effect of chemical threat category of nerve agents and novel threat agents.
- Pharmaceutical and biological pretreatments, treatments, antidotes or decontaminants and protectants.

Technical Barriers:

- Lack of pretreatments or antidotes that are quick acting, long lasting, easy to carry and use on the battlefield.
- Lack of appropriate experimental model systems to predict pretreatment or treatment efficacy and safety in humans.
- Lack of detailed molecular model of novel threat agents to understand the origin of their unique chemical properties.
- Potential performance decrement with pretreatment is being investigated.

Accomplishments:

Accomplishments are shown for the concept exploration, applied research, and basic research related to the development of pretreatments.

- Demonstrated that reactivation of organophosphate-inhibited acetylcholinesterase by oximes is accelerated in the presence of serum paraoxonase, suggesting that cholinesterases, oximes and organophosphorus hydrolases can work in tandem to hydrolyze or inactivate all organophosphates *in vivo* and *in vitro*.

- Demonstrated human serum butyrylcholinesterase (BuChE) was to be a single effective pretreatment drug against all organophosphate nerve agents in non-human primates without causing any performance decrement.
- Developed a joint program with WRAIR, USAMRICD, and the American Red Cross to prepare ~1,000 doses of human BuChE under GMP conditions.
- Initiated the evaluation of the immunologic response of repeated injections of homologous butyrylcholinesterase in monkeys, which will provide initial data leading to a pretreatment agent for humans, not only for soldiers but for any other first responders (civilians) to terrorist nerve gas release/attack or pesticide overexposure.
- Synthesized and evaluated 43 analogs of huperzine A (in collaboration with Georgetown University) and 11 analogs of tacrine (in collaboration with Universita Degli Studi Di Siena) as candidate pretreatment drugs for protection against organophosphate toxicity.
- Compared the efficacy of huperzine A and its analogs, tacrine and its analogs, and E2020 (Aricept) as pretreatment drugs for protection against organophosphate toxicity.
- Developed a fluorescent polarization assay to determine the interactions between proteins and peptides, and found that fluorescent Aβ peptide 1-40 binds to cholinesterases. The interaction between Aβ peptides and cholinesterases may influence neurodegeneration in Alzheimer's disease.
- Characterized five mutants of BuChE designed to hydrolyze nerve agents.
- Demonstrated that OPA hydrolase (PON 1) has the ability to catalyze the hydrolysis of VX as well as the G agents. Kinetic constants for that reaction are now being determined.
- Prepared crystals of unaged VX-inhibited AChE that refract to high resolution. For the first time we are able to see the precise orientation of this inhibitor in the active site of cholinesterase and thereby more accurately describe the requirements for nerve agent hydrolysis by genetically engineered mutants.
- Neutralized the glutamic acid group at position 337 in human carboxylesterase (CaE) which abolished activity for the substrate p-nitrophenylbutyrate. This result allowed the verification of the CaE molecular model with respect to the residues involved in the catalytic triad.
- Developed a theoretical model for the role of hydrolysis and CaE in protection against nerve agent poisoning.
- Discovered that sarin-inhibited CaE undergoes spontaneous reactivation.
- Compared OP specificity of CaE, BuChE and AChE and correlated differences to occurrence of specific amino acid residues.
- Determined that an antibody raised against a soman analogue linked to the carrier human serum albumin bound to the four individual stereoisomers of soman [C(+)P(+), C(+)P(-), C(-)P(+), and C(-)P(-)] but did not bind to the hydrolysis product of soman or to a set of structurally similar organophosphinates.
- Began sequencing the heavy and light chain genes used to encode each of three anti-soman antibodies, in order compare the respective genetic and deduced amino acid structures.
- Provided purified antibody to the Army Research Laboratory to attach to a solid support as a first step in making an immunodiagnostic 'ticket'.
- Determined that antibodies expressed in response to immunogens containing a rigid

pentavalent phosphorus transition state analogue (TSA) bound GD, the GD stereoisomers, GB, and structurally related analogues equally well but did not bind to a related set of phosphinates.

- Determined that antibodies against a 'bait and switch' TSA (G5D.2, A8E, IG5/F5/H6) bound all of the inhibitors equally well, but with IC50 values of ~1 μM, which suggested that antibodies against the rigid pentavalent and 'bait and switch' TSAs display different binding properties.
- Sequenced heavy and light chain genes of seven of the antibodies raised against the TSAs.

Research Category: Therapeutics/Diagnostics

The countermeasures, technical barriers, and accomplishments in the medical chemical defense research category of therapeutics/diagnostics are outlined below.

Countermeasures:

- Products that prevent or moderate vesicant injury.
- Medical countermeasures to minimize lethality, morbidity, and incapacitation of these agents.
- Specific casualty management techniques to improve survival and minimize lost duty time.
- Pharmaceutical/biological pretreatments, treatments, antidotes, or decontaminants/ protectants.

Technical Barriers:

- Need for quick-acting and long-lasting antidotes that are deployable.
- Lack of appropriate experimental model systems for treatment efficacy and safety in humans.
- Need for detailed molecular model of novel threat agents to understand the origin of their unique chemical properties.
- Lack of simple and sensitive field-portable diagnostic assays for CWA exposure.

Accomplishments:

- Demonstrated that by using matrix-assisted laser desorption ionization/time of flight (MALDI/TOF) mass spectrometer and whole spectrum protein profiling technique, distinct and consistent mass spectra can be obtained from blood, skin, or lung lavage samples to diagnose sulfur mustard exposure.
- Found that approximately 20% of circulating sulfur mustard binds with plasma proteins to form alkylated adducts. A sensitive GC/MS method was developed to hydrolyze the sulfur mustard adducts at the carboxyl terminal of proteins. The freed thiodiglycol was derivatized and monitored by mass spectroscopy. A lower detection limit of one nanomole of sulfur mustard was achieved.
- Found that human skin tissue exposed to HD becomes blistered and releases multiple inflammatory mediators. A multicomponent lotion containing a leukotriene antagonist was formulated and demonstrated to be effective in preventing HD blister formation.

- Observed with spin-labeled insulin and EPR techniques the alteration of insulin receptors on red blood cell membrane following HD exposure. The effect on insulin receptors was HD dose-dependent. The changes were detectable at 25 uM concentration four hours after exposure.
- Developed an *in vitro* model to screen topical ophthalmic protectants and treatments for HD injury using the bovine isolated cornea. Corneal injury was evaluated by corneal opacity, thickness, fluorescein dye penetration, and histopathology.
- Demonstrated efficacy of an ophthalmic solution containing taurine, sodium pyruvate, alphaketoglutarate, and pantothenate for counteracting the corneal damages caused by half sulfur mustard (2-chloroethyl ethyl sulfide, CEES).
- Demonstrated that corticosteroid and antibiotic treatment provide beneficial effects towards HD ocular injury, but the changes were transient following cessation of therapy suggesting that ophthalmic treatments may need to be administered for longer periods to obtain benefits.
- Observed that because HD casualties suffer burns of varying degrees of depth and severity, different treatment regimens are required. Therapies under investigation include laser debridement, temporary wound dressings, surgical excision, and autologous skin grafting. Pulse laser debridement of sulfur mustard wounds significantly shortened the wound healing process.
- Identified multiple bioengineering methods and measurements for evaluating HD injury. These include laser doppler perfusion imaging (to monitor capillary flow), trans-epidermal water loss (to assess skin barrier function), reflectance colorimetry (to measure erythema and pigmentation), ultrasound (to show degree of edema), conductance (to measure epidermal hydration), ballistometry (to indicate skin elasticities), and digital photography (wound contraction).
- Demonstrated in a human epidermis model that exposure to CEES induced programmed cell death (apoptosis) as evidenced by cytoplasmic blebbing and chromatin clumping, clearly observable in electron micrographs.
- Demonstrated that the potential vesicant antagonists niacinamide, zaldaride maleate, or leupeptin, used singly, did not provide significant protection from CEES exposure suggesting that simultaneous blockade of multiple pathways of potential cellular damage may be required to achieve notable beneficial effects.
- Established that the pro-inflammatory cellular mediators interleukin (IL)–1, IL–6, IL–8, tumor necrosis factor-β, and prostaglandin E_2 are not significantly affected by epidermal damage, suggesting that keratinocytes are not responsible for the inflammatory response induced by CEES.
- Demonstrated that heat shock protein-70A was not increased by exposure to CEES, thus suggesting the possibility that prior elevation of this cytoprotective protein could provide prophylaxis to the pathophysiological effects of CEES.
- Demonstrated that elevation of IL–1 receptor antagonist may be a useful biochemical metric of CEES-induced injury.
- Demonstrated that exposure of a human epidermis model to CEES resulted in the prominent release of IL–1 receptor antagonist which indicates that the acute response to half-mustard is characterized by a concomitant anti-inflammatory component.

- Developed a swine model to study and evaluate the efficacy of candidate therapeutic compounds and clinical interventions. Anesthesia in the weanling pig model by intramuscular Telazol®/Rompun® produced the most consistent results over time and was the drug of choice for future wound healing studies.
- Prepared polyurethane sponges containing mixtures of immobilized acetyl and butyrylcholinesterases and OP hydrolases for skin or drinking water decontamination. Cholinesterase sponges detoxified surrogate OPs at a greater than 500-fold excess in the presence of the oxime reactivator HI-6. The enzyme-immobilized sponges retained high activity at room temperature after more than 8 months.
- Prepared immobilized multi-enzyme sponges composed of cholinesterases and organophosphate hydrolases to replace single enzyme sponges for improved decontamination and detoxification of nerve agents.
- Demonstrated immobilized enzymes' remarkable retention of catalytic activity to environmental extremes (heat, cold, wet, dry, multiple use), and developed additives to sponges to improve removal of organophosphates from permeable surfaces.
- Developed a more versatile and accurate dipstick biosensor for organophosphates composed of immobilized cholinesterases to replace the current fielded detector.
- With commercial partners, prepared activated cotton fabrics to which organophosphate hydrolyzing enzymes were immobilized.
- Evaluated a therapeutic approach to treat phosgene-induced acute lung injury in a murine model. Mice fed butylated hydroxyanisole and n-propyl gallate had significantly increased survival rates. Post-treatment with buffers such as sodium carbonate, saline, N-acetylcysteine, L-2-oxothiazolidine-4-carboxylic acid enhanced survival of mice exposed to phosgene.
- Mice, following phosgene exposure, showed signs of respiratory acidosis with significant increases in serum potassium, total carbon dioxide, hematocrit and hemoglobin, with maximum changes observed at 8 hours and return to normal parameters at 24 hours.
- Determined that treatment with benzamide (poly ADP ribose polymerase inhibitor) did not reduce the mortality rates in mice after phosgene exposure. Treatment with 2-mercaptoethane sulfonic acid (MESNA) increased survival rate with increased -SH levels and decreased protein oxidation.
- Showed that in swine exposed to phosgene, ibuprofen infusion at half hour and then every one and a half hours for 24 hours prolonged survival time. The rate of pulmonary edema formation over the survival time decreased by 46%. Positive and expiratory pressure (PEEP) and 45% oxygen treatment were not effective.
- Showed in human plasma that the biotransformation of VX depended on two pathways; enzymatic and spontaneous hydrolyses. The spontaneous hydrolysis is a much slower process. Initially, the enzymatic hydrolysis was the predominant pathway but it underwent a product-limited kinetic mechanism and plateaued at later stage. This could explain the persistent toxic action of VX *in vivo*
- Demonstrated by LC/MS that in human serum the OP hydrolase selectively degraded the nontoxic VX P(+) stereoisomer at a faster rate than the toxic P(-) isomer.
- Initiated a collaborative effort with industry (Datex-Ohmeda, Inc.) to develop a prototype non-invasive methemoglobin monitor. A final hand-held, real-time monitor for

methemoglobin, oxyhemoglobin, carboxyhemoglobin, oxygen, and possibly cyanide is anticipated in the next two to three years.

Research Category: Reducing Reliance on Animals and Human Volunteers

- An *in vitro* model is being developed to evaluate the chronic effect of low dose exposure to nerve agents and other toxic compounds.
- An *ex vivo* neuronal model has been developed for rapid screening of neuroprotectants against seizures induced by organophosphate chemical warfare nerve agents, toxicity induced by excitatory amino acids, and EEG perturbations and seizures induced by NMDA.

D.1.3 Advanced Development Products

In advanced development, the goal is proof-of-principle and conducting all studies necessary to obtain FDA approval/licensure of drugs, vaccines, and devices. The medical R&D process links the materiel developer (U.S. Army Medical Research and Materiel Command, USAMRMC) with the combat and training developer (U.S. Army Medical Department Center and School, AMEDD C&S) and the logistician (U.S. Army Medical Materiel Agency, USAMMA) in addressing the threat and JMCBDRP requirements. Medical chemical defense products now in the advanced development phase are the following:

Product: Topical Skin Protectant (TSP)

Concept:

- Use perfluorinated formulations.
- Form nontoxic, nonirritating barrier film layer on skin.
- Augments Mission Oriented Protective Posture (MOPP).
- Protection against vesicant and nerve agents.

Accomplishments:

- Completed manufacturing development of the TSP.
- Completed sweating and absorption studies requested by the FDA.
- Prepared and submitted a New Drug Application to the FDA.

Product: Multichambered Autoinjector

Concept:

- Speed administration of life-saving antidotes against nerve agents.
- Replace two-Injector Mark I Nerve Agent Antidote Kit with single autoinjector.

Accomplishments:

- Production line upgrade underway.
- Received approval from the Training and Doctrine Command for the Operational Requirements Document for the multichambered autoinjector.

- Multichambered autoinjector transitioned to the Engineering and Manufacturing Development Phase (Phase 2) of the DoD 5000 Acquisition Process.
- Prepared a New Drug Application for submission to the FDA.

Product: Cyanide Pretreatment

Concept:

- Provide protection against incapacitation and lethality without performance degradation.
- Enhance soldier protection and sustainment.

Accomplishments:

- Prepared an Investigational New Drug Application.
- Developed an oral formulation for clinical studies.
- Identified unanticipated toxicity in non-human primates, suspended advanced development, and returned this effort to tech base for more studies.

D.2 MEDICAL BIOLOGICAL DEFENSE RESEARCH PROGRAM

D.2.1 Biological Defense Products

Advances in DoD medical R&D significantly impact the warfighting mission by sustaining unit effectiveness through conserving the fighting strength of our forces and supporting the nation's global military strategy, which requires the ability to effectively deploy and operate. Medical R&D products (materiel and non-materiel solutions) provide the foundation that ensures the fielding of a flexible, sustainable, modernized force across the spectrum of conflict and in the full breadth and depth of the battlefield. Overcoming medical threats and extending human performance have provided a significant increase in military effectiveness in the past and present the potential for future enhancement of military operational effectiveness. Some of the materiel and non-materiel solutions are fully licensed and available for use while others are in investigational new drug (IND) status, which may only be used consistent with Executive Order 13139. In 1997, a Prime Systems Contract under the Joint Vaccine Acquisition Program (JVAP), was activated to move mature solutions from the technology base through advanced development to FDA licensure and procurement of baseline stockpiles. Currently licensed and IND solutions for use in medical biological defense R&D include the following:

Vaccines and Antisera:

- Anthrax Vaccine (licensed)
- Smallpox Vaccine (licensed)
- Botulinum Toxoid Vaccine, Pentavalent (IND #3723)
- Botulinum Type F Toxoid Vaccine (IND #5077)
- Botulinum Antitoxin, Heptavalent Equine (Types A, B, C, D, E, F, and G) (IND #3703)
- Botulism Immune Globulin, Human (IND #1332)
- Botulism, Antitoxin, Heptavalent Equine, Types A, B, C, D, E, F, and G (IND #5077)
- Q Fever Vaccine, Purified Whole Cell, CM Residue, Formalin Inactivated, Gamma Irradiated (IND #3516)
- Tularemia Vaccine (IND #157)
- New smallpox vaccine (Vaccinia Virus, Cell Culture-derived) (IND #4984)
- Venezuelan Equine Encephalitis Virus Vaccine, TC-83 (IND #142)
- Eastern Equine Encephalitis Virus Vaccine (IND #266)
- Western Equine Encephalitis Virus Vaccine (IND #2013)

The status of medical materiel solutions being managed by the Joint Program Office for Biological Defense (JPO-BD) and JVAP are reported in Section D.2.3.

Technical Information and Guidance:

- Handbook "Medical Management of Biological Casualties," 1998.
- CD-ROM on "Management of Biological Warfare Casualties," 1999.
- NATO Handbook "Medical Aspects of NBC Defensive Operations, AMedP-6(B), Part II (Biological)," 1998.

D.2.2 Biological Defense Research and Development Accomplishments

The biological defense research and development technical barriers and accomplishments during FY99 are grouped by the following medical defense strategies against biological threats (bacteria, viruses, and toxins)g:

- Vaccines against bacterial agents
- Therapeutics for bacterial agents
- Vaccines against viral agents
- Therapeutics for viral agents
- Vaccines against toxin agents
- Therapeutics for toxin agents
- Diagnostics

Several projects and technologies are shared with other agencies, including the Department of Energy (DOE) and the Defense Advanced Research Projects Agency (DARPA). The DOE projects tie into the strengths of the DOE laboratories in developing advanced technologies in order to enable rapid detection of and response to a chemical or biological agent incident. DOE is not involved directly in protection and treatment of personnel, but actively assists DoD with drug/chemical database searches, DNA sequencing, advanced protein chemistry and modeling/simulation projects. Successful sequencing of plasmids found in the causative agents of plague and anthrax helped create the "lab on a chip". The extensive knowledge and databases available to DOE allow application of computational tools to predict sites of intervention by novel therapies against threat agents.

DARPA is pursuing multi-agent and broad-spectrum approaches, both to defend against current known threats and to anticipate potential future threats. Accomplishments of DARPA programs for FY99 include the following:

Medical Countermeasures Research and Development by DARPA:

- Demonstrated that manipulated mesenchymal stem cells (MSCs) can be transduced with the C fragment of the tetanus toxin to induce the production of antibodies.
- Identified over 300 novel DNA-binding monomers and 4 novel double stranded RNA-binding monomers to target the replicative intermediates of RNA viruses.
- Expressed active enzymes (phospholipase C, nuclease A) *in vivo* to produce a proprietary vaccine delivery system with potential for rapidly deployable applications for both military and civilian populations.
- Developed a peptide (P-12) with broad spectrum activity that has demonstrated

protection *in vivo* from a lethal dose of SEB as well as eliciting a more rapid immunization than normally occurs in the body.

- Developed a chimeric molecule (antigen presenting cell and T cell receptor subunits) to act as a Major Histocompatibility Complex (MHC) decoy protein, binding with SEB molecules and preventing pathogenesis.
- Developed an antiviral vaccine (patent pending) that exhibits potential for broad spectrum preventive and therapeutic activity with no toxicity or interference with normal cell proliferation.
- Demonstrated, through rabbit studies, that immunization may be possible through the consumption of an edible vaccine based on assembled epithelial transport molecules (TMs).
- Demonstrated 99.9% protection against the simulants of biological pathogens (BG) and chemical agents (DMMP) by utilizing a prototype helmet and filter system (Advanced Toxic Environment Combat Helmet and the Chem/Bio Photo/Electrocatalytic Filter Reactor).
- Confirmed that changes in gene expression, which were observed after *in vitro* exposure of human peripheral blood lymphocytes to SEB, were similar to changes observed in monkeys challenged with SEB. Gene changes in monkeys challenged with SEB appeared prior to onset of symptoms (30 minutes) and persisted up to at least 12 hours post-exposure.
- Showed 19 genes are altered after human lymphocytes are exposed to anthrax *in vitro*; many of these genes displayed unique altered expression.
- Isolated peripheral blood lymphoid cells and prepared RNA from anthrax-challenged monkeys for analysis of *in vivo* gene changes.
- Identified, in lymphoid cells exposed to plague and cholera toxin (*in vitro*), that some changes in gene expression were common to several toxins while others were unique to each specific toxin.
- Found that some genes that were altered by several toxic agents examined are not unique to a specific toxin but may still be indicative of certain common symptoms such as loss of regulation of vascular tone.

Advanced Medical Diagnostics:

- Demonstrated feasibility of using exhaled nitric oxide (NO) as an early marker of infection of BW exposure.
- Began development and testing of standardized procedures for a variety of sample types using the integrated DNA sample preparation cartridge developed last year. Developed a spore disruption attachment for preparing samples containing anthrax spores.
- Preliminary studies demonstrating feasibility of using engineered red blood cells to detect pathogen exposure in the body.
- Began studies evaluating use of "gene chips" (multigene arrays) to identify candidate host markers of infection/exposure.

Consequence Management Tools:

- ENCOMPASS (Enhanced Consequence Management Planning and Support System), an integrated set of consequence management tools, was developed and demonstrated with the Marine Corps Chemical and Biological Incident Response Force.

Medical biological defense research conducted or sponsored by the United States Army Medical Research and Materiel Command (USAMRMC) laboratories yielded the following accomplishments in FY99:

Medical Countermeasures Research and Development by the United States Army Medical Research Institute of Infectious Diseases (USAMRIID):

Bacterial Agents

The countermeasures, technical barriers, and accomplishments in the biological threat category of bacterial agents are outlined below.

Countermeasures:

- Vaccines for immunity against bacterial threat agents.
- Therapeutics for treatment of bacterial diseases.

Technical Barriers:

- Incomplete genetic information for all of the bacterial threat agents.
- Lack of appropriate animal model systems for investigation of some bacterial threats and countermeasures.
- Lack of suitable epidemiological situations in which to perform human clinical trials to evaluate efficacy of vaccines.
- Difficulty in field testing rapid identification kits under natural conditions.
- Difficulty in defining surrogate markers of protection.
- Necessity to enhance the otherwise limited data on which to base rational drug and antibody therapies for bacterial agents of interest.
- Necessity to establish and maintain capabilities to assess threats and provide countermeasures for new, emerging, and genetically engineered bacterial threats.

Accomplishments:

Vaccines:

- Completed annotation of the *Yersinia pestis* murine toxin plasmid DNA sequence.
- Completed annotation of the DNA sequence obtained from a small cryptic plasmid that is emerging in strains of *Y. pestis* isolated in the Peoples Republic of China.
- Determined the DNA sequence of 1,000 random *Francisella tularensis* clones as part of the genome sequencing project.
- Determined the DNA sequence of the *Y. enterocolitica* large virulence plasmid for comparison with the similar plasmid harbored by *Y. pestis*.
- Developed a simple, scaleable two-step purification method for the F1-V plague vaccine

candidate, and initiated short and long-term stability studies on both unformulated and formulated F1-V preparations.

- Completed preliminary F1-V efficacy experiment in both rodents and non-human primates, the results of which showed a high degree of protection against lethal aerosol and parenteral exposure to plague.
- Characterized the F1-V protein by additional biochemical/physical methods, to include mass spectrometry and x-ray crystallography.
- Completed preliminary potency experiments in mice, comparing several different F1-V preparations.
- Initiated development of a surrogate marker ELISA assay using a monoclonal antibody to the F1 protein and initiated evaluation of immune serum derived from dose-response studies in mice.
- Protected mice against lethal parenteral challenge with plague by passive transfer of F1-V immune serum from rabbits.
- Initiated studies of the utility of other plague antigens, especially YopD, as well as V antigens from different strains of *Yersinia*, as potentially useful immunogens.
- Initiated construction of allelic replacement vectors carrying various V antigen types, to support testing of vaccine candidates against potential *Y. pestis* strains encoding a non-consensus sequence V antigen.
- Continued collaboration with Los Alamos National Laboratories and Northern Arizona University on analysis of the genetic diversity of *Y. pestis* based on variable number tandem repeat (VNTR) alleles.
- Characterized the newly-developed *in vitro* bioassay for V, which is based on the lethal apoptotic effects of V on macrophages.
- Determined that a potentially protective live, attenuated (Pgm-) strain of *Y. pestis* which appeared promising in rodents had significant virulence for monkeys by the aerosol route.
- Initiated efforts to engineer additional attenuating mutations into Pgm- strains of *Y. pestis*, which might prove useful as live, attenuated vaccine candidates.
- Identified two new model systems in which to screen for attenuating mutations in *B. pseudomallei*, and determined that virulence in these models is not due to bacterial lipopolysaccharide, capsule, Type II secreted factors, or the flagellar apparatus.
- Developed the first transposon mutagenesis procedure for *B. mallei*, which will allow a greater understanding of the molecular biology of *B. mallei* and may lead to discovery of suitable vaccine candidates.
- Identified the putative capsule genes for *B. mallei*, which may be the first clearly defined virulence factors for this organism, as mutants that do not make capsule are avirulent in the hamster model of glanders.
- Developed PCR primers for putative type III secretion genes of *B. pseudomallei* and *B. mallei*, and used these primers to explore mutants for their relative virulence in animal models of infection.
- Protected mice from lethal *B. mallei* challenge by immunization with a vaccine containing irradiation-killed *B. mallei* whole cells and irradiation-killed *C. burnetii*, even though spleens contained significant *B. mallei* organisms.
- Initiated histopathological studies of mice challenged by aerosol with sublethal and lethal

doses of *B. mallei*, in support of comprehensive understanding of the pathogenesis of this disease and development of a suitable animal model for vaccine and therapeutic studies.

- Examined antigenic relationships, using immunoblot and ELISA, among the numerous strains of *B. mallei* and related organisms collected to date.
- Prepared various organic extracts of *B. mallei* to evaluate for sensitivity and specificity in an ELISA and for exploration as potential vaccine candidates.
- Conducted a comparative serological study of five different species of laboratory animals immunized with the licensed anthrax vaccine, using both ELISA and toxin neutralization assays, in support of studies to understand and differentiate among the different animal models.
- Characterized the isoelectric point of the three protein components of the two anthrax toxins (PA-EF and PA-LF) in order to better understand various genetic classifications of different isolates and their virulence patterns.
- Initiated studies on the ability of CpG oligonucleotides to protect animals from *B. anthracis* challenge, and found a small level of non-specific protection in mice.
- Completed aerosol challenge study in rabbits and rhesus monkeys of *B. anthracis* strains which were highly virulent in AVA-immunized guinea pigs, and found that the licensed vaccine provided excellent protection in both the monkey and the rabbit model.
- Completed studies in immunized rabbits comparing the virulence of *B. anthracis* spores with that of vegetative cells, and found that rabbits were completely protected against challenge with either form of the organism.
- Inserted the C-terminus of the heavy chain of the botulinum neurotoxin gene into the genome of *B. anthracis* by transposon-mediated mutagenesis in order to explore a live, attenuated, multivalent vaccine vector system.
- Characterized the DNA sequence for two genes involved in replication of *B. anthracis*, and which are essential for further development of cloning systems for expressing homologous and heterologous antigens in *B. anthracis*.
- Screened representative samples of Ames and V1B *B. anthracis* variants for vrrA type, which appears to be stable in these strains, and may potentially be useful as a marker to indicate the presence of discrete strains.
- Continued studies on the anti-spore activities of antitoxin antibodies to determine their role in protection early in infection; the antibodies stimulated phagocytosis of spores by macrophages and inhibited spore germination *in vitro*.
- Produced several neutralizing monoclonal antibodies against V antigen of *Y. pestis* to aid in identifying neutralizing epitopes in the V antigen and the development of a competitive ELISA.
- Collaborated with investigators at WRAIR developing *Brucella* sp. based vaccine delivery vector.

Therapeutics:

- Established, in accordance with internationally accepted clinical standards, a microdilution "minimum inhibitory concentration" (MIC) method for determining valid antibiotic susceptibility profiles for biological threat agents.
- Established MIC ranges for key strains of *B. anthracis*, *Y. pestis* and *B. mallei*; 28

antibiotics were tested on 11 strains of *B. mallei* and 4 strains of *B. mallei*; 29 antibiotics were screened against one specific strain of *B. anthracis*, and tests on over 30 additional strains were initiated.
- Initiated development of a new assay system based on bacterial ATP content as a rapid metabolic measure of antibiotic effects.

Diagnostics
- Discovered two types of insertion sequences in *B. mallei*, which may serve as useful diagnostic probes for pathogenicity.

Toxin Agents

The countermeasures, technical barriers, and accomplishments in the biological threat category of toxins are outlined below.

Countermeasures:
- Vaccines that produce long term protective immunity against toxin agents.
- Drugs that can be administered prior to toxin exposure and protect against toxin agents.
- Therapeutics for treatment of diseases/symptoms caused by toxin agents

Technical Barriers:
- Develop appropriate model systems that emulate human aerosol exposure and intoxication.
- Methods for induction of respiratory and mucosal immune responses that produce long term protective immunity at the agent's port of entry.
- Development of markers of pulmonary inflammation in animal models.
- Identification and development of appropriate animal models for investigation of surrogate endpoints of human clinical efficacy
- Retention of toxin antigenicity without toxic properties for vaccine candidate
- Insertion of stable genetic alteration of toxin biological targets to produce toxin-resistant biological targets.
- Generic protection from families of toxins with subtle alterations in toxic modes of action.
- Necessity to enhance the otherwise limited data on which to base rational drug and antibody therapies for toxin agents of interest.
- Necessity to establish and maintain capabilities to assess threats and provide countermeasures for new and emerging toxin threats.

Accomplishments:

Vaccines:
- Recombinant vaccine candidates against botulinum neurotoxin serotypes A, B, C, and F transitioned to JVAP/Prime System Contractor at Milestone I on September 10, 1999.
- Completed development of vaccine candidates for botulinum toxin serotype E as part of ORD.
- Completed development of vaccine candidates for botulinum toxin serotypes D and G.

- Focused on increasing the immunogenicity for botulinum vaccines for serotypes E and F.
- Showed that recombinant SE vaccines protected mice against sepsis infection by *Staphylococcus aureus.*
- Initiated SEB mucosal immunization studies using *Streptococcus gordonii*, cholera toxin, and hepatitis virus-like particles as delivery platforms.
- Demonstrated oral or nasal mucosal vaccination elicits protective antibodies against a lethal aerosol and intraperitoneal SEB challenge.
- Completed thirty-six month stability assessment on chemically deglycosylated ricin A chain vaccine candidate.
- Completed general safety, acute and repeat dose toxicity tests on chemically deglycosylated ricin A chain vaccine candidate.
- Established efficacy of chemically deglycosylated ricin A chain vaccine candidate in an aerosol challenge rodent model.
- Prepared information package to address suitability of the chemically deglycosylated ricin A chain vaccine candidate for human use with the FDA and industry.
- Developed models to evaluate ricin A chain subunit genetic enzymatic inactivation.
- Developed procedures to purify recombinant genetically inactivated ricin vaccine candidate.
- Selected one first generation recombinant staphylococcal enterotoxin vaccine candidate to recommend for transition to advanced development.
- Produced to GMP requirements the first recombinant vaccine candidate for staphylococcal enterotoxin type B.
- Prepared working cell banks and reference standards for the recombinant SE serotype A candidate in preparation for GMP production.
- Developed strategic preclinical assays for biological potency, formulation, and stability studies to support SE vaccine effort.
- Developed methods based on scanning and isothermal calorimetry for the physical characterization of recombinant staphylococcal enterotoxin vaccines used for formulation and stability studies of pre-GMP material.
- Completed adjuvant-vaccine co-formulation study for rSEB vaccine candidate.
- Evaluated efficacy of low dose recombinant SEB vaccine in rhesus monkeys against wild-type SEB.
- Characterized candidate vaccines for SEC1 and SED.
- Completed rSEB vaccination dosing and scheduling study in nonhuman primates; results will form the basis for recommendations of dose and schedule for human clinical trials.
- Demonstrated that the T-lymphocyte assay was useful in predicting the probability of survival in rhesus monkeys vaccinated with recombinant SEB vaccine and challenged by the aerosol route.
- Showed that the recombinant SEB vaccine protected T cells from becoming anergic in response to wild-type SEB in rhesus monkeys.
- Completed *in vitro* experiments establishing delivery of recombinant vaccines using mouse mesenchymal stem cells that differentiate into antigen presenting cells *in vivo.*
- Established human CD4 and human leukocyte antigen (HLA)-DR1, DR3, DQ6, and DQ8 transgenic colonies, class II-deficient mice. Showed that the lymphocytes obtained

from the humanized mice and humans reacted similarly to various biological threat agents.

- Developed a new surrogate assay for evaluating human immune responses based on dendritic cell cultures.
- Developed quantitative ELISA and *in vitro* neutralization assay for measurement of anti-ricin antibody to evaluate immune response in humans following vaccination.
- Developed *in vitro* protein evolution method based on bacteriophage-display for discovering new recombinant vaccines.

Therapeutics:

- Development of an *in vitro* model for screening novel competitive inhibitors as therapeutic agents for botulinum B toxin poisoning.
- Determined first complete, high-resolution three-dimensional crystal structure, for this family of botulinum neurotoxins (serotype A at 3.2 Angstroms) to be used as a foundation for further rational therapeutic drug design.
- Developed recombinant, enzymatically active, light chain for serotype A as a reagent for efforts focused on therapeutic countermeasures to botulinum neurotoxins.
- Demonstrated *in vitro* functional efficacy of replacement of cleaved botulinum target with botulinum-resistant SNAP-25 via protein/DNA technologies.
- Demonstrated that cells intoxicated by botulinum neurotoxin can be rescued and normal function restored by the intracellularly application of genetically engineered toxin-resistant protein or DNA.
- Demonstrated ability to target delivery into cholinergic nerves using the non-toxic botulinum serotype A transporter.
- Identified low molecular weight inhibitors of botulinum neurotoxin protease for serotypes A and B.
- Refined mass spectroscopy techniques using hydrogen-deuterium exchange to quantify protein structural components in botulinum neurotoxin targeted substrates and correlated them with other spectroscopic techniques.
- Used neutron scattering (in collaboration at the Department of Commerce, National Institute of Standards and Technology) to quantitatively examine BoNT's interaction with biological membranes and BoNT's channel-forming structure.
- Developed and refined computational chemistry techniques to thermodynamically evaluate protein-ligand interactions that will be used in screening massive chemical databases for compounds as potential inhibitors of BoNT enzymatic activity.
- Synthesized a short polypeptide that is the most potent inhibitor known (2 uM) for type A botulinum neurotoxin. This polypeptide will be used as a new lead compound for future combinatorial organic synthesis and high throughput screening for high affinity inhibitors.
- Developed high-throughput assays, suitable for screening large numbers of compounds for inhibitors of botulinum toxin proteolytic activity.
- Developed biosensor-based method to measure staphylococcal enterotoxin-receptor interactions for screening inhibitory molecules.
- Developed nonhuman primate incapacitation SE model.

- Demonstrated that passive transfer of antibody protects mice and nonhuman primates from the effects of SEB.
- Produced panels of reagent grade monoclonal antibodies to SE types A, B, C1, and D, which neutralized toxin activity *in vitro*.
- Developed computational model for rational drug design based on the co-crystal three-dimensional structure of SE type C3 and the T-cell receptor.
- Cloned and expressed genes that encode the major alleles of streptococcal and staphylococcal pyrogenic exotoxins.
- Developed and refined a novel fluorescence-based, cell-free enzymatic assay for evaluating ricin toxicity and screening potential inhibitors.
- Completed binding studies with *C. perfringens* iota toxin, a binary toxin and potential vehicle for delivering therapeutic agents to counteract the ill effects of botulinum, or other, toxins.
- Characterized toxicity of *C. perfringens* toxin types A, B, C, D, and E when administered to mice and rats by parenteral or aerosol routes, and found that toxicity was highly dependent on the toxin type and route of administration.
- Determined that spores and exotoxin of *C. perfringens* type A cause disease in parenterally inoculated mice and rats.
- Determined that the inhaled organism, spores or exotoxins are not pathogenic in mice, rats or hamsters.
- Initiated collaborative efforts to evaluate the anaerobic bacterial origins of saxitoxin.
- Initiated experiments to dissect the mechanism of action of lethal toxin of *B. anthracis* at molecular level; results suggest that MAP kinase family may not be the only target for the lethal toxin.
- Cloned and expressed single-chain class II receptors with covalently linked peptide for use as biomarkers for the study a variety of therapeutics against biological threat agents.

Viral Agents

The countermeasures, technical barriers, and accomplishments in the biological threat category of viral agents are outlined below.

Countermeasures:

- Vaccines for immunity against viral threat agents.
- Antibodies and antiviral drugs for treatment of viral disease.

Technical Barriers:

- Difficulty in optimizing and comparing different expression vectors for recombinant products (vaccines and antibodies).
- Need for rapid virus identification technology.
- Insufficient or incompletely understood animal model systems for investigation of viral threats and countermeasures.
- Necessity to develop and fully characterize animal models for eventual licensure of vaccines for which epidemiological realities disallow the possibility of efficacy data from human clinical trials.

- Need for multivalent vaccines and compatible vaccine platforms to protect against an array of unrelated viral agents.
- Difficulty with some agents in defining surrogate markers of protection.
- Necessity to enhance the otherwise limited data on which to base rational drug and antibody therapies for viral agents of interest.
- Necessity to establish and maintain capabilities to assess threats and provide countermeasures for new, emerging, and genetically engineered hazardous viruses.

Accomplishments:

Vaccines:

- Demonstrated in animal models that improved mucosal protection against Venezuelan equine encephalitis virus is induced by the molecularly defined, live-attenuated V3526 vaccine candidate.
- Demonstrated that subcutaneous administration of V3526, the candidate replacement vaccine for VEE subtype IA/B, induced systemic and mucosal protection more efficiently than the TC-83 vaccine currently available under IND; protection from lethal subcutaneous or aerosol challenge was evaluated in vaccinated mice clinically and immunohistochemically.
- Demonstrated the potential for wider utility of a promising BW defense vaccine platform by showing that VEE virus replicons expressing influenza HA protect alphavirus-immune mice from intranasal challenge.
- Showed that neurovirulence and tissue tropism of wild-type and attenuated strains of Venezuelan equine encephalitis virus were distinguishable in mice, the attenuated viruses (including vaccine candidates) having restricted tissue tropism compared to wild-type virus.
- Determined that pre-existing immunity to Eastern equine encephalitis virus, which interferes with the TC-83 Venezuelan equine encephalitis virus vaccine, does not interfere with the induction of VEE virus replicon-induced protection to influenza (HA-vaccinated) or Ebola virus (GP-vaccinated) in mice.
- Identified protective monoclonal antibody specific for the E3 protein of Venezuelan equine encephalitis virus.
- Began characterization of monoclonal antibodies to Western equine encephalitis virus (WEE), in order to define more precisely the requirements and immunological markers of WEE immunity.
- Produced and characterized human monoclonal antibody Fab fragments to vaccinia virus from a phage-display combinatorial library, and initiated an effort to exploit this technology for the production of antibodies useful in immunotherapy.
- Showed that DNA vaccination, with genes encoding the vaccinia virus proteins L1R and A33R, protects mice against a lethal poxvirus challenge.
- Constructed additional experimental vaccines, in both DNA and replicon vaccine platforms, for testing of individual vaccinia virus proteins that are candidates to elicit immunity to medically important orthopoxviruses.
- Used cDNA microarrays to document the induction of cytokine gene expression in Ebola virus-infected human monocytes, providing data on the possible influence of enhanced cellular gene expression in contributing to the pathogenesis of Ebola virus disease.

- Used cDNA microarrays to compare cellular gene expression in Ebola-Zaire and Ebola-Reston virus-infected primary human monocytes, and found different patterns of gene expression induced by highly virulent and putatively avirulent strains of Ebola virus.
- Demonstrated that just two vaccinations with Ebola GP or NP DNA, delivered by gene gun, were sufficient to provide 100% protection in mice challenged with Ebola virus, showing that. greater levels of immunogenicity and protective efficacy, with fewer vaccinations, can be achieved than we previously reported.
- In a collaborative study with WRAIR scientists, showed that cytotoxic T lymphocytes to Ebola Zaire virus are induced in mice by immunization with liposomes containing lipid A.
- Demonstrated durable immunity to Marburg virus by showing that nonhuman primates, which had been immunized one year previously and survived an otherwise lethal with Marburg virus, were resistant to re-challenge with the same strain of virus.
- Demonstrated that, in monkeys as shown previously in guinea pigs, the single most protective Marburg virus antigen may be insufficient by itself to protect against a distantly related strain of the virus, and that another antigen may be required in a broadly protective vaccine.
- Constructed a replicon-based Marburg virus vaccine containing glycoprotein from a strain of virus most distinct from the prototype, in order to begin to optimize antigenic content of a broadly protective Marburg virus vaccine.
- Demonstrated protective efficacy and immunogenicity in animal model systems with VEE replicons making the non-toxic 50 kDa carboxy-terminal fragment of the botulinum neurotoxin type A heavy chain (Hc), thereby providing data to support the safe and effective use of the VEE virus replicon as a vaccine vector.
- Showed the conceptual potential for multi-agent vaccines by demonstrating, in rodent models, that recombinant VEE RNA replicon vaccines provide efficient protection against Ebola, Marburg, influenza, Lassa, and Rift Valley fever viruses, as well as *B. anthracis* and botulinum neurotoxin.
- Showed conceptual potential for multi-agent vaccines by constructing and demonstrating efficacy in rodents with naked DNA vaccines for the *hantaviruses*—Seoul virus and Hantaan virus; the *filoviruses*—Ebola virus and Marburg virus; and the *flaviviruses*—Russian Spring Summer encephalitis virus and Central European encephalitis virus.
- Demonstrated expression, processing, and protective efficacy in mice of the structural proteins of Venezuelan equine encephalitis virus (VEE), made from recombinant baculovirus vectors
- Conducted arbovirus field ecology Studies in the Amazon Basin region of Peru, discovering several viruses in circulation including Eastern and Venezuelan equine encephalitis viruses, relevant to vaccine development efforts.

Therapeutics:

- Developed a method for genotyping and quickly identifying orthopoxviruses, by exploiting long-distance polymerase chain reaction (PCR) and restriction fragment polymorphism.
- Showed that Cidofovir® protects mice against lethal intranasal or aerosol cowpox virus challenge.

- Showed that Cidofovir® is a potential antiviral therapeutic antiviral agent for the treatment of smallpox and monkeypox infections, active against smallpox *in vitro* (work done by USAMRIID scientists at the CDC) and against monkeypox in nonhuman primates.
- Identified protective monoclonal antibodies to Ebola virus and the epitopes they bind, thereby showing the conceptual feasibility of antibody therapy and the worthiness of antibody induction by Ebola vaccines.
- Expanded a collaboration with Abgenix, Inc., to test the utility of their XenoMouse (TM) technology in making fully human monoclonal antibodies for therapeutic use against both filoviruses (Ebola and Marburg viruses) and poxviruses (vaccinia virus).
- Demonstrated that recombinant human interferon alpha hybrid B/D protects mice against lethal Ebola virus infection.
- Showed that S-adenosylhomocysteine hydrolase inhibitors inhibit Ebola virus *in vitro* and in a lethal mouse model, establishing a possible route toward antiviral drug therapy of filovirus infections.

Diagnostic Assays for Biological Warfare Threat Agents

The accomplishments in the diagnostic assays for biological warfare threat agents are outlined below. The objective of this effort is to develop the capability to confirm in biological samples the initial field diagnosis of a biological warfare threat agent.

Countermeasuress:

- Forward deployed, hand-held common diagnostic device.
- Field laboratory capability to identify biological threat agents.
- Reference laboratory for confirmation diagnostics.

Technical Barriers:

- Difficulty in field testing rapid identification kits under natural conditions.
- Lack of rapid confirmatory assays with "gold standard" sensitivity and specificity.
- Limited rapid deployable identification technology.

Accomplishments:

- Developed a plan and a strategy for multi-gene and multi-agent identification of disease pathogens.
- Developed a research plan in collaboration with Cepheid, Inc. to develop high through put system for biological or environmental sample processing.
- Developed a research plan with Nanogen, Inc. to develop an arrayable electronic system for gene detection.
- Showed that a panel of mouse monoclonal antibodies, made previously, includes antibodies potentially useful in the detection of multiple proteins shared among orthopoxviruses that are human pathogens.
- Demonstrated TaqMan™ (5' fluorescence-based probe hydrolysis) PCR assays capable of detecting between 10 and 1000 gene copies copies per reaction for the following agents: *B. anthracis* (6 assays), *Brucella*, *C. burnetii*, *F. tularensis*, *Y. pestis*, orthopox-

viruses (monkey pox, vaccinia and variola viruses), *C. botulinum* toxins A and B, and the simulants *Erwinia herbicola* and MS2 phage.

- Demonstrated PCR assays compatible with the Light Cycler™ rapid nucleic acid analysis device for the following agents: *B. anthracis*, *Y. pestis*, *C. botulinum* toxins A and B, orthopox virus, and the simulants *B. globigii* and *E. herbicola*.
- Demonstrated PCR assays compatible with the portable, battery-powered SmartCycler™ rapid nucleic acid analysis device for the following agents: *B. anthracis* (2 assays), *Clostridium* toxin A and B genes, *C. burnetii*, *F. tularensis*, and staphylococcus enterotoxin A and B genes.
- Evaluated portable, battery-powered, rapid nucleic acid analysis devices that can detect biological agents in less than 40 minutes after sample processing in a field deployable laboratory.
- Demonstrated rapid specimen processing of whole blood in less than 30 minutes using a portable automated device.
- Demonstrated solid phase methods for the rapid purification of nucleic acids without hazardous chemicals.
- Demonstrated rapid lysis of *B. anthracis* spores in less than 1 min using sonication in a closed cartridge prototype and purification of nucleic acids in less than 50 minutes.
- Evaluated dry down and stable reaction chemistries for gene amplification assays.
- Demonstrated increased sensitivity of electrochemiluminescence assays to detect ricin toxin, *C. botulinum* toxins, *Y. pestis* F1 antigen, staphylococcal enterotoxin A, and *B. anthracis* PA antigen to the femtogram level.
- Demonstrated that anthrax spores can be detected by swab sampling of the nose, face and hairy portions of the face in an animal model within 24 hours after exposure.
- Demonstrated a new isothermal gene amplification (non-PCR) detection method and specimen processing cartridge for the rapid identification of *Y. pestis*.
- Collaborating with Lawrence Berkeley National Laboratory on chromosomal DNA markers for the identification of *B. anthracis*. Developing PCR diagnostic assays based on markers identified.
- Developed specific antigen capture ELISA assays, under the auspices of the Common Diagnostics DTO, for *B. pseudomallei, C. perfringens,* Rift Valley fever virus, yellow fever virus and Dengue 2 virus using a rabbit and goat polyclonal antibodies as well as monoclonal antibodies.
- Developed improved monoclonal antibodies specific for *V. cholera* to use in an antigen capture ELISA assay.
- Developed a specific antigen capture ELISA assay for vaccinia virus using rabbit polyclonal and human recombinant antibodies.
- Developed a specific immunochromatographic hand-held assay for *C. perfringens* enterotoxin, Rift Valley fever virus, and Dengue 2 virus.
- Used the bidiffractive gating biosensor assay to detect the simulants ovalbumin and *B. globigii* at a joint field trial.
- Demonstrated sensitive immunodetection of *B. anthracis* PA antigen using time resolved fluorescence.
- Demonstrated effectiveness of recombinant Fab antibody in immunochromatograhpic hand-held assay for botulinum toxin A.

- Successfully substituted recombinant antibodies for monoclonal antibodies in current ELISA assays.
- Developed recombinant antibodies to *F. tularensis* and *Y. pestis* that are being incorporated into diagnostic assays.
- Demonstrated rapid methods for rapid nucleic acid analysis of orthopoxviruses by long PCR RFLP analysis.

D.2.3 Advanced Development Accomplishments

The Joint Program Office for Biological Defense (JPO-BD) is a DoD chartered agency to provide intensive centralized management of medical and non-medical programs to expedite materiel solutions for validated biological defense deficiencies. Vaccine products will be further developed by the Joint Vaccine Acquisition Program (JVAP), an ACAT II program under JPO-BD. Vaccines directed against high threat agents will be produced and stockpiled to fulfill a 1.2 million Troop Equivalent Doses (TEDs) requirement (Note: TED = the amount of vaccine required to immunize a service member to protect against a biological warfare agent.) Vaccines against low threat agents will be produced to fulfill a 300,000 TEDs requirement.

The following products have transitioned from the technology base to advanced development and are managed and funded by JPO-BD.

D.2.3.1 Botulism Immune Globulin (Human), Pentavalent (IND #1332)

- The IND remains open to accommodate emergency treatment requirements for exposure or possible exposure to botulinum toxin types A, B, C, D, or E.

D.2.3.2 Botulinum Type F Toxoid Vaccine (IND #5077)

- Completed the Phase 2 Safety and Immunogenicity clinical study of Botulinum Type F Toxoid Vaccine. The purpose of this study was to identify a vaccination schedule and route of vaccination that is safe and maximally immunogenic.
- A final report for the Phase 2 safety and immunogenicity clinical study was completed.
- Work has been stopped on the development of this product because it did not meet user requirements

D.2.3.3 Anthrax Vaccine Human Adsorbed

- The sale of Michigan Biologic Products Institute (MBPI) by the state of Michigan was finalized. MBPI was purchased by BioPort, which consists of the management team from MBPI and outside capital; it is a private sector entity without state of Michigan affiliation.
- Managed and funded efforts leading to the submission of a Biologic Licensure Application amendment to the FDA for Anthrax Vaccine Adsorbed. Data submitted to the FDA supports two separate efforts for the vaccine: (1) to reduce the current six-dose

schedule to a five-dose schedule, and (2) to license the vaccine to provide protection against aerosol exposure to anthrax.
- Managed the anthrax vaccine production and stockpile to ensure sufficient vaccine is available to support the Secretary of Defense's anthrax immunization efforts.
- DoD continued to provide technical assistance to BioPort to identify and correct FDA compliance issues.
- Funded and provided oversight of production facility upgrades and ancillary support function renovation at BioPort that are critical to maintaining anthrax vaccine availability.

D.2.3.4 Botulinum (Pentavalent) Toxoid Adsorbed (ABCDE) (IND#3723)

- A total of 348 volunteers were immunized under a clinical protocol in support of licensure application.
- A clinical protocol for a follow-on booster study was initiated.

D.2.3.5 Botulism Immune Globulin $F(ab')_2$, Heptavalent, Equine, Types A, B, C, D, E, F, & G IND (#7451)

- Contracted for continued stability testing of the product.
- Completed Phase 1 Safety and Pharmacokinetics clinical study.
- Provided Botulinum Antitoxin Standards to Battelle Medical Research and Evaluation Facility used for the development of the Pentavalent Botulinum Toxoid (ABCDE).
- Stability testing was conducted for this IND product.

D.2.3.6 Botulism Immune Globulin (Human), Pentavalent (IND #1332)

- The IND remains open to accommodate emergency treatment requirements for exposure or possible exposure to botulinum toxin types A, B, C, D, or E.

D.2.4 Joint Vaccine Acquisition Program (JVAP) Accomplishments

D.2.4.1 Prime Systems Contract

- The Secretary of the Army approved indemnification for the prime systems contractor.

D.2.4.2 Contingency Stockpile of Biological Defense (BD) Vaccines

- Stability testing capability to support continuing use of the Investigational New Drug (IND) stockpile has been established at Southern Research Institute (SRI), Frederick, Maryland facility. SRI, a sub-contractor to DynPort, LLC, has completed annual stability tests on all IND lots of Tularemia, Q-Fever, VEE, EEE, and WEE IND vaccines.

D.2.4.3 Advanced Development of the Tularemia Vaccine

- Under contract to Life Sciences Division, Dugway Proving Ground (DPG), the selected National Drug vaccine candidate was resuscitated on glucose cysteine blood agar and transparent PCA medium.
- Using the oblique light technique, the resuscitated cultures consisted primarily of the immunogenic blue phenotype necessary for vaccine development.
- A research seed was produced under contract to Life Sciences Division, DPG, for transfer to a GMP-compliant facility for production of master and working seed banks.
- Work started on animal model for safety at Defense Evaluation Research Agency (UK).

D.2.4.4 Advanced Development of the Q-fever Vaccine

- A site inspection of the selected manufacturing sub-contractor in Australia was conducted.
- Facility and product pre-IND meetings were held with the FDA.

D.2.4.5 Advanced Development of the Smallpox Vaccine

- Continued to review historical records and to identify technical and regulatory issues to form the basis for a scientifically sound, feasible plan for the advanced development of a cell culture smallpox vaccine.
- Submitted a clinical protocol to the FDA to evaluate the candidate vaccine administered by scarification.
- Filed an IND with the FDA to insure continued availability of previously manufactured Vaccinia Immune Globulin (VIG), which will allow the clinical trial to proceed.
- A manufacturing and licensure effort for a new VIG product has begun.
- Continued discussions with the Department of Health and Human Services about the feasibility of scale-up production for the DoD vaccine to obtain for a civilian stockpile.

D.2.4.6 Venezuelan Equine Encephalitis Vaccine

- Transitioned infectious clone vaccine candidate into advanced development.

D.2.4.7 Recombinant Botulinum Toxin Vaccine

- Transitioned monovalent botulinum toxin vaccine candidates into advanced development.

D.2.4.8 International Cooperative Research and Development

- The JVAP Project Management Office (PMO) continued technical discussions with representatives of the United Kingdom and Canada about cooperative research and development agreements for Biological Defense vaccine products. As a result of these discussions the JVAP PMO has developed U.S. documentation outlining a proposed

strategy and approach in negotiating a Tri-National Project Arrangement with the UK and Canada.

- The JVAP PMO participated extensively with the Medical Biological Development Research Directorate to achieve a Milestone 0 decision by the Medical Research Material Command (MRMC) to continue development of both U.S. and UK plague vaccine candidates. Each country will independently fund continued development of these vaccine candidates though at least to a Milestone I decision. This process will establish common exit criteria for a Milestone I decision.

D.2.4.10 Integrated Digital Environment (IDE)

In order to meet the Under Secretary of Defense for Acquisition, Technology & Logistics mandate to transition acquisition activities to an IDE by 2002, and to achieve the streamlining and savings associated with the mandate, a comprehensive plan to transition JVAP PMO acquisition activities to an Integrated Digital Environment was developed and approved by JPM-BD. As part of this effort, the JVAP-PMO established a high-speed direct data transmission line with DynPort, LLC that forms the basis for the IDE.

D.3 MEDICAL NUCLEAR (RADIOLOGICAL) DEFENSE RESEARCH PROGRAM

D.3.1 Fielded Products

Advances in medical R&D significantly effect the warfighting mission by sustaining unit effectiveness through conserving the fighting strength of our service members. The individual service member whose performance is decremented by illness is significantly more likely to become a traumatic casualty. In this era of small, but highly lethal forces, loss of only a few team members can dramatically diminish a unit's capability. Medical R&D products (materiel and non-materiel solutions) provide the foundation that ensures the fielding of a flexible, sustainable, modernized force across the spectrum of conflict and in the full breadth and depth of the battlefield. Overcoming medical threats and extending human performance have provided a significant increase in military effectiveness in the past and present the potential for future enhancement on military operational effectiveness. Some of the materiel and non-materiel solutions developed for use by medical radiological defense R&D are:

- Cytokine-based therapeutic applications to prevent the two major fatal syndromes—sepsis and uncontrolled bleeding—following acute radiation injury.
- Cytogenetic biodosimetry service operating to measure individual radiation exposure using blood samples.
- NATO Handbook on the Medical Aspects of NBC Defensive Operations, Volume 1-Nuclear (AMedP-6).
- Medical Effects of Ionizing Radiation (MEIR) Course—Training for approximately 350 Medical Department personnel in FY99.
- Videotapes and CD-ROM of MEIR course lectures produced for distribution to military medical units.

D.3.2 Nuclear Defense Research and Development Accomplishments

The nuclear (or radiological) defense research and development technical barriers and accomplishments during FY98 are grouped in the following threat categories:

- Prompt high-dose radiation.
- Protracted low-dose radiation.
- Combined radiation and chemical or biological agents.

"*Prompt high-dose radiation*" refers to the deposition of high levels of ionizing radiation energy in biological tissues in very short periods of time. Sources of high-energy radiation include emissions within the first 60 seconds of a nuclear weapon detonation and "criticality events" that occur when a nuclear reactor achieves peak energy output either accidentally or through an intentional act. The high linear-energy-transfer imparted by the neutrons of these sources causes significant tissue injury within seconds of exposure, resulting in both short and

long-term health consequences.

"*Protracted low-dose radiation*" refers to the deposition of low-energy radiation energy in biological tissues over extended periods of time. Sources of low-energy radiation include fall-out from nuclear weapon detonations, radiological dissemination devices, and any other source of environmental radiation contamination. Health consequences are generally intermediate to long-term and result from cumulative tissue injury accruing over time due to chronic exposure. Health consequences can be exacerbated further when radionuclides are deposited internally by ingestion, inhalation or through open wounds in the external integument.

"*Combined ionizing radiation and either chemical or biological agents*" refers to the amplified health consequences when chemical or biological insults are incurred in conjunction with radiological injury. Both clinical and non-clinical exposures to ionizing radiation compromise host defenses against a variety other stressors, including infectious agents and chemical toxicants. Exposures to doses of radiation and infectious or chemical agents that are by themselves sublethal can produce mortality rates of nearly 100% when combined.

The Medical Radiological Defense Research Program focuses on developing medical countermeasures to the health consequences of both prompt high-dose and protracted low-dose exposures to ionizing radiation. It also develops experimental data detailing combined NBC medical effects needed by computer modeling programs for casualty prediction. Specific research on medical countermeasures includes work on prophylactic and therapeutic drugs, drug delivery devices to enhance efficacy and simplify administration under field conditions, and combined prophylactic/therapeutic protocols to further enhance efficacy. Work also focuses on developing novel biological dosimetry techniques to measure individual absorbed doses. Knowledge of the dose of radiation absorbed helps guide medical treatment decisions and saves lives. It also provides field commanders with an assessment of the radiological health of deployed forces and leads to better-informed operational decision making.

Threat Category: Prompt High Dose Radiation

The countermeasures, technical barriers, and accomplishments in the threat area of prompt high dose radiation are outlined below.

Countermeasures:

- Advanced medical treatment strategies for radiation injuries.
- Drugs designed to increase resistance of soldiers to radiation and protect the soldier against radiation injury without compromising performance.
- Drugs designed to prevent the onset of radiation-induced performance decrements such as fatigue, nausea and vomiting.
- Biological dosimetry techniques for rapid injury assessment needed to guide medical treatment decisions and assessment of radiological health of combat units.

Technical Barriers:

- Need to minimize the performance-degrading effects of prophylactic drugs that otherwise have good efficacy for the prevention of radiological injury.
- Need to advance knowledge of cellular, sub-cellular, and molecular mechanisms of radiological injury to improve rational development of prophylactic and therapeutic drugs.
- Need to increase prophylactic drug stability in order to improve bioavailability and to enhance drug efficacy.
- Need for extending the stability of a prophylactic drug to allow its use in a slow-release delivery device for extended bioavailability and enhanced efficacy.
- Difficulty in identifying and calibrating biological markers that can both indicate the amount of absorbed radiation dose and differentiate whole-body from partial-body exposure.
- Inability to automate sample preparation and reducing sample preparation times of cytogenetic biodosimetry tests.

Accomplishments:

- Determined in preliminary studies that non-androgenic forms of androstene steroids represent a novel class of effective, nontoxic radioprotectants.
- Continued assessment and optimization of a combined radioprotectant, cytokine, and clinical support treatment modalities for enhancing survival following acute, lethal irradiation.
- Demonstrated the therapeutic advantage of combining two recombinant cytokines (IL-11 and G-CSF) into a single postexposure treatment of acute radiation injury.
- Completed initial experiments showing therapeutic efficacy with the novel use of a tissue-repair cytokine, keratinocyte growth factor, to manage radiation-induced gastrointestinal tissue injury and associated blood infections following exposure.
- Developed new prophylactic strategy for reducing acute radiation injury based on (a) low-toxicity drug selection, (b) pharmacologic quenching to further reduce toxic side effects, and (c) new drug delivery alternatives.
- Developed a novel high-throughput and rapid cytogenetic-based bioassay to assess biologically absorbed radiation dose over a broad dose range.
- Completed development of automated metaphase-finding software/hardware system for cytogenetic-based bioassays. Sample throughput is increased 3-fold and accuracy is significantly improved.

Threat Category: Protracted Low Dose Radiation

Countermeasures, technical barriers, and accomplishments in the area of protracted low dose radiation from nuclear fallout, radiological explosive devices, *etc.*, are outlined below.

Countermeasures:

- Advanced medical treatment strategies for protracted radiation to mitigate injuries from both external and internal sources of radioactivity.
- Drugs designed to protect personnel from the early and late effects of ionizing radiation

without compromising performance pharmacologic intervention strategies that protect against both early and late health effects arising from cellular and molecular damage caused by ionizing radiation.
- Improved techniques to detect and remove internally deposited sources of radioactivity
- Improved drug delivery systems that provide non-encumbering protection during the entire period of radiation exposure.
- Enhanced biodosimetry technique that can differentiate prior from recent exposures to radiation.

Technical Barriers:
- Lack of suitable radiation sources to study the effects of chronic exposure at relevant doses.
- Difficulty in manipulating cellular repair mechanisms.
- Toxicity of chelating agents used to remove sources of radioactivity.
- Brief periods in which traditional radioprotective drugs are active.
- Toxicity of radioprotective drugs used over protracted periods of time. Limited knowledge of DNA damage surveillance and repair mechanisms under protracted exposure conditions hinders development of pharmacologic agents to prevent late-arising cancers.
- Need to reduce the toxicity of heavy metal chelating agents while maintaining their efficacy.
- Need to extend bioavailability of prophylactic drugs to achieve maximum long-term protection.
- Potential cumulative toxicity of prophylactic drugs (antimutagenic and anticarcinogenic agents) when used for extended periods.
- Lack of a sustained drug delivery system of radioprotectants.
- Microbial resistance to antibiotics.
- Difficulty in identifying a persistent biological marker that indicates the amount of absorbed radiation dose for both recent and prior exposures.

Accomplishments:
- Identified a promising new, broad-spectrum, nontoxic pharmacologic that protects against radiation's cancer-inducing effects.
- Developed a foundation for an improved prophylactic strategy based on a better understanding of basic molecular and cellular mechanisms of the long-term consequences of prior radiation-induced tissue damage and repair.
- Established a drug assay to monitor effectiveness of slow-release radioprotective drugs under study.
- Developed novel protocols that leverage the quantitative precision and accuracy of a fluorogenic 5' nuclease PCR procedure to measure molecular responses to radiation and demonstrated that oncogene expression and mitochondria DNA deletions may represent new biological markers for quantifying radiation exposure.

Threat Category: Combined Ionizing Radiation and Either Chemical or Biological Agents

The countermeasures, technical barriers, and accomplishments in the threat area of combined effects of nuclear ionizing radiation with trauma, burns, infection, or chemical toxicants radiation and trauma, burns, and infection are outlined below.

Countermeasures:

- Therapeutic agents designed to decrease morbidity and mortality from multi-organ system failure due to the combined effects of radiation, trauma, burns, and infection or chemical toxicants.
- Radioprotective drugs designed to harden the soldier against the effects of radiation in combination with trauma, burns, infection, or chemical toxicants.
- Combined therapeutic agents designed to decrease morbidity and mortality from combined exposures and to enhance innate immune responses.
- Computer models for predicting casualties following combined exposure to low levels of ionizing radiation and biological warfare/chemical warfare agent aerosols.

Technical Barriers:

- No surrogate models for extrapolating data to humans.
- Limited animal models that are optimum for both radiation and a biological warfare or chemical warfare agent.
- Need to gain access to radiation sources and biological containment facilities in order to complete full range of experiments on combined effects of radiation and BW agents.
- Growing number of microbial organisms resistant to antibiotics.
- Accounting for variability in sensitivities of biological systems to different radiation qualities (*e.g.*, neutron *vs.* gamma radiation).
- Mechanism of action of cell-growth factors is not well understood.
- Sensitivity of bone marrow progenitor cells to low doses of ionizing radiation.

Accomplishments:

- Determined in rodent model that sub-lethal exposures to ionizing radiation and intratracheal-delivered spores of *B. anthracis* (Sterne) cause 60% to 20% increased mortality in naïve and vaccine-immune populations, respectively.
- Demonstrated for the first time in an animal model that combined exposure to a sublethal dose of radiation and *B. anthracis* spores (Sterne) results in opportunistic systemic infection from translocated enteric bacteria.
- Established capability to integrate health consequences of radiation/biological warfare agent interactions, extrapolated from animal model studies, into the Consequence Assessment Tool Set (CATS).
- Established the $LD_{50/30}$ of gamma radiation in the euthymic hairless rodent as a model for studies of the effects of combined exposure to radiation and mustard blistering agents.
- Demonstrated a 10,000-fold reduction of the $LD_{50/30}$ to mice from intraperionela challenge with Venezuelan Equine Encephalomyelitis (VEE) virus if the mice are first exposed to a sublethal dose of ionizing radiation.

D.3.3 Predevelopment Products

Technical developments in predevelopment products for medical radiological defense include the following:

- Androstene steroids as broad spectrum, nontoxic radioprotectants.
- "Slow release" radioprotectant for extended periods of protection.
- Cytokine therapeutic for the effective treatment of acute radiation injury of the gastrointestinal system.
- CATS model enhancements to incorporate radiation/BW interactions.
- Product improvement of the cytogenetic biodosimetry system by automation of satellite scoring subsystem to increase sample throughput.
- Rapid and sensitive method to measure urinary uranium concentration.

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Annex E

DoD Joint Service Chemical and Biological (CB) Defense Program Funding Summary

In accordance with 50 USC 1522, *Department of Defense Chemical and Biological Defense Program*, research, development, test and evaluation (RDT&E) and procurement for all DoD chemical and biological (CB) defense programs (with the exception of those biological warfare defense RDT&E programs conducted by the Defense Advanced Research Projects Agency, DARPA) are consolidated into defense-wide program element (PE) funding lines. Detailed funding information previously contained in this annex is provided annually to Congress in the DoD Joint Service Chemical and Biological Defense Program, President's Budget Submission, Research, RDT&E, Defense-Wide and Procurement, Defense-Wide budget exhibits, and in the Department of Defense Extract found in the Budget of the United States. These budget submissions provide a detailed account of prior year accomplishments and planned activities for the budget request period. Table E-1 (and Figure E-1) provides a summary of appropriated and requested funding from FY 1996 – FY 2005. Fiscal year 1996 was the first year in which all Service and Defense Agency CB defense programs were consolidated into defense-wide funding lines. Prior to FY 1996, funding was included in several separate Service and Defense Agency funding lines. Also, during FY 1996 approximately $30 million was transferred to the CB Defense Program procurement line from the Army's operations and maintenance (O&M) accounts for bio-defense vaccine acquisition. Much of the growth in program funding between FY 1996 and FY 1997 resulted from the transfer of funds between existing accounts rather than real growth in the overall DoD CB Defense Program.

Table E-2 provides a summary of expenditures by the DoD Chemical and Biological Defense Program. Expenditures represent the amount of checks issued or other payments made (including advances to others), net of refunds and reimbursements. The term is frequently used interchangeably with the term "outlays," which are the measure of government spending (*i.e.*, payments to liquidate obligations (other than the repayment of debt), net of refunds and offsetting collections.) It is important to note that funds appropriated for a given year may be expended incrementally over a period of years. Thus, expenditures shown in Table E-2 will be updated in following years to show total expenditures of appropriated funds.

Table E-1. Chemical and Biological Defense Program Appropriations Summary

Program Element (PE) ($ millions)	FY96‡	FY97‡	FY98‡	FY99‡	FY00‡	FY01*	FY02**	FY03**	FY04**	FY05**
0601384BP - Basic Research	26.492	28.372	25.263	28.505	44.040	33.197	30.990	30.004	30.973	31.969
0602384BP - Applied Research	68.571	70.823	69.632	62.301	97.400	73.600	83.185	84.480	74.872	76.467
0603384BP - Advanced Tech. Dev.	33.727	41.693	43.517	59.186	56.911	46.594	53.283	62.722	83.190	80.934
Science & Technology Base Subtotal	128.790	140.888	138.412	149.992	198.351	153.391	167.458	177.206	189.035	189.370
0603884BP - Demonstration/Validation	29.184	44.747	49.465	61.409	68.502	83.800	69.494	74.465	72.511	53.289
0604384BP - EMD	87.229	97.468	123.045	103.159	118.458	100.815	166.231	183.528	119.095	74.497
0605384BP - Management Support	6.954	17.936	21.137	25.099	24.553	23.907	24.515	25.009	24.667	25.385
0605502BP - Management Support/Small Business Innovative Research (SBIR)	0.000	0.000	5.612	5.638	0.000	0.000	0.000	0.000	0.000	0.000
RDT&E, Defense-Wide (D-W) Subtotal	252.157	301.039	337.671	345.297	409.864	361.913	427.698	460.208	405.308	342.541
0208384BP - Procurement, D-W Subtotal	135.647	232.952	233.943	295.189	381.156	473.936	425.870	440.165	486.037	518.767
CB Defense Program Total	*387.804*	*533.991*	*571.614*	*640.486*	*791.020*	*835.849*	*853.568*	*900.373*	*891.345*	*861.308*

‡ Total Obligation Authority (TOA)
* FY01 President's Budget Request
** Estimated (from FY01 President's Budget)

Table E-2. Chemical and Biological Defense Program Expenditures Summary

Program Element (PE) ($ millions)	FY96†	FY97†	FY98†	FY99†
RDT&E, Defense-Wide	241.096	269.429	299.879	168.222
Procurement, Defense-Wide	125.803	199.476	162.202	72.375
CB Defense Program Total	366.899	468.905	462.081	240.597

† Expenditures as of September 30, 1999.

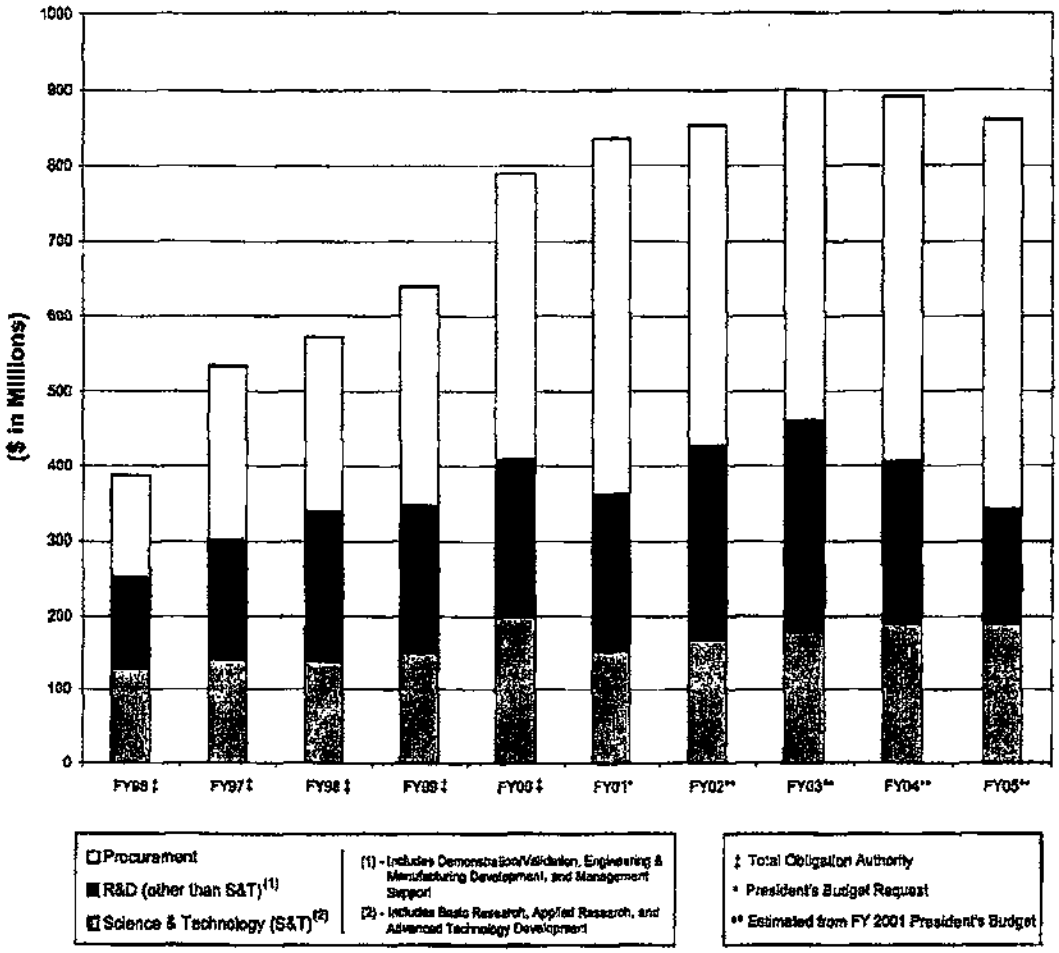

Figure E-1. Chemical and Biological Defense Program Appropriations Summary

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Annex F

Nuclear, Biological, and Chemical Defense Internet Sites

Following is a list of selected locations on the internet that may provide information about nuclear, biological, and chemical defenses. This list is not intended to be exhaustive, but rather to aid those in the research and analysis of NBC defense issues. Identification of a site here does not represent an endorsement by the Department of Defense nor any of its subordinate organizations, nor any responsibility for the content or accuracy of information provided at each site. Site locations (URLs) may change or be deleted, but were accurate as of January 3, 2000.

DefenseLink
http://www.defenselink.mil/
The official home page of the Department of Defense. Includes numerous reports and links to DoD organizations.

Defense Threat Reduction Agency
http://www.dtra.mil
Home page of the Defense Threat Reduction Agency). Includes information on each of the major mission areas and Directorates at DTRA.

CBIAC (Chemical Warfare/Chemical Biological Defense (CW/CBD) Information Analysis Center)
http://www.cbiac.apgea.army.mil/
CBIAC serves as the DoD focal point for CW/CBD technology. The CBIAC serves to collect, review, analyze, synthesize, appraise and summarize information pertaining to CW/CBD. It provides a searchable database for authorized users and links to many other CW/CBD related sites.

The NBC Medical Defense Information Server
http://www.nbc-med.org/
The Nuclear Biological and Chemical Medical (Med-NBC) web page contains extensive medical documentation, training material, audio-video clips, a powerful search engine, and links to other related internet sites.

The Army Medical Department Center and School
http://www.armymedicine.army.mil/armymed/
Provides extensive information about the Army's Medical Department. Includes information on doctrine development and the use of medical NBC defense products.

U.S. Army Soldier and Biological Chemical Command Information Server
http://www.sbccom.apgea.army.mil/
Home page of the U.S. Army Soldier and Biological Chemical Command.

Edgewood Chemical and Biological Center (ECBC) Home Page
http://www.sbccom.apgea.army.mil/RDA/ecbc/
ECBC is the Army's principal R&D center for chemical and biological defense technology, engineering, and service. Provides technical and other information on ECBCs products and services.

Joint Service Chemical Biological Information System (JSCBIS)
http://www.sarda.army.mil/jscbis/jscbis.htm
Provides financial and programmatic information for DoD's Chemical and Biological Defense Program. Requires user identification and password, which can be applied for through the home page.

Dugway Proving Ground Home Page
http://www.atc.army.mil/~dugway/
Home page of the U.S. Dugway Proving Ground, location of much of the field tests of chemical and biological defense equipment and repository of historical chemical and biological warfare information.

Chemical and Biological Weapons Nonproliferation Project
http://www.stimson.org/cwc/
This project serves as a problem-solver and an information clearinghouse in the general subject areas of CB treaties, chemical demilitarization (especially in Russia), CB terrorism, and related areas. Sponsored by The Stimson Center.

The PTS-OPCW-PrepCom Home Page
http://www.opcw.nl/
The home page of the Provisional Technical Secretariat, the Organization for the Prohibition of Chemical Weapons, and the Preparatory Commission of the Chemical Weapons Convention (CWC). Provides detailed information about the CWC, its implementation, and technical and background information on chemical weapons, chemical defenses, and related subjects.

United States Army Chemical School
http://www.wood.army.mil/usacmls/
Home Page for the US Army Chemical School at Fort Leonard Wood, MO. Provides information on the U.S. Army Chemical School which is one of the most advanced and sophisticated training centers for chemical and biological defense.

Harvard Sussex Program on CBW Armament and Arms Limitation
http://fas-www.harvard.edu/~hsp/
Provides files that promote the global elimination of chemical and biological weapons and to strengthen the constraints against hostile uses of biomedical technologies.

Medical Chemical and Biological Defense
http://mrmc-www.army.mil/
Provides information on Medical Chemical Defense Overview, Nerve, Agents, Cyanide, Skin Decontamination and Protection, Performance Effects of Protectant Drugs, and Chemical Casualty Management. Linked to the Medical Research and Materiel Command Home Page and the U.S. Army Medical Research Institute for Chemical Defense Home Page (http://chemdef.apgea.army.mil). Also provides information on Medical Biological Defense Overview, Diagnostic Assays, Viruses, Bacteria, and Toxins, Drugs, Vaccines, and Biological Casualty Management.

United States Army Medical Research Institute of Infectious Diseases
http://www.usamriid.army.mil
Home Page of the U.S. Army Medical Research Institute of Infectious Diseases, location of much of the science and technology research efforts for medical biological defense.

Armed Forces Radiobiological Research Institute (Medical Radiological Defense)
http://www.afrri.usuhs.mil/
Provides information on Medical Radiobiological research and education activities of the triservice Armed Forces Radiobiological Research Institute. The site includes information on the latest developments, products, resources, research approach, strategy, research teams/staff, outreach training, professional meetings, and links to related sites.

Defense Advanced Research Projects Agency (DARPA)
http://www.darpa.mil/
Home Page of DARPA describes basic and applied research and development projects being performed for DoD, including biological warfare defense projects though link to the Defense Sciences Office (http://www.darpa.mil/dso/), the Microsystems Technology Office (http://www.darpa.mil/mto/), and the Special Projects Office (http://www.darpa.mil/spo/).

Program Manager for Chemical Demilitarization
http://www-pmcd.apgea.army.mil/index.html
Provides information on the Chemical Stockpile Disposal Program, the Non-Stockpile Chemical Materiel Program, the Alternative Technologies Program, the Chemical Stockpile Emergency Preparedness Program, and the Cooperative Threat Reduction Office.

Joint Vaccine Acquisition Program
http://www.Armymedicine.army.mil/jvap
Home page of the Joint Vaccine Acquisition Program Office, provides program history, programmatic information concerning the DoD efforts to produce vaccines against biological warfare agents

Joint Program Office for Biological Defense
http://www.jpobd.net
Home page of the Joint Program Office for Biological Defense. The site is currently being developed and will include information concerning the DoD biological defense acquisition programs managed by the Joint Program Manager for Biological Defense to include enhanced detection systems, Hand Held Immunochromatographic Assays (HHAs), the Joint Field Trials (JFTs), medical products and vaccines.

NBC Industry Group
http://www.nbcindustrygroup.com/
Home page of the NBC Industry Group, an association of organizations supporting NBC defense, domestic preparedness, and the Chemical Weapons Convention.

Anthrax Vaccine Immunization Program
http://www.anthrax.osd.mil/
Home page of the Department of Defense total force anthrax vaccine immunization program.

Office of the Special Assistant for Gulf War Illness
http://www.gulflink.osd.mil/
Official website of the Special Assistant for Gulf War Illness. The site provides information regarding the findings of the office on Gulf War Illness and links to related information.

Monterey Institute of International Studies, Center for Nonproliferation Studies
http://cns.miis.edu/
Website provides links to original research and resources in nonproliferation, chemical and biological terrorism, and specific regional nonproliferation regimes.

Annex G

Statement Regarding Chemical and Biological Defense Programs Involving Human Subjects

The reporting requirement (50 USC 1523) for the annual report to Congress on the DoD Chemical and Biological Defense Program was modified by Section 1086 of the FY98 National Defense Authorization Act. The amendment requires the following information:

> A description of any program involving the testing of biological or chemical agents on human subjects that was carried out by the Department of Defense during the period covered by the report, together with a detailed justification for the testing, a detailed explanation of the purposes of the testing, the chemical or biological agents tested, and the Secretary's certification that informed consent to the testing was obtained from each human subject in advance of the testing on that subject.

Table F-1 provides a summary of prior and planned tests conducted by the Department of Defense, both directly or under contract, which involve the use of human subjects for the testing of chemical or biological agents. In summary, there has been no such testing since 1969 with biological agents, since 1975 for chemical agents, and no testing is planned.

Table F-1. Summary of Experiments and Studies with Human Subjects Involving the Use of Chemical or Biological Agents

November 25, 1969	–	Human biological agent testing ended
July 28, 1975	–	Human chemical agent testing ended
Since 1969/1975	–	No activities with human subjects involving exposure to biological agents (since 1969) nor chemical agents (since 1975) have occurred since testing ended

The Department is in full compliance with the requirements of all laws regarding the use of human subjects involving chemical or biological agents. DoD is involved in no experimentation or any other efforts which involve the exposure of human subjects to chemical or biological agents.

As part of the DoD Chemical and Biological Defense Program, DoD requires the use of small quantities of chemical and biological agents in the research, development, test and evaluation of detection, protection, and decontamination equipment and systems. Chemical and biological agents are also used in small quantities in training U.S. forces to operate in protective equipment and to operate detection and decontamination systems in a chemical or biological

environment. However, no research, development, test or evaluation involves the exposure of human subjects to chemical or biological agents.

Medical chemical and biological defense programs involve the use of human subjects in controlled clinical trials to test and evaluate the safety, immunogenicity, and other effects of medical products (drugs, vaccines, therapies, *etc.*) to protect against chemical and biological agents. The use of human subjects in these trials involves volunteers who have provided informed consent. All use of human subjects in these trials is in full compliance with the "Common Rule," Federal Policy for the Protection of Human Subjects, Food and Drug Administration (FDA) regulations, Federal Acquisition Regulations (FAR), DoD Directives and Instructions, and *all* other applicable laws, regulations, issuances, and requirements. No medical chemical or biological defense programs involving human subjects involves the exposure of these subjects to chemical or biological agents.

While DoD conducted tests involving the exposure of human subjects to chemical and biological agents in the past, all such tests and programs have been halted and disbanded. The United States formally renounced the "use of lethal biological agents and weapons, and all other methods of biological warfare" in National Security Decision 35, November 25, 1969. Human testing with lethal biological warfare agents was never done and testing with incapacitating biological warfare agents was ceased in 1969. The last human testing of chemical warfare agents occurred on July 25, 1975. Acting Secretary of Army Norman Augustine suspended testing of chemical compounds on human volunteers on July 28, 1975.

Tests involving the exposure of human subjects to chemical agents began in the 1940s and continued following World War II through the Cold War until the early 1970s. Such testing has been documented and reported to Congress. See for example, Department of Army, Inspector General Report, DAIG-IN 21-75, *Use of Volunteers in Chemical Agent Research*, March 1976. In addition, there was extensive congressional testimony on this subject during 1975 and 1976. DoD has not conducted any experimentation since that time involving the exposure of human subjects to chemical warfare agents.

Annex H

Congressional Reporting Requirement: 50 USC 1523

Text of Public Law Mandating Report on The Department of Defense Chemical and Biological Defense Program

Title 50 of the U.S. Code, Sec. 1523. Annual report on chemical and biological warfare defense
Implemented by Public Law 103-160, The FY94 National Defense Authorization Act

(a) Report required

The Secretary of Defense shall include in the annual report of the Secretary under section 113(c) of title 10, a report on chemical and biological warfare defense. The report shall assess--

(1) the overall readiness of the Armed Forces to fight in a chemical-biological warfare environment and shall describe steps taken and planned to be taken to improve such readiness; and

(2) requirements for the chemical and biological warfare defense program, including requirements for training, detection, and protective equipment, for medical prophylaxis, and for treatment of casualties resulting from use of chemical or biological weapons.

(b) Matters to be included

The report shall include information on the following:

(1) The quantities, characteristics, and capabilities of fielded chemical and biological defense equipment to meet wartime and peacetime requirements for support of the Armed Forces, including individual protective items.

(2) The status of research and development programs, and acquisition programs, for required improvements in chemical and biological defense equipment and medical treatment, including an assessment of the ability of the Department of Defense and the industrial base to meet those requirements.

(3) Measures taken to ensure the integration of requirements for chemical and biological defense equipment and material among the Armed Forces.

(4) The status of nuclear, biological, and chemical (NBC) warfare defense training and readiness among the Armed Forces and measures being taken to include realistic nuclear, biological, and chemical warfare simulations in war games, battle simulations, and training exercises.

(5) Measures taken to improve overall management and coordination of the chemical and biological defense program.

(6) Problems encountered in the chemical and biological warfare defense program during the past year and recommended solutions to those problems for which additional resources or actions by the Congress are required.

(7) A description of the chemical warfare defense preparations that have been and are being undertaken by the Department of Defense to address needs which may arise under article X of the Chemical Weapons Convention.

(8) A summary of other preparations undertaken by the Department of Defense and the On-Site Inspection Agency to prepare for and to assist in the implementation of the convention, including activities such as training for inspectors, preparation of defense installations for inspections under the convention using the Defense Treaty Inspection

Readiness Program, provision of chemical weapons detection equipment, and assistance in the safe transportation, storage, and destruction of chemical weapons in other signatory nations to the convention.

(9) A description of any program involving the testing of biological or chemical agents on human subjects that was carried out by the Department of Defense during the period covered by the report, together with a detailed justification for the testing, a detailed explanation of the purposes of the testing, the chemical or biological agents tested, and the Secretary's certification that informed consent to the testing was obtained from each human subject in advance of the testing on that subject.

Annex I

Acronyms and Abbreviations

Note: The acronyms and abbreviations in this annex reflect an extensive, though not exhaustive, list of terms related to the various and diverse CB defense activities. This definitions are authoritative definition and may have different meanings in other contexts.

-A-

AAAV – Advanced Amphibious Assault Vehicle
AAR – after action report
AARS – Advanced Airborne Radiac System
ABO – Agent of Biological Origin
ACAA – Automatic Chemical Agent Alarm
ACADA - Automatic Chemical Agent Detector
ACC – Air Combat Command
ACES – Air Force Command Exercise System
Ach – acetylcholine
ACOM – Atlantic Command
ACPLA – agent containing particle per liter of air
ACPM – Aircrew Protective Mask
ACTD – Advanced Concept Technology Demonstration
ADS – Area Detection System
AERP – Aircrew Eye/Respiratory Protection
AFIP – Armed Forces Institute of Pathology
AFMAN – Air Force Manual
AFMS – Air Force Medical Service
AFRRI – Armed Forces Radiobiology Research Institute
AG – Australia Group
AICPS – Advanced Integrated Collective Protective System
AIDET – Aircraft Interior Detector
AIT – Aeromedical Isolation Team
ALAD – Automatic Liquid Agent Detector
ALSA – Air Land Sea Application
AMAD – Automatic Mustard Agent Detector
AMC – U.S. Army Materiel Command
AMEDDC&S – Army Medical Department Center and School
ANCOC – Advanced NCO Course
ANG – Air National Guard
AN/VDR-2 – Portable dose-rate gamma/beta radiation meter
AN/VDR-13 – Compact, digital whole body radiation meter
APODS – Aerial Port of Debarkation
ARNG – Army National Guard
ARTEP – Army Training and Exercise Plan
ASA(ALT) – Assistant Secretary of the Army for Acquisition, Logistics & Technology
ASBREM – Armed Services Biomedical Research Evaluation and Management
ASCC – Air Standardization Coordinating Committee
ASD(HA) – Assistant Secretary of Defense for Health Affairs
ASD(SO/LIC) – Assistant Secretary of Defense for Special Operations and Low-Intensity Conflict
ATD – Advanced Technology Demonstration
AT/FP – Antiterrorism Force Protection
ATG – Afloat Training Group
ATH – Air Transportable Hospital
ATP – Adenosine Triphosphate
ATSD(NCB) – Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs
ATSO – Ability to Survive and Operate
AVIB – Aircrew Uniform Integrated Battlefield
AVIP – Anthrax Vaccine Immunization Program

-B-

B. anthracis – *Bacillus anthracis* (anthrax)
B. mallei– *Burkholderia mallei* (glanders)
BBS – Brigade Battle Simulation
BCTP – Battle Command Training Center
BD – biological detector (also, biological defense)
BDO – Battledress Overgarment
BDU – Battledress Uniform
BES – Budget Estimate Submission
BG – *Bacillus Globigii*
BIDS – Biological Integrated Detection System
BL – Biosafety Level
BNCOC – Basic Non-Commissioned Officer Course
BOG – Board of Governors
BoNT – Botulinum Neurotoxin
BoNT/A – Botulinum Neurotoxin A
BoNT/B – Botulinum Neurotoxin B
BRP – Basic Research Plan
BTN – below the neck
BuChE – butyrylcholinesterase
BVO/GVO – black vinyl overboot/green vinyl overboot
BW – biological warfare
BWC – Biological Weapons Convention

BWD – Biological Warfare Defense

–C–

C^4I – command, control, communication, computer, and intelligence
C. burnetii – *Coxiella burnetii* (Q fever)
CA – Commodity Area
CAA – Center for Army Analysis
CA/D – Chemical Activity/Depot
CaE – carboxylesterase
CAM – Chemical Agent Monitor (also, Commodity Area Manager)
CAMEX – Computer Assisted Map Exercise
CANA – Convulsant Antidote, Nerve Agent autoinjector
CANE – Combined Arms in a Nuclear/Chemical Environment
CAPDS – Chemical Agent Point Detection System
CARDS – Chemical Agent Remote Detection System
CASTFOREM – Combined Arms and Support Task Force Evaluation Model
CatOx – catalytic oxidation
CAWM – Chemical Agent Water Monitor
CB – chemical and biological (also C/B)
CBAT – Chemical Biological Augmentation Team
CBAWM – Chemical Biological Agent Water Monitor
CBD – chemical and biological defense
CBDP – Chemical/Biological Defense Program
CBIRF – Chemical Biological Incident Response Force
CBIS – CB Individual Sampler
CBM&S – Chemical/Biological Modeling & Simulation
CBMS – chemical biological mass spectrometer
CBNP – Chemical Biological Non-Proliferation
CBPS – Chemical Biological Protective Shelter
CBR – Chemical, Biological, and Radiological
CBR-D – Chemical, Biological, Radiological Defense
CBRNC – Chemical, Biological, Radiological & Nuclear Countermeasures
C/B-RRT – Chemical Biological Rapid Response Team
CBS – Corps Battle Simulation
CBSD – Chemical Biological Stand-off Detector
CBW – chemical and biological warfare
CCD – Camouflage, Concealment, and Deception
CDC – Centers for Disease Control and Prevention
CD-ROM – Compact Disk - Read Only Memory
CDTF – Chemical Defense Training Facility (at the U.S. Army Chemical School)
CEES – half mustard (2-chloroethyl ethylsulfide)
CEM – Concept Evaluation Model
CENTCOM – Central Command
CESM – Chemical Environment Survivability Mask
CESS – Chemical Environment Survivability Suit
CFD – Computational Fluid Dynamics
CFM – cubic feet per minute
CFR – Code of Federal Regulations
CHAMP – *Chemically/biologically Hardened Air* Management Plant
CHATH – Chemically/Biologically Hardened Air Transportable Hospital
ChE – Cholinesterase
CINC – Commander-in-Chief
CINCCENT – Commander-in-Chief Central Command
CINCPAC – Commander-in-Chief Pacific Command
CJCS – Chairman of the Joint Chief of Staff
CM – Chloroform-Methanol (also, consequence management)
CMO – Central MASINT Office
CMR – Chloroform-Methanol Residue
CMTC – Combat Maneuver Training Center
CNS – Central Nervous System
COBC – Chemical Officer Basic Course
COMMZ – Communications Zone
COMPTUEX – Composite Training Unit Exercise
CONOPS – Concept of Operations
CONUS – continental United States
COTS – Commercial Off-the-Shelf
CP – chemical protective (also, collective protection, or counterproliferation)
CPE – Collective Protection Equipment
CPO – Chemical Protective Overgarment
CPRC – Counterproliferation Review Council
CPS – Collective Protection System
CPU – Chemical Protective Undergarment
CRDA – Cooperative Research & Development Agreement
CRG – Compliance Review Group
CSST – Chemical Casualty Site Team
CT – Concentration over time
CTC – Combat Training Center
CTR – Cooperative Threat Reduction
CTS – Casualty Training System
CVC – Combat Vehicle Crewmen
CVIP – Chemical Vision Implementation Plan
CW – Chemical Warfare
CWA – Chemical Warfare Agent
CWC – Chemical Weapons Convention
CWCIWG – Chemical Weapons Convention Implementation Working Group
CWDD – Chemical Warfare Directional Detector (AN/KAS-1A)
CWICS – Chemical Weapons Interior Compartment System

–D–

DAB – Defense Acquisition Board
DAP – Decontaminating Apparatus Portable
DARPA – Defense Advanced Research Projects Agency
DATSD (CBD) – Deputy Assistant to the Secretary of Defense for Chemical/Biological Defense
DCSOPS – U.S. Army Deputy Chief of Staff for Operations
DDR&E – Director, Defense Research and Engineering
DEA – Data Exchange Agreement
DEPMEDS – Deployable Medical Systems
DEST – Domestic Emergency Response Team
DLA – Defense Logistics Agency
DMMP – Dimethyl Methyl Phosphonate
DNA – Deoxyribonucleic Acid
DNBI – Disease and Non-Battle Injury
DoD – Department of Defense
DoE – Department of Energy
DPE – Demilitarization Protective Ensemble
DPG – Defense Planning Guidance; Also Dugway Proving Grounds
DRB – Defense Review Board (also, Defense Resources Board, or Division Ready Brigade)
DRI – Defense Reform Initiative
DS2 – Decontamination Solution 2
DSCP – Defense Supply Center Philadelphia
DSO – Defense Sciences Office
DTO – Defense Technology Objective
DTAP – Defense Technology Area Plan
DTIRP – Defense Technical Inspection Readiness Program
DTLOMS – Doctrine, Training, Leader Development, Organization, Material, and Soldier/Personnel
DTO – Defense Technology Objective
DT/OT – developmental/operational testing
DTRA – Defense Threat Reduction Agency
DTRA(CB) – Defense Threat Reduction Agency's Chemical and Biological Defense Directorate

–E–

E. coli – *Escherichia coli*
ECBC – Edgewood Chemical & Biological Center
ECV – Expanded Capacity Vehicle
ED – ethyl dichlorarsine
EEE – Eastern Equine Encephalomyelitis
EEG – electroencephalographic
ELISA – Enzyme-Linked Immunosorbent Assay
EMD – Engineering and Manufacturing Development
ENCOMPASS – Enhanced Consequence Management Planning and Support System
EOD – Explosive Ordnance Disposal
EUCOM – European Command

–F–

F1 – Fraction 1
F1-V – Fraction 1 - "V" Antigen
Fab – Fragment Antigen Binding
FAR – Federal Acquisition Regulations
Fc – Fragment Crystallizable
FCBC – Field Management of Chemical and Biological Casualties Course
FDA – Food and Drug Administration
FDTE – Force Development Testing and Experimentation
FEST – Foreign Emergency Response Team
FLEETEX – Fleet Exercise
FM – Field Manual
FORCEM – Force Evaluation Model
FR – flame resistance
FUE – First Unit Equipped
FY – fiscal year
FY99 – Fiscal Year 1999
FYDP – Future Years Defense Plan

–G–

GA – tabun, a nerve agent
GAO – General Accounting Office
GB – sarin , a nerve agent
GC – gas chromatography
GD – soman, a nerve agent
GF – a nerve agent
GMP – Good Manufacturing Practice
GPFU – Gas Particulate Filter Unit
GPRA – Government Performance and Results Act

–H–

HAZWARN – NBC Hazardous Warning System
HAZWOPR – Hazardous Waste Operations and Emergency Response
hBuChE – Human Butrylcholinesterase
hCaE – Human Carboxylesterase
HD – sulfur mustard, a blister agent
HEPA – high efficiency particulate
HHA – Hand Held Immunochromatographic Assays
HMMWV – High Mobility Multipurpose Wheeled Vehicle
HN – Host Nation
HSC/YA – Human Systems Program Office
HTA – high threat area

–I–

IBAD – Interim Biological Agent Detector
IBMC – Industrial Base Maintenance Contract
ICAD – Individual Chemical Agent Detector
ICAM – Improved Chemical Agent Detector

ICDS – Improved Chemical Detection System
IDLH – Immediate Danger to Life and Health
IEG – Information Exchange Group
IET – Initial Entry Training
IL – Interleukin
IL CBDWS – In-Line Chemical Biological Defense Water System
IM – intramuscular
IMS – Ion Mobility Spectroscopy
IND – Investigational New Drug
IP – intraperitoneal
IPDS – Improved (chemical) Point Detection System
IPE – Individual Protective Equipment
IPT – Integrated Product Team
IR&D – Independent Research & Development
IR-LIDAR – Infrared Light Detection and Ranging
IS – Instrumentation System
ISD – Individual Soldier Detector
ITAP – Improved Toxicological Agent Protective Ensemble
ITS – Individual Training Standard
IVD – Individual Vapor Detector

—J—

JAWG – Joint Assessment Working Group
JBPDS – Joint Biological Point Detection System
JBREWS – Joint Biological Remote Early Warning System
JBSDS – Joint Biological Standoff Detection System
JBUD – Joint Biological Universal Detector
JCAD – Joint Chemical Agent Detector
JCBAWM – Joint Chemical Biological Agent Water Monitor
JCBUD – Joint Chemical and Biological Universal Detector
JCHEMRATES – Joint Chemical Defense Equipment Consumption Rates
JCPE – Joint Collective Protection Equipment
JCRS – Joint Canteen Refill System
JCS – Joint Chiefs of Staff
JFIRE – Joint CB Protective Firefighter Suit
JFOC – Joint Future Operational Capabilities
JFT – Joint Field Trail
JLAS – Joint Land, Aerospace, and Sea Simulation
JMAR – Joint Medical Asset Repository
JMCBDRP – Joint Medical Chemical and Biological Defense Research Program
JMCDRP – Joint Medical Chemical Defense Research Program
JMNS – Joint Mission Need Statement
JMRR – Joint Monthly Readiness Review
JNBCDB – Joint NBC Defense Board
JORD – Joint Operational Requirements Document
JPACE – Joint Protective Aircrew Ensemble
JPO-BD – Joint Program Office for Biological Defense
JRCAB – Joint Readiness Clinical Advisory Board
JRTC – Joint Readiness Training Center
JSA – Joint Service Agreement
JSAM – Joint Service Aviation Mask
JSCBIS – Joint Service Chemical Biological Information System
JSGPM – Joint Service General Purpose Mask
JSIG – Joint Service Integration Group
JSIMS – Joint Simulation System
JSLIST – Joint Service Lightweight Integrated Technology (individual protection)
JSLNBCRS – Joint Service Light NBC Reconnaissance System
JSLSCAD – Joint Service Lightweight Stand-off Chemical Agent Detector
JSMG – Joint Service Materiel Group
JSMLT – Joint Service Mask Leakage Tester
JSNBCRS – Joint Service NBC Reconnaissance System
JSTPCBD – Joint Science and Technology Panel for Chemical/Biological Defense
JSWILD – Joint Service Warning and Identification LIDAR Detector
JTASC – Joint Training and Analysis Center
JTAV – Joint Total Asset Visibility
JTC – Joint Training Council
JTCG – Joint Technology Coordinating Group
JTCOPS – Joint Transportable Collective Protection System
JTF – Joint Task Force
JTPCBD – Joint Technology Panel for Chemical and Biological Defense
JVAP – Joint Vaccine Acquisition Program
JWARN – Joint Warning and Reporting Network
JWFC – Joint Warfighting Center
JWSTP – Joint Warfighting S & T Plan

—L—

L – lewisite, a vesicant agent
LAM – Louisiana Maneuvers
LCBPG – Lightweight CB Protective Garment
LD_{50} – Median Lethal Dose
LDS – Lightweight Decontamination System
LHA – general purpose amphibious assault ship
LHD – general purpose amphibious assault ship (with internal dock)
LIDAR – LIght Detection And Ranging
LLC – limited liability corporation
LLR – Low Level Radiological
LMS – Lightweight Multipurpose Shelter
LNBCRS – Light NBC Reconnaissance System

LRBSDS – Long-Range Biological Stand-off Detection System
LSCAD – Lightweight Stand-off Chemical Agent Detector
LSCD – Laser Stand-off Chemical Detector
LSD – landing ship, dock
LSP – Logistics Support Plan
LWRS – Lightweight Reconnaissance System

–M–

M&S – Modeling and Simulation
M&S CA – Modeling and Simulation commodity Area
M&S R&D – Modeling and Simulation Research and Development
MAGTF – Marine Air Ground Task Force
MAJCOM – Major Command
MALDI – Matrix-Assisted Laser Desorption Ionization
MANAA – Medical Aerosolized Nerve Agent Antidote
MANSCEN – Maneuver Support Center
MANTECH – Manufacturing Technology
MASINT – Measures & Signatures Intelligence
MBDRP – Medical Biological Defense Research Program
MCBAT – Medical Chem-Bio Advisory Team
MCBC – Management of Chemical and Biological Casualties Course
MCPE – Modular Collective Protection System
MCU-2A/P – a chemical protective mask
MCWP – Marine Corps Warfighting Publication
MD – methyl dichlorarsine
MDS – Modular Decontamination System
MED – Medical
MEIR – Medical Effects of Ionizing Radiation
METL – Mission Essential Task List
metL, thrA – methionine biosynthesis
MEU – Marine Expeditionary Unit
MFR – Multi-Function Radiac Set
MICAD – Multipurpose Integrated Chemical Agent Detector
MIL STD – Military Standard
MLRS – Multiple Launch Rocket System
MNDRP – Medical Nuclear Defense Research Program
MNS – Mission Needs Statement
MOE– Measure of Effectiveness
MOP – Memorandum of Policy
MOPP – Mission Oriented Protective Posture
MOS – Military Occupational Specialist
MOU – Memorandum of Understanding
MPH – miles per hour
MPS – Mission Performance Standard (also, Multipurpose Protective Sock)
MPSP – Medical Program Sub-Panel
MRMC – Medical Research and Materiel Command
MS – Mass Spectrometry
MTW – Major Theater War
MULO – Multi-purpose Overboot
murE – murein biosynthesis

–N–

NAADS – Nerve Agent Antidote Delivery System
NAAG – NATO Army Armaments Group
NAAK – Nerve Agent Antidote Kit
NAAS – Nerve Agent Antidote System
NAPP – Nerve Agent Pyridostigmine Pretreatment
NATO – North Atlantic Treaty Organization
NBC – Nuclear, Biological, and Chemical
NBCDT – NBC Defense Training
NBC-E – nuclear, biological, and chemical-environment
NBCRS – NBC Reconnaissance System (Fox Vehicle)
NBCWP – NBC Defense Interservice Working Party
NCO – Non-Commissioned Officer
NDA – New Drug Application
NDI – Non-Developmental Item
NEPMU – Navy Environmental and Preventative Medicine Unit
NFPA – National Fire Protection Agency
NGIC – National Ground Intelligence Center
NICP – National Inventory Control Points
NIEX – No-Notice Interoperability Exercise
NIH – National Institute of Health
NO – nitric oxide
NSN – National Stock Number
NTA – Novel Threat Agent
NTC – National Training Center
NWP – Naval Warfare Publication

–O–

OAC – Officer Advance Course
OBC – Officer Basic Course
OG – Overgarment
O&M – Operations & Maintenance
OPCW – Organization for the Prohibition of Chemical Weapons (in The Hague)
OPR – Office of Primary Responsibility
ORD – Operational Requirements Document
OSD – Office of the Secretary of Defense
OSM3 – oximeter instrument
OTSG – Office of the Surgeon General

–P–

P3I – Pre-Planned Program Improvement
PACAF – Pacific Command

PACOM – Pacific Command
PAM – Preventative and Aerospace Medicine
PATS – Protective Assessment Test System
PB – President's Budget
PCPS – Portable Collective Protection System
PCR – polymerase chain reaction
PD – phenyl dichlorarsine
PDDA – Power Driven Decontamination Apparatus
PDM – Program Decision Memorandum
PDRR – Program Definition and Risk Reduction
PE – Program Element
PF – Positive Force Exercise
PICS – Personal Ice Cooling System
PIP – Product Improvement Program
PL 103-160 – Public Law 103-160, The National Defense Authorization Act of FY94
PMCD – Program Manager for Chemical Demilitarization
PMO – Product Management Office
POL – petroleum, oil, and lubricant
POM – Program Objectives Memorandum
PQS – Personnel Qualification
PR – Positive Response Exercise
PRG – Program Review Group
PROFIS – Medical NBC Professional Filler Course
PSA – Pressure Swing Adsorption

–Q–

QDR – Quadrennial Review
QNFT – Quantitative fit testing
QRR – Qualitative Research Requirements
QSTAG – Quadripartite Standardization Agreement
QWG – Quadripartite Working Group

–R–

RBC-AchE – red blood cell acetylcholinesterase
R&D – Research and Development
RDA – Research, Development, and Acquisition
RDTE (Also, RDT&E) – Research, Development, Test and Evaluation
RestOps – Restoration of Operations
RMC – Regional Medical Commands
RSCAAL – Remote Sensing Chemical Agent Alarm
RSTA – Reconnaissance, Surveillance, and Target Acquisition
RTP – Readiness Training Plan
rTSP – Reactive Topical Skin Protectant
RW – radiological/nuclear warfare

–S–

S&T – Science & Technology Base
SACPS – Selected Area Collective Protection System
SAF – Semi-Automated Forces
SAFEGUARD – Scanning Airborne Fourier Emission for Gaseous Ultraspectral Analysis and Radiometric Detection
SAG – Study Advisory Group
SALAD – Shipboard Automatic Liquid Agent Detector
Saratoga – a CB protective overgarment
SAT – Systems Approach to Training
SAW – Surface Acoustic Wave
SBA – Simulation Based Acquisition
SBCCOM – Solider, Biological and Chemical Command (U.S. Army)
SCALP – Suit Contamination Avoidance Liquid Protection
SCAMP – Shipboard Chemical Agent Monitor Portable
SCPE – Simplified Collective Protective Equipment
SCUD – surface-to-surface missile system
SD – Stand-off Detector
SD/ASM – Stand-off Detector for Armor System Modernization
SDK – Skin Decontamination Kit
SDS – Sorbent Decon System
SE – staphylococcal enterotoxins
SEA – Staphylococcal Enterotoxin A
SEB – Staphylococcal Enterotoxin B
SGXA – Air Force Surgeon General
SMART-CB – Special Medical Augmentation Response Team-Chemical/Biological
SMART-PM – Special Medical Augmentation Response Team-Preventative Medicine
SNCO – Staff-Noncommissioned Officer
SOF – Special Operations Forces
SOFCAS – Special Operation Forces Chemical Agent Detector
SOI – School of Infantry
SO/LIC – Special Operations and Low Intensity Conflict
SOMCBD – Special Operations Modular CB Detector
SORTS – Status of Resources and Training System
SPOD – Seaport of Debarkation
SRT – Specialty Response Team
S&T – Science & Technology
STANAG – standard agreement
STB – Supertropical Bleach
STEPO – Self-Contained Toxic Environment Protective Outfit
STEPO-I – Interim Self-Contained Toxic Environment Protective Outfit
STO – Science and Technology Objective
STRAC – Standards in Training Commission
STS – Specialty Training Standard

–T–

TAA – Total Army Analysis
TACWAR – Tactical Warfare
TAP – Toxicological Agent Protective boots and gloves
TARA – Technology Area Review and Assessment
TAV – Total Asset Visibility
TB – Technical Bulletin
TBM – Transportation of Biomedical Materials
TDA – table of distribution and allowances
TED – Troop Equivalent Dose
TEMPER – Tent Extendable Modular Personnel
TEU – Technical Escort Unit
TIC – Toxic Industrial Chemical
TIM – toxic industrial material
TSA – Transition State Analogue
TSG – The Surgeon General
TSP – Topical Skin Protectant
TSWG – Technical Support Working Group

–U–

UAV – Unmanned Aerial Vehicle
UDP – Unit Deployment Program
UN – United Nations
UNSCOM – United Nations Special Commission
USA – United States Army
USACHPPM – United States Army Center for Health Promotion and Preventive Medicine
USACMLS – US Army Chemical School
USAF – United States Air Force
USAMEDDC&S – U.S. Army Medical Department Center and School
USAMMA – U.S. Army Medical Materiel Agency
USAMMDA – U.S. Army Medical Materiel Development Activity
USAMRICD – U.S. Army Medical Research Institute of Chemical Defense
USAMRIID – U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC – U.S. Army Medical Research and Materiel Command
USANCA – United States Army Nuclear and Chemical Agency
USAR – US Army Reserve
USC – United States Code
USD(A&T) – Undersecretary of Defense (Acquisition and Technology)
USFK – U. S. Forces, Korea
USG – United States Government
USMC – United States Marines Corps
USN – United States Navy
USUHS – Uniformed Services University of the Health Sciences
UTC – Unit Type Code

–V–

VCA – Voice Communication Adapter
VCSA – Vice Chief-of-Staff of the Army
VEE – Venezuelan equine encephalomyelitis
VIC – Vector-In-Command
VIG – Vaccinia Immune Globulin
VLSTRACK – Vapor, Liquid, and Solid Tracking Model
VPU – Vapor Protective Undergarment
VTC – Video Teleconference
V&V – verification and validation
VVS – Vehicles, Vans and Shelters
VX – a nerve agent

–W–

WCF – Working Capital Fund
WEE – Western Equine Encephalomyelitis
WG – Working Group
WMD – weapons of mass destruction
WRAIR – Walter Reed Army Institute of Research
WRM – war reserve materiel
WRSI – War Reserves Secondary Items

–Y–

Y. pestis – *Yersinia Pestis* (Plague)

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CDC

April 28, 2000 / Vol. 49 / No. 16

MMWR™
MORBIDITY AND MORTALITY
WEEKLY REPORT

Surveillance for Adverse Events Associated with Anthrax Vaccination — U.S. Department of Defense, 1998–2000

Concerns about the potential use of anthrax as a biologic weapon prompted the U.S. Department of Defense (DoD) to announce on December 15, 1997, anthrax vaccination of all U.S. military personnel. This effort is coordinated by the Anthrax Vaccine Immunization Program (AVIP). AVIP plans a phased vaccination process to achieve total force protection against anthrax by 2004. The current phase of implementation includes vaccination of all service members and mission-essential DoD civilian employees assigned or deployed to high-threat areas. On the basis of program monitoring, as of April 12, 2000, 425,976 service members had received 1,620,793 doses of anthrax vaccine adsorbed (AVA) (Bioport, Inc.,* Lansing, Michigan). Some service members have cited concerns about vaccine safety and efficacy in their decision to refuse vaccination, despite the possibility of administrative or disciplinary actions. To assess anthrax vaccination safety, DoD has conducted surveys of vaccinated personnel. This report describes three completed or ongoing surveys (*1*). The findings indicate that rates of local reactions were higher in women than men and that no patterns of unexpected local or systemic adverse events have been identified.

Survey of Self-Reported Reactions to AVA, U.S. Forces, Korea

At one of the largest vaccination sites for United States Forces, Korea, a mandatory, self-administered prevaccination questionnaire was used to obtain data on health status (including pregnancy, if applicable), medication use, and reactions to the previous dose of AVA. The questionnaire was designed to record service members' concerns about AVA and their reports of adverse events (i.e., a medical condition following vaccination that could be related to the vaccine) to promote risk communication between health-care providers and service members. Data from 6879 questionnaires completed during September–October 1998 were reviewed. Approximately 37% (2531 of 6879) of respondents were service members receiving their first dose; records were analyzed for 4348 (63%) service members who already had received and could comment on their first (2427) or second (1921) vaccine doses.

*Use of trade names and commercial sources is for identification only and does not imply endorsement by CDC or the U.S. Department of Health and Human Services.

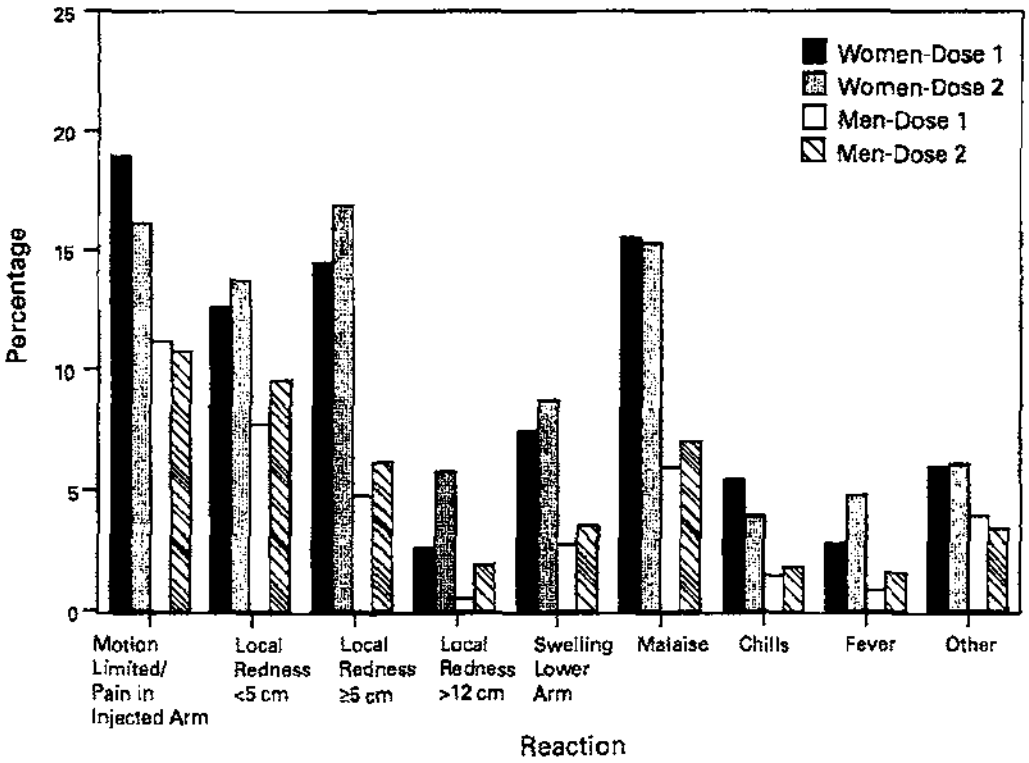
Anthrax Vaccination — Continued

Female service members reported higher rates of reactions to the previous dose of vaccine, regardless of the time period after vaccination (Figure 1). For both men and women, most reported that events were localized, minor, self-limited, and did not lead to impaired work performance, lost work time beyond that required to seek care, and/or a clinic visit or hospitalization. After the first or second dose, 82 (1.9%) of 4348 reported that their work performance had been limited to some extent or that they were placed on limited duty, 13 (0.3%) reported ≥1 day lost from work, 21 (0.5%) consulted a clinic for evaluation, and one (0.02%) required hospitalization for an injection site reaction.

Tripler Army Medical Center Survey of AVA Safety

Tripler Army Medical Center, Honolulu, Hawaii, assessed the frequency and nature of AVA adverse events in a cohort of 603 U.S. military health-care workers in the Korea Medical Augmentee Program. These personnel began receiving anthrax vaccination during September 1998. A self-administered questionnaire was used to collect data prospectively for systemic reactions. Data on local reactions were collected retrospectively for the first three doses and prospectively for the remaining doses. Persons responded to questions on symptoms, signs, time taken off from duty, hospitalizations, and medical visits. Medical records were reviewed and information was obtained from health-care providers about participants who sought medical care, missed one or more work shifts, or had any reaction that might exempt them from further vaccination. Data

FIGURE 1. Self-reported reactions to anthrax vaccine — United States Forces, Korea, September–October 1998



Anthrax Vaccination — Continued

collection up to the fourth AVA dose of the six-dose initial series was complete for 479 (79.4%) of 603 persons. Of the remaining 124 (20.6%), 11 were not vaccinated because of pregnancy, four were exempted from the survey for medical reasons, and the rest were lost to follow-up primarily because of reassignment.

After the first anthrax dose, 47 (7.9%) of 595 reported seeking medical advice and/or taking time off work for a complaint (e.g., muscle or joint aches, headache, or fatigue); after the second dose, 30 (5.1%) of 585; after the third dose, 16 (3.0%) of 536; and after the fourth dose, 17 (3.1%) of 536.

Vaccine Adverse Events Reporting System (VAERS)

DoD uses the CDC and Food and Drug Administration (FDA) Form VAERS-1 to report events potentially related to any vaccination to VAERS and to each military service's disease reporting system. VAERS reports related to anthrax vaccinations are consolidated for AVIP by the Defense Medical Surveillance System. As of April 7, 2000, 428 VAERS-1 reports had been received through DoD. Of these, 311 (72.7%) concerned systemic reactions, 78 (18.2%) were reports on mild or moderate local reactions, and 39 (9.1%) were for large or complicated local reactions. Thirty-six (8.4%) reactions met the DoD mandatory reporting criteria (i.e., hospitalization and/or time off duty >24 hours). None were related to suspected vaccine lot contamination.

A panel of civilian scientific and medical experts established by the U.S. Department of Health and Human Services at DoD's request reviewed all VAERS-1 reports, including those reported directly to FDA or CDC. As of March 21, 2000, the panel has not identified any unexpected patterns of adverse events among 674 reports reviewed.

Reported by: PA Sato, MD, M Ryan, MD, GC Gray, MD, Naval Health Research Center, San Diego, California. KJ Hoffman, MD, CN Costello, MD, United States Forces, Korea. GM Wassermann, MD, Tripler Army Medical Center, Honolulu, Hawaii. MV Rubertone, MD, SA Stanek, DO, US Army Center for Health Promotion and Preventive Medicine, Aberdeen Proving Grounds, Maryland. JD Grabenstein, PhD, Anthrax Vaccine Immunization Program Agency, Office of the Army Surgeon General, Falls Church, Virginia. JR Riddle, DVM, D Trump, MD, Office of the Assistant Secretary of Defense, US Dept of Defense, Washington, DC.

Editorial Note: Anthrax is considered a biologic weapons threat because of its stability in spore form, its ease of culture, the absence of natural immunity in industrialized nations, and severity of infection in its gastrointestinal and inhalational forms. If untreated, the case-fatality rate of inhaled anthrax exceeds 80% (*2,3*).

At least seven nations are suspected to have actively pursued biologic weapons programs (*3,4*). Anthrax also has been used at least once by terrorist groups (*3,4*). U.S. service members deployed to future military confrontations may be at risk for attack by biologic warfare agents. The DoD, through the AVIP, seeks to reduce these threats.

Human anthrax vaccine was licensed by FDA in 1970 as a six-dose primary series with annual boosters. It is an aluminum hydroxide-adsorbed, cell-free, noninfectious vaccine prepared from a noncapsulating, nonproteolytic anthrax strain. Licensing was based on safety data, the results of a controlled efficacy trial, and observational data documenting substantial protection against anthrax (*5,6*). Studies in nonhuman primates also have documented protection (*7*). The safety and efficacy of this vaccine was affirmed by an independent advisory panel in 1985 (*5*).

This mandatory vaccination program has posed substantial challenges to DoD. Some service members are reluctant to be vaccinated because of concern about adverse events. These concerns may be heightened by the number of doses required and by allegations linking vaccination with illnesses in Gulf War veterans. Conversely,

Anthrax Vaccination — Continued

some service members may not report adverse events after vaccination because of concerns that they will not be able to complete the vaccination series, thereby limiting career advancement options.

The findings in this report provide information on rates of local and systemic adverse events occurring after anthrax vaccination was delivered as part of a routine program rather than in clinical trials. The findings suggest that rates of local reactions were higher in women than men and that no patterns of unexpected local or systemic adverse events have been identified. Reasons for the higher rates in women are unknown.

The studies reported here are subject to several methodologic limitations, including sample size, the power to detect rare adverse events, loss to follow-up, and exemption of vaccine recipients with previous adverse events. For example, in the U.S. Forces, Korea, study, any service members medically deferred after a previous AVA dose would have been missed by the survey; therefore, adverse events may have been underreported. In the Tripler survey, data were collected retrospectively for the first three doses and then prospectively, potentially resulting in recall or observational bias. In addition, in the Tripler survey, the absence of an unvaccinated control group limited the ability to assess an association of adverse events with anthrax vaccination. The studies were not designed to detect or quantify chronic or long-term adverse events.

Ongoing activities at DoD, CDC, and FDA are targeted toward improving methods to communicate the benefits and risks for vaccination, enhancing surveillance for vaccine adverse events, and continuing to monitor the safety of the program. These interventions may be useful to enhance AVIP.

Risk-communication programs, such as the one in U.S. Forces, Korea, encourage a positive and supportive patient-provider relationship. Surveillance through the VAERS system to detect signals of potential adverse events followed by epidemiologic investigations to evaluate these signals remains important. Potential methodologies for monitoring safety include comparing vaccinated and unvaccinated groups or comparing groups shortly after vaccination with groups whose vaccinations were more distal.

Pilot studies have evaluated intramuscular vaccine administration to reduce rates of local adverse events. Additional studies are planned to expand these data and to determine whether the number of doses required in the primary vaccination series can be reduced while maintaining immunogenicity and protection.

AVIP maintains a World-Wide Web site (http://www.anthrax.osd.mil)[1] with information on the program and electronic mail access to AVIP staff. A toll-free information line for inquiries from health-care providers, service members, and the public also is available (telephone [877] 438-8222).

References

1. Friedlander AM, Pittman PR, Parker GW. Anthrax vaccine: evidence for safety and efficacy against inhalational anthrax. JAMA 1999;282:2104–6.
2. Brachman PS, Friedlander AM. Anthrax. In: Plotkin SA, Orenstein WA, eds. Vaccines. 3rd ed. Philadelphia, Pennsylvania: WB Saunders, 1999.
3. Inglesby T, Henderson D, Bartlett J, et al. Anthrax as a biological weapon: medical and public health management. JAMA 1999;281:1735–45.

[1] References to sites of non-CDC organizations on the Internet are provided as a service to *MMWR* readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of pages found at these sites.

Anthrax Vaccination — Continued

4. Mazzuchi JF, Claypool RG, Hyams KC, et al. Protecting the health of U.S. military forces: a national obligation. Aviation, Space, and Environmental Med 2000;71:260–5.
5. Food and Drug Administration. Biological products; bacterial vaccines and toxoids: implementation of efficacy review. Federal Register 1985;50:51002–117.
6. Brachman PS, Gold H, Plotkina SA, Fekaty FR, Werrin M, Ingraham NR. Field evaluation of a human anthrax vaccine. Amer J Pub Hlth 1962;52:432–45.
7. Dixon TC, Meselson M, Guillemin J, Hanna PC. Medical progress: anthrax. N Engl J Med 1999;341:815–26.

Serogroup W-135 Meningococcal Disease Among Travelers Returning From Saudi Arabia — United States, 2000

On April 9, 2000, CDC was notified by national public health agencies in several European countries of cases of serogroup W-135 meningococcal disease among pilgrims returning from the Hajj in Mecca and their close contacts. As of April 20, 2000, the New York City Department of Health had reported three cases of serogroup W-135 meningococcal disease in the United States.

One patient was a returning pilgrim who had been vaccinated with the meningococcal quadrivalent polysaccharide vaccine, and one was a household contact of a returning pilgrim. The third patient did not participate in the Hajj and had no household or other close contacts who had traveled to Mecca; however, 5 days before illness onset the patient may have interacted with returning pilgrims or their families. The three patients had no identified shared contacts or associations. Two patients had isolation of serogroup W-135 *Neisseria meningitidis* from the blood; in the third patient, the pathogen was isolated from joint fluid. Serogroup classification of the first two isolates has been confirmed as W-135 at CDC; both isolates were subserotype P1.5,2 by PorA gene sequencing. Multilocus enzyme electrophoresis typing results are pending. These are the only cases identified among the 11,000 pilgrims reported to have traveled from the United States to Saudi Arabia for this year's Hajj, which concluded on March 17. No deaths from W-135 meningococcal disease have been reported among pilgrims returning to the United States.

Reported by: A Fine, MD, M Layton, MD, New York City Dept of Health; A Hakim, Maimonides Medical Center, New York City. P Smith, MD, New York State Dept of Health. Div of Applied Public Health Training, Epidemiology Program Office; Meningitis and Special Pathogens Br, Div of Bacterial and Mycotic Diseases, National Center for Infectious Diseases; and EIS officers, CDC.

Editorial Note: As of April 20, 2000, 40 cases of serogroup W-135 meningococcal disease among Hajj pilgrims or their close contacts have been reported to the World Health Organization by national health authorities in the United Kingdom, France, the Netherlands, and Oman (*1*). In addition, 199 cases of meningococcal disease were reported from Saudi Arabia, including 30 of serogroup W-135 and 55 of serogroup A. This is the largest recorded outbreak of serogroup W-135 meningococcal disease. In the United States, W-135 accounts for 3%–4% of meningococcal disease (*2*) and previously has not been associated with an outbreak. Meningococcal disease most commonly is manifested as bacteremia or meningitis but can present as septic arthritis or pneumonia.

Prompted by a serogroup A meningococcal disease outbreak associated with the 1987 Hajj (*3,4*), Saudi Arabia began to require meningococcal vaccine for all entering

CDC
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October 30, 2002

CDR Eugene de Lara
Deployment Health Support Directorate
Office of the Deputy Assistant Secretary of Defense
Four Skyline Place
5113 Leesburg Pike, Suite 901
Falls Church, VA 22193

Dear Eugene,

I have enclosed a CD that contains all the presentations from the Anthrax Vaccine Research Program's Investigator's Conference. The files should be well organized and clearly identified, and I hope you won't have any trouble locating the information that you need for your presentation. Let me know if there is any supplemental information that I can get you. Additionally, I have enclosed a zip disc with my 'Anthrax University' presentation that provides an overview of the CDC program.

I can't tell you what a pleasure it was to meet you. I am so very grateful to you for inviting me to the pharmacy conference and having me seated at that table! It was such an enjoyable evening, and I will remember all of the nice, helpful people that I had the privilege of meeting. You should know that I now have a meeting with the dean of Mercer's school of pharmacy on Friday morning. You really did not have to go out of your way like you did to introduce me to so many pharmacy officers, but I am truly grateful for all that you did. In fact, I have the pharmacy coin sitting on my keyboard as a reminder of where I'm going. One day, I hope to be working along side you in Navy pharmacy, only several ranks below of course.

As always, I look forward to seeing you again and to working with you many times in the future. All the very best to you and your family.

Most sincerely,

Jennifer

LTJG Jennifer di Pietra
Epidemiologist, US Public Health Service
Anthrax Vaccine Research Program
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CENTERS FOR DISEASE CONTROL AND PREVENTION

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICE

Records of the Meeting Held on

June 20-21, 2001

Atlanta Marriott North Central Hotel
Atlanta, Georgia

TABLE OF CONTENTS

Meeting Attendance:

Committee members present were:

Dennis A. Brooks, M.D., M.P.H.
Richard D. Clover, M.D.
Jaime DeSeda, M.D.
Charles M. Helms, M.D., Ph.D.
David R. Johnson, M.D., M.P.H.
Myron J. Levin, M.D.
John F. Modlin, M.D.
Paul A. Offit, M.D.
Margaret B. Rennels, M.D.
Natalie J. Smith, M.D., M.P.H.
Lucy S. Tompkins, M.D., Ph.D.
Bonnie M. Word, M.D.

Ex-Officio members present were:

Dr. Ben Diniega, Department of Defense (DOD) Health Affairs.
Dr. Geoffrey Evans from the National Vaccine Injury Compensation Program (NVICP), Health Resources and Services Administration (HRSA).
Dr. Randy Graydon, Centers for Medicare and Medicaid Services (CMMs.), the Health Care Finance Administration (HCFA)
Dr. Sara Landry, National Institutes of Health (NIH), National Institute for Allergies and Infectious Diseases (NIAID)
Dr. Karen Midthun, Food and Drug Administration (FDA).
Dr. Martin Myers, National Vaccine Program Office.
Dr. Kristin Nichol, Department of Veterans Affairs (DVA).

Liaisons present were:

Dr. Jon Abramson, Chair, Committee on Infectious Diseases, American Academy of Pediatrics (AAP)
Dr. Eric France, American Association of Health Plans (AAHP)
Dr. Stan Gall, American College of Obstetricians and Gynecologists (ACOG).
Dr. Amy Groom, Indian Health Service (IHS)
Dr. Rudolph Jackson, National Medical Association (NMA)
Dr. Samuel Katz, Infectious Diseases Society of America (IDSA)
Dr. Martin Mahoney, American Academy of Family Physicians (AAFP).
Dr. Victor Marchessault, Committee on Immunization, Canada
Dr. Margarita Nava, Mexico, National Immunization Council and Child Health Program.
Dr. Kathy Neuzil, American College of Physicians (ACP).
MR. Kevin Reilly representing PHARMA, the manufacturers' association.
Dr. Gary Overturf, AAP Red Book
Dr. Bill Schaffner American Hospital Association (AHA)
Dr. Jane Siegel, Health Care Infection Control Practices Advisory Committee (HICPAC)

CDC staff present over the course of the meeting were:

Ali Abdel Moneim
Marta Ackers
Joseph Alen
Curtis Allen
Carlos Alonso
Larry Anderson
William Atkinson
Michele Bailey
Brad Bartholow
Roger Bernier
Achal Bhatt
Lynette Brammer
C.B. Bridges
Victor Cáceres
Lynn Carroll
Sarah Ceaser
Scott Campbell
Martin Cetron
Bob Chen
Susan Chu
Joanne Cono
Nancy Cox
Frank Destefano
Roz Dewart
Gary Euler
Dan Fishbein
Keiji Fukuda
K. Galil
Jayne Gaskins
Ramshidar Goli
Penina Haber
Stephen Hadler
Beth Hibbs
Anne Huang
Marika Iwani
Alison Johnson
Laurie Johnson
Jo Jones
Sharon Katz
Amy Khan
Duane Kilgus
Alexander Klimov
Katrin Kohl
Maureen Kolase
Andrea Krull
Martin Landry
Kim Lane
Charles Lebarch
Peng-yun Lu
Kevin Malone
Anthony Marfin
Dean Mason
Tim Mastro
Alison Mawle
Emily McGinley
Linda McKibben
Eleanor McLellan
Nazune Menka
Elaine Miller
Ann Moen
Gina Mootrey
Trudy Murphy
Allyn Nakashima
Serigne Ndiaye
Rick Nelson
Bill Nichols
Glen Nowak
Ron Nuse
Dennis O'Mara
Chima Ohuabunwo
Ida Onorato
Walter Orenstein
Pata Palihaardana
Mark Papanier
Larry Pickering
Jeri Pickett
Yaler Pleer
Robert Pless
Bette Pollard
Sylvia Powell
Pam Protzel Berman
Barbara Reynolds
Susan Riley
Jennifer Robinson
Lance Rodewald
Nancy Rosenstein
Renee Ross
Kari Sapsis
Susan Scheinman
Judy Schmidt
Ben Schwartz
James Sejvar
Stephen Sepe
Jane Seward
Kristine Sheedy
Abby Shefer
Diane Simpson
Jim Singleton
Vishnu-Priya Sneller
Dixie Snider
Pamel Srivastava
Shannon Stokley
Ray Strikas
Natarsha Thompson
Diane Urban
Turas Verstracten
Charles Vitor
Donna Weaver
Meghan Weems
Melinda Wharton
Craig Wilkins
Skip Wolfe
Karen Wooten
Lynn Zanardi

Members of other federal agencies present were:
C.D. Atreya, FDA/CBER
N.W. Baylor, FDA/CDC
Albert Kapikian, NIH
Linda Lambert, NIH/NIAID

Members of the public who attended the meeting were:
Betsy Alueham-VanPays, Wyeth
B.F. Anthony, Biologics Consulting Group
Lynn Baxter, Immunization Action Coalition
Joe Beaver, TN Immunization Program
Bryan Bechtel, Infectious Disease News
Karen Biscardi, Aventis
John Bluth, Aviron
Noëlle Broadnax, Northeast Health District
Pat Cannon, Wyeth Lederle Vaccine
Dan Casto, Merck & Co.
Jill Chamberlain, Vaccine Bulletin
Dack Dalrymple Dalrymple & Associates
Michael Decker, Aventis Pasteur
Carmen Deseda, Puerto Rico
Richard Dinovitz, Wyeth Lederle
Craig Engesser, Wyeth
Stephen Fields, Becton Dickinson
James Froesh, Aventis
Jayne Gilbert, Chiron Vaccines Usa
Ruth Gilmore, Georgia Immunization Program
Jesse Greene, South Carolina Depart. of Hlth
P.G. Gromi, Duhalle Polize
Neal Halsey, Johns Hopkins University
Claire Hannan, ASTHO
Scott Harward, GSK
Bill Hausdorff, Wyeth
Philip Hosbach, Aventis Pasteur
Dominick A. Iacuzio, Roche Lab, Inc.
Samual Katz, Duke University
Matt Kempf, Baxter Vaccines
Luc Kuykens, Merck
Tom Lalé, Merck
Len Lavenda, Aventis
Edgar Ledbetter, Nnii
Scott Litherland, Parallax Communications
Bill Mackey Merck
Susan Malone, Chatham Cnty Hlth. Depart.
Nestor Molfino, BaxterStan Music, Merck
Maria Nicholas, Virgin Islands Department of Health Immunization Program
Patricia Nolan, Rhode Island Health
Peter Paradiso, Wyeth
Tina Parisi, C&W Healthcare
Diane Peterson, Minnesota Depart. of Hlth.
Stanley Plotkin, Aventis
Jane Quinn, GSK
Cassandra Richards, Infectious Diseases in Children
Steven Rifkind, Physicians World
Jorden Robinson, GSK
Zeil Rosenberg, Becton Dickinson
Fred Ruben, Aventis
Brent Rutland, Aventis
Georgia Seibert, GA Immunization Program
Kristine Severyn, Vaccine Policy Institute
Elizabeth Shea, Ketchum, Washington, D.c.
Judith Shindman, Aventis Pasteur Ltd.
Alan J. Sievert, East Metro Health District
Nanette Stoback, Aventis
Matt Strasburger, Merck
Kathleen Stratton, Institute of Medicine (IOM)
Stacy Stuerke Merck
John Talarico, NYS Department of Health
L.J. Tan, American Medical Assoc. (AMA)
Dirk Teuwen, Aventis Pasteur
Lonnie E. Thomas, Henry Schein, Inc.
Eric Tischler, Aventis
T.F. Tsai, Wyeth
Miriam Tucker, Pediatric News`
Theresa Turski, GA Immunization Program
Carmen Vanterpool, Virgin Islands, St. Thomas, Department of Health
Tom Vernon, Merck
Peter Vigliarolo, Cooney Waters
Tom Waytes, Bio Port
Deborah Wexler, Immunization Action Coalition
Jocelyn Wright, GSK
Laura York, Wyeth
John Zahradnick, Aventis
Thomas Zink, GSK

CENTERS FOR DISEASE CONTROL AND PREVENTION
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES
Marriott Century Center
Atlanta, Georgia
October 17-18, 2001

Agenda Item	Purpose/Action	Presider/Presenter(s)
October 17		
8:30 Welcome Disclosure by Committee Members		Dr. J. Modlin (Chair, ACIP) Dr. D. Snider (CDC, OD)
9:15 Report of the Rotavirus Vaccine and intussusception working group	Information	Dr. S. Katz (Duke Univ.) Dr. M. Levin (Univ. of Colorado) Dr. G. Peter (NVAC)
10:00 BREAK		
10:30 Issues related to Influenza Vaccine Burden of influenza Summary of VRBPAC / possible time frame for LAIV Summary of TIV safety and efficacy Summary of feasibility/implementation issues Summary of program funding issues	Information Discussion	Dr. K. Fukuda (NCID, DVRD) Dr. K. Midthun (FDA, CBER) Dr. K. Neuzil (Univ. of Wash) Dr. K. Nichol (VA) Dr. B. Schwartz (NIP, ESD) Dr. N. Smith (CA Dept. of Hlth) Dr. T. Uyeki (NCID, DVRD) Dr. B. Word (ACIP)
12:15 Update on 2001-2002 influenza vaccine supply	Information	Mr. D. O'Mara (NIP, ISD)
12:30 LUNCH		
1:30 Hepatitis B Recommendation	Discussion Decision/Vote	Dr. H. Margolis (NCID,DVRD) Dr. Wm. Schaffner (Vanderbilt) Dr. J. Siegel (Univ. of Texas)
2:30 Inclusion of Twinrix in the VFC Program	VFC Vote	Dr. M. Wharton (NIP, ESD)
2:45 Childhood Harmonized Immunization Schedule	Discussion Decision	Dr. M. Cortese (NIP, ESD) Dr. N. Smith (Ca. Dept. Public Hlth.)
3:30 BREAK		
4:00 Adult Harmonized Schedule	Information Discussion	Dr. B. Schwartz (NIP, ESD) Dr. V. Sneller (NIP, ESD)
4:45 Use of OPV to Control Outbreaks of Poliomyelitis	Information	Dr. B. Schwartz (NIP, ESD)

Agenda Item	Purpose/Action	Presider/Presenter(s)
5:15 IOM Recommendations on Thimerosol	Discussion	Dr. M. McCormick (IOM) Dr. K. Stratton (IOM)
6:45 Public Comment		

7 :00 ADJOURN

October 18

8:00 Unfinished Business from Previous Day		Dr. J. Modlin (Chair, ACIP)
8:30 Updates	Information	
National Immunization Program		Dr. W. Orenstein (NIP, OD)
Food and Drug Administration		Dr. K. Midthun (FDA, CBER)
Vaccine Injury Compensation Program		Dr. G. Evans (HRSA)
National Institutes of Health		Dr. C. Heilman (NIH,NIAID)
National Vaccine Program		Dr. M. Myers (NVPO)
National Center for Infectious Diseases		Dr. A. Mawle (NCID, OD)

9:45 BREAK

10 :15 Proposal to decrease the time interval recommended to avoid pregnancy after receipt of rubella vaccine	Discussion Decision	Dr. S. Gall (ACOG) Dr. S. Reef (NIP, ESD)
10:45 Pneumococcal conjugate vaccine: effect of the Vaccine on invasive disease during 2000 and plan for tracking vaccine failures Update on vaccine supply	Information Discussion	Dr. C. Van Beneden (NCID, DBMD) Dr. C. Whitney (NCID, DBMD)
11:15 Update on varicella disease and varicella vaccine in the United States Vaccine coverage Status of child care and school requirements Vaccine effectiveness Varicella disease surveillance	Information Discussion	Dr. K Galil (NIP, ESD) Dr. A. Jumaan (NIP, ESD) Dr. J. Seward (NIP, ESD) Dr. R. Vessey (Merck)

12:15 LUNCH

1:15 The OSHA requirement for using safety engineered needles and implications for childhood immunization delivery	Information Discussion	Ms. L. Chiarello (NCID,DHQP) Ms. A. Hogan (OSHA) Dr. H. Yusuf (NIP, ISD)
2:15 Adaptation of vaccine formulary selection algorithm to web-accessible tool	Information	Dr. S. Jacobson (Univ. Ill.) Dr. E. Medina (Austral Eng. & Software) Dr. B. Weniger (NIP, ESD)
2:30 Public Comment		

2:45 ADJOURN

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES
MINUTES OF THE MEETING

JUNE 20-21, 2001

JUNE 20, 2001

OPENING COMMENTS/DISCLOSURES

Chairman Dr. John Modlin convened the meeting at 8:36 a.m., and introduced Dr. Dixie Snider, the ACIP Executive Secretary. Announcing liaison representatives changes, Dr. Snider welcomed Dr. Gary Overturf of the University of New Mexico Medical Center, as the liaison for the American Academy of Pediatrics; and Mr. Kevin Reilly, President of Wyeth Vaccines and Nutrition, liaison for the Pharmaceutical Research and Manufacturers of America. He announced that Dr. Larry Pickering had joined the National Immunization Program staff. Dr. David Salisbury will serve as the Ex-Officio representative from the London Department of Health and Dr. David Wilson will serve for the American Medical Association, but neither were present at this meeting.

ACIP terms were completed for three members, who may return to the October meeting if the current federal hiring freeze prevents seating their replacements. Certificates and a letter of appreciation from CDC Director Dr. Jeffrey Koplan were presented to retiring members Drs. Richard Clover, David Johnson, and Chuck Helms.

He announced the ACIP home page (www.cdc.gov/nip/acip), the October 17-18 date for the next meeting, and those for 2002: February 20-21, June 19-20, and October 16-17.

Dr. Snider reviewed the rules pertaining to the ACIP's function. The amended (December 2000) committee charter's addition of three new ACIP members raised the membership to 15 and, therefore, the quorum to 8. As the Executive Secretary, Dr. Snider may appoint Ex-Officio members as voting members in the absence of a quorum. Public comment is solicited at regular intervals of the agenda, but the Chair frequently recognizes brief comments from the floor.

Dr. Modlin drew the members attention to information distributed and announced this meeting's scheduled workgroup meetings. The Committee members and those attending in the audience then introduced themselves (see the attached list). The members also indicated any conflict of interest that may prevent them from voting or seconding a motion or a VFC resolution, but their participation in discussion of all issues was still allowed. Such disclosures from ex-officios, liaisons, and public attenders were welcomed as well.

Committee members present reporting potential conflicts were:
Dr. Myron Levin: Merck, Glaxo SmithKline (GSK) research support; GSK stock
Dr. Margaret Rennels: trial support from Wyeth Lederle, Aventis Pasteur, GSK, and Merck.
Dr. Richard Clover: Merck, Wyeth Lederle, GSK, and Astra Zeneca.
Dr. Paul Offit: co-inventor on a patent for a bovine human resortant rotavirus vaccine in development by Merck and Company.

Of the liaisons present:
Dr. Eric France, AAHP liaison: Wyeth and by Merck funding for vaccine trials he oversees.
Dr. Stan Gall: ACOG conducts vaccine trials for Merck and Glaxo SmithKline.
Dr. Kathy Neuzil, ACP liaison: research funding from Merck and Aventis Pasteur.
Dr. Benedict Diniega, Department of Defense (DOD): owns Bristol Meyers stock.

UPDATE: TETANUS TOXOID VACCINE SHORTAGE/DTaP SUPPLY

Mr. Dean Mason updated the committee on the shortage of tetanus and diphtheria toxoid vaccine. In the event of a critical shortage, the ACIP members had already supported a CDC recommendation on prioritization of Td use according to indication.

DTaP Supply: *Prioritization:* A March 16, 2001 *MMWR* article recommended DTaP usage according to certain priorities: first priority to vaccines to infants to complete the primary series (doses 1, 2, and 3 at 2, 4, and 6 months of age). In the event of shortages, the fourth dose would be deferred; in the event of a greater shortage, the fifth dose would be deferred. Those deferred children would be called back when vaccine supply was more adequate. The deferral decision was left up to the programs and providers.

Supply. The back orders (defined as CDC contract orders not filled by 14 days) reported at the February meeting had improved. Aventis Pasteur's 579,000 doses on back order shrank to 268,600; GlaxoSmithKline (GSK) had almost none as of June. Manufacturer reports were matched with CDC records to confirm the supply status.

Public Health Response to Shortage. The National Immunization Program (NIP) asked for state reports of the central inventory of their total DTaP doses, and all DTaP vaccine orders placed through CDC's contracts were closely monitored. Twenty states had central DTaP inventories with a <30 day supply; 23 at 31-60 days (probably the most any state would need); 9 at 61-90 days; and 4 with a >91-day supply. Some state orders were modified to ensure equitable distribution, considering the population base, number of children served in the public sector, inventory, doses on back order, and special needs/circumstances. The states were also urged to downsize their central inventories to <30 days. Weekly or semi-weekly communication was held with vaccine manufacturers and with the FDA.

Shortage Impact. In the last month, of CDC's 60+ grantees, 48 states (84%) had sufficient supply for the 5-dose series; 12 (21%) were cutting product supply to providers; 8 states had formally changed their policy; and 11 states (19%) indicated awareness of spot shortages. Currently, of the total back order of 424,500 doses, ~156,000 doses are <14 days on back order and are of less concern. The public and private sectors' vaccine need is ~17.3 million doses per year. The distribution is uneven (more needed during school-entry vaccine drives, etc.), but if evenly spread, it would be ~1.44 million doses/month. The two manufacturers, Aventis and GSK, project a supply of 10.4 million doses of DTaP for the balance of this year (1.733 million doses/month), and Glaxo could supply the U.S. with an additional 3.9 million doses. That extra production would total 14.3 million doses (2.383 million/month).

NIP estimates that 1.73 million doses/month are sufficient to return to the 5-dose schedule

for all children, as long as the DTaP orders through the CDC contract remain closely monitored to ensure equitable distribution, the state inventories gradually build up to 30-day maximums, and a steady vaccine supply of the projected amounts is maintained. Glaxo's additional 3.9 million doses would also allow catch-up for children's missed booster doses, perhaps eliminate the >15 day DTaP vaccine back orders, improve supply for school drives, and could allow state inventories to build up to 60 days.

In discussion, Dr. Katz commented that the problem of such recall of children for missed doses supports the development of a registry system. Dr. Orenstein stated the NIP's comfort with the supply's adequacy to ensure that five doses are available for all.

Tetanus/diphtheria (Td) Supply. Mr. Dean Mason, of the NIP, recalled Wyeth Lederle's announcement in December 2000 of its intent to stop production of tetanus, diphtheria, and tetanus toxoid vaccines due to production and thimerosal issues. Their provision of 32% of all diphtheria and tetanus products for the U.S. market in 1999 dropped to 19% in 2000. Aventis Pasteur is now the sole national producer of tetanus and diphtheria, aside from the small production at the University of Massachusetts Medical School.

The ACIP and AAP recommend on the use of Td, but CDC has no contract for Td. During the January through May 2001 shortage, Aventis established screening criteria and prioritized product according to the ACIP's guidelines (hospitals, emergency rooms, and public clinics, focusing on wound management, travelers, persons with <3 doses, pregnant women without vaccination within the past 10 years). In the first part of the year, hospitals received only 50 doses/week unless more were justified. The new Aventis policy allows 300 doses/month and more with appropriate justification. Individual practitioners are not receiving their previously-allocated 20 doses/month, and Td booster vaccine is not supplied. The Immigration and Naturalization Service suspended Td boosters for immigrants. Reserved product for natural disasters is kept in a central public health inventory station.

Mr. Mason summarized that the outlook for Td is of demand exceeding supply. The vaccine requires an 11-month production time and Aventis is working at full capacity. Tetanus is the limiting factor in producing DTaP, Td, T, DT, and DTaP/HBV. Improvement is not expected before early- to mid-2002.

MMWR Notice to Readers. Dr. Lynn Zanardi updated the committee on the recent *MMWR* Notice to Readers, which recommended: 1) delay of all Td booster doses until vaccine supplies are restored in 2002; 2) clinic implementation of a callback system for those patients with booster doses deferred to next year; 3) re-emphasis of Td use for priority indications, for which the Td supply should be adequate. The article reminded readers that the ACIP recommendations for wound management had not changed (in response to some practitioner inquiries about using DT and DTaP as a substitute for Td) and reminded health care providers to ask when the last Td was received by the patient to avoid unnecessary vaccinations. Institutions were asked to order vaccine for only their anticipated priority indications. Aventis can ship quickly upon emergency situations.

Aventis Pasteur Status Report. Dr. Philip Hosbach described Aventis Pasteur's production status. Their first priority is to produce more vaccine (a challenge with the

unexpected status of sole manufacturer and the 11-month production cycle), manage the current supply and build inventory to avoid further shortages. He expressed Aventis' appreciation of the ACIP recommendations of prioritization to avoid any further run on the available Td stocks, and requested its continuing help in communicating the necessary further steps to state health departments. Td demand is currently high, with warm weather, increased outdoor activities, and more natural disaster emergencies due to recent unpredictable weather. The current shipping policy targets only public health clinics and urgent care facilities. Production is now a 24/7 operation. Aventis expects to ease the supply restrictions in 2002, and perhaps later this year, and is seeking an FDA license for a Canadian Td facility to double the production capacity.

Current Aventis outreach includes a letter issued to 400,000 health care providers through the Postgraduate Institute of Medicine, summarizing the current recommendations for Td, and defining wound management and the related ACIP guidelines. A recall reminder letter and recall materials will also be sent this summer.

Discussion included:

- Dr. Smith: *How is Aventis addressing potential gaps, such as rural areas with relatively inaccessible hospitals?* Aventis is communicating with those health departments as well as medical societies to explore potentially necessary adjustments. At this time, the people are asked to come to the vaccine, if possible, and the health departments are notified of where the vaccine is shipped. Dr. Smith suggested that the Aventis cover letter include mention of travel to "diphtheria-endemic" areas.
- Dr. Abramson: *North Carolina is ignoring the recommendations since they have an adequate supply.* Mr. Mason knew of this; CDC is working with them.
- Dr. Deseda asked for Aventis' attention to Puerto Rico, reporting that in metropolitan San Juan, patients have been referred to some large pediatric groups by emergency rooms with short Td supply.
- Dr. Levin: *What planning is needed to ensure coverage if another vaccine ends up with a sole manufacturer?* Dr. Modlin responded that this is being studied by an NVPO/NVAC workgroup. The Secretary has requested a report. Dr. Orenstein cited the past use of vaccine storage and rotation contracts to deal with short-term interruptions. This is still in place for single-manufacturer vaccines (e.g., MMR and inactivated polio vaccine), and now is being reconsidered to include all the routine recommended vaccines.
- Ms. Diane Peterson: *What is the recommendation for routine vaccination of persons with occupational risk, not mentioned in the last MMWR?*. Mr. Mason confirmed that there is no current such provision, but any wound trauma commands product use.
- Dr. Clover: *What percent of the historical total distribution went to private physicians?* Mr. Mason reported 20 doses/month and more as justified, as well as through the public supply system. Mr. Hosbach agreed to check on the market percentage. Since they have only recently directly distributed the vaccine, they do not have those historical numbers, but current data are available.
- Dr. France: *Kaiser Permanente Colorado, has ~700 doses left now and expects to run out of tetanus by October or November. They have been limiting its use to dirty wounds and even prioritizing those.* Mr. Hosbach appreciated Kaiser's compliance with

the recommendations, but prioritizing wounds should not be necessary. Aventis will work with its customers to avoid the need for such decisions.

INFLUENZA VACCINE

Influenza Workgroup Report. The Influenza Workgroup reported on their review of the issues related to live-attenuated influenza vaccine (LAIV) and pediatric influenza vaccine. Dr. Bonnie Word summarized the ACIP recommendation to delay initiation of major campaigns, and providers' focus on vaccinating high-risk patients and deferring until December vaccinations of those aged 50-64 years and other healthy individuals. However, since many of those who deliver most vaccine to high-risk individuals reported not receiving the vaccine, the manufacturers were involved to find a solution.

The LAIV Workgroup sponsored an influenza workshop in May, to identify and address the concerns/issues related to LAIV, particularly its use among children; to review the current efficacy and safety data of the inactivated influenza vaccine; and to identify any knowledge gaps that could prevent formulating future options for using either live or inactivated influenza vaccine. Although intertwined, the issues of these two vaccines are still separate.

The meeting convened experts for general discussions of the impact of influenza on children, reviewing rates of pediatric infection and hospitalization, clinical complications and mortality among children. One issue to be discussed further is of unusual complications of acute necrotizing encephalopathy reported in Japan. The development of an LAIV was described for the workshop, and data were presented on the LAIV effectiveness/efficacy studies for children, healthy adults, the elderly, and high-risk adults (e.g., asthma, CF).

Four subgroup presentations provided literature reviews on:

1. The overall safety, effectiveness, and efficacy of vaccinating young children with inactivated influenza vaccine, and specifically its application to herd immunity, day care settings, and selected high-risk populations.
2. The potential for reversion of LAIV vaccine strains and potential for recombination of vaccine strains with wild viruses.
3. The potential biologic issues related to co-administration of LAIV with other childhood vaccines. It can be given with almost every pediatric immunization, while adult co-administration involves consideration of pneumococcal vaccine.
4. The potential for adverse immunologic effects in children who are repeatedly vaccinated against influenza.

Research gaps were identified for safety, feasibility, and economic issues. A second workshop is planned in September after the FDA review of the live attenuated vaccine license application.

Influenza Vaccine Workshop. Dr. Fukuda applauded Drs. Edwards, Brian Murphy, Wendy Keital, and Ruth Karron for the workshop, which he termed as the best scientific meeting he had attended in recent years. Each subgroup identified and reviewed the literature, and decided its presentation at the meeting in preconference calls, ensuring that ample time was allotted for discussion.

The impact of influenza in children was reviewed by Drs. Tim Uyeki and Bill Thompson. Influenza morbidity is substantial, and is probably generally under-reported and underappreciated in the medical community and the literature. Children's attack rates exceed those of adults in several different studies, and related hospitalization rates are higher in younger children than those older, as well as in children with high-risk conditions versus age-matched healthy children. The highest complication rate is in children aged <6 months, for whom vaccine is not approved. Vaccination rates among high-risk children are low (10-30%). Among the outstanding questions left from this group was whether vaccination of pregnant women really confers any protection to infants. Primary outpatient complications are otitis media and asthma. The very severe influenza-associated encephalopathy reported from Japan is of unclear etiology, although the data are impressive. That outcome has not yet been seen in the U.S.

Vaccine Safety and Effectiveness Review. The study exclusions of the literature review of the safety and effectiveness of inactivated vaccine use among young children were those of whole virus vaccine (not recommended for young children), foreign trivalent inactivated vaccines incompatible with U.S.-approved ones, and those of pre-1981 vaccines, which were lower in antigen than modern vaccines. The topics reviewed were trivalent inactivated vaccine and the possibility of herd immunity, and safety and immunogenicity in day care settings. Most of these studies supported the vaccine's effectiveness and immunogenicity with only local adverse reactions. The findings of the sparse literature of studies among high-risk populations (sickle cell anemia, asthma, diabetes) generally paralleled those for healthy children. The literature on the development of live-attenuated vaccines (LAV) and their effectiveness/efficacy indicate complex immunity issues. For example, post-vaccination immunity differs between live-attenuated vaccines and trivalent inactivated vaccines according to the naivete, sero-negativity or sero-positivity of the population. Studies sponsored by NIH, Wyeth, and Aviron demonstrated the effectiveness and efficaciousness of LAVs.

The literature on the potential reversion of LAIV strains to wild-type strains and that of vaccine strain gene reassortment with wild viruses indicate genetic stability in susceptible persons by both the A and B cold-adapted reassortant strains. While cold-adapted viruses also can reassort (exchange genes with other influenza viruses), they generally do so less often than wild-type viruses. In addition, there are no foreseen unique consequences from combinations of live-attenuated and wild-type virus genes. Nonetheless, the use of LAVs with novel hemaglutinin or neuraminidase antigens is not indicated if an aborted pandemic occurs, to avoid releasing those antigens and genes into the population. Similarly, it would not used in such scenarios as that of the Hong Kong H5 outbreak, because the LAV virus genes could recombine with the H5 virus to produce one more transmissible than the native virus.

The biologic issues related to the co-administration of LAV and other childhood vaccines are major, but still largely unstudied. The literature on adverse immunologic effects in children vaccinated annually was approached from two perspectives:

- The risk of reduced immunogenic response to future influenza vaccination or infection. One focus was on the Boskin hypothesis of a reduced immune response against influenza. The group found that repeat immunizations in children and adults were safe

and well-tolerated for both trivalent inactivated vaccine and LAV. However, there are theoretical risks associated with repeat immunizations (e.g., from repeated exposure to egg proteins). Further evaluation is needed of the safety, tolerability, and efficacy of both trivalent, inactivated, and live-attenuated influenza vaccines in young children. Particularly if LAV is recommended for routine use in young children, Phase IV studies of adverse events are definitely needed.

- The potential for unforeseen aberrant immune responses, as seen to the early RSV vaccines. No aberrant immune responses have been identified, but more data are needed. This is particularly true for young, unprimed children, for outpatient settings, and particularly for risk conditions such as asthma, and as related to encephalopathy and meningococcal infections. Updated dose-ranging studies are needed to explore, among other things, the protection conferred by maternal vaccination with trivalent inactivated vaccine to their infants. And for both LAV and trivalent vaccines, further safety studies would be welcome.

FDA's VRBPAC will review the Aviron live-attenuated product in July, hopefully allowing the review of Aviron's unpublished safety data at the September Influenza Workgroup meeting. That meeting will also address other important outstanding issues of annual influenza vaccination: its economics, logistic and feasibility issues for providers, the potential impact on programs and their funding, and the crowding of the immunization schedule.

Discussion included:

- Dr. France: *Rare adverse events linked to trivalent inactivated vaccine cannot be explored with a cohort of only ~200 families.* However, the Vaccine Safety Datalink (VSD) program will examine their data sets for anything unusual and hope to report by September or October.
- Dr. Levin: *Is there a meeting report, and among what immunocompromised groups was these vaccines' use discussed?* The extensive meeting notes are being compiled and edited and will be made available to the Committee. While there was some discussion about the vaccines' effects in HIV-infected and other immunocompromised children, the meeting's focus was on healthy rather than high-risk children, nor are there much data. What exists is mostly unpublished. Whether LAV vaccines pose a risk for that group, in particular, is a research need, and will be discussed in September.

Influenza Vaccine Utilization/Supply. Dr. James Singleton of the NIP provided updated data on influenza vaccine utilization. He shared a graph of vaccine coverage trends for those aged ≥65 years, 50-64; and 18-49, as measured by the Behavioral Risk Factor Surveillance System (BRFSS) and the National Health Interview Survey (NHIS) . The NHIS data showed a 69% coverage rate in 2000 among people ≥65 and ~23% in those aged 18-64. The 1998 vaccine coverage for high-risk groups was 43% among those aged 50-64 and 23% for those aged 18-49. Coverage may be plateauing among older people after the doubling of rates between 1989-1995.

Vaccine production. *Manufacturer data* of net doses distributed in the U.S. in 2000 indicates that 60 million adults were vaccinated. Compared to prior vaccination years, Northern California Kaiser data showed a drop in vaccination rates of those aged ≥65 years (whose numbers increased by ~30,000) from 70% to 60% from September through March.

communication was emphasized from this last season.

The public sector has limited involvement in purchasing, distribution, and administration. Targeting vaccine to high-risk groups will involve changing the behavior of both vaccine providers and recipients. Providers will need to get accustomed to serving only their high-risk patients first and deferring the rest; recipients who are not high-risk will need to learn to wait for vaccination until the supply is more plentiful later in the season. State and local public health departments have tried to help, but are limited by a lack of infrastructure, and many providers do not have reminder-recall systems.

Preparations In Process. This year, the CDC is developing voluntary approaches throughout the entire system of production, distribution, and administration to target high-risk patients early in the vaccination season. The options include:

1. *Distribution.* Shipping vaccine directly to providers with high-risk patients, perhaps as identified by the vaccine companies and distributors. Aventis Pasteur will fill at least 25% of every order to ensure their customers have vaccine early for high-risk patients.
2. Collaborate with mass clinic operations to encourage them to follow the ACIP/ NIP best practices, which were updated and widely distributed. This includes a patient self-screening form that can help identify those at high risk.
3. The states have been asked to develop a contingency plan for a vaccine delay, with criteria to guide redistribution of vaccine where appropriate and possible, focusing on the high-risk groups.
4. Provide more clear and explicit recommendations.
5. Strengthen existing partnerships and develop new ones as appropriate. This already has aided planning, communication, and monitoring efforts. A partial list of the partners involved was distributed.
6. A meeting with the AMA may be held in August before the vaccination season begins, to ensure that all plans are in place.
7. Increase CDC's contracts for vaccine through-purchase by state and local health departments, if needed to better help them to fill the gaps.
8. Plans to meeting with the distributors' trade organizations are being discussed, and with the vaccination contractors who immunize at nontraditional sites.
9. *Communication:* A letter from Dr. Orenstein was widely distributed in May to providers, and a similar one will go to pharmacists. Biweekly bulletins will be sent to all partners, who in turn are asked to re-convey this information to members/constituents. The NIP Website will post information, and the calls and partner meetings will continue on an ongoing basis, either regularly or *ad hoc* as needed. A mass media campaign will inform the general public again. The NIP Communications Office tracks news media coverage of stories to assess the communication with the public and to adjust as needed.
10. *Monitoring.* Communication about monitoring is frequent with the vaccine manufacturers, the FDA, and the Centers for Medicare and Medicaid Services (formerly HCFA).

Distribution. Mr. O'Mara shared data and information from the vaccine companies to discuss the 1999 and 2000 aggregate monthly distribution of influenza vaccine. The 2001 figures were projections. Distribution analysis used 1999 as a benchmark year,

acknowledging that no single year is actually "usual" or "average." He emphasized that these figures served only as a rough guide with which to project.

Based on data provided by the vaccine manufacturers, CDC anticipated a less extensive distribution delay than in 2000. The projected production for this season will be ~ 84 million doses. The delay is attributed, in part, to the retooling time required by the manufacturers to compensate for the dropout of one manufacturer. The monthly projected vaccine distribution for 2001-02 was charted, beginning in August and peaking from September through November. About 64% is expected to be distributed in October. Charted distribution data from 1999, 2000, and 2001 showed the previous delays. Where slightly more than a third was issued in October 2000, this year about two-thirds should be issued. Nonetheless, Mr. O'Mara cautioned again that other factors could exacerbate the delays, including production difficulties, uneven vaccine distribution, some early vaccination of young healthy individuals, and price speculation.

AMA Statement. Dr. L.T. Tan, of the American Medical Association (AMA), related their House of Delegates' Substitute Resolution 416 in December 2000. It included that the AMA will 1) "work all with appropriate agencies and organizations, including vaccine manufacturers, to prioritize the distribution channels for influenza vaccine to assure the vaccine is available to patients in accordance with CDC guidelines for high-risk patients;" and 2) "explore options for appropriate oversight of the supply, distribution, and marketing of influenza vaccines by appropriate agencies."

The large AMA/NIP joint meeting on March 27 resulted, which involved almost all the stakeholders of the production, distribution, and/or administration of the influenza vaccines. It was held to help the participants understand influenza vaccine supply, distribution, administration, and why influenza vaccine availability was delayed in 2000-2001. Many of the viewpoints expressed by the AMA physicians have already been addressed by the NIP, including:

1. The uneven distribution starved vaccine supply to physicians serving high-risk populations while supplying those who were not; they were caught between the distributors' shipment delays and their patients' demands for vaccine, forcing embarrassing referrals to the local food store vaccination clinic. The physicians felt they should be first to receive vaccine shipments, since they deliver to 60% of those at high risk.
2. Not only were the physicians notified too late of the revised ACIP recommendations, they felt that communication in general completely failed. Reading media accounts of the delay was the first notice to some providers.
3. Many providers knew that other physicians were not adhering to the guidelines, despite the release of the best practices late last season.
4. The terminology used in communicating the problem was ambiguous, which led some to a conspiracy theory. When "delay" actually translates to "shortage" regionally, credibility is lost, paranoia escalates, and such AMA resolutions are advanced which the organization must then act upon.

Perhaps the meeting's most important finding was the need to communicate to physicians when the vaccine supply is sufficient, and that, while not perfect, the current production and

distribution system is adequate. The AMA supported development of a contingency plan for when the vaccine supply is delayed or insufficient, which should be voluntary for both public and private sectors. They urged that as soon as manufacturer projections are available, they be issued to all involved to allow the coordination of messages to the public and providers. CDC was felt to be best suited to do this and to implement the contingency plan.

Improved communication is critical among all the stakeholders involved with influenza vaccine production, distribution, and delivery. Although it is improving, the fact that a problem will again exist this season had led to a Board of Trustees Report (#36) on the previous day. The Board committed to: 1) work on the second CDC/AMA meeting on influenza vaccine; 2) to communicate current ACIP recommendations, etc. to physicians and to assist CDC's dissemination of information on their Website; 3) to monitor progress in developing the contingency plan and an influenza pandemic plan which should involve the physicians on the front line as must as possible; and 4) to support mechanisms to include influenza vaccine supply in ensuring achievement of the Healthy People 2010 goals. This last is critical to the AMA, in view of many reports that reimbursement levels for influenza vaccine have not kept pace with its cost. Many now intend to refer healthy patients to public health departments.

Unfortunately, this report was received by the House at a time when the physicians, following Dr. Orenstein's advice to order vaccine early, were told that pre-orders had closed and further orders were not being taken. This contributed to the conspiracy theory, and resulted in a fifth resolution:

5. The AMA will immediately investigate issues, including cost, reimbursement, availability, and distribution, which may adversely affect the ability of physicians to provide influenza vaccine to their patients in the upcoming 2001-2002 influenza season.

Dr. Tan noted that this automatically involved the AMA's Washington D.C. office. However, the AMA is trying to work with CDC to keep response to these issues voluntary.

February 2000 ACIP Recommendation. Dr. Ben Schwartz presented the draft influenza recommendations developed by NIP, the NCID Influenza Branch, and the CDC Office of the Director, with input from the FDA and the ACIP Influenza Workgroup. He first reviewed the previous year's recommendations, which focused on high-risk patients and health care workers, determining local priorities to match those local needs, continuing vaccination beyond December, beginning with vaccination of those not at high risk in November, providing pneumococcal vaccine, and continuing focus on high-risk children. Two recommendations addressed mass campaigns to focus them on those at high risk, and those for health care organizations urged the use of proven effective techniques to increase vaccination of high-risk persons.

Little data from the last season has been analyzed to assess vaccine use, but some things have become clear: 1) stronger and more definitive recommendations are needed earlier in the season than the October publication of ACIP recommendations; 2) providers' ability to focus vaccination to high-risk individuals may be limited, and the growing nontraditional settings primarily service lower-risk individuals; 3) providers complained of distribution not

matching the need of high-risk patients. Of concern to both their professional societies and Congress, that led to proposals of a greater government role, including legislation. Vaccine redistribution as a rule did not occur last year, despite a CDC pilot-tested Website to facilitate such communication and exchange; and 4) finally, while late (November/December) vaccination increased, data suggest a drop in overall coverage, and little vaccine was ordered for December delivery. Of the 9 million CDC-guaranteed vaccine doses, only ~1.5 million were distributed.

Supplementary Language, Draft Recommendations. The primary goal of the draft recommendations is to create a prioritized system in which those aged ≥65 years who have chronic illnesses, and the medical personnel who care for them, are vaccinated early. Other goals are to maximize coverage of those at highest risk of severe influenza complications and to increase coverage in high-risk and targeted groups. As opposed to last year's focus on providers, this new approach is one of collaboration between providers, the public, manufacturers, distributors, and vendors, and health departments.

The draft statement summarizes the recommendations, outlines the reasons for the 2000-2001 season vaccine delay and the related manufacturing issues, as well as the projections for 2001-2002. The recommendations are specific for the various participants in the immunization system:

Providers

- "Providers should actively target vaccine available in September and October to persons at increased risk of influenza complications and to medical people who care for them." A table defines high-risk conditions and reminder recall systems are promoted.
- "Providers should continue vaccinating patients, especially those at high risk and in other target groups, through December and later as long as vaccine is available." The targeted groups are defined, including those aged 50-64 years old. Data are cited to support substantial duration of protection from a December vaccination. Health care organizations' assessment of influenza vaccination practices is urged, as is ensuring feedback to providers on coverage.

Public

- "Persons who are at high risk, including those who are ≥65 years of age or <65 who have underlying chronic illnesses, should seek vaccination in September and October or as soon as vaccination is available with their provider." Communication to encourage patients to seek vaccination throughout the season is urged.
- "Persons who are not at high risk are encouraged to defer seeking influenza vaccine until November and later when additional supply will become available." This is a new recommendation. Consultation with their provider is advised for those unsure of their status. Again, providers are encouraged to adopt a reminder/recall system for those who defer vaccination until later in the season.

Manufacturers/Distributors

- "Distribution of vaccine to work sites should be delayed until November." The worksite is a site where those are at high risk or elderly are less likely to be vaccinated. This delay should make substantially more vaccine available early to providers of high-risk patients. Manufacturers are encouraged to identify worksite orders placed by the doctor's name rather than by company name. The latter are urged to self-identify and indicate their willingness to receive vaccine later.

- Since vaccination campaigns often occur early, this recommendation could apply every year rather than only this influenza season.
- Apportionment of vaccine available early to ensure equitable distribution to all providers who ordered was encouraged.
- Manufacturers, distributors, and vendors were advised to inform providers of the amount of vaccine and the date of shipment so that they can contact their high-risk patients first.

Health Departments/Organizations

- "Groups that provide influenza vaccine services should develop contingency plans responding to a delay in vaccine distribution." Communication among partner organizations and the potential for redirection of vaccine to high-risk persons in the community was emphasized.

Mass Vaccination Campaign Sponsors

- Organizers of mass immunization campaigns not conducted in work places (e.g., senior centers, clinics, retail stores) should make special efforts to vaccinate the elderly and those at high risk of influenza complications. CDC offered materials that define high-risk groups and support a tiered approach, as well as useful screening forms.

Discussion included:

- Dr. Smith: *There may be undue pressure on providers and health departments from patients wanting vaccination; and add text about delaying mass campaigns till mid-October.* High-risk individuals seeking vaccination are advised to ask their providers about vaccine availability before going for vaccination. A recommendation for health departments, HMOs, and other mass vaccinators to wait and ensure vaccine availability before publicizing a mass campaign is reasonable.
- Dr. Offit: *Please summarize why vaccine distribution is delayed, since the scale-up problem from seed stocks was resolved last year.* Mr. Kevin Reilly, PHARMA liaison, cited the standard complexity of developing a new vaccine annually, and the reduction to three manufacturers from four in 1999, the benchmark year. Each manufacturer needs time to add more capacity/volume into their systems.
- Dr. Fred Rubin: *Replace the term "delays" in the title* of the recommendations to avoid an implication that this is another bad year, since the vaccine supply will be good. However, the term "delay" is appropriate in the text where now used.
- Dr. Abramson: *Cite the reasons for the delay*, particularly if a new framework for timing is advanced.
- Ms. Linda McKibbon, CDC Office of Health Care Partnerships: *Were recommendations considered specific to managed care organizations (MCO), and were standing orders programs considered?* Standing orders are specifically addressed in earlier ACIP publications. Managed care organizations are addressed under the recommendation for mass immunizers. MCOs are uniquely well positioned to respond to the recommendation for assessment and feedback.
- Dr. Schwartz: The only way to reach HP 2010 goals is to increase supply, which likely will require a longer period of production and administration of vaccine. He supported Dr. Abramson's suggestion of using this recommendation as a new a new norm of timing rather than a contingency plan or a single season model.
  - *Discussion of this as a new timing framework* included the following: Shifting the time

from October through December will leave a gap in years of early influenza outbreak, although the bulk of the Influenza Branch's data supports that seasonal peaks occur in January.

- The manufacturers responded: Mr. Hosbach/Aventis Pasteur: A managed distribution process to allow more regular vaccine supply will be more the norm at Aventis. Mr. Reilly, Wyeth: Vaccine supply will increase with production capacity. But as a general policy, expanding the recommended time period for vaccination is wise.
- Dr. Helms: *Issue this document as pertinent to this year only* and discuss a change over the next year. There are no hard data to support a change yet.
- Dr. Zimmerman: *A decision analysis is needed.* The advantage of delayed vaccination is the delivery of more doses; the disadvantage is the potential of not preventing influenza during the 21% of peak activity that occurs by December. Dr. Cox: There is sporadic and regional activity, and perhaps early outbreaks in nursing homes. There is an optimal time to vaccinate.

- Dr. Pat Noland, State of Rhode Island: *Be wary of advising patients to call physician offices*, a lesson learned from the meningococcal experience. Be very careful in crafting that public message to not imply that the physician has some control over supply. She also reported that Rhode Island distributors were not at all supportive of redistribution of vaccine, although some individual practices did share their shipments.
- Dr. Nichol also suggested: 1) *add providers under the text on vaccine distribution* to worksites, since many who administer to high-risk groups also do so to worksites; and 2) *strengthen the language about the importance of local initiatives* to join all stakeholders to the health departments to ensure even availability of vaccine; and 3) insert text about the vaccine ordering process and the legal authority under which providers can redistribute vaccine, in this document or on the Website.
- Dr. Tompkins: To make this a generic document for annual recommendations, drop "projected delay" from the title and change it to, for example, "Influenza Supply Distribution, Vaccine Supplementary Recommendations."
- Dr. Overturf: *Add young children to the section on household contacts of those at high risk, particularly since the issue of influenza immunization for children in general is pending.* This was discussed, but encouraging early vaccination for such a large group could hazard the supply to vaccinate those at highest risk.
- Dr. Orenstein: *Leave"delay" in the title*; dropping it risks missing the desired attention.
- Dr. Snider: *Consider the impact of the likely pending release of the live-attenuated vaccine.* He urged crafting solutions for the coming year and not thinking too many years in advance.
- Dr. France: Make the draft recommendation consistent with Dr. Orenstein's letter, particularly his request for the delay of mass vaccination programs in the latter half of October and perhaps in November, to avoid the need to reschedule these clinics.
- Dr. Modlin: The 1999 benchmark in use was the norm for four manufacturers. The three remaining must build capacity to increase the supply. A sentence should be added to indicate that while that is being addressed, this delay will occur. Dr. Smith also suggested defining "delay" right up front and specifying that it will not be as extensive as last year's.

The committee agreed to vote on accepting the draft recommendation with the following

changes: 1) define what "delay" means and explain and put it into context; 2) address the issue of those patients seeking vaccine early (September, October); and 3) address specific language on the inclusion of children as contacts of high-risk individuals; and 4) indicate ACIP's consideration of changing the timing paradigm of influenza vaccination that is likely be included in the statement next year. The vote was taken on the following morning.

HEPATITIS B IMMUNIZATION

Background. Dr. Susan Goldstein outlined the changing epidemiology of hepatitis B in the last 20 years and the new strategies to vaccinate high-risk adults in the United States. The current strategy focuses on prevention of perinatal transmission through routine screening of all pregnant women and vaccination of newborns born to hepatitis B surface-antigen-positive mothers; routine vaccination of adolescents; and selective vaccination of children, adolescents, and adults at increased risk for infection.

High-risk adults are defined as 1) injecting drug users (IDU), 2) sexually active homosexual and bisexual men, and 3) heterosexual men and women with >1 sexual partner in the previous 6 months, previous treatment for another sexually-transmitted disease, and commercial sex workers. Most STD clinic patients should be considered vaccination candidates; as well as 4) inmates of long-term correctional facilities. Other high-risk adults include household and sex contacts of persons with chronic HBV infection, those with occupational exposure, clients/staff of institutions for the developmentally disabled, chronic hemodialysis patients, and international travelers with potential exposure to blood or those traveling for >6 months.

Current Epidemiology. From 1987-1998, reported incidence of acute hepatitis B decreased 76%, from 13.8/100,000 to 3.3/100,000. However, this decline plateaued in the mid-1990's, while incidence remained stable. The overall trend was paralleled by age group for those aged 10-19 (attributed to hepatitis B vaccination), and age 20-29 (attributed to vaccination and behavioral changes such as injection and sex practices). The decline was 53% for those aged 30-39 and 38% for those 40-49. Those at major risk are heterosexuals, men who have sex with men (MSM), and IDUs. Rates have declined in all three of these major risk groups, but the epidemiology has shifted. Transmission through heterosexual activity rose from 21% in the 1980's to 38% in the 1990s, while those associated with MSM dropped 15% to 12%; and those for IDUs, from 20% to 14%. Data on trends in age for acute hepatitis B by risk group reflected a median increase in age of cases from 25 years from 1982-1988 to 30-32 years in 1994-1998.

A total of 56% of acute hepatitis B patients also have had another STD or been incarcerated, clearly presenting an opportunity for prevention of over half of all cases. Data on such missed vaccination opportunities by risk group were charted, and data from hepatitis B virus infection and related vaccination among MSM from the Young Men's Survey (MSM aged 15-22 years). Of those MSM, 11% had serologic evidence of hepatitis B infection, more than double the U.S. prevalence (4.8%). Their prevalence rose from 2% at age 15 to 17% by age 22. Only 9% were immunized against hepatitis B, only 27% knew about the vaccine, and only 9% thought they were at risk of HBV infection. This was despite 90% having a regular health care source; 65% were tested for HIV (most more than

once); and 13% had a previous STD diagnosis -- all missed opportunities to administer hepatitis B vaccine. This prompted a rethinking of CDC's immunization strategy, from targeting specific high-risk adults to targeting their frequently-used settings.

Missed Opportunities. Dr. Cindy Weinbaum noted the effective prevention immunizations for hepatitis A and B and their overlap with STD and HIV routes of transmission. The transmission of viral hepatitis is fostered by lack of service integration with successful hepatitis B vaccine programs in STD clinics, HIV/AIDS testing and counseling sites, family planning centers, drug treatment programs, harm-reduction programs including syringe exchange programs, Job Corps sites, and correctional facilities.

Since even one dose of the vaccine is efficacious in providing immunity for 50% of those vaccinated, it is well worth doing. Hepatitis B vaccination of those incarcerated has been recommended since 1982 to prevent infection both inside and outside of correctional facilities. It has been shown to be feasible and cost-effective. Successful examples were shared of high acceptance in Massachusetts and Texas correctional facilities and of STD clinics in San Diego, California.

But challenges to its implementation include: 1) funding. While rising numbers of juvenile detention facilities are signing up as VFC provider sites, adult vaccination is not covered; 2) the cost savings of pre-vaccination screening depends on local costs and the prevalence of immunity from past vaccination and past infection; and 3) the goal of three-dose completion is generally not feasible and perhaps should be changed to just one dose.

Policy Recommendations. Dr. Margolis cited the proven success of infant vaccination (90% 3-dose coverage) and even for the newer adolescent immunization (~60% in those aged 13-15 according to NHIS data). Demonstration projects have convinced NIP that vaccination of high-risk groups is both feasible and cost-effective when delivered through the good infrastructure of STD and HIV prevention. Vaccination of those at occupational risk and in correctional facilities is also feasible.

However, the lack of a national program is problematic. About 40 highly successful programs are run by states and local jurisdictions, but all are local endeavors with spotty funding. The CSTE and the American Social Health Association are conducting surveys to chronicle the activities underway. In the last 5-6 years, the recommendations have been rewritten to target specific adult risk groups (e.g., disease prevention in the chronic hemodialysis setting produced the current ~70% vaccination coverage). In the fall, new recommendations will address the prevention of viral hepatitis A, B, and C in correctional settings. Hepatitis B immunization has been supported by the IOM, the National Institute of Justice and the National Correctional Health Care Commission.

In the absence of a national program, CDC can provide technical assistance to local efforts, and can use 317 funds for some work. In adult immunization, Medicare funds the care of end-stage renal disease patients, but only funds hepatitis B vaccine at 80% versus 100% for influenza and pneumococcal vaccines. An OSHA rule requires employers to pay for vaccine, and ~5 states routinely vaccinate prison inmates. Medicaid does not cover hepatitis B vaccine. Many health plans do not provide first-dollar coverage, and gaining

coverage requires divulging risk factor status.

Dr. Margolis reported additions to this document:

1. The victims of sexual assault are addressed in language taken from the STD guidelines. There are no clinical or case control data, but based on post-exposure vaccine efficacy data and the expected frequency of the perpetrator's surface-antigen positivity, active post-exposure immunization is recommended in the text (rather than in background).
2. TwinRix®, the combination hepatitis A and B vaccine, was licensed for adults. That was added to the table of overlapping risk groups pertinent to the recommendations, and text will be written on that. Dr. Modlin noted the need for future ACIP discussion of whether specific recommendations for new combination vaccines are needed.

Discussion included:

- Dr. Stan Gall: *What is the current status of neonatal hepatitis vaccination since its temporary suspension due to thimerosal vaccine content and subsequent reinstitution with thimerosal now deleted?* Prior to July 1999, ~50% of U.S. infants were vaccinated from birth, according to the National Immunization Survey (NIS). That dropped ~70%. Recovery is now at about 30%, as the hospitals that dropped that vaccination from their standing orders slowly reinstitute it.
- Dr. Modlin: *About what proportion of adults are considered at risk or high risk; and how many of them are already seropositive?* Of the ~2 million people incarcerated in the U.S. long-term annually, 80% are susceptible. With 20% infected, that is 2 million. The numbers for IDUs and heterosexuals at risk are unknown. But the CDC-funded STD clinics see another ~2 million, with an unknown overlap to those in HIV counseling and testing sites. Including the IDUs, it could be in the 10-million range.
- Dr. Deseda: *A similar strategy of targeting high-risk populations was ineffective in the mid-1980s.* Agreed. Those CDC demonstration projects were in STD settings, not correctional facilities; a few were done with IDUs. The difference is the present ability of the public health infrastructure to access high-risk adults. That should provide pretty high coverage rates. Transmission cannot be eliminated for another 30 years unless the present adult vectors are addressed.
- Dr. Sam Katz: *What has happened with making 317 funds available for adult hepatitis B immunization?* Dr. Orenstein: The FY 2001 budget had an additional $42.5 million for infrastructure funding. Many states used that to strengthen their childhood programs to compensate for previous budget losses, rather than putting it into hepatitis B prevention. The 317 vaccine budget had no specific appropriation for hepatitis B vaccine for adults, even though that was an IOM recommendation.
- Dr. France: *Did you consider recommending, as done for PneumoVax® use by seniors, to give the vaccine if there is no history or statement of vaccination?* Operationally, this is what STD clinics are doing. To date, ~10% have already been vaccinated; the rest receive the vaccine.

Presentation of the HBV Statement

Review Report.

- Dr. William Schaffner found the statement to be strong and worthy of support. His

comments included:

1. For that one-third without good risk factor information, a separate statement may be advised to emphasize that group, necessary to the goal of interrupting and eliminating transmission.
2. There is a universal prevention concept up to age 19, after which the recommendations' underlying concept is hepatitis B control through individual and personal protection rather than elimination of transmission. The role remains undefined for the large portion of the 38% transmitted by heterosexuals who present to individual practitioners as opposed to prisons and STD clinics, the current emphases. Before the funding base needed to build a structure and reach out to partners is in place, a plan and recommendations are needed. A workgroup should be formed to research hepatitis B epidemiology and possible adult interventions. The ultimate goal should be to extend the universal immunization concept beyond age 19 to the periods of young adulthood when so many cases of hepatitis B occur.

- Dr. Jane Siegel added:
  1. Her hope that the document would convey that the recommendations for healthcare workers beyond acute care settings span the continuum of care, to outpatient and surgicenter settings.
  2. The document could better carry through a strong support for the birth dose. Dr. Margolis responded that the first recommendation could "recommend" that the first dose of vaccine be given during the newborn period," rather than "strongly encourage."
  3. The recommendations should be rated based on the evidence. While this recommendation in general is strongly supported by evidence, there are areas of less strong evidence and demonstration. Identifying those could help providers to allocate limited resources based on evidence.

Discussion included:

- Drs. France/Smith: *Adjust the (¶1, last sentence) recommendation to parallel the Harmonized Schedule and the General Recommendations*, to read "for infants at low risk of infection with hepatitis B virus, the hepatitis B vaccine series may be completed at any time after six months of age." Dr. Margolis agreed, except that the third dose should be given at six months among the high-risk populations due to early post-natal transmission.
- Dr. Abramson: *Adjust the wording to read "at six months of age"* rather than by six months, to parallel the General Recommendations' advice of four months between doses 2 and 3.
- Dr. Deborah Wexler, Immunization Action Coalition: *Consider clearer language specifying "at birth" or "during the newborn period."* This has been adjusted to be consistent with the STD guidelines, but just was not in the current draft at this meeting.
- Dr. Gall: *What is the policy about vaccination in pregnancy?* He recalled that it is safe to use in pregnancy and joked that a pregnant person "has one STD on board right there." Dr. Severyn objected to that levity. Dr. Margolis confirmed safety in pregnancy. The recommendation includes vaccinating pregnant women with risk factors, but not to routinely vaccinate pregnant women, based on overall risk to and cost-effectiveness for the 4 million pregnant women annually.
- Dr. Georges Peter: *Please share with the committee, when available, the AAP's*

changed recommendation about immunizing premature infants born of hepatitis B surface-antigen mothers; and ensuring that the Harmonized Schedule places hepatitis B directly under zero months. New data also suggest that the poor response in pre-term infants is better than thought. The schedules will be harmonized.

- Dr. Karen Midthun, FDA: *The package insert reference this vaccine as Pregnancy Category C (no animal or clinical data on reproductive toxicity). While that category does allow pregnant women to be vaccinated if clearly indicated, a blanket statement on safety should be qualified.* Accepted. Several trials have data on pregnant women inadvertently vaccinated and followed to the birth event (~200 instances). This does not provide strong confidence, but there has been no evidence of adverse events. The text addresses the issue of the risk versus the benefit in terms of HBV.
- Dr. France: *Add text about the strength of new epidemiology to support the success of hepatitis vaccination. And, is it really necessary to restart the series if a child receives dose 3 early; can't a fourth dose be given after 6 months?* Dr. Modlin: There are two issues, number of doses and catch-up. To be consistent with the childhood immunizations paradigm to not add additional doses regardless of the interval from the last dose, additional doses are not needed as long three doses are given. That can be dealt with outside of the statement.
- Dr. Kristine Severyn, Vaccine Policy Institute, Dayton, Ohio: *Much of this discussion is a bit disingenuous*; >95% of the population will never be exposed to hepatitis B, nor need they if they maintain "a wholesome, moral lifestyle".

Dr. Modlin thanked Dr. Margolis and his staff for the clearly immense amount of attention paid to this document in the last few months. He requested its careful review by all present and that comments be sent directly to Dr. Margolis within the next month. The statement will be reviewed again at the October meeting and, hopefully, voted upon. A workgroup is needed to begin addressing the broader and public policy issues raised.

VACCINE SAFETY ISSUES FOR YELLOW FEVER VACCINE

Should the ACIP yellow fever statement be modified?

Dr. Martin Cetron recalled two case reports in 1998 suggesting that the elderly may be at increased risk of adverse events from Yellow fever vaccine, and provided a background of the vaccine's origins. In use since the late 1930s, this vaccine has proven safety and efficacy. It has enabled the control of Yellow fever outbreaks in South America and Africa and is used to immunize persons traveling from developed countries to endemic areas.

Vaccine History. The live-attenuated yellow fever vaccine (LAYFV) was developed in 1927 from the serum of two yellow fever survivors, and the French neurotrophic virus was derived from that. Safety concerns about neurovirulence halted the use of the latter since 1982. The current vaccine produced stems from the Asibi strain, whose virulence was attenuated while preserving immunogenicity and protection. This is not a clonal derivative of a live virus, but a whole population of genetically homologous but distinctive virious. Early on, it produced higher rates of neurotropism and encephalitis, especially among children aged <6 months. However, this was greatly diminished with the development of a seed lot system, and it has been the United Nations standard since 1945. All vaccine now uses this

secondary seed lot, termed 17D vaccine type yellow fever virus, in two primary vaccine strains: 17DD, which is used in Brazil; and the 17D-204. A reference strain was derived from the latter, 17D-213, which is manufactured in Senegal and stored at WHO; 17DD is produced in Brazil. The two are very similar (>99.5%) in their sequence and their amino acid homology.

Adverse events (35) due to 17D were reported in the VAERS data 1990-98. They reflect a stepped risk of multi-systemic effects with increasing age (the mid-50s to 60s), with duration from 48-72 hours. These resulted in 14 hospitalizations and three deaths. A comparative validation of those observations done with collaborators in the U.K. used the hepatitis A control vaccine of the time, and produced no similar stepped increase in age-related reporting risks and no deaths among in >3 million doses. Another U.K. database on Arilvax® covered 1 million doses. It included 36 systemic adverse events and more other quickly-resolving non-serious events, and the same stepwise increase in risk. However, very few vaccine recipients were aged >75 years.

Dr. Cetron then described seven cases of a new yellow fever-like syndrome associated with 17D yellow fever vaccine. These occurred over the last five years among persons who received 17D-204 vaccine. Four were in the U.S. (aged 63-79), one in "Country X" (age 53), and two from Brazil (aged 5 and 22). Yellow fever is resurgent in the Americas and in Africa. It particularly threatens urbanized Brazil, where a massive vaccination campaign over the last 4-5 years has administered >38 million doses of yellow fever vaccine.

The syndrome onset is 2-5 days post-vaccination. All seven cases had multi-organ system failure and six died. Among five cases, four had the 17DD or 17D-204 vaccine-type virus isolated and sequenced. There was no wild-type yellow fever isolated from any of the patients. Dr. Cetron outlined the clinical description of wild-type yellow fever. The clinical syndrome in itself is not specifically pathognomomic. The broad differential diagnosis includes, for example, severe viral hepatitis or malaria, typhoid fever, leptospirosis, dengue, and other viral hemorrhagic fevers. The diagnosis requires histopathology.

VAERS, although a passive system, gives the best indication of incidence. Over nine years and 1.5 million doses among civilians, the incidence rate was ~1/400,000 and the case fatality rate was 3/1.5 million (1/500,000). This is similar to the occurrence of paralytic polio following the first OPV dose. The important element of all these cases is that, despite an aggressive search, no other pathogens were identified nor any other medical etiology to account for the syndrome. Clinically, all the cases shared rapid onset after vaccination; fever; myalgias and arthralgias; elevated liver enzymes and elevated bilirubin; profoundly low platelet counts; lymphocytopenia; low blood pressure requiring vasopressure support; renal failure requiring dialysis; and respiratory failure requiring ventilatory support.

Other possible explanations explored and discounted included previous receipt of yellow fever vaccine and receipt of other vaccines (no one was consistent). Slides of the liver biopsies done were shared, demonstrating a fairly classic but also nonspecific pathology. That highlighted the importance of the monoclonal immunohistochemical staining. The molecular sequencing on virus isolated from four cases (two Brazilian, two in the U.S.) noted no consistent mutation in envelope protein or immunodominant region to explain the

17-DD reversion to wild-type.

The evidence supporting a causal relationship includes striking temporal associations, the isolation of 17D vaccine virus from blood and multiple target organs, compatible histopathology in conjunction with a large amount of antigen, hepatic necrosis and myocarditis/myositis seen in Brazil and "Country X"; an absence of other pathologies/etiologies; that fact that the sepsis-like syndrome is similar in some ways to wild-type yellow fever; and multiple cases (7) involving multiple countries and both vaccine strain subtypes 17D-204 and 17DD. There is also precedent (oral polio, perhaps measles) and biologic plausibility for LAyFv to cause disease similar to the wild-type disease.

The evidence against a direct causal relationship includes some findings atypical of classic yellow fever, no consistent reversion to wild-type yellow fever genotype (Brazilian follow-up virulence research in primates showed no pathology); and that the syndrome was not reported prior to 1996, with close to a billion doses of yellow fever vaccine distributed.

Unanswered questions include the pathogenesis of this syndrome; whether it is a new or only a newly-recognized event (if rare, it would be difficult to detect; as it would still be if it has been masked in past outbreaks); and whether this is a clinical spectrum or an all-or-none phenomenon. Dr. Citron suspected the former, since cases have recovered, probably occurring in a continuum. The risk factors are unclear, including how many are host-related. Age may play a role, but not exclusively, and so may underlying host factors such as flavivirus susceptibility or resistance genes. Further research is needed on issues of vaccine strain and production.

There are no good quantitative incidence data yet, nor quantitative risk benefit analyses, but Dr. Cetron's bias placed more risk on entering a yellow fever outbreak area unvaccinated. The additional needed research includes animal virulence studies, full laboratory work-up of cases and perhaps retrospective reviews of suspect cases to define host risk factors.

The conclusions were:

- 17D is a possible cause of this syndrome; it is not clearly due to the emergence of a wild-type clone. It is not exclusively due to any one known clear mutation in vaccine type virus. It may be related to an idiosyncratic host response.
- Most cases occurred after primary immunization
- Incidence is really unknown.
- Yellow fever vaccine probably should be reserved for U.S. travelers to endemic and epidemic areas only; any other reason for administration other than medical risk is not advised.

Proposed Response. The proposed response is:

- Revise the 1990 ACIP statement on yellow fever; write informational letters to vaccination centers and practitioners; possibly change the package insert; and print notices in publications. The Brazilian and U.S. work is fast tracked for *Lancet* publication, as is the VAERS work in the next issue of *Emerging Infectious Disease*.
- Link passive reporting with the IDSA and International Travel Medicine Network of Providers to the VAERS system, and publish a protocol on how to work up such cases.

- Establish an active surveillance system of yellow fever vaccine (e.g., through the ~3600 certified yellow fever vaccination centers and other networks).

Discussion with Dr. Cetron included:

- Dr. Deseda: *What is normally expected from viremia or distribution of vaccine virus in target tissue?* In general, viral replication after vaccination is very contained and minimal and has a serologic response much milder than to wild-type. It is very unusual to see this amount of viral antigen in target tissue with histopathologic damage after vaccination.
- Dr. Offit: *What is the probable risk/benefit for a person aged >65 years traveling to an endemic or epidemic area?* The U.S. deaths are skewed toward the elderly at a reported rate of 1:50,000. There has been a resurgence of yellow fever in South America and in Africa and tourism data of U.S. travelers show a 300% increase of travel to South American yellow fever-endemic areas, and 10% to those in Africa. This rapidly increases the denominator of those exposed, and the manufacturers' rate of vaccine production has not kept pace. Modeling has produced a rough numerator and a denominator of coverage, and indicates a downward trend of 10-20%. And, after 75 years of no yellow fever importation, 4 cases in the U.S. and Europe came from South America (3) and the Cote D'Ivoire (1). Dr. Offit cited as another option, discouraging older persons from traveling to disease-endemic countries.
- Dr. Clover: *Do we know if the doses were given from single- or multi-dose vials, and what is known about the management of multi-dose vials?* All five of the cases in developed countries were from single-dose vials with no common lot number. But the Brazilian mass campaign used vaccine prepared in large amounts.
- Dr. Levin: *Did the older people who died have underlying illness?* Yes, but those were normal for an elderly population and did not require immunosuppressives, nor were there common immunodeficiencies. The young people in Brazil were HIV-negative.
- Dr. Helms: *The medications taken by the elderly may be hepatotoxic (e.g., acetaminophen).* Yes, and toxic exposures can cause some similar histopathology. But there were none such seen, and the variety of medications given to manage and support these patients were not hepatotoxic.
- Dr. Smith: *Please clarify the booster dose recommendations.* Research done among military recruits show durable immunity for 30-35 years and possibly for life. The WHO considered changing the decennial vaccination required by International Health Regulations, but there was some concern that the U.S. experience may not be transferrable globally. In addition, this syndrome appears to stem from primary immunization; the prior immunity of boosted vaccinees may give them much lower or no risk. The epidemiological differences seen may stem from differing proportions of elderly people being primarily exposed both to flavivirus and to yellow fever vaccine.
- Dr. Zimmerman: *Any way to estimate a risk-benefit ratio in perspective for areas to which people travel would be helpful.* Yes, but this is challenged, as with many vector-borne diseases, by focal outbreaks spread non-uniformly. Only regular global surveillance could provide a rational risk assessment. CDC is examining some of these issues in the development of recommendations for travelers at a sub-country-level risk profile, for malaria, yellow fever, and other diseases.
- Dr. Chen: *Are there any DOD data to indicate if this may be a new or newly recognized*

syndrome? DOD reports no experience with it, and they would have recognized it in otherwise young, healthy military recruits.

- Dr. Jim Presley, Aventis Pasteur: *This must be publicized, preferably by a CDC/FDA collaboration, but the Brazilian cases should be separated from the U.S. cases* due to 1) different strains (DD and 204); different monoclonal antibodies; and difference demonstrated in neurovirulence testing; and 2) the marked difference of the Brazilian cases: youth, no other obvious cause of death; acute illness quite compatible with yellow fever; typical yellow fever histopathology on autopsy and yellow fever virus in high titers isolated from a multitude of tissues. It should be further investigated whether there really is a syndrome of that nature in the U.S. Aventis Pasteur has already submitted a package insert amendment to the FDA to describe these cases.
- Dr. Tony Markham applauded Dr. Cetron and his collaborators' analysis of these cases, particularly with the sparse data available on the American cases. These cases must be taken seriously, particularly in any active surveillance done. The CDC's NCID Division of Vector-Borne Infectious Disease will provide the technical support to evaluate these cases to match the Brazilian level of investigation.

Dr. Clover reported that the Adult Immunization Workgroup had examined this syndrome when it was first presented, and agreed to review it again. A subgroup of volunteers was formed, of Drs. Deseda and Offit., and Dr. Midthun volunteered the services of Dr. Philip Markhoff, FDA's yellow fever expert. Dr. Snider added that CDC has an agreement with FDA to have an FDA representative on every relevant workgroup.

VACCINE SAFETY UPDATES

The Brighton Collaboration. Dr. Katrin Kohl outlined the activities of the Brighton Collaboration, which aims to develop standardized case definitions for adverse events following immunization. This began in fall 2000 under the coordination of Dr. Kohl and Dr. Jean Bonhoeffer, a Swiss academician. The collaboration is currently supported by CDC, WHO, and the European Research Program For Improved Vaccine Safety Surveillance, or EUSAFEVAC. Dr. Kohl outlined the five members of the Collaboration's Steering Committee and its structure.

Since vaccine-preventable diseases (VPD) are less frequent than vaccine adverse events in the developed countries, standardized case definitions are needed to assess immunization safety date in order to ensure ongoing trust in immunization programs. These definitions will allow comparison of safety data from around the world, maximize scientific output from pre- and post-licensure vaccine trial data and from post-marketing surveillance data, and advance scientific progress. Dr. Kohl demonstrated the diversity of safety methods used in recent clinical trials, which tracked fever at different cut-off points.

The case definitions will be developed through expert working groups, each of which will address one adverse events following Immunization (AEFI). These experts will collaborate with participants from the regulatory, public health, and scientific fields, as well as professional organizations and vaccine manufacturers. The target audiences include investigators, health officials, health care providers, and regulators involved in all levels of immunization and vaccine safety.

An inventory of existing case definitions from the literature (both published and not) will be compiled and reviewed by the workgroups, which will develop case definitions by consensus. They will be reviewed/validated by a broader workgroup including vaccine safety organizations and interested individuals; field tested when necessary and possible; and then globally disseminated.

The first AEFIs to be defined are fever, local reactions, intussusception, abnormal crying, convulsion, and hypotonic-hyporesponsive episode. The Local Reaction Workgroup has listed 16 different injection site reactions to be defined. There are currently 5-16 members in each of five workgroups. Those on fever, intussusception, and injection site reaction with abscess at injection site, have begun drafting their case definitions and their related parameters (e.g., in the fever group, stratification by type of vaccine in order to decide on the duration of follow-up needed post-immunization). A protocol for validation studies is in initial development.

The seven AEFIs tentatively to be defined include allergic reaction, rash, asthenia, paresthesia, SIDS, myalgia, and idiopathic thrombocytopenia. Their selection was based on the frequency and severity of occurrence or by public interest and funding concerns. A chart of the top ten serious and non-serious AEFIs reported to VAERS in the last decade and those being defined by the Collaboration showed a good parallel. The next set of adverse events to be defined will be selected in this month. Dr. Kohl invited review of their Website (brightoncollaboration.org, noting that there is no initial "www"). Draft definitions are hoped to be completed by September 2001; the final draft of the first six AEFI's by March of 2002; and the next seven workgroups to begin this December. She invited collaboration. On Dr. Neuzil's question, she explained that the definitions will include all age groups. Some may be stratified by age, depending on the adverse event.

IOM Immunization Safety Review Committee. Dr. Kathleen Stratton, of the Institute of Medicine's (IOM) Immunization Safety Review Committee, provided its first report. The Committee is sponsored by CDC and NIH to conduct a three-year project to serially address various vaccine safety concerns. For each, the Committee will assess the scientific plausibility of a causal link between the vaccine and the adverse event in question, the significance of the issue in a broader societal context, and then will recommend public health response actions. The Committee meets three times a year and will issue a brief consensus report 60 to 90 days after each meeting. There will be summaries developed for the public and outreach will be done to providers, researchers, policymakers, and the public.

The first meeting (March 2001) addressed MMR and autism; the thimerosal issue will be addressed in July in Boston (Dr. Stratton will return 2-3 months after that to report); and the discussion of multiple antigens and immune dysfunction will occur in November, probably in Seattle. The topics are chosen by the DHHS' Interagency Group (IAG).

The *plausibility assessment* and *causality determinations* are based on review of epidemiologic studies, knowledge of the adverse event's human pathogenesis, and relevant animal models. The *significance assessment* of the issue includes consideration of the burden (seriousness) of the VPD in question, its risk if immunization rates fall; its

treatability; the burden of the vaccine adverse event; the level of public concern; and other issues that the Committee feels are relevant (e.g., feasibility of research to resolve unanswered questions).

The Committee's *public health response* comments include recommendations on policy review, targeted recommendations on research and surveillance, and on communications. Aspects of policy review are outside of the Committee's domain, being under the auspices of others such as the ACIP. They will not overlap other committees' domains, but if their work indicates evidence sufficient to recommend to another specific committee for action, they will do so.

Committee Process.

- An open scientific meeting (that information is posted on the Website) and another one-day Committee meeting are held for each topic.
- The Committee reviews the published literature, and all information and reviews submitted by interested parties. All information is placed in a public access file.
- A background paper was commissioned on the first topic, MMR and autism. Although controversial, it was very effective in drawing many helpful comments when posted on the Website. The Committee reviewed them all. That process will probably continue, but probably with clearer caveats that the posted paper does not represent the Committee's view.
- The Committee reviews VAERS reports as possible, and hears about unpublished data at the public meeting held with the first scientific session. The report briefly discusses how unpublished data might be weighed. The more detail provided, the more that can be done; but because of the lack of peer review, it is doubtful is would sway a causality determination.
- Public access, aside from the public meeting, include a telephone number contact and multiple materials on the Website.
- IOM reports are extensively peer-reviewed (the MMR/Autism report had 17 reviewers), but the responsibility for the report lies with the Committee. The reviewers do not see the final report until it is released.

MMR and Autism Report. The Committee concluded that the evidence favors rejection of a causal relationship at a population level between MMR vaccine and autistic spectrum disorders, based upon a consistent body of epidemiologic evidence showing no such association at a population level.

- The epidemiologic data were taken from the Wakefield case series published in 1998 in the *Lancet* and from the 1998 Peltola et al study of 31 vaccinees recorded in the U.K.'s passive surveillance system. The Patja et al study published in the *Pediatric Infectious Disease Journal* in 2000 followed 169 vaccinees with 173 serious adverse events between 1982 and 1996. Neither of these latter two studies reported cases of autism.
- Three published ecologic studies: Dales et al (2001) studied children born between 1980-1994 in California who were diagnosed with autistic disorder. The General Practitioner's Research Database case study of 2001 followed 350 children in the U.K. aged ≤12 years diagnosed with autism between 1988-1999. Again, no trend emerged in the increasing rates of autism with the immunization. The Gilberg et al 1998 study reanalyzed data from a 1991 population study of autism to examine pre- and post-MMR

introduction rates. None of these showed an association with increased autism.

- The Taylor 1999 cross-sectional time series study provided the strongest data in three analyses of identified children. It showed no step-up in autism diagnoses after MMR introduction, no change in diagnosis age with vaccination age, and no clustering of diagnosis, parental concern, or autistic regression.
- Three unpublished reports also were reviewed by the Committee, from Dr. Elizabeth Miller (updating the Taylor study, with preliminary analyses supporting it); Dr. Fombonne (reporting a time series analysis reflecting a step-down rather than increase in autism incidence post-MMR introduction), and Dr. Wakefield (reporting rechallenged cases of regression after MMR vaccine, confirmation of the presence of measles virus, and typing that for wild- or natural-type vaccine strain).

Causality: The IOM approves of using case reports to support causality, but heard none of the depth reported at this meeting that could strengthen a causality argument. The biologic models linking MMR vaccine and autistic spectrum disorders were fragmentary. Too many events would be necessary for the MMR vaccine to cause autistic spectrum disorder.

- No relevant animal model has demonstrated a link between MMR vaccine and autistic spectrum disorder. Those that exist are inapplicable to postnatal insults such as the MMR vaccine.
- Nonetheless, the Committee did not exclude the possibility that the MMR vaccine could contribute to autistic spectrum disorder in a small number of children. The epidemiologic evidence, although consistent and all indicating no association, lacks the precision to assess rare occurrences of MMR vaccine responses that could lead to autistic spectrum disorders. And, although the proposed biologic models linking MMR vaccine were not established, neither were they disproved.

Recommendations. The Committee recommended continued studied because:

- The evidence is limited; no study was particularly exemplary or strong alone and all had flaws.
- The severe burden presented by autism requires a better understanding of the disease, and the burden of diseases prevented by the vaccine is very high. If this issue cannot be resolved to parents' satisfaction about the safety of the vaccine and immunization rates fell, the public health burden of natural measles, mumps, and rubella would be terrible.
- Although the Committee did not specify what sort of attention should be brought to bear, they made several specific targeted research recommendations:
  - Establishment of standardized case definitions or assessment protocols for autistic spectrum disorders.
  - Exploration of whether exposure to MMR vaccine is a risk factor for autistic spectrum disorders in a small number of children. But this is perhaps best delayed until there are biomarkers of either the risk for autistic regression or of one of the steps of the proposed biologic models).
  - Investigation of whether or not the measles vaccine strain virus is present in the intestines of some children with autistic spectrum disorders (to replicate/validate the Wakefield work).
  - Reports to VAERS should provide with as much detail and documentation as possible when any diagnosis of autistic spectrum disorders may be related.

- Study of the possible effects of different immunization exposures (e.g., children whose families declined their receiving the MMR vaccine). The Committee was very clear that this was not an encouragement of alternatives to the recommended immunizations, but rather an acknowledgment that some children are being immunized in a different way. Targeted clinical studies of these children or these families would be of interest.
- The Committee endorsed the existing research portfolio of CDC, NIH, and other funders on the risk factors and biologic markers of autistic spectrum disorder, in general.
- CDC and FDA should review their communications, particularly those on the Internet, to ensure that their information is not inflammatory and is unbiased about the putative link between MMR vaccine and autism.
- Tangential issues that could be addressed in the Committee's future include discussion between the vaccine and the public health professionals and the public about such questions as: why it is impossible to prove a negative relationship; what is an "acceptable" level of risk for a given vaccine benefit, and how is that best discussed with various stakeholders; how to best convey the meaning of terms such as "association" versus "causality" and what evidence supports them; and ways to research vaccine exposures not directly causing but perhaps triggering conditions of multi-factorial etiologies; the appropriateness of alternative immunization schedules or practices which might be requested in a clinical setting; and the general issues of vaccine and risk benefit communication.

In discussion with Dr. Stratton, Dr. Jackson asked how the report has been received. She replied "about what would be expected" in vaccine safety work. The pediatric and the public health community agree with much of it; the research recommendations and the call for no policy review were considered sensible. Some vaccine safety advocates approved of the report for the most part. Other groups are less happy, mostly with the emphasis of the conclusion rejecting the causal relationship based on the evidence, although the possibility cannot be ruled out.

Update on Thimerosal

Dr. Roger Bernier updated the committee on the progress of transitioning from a thimerosal-containing vaccine supply in the routine pediatric schedule to the present situation of a supply with no, or trace, amounts of thimerosal.

Background. When this first came to widespread public attention in July 1999, three vaccines on the routine schedule contained thimerosal as a preservative: hepatitis B, DTaP, and Hib. The ACIP encouraged clinicians and parents to immunize all infants even if the choice of individual vaccine products is limited for any reason. In October 1999, ACIP stated that those three vaccines can continue to be used beginning at two months, along with monovalent or combination vaccines that do not contain thimerosal as a preservative. Then, after the Vaccine Safety Datalink reports of a possible link to health effects associated with thimerosal, a second Joint Statement by the AAFP, AAP, ACIP, and the Public Health Service (PHS) recommended continuation of the current policy of moving rapidly to vaccines which are free of thimerosal as a preservative. Until an adequate supply of each vaccine is available, use of vaccines which contain thimerosal as a preservative was

still acceptable.

Since July 1999, hepatitis B has become thimerosal-free (by Merck in September 1999 and then by GSK in March 2000). All of the Hib supply is now thimerosal-free, as is the DTaP supply (Aventis Pasteur in March 2001 and GSK since 1997). Two other companies dropped out of the market. In fact, all the routine vaccines on the pediatric immunization schedule are now thimerosal-free. Others still containing it (e.g., influenza, Td, and DT) are not part of the routine immunization schedule. The remaining supply of thimerosal-containing DTaP vaccine is probably small and should be quickly finished. The Hib and hepatitis B vaccines last released into the public sector have not yet expired, but the remaining supply should be quite limited.

The ACIP has chosen not to express a vaccine preference relative to thimerosal. While that is now moot with the thimerosal-free product, expressing a preference would influence the use of any existing vaccine stocks containing thimerosal. The Committee was asked if it wished to continue the current policy, or to make a recommendation that could decrease the use of the small estimated number of hep B, Hib, and DTaP doses with thimerosal remaining in doctors' offices and public clinics.

Dr. Modlin thanked Dr. Bernier for the immense amount of time and intellectual energy he devoted to this issue and the balanced approach he provided. He also noted that, in addition to the policy implications, there could be implications for thimerosal-containing vaccines used throughout the world. Dr. Bernier agreed. The staff was not ready to identify options for the Committee on this day, but only requested an indication of its wishes.

Discussion with Dr. Bernier included:

- Dr. Chen: The Europeans are moving in the same direction as the U.S., as reported at the recent WHO Immunization Safety Meeting. There is some concern for the EPI but the schedule used there does not contain the amount of thimerosal exposure that led to the concern in the U.S.; the issues would just need to be framed properly.
- Dr. Zink of GSK stated that their hepatitis B vaccine is free of preservative.
- Dr. Snider: *Could there be any implication to other vaccines not now included in the schedule, such as LAIV if it is considered?* One of the potential consequences of making a change could be to change people's perceptions of other vaccines. Care would be needed about attaching the concept of hazard to thimerosal. The hepatitis B vaccine poses issues because it is both for infants and adults.
- Dr. Zimmerman: *Stating a preference can pose implications* for influenza, TD, and perhaps other things. Going beyond the present policy raises potential problems.

Dr. Tompkins moved to support the current policy. With no objection, **that was accepted** as the Committee's response.

Proposed Research on Thimerosal-Containing Vaccines and Developmental Deficits. Dr. Thompson summarized the background of guidelines of the Food and Drug Administration Modernization Act of 1997. This required a review of biologics containing, and the guidelines for, methylmercury and thimerosal's ethylmercury. Only studies on methylmercury were available. EPA's guidelines are the most stringent; the routine vaccine

schedule would exceed the EPA's standards for methylmercury exposure to children aged <6 months.

A June 2000 meeting reviewed analyses using the data of two VSD HMOs, Northern California Kaiser (NCK) and the Group Health Cooperative (GHC). That report associated cumulative ethylmercury exposure in the first year of life with language and speech delay, ADHD, tics, stammering, and unspecified developmental delays. However, the analysis had weaknesses, including in its statistical associations and inconsistent subsequent analyses.

A follow-up, two-phased, retrospective cohort study was proposed, with Phase I focusing on sensitivity versus specificity (through a broad range of neuropsychological tests, outcomes from the VSD screening analysis, and domains affected by methylmercury exposure reported in previous studies). Phase II would follow-up on Phase I with specificity to the deficits and patterns seen from Phase I. A larger sample size would be required, perhaps one with different children than in Phase I. An external multi-disciplinary panel review of the proposal in March commented:

- The study design's separation of Phase I and Phase II (3-5 years) was not efficient or timely. A hybrid study to increase the timeliness of the results and reduce the cost of the study was advised.
- Opinions differed as to whether low birth weight infants should be included or excluded.
- The potential bias of including the NCK as a study site, the source of the strongest results in the VSD screening analysis, was raised
- There are few ethylmercury studies available to guide definitions of the exposure groups and possible threshold effects.
- The consultants recommended conducting pharmacokinetic studies and extensive data collection on alternative exposures and potential confounders.
- Suggestions of outcome measures included: reducing the number of domains in the study; focusing the domains based on methylmercury studies and results, selecting highly sensitive but brief tests, and adding measures on speech and visual-spatial ability.
- The retrospective cohort design study was felt to be well worth doing, but opinion differed if the two-part study was a sound approach. There was also general opinion voiced that the Phase I results would not necessarily ensure finding any results in Phase II.
- There were no strong opinions to exclude NCK as a site, but there was general agreement that it should not be analyzed alone.
- Overwhelmingly, the panel believed that the association between thimerosal and autism could not be studied within this design. They recommended instead a case control study, which NIP will do. They also did not feel that a prospective cohort design study was imperative. Some disagreements about the correct interpretation of the results from a retrospective study related to ethical considerations.

A follow-up, similarly multidisciplinary meeting in May reviewed the revised test battery. The panel members added measures based on group input, and revised the protocol:
Design: Retrospective cohort study.
Cohort: Subjects will be selected based on cumulative thimerosal exposure from vaccines

at age 3 months, since the highest exposure per kilogram occurs at age 2 months if ACIP recommendations are followed.
Testing: Standard neuropsychological testing battery of all participants at age 7 and 9 years; confirmatory evaluations of children testing positive on certain screening tests. (In essence, Phase II will be done the same day as Phase I).
Exposure groups: Three: low (<25 µgm ethylmercury; medium: 25-62.5 µgm; and high: ≥62.5 µgm. This may be changed to two exposure groups, of those who received hepatitis B vaccine at birth versus not. Alternative exposure will also be researched: cumulative exposure at age 6 months, 1 year, and 2 years, with weight-adjusted analyses. So, although the sample will be selected based on cumulative exposure at 3 months, all exposures will be explored.
Exclusion criteria: Severe perinatal and selected congenital disorders, receipt of hepatitis B immunoglobulins, low birth weight babies (<2,500 gm) and gestational age <38 weeks.
Outcome measures: Phase I: verbal ability, visual-spatial ability, executive functioning and attention, short-term memory, fine manual motor tasks and achievement, language delay, speech delay, and ADHD; Phase II: a) characterization of prevalence estimates for language and speech deficits, and ADHD, testing those measured at 1.5 SD below national norms on selected Phase I measures; b) other exposures and potential confounders, including proxy measures for other forms of organic mercury, lead, PCB's, alcohol, and other drugs, and from abstracted medical records, questionnaire responses, and IQ tests to parents/caregivers.
Sample size Phase I: small; Phase II, ~3400 (assuming background prevalence of 2.5 in the low exposure group, with a power of 80% and a two-fold difference in neurodevelopmental delay rates) with ~1100 per exposure group (800-850 from each of four VSD HMOs).

Next steps: NIP review of the protocol; discussion of funding/budgeting; presentation to the IOM Immunization Safety Committee July meeting; identification of an independent contractor for the study planning phase (procedures, sampling frame, standardized testing, pilot and actual study).

Discussion with Dr. Thompson included:

- Dr. Modlin: *Why exclude low birth weight babies, the group most likely to be at risk and to signal?* The screening analysis indicated no effect from thimerosal exposure within low birth weight children; and great likelihood of poor neurodevelopmental outcomes in such children, who are also less likely to get immunized. Such confounding by contraindication requires a randomized trial. Dr. Modlin: *But this group is sizable, and is truly vulnerable to adverse effects of toxin exposure early in life; and the true confounding effects of low birth weight on adverse outcomes begin for those with gestational age of ≤30-32 weeks.* Dr. Chen: Most of the birth weights are ~2500 gm; only a very few are much lower, so this seems an artificial cut-off if a very low birth weight group was really desired. Discussion will continue with the IOM.
- Dr. Orenstein: *A decision has not been made to go forward with this study at this point,* pending review of budget considerations and priorities since thimerosal was removed from the supply. The major issues relate to vaccine injury compensation therapy and implications to the developing world.
- Drs. Jackson/Modlin: *Many African-American babies who are very well developed fail*

below the 2500 gm weight cut-off and would be excluded. Use something much lower than 38 weeks and 2,500 grams.

- Dr. Plotkin: *Phase I is generally a hypothesis-finding phase; but Phase II will only try to confirm the reality of that statistical difference among all the variables, among the same population?* Phase I is a more traditional toxicology study which uses continuous measures and ends when it is determined that the exposure caused "x" point difference in a particular outcome. This Phase II focuses on following up on the VSD results. It adds those screening measures' specific outcomes to the traditional toxicology study to follow up on the same individuals and accurately classify them as either speech-delayed, language-delayed, or ADHD. The multiple-measure issue is a known problem that will have to be addressed.
- Dr. Plotkin: *Will this be blinded for the parents, who probably are or will be aware of related lawsuits?* Yes. There has been discussion of how the design can reduce that potential confounder.
- Dr. Halsey: *Will the investigators and reviewers be masked to the exposures?* Yes. *Explore whether you can increase study power to be able to detect differences even if they are small (likely) and do not reach an odds ratio of two. The study should be done because of the added strength of a retrospective cohort analysis as compared to case control studies.*
- Ms. Lynn Redwood, of SafeMinds, *took exception to cohort selection based on age only to 3 months, and using 12.5 µg to separate the medium- and low-exposure groups. Mercury's long half-life will not reach peak blood concentrations until age 6 months.* Dr. Thompson responded that there is a very high positive correlation between 3- and 6-month cumulative exposure (~ 0.7-0.8), and the highest exposure per kilogram occurs at two months of age for most individuals. Ms Redwood: *Right. But then it says six months because of the stair-stepping of excretion concerns that need to be addressed.*

PUBLIC COMMENT was solicited, but the requesters, Dr. Zink and Ms. Redwood, had already spoken, so the meeting adjourned at 5:35 p.m.

JUNE 22, 2001

UNFINISHED BUSINESS

Review of the Edited Influenza Supplementary Statement

The meeting reconvened at 8:00 a.m. the following morning with a discussion of the edited influenza supplementary statement that Dr. Schwartz had provided for the members' overnight review. Dr. Schwartz summarized the changes made:

- Format changes placed the goals up front, with the description of production estimates and the recommendations, followed by the supporting data. The text under recommendations was simplified.
- A recommendation for mass immunizers was added, which includes local and state health departments.
- The recommendation about communication to high-risk patients was modified to avoid them all calling their physician's office about vaccine availability.
- Text was added to indicate that this year's situation may become the norm, and that

ACIP will consider later what recommendations should be routine as opposed to unique for this season.

Dr. Schwartz outlined several other issues for discussion:

- Use of the terminology of "delay" or "decreased early season availability." The advantages of the latter are: 1) to deflect concern about the causes of the delay; 2) to decrease public alarm; and 3) to potentially more accurately reflect the long-term situation. However, he felt the advantages of using "delay" still seem to be greater: 1) it accurately reflects the perceptions of physicians and of others in the system of what is the "norm;" 2) it better captures the stakeholders' attention; 3) it preserves CDC's credibility in the face of investigations and conspiracy theories; and 4) it accurately reflects this year's situation without assumptions about future production/distribution decisions.
- To provide perspective on the magnitude of the problem, he added text ("Distribution through October will be substantially greater than during 2000 when production delays occurred"). And, to avoid the confusion of addressing current and future objectives in a single document, he added as a goal a prioritized or phased system for this year while still emphasizing the Healthy People 2010 goals.
- To address close contacts of pediatric patients, the parenthetical comment can be revised to a footnote. Staff will work with the AAP to better clarify that issue.

Discussion with Dr. Schwartz included:

- Dr. Siegel (and general consensus): *Replace "those who care for them" with a more specific statement referencing health care workers* to make it very clear that they need to be immunized early.
- Dr. Neuzil: *Strengthen the text stating the importance that manufacturers, distributors, and vendors inform providers of the amount of vaccine available* under "Recommendations for Manufacturers"
- Ms. Linda McKibbon, CDC Office of Health Care Partnerships: *There are several places in the recommendations where the priority of distribution to nursing homes could be placed, including under providers for manufacturers and for health departments.* That can be done if the Committee desires, but there are some special concerns about the elderly population (waning immunity and October vaccination rather than earlier) that make it tricky. Text can be developed recognizing that groups such as the frail elderly (>65 years old) should be given priority for earlier vaccine, and that standing orders are one approach to improve immunization rates within this population.
- Dr. Nichol: *Perhaps include text to explain that references to "providers" includes health care organizations and long-term care, etc., as well as individual providers.* That could be added as a recommendation to manufacturers and distributors.

Dr. Word questioned the discussion, noting that nursing homes and chronic care facilities were already listed as priority groups. Dr. Modlin summarized the committee's consensus to allow Dr. Schwartz to work out the final wording with staff to reflect the Committee thoughts.

VOTE: *Conflicts:* Aventis, or Wyeth, or Medeva.

Dr. Johnson moved that the Committee support the supplementary statement as presented by Dr. Schwartz. Dr. Levin seconded the motion.
In favor: Levin, Brooks, Word, Tompkins, Helms, Offit, Johnson, Smith, Deseda, Modlin.
Opposed: None.
Abstentions: Rennels, Clover.
The motion passed.

Dr. Snider noted the two-stage process of the Committee's advice to CDC and then its decision of whether to accept those recommendations. He thanked the Committee and staff for their consistent excellent crafting of recommendations, such that they are generally accepted as advanced. He expected that any changes would be editorial rather than substantive issues, but if any of the latter are made, the Committee will be informed.

AGENCY UPDATES

National Immunization Program (NIP)

Dr. Orenstein reported the success of 35th National Immunization Conference from May 29-June 1. Over 1500 people participated in the agenda, which included a Cyber Café, a Webcast, and will produce a CD ("Everything You Want to Know About Immunization").

NIP Budget. The President's FY2002 budget submission included a 3% ($109 million) decrease for CDC overall, but a 4% increase for NIP. That includes $14 million for the 317 Grant Program (mostly for pneumococcal conjugate vaccine purchase); $4 million for vaccine safety activities; $1 million for global immunization activity (polio); $1 million for extramural research; and a mandated $2 million cost of living increase.

Pneumococcal conjugate vaccine. Early concern about uptake has lessened. As of May of 2001, >8 million doses were purchased, comparable to those of Hib-containing vaccines. However, since much of this is probably filling the pipeline, the implementation of pneumococcal conjugate vaccination is not at routine immunization levels; and the resource needs and necessary degree of catch-up remain unknown, especially for the state programs.

Eradication Programs. Measles in this hemisphere is still at record lows. PAHO data were shared showing ~90% immunization coverage. The U.S. had 86 cases in 2000 (a record low, 30% of which were importations and 18 of the 60 indigenous cases import-associated), and 60 cases as of June 9, 2001. Although this was higher than the prior year, 36% of the 60 were imported, and in perspective, there were 36,000 cases in 1990. There is no evidence for re-establishment of indigenous transmission. Canada, Mexico, and El Salvador also reported cases, and only Hispaniola appears to have indigenous transmission.

Polio eradication is making tremendous progress. Global polio funding increased in the FY 2001 budget by $1 million (to total ~$107). At the end of 2000, ~20 countries were considered endemic (mostly the Indian subcontinent and sub-Saharan Africa), a 99% reduction since the program's beginning in 1988. The target is to terminate transmission by

the end of 2002 and to certify eradication of polio (3 years without cases) by the end of 2005. Dr. Orenstein also presented the latest data on the Hispaniola outbreak. The Dominican Republic's last known case was identified on January 25. Haiti is doing less well, with the last known case's onset on April 29. Both countries are trying to terminate transmission with oral polio vaccine immunization.

Food and Drug Administration (FDA)

Dr. Midthun reported two meetings of the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC). During the March meeting, they discussed the license application for GlaxoSmithKline's (GSK) combination vaccine containing DTaP, hepatitis B, and inactivated poliovirus vaccine. Efficacy for the new combination product was based on a comparison of the immunologic responses induced by the combination vaccine vs. licensed vaccines (GSK's DTaP vaccine and hepatitis B vaccine, and Wyeth Lederle's OPV vaccine). The combination vaccine was non-inferior to the comparator vaccines with regard to all the antigens with the exception of the FHA component of the pertussis vaccine. The VRBPAC was split on whether efficacy had been demonstrated. The VRBPAC discussed the safety data but did not vote on the question of safety because of outstanding manufacturing issues. The VRBPAC agreed that additional safety data should be collected, especially in the context of concurrent immunization with Prevnar, as there were no data on such concomitant administration available. The majority of the committee indicated that these data should be obtained pre-licensure, although some members thought that this could be done post-licensure. The development of new conjugate pneumococcal vaccines was also discussed. Prevnar's® recommendation for routine use prevents a placebo-controlled efficacy study in the U.S. with any new such vaccine. The majority of the committee indicated that a demonstration of immunologic non-inferiority in comparison with Prevnar could be used to support efficacy, in lieu of clinical endpoint data. The question of how new serotypes would be evaluated was complex. Although it was agreed that this should be done based on immune response as well, it was not clear what the comparator should be.

In May, the VRBPAC discussed the use of adenovirus-transformed cells as a new substrate for producing vaccines (e.g., for HIV) that cannot be produced in more conventional cell substrates. The VRBPAC generally concurred with the FDA approach to date in evaluating the adenovirus-transformed cell substrates for tumorigenicity, oncogenicity, and adventitious agents, and provided additional helpful input on evaluation. The July meeting agenda includes discussion of Aviron's license application for live attenuated influenza virus vaccine.

New product approvals include the GSK TwinRix® combination hepatitis-A/-B vaccine for active immunization against hepatitis A and hepatitis B in individuals aged 18 or more years, and Aventis Pasteur's new preservative-free formulation of Tripedia®, which contains only a trace of

mercury (less than 0.5 mcg per dose versus 25 mcg per dose in previous formulation).

In response to Dr. Katz's question, Dr. Midthun confirmed that immunogenicity, efficacy and safety data obtained for vaccines tested in other countries can be used to support license applications for these products in the U.S.

National Vaccine Injury Compensation Program (NVICP)

Dr. Geoffrey Evans reported the monthly statistics for FY2001. An increase in claims from ~15 to ~18/month is probably due to more publicity about the Program and to a lag time for the claims filed. Claims for new vaccines include 343 for hepatitis-B (gathering medical records will require 3-5 years until adjudication) a few for Hib and varicella, and ten claims to date for rotavirus vaccine. The latter has no specific injury listed, but a Notice of Rulemaking is in development to add intussusception. When published as a final rule (in several years), an 8-year retroactive coverage period is likely. There have been 32 claims on DTaP. There are still about 20 pre-88 claims remaining. Awards totaling $1.25 billion have been paid to date. The Trust Fund balance is $1.67 billion; ~$200 million is collected annually.

DTP was the predominant vaccine cited in claims 1990-97 (73%), followed by MMR (11%) and OPV/IPV (5% each); rubella (3%), DT/Td/T, 2%; and others, 2%. Coverage for *pneumococcal conjugate vaccine* has caused some confusion. To be added to the Vaccine Injury Table (VIT), a vaccine must be recommended by CDC for routine administration to children, and Congress must impose an excise tax. Once done, coverage is retroactive for 8 years. The excise tax for conjugate pneumococcal vaccine predated licensure somewhat. The VIT included it Category XIII, which is reserved for new vaccines, and the coverage dates back to the effective data of the excise tax. Pneumococcal vaccine, except for the 23-valent pneumococcal vaccine given to adults and older children (since it is not a general-use recommendation), was included in May with no specific injury listed. The rule should be final in two years. The NVICP Website offers further explanation.

The "Vaccinate America's Children Now Act", which would reduce the vaccine excise tax, has some bipartisan congressional support, but its future is uncertain. On March 29, Reps. Dave Weldon and Jerry Nadler will discuss their bill in a press conference. Similar to the Vaccine-Injured Children's Compensation Act, it requires the burden of proof standard used in veterans' claims processes. This loose, non-science approach, does not require a positive association, but accepts effects "deemed to be vaccine-related by a fair and impartial person." It also extends the statute of limitations from 3 to 6 years for both death and injury claims, based on the petitioner's first knowledge of injury. Other provisions include family counseling reimbursement and the establishment of trusts.

A September 1999 hearing on the program and a recent bipartisan report recommended the establishment of a reasonable alternative standard, and consideration of how to increase the number of claims compensated. There is interest in this since the newer 12

vaccines/conditions do not have the clear outcomes of the vaccines of the original VIT, which still must show a causation-in-fact. The difficulty and cost of doing so for the new vaccines has caused a significantly increased number to be dismissed. To avoid the claimants' return to the tort system, standards that embrace both science and provide a more consistent approach are being pursued.

Discussion with Dr. Evans included:

- Dr. Abramson: *Were the hepatitis-B claims most from older people?* Of the first big bolus, ~50 claims were for persons aged ≤18; about half of those were neonatal doses. *What would be is the claims process for adverse reactions to influenza vaccine for high-risk children?*. They would go straight to the tort courts until there is a general-use recommendation for influenza vaccine issued.
- Dr. Chen: *One reason for these modifications is a major difference in the law's ultimate implementation versus its original intent.* He explained that changes to the VIT were to be based on science, but without funding provisions for doing the required scientific research. So annually, there is budget competition with NIP for vaccine purchase, etc., even though there is a $1.5 billion trust fund. The current Washington solution seems to be to simply remove the scientific aspect to allow faster and easier payments. He felt that the stakeholders involved (e.g., the AAP, industry) should protest the subversion of the law's original intent and make an alternative case for the law's modification.
- Dr. Levin: *Why is hepatitis-B so predominant in active claims, and what happens to the percentage dismissed; do they go to the tort system?* DTP lawsuits tracked through 1997 drop significantly. They seem to be not going through the tort system because they are included on the table; negligence need not be proven. Other reasons for its dominance include that the hepatitis B claims deadline was approaching, along with the attorneys' motivation to file claims after the related and very publicized French government action.

National Vaccine Program Office (NVPO). *Dr. Martin Myers* accepted the committee's good wishes on his announced intent to resign as NVPO Director. The Assistant Secretary for Health is beginning the process of identifying his successor, who will be based in Washington, since the NVPO is now a component of the DHHS Office of Public Health and Science. He will remain to ensure an orderly transition.

Dr. Myers described the relationship of the DHHS Interagency Group (IAG), whose membership is from federal agencies conducting vaccine-related activities (DHHS, DOD, USAID). It serves as a policy facilitator and coordinator. The related advisory committees include FDA's VRBPAC, the NVICP's Advisory Commission on Childhood Vaccines, and the National Vaccine Advisory Committee (NVAC) which advises the Assistant Secretary on vaccine policy issues.

Current NVPO activities include coordination of the Pandemic Influenza Plan, which includes a series of annexes (e.g,. infection control, triage and care for children, etc.). NVPO sponsored a technical workshop in March on the use of anti-viral drugs in the pandemic setting; reviewed the NIP's revision of the pediatric/adolescent and adult immunization standards; and it coordinates the Polio Laboratory Containment Activity.

Related to that, the CDC pilot study is complete; NIH's will be so in the next month; and pilot surveys will begin soon to complete a national inventory by year-end. The process will then begin of increasing the biocontainment level for work with wild-type poliovirus. NVAC briefed the Secretary on the vaccine supply issues, and a workgroup is examining the issues related to introduction of new vaccines. Another workgroup is developing guidelines for the states' use in implementing the recommendations for new vaccines. The vaccine supply delays and shortages have been subjects of much discussion. Topics include the shortages of influenza and tetanus-toxoid containing vaccines (except for the pediatric DTaP), and the shrinking list of producers of meningococcal, varicella, and DTaP vaccines. There are now no licensed producers of OPV for use in outbreak control in the U.S.

The NVAC and its Subcommittee on Vaccine Safety and Communication has been briefed by the IOM Vaccine Safety Committee and held a public forum about the process of identifying future topics. The Subcommittee was asked to consider the process of identifying and recommending future topics to the IAG for the IOM Committee to pursue.

A workshop on intussusception and rotavirus vaccines will be sponsored by NVPO to explore that attributable risk, since this is a critical vaccine for development both in the U.S. and worldwide. Documents of the Workshop on Aluminum in Vaccines are in press, and the Combination Vaccines Workshop will be in the July issue of *Clinical Infectious Diseases*.

Dr. Georges Peter, the NVAC Chair, commented on the NVAC's recommendations regarding the Polio Virus Laboratory Containment. Dr. Walter Dowdle presented the plan in detail. The participation and cooperation of laboratories nationally, private as well as governmental, was encouraged, to be sure of identifying all the stock. He also elaborated on the Workgroup on Public Health Options for Implementing Vaccine Recommendations. This was requested by ASTHO to help them establish priorities in developing school, day care (and perhaps college) immunization requirements. This does not involve identifying vaccines, but rather, suggesting ways with which the states can implement vaccine recommendations (from mandates to incentives). NVAC will sponsor three workshops across the country to hear the state health departments' perspectives, along with private groups, industry and other partners. A draft report by year-end is planned. Finally, he noted the nascent status of the Workgroup on Strengthening Vaccine Supply. There is now a need to address supply-related problems, which are broader than the current status of specific vaccines.

National Center for Infectious Diseases (NCID)

Dr. Allison Mawle reported the May 30, $70 million gift of the Bill and Melinda Gates Foundation to fund the development and production of a meningococcal A conjugate vaccine. This ten-year project is in partnership with the private sector, developed by a working group spearheaded by WHO and the Seattle-based Program for Appropriate Technology in Health (PATH). CDC is the leading technical partner. Sub-Saharan Africa has ~200 million people at risk for meningitis. So far in 2001, at least 40,000 people have been infected, and >4000 died (a probably under-reported total). The problem in developing a vaccine has been the lack of a guaranteed market.

Once the conjugate vaccine is developed, the foundation will oversee its evaluation in

Africa, licensure process, effectiveness and safety monitoring, and financing the vaccine for distribution. The latter will probably be linked to the Global AIDS Vaccine Initiative (GAVI) process. Finally, the vaccine will be introduced through mass and routine immunizations – including a vaccine useful among infants – to completely eliminate meningitis in Africa.

NCID was the CDC pilot project for polio laboratory containment, which went well. A Web-based interactive interface is now in development to survey all labs for those potentially holding wild polio cultures. Education about this initiative and process has begun with contact with professional organizations, most recently, the APHL meeting and with ASM.

GENERAL RECOMMENDATIONS ON IMMUNIZATION

Dr. William Atkinson reviewed the highlights of changes to the ACIP document of General Recommendations, which has been in revision for several years:

- Re-insertion of the definition pages.
- Related to the new four-day grace period, a footnote (Draft #5, page 12) recommending that physicians and other health care providers comply with local or state vaccination requirements when scheduling and administering vaccines.
- Addition of another footnote on page 12 exempting rabies and anthrax vaccines from the 4-day grace period, due to their unique schedules and spacing.
- Page 13, bottom text, revised to say that the IPV series "may be rather than "should be" completed before the first birthday.
- Page 15, additional text was inserted to exempt parenteral LAV not given simultaneously from repeated vaccination of those given <4 weeks apart, when the combination of yellow fever and measles vaccine is administered. Recent data indicate that yellow fever and measles vaccines probably do not interfere with each other. The yellow fever statement also will be amended, and the congruency of the General Recommendations and the new hepatitis statement will be ensured.
  - Dr. Peter: *Data are weak that indicate interference between two live virus vaccines given within 28 days parenterally.* That new recommendation will be changed. *Similarly, a viral infection within four weeks is not a contraindication for vaccination.* Dr. Jane Seward reported a Vaccine Safety Datalink (VSD) study indicating that MMR provided within 30 days before varicella vaccine led to an increased risk of varicella vaccine failure and breakthrough disease. When given on the same day, MMR vaccination shows no difference, but within 30 days, the risk of varicella vaccine failure rises, although that for OPV given within a month did not.
  - Dr. Gall: *Insert a paragraph on pages 45-46 to address pneumococcal vaccination during pregnancy.* That will be done.
  - Dr. Abramson: *Since a recent JAMA article indicates a potentially lower response to immunizations after a viral illness, a workgroup to study this seems advisable to suggest a recommendation.* There was general agreement to retain the amended text presented at this meeting (Page 15, lines 26-30) in order to err on the side of safety and to provide some guidance to frequent provider inquiries on this issue. The issue will be researched issue through a workgroup. Text will be added on the lack of clarity about this and that it will be studied further.
- A paragraph on Palivizumab® and its exception to interferences in the IG live vaccine section was added.

- On pages 19-22, the text on contraindications and precautions was combined and moved for more prominent placement toward the front. The Table (5) of Contraindications and Precautions was updated and retained. Text will be added to note that contraindications and precautions change, and to refer the reader to the Website for the latest updated table.
  - Dr. Levin suggested the same be done for the section on unknown or uncertain vaccination status. He also noted that the (page 20) National Standards for Pediatric Immunization Practices are now the Standards for Child and Adolescent Immunization.
- Wording on aspiration (page 24), previously recommended, was altered to parallel the Red Book statements, which are not a direct indication to aspirate.
- A large new section on jet injection was added, a very comprehensive piece developed by Dr. Bruce Weniger. The committee agreed to reduce this to ~2 paragraphs and to retain the ~30 references. A footnote was suggested to note that the entire document is available by request on the Website.
- Text (pages 31-32) on non-standard vaccination routes and sites was changed to only recommend repeat injections of those vaccines whose immunogenicity is known to be compromised if given in a route or site not recommended (i.e., currently, rabies and hepatitis-B vaccines given in the buttocks and hepatitis-B vaccine not given intramuscularly).
- Two paragraphs on syncope (pages 33-34) were added, including a policy change to parallel Red Book text, advising a 15-20 minute observation period after vaccination. This was supported by VAERS data on injuries from falls sustained after syncopal episodes, mostly among adolescents and within 15 minutes of vaccination. There was agreement that, although many childhood vaccines are given to children not yet walking, the term syncope is general enough to include unconsciousness or a lapse of consciousness, and can apply to other reactions. This change would not apply to massive immunization campaigns or administration of OPV. And, since this document cites expert opinion that persons be observed, it does not carry the weight of a recommendation as a new standard of care or any legal liability. Text will be added to indicate that most of the syncopal episodes have occurred among adolescents and adults.
- A brief section was added on acute vaccine reactions (page 34), to advise stocking epinephrine in case of anaphylaxis, and addressing the issue of safety needles and reduction of injection injuries. NIOSH reviewed and approved it.
- The thimerosal allergy section (page 42) was altered for clarification.
  - Dr. Word suggested *editing the text that "thimerosal as a preservative has been removed from pediatric vaccines," since it is in influenza vaccine.* That will be added.
  - Dr. Abramson: *Is the trace amount of thimerosal still present in some routine vaccines a problem for those allergic?* Dr. Midthun thought that must be assumed. A phrase will be added stating the potential presence of trace amounts of thimerosal. Dr. Zink, of GSK, supported that, noting the manufacturers' clarity that trace amounts of thimerosal may remain after the vaccine production process, but at levels undetectable by current scientific analyses.
- The international adoption section (page 47) was changed to the Immigrant/international adoption section, to clarify this as pertaining not just to

adoptees, but to anyone vaccinated outside the U.S.

- Dr. Smith: *The adoptee data are from a limited number of studies; we would not want to recommend serologic testing or revaccination of thousands of adoptees if a documented immunization is on hand.* The wording will be tweaked to specify this only if the validity of vaccine administration to an international adoptee or immigrant is in question.
- Dr. Overturf agreed to review this in relation to the 2003 Red Book, noting the absence of any table to suggested serological testing and specific approaches.
- Dr. Schwartz reported staff review of the studies' laboratory methods and their satisfaction that the data support the general adequacy of vaccination records. That reassurance could be better reflected in this draft. He offered to help to draft that and to involve the AAP as well. He also suggested the reinsertion of a table rather than the currently dense text.

- A resource directory will be added with a succinct listing of relevant Web and telephone resources, and the reference list will be refined.

Further discussion with Dr. Atkinson included:

- Dr. Levin: *Insert text on the conjugate pneumococcal vaccine.*
- Dr. Vernon, Merck Vaccine Division: *Include, in the Resource Directory, Web sites with good vaccine safety information* (e.g., the AAP).
- Dr. Chen: offered to help to incorporate other definitions (e.g., to distinguish between "reaction" and "adverse event") and suggested that the new text on management of acute vaccine reactions cross-reference to the VAERS reporting described later.
- Dr. France: *Can a statement be inserted about the impact of adequate reimbursement on vaccine coverage to encourage managed care organizations to cover them?* Dr. Peter: That recommendation was made two years ago in the NVAC statement, "Strategies for Sustaining Success," published in *JAMA*.
- Dr. Nichol: *Insert an explicit suggestion that not only primary care practitioners but some specialty practitioners administer immunizations to their patients.*
- Dr. Evans: *Insert text on vaccine risk communication; he offered such wording done by NVICP and the Red Book.* Two or three sentences will be inserted under patient information (page 61). Dr. Chen volunteered to help draft the language, noting also that the issue of VPD risk among people who are exempt might be addressed.
- Dr. Word: *Check whether the text about blood transfusions with packed red blood cells should reference 5 months, not 6 months.* All numbers will be checked for their consistency with previous ACIP publications.

Dr. Modlin asked for other small edits to be provided to Dr. Atkinson, who outlined a time line for next steps. Pending approval on this day, edits will be done in the next month and the document put through formal NIP clearance. *MMWR* cannot run this until September, meaning it will not be published until November. He will try to give it to them by August, in case a prior opening occurs. But if not, he hoped it could be published on or near November 12, the 25th publication anniversary of the very first General Recommendations document, which was three pages long and had no references.

Vote. ***Dr. Tompkins moved to accept the General Recommendations as proposed.***

The motion was seconded. There were no conflicts. With all in favor, **the motion passed,** to applause.

Dr. Atkinson offered to e-mail the final document to interested Committee members when it is cleared by NIP and prior to *MMWR*'s editorial work and clearance. Finally, he reported requests to share the document with Program Managers, even in draft form, before it is formally published, and asked the committee's opinion. There was no objection voiced.

UPDATE: DISCONTINUATION OF HUMAN RABIES VACCINE FOR INTRADERMAL PRE-EXPOSURE USE

Dr. Charles Rupprecht reported the unexpected news that Aventis, the only manufacturer producing the human rabies vaccine used for intradermal (ID) pre-exposure administration, had decided to cease production. They cited this as a business decision. ID rabies vaccine is only licensed in the U.S.

Causes for Concern. Rabies is the most significant global viral zoonosis. However, human rabies cases in the U.S. remain uncommon due to:

- Prevented exposure to rabid animals. But cases may be under-reported (e.g., an investigation by the CDC/California Health Department determined a February rabies death that was retrospectively diagnosed in June).
- Proper post-exposure prophylaxis after any exposure,
- Pre-exposure vaccination (PEV) of those considered at risk (e.g., veterinarians, animal control officers, and laboratory diagnosticians who may contact the rabies virus directly or indirectly). The priming provided by this vaccination simplifies the post-exposure management by eliminating the need for rabies immune globulin and requiring only two intramuscular booster immunizations on days 0 and 3. The PEV is delivered in three doses on days 0, 7, and 21, either intramuscularly or, with the now discontinued product, intradermally.
- However, this is a specialized niche. Since rabies is a zoonosis, not a contagious virus like polio or hepatitis, the vaccine is an orphan drug. As such, its discontinuation even further threatens rabies prevention and control. The licensure of the human diploid cell vaccine (HDCV) in 1980 released the first cell culture vaccine to the market, and was the first immunogenic and efficacious product. But the first HDCV was expensive (~$100/dose and requiring 3 doses). The ID vaccine licensed in 1986 for a single-use application allows a smaller dose. But in general, this vaccine's use was not extended to intradermal pre-exposure vaccinations except among Peace Corps workers in developing areas. To the present day, the literature support the economic benefit of continuous serological monitoring of those at risk and intradermally boosting only when the serology becomes undetectable.
- Those populations at risk make this supply termination of ID vaccine a concern; >80% of U.S. veterinary schools use ID rabies vaccination pre-exposure. Such students are a financially disadvantaged group on whom a greater cost will have an impact. There also are concerns about returning to the practice of dispensing multiple doses from a single-use vial for ID.
- There are similarly doubts about the efficacy of routine intramuscular vaccination when serological titers are undetectable.

- This lessens public health flexibility in an already orphan product.
- The global crisis of the availability of rabies immune globulin (RIg) causes grave concern. If ID vaccine can be quickly dropped due to a business decision because of the problems of the production and availability of the RIg used in the developing world, RIg could suffer a similar business decision at any time.

Ironically, rather than focusing on reservoir and vector controls (i.e., dogs in the developing world), the WHO is considering the use of ID vaccination of children. The recent CSTE meeting passed a unanimous statement of their concern over the possible discontinuation of RIG, and called for alternative techniques, methods or strategies to alleviate the related concerns.

Possible solutions include:
- Reconsideration of the business decision; CDC has requested that.
- Offering the intramuscular product at the intradermal price. New vaccines in general are considering this due to ID's cost-saving delivery mechanism.
- RFPs and Small Business (SBIR) grants seeking alternative, more economical biologicals for rabies prevention and control as a whole, should be issued by the NIH and FDA, CDC, NIP, etc. Or, FSS schedules could be used, under which the federal government becomes a broker and potentially a supplier to end-users.
- The problems with orphan biologicals suggest a serious need for federal government involvement.
- Renewed communication is needed for rabies prevention and control, here and abroad. A supplemental *MMWR* statement will be issued to advise those end-users.

Discussion with Dr. Rupprecht included:
- Dr. Offit: *Is the IM product used, but diluted, in the developing world?* Yes, WHO sanctioned this, especially with the shortage of RIg and because of the issues related to nerve tissue vaccine in the developing world. *Could discontinuing ID vaccine use in this country infer that ID is not as acceptable, perhaps driving those developing countries to the less-safe nerve cell vaccine?* CDC has worked with WHO and the PAHO for the last 10 years to replace the nerve tissue vaccines with ID vaccine, which we strongly promoted as safe and effective. A meeting next month will address that issue to avoid any such inadvertent message about the vaccine's utility or safety. *What is the price differential?* The price differential has been creeping closer within the last few years, but it was $65-70 for ID and $100-120 per IM dose.
- Mr. Hosbach, of Aventis, stated that Aventis did not make this decision lightly. But they knew that the IM product could fill the gap, as it is essentially the same vaccine. GMP requirements demand continuous facility maintenance and upgrade. This product serves a very small customer segment, but requires a very manual process. Aventis considered the potential investment to upgrade the facility to a more mechanized process (posing less risk to the human workers), but doing so would make the ID cost to far exceed that of the current IM product. So, Aventis allows all their ID customers to buy the IM vaccine initially at the ID price. That particularly targets the veterinary students, although many schools buy the vaccine for them, and many have their rabies vaccine reimbursed by insurance. However, Dr. Rupprecht disagreed; a CDC check of 27 schools found that the students bear most of those costs.

- Dr. Modlin: *Is the vaccine truly an orphan drug, or is it just in a small market?* CDC believes it is both, affected by its small market and by the little time/attention paid it. Dr. Midthun: Orphan drug status mainly refers to products considered for licensure, but the standards for safety and efficacy are the same.
- Mr. Reilly, of PHARMA, clarified further. No biologicals fit the orphan drug definition. The Orphan Drug legislation encouraged pharmaceutical drug manufacturer with the criteria of exclusivity and a sole presence on the market for a certain period of time.
- Dr. Offit: *Can we be assured that dropping ID vaccine here will not drive the use of nerve cell vaccine elsewhere?* Dr. Plotkin: ID development was driven by cost issues in the developing world. A tailored message is needed; that is, that the discontinuance of ID stemmed from its cost of production with manufacturing facility upgrade. But he felt that ID vaccination will remain; ACIP just needs to decide whether to recommend its off-label use. The IM vaccine is licensed for ID use in Asia and perhaps elsewhere.

Dr. Modlin noted that the Rabies Statement would have to be updated, and asked for volunteers for a Rabies Vaccine Workgroup. Drs. Offit, Brooks, Marchessault, and Plotkin did so. Dr. Jane Gilbert, of Chiron Vaccines, volunteered to serve as a consultant. Dr. Abramson added that the AAP will participate, since this will involve pre-exposure prophylaxis for traveling children. Dr. Midthun doubted that FDA would support sanctioning off-label use and use of a multi-use vial for single uses. She promised to supply an FDA representative to the workgroup. Dr. Snider also suggested in put from the WHO, and Dr. Wharton suggested the state public health veterinarians.

UPDATE ON DEVELOPMENT OF HIV VACCINE

Dr. Tim Mastro, of the NCHSTP Division of HIV/AIDS Prevention, reported on ongoing HIV vaccine trials and the issues related to preparing for activity after the trials' results are released, particularly regarding communication.

Globally, the 20-year old HIV epidemic has caused ~60 million HIV infections and ~25 million deaths. Of the ~36 million currently infected, ~25 million are in sub-Saharan Africa alone, and the prevalence rates of some southern African countries are ~30%. North America has ~900,000 prevalent HIV infections; the U.S. has had 750,000 AIDS cases and ~450,000 deaths. Global HIV incidence last year was ~5 million new infections (~15,000 daily), ~40,000 in the U.S. annually (>100/day).

The epidemic has accelerated in the last ten years, and a safe and effective HIV vaccine is needed to slow it down. Vaccine development has proven difficult for many reasons, including that natural HIV infection does not confer protective immunity; the lack of an ideal animal model with which to evaluate products; no known correlates of human protection; and great variability of HIV strains within a wide variety of genetic subtypes, whose importance is unknown as regards protective immunity.

To date, >70 Phase I and II HIV vaccine human clinical trials have been done, 12 in developing countries. Only one product advanced to Phase III clinical evaluation. Two efficacy trials of VaxGen's recombinant envelope protein gp120 preventive (not therapeutic) vaccines are underway in the U.S. and Thailand. The gp120 is expressed in mammalian

cells. VaxGen, under Dr. Don Francis, is funding its own trials. Both trials are of a bivalent product, each with 300 micrograms of each antigen in an alum adjutant, using T-cell and macrophage trophic virus strains. The VAX004 trial of AIDSVAX® B/B, mostly conducted in the U.S., is using two viral B strains, and VAX003 in Thailand is using one of the same B strains and a product with subtype E, the predominant HIV strain in Thailand. Both trials are randomized, double blind, and placebo-controlled. The AIDSVAX® gp120 vaccines primarily induce antibody. The AIDSVAX® B/B trial should be completed in the fourth quarter of 2002; the Thai trial of AIDSVAX® B/E should be completed by the third quarter of 2003.

Only two other Phase III trials are planned, both using the Aventis ALVAC® canarypox vector to deliver HIV antigen and induce cytotoxic T lymphocytes. The AIDSVAX® B/E and B/B also will be used as boosters in these. The U.S. Army's Phase II current ALVAC® plus SP120 trial in Thailand should produce a go/no go decision later this year, based both on the epidemiology and immunology determined. The Thai trim may include16-20,000 people in a community-based Phase III trial that may begin next year. The immunogenicity data of the NIH's HIV Vaccine Trial Network's large Phase II trial of an ALVAC product and the AIDSVAX® B/B will determine if a Phase III trial in North and perhaps Latin America, will begin potentially in 2003.

The VaxGen study model was shared, tracing the rationale for using gp120, the envelope of HIV. It is cloned into synthetic gp120 by genetic engineering in mammalian cells. Once purified, it is placed in a vaccine and injected to induce antibodies to gp120 and, hopefully, to block HIV infection. It's safely was demonstrated in >5,000 HIV-negative volunteers and >500 HIV-infected persons. When evaluated as a therapeutic vaccine, no serious adverse effects were found, only minimal reactogenicity.

An overview of the both AIDSVAX efficacy trials was provided. Ongoing evaluation is done of product safety and any trial-related social harms (e.g., discrimination). Community advisory boards are in place. The primary trial endpoint is HIV infection; secondary endpoints are: transient HIV infection, reduction in viral load and slowing of disease progression; product safety; sieve analysis (that the vaccine will protect against strains very similar to the vaccine strain, but not others); and behavioral effects of being in the vaccine trial.

The trials were each outlined.

- *VAX004, North America and the Netherlands*; sponsored by VaxGen; 61 local sites. CDC participation. Cohort: 5190 men who have sex with men (MSM) and 300 high-risk women. Vaccine: bivalent MN/B strain and a GNE/8, a macrophage trophic B strain. Schedule: 2:1 vaccine/placebo ratio. Trial duration: 3 years; expected completion: October 2002. First report on efficacy: November, 2001. 61 trial sites, centralized data management system and specimen handling.
  - Statistical power/sample size calculations: Primary endpoint/infection, 90% power, to reject the null hypothesis of vaccine efficacy of 30%, if the true VE was 67% using a two-sided test. Assumption: no vaccine effect until after immunization #3, HIV incidence of 1.5%; annual loss of 10% in year 1 and 5% each in years 2 and 3.
  - CDC role: Funds 6 trial sites in the VISION Vaccine Sub-studies Network. Cohort:

(n-800) 800 participants (18% of the full trial) and a comparison group. Focus: 1) *behavioral aspects*/motivation of participation, determinates of risk behavior and any change related to a trial; whether participants un-blind themselves (self-test to determine which test arm they are in); what contributes to good trial retention; whether people use post-exposure prophylaxis for sexual exposures, including antiretrovirals; 2) *Qualitative issues* through in-depth interviews and focus groups: perceptions of being in a trial, decision-making, motivations and trying to understand the trial experience; 3) Virologic aspects: antiretroviral resistance and genetic characterization of breakthrough strains; cellular and humoral mucosal immunity in both men and women; assessment of care after infection; individual site and community-level factors contributing to high enrollment levels, retention and protocol compliance.
  - NIH role: Funding lymphocyte collection from the HIV-negative participants to research correlates of protection.
  - Overall progress: 5400 enrollees, 94% male, median age of 37. Good follow-up (91% retention). Two serious adverse events (SAE) of cellulitis that resolved. Reduction of reported risky behaviors since baseline enrollment; minimal social harms reported.

- *Thailand* collaborators: Bangkok Metropolitan Administration (BMA), Mahidol University, VaxGen, CDC HIV/AIDS Collaboration in Bangkok. Cohort: 2,545 injecting drug users (IDU) in treatment programs; Vaccine: bivalent B/E virus vaccine; 7 doses, 1:1 ratio. Duration: 3 years; expected completion in 2003; first efficacy report November 2002.
  - Site characteristics/Bangkok: ~8 million people, explosive epidemic among IDUs for the last 12 years; ~30 - ~50% HIV prevalence among IDUs; an estimated ~40,000 active injecting heroin users; 17-clinic drug treatment program operating since the 1960s. Extensive review/approval of multiple IRBs.
  - Overall progress: Of 5,000 screened, 34% were HIV-seropositive; 93% male, median age of 26. Good follow-up (97% retention); no vaccine-related SAEs. Decrease in reported risk behaviors since enrollment; minimal social harms.
  - Problems: Incarceration is common, but continued voluntary follow-up has been possible.
- The two trials share a Data/Safety Monitoring Board. Chaired by Dr. Walter Dowdle, it has 10 multi-disciplinary committee members, both Americans and Thais, who meet twice a year. The 5 reviews to date have found no serious problems with trial conduct.
- Stopping rules: SAE safety concerns, increased susceptibility, rapid disease progression associated with vaccination. The procedure has not been set, if one trial reaches a stopping point, about what to do with the other trial, since they involve different challenges and products.

Future Considerations include a partially effective HIV vaccine. Efficacy could be characterized by protection from infection (efficacy for susceptibility); or by lowered transmissibility or infectiousness (to affect the epidemic and perhaps slow disease progression in the individual).

The set point of plasma HIV viral RNA levels, the viral load, is established ~6 months after primary infection. Viral load is directly related to the rate of disease progression and the

rate of infectiousness (high loads = rapid disease progression and high infectiousness). Without treatment, the period from infection to AIDS onset can vary from 2-20 years.

The assumption is that pre-existing antibodies from vaccination could blunt viremia and establish a systematic viral set point that could profoundly affect the disease progression and infectiousness. Partial vaccine effects could include a reduced chance of getting HIV-infected if exposed, protection from some modes of transmission (e.g., mucosal, not parenteral); protection from some strains of HIV and not others (e.g., strains within or across HIV subtypes); and lower the viral set point to slow disease progression and decrease infectiousness.

The Committee's advice on how to prepare for the results of these trials was invited, particularly with the U.S. trial's interim analysis due in 6 months. All the involved parties, including VaxGen, CDC, FDA, and NIH, should jointly interpret these results. Then, the planning for how to communicate these results must be done, before the trial's end as well as afterwards, to ensure a coordinated message of the results' meaning to the general public, affected communities, and the medical and public health communities.

A CDC multi-disciplinary consultation will be held in September in Atlanta to discuss the use of a partially effective HIV vaccine, identify important issues, and outline future research, including future HIV vaccine trials. If this product is licensed, placebo-controlled trials are unlikely. If not, the need to continue trials with realistic expectations must be conveyed. Among these realities are the complexity of issues involved in HIV vaccine implementation (e.g., vaccine demand, production capacity; HIV prevention and international implications; ethical and legal considerations; duration and breadth of protection; co-administration with other vaccines, etc.).

Discussion with Dr. Mastro included:

- Dr. Johnson: *What public communication is expected if the trial is not stopped this fall?* That is in discussion in CDC Office of Communication Office and VaxGen's communication staff. The message may be geared to adjusting expectations.
- Dr. Katz: *What effect is expected on the implementation and the initiation of trials with more promising antigens (e.g., cytotoxic lymphocytes, CD8, CDL stimulation) is this trial fails?* A trial is a failure if it does not produce interpretable results. If the trial definitively resolves gp120 as of low efficacy, that is a success. Without animal models and correlates of protection, that cannot be known yet. Nonetheless, a tremendous amount will be learned operationally from these trials about enrolling people, conducting an HIV vaccine trial, etc., all of which will benefit future trials. But the point was well taken. It must be clearly communicated that expecting a total success of a definitive vaccine from the *first* HIV vaccine trial is unrealistic. But the pace of vaccine evaluation must be accelerated, with 5 million HIV infections last year. Aside from the ALVAC® canarypox products, DNA vaccines are in development, and there will be questions of whether to proceed with the first or wait for the others with a good chance of high level efficacy.
- Dr. Nichol: *What is your study power to exclude a vaccine efficacy of zero (it seems it must be 100% to do so), and how will the results be interpreted if the confidence intervals are wider than they were for the power calculation?* There is more power to exclude zero with a vaccine efficacy that might be down in the 30% range. The VE of

67% shared at this meeting was just the stopping rule. There will be discussions with the FDA of what outcome might lead to licensure of this kind of a product.

- Dr. Abramson: *How strong is the educational effect (i.e., are you slowing down the rate of HIV infection in the placebo groups, and will this likely have an impact on the speed by which outcome can be determined?* That is the issue of study effect: if the prevention education and interventions are so well done that there is virtually no incidence in your trial population, there is no power to evaluate the vaccine. The incidence rates of the trials are not shared with investigators, but they are substantial and are consistent with the trial design. Despite communication, enough high-risk sex still occurs in the U.S. and injection drug use in Thailand, to ensure study power.
- Dr. Tompkins: *Will the therapy of patients who convert be individualized or standardized (and if so, what?)?* The North American trial did not assume responsibility for care of those infected in the trial, since it was due to risk behaviors, so the trial sites linked people to care in their own setting. The follow-up is standardized under the study protocol for assessment of viral load and CD4 counts. Treatment more standardized in Thailand since the BMA manages those people's care; their treatment standards are evolving. At the trial's commencement, it a 2-antiretroviral regimen for a CD4 count < 500, which is being re-evaluated now. The reality in Thailand, with their high HIV prevalence, is that they cannot afford to provide antiretrovirals for everyone in their system. Those in the trial actually have a higher standard of care than others in the BMA.
- Dr. Chen: *Is there a member of the Data Safety Monitoring Board who has expertise in rare disease epidemiology as well as infectious disease epidemiology?* That is uncertain; Dr. Dowdle is the Chair, and the Board is multi-disciplinary (ethicists, statisticians, Thai clinicians, community representatives, etc.).
- Dr. Christine Severyn, Vaccine Policy Institute: *Would you comment on the opposition of the late Dr. Albert Sabin to the development of an AIDS vaccine, which was recently supported at the April Vaccine Research Conference in Arlington, Virginia?* Dr. Mastro wished to be optimistic, but believed that the world needs a safe and effective HIV vaccine that can protect people from HIV.

HARMONIZED SCHEDULE

Format. Dr. Natalie Smith thanked the Harmonized Childhood Schedule Workgroup for their work. They decided to continue to publish an annual schedule in journals, CDC's hard copies, and on the Web, and to consider any major or urgent issues on a case-by-case basis. The format of the schedule was altered to appoximate that of the Minnesota State Health Department, which previously was presented to the ACIP. The schedule and footnotes are now on the same page. The recommended ages extend through 18 years. A column indicating the 11-12 year-old assessment may be changed to indicate an adolescent assessment, to promote assessment at every visit. Below a dotted line the vaccines for selected populations are listed (Hepatitis A, influenza, pneumococcal polysaccharide vaccines). Both color and black and white versions are available. The CDC Website and Hotline information are listed.

Content. Dr. Wharton reviewed the previous format developed by Dr. Jacqui Gindler and

others several years ago. It served well, but has been streamlined using some improvements developed by NIP partners:

- The footnotes are now columnar, and the schedule is on an 8½"x11" sheet (the format *MMWR* is moving to by 2002), enabling most of the previous text to be included but in a less cluttered fashion.
- The colors used allow even black and white printers to distinguish the differentiations. Another version can use white and striped bars for catch-up.
- Differences from the previous format are: 1) explicit indication of catch-up vaccination (the green-striped bars) for hepatitis-B, MMR-2, varicella, and pneumococcal conjugate vaccine; 2) the adolescent assessment visit is highlighted, although the column title could change; 3) additional vaccines for selected populations are included rather than the single hepatitis-A for selected populations before.

Remaining issues for consideration include:

- The bar width for hepatitis-B catch-up is wider than the others
- The title of the pneumococcal conjugate vaccine column is not matched by the pneumococcal vaccine line.
- Inclusion of pneumococcal polysaccharide vaccine with conjugate PPV/PCV.
- Placement of the "selected populations" line.
- Numerical indication of multiple doses involve some copyright issues (e.g., MMR-1, -2, etc.).
- Which vaccines to indicate for use in selected populations.

The Committee approved the change in format. Dr. Modlin reported his and Dr. Smith's discussion of solutions: 1) changing the bar widths to be uniform and 2) changing the pneumococcal conjugate title to pneumococcal vaccine, to include both vaccines and to allow pneumococcal polysaccharide to be included and appropriately labeled. The numerical indication of multiple doses could be resolved by 3) including a "#" number sign, and changing the label for range of "acceptable" dose to range of "recommended" dose. But the Committee's guidance was requested on the placement of the birth dose convention (e.g., the preferred first dose of hepatitis-B vaccine is at birth, so the label would be placed there), and on additional vaccines for selected populations.

Discussion of the elements included:

- Dr. Abramson: *I am concerned that citing vaccines for selected conditions could cause others to be forgotten (e.g., meningococcal vaccine).* Dr. Modlin: Vaccines could be added on an annual basis, based on whether they should be used in a general population.
- Dr. Overturf: *Why are the DTaP dose 5 and IPV dose 4 not in a gold bar?, and pneumococcal conjugate vaccine is marked for catch-up to ~5 years of age, but is licensed for safety to a higher age group and is given to certain high risk groups at higher ages.* The ACIP recommendation does not include the use of conjugate vaccine beyond five years of age in any group, even if so licensed. Such use of vaccine in older children is an issue for this schedule. The issue is addressed in the footnote, but additional wording for the footnote could be crafted when the schedule is adopted in October.
- Dr. Johnson: *Perhaps we should mark the recommended age with a lightly colored bar*

around DTaP, HIB, IPV and PPV in the 2, 5, 6-month columns. That is consistent with what was said before and could be changed.

- Dr. Zimmerman: *The MMR dose 2 differs from the old schedule.* That is to distinguish the routine dose 2 from the catch-up dose, a distinction now made with ovals. *Pneumococcal polysaccharide is not indicated in children with pure or simple asthma; confusion may result.* Dr. Clover: *List both.* The delineation can help practices stocking both to decide when to use each, a common question since the licensure of the conjugate vaccine
- Dr. Plotkin: *This is a good opportunity to support the recommendation of a birth dose of hepatitis-B, which unlike other vaccines, poses both programmatic and immunologic implications.* Dr. Zimmerman: It was moved to the birth dose in 1999, but some advocated putting it back in the middle to be consistent with the existing policy that prefers combination vaccines. Preferring both a birth dose and a combination vaccine is inconsistent. Dr. Modlin: Hopefully, this inconsistency will be resolved with the decision on the hepatitis-B vaccine statement in October.
- Dr. Wexler, Immunization Action Coalition: *1) Ensure that the table's bars go across to reflect every age, including the 7-10 year-olds to remind about that catch-up opportunity; and make the 14-18 year-old range, 13-18, to include all ages from 5-18. 2) Extend Td on the catch-up vaccination to age 18 years and IPV to age 17 to allow for immigrants, etc.; and 3) Hib catch-up should extend to age 5.* Dr. Wharton: The definition of "catch-up" was discussed in the Workgroup. The catch-up bars are confined to vaccines that either have relatively new recommendations or relatively new emphasis on policy implementation. Since there has been a longstanding recommendation about Td boosters, the bar is yellow, not green, for the first Td dose, which is a routine recommended booster, not a catch-up. The danger is that many catch-ups could be included, which could decrease the impact of those vaccines highlighted.
- Dr. Wexler: *Rather than overlaying the PPV with the PCV, insert an extra line.* Dr. Diane Peterson, Minnesota Department of Health, appreciated Dr. Wexler's comments, knowing from experience that "if there's anything that can be misinterpreted, it will be." The problem with adding columns (e.g., the recently-added 24-month column) is the necessarily decreasing font size. Minnesota has not had misunderstandings yet that assessments at other ages or catch-up should not be done, although it could happen.
- Dr. Peter: *I am very concerned that our attempt to be all-inclusive and to perhaps take the place of the detailed recommendations could lead to confusion and lose some of the initial purpose of having a universal schedule.* Dr. Orenstein agreed. The schedule was not designed to handle every situation and should be kept as simple as possible.
- Dr. Evans: *Can we insert something about safety (i.e., the legal requirements for reporting and the NVICP), which applies to all the vaccines listed?* He suggested 2-4 lines about VAERS and the NVICP to alert providers to their existence, and Websites or telephone numbers. Dr. Peterson: The back of the Minnesota schedule has catch-up schedules, vaccine reaction and disease reports, the VAERS number and the Website.
- Dr. Abramson: *Move everything under the dotted line to a second page.* Dr. Wharton: That would take hepatitis-A off, which was inserted last year, and could cause confusion if deleted again. Dr. Smith: It is important to emphasize influenza. Dr. Brooks liked the one-page format, which is easy for practice settings to post. He found

the dotted line acceptable, and commented that influenza vaccination is a key component of preventive health.

- Dr. Richard Jacobs, a member of the Academy's Education Program: 1) agreed that again changing the hepatitis-B text or bar will confuse practicing pediatricians; and 2) the Prevnar® conjugate pneumococcal vaccine in the green bar could be accompanied by the Hib catch-up. At least that component could be moved to a catch-up table of those preferred for select populations, but that could also include 23-valent unconjugated vaccine. That will be confusing. Perhaps the second page is disliked, but it has all the necessary explanatory footnotes. Without that, the table must be clear and free-standing.
- Dr. Zimmerman: *Please provide the next iteration for a July conference call.* Dr. Wharton said that will be done and summarized the changes for the next version: try to keep the pneumococcal polysaccharide vaccine; influenza and hepatitis-A with the dotted line; wait until the hepatitis-B statement is finalized to decide on the wording and bar format. She also asked if the Committee agreed that a catch-up schedule, if developed and approved in time, could be published concordantly with the harmonized schedule. There was general agreement.

Adult Harmonized Schedule

Dr. Vishnu-Priya Sneller named the partners in the long-discussed schedule of adult immunization: Drs. Neuzil and Schaffner for the ACP; Dr. Clover for the AAFP, and Dr. Gall for the ACOG. The advantages of standard immunization schedules for adults are the provision of standard guidelines for and increased visibility of harmonized immunizations by providers.; increased focus of provider organizations on the adult immunization issues; an opportunity to highlight the most important messages/changes in adult immunizations for media report annually; and increased adult immunization. The public health targets for the next decade include a 90% vaccination rate for those aged ≥65 years and 60% for those aged 18-64 for whom these vaccinations are recommended.

The *Process of Harmonizing the Adult Immunization Schedule* includes: communication with the representatives of those provider organizations which had issued immunization schedules to their members; current comparison of those to determine what needs to be harmonized; subsequently, future development of a schedule format for approval by the ACIP and provider organizations, and development of an annual review/revision process similar to that of the childhood schedule.

The recommendations of the ACIP (1991), ACP Green Book (1994), and the ACOG technical bulletins (1992 and 1992) on immunizations during pregnancy and rubella in pregnancy were reviewed and summarized by Dr. Sneller. Since they are fairly well harmonized, any real or perceived differences are now the focus:

- Decennial Td booster recommendations of ACIP and ACP.
- Revaccination of older adults with a 23-valent PPV recommended by ACIP and ACP. These differ both the strength of the recommendation (ACIP's being stronger) but also in the indications for revaccination (ACIP specifies; ACP's is unclear if the revaccination is single or multiple). ACP and ACIP also differ in wording on revaccination of persons with the 23-valent PPV for those vaccinated with the 14-valent PPV. However, this may be moot since most of those vaccinated with the 14-valent are probably already

revaccinated with the 23-valent.
- ACIP/ACP recommendations differ in strength about MMR measles vaccination of persons born prior to 1957.
- ACIP issued recommendations for hepatitis-A, meningococcal vaccine, varicella and Lyme disease since 1991. ACP has not published additional recommendations for adult immunizations.

Formats considered include 1) the graphic representation of the Minnesota State Health Department, which may be altered to collapse the first two columns to ages 19-49, to avoid changing annually when people "age out" of the measles vaccination age; 2) a tabular format on high risk patients with chronic disease or conditions for the easy review of sub-specialty practitioners; 3) another tabular format summarizing vaccinations for special populations. The one-page schedule is very similar to that of the childhood schedule, designed for ease of use and comfort of reference for those providing these immunizations.

Channels being considered to communicate this to the general public are the mailing list of the Immunization Action Coalition; the state health departments' communication channels and newsletter mailing lists; and medical specialty groups' Web or mailed newsletters. Once available, the adult immunization schedule could also be published by the media and other community-based organizations serving older adults, or those organizations addressing the prevention/management of chronic diseases.

At their meeting on this morning, the Adult Immunization Workgroup Subcommittee decided not to wait until the entire harmonization with the provider organizations is complete if that involves a substantial delay. They will, rather, work with the provider organizations to publish an article or report with a table indicating the areas of harmonization and describing the areas of disharmony being negotiated, and then provide updates later on.

Discussion included:
- Dr. Schaffner thanked those involved in this work, which could be a milestone in adult immunization activities. It could gain the attention of many of the scholarly and professional societies relating to adult patients and their practitioners.
- Dr. Zimmerman: 1) The AAFP immunization schedule (on their Website) will also have to be harmonized; 2) agreement should be sought on an age-based Minnesota-style schedule format, since details (revaccination, high risk groups, etc.) could take a long time to resolve.
- Dr. Ray Strikas, NIP: commended the work group for a nice and very encouraging beginning. He suggested publishing it around August or September to avoid overburdening the influenza season recommendations, and not publishing it during development/publication period of the childhood schedule, to avoid compounding the AAP's and CDC's work. He was unsure that a simple schedule could be quickly accomplished for the Td booster. With the Td shortage, this is significant issue has to be resolved before recommending on Td boosters.

LABORATORY-ACQUIRED MENINGOCOCCAL DISEASE

Dr. Nancy Rosenstein reported several recent accounts of laboratory-acquired

meningococcal disease that has caused great concern in the health care community. A high rate of meningococcal disease was found among laboratory workers, suggesting enhancement of the current guidelines for laboratory safety and a reinforcement of current ACIP vaccination guidelines.

Data Presentation. Dr. James Sejvar reported ~3,000 cases of meningococcal disease reported in the U.S. annually, with a case fatality rate of ~12%. *Neisseria meningitidis* is transmitted by close direct contact with respiratory secretions, and serogroups B, C and Y cause most disease in the U.S. The only U.S.-licensed vaccine is a quadrivalent polysaccharide that protects against serogroups A, C, Y and W135, but not B. It is safe and effective, but does not have 100% efficacy and requires repeat doses.

The CDC/NIH publication, *Biosafety in Biological and Biomedical Laboratories (BMBL)* classifies *Neisseria meningitidis* as a Biosafety Level (BSL) 2 organism. Guidelines advise the personal protection of laboratory coats and gloves and facial protection as appropriate, and the use of primary barriers such as biological safety cabinets (BSC) for procedures that might cause splashing, spraying or splattering of droplets. However, no such procedures of increased risk are listed.

MMWR reported two fatal cases of probable laboratory-acquired meningococcal disease in 1991, the first in the U.S. CDC then recommended that work with high concentrations or large quantities of organisms be conducted in a BSL-3 laboratory, and immunization of lab workers. In 1997, ACIP recommended consideration of vaccination for research, industrial and clinical lab personnel routinely exposed to *Neisseria meningitidis* in potentially aerosolized solutions. The general assumption was of risk primarily to research and industry personnel frequently exposed to these quantities, many of whom are thought to have been vaccinated. But the risk to clinical laboratory personnel was less clear.

Upon the cases of probable laboratory-acquired meningococcal disease last year, reported in close time proximity, CDC assessed the frequency of these infections to reconsider the laboratory safety/vaccination guidelines.

Members of various infectious disease, microbiology, and infection control professional organizations were contacted through electronic mail discussion groups. A case was defined as a laboratorian with a history of meningococcal disease consistent with acquisition in the laboratory setting, and with a serogroup matching a recently-handled specimen. Basic descriptive epidemiologic information was collected on behaviors and laboratory practices that might have predisposed exposure to aerosols or droplets, based on the known mechanism of meningococcus transmission.

This uncovered 16 previously unreported cases from six countries of probable laboratory-acquired meningococcal disease in the past 15 years, all among microbiologists and most cases among females. The cases split fairly evenly between serogroup B and C; 8 cases (50%) were fatal. Ten cases with information available indicated a median interval of 4 days between handling the probable source specimen and symptom onset. None of the reported cases occurred among workers in hematology, chemistry, or pathology.

A slide charting all cases reported in the past 15 years was shared. Of the 16 previously unreported cases, 6 were from the U.S. in the past five years. No one knows the number of microbiologists in the U.S. The denominator of laboratorians at risk was estimated by multiplying the ~3000 isolates of pathogenic meningococcus cultured in hospital laboratories annually by an average of three microbiologists handling it during the laboratory investigation. Over 5 years, this produced an average attack rate of 13/100,000 population at risk per year, compared to a rate of 0.2/100,000 for adults aged 30-59, the age group of most laboratory workers. Many of the case microbiologists were reported to have performed common microbiological laboratory procedures, but 15 of 16 cases did so outside of a BSC or aerosol screen.

The conclusions were: 1) that U.S. rates of laboratory-acquired meningococcal disease are much higher than initially suspected, and represent a substantial occupational hazard to microbiologists; 2) the high case fatality rate may be due to reporting bias, but could also reflect highly virulent strains and high density organisms encountered in the laboratory setting, compared to natural transmission; 3) that all of the cases were among microbiologists, and not workers in other sections of the laboratory, suggests that exposure to meningococcal isolates and not patient specimens represent the increased risk; 4) although not a breach in laboratory safety technique, almost every case manipulated the isolate on the benchtop and not in a BSC. A similar finding of high resulting disease risk came from a recent U.K. study. Importantly, all of the cases detected were in *clinical* laboratories, perhaps because safety guidelines may be stricter in research and industrial laboratories; and more of the latter personnel may have been vaccinated.

Based on these findings, laboratory safety should be emphasized for prevention of laboratory-acquired meningococcal disease, as should implementation of additional safety precautions when manipulating those isolates; specifically, doing so in a BSC. If a BSC is not available, other methods of aerosol protection may be appropriate. But, if adequate safety equipment is unavailable, the risk should be minimized and the isolate should be transferred to another laboratory.

The staff recommended:

- The use of the quadrivalent polysaccharide vaccine as an adjunctive measure in the protection of microbiologists as an additional safety precaution to minimize laboratorians' risk of infection and due to the limitations of the vaccine.
- Research and industrial laboratory scientists routinely exposed to *Neisseria meningitidis* in potentially aerosolized solutions should consider vaccination, and microbiologists should be educated about the increased risk of infection and the seriousness of illness so that laboratory leaders and individuals can make informed decisions regarding vaccination.
- In instances where *Neisseria meningitidis* is inadvertently handled outside of a biosafety cabinet, antimicrobial chemoprophylaxis should be considered for the exposed microbiologist.

These recommendations do not conflict with the current ACIP guidelines, and were suggested for incorporation into the next ACIP guidelines. The staff will next publish their findings and recommendations for laboratory safety and vaccination in the *MMWR*. The

endorsement of the American Society for Microbiology is expected, as well as other stakeholders. CDC plans to initiate prospective surveillance for cases of laboratory-acquired meningococcal disease, to continue to assess the rates among laboratorians and the effectiveness of the recommendations. Finally, the reassessment of current laboratory safety practices was encouraged.

Discussion with Dr. Sejvar and Dr. Rosenstein included:

- Dr. Tompkins: *1) What type of exposure is really relevant here? Most meningococcus isolated in the clinical lab is not in spinal fluid, but in sputum cultures, which cannot all be read in BSCs. Was any case caused by just opening the plate and doing the analysis, or were they all from concentrations of organism done in serological testing with its aerosolization?; and 2) It is unrealistic to expect a transfer of suspected meningococcus to another laboratory in the absence of a BSC.* The 6 U.S. cases used to calculate the rates had cultured isolates from either blood or cerebral spinal fluid; none from respiratory secretions. Data for all of the cases collected are not available, but CDC is trying to ascertain that. The common theme of the cases was the manipulation of isolates of culture outside of BSCs. No cases were reported among individuals in a lab who handle only specimens.
- Dr. Tompkins: *I understand that. But many labs use automated devices to read the blood culture, and the result is unknown until the sample is taken out, plated, and the gram stain is done. That is not an inherently dangerous step.* Dr. Rosenstein: We have struggled with this issue over the past 6 months, as Dr. Johnson can testify, having reported one of the initial cases. We have broadly vetted these recommendations with laboratory colleagues, both at CDC, those who write the safety guidelines, the state health departments reporting these cases, and ASM. They agreed with the specimen transfer – although perhaps it cannot always be accomplished – and that a suspicious CSF or blood culture should not be handled on open bench.
- Dr. Tompkins: *In thinking about patient care, laboratory capacity for specimen identification is critically important. There must be an alternative, such as a close-fitting TB mask, without a BSC. Transfer is just not acceptable.* Dr. Rosenstein: We support transfer if there is not appropriate aerosol protection. We hope that it will be determined if an aerosol guard or TB mask is sufficient, but that has not yet been done. We are trying to ensure understanding of the increased risk associated with common practices, such as reading these on the bench top. The role of laboratorians and other organizations is to determine whether a BSC is really needed or if simple aerosol shield is sufficient.
- Mr. Hosbach, Aventis Pasteur: *Vaccination is safe, and could be "recommended" rather than "considered".* The polysaccharide is limited in its lack of meningococcus B. But all of Aventis' workers in manufacturing are vaccinated routinely every five years, as the package insert recommends (3-5 years). Blood tests are also done to ensure adequate antibody responses and protection during exposure.
- Dr. Johnson: *Agreed.* ACIP's previous recommendations have been equivocal for laboratorians. Calculated risk to microbiologists handling meningococcal specimens shows a considerably higher risk than that for which ACIP recommends vaccine use in outbreak control. The recommendations already advise vaccination for those working in laboratories expected to encounter meningococcal isolates likely to be aerosolized.

Without opening up the entire statement, that point could be strengthened,

- Dr. Rosenstein: *We were struck that many microbiologists could be vaccinated for a very uncommon exposure, and still not prevent the serogroup B that constitutes half of these cases.*
- Dr. Clover: *Perhaps we could define what "routine" is in a clinical laboratory in the ACIP recommendation. And, the recommendation wording is stronger for college students' exposure risk (3/100,000) than here (13/100,000).* But Dr. Modlin advised caution about using the 13/100,000 number, which is only a rough calculation.
- Dr. Tompkins: expected that the ASM would prefer "should be considered" for such voluntary vaccines. Some lab Directors would probably highly recommend it, but another may have a lower risk assessment. But she agreed that college students should have a much lower risk than that for microbiologists. She was unaware of this lab safety problem, and she expected the educational effort behind this study to be its most important aspect. She advised "strongly considered" as a recommendation and leaving the decision up to the laboratory.
- Dr. Overturf: *Mandated or not, the issue of the immunization cost can be large for big laboratories with many microbiologists.* This is an issue on the laboratories' network. Many seem to want this, although who will pay is at question.
- Dr. Schaffner: *Agreed,* laboratorians are very interested in this. But apropos of which laboratories, he noted that one cannot recommend seat belts only for those driving fast. He expressed some worry that the prophylaxis aspect could require ciprodoxacin, which requires careful thought – not the least about the institution's legal liability.
- Dr. Helms: *Research into the basis of how these aerosols are generated is needed to see if something more systematic is occurring in the laboratory.* For example, the response to finding Legionella in a water system would not be prophylaxis for the patients or immunization, but finding the cause in the water system.
- Dr. Clover: *Can the denominator be better refined?* Dr. Rosenstein: We are open to suggestions, but 6 months of communication with laboratory organizations indicate that this is just not an existing number. If the 3 cases in 2000 that prompted this research is dropped, the number is significantly lower, but is still 7/100,000. In light of that, CDC felt compelled to issue a quick notification. And with the licensure of the meningococcal conjugate likely soon, the revision to incorporate that into the ACIP statement will also be an opportunity to revisit the language for laboratory workers and college students.

USE OF ECONOMIC EVALUATION FOR SETTING HEALTH POLICY

In response to the ACIP's request, Dr. Phaedra Corso, of the the Division of Prevention, Research and Analytic Methods, of CDC's Epidemiology Program Office, discussed economic evaluation: its basic methods, the issues related to interpreting the evaluations' results, and the related economic evaluation tools and training opportunities at CDC.

Policy Application. Components of feasibility addressed in crafting national health policy include biologic (i.e., a vaccine available to address the health outcome of interest); technical (vaccine administration); political and social (no unacceptable risks to parents or society in general); and economic (cost compared to the associated outcomes). Economic evaluation is the application of analytic methods to identify, measure, value and compare

the costs and consequences of interventions. *Identification* is the delineation of the possible interventions or strategies of interest. Quantitative *measurement* includes epidemiology, decision sciences, meta-analysis, and economic evaluation.

Economic evaluation includes several methods:
Cost benefit analysis converts the common denominator or the common outcome measure into dollars, to allow comparison across health and non-health outcomes. Its advantage is that it provides a list of all costs and benefits over time. Its theoretical basis is that all costs and benefits can be quantified in dollar terms for analysis. Costs that occur at different times (i.e., costs of intervention, delayed benefits) or different amounts of costs and benefits occurring over time can also be addressed by a cost benefit analysis. This analysis also provides the summary measure in one single value, the net present value (also referred to as net benefits or the benefit/cost ratio).

Cost utility analysis uses a health metric as the common denominator to compare different health interventions (e.g., quality-adjusted life years -- QALY -- or disability-adjusted life years -- DALY). This analysis incorporates length and quality of life, and allows their comparison through the concept of utility. Utility is the consumer preferences for being in a particular health state. Cost utility analysis allows the capture of the timing and duration of disease disability. It provides a ratio of the costs (the enumerator) divided by the common health metric (the denominator).

Cost Effectiveness Analysis: uses a common natural unit (e.g., cases prevented or lives saved). This analysis is used to compare the results of interventions that affect the same health outcome. It provides a summary measure as a ratio, with dollars in the enumerator and the natural units as the denominator.

Components of an economic evaluation:

1. *Framing the study*: involves five components: the study problem (health outcome of interest, and why), audience (the users of the economic evaluation, what are their information needs and their uses of the data), perspective (e.g., the entity bearing the costs and benefits of the intervention; or of society, regardless of who bears the costs), time frame (period in time during which the intervention occurs), and analytic horizon (the period during which all the intervention's costs and benefits occur – e.g., for vaccination, the entire influenza season). All five components should be explicitly defined at the outset of any economic evaluation.

2. *Quantifying costs* involves four types of costs: direct medical costs (diagnostic tests and procedures, drugs, medical supplies); direct non-medical costs (program administration, physical space, utilities, etc.); indirect costs (those associated with productivity losses); and intangible costs (fear, anxiety, pain of vaccination). Hard to quantify, the latter are typically not included in an economic evaluation, but are mentioned in the discussion section.

3. *Quantifying outcomes* in the *Cost Benefit Analysis* can be done from at least two approaches: a) The human capital or cost of illness approach uses lifetime earnings as a proxy for productivity losses due to either morbidity or premature mortality. This is a

conservative estimate; b) The willingness to pay approach is increasingly used in public health; and c) contingent valuation surveys (respondents are asked questions to gauge their marginal willingness to pay to rid themselves of a particular health condition, such as parents' willingness to pay to reduce the intussusception risk associated with rotavirus vaccine). This enables calculation of the value of a statistical life for use in a cost benefit analysis.

Quantification in a *Cost Utility Analysis* is achieved through utilities, which describe consumer preferences for being in a particular health state, or for reducing morbidity or mortality associated with an intervention. Utilities are rated from zero (worst case; death) to one (perfect health). In direct measurement of individual utilities, all the components of the health state are described (physical, mental, functional). They are then measured through rating scales (between 0-1); time-tradeoffs (willingness to trade a certain life duration in a bad health state for a shorter life duration in perfect health); standard gambles (how low the probability of death must be for a person to be indifferent between zero and one); and person-tradeoffs, in which a population-level utility is used for DALYs (how many poor health outcomes are tolerable to merit a certain number of good outcomes such as number of lives saved).

With these crude measures, one can calculate the quality-adjusted life years gained from an intervention, and compare the outcomes between doing an intervention and not doing one. On the other hand, if survival duration or life years saved is the measure, the quality of life associated with the intervention is not important.

Cost Effectiveness Analysis involves the difference between intermediate (persons immunized, cases prevented or disease averted) and final outcomes (life years or lives saved). The latter data are often not available, so many evaluations use intermediate outcomes. This is appropriate as long as it is explicitly stated.

4. *Sensitivity analysis* is an entire field to itself. It should always be done with an economic evaluation. Providing one point estimate for cost effectiveness or cost benefit analyses is inappropriate, because the point estimates vary depending upon population, incidence, and model parameters in general.

5. *Interpreting results* involves three myths, that: a) only programs with a positive net present value or a positive net benefit should be implemented; b) that programs with <$50,000 per QALY saved should be implemented; and c) cost savings equals cost effectiveness.

   A. The two summary measures of cost benefit analysis are net present value or net benefits (benefits minus cost) and benefit cost ratio (benefits divided by costs). The first is clearly a strong argument for investing in a program, since benefits outweigh costs. But there are 3 other factors involved in setting health policy: biological, technical, and political economic feasibility. In the fact of a negative net present value or benefit, other justifications are needed to recommend the policy. The previously-used benefit cost ratio (benefits divided by costs) is currently less used, because it results in a single number. For example, Program A costs are $1,

benefits are $10, producing a net present value of +$9. On the other hand, a multifaceted Program B's single ratio of 5 could be misleadingly less than Program A's, when in fact the its return on investment could be greater. As an example, the recent publication by Kristin Nichol in *Archives of Internal Medicine* about vaccination's direct and indirect costs (including those averted), benefits, and sensitivity analysis of the worst- and best-case scenarios.

B. Investing in programs that are <$50,000 per QALY saved is a hypothetical number with no empirical or theoretical basis. The dollar values have never been inflated to current-day dollars, so the number is fictitious. Dr. Corso used a comparison of vaccination to screening tests, demonstrating the superiority of the former.

C. "Cost effective" does not equate to "cost savings," a truth of particular interest to the ACIP and the vaccination field. Vaccinations were not considered cost saving 10-20 years ago, but now are known to be cost effective, if not cost saving. That means that relative to other clinical preventive services being done, vaccination programs are still extremely cost effective. But in calculating that, the population level is significant, since what may not be cost saving at a sub-level could be so at another level.

The conclusions are that 1) economic evaluation is valuable to the decision-making process and should always be included in setting health policy; and 2) interpreting these results is often complex and requires much more than a 45-minute presentation.

CDC has an intensive training course on the mechanics of cost benefit, cost utility, and cost effectiveness analysis. It also provides technical assistance, including a two-year post-doctoral Fellowship program involving economists throughout CDC. An economics contract with the Research Triangle Institute allows CDC program offices to commission economic evaluation to fill gaps in the literature. CDC is also developing a standardized methodology to allow universal comparison on cost utility analyses.

Discussion included:

- Dr. France: *It seems as though an HMO would always be interested in both the cost utility analysis (for general policy issues to compare it to other standardized accepted prevention programs) and cost effectiveness analysis (to decide on age levels of children to be immunized and the differing impacts) when reviewing some new policy.* Agreed. The cost effectiveness side is limited and suitable for the micro level, but for setting broader health policy at a national level, cost utility analysis is appropriate.
- Dr. France: *Is there an easy place to access comparisons when considering the cost utility of something?* Other clinical preventive services are probably the closest comparison to that. Those are called lead tables, which are increasingly published in peer review journals, so that may be a place to start. CDC's DPRAM office will help in that search, as well.

PUBLIC COMMENT was solicited. With no response, the meeting adjourned at 5:50 p.m. with Dr. Modlin's thanks to all the participants.

I hereby certify that, to the best of my knowledge, the foregoing Minutes are accurate and complete.

John F. Modlin, M.D., Chair

12 Oct 01

Date

(b)(6)
02/12/2003 12:14 PM

To: (b)(6) @OSAGWI
cc:

Subject: RE: FW: HA Update with Dr. chu

(b)(6)
I am working this issue. Probably needs to be in your system.

Thanks,
(b)(6)

---------- Forwarded by (b)(6) on 02/12/2003 12:08 PM ----------

(b)(6)
(b)(6) @ha.osd.mil> on 02/12/2003 11:37:40 AM

To: (b)(6) @deploymenthealth.osd.mil"" (b)(6) @deploymenthealth.osd.mil>
cc:

Subject: RE: FW: HA Update with Dr. chu

Great. Thanks.

(b)(6)

-----Original Message-----
From: (b)(6) @deploymenthealth.osd.mil
[mailto:(b)(6) @deploymenthealth.osd.mil]
Sent: Wednesday, February 12, 2003 11:33 AM
To: (b)(6)
Cc:
(b)(6)
Subject: Re: FW: HA Update with Dr. chu

Mam,
I'm here. Will work with MILVAX to tackle issue.

v/r,
(b)(6)

(b)(6)
(b)(6) ha.osd.mil> on 02/12/2003 11:22:51 AM

To: (b)(6)

cc:

(b)(6)

Subject: FW: HA Update with Dr. chu

Hey folks. Sorry to bother you. Could you have your NAVY anthrax POC check into the situation apparently reported to Dr. Chu where 2 marines in San Diego apparently refused anthrax vaccine and were subsequently sent to the theater anyway. He wants details on this matter for a 2pm meeting tomorrow! AND

and he wants an overall status report on refusals since reinitiating the program last June for next weeks update meeting (Feb 20 at 1400).

You can see by my email below I tried to punt but it didn't work. Can you satisfy the suspense for tomorrow (lets say, by noon)?

How hard would it be to pulse the system for the update next week?

(b)(6) will be the guy to work with up here to move this forward up the food chain. (b)(6) is "on assignment elsewhere" let me know.

(b)(6)

-----Original Message-----
From: (b)(6)
Sent: Wednesday, February 12, 2003 11:02 AM
To: (b)(6)
Subject: RE: HA Update with Dr. chu

Can you just have someone look into the two San Diego cases that Dr. Chu asked about. I'll get more time for the overall status report (like the following week?) Thanks, (b)(6)

-----Original Message-----

From: (b)(6)
(b)(6)

Sent: Wednesday, February 12, 2003 10:54 AM

To: (b)(6)

Subject: RE: HA Update with Dr. chu

Anthrax refusals? We just sent out a data call to do the annual congressional report to congress (due 1 April) There is no ongoing requirement levied on the Services to report refusals as they occur, because most are resolved after education or other counseling. A few continue through a more elaborate UCMJ process, and those are the ones that get reported through the annual data call.

I will be at Site R Thursday afternoon with (b)(6). Can we defer this issue?

(b)(6)

-----Original Message-----
From: (b)(6)
Sent: Wednesday, February 12, 2003 9:36 AM
To: (b)(6)
(b)(6)

Subject: HA Update with Dr. chu

It's Thursday at 2:00 pm. Two issues:

1. Brief 04 Budget (b)(6)

2. Info paper on anthrax refusals (b)(6)

Other topics? Thanks, (b)(6)

(b)(6)
Anthrax Program Liaison Officer for ASD (Health Affairs) and Deputy Program Director, Population Health, Deployment Health Support Directorate
(b)(6)

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

INFO MEMO

February 13, 2003, 7:00 AM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen Embrey, DASD, Force Health Protection and Readiness

SUBJECT: Information Paper - Two Marines Who Refused Anthrax Immunization Deployed to Kuwait

- Attached at TAB A is an information paper on the events reported in the February 8, 2003, San Diego Union-Tribune newspaper, and subsequently passed to Dr. Chu.
- TAB B is a copy of the Union-Tribune article regarding the two Marines, assigned to the 1st Marine Division, Camp Pendleton, CA, who refused the anthrax inoculations as preparation for deployment to Kuwait.
- These two Marines disobeyed a lawful order, which usually involves disciplinary action. They were not court-martialed; they were deployed to Kuwait. However, as reported in the article, these individuals will not be in a position to put other servicemembers at risk.
- Information provided by Headquarters Marine Corps indicate one Marine accepted non-judicial punishment, was ordered again to receive the shot, and again refused. Further action is being determined. The second Marine refused immunization after appropriate counseling and could face disciplinary action at a later date.
- TAB C is a press release dated January 30, 2003, which clarifies the Marine Corps policy on anthrax vaccine refusals.
- According to Captain Miracle of Headquarters, Marine Corps, Judge Advocate General's office, it is at the discretion of commander whether disciplinary action will be taken. If action is decided, it is also the commander's prerogative to delay disciplinary action based on operational commitments.
- Lieutenant Colonel (b)(6) Headquarters, Marine Corps, Current Operations section, indicated there is a forward legal support section in the theater of operations responsible for the matter.

COORDINATION: TAB D

Attachments:
As stated

Prepared by: CDR (b)(6), DHSD, (b)(6), PCDOCS# 46072

INFORMATION PAPER

Title: Information Paper - Two Marines Who Refused Anthrax Immunization Deployed to Kuwait

STATUS:

Two Marines from the 1st Division, Camp Pendleton refused to participate in the Anthrax Vaccine Immunization Program (AVIP), a mandatory program reintroduced June 28, 2002, and intended initially for those who will deploy to specifically identified high risk areas.

BACKGROUND:

An article appearing in the San Diego Union-Tribune February 8, 2003, reported on this occurrence that at the time resulted in no disciplinary action. These Marines were allowed to continue their deployment. A Marine Corps representative confirmed disciplinary action was deferred due to operational commitments.

Information provided by the Judge Advocate General's Office, Headquarters, Marine Corps, verified that the story is accurate and that further disciplinary action is pending. It was reiterated that the Anthrax Vaccine Immunization Program is a force health protection issue. If a servicemember refuses the vaccine, it is at the commander's discretion to manage the situation as he or she would for any failure to disobey a lawful order.

Options at the commander's disposal are administrative actions, such as non-judicial punishment (NJP), which could include an official entry into the Marine's service record, loss of rank, loss of pay, restriction to quarters, or extra duty. If a Marine refuses NJP, the case is referred to court-martial and he/she is afforded representation by defense counsel.

Lieutenant Colonel Gaynor, USMC, Headquarters, Marine Corps, Current Operations section, indicated there is a forward legal support section in the theater of operations responsible for the matter. Additionally, it was confirmed that these individuals will not be in any position to put other Marines or servicemembers at risk.

The Navy and Marine Corps implementation plans for anthrax immunizations, are consistent with the DoD Administrative and Clinical policies, clearly emphasizing the importance of these force protection efforts, and any refusals are considered disobeying a lawful order and subject to the Uniform Code of Military Justice.

OSD (HA) is providing an Anthrax Refusal Report to Congress in April 2003.

Prepared by: CDR (b)(6), DHSD, (b)(6)

Two Marines Who Balked At Vaccine Deployed

Both go to Kuwait, face penalty later

By Jeanette Steele, San Diego Union-Tribune staff writer- February 8, 2003

Two Marines who refused the military's mandatory anthrax vaccination are among thousands of Camp Pendleton-based troops deployed to Kuwait, according to officials.

The 1st Marine Division is deferring punishment and will allow them to serve in "duties that will not...unduly jeopardize them or their fellow Marines," said 1st Marine Division spokesman 2nd Lt. Eric Knapp.

There are no plans to court-martial them while in Kuwait, he said. That departs from previous Marine actions on anthrax refusal, which involved removal from deployment status and quick punishment.

It's unclear whether the two Marines have been charged, but in past years the Marine Corps has court-martialed others who refused the controversial vaccination. At least 37 service members were tried for refusing the vaccine when it was first mandated in the late 1990s. Another Pendleton Marine, Cpl. Anthony Fusco, currently faces court-martial for the same offense, which is disobeying a lawful order.

The Marines said preparation for a possible war and a commander's judgment influence punishment decisions. The division commander is Maj. Gen. James Mattis, who led the Marine forces into Afghanistan in late 2001.

"Although swift disposition of disciplinary proceedings is preferable in most instances, it is not unusual for operational commitments to delay such proceedings, especially when...related to real-world contingencies," Knapp said.

A Marine spokesman at the Pentagon said the two will face punishment later. "All Marines who continue to refuse the anthrax vaccination will be held accountable...for disobeying orders, eventually," said Lt. Col. Stephen Kay, a Marine-headquarters public-affairs officer.

One of the Marines is Lance Cpl. Kevin Lotz, a 21-year-old machine gunner stationed at the Twentynine Palms Marine base. His division is headquartered at Camp Pendleton. The other Marine's name wasn't available.

Lotz's mother, Kathleen Lotz of Arcata, said she's disappointed the Marines would punish him after he serves in a potential combat zone.

"I can't believe they would put a Marine on the front lines, fighting a war and risking his life every day, then bring him home only to court-martial him and give him a bad-conduct discharge," Lotz said. "All I can do as a mother is pray for his safety while in Iraq and trust in the history of honor the Marine Corps has."

By refusing the vaccinations, the two men put themselves at greater risk in an anthrax attack, Marine officials said. Anthrax is a deadly bacteria (sic) that the White House has said Saddam Hussein possesses and may use against U.S. troops.

"They have been ordered to take the vaccine and counseled about the necessity for protecting their bodies from the dangers of anthrax," Knapp said. "We expect them to take the vaccine and fulfill their enlistment oath." All other division Marines have been vaccinated, he said.

PRESS RELEASE:

Consolidated Public Affairs Office
For more information: Phone: (760) 725-5044
Marine Corps Base
Camp Pendleton, CA 92055-5019

PRESS RELEASE #03-016 Jan. 30, 2003

FOR IMMEDIATE RELEASE

MARINES CLARIFY POLICY FOR ANTHRAX IMMUNIZATION REFUSAL

As part of the 1st Marine Expeditionary Force Anthrax Vaccine Immunization Program, Marines assigned to I MEF are required to receive the anthrax vaccination on order. The purpose of the AVIP is to protect U.S. personnel from exposure to the anthrax threat.

Prior to vaccination, all personnel are required to receive unit-level counseling regarding the importance of anthrax vaccinations and the consequences of refusal.

The Marine Corps interprets initial refusal as a misunderstanding of the purpose and efficacy of the AVIP. Therefore, upon refusal, the unit's senior enlisted person and the unit's medical officer will provide individual counseling to the Marine. If the Marine then complies he is returned to full duty with no legal consequence.

If the Marine continues to refuse, the unit commander and the medical officer must individually counsel the Marine. If the Marine then complies, the Marine is returned to full duty with no legal consequence.

If the Marine continues to refuse, the unit commander can take administrative action, such as an official entry into the Marine's record book or non-judicial punishment. NJP is an administrative action which enables a commander to maintain the good order and discipline of the unit. NJP can result in loss of rank, loss of pay, restriction to quarters or extra duty.

A Marine has the option to refuse NJP and demand court-martial. When a Marine is referred to court-martial, he is afforded representation by defense counsel qualified under the Uniform Code of Military Justice.

Cpl. Anthony J. Fusco, Jr. of 9th Communications Battalion, I MEF Headquarters Group, was provided every counseling opportunity listed above. At every juncture, Cpl. Fusco refused vaccination.

In November and December 2002, the battalion's executive officer also personally counseled Cpl. Fusco on the requirement for anthrax vaccinations and the consequences of refusal to take the vaccination. He was ordered to take the vaccination but again refused.

In December 2002, Cpl. Fusco was offered NJP for violating Article 92 of the Uniform Code of Military Justice (refusal to obey lawful orders). When Cpl. Fusco was offered NJP, he asked his commander if he would still have to take the vaccination. The commander replied that even after NJP, Cpl. Fusco would be required to comply with I MEF policy and take the vaccination. When Cpl. Fusco learned this, he informed his commander that he would decline NJP. The commanding officer then referred him to a special court-martial.

The maximum punishment at special court-martial for violating Article 92 of the UCMJ is a bad-conduct discharge, six months confinement, reduction to paygrade E-1 and forfeiture of pay for six months.

SUBJECT: Information Paper - Two Marines Who Refused Anthrax Immunization Deployed to Kuwait

Coordination

Judge Advocate General's Office Headquarters, Marine Corps	(b)(6)	phoncon 02/12/03
Current Operations Section Head Quarters, Marine Corps		phoncon 02/12/03
CoS (HA):		_____
PDASD (HA):		_____

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CDC Anthrax Vaccine Safety & Efficacy Research Program

Interim Report

INSTITUTE OF MEDICINE

only page 1 provided due to licensing restrictions listed on originators website remaining 58 pages denied b5

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The National Academies
INSTITUTE OF MEDICINE

Committee to Review the
CDC Anthrax Vaccine Safety and Efficacy Research Program

Fifth Meeting
January 7, 2002
The Foundry Building, Room 2004
1055 Thomas Jefferson St., NW
Washington, DC

Agenda

Monday, January 7, 2002

9:00 a.m. **Open Session – call** to order, introductions, etc.
Phillip Brachman, M.D., Chair

9:15 Introductory Presentation - NIP Anthrax Vaccine Safety Activities Above & Beyond Research
- Pre- and Post-exposure IND use of AVA .
- The Vaccine Healthcare Center **(VHC)** Network Partnership with **DoD**

Randy Louchart, RN, MPH, Deputy Chief, **AVSA/ESD/NIP/CDC**

Addressing IOM Concerns and Input from External Expert Panels

9:45 Research Priorities and the Study of Long-Term Health Effects of AVA
Michael McNeil, MD, MPH, Chief, **AVSA/ESD/NIP/CDC**

10:45 Survey of Military Personnel about their Knowledge, Attitudes and Beliefs of AVA
Deborah Gust, **PhD, VSDA/ESD/NIP/CDC**

11:15 **Use of DMSS** to Test AVA Adverse Events Hypotheses
Ben Schwartz, MD, Associate Director of Science, **ESD/NIP/CDC**

11:45 Other AVA **Safety** Research Activities and Collaborations
– Questions and Comments NIP staff

12:00 p.m. Lunch Break

1 :00	Overview of **Efficacy** Component of CDC Anthrax Vaccine Program, Brad Perkins, MD, Chief, Meningitis and Special Pathogens Branch, **DBMD/NCID/CDC**
1:30	Update on Human Study Nina Marano
2:15	Update on Non-Human Primate Study Jai Lingappa and Dave **Ashford**
3:oo	Break
3:15	Update on Correlates **of** Protection Study Conrad Quinn
4:oo	Committee Members' Discussion: Comments, Questions, and Answers
5:oo	Adjourn

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Committee to Review the CDC Anthrax Vaccine Safety and Efficacy Research Program

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Committee to Review the CDC Anthrax Vaccine Safety and Efficacy Research Program

STATEMENT OF TASK

This committee will advise the Centers for Disease Control and Prevention (CDC) on the completeness and appropriateness of the CDC plan to respond to the Congressional mandate to study the safety and efficacy of anthrax vaccine, addressing: (1) risk factors for adverse reactions, including gender differences; (2) determining immunologic correlates of protection and documenting vaccine efficacy; (3) optimizing the vaccination schedule and routes of administration to assure efficacy while minimizing the number of doses required and the occurrence of adverse events. The CDC, the National Institutes of Health (NIH), and the Department of Defense (DOD) are directed by Congress to collaborate and cooperate fully in this effort.

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