



Department of Defense DIRECTIVE

NUMBER 5210.88

February 11, 2004

USD(I)

SUBJECT: Safeguarding Biological Select Agents and Toxins

- References:
- (a) Directive-Type Memorandum, "Safeguarding Biological Select Agents," February 4, 2003
 - (b) Title 42, Code of Federal Regulations, Part 73, "Department of Health and Human Services; Possession, Use, and Transfer of Select Agents and Toxins, Interim Final Rule," current edition
 - (c) Title 7, Code of Federal Regulations, Part 331, "Animal and Plant Health Inspection Service," and Title 9, Code of Federal Regulations, Part 121, "Department of Agriculture, Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins, Interim Rule," current edition
 - (d) [DoD 5200.2-R](#), "Personnel Security Program," January 1987
 - (e) through (i), see enclosure 1

1. PURPOSE

Pursuant to reference (a) this Directive establishes security policy and assigns responsibilities for safeguarding biological select agents and toxins.

2. APPLICABILITY AND SCOPE

This Directive 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 in the Department of Defense (hereafter referred to collectively as "the DoD Components") that furnish, have custody, or have possession of

biological select agents or toxins justified by a prophylactic, protective, bona fide research or other peaceful purpose to support biological defense programs, medical research, clinical diagnostic testing, or teaching.

2.2. All contracts through incorporation of its provisions into those contracts for which performance depends on access to DoD biological select agents or toxins.

2.3. Cooperative Research and Development Agreements and Memoranda of Agreement with other research partners and government agencies that involve furnished DoD biological select agents and toxins for a DoD effort.

3. DEFINITIONS

Terms used in this Directive are defined in enclosure 2.

4. POLICY

It is DoD policy that:

4.1. The Department of Defense shall be in full compliance with the provisions of the Biological Weapons Convention to which the United States is a party.

4.2. All DoD facilities using, possessing, transferring, or receiving biological select agents or toxins and contract facilities furnished DoD-supplied biological select agents or toxins, shall be registered in accordance with Title 42, Code of Federal Regulations, Part 73 and Title 7, Code of Federal Regulations, Part 331 (references (b) and (c)).

4.3. All biological select agents and toxins shall be properly safeguarded against loss, theft, diversion, and unauthorized access or use in accordance with the minimum standards in the instruction to be issued by the Under Secretary of Defense (Intelligence) (USD(I)).

4.4. A current list shall be maintained of all DoD and contractor facilities that work with, transport, or store DoD biological select agents and toxins identified by the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA), listed at references (b) and (c).

4.5. Individuals who have a legitimate need to handle or use biological select agents and toxins, or whose duties afford access to storage and work areas, storage

containers and equipment containing biological select agents or toxins shall be screened initially for suitability and reliability. This means that they shall be emotionally and mentally stable, trustworthy, and adequately trained to perform the assigned duties and shall be the subject of a current and favorably adjudicated National Agency Check with Local Agency Checks and Credit Checks for military and contractor employees and an Access National Agency Check with credit checks and written inquiries for civilian employees with a reinvestigation every 5 years and they shall be evaluated on a continuing basis using the criteria issued by the USD(I).

4.6. If access to classified information is required, the appropriate personnel security clearance investigation shall be requested in accordance with DoD 5200.2-R, reference (d).

4.7. A restricted person, as defined in section 73.8 of reference (b) and the Denial, Revocation, and Suspension of Registration Section of reference (c), may not have access to biological select agents or toxins.

4.8. Biosafety Level (BSL) 2, 3, and 4 facilities and laboratories containing biological select agents or toxins shall be designated as restricted areas, as defined in enclosure 2.

4.9. Visits, assignments, and exchanges of foreign nationals shall be processed in accordance with DoD Directive 5230.20 (reference (e)).

4.10. The DoD Components using biological select agents or toxins for combating terrorism shall be included in antiterrorism programs for a collective, proactive effort focused on the prevention and detection of terrorist attacks pursuant to the requirements, policy, and responsibilities specified in DoD Directive 2000.12 (reference (f)).

4.11. A security baseline vulnerability assessment shall be conducted, reviewed annually, or updated as a new vulnerability or threat becomes apparent. The threat assessment shall be reviewed and updated more frequently if the threat or other circumstances affecting security measures change.

4.12. Material weaknesses shall be reported in compliance with DoD Directive 5010.38 (reference (g)).

4.13. Export Control requirements for biological select agents and toxins shall be implemented in accordance with DoD Directive 2040.2 (reference (h)).

5. RESPONSIBILITIES

5.1. The Under Secretary of Defense for Intelligence shall:

5.1.1. Issue a DoD Instruction establishing the minimum security standards for safeguarding biological select agents and toxins.

5.1.2. Establish a Biological Personnel Reliability Program for individuals with access to biological select agents and toxins.

5.1.3. Conduct oversight visits to assess the adequacy of security safeguards for biological select agents and toxins.

5.1.4. Ensure the Director, Defense Intelligence Agency, produces a multidiscipline baseline threat assessment addressing the Foreign Intelligence and Security Services, terrorism, information operations, sabotage, and proliferation threats related to biological select agents and toxin triennially, or more frequently if required.

5.2. The Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs (ATSD(NCB)), under the Under Secretary of Defense (Acquisition, Technology, and Logistics) shall:

5.2.1. Establish and maintain a secure database of all biological select agents and toxins for certified activities at DoD-owned and -operated facilities registered with, and withdrawn from, the HHS Centers of Disease Control and Prevention (CDC), and/or the USDA Animal and Plant Health Inspection Service (APHIS) and of the register of current and previous Responsible and Alternate Responsible Officials.

5.2.2. Establish and maintain a secure database of all DoD-supplied biological select agents and toxins for certified activities at DoD contractor facilities registered with, and withdrawn from, the CDC and/or APHIS, and of the register of current and previous Responsible and Alternate Responsible Officials.

5.2.3. Establish procedures and a coordination plan for effective responses to accidents or incidents involving biological select agents or toxins.

5.3. The Heads of the DoD Components shall:

5.3.1. Ensure that Responsible and Alternate Responsible Officials are designated to fulfill requirements in accordance with references (b) and (c).

5.3.2. Ensure compliance with policy established herein to include planning and programming fiscal and personnel resources necessary to implement the policy.

5.3.3. Notify the ATSD(NCB) prior to registration of any new DoD BSL facility.

5.3.4. Ensure biological select agents, toxins, and facilities are registered in accordance with Federal, State, and local regulations, including CDC and APHIS guidelines.

5.3.5. Establish maximum allowable amounts of any reproducible select agent generated by growth in any liquid or solid media and/or maximum allowable quantities for toxins at each facility, to include research and/or test quantities, based on program requirements.

5.3.6. Develop a security plan that includes security measures designed to ensure that all biological select agents and toxins are safeguarded against loss, theft, diversion, and unauthorized access or use.

5.3.7. Develop procedures to comply with the minimum security standards issued by the USD(I).

5.3.8. Coordinate public releases of information regarding biological select agents or toxins with the Directorate, Freedom of Information and Security Review, Washington Headquarters Services, in accordance with DoD Instruction 5230.29 (reference (i)).

5.3.9. Establish and maintain a secure inventory database system to account for biological select agents and toxins for certified activities at DoD and DoD contractor BSL facilities registered with, and withdrawn from, the CDC and/or APHIS, and a register of current and previous Responsible and Alternate Responsible Officials. This information will be provided to the ATSD(NCB) upon request.


5.4. The Secretary of the Army shall:

5.4.1. Develop and coordinate security classification guidance, as appropriate, and provide that guidance to the DoD Components to ensure consistency in classification and dissemination of information related to biological select agents and toxins.

5.4.2. Stay current on the list of CDC and APHIS biological select agents and toxins and inform the USD(I) and the ATSD(NCB) of any changes in the lists.

6. EFFECTIVE DATE

This Directive is effective immediately.



Paul Wolfowitz
Deputy Secretary of Defense

Enclosures - 2

- E1. References, continued
- E2. Definitions

E1. ENCLOSURE 1

REFERENCES, continued

- (e) [DoD Directive 5230.20](#), "Visits, Assignments, and Exchanges of Foreign Nationals," August 12, 1998
- (f) [DoD Directive 2000.12](#), "DoD Antiterrorism Program (AT)," August 13, 2003
- (g) [DoD Directive 5010.38](#), "Management Control (MC) Program," August 26, 1996
- (h) [DoD Directive 2040.2](#), "International Transfers of Technology, Goods, Services, and Munitions," January 17, 1984
- (i) [DoD Instruction 5230.29](#), "Security and Policy Review of DoD Information for Public Release," August 6, 1999

E2. ENCLOSURE 2

DEFINITIONS

E2.1.1. Biosafety Levels (BSL). Specific combinations of work practices, safety equipment, and facilities designed to minimize the exposure of workers and the environment to infectious agents. There are four biosafety levels.

E2.1.2. Biological Agent. Living microorganism or their byproduct (toxins), when natural or modified, including viruses or infectious pathogens derived from them that causes disease or death in humans, plants, or animals. Biological agents may exist as purified and concentrated cultures, but may also be present in a variety of materials such as body fluids, tissues, soil samples, etc.

E2.1.3. Biological Select Agents and Toxins. Biological agents and toxins selected by the CDC and APHIS that present a high bioterrorism risk to national security and have the greatest potential for adverse public health impact with mass casualties of humans and/or animals or that pose a severe threat to plant health or to plant products. The lists of select agents and toxins, overlap select agents and toxins, and biological agents and toxins, are reviewed and updated by the CDC and APHIS, and are found in references (b) and (c). These agents are also known as high consequence livestock pathogens and toxins, non-overlap agents and toxins, and listed plant pathogens.

E2.1.4. Overlap Agents. Select agents and toxins regulated by both agencies, HHS and USDA, are identified as "overlap" select agents and toxins.

E2.1.5. Restricted Area. An area that entry is subject to special restrictions or control for security reasons, or to safeguard property or material. This does not include those designated areas restricting or prohibiting overflight by aircraft. Restricted areas may be of different types depending on the nature and varying degree of importance of the security interest, or other matter contained therein.

E2.1.6. Responsible Official. An individual designated by the Installation Commander/Head of the DoD Agency, certified and approved by the CDC or APHIS for access to biological select agents and toxins, and has the authority and responsibility to ensure requirements are met in accordance with references (b) and (c).

E2.1.7. Toxins. Toxins are poisonous compounds produced by a living organism. Unlike organisms, toxins cannot replicate.

E2.1.8. Vulnerability Assessment. An evaluation (assessment) to determine the vulnerability to a terrorist attack against an installation, unit, exercise, port, ship, residence, facility, or other site. Identified areas of improvement to withstand, mitigate, or deter acts of violence or terrorism. The process used to determine the susceptibility to attack from the full range of threats to the security of personnel, family members, and facilities, which provide a basis for determining antiterrorism measures that can protect personnel and assets from terrorist attacks.