BY ORDER OF THE
SECRETARY OF THE AIR FORCE

AIR FORCE POLICY DIRECTIVE 10-39

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Operations

SAFEGUARDING BIOLOGICAL SELECT AGENTS AND TOXINS

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This directive establishes the Air Force Biological Security Program and outlines policy to ensure the Air Force safeguards biological select agents and toxins in the manner prescribed by higher Department of Defense (DoD) guidance and the Code of Federal Regulations (CFR). This directive applies to all facilities under Air Force command (to include Air National Guard and Air Force Reserve Command facilities) using, possessing, transferring, or receiving biological select agents or toxins, as well as Air Force contracted facilities furnished DoD-supplied biological select agents or toxins. Compliance with this directive is mandatory for all applicable Air Force military, civilian, and contractor personnel.

Ensure that all records created as a result of processes prescribed in this publication are maintained in accordance with AFMAN 37-123 (will convert to 33-363) *Management of Records* and disposed of in accordance with the *Air Force Records Disposition Schedule (RDS)* located at **https://afrims.amc.af.mil**. To recommend changes or suggestions to this publication, use the Air Force Information Management Tool 847 and route it through the publishing channels to HQ USAF/A3SC for consideration.

1. The anthrax attacks in the fall of 2001 spurred several US Government policy initiatives to ensure biological select agents and toxins (BSAT) are adequately restricted, protected, and tracked. The USA PATRIOT Act of 2001 places restrictions on persons who possess select agents and provides criminal penalties for possession of such agents that cannot be justified for specified peaceful purposes. Subsequent entries in federal regulations added additional restrictions. The Secretary of Defense, through the Undersecretary of Defense for Intelligence (USD(I)), has released policy (DoD Directive 5210.88, *Safeguarding Biological Select Agents and Toxins*, February 11, 2004) that implements the requirements of the laws discussed above, along with additional safeguards specifically for DoD. These documents put in place significant requirements for access control, physical security, and personnel reliability.

2. This Air Force Policy Directive implements DoD Directive 5210.88, establishes a security and personnel reliability policy, and assigns responsibilities for safeguarding BSAT.

3. It is Air Force policy that:

3.1. The Air Force shall be in full compliance with the provisions of the Biological Weapons Convention to which the United States is a party.

3.2. All Air Force facilities using, possessing, transferring, or receiving biological select agents or toxins and Air Force contracted facilities furnished with DoD-supplied biological select agents or toxins, shall be registered in accordance with Title 42, Code of Federal Regulations, Part 73, *Possession, Use and Transfer of Select Agents and Toxins*, current addition, and Title 7, Code of Federal Regulations, Part 331, *Animal and Plant Health Inspection Service*, current edition, 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*, current edition. This policy does not apply to facilities meeting the exemption provisions of 42 CFR, Part 73 §73.6, 7 CFR, Part 331 §331.4 and 9 CFR, §121.4.

3.3. All BSAT shall be properly safeguarded against loss, theft, diversion, and unauthorized access or use in accordance with the minimum standards in the Air Force Instruction to be issued by HQ USAF/A3/5.

3.4. Individuals who have a legitimate need to handle or use BSAT, 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 they shall be emotionally and mentally stable, trustworthy, and adequately trained to perform the assigned duties. They shall also 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 five years. All individuals shall be evaluated on a continuing basis using the criteria issued by USD(I).

3.5. If access to classified information is required, the appropriate personnel security clearance investigation shall be requested in accordance with AFPD 31-5, *Personnel Security Policy Program.*

3.6. A restricted person, as defined in 42 CFR Part 73 §73.8 and the Denial, Revocation, and Suspension of Registration Section of 7 CFR Part 331, may not have access to biological select agents or toxins.

3.7. Biosafety Level (BSL) 2, 3, and 4 facilities and laboratories containing biological select agents or toxins shall be designated as controlled areas (as defined in **Attachment 1**).

3.8. Visits, assignments, and exchanges of foreign nationals shall be processed in accordance with AFI 16-107, *International Personnel Exchange Program (PEP)*, and AFI 16-201, *Air Force Foreign Disclosure and Technology Transfer Program.*

3.9. Air Force units using biological select agents or toxins for non-offensive applications to combat 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 AFI 10-245, *Air Force Antiterrorism (AT) Standards*.

3.10. Material weaknesses shall be reported to the Management Control Senior Responsible Official (SAF/FM) in compliance with AFI 65-201, *Management Control.*

3.11. Export Control requirements for BSAT shall be implemented in accordance with AFI 16-201.

4. The following outlines authorities and responsibilities.

4.1. Commanders of Air Force facilities that possess (or plan to possess) BSAT will:

4.1.1. Ensure that Responsible Officials (ROs) and Alternate Responsible Officials (AROs) are designated to fulfill requirements in accordance with DoD Directive 5210.88, 42 CFR Part 73, 2 CFR Part 331, and 9 CFR Part 121.

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

4.1.3. Notify HQ USAF/A3/5 prior to registration of any new BSL 2, 3, and 4 facilities or laboratories containing BSAT. In addition, AF Medical Service (AFMS) facilities notify HQ USAF/SG prior to registration.

4.1.4. Ensure BSAT and facilities are registered in accordance with Federal, State, and local regulations, including Department of Health and Human Services (HHS) Inspector General and US Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) requirements.

4.1.5. Develop a security plan that includes security measures designed to ensure all BSAT are safeguarded against loss, theft, diversion, and unauthorized access or use in accordance with DoD Directive 5210.88, 42 CFR Part 73, 2 CFR Part 331, and 9 CFR Part 121, AFI 35-101, *Public Affairs Policies and Procedures*, and AFPD 31-5.

4.1.6. Coordinate public releases of information regarding BSAT with the Directorate, Freedom of Information and Security Review, Washington Headquarters Services, in accordance with AFI 35-101.

4.1.7. Establish and maintain a secure inventory database system to account for BSAT for certified activities and a register of current and previous ROs and AROs. This information will be provided to HQ USAF/A3/5 and SG upon request.

4.2. HQ USAF/A3/5 will:

4.2.1. Establish Air Force policies and procedures for safeguarding BSAT and act as the official Air Force POC for BSAT issues with the Office of the Secretary of Defense, the Joint Staff, and other governmental agencies.

4.2.2. Maintain a current list of all Air Force facilities (to include contracted facilities) that work with, transport, or store DoD-owned or -provided BSAT designated by HHS and USDA, listed in 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121.

4.2.3. In conjunction with affected facilities, establish maximum allowable amounts of any reproducible select agent generated by growth in any liquid or solid medium and/or maximum allowable quantities of toxins at each facility, to include research and/or test quantities, based on program requirements.

4.2.4. In cooperation with HQ USAF/SG, coordinate public releases of information regarding BSAT with the Directorate, Freedom of Information and Security Review, Washington Headquarters Services, in accordance with AFI 35-101.

4.2.5. Ensure guidance for determining the suitability and reliability of military and civilian individuals who have a legitimate need to handle or use BSAT is developed and implemented in a

manner consistent with DoD and Air Force policies. HQ USAF/A3/5 will consult HQ USAF/A1 and SAF/GC on matters relating to labor laws and civilian position descriptions.

4.2.6. Notify the Assistant to the Secretary of Defense (Nuclear and Chemical and Biological Defense Programs) (ATSD(NCB)) prior to registration of any new DoD BSL facility.

4.3. HQ USAF/A4/7 will:

4.3.1. Ensure a security baseline vulnerability assessment is conducted annually and reviewed or updated as necessary when new threats or vulnerabilities become apparent.

4.3.2. Provide minimum standards for facility security plans and supporting physical security requirements, as appropriate, that ensure all BSAT are safeguarded against loss, theft, diversion, and unauthorized access or use in accordance with DoD Directive 5210.88, 42 CFR Part 73, 2 CFR Part 331, and 9 CFR Part 121, AFI 35-101, and AFPD 31-5.

4.4. HQ USAF/SG will:

4.4.1. Provide subject matter consultation to HQ USAF/A3/5 concerning select agent doctrine, policy, and AFMS facilities and capabilities.

4.4.2. Provide policy and guidance, as necessary, to assist AFMS facilities in:

4.4.2.1. Implementing Federal, State and Military select agent requirements.

4.4.2.2. Planning and programming for personnel, materiel and facilities to support select agent programs.

4.4.2.3. Preparing for Air Force select agent inspection activities.

4.4.2.4. Coordinating public releases of information regarding BSAT.

4.4.3. Maintain a current list of all AFMS facilities (to include contracted facilities) that work with, transport, or store DoD-owned or -provided BSAT designated by HHS and USDA, listed in 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121.

4.5. AFOSI will ensure considerations for facilities that maintain BSAT are incorporated into existing counterintelligence/force protection programs and vulnerability assessments.

4.6. SAF/AQ will ensure appropriate guidance is available for the update and development of contracts for services rendered for the Air Force that pertain to BSAT, to include contracted individuals who have a legitimate need to handle or use BSAT, or whose duties afford access to storage and work areas.

MICHAEL W. WYNN
Secretary of the Air Force

Attachment 1

GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION

References

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*

Title 7, Code of Federal Regulations, Part 33l, *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*

Title 31, United States Code, Section 3512

AFPD 31-5, *Personnel Security Policy Program*

AFI 10-245, *Air Force Antiterrorism (AT) Standards*

AFI 16-107, *International Personnel Exchange Program (PEP)*

AFI 16-201, *Air Force Foreign Disclosure and Technology Transfer Program.*

AFI 65-201, *Management Control*

AFI 35-101, *Public Affairs Policies and Procedures*

AFMAN 37-123, *Management of Records*

Abbreviations and Acronyms

AFI—Air Force Instruction

AFMAN—Air Force Manual

AFMS—Air Force Medical Service

AFPD—Air Force Policy Directive

APHIS—Animal and Plant Health Inspection Services

ARO—Alternate Responsible Official

BSL—Biosafety Levels

BSAT—Biological Select Agents and Toxins

CFR—Code of Federal Regulations

DoD—Department of Defense

HHS—United States Department of Health and Human Services

RDS—Records Disposition Schedule

RO—Responsible Official

USDA—United States Department of Agriculture

Terms

Alternate Responsible Official—The Alternate Responsible Official must meet all the requirements of the Responsible Official (RO) for certification and approval by the CDC or APHIS with authority and responsibility to ensure requirements are met in accordance with DoD Directive 5210.88, 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121, or act in the absence of the RO.

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.

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 listed in 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121. These agents are also known as high consequence livestock pathogens and toxins, non-overlap agents and toxins, and listed plant pathogens.

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.

Level 1 - Practices, safety equipment, and facility design and construction are appropriate for undergraduate and secondary educational training and teaching laboratories, and for other laboratories in which work is done with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy humans.

Level 2 - Practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, and other laboratories in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity.

Level 3 - Practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potential lethal infection.

Level 4 - Practices, safety equipment, and facility design and construction are applicable for work with dangerous and exotic agents that pose a high individual risk or life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy.

Controlled Area—An area to which entry is subject to special restrictions or control for security reasons, or to safeguard property or material. This does not necessarily include those designated areas restricting or prohibiting overflight by aircraft. Controlled areas may be of different types depending on the nature and varying degree of importance of the security interest, or other matter contained therein. NOTE: For the purposes of the Air Force Biological Security Program, the term “controlled area” meets the standards of what USD(I) guidance refers to as a “restricted area”.

Material Weakness—Specific instances of noncompliance with *Title 31, United States Code*, Section 3512 of such sufficient importance to warrant reporting of the control deficiency to the next higher level of management. Such weaknesses significantly impair or may impair the fulfillment of a DoD

Component's mission or operational objective; deprive the public of needed services; violate statutory or regulatory requirements; significantly weaken safeguards against fraud, waste, or mismanagement of funds, property, or other assets; or result in a conflict of interest. MC weaknesses should be identified using one of the 15 functional reporting categories, as defined in enclosure 4 or AFI 65-201.

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

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 BSAT, and has authority and responsibility to ensure requirements are met in accordance with DoD Directive 5210.88, 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121.

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

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, materiel, and facilities, which provide a basis for determining antiterrorism measures that can protect personnel and assets from terrorist attacks.