



Department of Defense INSTRUCTION

NUMBER 6205.4

April 14, 2000

ASD(S&TR)

SUBJECT: Immunization of Other Than U.S. Forces (OTUSF) for Biological Warfare Defense

- References: (a) [DoD Directive 6205.3](#), "DoD Immunization Program for Biological Warfare Defense," November 26, 1993
- (b) [DoD Directive 1404.10](#), "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees," April 10, 1992
- (c) [DoD Instruction 3020.37](#) "Continuation of Essential DoD Contractor Services During Crises," November 6, 1990
- (d) [DoD Instruction 1400.32](#), "DoD Civilian Work Force Contingency and Emergency Planning Guidelines and Procedures," April 24, 1995
- (e) through (h), see enclosure 1

1. PURPOSE

This Instruction implements policy, assigns responsibilities and prescribes procedures in accordance with reference (a) against validated biological warfare threats.

2. APPLICABILITY

This Instruction applies to:

2.1. The Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereafter referred to as "the DoD Components").

2.2. OTUSF personnel in regions designated as "high-threat" by the Chairman of

the Joint Chiefs of Staff (CJCS) in consultation with the Commanders in Chief of the Combatant Commands and the Director, Defense Intelligence Agency. The term "OTUSF" collectively refers to noncombatant, non-uniformed U.S. citizens, as well as other select non-U.S. personnel, not covered by reference (a), who are in high-threat regions. The specific categories of personnel covered by this Instruction are defined in section 5., below.

3. POLICY

It is DoD policy that the Combatant Commanders shall determine requirements for immunizing non-U.S. military personnel, whose support is vital to our capability to conduct a war when there is a threat or use of biological warfare agents.

4. RESPONSIBILITIES

4.1. The Under Secretary of Defense for Policy shall:

4.1.1. Review and approve the initial and subsequent annual implementation guidance for immunization of OTUSF personnel.

4.1.2. Review and approve all requests for exceptions to this policy, in coordination with the CJCS, USD(AT&L) and USD(P&R).

4.1.3. Establish and implement procedures to carry out the provisions of subparagraphs 5.2.3., 5.2.4., 5.3.2., and 5.4.3., below.

4.2. The Under Secretary of Defense for Acquisition, Technology, and Logistics shall coordinate on all acquisition, stockpile management and MOU development activities related to this policy and on all requests for assistance concerning this policy.

4.3. The Assistant Secretary of Defense for Health Affairs, under the Under Secretary of Defense for Personnel and Readiness, shall serve as the advisor to the Secretary of Defense for the DoD Immunization Program for Biological Warfare Defense and as a coordinating office on all medical matters related to this policy.

4.4. The Secretaries of the Military Departments shall:

4.4.1. Implement, monitor, evaluate and document biological weapons vaccine programs in their Department and establish procedures for coordinating and reporting the following information to the Executive Agent: the identification,

reporting and epidemiological evaluation of vaccine-associated adverse events, in accordance with FDA requirements.

4.4.2. Establish and implement procedures to carry out administration of the immunization, provision of information and communication material, documentation requirements, and immunization tracking for those personnel in Category 1 and subcategories 5.2.1.1. through 5.2.1.5. of Category 2.

4.5. The Secretary of the Army, as the DoD Executive Agent for the Immunization Program, shall:

4.5.1. Follow the responsibilities outlined in DoD Directive 6205.3 (reference (a)) in incorporating implementation of OTUSF requirements into the DoD immunization program.

4.5.2. Manage and administer the overall program and serve as the focal point for the submission of information from all Services relating to vaccine adverse events and vaccine projected program requirements. Monitor the Services' biological weapons immunization implementation plans and executing the Army's biological weapons immunization implementation plans.

4.6. The Chairman of the Joint Chiefs of Staff shall:

4.6.1. Coordinate the development of and review Combatant Commanders' implementation guidance for this policy.

4.6.2. Establish and implement procedures to carry out the provisions of subparagraphs 5.2.3., 5.3.2., and 5.4.3., below.

4.7. The Commanders of the Combatant Commands shall determine OTUSF requirements for their areas of responsibility and develop implementation guidance for those personnel in Category 1, in subcategories 5.2.1.1. through 5.2.1.5. of Category 2, and (as appropriate) in subcategories 5.3.1.1. and 5.3.1.2. of Category 3. Combatant Commanders shall coordinate between supported and supporting commands for the development of specific implementation guidance.

4.7.1. The guidance will be forwarded to the CJCS within 150 days of the effective date of this policy. Consistent with Joint Strategic Capabilities Plan guidance, Combatant Commanders tasked with developing CONPLANs for counterproliferation will thereafter include this guidance as part of the medical annex to counterproliferation CONPLANs. Combatant Commanders will review and update

OTUSF requirements annually after the initial assessment is provided to the CJCS.

4.7.2. The guidance shall include the total number of potential OTUSF personnel to be immunized and the breakout of OTUSF personnel by subcategory. For those personnel in Category 1, subcategories 5.2.1.1. through 5.2.1.3. of Category 2, and (as appropriate) subcategories 5.3.1.1. and 5.3.1.2. of Category 3, the guidance shall also include the method of tracking personnel who have received the vaccine.

4.8. Heads of the DoD Components shall carry out immunizations against biological warfare agents of "Other Than U.S. Forces" in accordance with this policy.

5. PROCEDURES

5.1. Category 1: Emergency-Essential DoD Civilian and Contractor Personnel Who Perform Essential Services

5.1.1. This category includes:

5.1.1.1. Emergency-essential U.S. national civilian employees of the Department of Defense, referred to in DoD Directive 1404.10 (reference (b)).

5.1.1.2. DoD contractors (or subcontractors) or employees of DoD contractors (or subcontractors) performing essential DoD contractor services, referred to in DoD Instruction 3020.37 (reference (c)).

5.1.2. Unless otherwise directed by the Secretary of Defense, immunization requirements, tracking and documentation applicable to military personnel under DoD Directive 6205.3 (reference (a)) shall also apply to Category 1 personnel assigned or designated to be deployed with those military personnel in a high-threat area.

5.1.3. The Secretary of Defense may direct immunizations as mandatory for Category 1 personnel. The DoD Components that employ emergency-essential DoD U.S. national civilian employees or that maintain contracts performing essential DoD contractor services shall ensure, in accordance with references (b) and (c), that all administrative and procedural actions necessary to implement such a requirement have been met. Where immunizations are mandatory for DoD contractors, subcontractors, or their employees, components shall ensure contracts are modified to implement this requirement.

5.2. Category 2: Other U.S. National Personnel

5.2.1. This category includes the following U.S. national personnel:

5.2.1.1. U.S. military family members.

5.2.1.2. Non-emergency-essential DoD civilian employees and other persons covered by DoD Instruction 1400.32 (reference (d)).

5.2.1.3. Family members of DoD civilian employees.

5.2.1.4. DoD contractor (and subcontractor) employees other than those performing essential DoD contractor services (referred to in subparagraph 5.1.1.2., above).

5.2.1.5. Family members of DoD contractor (and subcontractor) employees.

5.2.1.6. Employees of other U.S. Government (USG) Agencies.

5.2.1.7. Family members of employees of other USG Agencies.

5.2.1.8. Other USG contractor (and subcontractor) employees.

5.2.1.9. Family members of other USG contractor (and subcontractor) employees.

5.2.2. As necessary, personnel will be removed from threat areas in accordance with standard inter-agency procedures for crisis situations. If there is an imminent threat of hostilities, the USG will attempt to evacuate Category 2 personnel from the threat area. Evacuation, rather than immunization, is the primary means of addressing the threat for Category 2 personnel.

5.2.3. As an exception to the rule of subparagraph 5.2.2., above, Combatant Commanders may request authority to provide immunization for one or more designated groups of personnel within or among subcategories 5.2.1.1. through 5.2.1.5. The authority to approve such a request is reserved to the Secretary of Defense. The decision will be based on the feasibility of evacuation, availability of vaccine, impact on mission and other pertinent factors. For these Category 2 personnel to whom immunization is offered under this section, the following additional requirements apply:

5.2.3.1. Receipt of immunization will be on a voluntary basis.

5.2.3.2. For personnel in subcategories 5.2.1.1. through 5.2.1.3., the DoD Component will be responsible for implementation, to include administering the vaccine and maintaining medical and other related records. For personnel in subcategories 5.2.1.4. and 5.2.1.5., the responsibility will be with the DoD Component responsible for the contract.

5.2.4. Heads of other USG Agencies may decide to immunize their employees and family members, and may request vaccine from the Department of Defense (if the Department of Defense owns or controls the stocks of the vaccine) or purchase it directly from the manufacturer (if the vaccine is available commercially). When another USG Agency requests the vaccine from the Department of Defense, the authority to approve such a request is reserved to the Secretary of Defense. The decision will be based on the availability of the vaccine, impact on mission and other pertinent factors. If approved, the Department of Defense will provide the vaccine to other USG Agencies on a cost-reimbursement basis pursuant to the Economy Act (reference (e)).

5.3. Category 3: Other Personnel Supporting U.S. Military Operations

5.3.1. This category includes non-U.S. nationals who are required by the United States in conducting military operations. This category includes the following subcategories:

5.3.1.1. Personnel who are employees of the Department of Defense or a DoD contractor (or subcontractor) and who are not included in Categories 1 or 2.

5.3.1.2. Family members of personnel referred to in subparagraph 5.3.1.1., above.

5.3.1.3. Foreign personnel employed by the host-nation government or by contractors of the host-nation government.

5.3.1.4. Family members of personnel referred to in subparagraph 5.3.1.3., above.

5.3.2. Combatant Commanders may request authority to provide vaccine for one or more designated groups of personnel within or among the subcategories identified in subparagraph 5.3.1., above. The authority to approve such a request is reserved to the Secretary of Defense. The decision will be based on the availability of the vaccine, impact on mission and other pertinent factors. For Category 3 personnel

to whom immunization is offered under this section, the following additional requirements apply:

5.3.2.1. Receipt of immunization will be on a voluntary basis.

5.3.2.2. For personnel in subcategories 5.3.1.1. and 5.3.1.2., the DoD Component will be responsible for implementation, to include administering the vaccine and maintaining medical and other related records. For contract personnel, the responsibility will be with the DoD Component responsible for the contract.

5.3.2.3. For personnel in subcategories 5.3.1.3. and 5.3.1.4., the host nation will be responsible for implementation of the immunization initiative. The host nation will acquire the vaccine directly from the manufacturer (Direct Commercial Sales), or under the Arms Export Control Act (reference (f)), Foreign Assistance Act (reference (g)), or applicable Acquisition and Cross Servicing Agreement (reference (h)).

5.4. Category 4: Allied/Coalition Nation Personnel

5.4.1. This category includes host-nation and third-country personnel the U.S. may assist pursuant to an international agreement or as directed by the Secretary of Defense, such as allied/coalition military forces, government officials and emergency response personnel.

5.4.2. Allied/coalition nations should be strongly encouraged to develop national programs to immunize their forces, key support personnel and other national personnel as the allied/coalition governments may deem appropriate, against biological warfare agents. This is the primary means for immunizations for allied/coalition forces.

5.4.3. In cases in which it is not feasible to rely on the policy of subparagraph 5.4.2., above, Combatant Commanders may request authority to provide vaccine for one or more designated groups of personnel in Category 4. The final authority to approve such a request is reserved to the Secretary of Defense. The decision will be based on the availability of vaccine, impact on mission and other pertinent factors. If the request is approved by the Secretary of Defense, the foreign government will be responsible for implementation of the immunization initiative. The allied/coalition government will acquire the vaccine directly from the manufacturer (Direct Commercial Sales), reference (f) or reference (g).

5.5. Additional Implementation Policies

5.5.1. Priorities. For all four categories, the decision to provide vaccine will be made by the Secretary of Defense, upon the advice of the Combatant Commanders and the CJCS, and after coordination with the USD(P), USD(P&R), USD(AT&L), USD(C), General Counsel, DoD, and the Secretary of the Army (as the DoD Executive Agent for the Immunization Program). In deciding whether to provide vaccine to personnel in Category 4, coordination will also include the Secretary of State. The primary consideration for establishing priorities for immunizations will be mission impact.

5.5.2. Medical protocols. All immunizations provided or supported under this policy shall be provided consistent with medical protocols, requirements, standards and procedures established by the ASD(HA), which shall be consistent with applicable regulations and requirements of the U.S. Food and Drug Administration, including adverse events reporting.

5.5.3. Information and Communications Program. For all immunizations carried out under this policy by the DoD Components, a full information and communications program shall be implemented to assure that recipients receive accurate and complete information regarding the vaccine and the vaccine immunization program involved. With the exception of Category 1 personnel for whom the immunization is determined to be mandatory pursuant to subparagraph 5.1.3., above, information provided shall include a clear explanation that the immunization is voluntary. For all immunizations carried out under this policy by other than the DoD Components, the Department of Defense shall provide all necessary information to the receiving entity to allow it to carry out a comparable information and communication program for the benefit of its recipients of the vaccine.

5.5.4. Record-keeping Requirements

5.5.4.1. For immunizations provided under this policy, the following records shall be maintained: patient full name; social security number (if applicable), National Identity Number or other identification number; date of inoculation; name of vaccine; manufacturer; lot number; series number; dose/number of inoculation (first, second, etc.); route of administration (i.e., SQ, ID, IM, etc.); name of provider and location the vaccine was received. Additional records shall be maintained to assure accountability of the vaccine including date, time and means of shipping and receipt of the vaccine; exact locations of transfer; exact description, lot number and quantity of vaccine transferred; and full name of transferring and receiving personnel.

5.5.4.2. The responsibility for record-keeping rests with the DoD

Component, other USG Agency, allied/coalition government agency, or other organizational entity that receives the vaccine and has responsibility for providing the immunization. For the DoD Components, standard and uniform record-keeping specifications and systems will be established by the DoD Executive Agent for the Immunization Program (Secretary of the Army).

5.5.4.3. The DoD Components providing vaccinations under this policy to Category 2 or Category 3 personnel shall document the means used to inform them of the availability of the vaccine for their use on a voluntary basis. For those persons who choose to receive the vaccine, the DoD Component administering the vaccine will document that those persons were aware that the vaccination was voluntary and that they chose to receive it.

5.5.4.4. For Category 2 personnel identified in subcategories 5.2.1.6. through 5.2.1.9., Category 3 personnel identified in subcategories 5.3.1.3. and 5.3.1.4., and all Category 4 personnel, the documentation effecting the transfer of a vaccine pursuant to the Economy Act, the Arms Export Control Act, the Foreign Assistance Act, or applicable Acquisition and Cross Servicing Agreement will specify that the receiving USG Agency or allied/coalition government will comply with the record-keeping requirements of this subparagraph (5.5.4.).

5.5.5. In cases in which responsibilities for administration of the vaccine to authorized recipients and compliance with record-keeping and other implementation requirements rest under this policy with another USG Agency or allied/coalition government, the Secretary of Defense may approve assumption of some or all of these responsibilities by a DoD Component. However, any such responsibilities may be assumed only as approved by the Secretary of Defense and documented through express agreement between Department of Defense and the other organizational entity involved.

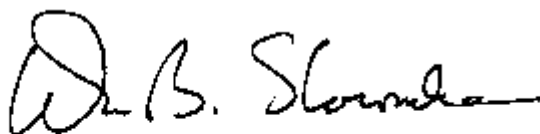
5.5.6. Liability. In cases under this policy in which vaccine is provided to another USG Agency under the Economy Act (reference (e)), the receiving Agency will agree to indemnify the Department of Defense for any liability of the Department of Defense arising from personal injury, death or other damage associated with use of the vaccine provided. In cases under this policy in which vaccine is provided to a foreign government under the Arms Export Control Act (reference (f)) or Foreign Assistance Act (reference (g)), the receiving government shall (absent a contrary requirement under treaty or international agreements) agree to indemnify the

Department of Defense and the United States Government for any liability of the Department of Defense arising from personal injury, death or other damage associated with use of the vaccine provided.

5.5.7. Continuity of Care. When appropriate, individuals who begin but do not complete a vaccination series before leaving a high-threat area may be given the opportunity, at the discretion of the DoD Component responsible, to continue with the vaccination series, consistent with the applicable medical protocol. The decision will be based on the circumstances of the individuals receiving the immunization (such as the likelihood of returning to a high-threat area), the high-threat area involved, the vaccine involved, and other pertinent factors.

6. EFFECTIVE DATE

This Instruction is effective immediately.

A handwritten signature in black ink, appearing to read "W. B. Slocombe". The signature is fluid and cursive, with a long horizontal stroke at the end.

Walter B. Slocombe
Under Secretary of Defense for Policy

Enclosures - 1

E1. References, continued

E1. ENCLOSURE 1

REFERENCES, continued

- (e) Section 1535 of title 31, "Economy Act"
- (f) "Arms Export Control Act," as amended, Chapter 39 of title 22, United States Code
- (g) "Foreign Assistance Act of 1961," as amended, Chapter 32 of title 22, United States Code
- (h) [DoD Directive 2010.9](#), "Mutual Logistic Support Between the United States and Governments of Eligible Countries and NATO Subsidiary Bodies," September 30, 1988