DEPARTMENT OF THE AIR FORCE

PLAN FOR IMPLEMENTING THE ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)

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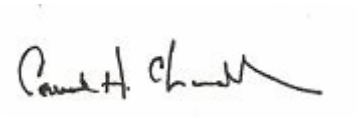

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Chapter 1 – INTRODUCTION **1**
Section 1.1 Purpose 1
Section 1.2 Background 1
Section 1.3 Key Messages 1
Section 1.4 Applicability and Scope 1

Chapter 2 – ROLES AND RESPONSIBILITIES **4**
Section 2.1 HQ USAF/A3/5 4
Section 2.2 HQ USAF/SG 4
Section 2.3 MAJCOMS 4
Section 2.4 Installation Commanders 4
Section 2.5 Installation Deployment Officers (IDO) 5
Section 2.6 Public Affairs 5
Section 2.7 Legal 5
Section 2.8 Contracting 6
Section 2.9 Unit Commanders 6
Section 2.10 Medical Commanders 6
Section 2.11 Installation AVIP Medical Officer-In-Charge (OIC) 7
Section 2.12 Immunization Clinic NCOIC 8
Section 2.13 Installation AVIP Team 9
Section 2.14 Installation AVIP Team Chairperson 9
Section 2.15 Individuals Subject to or Eligible for Anthrax Vaccinations 9

Chapter 3 – EDUCATION PLAN FOR AVIP **10**
Section 3.1 General 10
Section 3.2 Key Messages 10
Section 3.3 Education for Commanders 10
Section 3.4 Education for Individuals 11
Section 3.5 Education for Medical Personnel 11

Chapter 4 – MEDICAL ISSUES **13**
Section 4.1 Dosing Schedule 13
Section 4.2 Pregnancy 13

Section 4.3 Pre-Vaccination Screening 14
Section 4.4 Adverse Reactions 14
Section 4.5 Medical Exemptions 15
Section 4.6 Anthrax Vaccine Tracking and Documentation 17
Section 4.7 Medical Logistics/Vaccine Distribution 18

Chapter 5 – ADMINISTRATIVE ISSUES 19
Section 5.1 E-E Civilians 19
Section 5.2 ME Contractors 19
Section 5.3 Exceptions to Policy (ETPs) 20
Section 5.4 Waivers and Exemptions 20
Section 5.5 Healthcare Access Guidelines 21
Section 5.6 Refusal Management 23

Attachment 1 – REFERENCES 26
Attachment 2 – AVIP REGISTRY AGREEMENT 28
Attachment 3 – AVIP IMPLEMENTATION CHECKLIST 30
Attachment 4 – AVIP MONTHLY REPORT TEMPLATE 33
Attachment 5 – AVIP CHECKLIST FOR VACCINATORS 34
Attachment 6 – AVIP MTF CHECKLIST FOR CASES OF INITIAL VACCINE REFUSAL 35

Chapter 1

INTRODUCTION

1.1. Purpose. This plan provides Air Force guidance and direction for implementing the Anthrax Vaccine Immunization Program (AVIP) in accordance with the 12 October 2006 Deputy Secretary of Defense memorandum (Reference (B)) and the subsequent 6 December 2006 Under Secretary of Defense (Personnel and Readiness) (USD(P&R)) Implementation Guidance for the AVIP (Reference (A)). Implementation of this plan and the subsequent resumption of mandatory anthrax vaccinations will be carried out in accordance with the timelines established in the Deputy Chief of Staff for Air, Space, and Information Operations, Plans, and Requirements (AF/A3/5) implementation message.

1.2. Background.

1.2.1 On 12 Oct 06, the Deputy Secretary of Defense ordered the resumption of mandatory anthrax vaccinations for designated military personnel, emergency-essential and comparable Department of Defense civilian employees, and certain contractor personnel performing essential services based on geographic area of assignment or special mission roles. Additionally, the Deputy Secretary of Defense announced voluntary completion of the six-shot AVIP series and annual boosters for personnel who began the vaccine series but were unable to complete the entire shot series. Individuals may opt for voluntary vaccinations as long as they remain members of the armed forces or maintain civilian employee status covered by the AVIP.

1.3. Key Messages. Education of all levels of the command structure is imperative to ensure the success of this program. The key messages for the AVIP are:

1.3.1. Your health and safety are our #1 concern

1.3.2. The vaccine is safe and effective

1.3.3. The threat from anthrax is real and deadly

1.3.4. Vaccination offers a layer of protection, in addition to antibiotics and other measures, that is critical for members of the armed forces

1.4. Applicability and Scope.

1.4.1. The following personnel will resume mandatory anthrax immunizations, except as provided under applicable medical and administrative exemption policies:

1.4.1.1. Uniformed personnel, to include those assigned to U.S. Embassies, forces afloat, and civilian and contract Mariners under Commander, Military Sealift Command, serving in the U.S. Central Command (USCENTCOM) area of responsibility for 15 or more consecutive days.

1.4.1.2. Uniformed personnel assigned to the Korean Peninsula for 15 or more consecutive days.

1.4.1.3. In accordance with the Deputy Secretary of Defense memo dated 28 Jun 04 (Reference (G)), vaccinate uniformed DoD personnel designated as early deployers (C-Day to C+20) to the Korean Peninsula for 15 or more consecutive days, to include the U.S. Pacific Command Forward Deployed Naval Forces, against anthrax.

1.4.1.4. Upon notification by the Secretary of the Army as the Executive Agent that appropriate consultation procedures have been completed, and contingent upon compliance with any other necessary personnel procedures, emergency-essential (E-E) and equivalent DoD civilian employees assigned for 15 or more consecutive days to the USCENTCOM area of responsibility or to the Korean Peninsula. For this purpose, "equivalent" personnel means other personnel whose duties meet the requirements of 10 U.S.C. § 1580, but who have not been designated as "emergency-essential."

1.4.1.5. DoD contractor personnel carrying out mission-essential (M-E) services and assigned for 15 or more consecutive days to the USCENTCOM area of responsibility or Korea. Contracts must specify immunization as a requirement. Immunization will be provided through the Military Health System.

1.4.1.6. All special groups covered by previously approved exceptions to policy (ETP). Please see References J through O in Attachment 1 or refer to https://www.a3a5.hq.af.mil/a3s/a3sc/CCBRN_resource/biological/anthrax/index.asp (NIPRNET) or http://www.a3a5.hq.af.smil.mil/a3s/a3sc/CCBRNE_resource/biological/anthrax/index.asp (SIPRNET) for current listings. For more information on requesting or rescinding an ETP, please see paragraph 5.3 of this plan.

1.4.1.7. Other personnel designated by the Assistant Secretary of Defense for Health Affairs (ASD(HA)), upon recommendation of the Chairman of the Joint Chiefs of Staff, the Secretary of a Military Department or the Commandant of the Coast Guard, based on critical mission assignments.

1.4.1.8. Once an individual rotates out of the USCENTCOM area of responsibility or Korea, mandatory vaccinations will cease, unless the individual moves into a designated special mission, bio-defense unit, or other unit as described in 1.4.1.6 or 1.4.1.7 above. After rotation, if these individuals are not subject to mandatory anthrax vaccine, they may become eligible for voluntary vaccinations as outlined in paragraph 1.4.3 below.

1.4.2. All categories of personnel (listed above) on orders to the USCENTCOM area of responsibility or Korea may begin immunizations up to 60 days before deployment or arrival. Every effort should be made to provide at least three doses prior to deployment or Permanent Change of Station (PCS).

1.4.3. Personnel Eligible for Voluntary Vaccinations.

1.4.3.1 The following individuals are eligible for voluntary vaccinations based on current location or status (subject to medical exemptions).

1.4.3.1.1. U.S. government civilian employees and U.S. citizen contractor personnel other than those referred to in paragraph 1.4.1 assigned for 15 or more consecutive days to the USCENTCOM area of responsibility or Korea.

1.4.3.1.2. Adult family members, 18-65 years of age, accompanying DoD military and civilian personnel for 15 or more consecutive days to the USCENTCOM area of responsibility or Korea.

1.4.3.1.3. U.S. citizen adult family members, 18-65 years of age, accompanying U.S. contractor personnel for 15 or more consecutive days to the USCENTCOM area of responsibility or Korea.

1.4.3.1.4. Vaccine manufacturing and research personnel and others, as designated by the ASD(HA). ASD(HA) will approve these requests on a case-by-case basis.

1.4.3.2. The following individuals, who received at least one dose of anthrax vaccine and who are not subject to mandatory vaccination, will, subject to medical exemptions, be offered additional vaccine doses on a voluntary basis. Vaccines will be available at DoD MILVAX registered clinics.

1.4.3.2.1. Members of the Uniformed Services on active duty or in the Selected Reserve, regardless of current duty assignment, if they previously received, during the period 1998 to present, 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.

1.4.3.2.2. U.S. Government civilian employees of DoD, regardless of current duty assignment, if they previously received, during the period 1998 to present, at least one dose of anthrax vaccine and if they are not currently subject to mandatory vaccination.

Chapter 2

ROLES AND RESPONSIBILITIES

2.1. HQ USAF/A3/5.

2.1.1. As OPR for the AVIP, develop AF Implementation policy.

2.1.2. Provide program oversight.

2.1.3. Coordinate with other agencies (e.g., Military Vaccine (MILVAX) Agency, OSD, Joint Staff) on policy implementation and execution as appropriate.

2.1.4. Review and coordinate requests from MAJCOMs for exceptions to policy.

2.1.5. As appropriate, coordinate with USCENTCOM or USFK on in-theater implementation of the AVIP.

2.2. HQ USAF/SG.

2.2.1. OCR for the AVIP.

2.2.2. Provide oversight to clinical guidance as it relates to the AVIP.

2.3. MAJCOMs.

2.3.1 Designate A3 or A5 as MAJCOM OPR and SG as OCR for management of the AVIP.

2.3.2. Consult with installations on AVIP issues which require command support.

2.3.3. Coordinate requests for exceptions to policy with installations and HQ USAF A3/5.

2.4. Installation Commander.

2.4.1. Ensures compliance with the AVIP by maintaining oversight and ownership of the installation's AVIP implementation program.

2.4.2. Develops a base implementation plan consistent with DoD and AF guidance. The Air Force plan may be used as the foundation for the installation's implementation plan. The installation plan must address education, medical, and administrative issues. Detailed AF guidance on these topics is provided in Chapters 3-5.

2.4.3. Designates, in writing, a senior line officer as the installation AVIP Team Chairperson to oversee continued operation of the installation AVIP Team.

2.4.4. Directs the Medical Treatment Facility (MTF) Commander to designate, in writing, a Medical Officer-In-Charge (OIC) who will coordinate the medical administrative and clinical functions of the AVIP.

2.4.5. Ensures all installation personnel receive education on the AVIP as outlined in Chapter 3 of this plan.

2.4.6. Serves as approval authority for all administrative exemptions as appropriate.

2.4.7. Submits requests for exception to policy to MAJCOM A3 or A5 (as appropriate) for coordination.

2.4.8. If not already accomplished, in accordance with existing SAF/AQC guidance, identifies M-E services and inform the cognizant contracting officers.

2.5. Installation Deployment Officers (IDO).

2.5.1. Administer the Wing's deployment process IAW AFI 10-403, *Deployment Planning and Execution*.

2.5.2. Oversee coordination of all deploying units/individuals, as well as AVIP's effect on the deployment process (eligibility and processing line considerations).

2.5.3. Report numbers of personnel deploying, including deployment location and duration, to the AVIP Medical OIC for projection of vaccine requirements.

2.5.4. Member of Installation AVIP Team.

2.6. Public Affairs.

2.6.1. Provide support and facilitate proactive community education.

2.6.2. Coordinate responses to media inquiries.

2.6.2.1 The AVIP is a DoD program, therefore, ensure MILVAX is utilized as a resource for inquiries about administrative or clinical matters.

2.6.3. Member of Installation AVIP Team.

2.7. Legal.

2.7.1. Educate base personnel as needed on relevant legal issues.

2.7.2. Answer any inquiries regarding legal issues related to the AVIP (e.g., Freedom of Information Act requests and refusals to receive mandatory vaccinations).

2.7.3. Member of Installation AVIP Team.

2.8. Contracting.

2.8.1. In accordance with section 1.4.1.5 of this plan, ensure vaccination of US-national M-E contractor personnel is a requirement of the applicable contract.

2.8.1.1. Modify contracts that do not already cover the designated M-E services. Contracting officers should take appropriate actions to address: identification of the M-E services; the contractor's responsibility to identify their employees who will perform the M-E services during a crisis; funding and liability; and authorization for vaccination and related medical care.

2.8.2. Once M-E services are contractually covered, direct contractors to identify their vaccine eligible M-E employees.

2.8.3. Provide a list of M-E contractor employees to the applicable unit commanders and the Immunization Clinic NCOIC.

2.9. Unit Commanders.

2.9.1. Ensure unit personnel are educated on the AVIP in accordance with chapter 3 of this plan.

2.9.2. Provide a list of E-E civilian employees eligible to receive anthrax vaccinations to the installation medical treatment facility (MTF) (attention: Immunization Clinic NCOIC) as described in section 5.1 of this plan.

2.9.3. Identify M-E contractors eligible to receive anthrax vaccinations to the appropriate contracting officer and direct them to the MTF for vaccination as described in section 5.2 of this plan.

2.9.4. For personnel subject to mandatory vaccination, manage cases of individual refusal to receive the anthrax vaccine in accordance with section 5.6 of this plan. Begin taking refusal management steps as soon as possible following notification by the MTF of vaccine refusal by a unit member.

2.9.5. For unit personnel eligible to receive mandatory or voluntary anthrax vaccinations under an approved exception to policy, provide the Immunization Clinic NCOIC with a signed letter that identifies the individuals and the applicable exception to policy. This letter should be on file at the immunization clinic prior to directing personnel to the MTF for vaccination.

2.10. Medical Commander.

2.10.1. Provides oversight for all medical administrative and clinical aspects of AVIP.

2.10.2. Designates, in writing, an installation AVIP Medical OIC who will coordinate the medical administrative and clinical functions of the AVIP.

2.10.2.1. The AVIP Medical OIC should be someone in the immunization clinic's chain of command.

2.10.2.2. Air Reserve Components (ARC) only may select an enlisted Senior Health Technician as the AVIP Medical OIC if unable to fill this role with an officer.

2.10.3. Assign responsibility for commander notification of initial anthrax vaccine refusals to a designated medical officer. In most cases, the AVIP Medical OIC should be the responsible officer. See section 5.6.1 and Attachment 6.

2.10.4. Ensures appropriate medical personnel are educated on the clinical and policy aspects of the vaccine program (see Chapter 3).

2.10.5. Designates, in writing the medical representatives to the Installation AVIP Team (AVIP Medical OIC and Immunization Clinic NCOIC).

2.10.6. Ensures a process is in place for access to health care for anyone (including dependents) who may have an adverse reaction to the vaccine.

2.10.7. Ensures those receiving vaccination are offered education prior to administering the anthrax vaccine.

2.11. Installation AVIP Medical Officer-In-Charge (OIC).

2.11.1. Oversees education and training of healthcare providers on the current AVIP policy as described in section 3.5.

2.11.2. Coordinates with Installation Deployment Officers, Public Health Officers, Immunization Clinic NCOICs and Medical Logistics Officers to determine 90-day projected vaccine requirements. Forward the projected vaccine requirements to the medical logistics office. Consideration should be made for those volunteering to continue the vaccine series.

2.11.3. Requests appropriate number of AVIP tri-folds (most current version) as required for base education and start-up of AVIP.

2.11.3.1. Order AVIP tri-folds from the US Army Medical Materiel Agency (USAMMA).

2.11.3.2. It is acceptable to print the required copies from the MILVAX website.

2.11.3.3. Ensure the most current version of the AVIP tri-fold is readily available/distributed at education venues and within the MTF. Ensure destruction of all previous versions of the AVIP tri-folds.

2.11.4. Ensure a current compliance/registry agreement is on file. If one does not exist, submit Registry Agreement and Implementation Checklist to MILVAX and send copy to HQ USAF/A3SC after ensuring all checklist items have been completed (see Attachments 2 and 3).

2.11.5. Ensure memorandum received from MILVAX designating clinic as an AVIP Registered Immunization Activity before vaccination program begins unless clinic had previously provided anthrax vaccine.

2.11.6. Coordinate with Immunization Clinic NCOIC to ensure anthrax vaccinations are provided and documented in accordance with this plan.

2.11.7. Develop and submit monthly report (see Attachment 4). Reports for the preceding month are due to MILVAX by the 5th day of the month. Copies of the report should be provided to the MAJCOM AVIP POC and HQ USAF/A3SC (email to: AFA3SC.Workflow@pentagon.af.mil).

2.11.7.1. If a unit or agency fails to report, MILVAX agency will contact the alternate points of contact listed on the registry agreement. If necessary, the MILVAX Agency will contact the Air Force Surgeon General's office. Vaccine supply requests will not be honored for units that do not report according to these procedures.

2.11.8. Report any instances of involuntary immunizations given to personnel not subject to mandatory vaccination as soon as recognized. Do not wait for the next reporting cycle. Send a report to the MILVAX Agency and HQ USAF/A3SC, as well as up the chain of command as directed by local and MAJCOM policy. Use the template and contact information in Attachment 4 for this out-of-cycle reporting. The report shall include a full explanation of the circumstances involved and a description of the remedies to be implemented to prevent a recurrence.

2.11.9. Member of Installation AVIP Team**.**

2.12. Immunization Clinic NCOIC.

2.12.1. Ensure education and training of vaccinators on current AVIP policy is accomplished in accordance with section 3.5 of this plan.

2.12.2. Coordinate with AVIP Medical OIC to ensure anthrax vaccinations are provided and documented in accordance with this plan.

2.12.3. Member of the Installation AVIP Team.

2.13. Installation AVIP Team.

2.13.1. Membership includes representatives from the Wing Leadership, Legal, Medical (that will include the AVIP Medical OIC and Immunization Clinic NCOIC), Public Affairs, Intelligence, Chaplain, Contracting, Military Personnel Flight, and the Installation Deployment Officer.

2.13.2. The team chairperson is a senior line officer.

2.13.3. The team will review existing policy and guidance and ensure all members are fully educated on the AVIP under current conditions.

2.13.4. The team will provide recommendations and expertise for the local command structure for the re-introduction and maintenance of the AVIP.

2.13.5. Develop the installation AVIP implementation plan.

2.14. Installation AVIP Team Chairperson.

2.14.1. Oversees development of the installation AVIP implementation plan.

2.14.2. Provides oversight to the administrative functions of the AVIP.

2.14.3. Ensures pre-vaccination education is provided to commanders and individuals on the mandatory and voluntary components of the AVIP.

2.15. Individuals Subject to or Eligible for Anthrax Vaccination.

2.15.1. Receive education on the threat anthrax poses and information on the anthrax vaccine.

2.15.2. Read the AVIP tri-fold brochure.

2.15.3. For personnel subject to mandatory vaccination or voluntarily continuing the vaccination series, receive anthrax immunizations in accordance with the prescribed dosing schedule.

Chapter 3

EDUCATION PLAN FOR ANTHRAX VACCINATION

3.1. General. Education is the key to a successful anthrax vaccination program. Commanders at all levels are responsible for educating their personnel before vaccination. The primary mode of providing this education will be briefing materials and the AVIP tri-fold brochure (most current version) hereafter referred to as the "tri-fold". This educational program will inform personnel:

3.1.1. The Food and Drug Administration (FDA) has licensed the anthrax vaccine for prevention of anthrax disease in all types of exposure, including inhalation

3.1.2. Of the known and potential benefits and risks of anthrax vaccination

3.1.3. There is no other product approved by the FDA to prevent anthrax before exposure

3.1.4. Anthrax vaccinations are mandatory for selected individuals

3.1.5. Anthrax vaccinations are voluntary for selected individuals

3.1.6. Those individuals who previously began the anthrax vaccine series during the period 1998 to present and who are now resuming the anthrax series (whether on a mandatory or voluntary basis) will resume the series from where they left off per guidelines from the CDC's Advisory Committee on Immunization Practices (ACIP). They should not restart the series.

3.2. Key Messages.

3.2.1. Your health and safety are our #1 concern

3.2.2. The vaccine is safe and effective

3.2.3. The threat from anthrax is real and deadly

3.2.4. Vaccination offers a layer of protection in addition to antibiotics and other measures that is needed for certain members of the armed forces

3.3. Education for Commanders. Commanders at all levels are responsible for ensuring they are properly and fully educated on the AVIP. The primary modes of providing this education to commanders are the AVIP tri-fold brochure, the "AVIP Briefing for Leaders" and the "AVIP Briefing for Individuals," all available at http://www.anthrax.mil/AVIP2007/. Commanders will review all of these resources and are highly encouraged to also use their Installation AVIP team as an education resource.

3.4. Education for Individuals. All personnel (as identified in section 1.4 above) must receive education on the resumption of mandatory anthrax vaccinations for designated personnel and the voluntary components of the AVIP before receiving the anthrax vaccine. This applies to individuals beginning or resuming the vaccination series.

3.4.1. The primary mode of providing education to individuals is the AVIP tri-fold brochure developed by MILVAX. This brochure is available at the MTF or electronically at http://www.anthrax.mil/AVIP2007/. Prior to receiving the anthrax vaccine, individuals must have had the opportunity to review the AVIP tri-fold brochure.

3.4.1.1. Upon arrival at the MTF to receive the anthrax vaccine, individuals (military personnel, government civilian employees, contractors, and others) will be offered a copy of the AVIP tri-fold. Prior to administering the anthrax vaccine, the immunization technician will ask the individual if they have received a copy of the AVIP tri-fold brochure. If they have not, they should be offered the opportunity to view the brochure prior to receiving the immunization.

3.4.2. Commanders are responsible for ensuring eligible individuals are educated on the mandatory and voluntary components of the AVIP before individuals are subject to vaccination. Commanders should supplement the AVIP tri-fold brochure by presenting the "AVIP Briefing for Individuals" developed by MILVAX to unit personnel.

3.5. Education for Medical Personnel. Medical personnel are the primary source of information on the disease, the vaccine, and vaccine side effects. For those individuals who experience an adverse event associated with the vaccine, medical personnel will provide the appropriate treatment and referral, if necessary, for diagnosis and treatment of medical conditions.

3.5.1. Medical commanders will ensure that healthcare professionals and vaccinators involved with the AVIP review and comply with the implementation plan. Additional resources are available to support this education activity: the most current version of the tri-fold, the AVIP briefing slides (available at http://www.anthrax.mil/AVIP2007/), and the package insert shipped with each vial of the anthrax vaccine.

3.5.2. Medical personnel involved with the AVIP must understand healthcare-access guidance for all personnel affected by the AVIP policy, procedures for reporting in the Vaccine Adverse Events Reporting System (VAERS) and reasons for medical exemption from anthrax vaccination.

3.5.3. Personnel providing anthrax immunizations must acknowledge training on checklist items 4-8, and 12 in Attachment 3, AVIP Implementation Checklist.

3.5.3.1. The Immunization Clinic NCOIC will ensure proper documentation of the education provided to enlisted medical personnel. Documentation must be accomplished on AF Form 1098 in the enlisted 6-part folder for all SEI 453/454s; all Immunization

Back-Up Technicians (IBTs); and Immunization Augmentees (IAs) who may be used in support of the AVIP.

3.5.3.2. This training will be re-certified annually, and will be reviewed for currency upon arrival at a new duty station.

3.5.3.3. AVIP-required training must be accomplished and documented before personnel are authorized to provide anthrax vaccinations without immediate supervision.

3.5.4. Immunization technicians must be educated on the following requirements of the program.

3.5.4.1. Upon presenting to the Immunization Clinic, the technician will ask all personnel if they have received a copy of the AVIP tri-fold brochure prior to immunizing them. If they have not, they should be offered a copy of the most current version of the brochure.

3.5.4.2. Immunization technicians will verify that all personnel eligible for voluntary vaccination wish to receive the vaccine prior to vaccinating them.

3.5.4.3. Attachment 5, AVIP Checklist for Vaccinators can be used as a resource for personnel providing anthrax vaccinations. See section 5.6.1 for guidance on management of individual refusal of a mandatory vaccine.

3.5.5. The AVIP OIC will ensure education on the AVIP is accomplished for: clinical supervisors of vaccinators, preventive medicine and public health staff, relevant healthcare providers (e.g., allergy-immunology, ambulatory care, flight medicine, emergency care), and any other provider designated by the Medical Commander. Education must include the components listed in 3.5.2 as well as the information provided in the "AVIP Healthcare Provider's Briefing" available at: http://www.anthrax.mil/AVIP2007/.

Chapter 4

MEDICAL ISSUES

4.1. Dosing Schedule.

4.1.1. The dosage schedule for the anthrax vaccine is 0, 2, 4 weeks, followed by doses at 6, 12, and 18 months with an annual booster to sustain immunity. This is the only dosage schedule currently licensed by the FDA.

4.1.1.1. Do not administer the vaccine on a compressed or accelerated schedule. Under no circumstance is the vaccine to be given at shorter intervals than approved by the FDA. Contact the Vaccine Healthcare Center or MILVAX for questions on the vaccine schedule.

4.1.1.2. Vaccinations should be given on or as soon after recommended dates as possible. Whenever a vaccine dose is received after a scheduled date, adjust the subsequent doses accordingly to ensure the proper interval of time between doses.

4.1.1.3. All vaccinations are given subcutaneously and IAW the current scope of practice. The preferred site is the subcutaneous tissue over the deltoid region.

4.1.2. In cases in which the vaccine series was deferred, whether due to vaccine shortage, program interruption, or other reasons, individuals are not required or advised to restart the vaccine series.

4.1.2.1. Individuals resuming anthrax vaccinations, under this policy, will resume where they left off and continue the vaccine series at the appropriate shot intervals. This is consistent with prevailing medical practice and complies with guidance from the Centers for Disease Control and Prevention (CDC), its Advisory Committee on Immunization Practices (ACIP), and the Defense Health Board (DHB) and in consultation with the FDA.

4.1.2.2. When a dose cannot be provided on the specific date suggested by the schedule, provide it as soon as practical thereafter.

4.1.3. All individuals who begin the anthrax vaccine dosing series shall be informed of the recommended dosing schedule and be advised to return to the Immunization Clinic at the appropriate times under the schedule, as long as they remain eligible for AVIP. This information and advice is independent of whether the future doses are mandatory or voluntary for that individual.

4.2. Pregnancy. The anthrax vaccine is generally deferred during pregnancy.

4.2.1. Immunization clinics and providers will display a prominent sign directing women to alert the technician or provider if they think they might be pregnant.

4.2.2. All females of childbearing age will be asked about the possibility of pregnancy prior to receiving the vaccine. The following question, recommended by the CDC, will be used on any locally approved questionnaire/overprint: "For women: Are you pregnant or is there a chance you could become pregnant during the next month?"

4.2.3. Women who are uncertain about their pregnancy status shall be medically evaluated for pregnancy prior to immunization. If women have any questions or concerns, they should consult with their healthcare provider before receiving the vaccine.

4.2.4. In unusual circumstances, such as a confirmed exposure to anthrax bacillus in which the benefit of vaccination outweighs the risk to the fetus, they may be vaccinated IAW the CDC Advisory Committee on Immunization Practice Guidelines.

4.3. Pre-vaccination Screening. Medically screen patients prior to administering the anthrax vaccine to ensure there are no contraindications for receiving the vaccine. See section 4.5 below and Attachment 5 for more information on pre-vaccination screening.

4.4. Adverse Reactions.

4.4.1 General Information. Medical personnel must be prepared to manage perceived or actual adverse events after vaccination: how to minimize them, respond to them, and report them IAW AFJI 48-110. Treat each concern with care; some symptoms following anthrax vaccination may or may not be caused by the vaccination, but all deserve individual attention.

4.4.2 Immunization Technician's Role. Immunization technicians will have the most current version of the Anthrax Vaccine Tri-fold Brochure and other sources of information (e.g., vaccine information sheet – VIS) available in the clinic, which provide details on potential side effects. If a patient returns to the clinic after receiving a vaccination and indicates that they had an adverse reaction, the immunization technician can, again, provide these information sources to the patient. If the adverse reaction is anything more than a mild, local reaction, they should be referred to a provider. In every case, the patient should be given the option of seeing a provider.

4.4.3 Any serious adverse event temporally associated with receipt of a dose of anthrax vaccine should be immediately evaluated by a privileged healthcare provider. Adverse event management should be thoroughly documented in medical records.

4.4.4 The MILVAX Clinical Guidelines for Managing Adverse Events after Vaccination, available at: http://www.anthrax.mil/education/clinician/clinicians.asp, provide detailed guidance for clinicians on adverse events, treatment guidelines, medical exemption criteria, and the Vaccine Adverse Events Reporting System (VAERS). They also include advice for managing a large or persistent local reaction to previous anthrax vaccinations.

4.4.5. The DoD Vaccine Healthcare Centers should be utilized by providers as needed. This network is the DoD vaccine center of excellence for consultation and clinical care of those experiencing adverse events after vaccination. Contact information can be found at the following website: http://www.vhcinfo.org/vhcnet_contact.htm. In addition, providers can contact the DoD Vaccine Clinical Call Center at 1-888-210-6469. This call center is available 24 hours a day, 7 days a week.

4.4.6. Adverse reactions from DoD directed immunizations are line of duty conditions. Information on healthcare access can be found in section 5.5 of this plan.

4.4.7. Adverse Event Reporting.

4.4.7.1. In accordance with AFJI 48-110, sect. 2-10, healthcare providers report adverse events related to vaccines to VAERS. Reporting may be done through the VAERS website (http://www.vaers.hhs.gov) or by submitting hard copies of the report as directed. VAERS forms can be obtained from the VAERS website, ordered by calling 1-800-822-7967, or from the Air Force Complete Immunization Tracking Application (AFCITA).

4.4.7.2. Healthcare personnel are required to report adverse events resulting in hospitalization, a life-threatening event, lost duty time greater than 24 hours, an event related to suspected contamination of a vaccine vial and any event warranting permanent medical exemption from vaccination.

4.4.7.3. Health care providers are encouraged to report other adverse events that are considered unexpected in nature or severity.

4.4.7.4. Patients and their family members may also submit VAERS reports directly. IAW AFJI 48-110, healthcare personnel will assist the patient in completing the form, regardless of professional judgment about causal association to immunization.

4.4.7.5. Further guidance on documentation and where to send VAERS reports can be found in AFJI 48-110, sect. 2-10.f.

4.5. Medical Exemptions.

4.5.1. Individuals who have certain pre-existing conditions that preclude anthrax vaccination and some individuals who develop reactions during the vaccination series may warrant medical exemptions. These individuals must be identified so their status can be tracked in AFCITA and further vaccine administration appropriately managed. Granting medical exemptions is a medical function that must be performed by a privileged health care provider IAW AFJI 48-110, sect. 2-6.

4.5.2. There are two types of medical exemptions- temporary and permanent.

4.5.2.1. Temporary medical exemptions are indicated in situations where it is clinically inappropriate to administer the vaccine to an individual due to a condition that is expected to resolve or otherwise end. Examples include immunosuppressive therapy, serious acute diseases, post-surgical situations, pregnancy, and in some situations where a medical condition is being evaluated or treated. This would include significant vaccine-associated adverse events that are being evaluated, or while awaiting specialist consultation.

4.5.2.1.1. Temporary medical exemptions may be granted by any privileged military health care provider or based on the examination of a civilian provider. Temporary exemptions cannot exceed 365 days, and should be limited to the shortest duration necessary.

4.5.2.1.2. When evaluating individuals with possible adverse events following receipt of anthrax vaccine, use the Clinical Guidelines and/or advice from the DoD Vaccine Healthcare Centers to determine whether a medical exemption from subsequent doses of vaccine is indicated.

4.5.2.2. Permanent medical exemptions are generally warranted if the medical condition or adverse reaction is so severe that the risk of continued immunization is not justified.

4.5.2.2.1. Examples of situations which warrant a permanent medical exemption include severe reaction after a previous anthrax vaccination such that additional doses would pose an undue risk to the vaccine recipient, HIV infection or other chronic immune deficiencies, and evidence of immunity based on serologic antibody tests or documented previous anthrax infection.

4.5.2.2.2. If an individual's clinical case is complex or not readily definable, consult an appropriate medical specialist with vaccine safety assessment expertise, before a permanent medical exemption is granted. In addition, the original health care provider may consult with physicians located at the Vaccine Healthcare Center Network.

4.5.2.2.3. If the situation changes, a permanent medical exemption can be removed by a provider experienced in vaccine safety assessment.

4.5.2.3. Granting of medical exemptions may require a duty status change or deployment limitation for the individual. Any change in duty status/deployment eligibility due to a medical exemption must be processed IAW AFI 48-123, and/or additional AF guidance as released. The AVIP Medical OIC should consult with the Chief, Aerospace Medicine (SGP) for guidance as needed.

4.5.2.4. Use of medical exemption codes in AFCITA must be IAW AFJI 48-110, Table C-1.

4.5.2.5. If a patient disagrees with an initial medical decision or diagnosis, he or she may request a second opinion. If the patient disagrees with the second opinion, he or she may be referred directly to the Vaccine Healthcare Center Network.

4.6. Anthrax Vaccine Tracking and Documentation.

4.6.1. The Public Health Officer will:

4.6.1.1. Ensure personnel deploying to the USCENTCOM AOR are entered into the Deployment Tracking Module of Preventive Health Assessment and Individual Medical Readiness (PIMR) software. Individuals subject to mandatory anthrax vaccination based on their deployment location will be reflected as "red" in the AFCITA until they present to the Immunization Clinic and accept the anthrax vaccine.

4.6.1.1.1. Force Health Management (FHM) personnel will not sign off deployment checklists for personnel requiring mandatory anthrax vaccinations until/unless they are current for anthrax vaccinations in AFCITA.

4.6.1.2. Ensure FHM personnel send all eligible personnel requiring medical clearance for PCS to Korea to the Immunization Clinic for anthrax vaccinations as needed.

4.6.1.2.1. FHM personnel will not sign off on medical clearance forms for personnel PCSing to Korea who are subject to mandatory vaccinations, until/unless they are identified as current for anthrax vaccinations in AFCITA.

4.6.1.3. Send the Medical Status Report indicating personnel due or overdue for mandatory anthrax vaccine to unit commanders in accordance with local procedures.

4.6.2. The Immunization Clinic will record all vaccinations in AFCITA IAW current AF guidance. Ensure a copy of DD Form 2766C is forwarded to the individual's medical record (if needed), and inform the individual verbally and in writing, when the next dose is due. The AFCITA worksheet printout or the MILVAX "Next Dose" cards (available at this link: http://www.anthrax.mil/AVIP2007/) can be used for written notification.

4.6.2.1. The Immunization Clinic will assign individuals who are subject to mandatory vaccinations in preparation for PCS to Korea to the "Korea" immunization group in AFCITA. This will ensure that the mandatory anthrax vaccination requirement can be tracked.

4.6.2.2. Immunization clinic personnel will not sign off on deployment checklists or PCS medical clearance forms for individuals subject to mandatory vaccination until/unless they are identified as current for anthrax in AFCITA.

4.6.3. Records regarding individuals subject to mandatory vaccination who are identified as "due" for next dose will turn yellow in AFCITA and will be placed on the Unit Commander's Individual Medical Readiness Not Ready Report. If the individual does not

present to the Immunization Clinic during the “due” grace period, the individual’s record will become “overdue” and turn red in AFCITA. This will affect the unit’s Individual Medical Readiness (IMR) rate.

4.6.4. Records regarding individuals who volunteer for anthrax vaccinations will not change status in AFCITA (will remain coded green) and will not appear on immunization due rosters. Immunization clinic personnel must ensure that these individuals receive clear guidance on when to return for their next scheduled dose. Use of the MILVAX “Next Dose” card is highly encouraged for these individuals.

4.7. Medical Logistics/Vaccine Distribution. The US Army Medical Materiel Agency (USAMMA) is responsible for coordinating the distribution of anthrax vaccine within DoD. The Air Force Medical Operations Agency Procurement Services (AFMOA/SGSLC) is the AF distribution point of contact for this program. The Air Force POC can be contacted at DSN 343-4170, or Commercial 301-619-4170.

4.7.1. Base level medical logistics personnel can order the anthrax vaccine from USAMMA by using the on-line Air Force Anthrax Vaccine Request Form (instructions for ordering can be found at http://www.usamma.army.mil/vaccines/anthrax/antxhome.htm).

4.7.1.1. When USAMMA receives the vaccine order, they will ship AVIP tri-folds to the requestor (one for each dose ordered). Tri-folds sent with the vaccine are for Immunization Clinic use only. Installations needing tri-folds for other uses can print them locally from the MILVAX website (www.anthrax.mil/AVIP2007/).

4.7.1.2. USAMMA will check the MILVAX listing of registered AVIP Immunization Activities to ensure the requestor is registered to administer the anthrax vaccine. USAMMA will also verify that the requestor will be available to receive vaccine before authorizing shipment of vaccine.

4.7.2. Anthrax vaccine is heat and cold sensitive. The vaccine must be kept at the appropriate storage temperature range throughout the entire vaccination process. It should be removed just prior to giving the shot. This vaccine generally should not be "pre-drawn" for administration. The USAMMA web site provides additional guidance on handling, storage, transportation, and administration of anthrax vaccine.

Chapter 5

ADMINISTRATIVE ISSUES

5.1. Emergency-Essential (E-E) Civilians (per section 1.4.1 of this plan).

5.1.1. Unit commanders must identify US-national E-E civilian employees eligible for vaccination and direct them to a military medical unit for education, screening, and vaccination as appropriate. Unit commanders will provide a list of E-E civilians eligible for vaccination to the MTF/immunization clinic. E-E civilians must present proof they are an E-E employee (e.g., identification card) and immunization record, if available, to medical personnel.

5.1.2. For E-E civilians that are non-bargaining unit members, vaccinations will begin immediately.

5.1.3. For E-E civilians that are bargaining unit members who have already deployed (or are scheduled to arrive within 30 days) or currently reside in USCENTCOM or on the Korean Peninsula, vaccinations will begin immediately; post-implementation negotiations will be accomplished if immunizations requirements, in general, are not already a contractual requirement.

5.1.4. For E-E civilians that are bargaining unit members who are scheduled to, but have yet to deploy to USCENTCOM or the Korean Peninsula, impact and implementation bargaining may be required if the employees are not already required to receive immunizations, in general. Upon completion, the servicing civilian personnel flight will inform the military medical community that bargaining obligations have been completed and commanders will provide a list of E-E civilians eligible for vaccination to the MTF/immunization clinic.

5.2. Mission Essential (M-E) Contractor Employees (per section 1.4.1 of this plan).

5.2.1. Vaccination of US-national M-E contractor personnel will be a requirement of the applicable contract.

5.2.2. If not already done, commanders must, IAW existing SAF/AQC guidance, identify their M-E services and inform the cognizant contracting officers. Contracting officers will modify contracts that do not already cover the designated M-E services. Contracting officers should take appropriate actions to address: identification of the M-E services; the contractor's responsibility to identify their employees who will perform the M-E services during a crisis; funding and liability; and authorization for vaccination and related medical care.

5.2.3. Once M-E services are contractually covered, contracting officers will direct contractors to identify their vaccine eligible M-E employees. Contracting officers will provide a list of these employees to the unit commanders and the Immunization Clinic

NCOIC. Commanders will then direct M-E contractor personnel to a military medical unit for education, screening, and vaccination as appropriate.

5.3. Exceptions to Policy (ETPs). In accordance with References J through O (see Attachment 1), select groups previously granted ETPs will be subject to mandatory vaccinations (see https://www.a3a5.hq.af.mil/a3s/a3sc/CCBRN_resource/biological/anthrax/index.asp (NIPRNET) or http://www.a3a5.hq.af.smil.mil/a3s/a3sc/CCBRNE_resource/biological/anthrax/index.asp (SIPRNET) for currently approved ETPs).

5.3.1. Requesting ETPs.

5.3.1.1. ETPs for the AVIP require approval by the ASD(HA). There are two ways to request an ETP. The first is to submit an official request for an ETP from the Wing level through the MAJCOM to HQ USAF/A3SC for action. The second is to submit the request for an ETP through the appropriate COCOM, who will in turn submit it to the Director, Joint Staff. Generally, requests for ETPs should only be sent to the COCOM if the proposed ETP affects personnel from more than one Service.

5.3.1.2. To make the strongest case possible to the ASD(HA) for an ETP, requests from the Wing should have a cover memo from the Wing Commander that contains the request and supporting rationale. The memo should have an attached Point Paper that provides key figures on the situation that warrants the request. This includes information on the number of personnel to be vaccinated, the mission/role of the personnel, and the specific reason current policy does not permit vaccination. HQ USAF/A3SC can assist the Wing and MAJCOMs in drafting their requests and provide general advice on the likelihood of approval.

5.3.1.3. The Wing Commander should submit the request to their MAJCOM A3 or A5 (Operations or Plans directorate as appropriate) for endorsement and forwarding to HQ USAF/A3SC. HQ USAF/A3SC will staff the request through appropriate HAF offices and then forward it to the Director, Joint Staff, who (if they concur with the request) will then staff it to the ASD(HA) for approval.

5.3.2. Execution of ETPs. Upon final approval of an ETP, the MAJCOM SG POC will provide guidance to the appropriate installation medical personnel on the proper methodology for identifying/recording the personnel impacted by the ETP in AFCITA.

5.4. Waivers and Exemptions.

5.4.1. Religious Waivers. Guidance for religious waivers can be found in AFJI 48-110, Immunizations and Chemoprophylaxis, section 2.6. (b) (3). IAW this AFJI, the Air Force does not grant permanent immunization exemptions for religious reasons. The MAJCOM Commander is the approval and revocation authority for temporary exemptions.

5.4.2. Administrative and Medical Exemptions. It is desirable that all personnel deploying to higher-threat areas receive at least their first three doses prior to deployment. In those rare

instances when an individual is not able to take or continue the anthrax series due to: (1) an administrative exemption, granted by a commander or supervisor; or (2) a medical exemption granted by a privileged healthcare provider (e.g. physicians, nurse practitioners, and physician assistants), the individual is still deployable.

5.4.2.1. Administrative Exemptions (see Reference D).

5.4.2.1.1. Administrative exemptions are authorized by AF/A1 for military members, E-E civilians, and specified contractors who meet specific criteria.

5.4.2.1.2. Commanders may exempt from the AVIP personnel normally subject to mandatory vaccination who are separating within 180 days who meet the following conditions: (a) they are not currently assigned or deployed to a designated higher threat area, (b) they are not scheduled to perform duty in a designated higher threat area (including temporary duty); and, (c) the commander has not directed vaccination because of overriding mission requirements. Granting administrative exemptions is a personnel function, usually controlled by an individual's unit.

5.4.2.1.3. Official documentation (i.e., from the Squadron Commander, MPF) including the administrative code and duration (specific date, temporary, indefinite) of exemption will be presented to the Immunization Clinic. Validated administrative exemptions will then be entered into AFCITA by the Immunization Clinic staff.

5.4.2.2. Medical Exemptions. Medical exemptions may be temporary or permanent and may be based on pre-existing conditions or result from vaccine adverse reactions. Detailed information on medical exemptions can be found in section 4.5 of this plan. Commanders should contact the installation AVIP Medical OIC if they need more information on this issue.

5.5. Healthcare Access Guidelines. At the time of immunization, all vaccine recipients will be provided information on potential adverse events, the 24 hour number for the DoD Vaccine Clinical Call Center, and the toll-free number for the Military Medical Support Office (MMSO). This information is found in the AVIP tri-fold brochure, which will be provided to all personnel receiving the anthrax vaccine.

5.5.1. Whenever an individual presents to an MTF expressing a belief that the condition for which the treatment is sought is related to an immunization received in a DoD clinic, they are authorized initial or emergency care to evaluate and treat an actual or perceived adverse reaction. Care may also be provided by a civilian medical facility in the following circumstances: an individual believes the situation to be an emergency and the civilian hospital is the nearest facility or an individual is on leave status, TDY or in a non-duty status (ARC personnel) and there are no MTFs within 50 miles. Pre-approval may still be required depending on the specific circumstances when not an emergent situation.

5.5.1.1. ARC Personnel. An adverse reaction from a DoD-directed immunization is a line-of-duty condition. Therefore, medical care must be provided for an ARC member who believes his/her medical complaint is related to receiving the DoD-directed immunization. Evaluation or treatment will not be denied or delayed, pending a line-of-duty determination. Once treatment has been rendered or the individual's emergent condition is stabilized, a Line of Duty and/or Notice of Eligibility will be determined as soon as possible.

5.5.1.1.1. ARC personnel should notify their Reserve Medical Unit (RMU) to obtain LOD related paper work if it is not an emergent situation. After the emergency is resolved the member must notify their RMU to complete the LOD for services rendered. The LOD is also required for authorization of care to continue as deemed by medical authority. Contact the Military Medical Support Office (MMSO) at 1-888-MHS MMSO (1-888-647-6676) as soon as possible when seeking care from their personal healthcare providers or any non-military treatment facility.

5.5.1.1.2. AFR and ANG may supplement this plan with additional guidance on LOD/Eligibility requirements for their personnel as needed.

5.5.1.2. DoD E-E Civilians. DoD E-E civilians who are required to take the vaccine must also be provided with options for receiving medical care in the event they believe their medical complaint is related to the DoD administered vaccine. The following steps should be taken if they believe they have suffered an adverse reaction to a DoD administered vaccine and they would like to seek medical attention.

5.5.1.2.1. E-E civilians should contact their supervisor or Civilian Personnel Flight (CPF) and specify that they believe they have suffered a reaction and would like medical attention. Additionally, they should notify the DoD medical facility that administered the vaccine in question.

5.5.1.2.2. The CPF will provide them with a Federal Employees' Compensation Act (FECA) claim form.

5.5.1.2.3. The installation or agency Injury Compensation Program Administrator (ICPA) will explain the options under the FECA and, if requested, arrange for a medical examination and/or treatment authorization form (CA-16) to be issued. Initially, individuals may select a physician of their choice or request treatment at the nearest military MTF, if available.

5.5.1.2.4. Upon receiving authorization for medical care, E-E civilians should proceed to the treating facility without delay. They should request that the treating physician provide the CPF and the MTF with a copy of the initial medical report. The original medical report should be forwarded to the Department of Labor's Office of Workers' Compensation Programs.

5.5.1.2.5. Encourage individuals to maintain contact with their supervisor and the CPF throughout the period of treatment regarding their ability to return to duty. The ICPA at the installation or agency can assist with return-to-duty efforts, as well as subsequent queries regarding FECA benefits.

5.5.1.3. DoD contractors. DoD contractor employees who are required to take the vaccine must also be provided with options for receiving medical care in the event they believe their medical complaint is related to the DoD administered vaccine.

5.5.1.3.1. Contractor employees should contact their supervisor and make the situation known. Concurrently, they should notify the DoD medical facility that administered the vaccine of the adverse event. If they need to obtain medical care, they should request guidance from their employer as to what procedures they need to follow and/or which claims forms they need to complete as dictated by the company's compensation carrier. They should request the treating medical facility provide a copy of any medical report related to the suspected vaccine adverse event.

5.6. Refusal Management.

5.6.1. Management of Initial Vaccine Refusal in the Immunization Clinic.

5.6.1.1. If an individual subject to mandatory vaccination, as identified in paragraph 1.4.1 of this plan, refuses an anthrax vaccination in the immunizations clinic, the technician should notify the Immunization Clinic NCOIC/OIC before that individual leaves the clinic. The NCOIC/OIC (or technician if they're not available) should verify again that the individual is subject to mandatory vaccination and that the individual has been offered the tri-fold and the opportunity to ask questions and have them answered about information in the tri-fold.

5.6.1.2. If the individual still chooses to refuse the anthrax vaccine, clinic personnel will follow the steps outlined in Attachment 6, AVIP MTF Checklist for Cases of Initial Vaccine Refusal. Clinic personnel will complete steps 1-4 of Attachment 6 before the individual leaves the immunization clinic.

5.6.1.3. Immunization clinic personnel will ensure documentation is completed as required in Attachment 6 and notify the AVIP Medical OIC (or locally designated officer) of the refusal in a timely manner.

5.6.1.4. The AVIP Medical OIC (or locally designated officer) will notify the individual's commander or designee of the refusal as defined in Attachment 6 within 24 hours. This notification is an accountable notification under the Health Information Portability and Accountability Act (HIPAA), and must be accounted for using the Protected Health Information Management Tool (PHIMT) or the MTF's approved method.

5.6.1.5. Immunization clinic personnel will not assign an exemption code in AFCITA to individuals initially refusing anthrax vaccination.

5.6.1.6. Cases of initial vaccine refusal should be handled with the appropriate regard to the individual's privacy. There is no requirement for MTFs to track individuals, or numbers of individuals initially refusing the anthrax vaccine, and there should be no reporting of these refusals outside the chain of command. Any inquiries concerning anthrax refusals should be referred to the installation Freedom of Information Act (FOIA) office with a copy to the installation legal office.

5.6.2. Military Members. Requiring a military member to take the anthrax vaccine constitutes a lawful order. However, the member's commander may exercise his or her discretion in handling refusal cases. If an individual indicates he or she is going to refuse the anthrax vaccination or has initially refused an anthrax vaccination the following approach should be used.

5.6.2.1. Find out why the individual is reluctant

5.6.2.2. Provide the member with appropriate education

5.6.2.3. Combinations of concerns may require education by a number of people; for example:

5.6.2.3.1. Concerns with vaccine safety or efficacy should be sent to the supporting medical organization (if not previously accomplished). Medical education should be tailored to the specific concerns of the individual (efficacy, reproduction, allergic reactions, etc.) and should be accomplished by a health care provider knowledgeable about the anthrax vaccine and who is able to address the specific medical concerns of the individual. The medical counseling will be documented in the individual's medical record.

5.6.2.3.2. Concerns with the threat should be addressed by intelligence personnel (either medical or line).

5.6.2.3.3. If the member is still reluctant after additional education, send the member to the Area Defense Counsel for an explanation of the potential consequences of his/her refusal.

5.6.2.4. After the appropriate counseling, commanders should again order the individual to take the vaccine.

5.6.2.5. If the member still refuses, consult with JA for appropriate action.

5.6.3. E-E Civilian-Specific Actions

5.6.3.1. E-E civilian employees who do not receive the DoD-directed vaccination and therefore cannot perform their E-E duties are subject to provisions in AFI 36-507, Mobilization of the Civilian Work Force.

5.6.3.2. These provisions may include assigning an alternate to the E-E duties, reassignment of the employee, or adverse action including termination of employment. Such employees should be counseled by their supervisors in consultation with the servicing CPF, regarding possible ramifications of refusing the vaccination.

5.6.3.3. Recommend and provide medical or intelligence education if their concerns are in those areas.

5.6.4. Contractor-Specific Actions. Contract employees who do not receive the DoD-directed vaccination are subject to provisions of their contract. Recommend and provide medical or intelligence education if their concerns are in those areas. Contact SAF/AQCX for further guidance.

Attachment 1

REFERENCES

A. Under Secretary of Defense for Personnel and Readiness Memorandum, "Implementation of the Anthrax Vaccine Immunization Program (AVIP)," December 6, 2006

B. Deputy Secretary of Defense Memorandum, "Anthrax Vaccine Immunization Program (AVIP)," October 12, 2006

C. Under Secretary of Defense for Personnel and Readiness Memorandum, "Administrative and Clinical Execution Guidance for Reintroduction of the Anthrax Vaccine Immunization Program (AVIP)," August 6, 2002

D. Under Secretary of Defense for Personnel and Readiness Memorandum, "Policy on Administrative Issues Related to the Anthrax Vaccination Program," August 6, 2002

E. Assistant Secretary of Defense for Health Affairs Memorandum, "Policy on Clinical Issues Related to Anthrax Vaccination," August 6, 2002

F. Deputy Secretary of Defense Memorandum, "Reintroduction of the Anthrax Vaccine Immunization Program (AVIP)," June 28, 2002

G. Deputy Secretary of Defense Memorandum, "Expansion of Force Health Protection Anthrax and Smallpox Immunization Programs for DoD Personnel," June 28, 2004

H. Under Secretary of Defense for Personnel and Readiness Memorandum, "Expansion of Force Health Protection Anthrax and Smallpox Immunization Programs for Emergency-Essential and Equivalent Department of Defense Civilian Personnel," September 22, 2004

I. Army Regulation 40-562/BUMEDINST 6230.15A/AFJI 48-110 CG COMDTINST M6230.4F, "Immunizations and Chemoprophylaxis," September 29, 2006

J. Assistant Secretary of Defense for Health Affairs Memorandum, "Request for Exception to Policy for Smallpox and Anthrax Vaccinations for Selected NORTHCOM Forces," March 3, 2003

K. Assistant Secretary of Defense for Health Affairs Memorandum, "Exception to Policy for Anthrax Vaccinations for Select Airborne Warning and Control System Personnel," May 24, 2004

L. Assistant Secretary of Defense for Health Affairs Memorandum, "Exception to Policy for Anthrax Vaccinations for Select Airborne Warning and Control System Personnel," December 1, 2003

M. Assistant Secretary of Defense for Health Affairs Memorandum, “Exception to Policy for Priority Group II Anthrax Vaccinations for Selected United States Air Forces in Europe (USAFE) Personnel,” September 4, 2003

N. Assistant Secretary of Defense for Health Affairs Memorandum, “Exception to Policy for Anthrax Vaccination for Selected AMC Personnel,” March 10, 2003

O. Under Secretary of Defense for Personnel and Readiness Memorandum, “Exception to Policy of Anthrax Vaccination of Forward Deployed Forces (FDNF) and III Marine Expeditionary Force (MEF) in the Resumption of Anthrax Vaccination Program (AVIP) under the Emergency Use Authorization (EUA),” August 17, 2005

Attachment 2

AVIP REGISTRY AGREEMENT

AVIP Medical Officer-in-Charge (OIC): read, sign, and return to addresses below after Medical Commander has also signed acknowledgment.

I have read and understand the USAF AVIP Implementation Plan describing the requirements for anthrax immunization, dated January 2007, at this url: https://www.a3a5.hq.af.mil/a3s/a3sc/CCBRN_resource/biological/anthrax/index.asp.

Each of the items on the checklist (AF Implementation Plan, Attachment 3) has been fulfilled for our unit or activity. I have included a copy of the completed checklist with this request. I understand the monthly reporting requirements (AF Implementation Plan, Attachment 4). If the Military Vaccine (MILVAX) Agency does not receive a report on time, they may contact the people named below to obtain another copy.

For medical units: My staff has informed or reminded every healthcare worker with responsibilities for administering anthrax immunizations (including immunization backup technicians) of the importance of confirming which category of the policy (mandatory or voluntary) a person is in before administering the anthrax vaccine. For personnel for whom the vaccination is voluntary, the actual staff member administering the vaccine will verbally confirm this before the actual injection. These steps are intended to prevent medication errors.

Our unit or activity is ready to comply with the DoD policies for anthrax vaccination. I accept responsibility for AVIP education and monthly reporting.

If I am assigned other duties and am no longer the AVIP Medical OIC, I will notify the MILVAX Agency before departure. I will instruct my replacement to complete his or her own Registry Agreement and forward it to the MILVAX Agency.

_____	_____	_____
AVIP Medical OIC (printed name, title)	(signature)	(date)

DSN telephone: E-mail address:
Commercial telephone:

_____	_____	_____
Medical Commander (printed name, title)	(signature)	(date)

This agreement corresponds to immunization team(s) for the following unit, activity, or vaccination clinic: (Unit or activity name, address and zip code)

Unit/Activity/Clinic Name:_____

Address:_____ Zip Code:_____ -____

The medical activity storing anthrax vaccine and administering the anthrax immunizations, medical unit or activity name, address and zip code (not required if same as above).

Unit/Activity/Clinic Name:_____

Address:_____ Zip Code:_____ -____

Alternate points of contact- at least one is required (Name, DSN telephone number, email)

	Name	DSN	Email
1.			
2.			
3.			

Send To: Director, Military Vaccine Agency, fax: 703-681-4692, DSN 761-4692
NIPR: AVIPreports@amedd.army.mil
SIPR: vaccines@hqda-S.army.Smil.mil
Voice: 703-681-5101, DSN 761-5101.
Director will return an acknowledgment letter, authorizing receipt of anthrax vaccine shipments.

Courtesy Copy To: HQ USAF/A3SC, fax: 703-614-7221, DSN 224-7221
NIPR: AFA3SC.Workflow@pentagon.af.mil
SIPR: AFA3SC.Workflow@af.pentagon.smil.mil
Voice: 703-614-5954, DSN 224-5954
Please use subject line “AVIP OIC”

Attachment 3

AVIP IMPLEMENTATION CHECKLIST

Unit: _____ Location:_____

AVIP Medical OIC: _____ Date Checklist Completed: _____

Ensure these items have been completed before giving anthrax vaccinations (reassess items on this checklist periodically):

[ ] 1. Collect all previous AVIP tri-folds from Dec 2005 or earlier and discard them. Do not retain them for future use. Be sure to remove obsolete tri-folds from pamphlet racks in waiting rooms, on bulletin boards, intranets, etc.

[ ] 2. Obtain sufficient AVIP tri-folds dated 12 Oct 06 or later, enough to give a personal copy to each person to be vaccinated, one for each dose. Each anthrax vaccine shipment will include AVIP tri-fold brochures equal to the number of doses ordered. Additional color copies of these revised tri-folds are available by emailing usammadoc@det.amedd.army.mil or at www.anthrax.mil/AVIP2007/.

[ ] 3. Obtain AVIP briefing slides. Available from www.anthrax.mil/AVIP2007 If you need these slides shipped to you in hard copy or on a CD-ROM, call 877-GET-VACC or send an email request to AVIPReports@amedd.army.mil, SIPRNET vaccines@hqda-S.army.Smil.mil.

[ ] 4. Coordinate with supporting medical activity or ensure organic medical support has required AVIP training for vaccinators and healthcare providers. Assure all vaccinators (primary and back-up), clinical supervisors of vaccinators, preventive medicine and public health staff, and relevant healthcare providers (e.g., allergy-immunology, ambulatory care, flight medicine, emergency care) are familiar with the clinical science for anthrax vaccine and DoD requirements. Use training course available at www.anthrax.mil/education/. Annotate training records accordingly. Vaccinators acknowledge the content in the following materials:

a. HQ USAF/A3/5 message, "Implementation of Mandatory Anthrax Vaccine Immunization Program," January 2007.

b. AVIP healthcare provider briefing slides at www.anthrax.mil/AVIP2007/.

c. BioThrax package insert: available with every vaccine vial or at www.emergentbiosolutions.com/pdf/emergent_biothrax_us.pdf.

d. AVIP tri-fold brochure dated 12 Oct 06 or later.

e. Reporting procedures for Vaccine Adverse Events Reporting System (VAERS) at www.vaers.hhs.gov .

f. Some medical conditions may require temporary or permanent medical exemptions from anthrax immunization (e.g. serious allergic reactions to anthrax vaccination, moderate or severe illness, pregnancy, latex anaphylactic sensitivity, immune-suppressive conditions, Guillian-Barré syndrome, previous anthrax infection). Medical providers should be familiar with package insert prescribing information and grant appropriate exemptions. Exemptions must be documented in electronic tracking system and all temporary exemptions must have an end date indicated. The most effective way to identify early pregnancy is to ask discreetly for date of last menstrual period and whether the last menses was normal and on time. Offer pregnancy testing before any immunization.

[ ] 5. Assure health care personnel are trained and that the Immunization Clinic NCOIC documents training for immunization technicians, IBTs and IAs as appropriate in their formal training record.

[ ] 6. Understand criteria for eligibility for anthrax vaccination (Under Secretary of Defense (P&R) memo, 6 Dec 06; HQ USAF Plan for Implementing the AVIP, January 2007, available at https://www.a3a5.hq.af.mil/a3s/a3sc/CCBRN_resource/biological/anthrax/index.asp.

[ ] 7. Understand that AVIP includes a mandatory component and a voluntary component, including (a) who has the right to decline vaccination, (b) the reasons why the military and civilian leadership of the Armed Forces strongly recommends immunization for military members under the voluntary program.

[ ] 8. Inform or remind every healthcare worker with responsibilities for administering anthrax vaccinations (including immunization back-up technicians) of the importance of confirming the category (mandatory or voluntary) of personnel receiving anthrax vaccination before the actual injection. This step is intended to prevent medication errors. Healthcare workers will also verify which dose number the vaccination is in the series (ensuring it is due), inform the recipient when the next dose will be due, and make sure the vaccination is entered into the immunization tracking system (AFCITA).

[ ] 9. Assure clinic has sufficient trained personnel with passwords to enter vaccination data into AFCITA at the time of vaccination or has a plan to train them expeditiously and can assuredly record immunizations on SF Form 601, DD Form 2766, Deployable Medical Record, PHS Form 731, or similar form.

[ ] 10. Assure AVIP OIC and commander understand reporting requirements. These reports go to the Military Vaccine Agency, at the direction of the Deputy Secretary of Defense.

[ ] 11. Assure OIC or commander understands the need for officer(s) not directly involved in the AVIP to perform spot checks of anthrax immunizations operations to assure that tri-folds

are being provided and voluntary vaccine recipients are not receiving anthrax as a mandatory vaccination.

[ ] 12. Assure clinic and medical logistics personnel have been trained in cold-chain management procedures, including prompt refrigeration of anthrax vaccines upon receipt. Alarm systems are used to protect large inventories.

[ ] 13. Assess available inventory of anthrax vaccine (e.g., in medical logistics warehouse). Arrange for shipment of initial quantity of anthrax vaccine, but clinics may not take physical possession of the vaccine until Military Vaccine Agency provides email approval of the registry agreement.

Reassess items on this checklist periodically.

Attachment 4

AVIP MONTHLY REPORT TEMPLATE

MEMORANDUM FOR Director, Military Vaccine (MILVAX) Agency

Fax: 703-681-4692, DSN 761-4692. Voice 877-GET-VACC. DSN 761-5101
NIPR: AVIPreports@amedd.army.mil
SIPR: vaccines@hqda-S.army.Smil.mil

SUBJECT: Report of Compliance with Conditions for Anthrax Vaccine Immunization Program (AVIP)

1. Report for the month of: _____

a. [If the following sentence is true, submit it as your report. If the following sentence is not true, change the text to explain what occurred to make the proposed text untrue. Be sure to specify the number of people vaccinated without an option to refuse and be prepared to provide a list of their names.]

No one covered by the voluntary policy received anthrax immunization against his or her will, or without being informed of their right to decline vaccination, or otherwise in violations of their right to decline, at this unit.

b. Remedy. [If applicable, describe here steps taken to prevent noncompliance with DoD policy from happening again. If not applicable, state "not applicable."]

2. Our unit administered _____ doses of anthrax vaccine during this period.

3. I certify the accuracy of this report to the best of my knowledge.

_____ _____ _____
Name Title Date

If faxed, sign on line above. If emailed, send as scanned PDF document or from approving authority's or alternate official's email account.

Contact email: _____

Contact telephone #: _____

Unit Address and Zip Code: _____

Activity/Unit/AFB/AB: _____

Attachment 5

AVIP CHECKLIST FOR VACCINATORS

[ ] I. Verify whether vaccine is mandatory for individual or voluntary.

Mandatory vaccine for following personnel (see section 1.4.1):
- Must be military member, emergency essential DoD civilian, or mission essential DoD contractor deploying/PCSing/living in designated geographic areas for 15 or more consecutive days *(currently CENTCOM AOR and Korean peninsula ONLY)*
- Some specifically designated units/personnel mandatory due to ETPs, (individuals should be identified on signed letter from the applicable unit commander) consult AVIP Plan/OIC/MAJCOM/Air Staff with questions

Voluntary vaccine for following personnel (see section 1.4.3):
- Any member who has previously received at least 1 dose anthrax vaccine, including adult family members.
- Additional persons eligible for voluntary vaccination based on location or status as defined in the current AF AVIP Plan.

[ ] II. Verify individual has no medical contraindication to anthrax vaccination. If individual answers YES to any question below, consult with medical provider for disposition.

1. For women: Are you pregnant, or is there a chance you could become pregnant in the next month?
2. Have you had any serious adverse reaction to a previous anthrax vaccination?
3. Do you have a weakened immune system? (This may be caused by cancer, cancer tx, HIV/AIDS, or immunosuppressive meds)
4. Are you currently suffering from an active moderate or severe illness?
5. Have you ever had an active anthrax infection?
6. Have you ever had Guillain-Barre Syndrome (GBS)?
7. Have you ever had a serious allergic reaction to latex?

[ ] III. Offer individual Anthrax Educational Tri-fold, give time to go over tri-fold and ask any questions about the vaccine.

[ ] IV. Administer vaccine and update AFCITA. If individual subject to mandatory vaccination due to PCS to Korea, add individual to “Korea” immunizations group in AFCITA. Print out new DD 2766C for medical record. Give individual date for next scheduled dose.

[ ] V. If vaccine is mandatory and individual refused the vaccine, notify NCOIC/OIC to complete steps in AVIP Initial Refusal checklist with individual in clinic.

Attachment 6

AVIP MTF CHECKLIST FOR CASES OF INITIAL VACCINE REFUSAL

Completed in the Immunizations Clinic

[ ] 1. Verify that vaccine is mandatory for individual. See AF AVIP Plan for personnel covered by mandatory vaccination requirement.

[ ] 2. Verify that individual has been offered the educational tri-fold and been given the opportunity to ask any questions about information in the tri-fold.

[ ] 3. Verify that individual wishes to refuse the mandatory anthrax vaccine. Verify name of individual's unit CC. Do not sign off on any medical clearance paperwork that includes a mandatory anthrax vaccination requirement. Do not assign an exemption code in AFCITA.

[ ] 4. Read the following to the individual before they leave the immunization clinic after a refusal:

"You have initially refused a mandatory anthrax vaccination. The medical unit will notify your CC or his designee of this refusal.

The immunizations clinic will not sign off on your medical clearance for deployment and/or PCS as you currently do not meet requirements, and we will document this vaccine refusal in your medical record. If you decide to accept the vaccine at a later time, the vaccination will be documented in your immunization record, and the immunizations clinic will sign off all applicable PCS and/or deployment paperwork."

[ ] 5. Print out a current copy of the individual's DD 2766C, write out the following statement on the form and sign and date it:

"This individual refused a mandatory anthrax vaccination today after they were offered the AVIP tri-fold for education about the vaccine. They were notified that medical clearance paperwork can't be signed off without this vaccination and their CC would be informed of this initial refusal. The AVIP OIC [or locally designated officer] was notified of the refusal."

Send a copy of the annotated and signed DD 2766C to the AVIP OIC or locally designated officer and forward the original to medical records for inclusion in the permanent medical record.

[ ] 6. Notify AVIP OIC or your locally designated officer of individual's refusal.

Completed by the AVIP OIC or locally designated officer for CC notification

[ ] 1. Send individual's commander (or designee) an email notification of initial anthrax vaccine refusal within 24 hours.

a. Type (or cut/paste) the following or similar information into the text box:

"Sir/Ma'am,

[INSERT: Name, grade, last 4 of member's SSAN, Member's Unit/Organization]

The individual listed above has refused to accept a mandatory anthrax vaccination after being offered initial education about the vaccine in the immunization clinic.

The member was counseled that the medical unit would notify you of this refusal. His/her deployment/PCS paperwork has not been signed off for medical clearance, as he/she does not currently meet requirements.

Please contact [INSERT Local POC's contact info here] for questions about this issue.

Signed"

[ ] 2. Follow up email notification with a phone call to individual's commander or designee to ensure receipt of notification.

[ ] 3. Enter the email into the Protected Health Information Management Tool (PHIMT) or account for it using the MTF's approved method for accounting for HIPAA disclosures. Do not enter a copy of the email into the patient's medical records.