ARMY ANTHRAX VACCINE IMMUNIZATION PROGRAM PLAN
REFERENCES: See ANNEX A

1. SITUATION.

a. The Deputy Secretary of Defense signed a 28 Jun 02 memorandum directing the Department of Defense (DoD) resume the Anthrax Vaccine Immunization Program (AVIP), in accordance with Food and Drug Administration (FDA) guidelines and consistent with the best practice of medicine, beginning with personnel at highest risk. The mandatory scope of the AVIP shall encompass all personnel assigned to or deployed for more than 15 days in higher threat areas (HTAs) defined in paragraph 3.a.(2) whose performance is essential for certain mission critical capabilities. Near-term AVIP implementation may also include other personnel determined by the Assistant Secretary of Defense for Health Affairs, in consultation with the Chairman of the Joint Chiefs of Staff, to be at higher risk of exposure to anthrax.

b. The AVIP is a command responsibility as part of force health protection. Commanders are responsible for program implementation, to include education of their personnel, tracking of the anthrax immunization series, and compliance with the dosing schedule.

c. The Secretary of the Army remains the Executive Agent of the AVIP, responsible for vaccine acquisition and stockpiling; to manage and direct the vaccination of identified personnel withjn the Uniformed Services consistent with DoD policy, the threat, availability of FDA-released anthrax vaccine, and priorities established by the Chairman of the Joint Chiefs of Staff; issue operational instructions to the Services; serve as a focal point for submission of information from the Services; monitor Services' implementation; recommend appropriate changes in the AVIP to the Assistant Secretary of Defense (Health Affairs); execute the Army's implementation plan; and report quarterly on program execution.

d. The Office of The Surgeon General, through their Anthrax Vaccine Immunization Program Agency, will perform the day-to-day functions assigned to SECARMY for all Executive Agent functions, except vaccine acquisition and stockpiling, and keep the SECARMY informed through The Vice Chief of Staff, Army.

e. The Program Executive Office for Chemical and Biological Defense (PEOCBD)—formerly the Joint Program Office for Biological Defense (JPO-BD)—will perform the function of vaccine acquisition and stockpiling assigned to SECARMY, assuring an adequate supply of anthrax vaccine, and defining production capabilities on behalf of all Services. PEOCBD will keep the AVIP Agency informed of all vaccine acquisition, stockpiling, and production issues.

f. The U.S. Food and Drug Administration (FDA)-approved dosing schedule for this vaccine requires a series of six vaccinations (at 0, 2 and 4 weeks, then 6, 12, and 18 months after the first immunization) followed by annual boosters. It is important for personnel to stay on this approved schedule. Personnel affected by this new policy, who previously began the anthrax vaccine dosing series, but deferred dosing during AVIP Slowdowns, will resume vaccinations where they left off. Those individuals will continue as soon as their units begin vaccination. They will not begin the six-dose series over again at dose one. This is consistent with guidance from the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices and consultation with the FDA.

g. Immunizations under this policy will be given to the designated at-risk personnel, including soldiers, Emergency-Essential Department of the Army (DA) civilians and DoD contractors. Vaccination is mandatory for these personnel, except as provided under applicable administrative (ANNEX B) and medical (ANNEX C) exemption policies.

h. For force protection purposes, personnel are considered deployable if they have begun the 6-dose series, regardless of whether or not the series has been completed. However, it is desirable that all personnel deploying to higher-threat areas receive at least their first three doses prior to deployment to reduce the logistical burden on the Combatant Commander. Ideally, deployers should start the series no later than 45 days before deployment. In those rare instances when an individual is not able to take or

continue the anthrax series due to: (1) an administrative exemption, granted by a commander or supervisor, discussed in detail in ANNEX B; or (2) a medical exemption granted by a privileged healthcare provider (e.g. physicians, nurse practitioners, and physician assistants), discussed in detail in ANNEX C; he/she is still deployable.

2. MISSION. Headquarters Department of the Army (HQDA) implements the DoD Anthrax Vaccine Immunization Program Resumption to protect personnel at higher risk against anthrax.

3. CONCEPT OF OPERATIONS.

a. **Identify and Vaccinate Only Eligible Personnel IAW DoD Policy.** The Army will vaccinate personnel over a multi-year period in accordance with (IAW) the FDA immunization schedule, and Office of the Secretary of Defense (OSD) and Joint Chiefs of Staff (JCS) guidance (ANNEX A).

(1) Priority 1. Designated special mission units (SMUs) and personnel involved in anthrax research and anthrax vaccine manufacturing. DoD has been vaccinating these personnel since the Jun 01 Slowdown Policy; vaccination of these personnel continue today. Commanders will submit requests for additional personnel/units to be designated an SMU, because their duties or occupations place them at increased risk for exposure to *Bacillus anthracis* through MACOMs to HQDA, Office of The Surgeon General, AVIP Agency, 5109 Leesburg Pike, Falls Church, VA 22041 for coordination with and approval by HQDA, CJCS and ASD(HA).

(2) Priority 2. Forces assigned or deployed to the HTA for greater than 15 consecutive days. *[Section deleted from the web version; military personnel refer to the message passed through military channels.]*

(a) Commanders will submit requests for exceptions (for example, persons rotating into HTA repeatedly for more than 15 cumulative days in a 12-month period) through MACOMs to HQDA, Office of The Surgeon General, AVIP Agency, 5109 Leesburg Pike, Falls Church, VA 22041 for approval and coordination with gaining Combatant Command, CJCS and ASD(HA).

(b) IAW Ref 9, ANNEX A, personnel currently deployed in the HTA, but due to rotate out of the HTA on or before 4 Nov 02 will not begin the anthrax vaccine series.

(3) Priority 3. Designated early-deploying forces. Not OSD approved for execution.

(4) Priority 4. Forces stationed or assigned in Korea. Not OSD approved for execution.

AT THIS TIME, OSD HAS APPROVED VACCINATIONS FOR PRIORITIES 1 AND 2 ONLY; Army will publish additional execution guidance once OSD approves Priorities 3 and/or 4.

(5) For persons who: had previously begun the six shot series but had not completed it due to DoD Slowdown Policies of Jul 00, Nov 00, or Jun 01; and will not begin now because they are not eligible by this new policy under Priorities 1, 2, 3, or 4; completion of their vaccination series will be deferred until further notice by HQDA. DoD is committed to complete their vaccination series IAW the FDA-approved schedule as soon as adequate FDA-release anthrax vaccine is available. When authorized, these persons will not begin the dosing series over at dose one, but will continue the series at the dose they left off.

b. **Mandatory Vaccination Policy.** Military personnel under this policy will initiate and complete the immunization schedule, unless specifically exempted through: (1) an administrative exemption, granted by a commander or supervisor, discussed in detail in ANNEX B; or (2) a medical exemption granted by a privileged healthcare provider (e.g. physicians, nurse practitioners, and physician assistants), discussed in detail in ANNEX C. As with all immunizations, military personnel do not have the option to be immunized. IAW AR 600-20, Army Command Policy, commanders can order their soldiers to be

immunized. Although each case will be determined on its own merits, soldiers refusing an order may face adverse administrative action or disciplinary action under the Uniform Code of Military Justice. Coordinate actions subsequent to any vaccination refusal with your servicing judge advocate or legal advisor. ANNEX B discusses vaccination refusal management further.

c. **Vaccine Requisition and Distribution.** The U.S. Army Medical Materiel Agency (USAMMA) will coordinate the distribution of the vaccine to the supporting medical supply activities of all Services per ANNEX D. Priority 1 and 2 initial distribution is already in place. End-users will directly requisition vaccine IAW USAMMA guidelines in ANNEX D as required for AVIP sustainment.

d. **Education of Personnel to be Vaccinated.** Commanders and Army leaders at all levels are responsible to educate their personnel before vaccination. At a minimum, Commanders and other leaders will brief their eligible personnel and provide them a copy of the informational trifold as outlined in ANNEX E. Your local medical treatment facility will maintain a stock of trifolds for your use. Team with local healthcare providers and other subject matter experts (e.g. judge advocate general and public affairs offices) to assist with this education and answer questions upfront. Your education tools are always available at www.anthrax.mil. Annex E also details the Army's AVIP public affairs strategy.

e. **Adverse Event Management.** Get persons appropriate medical evaluation if they experience symptoms following anthrax vaccination. Some symptoms/complaints may be caused by the vaccine—others may not—but each deserve appropriate medical attention, individual concern, and empathy. If symptoms persist, providers, leaders, or patients may contact the Walter Reed Vaccine Healthcare Center at 202.782.0411, for appropriate consultation, advice, and specialized medical management. Report adverse reactions IAW ANNEX C and AR 40-562. AVIP Agency will track reports of adverse events and report to The Surgeon General routinely.

f. **Immunization Tracking and Compliance.** Commanders and healthcare personnel have dual roles ensuring anthrax vaccinations are documented in healthcare records and the Army's automated immunization tracking system, the Medical Protection System (MEDPROS) IAW ANNEXES C and K. The HQDA standard for AVIP execution is 90% compliance of eligible personnel receiving their anthrax vaccinations and 90% compliance of personnel receiving each dose within 30 days of scheduled due date. HQDA will monitor Army MACOMs' performance using these metrics through MEDPROS. MEDPROS not only tracks the immunization record, but offers commanders a powerful tool to manage AVIP immunization within their units from there desktop computer.

g. **Coordinating Vaccination.** The Army will use military medical assets (including those organic to the units); Veterans Administration Sharing Agreement, an MOA with the Public Health Service's Federal Occupation Health Division, and a private sector contract to deliver this immunization series. The U.S. Army Medical Command (USAMEDCOM), Army National Guard (ARNG) (ANNEX H), and U.S. Army Reserve (USAR)(ANNEX I) will assist these medical providers to execute this plan.

4. RESPONSIBILITIES.

a. Army MACOMs.

(1) Develop supporting plans to execute anthrax immunizations IAW this plan.

(2) Incorporate anthrax vaccination information IAW ANNEX E into Command Information Programs.

(3) Implement procedures to ensure that in-processing and out-processing at subordinate installations include a screen to ascertain anthrax immunization status and ensure compliance with this plan.

b. Office of The Surgeon General//US Army Medical Command.

(1) Provide immunization support in coordination with Army MACOMs in support of their immunization plans.

(2) Provide immunization support to the Army National Guard and U.S. Army Reserves IAW ANNEXES H and I, respectively.

(3) Provide immunization support to other Services IAW OASD(HA) guidance.

(4) Provide vaccine and ancillary supplies IAW ANNEX D, to units conducting immunizations.

(5) Develop and disseminate medical information, policy, and doctrine as required.

(6) Receive and consolidate reports of adverse events from all Services. Provide summary reports to The Army Surgeon General.

c. The Program Executive Office for Chemical and Biological Defense (PEOCBD).

(1) Execute procedures to procure and store the anthrax vaccine IAW OSD guidelines.

(2) Program future resources necessary to support the Department's Medical Biological Defense Program against anthrax.

5. COORDINATING INSTRUCTIONS.

a. Direct coordination with Navy, Marine Corps, Air Force, and Coast Guard medical facilities is authorized.

b. Funding for vaccine will be provided by the PEOCBD. Ancillary supplies will be funded from the Defense Health Program (DHP).

c. MACOMs have the authority to execute this plan and vaccinate Priorities 1 and 2 immediately upon meeting the requirements for: appropriate identification of personnel to be vaccinated IAW DoD policy; vaccine distribution and storage; prevaccination education; documentation and tracking immunizations and compliance with the dosing schedule; and ability to evaluate and report suspected adverse reactions, all outlined in this plan.

d. Proponent of this plan is the Office of The Surgeon General, Directorate of Healthcare Operations, AVIP Agency, DASG-HCA, DSN 761-5101, COMM (703) 681-5101.

6. ANNEXES.

a. ANNEX A, REFERENCES
b. ANNEX B, ADMINISTRATIVE CONSIDERATIONS AND GUIDANCE
c. ANNEX C, MEDICAL CONSIDERATIONS AND GUIDANCE
d. ANNEX D, LOGISTICS
e. ANNEX E, EDUCATION/COMMUNICATIONS PLAN
f. ANNEX F, REPORTING REQUIREMENTS
g. ANNEX G, PERSONNEL
h. ANNEX H, ARMY NATIONAL GUARD
i. ANNEX I, U.S. ARMY RESERVE
j. ANNEX J, DEPARTMENT OF THE ARMY CIVILIANS AND DOD CONTRACTORS
k. ANNEX K, IMMUNIZATION TRACKING

ANNEX A - REFERENCES

1. Department of Defense Directive (DoDD) 6205.3, DoD Immunization Program for Biological Warfare Defense, 26 November 1993. http://www.dtic.mil/whs/directives/corres/pdf/d62053_112693/d62053p.pdf

2. AR 40-2, Army Medical Treatment Facilities General Administration, 15 March 1983. http://www.usapa.army.mil/pdffiles/r40_2.pdf

3. AR 40-68, Quality Assurance Administration, 20 December 1989. http://www.usapa.army.mil/pdffiles/r40_68.pdf

4. Air Force Joint Instruction 48-110, Army Regulation 40-562, BUMEDINST 6230.15, and CG COMDTINST M6230.4E, Immunizations and Chemoprophylaxis, 1 November 1995. http://www.e-publishing.af.mil/pubfiles/af/48/afji48-110/afji48-110.pdf

5. Package Insert, Anthrax Vaccine Adsorbed (BioThrax) BioPort Corporation, Lansing, Michigan, January 2002. http://www.bioport.com/AnthraxVaccine/Insert/biopava0131022LB.pdf

6. Memorandum of Understanding Between the U.S. Army Medical Command and U.S. Army Reserve Command, 11 May 1995.

7. Memorandum, Deputy Secretary of Defense, subj: Reintroduction of the Anthrax Vaccine Immunization Program (AVIP), June 28, 2002. http://www.anthrax.mil/media/pdf/resumptionpolicy.pdf

8. Memorandum, Under Secretary of Defense (Personnel and Readiness), subj: Administrative and Clinical Execution Guidance for Reintroduction of the Anthrax Vaccine Immunization Program (AVIP), August 6, 2002. http://www.anthrax.mil/media/pdf/exeguidance.pdf

9. Memorandum, Under Secretary of Defense (Personnel and Readiness), subj: Policy on Administrative Issues Related to the Anthrax Vaccine Immunization Program (AVIP), August 6, 2002. http://www.anthrax.mil/media/pdf/AdminIssues.pdf

10. Memorandum, Assistant Secretary of Defense (Health Affairs), subj: Policy on Clinical Issues Related to Anthrax Vaccination, August 6, 2002. http://www.anthrax.mil/media/pdf/ClinicalIssues.pdf

ANNEX B - ADMINISTRATIVE CONSIDERATIONS AND GUIDANCE

1. Administrative Exemptions.

a. This section provides criteria for administrative exemptions for selected military and non-military personnel (U.S. service members, DoD emergency-essential (E-E) civilian employees, other designated civilian personnel and comparable contractor personnel). It does not apply to medical exemptions covered in ANNEX C. Army commanders and civilian supervisors at all levels are designated as exemption authority for Service members, Emergency Essential (EE) and other designated civilian employees and comparable contractor and other personnel.

b. Administrative exemption is applicable to retiring and separating personnel (without Reserve Component (RC) obligations and who do not plan to immediately re-enlist) and civilian employees and contractor personnel departing a position subject to the AVIP with 180 days or less of service or employment remaining. This administrative exemption does not apply to personnel whom the commander determines shall receive the vaccine because of overriding mission requirements IAW paragraph 2.d., this ANNEX.

c. Commanders shall exempt from the AVIP those personnel separating within 180 days (as described further below) who meet all of the following conditions: (a) they are not currently assigned or deployed to a designated higher threat area; (b) they are not scheduled to perform duty in a designated higher threat area; and, (c) the commander has not directed vaccination because of overriding mission requirements. Personnel who meet these criteria should immediately identify themselves to their commanders and supervisors.

d. To calculate the 180-day period, the following specifications apply. For retiring or separating military personnel the applicable period is 180 days prior to their approved date of retirement or separation. RC members must have approved retirement orders to be effective within 180 days, reassignment date to the IRR, or expirations of enlistment within 180 days prior to consideration for exemption from the series. Those personnel who are separating from active duty but continuing service with the Selected Reserve must continue the entire series regardless of the mobility status. For EE and other designated civilian and comparable employees and contractor personnel subject to the AVIP because of performance of essential contractor services, the applicable period is 180 days prior to the effective date of retirement, resignation, separation or reassignment out of a position subject to the AVIP. All other reserve personnel categories (e.g. IRR, IMA), when mobilized, are subject to anthrax vaccination per this plan.

e. The policy is effective immediately for servicemembers and civilian personnel who are not members of a bargaining unit. Civilian personnel affected by this policy who are members of bargaining units will be considered for exemption consistent with applicable personnel management procedures. All bargaining obligations will be fulfilled IAW Federal Services Labor-Management Plans.

f. Commanders will use the following exemption codes for electronic tracking of administrative exemptions:

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
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

2. Anthrax Vaccine Refusal Management. Commanders will manage refusal to take the anthrax vaccine (or any vaccine) as they would address any refusal to obey a lawful order and IAW AR 600-20, Army Command Policy. Always coordinate vaccine refusal management with your servicing judge advocate or legal advisor. The following specific guidance comes from AR 600-20, Paragraph 5-4:

a. “Soldiers…will usually be required to submit to medical care considered necessary to preserve his or her life, alleviate undue suffering, or protect or maintain the health of others.…Commanders may order the…medical treatment of any soldier in their command when warranted.”

b. “Under normal circumstances, actions will not be taken to involuntarily immunize soldiers.[e.g. hold them down or otherwise restrain them]”

c. Commanders will:

(1) Ensure soldiers understand the purpose of the vaccine.

(2) Ensure soldiers are advised of both the endemic, natural threat and potential use as a biological weapon agent.

(3) Ensure soldiers are educated about the vaccine and have been afforded the opportunity to discuss concerns with medical authorities.

(4) Counsel the soldier, in writing, on his or her requirement to be immunized and ramifications for failure to follow a lawful order.

(5) Order the soldier to receive the immunization.

d. The General Court-Martial Convening Authority will determine conditions of imminent threat and may delegate authority to order involuntary immunization to subordinate commanders.

ANNEX C - MEDICAL CONSIDERATIONS/GUIDANCE

1. REFERENCES.

a. Air Force Joint Instruction 48-110, Army Regulation 40-562, BUMEDINST 6230.15, and CG COMDTINST M6230.4E, Immunizations and Chemoprophylaxis, November 1, 1995. http://www.e-publishing.af.mil/pubfiles/af/48/afji48-110/afji48-110.pdf

b. Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices. General Recommendations on Immunization. MMWR 2002;51(RR-2):1-35. ftp://ftp.cdc.gov/pub/Publications/mmwr/rr/rr5102.pdf

c. Package Insert, Anthrax Vaccine Adsorbed (Biothrax), BioPort Corporation, Lansing, Michigan, January 2002. http://www.bioport.com/AnthraxVaccine/insert/avainsert.asp

d. Brachman, P.S., and Friedlander, A.M. Chapter 24, "Anthrax," *In* Vaccines, 3rd Ed., S.A. Plotkin and W. A. Orenstein, Eds., W.B. Saunders Co., Philadelphia, PA, 1999.

e. Detailed Safety Review of Anthrax Vaccine Adsorbed, 25 March, 2002 http://www.anthrax.mil/media/pdf/safety_rev.pdf

f. Clinical Guidelines for Managing Adverse Events After Vaccination, http://www.anthrax.mil/media/pdf/cpguidelines.pdf

g. Vaccine Adverse Event Reporting System online reporting https://secure.vaers.org/VaersDataEntryintro.htm

h. Vaccine Adverse Event Reporting System Form VAERS-1, http://www.fda.gov/medwatch/safety/vaers1.pdf

i. Assistant Secretary of Defense (Health Affairs) Memorandum, Policy on Clinical Issues Related to Anthrax Vaccination, 06 Aug 2002. http://www.anthrax.mil/media/pdf/ClinicalIssues.pdf

2. GENERAL INFORMATION.

a. Vaccine Description.

(1) Anthrax Vaccine Adsorbed is a sterile product made from filtrates of cultures of a non-virulent strain of *B. anthracis* that elaborates a protein called the protective antigen (PA). The FDA approved the vaccine in 1970 for use in humans to promote increased resistance to *B. anthracis* by active immunization. The BioPort Corporation under FDA License No. 1260 manufactures anthrax vaccine (Ref. C this ANNEX).

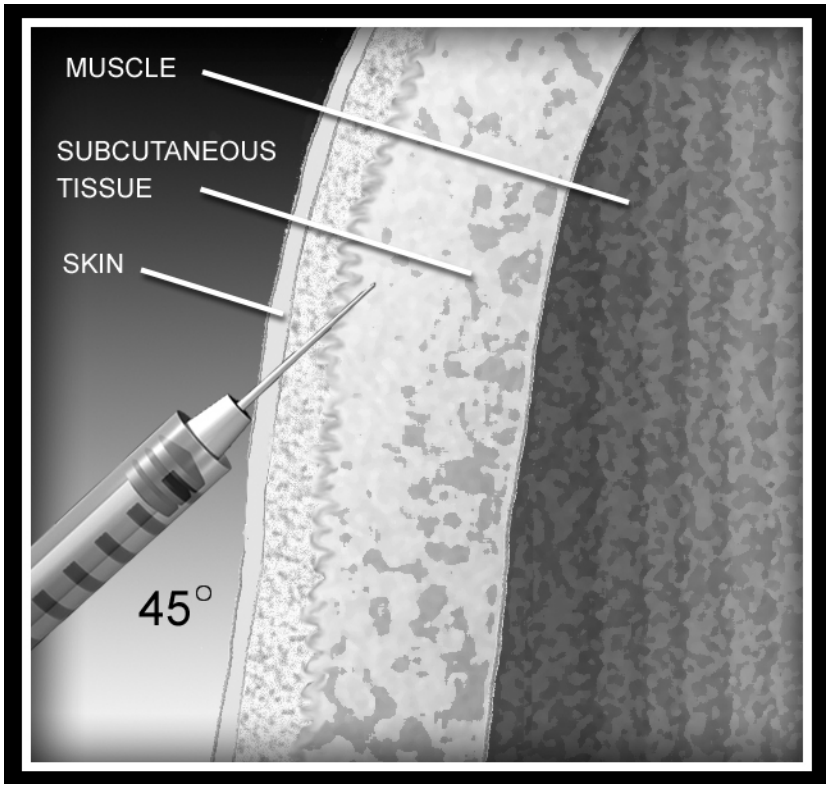
(2) The final product is formulated to contain 1.2 mg/mL aluminum, added as aluminum hydroxide in 0.85% sodium chloride. The product is formulated to contain 25 mg/mL benzethonium chloride and 100 mg/mL formaldehyde, added as preservatives. Each lot must pass specific tests for potency, purity, sterility, and general safety before release from the manufacturer.

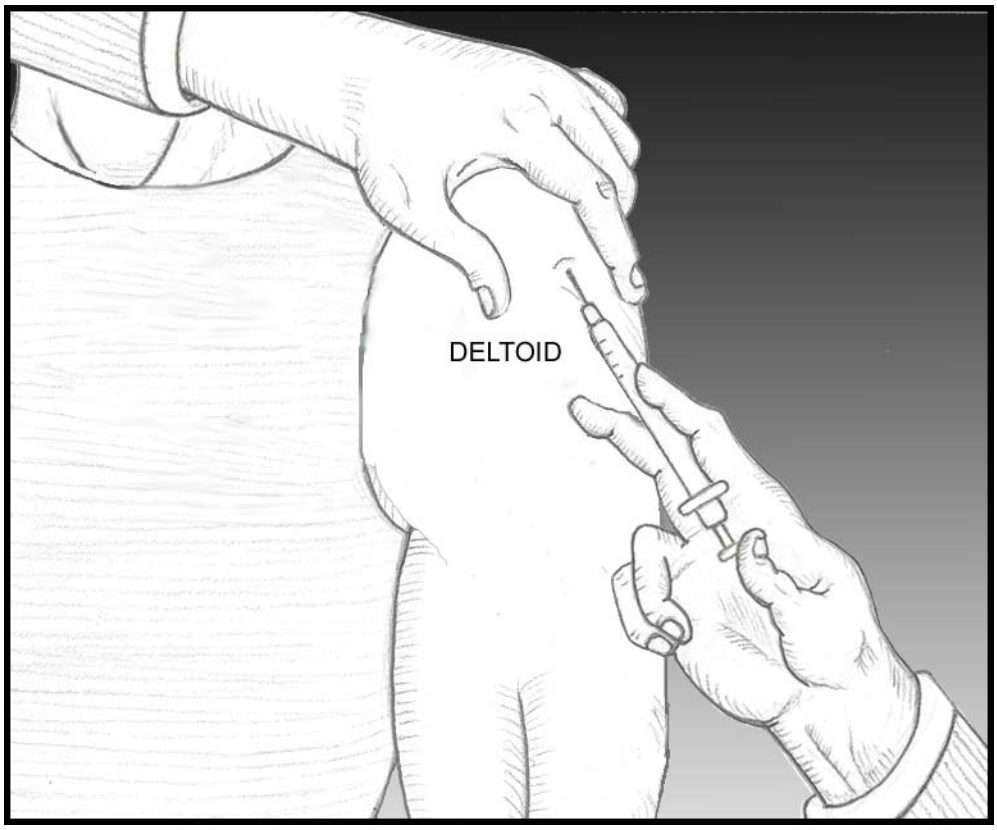
(3) The vaccine is supplied in 6.1-milliliter (mL) vials to supply 10 doses per vial. Vaccine should be stored and shipped under refrigeration IAW ANNEX D. Do not freeze. Once opened, properly stored vials may be used until the expiration date. Shake vial before use to assure homogeneous distribution of contents. Inspect contents for particulate matter or discoloration.

(4) Indications and usage. Immunization with Anthrax Vaccine Adsorbed is recommended for individuals with a high risk of exposure to *B. anthracis*. It has been used in the private sector to immunize individuals who may come into contact with *B. anthracis* contaminated animal products

(e.g., hides, hair, bones), individuals conducting diagnostic or research activities who are at risk of coming into contact with the spores, and for high risk individuals (e.g., at-risk veterinarians) who may handle infected animals.

Figure 1. Proper technique for subcutaneous immunization with Anthrax Vaccine Adsorbed.





b. Dosage and Administration.

(1) Dosage.

(a) Primary immunization consists of three subcutaneous injections, 0.5 ml each, ideally given 2 weeks apart (0, 2, and 4 weeks) followed by three additional subcutaneous injections, 0.5 ml each, given at 6, 12 and 18 months from the first injection (Ref. c this ANNEX). If the FDA-approved schedule cannot be adhered to, follow procedures in Part 5 (c) this ANNEX.

(b) After the six-shot series has been completed, booster injections of 0.5 mL of anthrax vaccine at one-year intervals are required by the FDA approved dosing schedule to maintain full immunity.

(2) Administration Issues.

(a) Vaccination procedures will be consistent with information provided in refs a. and c. Needle and syringe method is indicated for this vaccine. Do not use jet injector immunization devices. Preferred injection site is the subcutaneous tissue over the deltoid muscle, with a short (less than one inch) needle at a 45-degree angle to the skin surface. See Figure 1. Unusually lean people might avoid injection-site reactions by vaccination in the anterolateral thigh.

(b) Rotate anatomic sites for subsequent doses of vaccine. Left-right-left is a common sequence. Anthrax Vaccine Adsorbed may be administered concurrently with other common immunizations, but use separate syringes and different anatomic sites. Do not syringe-mix Anthrax Vaccine Adsorbed with any other product. As always, appropriate clinical judgment is warranted.

3. MEDICAL RECORD KEEPING.

a. A permanent entry will be made in the individual's health record IAW AR 40-39, after each dose of anthrax vaccine is administered. Entry will include the date of immunization, name of vaccine, manufacturer, lot number, series number, dose and route of administration, site of administration (e.g. right anterior upper arm) and name of healthcare provider involved in vaccine administration. Immunization will all also be noted on Department of Health and Human Services Form PHS 731, (International Certificates of Vaccination).

b. For deployment, use the DD Form 2766 folder, (Adult Preventative and Chronic Care Flow sheet) to accompany the individual to the field; copies will remain in the individual's health record.

c. Implement quality control and quality assurance measures IAW AR 40-68 to ensure the accuracy of these entries.

d. A copy of this information will be kept on file in the clinic or MTF that administered the anthrax vaccine for at least two years so that if electronic information is questioned, validation can be obtained from the written copy.

4. AUTOMATED IMMUNIZATION TRACKING SYSTEM (ITS).

a. All unit immunizations will be posted and tracked IAW Annex K in the Army's ITS, Medical Protection System (MEDPROS), the HQDA standard for tracking all individual medical readiness indicators in the active and reserve components. Leaders at all levels can track individual and unit compliance using MEDPROS from their desktop. Although various local automated health record systems may be used by clinicians as approved by OTSG/MEDCOM for clinical front-end entry, HQDA requires automated feed into MEDPROS. Local systems not automatically feeding into MEDPROS will not be used.

b. Commanders and healthcare providers are responsible to ensure all anthrax immunizations for their assigned personnel are recorded in MEDPROS within 24 hours of the immunization event.

5. POLICY FOR UNINTENDED DEVIATION FROM IMMUNIZATION SCHEDULE.

a. Full immunization with Anthrax Vaccine Adsorbed requires six doses to be administered over 18 months and subsequent annual boosters as delineated in paragraph 2b(1). This schedule is the only regimen shown to protect humans against naturally occurring anthrax (Ref d this ANNEX).

b. The full immunization schedule, as described above, is a matter of DoD policy. Take reasonable steps to ensure that shots are given on or as soon after recommended dates as possible. Commanders are responsible for assuring that unit personnel are available at the appropriate time for immunization. Although much of the guidance described below addresses late or missed doses, compressing or accelerating the vaccine series must also be avoided.

c. The following procedure will be followed for individual variation from the above schedule:

(1) Once the series is initiated, subsequent doses will be administered as soon as possible, but not earlier than the minimum required intervals specified in paragraph 2b. Timing of each dose after the first should be based on the date of the immediately prior dose, not necessarily the date of the first dose.

(2) Annual boosters that are missed should be administered at the earliest possible date, adjusting the subsequent booster schedule accordingly.

(3) It is never necessary to re-start the primary series. The primary series of six doses must be completed only once, even if prolonged intervals occur between doses. Provide the next dose at the earliest possible date and continue to follow the prescribed schedule.

(4) This guidance is intended for the rare exception where immunization is inadvertently missed. The FDA-approved immunization schedule as described in Part 5.a. is DoD policy.

6. PRE-VACCINATION REQUIREMENTS

a. Commanders and medical staff will ensure that vaccine recipients are provided adequate information on the vaccine, its safety, its benefits, possible adverse events and the need for adherence to the immunization schedule prior to the first anthrax vaccination. Informational brochures at Appendix 1, ANNEX E, will be distributed to all personnel, military and civilian, before receiving this vaccine.

b. Commanders will provide all soldiers with a briefing on anthrax and the vaccination program. The briefing at Appendix 4, ANNEX E, is provided for this purpose.

c. Personnel will be given the opportunity to ask questions of healthcare providers prior to vaccination.

d. The national standard of practice for all immunizations, including the anthrax vaccine, shall be adhered to when immunizing personnel. This includes medical screening prior to immunization. Screening shall be conducted for medical conditions for which immunization deferral or further medical evaluation before immunization is indicated.

e. Healthcare professionals and staff play key roles in this program, both in its execution as well as providing expert advice to soldiers and commanders. They must become familiar with key aspects of anthrax the disease and the anthrax vaccine. All must read the package insert (Ref. C this ANNEX) and be familiar with the informational briefings referenced at Appendices 4 and 6 ANNEX E. Healthcare providers should read the comprehensive review of safety studies available at the AVIP website (Ref. e this ANNEX) and the Institute of Medicine report on the anthrax vaccine (Appendix 3, ANNEX E). These will be crucial in communicating to the troops that the vaccine is safe and effective.

f. Medical personnel must understand the potential adverse events that are possible after anthrax vaccination. They must know how to minimize them, how to respond to them and report them IAW Part 8 this ANNEX. Medical personnel will not only administer the vaccine, but will likely be the "front line"—responding to troops questions and concerns. Medical personnel must treat each concern with care, some symptoms following anthrax vaccination may or may not be caused by the vaccination, but all deserve individual attention.

7. MEDICAL EXEMPTIONS FROM ANTHRAX VACCINATION.

a. The vast majority will complete the vaccine series. Some individuals will have either acute or chronic pre-existing conditions that may warrant medical exemption from anthrax vaccination. Furthermore, a small proportion of individuals will develop a more serious reaction during the vaccination series that may warrant medical exemptions, temporary or permanent, from further anthrax vaccination.

b. Medical exemptions are categorized as medical temporary (MT) or medical permanent (MP). Examples of situations that could warrant a medical exemption can be found in Part 10 of this ANNEX. Privileged healthcare providers (e.g. physicians, nurse practitioners, and physician assistants) may grant both temporary and permanent medical exemptions.

c. If an individual's clinical case is complex or not readily definable, privileged healthcare providers may consult an appropriate medical specialist with vaccine safety assessment expertise before a permanent medical exemption is granted. In addition, the original healthcare provider may consult with physicians located at the Walter Reed Vaccine Healthcare Center (VHC), DoD's vaccine center of excellence, 202.782.0411.

d. If a patient disagrees with an initial medical decision or diagnosis, he or she may request a second opinion. If the second opinion is one with which the patient disagrees, he or she may be referred directly to the VHC.

8. ADVERSE EVENTS.

a. Local Reactions. Like all vaccines, anthrax vaccine may cause soreness, redness, itching, and swelling at the injection site. Up to 30% of men and 60% of women report mild local reactions, but these reactions usually last only a few days. For both genders, between 1% and 5% report moderate local reactions of 1 to 5 inches in diameter. Larger reactions occur about once per hundred vaccinees or less. A lump at the site occurs commonly, usually lasting for a few weeks, before going away on its own if left alone. More severe local reactions are rare, occurring in less than 1 percent of those vaccinated. These reactions include swelling that extends to the elbow or forearm that can limit its movement, or a rash that is limited to the arm (Ref. c this ANNEX).

b. Systemic Reactions. Systemic reactions (reactions beyond the injection site) are seen in approximately 5% to 35% of vaccines. Those reactions include muscle aches, joint aches, headaches, malaise, rashes, chills, low-grade fever, nausea, or related symptoms. These symptoms usually resolve in less than a week (Ref. c, this ANNEX).

c. Serious Reactions. Signs of serious allergic reaction include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heartbeat, or dizziness. Serious allergic reactions are extremely rare (Ref. c this ANNEX).

d. Managing Adverse Events. Detailed clinical guidelines for the management of adverse events after vaccination can be found at Ref. f this ANNEX.

9. ADVERSE EVENT RECORDING AND REPORTING.

a. Document all significant adverse events in the individual's health record. Mandatory information for adverse event reporting consists of identification of the vaccine, the lot number and manufacturer, the date of administration, the name and location of the medical facility, the type and severity of the event. In addition to recording the event in the health record, all adverse vaccine events resulting in HOSPITALIZATION or TIME LOST FROM DUTY (MORE THAN 24 HOURS) must be reported using the Vaccine Adverse Events Reporting System (VAERS-1) Form. Further, the patient or healthcare provider is encouraged to report other adverse events that in the provider's professional judgment appear to be unexpected in nature and severity. Submission of a VAERS report is not an indictment against the vaccine, vaccine administrator, health care facility, chain of command, or an individual, it simply facilitates review of temporally associated conditions and adds to the safety database on the vaccine.

(1) Medical personnel will submit VAERS reports to the supporting USAMEDCOM MTF. The MTF Pharmacy and Therapeutics Committee will review each report.

(2) The Chairman, MTF Pharmacy and Therapeutics Committee, will submit reports to the FDA's Vaccine Adverse Event Reporting System, PO Box 1100, Rockville, MD 20849-1100 (See ANNEX A, references 2 and 3). Reports can also be submitted directly to the FDA on-line. (Ref. g this ANNEX)

(3) The Chairman, MTF Pharmacy and Therapeutics Committee will also provide a copy of the VAERS-1 report to the Reportable Disease Project Officer at the Army Medical Surveillance Activity (AMSA), U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM), Building T-20, Walter Reed Army Medical Center, Washington, DC 20307-5100, DSN 662-04741 or commercial 202-782-0471. Reportable adverse events will also be reported to AMSA, through the MTF preventive medicine activity using the automated reportable events system.

(4) VAERS-1 forms are available directly from the Internet at the website referenced at Ref h this ANNEX or can be obtained by calling 1-800-822-7967, Monday – Friday, 0800 – 1700 ET.

(5) A VAERS report should be filed for any permanent medical exemption due to a vaccine related adverse event.

b. Adverse event reports from National Guard and Army Reserve units will be filed through command channels to the appropriate ARNG State Area Command (STARC) or Army Reserve intermediate headquarters—Reserve Support Command (RSC), 7th Army Reserve Command (7th ARCOM), U.S. Army Special Operations Command (USASOC), or Army Reserve Personnel Command (AR-PERSCOM), as applicable—to the appropriate AMEDD Regional Medical Command (RMC). The RMC will ensure an appropriate Pharmacy and Therapeutics Committee reviews the reports and forwards them IAW Part 8.a.

c. USACHPPM will also receive consolidated adverse event reports from each Service through the Defense Medical Surveillance System (DMSS) and provide quarterly status reports to USAMEDCOM.

10. CONTRAINDICATIONS AND PRECAUTIONS.

a. Contraindications.

(1) A hypersensitivity reaction to a previous dose of the vaccine or one of its components is a contraindication to immunization with this vaccine (Ref. c and d this ANNEX). The local and systemic events of the type described in Part 7 this ANNEX, considered alone, do not typically represent significant hypersensitivity. Immunization is contraindicated in persons who develop events such as angioedema, generalized hives or other manifestations of potentially life-threatening anaphylaxis. Persons manifesting these or similar events should not receive additional vaccine without prior consultation with an allergist or infectious disease specialist. Results of this consultation and any limitation on additional doses of anthrax vaccine must be clearly documented in the individual medical record (code MT or MP in the immunization tracking systems).

b. Precautions.

(1) Routine immunization precautions against allergic and anaphylactic reaction should be followed IAW AR 40-562. Personnel with a possible history of latex sensitivity should be observed for 15 minutes for any sign of hypersensitivity reaction because the vial stopper contains dry natural rubber.

(2) Defer immunization for any person with an active infection with fever. Persons with moderate or severe acute illness should also defer vaccination until recovery (MT).

(3) Patients with impaired immune responsiveness due to congenital or acquired immunodeficiency, or immunosuppressive therapy may not be adequately immunized following administration of the anthrax vaccine. Vaccination during chemotherapy, high dose corticosteroid therapy of greater than 2-week duration, or radiation therapy may result in a suboptimal response. Deferral of vaccination for 3 months after completion of such therapy should be considered (MT).

(4) Individuals with HIV infection are not deployable and therefore are not likely to require anthrax immunization. There are no data on the safety or effectiveness of anthrax vaccine in HIV-infected individuals. Although the vaccine is likely to pose no risk to HIV-infected persons, the adequacy of the immune response to the vaccine in these persons is unknown. If clearly needed, anthrax vaccine should be administered to individuals with HIV infection. For example, a non-vaccinated individual with HIV infection who is exposed to anthrax spores should be immunized as part of post-exposure treatment (MP).

(5) Pediatric Use/Use in the Elderly: Anthrax Vaccine Adsorbed is not approved for pediatric use (persons 18 years or younger) or for those older than 65 years of age because it has not been studied in these populations.

(6) The anthrax vaccine should not be administered to individuals with a history of Guillain-Barré Syndrome (GBS) unless there is a clear benefit that outweighs the potential risk of a recurrence (MP).

(7) Evidence of immunity based on serologic antibody tests or documented previous anthrax infection. History of anthrax disease may increase the potential for severe local adverse reactions. (MP).

(8) Pregnancy and breastfeeding.

(a) Although the risks associated with immunization during pregnancy are largely theoretical, prudence dictates that routine anthrax immunization be deferred during pregnancy (MT). To ensure that pregnant women are not immunized inadvertently, the following procedure will be followed:

i Before immunization, each woman of child-bearing age will be provided information concerning immunizations and pregnancy. In addition to general information on this topic, specific information on the vaccine will be provided.

ii Provided with this information and the opportunity to read it, each woman will be asked if she is pregnant or could be pregnant.

iii Each woman will be asked if she would like to have test performed to confirm a possible pregnancy. A urine pregnancy test is sufficient for verification.

iv Each woman and the medical personnel conducting the the interview will document the interview by initialing and dating the general information. The sheet will be maintained in the woman's medical record.

v If the woman states that she is not pregnant or if she found not to be pregnant on testing, then she will be immunized.

vi If pregnancy is suspected, immunization will be deferred until a pregnancy test is completed. If the test is positive, immunization will only be given if clinically indicated.

(b) It is not known if the anthrax vaccine can cause fetal harm if administered to a pregnant woman or if it can affect reproductive capacity. Any episodes of immunization with anthrax vaccine during pregnancy must be documented in the woman's medical record. Woman should be counseled that although there is limited data on anthrax vaccine during pregnancy, inactivated viral and bacterial vaccines, like Anthrax Vaccine Adsorbed, are generally thought to pose little risk to the woman or the fetus (Ref. B this ANNEX).

(c) As with other inactivated vaccines, there is no medical reason to delay pregnancy following administration of anthrax vaccine (Ref. B this ANNEX).

(d) Breast-feeding (lactation). IAW with Advisory Committee on Immunization Practices (ACIP) guidelines for inactivated vaccines, there is no reason to interrupt breast-feeding for immunization of a lactating mother with anthrax vaccine. (Ref. B this ANNEX).

(9) Carcinogenesis: To date, scientific studies show that Anthrax Vaccine Adsorbed has no carcinogenic effects. There is no scientific evidence to suggest that anthrax vaccine, or any other inactivated vaccine, should have such an effect.

(10) Blood donations. The American Association of Blood Banks (AABB) and the Food and Drug Administration allow blood donations following anthrax vaccination without any vaccine-related restrictions. For more information, see the Internet resources of the Armed Services Blood Program Office (http://www.tricare.osd.mil/asbpo), including http://www.tricare.osd.mil/asbpo/asb_immu.html. Date Source: The American Association of Blood Banks (http://www.AABB.org)1801 Glenbrook Road, Bethesda, MD 20814-2749, 301-907-6977, Standards for Blood Bank and Transfusion Services, 19th ed., Standard B2.600.

11. The point of contact for this Annex is the Preventive Medicine Staff Officer at Office of The Surgeon General, HQDA, ATTN: DASG-HS-PM, DSN 761.3160; COMM (703) 681-3160.

ANNEX D - LOGISTICS

1. PURPOSE. To provide the logistics concept of operations for the Army Anthrax Vaccine Immunization Program Plan.

2. GENERAL INFORMATION. The following information on the FDA licensed anthrax vaccine is provided:

a. NSN: 6505--01--399--6828

b. Nomenclature: Anthrax Vaccine Adsorbed (BioThrax®)

c. Unit of Issue: Ten 0.5-mL doses per 6.1 ml multi-dose vial.

d. Shelf life: up to 18 months

e. Storage: Store product at 2 to 8 degrees C (36 - 46 degrees F). DO NOT FREEZE.

f. Acquisition Advice Code: A

g. Dosage: Primary immunization series consists of six subcutaneous injections, 0.5 mL each, given IAW ANNEX C.

h. Cost: The anthrax vaccine will be provided through USAMMA at no cost to units. Ancillary supplies are the responsibility of the receiving activity (see Part 5 for recommended ancillary supplies). The current contract includes manufacturer distribution to first destination. Transportation will be conducted by a commercial freight forwarder for all destinations.

3. CONCEPT OF OPERATION. Logistics Overview.

a. The U.S. Army Medical Materiel Agency (USAMMA) will coordinate the allocation and distribution of the anthrax vaccine with the AVIP Agency.

b. The vaccine is centrally funded by the Program Executive Office for Chemical and Biological Defense (PEOCBD)--formerly Joint Program Office for Biological Defense (JPO-BD)--and stored at the manufacturer, BioPort. 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.armymedicine.army.mil/usamma). Notified units will submit their initial requisition for a 60-90 day supply requirement. Units must make plans for submitting their subsequent requisitions of vaccines at 90-day intervals (with sufficient order ship times).

c. When a requisition for the vaccine has been validated and approved by the AVIP Agency, USAMMA will forward the requisition to the manufacturer, BioPort. Vaccine will then be distributed to the requesting activity.

4. RESPONSIBILITIES.

a. Office of the Surgeon General (OTSG)/U.S. Army Medical Command, AVIP Agency.

(1) Oversight for the Anthrax Vaccine Immunization Program.

(2) Management of the distribution of vaccine worldwide.

(3) Validation of off-line requisitions from units against the HQDA unit priority lists.

b. U.S. Army Medical Materiel Agency.

(1) Coordinate the release of vaccine with BioPort.

(a) Number of vials to be released

(b) Address of Ship-to activity (Since commercial carriers will be used, street, specific building/room number, POC, and phone number must be provided for each shipment; no PO boxes or APO/FPOs).

(2) Coordinate the receipt of vaccine with the activity.

(3) Provide the activity advanced shipping information.

(4) Provide the activity authorization/release of vaccine for use. If immediate release of vaccine is necessary the receiving activity is required to contact USAMMA and follow “green light/red light” instructions. (Ref. Appendix A)(5) Provide the activities vaccine redistribution instructions for vaccine when required. (Ref. Appendix B)

(5) Provide the activities disposition instructions for vaccine when required. (Ref. Appendix C this ANNEX)

c. Installation Medical Supply Activities (IMSAs)/Medical Logistics Battalions

(1) Receive and forward off-line requisitions (via USAMMA web site) from supported units. Requisitions forwarded to USAMMA will include the following:

(a) Number of vials requested.

(b) Justification (in a secure environment).

(c) Requestor (IMSA) Info: POC, phone number, fax number.

(d) Regional Medical Command (RMC).

(e) Ship to Address (including building/room number).

(f) Ship to POC Info: POC, phone number, email address, alternate POC, alternate phone number, alternate email address, fax number.

(2) If the IMSA is the ultimate destination:

(a) Establish due in for the vaccine.

(b) Notify USAMMA POC upon receipt of vaccine with the following data:

i Receipt of vaccine.

ii Number of vials received by lot number.

iii Condition of vaccine.

iv Shipment discrepancies (i.e., incorrect quantity, damaged shipment, etc.), if

applicable.

v Airway bill tracking number for return of temperature monitor(s).

(c) Return the temperature control monitor(s) to USAMMA, 1423 Sultan Drive, Suite 100, Fort Detrick, MD 21702-5001, in provided FEDEX/DHL envelopes.

(d) Once released by USAMMA, vaccine may be administered by immunization personnel.

(3) Maintain records reflecting quantities, lot numbers, and units the lots were distributed to.

(4) Provide supply status reports to your RMC, Medical Command, or chain of commands as required.

d. If unit is ultimate destination.

(1) Submit requests for vaccine via IMSA/MEDLOG BN. The IMSA/MEDLOG BN will submit off-line requisitions through the USAMMA web site. Requisitions forwarded to USAMMA will include the following:

(a) Number of vials requested.

(b) Justification

(c) Requestor (IMSA) Info: POC, phone number, fax number.

(d) Servicing Regional Medical Command (RMC).

(e) Ship to Address (including building/room number); Ship to POC Info: POC, phone number, email address, alternate POC, alternate phone number, alternate email address, fax number.

(2) Establish due in for the vaccine.

(3) Notify USAMMA POC upon receipt of vaccine with the following data:

(a) Receipt of Vaccine.

(b) Number of vials received by lot number.

(c) Condition of vaccine.

(d) Shipment discrepancies (i.e., incorrect quantity, damaged shipment, etc.), if applicable.

(e) Airway bill tracking number for return of temperature monitor(s).

(4) Return the temperature control monitor(s) to USAMMA, 1423 Sultan Drive, Suite 100, Fort Detrick, MD 21702-5001, in provided FEDEX/DHL envelopes.

(5) Once released by USAMMA, vaccine may be administered by immunization personnel.

(6) Maintain records reflecting lot numbers and quantities.

(7) Provide supply status reports to your RMC, Medical Command, or chain of command as

required.

(8) Submit requisitions for ancillary supplies to IMSA/MEDLOG BN.

(9) Schedule subsequent off-line requisitions of vaccine at 90-day intervals (allow for order-ship time).

5. ANCILLARY SUPPLIES. The following is the preferred list of ancillary supplies for the administration of anthrax vaccine, adsorbed:

NSN	ITEM	U/I	
6515-00-655-5751[1]	5/8 inch, 25 gauge needle	pg	
and			
6515-00-982-4206[1]	Tuberculin, 1cc syringe,	pg	
or			
6515-00-982-4205[1]	Needle and Syringe Hypo 1cc	pg	
6510-00-786-3736	Cotton, isopropyl (alcohol pad)	pg	100s
6510-00-782-2700	Sponge gauze 2X3 inch (gauze)	pg	
	Gloves		bx
	Sharps container		

[1]Note: the needle and syringe can be purchased as a single unit or separately.

Activities may substitute alternative ancillary supplies based on local availability and clinician preference so long as selected method delivers a subcutaneous dose of 0.5ml of anthrax vaccine, adsorbed.

NOTE: 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 per AR 40-562, paragraph 4.4.

6. SUPPORTING EQUIPMENT. (Ref. Appendix D)

4110-01-459-3690	VaxiCool	$3,335.00	ea
6515-01-475-8145	VaxiPac	$152.62	ea
6850-01-475-8133	VaxiSafe	$6.00	ea
	Endurotherm Box		
	TempTale (temperature monitor)		

7. COORDINATING INSTRUCTIONS. USAMMA POCs listed below will serve as points of contact for questions and/or problems experienced at MTFs relative to the requisitioning, shipment of materiel, and supporting equipment issues. Clinical and policy questions should be addressed to the AVIP Agency POC listed below.

a. POCs at USAMMA:

(1) USAMMA Distribution Operations Center (formerly Focused Distribution Management Branch) Comm: (301) 619-4121, 4128, 4411, 4318, 4198, 4320 DSN: 343-4121, 4128, 4411, 4318, 4198, 4320, FAX: 343-4468

(2) Website: http://www.armymedicine.army.mil/usamma.

(3) Deputy Director, AVIP Distribution Operations & USAMMA Pharmacy Consultant Comm: (301) 619-4307 DSN: 343-4307

b. Implementation Plan/Policy POC at AVIP Agency:

Chief Army Analyst, Comm: (703) 681-2848, DSN: 761-2848

APPENDIX 1 to ANNEX D

TempTale Monitor

The Distribution Operations Center (DOC) has a system in place for immediately checking the validity of the vaccine and for releasing the vaccine. The following procedures apply:

- If vaccine is needed immediately, contact the Distribution Operations Center at Commercial # 301-619-4121/4128/4411/4198/4318/4320, DSN 343, before opening box.
- Upon receipt of the vaccine, with a person from the DOC on the phone, open the container and remove the packing materials until you reach the TempTale monitor. Remove the monitor from the box.
- When looking at the face of the TempTale monitor, you will notice two light emitting diodes (LEDs) recessed towards the bottom of the label. One is a red light and the other is a green light.
- Turn the bottom of the TempTale towards you. You will notice two holes. One hole will have a silver ring around it and the other hole will not.
- While observing the lights on the face of the TempTale monitor. Insert a pen in the hole without the silver ring.
- One of the lights will flash at you.
- **If the light is Green.** Your vaccine has arrived within its temperature range. At this time the DOC will release the vaccine for immediate use.
- Place the vaccine into proper refrigeration, which is between 2 to 8 degrees C (36 to 46 F).
- **If the light is Red**. Your vaccine did not arrive within its temperature range and you will receive further instructions from the DOC.
- Vaccine is **NOT** released for use until you get approval from the Distribution Operations Center.
- Return the TempTale and any other material that may be requested, back to the Distribution Operations Center.

If the vaccine is not needed immediately and it is an Outside the Continental United States (OCONUS) location then all that is needed is a check on the lights on the monitor. The DOC will be notified that vaccine has been received and a report will be given on the color of the light. Vaccine will not be released until the DOC receives the TempTale monitor back from recipient and downloads the information.

- **Note: Red and Green light check procedures are designed to validate that the temperature of the vaccine was maintained within acceptable ranges during transport.**

APPENDIX 2 to ANNEX D

REDISTRIBUTION OF THE
ANTHRAX VACCINE ADSORBED (AVA)
STANDARD OPERATING PROCEDURE (SOP)

1. **GENERAL INFORMATION**

   a. PURPOSE: This SOP is intended to establish detailed procedures and effective command and control for redistribution of AVA.

   b. OBJECTIVES:

   1. To minimize loss due to expiration by redistribution throughout military organizations.

   2. To ensure proper handling techniques and transportation requirements are established for redistribution of the AVA.

   c. APPLICABILITY: The procedures contained herein are applicable to all military activities receiving the anthrax vaccine.

2. **ANTHRAX VACCINE INFORMATION:** The vaccine must be refrigerated and maintained at temperatures between 2 and 8 degrees Celsius (36 to 46 degrees Fahrenheit). **DO NOT FREEZE**. AVA is a non-extendable Shelf Life Code Type 1 item.

3. **IDENTIFY VACCINE**: Failure to Identify vaccine that will not be administered prior to expiration cannot be permitted. Units must review forecasted immunizations to determine if they will be able to administer on-hand vaccine prior to its expiration date. Activities must notify the USAMMA Distribution Operations Center (DOC) at least thirty (30) days before the expiration date to permit the redistribution of the vaccine to a site that can use it before it expires. The DOC must be contacted to coordinate the redistribution of vaccine for any distance that requires greater than 45 minutes traveling time.

4. **VACCINE TRANSPORTATION REQUIREMENTS:** Routine shipments of the vaccine are accomplished via DoD approved packaging and shipping containers. In the event redistribution of the vaccine becomes necessary and is approved by the DOC and the respective service agency; the approved method of accomplishing redistribution is via the use of the VaxiCool® or VaxiPac®. The VaxiCool® is a commercially procured vaccine refrigeration system the U.S. Army Medical Materiel Agency (USAMMA) purchased for transport and short term storage of the anthrax vaccine exclusively for all redistribution missions. The VaxiPac® is a commercially procured patented phase change material (PCM) container designed to maintain vaccine at the appropriate temperature (2 – 8 degrees Celsius). The Service Medical Logistic Field Operating Agencies (FOAs) should have several containers available to accommodate multiple deliveries. The DOC will provide all guidance and written instructions to the activities losing or gaining vaccine.

5. **REDISTRIBUTION PROCEDURES:**

   a. Activities will report vaccine inventories on hand with a shelf life of 120 days or less based on the lot expiration dates. The report will include lot numbers, quantities and storage temperature history. If additional reporting is required, it will be so stipulated by the DOC, USAMMA.

   b. Reports can be phoned or faxed to: DOC, USAMMA, ATTN: Mrs. Bonnie Pereschuk, Mr. David Orgler, Mrs. Kandi Barnhart, Ms. Liz Andrews, Mr. Ruben Gueits, or Mrs. Kitty Reese at DSN 343-4121/4128/4411/4198/4318/4320; or (301) 619-4121/4128/4411/4198/4318/4320, FAX x4468.

c. The DOC will provide the losing activity detailed packing instructions for the VaxiCool® or VaxiPac® container; gaining activities will be provided receiving and processing matrix for the transported vaccine.

d. An empty VaxiCool® or VaxiPac® container with shipping labels and a serial numbered security seal will be sent to the losing activity. If the container is damaged, refuse receipt and notify DOC immediately with details of refusal.

e. If container is in satisfactory condition, receive and process documents and pack vaccine in accordance with instructions provided.

f. With the provided pre-addressed, overnight express-mail label, send the VaxiCool® or VaxiPac® to the gaining unit.

g. Call DOC to confirm overnight express-mail airbill tracking number, and security seal serial number for the shipment.

h. Upon receipt of the vaccine the gaining activity will immediately inspect the VaxiCool® or VaxiPac®, security seal for serial number accuracy and contents for damage. If container contains a TempTale monitor, please confirm with DOC for procedures.

i. If container or contents are damaged, refuse shipment and notify the DOC immediately with details.

j. If container is in satisfactory condition, receive and immediately secure vaccine in the required refrigerated storage environment (2° to 8° Celsius or 36° to 46° Fahrenheit) **DO NOT FREEZE.** Call DOC to confirm receipt.

k. Process documents and vaccine in accordance with the information provided.

l. Request commercial carrier to wait for the VaxiCool® or VaxiPac®. Ship container back to DOC using the provided pre-addressed, overnight, express-mail label.

m. Call DOC to confirm overnight express-mail label tracking number.

n. Establish stock record accountability of vaccine IAW Service regulations.

o. DO NOT RELEASE THE VACCINE TO END-USER UNTIL AUTHORIZED BY THE DOC.

p. Only those vials maintained at the Medical Logistics Activity will be redistributed within the services.

6. Points of Contact:

ARMY (Executive Agent)
USAMMA Distribution Operations Center (DOC)
DSN 343-4121/4128/4411/4198/4318/4320 or (301) 619-4121/4128/4411/4198/4318/4320
FAX x4468
Bonnie.Pereschuk@amedd.army.mil

AIR FORCE
MSGT (S) Dale Clark:
DSN 343-4172 or (301) 619-4172 or
PAGER (888) 587-9892, FAX x2557
Dale.Clark@Ft-Detrick.af.mil

NAVY
HM1 Victor Inniss
DSN 343-7117 or (301) 619-7117
veinniss@us.med.navy.mil

APPENDIX 3 to ANNEX D

DISPOSITION INSTRUCTIONS FOR
ANTHRAX VACCINE

1. PURPOSE: To provide guidance and procedures for the proper disposition of compromised or expired Anthrax vaccine and the preparation of the Executive Summary and Destruction Memorandum.

2. REFERENCE: Hazardous and Medical Waste Program**,** U.S. Army Center for Health Promotion and Preventive Medicine, Aberdeen Proving Ground, MD (USACHPPM), and Military Item Disposal Instructions (MIDI).

3. APPLICABILITY: The procedures contained herein are applicable to all DoD activities receiving the Anthrax vaccine.

4. EXECUTIVE SUMMARY (EXSUM) PROCEDURES: DoD Activities are responsible for reporting any loss of anthrax vaccine, due to expiration, or loss of efficacy by another means, i.e. exceeding required temperature parameters.

The following EXSUM requirements must be reported in memorandum format:

a. DoD activity will prepare the EXSUM within 24 hours upon discovery of compromised vaccine.

b. No longer than one page in length.

c. Explain the circumstances surrounding the loss of vaccine potency or why the activity did not use the vaccine.

d. Complete list of Lot number(s).

e. Complete count of whole vial(s).

f. Detailed explanation of course of corrective action to preclude future loses of vaccine.

g. List of names and telephone numbers of points of contacts.

The EXSUM should be routed up the chain of command for review and endorsement before faxing to the UNITED STATES ARMY MEDICAL MATERIEL AGENCY (USAMMA) Distribution Operations Center (DOC). **The DOC must receive the EXSUMS from sites that identified vaccine for destruction before replacement vaccine will be shipped.**

5. DISPOSAL PROCEDURES: DoD Activity's are responsible for disposal of compromised or expired vaccine. The Anthrax vaccine is considered non-hazardous waste. **DO NOT DISCHARGE THIS ITEM INTO A SANITARY SEWER.**

a. Activities will report vaccine inventories on hand to be destroyed to their respective logistic agencies. The report will include information regarding lot numbers and quantities.

b. Activities must prepare a destruction document detailing the specific Lot number(s) and quantity of vaccine destroyed. The disposal code for item 6505-01-399-6828 (Anthrax Vaccine Adsorbed) is CA01.

c. EXSUM and DESTRUCTION DOCUMENT should be sent to:

ARMY (Executive Agent)
USAMMA Distribution Operations Center (DOC)
DSN 343-4121/4318/4411/4198/4320/4128
COM: (301) 619-4121/4318/4411/4198/4320/4128
FAX: DSN 343-4468 COM: 301-619-4468
Bonnie.Pereschuk@det.amedd.army.mil

6. METHODS FOR DISPOSAL: Explanation for disposal are detailed in the following MIDI Website: http://chppm-www.apgea.army.mil/newmidi/longview.aspx?Param=CA01

The following procedures are in place in the event the above mentioned disposal methods are not available or immediate disposal is necessary:

a. Contact the DOC and provide information regarding lot numbers and quantities. The DOC will provide further shipping guidance.

b. Remove each vial from its package.

c. Tear or shred the insert and package and dispose of as regular waste.
d. Deface the label on each vial with red permanent marker.

e. The activity will pack the container according to instructions provided and mail the container to DOC.

f. The activity will call the USAMMA, DOC, and provide overnight express-mail tracking number for the container.

7. QUESTIONS OR CONCERNS: Those charged with the disposal and destruction should address all questions or concerns to USAMMA at DSN 343-4307/4309 or (301)-619-4307/4309, FAX x4189.

Changes or updates to this SOP must be brought to the attention of the Distribution Operations Center (DOC), UNITED STATES ARMY MEDICAL MATERIEL AGENCY (USAMMA).

APPENDIX 4 to ANNEX D

AVIP Plan
Logistics Annex
Equipment

The U.S. Army Medical Materiel Agency **(**USAMMA) has been tasked with the responsibility for worldwide distribution of the anthrax vaccine for the Department of Defense (DoD). Vaccine must be maintained within controlled temperature limits while it is in transit. Exceeding these temperature limits results in loss of vaccine potency. The following containers are currently in use in support of the Anthrax Vaccine Immunization Program (AVIP):

The VaxiCool: Is a commercially procured, high-efficiency refrigerator system specially designed for the local transport and/or temporary storage of the Anthrax vaccine and other temperature-sensitive pharmaceuticals.

----Manufacturer: Energy Storage Technologies (EST), Dayton, OH
----Model: VX30PPNR
----NSN: 4110-01-459-3690
----Material: It is comprised of Vacupanel Insulation designed to maintain vaccine at 2 - 8 degrees Celsius.
----Payload: 400 vials maximum.
----Alternate Power sources: 110 AC (220 w/special cable), car battery, solar panels, car cigarette lighter
----Batteries: 2-12 volt/12 or 14 Amp gel cell batteries.
----Total Purchased: 112
----Price: $3,335

The VaxiCool can maintain temperature after being disconnected from a power source for up to 4 days on internal batteries and 16-24 hours more based on its insulation capabilities.

The VaxiPac: The VaxiPac is a small, commercially procured, high-efficiency insulated container used for transport of the Anthrax Vaccine and other temperature-sensitive pharmaceuticals. It uses a product called VaxiSafe to maintain temperature. The VaxiSafe is composed of a Phase Change Material (PCM) that hardens at 6 degrees Celsius and protect against varying temperatures. The VaxiPac comes with 5 VaxiSafes from the manufacturer.

----Manufacturer: Energy Storage Technologies (EST), Dayton, OH
----NSN: 6515-01-475-8145
----Material: It is comprised of Vacupanel Insulation.
----Payload: 1 to 24 vials maximum.
----Total Purchased: 300
----Price: $152.62 ea
----VaxiSafe Price: $6.00 ea

The VaxiPac is used for re-distributions for up to 24 hours.

Endurotherm Boxes: A complete packing system was designed to ensure the cold chain is not broken. They are available in three different sizes small, medium and large. Vaccine is shipped from the manufacturer (BioPort) using the Endurotherm boxes which have gone through various testing protocols. This box can maintain the required temperature for up to 7 days.

-----Manufacturer: Insulated Shipping Container (ISC), Inc., Phoenix, AZ
-----Material: It is comprised of two corrugate layers injected with polyurethane foam within a mold. The end product is a rigid, one piece, three layer laminate container.
-----Payload, weight and contents prices:

- Small Box: 1-20 vials; packed wt - 15 lbs, contains (6) 24 oz Gel packs, (1) small box insert, packing peanuts, tape, labels, (1) cardboard separator and (1) temptale = $59.00
- Medium Box: 53-110 vials; packed wt - 25 lbs, contains (9) 24 oz Gel packs, (1) large box insert, packing peanuts, tape, labels, (1) large cardboard separator and (1) TempTale - 64.32
- Large Box: 440 vials; packed wt - 75 lbs, contains (13) 24 oz Gel packs, (4) large box inserts, packing peanuts, tape, labels, (1) large cardboard separator and (1) TempTale = 95.70

ANNEX E – EDUCATION/COMMUNICATIONS PLAN

1. GENERAL. The Department of Defense will resume the Anthrax Vaccine Immunization Program (AVIP), in accordance with FDA guidelines and consistent with the best practice of medicine, beginning with personnel at highest risk.

2. OBJECTIVE. Ensure full understanding and acceptance of the Anthrax Vaccine Immunization Program by soldiers, DA civilians, and their families, Congress, the American public, and the media.

3. GOALS.

a. Inform all stakeholders that to immunize U.S. forces using anthrax vaccine is the right thing to do to best protect personnel against anthrax.

b. Gain soldier, family member, Congressional, public, and media support for the vaccination of U.S. forces against anthrax.

c. Use this opportunity to inform the American public that biological warfare is a potential threat to our forces.

4. MESSAGES.

a. Your health and safety are our number 1 concerns.

(1) We care about you and your families.

(2) Vaccines have kept troops healthy since the days of George Washington.

(3) This vaccine helps you complete your mission and return home safely.

b. Anthrax vaccine is safe and effective

(1) U.S. anthrax vaccine has been FDA-licensed since 1970.

(2) The National Academy of Sciences and six panels of civilian scientists confirm that anthrax vaccine works and is safe.

(3) Research shows anthrax vaccine protects.

c. The threat from anthrax is deadly and real.

(1) Anthrax is a top choice for use as a biological-warfare agent.

(2) The most deadly form of anthrax, inhalational anthrax, is the form most expected on the battlefield.

(3) You can be infected with anthrax and not know it, until it's too late.

d. Vaccination offers a layer of protection, in addition to antibiotics and other measures, needed for certain members of the armed forces.

5. CONCERNS.

a. The DoD learned that service members, friends and family, and the American public have many concerns. The following list is an example of concerns from individuals:

(1) The threat: individuals have questioned the validity and the relevance of the threat (how likely is it that a potential adversary will use these weapons--Is the AVIP necessary)

(2) People have questioned the overall effectiveness of anthrax vaccine (If exposed, are we protected?)

(3) People have general and specific questions about the safety of the vaccine, especially, long-term health consequences. These include specific questions about the health of Gulf War Veterans.

(4) It is important to give correct information to people first. Many times people research information on their own and base decisions and beliefs on what they've heard from others (internet rumors, urban legends, media) instead of scientific, verifiable facts.

(5) Leaders want good, clear guidance on how to execute the program correctly People and commanders are concerned about the consequences of noncompliance (refusals, poor performance, etc.)

6. CONCEPT OF OPERATION.

a. Education.

(1) Before vaccination, Commanders will ensure that vaccine recipients are provided adequate and accurate information on the threat, the vaccine, its safety, its benefits, and the need for adherence to the immunization schedule. Commanders will provide all soldiers, DA civilian personnel and civilian contractors with a briefing on anthrax and the vaccination program. The briefing at Appendix 4, this ANNEX, is provided for this purpose. An informational brochure, Appendix 1, this ANNEX, will be distributed to all soldiers, DA civilian personnel and civilian contractors respectively, prior to receiving the first shot of this vaccine, or their next shot after deferral through recent DoD slowdown policies. Your local medical treatment facility maintains stocks of trifolds for use. All approved educational material are always available on the web: www.anthrax.mil.

(2) Commanders are encouraged to provide education for family members of soldiers and civilians receiving anthrax vaccinations. For example, this can be accomplished through family support group meetings at unit level and town hall meetings at installation level. Commanders may use the briefing at Appendix 4, this ANNEX, for this purpose.

(3) Healthcare professionals and staff play key roles in this program, both in its execution as well as providing expert advice to soldiers and commanders. They must become familiar with all aspects of anthrax and Anthrax Vaccine Adsorbed. The briefing at Appendix 5, this ANNEX, is provided for this purpose.

(4) Commanders should coordinate educational meetings and briefings to ensure full participation by healthcare subject matter experts (SME) and PAO staff. The AVIP Agency conducts Quarterly Spokesperson Trainings in the national capitol region for individuals that are likely to represent the installation and are used as an AVIP SME. For schedule calendars and attendance, contact the AVIP Agency at 1.877.GETVACC.

(5) You can get more information on all aspects of the Anthrax Vaccine Immunization Program at the official AVIP website, www.anthrax.mil. You can also call the AVIP Agency's toll-free information line at 1-877-GETVACC, which is staffed Monday through Friday, 0800-1800 Eastern Standard Time. You can send email inquiries to avip@otsg.amedd.army.mil.

b. Public Affairs. Public Affairs Offices Army-wide will use informational products developed and designed by OTSG/MEDCOM's AVIP Agency and approved by DoD to garner internal-Army and external

support of the AVIP, including the DoD provided worldwide Public Affairs Guidance (para 6.c.(3) this Annex), all available on the DoD AVIP Website: www.anthrax.mil.

c. Responsibilities.

(1) Army Commanders:

(a) Oversee coordination and execution of this plan.

(b) Identify spokespersons and points of contact at all levels of command for soldiers, family members, and media.

(c) Ensure military and civilian personnel and family members of soldiers are briefed on local vaccination plans - coordinate with local hospital commander for clinical expert assistance.

(d) Ensure these efforts are coordinated with local medical treatment facility commanders or their representatives.

(e) Ensure these efforts are coordinated with respective public affairs officers.

(2) Army Medical Treatment Facility Commanders:

(a) Oversee coordination and execution of all clinical aspects of this plan.

(b) Coordinate with local commanders the medical aspects of the education/communications plan. Maintain stocks of printed trifolds for local commanders' use educating their personnel. Trifolds can be printed directly from the web, www.anthrax.mil, or ordered through AVIP Agency, 1-877-GETVACC (staffed Monday through Friday, 0800-1800 Eastern Standard Time), by sending an email to avip@otsg.amedd.army.mil.

(c) Ensure medical activity personnel receive the health care providers briefing and have access to the clinical questions and answers referenced in Appendix 7 this ANNEX.

(d) Ensure local medical personnel are briefed on local vaccine implementation plans.

(e) Identify a clinical subject matter expert to participate in interviews with local and civilian media.

(f) Identify a medical subject matter expert(s) to provide or assist with briefings to soldiers and family support groups.

(g) Identify a medical subject matter expert or office by name and phone number to be included on all soldier, family member, and civilian educational material. It is critical that the POC(s) responsible for answering these calls be able to address the questions or get answers to callers quickly and accurately.

(3) Army Public Affairs: HQDA released DoD public affairs guidance to Army MACOMs and installations under two messages: R 290223Z JUN 02 SUBJ: PUBLIC AFFAIRS GUIDANCE - RESUMPTION OF ANTHRAX VACCINE, AND 290245Z JUN 02 SUBJ: RESUMPTION OF AVIP - CONTINUED. These messages provide guidance and approved Q & A for addressing the media and/or general public.

(4) MACOM Public Affairs Officers. Use questions and answers referenced in this annex, Appendix 7 this ANNEX, and HQDA-issued DoD PAO guidance mentioned above to respond to media inquiries.

7. MEDCOM Public Affairs will conduct an analysis of news coverage. All MEDCOM PAOs are requested to forward news clippings with regard to the announcement to: Rick Sonntag, 210-221-7163, MEDCOM Public Affairs Office, Fax 210-221-8483, DSN 471-8483.

APPENDIX 1 to ANNEX E—(EDUCATION/COMMUNICATIONS PLAN)
TRIFOLD
http://www.anthrax.mil/media/pdf/brochure.pdf

APPENDIX 2 to ANNEX E—(EDUCATION/COMMUNICATIONS PLAN)
ANTHRAX VACCINE INFORMATION STATEMENT FROM THE CDC
http://www.anthrax.mil/media/pdf/vac_statement.pdf

APPENDIX 3 to ANNEX E (EDUCATION/COMMUNICATIONS PLAN)
IOM Report (Anthrax Vaccine Safety) *The Anthrax Vaccine: Is It Safe? Does It Work?*
http://www.nap.edu/catalog/10310.html

APPENDIX 4 to ANNEX E (EDUCATION/COMMUNICATION PLAN)
INDIVIDUAL'S BRIEFING
http://www.anthrax.mil/media/pdf/indvbrief.pdf

APPENDIX 5 to ANNEX E (EDUCATION/COMMUNICATIONS PLAN)
COMMANDERS' BRIEFING
http://www.anthrax.mil/media/pdf/ldrbrief.pdf

APPENDIX 6 to ANNEX E (EDUCATION/COMMUNICATIONS PLAN)
CLINICIAN'S BRIEFING
http://www.anthrax.mil/media/pdf/hcpbrief.pdf

APPENDIX 7 to ANNEX E (EDUCATION/COMMUNICATIONS PLAN)

STAKEHOLDER (Persons with AVIP Interest or Potential Interest) LIST

1. All military members of all services, DoD civilian employees and DoD contractors, especially those who will be vaccinated.

2. Family members of persons who will be vaccinated.

3. Local, regional, national and international media.

4. Communities near installations with military who will be vaccinated.

5. State and local governments.

    a. Governors and representatives of states where Army installations are located.

    b. Local officials in areas near installations where soldiers reside.

6. Congress.

7. Civilian Aides to the Secretary of the Army.

8. Internal audiences.

    a. All soldiers who will be vaccinated.

    b. All DA civilian employees and contractors who will be vaccinated.

    c. Family members of Army personnel who will be vaccinated.

    d. Army senior leaders.

    e. Army commanders at all levels.

    f. All MEDCOM personnel.

    g. Officials who will be educating soldiers.

    h. Officials who will vaccinate soldiers.

9. Army Public Affairs Officers.

APPENDIX 8 to ANNEX E (EDUCATION/COMMUNICATIONS PLAN)--QUESTIONS AND ANSWERS

1. The Department of Army Public Affairs (SAPA-PCD), G-3, Chemical/NBC Defense (DAMO-FDB), the Army Surgeon General (DASG-RDZ), and Army Medical Command (MCPA), developed the questions and answers and serve as starting points for information that may be requested by the news media or within DoD.

http://www.anthrax.mil/resource/qna/q_a.asp

Points of Contact:

MEDCOM Public Affairs: 210-221-7163 or DSN 471-6213

Army Public Affairs: 703-697-7550 or DSN 227-7550

ANNEX F - REPORTING REQUIREMENTS

1. REFERENCES

Assistant Secretary of Defense for Health Affairs memorandum, 15 Oct 1999, Policy for Reporting Adverse Events Associated with the Anthrax Vaccine (http://www.anthrax.mil/media/pdf/vaers.pdf)

2. GENERAL

Adverse events associated with the anthrax vaccine will be reported IAW Ref. this ANNEX and Annex C of this plan.

ANNEX G - PERSONNEL

1. SCOPE. This Annex applies to all members of the active Army, the Army National Guard (ARNG), and the U.S. Army Reserve (USAR).

2. PURPOSE. To provide the personnel concept of operations and assign responsibility for the implementation of the Army's Anthrax Vaccine Immunization Program (AVIP).

3. REFERENCES.

a. DoD Directive 6205.3, DoD Immunization Program for Biological Warfare Defense, 26 Nov 93.
- http://www.dtic.mil/whs/directives/corres/pdf/d62053_112693/d62053p.pdf

b. AR 27-10, Military Justice, 6 Sep 02.
- http://www.usapa.army.mil/pdffiles/r27_10.pdf

c. AR 40-562, Immunizations and Chemoprophylaxis, 1 Nov 95.
- http://www.usapa.army.mil/pdffiles/r40_562.pdf

d. AR 220-1, Unit Status Reporting,15 Nov 01.
- http://www.usapa.army.mil/pdffiles/r220_1.pdf

e. AR 600-8 Military Personnel Management, 1 Oct 89.
- http://www.usapa.army.mil/pdffiles/r600_8.pdf

f. AR 600-8-11, Reassignment, 1 Oct 90.
- http://www.usapa.army.mil/pdffiles/r600_8_11.pdf

g. AR 600-8-101, Personnel Processing (In-and Out-and Mobilization Processing), 1 Mar 97.
- http://www.usapa.army.mil/pdffiles/r600_8_101.pdf

h. AR 600-8-104, Military Personnel Information Management/Records, 27 Apr 92.
- http://www.usapa.army.mil/pdffiles/r600_8_104.pdf

i. AR 600-8-105, Military Orders, 28 Oct 94.
- http://www.usapa.army.mil/pdffiles/r600_8_105.pdf

j. AR 600-20, Army Command Policy, 13 May 02.
- http://www.usapa.army.mil/pdffiles/r600_20.pdf

k. AR 614-6, Permanent Change of Station Policy, 7 Oct 85.
- http://www.usapa.army.mil/pdffiles/r614_6.pdf

l. AR 614-30, Overseas Service, 30 Aug 01.
- http://www.usapa.army.mil/pdffiles/r614_30.pdf

m. DA PAM 600-8, Management and Administration Procedures, 1 Aug 86.
- http://www.usapa.army.mil/pdffiles/p600_8.pdf

n. Under Secretary of Defense (Personnel and Readiness) memorandum, Policy on Administrative Issues Related to the Anthrax Vaccine Immunization Program (AVIP), dated 06 Aug 02.
- http://www.anthrax.mil/media/pdf/AdminIssues.pdf

4. CONCEPT OF OPERATIONS. The Army will implement a phased program to vaccinate all members of the Active Army and Reserve Components deployed to the HTAs in accordance with the FDA immunization schedule and OSD and JCS guidance. This annex delineates responsibilities and establishes personnel policy guidance for the establishment of new personnel regulatory and procedural directives.

5. PLANNING ASSUMPTIONS.

a. OTSG administers the Medical Protection System (MEDPROS) automated immunization tracking system to track anthrax immunizations.

b. Interim personnel regulatory changes and policy guidance will be approved and published prior to immunizing the force.

c. Personnel record keeping and movement processing will incorporate administrative redundancies to ensure accurate tracking during movement.

d. A small percentage of the force may experience vaccination adverse events sufficient to warrant termination of the vaccine schedule, which may require assignment limitations.

e. The MOS/Medical Retention Board (MMRB) and Medical Evaluation Board (MEB) system will establish assignment limitations in conjunction with medical authority.

6. RESPONSIBILITIES.

a. Deputy Chief of Staff for Personnel G-1.

(1) Coordinate with U.S. Military Entrance Processing Command (USMEPCOM) all personnel policies pertaining to pre-accession considerations concerning anthrax immunizations.

(2) Observe medical guidelines established by the Surgeon General in ANNEX C when originating personnel vaccination directives.

b. Deputy Chief of Staff for Operations G-3.

(1) In conjunction with the Deputy Chief of Staff for Personnel, update procedures for readiness reporting which incorporates unit anthrax immunization status.

(2) Establish and/or validate priorities for units and personnel to receive the anthrax vaccine.

c. The Surgeon General.

(1) Advise the G-1, G-3 and the Office of the Assistant Secretary of the Army, (Manpower and Reserve Affairs) on all clinical policy decisions, that impact personnel and readiness regulations. Clinical policy must be set prior to incorporation of new personnel policy into existing regulations.

(2) Ensure personnel exhibiting adverse events after anthrax vaccination are properly profiled. Establish clinical guidelines and establish profile policy for clinicians. Personnel with P3 profiles will enter the MOS/Medical Retention Board process to determine assignment limitations, if any.

(3) Establish appropriate physician profiles for soldiers experiencing adverse events after anthrax immunizations that preclude further vaccination.

(4) Establish medical policies and implement procedures that delineate populations for which anthrax immunizations are medically contraindicated or not required. Select individuals are exempt from anthrax immunizations and therefore utilization policies must be considered.

d. Commander, Total Army Personnel Command (PERSCOM).

(1) Establish regulatory policy and procedural requirements to ensure anthrax immunization schedule status is properly documented in orders prior to movement of personnel.

(2) Establish in- and out-processing controls that cause soldiers on assignment instructions to HTAs to complete the first three anthrax immunizations prior to permanent change of station.

(3) Incorporate anthrax immunization requirements and documentation into all Soldier Readiness Processing (SRP) regulatory guidance.

e. Chief, National Guard Bureau (NGB).

(1) Advise DCSPER regarding the impact of the AVIP on National Guard personnel and units.

(2) Develop and coordinate National Guard anthrax immunization policy for State Area Commands and the Air National Guard.

(3) Develop policy and procedures for documenting immunization adverse event medical profiles in personnel and medical records so they can be used for readiness and mobilization processing.

(4) Establish a business process to monitor the incidents of adverse event that occur after the soldier has been released from military control (i.e. annual training, BCT, AIT).

f. Chief, Army Reserves (CAR).

(1) Advise G-2 regarding the impact of the AVIP on USAR personnel and units.

(2) Develop and coordinate USAR anthrax immunization policy for major commands, and the U.S. Army Reserve Personnel Command (AR-PERSCOM).

(3) Develop policy and procedures for documenting immunization adverse event medical profiles in personnel and medical records so they can be used for readiness and mobilization processing.

(4) Establish a business process to monitor the incidents of adverse event that occur after the soldier has been released from military control (i.e. after annual training, BCT, AIT).

ANNEX H - ARMY NATIONAL GUARD

1. PURPOSE. Provide the Army National Guard (ARNG) concept of operations and planning guidance to the States and Territories for implementing the Anthrax Vaccine Immunization Program (AVIP).

2. SCOPE. This annex applies to all members of the Army National Guard.

3. Planning assumptions:

a. ARNG soldiers participating in HTAs such as homeland security missions and/or units likely to deploy in support of specific theater of operation where the threat of anthrax is likely, may be included in Priorities 1 and 2.

b. All other ARNG soldiers will be placed into the appropriate Priority Category upon notification/selection for selection in an operation located within an HTA.

c. The DA Plan and this annex allow maximum flexibility to the states to use internal and external resources.

d. The Weapons of Mass Destruction (WMD) - Civil Support Teams will respond to terrorist threats that will require early immunizations of CST team members. (Priority 1)

e. The immunization status of each ARNG member will be tracked by the State Area Command (STARC) using the DA approved tracking system at ANNEX K (MEDPROS). The system will interface & update DEERS.

f. The FDA-approved 6-dose series will continue to be the requirement throughout the period of implementation unless notified of an FDA-approved regimen change.

g. DoD will fund additional expenses associated with administration of this program. These costs include, but are not limited to the following: contracts, ancillary supplies, shipping, man-days/per diem/travel for additional training assemblies required for soldiers administering the program and for those receiving the injections, and incapacitation pay for treatment of those having adverse reactions.

h. The ARNG will have access to any contracted resources and funding to contract resources to administer the vaccine.

4. RESPONSIBILITIES.

a. G1 Chief, Human Resources Division

(1) Develop and coordinate the AVIP for ARNG.

(2) Ensure the procurement of vaccine and ancillary supplies required to implement the Anthrax Vaccine Immunization Program within the National Guard.

b. The ARNG Program Analysis, and Evaluation Division (NGB-ARA). Develop requirements for submission to appropriate Program Evaluation Group (PEG) for the purpose of competing in the Program Objective Memorandum (POM) process.

c. The ARNG Information Management Division (NGB-AIS). Ensure adequate communication support for tracking mechanisms.

d. The ARNG Policy and Communications Office (NGB-ARZ-PC). Develop a public affairs plan in coordination with DoD, DA, and NGB-PA.

e. The ARNG Surgeon's Office (NGB-ARS). Provide related medical policy and guidance.

f. State TAG will:

(1) Ensure ARNG personnel are immunized against anthrax IAW Army guidance.

(2) Develop State plan for implementation of AVIP.

(3) Track unit immunization status and provide reports as required.

g. State Area Command (STARC) Medical Detachment will coordinate:

(1) Immunizations in support of state plan.

(2) Annotation of immunizations in medical record and the DA automated tracking system (MEDPROS) IAW ANNEX K..

(3) Commanders requirements for patient education support.

(4) Adverse event reporting.

(5) Requisition required vaccine and ancillary supplies IAW overall Army plan.

5. CONCEPT OF OPERATIONS.

a. Implementation. The ARNG will implement the AVIP IAW priorities established by the Office of the Secretary of Defense (OSD) and the Joint Chiefs of Staff. Reserve Component personnel shall be in a duty status when receiving a DoD directed immunization. Additional guidance on ARNG Program Implementation will be published for the states as an "All States Log Memorandum."

b. Method of Immunization. Implementation of the immunization plan will be based on the state plan to be administered by the STARC Medical Detachment. Resources to vaccinate personnel/units may be used as appropriately coordinated, to include organic medical assets, active component facilities, public health service, or VA medical assets, or private sector contractor. The STARC Medical Detachment will administer the annual booster.

c. Record Keeping. Immunizations will be noted in Public Health Service Form PHS 731 (Shot Record) and the DD Form 2766 (Immunization Record). If an individual is to be reassigned, the patient record will be flagged to clearly show the dates for scheduled completion of the initial and booster series.

d. Tracking System. Immunizations will be entered into MEDPROS IAW ANNEX K. In anticipation of mass immunizations and mandatory automated tracking, the STARC will identify all personnel requiring access to the automated tracking system, ensure they meet access requirements, and determine the data access level.

e. Logistics. On execution, USP&FO will be responsible for initiating requests for vaccine IAW ANNEX D. USAMMA will direct the distribution of the vaccine and ancillary supplies, as applicable, to the sites designated in the request.

f. Adverse Events. Commanders will establish a mechanism to monitor incidents of adverse event, to include those that occur after the soldier has been released from military control, IAW ANNEX C. National Guard members who experience adverse events and are seeking health services outside of a Military Treatment Facility must contact the Military Medical Support Office (MMSO) at 1-888-647-6676 for guidance.

g. PAO Information. Commanders at all levels will support an aggressive command information program in support of the AVIP IAW ANNEX E.

h. Command Responsibility. The execution of the AVIP is a command responsibility. The Adjutants General and Commanders at all levels will coordinate with supporting medical activities to ensure that soldiers receive required immunizations.

6. POC: ARNG- Health Care Operations Officer DSN 327-9066 or comm. 703-607-9066.

ANNEX I - U.S. ARMY RESERVE

1. PURPOSE: This annex defines the application of the concept of operations from the basic Anthrax Vaccine Immunization Program (AVIP) Plan to the U.S. Army Reserve (USAR).

2. SCOPE: This annex applies to all members of the USAR.

3. CONCEPT OF OPERATIONS:

a. Upon order of HQDA, USAR personnel will begin implementation of the AVIP. The following USAR organizations will establish policies and procedures governing administration of the AVIP for their designated soldier populations per Part 3.b. of the basic plan and Annex F.

(1) USARC for CONUS and Puerto Rico based Troop Program Unit (TPU) soldiers under its command and control.

(2) United States Army Europe (USAREUR) and 7th Army Reserve Command (7th ARCOM) for soldiers in their Area of Responsibility (AOR).

(3) United States Army Pacific (USARPAC) and 9th Regional Support Command (9th RSC) for soldiers in their AOR.

(4) US Army Special Operations Command (USASOC) for assigned USAR TPU and Individual Mobilization Augmentee (IMA) soldiers.

(5) U.S. Army Reserve Personnel Command (AR-PERSCOM) for IMA (other than USASOC) and Individual Ready Reserve (IRR) soldiers.

b. Commanders will schedule immunizations in compliance with the FDA-approved vaccination series schedule while avoiding training disruptions. Maximum coordination with other active, USAR, and ARNG commands at the regional level – i.e. Regional Support Commands (RSCs), State Area Command (STARC), and Regional Medical Commands (RMCs) – is encouraged to produce economies of scale and minimize disruption to training. Reserve component personnel will be in a duty status when receiving a DoD directed immunization.

c. Department of Defense and Federal facilities available for USAR execution of the AVIP. Immunizations should be available at times and places other than at TPU locations during drill weekends or during Annual Training. This is due to geographic dispersion of units, medical requirements associated with providing immunizations, personnel turnover, and absences from drill. The United States Army Medical Command (MEDCOM) will assist the USAR in determining the optimal location and method for completing the AVIP series. Every effort will be made to ensure that anthrax vaccine is available in the selected DoD, other Federal, or contract facilities to ensure that soldiers can obtain immunizations on the day that is required for their individual immunization schedule.

d. Command responsibility. The execution of the AVIP is a command responsibility. USAR Commanders at all levels will coordinate with supporting activities to ensure that soldiers receive the required immunization per the schedule outlined in the basic plan, unless specifically exempted through: (1) an administrative exemption, granted by a commander or supervisor, discussed in detail in ANNEX B; or (2) a medical exemption granted by a privileged healthcare provider (e.g. physicians, nurse practitioners, and physician assistants), discussed in detail in ANNEX C.

e. Method of immunization. The primary method of delivery for the initial six immunization series will be by contract provider via the Federal Strategic Health Alliance (FEDS_HEAL) program. FEDS_HEAL providers include the Department of Health and Human Services Division of Federal Occupational Health (FOH), Department of Veterans Affairs (VA) medical assets, and subcontracted civilian providers. Other

resources may be used as appropriately coordinated, to include organic medical assets and active component facilities of all Services.

f. Contract Funding. Upon request, OCAR Program Analysis and Evaluation (PAE) Division will provide input to MEDCOM Resource Management concerning development of any USAR Statement of Work (SOW) for use by Federal Agencies or civilian contractors.

g. Prioritization of Troop Populations. The USARC, AR-PERSCOM, 7th ARCOM, 9th RSC, and USASOC will prioritize troop populations to receive immunization IAW HQDA prioritization guidance. Priorities will be as follows::

(1) Forces assigned or rotating to higher threat areas as delineated.

(2) Selected Reserve (SELRES) forces.

(3) Remainder of Total Force and accessions.

h. Record keeping. Annotation of immunizations to medical records (MEDPROS, SF 601, and PHS Form 731) per the basic plan will be accomplished by the medical treatment facility or contractor administering the vaccination.

i. Tracking System. Immunizations will be entered into the DA-designated automated immunization tracking system (MEDPROS) IAW ANNEX K and reported IAW ANNEX F. Commanders, USARC, AR-PERSCOM, 7th ARCOM, 9th RSC, and USASOC will develop procedures to identify all personnel requiring access to the automated tracking system, ensure they meet access requirements, and determine data access level IAW Annex K.

j. Logistics. The U.S. Army Medical Material Agency (USAMMA) will direct the distribution of the vaccine to FEDS_HEAL providers, USAR units and, when applicable, supporting Installation Medical Supply Activities (IMSAs) per ANNEX D. IMSAs will coordinate directly with the designated medical facilities or providers for distribution of the vaccine to the immunization sites. Ancillary supplies will be the responsibility of the immunizing entity per the basic plan.

k. Adverse Events.

(1) Commanders will establish a mechanism to monitor the incidents of adverse events that occur after the soldier has been released from military control. See ANNEX C, Part 8.e., for adverse event reporting requirements.

(2) Army Reserve members who experience adverse events and are seeking health services outside of a Military Treatment Facility must contact the Military Medical Support Office (MMSO) at 1-888-647-6676 for guidance.

(3) 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.

l. Public Affairs Office (PAO) Information. Commanders at all levels will support an aggressive command information program in support of the AVIP. Commanders must use and will not deviate from the PAO information provided by HQDA. This program will include:

(1) Threat briefing.

(2) AVIP specific information as outlined in the basic plan and ANNEX E.

m. Resource Management. The Office of the Chief, Army Reserve (OCAR), PAE Division, will provide MEDCOM with the USAR AVIP cost estimates for the development of Program Objective

Memorandum (POM) submission to the DHP. This funding estimate will provide for immunization services and for future AVIP activities extending beyond the initial five-year program defined in the basic plan as determined by DoD and HQDA.

4. RESPONSIBILITIES.

a. OCAR will provide appropriate USAR immunization prioritization guidance (for identification of USAR units and personnel to be immunized) through command channels to USARC, AR-PERSCOM, 7th ARCOM, 9th RSC, and USASOC.

b. USARC will develop an implementation plan in coordination with MEDCOM.

c. AR-PERSCOM will develop an implementation plan in coordination with MEDCOM.

d. 7th ARCOM will develop an implementation plan in coordination with European Regional Medical Command and MEDCOM.

e. 9th RSC will develop an implementation plan in coordination with Pacific Regional Medical Command, Western Regional Medical Command, 18th Medical Command, and MEDCOM.

f. USASOC will develop an implementation plan for assigned USAR soldiers in coordination with MEDCOM.

ANNEX J - DEPARTMENT OF THE ARMY CIVILIANS AND DOD CONTRACTORS

1. GENERAL.

a. Anthrax vaccination will be mandatory for DA civilians in designated “Emergency Essential” (E-E) positions and contractor personnel, carrying out “mission essential’ (ME) services, assigned, deployed to or on temporary duty in the HTAs for a period of more than 15 days. Ensure all bargaining obligations are fulfilled IAW Federal Services Labor Management Relations Statute. MACOM Commanders may also identify and recommend other cohorts of personnel for vaccination against anthrax, if they deem their occupations may place then at higher risk for exposure to anthrax. Send requests to HQDA, Office of The Surgeon General, AVIP Agency, 5109 Leesburg Pike, Falls Church, VA 22041 for coordination with and approval by HQDA, CJCS and ASD(HA).

b. EE civilians and ME contractors are those personnel whose performance is considered to be essential for certain mission critical capabilities.

c. DoD Directive 6205.3, DoD Immunization Program for Biological Warfare Defense, dated 26 November 1993, applies to essential DoD civilian personnel, and personnel of other Federal Departments, when assigned as part of the U.S. Armed Forces. DoD Directive 1404.10, “Emergency-Essential (E-E) DoD U.S. Civilian Employees”, addresses policy to ensure the continued performance of civilians that have been designated E-E before crisis situations; it also addresses civilians who have not been previously designated E-E, but whose continued performance is deemed essential to support combat-essential systems. DoD Instruction 3020.37, “Continuation of Essential DoD Contractor Services During Crises”, dated 6 November 1990, with Change 1 dated 26 January 1996, states that employees designated as mission essential must be identified as such in the contract statement of work (SOW). DoD civilians and contractors are subject to the same vaccination requirements as active-duty personnel upon deployment. For contract personnel the designation as "Emergency Essential" would appear in your contract.

d. Command-directed anthrax vaccinations are administered without charge to civilian employees.

e. E-E civilians and ME contractors will be vaccinated IAW with MACOM guidelines, in most cases going to the nearest MTF for vaccination. A SOW would be presented to show eligibility for vaccination.

2. CONSENT FOR IMMUNIZATION.

a. In most cases, civilian employee immunization is by consent. All employees will be encouraged to accept anthrax immunization when offered. However, in instances where anthrax vaccination for civilians is considered to be mandatory, vaccination will be determined by the appropriate authority to be a condition of employment.

b. The effect on a Department of the Army employee who refuses immunization when indicated will be determined by the supervisor and commander in conjunction with representatives of the Civilian Personnel Office. Army policy requires that management first consider taking a non-adverse action, such as a reassignment to a non-E-E position; identification of an alternate employee who is willing to be immunized and serve as an E-E; curtailment of tour, etc. If none of these are possible, the E-E could be subject to adverse actions, up to and including, removal from the federal service for failure to meet a condition of employment. Refusal of anthrax immunization should be documented in appropriate personnel and health records.

3. DOCUMENTATION.

a. Communication. Supervisors will be responsible for ensuring that employees are adequately trained and aware of the health risk of anthrax as a biological weapon, and document that this training was received.

b. Refusal of immunization must be documented as indicated in Part 2. b. in this ANNEX.

c. Health records.

(1) All anthrax immunizations will be recorded in the appropriate health record and on a PHS Form 731. Written entries will contain the data elements described in ANNEX C. Civilian anthrax immunizations will also be recorded in MEDPROS IAW ANNEX K.

(2) Department of the Army Civilian Employee and DoD Contractor immunizations will be entered into the automated data system for tracking IAW ANNEX K.

(3) Serious adverse events to immunization will be recorded in the occupational health record, and reported through the Army Medical Surveillance System IAW ANNEX C,.

ANNEX K - IMMUNIZATION TRACKING SYSTEM

1. PURPOSE. To provide the concept of operations for tracking anthrax vaccinations using automated Immunization Tracking System (ITS).

2. GENERAL INFORMATION.

a. The Army will vaccinate forces against anthrax IAW the FDA immunization schedule and DoD policy. The Anthrax Vaccine is a 6 shot series administered over a period of 18 months IAW ANNEX C.

b. Soldiers who start the vaccination series may change duty stations, be deployed and/or be on leave before completion of the series. An automated ITS provides visibility to these personnel and their immunization status, and ensures that their immunization history will be annotated in their permanent electronic data record.

3. CONCEPT OF OPERATIONS.

a. The Army uses the Medical Protection System (MEDPROS) as its automated ITS to track anthrax vaccinations. MEDPROS is a subset of the Medical Operational Data System (MODS). The MODS system resides on a mainframe computer system at the Pentagon. MEDPROS is a modern, easy to use, web-based tracking system, accessed from the internet at http://www.mods.army.mil/.

(1) Users may request a LOGON ID directly from the website or may call the MODS help desk at the numbers below for assistance. The MODS help-desk is manned 24 hours a day to assist you with MEDPROS-related questions.

(2) Required ITS data elements include: patient name, SSAN, date of immunization, name of vaccine, series number, lot number, manufacturer, dose and route of administration, name of provider, and date next dose due.

(3) All anthrax immunizations will be recorded in MEDPROS within 24 hours of the immunization event.

(4) Immunizations will be posted in the patient's regular health record IAW ANNEX C.

b. MEDPROS Training. Classroom training is available at the MODS contractor main location INCONUS in northern Virginia. Additionally, civilian MODS contractors will be available on a limited basis for off-site training. The MODS contractor and the AVIP Agency also have regional analysts who are available on a limited basis to provide "train the trainer" courses across MEDCOM and the Army. To arrange MEDPROS training, contact the MODS help desk or call the AVIP Agency senior program analyst at the numbers below.

(1) Classes are 12-16 hours long (depending on level of training) and include orientation, demonstration, and practical exercises. For off-site training, a classroom with computer terminals is required with no more than two students per terminal. Terminals must be able to access a Local Area Network (LAN), a Wide Area Network (WAN), or have modems for Terminal Server Access Connection System (TSACS)/internet access. (Enhanced Remote Immunization Data Entry System (RIDES-E) has been developed for assets that do not have LAN, WAN or internet access. RIDES-E requires the use of a lap top computer with a CD reader. You can contact the MODS help desk for information on implementing this system.)

(2) Those personnel who actually enter immunization data (into MEDPROS) at point of service of immunizations should be targeted for training; i.e. personnel at immunization clinics, Troop Medical Clinics and all levels of Command through battalion level who are responsible to the Commander to enforce vaccination schedules and keep the Commander informed (Battalion/ Brigade S1s, PSNCOs,

etc). Ideally, personnel/units who are scheduled for deployment to a HTA should get MEDPROS training BEFORE they deploy, as training INCONUS is not as problematic.

c. Other Services' military members, Department of Defense Civilian Employees and DoD Contractors may receive their vaccinations at Army MTFs IAW this plan and will be tracked using MEDPROS. Immunizations will be recorded in MEDPROS for non-military Army personnel by adding their names utilizing the task force function. The MEDPROS system will report anthrax immunization data to DEERS. Other services will gain visibility of their members vaccinated in Army facilities from the DEERS reports. MEDPROS will also read data from DEERS and record confirmation of soldiers receiving anthrax immunizations from another service (MEDPROS queries DEERS on a monthly basis for this purpose). DEERS is the central repository for the anthrax immunization data and will provide reports as required.

4. RESPONSIBILITIES.

a. U.S. Army Medical Command.

(1) Field MEDPROS and RIDES-E and train users.

(2) Provide oversight for Anthrax Immunization Tracking Program.

(3) Maintain quality control of the immunization tracking process performing checks for accuracy as necessary and ensuring that all anthrax immunizations are recorded within the MEDPROS system within 24 hours of the immunization event.

b. 18th Medical Command.

(1) Provide oversight for Anthrax Immunization Tracking Program on the Korean Peninsula.

(2) Record all Anthrax immunizations within the MEDPROS system within 24 hours of the immunization event.

(3) Maintain quality control of the immunization tracking process performing checks for accuracy as necessary. Report discrepancies to HQ MEDCOM.

5. REPORTING: The following reports will be available from MEDPROS:

a. Individual immunization status report by SSN.

b. List of personnel by UIC that are due for a specific immunization by type and series.

c. Percent of personnel by UIC who are due a specific immunization by type and series.

d. Percent of personnel by UIC who have completed an immunization series.

e. List of personnel by UIC who have completed dose X of a given immunization series.

f. Percent of personnel who have completed dose X of a specified immunization series.

6. COORDINATING INSTRUCTIONS. USAMEDCOM DCSOPS will serve as the single point of contact for questions and/or problems experienced with MEDPROS. POCs for MEDPROS are:

a. USAMEDCOM DCSOPS: Medical Readiness and Training Branch, Operations Division
Comm: (210) 221-7124
DSN: 471-7124

FAX: 471-7061

b. MODS Help Desk
ASM Research, MODS Project Office:
Comm: (703) 681-4976/5008 or 1-888-849-4341
DSN: 761-4976/5008
Int'l toll-free, Korea: 0-130-81-9261
Int'l toll-free, Germany: 00798-14-8002803

c. AVIP Agency, Senior Program Analyst
MEDPROS training coordinator.
Comm: 1-703-681-1692 or 1-888-GETVACC