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COMDTINST M6230.3B
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COMMANDANT INSTRUCTION M6230.3B

Subj: COAST GUARD ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)

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

1. PURPOSE. This Manual establishes policy, assigns responsibilities, and provides guidelines regarding the Coast Guard Anthrax Vaccine Immunization Program (AVIP), unit prioritization, automated tracking system and reporting requirements, logistics, communications/education, military personnel guidance, and civilian personnel guidance.
2. ACTION. Area, district, and sector commanders, commanders of maintenance and logistics commands, commanding officers of integrated support commands, commanding officers of headquarters units, assistant commandants for directorates, Judge Advocate General and special staff elements at Headquarters shall ensure compliance with the provisions of this Manual. Internet release is authorized.
3. DIRECTIVES AFFECTED. Coast Guard Anthrax Vaccine Immunization Program, COMDTINST M6230.3A is cancelled.
4. ENVIRONMENTAL ASPECT AND IMPACT CONSIDERATIONS. Environmental considerations were examined in developing this Manual and are incorporated herein.
5. PROCEDURE. No paper distribution will be made of this Manual. Official distribution will be via the Coast Guard Directives System CD-ROM. An electronic version will be located on the Information and Technology (CG-612) websites at <http://cgcentral.uscg.mil/> (once in CG Central, click on the resources tab then directives) and <http://www.uscg.mil/ccs/cit/cim/directives/welcome.htm>. This Manual will also be made

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available via the Commandant (CG-112) Publications and Directives website at <http://www.uscg.mil/hq/g-w/g-wk/wkh/pubs/index.htm>.

6. 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 the Department of Defense (DoD) announced the establishment of the Anthrax Vaccination Immunization Program (AVIP) for U.S. military forces.
- b. Due to a temporary shortage in the supply of licensed vaccine, 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 AVIP. On 27 October 2004, the U.S. District Court for the District of Columbia placed an injunction on mandatory anthrax vaccinations.
- c. On 10 December 2004, the Deputy Secretary of Defense determined that there was a significant potential for a military emergency involving an attack with anthrax on U.S. military forces. Since April 2005, the AVIP has been conducted under an Emergency Use Authorization (EUA) issued by the Food and Drug Administration (FDA).
- d. On 19 December 2005, officials from the FDA issued a final order finding that anthrax vaccine protects against all routes of exposure to anthrax spores, including inhalation. After evaluation of the full scientific literature and assessing comments from the public submitted in early 2005, the FDA reaffirmed its previous conclusions. Because this regulatory action removed the basis and need for the EUA, it was not necessary for DoD to seek renewal of the EUA for use of anthrax vaccine to prevent inhalational anthrax. The EUA expired on 14 January 2006.
- e. On 12 October 2006, the Deputy Secretary of Defense issued a memorandum, announcing the resumption of the mandatory AVIP, consistent with the FDA guidelines and the best practice of medicine.
- f. On 6 December 2006, the Under Secretary of Defense for Personnel and Readiness issued detailed instructions to the military services to resume mandatory anthrax immunizations.

7. POLICY. All Coast Guard Active Duty and SELRES members and assigned PHS officers affected by this policy will be vaccinated unless medically or administratively exempted.

8. RESPONSIBILITIES.

- a. Commandant (CG-1121) has the overall responsibility for the policy associated with the Coast Guard 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, 3, 4, and 5 of this Manual.
- b. Commandant (CGPC-rpm) will address policy issues within the Reserve component.
- c. Commandant (CG-0922) will coordinate public affairs issues.
- d. Commandant (CG-0921) will coordinate congressional queries and briefings.

- e. Commanders, MLC will assume responsibility for plan overview. They will direct MLC(k) to ensure units have the requisite support and supplies (vaccines and ancillaries) to administer and monitor the program, and ensure compliance. Further responsibilities are outlined in Chapters 1, 3, 4, and 5 of this Manual.
 - f. Coast Guard clinics' and sickbays' responsibilities are outlined in Chapters 1, 3, 4, and 5 of this Manual.
 - g. Unit commanding officers will educate their personnel regarding the need for and safety of the vaccination program. Further responsibilities are outlined in Chapters 1, 3, 4, and 5 of this Manual.
 - h. Individual service member responsibilities are outlined in Chapter 1 of this Manual.
9. FORMS / REPORTS. The forms called for in this Manual are available in USCG Electronic Forms on the Standard Workstation or on the internet:
<http://www.uscg.mil/ccs/cit/cim/forms1/welcome.htm> or intranet:
<http://cgweb2.comdt.uscg.mil/CGForms/Welcome.htm>. Forms related to the AVIP can also be found on the [CG-1121 AVIP Web Site](#). The Drug Sensitivity Sticker form CG—5266, STOCK NUMBER 7530-01-GF2-9690, may be ordered through the Engineering Logistics Center (ELC) in Baltimore, MD. The Anthrax Trifold Information Brochure can be found at the anthrax vaccination program website www.anthrax.mil/AVIP2007 and the [CG-1121 AVIP Web Site](#). Clinics will receive an Anthrax Trifold for each dose of anthrax that they order. All enclosures may be reproduced locally. The [Adult Prevention and Chronic Care Flow Sheet, Form DD-2766](#), is a restricted form, contact the forms manager for additional forms.

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Enclosures:

- (1) TREATMENT OF RESERVES COMPONENT MEMBERS RELATED TO IMMUNIZATIONS
- (2) ADMINISTRATIVE AND MEDICAL EXEMPTION CODES FOR MRS

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CHAPTER 1. ANTHRAX VACCINATION IMPLEMENTATION PROGRAM

A. PURPOSE.

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

B. OVERVIEW.

1. DoD Immunization Program for Biological Warfare. DoD Immunization Program for Biological Warfare, DoD Directive 6205.3, 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. Program Executive Office for Chemical and Biological Defense (PEOCBD). The Program Executive Office for Chemical and Biological Defense (PEOCBD), resourced by DoD, will procure and maintain an adequate stockpile of vaccines and define 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. Dose Schedule. The primary immunization for the anthrax vaccine, which is licensed by the FDA, 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. MLC's responsibilities. MLC is responsible for program oversight to ensure that clinics have the tools to implement this program.
5. Commanding Officers responsibilities. Commanding Officers are responsible for ensuring members are compliant with this program.
6. Coast Guard clinics/sickbays responsibilities. Coast Guard clinics/sickbays have full responsibility for implementing and tracking members who qualify for mandatory or voluntary participation in the Coast Guard AVIP.

C. POLICY.

1. Mandatory Vaccination.
 - a. The following personnel will resume mandatory anthrax immunizations, except as provided under applicable medical and administrative exemption policies:
 - (1) Coast Guard personnel serving in the U.S. Central Command (USCENTCOM) area of responsibility (AOR) for 15 or more consecutive days.

- (2) Coast Guard personnel assigned to the Korean Peninsula for 15 or more consecutive days.
 - (3) Coast Guard National Strike Force.
 - (4) Other Coast Guard personnel designated by Commandant (CG-1121) based upon critical mission assignments. These critical mission designations will be assigned on a case-by-case basis as the need arises.
- b. Coast Guard personnel in the mandatory vaccination program will resume immunizations from the last documented vaccination given in the series. They will not restart the series or skip or repeat any vaccination in the series. Vaccinations will continue until the six-shot series is complete, followed by annual boosters. However, Coast Guard personnel will only receive mandatory anthrax vaccinations while they are in designated higher threat areas (CENTCOM and Korea) or while assigned to units with special or critical mission roles (as listed in (3) and (4) above). Once these personnel are no longer in designated higher threat areas or assigned to applicable units, they should be offered and encouraged to receive the anthrax vaccination on a voluntary basis (see section 2 below). Inter-Service or Inter-Component transfers who meet the requirements in Chapter 1, Section C. 1. a. of this manual, will continue the series in accordance with the FDA approved dosage and administration protocol.
 - c. Civilians: Coast Guard civilian personnel whose duties classify them as rapid deployment in support of Coast Guard operations in CENTCOM and Korea shall be vaccinated upon notification for deployment to these AORs. 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.
 - d. Members refusing vaccination shall be counseled that refusing the anthrax vaccine will not prevent them from being deployed. Additional force health protection measures will be used during their deployment in the event the member has been exposed to anthrax (e.g. treatment with appropriate antibiotics).
 - (1) 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.
 - (2) 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.
 - e. 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.

2. Voluntary Vaccination.

- a. The following individuals are eligible for voluntary vaccinations based on current location or status:

- (1) U.S. Government civilian employee and U.S citizen contractor personnel who have been assigned for 15 or more consecutive days to USCENTCOM AOR or Korea.
 - (2) Adult family members, 18-65 years of age, accompanying military and civilian personnel for 15 or more consecutive days to USCENTCOM AOR or Korea.
 - (3) U.S. citizen adult family members, 18-65 years of age, accompanying U.S. contractor personnel for 15 or more consecutive days to USCENTCOM AOR or Korea.
 - (4) Vaccine manufacturing and research personnel and others, as designated by the Assistant Secretary of Defense (Health Affairs) (ASD(HA)). ASD(HA) will approve their requests on a case-by-case basis.
- b. The following individuals who received at least one dose of anthrax vaccine during or after 1998 and who are not subject to mandatory vaccination shall (subject to medical exemptions) be offered additional vaccine doses, consistent with the FDA-approved dosing schedule, on a voluntary basis:
- (1) Members of the Uniformed Services on active duty or in the SELRES, regardless of duty assignment, if they previously received at least one dose of anthrax vaccine and if they are not currently subject to mandatory vaccination. For these individuals, continuing the dosing series is recommended but not required.
 - (2) U.S. Government civilian employees of any of the military services, regardless of current duty assignment, if they previously received at least one dose of anthrax vaccine and if they are not currently subjected to mandatory vaccination.
3. Availability. Vaccines will only be available at clinics that have been authorized by the MILVAX Agency to administer the anthrax vaccine.
4. Supplies. United States Army Medical Material Agency (USAMMA) will coordinate with the PEOCBD to ensure adequacy of vaccine supplies and the distribution to all Services. Commandant (CG-1121) will provide total Coast Guard vaccine requirements to USAMMA. Chapter 4 provides detailed logistics information.
5. Mandatory readiness initiative. 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 when in a high threat area or in critical mission assignments.
6. Responsibilities. Commanders, MLC will direct MLC(k) to assist with developing, maintaining, and monitoring implementation plans. Unit commanders will ensure implementation and maintenance of the Coast Guard AVIP within their units. Coast Guard Health Services personnel will coordinate and facilitate immunization of Coast Guard personnel (Chapter 4). Personnel in the Coast Guard AVIP are authorized to receive their anthrax immunization from DoD Medical Treatment Facilities (MTFs) if unable to obtain through Coast Guard medical facilities. Coast Guard clinics/sickbays will follow the Coast Guard AVIP Education and Communications programs provided in Chapter 5.

7. Record keeping. Medical record keeping (including reporting certain adverse reactions) will be maintained to document immunizations in accordance with Chapter 3 of this Manual.
8. Distribution. USAMMA will coordinate the distribution of the vaccination to the supporting medical supply activities for all Services. Commandant (CG-1121) will serve as Coast Guard Liaison with USAMMA. Units will furnish vaccine requirements to the supporting Health Services Clinic. Clinics will order through MLC(k) via Commandant (CG-1121) to USAMMA (see Chapter 5).

D. 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 Coast Guard AVIP or from receiving a scheduled dose of the vaccine. These exemptions fall into three categories: medical, administrative or special exemption.

1. Medical exemptions. 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 specific duration. A medical officer may authorize temporary medical exemptions. Permanent medical exemptions may only be authorized by Commandant (CG-1121).
2. Administrative exemptions. Administrative exemptions from the immunization schedule are authorized for personnel by the individual's unit commanding officer for the following reasons:
 - a. Missing in action or prisoner of war status.
 - b. Pending administrative or disciplinary actions due to vaccine refusal.
 - c. Absent without leave or imprisonment.
 - d. While in transit on a permanent change of station move.
 - e. Temporary duty or other extended absences from home station exceeding 30 days.
 - f. Legal discharge, separation, resignation or retirement. Commanding Officers may exempt personnel who are separating from the Coast Guard and are not on duty status in a Joint Staff designated higher threat area from the Coast Guard AVIP scheduling as indicated:
 - (1) Retiring Personnel. Service members who are retiring are exempt from the Coast Guard AVIP schedule no more than 180 days prior to their approved date of retirement or upon receipt of retirement orders, whichever occurs first.
 - (2) Separating Personnel. Service members who are separating from service may be exempt from the Coast Guard AVIP schedule no more than 180 days before their approved date of separation.
 - (3) Coast Guard civilian personnel whose duties classify them as having status equivalent to deployable forces in support of Coast Guard operations in higher threat areas who are resigning from service and are not on duty status in a Joint Staff designated higher threat area may be exempt from the Coast Guard AVIP scheduling as indicated:

- (a) Retiring Personnel. Coast Guard civilians who are retiring are exempt from the Coast Guard AVIP schedule no more than 180 days before the date reflected on their retirement papers.
- (b) Resigning Personnel. Coast Guard civilians who are resigning from service may be exempt from the Coast Guard AVIP schedule upon receipt of a signed resignation with an effective date no more than 180 days.
- (c) 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 Coast Guard AVIP upon presentation of evidence verifying their transfer/reassignment.

E. RESPONSIBILITIES.

1. Commandant (CG-1121) shall.

- a. Develop and disseminate medical education, information, policy, and doctrine to the MLC(k)s as required in accordance with the Coast Guard AVIP.
- b. Provide consolidated reports of adverse reactions to the Army Executive Agent in accordance with Chapter 4. Commandant (CG-1121) obtains copies of Vaccine Adverse Events Reporting System (VAERS) reports via the mechanism identified in Chapter 7 of the Medical Manual, COMDTINST M6000.1(series).
- c. Function as liaison between MLC(k)s and USAMMA to procure vaccine supplies for the Coast Guard.
- d. Provide timely notification to MLC(k)s regarding any changes to designated units or individual mobilizations to high threat areas.

2. Commanders, Maintenance and Logistics Commands shall ensure the MLC(k)s.

- a. Coordinate with USAMMA through Commandant (CG-1121) and other appropriate vendors to ensure sufficient vaccines and ancillary supplies are available to units conducting immunizations in accordance Chapters 2 and 3 of this Manual.
- b. Post educational briefing materials on the anthrax vaccination program on the MLC website located at CG Central>Organizational Information>MLCA Divisions or (MLCP Divisions) >Health and Safety>KOM. This information is also provided through the DoD website: www.anthrax.mil/AVIP2007.
- c. Post educational briefing materials for Coast Guard medical officers on the MLC website located at CGCENTRAL>Organizational Information> MLCA Divisions or (MLCP Divisions) >Health and Safety>KOM. This information is also provided through the DoD website: www.anthrax.mil/AVIP2007 (Health care Providers Briefing).

3. Coast Guard clinics and sickbays. Coast Guard clinics and sickbays that have been authorized by the MILVAX Agency to administer the anthrax vaccine shall:

- a. Have full responsibility for implementing and tracking members who qualify for the mandatory or voluntary AVIP. The clinic should utilize the Coast Guard Medical Readiness System for tracking purposes.

- b. Provide support to the Commandant's immunization plans for all Coast Guard Personnel (Active Duty, Selected Reserve and others) as required to support the Coast Guard AVIP.
 - c. Provide educational briefing materials on the anthrax vaccination program to required personnel. An approved briefing package will be posted on the MLC(k) website, and is also located at the DoD website -www.anthrax.mil/AVIP2007 (Individuals' Briefing).
 - d. Complete registry agreement with MILVAX in order to participate in the AVIP to order and administer anthrax vaccine. The registry agreement and checklist are available at www.anthrax.mil/AVIP2007.
 - e. Ensure that mandatory vaccinations are given only to those personnel designated as mandatory participants in this Manual.
 - f. Offer voluntary vaccinations to those personnel who have previously participated in the AVIP based on verification of previous vaccinations in the medical record and/or MRS.
 - g. Inform all individuals who begin the anthrax vaccine dosing series of the recommended dosing schedule and advise them to return to the vaccination clinic at the appropriate times under the schedule.
 - h. 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 Coast Guard AVIP.
 - i. Coordinate the immunization of Coast Guard personnel at Coast Guard clinics/sickbays, DoD MTFs/sickbays and/or Coast Guard unit facilities and ensure data entry is completed.
 - j. 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).
 - k. Ensure personnel receiving the Anthrax vaccine have been educated about the AVIP. Prior to initial immunization, ensure that personnel are provided the Anthrax Trifold Brochure (this brochure can be downloaded from the following web site www.anthrax.mil/AVIP2007) with specific information regarding the vaccine, its safety, benefits, and the need for adherence to the immunization schedule. (The Trifold should also be offered to personnel prior to each subsequent immunization). The provision of this information will be documented by health services personnel on the Anthrax Immunization Record CG-5665 overprint. This form can be accessed through the following web site: <http://www.uscg.mil/forms/default.asp>.
 - l. Meet the medical reporting requirements noted in Chapter 3 of this Manual.
4. Unit Commanding Officers shall.
- a. Have the ultimate responsibility to ensure their personnel meet the standards of this instruction.

- b. Determine anthrax vaccine needs on a monthly basis, at least 30 days in advance, and coordinate with cognizant medical Point of Contact (POC) to ensure that personnel are to be immunized on schedule (Chapters 3 and 4).
- c. Ensure all assigned service members are available for anthrax vaccination in accordance with the FDA schedule of vaccination.
- d. Ensure all assigned service members reported as overdue for vaccination (as reported from the Coast Guard clinic/sickbay) receive or have received scheduled vaccinations. If overdue reports are incorrect, the clinics/sickbays must update the correct information in the Medical Readiness System (see Chapter 3). If there is an ongoing issue regarding non-compliance, the clinic should contact the appropriate MLC(k) to discuss the unit's or member's non-compliance.

5. Service Members shall.

- a. Read and take all steps necessary to understand the Trifold brochure, "What You Need to Know about Anthrax Vaccine".
- b. Report to appropriate Coast Guard clinic, sickbay, USMTF, 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.

F. COORDINATING INSTRUCTIONS.

- 1. Uniformed Medical Treatment Facilities. Direct coordination with USMTFs to complete unit or individual immunizations is authorized.
- 2. MLC(k) and United States Army Medical Material Agency (USAMMA). MLC(k)s will coordinate with USAMMA through Commandant (CG-1121) for vaccine supplies to be sent to appropriate Coast Guard clinics.

CHAPTER 2. MEDICAL CONSIDERATION AND GUIDANCE

A. VACCINE CHARACTERISTICS.

1. 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). Disposal of Anthrax should be in accordance with information provided on the Disposition link at the following web site:
<http://www.usamma.army.mil/vaccines/anthrax/antxhome.cfm>.
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 be avoided. Unusually lean people might avoid injection-site reactions by receiving the 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) Personnel on orders to USCENTCOM AOR or Korea may begin immunizations up to 120 days before deployment or arrival. Every effort should be made to provide at least three doses prior to deployment.
 - (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 Anthrax Trifold Brochure or other Commandant (CG-1121) 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 health care providers prior to vaccination. Service member will sign the [Anthrax Immunization Record, CG-5665](#) that they have received the Trifold and had the opportunity to ask questions prior to immunization. File the Anthrax Immunization Record, CG-5665 in the members Health Record under the Immunization Record, SF-601. (These forms can also be located at the [CG-1121 AVIP Web Site](#)).
- (7) At the time of immunization, personnel are to be provided documentation that identifies date and location of immunization, location of the nearest USMTFs (or civilian hospital), and the toll-free telephone number of the Military Medical Support Office (MMSO), in the event medical treatment is required from non-MTFs.
- (8) As with most other immunizations, aviation personnel are automatically grounded for 12 hours after receiving the anthrax vaccine.

B. MEDICAL RECORD KEEPING.

1. Where to document immunization. Each dose of anthrax vaccine administered will be documented by the administering clinic or sickbay with entries in four separate locations:
 - a. The individual patient's medical record in section V, on the [Anthrax Immunization Record CG-5665](#), or a [Health Record-Immunization Form, SF-601](#) overprint, "Anthrax Vaccine Record" from a DoD service may be used;
 - b. The individual patient's medical record on the Adult Preventive and Chronic Care Flow Sheet, DD 2766;
 - c. The immunization tracking module in the Medical Readiness System (MRS) which will transfer the information to the Defense Enrollment and Eligibility Reporting System (DEERS) and
 - d. An entry documenting counseling and vaccination in one of the following:
 - (1) Programing Graphical User Interface (PGUI)
 - (2) Composite Health Care System (CHCS)
 - (3) Armed Forces Health Longitudinal Technology Application(AHLTA).
2. What to document. The first 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. Additional documentation. Additionally, the Anthrax Immunization Record, CG-5665 overprint will include route of administration and name of the provider, and date/provider's initials documenting the provision of the Anthrax Trifold Brochure. (See the [CG-1121 AVIP Web Site](#) for forms).

4. Quality control and quality assurance. 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. Background. 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. Procedures. 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.
 - b. Only one situation calls for restarting the vaccine series with the first dose: If 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. Coast Guard medical personnel should contact the appropriate clinic, MLC(k) and/or Commandant (CG-1121) 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.

Health care 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 Anthrax Trifold. Provision of the Anthrax Brochure will be documented on the Anthrax Immunization Record, CG-5665 prior to the first immunization.

E. ADVERSE REACTIONS.

Health care providers may use information from the clinical guidelines for adverse events after vaccination found on the [CG-1121 AVIP Web Site: http://www.uscg.mil/hq/g-w/g-wk/wkh/avip/](http://www.uscg.mil/hq/g-w/g-wk/wkh/avip/) or the DoD AVIP website: www.anthrax.mil/AVIP2007.

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 $\geq 100.5^{\circ}\text{F}$), malaise, muscle and joint aches, headache, or related symptoms may occur in 5% to 35% of vaccines. These symptoms are generally mild, respond to acetaminophen and/or NSAIDs and last less than 72 hours.

3. Serious reactions. 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 3. At the local level, units may decide to track mild or moderate reactions.

5. Reserves. 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 (BIOTHRAX™). 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 is 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. MEDICAL REPORTING

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 DEERS database.

B. IMMUNIZATION TRACKING SYSTEM (ITS).

The Medical Readiness System (MRS) is mandated as the ITS for anthrax vaccination for Coast Guard personnel, both Active Duty and SELRES, receiving immunizations within the Coast Guard system. All Coast Guard medical facilities/personnel providing immunization services are required to be familiar with MRS and its use.

1. Coast Guard members. 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 USMTFs or sickbays or designated Coast Guard unit facilities. Medical unit personnel will ensure the immunization data shall be entered into MRS.
2. DoD members. 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 on the Anthrax Immunization Record CG-5665 or Health Record Immunization Record, SF-601 which can be copied into the 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 Anthrax Immunization Record CG-5665 (or Health Record Immunization Record SF-601) overprint data (by a hardcopy or fax) to Commandant (CG-1121) for delivery to the appropriate service representative.
3. Coast Guard members at DoD MTF. 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. The member shall bring a copy of the Anthrax Immunization Record CG-5665 to their Health Record Custodian to be placed in their Medical Record. This information must also be entered into the MRS System by the units supporting CG Medical Clinic.

C. REPORTING REQUIREMENTS.

1. Medical record. Documentation of all anthrax vaccinations must be made in the medical record. In as much as the standard Health Record Immunization Record SF-601 is not suitable for recording all required data elements for anthrax vaccinations, an Anthrax Immunization Record CG-5665 shall be prepared. This is provided on the following web site: <http://www.uscg.mil/forms/cg.asp> or the [CG-1121 AVIP Web Site](#). The personal information must include name, social security number, date of birth and unit name/department ID.
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. PGUI/CHCS/AHLTA. Document counseling and vaccination in PGUI/CHCS/AHLTA.
4. Exemptions. Exemptions (exceptions), both medical and administrative, will be recorded in the MRS database. The proper codes to use may be found at Enclosure (2). Several exemptions are considered indefinite and no end date is entered in MRS. Any exemption that is not indefinite (e.g. Med, Temp) must have an exemption end date recorded in the database.
5. Data Requirements. Automated tracking of immunizations **is required** for military personnel only.

D. ADVERSE EVENTS REPORTING.

1. Where to enter data. 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 Anthrax Immunization Record CG-5665, the Adult Preventive and Chronic Care Flow Sheet, DD2766, the Drug Sensitivity Sticker, CG 5266 (if anaphylactic reaction has occurred) and the Chronological Record of Care, SF-600. An adverse reaction should be documented in a PGUI/CHCS/AHLTA entry (e.g. SOAP entry and allergy module update).
2. When to report a problem. All adverse vaccine reactions resulting in hospitalization or duty time lost (in excess of 24 hours), as well as due to suspected lot contamination, shall be reported on the Vaccine Adverse Event Report System (VAERS)-1 form. VAERS forms and information can 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. Distribution of forms. For VAERS-1 forms completed at Coast Guard units/facilities, the original is forwarded to the FDA. A copy of the completed VAERS form will be retained on file at the local command or unit and a copy shall be provided to Commandant (CG-1121). Commandant (CG-1121) will provide the Commander, U.S. Army Center for Health Promotion and Preventive Medicine, Aberdeen Proving Ground, MD 21010-5422, with copies of Coast Guard adverse event or reaction reports.
4. Report originators. Anyone may report a vaccine-associated event through VAERS to the FDA. Health care providers should assist in the completion and forwarding of a VAERS-1 form for any vaccine recipient desiring to complete one. Health care providers assisting in the VAERS process are not expected to determine the causality by the anthrax vaccine, but only establish that a temporal relationship exists between the immunization and the possible adverse reaction.

CHAPTER 4. 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. 36°- 46°F (2°- 8 °C). **NOT TO BE FROZEN.** Clinics/sickbays should review the "Proper Storage Requirements For the Anthrax Vaccine/Update (DOD-MMQC-00-1034) document found on the USAMMA website:
<http://www.usamma.army.mil/vaccines/anthrax/antxhome.cfm> Note: All refrigeration devices used for the storage of Anthrax Vaccine must have a temperature-indicating device. Temperature readings need to be annotated every 12 hours to include weekends and holidays and a record of these readings will be maintained at the location of the refrigeration device. Although an audible temperature alarm is no longer required, it is an additional measure recommended by USAMMA.
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. POLICY.

1. Funding. The vaccine is centrally funded by PEOCBD. 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 USAMMA. All requests/requisitions for vaccine will be coordinated with USAMMA by the MLC(k)s via Commandant (CG-1121).
2. Schedule. The Coast Guard will vaccinate personnel in accordance with the FDA immunization schedule described in Chapter 2.

D. RESPONSIBILITIES.

1. Commandant (CG-1121). Commandant (CG-1121) function as a liaison between the Coast Guard and USAMMA to determine changes to program and requirements and provide approval for orders from MLC(k)s.
2. Commander, MLC will ensure the MLC(k)s.
 - a. Ensure oversight of the Coast Guard AVIP within their area of responsibility.

- b. Provide AVIP information on the MLC(k) website.
 - c. Oversee logistics for the Coast Guard AVIP
 - d. Submit to USAMMA vaccine, through Commandant (CG-1121), product requisitions that include:
 - (1) The number of vials to be released.
 - (2) Ship-to address. Note: Since commercial carriers will be used for United States and Puerto Rico delivery, specific building/room number, 2 POCs, and phone numbers must be provided for each shipment.
 - (3) Requisitions will be emailed to Commandant (CG-1121) for approval and forwarding via email to USAMMA.
 - e. 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.
 - f. Notify USAMMA (copy to: Commandant (CG-1121) of any delays, discrepancies or problems with shipment. Coordinate with respective destination points the receipt date for appropriate, timely handling of each 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.***
3. Coast Guard clinics/sickbays.
- a. Notify unit commanders of all service members reported as overdue for vaccine doses more than 30 days.
 - b. Receive, store (refrigerate), and redistribute vaccine received for the Coast Guard 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.usamma.army.mil/vaccines/anthrax/antxhome.cfm> (See Storage Redistribution hyperlinks on the left side of the web page)
 - c. Have full responsibility for implementing and tracking members that qualify for mandatory or voluntary participation in the Coast Guard AVIP.
 - d. Coordinate transfer of vaccine to units if they have storage and immunization capabilities.
 - e. Coordinate the vaccination of personnel in units without storage and immunization capabilities. This may occur by scheduling immunizations at Coast Guard clinics/sickbays, USMTFs/sickbays or by coordinating to have immunizations given at an operational unit facility by a Coast Guard medical representative (e.g., IDHS, Clinic HS). Information may be obtained from the AOR clinic as to the location of DoD vaccination points that may be located near remote Coast Guard units.
 - f. Provide vaccination services to DoD personnel presenting to Coast Guard medical facilities for scheduled 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 USMTF to have unit personnel scheduled for anthrax vaccination in accordance with FDA immunization schedule.

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CHAPTER 5. COMMUNICATIONS AND EDUCATION PLAN

A. PURPOSE.

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

B. BACKGROUND.

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. Gulf War-related illnesses. 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. Refusal. As with other vaccinations required by the military, service members may not refuse the anthrax vaccine if in a mandatory status. Informed consent for military personnel is not required for FDA-licensed immunizations. Coast Guard members who refuse vaccination may be subject to administrative or disciplinary action or both, at the discretion of the commander, for disobeying a lawful order.
3. Other Medical conditions. Coast Guard personnel (Active Duty and SELRES) 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 Coast Guard AVIP. Anyone with a fever (temperature $\geq 100.5^{\circ}$ F) will defer vaccination until the illness has resolved.

C. OBJECTIVES.

Ensure full understanding and support of the Coast Guard 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. Information. 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. Support. Gain the support of Coast Guard personnel and their families for the vaccination of U.S. forces against anthrax.

3. Threat reality. 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. Protective measures. 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. Greatest threat. Anthrax is the greatest biological warfare threat faced by U.S. forces.
3. Anthrax is lethal. Inhaled anthrax is almost always lethal to those who become infected.
4. Federal Drug Administration approved. 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. Safe. The vaccine is safe and effective.
6. Dosage. 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. Coast Guard military personnel. All Coast Guard personnel who will be vaccinated and their families (regular, SELRES and others).
2. Coast Guard civilian personnel. Coast Guard civilian personnel who will be vaccinated and their families.
3. Coast Guard leadership.
4. Coast Guard Health Services personnel.

F. RESPONSIBILITIES.

1. Commandant (CG-0922) will.
 - a. Provide coverage of immunization program in internal Coast Guard media.
 - b. Provide communication tools about the immunization program to Coast Guard Public Affairs Officer for their internal and external information needs.
 - c. Respond to media inquiries and assist Coast Guard district PAOs in responding to media queries.
 - d. Provide Commandant (CG-1121) any relevant information received from other sources.
 - e. Function as Coast Guard liaison to DoD public affairs offices and workgroups with regard to the Coast Guard AVIP.

2. Commandant (CG-0921). Commandant (CG-0921) will coordinate response to congressional queries, as appropriate.
3. Commandant (CG-1121) 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 MLC(k)s for distribution to the appropriate audiences.
 - c. Refer media queries from outside the Coast Guard to Commandant (CG-0922).
 - d. Refer congressional queries and briefings to Commandant (CG-0921).
 - e. Make available, through the Coast Guard AVIP website and the MLC(k)s, briefings and other educational materials targeted to commanding officers, other senior leaders, medical officers and other Health Services personnel.
4. MLC(k). MLC(k) will post AVIP information for clinics/sickbays on their web pages on CG Central. CG Central>Organizational Information>MLC Unit>Health and Safety>KOM.
5. Health Services Personnel will.
 - a. Be familiar with the contents of the medical officers briefing, senior leaders briefing and other material available at www.anthrax.mil/AVIP2007.
 - b. Find answers to all medical questions asked about the anthrax medical threat, vaccine and Coast Guard AVIP. If necessary, contact Commandant (CG-1121), MLC(k) and Coast Guard Clinic personnel responsible for overseeing the Coast Guard 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 Coast Guard AVIP.
 - b. Be available to answer questions from HS personnel administering program at sites remote from Coast Guard clinics.
 - c. Become familiar with relevant aspects of the AVIP and the anthrax vaccine. They must read and be familiar with the information from the anthrax vaccine product insert and be familiar with the medical officer's briefing. Medical personnel, as subject matter experts, will assist commanders with required unit briefings whenever possible.
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 at www.anthrax.mil/AVIP2007.

- c. Ensure that personnel receiving the vaccine are afforded the opportunity to review the Anthrax Trifold Brochure at www.anthrax.mil/AVIP2007.
 - d. Ensure that personnel receiving the vaccination are given the opportunity to ask questions about the vaccine and its administration.
8. Additional Guidance. 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/AVIP2007.

SUBJECT: Treatment of Reserve Component (RC) Members at Military Medical Treatment Facilities (MTF) for Health Care Related to an Immunization. On July 20, 1999, the Assistant Secretary of Defense (Health Affairs) issued guidance to the Service Secretaries that emphasizes the responsibility of MTF commanders to ensure that they provide care for RC members who seek care for a vaccination-related health problem. This care includes medical evaluation and treatment, as appropriate.

It is the responsibility of unit commanders to ensure their members are immunized and ready for deployment. It is also necessary for the unit commander to advise their reservists, both those who are assigned permanently and those assigned temporarily, that they may seek medical care if they have an adverse reaction to any immunization. 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.

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

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

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

