UNDER SECRETARY OF DEFENSE
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PERSONNEL AND READINESS

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
ASSISTANT SECRETARIES OF DEFENSE
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
INSPECTOR GENERAL, DEPARTMENT OF DEFENSE
DIRECTORS OF DEFENSE AGENCIES
COMMANDANT OF THE US COAST GUARD

SUBJECT: Implementation of Resumption of the Anthrax Vaccine Immunization Program (AVIP) Under Emergency Use Authorization (EUA)

References: (a) Deputy Secretary of Defense Memorandum, "Resumption of the Anthrax Vaccine Immunization Program (AVIP) Under Emergency Use Authorization (EUA)," April 25, 2005

(b) Food and Drug Administration: Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Availability, 70 *Federal Register* 5452-5256, February 2, 2005 (WWW.FDA.GOV/CBER/VACCINE/ANTHRAXEUA.HTM)

Reference (a) directed the Military Services to amend their anthrax vaccination plans to resume the AVIP under conditions set forth in the EUA issued January 27, 2005 (reference (b)) and directed the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) to issue these detailed instructions to implement that resumption.

1. Applicability and Scope.

The following categories of individuals are eligible for vaccination under the EUA.

1.1. Uniformed personnel, to include forces afloat, and civilian and contract Mariners under Commander, Military Sealift Command serving in the Central Command area of responsibility for 15 or more consecutive days.

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

1.3. Uniformed personnel assigned to special mission units, units with biowarfare- or bioterrorism-related missions, and other specially designated missions, as recommended by the Chairman of the Joint Chiefs of Staff (or designee) and approved by the USD(P&R).

1.4. Upon notification by the Executive Agent that appropriate consultation procedures have been completed, emergency-essential and equivalent DoD civilian employees assigned for 15 or more consecutive days to the U.S. Central Command area of responsibility or Korea. For this purpose, "equivalent" personnel means other personnel whose duties meet all the requirements of 10 U.S.C. § 1580, but who have not been designated as "emergency-essential."

1.5. DoD contractor personnel carrying out mission-essential services and assigned for 15 or more consecutive days to the U.S. Central Command area of responsibility and Korea, if provided for in the contract.

1.6. In the U.S. Central Command area of responsibility and Korea, the following categories of individuals, upon request:

1.6.1. U.S. government civilian employees and U.S. citizen contractor personnel other than those referred to in paragraphs 1.4 and 1.5.

1.6.2. Adult family members, 18-65 years of age, accompanying DoD military and civilian personnel.

1.6.3. U.S. citizen adult family members, 18-65 years of age, accompanying U.S. contractor personnel if provided for in the contract.

1.7. Other individuals approved by USD(P&R), consistent with reference (b). The Secretaries of the Military Departments, Commandant of the Coast Guard, and Combatant Commanders may, based on critical mission impact, recommend to USD(P&R) for eligibility for vaccination under the EUA other personnel who are at heightened risk of exposure due to attack with anthrax.

2. <u>EUA Condition: Information to Healthcare Providers</u>.

As required by reference (b), a condition of the EUA is that the Services and affected Defense Agencies shall implement an educational and information program for healthcare providers and authorized dispensers (i.e., vaccinators) conducting the vaccinations. The following requirements apply.

2.1. This education program will inform healthcare providers that:

a. The FDA has issued the EUA for preventing inhalation anthrax,

b. Of the significant known and potential benefits and risks of anthrax vaccination (and the extent to which benefits and risks are unknown),

c. That no other product is approved by FDA to prevent anthrax before exposure,

d. Of the non-vaccine alternatives that are available and of their risks and benefits. It will also provide them the information that must be provided to potential vaccine recipients under section 3, below.

2.2. The manufacturer's package insert will be distributed with all vials of anthrax vaccine and will be available to healthcare providers and vaccinators. The insert also appears at www.bioport.com/AnthraxVaccine/Insert/AVAInsert.asp.

2.3. Healthcare-access guidance for all active, reserve, civilian and contractor personnel, and others affected by this policy will be provided. Guidance shall include, as appropriate, information on access to care for personnel located near or on a military installation, in a remote location, or in a travel duty or leave status.

2.4. Additional education and information materials for providers will be provided through the Executive Agent, and will be available electronically at www.anthrax.mil/eua.

2.5. Healthcare providers and vaccinators shall be familiar with all educational information provided to recipients, including the option to refuse information.

3. Condition of EUA: Information to Potential Recipients and Option to Refuse.

AVIP is a Commander's program. As required by reference (b), Commanders shall implement an educational and information program for potential recipients of vaccination and assure that they have the option to refuse. The following requirements apply.

3.1. This education program will inform potential recipients that the FDA has issued the EUA for preventing inhalation anthrax, of the significant known and potential benefits and risks of anthrax vaccination (and the extent to which such benefits and risks are unknown), that no other product is approved by FDA to prevent anthrax before exposure, that individuals have the option to accept or refuse anthrax vaccination, of the potential health and mission consequences of refusing administration, and of the alternatives to vaccination and of their risks and benefits.

3.2. All individuals eligible for anthrax vaccination under the EUA will be informed that: "You may refuse anthrax vaccination under the EUA, and you will not be punished. No disciplinary action or adverse personnel action will be taken. You will not be processed for separation, and you will still be deployable. There will be no penalty or loss of entitlement for refusing anthrax vaccination."

3.3. Personnel identified in paragraphs 1.1 through 1.5, above, shall be informed: "Your military and civilian leaders strongly recommend anthrax vaccination."

3.4. The required mode of providing this education to individuals will take the form of the AVIP trifold brochure – EUA Edition – dated April 5, 2005, or later. Each individual will be provided a copy of this brochure before being offered the vaccination. Through sign-in log or similar means, a record will be established to document that the trifold brochure was provided.

3.5. The brochure will be supplemented with education via, whenever possible, a set of standard briefing slides. Education and information materials for potential recipients will be provided through the Military Vaccine Agency, and be available electronically at www.anthrax.mil/eua.

3.6. Military leaders at all levels will respect this option to refuse during the EUA period. For individuals who express initial doubts about the value of anthrax vaccination, counseling may reinforce education and information messages and answer questions or concerns, but may not coerce.

3.7. Individuals referred to in paragraphs 1.1 through 1.5, above, who have refused anthrax vaccination during the EUA period should not be offered anthrax vaccination again, except in changed circumstances (e.g., at a new duty location, after the passage of a substantial period of time, such as 30 or more days). However, an individual eligible for anthrax vaccination may change his or her mind at any time and receive vaccination.

4. Record-Keeping.

Each Component is responsible for implementing a comprehensive immunization tracking system that incorporates member data, unit data, date of vaccination, and vaccine lot information. Each Service shall monitor documentation of immunization data. The information must be recorded in the individuals' medical record. Immunization tracking systems will record the exemption code "MD" for personnel who decline anthrax vaccination.

5. Other Requirements and Provisions.

5.1. Each Military Service and affected Defense Agency shall implement operational plans, consistent with references (a) and (b) and this memorandum, to administer the vaccinations to personnel initiating or resuming the vaccination series.

5.2. Personnel on orders to the U.S. Central Command area of responsibility or Korea may begin vaccinations up to 60 days before deployment or arrival.

5.3. During the period of the EUA, the policy of continuing the vaccine dosing series of six shots plus boosters for all personnel who begin it is suspended for personnel without a continuing duty assignment associated with the heightened risk of exposure.

5.4. Previously established medical exemptions and clinical policies (except as provided in paragraph 5.3, above) remain in effect, including policies relating to vaccine-associated adverse events. The Assistant Secretary of Defense (Health Affairs) may revise or supplement clinical policies.

5.5. Previously established policies applicable to vaccinations of Reserve Component personnel, when covered under section 1, above, remain in effect.

5.6. Clinical sites authorized to provide vaccinations during the EUA period will be restricted under procedures set by the Executive Agent.

5.7. Anthrax vaccinations may be provided in other venues (e.g., embassies and missions of the Department of State), provided that the requirements in this memorandum and reference (b) are met.

5.8. A U.S. District Court injunction against mandatory vaccinations remains in effect for the present time. A copy of the Court's Order and Opinion (available at www.anthrax.mil) shall be available at every vaccination clinic for potential vaccine recipients to read. The Executive Agent shall establish verification and reporting requirements to ensure compliance with the current prohibition on mandatory vaccinations. The Court has ordered DoD to provide weekly reports to the Court regarding compliance with the prohibition on mandatory injunctions.

5.9. Previously established management responsibilities remain in effect. The Secretary of the Army shall continue to function as Executive Agent, managing and administering the overall program and acting as focal point for the submission of information from the Services and projected vaccine program requirements. The Executive Agent shall issue operational instructions to the Services and coordinate and monitor Service implementation of the program. The Military Vaccine Agency is recognized as the operational activity of the Executive Agent.

5.10. The senior military official from each of the Services previously assigned to direct and implement their respective anthrax vaccine implementation plan shall continue in this role. As such, they will implement, monitor, evaluate and document the AVIP in their respective Services. Defense Agency AVIP officials responsible for their AVIP execution shall conform to the same standards.

5.11. The EUA is currently scheduled to expire July 27, 2005. At that time, other initiatives may result in resumption of the normal AVIP, including mandatory vaccinations for selected personnel. Alternatively, the EUA may be extended or other direction may be provided.

As directed by the Deputy Secretary, resumption of the AVIP requires scrupulous attention to the terms and conditions of the EUA. The AVIP remains a critically important component of the Force Health Protection program for the Armed Forces.

David S.C. Chu