DEPARTMENT OF THE NAVY
OFFICE OF THE SECRETARY
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SECNAVINST 6230.4
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SECNAV INSTRUCTION 6230.4

From: Secretary of the Navy
To: All Ships and Stations

Subj: DEPARTMENT OF THE NAVY (DON) ANTHRAX VACCINATION IMPLEMENTATION PROGRAM (AVIP)

Ref: (a) DoD Directive 6205.3 of 23 Nov 93 (NOTAL)
(b) SECNAVINST 6230.3 of 16 Nov 94
(c) OPNAVINST 3060.7A of 1 Oct 97 (NOTAL)

Encl: (1) DON Anthrax Vaccination Implementation Plan (AVIP)

1. Purpose. To establish Department of the Navy (DON) policy and assign responsibilities for the Anthrax Vaccination Implementation Program (AVIP) in accordance references (a) through (c).

2. Applicability. Applies to all commands and components of the Department of the Navy.

3. Background. The threat of biological warfare remains a constant risk to U.S. forces. Recent assessments have identified anthrax as the primary biological threat facing American service men and women today. As authorized by the provisions of reference (a), on 15 December 1997, the Secretary of Defense announced that all U. S. military forces, active and selected portions of the reserve component, will be immunized against the biological agent anthrax. This force-wide protective measure is the only way to ensure adequate protection against a threat which is lethal to unprotected individuals exposed to concentrations of the agent.

4. Policy. DON policy is to immunize personnel against validated biological warfare threats in sufficient time to develop immunity before deployment. Enclosure (1) provides DON anthrax vaccination implementing policies and guidance to all Navy and Marine Corps personnel and is effective upon receipt. The following are the vaccination priorities:

a. Personnel assigned to high-threat areas.

b. Personnel predesignated for immediate contingency deployment.

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c. Personnel identified and scheduled for deployment on an imminent or ongoing contingency operation to a high-threat area.

5. Responsibilities

a. The Assistant Secretary of the Navy (Manpower and Reserve Affairs) has overall responsibility for the policy associated with the AVIP. The AVIP is both a commanders' program and a medical program. The Chief of Naval Operations (CNO) and Commandant of the Marine Corps (CMC) will assume overall responsibility for the implementation and execution of this plan, including appropriate monitoring, evaluating and documenting the program. They will ensure commanders have the requisite supplies (vaccine and ancillaries) to administer the program and commanders must monitor and ensure compliance.

b. The Surgeon General of the Navy/Chief, Bureau of Medicine and Surgery has logistics oversight for the DON's AVIP. The Surgeon General transmits the instructions of the Assistant Secretary of Defense for Health Affairs about this and other biological warfare defense to subordinate units through established directives. Additionally, the Surgeon General will provide the Department of Defense Executive Agent, the Secretary of the Army, with projected anthrax vaccine program requirements and is responsible for providing funding in execution for anthrax vaccination ancillary supplies at Claimancy 18 administration points.

c. The Joint Program Office for Biological Defense (JPO-BD) centrally funds this program with no cost incurred by DON activities for the vaccine.

d. Fleet and Marine Force Commanders will program and budget for anthrax vaccination ancillary supplies at their respective operational administration points.

6. Form. SF 601 (10-75), Health Record - Immunization Record, is provided at Annex C to enclosure (1), page C-1-1.

John H. Dalton

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DON ANTHRAX VACCINATION IMPLEMENTATION PROGRAM (AVIP)

BASIC PLAN

1. **PURPOSE.** To establish policy, assign responsibilities, and prescribe procedures to be followed in peacetime and during contingencies for the vaccination of naval forces against anthrax for which a vaccine exists, approved by the Food and Drug Administration (FDA), for designated high threat regions as specified by the Chairman, Joint Chiefs of Staff (CJCS).

2. **OVERVIEW**

a. Department of Defense Immunization Program for Biological Warfare Defense (DoDD 6205.3) sets DoD policy for the use of vaccines for biological defense. The anthrax vaccine meets each of the requirements outlined in this directive. Secretary of Defense has designated the Secretary of the Army as the Executive Agent.

b. Program Budget Decision (PBD) 708 directs funding for vaccine procurement, testing, storing, production facility upgrading, and shipping of vaccine from Michigan Biological Products Institute (MBPI) to designated logistic distribution points; i.e., Fleet Industrial Support Centers (FISC) for Navy units and Military Treatment Facilities for Marine Corps units.

c. Office of the Chief of Naval Operations, Medical Resources, Plans and Policy (OPNAV N931) and Headquarters, Marine Corps, Installations and Logistics (I&L) will provide total vaccine requirements for DON to United States Army Medical Materiel Agency (USAMMA) via Naval Medical Logistics Command (NAVMEDLOGCOM).

d. The Joint Program Office for Biological Defense (JPO-BD) will procure and maintain an adequate stockpile of vaccines and defined production capabilities for all Services. Unlike vaccines used for preventive medicine, vaccines used specifically for biologic defense are controlled by the congressionally established JPO-BD. JPO-BD also controls the funds allocated for research, development and acquisition of these vaccines and will fund the initial force immunizations.

e. The current (FDA) immunization schedule for this vaccine requires a total of six immunizations. Primary immunization consists of a total of six subcutaneous injections, 0.5 ml each. The first three are given 2 weeks apart (D-0, D+14, D+28), followed by three additional subcutaneous injections, 0.5 ml each, given at D+6M (from the first dose), D+12M (from the first dose), and D+18M (from the first dose). Subsequent booster injections of 0.5 ml at 1-year intervals, upon completion of the basic series, are required to maintain immunity. Annex A details medical considerations pertaining to anthrax vaccination.

f. This plan was developed cooperatively by the Office of the Chief of Naval Operations; Headquarters, United States Marine Corps; and Headquarters, United States Coast Guard. U. S. Coast Guard will publish their own plan.

g. Implementation of this plan is a command responsibility at all levels.

3. **ASSUMPTIONS**

a. Office of the Secretary of Defense (OSD) will approve the plan execution in a phased manner. The first phase will inoculate forces deployed in high threat areas. The remainder of the total force will be vaccinated in one or more phases (annex B).

b. OSD will provide guidance for the immunization of personnel other than U.S. Forces (OTUSF). This may include routine immunization of non-active duty and reserve personnel, and immunization under conditions of imminent use or after use of the biological agent.

c. Adequate supplies of vaccines will be available to execute this plan.

d. At execution, an automated immunization tracking system will be in place (annex C).

e. Commanders-in-Chief (CINCs) will require that at least the first three doses will be received by all personnel who will remain in theater for periods of 30 days or greater prior to arrival in designated high threat areas. The remaining doses (immunizations 4-6) will be completed in accordance with the FDA schedule.

f. Immunizations will commence after receipt of an OSD execute order.

g. Friendly Forces. Each service will conduct immunizations in accordance with service-provided prioritization lists (annex B for Navy and Marine Corps).

4. **MISSION**. On order, DON implements the DoD immunization policy in accordance with DoDD 6205.3 and the Joint Chiefs of Staff's (JCS) planning guidance.

5. **CONCEPT OF OPERATIONS**

a. DON will vaccinate all active duty and reserve components of the Navy and USMC in accordance with the FDA immunization schedule, and OSD and JCS guidance. Naval forces will be vaccinated in a phased program whereby those units deployed or

deploying to designated high threat areas (annex B) are immunized first. This includes personnel reporting to these units and personnel on temporary duty in these areas for 30 days or greater.

b. United States Army Medical Materiel Agency (USAMMA) will coordinate with the Joint Program Office-Biological Defense (JPO-BD) to ensure adequacy of vaccine supplies and the distribution to all Services. OPNAV N931 and HQMC(I&L) will provide total vaccine requirements for DON to USAMMA via Naval Medical Logistics Command (NAVMEDLOGCOM). Annex D provides detailed logistics information for Navy and Marine Corps.

c. This is a readiness initiative. Unless specifically exempted by the operations plan or by competent medical authority, detailed below, all personnel are required to initiate and complete the immunization schedule. Naval and Marine Corps commanders are responsible for ensuring the proper execution of this program and will track percentage of personnel requiring immunizations that have completed each of the three phases discussed below. The first report will be submitted as specified in annex C.

d. Individual immunizations will be carried out in three phases:

(1) Phase 1 is the preparation phase and is completed when the first immunization is given.

(2) Phase 2, Short Term Immunizations, is completed when the third immunization is given.

(3) Phase 3, Long Term Immunizations, is completed when the sixth shot is given (18 months after the initial immunization). From this point on, annual booster immunizations will become a part of unit readiness reporting.

e. JPO-BD has been directed to maintain pre-determined vaccine inventories. This requires the production capability to maintain inventories of vaccine and the ability to meet surge requirements while complying with FDA regulatory requirements. Funding will be driven by requirements.

f. Navy and Marine Corps commanders will develop and monitor execution plans and provide required reports as set forth in annex C. Unless specifically exempted by this plan or by competent medical authority, personnel in designated units are required to initiate and complete the immunization schedule.

g. Navy medical department assets will be used to complete this immunization series. Medical Treatment Facilities (MTFs) with BUMED assistance will provide additional medical support as required to any operational unit to execute this plan.

h. Initial force (Active and Reserve) immunization will be carried out over a period to be determined. Designated units (annex B) will begin immunizations in accordance with prescribed prioritization timelines upon receipt of the execute order.

i. Medical record keeping (to include adverse reactions) will be accomplished in accordance with annex C.

j. USAMMA will coordinate the distribution of the vaccine to the supporting medical supply activities of all Services. NAVMEDLOGCOM will serve as the Navy and Marine Corps liaison with USAMMA. Based on the annex B prioritized list, NAVMEDLOGCOM will push the initial four doses of the vaccine series to respective units. These units will then be required to submit a no cost requisition to NAVMEDLOGCOM for the final two doses in the initial series as well as subsequent vaccine requirements to include annual booster doses.

k. Navy and Marine Corps commanders will execute the command information programs in accordance with the guidance provided by DON Public Affairs Plan (annex E).

6. **RESPONSIBILITIES**

a. <u>All Navy and Marine Corps Activities</u>

(1) Execute command anthrax immunizations in accordance with the unit priorities listed in annex B. Organic assets should be utilized first, then if additional assistance is needed, local health service support (HSS) assets can be sought as required to ensure completion of the immunizations in the time frame required.

(2) Provide percentage of units completing each of the phases in accordance with annex C. Initial reports are due 1 month after the start date listed. Quarterly reports are required thereafter.

(3) Incorporate anthrax as a part of unit readiness reporting as outlined in annex C.

(4) Provide education briefing on the anthrax vaccination program to all personnel using the approved DON Commander's Briefing packet. This information is available through the Navy Environmental Health Center web site: http://www-nehc.med.navy.mil/prevmed/index.htm.

(5) Additionally, at the time of vaccination:

(a) Sufficient notice will be provided to units regarding time, location and importance of immunizations in order for all personnel to arrange schedules to be present for the education brief and the vaccination.

(b) Individuals to be vaccinated will be provided specific information, prior to each dose, regarding the vaccine, its safety, the benefits, and the need for adherence to the immunization schedule. The provision of this information will be documented by health care personnel in the shot record on the PHS 731 (to be maintained with the health record) and in the individual's medical record.

b. Chief, Bureau of Medicine and Surgery (BUMED)

(1) Develop and disseminate medical information, policy, and doctrine as required in accordance with the plan.

(2) Ensure sufficient vaccines and ancillary supplies, as required, to units conducting immunizations in accordance with the prioritizations provided in annexes B and D.

(3) Provide consolidated reports of adverse reactions to the Army as Executive Agent in accordance with annex C.

(4) Ensure all medical department personnel have received and understand the information in the AVIP briefing for medical personnel.

c. Navy Medical Activities (to include ships and stations with medical department personnel)

(1) Provide support of the DON immunization plans for all naval components (Active, Reserve and others) as required to support DON AVIP.

(2) Provide immunizations to personnel from other Services in accordance with the Office of the Assistant Secretary of Defense (Health Affairs) (OASD (HA)) guidance.

(3) Provide summary reports (to include adverse reactions) in accordance with annex C.

7. **COORDINATING INSTRUCTIONS**

a. Direct coordination with Army and Air Force medical facilities to complete unit or individual immunization is authorized.

b. Funding for the vaccines will be provided by the Joint Program Office - Biological Defense (JPO-BD). Ancillary supplies will be funded by each Service.

8. **ANNEXES**

a. ANNEX A, MEDICAL CONSIDERATIONS AND GUIDANCE

b. ANNEX B, UNIT PRIORITIZATION

c. ANNEX C, AUTOMATED TRACKING SYSTEM AND REPORTING REQUIREMENTS

d. ANNEX D, LOGISTICS

e. ANNEX E, PUBLIC AFFAIRS PLAN

f. ANNEX F, MILITARY PERSONNEL GUIDANCE

g. ANNEX G, CIVILIAN PERSONNEL GUIDANCE

h. ANNEX H, NAVAL RESERVE

ANNEX A

MEDICAL CONSIDERATIONS AND GUIDANCE

1. GENERAL INFORMATION

a. Vaccine Characteristics

(1) Anthrax Vaccine Adsorbed is a sterile product manufactured by the Michigan Biologic Products Institute, Lansing, Michigan 48909. It is licensed (U.S. License No. 99, 1970) by the U.S. Food and Drug Administration (FDA) for human use to promote increased resistance to *Bacillus anthracis (B. anthracis)* by active immunization. The vaccine affords protection by stimulating the immune system to produce antibodies that prevent production of pathogenic toxins by *B. anthracis*.

(2) Anthrax vaccine is a formalin-inactivated vaccine that contains no living organisms; it is impossible to contract the disease anthrax from the vaccine. Anthrax vaccine for humans is made from cultures of avirulent and nonencapsulated (attenuated) strains of *B. anthracis*. The cultures are grown in a synthetic liquid medium and filtered; the filtrate contains predominantly protective antigen, one component of both toxins produced by the bacterium. The final vaccine contains no more than 2.4 mg aluminum hydroxide (equivalent to 0.83 mg aluminum) per 0.5 ml dose. Formaldehyde, in a final concentration not to exceed 0.02 percent, and benzethonium chloride, 0.0025 percent, are added as preservatives. The vaccine's potency is confirmed according to FDA regulations (21 Code of Federal Regulations, 620.23).

(3) Anthrax vaccine is supplied in 5.2 ml, multidose vials containing ten (10) 0.5 ml doses each.

(4) Handling and storage. Vials of anthrax vaccine should be stored in a refrigerator and maintained between 36 and 46 degrees Fahrenheit (2 to 8 degrees Celsius). DO NOT FREEZE. Once a vial is opened, the vaccine can be used until the expiration date, as long as it is properly stored. **Anthrax vaccine which has been frozen, or showing signs of contamination, discoloration, or deterioration, should be discarded and reported in accordance with BUMEDINST 6210.3 and 6230.15.**

(5) Indications and usage. Immunization with anthrax vaccine is recommended for individuals with a high risk of exposure to *B. anthracis*. Since it was first licensed by the U.S. Food and Drug Administration in 1970, the vaccine has been used safely and routinely administered to veterinarians, laboratory workers, livestock handlers, and other individuals who

may come into contact with *B. anthracis* infected animal products, e.g., hides, hair, meat or bones.

b. Vaccination Schedule and Administration

(1) Vaccination Schedule

(a) Primary immunization consists of a total of six subcutaneous injections, 0.5 ml each. The first three are given 2 weeks apart (D-0, D+14, D+28), followed by three additional subcutaneous injections, 0.5 ml each, given at D+6M (from the first dose), D+12M (from the first dose), and D+18 M (from the first dose).

(b) It is desirable that all personnel assigned to high threat areas receive their first three shots prior to deployment. In those rare instances when an individual is not able to take or continue the anthrax series due to medical or administrative reasons, that individual is still deployable.

(c) Annual booster vaccinations of 0.5 ml, given on the anniversary of the D+18M dose, are required to maintain immunity.

(2) Administration Issues

(a) Vaccination procedures will be consistent with information provided in Department of Defense Immunization Program for Biological Warfare Defense (DoD Directive 6205.3) and Navy Mobilization Processing Guide (OPNAVINST 3060.7A (NOTAL)) above. Needle and syringe method is indicated for this vaccine; ***jet injector immunization devices will not be used to administer anthrax vaccine***.

(b) An individual's availability and adherence to the immunization schedule shall be a matter of command attention and discipline. Commanders shall enforce the immunization schedule. Once the immunization series is started, it will be completed and appropriate boosters administered until termination of military service.

(c) Since the Anthrax Vaccine Adsorbed is a FDA-licensed product, individual informed consent is not required (as would be necessary for an investigational new drug (IND)). Commanders and medical staff will insure vaccine recipients are provided adequate information on the vaccine, its safety, its benefits, and the need for adherence to the immunization schedule. See paragraph 5 of this annex for further guidance on recommended educational material.

2. **MEDICAL RECORD KEEPING**

a. Each dose of anthrax vaccine administered will be documented by entries in three separate locations. Required data elements include: date of immunization, name of immunization given, dosage number in the multidose series, lot number, manufacturer, and date next dose due. In addition to the above required fields being completed, the SF-601 will ensure that the fields for route of administration and name of provider are completed, as well. Local quality control and quality assurance measures shall be implemented to ensure the accuracy of these entries. The three locations in which the administration of each dose of anthrax vaccine will be recorded are:

(1) The individual patient's medical record on SF-601, Health Record-Immunization Record.

(2) The individual's Department of Health and Human Services Form PHS 731, International Certificate of Vaccination (yellow shot card to be kept with the medical record).

(3) The immunization tracking module of the Shipboard Automated Medical System (SAMS).

b. Through the use of an automated immunization tracking system (annex C), anthrax vaccine immunization history will be annotated in an individual's data record. Required data elements listed in paragraph 3a will be recorded.

3. **POLICY FOR UNINTENDED DEVIATION FROM IMMUNIZATION SCHEDULE**

a. The licensed vaccine against the threat of anthrax requires six doses to be administered over an 18-month schedule. Doses are to be administered according to the following schedule: 0, 2 weeks, 4 weeks; 6 months, 12 months, and 18 months.

b. It is not known how much the standard vaccine schedule can be altered and still offer adequate protection. Therefore, the vaccination schedule as described herein is DoD and DON policy. It is the intent of DoD and DON to adhere to the prescribed vaccination schedule. **It is a command responsibility to assure personnel receiving this vaccine are available at the appropriate time for vaccination.** While the vaccine schedule must be followed as closely as possible, this may not always happen.

c. The following procedure will be followed for personnel who deviate from the above schedule:

(1) If a person is late for a vaccination, the series should not be restarted, unless the last dose was given greater than 3 years previously. Delinquent vaccinations should be given

as soon as possible, with the series adjusted to conform to the standard intervals in the schedule. For example, a person late for the second shot will receive the second shot as soon as possible. The third shot will be administered 2 weeks (14 days) after the second shot. The fourth shot will be administered 5 months after the third shot. The fifth shot will be administered 6 months after the fourth shot. The sixth shot will be administered 6 months after the fifth shot, followed by annual boosters.

(2) Annual boosters that are missed should be continued at the earliest possible date, adjusting the subsequent booster schedule accordingly.

(3) Any person who last received anthrax vaccine as part of Operation DESERT STORM/DESERT SHIELD, but did not complete the six dose series with adequate boosters, should restart the series.

4. **PRE-VACCINATION INFORMATION REQUIREMENTS.** Health care providers and medical staff will insure vaccine recipients are provided adequate information on the vaccine, its safety, its benefits, and the need for adherence to the immunization schedule. This requirement can be met by providing vaccine recipients with the standard Navy tri-fold brochure, entitled "What Everyone Should Know About the Anthrax Vaccine." This form, provided as appendix 1, will serve as the Vaccination Information sheet (VIS) for the anthrax vaccine.

5. **ADVERSE REACTIONS**

a. Local Reactions

(1) Mild local reactions are reported to occur in approximately 30 percent of recipients and consist of erythema (redness) and induration (slight swelling) less than 5 cm in diameter at the injection site associated with warmth, itching and tenderness. Immunizations with anthrax vaccine can result in discomfort at the injection site. These reactions usually occur within 24 hours and begin to subside by 48 hours. Erythema, if present, can occasionally increase to 3-5 cm in diameter. Local reactions tend to increase in severity by the 5th injection and then may decrease in severity with subsequent doses. Mild local reactions can be minimized by alternating injection sites between both arms for the first 3 doses.

(2) Moderate local reactions occur in approximately 4 percent of recipients and consist of erythema and induration exceeding 5 cm diameter. Some recipients may develop a non-tender subcutaneous nodule at the injection site; these nodules can persist for up to 2 months, but resolve without treatment. When administering subsequent doses, one should check for the presence of a subcutaneous nodule and if present, avoid injecting

the vaccine into it. A moderate local reaction can also occur if the vaccine is given to anyone with a past history of anthrax infection.

(3) Severe local reactions are reported to occur in less than 1 percent of recipients and are characterized by reactions at the vaccination site as described above and edema that may extend to the elbow or forearm.

b. Systemic Reactions. Systemic reactions, such as fever, malaise and headache, are extremely rare with this vaccine (less than 0.2 percent or less than two per thousand).

c. Supporting Data

(1) The Michigan Biologic Products Institute (MBPI) - the manufacturer and license holder - indicated in a letter to the Food and Drug Administration that "... *there is no evidence from records at the Michigan Department of Public Health that Anthrax Vaccine Adsorbed is associated with chronic or permanent local or systemic effects. ... Since licensure of this vaccine, few reports of adverse events have been received. ... No reports of adverse events were received during the Persian Gulf conflict and none have been received since that time.*"

(2) Clinical trials conducted by the Centers for Disease Control and Prevention (Department of Health and Human Services) and involving approximately 16,500 doses of Anthrax Vaccine Adsorbed, indicated that the vaccine is safe. No reactions were noted in the large proportion of vaccine recipients. Despite an early study reporting reactions for 34 percent of recipients administered the initial series, more recent studies report reactions in 3-14 percent of immunizations administered from several different lots of the vaccine and across several different years. Reports for booster doses were similar with reaction rates of 3-23 percent of booster doses administered.

(a) Most reactions reported were local and mild in nature (erythema only; edema or induration which is measurable, but 30 mm or less in any one diameter).

(b) Severe local reactions (any reaction measuring more than 120 mm in any one diameter or any reaction accompanied by marked limitation of motion of the arm or marked axillary tenderness) were reported for 1 percent or less of the doses given in any study during the 5-year period. Across all study periods, a total of only four systemic reactions were reported--two with chills and fever, one with fever; one recipient reported feeling ill with general body aches for 24 hours. No chronic or permanent pathological conditions were reported for either the local reactions or the few systemic reactions encountered.

c. Reporting Requirements. Adverse event description, recording, and reporting requirements are provided in annex C. At the local level, units may want to track mild or moderate reactions insofar as these may prompt attention in ensuring proper technique in vaccine administration.

6. **CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS**

a. Contraindications. A severe hypersensitivity reaction to a previous dose of the vaccine, requiring a Vaccine Adverse Events Reporting System (VAERS) report, is a contraindication to further immunization with this vaccine, or a vaccine component.

b. Warnings

(1) Any active infection with fever is generally considered reason for temporary deferral of immunization.

(2) Individuals receiving a course of therapy (e.g., corticosteroids) that would tend to depress the immune response may be inadequately immunized if the recommended dosage schedule is followed. For personnel with temporarily suppressed immune systems (e.g. due to therapy), immunization should be deferred until after the course of therapy.

(3) While HIV positivity is not an absolute contraindication, HIV positive individuals will not be routinely immunized. However, there may be instances of anthrax vaccination of individuals who have unknowingly seroconverted for HIV since the last annual force test. Such non-immunosupressed individuals should not be adversely affected by vaccination. However, the immune response of such individuals may not be as robust as individuals who are HIV negative.

c. Precautions

(1) General. Routine immunization precautions against allergic and anaphylactic reaction should be followed, in accordance with BUMEDINST 6230.15. These include the ready availability of epinephrine solution, 1:1000, for immediate use in case of an anaphylactic reaction, and the ability to manage an airway.

(2) Pregnancy

(a) Anthrax vaccine, like all other vaccines in the U.S., is classified as "pregnancy category C" which means that animal reproduction studies have not been conducted with anthrax vaccine. Therefore, prudent medical practice dictates that anthrax vaccinations should be routinely deferred during pregnancy unless clinically indicated. While routine pregnancy testing is not indicated before vaccination, every woman must be

questioned about the possibility of pregnancy, in accordance with BUMEDINST 6230.15. Women who state that they are pregnant or suspect that they might be pregnant, will be deferred from vaccination until after they have been evaluated and determined to not be pregnant.

(b) According to the Advisory Committee on Immunization Practices (ACIP), "there is no convincing evidence of risk from vaccinating pregnant women with inactivated virus or bacterial vaccines or toxoids." Subsequently, anthrax vaccine, like any other inactivated vaccine, is not expected to cause fetal harm; if vaccine is inadvertently given to a pregnant woman, no adverse pregnancy outcome is expected. However, animal reproduction studies regarding anthrax vaccine have not been conducted. Therefore, pregnant women will not receive anthrax vaccine unless anthrax exposure occurs or is imminent. If a woman becomes pregnant after beginning the vaccine series, an entry will be made in her medical record and the series will be suspended until she is no longer pregnant. When she is no longer pregnant, the vaccine series will continue. Example, if you received one shot and became pregnant, you would receive the second, and subsequent shots when you are no longer pregnant.

(3) Breast-feeding (lactation). "Neither killed nor live vaccines affect safety of breast-feeding for mothers or infants." (ACIP). There is no scientific evidence to support interrupting breast-feeding for immunization of a lactating mother with anthrax vaccine. Therefore, DON policy will be to resume the anthrax vaccination series, regardless of breast feeding status, after return to duty following completion of pregnancy convalescent leave.

(4) Pediatric Use/Use in the Elderly. Anthrax Vaccine Adsorbed should be administered only to healthy individuals between 18 and 65 years of age since clinical studies have been conducted exclusively in that age group.

ANNEX B

UNIT PRIORITIZATION INFORMATION AND VACCINE FLOW

1. **PURPOSE.** To provide the concept of operations for unit prioritization for the Navy and Marine Corps Anthrax Vaccine implementation plan.

2. **SCOPE.** This annex applies to all naval components (Active duty, Reserve and others).

3. **CONCEPT OF OPERATIONS.** Personnel assigned to Joint or other Services will have their immunizations administered by the medical treatment facility (regardless of its Service) providing medical support to the unit to which the individual is assigned. Immunization of Navy and Marine Corps units will be accomplished according to the following three phases:

a. PHASE I - Immunization of personnel assigned, reporting to, or on temporary duty (for 30 days or greater) to units deployed to high threat areas. It is desirable that all personnel assigned to high threat areas receive their first three shots prior to deployment. In those rare instances when an individual is not able to take or continue the anthrax series due to medical or administrative reasons, that individual is still deployable. Phase I information shall be obtained from Navy fleet force providers (i.e., component commanders) and Naval Component Commander (i.e., Commander In Chief, U.S. Naval Forces, Europe (CINCUSNAVEUR), Commander. U.S. Naval Forces Central Command (COMUSNAVCENT)); and forwarded to the Naval Medical Logistics Command for action. Refer to annex D for logistics application.

b. PHASE II - Immunization of personnel assigned or reporting to units identified in Time Phased Force Deployment Data (TPFDD), as having a Latest Arrival Date (LAD) of C+35 or earlier, in support of operations plans (OPLANS) for high threat areas. This information shall be obtained from Navy fleet force providers (i.e., component commanders) and Naval Component Commander (i.e., CINCUSNAVEUR, COMUSNAVCENT); and forwarded to the Naval Medical Logistics Command for action. Refer to annex D for logistics application.

c. PHASE III - Immunization of personnel assigned or reporting to all other Navy and Marine Corps units, including the remainder of the Reserve personnel.

d. Individuals assigned to headquarters staffs may find they are subject to deployment on short notice, such as intelligence and security staff personnel. These personnel should initiate the vaccination series at the nearest MTF prior to deployment.

ANNEX C

AUTOMATED IMMUNIZATION TRACKING SYSTEM AND REPORTING REQUIREMENTS

1. AUTOMATED TRACKING SYSTEMS

a. Purpose. To ensure the success of the anthrax immunization plan, an automated immunization tracking system is mandated. Additionally, OASD(HA) has directed that all immunization data of military members be entered into the Defense Enrollment Eligibility Reporting System (DEERS).

b. Choice of Systems

(1) The Shipboard Non-tactical Automatic Data Processing Program (SNAP) Automated Medical System (SAMS) has been selected as the tracking system for anthrax and all other immunizations for the following commands and activities:

(a) All medical treatment facilities (MTFs) and branch clinics.

(b) All ships, submarines, and other operational units.

(c) All Active Duty and Reserve Marine Corps units.

(2) The Reserve Standard Training, Administration, and Readiness Support (RSTARS) System will continue to be used to track all immunizations administered to Selected Navy Reserve personnel. Reserve personnel receiving any portion of the anthrax vaccination series from a site that does not have the RSTARS resident will:

(a) Have their anthrax immunization data loaded into SAMS (if at a Navy or Marine Corps site), Military Immunization Tracking System (MITS) (if at an Air Force site), or Force Medical Protection System (MEDPRO) (if at an Army site). All three systems will then transfer data into DEERS.

(b) Additionally, reserve personnel will provide anthrax immunization documentation (SF-601) to their reserve center RSTARS coordinator for entry into RSTARS. When on-line, RSTARS will be able to acquire data from the DEERS database obviating the need for reserve personnel to provide SF-601 immunization information to the RSTARS coordinator.

(3) Individual Ready Reserves (IRRs) and Individual Mobilization Augmentees (IMAs), when mobilized, will initiate the vaccination series, be entered into SAMS, and subsequently transferred to DEERS. NMPS sites will be augmented by medical personnel with SAMS support to fulfill this function.

(4) Marine Corps units may continue to use other automated systems to track all other immunizations until an interface engine is written to import immunization data from other automated systems into SAMS.

c. Demographic Data

(1) In order to alleviate the entry of individual demographic data during initial implementation of SAMS 7.04 to Navy MTFs, Naval Medical Information Management Center (NAVMEDINFOMGTCEN) will provide each MTF with a demographic database file. This database file will contain all current demographic data on all active duty personnel assigned within a 50-mile radius of the MTF. This demographic data can be obtained from NAVMEDINFOMGTCEN via FTP (File Transfer Protocol).

(2) If a record is not found in the local SAMS database for a military member who presents for an immunization, demographic data (name, social security number, etc.) must be entered so that the immunization transaction is tracked in SAMS. When an individual transfers to a new command, his or her SAMS record, including immunization data, can be e-mailed to the receiving operational command or MTF, for entry into their SAMS database, placed on a 3 1/2 inch floppy disk provided to the member, or placed in the medical record.

2. **REPORTING REQUIREMENTS**

a. Medical Record. Documentation of all anthrax vaccinations must be made in the medical record. Inasmuch as the current SF 601 is not suitable for recording all required data elements for anthrax vaccinations, an SF 601 overprint, Anthrax Vaccination Record, has been prepared. This is provided as appendix (1) to annex A and should be reproduced for local use. Documentation of anthrax vaccinations should also be entered on the U.S. Public Health Service International Certificate of Vaccination, PHS 731 ("yellow shot card").

b. DEERS Database. DEERS has been designated as the central repository for all immunizations administered to active duty and reserve personnel. With this data residing in DEERS, command or unit immunization compliance rates can be obtained. The ability will soon be available to obtain data on an individual's immunization status. This will be particularly helpful if a paper copy of immunization data is not available, or for example, to determine what anthrax dose is next due for an individual.

c. Central SAMS Repository. A central repository maintained at NAVMEDINFOMGTCEN will receive all anthrax and other immunization data entered into SAMS. NAVMEDINFOMGTCEN will transmit aggregated data from all SAMS sites to DEERS on a weekly basis, through an interface.

d. Data Transfer

(1) Each command or activity using SAMS must transmit immunization data to NAVMEDINFOMGTCEN. This transfer of immunization data will occur as follows:

(a) MTFs will submit immunization data on a weekly basis via FTP or e-mail.

(b) All ships and submarines, including other operational units, will submit immunization data on a weekly basis or as operational constraints permit. Data transmission may occur via FTP, e-mail, or Supply Automated Logistics Transfer System (SALTS).

(c) Active Duty and Reserve Marine Corps activities will submit immunization data on a weekly basis or as operational constraints permit. Data transmission may occur via FTP, e-mail, or SALTS (Supply Automated Logistics Transfer System).

(2) If electronic transfer of SAMS data is not feasible, data can be placed on a 3 1/2 inch floppy disk and mailed to NAVMEDINFOMGTCEN.

(3) Navy Reserve Activities will continue to enter immunization data in RSTARS for SELRES. Data will be aggregated into the Reserve Headquarters Support (RHS) System in New Orleans for transfer to DEERS through an interface. RSTARS will be submitted weekly to RHS and transmitted monthly to DEERS. SAMS will be used for IRRs and IMAs at NMPSs.

e. Data Requirements

(1) Though automated tracking of immunizations is required only for military personnel at this time, other DoD beneficiaries can be entered into SAMS. When SAMS creates a data file for transfer to NAVMEDINFOMGTCEN, it uses the FMP (family member prefix) code, restricting submission of data to military members only.

(2) The DEERS database has established fields for the following required data elements: social security number, immunization given, date of immunization administration, immunization lot number, manufacturer of immunization, dosage number within a multi-dose series, and date next dose due. Only SAMS version 7.04 provides all these data elements. Use of

previous versions of SAMS for immunization tracking is not allowed.

(3) An upgraded version of the medical module within RSTARS, with fields for anthrax immunization and all required data elements, is under development and will be available in April 1998.

3. **REPORTS OF IMMUNIZATION STATUS**

a. DEERS Reports. A central repository of all immunizations administered to active duty and reserve personnel provides the opportunity to obtain reports of immunization status on the command, unit, and individual levels. DEERS has been required to provide the following reports, available to authorized users:

(1) Individual Immunization Status Report.

(2) Report of Personnel Due for a Specific Immunization (provides a list of personnel due for a specific immunization(s)).

(3) Report of Unit Immunization Status (provides percentage of personnel within a command or unit who are due for a specific immunization).

(4) Report of Unit Compliance (provides percentage of personnel within a command or unit who have completed an immunization series).

(5) Report of Immunization Series Status (provides a list of personnel who have completed dose "X" of a given immunization series, for example dose 3 of anthrax).

(6) Report of Unit Immunization Series Compliance (provides percentage of personnel within a command or unit who have completed dose "X" of a given immunization series).

b. DEERS Website

(1) DEERS will have a website available by 1 May 1998 which will provide authorized users access to the DEERS database to obtain the standard reports noted above. The capability to provide all these reports, as well as to conduct ad hoc queries to the database, is under development. When the website is functional, it is anticipated that the ability to obtain unit reports of unit compliance will be available. Availability of other reports and data query capabilities will follow.

(2) When the website is functional, access will be initially limited to a restricted number of authorized users from MTFs and operational units, including TYCOMs. As the capability

to sustain larger numbers of users is achieved, greater numbers of users will be added.

4. **ADVERSE EVENTS REPORTING**

a. Adverse events or reactions to immunizations must be entered into SAMS as well as in the medical record with entries on SF 601 AND SF 600. Refer to BUMEDNOTE 6230, Immunization Requirements and Recommendations for specific guidance and instructions.

b. Report all adverse vaccine reactions resulting in hospitalization or time lost from duty (more than 24 hours), using the Health and Human Services Vaccine Adverse Events Reporting System (VAERS) form (found in BUMEDNOTE 6230). (VAERS forms and information can also be obtained by calling 1-800-822-7967.) Other reactions will not be reported unless contamination of lots is suspected. A copy of the completed VAERS form will be retained on file at the local command or unit and a copy will be sent to the Navy Environmental Health Center (NAVENVIRHLTHCEN), Preventive Medicine Directorate, 2510 Walmer Avenue, Norfolk, Virginia 23513-2617.

c. Adverse events or reactions will also be reported to NAVENVIRHLTHCEN through the Naval Disease Reporting System (NDRS). NAVENVIRHLTHCEN will provide the U. S. Army Center for Health Promotion and Preventive Medicine copies of the reports of adverse events or reactions from the Navy and Marine Corps.

HEALTH RECORD — ANTHRAX IMMUNIZATION RECORD

All entries in ink to be made in block letters

Date Vaccine Information Sheet Provided:

Date Given	Dosage No. or booster	Dosing Schedule (from Day 0)	Dose (ml)	Site (left or right arm)	Lot Number	Provider	Administering Facility	Comments
	1	Day 0	0.5					
	2	2 weeks	0.5					
	3	4 weeks	0.5					
	4	6 months	0.5					
	5	12 months	0.5					
	6	18 months	0.5					
	Booster	Annual	0.5					
	Booster	Annual	0.5					
	Booster	Annual	0.5					
	Booster	Annual	0.5					
	Booster	Annual	0.5					
	Booster	Annual	0.5					
	Booster	Annual	0.5					
	Booster	Annual	0.5					
	Booster	Annual	0.5					
	Booster	Annual	0.5					

Anthrax Vaccine Dosing

Basic vaccination series consists of 6 shots over 18 months, given as indicated above. The following intervals between doses must be maintained: the 2nd dose is given 2 weeks after the 1st dose; the 3rd dose is given 2 weeks after the 2nd dose; the 4th dose is given 5 months after the 3rd dose; the 5th dose is given 6 months after the 4th dose; and the 6th dose is given 6 months after the 5th dose. If one is late for a dose, or strays from the established schedule, the next dose due should be given, with the intervals for the remaining doses maintained. A booster dose should be administered every 12 months. If an adverse reaction occurs following an anthrax vaccination, note in "comments" block above and on a SF 600. If a severe reaction occurs, further administration of anthrax vaccine should be discontinued.

Unless otherwise indicated, the manufacturer of Anthrax Vaccine, Adsorbed, is Michigan Biologic Products Institute

PATIENT'S IDENTIFICATION *(Mechanically Imprint, Type or Print)*:

Patient's Name—last, first, middle initial; Sex; Age or Year of Birth; Relationship to Sponsor; Component/Status; Department/Service.

Sponsor's Name—last, first, middle initial; Rank/Grade; SSN or Identification Number; Organization.

SF 601 Overprint 4/98

601-105

IMMUNIZATION RECORD
Standard Form 601—October 1975 (Rev.)
General Services Administration & Interagency Committee on Medical Records
FPMR (41 CFR) 201-45.505

ANNEX D

LOGISTICS

1. **PURPOSE**. To provide the logistics concept of operations for the Anthrax Vaccine Implementation Plan as it pertains to Navy and Marine Corps Units.

2. **GENERAL INFORMATION.** The following information on the FDA-licensed Anthrax Vaccine is provided:

a. NSN: 6505-01-399-6828.

b. Unit of Issue: Ten 0.5ml doses per 5.2ml multi-dose vial.

c. Shelf life: 12 months after shipment from the manufacturer.

d. Storage: Store product at 36^0 - 46^0F (2^0 to 8^0C). DO NOT FREEZE.

e. Acquisition Advice Code: A.

f. Dosage: Primary immunization consists of three subcutaneous injections, 0.5 ml each, given 2 weeks apart (D-0, D+14, D+28) followed by three additional subcutaneous injections, 0.5 ml each, given at D+6M (from the first dose), D+12M (from the first dose), and D+18M (from the first dose). Subsequent booster injections of 0.5 ml at 1-year intervals, upon completion of the basic series, are required to maintain immunity.

g. Cost: The anthrax vaccine is centrally funded (Joint Program Office for Biological Defense (JPO-BD)) with no cost to activities for the vaccine. The Bureau of Medicine and Surgery will be responsible for providing funding for ancillary supplies at Claimancy 18 administration points. The Fleet and Fleet Marine Force (FMF) will be responsible for funding at their operational administration points (see paragraph 6 for recommended ancillary supplies). The current contract includes manufacturer distribution to first destination in CONUS. If transportation is required for OCONUS delivery, appropriate regional Defense Distribution Depot will charge the corresponding Type Commander (TYCOM) for transportation cost.

3. **FACTS.** The unit priority list will be obtained from Navy and Marine Corps components by the Naval Medical Logistics Command and implemented in a phased manner (annex B).

4. **CONCEPT OF OPERATIONS**

a. Logistics Overview

(1) The vaccine is centrally funded by the JPO-BD and stored at the manufacturer, MBPI. The vaccine is not a DSCP depot stocked item. The U.S. Army is the lead agent for anthrax vaccine. U.S. Army Medical Materiel Agency (USAMMA) serves as the central point of contact with MBPI. All requests/ requisitions for vaccine will be coordinated with USAMMA via the respective service logistics agency (for Navy/Marine Corps this is NAVMEDLOGCOM). Figure D-1 depicts vaccine distribution.

(2) The Navy & Marine Corps will vaccinate forces (active and reserve components) in accordance with the FDA immunization schedule (six-shot basic series with annual booster) and DoD/DON guidance. **Based the prioritized list in annex B, NAVMEDLOGCOM, in cooperation with USAMMA, will push the first four doses of the immunization series to designated units.** Due to the 1-year shelf life of the vaccine, activities MUST submit requisitions for subsequent vaccine requirements to NAVMEDLOGCOM. (This procedure applies to the final two doses of the basic immunization series and subsequent annual boosters doses.)

b. USN Overview/Concept of Operations

(1) Medical materiel flow, supporting Navy ships deployed or under work-up, is currently integrated with the standard naval supply systems. Requirements are usually submitted through a chain of retail, intermediate, and wholesale levels via the established Military Standard Requisition and Issue Program (MILSTRIP) to reach an ultimate source of supply or processing activity.

(2) For this immunization plan, ships, submarines, and aviation squadrons in homeport identified to be at risk or scheduled for deployment will receive their initial vaccine supply and re-supply through normal supply channel. Deployed ships, submarines, and aviation squadrons will receive their vaccine supply and re-supply through established supply channels. As stated above, the vaccine is a no cost issue for the Fleet, however, the cost of ancillary supplies (paragraph 6) will be borne by administration points as stated in paragraph 2g.

c. USMC Overview/Concept of Operations

(1) Class VIIIA (medical/dental) materiel flow in the Marine Corps is usually supported by the Medical Logistics Companies of the Force Service Support Groups (FSSG) through issue and reconstitution of war reserve assets of established allowance blocks. The SASSY Management Units (SMUs), also under the FSSGs, provide resupply support to using units refilling exhausted Echelon 1a (Corpsman level) supply requirements.

(2) The Marine Corps immunization requirements are supported by Navy Medicine and are outside of the established class VIII supply flow. This means that MTFs co-located with the Marine Expeditionary Force (MEF) will provide distribution and/or administrative support to the MEFs.

(3) The Marine Expeditionary Units (MEUs) are the Marine Corps task-organized force deployed to support the readiness requirements of the DON. These units deploy onboard ships of the Amphibious Readiness Group (ARG) for 6 to 8 months at a time. Each MEF employs three rotating MEUs with the exception of the 3d MEF at Okinawa which employs one.

(4) Distribution of vaccine for working up MEUs rests with the established Navy supply line. The MTFs supporting the 1st, 2d, and 3d MEFs will serve as distribution and/or administration point for this vaccine.

(5) Distribution and administration of vaccine for deployed MEUs rests with the established Marine Corps supply/resupply flow. This is achievable through the SASSY Management Units (SMU). The vaccine supply flow originating from continental United States source passes through the SMUs, established Navy supply channels, for final distribution to deployed MEUs onboard the ARGs.

5. **RESPONSIBILITIES**

a. Bureau of Medicine and Surgery

(1) Overall logistics oversight for the DON's Anthrax Immunization Program.

(2) Provide Claimancy 18 administration point funding for ancillary supplies.

b. Fleet Commanders-in-Chief

(1) Responsible for ensuring implementation of the Anthrax Immunization Program within their area of responsibility (AOR).

(2) Provide Fleet administration point funding for ancillary supplies.

(3) After notification of vaccine shipment by NAVMEDLOGCOM, ensure units have received shipment. Notify NAVMEDLOGCOM of any delays, discrepancies or problems with shipment.

(4) Coordinate receipt and transportation with respective destination point for appropriate, timely handling of each

Anthrax vaccine shipment. **Note: This responsibility is key to the successful implementation of this plan. Strict compliance with storage requirements (refrigeration) is imperative and must be stressed to all personnel in the logistics pipeline. This vaccine is in short supply, non-compliance with storage requirements will prevent necessary units from being fully immunized. Appropriate handling (refrigeration) is of the highest importance upon receipt and during transportation.**

c. Commander, Marine Forces (MARFOR)

(1) Commander, Marine Forces (Pacific, Atlantic, Europe, and Reserves) will provide NAVMEDLOGCOM via Headquarters, U. S. Marine Corps (I&L)/(N931) the initial amount of four-dose immunization requirements for identified at-risk forces (annex B).

(2) Provide MARFOR administration point funding for ancillary supplies.

(3) Commander, Marine Forces will ensure MEUs working up to deploy receive four required doses of the vaccine and will coordinate clinical, logistical, and/or administrative support with cognizant naval MTF commander to immunize all deploying members.

(4) Commander, Marine Forces will ensure deployed MEUs will obtain required doses from SMUs via supporting CLF. MEU commanders will coordinate clinical, logistical, and/or administrative support with CTF Commander to immunize all deployed members. MEU Commanders will continue to coordinate with supporting naval MTF upon return from deployment to complete the immunization regimen.

(5) Ensure NAVMEDLOGCOM is notified 90 days prior to expiration of remaining vaccine within the AOR.

d. Naval Medical Logistics Command (NAVMEDLOGCOM)

(1) Submit DON requirements to USAMMA in accordance with annex B prioritized list. This includes:

(a) The number of vials to be released.

(b) Ship to Address (i.e., MTF/Defense Depot). Note: Since commercial carriers will be used for continental United States (CONUS) delivery, specific building/room number, POC, and phone number must be provided for each shipment; no post office boxes or Army Post Office (APO)/Fleet Post Office (FPO).

(c) Mark-for address (UIC and name of unit to be vaccinated).

e. Document Number

(1) USN units: NAVMEDLOGCOM will coordinate delivery to Defense Distribution Depot via message to unit as well as notify Fleet and Industrial Supply Center (FISC)/CINC/TYCOM for their respective units.

(2) USMC units: NAVMEDLOGCOM will coordinate delivery to local MTF via message to unit as well as notify MARFOR, for their respective units.

(3) NAVMEDLOGCOM will establish a database to track quantity received by unit as well as a tickler file to remind units to submit no cost requisitions for subsequent doses of vaccination series as well as annual booster doses.

(4) Receive and process, through USAMMA/MBPI, requisitions for subsequent doses for supported units (for tracking purposes, do not consolidate requisitions). Requisitions forwarded to USAMMA will include the following:

(a) Unit provided requisition data.

(b) In the clear, ship to address of supporting MTF or Defense Distribution Depot.

(c) POC and phone number at the MTF and Unit.

(5) Act as DON liaison with USAMMA.

(6) Provide supply/shipment/receipt status reports to OPNAV N931, HQMC, BUMED, CINC, TYCOM/MARFOR as required.

f. U.S. Army Medical Materiel Agency (USAMMA)

(1) Process requisitions for vaccine from MBPI.

(2) Forward shipment information to NAVMEDLOGCOM upon release of vaccine by MBPI (see MBPI responsibility below).

g. Medical Treatment Facilities (MTFs)

(1) Navy MTFs will receive, store (refrigerate), and distribute vaccine for this immunization plan in coordination with co-located Marine Forces Commanders based on annex B priority list.

(2) Coordinate receipt of vaccine with intended Unit.

(3) Notify NAVMEDLOGCOM Supply POC the following data:

(a) Document number.

(b) Date vaccine received.

(c) Quantity (vials) received by Lot number.

(d) Any discrepancies (breakage, temperature, etc.).

(e) Date vaccine provided to unit to be immunized.

h. First Destination and Distribution Point (i.e., DDNV, MTFs)

(1) Receive and deliver vaccine for this immunization plan to the Mark For Addressee.

(2) Coordinate all aspects of this program with CINC, TYCOM, and NAVMEDLOGCOM.

(3) Provide NAVMEDLOGCOM Supply POC (301) 619-3086 or Fax (301) 619-3087 DSN 343-xxxx the following data:

(a) Document number.

(b) Date vaccine received.

(c) Quantity (vials) received by Lot number.

(d) Any discrepancies (breakage, temperature, etc.).

(e) Date vaccine provided to unit to be immunized.

(4) Notify the naval transportation customer service officer of impending shipment, providing Transportation Control Number, Piece, Weight, and Cube information, so the naval transportation customer service officer can alert aerial terminals and down line sections.

Note: Special attention needs to be devoted to proper handling and storage (i.e. refrigeration) of this vaccine. Vaccine supply is limited, waste due to improper handling can result in deploying units not receiving adequate immunization.

i. Units

(1) USN units: Receive vaccine through normal supply channel, assure adequate refrigeration capability is available to store used vaccine. USMC units: Coordinate delivery/pickup/ administration of vaccine with MTF.

(2) Obtain ancillary supplies (see paragraph 6) for vaccination administration.

(3) Notify immediate superior in the chain of command (ISIC)/chain of command (COC)/TYCOM or MARFOR/NAVMEDLOGCOM Supply point of contact, via message, of receipt of vaccine (see example below):

FM UNIT
TO NAVMEDLOGCOM FT DETRICK MD//62//
INFO ISIC
MEF
MARFOR
TYCOM
CINC
FISC
DDNV/DDJX/DDSD AS APPROPRIATE
UNCLAS //N06710//
SUBJ/RECEIPT OF ANTHRAX VACCINE BY *UNIT NAME* (UIC)//
RMKS/1. DOCUMENT NO.
2. NO. OF VIALS RECV'D BY LOT NO.
NO. OF VIALS LOT NO.
3. DATE RECV'D:
4. CONDITION OF VACCINE (ADEQUATELY REFRIGERATED_)
5. SHIPMENT DISCREPANCIES: (WAS TEMPERATURE MONITOR INCLUDED?)
6. EXCESS VACCINE ON BOARD (NO. OF VIALS) ***Don't report open vials***. //
BT

(4) Schedule subsequent requisitions of vaccine at 6-month intervals (***allow 60 days order-ship time***).

(5) Submit no cost requisition for subsequent doses (doses 5 & 6 and booster doses) of vaccine to NAVMEDLOGCOM (Fax (301) 619-3087 or DSN 343-3087) with the following data:

(a) Number of vials (10 doses per vial) required.

(b) Document number.

(c) POC and phone number.

(d) Servicing Distribution Depot/MTF (for ship to address).

(e) Command name.

j. Michigan Biologic Products Institute (MBPI)

(1) Ship vaccine in accordance with instructions provided by USAMMA via NAVMEDLOGCOM.

(2) MBPI will provide the following data back to USAMMA for each shipment:

(a) Number of vials shipped by lot number.

(b) Date shipped.

(c) Shipping data (carrier, tracking number, etc.).

(d) Document number.

6. **ANCILLARY SUPPLIES.** A proposed list of ancillary supplies includes, but is not limited to, the following:

NSN	NOMENCLATURE	U/I	U/PRICE
6515-00-982-4205	Needle and Syringe Hypo, Tuberculin, 100s	PG	$8.56
6510-00-786-3736	Pad Isopropyl Impregnated, 1.5X2", 100s	PG	$0.70
6510-00-782-2700	Sponge Surgical GZ 2X2", 200s	PG	$2.84
6515-00-051-1950	Gloves En Purpose MED, Pals, Disposable, 100s	PG	$4.88
6530-01-183-2863	Disposal Container Hypo Nil & Sir, 6.9Qt, 12s	PG	$26.19

7. **COORDINATING INSTRUCTIONS**

a. The Joint Staff will allocate the initial quantities of vaccine to the services. The Joint Staff will also resolve competing priorities among the services.

b. NAVMEDLOGCOM is the point of contact for questions and/or problems experienced at Distribution Depot and MTFs. Requisition/distribution Navy points of contact are:

Clinical POC:
NAVMEDLOGCOM (Code 06)
(301) 619-3065, DSN: 343-3065, FAX: (301) 619-3087, DSN 343-3087

Supply POC:
NAVMEDLOGCOM (Code 06A)
(301) 619-3086, DSN: 343-3086, FAX: (301) 619-3087, DSN 343-3087

NAVMEDLOGCOM (Code 62)
(301) 619-7118, DSN: 343-7118, FAX: (301) 619-3087, DSN 343-3087

VACCINE DISTRIBUTION

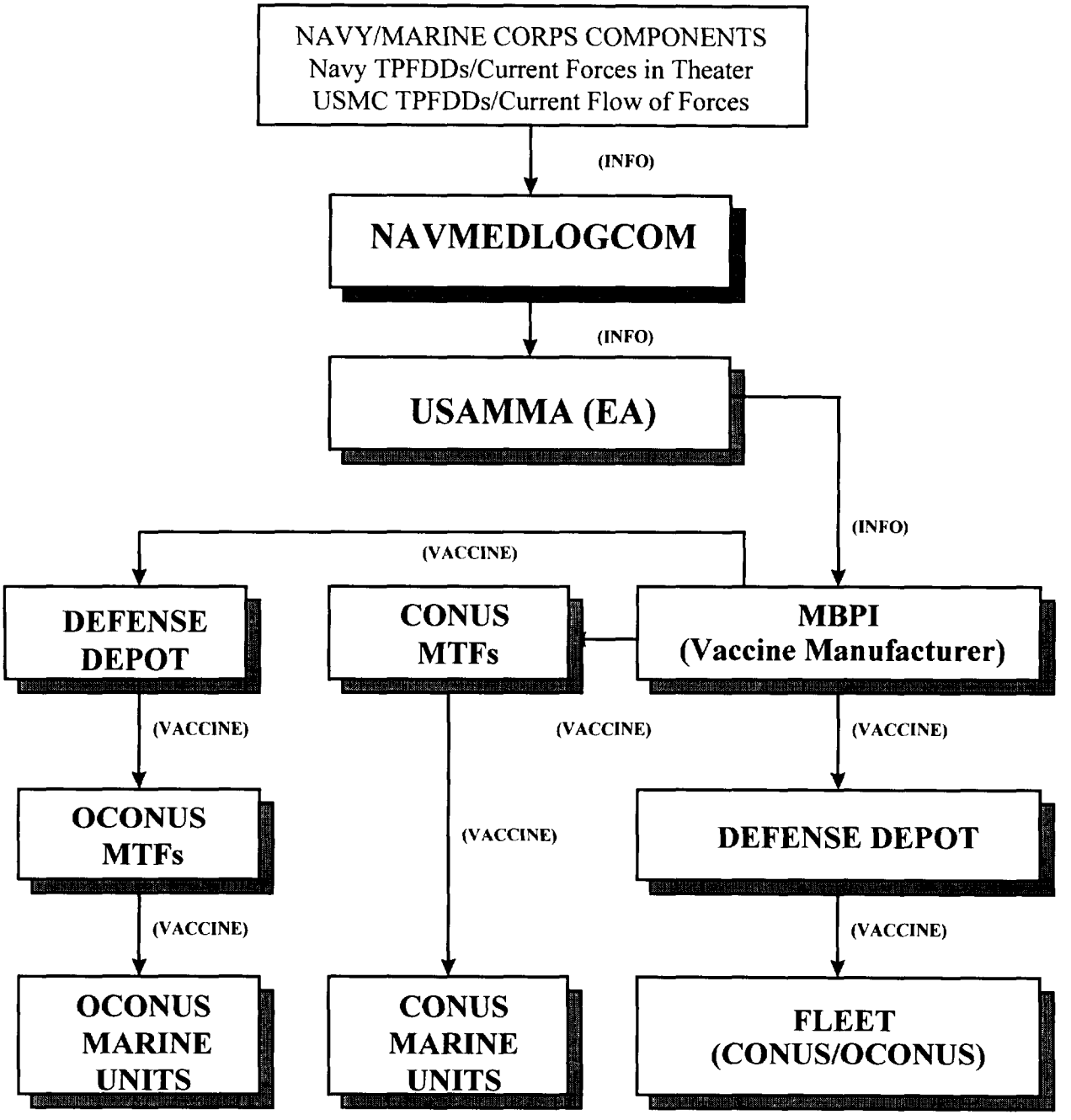


Figure D-1

ANNEX E

PUBLIC AFFAIRS PLAN

1. **PURPOSE**. To disseminate DON Public Affairs protocol and guidance for the DoD-directed Anthrax Immunization policy.

2. **BACKGROUND**. The DoD announced 15 December 1997 that in early summer 1998 it will begin the immunization of select U.S. military members and units using the anthrax biological vaccine. All military personnel will eventually be inoculated over the next several years. Internal and external public affairs support will be required to explain the inoculation plan.

a. Biological and chemical vaccines have been perceived by many as a possible cause for health concerns of Gulf War veterans. There is no medical evidence that links the anthrax vaccination to Gulf War illnesses. Because of these perceptions surrounding the cause of Gulf War veterans' health concerns, many military members may ask for informed consent as a part of the biological vaccine before they receive an anthrax immunization, and may want the right to refuse vaccination without risk of reprisal. As with all other vaccinations required by the military, service members may not refuse the anthrax vaccination.

b. Military members may also be concerned about how the anthrax vaccination affects their existing medical conditions. Personnel who are pregnant will not take this vaccine. If a service member becomes pregnant during the series, the immunization series will be deferred until the member is no longer pregnant.

3. **OBJECTIVES**. Ensure full understanding and support of the anthrax immunization program by Sailors and Marines, their families, the Congress, the American public and the media. Provide planning guidance to all Navy and Marine Corps public affairs officers and Navy Medical Department personnel to ensure full understanding of the anthrax immunization program by Sailors, Marines, their families, medical staffs, Congress, the American public and the media. Objectives include:

a. Inform all personnel that to immunize U.S. forces using anthrax vaccine is the right thing to do to eliminate anthrax as a threat to U.S. forces.

b. Gain the support of Sailors, Marines, their families, Congress, and the American public for the vaccination of U.S. forces against anthrax.

c. Use this opportunity to inform the American public that biological warfare is a potential threat to our combat forces.

4. **TALKING POINTS**. In accordance with SECDEF WASHINGTON DC 151342Z DEC 97, the following talking points will be emphasized:

a. We are vaccinating because vaccination provides the best possible protection for U.S. forces against anthrax.

b. Anthrax is the greatest biological warfare threat faced by U.S. forces.

c. Anthrax is 99 percent lethal to those who become infected.

d. The anthrax vaccine is Federal Drug Administration approved and licensed, and has been in use since 1970 among populations at risk, especially those working with livestock.

e. The vaccine is safe and effective.

f. Fewer people experience side effects from anthrax vaccine than from other common vaccines.

g. The anthrax vaccination requires six shots over 18 months, plus annual boosters after the series of six shots.

5. **AUDIENCES**. Public affairs information will be targeted to the following audiences:

a. All Sailors and Marines, especially those who will be part of the initial group to be vaccinated.

b. Navy and Marine Corps personnel who will be vaccinated and their families.

c. Navy and Marine Corps leadership.

d. Navy Medical Department personnel.

e. State and local governments and community leaders.

f. Congressional leaders.

6. **CONCEPT OF OPERATIONS**. Navy and Marine Corps public affairs officers will implement this plan in accordance with established timetables and priorities upon receipt of execution instructions.

a. Public Affairs Plan

(1) DoD announced in a news release, 15 December 1997, that in May/June 1998 the U.S. will begin the immunization of select U.S. military members and units against the biological warfare agent anthrax.

(2) Prior to the start of immunization, DoD will publish and provide to all service public affairs offices an embargoed news release announcing the units that will be vaccinated and the date the immunizations will begin.

(3) Until the date has been set for release, the date of release will be known as R-day.

(4) DoD's news release will be embargoed for release to the public until 1400 EST on R-day. However, the final release will be pre-positioned at the public affairs offices of major Navy line commands and major Marine Corps commands on the morning of R-day to facilitate widespread dissemination.

7. **RESPONSIBILITIES**

a. Department of Defense Public Affairs

(1) Select R-day.

(2) Coordinate with all services' public affairs offices to prepare final news release for R-day.

b. Navy Chief of Information (CHINFO)

(1) Provide embargoed release to major command Public Affairs Officers (PAOs).

(2) Provide coverage of immunization program in internal Navy media.

c. BUMED Public Affairs

(1) Provide embargoed release to all Navy Medical Department Commanding Officers and Public Affairs Officers (PAOs).

(2) Coordinate with CHINFO on information for use in internal Navy media products.

(3) Provide information in Navy Medical Department internal information products.

(4) Coordinate with Headquarters Marine Corps PAO for distribution of information in Marine Corps internal information products.

(5) Respond to media inquiries and assist local medical department PAOs in responding to media queries.

d. Naval Medical Centers, Naval Hospitals and Clinics, and their Navy Medical Department Commands

(1) Designate command PAO to respond to media inquiries using public affairs guidance from DoD and BUMED.

(2) Keep BUMED PAO advised of media queries. Queries beyond the scope of the latest public affairs guidance, should be referred to BUMED PAO.

(3) Coordinate local media photo opportunities when immunization process begins in accordance with BUMED public affairs guidance, keeping BUMED PAO advised.

(4) Provide media coverage updates and news clippings to BUMED Public Affairs Office.

(5) Coordinate with and provide media updates to the Responsible Line Commander's public affairs office.

(6) Coordinate congressional queries and briefings with Special Assistant for Congressional Legislative Affairs (MED -- 09X).

e. Marine Corps Public Affairs

(1) Distribute public affairs guidance to fleet PAOs.

(2) Disseminate information in Marines Corps internal information products.

Anthrax Vaccine Questions and Answers

The Department of Defense is considering a new force protection measure for the safety of military personnel. When approved, a vaccination program against the biological warfare agent anthrax will be administered to all active duty and reserve personnel.

The vaccination program will consist of a series of six inoculations over an 18-month period, and with initial emphasis on those service members deployed to high biological warfare threat areas in Southwest and Northeast Asia and service members who deploy early to those areas. The vaccine is FDA-licensed and exhibits few side effects.

Q1. Why is the vaccination needed?

A1. The current world threat environment and the unpredictable nature of terrorism make it prudent to include biological warfare defense as part of our force protection planning. Anthrax is 99 percent lethal to unprotected individuals exposed to battlefield concentrations of the agent.

Q2. Why has it taken 3 years to implement this program?

A2. Applying any program, procedures or process to the entire U.S. military force is a complicated and expensive process than must be thoroughly planned and carefully executed to achieve the desired results. The anthrax vaccine is already used to protect some of our military and civilian employees, but the decision to vaccinate the total force is much more difficult. Protection against anthrax is particularly challenging because the protocol requires multiple vaccinations to achieve immunity, and thus involves significant administrative and logistical issues.

Q3. Who approved the vaccination program? On what authority?

A3. The Secretary of Defense has concluded that vaccination is necessary for force protection. But vaccinations won't begin until four conditions are met:

- Supplemental testing, consistent with Food and Drug Administration standards to assure sterility, safety, potency and purity of vaccine;
- Implementation of a system for fully tracking anthrax immunizations;
- Approval of appropriate operational plans to administer the immunizations and communications plans to inform military personnel of the overall program;
- Review of health and medical plans of the program by an independent expert.

Q4. How is the policy applied?

A4. In November 1993, DoD established the policy, responsibilities and procedures for stockpiling biological agent vaccines and determined which personnel should be immunized and when the vaccines should be administered. The policy, DoD Directive, 6205.3, specifically states that personnel assigned to high threat areas and those pre-designated for immediate contingency deployment to these areas (such as personnel in units with deployment dates up to 30 days after mobilizations) should be vaccinated in sufficient time to develop immunity prior to deployment.

Q5. What is anthrax?

A5. Anthrax is an infectious disease that normally afflicts animals, especially cattle and sheep. Anthrax spores can be produced in a dry form which may be stored and ground into particles. When inhaled by humans, these particles cause severe pneumonia and death within a week.

Q6. Has any country ever used it as a weapon?

A6. No, but several countries are believed to have incorporated anthrax as a biological warfare agent in weapons.

Q7. Has the threat of biological warfare changed?

A7. The threat of biological warfare remains a constant risk to U.S. forces. DoD analysts maintain an updated evaluation of the level of threat, adjusting the information as necessary to reflect the risk to U.S. operations.

Q8. How real is the threat?

A8. Very real. Our assessments of the potential offensive biological threat facing American Service men and women indicates it is necessary to have a robust biological defense program today.

Q9. When will vaccinations begin?

A9. Vaccinations will occur in three phases. Inoculations of personnel in high-threat areas will begin about 6 months from date of announcement that was made mid-Dec 97. Next will be early deployers. General vaccination of the force will follow. Michigan Biologic Products Institute, under contract to the Department of the Army, has produced and stockpiled the vaccine to support inoculation of the force.

Q10. How will the program be implemented?

A10. Each service participated in the development of the armed forces immunization plan. The vaccine will be centrally procured, but the task of immunizing will be decentralized.

Q11. How many military members will be vaccinated?

A11. The total force will be vaccinated. Could total 2.4 million including more than 1 million members of the National Guard and Reserves.

Q12. What vaccine will military members be given?

A12. Military members will receive "Anthrax Vaccine Adsorbed (injected)." It is a sterile commercial product manufactured by the Michigan Biologic Products Institute, Lansing, Michigan. It is fully licensed (US license No. 99, 1970) by the U.S. Food and Drug Administration (FDA) for human use and has had an excellent safety record.

Q13. How does the vaccine work?

A13. The vaccine promotes increased resistance to anthrax by active immunization. The recipient develops protection by means of antibodies and other immune mechanisms to the bacterium following immunization.

Q14. What is the protocol for this vaccine? How many shots does it take?

A14. Immunization consists of three subcutaneous (under the skin) injections, 0.5 ml each, given 2 weeks apart followed by three additional subcutaneous injections, 0.5 ml each, given at 6, 12, and 18 months. After the initial vaccination schedule is completed, an annual booster is required to maintain ongoing immunity.

Q15. How long does it take after the first shot before protection is achieved?

A15. The best protection from anthrax exposure is achieved following the full course of six inoculations.

Q16. How long does the vaccine remain effective, once administered? Does it require a booster of any kind?

A16. Annual booster injections of the vaccine are needed to maintain immunity.

Q17. Who developed the vaccine?

A17. The product was developed and is manufactured by the Michigan Biologic Products Institute, Lansing, Michigan.

Q18. Who is producing the vaccine for DoD?

A18. Michigan Biologic Products Institute.

Q19. Is the vaccine available outside of DoD?

A19. The Michigan Department of Public Health produces the anthrax vaccine commercially, and the product is therefore

available to the general medical community for appropriate use. The Department of Defense has recently contracted with Michigan Biologic Products Institute to fulfill requirements for a stockpile, however, a supply is available for continued support of routine use for at-risk personnel (veterinarians, state health offices, personnel involved in animal product processing, etc.).

Q20. Has this vaccine been used in the past? How many times? By the military?

A20. Yes, the vaccine has been routinely administered to populations at risk (veterinarians, laboratory workers, civilians working with live-stock) for several years. The Michigan Biologic Products Institute estimates private sector usage at between 400 to 500 doses per year. This vaccine has been purchased by the Army since 1970 for use by at-risk laboratory workers (estimated at between 500 to 1000 total recipients), and it was used during the Gulf War (approximately 150,000 recipients) to immunize U.S. forces against Iraq's production of biological weapons. The military currently immunizes people working in at-risk jobs and some 3,000 personnel assigned to special operations units, the Army Technical Escort Unit and the Marine Chemical-Biological Initial Response Force (CBIRF).

Q21. Was it FDA-licensed at the time it was given?

A21. Yes. It was licensed by the FDA in 1970.

Q22. What other countries are developing anthrax vaccines?

A22. Two other countries, Great Britain and Russia, are known to have a vaccine for anthrax. The vaccine developed by the British is similar in production methods to that used by the United States, although it is not exactly the same vaccine. The Russian vaccine is based on a live, attenuated strain of the bacteria that causes the disease.

Q23. Why immunize at all? Why not treat with antibiotics after exposure?

A23. Immunization is the safest, most effective way to provide protection against anthrax. Medical treatment after exposure is significantly less effective.

Q24. Is this vaccine FDA approved?

A24. Yes. It is fully licensed (U.S. license no. 99, 1970) by the U.S. Food and Drug Administration (FDA) for human use.

Q25. How safe is the vaccine?

A25. The vaccine is safe. It is a formalin inactivated vaccine, which means that it uses dead bacteria as opposed to live bacteria, which have a higher risk. In that respect, it is very similar to the diphtheria, whooping cough (pertussia), and

tetanus vaccinations (DPT) that all children in America receive before they can enter public school. There is no evidence from records at Michigan Biologic Products Institute that Anthrax Vaccine Adsorbed (injected) is associated with chronic or permanent local or systemic effects. Since it was first licensed in 1970, no reports of significant adverse effects have been reported to the Michigan Biologic Products Institute.

Q26. What are some of the side effects from taking this vaccine?

A26. The temporary side effects observed from the anthrax vaccine are similar in number and severity to those seen with other immunizations. For example, mild discomfort at the inoculation site or low grade fever.

Q27. Can the vaccine be taken by military members who are pregnant or are breast feeding?

A27. Personnel who are pregnant should not take this vaccine unless anthrax exposure occurs or is imminent. The vaccination program will be deferred until the member is no longer pregnant. The anthrax vaccine can be given to women who are breast feeding.

Q27a. What other medical conditions will preclude a member from receiving the vaccine?

A27a. HIV positive individuals should not be immunized unless anthrax exposure occurs or is imminent. However, their immune response may not be adequate to protect them against the disease.

Q28. Is there a requirement for long-term follow-up after this vaccine is administered?

A28. No. This is an FDA-licensed product and does not require follow-up. Required medical records will be maintained.

Q29. What is the cost of the vaccination program?

A29. When all associated costs (transportation, storage, administration, etc.) are included, the cost to immunize an estimated 2.4 million personnel (over a 6-year period) is approximately $130 million.

Q30. Will service members have a choice in receiving the vaccine?

A30. No. This series of inoculations will be treated the same as other inoculations required for service members to be deployed. All service members will be required to take the vaccination in accordance with the DoD directive for the purpose of protecting our forces unless medically deferred.

Q31. Has anthrax been weaponized? By whom?

A31. We do not discuss specific threat information. However, the threat exists and the department wants to do everything it can to protect our forces.

Q32. Is the anthrax vaccine an experimental drug?

A32. No. The anthrax vaccine is fully licensed by the FDA and has been in use since 1970. Veterinarians, leather workers, researchers, and others are routinely vaccinated against anthrax.

Q33. Isn't this vaccine considered a possible cause of Gulf War illnesses?

A33. No. Several scientific bodies have addressed this issue and to date, there is no scientific information to that affect. The Presidential Advisory Committee on Gulf War Veterans' Illnesses (1996) concluded that it is unlikely that health effects reported by Gulf War veterans today are the result of exposure to the anthrax vaccine used alone or in combination with the botulinum toxoid vaccine. The Presidential Advisory Committee also considered the health effects of receiving multiple vaccine..."the human immune system has evolved the capability to deal with thousands of foreign substances, to sort them out, and to regulate the immune response. Humans live among a vast population of hostile microorganisms, and vaccinations -- even multiple, contemporaneous vaccinations -- are a small part of total immune stimulation. Individual vaccines can cause adverse effects, but several studies of the effects of giving multiple vaccinations at one time have found no adverse effects associated with the practice. Research on this issue continues, but based on available evidence, the Committee believes it is unlikely that multiple vaccines are responsible for illnesses reported today by Gulf War veterans."

Q34. Who is the executive agent for the biological immunization effort?

A34. DoD Directive 6205.3 designates the Secretary of the Army as the executive agent for the DoD immunization program for biological warfare defense.

Q35. Are vaccines being developed for other biological agents?

A35. Yes, vaccines are being developed, whenever appropriate, for all validated biological threat agents.

Q36. If there is a war, is there enough vaccine stockpiled to inoculate the entire force?

A36. Provisions have been made to vaccinate the entire force.

Q37. How is the Navy going to track the immunization process since it takes 18 months to complete?

A37. The SNAP Automated Medical System (SAMS) has been selected as the tracking system for anthrax and all other immunizations

for all medical treatment facilities (MTFs) and branch clinics; all ships and submarines and other operational units; and all Active Duty and Reserve Marine Corps units. The Reserve Standard Training, Administration, and Readiness Support (RSTARS) System will continue to be used to track all immunizations administered to Navy Reserve personnel. The use of any other automated system to track anthrax immunizations is not authorized. Marines may continue to use other automated systems to track other immunizations until an interface engine is written to import immunization data from other automated systems into SAMS.

Q38. At what point during the immunization process will Sailors and Marines be allowed to deploy to a high-risk location?

A38. Present guidance is that three of the six shots will afford sailors and Marines an adequate degree of immunity to deploy. They will complete the six shot series and continue with the annual booster until discharge or released from their Service obligation.

Q39. If military members refuse to be immunized, will they be discharged or court-martialed?

A39. Since this is a mandatory program, those refusing the vaccine will be subject to disciplinary procedures.

Q40. What mechanism is in place to protect family members who may be residing with a military sponsor in a high-risk area?

A40. Further guidance on this is forthcoming.

Q41. Will DoD civilians be vaccinated?

A41. Immunization against anthrax is indicated for those employees (Department of Navy civilians) whose duties classify them "Mission Essential" and place them at risk for exposure to anthrax used as a biological weapon in a combat, or operational, setting.

Q42. Will military members receive any educational information about the anthrax vaccine? How will this information be presented to soldiers?

A42. Yes. Educational materials have been designed in coordination with the other Services for commanders in the field, the Service member, and medical department personnel to be distributed prior to commencing vaccination.

Q43. What units will be vaccinated and when is the immunization process slated to begin?

A43. DON is following the Secretary of Defense guidance which states that personnel deploying to high threat areas will receive

the vaccination first, then early deployers, followed by other Service members.

Q44. What are biological agents and how are they different from chemical agents?

A44. Biological agents are disease producing, micro-organisms or organic biocides (substance capable of destroying human life) used to destroy livestock, crops or human life. Chemical warfare is conducted using chemicals other than explosives especially irritants, asphyxiants, contaminants, poisons and incendiaries (capable of causing fire).

Q45. How are biological agents deployed?

A45. Biological agents can be deployed in numerous ways from simple spray devices to ballistic missiles. The agents are often difficult to detect, symptoms are delayed, and without preventive medical efforts such as vaccinations, the results can be devastating and wide spread.

-END-

ANNEX F

MILITARY PERSONNEL

1. **PURPOSE**. To provide the military personnel concept of operations and assign responsibility for the implementation of the Naval Anthrax Vaccination Implementation Program (AVIP).

2. **SCOPE**. This annex applies to all members of the active and reserve Naval Forces: U.S. Navy and U.S. Marine Corps. This series of inoculations will be treated the same as other inoculations required for service members. All service members will be required to take the vaccination in accordance with the DoD Directive 6205.3 for the purpose of protecting our forces unless medically deferred.

3. **CONCEPT OF OPERATIONS**. The Navy and Marine Corps will implement a phased program to vaccinate all members of the Active and Reserve Naval Forces in accordance with the FDA immunization schedule and OSD and JCS guidance. This annex delineates responsibilities and establishes personnel policy guidance for the establishment of new personnel regulatory and procedural directives.

4. **ASSUMPTIONS**

a. Implementation of a system for fully tracking anthrax immunizations will be established by the Chief of Naval Operations and Commandant of Marine Corps prior to start of the immunization program.

b. Interim personnel regulatory changes and policy guidance will be approved and published prior to immunizing the force.

c. Personnel record keeping and movement processing will incorporate administrative redundancies to ensure accurate tracking during movement.

d. It is anticipated that fewer than 0.2 percent of the force will experience adverse reactions necessitating termination of the vaccine schedule, which will require assignment limitations.

e. The Physical Evaluation Board (PEB) medical board system may recommend assignment limitations for those unable to complete the immunization series due to severe reaction or a disabling sensitivity.

f. Anthrax poses a biological warfare threat, and protection of the force by the immunization is a readiness and force protection issue. Personnel readiness reporting will incorporate unit anthrax immunization status.

5. **RESPONSIBILITIES**

a. Chief of Naval Personnel. Ensure proper screening and treatment of Reserve and civilian personnel in accordance with OPNAVINST 3060.7A (NOTAL) and Naval Military Personnel System procedures.

b. Office of the Chief of Naval Operations, Medical Resources, Plans and Policy (OPNAV N931)

(1) Update procedures for readiness reporting which incorporates unit anthrax immunization status.

(2) Conduct medical coordination with Navy fleet force provider and/or Naval Component Commanders to establish unit priorities to receive anthrax vaccine (annex B).

c. Bureau of Medicine and Surgery

(1) Advise Office of the Chief of Naval Operations, Bureau of Naval Personnel, Headquarters Marine Corps, Commander, Naval Reserve Force, and the Office of the Assistant Secretary of the Navy, (Manpower and Reserve Affairs) on all immunization and prophylaxis policy decisions which impact personnel and readiness regulations. Immunization and prophylaxis policy must be set prior to incorporation of new personnel policy into existing regulations.

(2) Ensure personnel exhibiting adverse reactions to anthrax vaccine are properly examined through the PEB process. Establish clinical guidelines and referral policy for clinicians. Personnel with PEB findings will be processed to determine assignment limitations, if any.

(3) Establish guidelines for incorporation in orders and personnel files to ensure proper tracking, review, and processing of the anthrax vaccine prior to movement of personnel and during in-processing.

(4) Establish new regulatory policy and procedural requirements to ensure anthrax immunization schedule status is properly documented in permanent change of station (PCS) orders and personnel and medical records prior to transfer of all active and reserve personnel.

(5) It is desirable that all personnel assigned to high threat areas receive their first three shots prior to deployment. In those rare instances where an individual is not able to take or continue the anthrax series due to medical or administrative reasons, he/she is still deployable. Unless otherwise directed by Fleet or Unified Commanders, reservists undergoing recall/mobilization processing at NMPS will not be held pending

completion of the first three shots. Initial (or next in the series) shots will be administered at the gaining command.

(6) Establish personnel policies which delineate those populations for which immunizations are medically contraindicated or not required. Select individuals are exempt from anthrax immunizations and therefore utilization policies must be considered for the following personnel:

(a) Pregnant personnel will not be given the immunizations. If found to be pregnant during the series, vaccinations will be suspended until the member is no longer pregnant.

(b) HIV positive individuals should not be immunized.

(c) Current FDA protocol is approved for age categories 18 through 65. OASD(HA) is requesting a waiver in this protocol which will be disseminated via separate cover when approved.

(d) Vaccine series will be terminated for personnel with severe hypersensitivity reactions.

(e) Personnel with temporarily suppressed immune systems, due to therapy or acute febrile illness, will have the immunization series delayed during the course of therapy.

(f) In conjunction with the Chief of Naval Operations, establish personnel readiness policy standards and procedures for readiness reporting which incorporate unit anthrax immunization status.

d. Chief, Naval Reserve Forces and Marine Corps Reserve Forces

(1) Advise Chief of Naval Personnel (CHNAVPERS) regarding the impact of the AVIP on drilling reserve personnel and units. Commanding Officer, Naval Reserve Personnel Center, New Orleans will report the impact on non-drilling reservists to the Chief of Naval Personnel. Commander, Marine Corps Reserve Force report impact to Headquarters, Marine Corps as directed.

(2) Prioritize personnel for receipt of anthrax vaccination.

(3) Incorporate immunization adverse reaction assignment limitations into assignment process.

(4) Establish a business process to monitor the incidence of adverse reactions that occur after personnel have been

released from military control (i.e., annual training, active duty for special work).

(5) Execute the anthrax immunization policy for reserve forces of the Navy and Marine Corps.

ANNEX G

CIVILIAN PERSONNEL

1. REFERENCES

a. Department of Defense Directive, DoDD 6205.3, DoD Immunization Program for Biological Warfare Defense, 26 November 1993 (NOTAL).

b. BUMEDINST 6230.15, Air Force Joint Instruction 48-110, Army Regulation 40-562, and CG COMDTINST M6230.4E, Immunizations and Chemoprophylaxis (NOTAL).

c. Package Insert, Anthrax Vaccine Adsorbed, Michigan Biological Products Institute

2. **PURPOSE**. To provide the civilian personnel concept of operations and assign responsibility for the implementation of the Department of the Navy Anthrax Vaccination Implementation Program (AVIP).

3. **SCOPE**. This Annex applies to all civilian employees of the DON.

4. **APPLICABILITY**

a. Overall policy. Federal civilian employees and other groups having status equivalent to deployable forces serving under the auspices of the DON are subject to the same immunization requirements as active duty personnel. Commanding officers must comply with 5 Code of Federal Regulations (CFR) 339.205 prior to requiring immunization of federal civilian employees. Questions regarding the application of this policy to contract employees will be addressed by the cognizant contracting activity.

b. Immunization against anthrax is indicated for those employees (DON civilians) whose duties classify them "Mission Essential" and place them at risk for exposure to anthrax used as a biological weapon in a combat or operational setting.

c. For the purposes of this plan, risk does not include the potential for anthrax used in acts of terrorism against noncombatants. Examples of employees who should be immunized include those who work in, or are likely to be deployed to, areas of operations identified as high risk.

d. Ultimately, the commander determines which employees are at sufficient risk to warrant immunization.

e. Command-directed anthrax immunization is administered without charge to the employee.

4. **CONSENT FOR IMMUNIZATION**

a. Civilian employee immunization is by informed consent. Employees will be encouraged to accept anthrax immunization when offered. However, in certain instances, anthrax immunization might be determined by the appropriate authority to be a condition of employment. A Vaccine Information Sheet will be provided to all vaccine recipients.

b. The effect on an employee who refuses immunization, when indicated, will be determined by the supervisor and commander in conjunction with representatives of the Civilian Personnel Office. Refusal of anthrax immunization must be documented in the employee personnel record and the occupational health record.

5. **DOCUMENTATION**

a. Risk communication. Commanders will be responsible for ensuring that employees are adequately trained and aware of the health risk of anthrax as a biological weapon, and document that this training was received.

b. Refusal. Refusal of immunization must be documented as indicated in 4b above.

c. Health records

(1) All anthrax immunizations will be recorded in the occupational health record and on a PHS Form 731. Written entries will contain the data elements described in annex A.

(2) Employee immunizations will be entered into the automated data system for tracking in the manner described in annex C.

(3) Serious adverse reactions to immunization will be recorded in the occupational health record, and reported to NAVENVIRHLTHCEN in the manner described in annex C.

ANNEX H

UNITED STATES NAVAL RESERVE AND UNITED STATES MARINE CORPS RESERVE

1. **PURPOSE.** This annex defines the application of the concept of operations from the basic plan to the Selected U.S. Naval Reserve (USNR), and the Selected Marine Corps Reserve (SMCR).

2. **SCOPE.** This annex applies to all members of the USNR and SMCR.

3. **CONCEPT OF OPERATIONS**

a. Personnel. All USNR/SMCR personnel will receive anthrax immunization in accordance with annex B. Additional medical department personnel support will be coordinated with BUMED.

b. Facilities

(1) Due to the complexity of the immunization schedule, geographic dispersion of units, logistical/medical requirements associated with providing immunizations, personnel turnover, and unavoidable drill absences, immunization opportunities must be made available at times and locations other than Reserve units on drill weekends. The vaccine needs to be available at identified facilities in order for reservists to obtain immunizations as required by the immunization schedule.

(2) MTFs at Navy Mobilization Processing Sites will be augmented by additional medical personnel to assist with vaccination of SELRES and IRR personnel. Request will be made through OPNAV N931.

c. Method. Immunization of USNR/SMCR personnel will be accomplished through identified Naval Reserve Activities (NRA) and Marine Corps Reserve Training Centers (MCRTC) military medical treatment facilities (MTFs), and where necessary, contract providers. This system of service providers will be initiated and administered by Commander, Naval Reserve Force (COMNAVRESFOR).

d. Prioritization. COMNAVRESFOR; Commander Marine Forces Reserve (COMMARFORRES) and Naval Reserve Personnel Center (NAVRESPERSCEN); and Marine Corps Reserve Support Command (MCRSC) will prioritize troop populations to receive immunizations in accordance with the following priorities.

(1) In accordance with annex B.

(2) Early deploying Selected Reserve (SELRES) and Individual Mobilization Augmentees (IMA).

(3) Remaining SELRES, IMAs and IRRs.

e. Documentation. Annotation of immunizations in medical records (SF 601, and PHS Form 731) per the basic plan will be accomplished by the health care provider administering the vaccination.

f. Tracking. Documenting and updating immunizations and adverse reactions data into the designated automated record keeping system (annex C) will be the responsibility of:

(1) Naval reserve activity medical department representative.

(2) Inspector - Instructor Hospital Corpsman.

(3) NRPC for IRR personnel.

(4) MCRSC for IMA and IRR personnel.

g. Logistics. NAVMEDLOGCOM will coordinate distribution of the vaccine and ancillary supplies (to include the handling, storage and disposal of bio-hazardous materials) in accordance with local laws and ordinances and annex D.

h. Adverse Reactions. COMNAVRESFOR/MARFORRES/HQMC (RAM3) will establish a mechanism to monitor and document adverse reactions which occur after the reservist has been released from duty (Annual Training (AT), Active Duty for Training (ADT), Inactive Duty Training (IDT), Inactive Duty Training Travel (IDTT), Active Duty for Special Work (ADSW)). See annex C for adverse reactions and reporting requirements, and SECNAVINST 1770.3B for incapacitation benefits eligibility.

i. Force Education. Commanders, medical department personnel, and Service members will receive Anthrax information packages for force education. Commanders will support and ensure that this information is distributed through appropriate all-hands education venues.

j. Command Responsibility. The execution of the AVIP is a command responsibility. Commanders at all levels will coordinate with supporting activities to ensure reservists receive required immunizations per the schedule outlined in the Basic Plan and annex A. Reservists will be immunized during periods of IDT, IDTT, AT, ADT, or ADSW.

k. Resource Management. BUMED, with input from COMNAVRESFOR/ COMMARFORRES, will submit AVIP requirements for funding of immunization services and future AVIP activities (i.e., those requirements beyond the initial 6-year program

defined in the basic plan). Refer to annex D for logistics concerns.

4. **RESPONSIBILITIES**

a. Chief of Naval Operations (CNO)

(1) Fleet Naval Medical Components and OPNAV N931 will coordinate with Navy fleet force providers and/or Navy Component Commanders to issue initial and subsequent unit prioritization lists (annex B).

(2) COMNAVRESFOR will distribute the prioritization list to subordinate commands and NRPC.

b. Commandant of the Marine Corps (CMC)

(1) Headquarters Marine Corps (MPP60) will issue initial and subsequent unit prioritization list (annex B).

(2) COMMARFORRES will distribute the prioritization list to subordinate commands and MCRSC.

c. Chief, Naval Medicine and Surgery (BUMED)

(1) BUMED will ensure arrangements are made with appropriate facilities for administration of immunizations within geographic proximity to the reservist, in coordination with COMNAVRESFOR.

(2) Coordination with appropriate facilities include NRAs/MCRTC, military MTFs, Veterans Affairs Hospitals and clinics, the United States Public Health Service, and local DoD contract treatment facilities.

d. Naval Medical Logistics Command (NAVMEDLOGCOM). Ensure distribution of vaccine to appropriate facilities.

e. Commander, Naval Reserve Force (COMNAVRESFOR)

(1) Will notify units identified for immunization.

(2) Will provide BUMED and NAVMEDLOGCOM with reserve population demographics to be used in support of AVIP.

e. Commander, Marine Forces Reserve (COMMARFORRES)

(1) Will notify units identified for immunization.

(2) Will provide BUMED with reserve population demographics to be used in support of AVIP.

f. Naval Reserve Personnel Center

(1) Will notify individual ready reserve (IRR) personnel requiring immunizations.

(2) Will provide BUMED and COMNAVRESFOR with a summary of IRR personnel demographics to be used in support of AVIP.

(3) Will ensure IRR personnel requiring immunizations receive coordinating instructions which clearly identify the authorized immunization sites and points of contact.

g. Marine Corps Reserve Support Command (MCRSC)

(1) Will notify IRR personnel requiring immunizations.

(2) Will provide BUMED and COMMARFORRES with a summary of IRR personnel demographics to be used in support of AVIP.

(3) Will ensure IRR personnel requiring immunizations receive coordinating instructions which clearly identify the authorized immunization sites and points of contact.