COMMANDANT INSTRUCTION 6230.3D

Subj: COAST GUARD ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)

(b) Information and Life Cycle Management Manual, COMDTINST M5212.1 (series)
(c) Department of Defense (DOD) Immunization Program for Biological Warfare Defense, DOD Directive 6205.3
(d) United States Coast Guard Countering Weapons of Mass Destruction Capabilities Manual (CWMD Manual), COMDTINST M3400.51 (series)
(e) Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases Manual, COMDTINST M6230.4 (series)

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

2. ACTION. All CG Commanders, Commanding Officers, Officers-In-Charge, Deputy/Assistant Commandants, and Chiefs of Headquarters staff elements must comply with the provisions of this Instruction. Internet release is authorized.

3. DIRECTIVES AFFECTED. Coast Guard Anthrax Vaccine Immunization Program (AVIP) Manual, COMDTINST M6230.3C, is hereby 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 CG personnel and is not intended to nor does it impose legally-binding requirements on any party outside the CG.

5. MAJOR CHANGES. This Instruction clarifies and revises which personnel are mandated to receive the anthrax vaccine. It also no longer contains technical guidance more appropriate for a depot-level publication in accordance with the Mission Support Business Model.
6. **ENVIRONMENTAL ASPECTS AND IMPACT CONSIDERATIONS.**

   a. The development of this Instruction and the general policies contained within it have been thoroughly reviewed by the originating office in conjunction with the Office of Environmental Management, Commandant (CG-47). This Instruction is categorically excluded under current Department of Homeland Security (DHS) categorical exclusion (CATEX) A3 from further environmental analysis in accordance with "Implementation of the National Environmental Policy Act (NEPA), DHS Instruction Manual 023-01-001-01 (series).

   b. This Instruction 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 policy in this Instruction 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 applicable environmental mandates.


8. **RECORDS MANAGEMENT CONSIDERATIONS.** This Instruction has been thoroughly reviewed during the directives clearance process, and it has been determined there are further records scheduling requirements, in accordance with Federal Records Act, 44 U.S.C. 3101 et seq., National Archives and Records Administration (NARA) requirements, and Reference (a). This Instruction does not have any significant or substantial change to existing records management requirements. See Reference (b) for specific records management and privacy requirements in regards to storage of medical records.

9. **OVERVIEW.**

    a. Department of Defense (DOD) Immunization Program for Biological Warfare. Reference (c) 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.

    b. 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. Under JPEO-CBD, the Joint Project Manager Medical Countermeasure Systems (JPM MCS) administers the
Joint Vaccine Acquisition Program (JVAP), which procures and maintains adequate stockpiles of anthrax vaccine to vaccinate and protect required DOD and CG personnel in the event of exposure (possible or definite) to anthrax. DOD and CG’s anthrax vaccine requirement is being met through an Interagency Agreement with the Department of Health and Human Services (HHS), under which the DOD and CG draw upon supplies held within the Strategic National Stockpile (SNS).

c. **CG Countering Weapons of Mass Destruction (CWMD) Program.** The CG CWMD Program is managed by Commandant (CG-721). Reference (d) describes the capabilities provided to enhance the Coast Guard’s ability to provide force protection in support of response operations in or near a Chemical, Biological, Radiological, and Nuclear (CBRN) contaminated environment. The AVIP, along with other medical pre-treatment and medical countermeasure programs, is a subset of the overall force protection capabilities provided to CG forces in support of CBRN response operations. For CG forces without active immunization from the anthrax vaccine, antibiotics (e.g., doxycycline and/or ciprofloxacin) may be effective treatment for personnel exposed during and after an anthrax incident.

d. **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. Pre-exposure anthrax vaccination will be given as recommended by the FDA approved administration cycle. The link to the FDA is: [https://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/UCM074923.pdf](https://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/UCM074923.pdf)

10. **POLICY.**

a. **Mandatory Vaccination with Anthrax Vaccine.**

   (1) The CG AVIP applies to CG military personnel. CG dependents who require anthrax vaccination by virtue of accompanying a CG service member on a remote assignment will be handled by a CG clinic or DOD MTF on a case-by-case basis.

   (2) The AVIP is a mandatory program for the following CG personnel (unless medically or administratively exempted): Deployable specialized forces (DSF) personnel (e.g., Maritime Security Response Team (MSRT), Maritime Safety and Security Team (MSST), Tactical Law Enforcement Team (TACLET), Port Security Unit (PSU), and National Strike Force (NSF)), International Port Security personnel, and any personnel deploying to DOD Geographic Combatant Commands (COCOM) requiring anthrax vaccination for theater entry.

   (3) When indicated, this vaccine is a required immunization unless medically
exempted (e.g., for pregnancy) by competent medical authority or administratively exempted by command authority. The Clinical Consultation Services (CCS) section of the Immunization Healthcare Branch, Defense Health Agency (DHA-IHB) (https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Clinical-Consultation-Services) is available to assist healthcare personnel with medical consultation when members refuse or have serious concerns about vaccination.

(4) Members refusing vaccination will show as Partially Medically Ready from an Individual Medical Readiness standpoint, but can still be ordered to deploy on the order of their commanding officer.

(5) Absent an exemption, military personnel who refuse to be vaccinated may be in violation of Article 92 of the Uniform Code of Military Justice (UCMJ) for failure to obey a lawful order or for being derelict in the performance of their duties. United States Coast Guard Regulations 1992, COMDTINST M5000.3 (series), Chapter 8, section 8-2-1 (21) requires persons in the Coast Guard to permit action to be taken to immunize them against disease, as prescribed by competent authority. Any military service member who refuses to be vaccinated or fails to comply with a lawful order to be vaccinated may be subject to disciplinary proceedings under the UCMJ or other appropriate administrative proceedings.

(6) Voluntary vaccination is authorized for members of the Uniformed Services on active duty or in the Selected Reserves (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. In this case, SELRES members receive the vaccination through the Reserve Health Readiness Program unless called to active duty for more than 30 days.

b. **Availability.** Vaccines will only be available at clinics and sickbays that have been authorized by Commandant (CG-112) to administer the anthrax vaccine.

c. **Supplies.** United States Army Medical Material Agency (USAMMA) will coordinate with the JPEO-CBD to ensure adequacy of vaccine supplies and the distribution to CG clinics. Commandant (CG-112) will provide total CG vaccine requirements to USAMMA upon request.

d. **Distribution.** USAMMA will coordinate the distribution of the vaccine to the supporting medical supply activities for all services. Commandant (CG-112) will serve as the CG liaison with USAMMA. Units will furnish vaccine requirements to the supporting clinic. Clinics will order through the Health, Safety and Work-Life Service Center (HSWL SC) via Commandant (CG-112) to USAMMA.

e. **Record keeping.** Service Treatment Record (STR) keeping (including reporting
adverse reactions) will be maintained to document immunizations IAW Paragraph 13.b of this Instruction.

11. **ADMINISTRATIVE EXEMPTIONS.** Administrative exemptions from anthrax vaccination are authorized for personnel by the individual’s Commanding Officer or Officer-In-Charge for the reasons found in Reference (e). Although religions exemptions are considered a type of administrative exemption, they must be coded as “Medically Declined” (MD) in the Medical Readiness Reporting System (MRRS).

12. **MEDICAL EXEMPTIONS.**

   a. **General Information.** Some individuals will have either acute or chronic pre-existing conditions that may warrant medical exemption from anthrax vaccination. Furthermore, a small proportion of individuals will develop a more serious reaction after vaccination that may warrant medical exemptions, temporary or permanent, from further anthrax vaccination.

   (1) In an anthrax emergency, there are no absolute contraindications to vaccinating people with a high-risk exposure to anthrax spores. Prior contraindications to vaccination could be overshadowed by personal risk of anthrax disease. Anthrax vaccine would be made available for people exempted during pre-outbreak vaccination programs or even in a post-exposure setting (as an off-label use). If a relative contraindication to vaccination exists, the risk for experiencing serious vaccination complications must be weighed against the risks for experiencing a potentially fatal anthrax infection.

   (2) Granting medical exemptions is a medical function performed by a privileged healthcare provider. The provider will grant individual exemptions when medically warranted, with the overall health and welfare of the patient clearly in mind, balancing potential benefits with the risks while taking into consideration the threat situation. Medical exemptions are not based on preferences of the patient.

b. **Temporary and Permanent Medical Exemptions.** A list of types of medical exemptions can be found in Reference (e). The two most common annotated medical exemption categories are “Medical Temporary” (MT) and “Medical Permanent” (MP). Annotate the patient’s STR and the Immunization Tracking System (ITS) with these codes, and update them as appropriate. In the event of a confirmed anthrax exposure, permanent exemptions could be rescinded, based on individual risk. Note that personnel who have a past medical history constitute a special situation; see paragraph 12.b(2)(ii) below.

   (1) Temporary.

      (a) Temporary medical exemptions are warranted when a provider has a concern about the safety of immunizations in people with certain clinical
conditions. The vaccine’s package insert contains examples of situations that warrant a temporary medical exemption (e.g., temporarily immune-suppressed people and pregnant women). The Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) notes that people with latex hypersensitivity should be vaccinated with caution.

(b) In situations where a medical condition is being evaluated or treated, a temporary deferral of anthrax vaccination may be warranted, up to a maximum of 12 months. This would include significant vaccine-associated adverse events that are being evaluated or while awaiting specialist consultation. The attending provider will determine the deferral interval, based on individual clinical circumstances.

(2) Permanent.

(a) Medical Permanent exemptions are generally warranted if the medical condition or adverse reaction is so severe or unremitting that the risk of subsequent immunization is not justified. In the case of anthrax vaccine, these permanent exemptions could be lifted if the individual had an exposure to anthrax spores. Examples of situations warranting a permanent medical exemption will appear in the vaccine’s package insert (e.g., life-threatening allergy to vaccine component, immune-suppressed people).

(b) People who have actually had anthrax disease in the past are a special case. Decisions about vaccinating such people should be made by a specialist in Allergy/Immunology Medicine. Contact the CCS section of the DHA-IHB (https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Clinical-Consultation-Services) for assistance.

(c) If a permanent medical exemption is indicated, follow Reference (e) for granting such exemptions. If the situation changes, an appropriate medical specialist can remove a medical exemption.

(d) A permanent medical exemption renders a CG service member ineligible for assignment to DSF units.

(e) A permanent medical exemption may prevent a CG service member from deploying under the Operational Control of a DOD COCOM. The gaining COCOM Command Surgeon will determine if such a CG service member meets theater entry requirements.

(3) Immune. Use this code to indicate that a patient has either had anthrax disease (but only on the advice of an Allergist/Immunologist) or has been successfully
immunized. Do not set an end date greater than one year from the date of the last vaccination.

(4) If an individual's clinical case is complex or not readily definable, health care providers should consult an appropriate medical specialist with vaccine safety-assessment expertise before granting a permanent medical exemption. In addition, providers may consult with Allergy/Immunology specialists at the CCS, DHA-IHB, at [https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Clinical-Consultation-Services](https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Clinical-Consultation-Services) or by calling 877-438-8222. In such cases, providers will document specialty consultation in the individual's STR, including the considerations and reasons why a temporary or permanent medical exemption is or is not granted.

(a) **Exemption Referral.** An individual who disagrees with a provider's recommendation regarding an exemption may request a referral for a second opinion. In such cases, the individual will be referred to a provider experienced in vaccine adverse event management who has not been involved in the decision-making to this point. This provider may be at the same facility or, when applicable, at a referral facility. If the patient disagrees with the second opinion, he or she may be referred directly to the CCS. Commandant (CG-112) retains the authority to review all appealed exemption determinations and may delegate this authority to individuals with appropriate expertise within their organization.

(b) **Specialty Consultation.** Each clinic administrator will assist patients in obtaining appropriate specialty consultations expeditiously and in resolving patient difficulties. Specialists may grant permanent medical exemptions. Return of a patient to his or her primary care provider is not required if the referring specialist deems a permanent medical exemption is warranted. A Vaccine Adverse Event Reporting System (VAERS) report must be completed for any permanent medical exemption granted due to a vaccine related adverse event. If providers have questions about contraindications, the need for an exemption, adverse events after vaccination or possible contact transfer, they can contact the CCS.

13. **MEDICAL REPORTING.**

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

b. **IMMUNIZATION TRACKING SYSTEM (ITS).** Currently, MRRS is mandated as
the ITS for anthrax vaccination for CG personnel receiving immunizations within the CG system. All CG medical facilities/personnel providing immunization services are required to be familiar with MRRS and its use.

(1) **Coast Guard members.** CG units having members requiring initial or subsequent doses (e.g., annual boosters) of anthrax vaccine will ensure those members receive their vaccination from CG clinics/sickbays or DOD Military Treatment Facilities (MTFs). Medical unit personnel will ensure the immunization data is entered into the appropriate ITS.

(2) **DOD members.** DOD members may receive initial or subsequent doses of anthrax vaccine from a CG clinic/sickbay. For these non-CG service members, an entry will be made in the appropriate ITS. The ITS will transmit the immunization data to DEERS. The member must notify his or her medical readiness point of contact to ensure the immunization data in DEERS is uploaded into their service specific ITS.

(3) **Coast Guard members at DOD MTFs.** The servicing CG clinic or assigned IDHS will enter the vaccine data for CG personnel vaccinated at DOD MTFs into local service component ITS. This data will automatically download to DEERS.

c. **REPORTING REQUIREMENTS.**

(1) **Service Treatment Record.** Documentation of all anthrax vaccinations must be made in the STR on DD Form 2766 (MRRS version is acceptable). Document counseling and vaccination in the appropriate electronic health record (if available).

(2) **Exemptions.** The servicing CG clinic or assigned IDHS will record all exemptions (exceptions), both medical and administrative, in the ITS. The proper codes to use may be found in Reference (e). Several exemptions are considered indefinite and no end date is entered in the ITS. Any exemption that is not indefinite (e.g., MT) must have an exemption end date recorded in the ITS.

d. **ADVERSE EVENTS REPORTING.**

(1) **Where to enter data.** The servicing CG clinic or assigned IDHS will enter all adverse events or reactions to immunizations into MRRS under comments section, as well as in the STR.

(2) **When to report a problem.** The servicing CG clinic or assigned IDHS must report all adverse vaccine reactions resulting in hospitalization or duty time lost (in excess of 24 hours), as well as due to suspected lot contamination, in the Vaccine Adverse Event Report System (VAERS). VAERS forms and information can be obtained by calling 1-800-822-7967 or from the Web at
https://vaers.hhs.gov/reportevent.html; reports can filed online. Additionally, the servicing CG clinic or assigned IDHS should file a VAERS report for any permanent medical exemption due to a vaccine related adverse event. Other reactions may be reported to VAERS, either by a healthcare provider or the vaccinated individual.

3) **Distribution of forms.** If a paper or Portable Document Format (PDF) VAERS form is completed at a CG unit/facility, 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. If a report is completed online, document that the report was made in the patient’s STR.

4) **Report originators.** Anyone may report a vaccine-associated event through VAERS to the FDA. Healthcare providers should assist in the completion and forwarding of a VAERS report for any vaccine recipient desiring to complete one. Healthcare 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.

14. **RESPONSIBILITIES.**

a. **Commandant (CG-11).** Provides technical expertise to the Commandant for the prevention of the anthrax disease threat.

b. **Commandant (CG-112).**

   1) Develops and disseminates medical education, information, policy, and doctrine to the field as required in accordance with the CG AVIP.

   2) Functions as liaison between HSWL SC and USAMMA to order vaccine supplies for the CG.

   3) Provides approval for anthrax vaccine orders from HSWL SC.

   4) Provides timely notification to the field regarding any changes to designated units or individual mobilizations to high threat areas. Such notifications may be classified.

   5) Maintains a liaison with AVIP program managers in other services, keeping current with the latest educational and communications information available.

   6) Forwards new information/briefings to HSWL SC for distribution to the appropriate audiences.

   7) Refers media queries from outside the CG to Commandant (CG-0922).
(8) Refers congressional queries and briefings to Commandant (CG-0921).

c. Commandant (CG-0922)

(1) Responds to media inquiries and assist CG District Public Affairs Officers in responding to media queries.

(2) Provides Commandant (CG-112) any relevant information received from other sources.

(3) Functions as the CG liaison to any DOD public affairs offices and workgroups with regard to the CG AVIP.

d. Commandant (CG-0921). Coordinates response to congressional queries, as appropriate.

e. Health, Safety, and Work-Life Service Center.

(1) Coordinates with USAMMA through Commandant (CG-112) to ensure sufficient vaccines and ancillary supplies are available to units.

(2) Executes logistics management for the CG AVIP.

(3) Maintains the Interagency Support Agreement between the CG and USAMMA for the CG AVIP.

(4) Executes funding for the CG AVIP.

(5) Ensures executive summaries (EXSUMs) for vaccine destruction are routed to USAMMA through Commandant (CG-112).

f. Unit Commanding Officers and Officers-In-Charge.

(1) Have the ultimate responsibility to ensure their personnel meet the standards of this Instruction.

(2) 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 immunized on schedule (e.g., annual boosters).

(3) Ensure all required personnel are available for anthrax vaccination in accordance with this Instruction.

(4) Ensure all assigned personnel reported as overdue for vaccination (as reported from the 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.

g. Coast Guard clinics and sickbays. CG clinics and sickbays that have been
authorized by Commandant (CG-112) to administer the anthrax vaccine must:

(1) Have full responsibility for implementing the AVIP.

(2) Complete a registry agreement with USAMMA in order to participate in the
AVIP to order and administer anthrax vaccine. To complete a registry
agreement, contact USAMMA’s Distribution Operations Center (DOC) at (301)
619-9539, or send an email inquiry to usarmy.detrick.medcom-
usamma.mbx.doc@mail.mil.

(3) Provide vaccination for CG personnel at CG clinics and sickbays and ensure data
entry is completed. Clinics and sickbays should use the designated electronic
ITS (e.g., MRRS) for tracking purposes.

(4) Provide the anthrax vaccination to personnel from other services who are
enrolled in the DOD AVIP in accordance with OASD (HA) guidance.

(5) 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 -
https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-
Healthcare/Vaccine-Preventable-Diseases/Anthrax/Anthrax-Resource-Center).
The brochure and VIS provide specific information regarding the vaccine, its
safety, benefits, and the need for adherence to the immunization schedule.

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

(7) Ensure that reservists, both those who are assigned permanently and those
assigned temporarily, understand they may seek CG medical care if they have
an adverse reaction to any immunization required by the CG.

h. Privileged Healthcare Providers.

(1) Must complete the DHA-IHB AVIP training (found on Joint
Knowledge Online (JKO),
49488532249&course_prefix=DHA&course_number=US080) prior to
supervising or administering anthrax vaccine. This will be verified by
the Health Services Administrator.
(2) Must provide counseling (one on one or in a group setting) to personnel receiving the anthrax vaccination.

(3) Must grant medical exemptions in accordance with Paragraph 12 of this Instruction. Only physicians can evaluate patients for religious exemptions; see Reference (e). Record all exemptions in the appropriate ITS and in the STR.

i. Health Services Technicians and Nurses who administer anthrax vaccine. Complete the DHA-IHB AVIP training (as in 14.h(1) above) prior to supervising or administering anthrax vaccine.

j. Coast Guard Personnel.

(1) Read and take all steps necessary to understand the “What You Need to Know about Anthrax Vaccine” Brochure.

(2) Read the anthrax VIS.

(3) Report to appropriate CG clinic, sickbay, DOD MTF, or other designated facility for the anthrax vaccinations and any follow up evaluation.

(4) Report adverse reactions to the appropriate CG clinic, sickbay, or DOD MTF.

15. ADDITIONAL GUIDANCE. Additional information for commanders and medical personnel. There is a significant amount of misleading and inflammatory misinformation circulating in the media and on the internet regarding the AVIP and the vaccine. Accurate information can be found on the web at https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/Anthrax/.

16. FORMS/REPORTS. Forms related to the AVIP can also be found on the following site: https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/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, DD Form 2766, is a restricted form; contact the DOD forms manager for additional forms.

17. REQUEST FOR CHANGES. Units and individuals may recommend changes via the chain of command to: hqs-dg-lst-cg-112@uscg.mil.

ERICA G. SCHWARTZ /s/
Rear Admiral, U.S. Public Health Service
Director of Health, Safety, and Work-Life