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United States
Coast Guard

COAST GUARD ANTHRAX VACCINE IMMUNIZATION PROGRAM (CG-AVIP)

COMDTINST M6230.3A

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Subj: COAST GUARD ANTHRAX VACCINE IMMUNIZATION PROGRAM (CG AVIP)

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

1. PURPOSE. This Manual establishes policy, assigns responsibilities, and provides guidelines regarding the Coast Guard Anthrax Vaccine Immunization Program (CG AVIP), unit prioritization, automated tracking system and reporting requirements, logistics, communications/education, military personnel guidance, and civilian personnel guidance.

2. ACTION. Area and district commanders, commanders of maintenance and logistics commands, commanding officers of headquarters units, assistant commandants of directorates, Chief Counsel, and special staff officers at Headquarters shall comply with the procedures of this Manual.

3. DIRECTIVES AFFECTED. Coast Guard Anthrax Vaccine Immunization Program (CG-AVIP), COMDTINST M6230.3 is cancelled.

4. BACKGROUND.

a. The threat of biological warfare remains a risk to U.S. forces. Recent assessments have identified anthrax as the primary biological threat facing American service men and women today. On 15 December 1997, the Secretary of Defense announced that U. S. military forces—active and selected portions of the reserve component—would be immunized against anthrax.

b. Due to a temporary shortage of in the supply of licensed vaccine, the AVIP was put in a slowdown status, whereby only designated special mission units were being immunized. On 28 June 2002, the Deputy Secretary of Defense announced the resumption of the Anthrax Vaccine Immunization Program (AVIP). The Coast

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c. Guard is a full participant in this Force Protection program. To best manage the supply of available vaccine, resumption of immunizations will be done on a prioritized basis as outlined below.

d. Unlike vaccines used for preventive medicine, vaccines used specifically for biological defense are controlled by the congressionally established Program Executive Office for Chemical and Biological Defense (PEOCBD)--formerly Joint Program Office for Biological Defense (JPO-BD). The PEOCBD procures and maintains adequate stockpiles of vaccines and defined production capabilities for all Services. The PEOCBD also controls the funds allocated for research, development, and acquisition of these vaccines and funds the force vaccine supply.

5. POLICY. Coast Guard policy is to immunize all Coast Guard Active Duty, Selected Reserve (SELRES) and assigned Public Health Service (PHS) personnel between the ages of 18 and 65 against validated biological warfare threats in sufficient time to develop immunity before deployment. For the purposes of this Manual, active duty personnel include any personnel in EAD status and SELRES includes any personnel in ADSW status. Chapter 1 provides Coast Guard anthrax vaccination implementing policies and guidance for all personnel and is effective upon receipt. The following are the vaccination priorities for the Coast Guard as outlined in ALCOAST 397/02. (note: only priority 1 and 2 are authorized for vaccination at the time of publication of this Manual):

a. Priority 1: Personnel in units authorized by the Deputy Secretary of Defense as designated special mission units, as well as manufacturing and Department of Defense research personnel and others involved in anthrax vaccine research.

b. Priority 2: Immunization of personnel assigned, reporting to, or on temporary duty to units deployed to land-based duty for 15 consecutive days or more in designated higher threat areas. The countries designated as higher threat areas are described in ALCOAST 397/02. Determination of changes to higher threat area designation will be made by the Secretary of Defense. It is preferable that all personnel assigned to higher threat areas receive their first three shots prior to deployment. Otherwise, the series will begin or continue in theater. *If a member is not vaccinated due to inadequate notification time, medical or administrative (including refusal) reasons, he or she is still deployable.*

c. Priority 3: Immunization of personnel assigned to Coast Guard alert forces, Coast Guard and PHS medical officers, and Health Service Technicians (HS) if not already entered in to the AVIP in priority 1 or 2.

(1) Personnel assigned to the following Coast Guard alert forces: WHECs, WMECs, WPBs (110' only), WAGB, WLB (OCONUS only), Port Security Units (PSU), Air Stations, Law Enforcement Detachments/Tactical Law Enforcement Teams (LEDETs/TACLETs), Harbor Defense Command Units/Naval Coastal Warfare Groups (HDCU/NCWGRU), Activities Europe (ACTEUR), Far East Activities (FEACT), Marine Field Units, and National Strike Force. This includes any personnel in units identified as having an

arrival date of 35 days or earlier, in support of operations plans (OPLANS) for high threat areas. This also includes Marine Inspectors that regularly travel to one or more of the high threat areas.

(2) Coast Guard and PHS medical officers and Health Service Technicians (HS and HSD) will begin the CG AVIP in priority 3, if not already begun. Recruits in Basic Training, OCS, DCO School and Coast Guard Academy graduates who have orders to these alert units will receive at least the first dose prior to departing the training program, if possible.

d. Priority 4: Forces stationed or assigned in Korea if not already included under priority 1, 2 or 3.

e. Once entering the resumed CG AVIP, personnel immunized will remain in the program, continuing to receive scheduled doses, while on active duty or in a SELRES member status, unless subject to exemptions outlined in Chapter 1. Personnel who have received anthrax vaccine prior to 1 July 02, but are not subject to priority 1 or 2 above, will remain in deferred status until further notice. It is anticipated that these personnel will eventually resume their vaccinations, with the next dose due, as this program progresses.

f. Civilians: Per ref (a), Coast Guard civilian personnel whose duties classify them as rapid deployment in support of Coast Guard operations in higher threat areas shall be vaccinated upon notification for deployment to a higher threat area. The effect on an employee who refuses immunization, when indicated, will be determined by the supervisor and commander in conjunction with representatives of the Civilian Personnel Office. For the purposes of the CG AVIP, higher threat does **not** include the potential for anthrax used in acts of terrorism against non-combatants, to include family members in higher threat areas. The CG AVIP does not apply to family members.

g. This vaccine is a required immunization unless exempted (e.g., for pregnancy) by competent medical authority.

h. If a member refuses vaccination, he or she remains deployable.

i. Refusal to be vaccinated, or failure to comply with a lawful order to be vaccinated is a violation of Coast Guard Regulations, COMDTINST M5000.3 (series), Chap 8, section 8-2-1.A (21) and Article 92 of the Uniform Code of Military Justice (UCMJ). Any member who refuses to be vaccinated or fails to comply with a lawful order to be vaccinated is subject to disciplinary proceedings under the UCMJ or other appropriate administrative proceedings at the unit commander's discretion.

j. Any member who refuses to submit to measures considered by competent medical or dental officers to be necessary to render the member fit for duty may

be processed for separation from the Coast Guard in accordance with applicable regulations.

6. RESPONSIBILITIES.

a. Commandant (G-WK) has the overall responsibility for the policy associated with the CG AVIP and will provide the Department of Defense Executive Agent, the Secretary of the Army, with annual projected anthrax vaccine program requirements. Further responsibilities are outlined in Chapters 1, 4, 5, and 6 of this Manual.

b. Commandant (G-O and G-M) will notify G-WK regarding authorized changes to Coast Guard units designated as early deployable (35 days or less) or otherwise on high alert status. Additionally, they will notify G-WK of any unit or person (military or civilian) receiving orders to deploy to a higher threat area, in sufficient time to allow the vaccine to be administered. Further responsibilities are outlined in Chapter 6 of this Manual.

c. Commandant (G-WTR) will address policy issues within the Reserve component. The MLCs will ensure implementation.

d. Commandant (G-IPA) responsibilities are outlined in Chapter 6 of this Manual.

e. Commandant (G-ICA) will coordinate congressional queries and briefings.

f. The commanders of maintenance and logistics commands (MLCs) will assume responsibility for the implementation and execution of this plan, including appropriate monitoring, evaluating and documenting of the program. MLCs will ensure units have the requisite support and supplies (vaccines and ancillaries) to administer and monitor the program, and ensure compliance. Further responsibilities are outlined in Chapters 1, 4, 5, and 6 of this Manual.

g. Coast Guard Clinics and Sickbays responsibilities are outlined in Chapters 1, 4, 5, and 6 of this Manual.

h. Unit commanding officers will educate their personnel regarding the need for and safety of the vaccination program. Further responsibilities are outlined in Chapters 1, 4, 5, and 6 of this Manual.

i. Individual service member responsibilities are outlined in Chapter 1 of this Manual.

7. ENCLOSURES. Enclosure (1) provides the policy for medical treatment of Reserve Component personnel related to immunizations. Enclosure (2) provides the Anthrax Immunization Record CG 5665 (02-00). Enclosure (3) provides the Vaccine Adverse Events Reporting System (VAERS) Form. Enclosure (4) provides the Coast Guard Anthrax Vaccine Information Brochure (VIB), “What You Need to Know about Anthrax Vaccine”.

Enclosure (5) provides the exemptions (exception) codes for immunizations for use in MRS database.

8. FORMS AVAILABILITY. Enclosure (2), Anthrax Immunization Record CG-5665 (2-00) is available on Coast Guard SYSIII Jet Form Filler. Enclosure (3) is available on Coast Guard SYSIII in Jet Form Filler and on the Internet at http://www.fda.gov/cber/vaers/report.htm. All enclosures may be reproduced locally as needed.

T. W. ALLEN
CHIEF OF STAFF

Encl: (1) Treatment of Reserve Component members related to immunizations.
(2) Anthrax Immunization Record CG-5665 overprint.
(3) Vaccine Adverse Events Reporting System (VAERS).
(4) Coast Guard Anthrax Vaccine Information Brochure (VIB) (Trifold Brochure).
(5) Exemption (exception) codes for Immunizations for use in MRS database.

COAST GUARD ANTHRAX VACCINE IMMUNIZATION PROGRAM (CG-AVIP)

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CHAPTER 1

ANTHRAX VACCINE IMMUNIZATION PROGRAM

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CHAPTER 1. ANTHRAX VACCINATION IMPLEMENTATION PROGRAM

A. PURPOSE.

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

B. OVERVIEW.

1. The Department of Defense (DoD) Directive, Immunization Program for Biological Warfare Defense, prescribes DoD policy for the use of vaccines for biological defense. The anthrax vaccine meets each of the requirements outlined in this directive. The Secretary of Defense has designated the Secretary of the Army as the Executive Agent for the Program.

2. The Program Executive Office for Chemical and Biological Defense (PEOCBD)--formerly Joint Program Office for Biological Defense (JPO-BD), resourced by DoD, will procure and maintain an adequate stockpile of vaccines and defined production capabilities for all Services. Unlike vaccines used for protection from endemic disease threats, vaccines used specifically for biological defense are controlled by the congressionally established PEOCBD. PEOCBD also controls the DoD money allocated for research, development and acquisition of these vaccines and funds the initial force immunizations.

3. The Anthrax Vaccine, Adsorbed, hereafter referred to as "Anthrax Vaccine," is licensed by the Food and Drug Administration (FDA). Primary immunization currently consists of six subcutaneous injections, 0.5 ml each. The first dose is given on Day zero (D). Subsequent doses are given on D+14 Days, D+28 Days, D+6 Months, D+12 Months, and D+18 Months. Annual 0.5-ml booster injections, beginning one year after the last dose of the primary series, are required to maintain immunity. Chapter 2 of this Manual details vaccine dosing and medical considerations pertaining to anthrax vaccination.

4. Commanders, Maintenance and Logistics Commands are responsible for the implementation of this program.

C. ASSUMPTIONS.

1. Office of the Secretary of Defense (OSD) has determined that all Services will execute their AVIPs according to priority as outlined in Chapter 3. Currently, only priorities 1 and 2 are in effect. As supply of vaccine increase, the AVIP will advance to priorities 3 and beyond.

2. Adequate supplies of vaccines will be available from DoD to execute this plan.

3. At execution, an automated immunization tracking system will be in place (see Chapter 4 of this Manual).

4. Whenever possible, the first three doses will be given prior to arrival in a designated high threat area. Doses will be administered in accordance with FDA schedule.

D. CONCEPT OF OPERATIONS.

1. All Coast Guard Active Duty and SELRES members, and assigned PHS officers affected will be vaccinated according to the priorities outlined in Chapter 3. Currently only designated special mission units and those units and individuals deployed or deploying (including temporary duty) to land-based duty for 15 consecutive days or more in designated higher threat areas are authorized to be immunized.

2. United States Army Medical Material Agency (USAMMA) will coordinate with the PEOCBD to ensure adequacy of vaccine supplies and the distribution to all Services. Commandant (G-WKH) will provide total Coast Guard vaccine requirements to USAMMA. Chapter 5 provides detailed logistics information.

3. This is a mandatory readiness initiative. Unless specifically exempted by the commanding officer or by competent medical authority (detailed below and in Chapter 2), all Coast Guard military personnel affected are required to initiate and complete the immunization schedule.

   a. **If a member refuses vaccination, he or she remains deployable.**

   b. **Refusal to be vaccinated, or failure to comply with a lawful order to be vaccinated is a violation of Coast Guard Regulations, COMDTINST M5000.3B (series), Chap 8, section 8-2-1.A (21) and Article 92 of the Uniform Code of Military Justice (UCMJ). Any member who refuses to be vaccinated or fails to comply with a lawful order to be vaccinated is subject to disciplinary proceedings under the UCMJ or other appropriate administrative proceedings at the unit commander's discretion.**

   c. **Any member who refuses to submit to measures considered by competent medical or dental officers to be necessary to render the member fit for duty may be processed for separation from the Coast Guard in accordance with applicable regulations.**

4. Per ref (a), Coast Guard civilian personnel whose duties classify them as having status equivalent to deployable forces in support of Coast Guard operations in higher threat areas shall be vaccinated upon notification for deployment to a higher threat area. In certain instances, anthrax immunization might be determined by appropriate authority to be a condition of employment. The effect on an employee who refuses immunization, when indicated, will be determined by the supervisor and commander in conjunction with representatives of the Civilian Personnel Office.

5. Civilians in non-mission essential jobs and family members of all military and civilian personnel will not currently be offered the vaccination. The policy is that these personnel will be removed from the higher threat areas in accordance with the standard interagency procedures for crisis situations. If there is an imminent threat of hostilities, the US Government will attempt to evacuate these personnel from the threat area. Evacuation, rather than immunization, is the primary means of addressing the threat for these personnel.

6. Commanders, Maintenance and Logistic Commands (k) will develop, maintain, and monitor implementation plans and provide required reports as set forth in Chapter 4. Unit commanders will ensure implementation and maintenance of the CG AVIP within their units. Coast Guard Health Services personnel will coordinate and facilitate immunization of Coast Guard personnel (Chapter 5). Personnel in the CG AVIP are authorized to receive their anthrax immunization from DoD Medical Treatment Facilities (MTFs) if unable to obtain through Coast Guard facilities.

7. Immunization of Coast Guard Active Duty and Selected Reserve personnel will be carried out over a period to be determined. Designated units will begin immunizations in accordance with prescribed prioritization timelines (Chapter 3).

8. Medical record keeping (including reporting certain adverse reactions) will be maintained to document immunizations in accordance with Chapter 4 of this Manual.

9. USAMMA will coordinate the distribution of the vaccination to the supporting medical supply activities for all Services. Commandant (G-WKH) will serve as Coast Guard Liaison with USAMMA. Units will furnish vaccine requirements to the supporting Health Services Clinic. Clinics will order through MLC(k) via G-WKH-1 to USAMMA (see Chapter 5).

10. MLC(k)s will oversee the CG AVIP Education and Communications programs provided in Chapter 6.

E. EXEMPTIONS. The vaccine is approved for healthy individuals from 18 to 65 years of age. There are situations that may, temporarily or permanently, preclude an individual from entering into the CG AVIP or from receiving a scheduled dose of the vaccine. These exemptions fall into two categories: medical and administrative.

1. Temporary or permanent **medical** exemptions are authorized for individuals who are clinically evaluated and are shown to have compromised immune systems, history of severe local and systemic adverse reactions to the vaccine, or are pregnant. Health care providers will determine if an individual with a medical condition will continue with the anthrax vaccine or be exempt for a specified duration. A medical officer may authorize temporary medical exemptions. Permanent medical exemptions may only be authorized by Commandant (G-WK).

2. **Administrative** exemptions from the immunization schedule are authorized for personnel by the individual's unit commander for the following reasons:

   a. Missing in action or prisoner of war status.

   b. Pending administrative or disciplinary actions due to vaccine refusal.

   c. Absent without leave or imprisonment.

   d. While in transit on a permanent change of station move.

   e. Temporary duty or other extended absences from home station exceeding 30 days.

   f. Legal discharge, separation, resignation or retirement as described below.

3. Commanders may exempt personnel who are separating from the Coast Guard and are not on duty status in a Joint Staff designated higher threat area from the CG AVIP scheduling as indicated:

   a. Retiring Personnel. Service members who are retiring are exempt from the CG AVIP schedule no more than 180 days prior to their approved date of retirement or upon receipt of retirement orders, whichever occurs first.

   b. Separating Personnel. Service members who are separating from service may be exempt from the CG AVIP schedule no more than 180 days before their approved date of separation.

   c. Inter-Service or Inter-Component transfers will not be exempt from the CG AVIP schedule and will continue the series in accordance with the FDA approved dosage and administration protocol.

   d. Coast Guard civilian personnel whose duties classify them as having status equivalent to deployable forces in support of Coast Guard operations in higher threat areas who are resigning from service and are not on duty status in a Joint Staff designated higher threat area may be exempt from the CG AVIP scheduling as indicated:

      (1) Retiring Personnel. Coast Guard civilians who are retiring are exempt from the CG AVIP schedule no more than 180 days before the date reflected on their retirement papers.

      (2) Resigning Personnel. Coast Guard civilians who are resigning from service may be exempt from the CG AVIP schedule upon receipt of a signed resignation with an effective date no more than 180 days.

      (3) Reassigned/Transferred Personnel. Coast Guard civilians who are being reassigned to a non-mission-essential position within Coast Guard or who are transferring to a non-Coast Guard agency will be exempt from the CG AVIP upon presentation of evidence verifying their transfer/reassignment.

F. <u>RESPONSIBILITIES</u>.

1. Commandant (G-WK) shall:

   a. Develop and disseminate medical education, information, policy, and doctrine to the MLCs as required in accordance with the CG AVIP.

   b. Provide consolidated reports of adverse reactions to the Army Executive Agent in accordance with Chapter 4.

   c. Function as liaison between MLC(k)s and USAMMA to procure vaccine supplies for the Coast Guard.

2. Commanders, Maintenance and Logistics Commands shall:

   a. Implement command immunizations in accordance with unit prioritization listed in Chapter 3 of this Manual.

b. Coordinate with USAMMA through G-WKH-1 and other appropriate vendors to ensure sufficient vaccines and ancillary supplies are available to units conducting immunizations in accordance Chapters 3 and 4 of this Manual.

c. Provide educational briefing materials on the anthrax vaccination program to all personnel. An approved briefings package located at the DOD Web Site: www.anthrax.mil under "education toolkit" may be used for this purpose. Additional information is available through the CG's AVIP Website: www.uscg.mil/anthrax.htm and the Navy's Environmental Health Center Web Site: http://www-nehc.med.navy.mil/prevmed/epi/anthrax.htm.

d. Ensure all medical officers have received and understand the information in the Healthcare Providers Briefing available at www.anthrax.mil under "education toolkit".

3. Coast Guard Clinics/Sickbays shall:

a. Provide support to the Commandant's immunization plans for all Coast Guard Personnel (Active Duty, Selected Reserve and others) as required to support the CG AVIP.

b. Provide sufficient notice to units regarding time, location, and importance of immunization in order for all personnel to arrange schedules to ensure maximum participation in the CG AVIP.

c. Coordinate the immunization of Coast Guard personnel at Coast Guard clinics/sick bays, DoD MTFs/sickbays and/or Coast Guard unit facilities.

d. Provide immunizations to personnel from other Services who have begun the vaccine series and are enrolled in the DoD AVIP in accordance with the Office of the Assistant Secretary of Defense, Health Affairs (OASD(HA)) guidance. On rare occasions, a member of a DoD service may need to begin the AVIP through a Coast Guard facility. This should be coordinated in advance with the appropriate MLC(k).

e. Ensure personnel receiving the Anthrax vaccine have been educated about the AVIP. Prior to initial immunization, ensure that personnel are provided the current Coast Guard Anthrax Vaccine Information Brochure (VIB) (Enclosure 4) with specific information regarding the vaccine, its safety, benefits, and the need for adherence to the immunization schedule. The VIB may be photocopied as needed. To be viewed properly, the VIB should be copied as a 2-sided document and folded in thirds. Additionally, the VIB may be found at http://www.uscg.mil/anthrax.htm. The provision of this information will be documented by health services personnel on the Anthrax Immunization Record CG-5665 overprint prior to the first immunization. The VIB should be offered to personnel prior to each subsequent immunization.

f. Ensure service members receiving an anthrax immunization are instructed when their next dose is due.

g. Provide summary reports (include adverse reactions) in accordance with Chapter 4.

4. Unit Commanders shall:

a. Determine anthrax vaccine needs on a monthly basis, at least 30 days in advance, and coordinate with cognizant medical POC to ensure that personnel are to be immunized on schedule (Chapters 4 and 5).

b. Ensure all assigned service members are available for anthrax vaccination in accordance with the FDA schedule of vaccination.

c. Ensure all assigned service members reported as overdue for vaccination (as reported from MLC(k)) receive or have received scheduled vaccinations. If overdue reports are incorrect, update the correct information in the Medical Readiness System (see Chapter 4).

d. Provide educational briefing materials on the anthrax vaccination program to all personnel. An approved briefings package located at the DOD Web Site: www.anthrax.mil under "education toolkit" may be used for this purpose. Additional information is available through the CG's AVIP Website: www.uscg.mil/anthrax.htm and the Navy's Environmental Health Center Web Site: http://www-nehc.med.navy.mil/prevmed/epi/anthrax.htm.

e. Prior to initial immunization, ensure that personnel are provided the current Coast Guard Anthrax Vaccine Information Brochure (VIB) (Enclosure 4) with specific information regarding the vaccine, its safety, benefits, and the need for adherence to the immunization schedule. The VIB may be photocopied as needed. To be viewed properly, the VIB should be copied as a 2-sided document and folded in thirds. Additionally, the VIB may be found at http://www.uscg.mil/anthrax.htm. The VIB should be offered to personnel prior to each subsequent immunization.

5. Service Members shall:

a. Read and take all steps necessary to understand the VIB (Trifold) brochure, "What You Need to Know about Anthrax Vaccine".

b. Report to appropriate Coast Guard clinic, sickbay, DoD MTF, or other designated facility for vaccinations on schedule (first vaccine on order of commander, follow-up vaccines in accordance with the FDA schedule of vaccination.)

c. Report adverse reactions to the appropriate Coast Guard clinic/sickbay or MTF.

G. COORDINATING INSTRUCTIONS.

1. Direct coordination with Uniformed Services Medical Treatment Facilities (USMTFs) to complete unit or individual immunizations is authorized.

2. MLC(k)s will coordinate with USAMMA through G-WKH-1 for vaccine supplies to be sent to appropriate Coast Guard clinics.

CHAPTER 2

MEDICAL CONSIDERATIONS AND GUIDANCE

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CHAPTER 2. MEDICAL CONSIDERATION AND GUIDANCE

A. VACCINE CHARACTERISTICS.

1. Licensing. Anthrax Vaccine Adsorbed is manufactured by the Bioport Corporation (formerly Michigan Biologic Products Institute), Lansing, Michigan 48909. It is licensed by the FDA (U.S. License No. 99, 1970) for human use to promote increased resistance to *Bacillus anthracis* (*B. anthracis*).

2. Mechanism of Action. Anthrax vaccine works by active immunity. It stimulates the immune system to produce antibodies that prevent *B. anthracis* from producing disease-causing toxins.

3. Composition. Anthrax vaccine is a sterile product made from a strain of the bacteria that does not cause disease (attenuated strains of *B. anthracis*). In addition, the attenuated strain is formalin-inactivated, or killed and only a small part (antigen) of the killed bacteria actually goes into the vaccine. It is impossible to contract the disease anthrax from the vaccine. As with many other pharmaceuticals, this vaccine contains a negligible amount of formaldehyde as a preservative.

4. Dosage. Anthrax vaccine is supplied in 5.2-ml multi-dose vials containing ten 0.5-ml doses each.

5. Handling and Storage. Vials of anthrax vaccine shall be maintained between 36 and 46 degrees Fahrenheit (2 to 8 degrees Celsius), but NOT FROZEN. Once a vial is opened, as long as it is properly stored and not contaminated, the vaccine can be used for 12 months or until the expiration date, whichever is sooner. Anthrax vaccine that has been frozen or shows signs of contamination, discoloration, or deterioration should be discarded and reported to the appropriate MLC(k).

6. Indication and Usage. Immunization with anthrax vaccine is recommended for individuals with a high risk of exposure to *B. anthracis*. Since it was first licensed by the FDA in 1970, the vaccine has been safely and routinely administered to veterinarians, laboratory workers, livestock handlers, and other individuals who may come into contact with *B. anthracis*-infected animal products, e.g. hides, hair, meat, and bones. The current threat of biological attack causes military service to be considered a high risk factor for exposure to *B. anthracis*.

   a. Vaccination Schedule and Administration.

      (1) Needle and syringe method is indicated for this vaccine; **jet injector immunization devices will not be used**. The only syringe (1cc) and needle, which shall be used to administer the vaccine, is the tuberculin syringe, National Stock Number (NSN) 6515-00-982-4205 or available through Prime Vendor.

      (2) Primary immunization consists of six subcutaneous 0.5-ml injections. The first dose is given on Day zero (D). Subsequent doses are given on D+14 Days, D+28 Days, D+6 Months, D+12 Months, and D+18 Months.

(3) Preferred injections site is the subcutaneous tissue over the deltoid muscle, with a short needle at a 45-degree angle with the skin surface. Injections over the posterior arm (triceps) should avoided. Unusually lean people might avoid injection-site reactions by vaccination in the anterolateral thigh.

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

(5) Occasionally, an immunization may not be given exactly on its due date and the standard dosing interval should be used to determine the date of the next dose. **Standard dosing intervals**, therefore, are as follows:

(a) Between doses 1 and 2: 2 weeks

(b) Between doses 2 and 3: 2 weeks

(c) Between doses 3 and 4: 5 months

(d) Between doses 4 and 5: 6 months

(e) Between doses 5 and 6: 6 months

(6) Annual 0.5-ml booster vaccinations are given on every anniversary of the last dose of the primary series.

(7) All personnel assigned to higher threat areas are to receive their first three shots prior to deployment, if possible. If deployment occurs less than one month after notification of deployment, as many shots as possible (IAW the approved vaccine schedule in Paragraph A.6.a. (2)) shall be given. The series will continue in theater.

b. Administrative Issues.

(1) An individual's availability and adherence to the immunization schedule shall be a matter of command attention and discipline.

(2) Once the immunization series is started under the current prioritization sequence, it will be continued (including appropriate boosters) until termination of military service—active and reserve. Personnel who have received anthrax vaccine prior to 1 July 02, but are not subject to priority 1 or 2, will remain in deferred status until further notice. It is anticipated that these personnel will eventually resume their vaccinations, with the next dose due, as this program progresses.

(3) In those rare instances when an individual cannot start or continue the anthrax series due to medical or administrative reasons, he or she remains deployable.

(4) 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 by

immunizing personnel for medical conditions for which immunization deferral or further medical evaluation before immunization is indicated (see section F. below).

(5) Individual informed consent (as would be necessary for an investigational new drug) is not required for this FDA-licensed product. Vaccine recipients will be provided with educational materials, via the appropriate Coast Guard Anthrax Vaccine Information Brochure (VIB) (Enclosure 4) or other G-WK approved Anthrax Vaccine Information source, on the vaccine's safety and benefits and on the need for adherence to the immunization schedule.

(6) All personnel will be given the opportunity to ask questions of healthcare providers prior to vaccination. Service member will sign the CG-5665 that they have received the VIB and had the opportunity to ask questions prior to immunization.

(7) At the time of immunization, personnel are to be provided documentation that identifies date and location of immunization, location of the nearest MTFs (military and/or civilian), and the toll-free telephone number of the Military Medical Support Office (MMSO), in the event medical treatment is required from non-military treatment facilities.

(8) As with most other immunizations, aviation personnel are automatically grounded for 12 hours after receiving the anthrax vaccine.

B. MEDICAL RECORD KEEPING.

1. Each dose of anthrax vaccine administered will be documented by entries in three separate locations.

   a. The individual patient's medical record on Anthrax Immunization Record CG-5665 overprint, Health Record-Immunization Form (Enclosure 2) (alternatively a SF-601 overprint, "Anthrax Vaccine Record" from a DoD service may be used) and on NAVMED 6150-Problem Summary Sheet or DD 2276, when available.

   b. The individual's yellow shot card (Department of Health and Human Services Form PHS-731, "International Certificate of Vaccination").

   c. The immunization tracking module in the Medical Readiness System (MRS) on the Coast Guard Human Resources Management System (CGHRMS) system, which will transfer the information to the Defense Enrollment and Eligibility Reporting System (DEERS).

2. All three documentation locations shall include the following data elements: date of the immunization, name of immunization given, dosage number in the multiple-dose series, lot number, manufacturer, and next dose due-date.

3. Additionally, the CG-5665 overprint will include route of administration and name of the provider, and date/provider's initials documenting the provision of the Anthrax VIB educational material.

4. Local quality control and quality assurance measures shall be implemented to ensure accuracy and timeliness of these entries.

C. POLICY FOR UNINTENDED DEVIATION FROM IMMUNIZATION SCHEDULE.

1. Although the Commandant's policy is to adhere to the prescribed vaccination schedule and to hold commanders responsible for timeliness of vaccination, extenuating circumstances may prevail. However, it is not currently known whether deviation from the standard vaccine schedule alters effectiveness. The greater the deviation from the standard vaccine schedule, the less assurance of protection.

2. The following procedure will be applied to personnel who deviate from the prescribed schedule:

   a. In general, if a person is late for a vaccination in the primary series, they will not restart the series, but resume as soon as possible with the next dose due. They will continue according to the standard dosing interval from that dose onward (see 6.A.3.(a)).

   b. Only one situation calls for restarting the vaccine series with the first dose:

      (1) A person who reports receiving any dose of anthrax vaccine as part of Operation Desert Shield/Storm or later or as part of service with another branch of the Armed Forces, but is unable to provide documentation. CG medical personnel should contact the appropriate MLC(k) and/or G-WKH-1 to determine if documentation may exist in DEERS. (If documented, resume the series beginning with the next dose due and continue according to the standard dosing schedule).

   c. Regardless of the time interval from the end of primary series, a missed annual booster does not indicate repeating the primary series. The annual booster should be administered at the earliest possible date, and the subsequent annual booster schedule adjusted accordingly (i.e., on the anniversary date of the make-up booster).

   d. A dose is considered overdue if it is not given within 30 days of the scheduled due date. Failure to receive the shot in this 30-day window will cause the individual to be highlighted in the DEERS system as non-compliant. The second and third dose should **never** be given earlier than the due date. The remaining doses should not be given earlier than the scheduled due date unless authorized, in advance, by a medical officer.

D. PRE-VACCINATION INFORMATION REQUIREMENTS. Healthcare providers and medical staff will ensure vaccine recipients are provided adequate information on the vaccine, its safety, benefits, and on the need for adherence to the immunization schedule. This requirement can be met by providing vaccine recipients with the appropriate standard DoD/Coast Guard brochure entitled "What You Need to Know About Anthrax Vaccine" (Enclosure 4), which will serve as an approved VIB for the anthrax vaccine. Provision of the Anthrax VIB will be documented on the CG-5665 overprint prior to the first immunization.

E. ADVERSE REACTIONS. Healthcare providers may use information from the clinical guidelines for adverse events after vaccination found on the CG AVIP website: www.uscg.mil/anthrax.htm or the DoD AVIP website: www.anthrax.mil.

1. Local Reactions.

   a. Immunization with anthrax vaccine can result in discomfort at the injection site. The injection itself usually causes stinging which resolves within minutes. **Mild local reactions** are reported to occur in up to 30% of men and 60% of women and consist of 1-4 cm of erythema (redness) with slight local tenderness and/or swelling appearing the first day and usually resolving within 72 hours.

   b. Many vaccine recipients develop a small, painless, subcutaneous nodule at the injection site. The nodule can persist for up to 2 months, but resolves without treatment. Administration of subsequent doses should avoid injecting the vaccine into a subcutaneous nodule.

   c. **Moderate local reactions** occur in approximately 1-5 percent of recipients and consist of erythema, swelling exceeding 5-cm diameter, firmness of the skin, warmth, itching, and tenderness. These reactions peak at 1-2 days and resolve by 2-3 days.

   d. Local reactions tend to increase in severity through the 5th dose and decrease with subsequent doses. Alternating injection sites between both arms for the first three doses can reduce the likelihood of local reactions and is highly recommended.

   e. A moderate local reaction can also occur if the vaccine is given to anyone with a past history of anthrax infection.

   f. **Severe local reactions** are reported to occur in less than 1 percent of recipients and are characterized by reactions at the vaccination site as described above measuring more than 12 cm with local tenderness and swelling that may extend to the elbow or forearm.

2. Systemic Reactions. Systemic reactions, such as fever (temperature ≥100.5^{o}F), malaise, muscle and joint aches, headache, or related symptoms are may occur in 5% to 35% of vaccinees. These symptoms are generally mild, respond to acetaminophen and/or NSAIDs and last less than 72 hours.

3. Serious events, such as those requiring hospitalization, are rare for any vaccine. For anthrax vaccine, they happen about once per 50,000 doses. Severe allergic reactions occur less than once per 100,000 doses.

4. Reporting Requirements. Adverse event description, recording, and reporting requirements are provided in Chapter 4. At the local level, units may decide to track mild or moderate reactions.

5. Reserve component personnel are eligible for care in the event of an adverse reaction to an immunization that requires medical care per the policy outlined in Enclosure (1).

F. CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS.

1. Contraindications. A severe hypersensitivity/allergic reaction to a previous dose of the vaccine, whether or not it resulted in lost duty time or hospitalization, is a contraindication to further immunization with this vaccine unless cleared by an allergist/immunologist.

2. Warnings.

   a. Any active infection with fever is generally considered reason for temporary deferral of immunization.

   b. Individuals receiving a course of therapy (e.g., corticosteroids) that would tend to depress the immune response may be inadequately immunized if the recommended dosage schedule is followed. For personnel with temporarily suppressed immune systems (e.g., due to therapy), immunizations should be deferred until after the course of therapy.

   c. Being sero-positive for HIV is not an absolute contraindication to anthrax vaccination. Sero-positive individuals are not expected to be harmed by receiving the vaccine. However, since their immune system may be suppressed leading to potentially inadequate immune response, HIV sero-positive individuals will not be routinely immunized. Individuals who have unknowingly sero-converted for HIV since their last test could inadvertently receive anthrax vaccination. Such individuals are not likely to be immunosuppressed although their immune response may not be as strong.

   d. 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.

3. Precautions.

   a. General. Routine immunization precautions against allergic and anaphylactic reaction should be readily available. These precautions include epinephrine solution 1:1000, and airway management ability.

   b. Pregnancy.

      (1) Anthrax vaccine, like other vaccines in the U.S., is classified, in accordance with the Code of Federal Regulations (21 CFR 201.57), as “PREGNANCY CATEGORY C." Animal reproduction studies have not been conducted with Anthrax Vaccine Adsorbed. Therefore, prudent medical practice dictates that anthrax vaccinations should be deferred during pregnancy unless medically indicated (i.e., known or imminent exposure).

      (2) The Center’s for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP), in the 28 January 1994 Morbidity and Mortality Weekly Report, p. 21, states that “there is no convincing evidence of risk from vaccinating pregnant women with inactivated virus or bacterial vaccines [including anthrax vaccine] or toxoids.”

      (3) While routine pregnancy testing is not indicated before vaccination, every woman must be questioned, prior to vaccination, about the possibility of

pregnancy. Women who state that they are pregnant or suspect that they might be pregnant, will be deferred from vaccination until after a negative pregnancy evaluation. A woman who states that she would like to be tested prior to immunization will have the pregnancy test done. A urine pregnancy test is sufficient for verification purposes.

(4) If a woman becomes pregnant after beginning the vaccine series, an entry will be made in her medical record and the series will be suspended until she is no longer pregnant. When she is no longer pregnant, the vaccine series will resume and follow the standard dosing interval schedule from the point in the schedule where it was interrupted. For example, if a woman received one shot and became pregnant, she would receive the second and subsequent shots when she was no longer pregnant.

(5) 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 inadvertent episode of immunization with anthrax vaccine during pregnancy must be documented in the woman's medical record. The woman should be counseled that although there is limited data on anthrax vaccine during pregnancy, inactivated viral and bacterial vaccines like Anthrax Vaccine are generally thought to pose little risk to the woman or the fetus.

c. Breast-feeding (lactation). "Neither killed nor live vaccines affected safety of breast-feeding for mother or infants" (ACIP, 28 January 1994 Morbidity and Mortality Weekly Report, p. 20). There is no scientific evidence to support interrupting breast-feeding for anthrax vaccine immunization of a lactating mother. Therefore, Commandant policy will be to resume the anthrax vaccination series, regardless of breast-feeding status, after return to duty following completion of pregnancy convalescent leave.

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

e. Blood donations. The American Association of Blood Banks (AABB) and the Food & 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.

f. Pediatric use/use in the elderly. Anthrax Vaccine should be administered only to those healthy individuals between 18 and 65 years of age since clinical studies have been conducted exclusively in that age group.

CHAPTER 3

UNIT PRIORITIZATION INFORMATION

PURPOSE 3-1

SCOPE 3-1

CONCEPT OF OPERATIONS 3-1

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CHAPTER 3. UNIT PRIORITIZATION INFORMATION

A. PURPOSE. To provide the concept of operations for unit prioritization for the Coast Guard AVIP.

B. SCOPE. This Chapter applies to all Coast Guard components Active Duty, Selected Reserve, assigned PHS officers and designated Coast Guard civilian personnel.

C. CONCEPT OF OPERATIONS. Personnel assigned to Joint or other Services will have their immunizations administered by the medical treatment facility (MTF), regardless of its Service, providing medical support to the unit to which the individual is assigned. Immunization of Coast Guard personnel will be accomplished according to the following priorities. (note: only priority 1 and 2 are authorized at the time of publication of this Manual).

1. Priority 1: Personnel authorized by the Deputy Secretary of Defense as designated special mission units, as well as manufacturing and Department of Defense research personnel and others involved in anthrax vaccine research.

2. Priority 2: Immunization of personnel assigned, reporting to, or on temporary duty to units deployed to land-based duty for 15 consecutive days or more in designated higher threat areas. The countries designated as higher threat areas are described in ALCOAST 397/02. Determination of changes to higher threat area designation will be made by the Secretary of Defense. It is preferable that all personnel assigned to higher threat areas receive their first three shots prior to deployment. Otherwise, the series will begin or continue in theater. *If a member is not vaccinated due to inadequate notification time, medical or administrative (including refusal) reasons, he or she is still deployable*.

   a. It is preferable that all personnel assigned to higher threat areas receive their first three shots prior to deployment. Absent this, the series will begin or continue in theater.

   b. If a member is not vaccinated due to inadequate notification time, medical or administrative (including refusal) reasons, he or she is still deployable.

   c. Upon notification of units scheduled to deploy to higher threat areas, Commandant (G-O) or (G-M) will forward this information to Commandant (G-WKH-1) for action. Refer to Chapter 5 for logistics application.

3. Priority 3. Immunization of personnel assigned to Coast Guard alert forces, Coast Guard and PHS medical officers, and Health Service Technicians (HS) if not already entered in to the AVIP in priority 1 or 2.

   a. Personnel assigned to the following Coast Guard alert forces: WHECs, WMECs, WPBs (110' only), WAGB, WLB (OCONUS only), Port Security Units (PSU), Air Stations, Law Enforcement Detachments/Tactical Law Enforcement Teams (LEDETs/TACLETs), Harbor Defense Command Units/Naval Coastal Warfare Groups (HDCU/NCWGRU), Activities Europe (ACTEUR), Far East Activities (FEACT), Marine Field Units, and National Strike Force. This includes any personnel in units identified as having an arrival date of 35 days or earlier, in

support of operations plans (OPLANS) for high threat areas. This also includes Marine Inspectors that regularly travel to one or more of the high threat areas.

b. Coast Guard and PHS medical officers and Health Service Technicians (HS and HSD) will begin the CG AVIP in this phase, if not already begun. Recruits in Basic Training, OCS, DCO School and Coast Guard Academy graduates who have orders to these alert units will receive at least the first dose prior to departing the training program, if possible.

4. Priority 4. Personnel stationed or assigned in Korea if not already included under priority 1, 2 or 3.

5. Individuals assigned to Headquarter staffs (such as intelligence and security staff personnel) and others may find they are subject to deployment on short notice. During priority 2, these personnel should initiate the vaccination series at the nearest MTF prior to deployment. If vaccination prior to deployment is impossible, the series shall begin immediately upon entry into theater. These personnel should otherwise begin vaccination during priority 3.

6. Per ref (a), Coast Guard civilian personnel whose duties classify them as rapid deployment in support of Coast Guard operations in higher threat areas shall be vaccinated upon notification for deployment to a higher threat area.

CHAPTER 4

AUTOMATED IMMUNIZATION TRACKING SYSTEM

PURPOSE 4-1

IMMUNIZATION TRACKING SYSTEM (ITS) 4-1

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- MRS DATABASE 4-2
- DATA REQUIREMENTS 4-2

ADVERSE EVENTS REPORTING 4-2

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CHAPTER 4. AUTOMATED IMMUNIZATION TRACKING SYSTEM

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

B. IMMUNIZATION TRACKING SYSTEM (ITS): The Medical Readiness System (MRS) on CGHRMS is mandated as the ITS for anthrax vaccination for Coast Guard personnel, both Active Duty and Selected Reserve, receiving immunizations within the CG system. All CG medical facilities/personnel providing immunization services are required to be familiar with MRS and its use.

1. Coast Guard units having members (military or civilian) requiring initial or subsequent doses of anthrax vaccine will ensure those members receive their vaccinations on schedule from Coast Guard or DOD MTFs or sickbays or designated Coast Guard unit facilities**. Medical unit personnel will ensure the immunization data shall be entered into MRS.**

2. DoD members may receive initial or subsequent doses of anthrax vaccine from a Coast Guard clinic/sickbay**. MRS is unable to accept entry of non-CG personnel data. For these non-CG service members, an entry will be made by CG-5665 (or SF-601) overprint into DoD service member's medical record. It is expected that the providing Service** (in this case the Coast Guard) **will furnish this information to DEERS; therefore, the Coast Guard MTF shall supply the CG-5665 (or SF-601) overprint data (by a hardcopy or fax) to G-WKH-1 for delivery to the appropriate service representative.**

3. The vaccination data for Coast Guard personnel vaccinated at DoD MTFs/sickbays will be entered into local service component tracking systems, all of which download to DEERS.

C. REPORTING REQUIREMENTS.

1. Medical record. Documentation of all anthrax vaccinations must be made in the medical record. In as much as the standard SF-601 is not suitable for recording all required data elements for anthrax vaccinations, a CG-5665 overprint, Anthrax Vaccination Record, has been prepared. This is provided as Enclosure (2), and it should be reproduced for local use. This form may also be downloaded from the Operational Medicine website http://www.uscg.mil/anthrax.htm. The personal information must include name, social security number, date of birth and unit name/department ID. (If a DoD Anthrax Immunization Record SF-601 overprint is used, all required data elements will be noted.) Documentation of anthrax vaccinations shall also be entered on the PHS 731 ("yellow shot card").

2. MRS Database. The MRS database of immunizations provides a central location to provide command, unit, or individual immunization information. This feature will be particularly useful, in the absence of a paper copy of the immunization record, to determine which anthrax dose is next due for an individual, to determine unit needs in advance, or to track unit compliance rates.

3. Exemptions. Exemptions (exceptions), both medical and adminsitrative, will be recorded in the MRS database. The proper codes to use may be found at enclosure (5). Several exemptions are considered indefinite and no end date is entered in MRS. Any exemption that is not indefintite (e.g. Med, Temp) must have an exemption end date recorded in the database.

4. Data Requirements. Automated tracking of immunizations **is required** for military personnel only.

D. ADVERSE EVENTS REPORTING.

1. Adverse events or reactions to immunizations must be entered into MRS under comments section, as well as in the medical record with entries on the CG-5665 overprint, the NAVMED 6150 Problem Summary Sheet, the CG5266 Drug Sensitivity Sticker (if anaphylactic reaction has occurred) and the SF-600. (Note: Immunization will be recorded on DD2276 when this form replaces NAVMED 6150 problem summary sheet)

2. All adverse vaccine reactions resulting in hospitalization or duty time lost (in excess of 24 hours), as well as due to suspected lot contamination, shall be reported on the VAERS-1 form in Enclosure (2). (VAERS forms and information can also be obtained by calling 1-800-822-7967 or from the Web at: http://www.fda.gov/cber/vaers/vaers.htm). Additionally, a VAERS report should be filed for any permanent medical exemption due to a vaccine related adverse event. Other reactions may be reported to VAERS, either by a health care provider or the vaccinated individual.

3. For VAERS-1 forms completed at Coast Guard units/facilities, the original is forwarded to the FDA. A copy of the completed VAERS form will be retained on file at the local command or unit and a copy shall be provided to Commandant (G-WKH-1). G-WKH-1 will provide the Commander, U.S. Army Center for Health Promotion and Preventive Medicine, Aberdeen Proving Ground, MD 21010-5422, with copies of Coast Guard adverse event or reaction reports.

4. Anyone may report a vaccine-associated event through VAERS to the FDA. Health care providers should assist in the completion and forwarding of a VAERS-1 form for any vaccine recipient desiring to complete one. Health care providers assisting in the VAERS process are not expected to determine the causality by the anthrax vaccine, but only establish that a temporal relationship exists between the immunization and the possible adverse reaction.

CHAPTER 5

LOGISTICS

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CHAPTER 5. LOGISTICS

A. PURPOSE. The purpose is to provide the logistics concept of operations for the Coast Guard AVIP.

B. GENERAL INFORMATION. The following information on the FDA-licensed Anthrax Vaccine Adsorbed is provided:

1. NSN: 6505-01-399-6828
2. Unit of issue. Ten 0.5 ml dose per 5.2 ml multi-dose vial.
3. Shelf life. Given proper storage and lack of contamination, 12 months after opening or until expiration date, whichever is earlier.
4. Storage temperature. 36º- 46ºF (2º- 8 ºC). ***NOT TO BE FROZEN***.
5. Dosage. Primary immunization consists of six subcutaneous injections of 0.5 ml each given over a period of 18 months. Subsequent booster injections of 0.5 ml are given subcutaneously at 1-year intervals after the primary series.
6. Cost. Although DoD centrally funds the anthrax vaccine product, individual Services are responsible for the ancillary supplies, logistic support, information management, and personnel travel required to administer the vaccine program.

C. PRIORITY. The unit priority list is defined in Chapter 3, Paragraph C of this Manual.

D. CONCEPT OF OPERATIONS.

1. 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). It is not a DSCP depot stocked item, but is stored at the manufacturer, Bioport Corporation. whose central point of contact for the military is U. S. Army Medical Material Activity (USAMMA). All requests/requisitions for vaccine will be coordinated with USAMMA by the MLC(k)s via G-WKH-1.
2. The Coast Guard will vaccinate personnel in accordance with the FDA immunization schedule described in Chapter 2, Paragraph A.6.a.(2). Based on the prioritized list in Chapter 3, Paragraph C of this Manual, USAMMA, on order of the MLC(k)s through G-WKH-1, will send the first four doses of the vaccine to designated clinics or sickbays. Requisitions for subsequent vaccine requirements must be submitted to MLC(k).

E. RESPONSIBILITIES.

1. Commandant (G-WKH-1).
   a. Function as liaison between the Coast Guard and USAMMA to determine changes to program and requirements and provide approval for orders from MLC(k)s.
2. Commander, Maintenance and Logistics Commands.
   a. Ensure implementation of the CG AVIP within area of responsibility.

b. Oversee logistics for the CG AVIP

c. Submit to USAMMA vaccine, through G-WKH-1, product requisitions that include:

(1) The number of vials to be released.

(2) Ship-to address. Note: Since commercial carriers will be used for United States and Puerto Rico delivery, specific building/room number, 2 POCs, and phone numbers must be provided for each shipment.

(3) Requisitions will be emailed to G-WKH-1 for approval and forwarding via email to USAMMA.

d. When necessary, assist units with funding for ancillary supplies. Information may be obtained from USAMMA as to DoD vaccination points that may be located near remote Coast Guard units.

e. Notify USAMMA (copy to: Commandant (G-WKH-1) of any delays, discrepancies or problems with shipment. Coordinate with respective destination points the receipt date for appropriate, timely handling of each Anthrax vaccination shipment. ***Note:*** ***Strict compliance with storage requirements (refrigeration) during transportation and upon receipt is imperative and must be stressed to all personnel in the logistics pipeline.***

f. Notify unit commanders of all service members reported as overdue for vaccine doses more than 30 days.

3. Coast Guard clinics/sickbays

a. Receive, store (refrigerate), and redistribute vaccine received for the CG AVIP in accordance with anthrax vaccine cold-chain management guidelines outlined by USAMMA. Current storage and redistribution standard operating procedures can be found at http://www.armymedicine.army.mil/USAMMA/anthrax/antxhome.htm. (See Storage and Redistribution hyperlinks on the left side of the web page)

b. Coordinate transfer of vaccine to units if they have storage and immunization capabilities.

c. Coordinate the vaccination of personnel in units without storage and immunization capabilities. This may occur by scheduling immunizations at Coast Guard clinics/sickbays, DoD MTFs/sickbays or by coordinating to have immunizations given at an operational unit facility by a Coast Guard medical representative (e.g., Group HS, Clinic HS). Information may be obtained from the MLC(k) as to the location of DoD vaccination points that may be located near remote Coast Guard units.

d. Provide vaccination services to DoD personnel presenting to Coast Guard medical facilities for scheduled anthrax shots. Personnel should have documentation verifying either need for an anthrax immunization (e.g. shot record, CG-5665 or SF-601 overprint) or need to begin the immunization series (e.g. orders to deploy).

4. Unit to be vaccinated.

a. If capable of storing and administering vaccine: Receive and store (refrigerate) vaccine product. Immunize personnel in accordance with FDA immunization schedule for anthrax vaccine.

b. If not capable of storing and administering vaccine: Coordinate with nearest Coast Guard medical facility or DoD MTF to have unit personnel scheduled for anthrax vaccination in accordance with FDA immunization schedule.

CHAPTER 6

COMMUNICATIONS/EDUCATION PLAN

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TALKING POINTS 6-2

AUDIENCES 6-2

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CHAPTER 6. COMMUNICATIONS/EDUCATION PLAN

A. PURPOSE. The purpose is to disseminate Commandant's education and communications protocol and guidance for the CG AVIP.

B. BACKGROUND. The DOD announced 15 December 1997 that in early summer 1998 it would begin the immunization of select U.S. military personnel and units using the anthrax vaccine. The vaccine program was started early in March 1998. Due to a temporary shortage in supply of licensed vaccine the AVIP entered a slowdown period. On 28 June 2002, the Deputy Secretary of Defense announced the resumption of the Anthrax Vaccine Immunization Program (AVIP). The Coast Guard is a full participant in this Force Protection program. Throughout the periods of conception and early implementation of the program, it has been clear that internal and external education programs and public affairs support is required.

1. Biological and chemical warfare countermeasures, including vaccines, have been perceived by some people as possible causes for health concerns of Gulf War veterans. Although no scientific evidence links the anthrax vaccination to Gulf War-related illnesses, these perceptions may cause some military members to ask to sign informed consent waivers before they receive the vaccine. Others may want the right to refuse vaccination without risk of reprisal.

2. As with other vaccinations required by the military, service members may not refuse the anthrax vaccine. Informed consent for military personnel is not required for FDA-licensed immunizations. Coast Guard members who refuse vaccination may be subject to administrative or disciplinary action or both, at the discretion of the commander, for disobeying a lawful order.

3. Coast Guard personnel (Active Duty and Selected Reserve) may also be concerned about how the anthrax vaccination affects their existing medical conditions. A Coast Guard member who is pregnant will defer initiation or continuation of the vaccine series until she is no longer pregnant. This policy is a safeguard; there are no known risks to fetuses. Coast Guard personnel who are HIV positive or otherwise immunocompromised (e.g., on corticosteroid therapy) will not routinely be given the vaccine because they are unlikely to develop an antibody response. Personnel with a history of severe hypersensitivity reaction to a previous dose or allergy to any vaccine component will be omitted from the CG AVIP. Anyone with a fever (temperature ≥100.5° F) will defer vaccination until the illness has resolved.

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

1. Inform all personnel that to immunize using anthrax vaccine is a necessary part of the plan to eliminate anthrax as a threat to U.S. forces at risk.

2. Gain the support of Coast Guard personnel and their families for the vaccination of U.S. forces against anthrax.

3. Use this opportunity to inform the American public that biological warfare is a very real threat to our forces and mission readiness.

D. TALKING POINTS. The following talking points will be emphasized:

1. We are immunizing because the vaccine, along with personal protective measures (e.g., mask), provides the best possible protection for U.S. forces against anthrax.

2. Anthrax is the greatest biological warfare threat faced by U.S. forces.

3. Inhaled anthrax is almost always lethal to those who become infected.

4. The anthrax vaccine is Federal Drug Administration approved, licensed, and has been in use since 1970 among populations at risk, especially those working with livestock.

5. The vaccine is safe and effective.

6. The anthrax vaccination requires six shots over 18 months, followed by annual boosters.

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

1. All Coast Guard personnel who will be vaccinated and their families (regular, Selected Reserve and others).

2. Coast Guard civilian personnel who will be vaccinated and their families.

3. Coast Guard leadership.

4. Coast Guard Health Services personnel.

F. RESPONSIBILITIES.

1. Commandant (G-IPA) will:

a. Provide coverage of immunization program in internal Coast Guard media.

b. Provide communication tools about the immunization program to Coast Guard PAOs for their internal and external information needs.

c. Prepare a CG AVIP handout that can be reproduced locally as a handout for each Coast Guard member receiving the vaccine.

d. Respond to media inquiries and assist Coast Guard district PAOs in responding to media queries.

e. Provide Commandant (G-WKH-1) any relevant information received from other sources.

f. Function as Coast Guard liaison to DoD public affairs offices and workgroups with regard to the CG AVIP.

2. Commandant (G-O, G-M, and G-WTR) will:

a. Coordinate response to congressional queries, as appropriate.

3. Commandant (G-WKH-1) will:

   a. Maintain a liaison with AVIP program managers in other Services, keeping current with the latest educational and communications information available.

   b. Forward new information/briefings to the MLCs for distribution to the appropriate audiences.

   c. Refer media queries from outside the Coast Guard to Commandant (G-IPA).

   d. Refer congressional queries and briefings to Commandant (G-ICA).

   e. Develop, with the assistance of Coast Guard Headquarters Public Affairs, and make available, through the MLCs, the Coast Guard Anthrax Vaccine Information Brochure (enclosure 4) to all recipients of the Anthrax vaccine.

   f. Make available, through the CG AVIP website and the MLCs, briefings and other educational materials targeted to commanding officers, other senior leaders, medical officers and other Health Services personnel.

4. Maintenance and Logistics Commands will:

   a. Coordinate distribution of educational materials within their area of responsibility, to unit commanders and medical personnel, as required.

5. Health Services Personnel will:

   a. Be familiar with the contents of the medical officers briefing, senior leaders briefing and other material available at http://www.uscg.mil/anthrax.htm or www.anthrax.mil.

   b. Find answers to all medical questions asked about the anthrax medical threat, vaccine and CG AVIP. If necessary, contact HQ and MLC(k) personnel responsible for overseeing the CG AVIP.

6. Designated Medical Officer Advisors and Designated Supervising Medical Officers will:

   a. Ensure that all HS personnel under their purview have been fully educated on the CG AVIP.

   b. Be available to answer questions from HS personnel administering program at sites remote from Coast Guard clinics.

7. Commanding officers of units receiving vaccine administration will:

   a. Ensure that medical personnel providing the immunization services have reviewed the medical officers briefing.

   b. Ensure that they and other senior leadership of units receiving the vaccine have reviewed the information provided in the Leaders' briefing at http://www.uscg.mil/anthrax.htm or www.anthrax.mil.

   c. Ensure that personnel receiving the vaccine are afforded the opportunity to review the Coast Guard Anthrax Vaccine Information Brochure (Enclosure 4).

d. Ensure that personnel receiving the vaccination are given the opportunity to ask questions about the vaccine and its administration.

7. Additional information for commanders and medical personnel:

a. Commanders will be familiar with the information in the leaders' briefing and will ensure that all members are provided a briefing on anthrax and the vaccination program. The information/briefings found at http://www.uscg.mil/anthrax.htm or DoD's AVIP site at www.anthrax.mil may be used. If unable to obtain educational materials, contact appropriate MLC(k) or supporting medical unit.

b. Commanders and supporting medical personnel will ensure that prior to the first anthrax vaccination, vaccine recipients are provided adequate information on the vaccine, its safety, its benefits, and the need for adherence to the immunization schedule. The Coast Guard Anthrax Vaccine Informational Brochure, provided as Enclosure 4, shall be distributed to all military personnel, Coast Guard civilian personnel, and civilian contractors before they receive this vaccine and they will be given an opportunity to read the sheet prior to vaccination.

c. Medical personnel play key roles in this program, both in its execution as well as providing expert advice to service members and commanders. They must become familiar with relevant aspects of anthrax and Anthrax Vaccine Adsorbed. They must read and be familiar within the information from the Anthrax Vaccine Adsorbed product insert and be familiar with the medical officer's briefing. Medical personnel, as subject matter experts, will assist commanders with required unit briefings whenever possible.

d. There is a significant amount of misleading and inflammatory misinformation circulating in the media and on the Internet regarding the AVIP and the vaccine. Accurate information can be found on the web at: www.anthrax.mil and http://www-nehc.med.navy.mil/prevmed/immun/anthrax.htm. Additionally, this Manual with enclosures as well as several other informative links may be found on the G-WKH-1, Coast Guard Operational Medicine web page at: http://www.uscg.mil/anthrax.htm.

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

Section 1074a of Title 10, United States Code authorizes RC members medical care appropriate for the treatment of an injury, illness or disease incurred or aggravated while performing active duty for less than 30 days, or inactive duty training. On July 20, 1999, the Assistant Secretary of Defense (Health Affairs) issued guidance to the Service Secretaries that emphasizes the responsibility of MTF commanders to ensure that they provide care for RC members who seek care for a vaccination-related health problem. This care includes medical evaluation and treatment, as appropriate.

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

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

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

HEALTH RECORD

ANTHRAX IMMUNIZATION RECORD

This form is subject to the Privacy Act Statement of 1974

Section 1 - ANTHRAX VACCINE INFORMATION CERTIFICATION

1. I have been given an Anthrax Vaccine Information Brochure (VIB):
   What You Need To Know About Anthrax Vaccine
   ☐ YES ☐ NO
2. I have been given the opportunity to ask questions about the Anthrax Vaccine prior to receiving the immunization

3. Signature	4. SSN	5. Date

Section II - ADMINISTRATION OF ANTHRAX VACCINE

Date Given	Dose No.	Dosing Schedule (from day 0)	Dose (ml)	Site (left or right arm)	Lot Number	Provider Facility/ Location	Administered By Printed or Stamped signature	Comments	Next Dose Due
	1	Day 0	0.5						
	2	2 Weeks	0.5						
	3	4 weeks	0.5						
	4	6 Months	0.5						
	5	12 Months	0.5						
	6	18 Months	0.5						
	B	Annual	0.5						
	B	Annual	0.5						
	B	Annual	0.5						
	B	Annual	0.5						
	B	Annual	0.5						

Exemption	Date Exemption Begins	Anticipated date of exemption completion	Actual date of Exemption Completion

Unless noted in comments, all doses will be given with vaccine manufactured by Bioport Corp.

Basic vaccination series consists of 6 shots over 18 months, given as indicated above. The following intervals between doses must be maintained. The 2nd dose is given 2 weeks after the 1st dose; the 3rd dose is given 2 weeks after the 2nd dose; the 4th dose is given 5 months after the 3rd dose; the 5th dose is given 6 months after the 4th dose; and the 6th dose is given 6 months after the 5th dose. If one is late for a dose or strays from the established schedule, the next dose due should be given, with the intervals for the remaining doses maintained. A booster dose should be administered every 12 months. If an adverse reaction occurs following an anthrax vaccination, note in "comments" block above and on a SF 600. If a severe reaction occurs, further administration of anthrax vaccine should be temporarily discontinued until further evaluation and consultation is completed.

Pregnancy: All women must be asked prior to receiving the vaccine if they are or might be pregnant. This will be asked in as private a setting as reasonably available. If the answer is yes, or possibly, the vaccine will be deferred until a confirmatory pregnancy test is done. If the pregnancy test is negative, the anthrax vaccine will be administered. If the pregnancy test is positive (confirmatory), administration of the vaccine will be deferred until the conclusion of the pregnancy. This temporary deferment will be noted above in the exemptions block as due to pregnancy. The date confirmed is listed as the date the exemption begins.

Patient's Identification (Mechanically Imprint, Type or Print):

Required: Name:

SSN:

DOB:

UNIT:

OPFAC:

VACCINE ADVERSE EVENT REPORTING SYSTEM

VAERS

24 Hour Toll Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100

PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only

VAERS Number _____

Date Received _____

Patient Name:

Last First M.I.

Address

City State Zip

Telephone no. (____) _____

Vaccine administered by (Name):

Responsible Physician _____

Facility Name/Address

City State Zip

Telephone no. (____) _____

Form completed by (Name):

Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other

Address *(if different from patient or provider)*

City State Zip

Telephone no. (____) _____

1. State

2. County where administered

3. Date of birth ___/___/___ mm dd yy

4. Patient age

5. Sex ☐ M ☐ F

6. Date form completed ___/___/___ mm dd yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:

- ☐ Patient died (date ___/___/___ mm dd yy)
- ☐ Life threatening illness
- ☐ Required emergency room/doctor visit
- ☐ Required hospitalization (_____days)
- ☐ Resulted in prolongation of hospitalization
- ☐ Resulted in permanent disability
- ☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination ___/___/___ mm dd yy Time _____ AM PM

11. Adverse event onset ___/___/___ mm dd yy Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
- ☐ Private doctor's office/hospital
- ☐ Public health clinic/hospital
- ☐ Military clinic/hospital
- ☐ Other/unknown

16. Vaccine purchased with:
- ☐ Private funds
- ☐ Public funds
- ☐ Military funds
- ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medial conditions(specify)

20. Have you reported this adverse event previously? ☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under

22. Birth weight _____ lb. _____ oz.

23. No. of brother and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/Immunization project

24. Mfr./imm. proj. report no.

25. Date received by mfr./imm.proj.

26. 15 day report? ☐ Yes ☐ No

27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

"Fold in thirds, tape & mail - DO NOT STAPLE FORM"

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

BUSINESS REPLY MAIL

FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE

VAERS
P.O. Box 1100
Rockville MD 20849-1100

DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed)

GENERAL

Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)

Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.

Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.

These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine orthat person's legal representativewill not be made available tothe public, but may be available to the vaccinee or legal representative.

Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms diagnosis, treatment and recovery should be noted.

Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.

Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please

Item 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.

Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.

Item 13: List ONLY those vaccines given on the day listed in Item 10.

Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.

Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.

Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.

Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).

Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.

Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one priorvaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.

Item 26: This space is for manufacturers' use only.

YOUR HEALTH & SAFETY ARE OUR #1 CONCERNS

- **We care about you and your families.**
- **Vaccines have kept troops healthy since the days of George Washington.**
- **This vaccine helps you complete your mission and return home safely.**

ANTHRAX VACCINE IS SAFE AND EFFECTIVE

- **U.S. anthrax vaccine has been FDA-licensed since 1970.**
- **The National Academy of Sciences and six panels of civilian scientists confirm that anthrax vaccine works and is safe.** **www.nap.edu/catalog/10310.html**
- **Research shows anthrax vaccine protects.**

THE THREAT FROM ANTHRAX IS DEADLY AND REAL

- **Anthrax is a top choice for use as a biological-warfare agent.**
- **The most deadly form of anthrax, inhalational anthrax, is the form most expected on the battlefield.**
- **You can be infected with anthrax and not know it, until it's too late.**

VACCINATION OFFERS A LAYER OF PROTECTION, IN ADDITION TO ANTIBIOTICS AND OTHER MEASURES, NEEDED FOR CERTAIN MEMBERS OF THE ARMED FORCES

cut here

Information about anthrax vaccine…

➢ The FDA-licensed dosing schedule is 0-2-4 weeks, 6-12-18 months, plus annual boosters, given subcutaneously at an angle, just under the skin.

➢ Injection site reactions, such as a burning sensation, redness and swelling are common. Local reactions occur in 30% of men and 60% of women. Anthrax vaccine often causes a lump under the skin where the vaccine is injected. These lumps can last a few weeks, but they go away on their own.

➢ Systemic reactions, such as headaches or a fever are less common than injection site reactions. These occur at rates similar to other vaccines 5-35%.

➢ Adverse events after vaccination are reported to the Vaccine Adverse Event Reporting System (VAERS). VAERS forms are available at **www.vaers.org** or call **800.822.7967.** Health care workers and vaccine recipients are encouraged to report via the VAERS system any severe reactions that might occur within 30 days of vaccine injection, require medical treatment and/or interfere with work or recreation. VAERS reporting is required with reactions that cause hospitalization or loss of work for 24 hours or more.

WHAT YOU CAN EXPECT FROM ANTHRAX VACCINE

Who should <u>not</u> get the anthrax vaccine?

✓ Some people should not get anthrax vaccine or should wait:

- Serious reaction to a prior dose raising concerns about safety of next dose
- Pregnancy
- HIV and immunosuppressed individuals
- Recovered from cutaneous skin anthrax

✓ You can request an evaluation for a medical exemption from your provider. If you or your provider need assistance with medical exemption questions, the Walter Reed Vaccine Healthcare Center (VHC) is available for consultation services or referral for a second opinion.

What side effects can I expect?

✓ A burning sensation often occurs immediately after getting anthrax vaccine and can last about a minute.

✓ Like other vaccines, anthrax vaccine may cause soreness, redness, itching, and swelling at the injection site.

✓ Up to 30% of men and 60% of women report local reactions, but these reactions usually last only a few days. A lump at the site occurs commonly, up to 50% of the time, lasting for a few weeks.

✓ Larger reactions occur in about 1-4% of vaccinees.

✓ Beyond the injection site, 5% to 35% may notice such symptoms as muscle or joint aches, headaches, rashes, chills, low-grade fever or nausea. These symptoms usually go away in less than a week.

✓ Any vaccine, like all prescription drugs, can cause serious reactions including those requiring hospitalization or medical care. Severe allergic reactions occur less than once per 100,000 doses.

How many shots will I get?

✓ The FDA-licensed schedule for anthrax vaccine is 6 doses given over 18 months: 0-2-4 weeks, 6-12-18 months, plus annual boosters. It's important to complete the series.

Is this vaccine safe and effective?

✓ Yes. Study after study shows people vaccinated against anthrax are as healthy as unvaccinated people. However, like all drugs, anthrax vaccine may rarely cause adverse reactions resulting in illness where a medical exemption is indicated.

✓ America's best scientists, serving on a committee of the National Academy of Sciences, said that anthrax vaccine, "as licensed, is an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains of *B. anthracis*."

What about long-term side effects?

✓ This vaccine has been used for over 30 years. No serious adverse events with prolonged illness have been detected. But we continue to look.

If I'm having a health problem/adverse event related to vaccination, what should I do?

✓ First, if a health problem occurs following any vaccine, seek medical care to take care of your immediate health problem! If your symptoms persist, you or your provider may contact the Walter Reed Vaccine Healthcare Center at **202.782.0411**. Then follow the information below and on the cut-out card to file a report with the Vaccine Adverse Event Reporting System (VAERS). We are committed to giving you the best-individualized care, no matter what caused the problem.

When do I file a VAERS report?

✓ Adverse events after vaccination are reported to the Vaccine Adverse Event Reporting System (VAERS). VAERS forms are available at **www.vaers.org** or call **800.822.7967**. Health care workers and vaccine recipients are encouraged to report via the VAERS system any severe reactions that might occur within 30 days of vaccine injection that require medical treatment and/or interfere with work or recreation. VAERS reporting is required with reactions that cause hospitalization or loss of work for 24 hours or more.

✓ You or any healthcare provider (civilian or military) treating you may contact the Walter Reed Vaccine Healthcare Center (VHC) for assistance with preparing and submitting a VAERS report or vaccine adverse event consultation.

If I started anthrax vaccinations, but had doses delayed, do I have to restart the series?

✓ No, you will not have to restart the series. You will simply pick up where you left off. This is consistent with national guidelines from the CDC's Advisory Committee on Immunization Practices.

✓ The protection of each additional dose builds on the immune response to earlier doses and delays in timing do not interfere with the response. This is like climbing steps on a ladder towards full protection.

What about Reserve Component (RC) units that drill every 4 weeks?

✓ Your unit commander, in coordination with the medical authority responsible for immunizations, will schedule your vaccinations in a timely manner in order to ensure no doses are missed and you are provided fullest protection.

I'm in the Reserves/National Guard. If I have an adverse event, can I go to a military hospital or clinic?

✓ Adverse events after military directed vaccinations are in "line-of-duty" (LOD). Some RC members may seek medical care from their private physicians, while others may seek medical care at a local military Medical Treatment Facility (MTF).

✓ Those who seek treatment for an adverse event related to an official immunization will be treated. Any necessary line-of-duty (LOD) documents shall be completed after the person is treated. If you see a NON-military provider, be sure to notify your commander for the proper paperwork for a LOD/Notice of Eligibility determination.

✓ Evaluation or treatment will not be denied or delayed, pending a line-of-duty determination.

✓ For civilian health services outside a military Medical Treatment Facility call: **888.MHS.MMSO (888.647.6676)**

What if I'm pregnant, breast-feeding or if I'm planning on having children?

✓ Good medical practice defers vaccination during pregnancy, unless clearly needed. If you are unsure if you are pregnant, you may request a pregnancy test from your regular medical provider.

✓ A study at Fort Stewart found that vaccinated women get pregnant and give birth at the same rate as unvaccinated women. The outcomes of the pregnancies are also comparable in vaccinated and unvaccinated women.

✓ The Centers for Disease Control and Prevention (CDC) reports that vaccines are safe both for nursing mothers and their breast-fed infants.

✓ There is no medical reason for vaccinated women or the partners of vaccinated men to delay child bearing.

Anthrax Vaccine Immunization Program

For more information contact:

- **AVIP Agency Website: www.anthrax.mil**
  E-Mail: **avip@amedd.army.mil**
  Toll-Free: **877.GETVACC**
- **CDC National Immunization Hotline: 800.232.2522**
- **Walter Reed Vaccine Healthcare Center: 202.782.0411**

Information for Civilian Healthcare Providers: If a Reserve Component or Active Duty member of the Armed Forces presents at your office for a condition they believe may be an adverse event caused by a vaccination, please provide care appropriate to their condition and contact the following as soon as possible for coordination and payment:

For civilian health services outside a Military Treatment Facility call: **888.MHS.MMSO (888.647.6676)**

WHAT YOU NEED TO KNOW ABOUT ANTHRAX VACCINE

For more information

www.anthrax.mil

e-mail us at:

avip@amedd.army.mil

877-GETVACC

September 2002

Reserved– To be used for Local Point of Contact Information

Exemptions (exception) codes for Immunizations for use in MRS database

Medical Exemption Codes:

Code	MRS Code	Meaning	Explanation or Example	Duration
MI	**Med, Immune**	Medical, Immune	Evidence of immunity (e.g., serologic antibody test); documented previous infection (e.g., chickenpox)	Indefinite
MR	**Med, React**	Medical, Reactive	Severe adverse reaction after immunization (e.g., anaphylaxis)	Indefinite
MT	**Med, Temp**	Medical, Temporary	Pregnancy, hospitalization, temporary immune suppression, convalescent leave, any temporary contraindication to immunization	Specified period
MP	**Med, Perm**	Medical, Permanent	HIV infection, pre-existing allergy permanent immune suppression. Can be reversed if the condition changes.	Indefinite
MD	**Med, Declin**	Medical, Declined	Declination of optional vaccines (not applicable to anthrax vaccine), religious waivers	Indefinite
MS	**Med, Supp**	Medical, Supply	Exempt due to lack of vaccine supply	Indefinite

Administrative Exemption Codes:

Code	Code	Meaning	Explanation or Example	Duration
AD	**Admin, Dcsd**	Administrative, Deceased	Service member is deceased	Indefinite
AL	**Admin, Eml**	Administrative, Emergency Leave	Service member is on emergency leave	Max 1 month
AM	**Admin, Msg**	Administrative, Missing	Missing in action, prisoner of war	Indefinite
AP	**Admin, Pcs**	Administrative, PCS	Permanent change of station	Max 3 months
AR	**Admin, Rfsl**	Administrative, Refusal	UCMJ Actions	Until resolution
AS	**Admin, Sep**	Administrative, Separation	Discharge, separation, retirement	
AT	**Admin, Temp**	Administrative, Temporary	AWOL, legal action pending	Max 3 months