

2100 Second Street, S.W. Washington, DC 20593-0001 Staff Symbol: CG-11 Phone: (202) 475-5173

Fax: (202) 475-5909

COMDTINST M6230.10 MAR 03 2008

#### **COMMANDANT INSTRUCTION M6230.10**

Subj: COAST GUARD SMALLPOX VACCINE PROGRAM (SVP)

(a) Immunizations and Chemoprophylaxis, COMDTINST M6230.4 (series) Ref:

- (b) Privacy Incident Response, Notification, and Reporting Procedures for Personally Identifiable Information (PII), COMDTINST 5260.5(series)
- 1. PURPOSE. This Manual establishes policy, assigns responsibilities, and provides guidelines regarding the Coast Guard Smallpox Vaccine Program (SVP), unit prioritization, automated tracking system and reporting requirements, logistics, communications/education, military personnel guidance, and civilian personnel guidance.
- 2. ACTION. Area, district, and sector commanders, commanders of maintenance and logistics commands, commander deployable operations group, commanding officers of integrated support commands, commanding officers of headquarters units, assistant commandants for directorates, Judge Advocate General and special staff elements at Headquarters shall ensure compliance with the provisions of this Manual. Internet release is authorized.
- 3. **DIRECTIVES AFFECTED**. None.
- 4. PROCEDURE. No paper distribution will be made of this Manual. Official distribution will be via the Coast Guard Directives System CD-ROM. An electronic version will be located on the Information and Technology (CG-612) websites at http://cgcentral.uscg.mil/ (once in CG Central, click on the resources tab then directives) and http://www.uscg.mil/directives. This Manual will also be made available via the Commandant (CG-112) Publications and Directives website at http://www.uscg.mil/hq/gw/g-wk/wkh/pubs/index.htm

	а	b	С	d	е	f	g	h	i	j	k	-1	m	n	0	р	q	r	S	t	u	٧	W	Х	у	Z
Α	3	2	3	2	3	2	1	1	2	1		1	1	1	1	1	1		1		3					
В	3	2	15	2	15	2	2	15	2	1	2	6	2	3	1		10	3	1	1	1	1	1	1	1	1
С	4	4	1	3	2	1	1	1	2		5	1	1	1	1	3	2	1	1	2	2	2	1	1	1	1
D	1	2	1	4			1	2			1	1		1	1	1	1			2			1			
E	2	2		1	1			1	1										1							
F																	1	1	1							
G			)	٥	٥																					

DISTRIBUTION - SDL No. 148

#### 5. BACKGROUND.

The threat of biological warfare and terrorism remains a risk to U.S. forces. Recent assessments have identified smallpox as a biological threat facing American service men and women today. The Deputy Secretary of Defense approved the Department of Defense (DoD) Smallpox Response Plan and directed execution of the Smallpox Vaccination Program (SVP) in accordance with Food and Drug Administration (FDA) guidelines and consistent with the best practice of medicine, to protect selected personnel at highest risk and preserve certain mission critical capabilities. This program supports the national smallpox preparedness plans, but is tailored to the unique requirements of the Armed Forces. The Coast Guard is a full participant in this Force Health Protection program.

## 6. POLICY.

All Coast Guard Active Duty, Selected Reserve (SELRES) members, assigned Public Health Service (PHS) officers, and certain civilians who are affected by this policy will be vaccinated unless medically or administratively exempted

#### 7. RESPONSIBILITIES.

- a. Commandant (CG-1121) has the overall responsibility for the policy associated with the Coast Guard SVP and will provide the Department of Defense Executive Agent, the Secretary of the Army, with annual projected smallpox vaccine program requirements. Further responsibilities are outlined in Chapters 1, 3, 4, and 5 of this Manual.
- b. Commandant (CGPC-rpm) will address policy issues within the Reserve component.
- c. Commandant (CG-0922) will coordinate public affairs issues.
- d. Commandant (CG-0921) will coordinate congressional queries and briefings.
- e. Commanders, MLC will assume responsibility for plan overview. They will direct MLC(k)s to ensure units have the requisite support and supplies (vaccines and ancillaries) to administer and monitor the program, and ensure compliance. Further responsibilities are outlined in Chapters 1, 3, 4, and 5 of this Manual.
- f. Coast Guard clinics' and sickbays' responsibilities are outlined in Chapters 1, 3, 4, and 5 of this Manual.
- g. Unit commanding officers will educate their personnel regarding the need for and safety of the vaccination program. Further responsibilities are outlined in Chapters 1, 3, 4, and 5 of this Manual.
- h. Individual service member responsibilities are outlined in Chapter 1 of this Manual.

- 8. <u>ENVIRONMENTAL ASPECT AND IMPACT CONSIDERATIONS</u>. Environmental considerations were examined in developing this Manual and are incorporated herein.
- 9. FORMS / REPORTS. The electronic forms called for in this Manual are available in the USCG Electronic Forms library on the Standard Workstation, on the Internet at Internet: <a href="http://www.uscg.mil/forms/">http://www.uscg.mil/forms/</a>, on the Intranet at <a href="http://cgweb2.comdt.uscg.mil/CGFORMS/Welcome.htm">http://cgweb2.comdt.uscg.mil/CGFORMS/Welcome.htm</a>, and CG Central at <a href="http://cgcentral.uscg.mil/">http://cgcentral.uscg.mil/</a> Forms related to the SVP can also be found on the following site <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>. The Smallpox Trifold Information Brochure can be found at the Smallpox vaccination program website <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>. Clinics will receive a Smallpox Trifold for each dose of Smallpox that they order. All enclosures may be reproduced locally. The <a href="https://www.smallpox.army.mil/education/toolkit.asp">https://www.smallpox.army.mil/education/toolkit.asp</a>. Clinics will receive a Smallpox Trifold for each dose of Smallpox that they order. All enclosures may be reproduced locally. The <a href="https://www.smallpox.army.mil/education/toolkit.asp">https://www.smallpox.army.mil/education/toolkit.asp</a>. Clinics will receive a Smallpox Trifold for each dose of Smallpox that they order. All enclosures may be reproduced locally. The <a href="https://www.smallpox.army.mil/education/toolkit.asp">https://www.smallpox.army.mil/education/toolkit.asp</a>. Clinics will receive a Smallpox Trifold for each dose of Smallpox that they order. All enclosures may be reproduced locally. The <a href="https://www.smallpox.army.mil/education/toolkit.asp">https://www.smallpox.army.mil/education/toolkit.asp</a>. Clinics will receive a Smallpox Trifold for each dose of Smallpox that they order. All enclosures may be reproduced form, contact the forms manager for additional forms.

Mark J. Tedesco /s/ Director of Health and Safety

# COMDTINST M6230.10

RECORD OF CHANGES									
CHANGE NUMBER	DATE OF CHANGE	DATE ENTERED	BY WHOM ENTERED						

# TABLE OF CONTENTS

CHA	PTER 1. SMALLPOX VACCINATION PROGRAM	1-1
A.	PURPOSE	1-1
B.	OVERVIEW	1-1
C.	POLICY	1-2
D.		1-3
E.	COORDINATING INSTRUCTIONS.	1-6
СНА	PTER 2. MEDICAL CONSIDERATION AND GUIDANCE	2-1
A.		2-1
B.	INDICATIONS AND USAGE.	2-1
C.	DOSAGE AND ADMINISTRATION.	2-1
D.	EXPECTED REACTIONS	2-2
E.	CLINICAL GUIDANCE REFERENCES.	2-2
F.	MEDICAL SCREENING BEFORE IMMUNIZATION.	2-2
G.	PREGNANCY SCREENING.	2-3
Н.	ADMINISTRATIVE EXEMPTIONS.	
I.	MEDICAL EXEMPTIONS.	2-4
J.	CLINICAL CONSULTATION RESOURCES.	2-7
K.	VACCINATION	2-7
L.	REVACCINATION	
M.	TIMING AND SPACING OF OTHER VACCINATIONS	2-9
N.	CARE OF THE VACCINATION SITE.	2-9
O.	ADVERSE-EVENT MANAGEMENT.	2-11
P.	BLOOD DONOR DEFERRAL	2-14
СНА	PTER 3. MEDICAL REPORTING	3-1
Α.		
B.	IMMUNIZATION TRACKING SYSTEM (ITS)	3-1
C.	REPORTING REQUIREMENTS.	
D.		
СНА	PTER 4. LOGISTICS	4-1
A.		
В.	GENERAL INFORMATION.	
C.	LOGISTICS OVERVIEW.	
D.	RESPONSIBILITIES.	
E.	ANCILLARY SUPPLIES.	
F		

# COMDTINST M6230.10

CHAI	TER 5. COMMUNICATIONS AND EDUCATION PLAN	5-1
A.	PURPOSE	5-1
	BACKGROUND.	
	OBJECTIVES	
	TALKING POINTS.	
	AUDIENCES.	
	RESPONSIBILITIES.	

# Enclosures:

- Treatment of Reserve Component Members Related To Immunizations
  Administrative and Medical Exemption Codes for MRS

#### CHAPTER 1. SMALLPOX VACCINATION PROGRAM

#### A. PURPOSE.

To establish policy, assign responsibilities, and prescribe procedures for the vaccination of Coast Guard active duty, reservists, assigned Public Health Service (PHS) personnel and mission-essential Coast Guard civilians against the biological warfare threat of smallpox.

#### B. OVERVIEW.

- 1. <u>DoD Immunization Program for Biological Warfare</u>. The Immunization Program for Biological Warfare Defense, DoD Directive 6205.3, prescribes DoD policy for the use of vaccines for biological defense. The smallpox vaccine meets each of the requirements outlined in this directive. The Secretary of Defense has designated the Secretary of the Army as the Executive Agent for the Program.
- 2. Program Executive Office for Chemical and Biological Defense (PEOCBD). Unlike vaccines used for preventive medicine, vaccines used specifically for biological defense are controlled by the congressionally established Program Executive Office for Chemical and Biological Defense (PEOCBD) formerly Joint Program Office for Biological Defense (JPO-BD). The PEOCBD procures and maintains adequate stockpiles of vaccines and defined production capabilities for all Services. The PEOCBD also controls the funds allocated for research, development, and acquisition of these vaccines and funds the force vaccine supply.
- 3. <u>Smallpox Vaccine</u>. The smallpox (vaccinia) vaccine, ACAM2000<sup>TM</sup>, hereafter referred to as "smallpox vaccine," is licensed and approved by the Food and Drug Administration (FDA). ACAM2000<sup>TM</sup> is indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection. The smallpox vaccine is a live vaccinia virus derived from plague purification cloning from Dryvax and grown in African Green Monkey kidney (Vero) cells. The smallpox vaccine does not contain smallpox virus (variola) and cannot spread or cause smallpox. Smallpox vaccine will be administered in the standard full-strength concentration (as per original labeled reconstitution instructions), unless the Centers for Disease Control and Prevention (CDC), FDA, or other responsible health authority issues explicit instructions to contrary. Chapter 2 of this Manual details vaccine dosing and medical considerations pertaining to smallpox vaccination. Dryvax® vaccine should no longer be used.
- 4. <u>MLC's Responsibilities</u>. MLC is responsible for program oversight to ensure that clinics have the tools, instructions and training to implement this program.
- 5. <u>Commanding Officers responsibilities</u>. Commanding Officers are responsible for ensuring members are compliant with this program.
- 6. <u>Coast Guard clinics/sickbays responsibilities</u>. Coast Guard clinics/sickbays have full responsibility for implementing and tracking members who qualify for participation in the Coast Guard SVP.

#### C. POLICY.

- 1. Mandatory Vaccination.
  - a. The SVP is a mandatory program for Coast Guard Active Duty, SELRES members and PHS Officers (unless medically or administratively exempted) assigned to the following units / positions:

Activities Europe / Far East Activities	Healthcare workers (CG & PHS officers,
	Health Services Technicians (HS) and Medical
	Administrative personnel)
Afloat Units	Harbor Defense Command Units
Air Stations	Loran Stations
Container Inspection Training & Assistance	NESU / ESU
Team	
Deployable Operations Group (DOG)	Sectors (including but not limited to: Aids to
	Navigation Teams, Vessel Traffic Services,
	Small Boat Stations)
Environmental Health Officers	Training Centers (including but not limited to:
	Students, Faculty, Cadets, Recruits, OCS
	students, ROCI students, DCO students, the
	USCG Band)

- b. Civilians. The SVP is a mandatory program for Coast Guard civilian personnel whose duties classify them as rapid deployment in support of Coast Guard operations in higher threat areas. These civilians shall be vaccinated upon notification for deployment to a higher threat area. The effect on a civilian employee, who refuses immunization, when indicated, will be determined by the supervisor and commander in conjunction with representatives from the Civilian Personnel Office. For the purposes of the Coast Guard SVP, higher threat area does not include the potential for smallpox used in acts of terrorism against noncombatants, to include family members in higher threat areas. The Coast Guard SVP does not apply to family members.
- c. This vaccine is a required immunization unless medically exempted (e.g., for pregnancy) by competent medical authority or administratively exempted by command authority. The MLC (k) is available to assist field medical staff with further medical evaluation when members refuse vaccination.
  - (1) If a member refuses vaccination, he or she remains deployable.
  - (2) Refusal to be vaccinated, or failure to comply with a lawful order to be vaccinated is a violation of Coast Guard Regulations, COMDTINST M5000.3 (series), Chapter 8, section 8-2-1.A (21) and Article 92 of the Uniform Code of Military Justice (UCMJ). Any member who refuses to be vaccinated or fails to comply with a lawful order to be vaccinated is subject to disciplinary

proceedings under the UCMJ or other appropriate administrative proceedings at the unit commander's discretion.

- 2. <u>Availability</u>. Vaccines will only be available at clinics that have been authorized by the MILVAX Agency to administer the smallpox vaccine.
- 3. <u>Supplies</u>. United States Army Medical Material Agency (USAMMA) will coordinate with the PEOCBD to ensure adequacy of vaccine supplies and the distribution to all Services. Commandant (CG-1121) will provide total Coast Guard vaccine requirements to USAMMA. Chapter 4 provides detailed logistics information.
- 4. <u>Mandatory readiness initiative</u>. This is a mandatory readiness initiative. Unless specifically exempted by the commanding officer or by competent medical authority (detailed below and in Chapter 2), all Coast Guard military personnel affected are required to receive the smallpox vaccine.
- 5. Responsibilities. Commanders, MLC will direct MLC (k) to assist with developing, maintaining, and monitoring implementation plans. Unit commanders will ensure implementation and maintenance of the Coast Guard SVP within their units. Coast Guard Health Services personnel will coordinate and facilitate immunization of Coast Guard personnel using Medical Readiness System (MRS) / Medical Readiness Reporting System (MRRS) (Chapter 4). Personnel in the Coast Guard SVP are authorized to receive their smallpox immunization from DoD Medical Treatment Facilities (MTFs) if unable to obtain through Coast Guard medical facilities. Coast Guard clinics/sickbays will follow the Coast Guard SVP Education and Communications programs provided in Chapter 5.
- 6. <u>Record keeping</u>. Medical record keeping (including reporting certain adverse reactions) will be maintained to document immunizations in accordance with Chapter 3 of this Manual
- 7. <u>Distribution</u>. USAMMA will coordinate the distribution of the vaccine to the supporting medical supply activities for all Services. Commandant (CG-1121) will serve as Coast Guard Liaison with USAMMA. Units will furnish vaccine requirements to the supporting Health Services Clinic. Clinics will order through MLC(k) via Commandant (CG-1121) to USAMMA (see Chapter 4).

#### D. RESPONSIBILITIES.

- 1. <u>Commandant (CG-1121)</u>.
  - a. Develop and disseminate medical education, information, policy, and doctrine to the MLC (k)s as required in accordance with the Coast Guard SVP.
  - b. Provide consolidated reports of adverse reactions to the Army Executive Agent in accordance with Chapter 4. Commandant (CG-1121) obtains copies of Vaccine

- Adverse Events Reporting System (VAERS) reports via the mechanism identified in Chapter 7 of the Medical Manual, COMDTINST M6000.1(series).
- c. Function as liaison between MLC(k)s and USAMMA to procure vaccine supplies for the Coast Guard.
- d. Provide timely notification to MLC (k)s regarding any changes to designated units or individual mobilizations to high threat areas. This notification will be classified.
- 2. Commanders, Maintenance and Logistics Commands shall ensure the MLC (k)s.
  - a. Coordinate with USAMMA through Commandant (CG-1121) and other appropriate vendors to ensure sufficient vaccines and ancillary supplies are available to units conducting immunizations in accordance with Chapters 2 and 3 of this Manual.
  - b. Post educational briefing materials on the smallpox vaccination program on the MLC website located at CG Central>Organizational Information>MLCA Divisions or (MLCP Divisions) >Health and Safety>KOM. This information is also provided through the DoD website: <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>.
  - c. Post educational briefing materials for Coast Guard medical officers on the MLC website located at CGCENTRAL>Organizational Information> MLCA Divisions or (MLCP Divisions) >Health and Safety>KOM. This information is also provided through the DoD website: <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>.
- 3. <u>Coast Guard clinics and sickbays</u>. Coast Guard clinics and sickbays that have been authorized by the MILVAX Agency to administer the smallpox vaccine shall:
  - a. Have full responsibility for implementing the SVP and tracking members in the SVP. The clinic should use MRS / MRRS for tracking purposes.
  - b. Provide support to the Commandant's immunization plans for all Coast Guard Personnel (Active Duty, Selected Reserve and others) as required to support the Coast Guard SVP.
  - c. Provide educational briefing materials on the smallpox vaccination program to required personnel (those individuals receiving the vaccine). An approved briefing package will be posted on the MLC (k) website, and is also located at the DoD website <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>. The slide presentation on the MILVAX website is a highly recommended tool to use for educating patients.
  - d. Complete registry agreement with MILVAX in order to participate in the SVP to order and administer smallpox vaccine. The registry agreement and checklist are available at <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>.
  - e. Coordinate the immunization of Coast Guard personnel at Coast Guard clinics/sickbays, DoD MTFs/sickbays and/or Coast Guard unit facilities and ensure data entry is completed.

- f. Provide immunizations to personnel from other Services who are enrolled in the DoD SVP in accordance with the Office of the Assistant Secretary of Defense, Health Affairs (OASD(HA)) guidance. On rare occasions, a member of a DoD service may need to begin the SVP through a Coast Guard facility. This should be coordinated in advance with the appropriate MLC (k).
- g. Ensure personnel receiving the smallpox vaccine have been educated about the SVP. Prior to initial immunization, ensure that personnel are provided the Smallpox Trifold Brochure (this brochure can be downloaded from the following web site <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>) with specific information regarding the vaccine, its safety, benefits, and the need for adherence to the immunization schedule (i.e. revaccination every 10 years). The provision of this information will be documented by health services personnel on the Modified SF 600, Chronological Record of Care Smallpox Vaccination Initial Note (block 8). This form can be accessed through the following web site: <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>
- h. Meet the medical reporting requirements noted in Chapter 3 of this Manual.

#### 4. Privileged Health Care Providers.

- a. Must be onsite when the smallpox vaccination is given.
- b. Must provide counseling (one on one or in a group setting) to personnel receiving the smallpox vaccination.
- c. Must review and sign the appropriate smallpox SF 600 overprint (e.g. Initial Note, Routine Follow Up Note).
- d. Must grant medical exemptions per Chapter 2 of this instruction. Only physicians can evaluate patients for religious exemptions see reference (a). Record all exemptions in MRS / MRRS and in the health record on the SF-600.

#### 5. Unit Commanding Officers.

- a. Have the ultimate responsibility to ensure their personnel meet the standards of this instruction.
- b. Determine smallpox vaccine needs on a monthly basis, at least 30 days in advance, and coordinate with the cognizant medical Point of Contact (POC) to ensure that personnel are to be immunized on schedule (e.g. revaccination every 10 years) (Chapters 3 and 4).
- c. Ensure all assigned service members are available for smallpox vaccination in accordance with this instruction.
- d. Ensure all assigned service members reported as overdue for vaccination (as reported from the Coast Guard clinic/sickbay) receive or have received the smallpox vaccination. If overdue reports are incorrect, the clinics/sickbays must update the correct information in the MRS / MRRS (see Chapter 3). If there is an

ongoing issue regarding non-compliance, the clinic should contact the command to discuss the unit's or member's non-compliance.

#### 6. Service Members.

- a. Read and take all steps necessary to understand the Trifold brochure, "What You Need to Know about Smallpox Vaccine".
- b. Report to appropriate Coast Guard clinic, sickbay, Uniformed Services Medical Treatment Facilities (USMTF), or other designated facility for the smallpox vaccination and follow up evaluation.
- c. Report adverse reactions to the appropriate Coast Guard clinic/sickbay or MTF.

#### E. COORDINATING INSTRUCTIONS.

- 1. <u>USMTFs</u>. Direct coordination with USMTFs to complete unit or individual immunizations is authorized.
- 2. <u>U.S. Army Medical Materiel Agency (USAMMA)</u>. MLC (k)s will coordinate with USAMMA through Commandant (CG-1121) for vaccine supplies to be sent to appropriate Coast Guard clinics.

#### CHAPTER 2. MEDICAL CONSIDERATION AND GUIDANCE

#### A. VACCINE CHARACTERISTICS.

- 1. <u>Vaccine Description</u>. The smallpox vaccine is lyophilized powder reconstituted with packaged diluent. After reconstitution, each vial has approximately 100 doses of 0.0025 mL of live vaccinia virus containing 2.5 − 12.5 10<sup>5</sup> plaque forming units. The vaccine contains a small amount of neomycin and polymyxin. ACAM2000<sup>TM</sup> is reconstituted by adding 0.3 mL of diluent to the vial containing lyophilized vaccine. The vaccine should only be reconstituted with 0.3 mL of the diluent provided. The bottle of diluent supplied with the smallpox vaccine contains more liquid than is needed to reconstitute the vaccine. Clinic personnel must make sure to use the correct (0.3 mL) amount and prevent over pressurizing the vaccine vial with too much volume.
- 2. <u>Vaccine Reconstitution</u>. The vaccine vial should be removed from cold storage and brought to room temperature before reconstitution. Reconstituted vial should be inspected visually for particulate matter and discoloration prior to administration. If particulate matter or discoloration is observed, the vaccine should not be used and the vials should be disposed of safely.

### B. INDICATIONS AND USAGE.

ACAM2000<sup>TM</sup> is indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.

#### C. DOSAGE AND ADMINISTRATION.

- 1. <u>Dosage</u>. The vaccine is administered in one dose. Inoculate the recipients with a bifurcated needle holding one drop of vaccine. 15 punctures for primary and for revaccination. Evidence of a prior primary smallpox vaccination includes medical record documentation, or a characteristic Jennerian scar. Presumptive evidence includes entry into U.S military service before 1984, or birth in the United States before 1970. People vaccinated with the smallpox vaccine in the past 10 years do not require revaccination, except specific laboratory workers involved with orthopox virus research, who may require more frequent vaccination. Refer to the following web site: <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a> for detailed instruction on dosage and administration.
- 2. Administration. The bifurcated needle method is indicated for this vaccine. The site of vaccination is the upper arm over the insertion of the deltoid muscle. Other optional sites are described in the vaccine package insert located at the following web site: <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>. As always, appropriate clinical judgment is warranted. No skin preparation should be performed unless the skin at the intended site of vaccination is obviously dirty, in which case an alcohol swab may be used to clean the area. If alcohol is used, the skin must be allowed to dry thoroughly to prevent inactivation of the live vaccine virus by the alcohol. Do not vaccinate near the site of an active skin lesion or rash. Tattooed skin is not a contraindication for site

selection but should be considered where evaluation of a take may be impaired. Avoid skin folds where drying is impeded. Any skin condition that may interfere with the immune response to vaccination should be carefully evaluated before vaccination. Refer to the following web site <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>.

#### D. <u>EXPECTED REACTIONS</u>.

- 1. <u>Response</u>. In a nonimmune person who is not immunosuppressed, the expected response to primary vaccination is the development of a papule at the site of vaccination 2-5 days after administration. The papule becomes vesicular; the pustule reaches it maximum size in 8-10 days. The pustule dries and forms a scab, which separates in 14-21 days after vaccination, leaving a scar.
- 2. <u>Reaction</u>. Vaccination can produce swelling and tenderness of the regional lymph nodes. Fever, eythematous, or urticarial rashes can occur.
  - a. If a person does not manifest a characteristic vaccination reaction 6 to 8 days after the smallpox vaccination, that person should receive a single revaccination with 15 punctures (jabs) at a separate site. Individuals previously vaccinated, especially if they have received multiple doses, may not respond to smallpox vaccine because of current immunity.
  - b. Revaccination should not be repeated more than once in the short term. People previously vaccinated who do not respond with a visible skin lesion after two attempts should be considered medically immune. Others should be referred for immunologic evaluation.

#### E. CLINICAL GUIDANCE REFERENCES.

- 1. <u>Centers for Disease Control Guidance</u>. Health care workers must follow the guidance in the vaccine package insert (particularly for information on contraindications to vaccination) and guidance from the CDC, which formally publishes recommendations from the Advisory Committee for Immunization Practice (ACIP), for the administration of vaccines unless superseded by Coast Guard or DoD policy.
- 2. <u>DoD Guidance</u>. DoD clinical policy is defined in the ASD (HA) memo, "Clinical Policy for the DoD Smallpox Vaccination Program (SVP)", which will be released on the following web site: <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>.

#### F. MEDICAL SCREENING BEFORE IMMUNIZATION.

1. Medical Screening. Medical screening before vaccination for contraindications in vaccine recipients and their household contacts is essential to prevent serious complications. Contraindications will be documented in the medical record and MRS / MRRS. Screening must be conducted in a manner that Service Members can freely ask questions and get reliable answers (One on one or in a group setting). The standard of practice for all immunizations includes medical screening before immunization. Unique for smallpox vaccine is the need to screen for risks among household contacts. Education and screening shall be conducted to document medical conditions for which

immunization exemption (temporary or permanent) or further medical evaluation before immunization is indicated. Standardized screening tools and follow up questionnaires are provided on the following web site:

http://www.smallpox.army.mil/education/toolkit.asp.

2. Human Immunodeficiency Virus (HIV) Screening. Infection with HIV is a contraindication to smallpox vaccination. Service members will be up-to-date in accordance with HIV screening policies before a smallpox vaccination is given. Service members who are concerned that they could have a HIV infection may request additional HIV testing. DoD / Coast Guard, civilian employees and contractors to be vaccinated against smallpox will be offered HIV testing in a confidential setting, with results communicated to the potential vaccinee before vaccination. HIV testing is recommended for anyone who has a history of a risk factor for HIV infection, especially since his or her last HIV test, and who is not sure of his or her HIV-infection status. Because known risk factors cannot be identified for some people infected with HIV, people concerned that they could be infected should be tested.

#### G. PREGNANCY SCREENING.

- 1. <u>Deferral Requirements</u>. Defer smallpox vaccinations until after pregnancy, except in emergencies where personal benefit from vaccination outweighs the risks. During a smallpox outbreak, pregnant women with a high risk exposure to smallpox may be vaccinated because the benefits of vaccination would outweigh its risks.
- 2. <u>Fetal Vaccinia</u>. On rare occasions, typically after primary (first) vaccination, vaccinia virus has been reported to cause fetal vaccinia infection. Fetal vaccinia usually results in stillbirth or death of the infant shortly after delivery. Since the inception of the DoD smallpox vaccination program there have been no reported cases of fetal vaccinia. Vaccinia vaccine is not known to cause congenital malformations.
- 3. Pregnancy Precautions. All immunization clinics will display in a prominent place a written warning against unintentionally vaccinating pregnant women. This warning must be visible during the screening process. Women of childbearing potential are to be questioned / screened for pregnancy before receiving immunizations. Women who are uncertain about pregnancy status shall be medically evaluated for pregnancy before immunization. Because the requirement for smallpox vaccination is based largely on occupational risk, defer vaccination for pregnant women at least until the resumption of full duties following pregnancy, or later as postpartum care may require. In addition, all women receiving a smallpox vaccination will be instructed to avoid becoming pregnant for at least four weeks after their smallpox vaccination. All cases of pregnant women being inadvertently vaccinated will be referred to the DoD Smallpox Vaccine Pregnancy Registry at the Naval Health Research Center (NHRC) San Diego, CA. <a href="http://www.smallpox.mil/event/pregnancy.asp">http://www.smallpox.mil/event/pregnancy.asp</a> or Tel (619) 553-9255.

#### H. ADMINISTRATIVE EXEMPTIONS.

- 1. <u>Administrative exemptions</u>. Administrative exemptions (Enclosure 2) from smallpox vaccination are authorized for personnel by the individual's unit commanding officer for the following reasons:
  - a. Missing in action or prisoner of war status.
  - b. Pending administrative or disciplinary actions due to vaccine refusal.
  - c. Absent without leave or imprisonment.
  - d. While in transit on a permanent change of station move.
  - e. Temporary duty or other extended absences from home station exceeding 30 days.
  - f. Legal discharge, separation, resignation or retirement. Commanding Officers may exempt personnel who are separating from the Coast Guard and are not on duty status in a Joint Staff designated higher threat area from the Coast Guard SVP scheduling as indicated:
    - (1) Retiring Personnel. Service members who are retiring are exempt from the Coast Guard SVP no more than 180 days prior to their approved date of retirement or upon receipt of retirement orders, whichever occurs first.
    - (2) Separating Personnel. Service members who are separating from service may be exempt from the Coast Guard SVP no more than 180 days before their approved date of separation.
    - (3) Coast Guard civilian personnel whose duties classify them as having status equivalent to deployable forces in support of Coast Guard operations in higher threat areas who are resigning from service and are not on duty status in a Joint Staff designated higher threat area may be exempt from the Coast Guard SVP scheduling as indicated:
      - (a) Retiring Personnel. Coast Guard civilians who are retiring are exempt from the Coast Guard SVP no more than 180 days before the date reflected on their retirement papers.
      - (b) Resigning Personnel. Coast Guard civilians who are resigning from service may be exempt from the Coast Guard SVP upon receipt of a signed resignation with an effective date no more than 180 days.
- 2. <u>Reassigned/Transferred Personnel</u>. Coast Guard civilians who are being reassigned to a non-mission-essential position within Coast Guard or who are transferring to a non-Coast Guard agency will be exempt from the Coast Guard SVP upon presentation of evidence verifying their transfer/reassignment.

#### I. MEDICAL EXEMPTIONS.

1. <u>General Information</u>. Some individuals will have either acute or chronic pre-existing conditions that may warrant medical exemption from smallpox vaccination. In some cases, vaccination should be withheld if the individual cannot avoid household contact with another person with contraindicating conditions. Furthermore, a small proportion

of individuals will develop a more serious reaction after vaccination that may warrant medical exemptions, temporary and permanent, from further smallpox vaccination.

- a. In a smallpox emergency, there are no absolute contraindications to vaccinating people with a high-risk exposure to an infectious case of smallpox (e.g., face-to-face contact). Prior contraindications to vaccination could be overshadowed by personal risk of smallpox disease. Smallpox vaccine would be made available for people exempted during pre-outbreak vaccination programs. People at greatest risk for experiencing serious vaccination complications are often those at greatest risk for death from smallpox. If a relative contraindication to vaccination exists, the risk for experiencing serious vaccination complications must be individually weighed against the risks for experiencing a potentially fatal smallpox infection.
- b. Granting medical exemptions is a medical function performed by a privileged healthcare provider. The provider will grant individual exemptions when medically warranted, with the overall health and welfare of the patient clearly in mind, balancing potential benefits with the risks while taking into consideration the threat situation. Medical exemptions are not based on preferences of the prospective vaccinee for or against vaccinations.
- 2. <u>Temporary and Permanent Medical Exemptions</u>. The two most common annotated medical exemption categories are Medical Temporary (MT) and Medical Permanent (MP) (See Enclosure 2). Annotate the Service Member's records and MRS / MRRS with these codes, and update them as appropriate. In the event of a confirmed smallpox outbreak, permanent exemptions could be lifted, based on individual risk.

#### a. Temporary

- (1) People who have household contact with a person who has a contraindication to smallpox vaccination (e.g., immune-suppressed people, people with atopic dermatitis or eczema, pregnant women) shall either have alternative housing arrangements or be exempted from smallpox vaccination until the household-contact situation is no longer applicable. Avoidance of contact should continue for 30 days after vaccination and until the vaccine site is healed.
- (2) Military-unique berthing settings require similar precautions. Exempt individuals should be physically separated and exempt from duties that pose the likelihood of contact with potentially infectious materials (e.g., clothing, towels, linen) from recently vaccinated people. This separation will include not having the vaccine recipient share or alternate use of common sleeping space (e.g., cot, bunk, berth) with people with contraindications to vaccination.
- (3) Temporary medical exemptions are warranted when a provider has a concern about the safety of immunizations in people with certain clinical conditions. The vaccine's package insert contains examples of situations that warrant a temporary medical exemption (e.g., immune-suppressed people and pregnant women). The ACIP notes that people with acute, chronic, or exfoliative skin

- conditions (e.g., burns, impetigo, varicella zoster, herpes, psoriasis, severe or uncontrolled acne) may also be at higher risk for inadvertent inoculation and should not be vaccinated until the condition resolves or a provider affirms it is under maximal control.
- (4) In situations where a medical condition is being evaluated or treated, a temporary deferral of smallpox vaccination may be warranted, up to a maximum of 12 months. This would include significant vaccine-associated adverse events that are being evaluated or while awaiting specialist consultation. The attending physician will determine the deferral interval, based on individual clinical circumstances.

#### b. Permanent

- (1) Medical Permanent exemptions are generally warranted if the medical condition or adverse reaction is so severe or unremitting that the risk of subsequent immunization is not justified. In the case of smallpox vaccine, these permanent exemptions could be lifted if the individual had face-to-face contact with someone contagious with smallpox. Examples of situations warranting a permanent medical exemption appear in the vaccine's package insert (e.g., life-threatening allergy to vaccine component, immune-suppressed people, people infected with human immunodeficiency virus, people with atopic dermatitis or eczema or a past history of those disorders). People with contraindicating skin conditions who received smallpox vaccine earlier in life may be revaccinated after medical consultation for individual risk-benefit decision making.
- (2) If a permanent medical exemption is indicated, follow reference (a) for granting such exemptions. If the situation changes, an appropriate medical specialist can remove a medical exemption.
- c. If an individual's clinical case is complex or not readily definable, healthcare providers should consult an appropriate medical specialist with vaccine safety-assessment expertise, before granting a permanent medical exemption. In addition, providers may consult with physicians in the Vaccine Healthcare Centers (VHC) Network, <a href="www.vhcinfo.org">www.vhcinfo.org</a>. In such cases, providers will document specialty consultation in the individual's health record, including the considerations and reasons why a temporary or permanent medical exemption is or is not granted.
- 3. Exemption Referral. An individual who disagrees with a provider's recommendation regarding an exemption may request a referral for a second opinion. In such cases, the individual will be referred to a provider experienced in vaccine adverse-event management who has not been involved in the decision-making to this point. This provider may be at the same facility or, when applicable, at a referral facility. If the patient disagrees with the second opinion, he or she may be referred directly to the VHC Network. Medical commanders retain authority to review all appealed exemption determinations and may delegate this authority to individuals with appropriate expertise within their organization.

4. Specialty Consult. Each clinic administrator will assist people in obtaining appropriate specialty consultations expeditiously and in resolving patient difficulties. Specialists may grant permanent medical exemptions. Return of the patient to his or her primary-care provider is not required if the referring specialist deems a permanent medical exemption is warranted. A Vaccine Adverse Event Reporting System (VAERS) report should be filed for any permanent medical exemption due to a vaccine related adverse event.

#### J. CLINICAL CONSULTATION RESOURCES.

If providers have questions about contraindications, the need for an exemption, adverse events after vaccination or possible contact transfer, they can contact the DoD Vaccine Healthcare Centers at 202-782-0411, <a href="www.vhcinfo.org">www.vhcinfo.org</a>. They can also contact the DoD Vaccine Clinical Call Center 24 hours a day, 7 days a week. That number is 1-866-210-6469.

#### K. VACCINATION.

- 1. Who Administers Smallpox? Only appropriately trained and qualified medical personnel, upon the order of an appropriately privileged health care provider, will administer smallpox vaccine. People who administer smallpox vaccine must be vaccinated themselves. While it is not a contraindication, pregnant females with a current smallpox status are discouraged from administering the smallpox vaccine. The preference to vaccinate smallpox vaccinators is based on the risk of inadvertent inoculation from repetitive handling of the vaccine. People may administer smallpox vaccine within one day after being vaccinated.
- 2. <u>Procedures.</u> Smallpox vaccination shall consist of 15 punctures (jabs) with a bifurcated needle for a primary (first) vaccination and for revaccination, see package insert. People vaccinated with smallpox vaccine in the past 10 years do not require revaccination, except specific laboratory workers involved with orthopox virus research, who may require more frequent vaccination.
  - a. The Chief Health Services Division (CHSD) will use standardized materials to train smallpox vaccinators. The CHSD will assess vaccination technique by evaluating the vaccination take rates among the first cohort of people (e.g., 50 to 100) vaccinated by each vaccinator. Published studies found take rates > 95% with appropriate technique.
  - b. The CHSD will assure that proper screening of vaccine recipients occurs before vaccination. Access to providers experienced in benefit-risk assessment will be made available to vaccine recipients and vaccinators. The CHSD will facilitate prompt evaluation of vaccine recipients with adverse events or side effects that interfere with the ability to work. The DoD's Clinical Guidelines "Guide for Managing Adverse Events After Vaccination" was created to help medical personnel individually manage and document adverse events after vaccination. This document can be found under "Safety/Adverse Events" on the MILVAX

website (<a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>) or under "Providers", "Management of Adverse Events" on the VHC website at (<a href="https://www.vhcinfo.org">www.vhcinfo.org</a>).

#### 3. Take Assessment.

- a. Assessment of vaccine is required for health care workers and members of smallpox response teams who will travel into a smallpox outbreak area. Other persons receiving vaccine should also have vaccine take assessed. To assess vaccine take, medical personnel trained in vaccination evaluation will inspect the vaccination site at 6 to 8 days after vaccine administration. Reactions will be categorized as "Major Reaction" or "Equivocal" in accordance with the World Health Organization criteria see the following web site: <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>. To accommodate individuals for whom "take" assessment is not feasible, all persons receiving smallpox vaccine will be instructed to report to the vaccination clinic if they do not develop a characteristic smallpox vaccination reaction.
- b. Formation of a major cutaneous reaction by day six to eight is evidence of a successful 'take' and acquisition of protective immunity. An equivocal reaction is any reaction that is not a major reaction, and indicates a non-take due to impotent vaccine or inadequate vaccination technique. Individuals who are not successfully vaccinated (i.e. equivocal after primary vaccination) may be revaccinated in an attempt to achieve a satisfactory take. If a repeat vaccination is given and no visible cutaneous reaction is noted individuals should be referred for immunologic evaluation.
- c. Accurate documentation of both vaccination and take is required. Vaccination will be documented in the individual health record (Using the Modified SF 600 Routine Follow Up Note) and MRS / MRRS. In addition, vaccination take will be documented in individual health records immediately beneath the vaccination entry by writing the date of assessment and the type of reaction: Major Reaction or Equivocal.
- 4. <u>Informed consent</u>. Individual informed consent (as would be necessary for an investigational new drug) is not required for this FDA-licensed product. Vaccine recipients will be provided with educational materials, via the appropriate Smallpox Trifold Brochure on the vaccine's safety and benefits
- 5. Personal Protective Equipment. Persons administering vaccines will follow necessary precautions to minimize risk of spreading diseases. Because of the nature of the vaccine container and method of administration, personnel preparing and administering the vaccine should wear surgical or protective gloves and avoid contact of vaccine with skin, eyes, or mucous membranes. Special consideration should be observed while adding diluent to the vaccine vial to prevent spraying in the eyes. Gloves should be changed between patients.

6. <u>Aviation Personnel</u>. As with most other immunizations, aviation personnel are automatically grounded for 12 hours after receiving the smallpox vaccine/

#### L. REVACCINATION.

- 1. <u>Prior vaccination</u>. Prior vaccination may modify (reduce) the cutaneous response upon revaccination such that the absence of a cutaneous response does not necessarily indicate vaccination failure. If a previously vaccinated person does not manifest a characteristic vaccination reaction 6 to 8 days after smallpox vaccination, that person does not require revaccination in an attempt to elicit a cutaneous response.
- 2. <u>Revaccination</u>. Individuals should be revaccinated if more than 10 years have elapsed since the last smallpox vaccination. Persons at continued high risk of exposure to smallpox (e.g., research laboratory workers handling variola virus) should receive repeat ACAM2000 vaccinations every 3 years.

#### M. TIMING AND SPACING OF OTHER VACCINATIONS.

- 1. <u>Live Vaccine</u>. General recommendations from the ACIP accept administration of live and inactivated vaccines simultaneously or at any interval. The only major restriction to combining vaccinations is with multiple live-virus vaccines, which should either be given simultaneously or separated by 28 days or more. There are limited data evaluating the simultaneous administration of smallpox vaccine with other live-virus vaccines. It is desirable to separate varicella (chickenpox) and smallpox (vaccinia) vaccinations by 28 days, because of the potential to confuse attribution of lesions that may result in vaccine recipients.
- 2. Other Vaccines. ACAM2000™ may be administered concurrently with other common inactivated vaccines. The vaccine should not be administered simultaneously with other live viruses and should be separated from varicella (chickenpox) vaccinations by 28 days to limit potential to confuse attribution of lesions that may result in vaccine recipients. Do not administer other vaccines near the smallpox vaccination site. Needles should be discarded in labeled, puncture-proof "sharps" containers to prevent inadvertent needle stick injury or reuse.

#### N. CARE OF THE VACCINATION SITE.

#### 1. Caring for the vaccination site.

a. Vaccinia virus is present on the skin at the vaccination site up to 30 days after vaccination or until the site is healed. During that time, care must be taken to prevent spread of the virus to another area of the body or to another person by inadvertent contact. Disease transmission from intact scabs is unlikely, but high-risk individuals may be vulnerable to scab particles. The DoD's / Coast Guard's goal is to reduce this risk as much as possible.

- b. The most important measure to prevent inadvertent contact spread from smallpox vaccination sites is thorough hand washing (e.g., alcohol-based waterless antiseptic solution, soap and water) after contact with the vaccination site.
- c. To avoid secondary infection, commanders and other leaders will direct physical activities so that smallpox vaccination sites are not subject to undue pressure (likely to burst a pustule), rubbing, or immersion sufficiently prolonged to cause tissue breakdown or secondary infection. Activities that complicate vaccine site care and cleanliness should be avoided during the post-vaccination healing period. For example, clothing and load-bearing equipment will be arranged in a manner to avoid excessive pressure or rubbing at the vaccination site. Avoid contact sports, such as wrestling.
- d. Appropriate care should be taken to prevent the spread of vaccinia virus from the vaccination site. The following special precautions will be observed. The vaccination site must be completely covered with a semipermeable bandage. Keep site covered for 30 days or until the site is healed. Wearing clothing with sleeves covering the vaccination site and/or using a loose, porous bandage (e.g., standard Band-Aid®, a piece of gauze attached with adhesive or paper tape around each edge) to make a touch-resistant barrier can reduce the opportunity for contact transfer until the scab falls off on its own. The vaccinee should change the bandage every 1 to 3 days, as this will keep skin at the vaccination site intact and will minimize softening. Do not apply salves or ointments on the vaccination site.
- e. Used bandages along with the vaccination scab should be disposed of as biohazardous waste. If biohazardous waste receptacles are not available these items should be disposed in sealed plastic bags (e.g., Zip-Loc® bag) with a small amount of bleach. Clothing, towels, sheets, or other cloth materials that have had contact with the site can be decontaminated with routine laundering in hot water with detergent and/or bleach. Normal bathing can continue, but it is best to keep the vaccination site dry by using a waterproof bandage during bathing. Avoid rubbing the vaccination site.
- f. Close physical contact with infants less than one year of age should be minimized for 30 days after vaccination and the vaccine site is healed. If unable to avoid infant contact, wash hands before handling an infant (e.g., feeding, changing diapers) and ensure that the vaccination site is covered with a semipermeable bandage and clothing. It is preferable to have someone else handle the infant. Smallpox vaccine is not recommended for use with nursing mother under non-emergency conditions.
- g. Swimming required for training or official duties should continue. A water proof occlusive dressing (e.g. Tegaderm / Opsite) shall be used while swimming.
- 2. <u>Health care workers procedures</u>. Recently vaccinated healthcare workers should minimize contact with unvaccinated patients, particularly those with immunodeficiencies and those with current skin conditions, such as burns, impetigo, contact dermatitis, chickenpox, shingles, psoriasis, or uncontrolled acne. Contact with

the above individuals should be minimized for 30 days after vaccination or the vaccine site is healed. Even patients vaccinated in the past may be at increased risk due to current immunodeficiency. If contact with unvaccinated patients is essential and unavoidable, healthcare workers can continue to have contact with patients, including those with immunodeficiencies, as long as the vaccination site is well-covered and thorough hand-hygiene is maintained. In this setting, a more occlusive dressing might be appropriate. Semipermeable polyurethane dressings (e.g., Opsite®, Tegaderm®) are effective barriers to vaccinia and recombinant vaccinia viruses. However, exudate may accumulate beneath the dressing, and care must be taken to prevent viral contamination when the dressing is removed. In addition, accumulation of fluid beneath the dressing may increase tissue breakdown at the vaccination site. To prevent accumulation of exudates, cover the vaccination site with dry gauze, and then apply the dressing over the gauze. The dressing should be changed every one to three days (according to type of bandaging and amount of exudate), such as at the start or end of a duty shift. Military treatment facilities should develop plans for site-care stations, to monitor workers' vaccination sites, promote effective bandaging, and encourage hand hygiene. Wearing long-sleeve clothing can further reduce the risk for contact transfer. The most critical measure in preventing inadvertent contact spread is thorough hand-hygiene after changing the bandage or after any other contact with the vaccination site.

#### O. ADVERSE-EVENT MANAGEMENT.

1. <u>Side effects</u>. As with any vaccine, some individuals receiving smallpox vaccine will experience side effects or adverse events. Adults vaccinated for the first time may develop a clinical illness with injection-site inflammation, muscle aches, and fatigue, most often on days 8 to 9 after vaccination. This illness may interfere with work. In addition, smallpox vaccine exhibits a unique adverse-event profile including myocarditis and/or pericarditis, encephalitis, progressive vaccinia, eczema vaccinatum, and other serious conditions.

#### 2. Adverse effects.

- a. Ongoing evaluation of health outcomes among Armed Forces personnel indicates individuals vaccinated for smallpox are at higher risk for myocarditis and/or pericarditis than those not vaccinated. The CDC ACIP recommends exempting individuals with known cardiac condition(s) and persons with three or more known major cardiac risk factors. Personnel with the following cardiac conditions will be exempted: myocardial infarction, angina pectoris, cardiomyopathy, congestive heart failure, stroke, transient ischemic attacks, chest pain or shortness of breath with activity associated with a heart condition, other coronary artery disease, and other heart conditions under the care of a physician. Persons with any of the listed conditions should be exempted from smallpox vaccination.
- b. The following cardiac risk factors should be identified during pre-immunization processing: current cigarette smoking, hypertension, hypercholesterolemia, diabetes mellitus, and family history of heart disease in 1<sup>st</sup> degree relative with onset before age 50. Persons with three or more of the above referenced risk

factors should be exempted from receiving smallpox vaccine. Along with the ACIP, Health Affairs recommends that recent smallpox vaccine recipients who have a cardiac condition or three or more major cardiac risk factors be evaluated by a health care professional if they develop any symptoms of chest pain, shortness of breath, or other symptoms of heart disease. All people with heart disease or risk factors should receive the routine care recommended for persons with these conditions (see the following site for additional information <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>).

#### 3. Vaccine health care referral.

- a. All Coast Guard personnel who received their smallpox vaccine while in a duty status, with a clinically verified diagnosis of post-smallpox vaccine myopericarditis, will be enrolled in the central registry maintained by the VHC network and be followed for a minimum of 24 months from the date of initial diagnosis. Patient informed consent is not required as part of enrollment. Identified cases should be submitted to VAERS. Upon enrollment, VHC staff help ensure appropriate follow-up in coordination with the patient's case manager (www.vhcinfo.org). Those individuals requiring medical treatment/evaluation should be retained on Active Duty pending resolution of the medical condition or completion of the disability evaluation. Coordination with the Military Medical Support Office (1-888-MHS-MMSO) will be required to provide appropriate civilian medical follow up and payment arrangements for Reserve Component personnel.
- b. To support clinicians seeking multi-disciplinary consultation, the Military Vaccine (MILVAX) Agency established a 24/7 toll-free number for short-notice teleconferencing. Clinicians wishing to consult via this teleconference bridge with VHC staff and/or military cardiologists regarding optimal care should call the DoD Vaccine Clinical Call Center at (866) 210-6469. Additional consultative support is available via e-mail at ASKVHC@amedd.army.mil
- c. DoD Clinical Guidelines for Management of Adverse Events After Vaccination offers useful advice. These clinical guidelines are available at the MILVAX Agency web site at <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a> and at the VHC web site at <a href="http://www.smallpox.army.mil/education/toolkit.asp">www.vhcinfo.org</a>.
- d. Vaccinia Immune Globulin (VIG) is indicated for the treatment or modification of certain conditions induced by the smallpox vaccine. Consultation with a board-certified infectious-disease or allergy-immunology specialist is required prior to administration. The VHC Network will provide and coordinate professional consultation services to optimize clinical use of VIG, and then maintain a registry of patients treated with VIG. Long-distance consultations will be arranged via the VHC Network's Vaccine Clinical Call Center (866-210-6469). Infectious Disease (ID) or Allergy Immunologist (AI), in consultation with the VHC, and CDC physician, authorizes release of VIG. VIG is requested directly from the CDC by calling the CDC Director's Emergency Operation Center (DEOC) at (770) 488-

- 7100 and request to speak with the Division of Bioterrorism Preparedness and Response (DBPR) on-call person. The CDC is the release authority for VIG.
- 4. <u>Adverse event procedures</u>. Adverse reactions from DoD-directed immunizations are line-of-duty conditions.
  - a. Immunizations are provided as part of the DoD's Force Health Protection program. At the time of immunization, personnel are to be provided documentation that identifies date and location of immunization, general information on typical responses to vaccination, common and serious adverse events, location of the nearest military treatment facilities (MTFs), and the toll-free telephone number (1-888-MHS-MMSO) of the Military Medical Support Office (MMSO), in the event medical treatment is required from non-military treatment facilities. Emergency-essential DoD civilian employees and contractor personnel carrying out mission-essential services are entitled to the same treatment and necessary medical care as given to the Service Members. This includes follow-up and/or emergency medical treatment from the MTF or treatment from their personal healthcare providers or non-military treatment facilities for emergency medical care as a result of immunizations required by their DoD employment.
  - b. When a vaccine recipient presents at an MTF, expressing a belief that the condition for which treatment is sought is related to an immunization received during a period of duty, the person must be examined and provided necessary medical care. Once treatment has been rendered or the individual's emergent condition is stabilized, Line of Duty and/or Notice of Eligibility will be determined as soon as possible. Reserve Component members and their family members, who seek medical attention as a result of adverse reactions from DoD / Coast Guard directed immunizations should:
    - 1) Immediately seek medical attention if an emergency and contact MMSO and their command as soon as possible, or
    - 2) Contact MMSO and their unit command for referral to the nearest treatment facility and to ensure payment for care and entitlements.
  - c. In the case of emergency-essential civilian employees presenting to a military treatment facility or occupational health clinic, the initial assessment and any needed emergency care should be provided consistent with applicable occupational health program procedures. In the case of contractor personnel covered by the vaccination policy presenting to a military medical treatment facility or occupational health clinic, Secretarial-designee authority shall be used, consistent with applicable DoD / Coast Guard policy, to allow an initial assessment and needed emergency care. This policy will facilitate awareness by our medical professionals of adverse events and provide to the patient medical expertise regarding vaccine events not necessarily available in the civilian medical community. This use of Secretarial-designee authority does not change the overall responsibility of the contractor under workers' compensation program for all work-related illnesses, injuries, or disabilities.

d. A privileged healthcare provider and any specialists, as indicated, should immediately evaluate any vaccinee with a serious adverse event temporally associated with receiving smallpox vaccination.

## 5. Vaccine Adverse Event Reporting System (VAERS).

- a. VAERS reports shall be filed per the Medical Manual for those events resulting in hospital admission, lost duty time or work of 24 hours or more, adverse event suspected to result from contamination of a vaccine vial, or death. Further, healthcare providers are encouraged to report other adverse events that in the provider's professional judgment appear to be unexpected in nature or severity. This is to include autoinoculation (or inadvertent infections). In other situations in which the patient wishes a VAERS report to be submitted, the healthcare provider will work with the patient to submit one without regard to causal assessment. VAERS report forms may be obtained by accessing www.vaers.org or by calling 1-800-822-7967. The DoD / Coast Guard forwards all VAERS reports to the FDA and the CDC without restriction.
- b. Adverse-event management should be thoroughly documented in medical records. Precisely code smallpox vaccine medical encounters. A copy of the VAERS report will be filed in an individual's medical record after submitting the original form through DoD / Coast Guard reporting channels. Providers are encouraged to provide a copy of the VAERS report to the patient.

#### P. BLOOD DONOR DEFERRAL.

Because there is a significant donor deferral period associated with smallpox vaccination, it is critical that there is coordination with local military and civilian donor center collection schedules to reduce the impact on the readiness and availability of the military blood supply. Individuals who receive the vaccination and have no complications will be deferred from donating blood for 30 days after vaccination. Individuals with vaccine complications will be deferred for 14 days after all vaccine complications have completely resolved.

#### CHAPTER 3. MEDICAL REPORTING

#### A. PURPOSE.

The purpose is to ensure the success of the SVP by tracking Coast Guard personnel immunized with smallpox vaccine. An automated immunization tracking system is mandated by the Office of the Assistant Secretary of Defense, Health Affairs (OASD (HA)). Additionally, OASD (HA) has directed that all immunization data of military members be entered into the Defense Enrollment and Eligibility Reporting System (DEERS) database.

## B. IMMUNIZATION TRACKING SYSTEM (ITS).

MRS / MRRS is mandated as the immunization tracking system for smallpox vaccination for Coast Guard personnel receiving immunizations within the Coast Guard system. All Coast Guard medical facilities/personnel providing immunization services are required to be familiar with MRS / MRRS and its use. (The Coast Guard is transitioning to MRRS and SVP data will be captured in this data base when it becomes operational).

- 1. <u>Coast Guard members</u>. Coast Guard units having members (military or civilian) requiring initial or subsequent doses (e.g. revaccination every 10 years) of smallpox vaccine will ensure those members receive their vaccination from Coast Guard clinic / sickbays or DOD MTFs. Medical unit personnel will ensure the immunization data is entered into MRS / MRRS.
- 2. <u>DoD members</u>. DoD members may receive initial or subsequent doses of smallpox vaccine from a Coast Guard clinic/sickbay. For these non- Coast Guard service members, an entry will be made in MRRS. MRRS will transmit the immunization data to DEERS. (MRS is unable to accept entry of non-Coast Guard personnel data). An entry will also be made on a SF-600 overprint for entry into the DoD service member's medical record. The member must notify his or her medical readiness POC (e.g. corpsman) to ensure the immunization data in DEERS is uploaded into their service specific medical readiness system.
- 3. <u>Coast Guard members at DoD MTF</u>. The vaccination data for Coast Guard personnel vaccinated at DoD MTFs/sickbays will be entered into local service component tracking systems, all of which download to DEERS.

#### C. REPORTING REQUIREMENTS.

- Medical record. Documentation of all smallpox vaccinations must be made in the following locations in the Medical Record: the Immunization Record SF-601, Smallpox Vaccination Modified SF-600 and the Adult Preventive and Chronic Care Flow Sheet DD 2766.
- 2. MRS/MRRS Database. The MRS / MRRS database of immunizations provides a central location to provide command, unit, or individual immunization information. This feature will be particularly useful, in the absence of a paper copy of the immunization record, to determine which if a smallpox dose is due for an individual, to determine unit needs in advance, or to track unit compliance rates.
- 3. <u>PGUI/CHCS/AHLTA</u>. Document counseling and vaccination in PGUI/CHCS/AHLTA.

4. <u>Exemptions</u>. Exemptions (exceptions), both medical and administrative, will be recorded in the MRS/MRRS database. The proper codes to use may be found in Enclosure 1. Several exemptions are considered indefinite and no end date is entered in MRS. Any exemption that is not indefinite (e.g. Med, Temp) must have an exemption end date recorded in the database.

#### D. ADVERSE EVENTS REPORTING.

- 1. Where to enter data. Adverse events or reactions to immunizations must be entered into MRS / MRRS under comments section, as well as in the medical record with entries on the Smallpox Vaccination Modified SF-600, the Adult Preventive and Chronic Care Flow Sheet DD-2766, the Drug Sensitivity Sticker CG-5266 (if anaphylactic reaction has occurred).
- When to report a problem. All adverse vaccine reactions resulting in hospitalization or duty time lost (in excess of 24 hours), as well as due to suspected lot contamination, shall be reported on the VAERS-1 form (VAERS forms and information can also be obtained by calling 1-800-822-7967 or from the Web at: <a href="http://www.fda.gov/cber/vaers/vaers.htm">http://www.fda.gov/cber/vaers/vaers.htm</a>). Additionally, a VAERS report should be filed for any permanent medical exemption due to a vaccine related adverse event. Other reactions may be reported to VAERS, either by a health care provider or the vaccinated individual.
- 3. <u>Distribution of forms</u>. For VAERS-1 forms completed at Coast Guard units/facilities, the original is forwarded to the FDA. A copy of the completed VAERS form will be retained on file at the local command or unit and a copy shall be provided to Commandant (CG-1121). Commandant (CG-1121) will provide the Commander, U.S. Army Center for Health Promotion and Preventive Medicine, Aberdeen Proving Ground, MD 21010-5422, with copies of Coast Guard adverse event or reaction reports.
- 4. Report originators. Anyone may report a vaccine-associated event through VAERS to the FDA. Health care providers should assist in the completion and forwarding of a VAERS-1 form for any vaccine recipient desiring to complete one. Health care providers assisting in the VAERS process are not expected to determine the causality by the smallpox vaccine, but only establish that a temporal relationship exists between the immunization and the possible adverse reaction.

#### **CHAPTER 4. LOGISTICS**

#### A. PURPOSE.

To provide the logistics concept of operations for the SVP.

## B. GENERAL INFORMATION.

The following information on smallpox (vaccinia) vaccine is provided:

- 1. <u>Stock number</u>. NSN: 6505-01-559-0815 [The only lot number is VV04-003A), CVX = 75, MVX = BAH
- 2. Nomenclature. Smallpox Vaccine Vaccinia (ACAM2000™), Live with Diluent, syringes, and needles. DoD uses the same FDA approved vaccine that is maintained in the strategic national stockpile (SNS), therefore all DoD stock will have the "Strategic National Stockpile Use Only" printed on its label. The CDC unit of issue is package "pkg".
- 3. <u>Unit of Issue</u>. 100-dose vial with diluent, 100 bifurcated needles, and 1 tuberculin syringe for vaccine reconstitution
- 4. Shelf life. Prior to reconstitution, ACAM2000<sup>™</sup> vaccine retains a potency of 1.0 x 10<sup>8</sup> PFU or higher per dose for at least 18 months when stored at refrigerated temperatures of +2 to 8 C (36 to 46 F). After reconstitution, ACAM2000<sup>™</sup> may be administered during a 6 to 8 hour workday at room temperature (20 to 25 C, 68 to 77 F). Reconstituted ACAM2000<sup>™</sup> may be stored in a refrigerator (2 to 8 C, 36 to 46 F) no longer than 30 days, after which it should be discarded as biohazardous waste. The reconstituted vaccine can remain at room temperature for 6-8 hours each day for 30 days.
- 5. <u>Storage</u>. Unreconstituted ACAM2000<sup>TM</sup> will be distributed and stored at 2 to 8 C (36 to 46 F). Unreconstituted ACAM2000<sup>TM</sup> should not be exposed to room temperature conditions for more than 48 hours.
- 6. <u>Dosage</u>. 1 Drop administered via bifurcated needle per instructions in Chapter 2.
- 7. <u>Cost.</u> The smallpox vaccine will be provided through USAMMA at no cost to units. Ancillary supplies are the responsibility of the receiving activity. The current contract includes manufacturer distribution to first destination. Transportation will be conducted by a commercial freight forwarder for all destinations.

#### C. LOGISTICS OVERVIEW.

- 1. <u>Allocation and distribution</u>. The U.S. Army Medical Materiel Agency (USAMMA) will coordinate the allocation and distribution of the smallpox vaccine with the Military Vaccine Office.
- 2. <u>Funding</u>. The vaccine is centrally funded by the PEOCBD formerly JPO-BD. The vaccine is not a Defense Supply Center Philadelphia, stocked item; therefore, requisitions for the vaccine will be submitted off-line to United States Army Medical

- Materiel Agency (USAMMA). USAMMA has web-based ordering capability http://www.usamma.army.mil/vaccines/smallpox/index.cfm.
- 3. Requisition. When a requisition for the vaccine has been validated and approved by the Military Vaccine Office, USAMMA will forward the requisition to the National Pharmaceutical Stockpile. Vaccine will then be distributed to the requesting activity.

#### D. RESPONSIBILITIES.

- 1. Commandant (CG-1121). Commandant (CG-1121) function as liaison between the Coast Guard and USAMMA to determine changes to program and requirements and provide approval for orders from MLC (k)s.
- 2. Commander, MLC will ensure the MLC (k)s.
  - a. Ensure oversight of the Coast Guard SVP within area of responsibility.
  - b. Provide SVP reference information on the MLC (k) website.
  - c. Oversee logistics for the Coast Guard SVP
  - d. Submit to USAMMA, through Commandant (CG-1121), product requisitions that include:
    - (1) The number of vials to be released.
    - (2) Ship-to address. Note: Since commercial carriers will be used for United States and Puerto Rico delivery, specific building/room number, 2 POCs, and phone numbers must be provided for each shipment.
  - e. Requisitions will be emailed to Commandant (CG-1121) for approval and forwarding via email to USAMMA.
  - f. Notify USAMMA (copy to: Commandant (CG-1121) of any delays, discrepancies or problems with shipment. Coordinate with respective destination points the receipt date for appropriate, timely handling of each smallpox vaccination shipment. <a href="Note: Strict compliance with storage requirements">Note: Strict compliance with storage requirements (refrigeration) during transportation and upon receipt is imperative and must be stressed to all personnel in the logistics pipeline.</a>

#### 3. Coast Guard clinics/sickbays.

- a. Notify unit commanders of all service members reported as overdue for vaccine doses more than 30 days.
- b. Receive, store (refrigerate), and redistribute vaccine received for the Coast Guard SVP in accordance with smallpox vaccine cold-chain management guidelines outlined by USAMMA. Current storage and redistribution standard operating procedures can be found at <a href="http://www.usamma.army.mil/vaccines/smallpox/index.cfm">http://www.usamma.army.mil/vaccines/smallpox/index.cfm</a>. (See Cold Chain Management Process & Procedures/Packing Protocols on the left side of the web page).

- c. Have full responsibility for implementing the SVP and tracking members who qualify for participation in the Coast Guard SVP.
- d. Coordinate transfer of vaccine to units if they have storage and immunization capabilities.
- e. Coordinate the vaccination of personnel in units without storage and immunization capabilities. This may occur by scheduling immunizations at Coast Guard clinics/sickbays, DoD MTFs/sickbays or by coordinating to have immunizations given at an operational unit facility by a Coast Guard medical representative (e.g., Group HS, Clinic HS). Information may be obtained from the MLC (k) as to the location of DoD vaccination points that may be located near remote Coast Guard units.
- f. Provide vaccination services to DoD personnel presenting to Coast Guard medical facilities for scheduled smallpox shots. Personnel should have documentation verifying their need for a smallpox immunization (e.g. orders to deploy).

#### 4. Unit to be vaccinated.

- a. If capable of storing and administering vaccine: Receive and store (refrigerate) vaccine product. Immunize personnel in accordance with FDA immunization schedule (e.g. revaccinate every 10 years) for smallpox vaccine.
- b. If not capable of storing and administering vaccine: Coordinate with nearest Coast Guard medical facility or DoD MTF to have unit personnel scheduled for smallpox vaccination.

#### E. ANCILLARY SUPPLIES.

Order ancillary supplies (e.g. Cotton, isopropyl (alcohol pad), sponge gauze 2X3 inch (gauze)) via normal medical supply procedures. It is expected that resuscitative equipment will be in the immediate vicinity where immunizations are administered. A capability to administer immediate first aid and medical care in the event of an anaphylactic or other allergic reaction will exist at all immunization sites.

#### F. SUPPORTING EQUIPMENT.

Order supporting equipment (e.g. VaxiCool VaxiPac VaxiSafe, Endurotherm Box TempTale (temperature monitor)). via normal medical supply procedures. For additional information on VaxiCool go to the following web site: <a href="http://www.usamma.army.mil/vaccines/smallpox/index.cfm">http://www.usamma.army.mil/vaccines/smallpox/index.cfm</a> Note – VaxiCool must be tracked and returned to their original location for further use.

This page left blank

#### CHAPTER 5. COMMUNICATIONS AND EDUCATION PLAN

## A. PURPOSE.

The purpose is to disseminate Commandant's education and communications protocol and guidance for the Coast Guard SVP.

#### B. BACKGROUND.

The Coast Guard is a full participant in the SVP. Internal and external education programs and public affairs support is required.

- 1. <u>Gulf War-related illnesses</u>. Biological and chemical warfare countermeasures, including vaccines, have been perceived by some people as possible causes for health concerns of Gulf War veterans. Although no scientific evidence links the smallpox vaccination to Gulf War-related illnesses, these perceptions may cause some military members to ask to sign informed consent waivers before they receive the vaccine. Others may want the right to refuse vaccination without risk of reprisal.
- 2. <u>Refusal</u>. As with other vaccinations required by the military, service members may not refuse the smallpox vaccine. Informed consent for military personnel is not required for FDA-licensed immunizations. Coast Guard members who refuse vaccination may be subject to administrative or disciplinary action or both, at the discretion of the commander, for disobeying a lawful order.
- 3. Other Medical Conditions. Coast Guard personnel may also be concerned about how the smallpox vaccination affects their existing medical conditions. See Chapter 2 for contraindications and precautions.

#### C. OBJECTIVES.

Ensure full understanding and support of the Coast Guard SVP by Coast Guard personnel, their families, and the media by providing education and planning guidance to all Coast Guard commanders, unit senior leadership, Coast Guard public affairs officers and Coast Guard health services personnel. Objectives include:

- 1. <u>Information</u>. Inform all personnel that to immunize using smallpox vaccine is a necessary part of the plan to eliminate smallpox as a threat to U.S. forces at risk.
- 2. <u>Support</u>. Gain the support of Coast Guard personnel and their families for the vaccination of U.S. forces against smallpox.
- 3. <u>Threat reality</u>. Use this opportunity to inform the American public that biological warfare is a very real threat to our forces and mission readiness.

#### D. TALKING POINTS.

The following talking points will be emphasized:

- 1. Threats. Smallpox is deadly and would disrupt military missions.
  - a. Contagious. Smallpox is a disease that spreads quickly from one person to another.

- b. Dangerous. Smallpox has been feared for hundreds of years.
- c. Disruptive. A smallpox outbreak would significantly affect military readiness.
- 2. <u>Precautions</u>. Smallpox vaccine prevents smallpox, but requires very careful use.
  - a. The World Health Organization used smallpox vaccine to eradicate natural smallpox from the planet.
  - b. All vaccines cause side effects, but smallpox vaccine has unique features that require special handling.
  - c. Don't touch the smallpox vaccination site, so you don't spread virus somewhere else, either on your body or somebody else's.
  - d. Very rarely, smallpox vaccine can cause serious side effects.
  - e. Some people should not get smallpox vaccine, except under emergency situations.
  - f. The Defense Department and Coast Guard will use smallpox vaccine licensed by FDA, unless there is a smallpox outbreak. In an outbreak, the Defense Department and Coast Guard may use investigational supplies of vaccine that FDA permits to be used.
- 3. Our people. Preserving the health and safety of our people are our top concern.
  - a. Healthy service members complete their missions. Vaccines will keep you and your team healthy.
  - b. Vaccines have kept troops healthy since the days of George Washington
  - c. Vaccination offers a layer of protection, in addition to other measures, needed for certain members of the Armed Forces.
- 4. <u>National strategy</u>. The Coast Guard smallpox vaccination program is part of our national strategy to safeguard Americans against smallpox attack.
  - a. The Defense Department and Coast Guard are working with other federal departments to strengthen America's defenses against smallpox.
  - b. The government has been preparing for some time for the remote possibility of an outbreak of smallpox as an act of terror.

#### E. AUDIENCES.

Education and Public Affairs information will be targeted to the following audiences:

- 1. <u>Coast Guard personnel</u>. All Coast Guard personnel who will be vaccinated and their families (Regular, SELRES and others).
- 2. <u>Coast Guard civilian personnel</u>. Coast Guard civilian personnel who will be vaccinated and their families.
- 3. Coast Guard leadership.

4. Coast Guard Health Services personnel.

#### F. RESPONSIBILITIES.

- 1. Commandant (CG-0922).
  - a. Provide coverage of immunization program in internal Coast Guard media.
  - b. Provide communication tools about the immunization program to Coast Guard PAOs for their internal and external information needs.
  - c. Respond to media inquiries and assist Coast Guard district PAOs in responding to media queries.
  - d. Provide Commandant (CG-1121) any relevant information received from other sources.
  - e. Function as Coast Guard liaison to DoD public affairs offices and workgroups with regard to the Coast Guard SVP.
- 2. <u>Commandant (CG-0921)</u>. Coordinate response to congressional queries, as appropriate.
- 3. Commandant (CG-1121).
  - a. Maintain a liaison with SVP program managers in other Services, keeping current with the latest educational and communications information available.
  - b. Forward new information/briefings to the MLC (k)s for distribution to the appropriate audiences.
  - c. Refer media queries from outside the Coast Guard to CG-0922
  - d. Refer congressional queries and briefings to CG-0921
  - e. Make available, through the Coast Guard Headquarters Operational Medicine website and the MLC (k)s, briefings and other educational materials targeted to unit commanders, other senior leaders, medical officers and other Health Services personnel.
  - f. Provide MLC (k) and clinics with any new updates regarding side effects.
- 4. <u>MLC (k)</u>. MLC (k) will post SVP information for clinics/sickbays on their websites. Ensure that SVP information is posted on CG Central MLC (k) Operational Medicine website.

#### 5. Health Services Personnel.

- a. Be familiar with the SVP policies and resources by reviewing the SVP website at <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>. As with other vaccine immunization programs, experience shows that education is pivotal to program success and acceptance.
- b. Assist Commanding Officers in ensuring that all personnel mandated to receive this vaccine are provided an oral brief by medical personnel covering topics using the

Individual's Briefing at <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>. Briefers should emphasize: vaccination site care, frequent hand washing with soap and water to prevent autoinoculation and cross-inoculation, and frequent laundering of clothing and personal items (e.g., towels, sheets) in hot water and bleach. Every member eligible for the vaccine shall be provided the Smallpox Vaccine Trifold that can be found at <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>. The complete Trifold will include local information/contact numbers for the member in the event he/she experiences an adverse reaction.

- Ensure each member designated to receive the smallpox vaccine completes the Initial Medical Note used for screening for contraindications (SF-600), (located at http://www.smallpox.army.mil/resource/forms.asp) to determine vaccine eligibility. All personnel will be educated about smallpox and smallpox vaccination before vaccination. The ACAM2000-brand smallpox medication guide and the most current Department of Defense (DoD) version of the Smallpox Vaccine Trifold Brochure (available under "Education Toolkit" at http://www.smallpox.army.mil/education/toolkit.asp will be provided to vaccinees prior to vaccination. Educational materials provided shall address the rationale, contraindications, criteria for medical exemptions for Service Members or their household contacts, benefits, expected response at the vaccination site, side effects, risks to household contacts, vaccination-site care, and other medical information concerning the vaccine. Emphasize the importance of household contact information in determining vaccine eligibility. Members must have access to healthcare providers to answer any questions or concerns. Women will be questioned in as private setting as possible about whether there is any possibility that they are pregnant. An answer of yes or unsure requires a pregnancy test. If the test is negative, vaccination of the individual may proceed. All members being screened will have in their medical records documentation that their HIV test is upto-date per Coast Guard policy.
- d. Understand the clinical aspects of this vaccine and the potential for adverse events after vaccination. Know how to manage the spectrum of adverse events, including the requirements to submit a VAER. Be familiar with the smallpox website resources, especially the Health Care Provider's Briefing and Online Training located at <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>.
- e. Be designated in writing by the command as qualified to administer the smallpox vaccine. Personnel who attended the 4-day DoD Smallpox Preparedness Training Conference and the Hands-On Vaccination Training are eligible for certification to administer the vaccine without additional training. Other medical personnel who will be vaccinators may be so designated by the command after completing the 4-hour vaccinator training (at <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>). As a check on proper vaccination technique, CHSDs shall ensure that each vaccinator has a take rate above 90%. Commands can use the Initial Competency Assessment form found on <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a> to help document vaccine administration competency.

f. Find answers to all medical questions asked about the smallpox medical threat, vaccine and Coast Guard SVP. If necessary, contact Commandant (CG-1121) and MLC (k) personnel responsible for overseeing the Coast Guard SVP.

# 6. <u>Designated Medical Officer Advisors and Designated Supervising Medical Officers</u> will.

- a. Ensure that all HS personnel under their purview have been fully educated on the Coast Guard SVP.
- b. Be available to answer questions from HS personnel administering program at sites remote from Coast Guard clinics.
- c. Become familiar with relevant aspects of the SVP and the smallpox vaccine. They must read and be familiar within the information from the smallpox vaccine product insert and be familiar with the medical officer's briefing. Medical personnel, as subject matter experts, will assist commanders with required unit briefings whenever possible.
- d. Review responsibilities in Chapter 2 of this instruction.
- e. Healthcare providers will remain alert to modifications in clinical recommendations as the smallpox vaccination program continues. Personnel involved in this program should regularly review the following websites for new clinical information and educational resources: Military Vaccine (MILVAX) Agency website at <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>, the Vaccine Health Centers (VHC) Network at <a href="www.vhcinfo.org">www.vhcinfo.org</a> and the Centers for Disease Control and Preventions (CDC) at <a href="www.bt.cdc.gov/agent/smallpox">www.bt.cdc.gov/agent/smallpox</a>. However, nothing in this memorandum will be superseded except by subsequent memoranda from the Assistant Secretary of Defense (Health Affairs).

## 7. Commanding officers of units receiving vaccine administration will.

- a. Ensure that medical personnel providing the immunization services have reviewed the medical officers briefing.
- b. Ensure that they and other senior leadership of units receiving the vaccine have reviewed the information provided in the Leaders' briefing at <a href="http://www.smallpox.army.mil/education/toolkit.asp">http://www.smallpox.army.mil/education/toolkit.asp</a>.
- c. Ensure that personnel receiving the vaccine are afforded the opportunity to review the Smallpox Vaccination Trifold.
- d. Ensure that personnel receiving the vaccination are given the opportunity to ask questions about the vaccine and its administration.
- e. Ensure reservists, both those who are assigned permanently and those assigned temporarily, that they may seek medical care if they have an adverse reaction to any immunization (See Enclosure 2).
- 8. <u>Additional Guidance</u>. Additional information for commanders and medical personnel. There is a significant amount of misleading and inflammatory misinformation

circulating in the media and on the Internet regarding the SVP and the vaccine. Accurate information can be found on the web at: www.vaccines.army.mil.

- a. Privacy. Unintended disclosure of PII constitutes a privacy incident. Personnel shall immediately report suspected or confirmed privacy incidents to the unit Commanding Officer upon discovery in accordance with reference (b).
- b. This instruction does not have any requirements for individuals to send PII via email. If an e-mail is generated containing PII information add the following statement: (This message contains PII and shall only be forwarded to personnel who are authorized and have the need to see it. If you feel you have received this information in error, notify the originator so appropriate action may be taken. DO NOT REPLY TO ALL)

# **Medical Exemption Codes**

Code	Meaning	Explanation or Example	Duration
MA	Medical Assumed	Prior immunization reasonably inferred from individual's past experiences (for example, basic military training), but documentation is missing. Code used to avoid superfluous immunization. Code can be reversed upon further review.	Indefinite
MI	Medical, Immune	Evidence of immunity. For smallpox, documented infection (indefinite exemption) or documented confirmed "take" in medical records within the past 10 years.	Up to 10 years
MR	Medical, Reactive	Permanent restriction from receiving additional doses of smallpox vaccine. Severe adverse reaction after immunization (e.g., anaphylaxis). File VAERS report.	Indefinite
МТ	Medical, Temporary	Pregnancy, hospitalization, temporary immune suppression, convalescent leave, pending medical evaluation board, events referred for medical consultation, any temporary contraindication to immunization, (e.g., smallpox vaccine and household-contact situation).	Up to 365 days
MP	Medical, Permanent	HIV infection, atopic dermatitis, certain cardiac conditions, prolonged or permanent immune suppression, other condition determined by physician. Can be reversed if the condition changes.	Indefinite
MD	Medical, Declined	Declination of optional vaccines (not applicable to many military vaccinations), religious waivers.*	Indefinite
MS	Medical, Supply	Exempt due to lack of vaccine supply.	Indefinite

<sup>\*</sup>Religious waivers are administrative exemptions, however for MRS / MRRS entries they will be coded as medical exemptions (MD)

# Administrative Exemptions Codes

Code	Meaning	Explanation or Example	Duration
AD	Administrative, Deceased	Service member is deceased	Indefinite
AL	Administrative, Emergency Leave	Service member is on emergency leave	Max 1 month
AM	Administrative, Missing	Missing in action, prisoner of war	Indefinite

# Enclosure (1) COMDTINST M6230.10

AP	Administrative, PCS	Permanent change of station	Max 3 months
AR	Administrative, Refusal	UCMJ Actions	Until resolution
AS	Administrative, Separation	Discharge, separation, retirement	Indefinite
AT	Administrative, Temporary	AWOL, legal action pending	Max 3 months

# Treatment of Reserve Component (RC) Members at Military Medical Treatment Facilities (MTF) for Health Care Related to an Immunization

On July 20, 1999, the Assistant Secretary of Defense (Health Affairs) issued guidance to the Service Secretaries that emphasizes the responsibility of MTF commanders to ensure that they provide care for RC members who seek care for a vaccination-related health problem. This care includes medical evaluation and treatment, as appropriate.

It is the responsibility of unit commanders to ensure their members are immunized and ready for deployment. It is also necessary for the unit commanders to advise their reservists, both those who are assigned permanently and those assigned temporarily, that they may seek medical care if they have an adverse reaction to any immunization. Unit commanders will ensure a line of duty determination is completed for all adverse events, regardless of whether or not medical care is sought or the source of such care.

Some RC members may seek medical care from their private physicians while others may seek medical care at a local MTF. This will vary by individual and circumstances. Regardless of the source of the care, each Reserve component should ensure that procedures are in place to facilitate prompt evaluation and treatment of its members in the event of an adverse reaction, which includes care at an MTF. Members must be advised of these procedures and provided information related to pay status or compensation issues.

Our Reserve component members trust that they will be cared for if injured in the line of duty. As leaders, we have a duty to ensure that this trust is justified. Therefore, please take the appropriate action to inform the members of your Reserve component regarding adverse immunization reactions and the appropriate procedures in the event of such a reaction.

A message is required to provide specific direction and guidelines on how to proceed to capture all reservists who may have had a reaction. This message would also include how to access care and how to report their reaction to their command and CG medical.