



COMDTINST M6230.3C  
22 AUG 2014

COMMANDANT INSTRUCTION M6230.3C

Subj: COAST GUARD ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)

Ref: (a) Immunizations and Chemoprophylaxis, COMDTINST M6230.4 (series)  
(b) Coast Guard Medical Manual, COMDTINST M6000.1 (series)

1. **PURPOSE.** This Manual establishes policy, assigns responsibilities, and provides guidelines regarding the 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.** All Coast Guard unit commanders, commanding officers, officers-in-charge, deputy/assistant commandants, and chiefs of Headquarters staff elements shall comply with the provisions of this Manual. Internet release is authorized.
3. **DIRECTIVES AFFECTED.** Coast Guard Anthrax Vaccine Immunization Program (AVIP) Manual, COMDTINST M6230.3B, is cancelled.
4. **DISCLAIMER.** This guidance is not a substitute for applicable legal requirements, nor is it itself a rule. It is intended to provide operational guidance for Coast Guard personnel and is not intended to nor does it impose legally-binding requirements on any party outside of the Coast Guard.
5. **MAJOR CHANGES.** This Manual clarifies and revises which personnel are mandated to receive the anthrax vaccine and the new dosing route and schedule.
6. **IMPACT ASSESSMENT.** Commandant (CG-11) provides oversight for the AVIP. Commandant (CG-13) will address policy issues within the Reserve component. Commandant (CG-0922) will coordinate public affairs issues. Commandant (CG-0921) will coordinate congressional queries and briefings.

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NON-STANDARD DISTRIBUTION:

7. ENVIRONMENTAL ASPECT AND IMPACT CONSIDERATIONS.

- a. The development of this Manual and the general policies contained within it have been thoroughly reviewed by the originating office in conjunction with the Office of Environmental Management, and are categorically excluded (CE) under current USCG CE #33 from further environmental analysis, in accordance with Section 2.B.2. and Figure 2-1 of the National Environmental Policy Act Implementing Procedures and Policy for Considering Environmental Impacts, COMDTINST M16475.1 (series). Because this Manual contains guidance on, and provisions for, compliance with applicable environmental mandates, Coast Guard categorical exclusion #33 is appropriate.
- b. This directive will not have any of the following: significant cumulative impacts on the human environment; substantial controversy or substantial change to existing environmental conditions; or inconsistencies with any Federal, State, or local laws or administrative determinations relating to the environment. All future specific actions resulting from the general policies in this Manual must be individually evaluated for compliance with the National Environmental Policy Act (NEPA), Department of Homeland Security (DHS) and Coast Guard NEPA policy, and compliance with all other environmental guidance provided within it for compliance with all applicable environmental laws prior to promulgating any directive. All applicable environmental considerations are addressed appropriately in this Manual.

8. DISTRIBUTION. No paper distribution will be made of this Manual. An electronic version will be located on the following Commandant (CG-612) web sites. Internet: <http://www.uscg.mil/directives/>, Intranet: <http://cgweb.comdt.uscg.mil/CGDirectives/Welcome.htm>, and CGPortal: <https://cgportal2.uscg.mil/library/directives/SitePages/Home.aspx>.

9. RECORDS MANAGEMENT CONSIDERATIONS. This Manual has been evaluated for potential records management impacts. The development of this Manual has been thoroughly reviewed during the directives clearance process, and it has been determined there are records scheduling requirements, in accordance with Federal Records Act, 44 U.S.C. 3101 et seq., National Archives and Records Administration (NARA) requirements, and the Information and Life Cycle Management Manual, COMDTINST M5212.12 (series). This policy does not have any significant or substantial change to existing records management requirements.

10. FORMS / REPORTS. The forms referenced in this Manual are available in USCG Electronic Forms on the Standard Workstation or on the Internet: <http://www.uscg.mil/forms/>; CG Portal: <https://cgportal2.uscg.mil/library/directives/SitePages/Home.aspx>; and Intranet: <http://cgweb.comdt.uscg.mil/CGForms>. Forms related to the AVIP and the Anthrax Trifold Information Brochure can be found on the MILVAX website <http://www.vaccines.mil/Anthrax>. Clinics and sickbays 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.

11. REQUEST FOR CHANGES. Units and individuals may recommend changes by writing via the chain of command to: Commandant (CG-1121); U.S. Coast Guard; STOP 7907; 2703 MARTIN L. KING JR. AVE SE; WASHINGTON, DC 20593-7907.

Maura K. Dollymore /s/  
Rear Admiral, U.S. Coast Guard  
Director of Health, Safety and Work-Life

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## CHAPTER 1. ANTHRAX VACCINATION IMMUNIZATION PROGRAM (AVIP)

- A. PURPOSE. To establish policy, assign responsibilities, and prescribe procedures for the vaccination of Coast Guard active duty, reserves, assigned Public Health Service (PHS) personnel and mission-essential Coast Guard civilians (government service and contractors) against the biological warfare threat of anthrax.
- B. OVERVIEW.
1. Department of Defense (DoD) Immunization Program for Biological Warfare. The Department of Defense Immunization Program for Biological Warfare Defense, 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. Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD). Unlike vaccines used for preventive medicine, vaccines used specifically for biological defense are controlled by the JPEO-CBD. JPEO-CBD's Chemical Biological Medical Systems (CBMS) and Joint Vaccine Acquisition Program (JVAP) procure and maintain adequate stockpiles of anthrax vaccine to vaccinate and protect required DoD and Coast Guard personnel from potential exposure to anthrax. DoD and Coast Guard's anthrax vaccine requirement is being met through an Interagency Agreement with the Department of Health and Human Services (DHHS), under which the DoD and Coast Guard draw upon supplies held within the Strategic National Stockpile (SNS).
  3. Anthrax Vaccine. The anthrax vaccine, Biothrax™ or Anthrax Vaccine Adsorbed (AVA) is licensed and approved by the Food and Drug Administration (FDA). Biothrax™ is indicated for active immunization for the prevention of disease caused by *Bacillus anthracis*, in persons 18 to 65 years of age at high risk for exposure. Anthrax vaccination will be given as a series of five 0.5-ml intramuscular doses at 0, 4 weeks, 6 months, 12 months, and 18 months, with boosters given annually to maintain immunity. Chapter 2 of this Manual details vaccine dosing and medical considerations pertaining to anthrax vaccination.
- C. POLICY.
1. Mandatory Vaccination.
    - a. The AVIP is a mandatory program for the following Coast Guard personnel (unless medically or administratively exempted):
      - (1) Deployable Specialized Forces and any personnel deploying to combatant commands requiring anthrax vaccination for entry.
      - (2) Coast Guard personnel serving or assigned in the U.S. Central Command (USCENTCOM) area of responsibility (AOR) for 15 or more consecutive days.
      - (3) Other Coast Guard personnel designated by Commandant (CG-11) 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 five-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 para (3) above). Once these personnel are no longer in designated higher threat areas or assigned to applicable units, they should be offered and are 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 United States Coast Guard Regulations 1992, 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.
  - (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.

## 2. Voluntary Vaccination.

- a. The following individuals are eligible for voluntary vaccinations based on current location or status:
  - (2) 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.
  - (3) Adult family members, 18-65 years of age, accompanying military and civilian personnel for 15 or more consecutive days to USCENTCOM AOR or Korea.
  - (4) 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.
  - (5) 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.
- a. 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 and sickbays that have been authorized by Commandant (CG-112) to administer the anthrax vaccine.
4. Supplies. United States Army Medical Material Agency (USAMMA) will coordinate with the JPEO-CBD to ensure adequacy of vaccine supplies and the distribution to Coast Guard clinics. Commandant (CG-112) will provide total Coast Guard vaccine requirements to USAMMA. Chapter 4 provides detailed logistics information.
5. Distribution. USAMMA will coordinate the distribution of the vaccine to the supporting medical supply activities for all Services. Commandant (CG-112) will serve as Coast Guard liaison with USAMMA. Units will furnish vaccine

requirements to the supporting clinic. Clinics will order from USAMMA through the Health, Safety and Work-Life Service Center (HSWL SC) via Commandant (CG-112) (see Chapter 4).

6. Record keeping. Health record keeping (including reporting certain adverse reactions) will be maintained to document immunizations in accordance with Chapter 3 of this Manual.

D. RESPONSIBILITIES.

1. Commandant (CG-112).
  - a. Develop and disseminate medical education, information, policy, and doctrine to the field as required in accordance with the Coast Guard AVIP.
  - b. Maintain the Interagency Support Agreement between the Coast Guard and JPEO-CBMS/JVAP for the Coast Guard AVIP.
  - c. Provide funding for the AVIP.
  - d. Function as liaison between HSWL SC and USAMMA to procure vaccine supplies for the Coast Guard.
  - e. Provide approval for anthrax vaccine orders from HSWL SC.
  - f. Provide timely notification to the field regarding any changes to designated units or individual mobilizations to high threat areas. This notification will be classified.
2. Health, Safety and Work-Life Service Center.
  - a. Coordinate with USAMMA through Commandant (CG-112) and other appropriate vendors to ensure sufficient vaccines and ancillary supplies are available to units conducting immunizations in accordance with Chapters 2 and 3 of this Manual.
  - b. Oversee logistics for the Coast Guard AVIP in accordance with Chapter 4 of this Manual.
  - c. Ensure executive summaries (EXSUM) for vaccine destruction are routed to USAMMA through Commandant (CG-112).
3. Unit Commanding Officers.
  - a. Ensure their personnel meet the standards of this Manual.
  - b. Determine anthrax vaccine needs on a monthly basis, at least 30 days in advance, and coordinate with the cognizant medical clinic or sickbay to ensure that personnel are to be immunized on schedule (Chapters 3 and 4).
  - c. Ensure all required personnel are available for anthrax vaccination in accordance with this Manual.
  - d. Ensure all assigned personnel reported as overdue for vaccination via Coast Guard Business Intelligence (CGBI) System receive or have received the

anthrax vaccination. If there is an ongoing issue regarding non-compliance, the command should discuss with the cognizant clinic or sickbay.

4. Coast Guard clinics and sickbays. Coast Guard clinics and sickbays that have been authorized by Commandant (CG-112) to administer the anthrax vaccine shall:
  - a. Have full responsibility for implementing the AVIP.
  - b. Complete a registry agreement with USAMMA in order to participate in the AVIP to order and administer anthrax vaccine. The registration form is available at <http://www.usamma.army.mil/registration.cfm>.
  - c. Provide vaccination for Coast Guard personnel at Coast Guard clinics and sickbays and ensure data entry is completed. Clinics and sickbays should use the designated electronic immunization tracking system (ITS) (e.g., Medical Readiness Reporting System (MRRS)) for tracking purposes.
  - d. Provide the anthrax vaccination to personnel from other services who are enrolled in the DoD AVIP in accordance with the Office of the Assistant Secretary of Defense, Health Affairs (OASD(HA)) guidance.
  - e. Ensure personnel receiving the anthrax vaccine have been educated about the AVIP. Prior to administering the anthrax vaccine, ensure that personnel are provided the Anthrax Trifold Brochure and the Vaccine Information Sheet (VIS) Biothrax™ (these can be downloaded from the following web site - <http://www.vaccines.mil/Anthrax>). The brochure and VIS provide specific information regarding the vaccine, its safety, benefits, and the need for adherence to the immunization schedule.
5. Privileged Coast Guard Healthcare Providers.
  - a. Must provide counseling (one on one or in a group setting) to personnel prior to receiving the anthrax vaccination.
  - b. Must complete the MILVAX AVIP training prior to supervising or administering anthrax vaccine.
  - c. Must grant medical exemptions per Chapter 2 of this Manual. Only physicians can evaluate patients for religious exemptions - see reference (a). Record all exemptions in the appropriate ITS and in the health record on the Medical Record - Chronological Record of Medical Care, SF-600.
6. Anthrax Vaccinators. Only appropriately trained and qualified medical personnel will administer the anthrax vaccine. Anthrax vaccinators are required to complete the DoD Anthrax Vaccination Training. The approved course is sponsored by MILVAX. A certificate of completion will be available for download after the completion of the training. All completed certificates must be sent to Commandant (CG-1122) for tracking purposes. The training is located at <http://www.vaccines.mil/Training>. The training is required only once.

7. Coast Guard personnel.
  - a. Read and take all steps necessary to understand the Trifold brochure, “What You Need to Know about Anthrax Vaccine”.
  - b. Read the anthrax VIS.
  - c. Report to appropriate Coast Guard clinic, sickbay, DoD Medical Treatment Facilities (MTF), or other designated facility for the anthrax vaccination and follow up vaccinations.
  - d. Report adverse reactions to the appropriate Coast Guard clinic, sickbay or MTF.

## CHAPTER 2. MEDICAL CONSIDERATION AND GUIDANCE

A. VACCINE CHARACTERISTICS.

1. Licensing. Anthrax Vaccine Adsorbed is manufactured by the Emergent Biosolutions. It is licensed by the FDA 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 strain 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.

B. INDICATIONS 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*.

C. DOSAGE AND ADMINISTRATION.

1. Dosage. Anthrax vaccine is supplied in 5-ml multi-dose vials containing ten 0.5-ml doses each.
2. Vaccination Schedule.
  - a. Primary immunization consists of five intramuscular 0.5-ml injections. The first dose is given on Day zero (D). Subsequent doses are given on D+28 Days, D+6 Months, D+12 Months, and D+18 Months.
  - b. 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.
  - c. Annual 0.5-ml booster vaccinations are given on every anniversary of the last dose of the primary series.
  - d. All personnel assigned to higher threat areas are to receive their first two shots prior to deployment, if possible. The series will continue in theater.

3. Administrative Issues.

- a. An individual's availability and adherence to the immunization schedule shall be a matter of command attention and discipline.
- b. 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 two doses prior to deployment.
- c. 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.
- d. The national standard of practice for all immunizations, including the anthrax vaccine, shall be adhered to when immunizing personnel. This includes medical screening prior to immunization. Screening shall be conducted by healthcare personnel for medical conditions which immunization deferral or further medical evaluation before immunization is indicated.
- e. 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-112) approved Anthrax VIS, on the vaccine's safety and benefits and on the need for adherence to the immunization schedule.
- f. At the time of immunization, personnel are to be provided documentation that identifies date and location of immunization, location of the nearest DoD MTFs (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.
- g. As with most other immunizations, aviation personnel are grounded for 12 hours after receiving the anthrax vaccine and may return to flight automatically if not experiencing any side effects. Otherwise, Flight Surgeon evaluation is required for return to flight status.

ADVERSE REACTIONS. Health care providers may use information from the clinical guidelines for adverse events after vaccination found on <http://www.vaccines.mil/Anthrax>. The most common (>10%) local (injection-site) adverse reactions observed in clinical studies were tenderness, pain, erythema, edema, and arm motion limitation. The most common ( $\geq 5\%$ ) systemic adverse reactions were muscle aches, fatigue, and headache.

D. CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS.

1. Hypersensitivity Reactions. Acute allergic reactions, including anaphylaxis, have occurred with Biothrax™. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

2. Latex Sensitivity. The stopper of the vial contains dry natural rubber and may cause allergic reactions to patients with a possible history of latex sensitivity.
3. Pregnancy. BioThrax can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus. All cases of pregnant women being inadvertently vaccinated will be referred to the Biothrax Vaccine in Pregnancy Registry at the Naval Health Research Center (NHRC) San Diego, CA – Email: [NHRC-BirthRegistry@med.navy.mil](mailto:NHRC-BirthRegistry@med.navy.mil), Phone: 1-619-553-9255.
4. History of Anthrax Disease. History of anthrax disease may increase the potential for severe local adverse reactions.
5. Altered Immunocompetence. If BioThrax is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be diminished.
6. 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>). 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.

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## CHAPTER 3. MEDICAL REPORTING

- A. PURPOSE. The purpose is to ensure the success of the AVIP by tracking Coast Guard personnel immunized with anthrax vaccine. An automated ITS is mandated by 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). To comport with OASD (HA) requirements, Coast Guard will contract or maintain an ITS (prescribed by Commandant (CG-11)). All Coast Guard medical facilities/personnel providing immunization services are required to be familiar with the current ITS.
1. DoD members. DoD members may receive initial or subsequent doses of anthrax vaccine from a Coast Guard clinic/sickbay. For these non-Coast Guard service members, an entry will be made in the appropriate ITS. The ITS will transmit the immunization data to DEERS. An entry will also be made on a Medical Record - Chronological Record of Medical Care, SF-600 overprint for entry into the DoD service member's health record. The member must notify his or her medical readiness POC (e.g. corpsman) to ensure the immunization data in DEERS is uploaded into their service specific ITS.
  2. Coast Guard members at a DoD MTF. The vaccination data for Coast Guard personnel vaccinated at DoD MTFs will be entered into local service component ITS which will download to DEERS.
- C. REPORTING REQUIREMENTS.
1. Health record. Documentation of all anthrax vaccinations must be made in the Adult Preventive and Chronic Care Flow Sheet, DD Form 2766 (MRRS version is acceptable). Document counseling and vaccination in the appropriate electronic health record.
  2. Exemptions. Exemptions (exceptions), both medical and administrative, will be recorded in the ITS. The proper codes to use may be found in Enclosure (1). Several exemptions are considered indefinite and no end date is entered in the ITS. Any exemption that is not indefinite (e.g. Med, Temp) must have an exemption end date recorded in the ITS.
- D. ADVERSE EVENTS REPORTING
1. Where to enter data. Adverse events or reactions to immunizations must be entered into MRRS under comments section, as well as in the medical record.
  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.
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. To provide the logistics concept of operations for the 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 doses 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.amedd.army.mil/avip\\_index.cfm](http://www.usamma.amedd.army.mil/avip_index.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. Cost. The anthrax vaccine will be provided through USAMMA at no cost to units. Ancillary supplies are the responsibility of the receiving activity. The current contract includes manufacturer distribution to first destination. Transportation will be conducted by a commercial freight forwarder for all destinations.
- C. LOGISTICS OVERVIEW
1. Allocation and distribution. USAMMA will coordinate the allocation and distribution of the anthrax vaccine with Commandant (CG-112).
  2. Ordering. USAMMA has web-based ordering capability located at [http://www.usamma.amedd.army.mil/avip\\_index.cfm](http://www.usamma.amedd.army.mil/avip_index.cfm).
  3. Requisition. When a requisition for the vaccine has been validated and approved by Commandant (CG-112), USAMMA will forward the requisition to the National Pharmaceutical Stockpile. Vaccine will then be distributed to the requesting activity.
- D. RESPONSIBILITIES
1. Commandant (CG-112). Functions as liaison between the Coast Guard and USAMMA to provide approval for orders from HSWL SC.
  2. HSWL SC.
    - a. Submits to USAMMA, through Commandant (CG-112), 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.
  - b. Emails requisitions to Commandant (CG-112) for approval and forwarding to USAMMA.
  - c. Notifies USAMMA (copy to: Commandant (CG-112) 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. 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. 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.amedd.army.mil/doc.cfm>. (See Cold Chain Management Process & Procedures/Packing Protocols).
  - b. 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 HSWL SC as to the location of DoD vaccination points that may be located near remote Coast Guard units.
  - c. Report lot number, expiration date, and quantity of any unopened vials of anthrax vaccine to HSWL SC upon receiving monthly data call e-mail. Replies are also required for those locations with no unopened vials in stock. HSWL SC will, in turn, forward data to USAMMA.

## Exemptions (exception) codes for Immunizations for use in MRRS

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

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