



COMDTINST M6230.10A
22 AUG 2014

COMMANDANT INSTRUCTION M6230.10A

Subj: COAST GUARD SMALLPOX VACCINE PROGRAM (SVP)

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

1. PURPOSE. This Manual establishes policy, assigns responsibilities, and provides guidelines regarding the Coast Guard Smallpox Vaccine Program (SVP), 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. Internet release is authorized.
3. DIRECTIVES AFFECTED. Coast Guard Smallpox Vaccine Program (SVP) Manual, COMDTINST M6230.10, is cancelled.
4. PROCEDURE. No paper distribution will be made of this Manual. Official distribution will be via the Coast Guard Directives System DVD. An electronic version will be located on the following Commandant (CG-612) web sites. Intranet: <http://cgweb.comdt.uscg.mil/CGDirectives/Welcome.htm>, Internet: <http://www.uscg.mil/directives/> and CGPortal: <https://cgportal.uscg.mil/delivery/Satellite/CG612>.
5. MAJOR CHANGES. This Manual clarifies and revises which personnel are mandated to receive the smallpox vaccine.
6. 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

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NON-STANDARD DISTRIBUTION:

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.

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), Council on Environmental Policy NEPA regulations at 40 CFR Parts 1500-1508, DHS and Coast Guard NEPA policy, and compliance with all other environmental mandate

8. 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://cgportal.uscg.mil/delivery/Satellite/uscg/References>; and Intranet: <http://cgweb.comdt.uscg.mil/CGForms>. Forms related to the SVP can also be found on the following site <http://www.vaccines.mil/Smallpox>. The Smallpox Trifold Information Brochure and the FDA Medication Guide can be found at the Smallpox vaccination program website <http://www.vaccines.mil/Smallpox>. Clinics and sickbays will receive a Smallpox Trifold for each dose of Smallpox 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.

Maura K. Dollymore /s/
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Director of Health, Safety and Work-Life

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Enclosures:

(1) Medical Exemption Code

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CHAPTER 1. SMALLPOX VACCINATION 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 of smallpox.

B. OVERVIEW.

1. DoD Immunization Program for Biological Warfare. The Department of Defense (DoD) Immunization Program for Biological Warfare Defense, DoD Directive 6205.3, prescribes DoD policy for the use of vaccines for biological defense. The smallpox 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 smallpox vaccine to vaccinate and protect required DoD and Coast Guard personnel from potential exposure to smallpox. DoD and Coast Guard's smallpox 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. Smallpox Vaccine. The smallpox vaccine, ACAM2000™ is licensed and approved by the Food and Drug Administration (FDA). ACAM2000™ is indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection. The smallpox vaccine is a live vaccinia virus derived from plague purification cloning from Dryvax and grown in African Green Monkey kidney (Vero) cells. The smallpox vaccine does not contain smallpox virus (variola) and cannot spread or cause smallpox. The smallpox vaccine will be administered in the standard full-strength concentration (in accordance with the original labeled reconstitution instructions), unless the Centers for Disease Control and Prevention (CDC), FDA, or other responsible health authority issues explicit instructions to the contrary. Chapter 2 of this Manual details vaccine dosing and medical considerations pertaining to smallpox vaccination. Dryvax® vaccine should no longer be used.

C. POLICY.

1. Mandatory Vaccination.

- a. The SVP is a mandatory program for the following Coast Guard 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,

healthcare personnel (e.g., Coast Guard, Public Health Service officers, health services technicians, and medical administrative personnel), and any personnel deploying to combatant commands requiring smallpox vaccination for entry.

- b. Civilians. The SVP is a mandatory program for Coast Guard civilian personnel whose duties classify them as rapid deployment in support of Coast Guard operations in higher threat areas. These civilians shall be vaccinated upon notification for deployment to a higher threat area. The effect on a civilian employee, who refuses immunization, when indicated, will be determined by the supervisor and commander in conjunction with representatives from the Civilian Personnel Office. For the purposes of the Coast Guard SVP, higher threat area does not include the potential for smallpox used in acts of terrorism against non-combatants, to include family members in higher threat areas. The Coast Guard SVP does not apply to family members.
 - c. Voluntary vaccination is not authorized.
 - d. This vaccine is a required immunization unless medically exempted (e.g., for pregnancy) by competent medical authority or administratively exempted by command authority. The DoD Vaccine Healthcare Centers Network (VHCN) (<http://www.vhcinfo.org>) is available to assist healthcare personnel with medical consultation when members refuse vaccination.
 - (1) If a member refuses vaccination, he or she remains deployable.
 - (2) Refusal to be vaccinated, or failure to comply with a lawful order to be vaccinated may be a violation of United States Coast Guard Regulations 1992, COMDTINST M5000.3 (series), Chapter 8, section 8-2-1(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. Availability. Vaccines will only be available at clinics and sickbays that have been authorized by Commandant (CG-112) to administer the smallpox vaccine.
 3. 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.
 4. 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 through the Health, Safety and Work-Life Service Center (HSWL SC) via Commandant (CG-112) to USAMMA (see Chapter 4).

5. 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-11). Provides technical expertise to the Commandant for the prevention of the smallpox disease threat.
2. Commandant (CG-112).
 - a. Develop and disseminate medical education, information, policy, and doctrine to the field as required in accordance with the Coast Guard SVP.
 - b. Maintain the Interagency Support Agreement between the Coast Guard and CBMS-JVAP for the Coast Guard SVP.
 - c. Provide funding for the SVP.
 - d. Function as liaison between HSWL SC and USAMMA to procure vaccine supplies for the Coast Guard.
 - e. Provide approval for smallpox 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.
3. 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 SVP in accordance with Chapter 4 of this Manual.
 - c. Ensure executive summaries (EXSUM) for vaccine destruction are routed to USAMMA through Commandant (CG-112).
4. Unit Commanding Officers.
 - a. Have the ultimate responsibility to ensure their personnel meet the standards of this instruction.
 - b. Determine smallpox 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 (e.g., revaccination every 10 years) (Chapters 3 and 4).
 - c. Ensure all required personnel are available for smallpox vaccination in accordance with this Manual.

- d. Ensure all assigned personnel reported as overdue for vaccination (as reported from the Coast Guard Business Intelligence (CGBI) System) receive or have received the smallpox vaccination. If there is an ongoing issue regarding non-compliance, the command should discuss with the cognizant clinic or sickbay.
5. Coast Guard clinics and sickbays. Coast Guard clinics and sickbays that have been authorized by Commandant (CG-112) to administer the smallpox vaccine shall:
 - a. Have full responsibility for implementing the SVP.
 - b. Complete a registry agreement with USAMMA in order to participate in the SVP to order and administer smallpox 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 smallpox vaccination to personnel from other services who are enrolled in the DoD SVP in accordance with the Office of the Assistant Secretary of Defense, Health Affairs (OASD(HA)) guidance.
 - e. Ensure personnel receiving the smallpox vaccine have been educated about the SVP. Prior to administering the smallpox vaccine, ensure that personnel are provided the Smallpox Trifold Brochure and the FDA Medication Guide for ACAM2000™ (these brochures can be downloaded from the following web site - <http://www.vaccines.mil/Brochures/Smallpox>). The brochure and guide provide specific information regarding the vaccine, its safety, benefits, and the need for adherence to the immunization schedule (i.e. revaccination every 10 years). The provision of this information will be documented by health services personnel on the Chronological Record of Medical Care (Smallpox Vaccination Initial Note), SF-600 SVP Overprint (block 8). This form can be accessed through the following web site - http://www.vaccines.mil/documents/1143SPX_initial_note_page_1_2.pdf. Clinics should also consider providing members with Smallpox Vaccine Household Contacts Brochure to bring home to family members. This brochure can be downloaded from the following web site - <http://www.vaccines.mil/Brochures/Smallpox>).
6. Privileged Healthcare Providers.
 - a. Must be onsite when the smallpox vaccination is given.
 - b. Must provide counseling (one on one or in a group setting) to personnel receiving the smallpox vaccination.
 - c. Must review and sign the Chronological Record of Medical Care (Smallpox Vaccination Initial Note/Routine Follow Up Note), SF-600 SVP Overprint.

- d. Must grant medical exemptions in accordance with Chapter 2 of this instruction. 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 Chronological Record of Medical Care (Smallpox Vaccination Initial Note), SF-600 SVP Overprint.
7. Coast Guard Personnel.
- a. Read and take all steps necessary to understand the Trifold brochure, “What You Need to Know about Smallpox Vaccine.”
 - b. Read the FDA-mandated Medication Guide for ACAM2000™.
 - c. Report to appropriate Coast Guard clinic, sickbay, DoD Medical Treatment Facilities (MTF), or other designated facility for the smallpox vaccination and follow up evaluation.
 - d. Report adverse reactions to the appropriate Coast Guard clinic, sickbay, or MTF.

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CHAPTER 2. MEDICAL CONSIDERATION AND GUIDANCE

A. VACCINE CHARACTERISTICS.

1. Vaccine Description. The smallpox vaccine is lyophilized powder reconstituted with packaged diluent. After reconstitution, each vial has approximately 100 doses of 0.0025 mL of live vaccinia virus containing 2.5 – 12.5 10^5 plaque forming units. The vaccine contains a small amount of neomycin and polymyxin. ACAM2000™ is reconstituted by adding 0.3 mL of diluent to the vial containing lyophilized vaccine. The vaccine should only be reconstituted with 0.3 mL of the diluent provided. The bottle of diluent supplied with the smallpox vaccine contains more liquid than is needed to reconstitute the vaccine. Clinic personnel must make sure to use the correct (0.3 mL) amount.
2. Vaccine Reconstitution. The vaccine vial should be removed from cold storage and brought to room temperature before reconstitution. Reconstituted vial should be inspected visually for particulate matter and discoloration prior to administration. If particulate matter or discoloration is observed, the vaccine should not be used and the vials should be disposed of safely.

B. INDICATIONS AND USAGE. ACAM2000™ is indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.

C. DOSAGE AND ADMINISTRATION.

1. Dosage. The vaccine is administered in one dose. Inoculate the recipients with a bifurcated needle holding one drop of vaccine. Fifteen punctures are required for primary vaccination and for revaccination. Evidence of a prior primary smallpox vaccination includes health record documentation or a characteristic Jennerian scar. Presumptive evidence includes entry into United States (U.S.) military service before 1984, or birth in the U.S. before 1970. Individuals vaccinated with the smallpox vaccine in the past 10 years do not require revaccination, except specific laboratory workers involved with orthopox virus research, who may require more frequent vaccination. Refer to the following web site: <http://www.vaccines.mil/Smallpox> for detailed instruction on dosage and administration.
2. Administration. The bifurcated needle method is indicated for this vaccine. The site of vaccination is the upper arm over the insertion of the deltoid muscle. Other optional sites are described in the vaccine package insert located at the following web site: <http://www.vaccines.mil/Smallpox>. As always, appropriate clinical judgment is warranted. No skin preparation should be performed unless the skin at the intended site of vaccination is obviously dirty, in which case an alcohol swab may be used to clean the area. If alcohol is used, the skin must be allowed to dry thoroughly to prevent inactivation of the live vaccine virus by the alcohol. Do not vaccinate near the site of an active skin lesion or rash. Tattooed skin is not a contraindication for site selection but should be considered where evaluation of a take may be impaired. Avoid skin folds where drying is impeded. Any skin condition that may interfere with the immune response to vaccination should be carefully evaluated before vaccination. Refer to the following web site: <http://www.vaccines.mil/Smallpox>. Needles should be discarded in

labeled, puncture-proof “sharps” containers to prevent inadvertent needle stick injury or reuse.

D. EXPECTED REACTIONS.

1. Response. In a non-immune person who is not immunosuppressed, the expected response to primary vaccination is the development of a papule at the site of vaccination two to five days after administration. The papule becomes vesicular; the pustule reaches its maximum size in eight to 10 days. The pustule dries and forms a scab, which separates in 14 to 21 days after vaccination, leaving a scar.
2. Reaction. Vaccination can produce swelling and tenderness of the regional lymph nodes. Fever, erythematous, or urticarial rashes can occur.
 - a. If a person does not manifest a characteristic vaccination reaction six to eight days after the smallpox vaccination, that person should receive a single revaccination with 15 punctures (jabs) at a separate site. Individuals previously vaccinated, especially if they have received multiple doses, may not respond to smallpox vaccine because of current immunity.
 - b. Revaccination should not be repeated more than once in the short term. People previously vaccinated who do not respond with a visible skin lesion after two attempts should be considered medically immune. Others should be referred to the VHCN for immunologic evaluation.

E. CLINICAL GUIDANCE REFERENCES.

1. CDC Guidance. Healthcare workers must follow the guidance in the vaccine package insert (particularly for information on contraindications to vaccination) and guidance from the CDC, which formally publishes recommendations from the Advisory Committee for Immunization Practice (ACIP), for the administration of vaccines unless superseded by Coast Guard or DoD policy.
2. DoD Guidance. DoD clinical policy is defined in the ASD (HA) memo, “Clinical Policy for the DoD Smallpox Vaccination Program (SVP)”, which can be found on the following web site: <http://www.vaccines.mil/Smallpox> (under Policies).

F. MEDICAL SCREENING BEFORE IMMUNIZATION.

1. Medical Screening. Medical screening before vaccination for contraindications in vaccine recipients and their household contacts is essential to prevent serious complications. Contraindications will be documented in the health record and ITS. Screening must be conducted in a manner that personnel can freely ask questions and get reliable answers (one-on-one or in a group setting). The standard of practice for all immunizations includes medical screening before immunization. Unique for smallpox vaccine is the need to screen for risks among household contacts. Education and screening shall be conducted to document medical conditions for which immunization exemption (temporary or permanent) or further medical evaluation before immunization

is indicated. Standardized screening tools and follow up questionnaires are provided on the following web site: <http://www.vaccines.mil/Smallpox>.

2. Human Immunodeficiency Virus (HIV) Screening. Infection with HIV is a contraindication to smallpox vaccination. Personnel will be up-to-date in accordance with HIV screening policies before a smallpox vaccination is given. Personnel who are concerned that they could have a HIV infection may request additional HIV testing. DoD / Coast Guard, civilian employees and contractors to be vaccinated against smallpox will be offered HIV testing in a confidential setting, with results communicated to the potential vaccinee before vaccination. HIV testing is recommended for anyone who has a history of a risk factor for HIV infection, especially since his or her last HIV test, and who is not sure of his or her HIV-infection status. Because known risk factors cannot be identified for some people infected with HIV, people concerned that they could be infected should be tested.
3. Pregnancy Screening.
 - a. Deferral Requirements. Defer smallpox vaccinations until after pregnancy, except in emergencies where personal benefit from vaccination outweighs the risks. During a smallpox outbreak, pregnant women with a high risk exposure to smallpox may be vaccinated because the benefits of vaccination would outweigh its risks.
 - b. Fetal Vaccinia. On rare occasions, typically after primary (first) vaccination, vaccinia virus has been reported to cause fetal vaccinia infection. Fetal vaccinia usually results in stillbirth or death of the infant shortly after delivery. Since the inception of the DoD SVP there have been no reported cases of fetal vaccinia. Vaccinia vaccine is not known to cause congenital malformations.
 - c. Pregnancy Precautions. All immunization clinics providing the smallpox vaccine will display in a prominent place a written warning against unintentionally vaccinating pregnant women. This warning must be visible during the screening process. Women of childbearing potential are to be questioned / screened for pregnancy before receiving immunizations. Women who are uncertain about pregnancy status shall be medically evaluated for pregnancy before immunization. Because the requirement for smallpox vaccination is based largely on occupational risk, defer vaccination for pregnant women at least until the resumption of full duties following pregnancy, or later as postpartum care may require. In addition, all women receiving a smallpox vaccination will be instructed to avoid becoming pregnant for at least four weeks after their smallpox vaccination. All cases of pregnant women being inadvertently vaccinated will be referred to the National Smallpox Vaccine in Pregnancy Registry at the Naval Health Research Center (NHRC) San Diego, CA – Email: NHRC-BirthRegistry@med.navy.mil, phone: 1-619-553-9255.

G. ADMINISTRATIVE EXEMPTIONS.

1. Administrative exemptions. Administrative exemptions (enclosure 1) from smallpox vaccination 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 SVP scheduling as indicated:
 - (1) Retiring Personnel. Service members who are retiring are exempt from the Coast Guard SVP 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 SVP 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 SVP scheduling as indicated:
 - (a) Retiring Personnel. Coast Guard civilians who are retiring are exempt from the Coast Guard SVP 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 SVP upon receipt of a signed resignation with an effective date no more than 180 days.
2. 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 SVP upon presentation of evidence verifying their transfer/reassignment.

H. MEDICAL EXEMPTIONS.

1. General Information. Some individuals will have either acute or chronic pre-existing conditions that may warrant medical exemption from smallpox vaccination. In some cases, vaccination should be withheld if the individual cannot avoid household contact with another person with contraindicating conditions. Furthermore, a small proportion of individuals will develop a more serious reaction after vaccination that may warrant medical exemptions, temporary and permanent, from further smallpox vaccination.
 - a. In a smallpox emergency, there are no absolute contraindications to vaccinating people with a high-risk exposure to an infectious case of smallpox (e.g., face-to-face contact). Prior contraindications to vaccination could be overshadowed by personal risk of smallpox disease. Smallpox vaccine would be made available for people exempted during pre-outbreak vaccination programs. People at greatest risk for experiencing serious vaccination complications are often those at greatest risk for death from smallpox. If a relative contraindication to vaccination exists, the risk for experiencing serious vaccination complications must be individually weighed against the risks for experiencing a potentially fatal smallpox infection.
 - b. 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 prospective vaccinee for or against vaccinations.
2. Temporary and Permanent Medical Exemptions. The two most common annotated medical exemption categories are Medical Temporary (MT) and Medical Permanent (MP), see enclosure 1. Annotate the Service Member's records and ITS with these codes, and update them as appropriate. In the event of a confirmed smallpox outbreak, permanent exemptions could be lifted, based on individual risk.
 - a. Temporary
 - (1) People who have household contact with a person who has a contraindication to smallpox vaccination (e.g., immune-suppressed people, people with atopic dermatitis or eczema, pregnant women) shall either have alternative housing arrangements or be exempted from smallpox vaccination until the household-contact situation is no longer applicable. Avoidance of contact should continue for 30 days after vaccination and until the vaccine site is healed.
 - (2) Military-unique berthing settings require similar precautions. Exempt individuals should be physically separated and exempt from duties that pose the likelihood of contact with potentially infectious materials (e.g., clothing, towels, linen) from recently vaccinated people. This separation will include not having the vaccine recipient share or alternate use of common sleeping space (e.g., cot, bunk, berth) with people with contraindications to vaccination.

- (3) 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., immune-suppressed people and pregnant women). The ACIP notes that people with acute, chronic, or exfoliative skin conditions (e.g., burns, impetigo, varicella zoster, herpes, psoriasis, severe or uncontrolled acne) may also be at higher risk for inadvertent inoculation and should not be vaccinated until the condition resolves or a provider affirms it is under maximal control.
- (4) In situations where a medical condition is being evaluated or treated, a temporary deferral of smallpox 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 physician will determine the deferral interval, based on individual clinical circumstances.

b. Permanent

- (1) 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 smallpox vaccine, these permanent exemptions could be lifted if the individual had face-to-face contact with someone contagious with smallpox. Examples of situations warranting a permanent medical exemption appear in the vaccine's package insert (e.g., life-threatening allergy to vaccine component, immune-suppressed people, people infected with human immunodeficiency virus, people with atopic dermatitis or eczema or a past history of those disorders). People with contraindicating skin conditions who received smallpox vaccine earlier in life may be revaccinated after medical consultation for individual risk-benefit decision making.
 - (a) The CDC ACIP recommends exempting individuals with known cardiac condition(s) and persons with three or more known major cardiac risk factors. Personnel with the following cardiac conditions will be exempted: myocardial infarction, angina pectoris, cardiomyopathy, congestive heart failure, stroke, transient ischemic attacks, chest pain or shortness of breath with activity associated with a heart condition, other coronary artery disease, and other heart conditions under the care of a physician. Persons with any of the listed conditions should be exempted from smallpox vaccination.
 - (b) The following cardiac risk factors should be identified during pre-immunization processing: current cigarette smoking, hypertension, hypercholesterolemia, diabetes mellitus, and family history of heart disease in 1st degree relative with onset before age 50. Persons with three

or more of the above referenced risk factors should be exempted from receiving smallpox vaccine.

- (2) If a permanent medical exemption is indicated, follow reference (a) for granting such exemptions. If the situation changes, an appropriate medical specialist can remove a medical exemption.
- c. If an individual's clinical case is complex or not readily definable, healthcare providers should consult an appropriate medical specialist with vaccine safety-assessment expertise, before granting a permanent medical exemption. In addition, providers may consult with physicians in the VHCN at <http://www.vhcinform.org>. In such cases, providers will document specialty consultation in the individual's health record, including the considerations and reasons why a temporary or permanent medical exemption is or is not granted.
3. 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 VHCN. Commandant (CG-112) retains authority to review all appealed exemption determinations and may delegate this authority to individuals with appropriate expertise within their organization.
4. Specialty Consult. Each clinic administrator will assist people in obtaining appropriate specialty consultations expeditiously and in resolving patient difficulties. Specialists may grant permanent medical exemptions. Return of the 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 should be completed for any permanent medical exemption 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 DoD VHCN Clinical Services 24 hours a day, 7 days a week at 1-866-210-6469 or send a secure message at <https://askvhc.wramc.amedd.army.mil/>.

I. VACCINATION.

1. Who Administers Smallpox?

- a. Only appropriately trained and qualified medical personnel, upon the order of an appropriately privileged healthcare provider, will administer smallpox vaccine. Smallpox vaccinators are required to complete the DoD Smallpox Vaccination Training. Completion of this training program satisfies the DoD and Coast Guard requirement that all healthcare personnel participating in the SVP first complete an approved course of smallpox vaccination training. The approved course is sponsored by MILVAX and it includes eight modules and can be completed in

approximately 2.5 hours. A certification of completion will be available for download after the complete of the modules. All completed certificates must be sent to Commandant (CG-1122) for tracking purposes. The training is located at <http://www.vaccines.mil/default.aspx?cnt=ImzU/SmallpoxTraining>. The training is required only once.

- b. All smallpox vaccinators should complete the Initial Competency Assessment for Smallpox Vaccine Reconstitution and Smallpox Vaccine Administration located at <http://www.vaccines.mil/Smallpox> (under Immunization University). Competency should be assessed on an annual basis.
 - c. People who administer smallpox vaccine must be vaccinated themselves. While it is not a contraindication, pregnant females with a current smallpox status are discouraged from administering the smallpox vaccine. The preference to vaccinate smallpox vaccinators is based on the risk of inadvertent inoculation from repetitive handling of the vaccine. People may administer smallpox vaccine within one day after being vaccinated.
2. Procedures. Smallpox vaccination shall consist of 15 punctures (jabs) with a bifurcated needle for a primary (first) vaccination and for revaccination, see package insert. People vaccinated with smallpox vaccine in the past 10 years do not require revaccination, except specific laboratory workers involved with orthopox virus research, who may require more frequent vaccination.
- a. The cognizant healthcare provider will assess vaccination technique by evaluating the vaccination take rates among the first cohort of people vaccinated by each vaccinator. Published studies found take rates greater than 95 percent with appropriate technique.
 - b. The cognizant healthcare provider will assure that proper screening of vaccine recipients occurs before vaccination. Access to providers experienced in benefit-risk assessment will be made available to vaccine recipients and vaccinators. A healthcare provider will facilitate prompt evaluation of vaccine recipients with adverse events or side effects that interfere with the ability to work. Healthcare providers should contact the VHCN for additional guidance.
3. Take Assessment.
- a. Assessment of vaccine is required for healthcare personnel and members of smallpox response teams who will travel into a smallpox outbreak area. Other persons receiving vaccine should also have vaccine take assessed. To assess vaccine 'take', healthcare personnel trained in vaccination evaluation will inspect the vaccination site at six to eight days after vaccine administration. Reactions will be categorized as "Major Reaction" or "Equivocal" in accordance with the World Health Organization criteria. To accommodate individuals for whom 'take' assessment is not feasible, all persons receiving smallpox vaccine will be instructed

to report to the vaccination clinic if they do not develop a characteristic smallpox vaccination reaction.

- b. Formation of a major cutaneous reaction by day six to eight is evidence of a successful 'take' and acquisition of protective immunity. An equivocal reaction is any reaction that is not a major reaction, and indicates a non-take due to impotent vaccine or inadequate vaccination technique. Individuals who are not successfully vaccinated (i.e. equivocal after primary vaccination) may be revaccinated in an attempt to achieve a satisfactory take. If a repeat vaccination is given, and no visible cutaneous reaction is noted, individuals should be referred for immunologic evaluation.
 - c. Accurate documentation of both vaccination and take is required. Vaccination will be documented in the individual health record (using the Chronological Record of Medical Care (Smallpox Vaccination Clinical/Routine Follow Up Note, SF-600 SVP Overprint)) and ITS. In addition, vaccination take will be documented in individual health records immediately beneath the vaccination entry by writing the date of assessment and the type of reaction: Major Reaction or Equivocal.
4. Informed consent. 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 Smallpox Trifold Brochure and FDA Medication Guide on the vaccine's safety and benefits.
 5. Personal Protective Equipment. Persons administering vaccines will follow necessary precautions to minimize risk of spreading diseases. Because of the nature of the vaccine container and method of administration, personnel preparing and administering the vaccine should wear surgical or protective gloves and avoid contact of vaccine with skin, eyes, or mucous membranes. Special consideration should be observed while adding diluent to the vaccine vial to prevent spraying in the eyes. Gloves should be changed between patients.
 6. Aviation Personnel. As with most other immunizations, aviation personnel are automatically grounded for 12 hours after receiving the smallpox vaccine.

J. REVACCINATION.

1. Prior vaccination. Prior vaccination may modify (reduce) the cutaneous response upon revaccination such that the absence of a cutaneous response does not necessarily indicate vaccination failure. If a previously vaccinated person does not manifest a characteristic vaccination reaction six to eight days after smallpox vaccination, that person does not require revaccination in an attempt to elicit a cutaneous response.
2. Revaccination. Individuals should be revaccinated if more than 10 years have elapsed since the last smallpox vaccination. Persons at continued high risk of exposure to

smallpox (e.g., research laboratory workers handling variola virus) should receive repeat ACAM2000™ vaccinations every three years.

K. TIMING AND SPACING OF OTHER VACCINATIONS.

1. Live Vaccine. General recommendations from the ACIP accept administration of live and inactivated vaccines simultaneously or at any interval. The only major restriction to combining vaccinations is with multiple live-virus vaccines, which should either be given simultaneously or separated by 28 days or more. There are limited data evaluating the simultaneous administration of smallpox vaccine with other live-virus vaccines. It is desirable to separate varicella (chickenpox) and smallpox (vaccinia) vaccinations by 28 days, because of the potential to confuse attribution of lesions that may result in vaccine recipients. As with other live vaccines, tuberculin skin testing (TST) can be done before or on the same day as smallpox vaccination, but TSTs should be deferred at least four weeks after smallpox vaccination.
2. Other Vaccines. ACAM2000™ may be administered concurrently with other common inactivated vaccines. Do not administer other vaccines near the smallpox vaccination site.

L. CARE OF THE VACCINATION SITE.

1. Caring for the vaccination site.
 - a. Vaccinia virus is present on the skin at the vaccination site up to 30 days after vaccination or until the site is healed. During that time, care must be taken to prevent spread of the virus to another area of the body or to another person by inadvertent contact. Disease transmission from intact scabs is unlikely, but high-risk individuals may be vulnerable to scab particles. The DoD's and Coast Guard's goal is to reduce this risk as much as possible.
 - b. The most important measure to prevent inadvertent contact spread from smallpox vaccination sites is thorough hand washing (e.g., alcohol-based waterless antiseptic solution, soap and water) after contact with the vaccination site.
 - c. To avoid secondary infection, commanders and other leaders will direct physical activities so that smallpox vaccination sites are not subject to undue pressure (likely to burst a pustule), rubbing, or immersion sufficiently prolonged to cause tissue breakdown or secondary infection. Activities that complicate vaccine site care and cleanliness should be avoided during the post-vaccination healing period. For example, clothing and load-bearing equipment will be arranged in a manner to avoid excessive pressure or rubbing at the vaccination site. Avoid contact sports, such as wrestling. Swimming required for training or official duties should continue. A water proof occlusive dressing (e.g., Tegaderm / Opsite) shall be used while swimming.
 - d. Appropriate care should be taken to prevent the spread of vaccinia virus from the vaccination site. The following special precautions will be observed. The

vaccination site must be completely covered with a semipermeable bandage. Keep site covered for 30 days or until the site is healed. Wearing clothing with sleeves covering the vaccination site is recommended. The vaccinee should change the bandage every one to three days, as this will keep skin at the vaccination site intact and will minimize softening. Do not apply salves or ointments on the vaccination site.

- e. Used bandages along with the vaccination scab should be disposed of as biohazardous waste. If biohazardous waste receptacles are not available these items should be disposed in sealed plastic bags (e.g., Zip-Loc® bag) with a small amount of bleach. Clothing, towels, sheets, or other cloth materials that have had contact with the site can be decontaminated with routine laundering in hot water with detergent and/or bleach. Normal bathing can continue, but it is best to keep the vaccination site dry by using a waterproof bandage during bathing. Avoid rubbing the vaccination site.
 - f. Close physical contact with infants less than one year of age should be minimized for 30 days after vaccination and the vaccine site is healed. If unable to avoid infant contact, wash hands before handling an infant (e.g., feeding, changing diapers) and ensure that the vaccination site is covered with a semipermeable bandage and clothing. It is preferable to have someone else handle the infant. Smallpox vaccine is not recommended for use with nursing mother under non-emergency conditions.
2. Healthcare personnel procedures. Recently vaccinated healthcare personnel should minimize contact with unvaccinated patients, particularly those with immunodeficiencies and those with current skin conditions, such as burns, impetigo, contact dermatitis, chickenpox, shingles, psoriasis, or uncontrolled acne. Contact with the above individuals should be minimized for 30 days after vaccination or the vaccine site is healed. Even patients vaccinated in the past may be at increased risk due to current immunodeficiency. If contact with unvaccinated patients is essential and unavoidable, healthcare personnel can continue to have contact with patients, including those with immunodeficiencies, as long as the vaccination site is well-covered and thorough hand-hygiene is maintained. In this setting, a more occlusive dressing might be appropriate. Semipermeable polyurethane dressings (e.g., Opsite®, Tegaderm®) are effective barriers to vaccinia and recombinant vaccinia viruses. However, exudate may accumulate beneath the dressing, and care must be taken to prevent viral contamination when the dressing is removed. In addition, accumulation of fluid beneath the dressing may increase tissue breakdown at the vaccination site. To prevent accumulation of exudates, cover the vaccination site with dry gauze, and then apply the dressing over the gauze. The dressing should be changed every one to three days (according to type of bandaging and amount of exudate), such as at the start or end of a duty shift. MTFs should develop plans for site-care stations, to monitor workers' vaccination sites, promote effective bandaging, and encourage hand hygiene. Wearing long-sleeve clothing can further reduce the risk for contact transfer. The most critical measure in preventing inadvertent contact spread is thorough hand-hygiene after changing the bandage or after any other contact with the vaccination site.

M. ADVERSE-EVENT MANAGEMENT.

1. Side effects. As with any vaccine, some individuals receiving smallpox vaccine will experience side effects or adverse events. Adults vaccinated for the first time may develop a clinical illness with injection-site inflammation, muscle aches, and fatigue, most often on days eight to nine after vaccination. This illness may interfere with work. In addition, smallpox vaccine exhibits a unique adverse-event profile including myocarditis and/or pericarditis, encephalitis, progressive vaccinia, eczema vaccinatum, and other serious conditions.
2. Adverse effects.
 - a. Ongoing evaluation of health outcomes among DoD and Coast Guard personnel indicates individuals vaccinated for smallpox are at higher risk for myocarditis and/or pericarditis than those not vaccinated.
 - b. Along with the ACIP, DoD Health Affairs recommends that recent smallpox vaccine recipients who have a cardiac condition or three or more major cardiac risk factors be evaluated by a healthcare professional if they develop any symptoms of chest pain, shortness of breath, or other symptoms of heart disease. All people with heart disease or risk factors should receive the routine care recommended for persons with these conditions (see the following site for additional information <http://www.vaccines.mil/Smallpox>).
 - c. All cases of myopericarditis secondary to receipt of ACAM2000™ must be referred to the ACAM2000™ Myopericarditis Registry. Additional information regarding the registry can be found at their website at <http://www.myopericarditisregistry.org/>. Providers can contact the Registry at 1-619-553-9255 or send an email at NHRC-VaccineRegistry@med.navy.mil.
3. VHCN referral.
 - a. All Coast Guard personnel who received their smallpox vaccine while in a duty status, with a clinically verified diagnosis of post-smallpox vaccine myopericarditis, will be enrolled in the central registry maintained by the VHCN and be followed for a minimum of 24 months from the date of initial diagnosis. Patient informed consent is not required as part of enrollment. Identified cases should be submitted to VAERS. Upon enrollment, VHCN staff help ensure appropriate follow-up in coordination with the patient's case manager (www.vhcinfo.org). Those individuals requiring medical treatment/evaluation should be retained on active duty pending resolution of the medical condition or completion of the disability evaluation. Coordination with the Reserve and Service Member Support Office (RSMSO) Great Lakes (1-888-MHS-MMSO) will be required to provide appropriate civilian medical follow up and payment arrangements for reserve component personnel.
 - b. Vaccinia Immune Globulin (VIG) is indicated for the treatment or modification of certain conditions induced by the smallpox vaccine. Consultation with a board-certified infectious-disease or allergy-immunology specialist is required prior to

administration. The VHCN will provide and coordinate professional consultation services to optimize clinical use of VIG, and then maintain a registry of patients treated with VIG. Long-distance consultations will be arranged via the VHCN Clinical Services (866-210-6469). Infectious disease (ID) or allergy immunologist (AI), in consultation with the VHC, and CDC physician, authorizes release of VIG. VIG is requested directly from the CDC by calling the CDC Director's Emergency Operation Center (DEOC) at (770) 488-7100 and request to speak with the Division of Bioterrorism Preparedness and Response (DBPR) on-call person. The CDC is the release authority for VIG.

4. Adverse event procedures. Adverse reactions from DoD and Coast Guard directed immunizations are line-of-duty conditions.
- a. Immunizations are provided as part of the DoD's Force Health Protection program. At the time of immunization, personnel are to be provided documentation that identifies date and location of immunization; general information on typical responses to vaccination, common and serious adverse events; location of the nearest MTF; and the toll-free telephone number (1-888-MHS-MMSO) of the RSMSO, in the event medical treatment is required from non-MTF. Emergency-essential DoD and Coast Guard civilian employees and contractor personnel carrying out mission-essential services are entitled to the same treatment and necessary medical care as given to the service member. This includes follow-up and/or emergency medical treatment from the MTF or treatment from their personal healthcare providers or non-MTFs for emergency medical care as a result of immunizations required by their DoD or Coast Guard employment.
 - b. When a vaccine recipient presents at an MTF, expressing a belief that the condition for which treatment is sought is related to an immunization received during a period of duty, the person must be examined and provided necessary medical care. Once treatment has been rendered or the individual's emergent condition is stabilized, line of duty and/or notice of eligibility will be determined as soon as possible. Reserve component members and their family members, who seek medical attention as a result of adverse reactions from DoD / Coast Guard directed immunizations should:
 - 1) Immediately seek medical attention if an emergency and contact RSMSO and their command as soon as possible, or
 - 2) Contact RSMSO and their unit command for referral to the nearest treatment facility and to ensure payment for care and entitlements.
 - c. In the case of emergency-essential civilian employees presenting to a military treatment facility or occupational health clinic, the initial assessment and any necessary emergency care should be provided consistent with applicable occupational health program procedures. In the case of contractor personnel covered by the vaccination policy presenting to a military medical treatment facility or occupational health clinic, Secretarial-designee authority shall be used, consistent with applicable DoD or Coast Guard policy, to allow an initial assessment and necessary emergency care. This policy facilitates awareness of

potential adverse vaccine events for medical professionals and provides the patient medical resources not necessarily available in the civilian medical community. This use of Secretarial-designee authority does not change the overall responsibility of the contractor under workers' compensation program for all work-related illnesses, injuries, or disabilities.

- d. A privileged healthcare provider and any specialists, as indicated, should immediately evaluate any vaccinee with a serious adverse event temporally associated with receiving smallpox vaccination.

5. Vaccine Adverse Event Reporting System (VAERS).

- a. VAERS reports shall be completed for those events resulting in hospital admission, lost duty time or work of 24 hours or more, adverse event suspected to result from contamination of a vaccine vial, or death. Further, healthcare providers are encouraged to report other adverse events that in the provider's professional judgment appear to be unexpected in nature or severity. This is to include autoinoculation (or inadvertent infections). In other situations in which the patient wishes a VAERS report to be submitted, the healthcare provider will work with the patient to submit one without regard to causal assessment. VAERS report forms may be obtained by accessing http://vaers.hhs.gov/resources/vaers_form.pdf or by calling 1-800-822-7967.
- b. Adverse-event management should be thoroughly documented in the individual health record. Precisely code smallpox vaccine medical encounters. A copy of the VAERS report will be filed in an individual's health record after submitting the original form to the FDA. Providers are encouraged to provide a copy of the VAERS report to the patient. VAERS reports should also be forwarded to the cognizant Pharmacist to be included in Pharmacy and Therapeutics meeting minutes.

- N. BLOOD DONOR DEFERRAL. Because there is a significant donor deferral period associated with smallpox vaccination, it is critical that there is coordination with local military and civilian donor center collection schedules to reduce the impact on the readiness and availability of the military blood supply. Individuals who receive the vaccination and have no complications will be deferred from donating blood for 30 days after vaccination. Individuals with vaccine complications will be deferred for 14 days after all vaccine complications have completely resolved.

CHAPTER 3. MEDICAL REPORTING

A. PURPOSE. The purpose is to ensure the success of the SVP by tracking Coast Guard personnel immunized with smallpox 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 ITS for smallpox vaccination for Coast Guard personnel receiving immunizations within the Coast Guard system. All Coast Guard medical facilities/personnel providing immunization services are required to be familiar with MRRS and its use. (The Coast Guard is transitioning to the Integrated Health Information System (IHIS) and SVP data will be captured in IHIS when it becomes operational).

1. Coast Guard members. Coast Guard units having members (military or civilian) requiring initial or subsequent doses (e.g., revaccination every 10 years) of smallpox vaccine will ensure those members receive their vaccination from Coast Guard clinics/sickbays or DoD 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 smallpox 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 Chronological Record of Medical Care (Smallpox Vaccination Initial Note), SF-600 SVP 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.
3. Coast Guard members at 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 smallpox vaccinations must be made in the following locations in the Medical Record: Chronological Record of Medical Care (Smallpox Vaccination Initial Note), SF-600 SVP Overprint and the Adult Preventive and Chronic Care Flow Sheet, Form DD 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.

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CHAPTER 4. LOGISTICS

- A. PURPOSE. To provide the logistics concept of operations for the SVP.
- B. GENERAL INFORMATION. The following information on smallpox (vaccinia) vaccine is provided:
1. Stock number. NSN: 6505-01-559-0815 - The only lot number is VV04-003A, CVX = 75, MVX = BAH
 2. Nomenclature. Smallpox Vaccine Vaccinia (ACAM2000™), live with diluent, syringes, and needles. DoD uses the same FDA approved vaccine that is maintained in the strategic national stockpile (SNS), therefore all DoD stock will have the “Strategic National Stockpile Use Only” printed on its label. The CDC unit of issue is package “pkg”.
 3. Unit of Issue. A 100-dose vial with diluent, 100 bifurcated needles, and one tuberculin syringe for vaccine reconstitution.
 4. Shelf life. Prior to reconstitution, ACAM2000™ vaccine retains a potency of 1.0×10^8 PFU or higher per dose for at least 18 months when stored at refrigerated temperatures of two to eight C (36 to 46 F). After reconstitution, ACAM2000™ may be administered during a six to eight hour workday at room temperature (20 to 25 C, 68 to 77 F). Reconstituted ACAM2000™ may be stored in a refrigerator (two to eight C, 36 to 46 F) no longer than 30 days, after which it should be discarded as biohazardous waste. The reconstituted vaccine can remain at room temperature for 6-8 hours each day for 30 days.
 5. Storage. Unreconstituted ACAM2000™ will be distributed and stored at two to eight C (36 to 46 F). Unreconstituted ACAM2000™ should not be exposed to room temperature conditions for more than 48 hours.
 6. Dosage. One drop administered via bifurcated needle per instructions in Chapter 2.
 7. Cost. The smallpox 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 smallpox vaccine with Commandant (CG-112).
 2. Ordering. USAMMA has web-based ordering capability located at http://www.usamma.army.mil/spx_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, two 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 smallpox 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 SVP in accordance with smallpox vaccine cold-chain management guidelines outlined by USAMMA. Current storage and redistribution standard operating procedures can be found at http://www.usamma.army.mil/spx_index.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. Order ancillary supplies (e.g., cotton, isopropyl (alcohol pad), sponge gauze 2x3 inch) via normal medical supply procedures. It is expected that resuscitative equipment will be in the immediate vicinity where immunizations are administered. A capability to administer immediate first aid and medical care in the event of an anaphylactic or other allergic reaction will exist at all immunization sites.
 - d. Order supporting equipment (e.g., VaxiCool, VaxiPac, VaxiSafe, Endurotherm Box, TempTale (temperature monitor)) via normal medical supply procedures. For additional information on VaxiCool go to the following web site: http://www.usamma.army.mil/spx_index.cfm. Note – VaxiCool must be tracked and returned to their original location for further use.

- e. 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.

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 SVP.
- B. BACKGROUND. The Coast Guard is a full participant in the SVP. 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 smallpox 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 smallpox vaccine. Informed consent for military personnel is not required for FDA-licensed immunizations. Coast Guard members who refuse vaccination may be subject to administrative or disciplinary action, or both, at the discretion of the commander, for disobeying a lawful order.
 3. Other Medical Conditions. Coast Guard personnel may also be concerned about how the smallpox vaccination affects their existing medical conditions; see Chapter 2 for contraindications and precautions.
- C. OBJECTIVES. Ensure full understanding and support of the Coast Guard SVP 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 smallpox vaccine is a necessary part of the plan to eliminate smallpox 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 smallpox.
 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. Threats. Smallpox is deadly and would disrupt military missions.
 - a. Contagious. Smallpox is a disease that spreads quickly from one person to another.
 - b. Dangerous. Smallpox has been feared for hundreds of years.
 - c. Disruptive. A smallpox outbreak would significantly affect military readiness.
 2. Precautions. Smallpox vaccine prevents smallpox, but requires very careful use.
 - a. The World Health Organization used smallpox vaccine to eradicate natural smallpox from the planet.

- b. All vaccines cause side effects, but smallpox vaccine has unique features that require special handling.
 - c. Don't touch the smallpox vaccination site, so you don't spread virus somewhere else, either on your body or somebody else's.
 - d. Very rarely, smallpox vaccine can cause serious side effects.
 - e. Some people should not get smallpox vaccine, except under emergency situations.
 - f. DoD and the Coast Guard will use smallpox vaccine licensed by FDA, unless there is a smallpox outbreak. In an outbreak, DoD and the Coast Guard may use investigational supplies of vaccine that FDA permits to be used.
3. Our people. Preserving the health and safety of our people is our top concern.
- a. Healthy service members complete their missions. Vaccines will keep you and your team healthy.
 - b. Vaccines have kept troops healthy since the days of George Washington.
 - c. Vaccination offers a layer of protection, in addition to other measures, needed for certain members of the Armed Forces.
4. National strategy. The Coast Guard smallpox vaccination program is part of our national strategy to safeguard Americans against smallpox attack.
- a. DoD and Coast Guard are working with other federal departments to strengthen America's defenses against smallpox.
 - b. The government has been preparing for some time for the remote possibility of an outbreak of smallpox as an act of terror.
- E. AUDIENCES. Education and public affairs information will be targeted to the following audiences:
1. Coast Guard personnel. All Coast Guard personnel who will be vaccinated and their families (AD, 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 healthcare personnel.

F. RESPONSIBILITIES.

1. Commandant (CG-0922)
 - a. Provide coverage of immunization program in internal Coast Guard media.
 - b. Provide communication tools about the immunization program to Coast Guard PAOs for their internal and external information needs.
 - c. Respond to media inquiries and assist Coast Guard district PAOs in responding to media queries.
 - d. Provide Commandant (CG-112) 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 SVP.
2. Commandant (CG-0921). Coordinate response to congressional queries, as appropriate.
3. Commandant (CG-112).
 - a. Maintain a liaison with SVP program managers in other Services, keeping current with the latest educational and communications information available.
 - b. Forward new information/briefings to HSWL-SC 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).
4. HSWL SC. HSWL SC will post SVP information for clinics/sickbays on their websites.
5. Health Services Personnel.
 - a. Be familiar with the SVP educational resources by reviewing the SVP website at <http://www.vaccines.mil/Smallpox>. As with other vaccine immunization programs, experience shows that education is pivotal to program success and acceptance.
 - b. Assist commanding officers in ensuring that all personnel mandated to receive this vaccine are provided an oral brief by medical personnel covering topics using the individual's briefing at <http://www.vaccines.mil/Smallpox>. Briefers should emphasize: vaccination site care, frequent hand washing with soap and water to prevent autoinoculation and cross-inoculation, and frequent laundering of clothing and personal items (e.g., towels, sheets) in hot water and bleach.
 - c. Find answers to all medical questions asked about the smallpox medical threat, vaccine, and Coast Guard SVP. If necessary, contact Commandant (CG-112) and HSWL SC personnel responsible for overseeing the Coast Guard SVP.
6. Commanding officers of units receiving vaccine administration.

- a. Ensure that they and other senior leadership of units receiving the vaccine have reviewed the information provided in the leaders' briefing at <http://www.vaccines.mil/Smallpox>.
 - b. Ensure that personnel receiving the vaccination are given the opportunity to ask questions about the vaccine and its administration.
 - c. Ensure 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.
7. 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 SVP and the vaccine. Accurate information can be found on the web at: <http://www.vaccines.mil/Smallpox>.

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Medical Exemption Codes

Code	Meaning	Explanation or Example	Duration
MA	Medical Assumed	Prior immunization reasonably inferred from individual's past experiences (for example, basic military training), but documentation is missing. Code used to avoid superfluous immunization. Code can be reversed upon further review.	Indefinite
MI	Medical, Immune	Evidence of immunity. For smallpox, documented infection (indefinite exemption) or documented confirmed "take" in medical records within the past 10 years.	Up to 10 years
MR	Medical, Reactive	Permanent restriction from receiving additional doses of smallpox vaccine. Severe adverse reaction after immunization (e.g., anaphylaxis). File VAERS report.	Indefinite
MT	Medical, Temporary	Pregnancy, hospitalization, temporary immune suppression, convalescent leave, pending medical evaluation board, events referred for medical consultation, any temporary contraindication to immunization, (e.g., smallpox vaccine and household-contact situation).	Up to 365 days
MP	Medical, Permanent	HIV infection, atopic dermatitis, certain cardiac conditions, prolonged or permanent immune suppression, other condition determined by physician. Can be reversed if the condition changes.	Indefinite
MD	Medical, Declined	Declination of optional vaccines (not applicable to many military vaccinations), religious waivers.*	Indefinite
MS	Medical, Supply	Exempt due to lack of vaccine supply.	Indefinite

*Religious waivers are administrative exemptions, however for MRS / MRRS entries they will be coded as medical exemptions (MD)

Administrative Exemptions Codes

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