

R 201855Z MAY 05 ZYB MIN ZYW PSN 400846I22
FM CNO WASHINGTON DC//DNS//
TO NAVADMIN
BT
UNCLAS //N02300//
NAVADMIN 110/05
MSGID/GENADMIN/CNO WASHINGTON DC/DNS/MAY//
SUBJ/EMERGENCY USE AUTHORIZATION TO RESUME ANTHRAX VACCINATIONS//
REF/A/DOC/DEPSECDEF/YMD:20040628//
REF/B/MSG/CNO (N09) WASHINGTON DC/010012ZSEP2004//
REF/C/DOC/ASD (FMP)/YMD:20010625//
REF/D/DOC/ASD (NS AND CP)/YMD:19931126//
REF/E/DOC/ASD (FMP)/YMD:19920410//
REF/F/DOC/ASD (FMP)/YMD:19960126//
REF/G/DOC/USD (P AND R)/YMD:20040922//
REF/H/DOC/USD (P AND R)/YMD:20020806//
REF/I/DOC/ASD (HA)/YMD:20020806//
REF/J/DOC/SECDEF/YMD:20041027//
REF/K/DOC/SECNAVINST 6230.4A/YMD:19980428//
REF/L/MSG/CNO (N09) WASHINGTON DC/290118ZOC2004//
REF/M/DOC/FDA/YMD:20050202//
REF/N/DOC/DEPSECDEF/YMD:20050425//
REF/O/DOC/USD (P AND R)/YMD:20050429//
NARR/REF A IS DEPUTY SECRETARY OF DEFENSE (DEPSECDEF) MEMO DIRECTING
EXPANSION OF ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP) AND
SMALLPOX IMMUNIZATION PROGRAM (SVP) FOR DOD PERSONNEL. REF B IS
NAVADMIN 201/04 DIRECTING EXPANSION OF AVIP AND SVP. REF C IS
ASSISTANT SECRETARY OF DEFENSE, FORCE MANAGEMENT POLICY (ASD(FMP))
MEMO NOTIFYING EMERGENCY-ESSENTIAL EMPLOYEES REGARDING AVIP
REQUIREMENTS. REF D IS DOD DIRECTIVE 6205.3, IMMUNIZATION PROGRAM
FOR BIOLOGICAL WARFARE DEFENSE. REF E IS DOD DIRECTIVE 1404.10,
EMERGENCY-ESSENTIAL DOD CITIZEN CIVILIAN EMPLOYEES. REF F IS THE
DOD INSTRUCTION 3020.37, CONTINUATION OF ESSENTIAL DOD CONTRACTOR
SERVICES DURING CRISIS. REF G IS UNDER SECRETARY OF DEFENSE,
PERSONNEL AND READINESS (USD (P AND R)) MEMO DIRECTING EXPANSION OF
FORCE HEALTH PROTECTION ANTHRAX AND SMALLPOX IMMUNIZATION PROGRAMS
FOR EMERGENCY-ESSENTIAL AND EQUIVALENT DOD CIVILIAN EMPLOYEES. REF
H IS USD (P AND R) POLICY MEMO ON ADMINISTRATIVE ISSUES RELATED TO
THE AVIP. REF I IS ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
(ASD(HA)) POLICY MEMO ON CLINICAL ISSUES RELATED TO ANTHRAX
VACCINATION. REF J IS SECDEF MEMO DIRECTING TO TEMPORARILY STOP
GIVING ANTHRAX IMMUNIZATIONS TO ALL DOD PERSONNEL. REF K IS
SECNAVINST 6230.4A, DEPARTMENT OF THE NAVY (DON) ANTHRAX VACCINATION
IMPLEMENTATION PROGRAM (AVIP). REF L IS NAVADMIN 245/04 DIRECTING
ANTHRAX VACCINE IMMUNIZATION PROGRAM PAUSE. REF M IS FOOD AND DRUG
ADMINISTRATION (FEDERAL REGISTER DOCKET NO. 2005N-0040, VOL 70)
AUTHORIZATION OF EMERGENCY USE OF ANTHRAX VACCINE ADSORBED (AVA) FOR
PREVENTION OF INHALATION ANTHRAX BY INDIVIDUALS AT HEIGHTENED RISK
OF EXPOSURE DUE TO ATTACK WITH ANTHRAX. REF N IS DEPSECDEF MEMO
DIRECTING RESUMPTION OF AVIP UNDER EMERGENCY USE AUTHORIZATION
(EUA). REF O IS USD (P AND R) MEMO DIRECTING IMPLEMENTATION OF
RESUMPTION OF THE AVIP UNDER EUA.//
POC/KARI BUCHANAN/LCDR/CNO N931D5/LOC:WASHINGTON DC/TEL:703-601-1716
/TEL:DSN 329-1716/EMAIL:KARI.BUCHANAN@NAVY.MIL//
RMKS/1. BACKGROUND. ON 10 DEC 04, THE DEPSECDEF DETERMINED THAT
THERE IS A SIGNIFICANT POTENTIAL FOR A MILITARY EMERGENCY INVOLVING
UNITED STATES MILITARY FORCES AND AN ATTACK WITH ANTHRAX. ON 22 DEC

04, THE ASD(HA) REQUESTED THAT THE FOOD AND DRUG ADMINISTRATION (FDA) ISSUE AN EMERGENCY USE AUTHORIZATION (EUA) REGARDING AVA TO PREVENT INHALATION ANTHRAX (REF L). THE SECRETARY OF HEALTH AND HUMAN SERVICES, ON 14 JAN 05, DECLARED AN EMERGENCY JUSTIFYING THE EMERGENCY USE OF AVA. FDA ISSUED THE EUA ON 27 JAN 05 (REF M). ON 1 APR 05, THE US DISTRICT COURT FOR THE DISTRICT OF COLUMBIA MODIFIED ITS INJUNCTION AGAINST ANTHRAX IMMUNIZATIONS. THUS, IN ACCORDANCE WITH REFS A-K, N AND O, DOD IS AUTHORIZED TO RESUME ANTHRAX IMMUNIZATIONS, UNDER EUA RESTRICTIONS, FOR ALL PERSONNEL INCLUDED IN REF O. IMPORTANT NOTES:

A. COURT ORDERED PAUSE ON THE "MANDATORY" AVIP REMAINS IN EFFECT.

B. UNDER THE EUA, PERSONNEL MAY DECLINE ANTHRAX IMMUNIZATIONS WITHOUT HARASSMENT, COERCION OR ADMINISTRATIVE PUNISHMENT.

C. IMMUNIZATIONS UNDER EUA RESTRICTIONS ARE APPROVED FOR A SIX MONTH PERIOD WHICH WILL EXPIRE NLT 27 JUL 05, UNLESS EXPLICITLY EXTENDED.

D. PER REF N, VOLUNTARY IMMUNIZATIONS OF LABORATORY RESEARCH PERSONNEL AGAINST CUTANEOUS ANTHRAX ARE NOT SUBJECT TO COMPLIANCE WITH THE EUA AVIP AND ARE AUTHORIZED TO CONTINUE.

2. EUA AVIP. AS DIRECTED BY DOD IN REF O, THE NAVY WILL INITIATE THE EUA AVIP FOR MILITARY AND CIVILIAN PERSONNEL UNDER SPECIFIC CONDITIONS OUTLINED IN REFERENCES M, N AND O, AS DELINEATED BELOW.

A. THE EUA WAS GRANTED BY THE FDA WITH THE CONDITION THAT PERSONNEL DESIGNATED TO RECEIVE THE ANTHRAX IMMUNIZATION MAY ACCEPT OR DECLINE THE ANTHRAX IMMUNIZATION WITHOUT PUNISHMENT OR COERCION AND WILL REMAIN DEPLOYABLE.

B. EFFECTIVE 29 APRIL 05, ONLY ELIGIBLE COMMANDS WHO MEET THE REQUIREMENTS CONTAINED IN THIS MESSAGE ARE AUTHORIZED TO BEGIN THE EUA AVIP. THE US DISTRICT COURT IN WASHINGTON DC GRANTED PERMISSION TO INITIATE THE EUA AVIP UNDER FDA GUIDELINES PROVIDED THAT DOD STRICTLY COMPLY WITH ALL FDA AND LEGAL REQUIREMENTS. NON-COMPLIANCE WITH THE EUA AVIP WILL NOT BE TOLERATED AND MAY RESULT IN PUNITIVE AND/OR ADMINISTRATIVE ACTION. VIOLATIONS OF THE EUA WILL BE REPORTED TO SERVICE POC AS SOON AS RECOGNIZED.

C. COMMANDING OFFICERS (CO) AND OFFICERS-IN-CHARGE (OIC) OF UNITS TO BE IMMUNIZED AGAINST ANTHRAX MUST COMPLETE THE COMPLIANCE AGREEMENT AVAILABLE AT WWW.ANTHRAX.MIL[FORWARD SLASH]EUA WEBSITE.

(1) THE COMPLIANCE AGREEMENT WILL BE SUBMITTED TO MILVAX AGENCY VIA THE SERVICE POC.

(2) LOGISTICS COMMANDS WILL NOT SHIP ANTHRAX VACCINE TO UNITS UNTIL THE COMPLIANCE AGREEMENT STATEMENT IS RECEIVED BY THE SERVICE POC.

(3) THE COMPLIANCE AGREEMENT STATEMENT HOLDS THE CO OR OIC ACCOUNTABLE FOR STRICT COMPLIANCE WITH ALL EUA AVIP REQUIREMENTS.

3. VACCINE ELIGIBILITY. THOSE CURRENTLY ELIGIBLE TO RECEIVE EUA ANTHRAX IMMUNIZATIONS ARE:

A. MILITARY AND MILITARY SEALIFT (CIVILIAN AND CONTRACT MARINERS) PERSONNEL WITHIN THE US CENTRAL COMMAND (USCENTCOM) AREA OF RESPONSIBILITY (AOR) INCLUDING FORCES AFLOAT PER REF O FOR 15 OR MORE CONSECUTIVE DAYS.

B. US FORCES KOREA ASSIGNED TO THE KOREAN PENINSULA FOR 15 OR MORE CONSECUTIVE DAYS. THIS EXCLUDES, REPEAT EXCLUDES, C TO C+20 FORCES AND USPACOM FORWARD DEPLOYED NAVAL FORCES PREVIOUSLY IDENTIFIED FOR ANTHRAX IMMUNIZATIONS IN REF B.

C. FAMILY MEMBERS (AGES 18 TO 65) OF CATEGORIES ABOVE WHO RESIDE IN USCENTCOM AOR OR WITH US FORCES KOREA.

D. UNIFORMED PERSONNEL ASSIGNED TO SPECIAL MISSION UNITS, UNITS WITH BIOWARFARE OR BIOTERRORISM RELATED MISSIONS, AND OTHER

SPECIALLY DESIGNATED MISSIONS AS RECOMMENDED BY THE CHAIRMAN OF THE JOINT CHIEFS OF STAFF (OR DESIGNEE) AND APPROVED BY USD (P AND R).

E. PERSONNEL THAT ARE PERMANENT PARTY, OR ON TEMPORARY DUTY FOR 15 OR MORE CONSECUTIVE DAYS ASSIGNED TO LOCATIONS AND MISSIONS SPECIFIED ABOVE MAY BEGIN ANTHRAX IMMUNIZATIONS UP TO 60 DAYS BEFORE DEPARTURE EXCEPT AS INDICATED IN PARA 6 OF THIS MESSAGE. PERSONNEL MUST BE IN RECEIPT OF ORDERS TO RECEIVE EUA ANTHRAX IMMUNIZATIONS.

F. PERSONNEL WILL ONLY RECEIVE ANTHRAX IMMUNIZATIONS WHILE ASSIGNED TO SPECIFIED DUTIES AND OR GEOGRAPHIC LOCATIONS LISTED ABOVE. UPON RETURN FROM LOCATIONS OR WITH CHANGE IN DUTY STATUS IDENTIFIED ABOVE, PERSONNEL WILL NO LONGER RECEIVE ANTHRAX IMMUNIZATIONS. THE REQUIREMENT TO COMPLETE THE FDA APPROVED DOSING SCHEDULE IS SUSPENDED UNDER THE EUA.

G. DO NOT BEGIN EUA ANTHRAX IMMUNIZATIONS FOR DOD EMERGENCY ESSENTIAL CIVILIANS AND OTHER MISSION ESSENTIAL CONTRACTORS SERVING IN USCENTCOM AOR OR THE KOREAN PENINSULA UNTIL FURTHER GUIDANCE IS ISSUED.

H. THE EUA ANTHRAX IMMUNIZATIONS MAY BE PROVIDED IN OTHER VENUES FOR DOD PERSONNEL (E.G., EMBASSIES AND MISSIONS OF THE DEPARTMENT OF STATE), PROVIDED THAT THE REQUIREMENTS IN THIS MESSAGE AND REF O ARE FULFILLED.

4. EUA AVIP EDUCATION. CO AND OICS ARE RESPONSIBLE FOR EDUCATING THEIR PERSONNEL PRIOR TO RECEIVING EUA ANTHRAX IMMUNIZATIONS.

A. CO AND OICS WILL ENSURE ALL PERSONNEL ELIGIBLE UNDER THE EUA RECEIVE THE FOLLOWING SPECIFIC EDUCATION:

- (1) FDA ISSUED THE EUA FOR PREVENTING INHALATIONAL ANTHRAX.
- (2) MILITARY AND CIVILIAN LEADERSHIP STRONGLY RECOMMEND ANTHRAX IMMUNIZATIONS AS A FORCE HEALTH PROTECTION MEASURE. IMMUNIZATIONS PROTECT INDIVIDUALS, UNITS, AND THEIR MILITARY MISSION.
- (3) THE SIGNIFICANT KNOWN AND POTENTIAL BENEFITS AND RISKS OF ANTHRAX VACCINE.
- (4) NO OTHER PRODUCT IS APPROVED BY FDA TO PREVENT ANTHRAX BEFORE EXPOSURE.
- (5) INDIVIDUALS HAVE THE OPTION TO ACCEPT OR DECLINE ANTHRAX VACCINE.
- (6) THE MEDICAL CONSEQUENCES OF REFUSING THE VACCINE (E.G. VULNERABILITY TO LETHAL ANTHRAX INFECTION)
- (7) ALTERNATIVE POST EXPOSURE TREATMENT OPTIONS, IF ANY.

B. CO AND OIC'S WILL INFORM ALL INDIVIDUALS ELIGIBLE FOR EUA ANTHRAX IMMUNIZATIONS "YOU MAY DECLINE ANTHRAX IMMUNIZATION UNDER THE EUA, AND YOU WILL NOT BE PUNISHED. NO DISCIPLINARY ACTION OR ADVERSE PERSONNEL ACTION WILL BE TAKEN. YOU WILL NOT BE PROCESSED FOR SEPARATION, AND YOU WILL STILL BE DEPLOYABLE. THERE WILL BE NO PENALTY OR LOSS OF ENTITLEMENT FOR REFUSING ANTHRAX IMMUNIZATIONS."

C. THE PRIMARY MODE OF EDUCATION IS THE EUA AVIP TRIFOLD DATED 5 APRIL 2005 OR LATER. EACH INDIVIDUAL WILL BE PROVIDED A COPY OF THE EUA AVIP TRIFOLD BROCHURE BEFORE EACH ANTHRAX IMMUNIZATION. NO ANTHRAX IMMUNIZATION WILL BE GIVEN UNLESS AN EUA AVIP TRIFOLD BROCHURE IS DISTRIBUTED BEFORE EACH DOSE.

- (1) ALL EARLIER VERSIONS OF THE AVIP TRIFOLD BROCHURES WILL BE COLLECTED AND DISCARDED OR RECYCLED. DO NOT RETAIN THEM FOR FUTURE USE. BE SURE TO REMOVE OBSOLETE AVIP TRIFOLD BROCHURES FROM PAMPHLET RACKS IN WAITING ROOMS, ON BULLETIN BOARDS, INTRANETS, ETC.
- (2) EUA AVIP TRIFOLD BROCHURES WILL BE MAILED TO UNITS ONCE THE COMPLIANCE AGREEMENT IS SUBMITTED AND AN ANTHRAX VACCINE ORDER IS APPROVED.
- (3) EUA AVIP TRIFOLD BROCHURES CAN BE DOWNLOADED FROM THE MILVAX

WEBSITE LISTED IN PARA 4B AND REPRODUCED IF NECESSARY.

D. CO AND OIC'S WILL SUPPLEMENT THE EUA AVIP TRIFOLD BROCHURE WHENEVER POSSIBLE WITH A STANDARD EUA AVIP BRIEFING AVAILABLE ON THE MILVAX WEBSITE (WWW.ANTHRAX.MIL[FORWARD SLASH]WHATSNEW[FORWARD SLASH]EUA). IF UNABLE TO ACCESS THIS BRIEF, OR IF YOU NEED THE BRIEF SHIPPED TO YOU IN HARD COPY OR ON A CD-ROM, SEND AN EMAIL REQUEST TO: ON NIPRNET VACCINES@OTSG.AMEDD.ARMY.MIL OR ON SIPRNET OTSG.OPSCENTER21OPNS@HQDA-S.ARMY.SMIL.MIL (ON THE SUBJECT LINE INDICATE "ATTENTION: MILVAX").

(1) CO AND OIC'S SHOULD DEVELOP TEAMS OF LOCAL HEALTHCARE PROVIDERS AND OTHER SUBJECT MATTER EXPERTS (E.G., JUDGE ADVOCATE GENERAL, PUBLIC AFFAIRS OFFICE) TO ASSIST WITH EUA AVIP BRIEFINGS.

(2) QUESTIONS SHOULD BE ANSWERED PROACTIVELY AND UPFRONT.

E. CO AND OIC'S WILL KEEP A DATED ROSTER OF PERSONNEL PROVIDED AN EUA AVIP TRIFOLD BROCHURE AND BRIEF. THE ROSTER WILL BE ENTITLED "I RECEIVED AN EUA TRIFOLD FOR ANTHRAX VACCINE". THESE ROSTERS WILL BE RETAINED AT THE COMMAND AND AVAILABLE TO VALIDATE COMPLIANCE.

(1) EUA AVIP TRIFOLD BROCHURES ARE INTENDED FOR PERSONAL ISSUE TO VACCINE CANDIDATES. DO NOT COLLECT SIGNATURES ON THESE BROCHURES.

(2) PERSONNEL DO NOT SIGN THAT THEY ACCEPT OR DECLINE ANTHRAX IMMUNIZATIONS UNDER THE EUA. THEY ARE SIGNING THAT THEY RECEIVED THE EDUCATION.

(3) A COPY OF THE EDUCATION ROSTER SHALL BE SUBMITTED TO THE MEDICAL ACTIVITY ADMINISTERING THE EUA ANTHRAX IMMUNIZATIONS. THE MEDICAL ACTIVITY SHALL VERIFY THAT ALL PERSONNEL HAVE RECEIVED APPROPRIATE EDUCATION PRIOR TO ADMINISTERING EUA ANTHRAX IMMUNIZATIONS.

F. HEALTHCARE PROVIDERS (E.G., PREVENTIVE MEDICINE AND PUBLIC HEALTH STAFF, AMBULATORY CARE, ALLERGY-IMMUNOLOGY, FLIGHT MEDICINE, AND EMERGENCY CARE) AND VACCINATORS WILL BE KNOWLEDGEABLE ON THE FOLLOWING TOPICS:

(1) EUA AVIP HEALTHCARE PROVIDER BRIEF AT WWW.ANTHRAX.MIL[FORWARD SLASH]EUA.

(2) BIOTHRAX PACKAGE INSERTS, AVAILABLE WITH EVERY VACCINE VIAL OR AT WWW.BIOPORT.COM[FORWARD SLASH]ANTHRAXVACCINE[FORWARD SLASH]INSERT[FORWARD SLASH]AVAININSERT.ASP.

(3) THE EUA AVIP TRIFOLD BROCHURE DATED 5 APR 2005 OR LATER.

(4) INFORMATION IN PARA 4 OF THIS MESSAGE.

(5) REPORTING PROCEDURES FOR VACCINE ADVERSE EVENTS REPORTING SYSTEM(VAERS) AT WWW.VAERS.ORG.

(6) CONTRAINDICATIONS FOR ANTHRAX IMMUNIZATIONS AND INITIATING MEDICAL EXEMPTION ASSESSMENTS PER REF I (E.G., PREVIOUS SERIOUS ALLERGIC REACTIONS TO ANTHRAX IMMUNIZATIONS, PRESENCE OF CURRENT MODERATE OR SEVERE ILLNESS, PREGNANCY, LATEX SENSITIVITY, IMMUNE-SUPPRESSIVE CONDITIONS, GUILLIAN-BARRE SYNDROME, RECOVERED FROM ANTHRAX INFECTION IN THE PAST).

(7) PROCEDURES TO IDENTIFY EARLY PREGNANCY TO INCLUDE OFFERING PREGNANCY TESTING BEFORE ANY IMMUNIZATION.

G. A COPY OF THE US DISTRICT COURT'S 27 OCT 04 "ORDER AND OPINION OF INJUNCTION" MUST BE READILY AVAILABLE AT THE IMMUNIZATION SITES FOR VACCINEES TO READ. COPIES WILL BE SHIPPED WITH THE EUA AVIP TRIFOLD BROCHURES FROM USAMMA. THE DOCUMENT IS ALSO AVAILABLE AT WWW.ANTHRAX.MIL[FORWARD SLASH]EUA.

5. OPTION TO DECLINE. THE FDA GRANTED THE EUA WITH THE CONDITION THAT PERSONNEL DESIGNATED TO RECEIVE THE ANTHRAX IMMUNIZATION MAY ACCEPT OR REFUSE THE IMMUNIZATION. PERSONNEL CHOOSING TO DECLINE THE ANTHRAX IMMUNIZATION WILL NOT BE PUNISHED, HARASSED OR COERCED. COMMANDERS WILL RESPECT THE INDIVIDUAL'S DECISION TO DECLINE ANTHRAX

IMMUNIZATIONS DURING THE EUA.

A. IF A SERVICEMEMBER EXPRESSES DOUBTS ABOUT RECEIVING THE ANTHRAX IMMUNIZATION, THE CO OR OIC MAY OFFER ADDITIONAL EDUCATION ON THE RISKS OF DECLINING THE VACCINE. CO OR OIC WILL ENSURE SERVICEMEMBER RECEIVES THE EUA AVIP TRIFOLD BROCHURE DATED 5 APR 05 OR LATER. AT A MINIMUM, THE ADDITIONAL EDUCATION SHOULD COVER THE FOLLOWING POINTS:

- (1) ANTHRAX SPORES ARE LETHAL.
- (2) ANTHRAX SPORES CAN BE INHALED UNKNOWINGLY.
- (3) ANTHRAX VACCINE IS 92.5 PERCENT EFFECTIVE IN PREVENTING ANTHRAX INFECTION.
- (4) ANTHRAX IMMUNIZATION MAY BE DECLINED UNDER THE EUA WITHOUT RETRIBUTION, HARASSMENT OR PUNISHMENT.
- (5) SERVICE MEMBER WILL REMAIN DEPLOYABLE IF ANTHRAX IMMUNIZATION IS DECLINED UNDER THE EUA.
- (6) DECLINING ANTHRAX IMMUNIZATIONS COULD RESULT IN MEMBER'S DEATH AND IMPACT THE UNIT'S ABILITY TO ACCOMPLISH THE MISSION.

B. IF A MEMBER CHOOSES TO EXERCISE THE OPTION TO DECLINE ANTHRAX IMMUNIZATIONS DURING EUA, CO AND OICS WILL RESPECT THAT INDIVIDUAL'S DECISION. NO DISCIPLINARY ACTION WILL BE TAKEN BY THE CHAIN OF COMMAND. CO AND OICS WILL ENSURE THE MEMBER IS NOT HARASSED OR COERCED TO RECEIVE ANTHRAX IMMUNIZATIONS.

(1) MEMBERS WHO DECLINE EUA ANTHRAX IMMUNIZATIONS WILL NOT BE OFFERED ANTHRAX IMMUNIZATIONS AGAIN UNTIL A CHANGE OF CIRCUMSTANCES OCCURS (E.G., CHANGE OF DUTY, CHANGE OF LOCATION, PASSAGE OF AT LEAST 30 DAYS).

(2) MEMBERS MAY CHANGE THEIR DECISION AND REQUEST ANTHRAX IMMUNIZATIONS AT ANY TIME PROVIDED THEY ARE STILL ELIGIBLE TO RECEIVE THE ANTHRAX IMMUNIZATION UNDER THE EUA. (NOTE THAT THE BODY'S IMMUNE SYSTEM REQUIRES TIME TO DEVELOP IMMUNITY TO ANTHRAX).

(3) IF A MEMBER ACCEPTS AN ANTHRAX IMMUNIZATION, THE MEMBER MAY ELECT NOT TO RECEIVE A SUBSEQUENT DOSE UNDER THE EUA AVIP.

6. RESERVE COMPONENT (RC) PERSONNEL. IN ADDITION TO PARA 3, RC PERSONNEL MUST MEET THE FOLLOWING CONDITIONS IN ORDER TO RECEIVE EUA ANTHRAX IMMUNIZATIONS.

A. SPECIFIC CRITERIA FOR RC PERSONNEL ARE AS FOLLOWS:

(1) RC PERSONNEL IN RECEIPT FOR ORDERS OF LESS THAN 30 DAYS WILL RECEIVE EUA ANTHRAX IMMUNIZATIONS AT SUPPORTED COMMAND IN THEATER. SUPPORTED COMMAND CO OR OIC IS RESPONSIBLE FOR EUA ANTHRAX EDUCATION.

(2) RC INDIVIDUAL MOBILIZATION AUGMENTEES WILL RECEIVE EUA ANTHRAX IMMUNIZATIONS AT NAVY MOBILIZATION PROCESSING SITES. NMPS CO OR OIC IS RESPONSIBLE FOR EUA ANTHRAX EDUCATION. RC MEMBERS WILL RECEIVE THE INITIAL ANTHRAX IMMUNIZATION AT THE NMPS AND ANY SUBSEQUENT IMMUNIZATIONS AT I-STOPS AND ULTDUSTA. IT IS NOT REQUIRED THAT PERSONNEL HAVE INITIAL SERIES OF THREE ANTHRAX IMMUNIZATIONS PRIOR TO DEPLOYING TO THEATER.

(3) RC UNITS WITH ORDERS MEETING CRITERIA IN PARA 3 MUST COMPLY WITH EUA AVIP REQUIREMENTS AND RECEIVE RC SERVICE POC APPROVAL BEFORE ORDERING AND ADMINISTERING ANTHRAX VACCINE. RC UNIT CO OR OIC IS RESPONSIBLE FOR EUA ANTHRAX EDUCATION.

B. RC MEMBERS MUST BE IN A DUTY STATUS WHEN RECEIVING ANY DOD-DIRECTED IMMUNIZATION.

C. AN ADVERSE REACTION TO A DOD-DIRECTED IMMUNIZATION IS A LINE OF DUTY (LOD) CONDITION.

(1) RC MEMBERS WHO INCUR OR AGGRAVATE ANY INJURY, ILLNESS, OR DISEASE WHILE PERFORMING ACTIVE DUTY FOR LESS THAN 30 DAYS, OR ON INACTIVE DUTY TRAINING ARE ENTITLED TO MEDICAL CARE APPROPRIATE FOR

THE TREATMENT OF THE INJURY, ILLNESS, OR DISEASE.

(2) WHEN AN RC MEMBER PRESENTS FOR TREATMENT AT A MILITARY TREATMENT FACILITY EXPRESSING A BELIEF THAT THE CONDITION FOR WHICH TREATMENT IS SOUGHT IS RELATED TO RECEIVING AN IMMUNIZATION DURING A PERIOD OF DUTY, THE MEMBER MUST BE EXAMINED AND PROVIDED NECESSARY MEDICAL CARE. SUBMIT REPORTS TO THE VACCINE ADVERSE EVENTS REPORTING SYSTEM(VAERS) (WWW.VAERS.ORG).

(3) WHEN TREATMENT HAS BEEN RENDERED OR THE INDIVIDUAL'S EMERGENT CONDITION IS STABILIZED, A LINE OF DUTY-NOTICE OF ELIGIBILITY WILL BE DETERMINED AS SOON AS POSSIBLE. FOR INJURIES, ILLNESSES, OR DISEASE UNRELATED TO DUTY, RC MEMBERS SHOULD SEEK MEDICAL ATTENTION FROM THEIR PERSONAL HEALTHCARE PROVIDERS.

(4) RESERVE MEDICAL DEPARTMENT REPRESENTATIVES WILL ENSURE ACCURATE LOD DATA IS ENTERED IN MEDICAL READINESS REPORT SYSTEM (MRRS), FORMERLY KNOWN AS RAMIS.

7. DOSING SCHEDULE. UNDER THE EUA AVIP, THE DOSING SCHEDULE IS AS FOLLOWS:

A. PERSONNEL RESUMING ANTHRAX IMMUNIZATIONS UNDER THIS POLICY WILL CONTINUE THE DOSING SCHEDULE WHERE THEY LEFT OFF. THEY WILL NOT NEED TO REPEAT ANY DOSES ALREADY RECEIVED IN THE SERIES OR RESTART THE SERIES. THIS IS CONSISTENT WITH GUIDANCE FROM THE CENTERS FOR DISEASE CONTROL (CDC), ITS ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP), AND THE FDA. WHEN A DOSE CANNOT BE PROVIDED ON THE SPECIFIC DATE SUGGESTED BY THE SCHEDULE, PROVIDE IT AS SOON THEREAFTER AS PRACTICAL.

B. DURING THE PERIOD OF THE EUA, THE POLICY OF CONTINUING THE VACCINE DOSING SERIES (SIX SHOTS PLUS BOOSTERS) IS SUSPENDED FOR PERSONNEL WITHOUT CONTINUING DUTY ASSIGNMENT INDICATED IN PARA 3, ASSOCIATED WITH THE HEIGHTENED RISK OF EXPOSURE.

8. ANTHRAX IMMUNIZATIONS TRACKING. ALL IMMUNIZATION DATA WILL BE ENTERED INTO THE MEMBER'S MEDICAL RECORD, THE YELLOW SHOT CARD (PHS 731), AND AN APPROVED ELECTRONIC TRACKING SYSTEM (ETS) THAT TRANSMITS DATA TO DEERS. CURRENTLY THOSE SYSTEMS ARE THE SHIPBOARD NON-TACTICAL ADP PROGRAM (SNAP) AUTOMATED MEDICAL SYSTEM (SAMS), THE MRRS, AND COMPOSITE HEALTH CARE SYSTEM VERSION II (CHCS II). CHCS VERSION I DOES NOT TRANSMIT IMMUNIZATION DATA TO DEERS AND THEREFORE IS NOT AN APPROVED SYSTEM FOR IMMUNIZATION TRACKING.

A. TO ENSURE ACCURACY OF ETS ENTRIES, THE DATE OF ANTHRAX IMMUNIZATION AS RECORDED IN THE MEDICAL RECORD MUST BE THE SAME DATE RECORDED IN THE ETS. FOR ALL SYSTEMS, MANUALLY OVERRIDE TIME-DATE DEFAULT TO ACCURATELY REFLECT THE CORRECT IMMUNIZATION ADMINISTRATION DATE.

B. ALL REFUSALS SHALL BE DOCUMENTED IN THE MEDICAL RECORD (SF 600). SF 600 ENTRIES SHALL STATE: "MEMBER REFUSED EUA ANTHRAX IMMUNIZATION."

C. REFUSALS SHALL BE ENTERED INTO THE ETS UNDER THE CODE "MD" FOR MEDICALLY DECLINED.

9. REPORTING REQUIREMENTS. EUA AVIP ELIGIBLE UNIT CO AND OIC'S WILL PROVIDE WEEKLY REPORTS. THE FOLLOWING INFORMATION WILL BE ATTESTED TO: NO ONE RECEIVED ANTHRAX VACCINATION AGAINST HIS OR HER WILL, OR WITHOUT BEING INFORMED OF THE OPTION TO DECLINE, OR OTHERWISE IN VIOLATION OF THE OPTION TO DECLINE, AT THIS UNIT FOR THIS INTERVAL.

A. IN EVERY CASE IN WHICH ANTHRAX IMMUNIZATIONS WERE GIVEN WITHOUT BEING INFORMED OF THE OPTION TO DECLINE, OR OTHERWISE IN VIOLATION OF THE OPTION TO DECLINE, A REASON MUST BE PROVIDED AS WELL AS STEPS TAKEN TO PREVENT THIS FROM HAPPENING IN THE FUTURE. REPORT FORMATS ARE AVAILABLE AT WWW.ANTHRAX.ARMY.MIL WEBSITE AND WILL ALSO BE SENT

WITH EACH SHIPMENT OF VACCINE.

B. ACTIVE AND RESERVE UNITS REPORTS WILL BE SUBMITTED TO THE FOLLOWING

(1) MILITARY VACCINE AGENCY (MILVAX). CONTACT INFORMATION FOR MILVAX IS BY NIPR VACCINES@OTSG.AMEDD.ARMY.MIL OR SIPR: OTSG.OPSCENTER21OPNS@HQDA-S.ARMY.SMIL.MIL OR FAX (COMM) 703-681-4692, (DSN) 782-4692.

(2) NAVY AVIP OFFICE. CONTACT INFO IS BY NIPR EUA-AVIP@US.MED.NAVY.MIL OR FAX (COMM) 703-601-2010, (DSN) 329-2010. SIPR ADDRESS IS: OPNAV_VACCINES_N931@CNO.NAVY.SMIL.MIL.

C. REPORTS WILL BE SUBMITTED BY MONDAY OF EACH WEEK FOR THE PREVIOUS WEEK'S ACTIVITY, NO LATER THAN 1600 EST (2100 ZULU). NEGATIVE REPORTS REQUIRED.

D. WEEKLY REPORTS ARE NOT REQUIRED ONCE A UNIT NO LONGER MEETS EUA AVIP ELIGIBILITY REQUIREMENTS AS DELINEATED PARA 3. THE UNIT'S FINAL WEEKLY REPORT WILL SERVE AS A CLOSEOUT REPORT AND MUST INDICATE THAT THE UNIT NO LONGER MEETS ELIGIBILITY REQUIREMENTS.

10. EUA AVIP OVERSIGHT. COMPLIANCE WITH EUA AVIP REQUIREMENTS WILL BE INCORPORATED INTO CURRENT INSPECTION PROCESSES. CO AND OICS SHALL CONDUCT INTERNAL AUDITS OF THEIR COMPLIANCE UTILIZING NEUTRAL PARTIES NOT ENGAGED IN EUA AVIP IMPLEMENTATION.

11. VACCINE DISTRIBUTION.

A. DISTRIBUTION OF ANTHRAX VACCINE WILL BE LIMITED TO SITES WHERE CO AND OIC'S HAVE SUBMITTED COMPLIANCE AGREEMENTS.

B. UPON SERVICE POC APPROVAL, NAVAL MEDICAL LOGISTICS COMMAND (NMLC) WILL LIAISON WITH THE U.S. ARMY MEDICAL MATERIEL AGENCY (USAMMA) TO COORDINATE THE DISTRIBUTION OF ANTHRAX VACCINE PER REF K. APPROVED END-USERS WILL DIRECTLY REQUISITION VACCINE USING USAMMA WEBSITE WWW.USAMMA.ARMY.MIL[FORWARD SLASH]VACCINES.

(1) EUA AVIP TRIFOLD BROCHURES WILL BE SHIPPED TO EACH REQUESTING UNIT PRIOR TO VACCINE SHIPMENT. NO VACCINE WILL BE SHIPPED UNTIL USAMMA RECEIVES CONFIRMATION THAT BROCHURES HAVE BEEN RECEIVED. RECEIVING COMMAND WILL CONFIRM WITH USAMMA THAT BROCHURES HAVE BEEN RECEIVED.

(2) ALL SHIPMENTS OF ANTHRAX VACCINE WILL CONTAIN A COPY OF THE PACKAGE INSERT AND THE US DISTRICT COURT'S 27 OCT 2004 OPINION.

C. ACTIVITIES MUST HAVE SUFFICIENT REFRIGERATION CAPACITY TO PRESERVE VACCINE INTEGRITY, INCLUDING TEMPERATURE ALARMS AND BACK UP POWER CAPACITY. ENSURE PERSONNEL HAVE BEEN TRAINED IN COLD CHAIN MANAGEMENT PROCEDURES, INCLUDING PROMPT REFRIGERATION OF VACCINE UPON RECEIPT.

12. SERVICE POC'S ARE AS FOLLOWS:

A. ACTIVE POC: LCDR K. BUCHANAN AVAILABLE AT NIPR KARI.BUCHANAN@NAVY.MIL; SIPR BUCHANAN.KARI@CNO.NAVY.SMIL.MIL; OR FAX (COMM) 703-601-2010, (DSN) 329-2010.

B. RESERVE POC: CDR M. JACOBSEN AVAILABLE AT NIPR MARY.JACOBSEN@NAVY.MIL; SIPR JACOBSEN.MARY@CNO.NAVY.SMIL.MIL; OR FAX (COMM) 703-614-7746, (DSN) 224-7746.

13. THE ANTHRAX VACCINE IMMUNIZATION PROGRAM REMAINS A COMMANDER'S FORCE PROTECTION RESPONSIBILITY. COMMANDERS WILL FOLLOW GUIDANCE PROVIDED IN REFERENCES A-K, M, N AND O TO PROPERLY IDENTIFY AND EDUCATE SERVICE MEMBERS AND DOD CIVILIANS TO BE IMMUNIZED, TRACK IMMUNIZATIONS, AND ENSURE APPROPRIATE MEDICAL EVALUATION IF VACCINEES EXPERIENCE SYMPTOMS FOLLOWING ANY VACCINATION. COMMANDERS WILL RESPECT THE OPTION TO DECLINE ANTHRAX IMMUNIZATIONS DURING THE EUA.

14. MESSAGE WILL EXPIRE 27 JUL 05 UNLESS EXPLICITLY EXTENDED.

15. RELEASED BY VADM A. T. CHURCH III, DIRECTOR, NAVY STAFF.//
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