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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 (BSAT) in the manner prescribed by higher Department of Defense (DoD) guidance. It implements DoD Directive (DoDD) 5210.88, *Safeguarding Biological Select Agents and Toxins*, assigns responsibilities and authorities for safeguarding BSAT, and establishes the requirement for a Biological Personnel Reliability Program (BPRP). This Directive applies to all facilities under Air Force command using, possessing, transferring, or receiving BSAT, as well as Air Force contracted facilities furnished with DoD-supplied BSAT. 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 33-363, *Management of Records*, and disposed of in accordance with the *Air Force Records Disposition Schedule (RDS)* located at <https://www.my.af.mil/afirms/afirms/afirms/rims.cfm>. To recommend changes or suggestions to this publication, use the Air Force Form 847, *Recommendation for Change of Publication*, and route it through the appropriate chain of command to the publication OPR for consideration.

SUMMARY OF CHANGES

This revision clarifies roles and responsibilities for ensuring the safeguarding of BSAT and establishes the requirement for an Air Force BPRP. This revision adds responsibilities specific to Air Force Major Commands (MAJCOMs) that oversee installations/facilities registered to

possess BSAT, as well as responsibilities specific to commanders of installations that have tenant units registered to possess BSAT; and it omits operational-level guidance already detailed in DoDI 5210.89_AFI 10-3901, *Minimum Security Standards for Safeguarding Biological Select Agents and Toxins*.

1. Background. The anthrax attacks in the fall of 2001 spurred several U.S. Government policy initiatives to ensure BSAT are adequately restricted, protected, and tracked. The USA PATRIOT Act of 2001 places restrictions on the possession of 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)), released policy (DoDD 5210.88 and DoD Instruction (DoDI) 5210.89, *Minimum Security Standards for Safeguarding Biological Select Agents and Toxins*) implementing the requirements of the laws discussed above, along with additional safeguards specifically for DoD. On 2 July 2010, the President issued Executive Order 13546, "Optimizing the Security of Biological Select Agents and Toxins," which highlights the importance of BSAT research to national security and further emphasizes the unique security concerns associated with BSAT. These documents establish significant requirements for access control, physical security, and personnel reliability.

2. Policy. It is Air Force policy that:

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

2.2. All Air Force facilities using, possessing, transferring, or receiving BSAT, and Air Force contracted facilities furnished with DoD-supplied BSAT, shall be registered as described in DoDD 5210.88, in accordance with Title 42, Code of Federal Regulations (CFR), Part 73, *Select Agents and Toxins*, current edition; Title 7, CFR, Part 331, *Possession, Use, and Transfer of Select Agents and Toxins*, current edition; and Title 9, CFR, Part 121, *Possession, Use and Transfer of Select 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 Part 121 §121.4.

2.3. All BSAT shall be properly safeguarded against loss, theft, diversion, and unauthorized access or use in accordance with the minimum standards contained in the Air Force supplement to DoDI 5210.89 (DoDI 5210.89_AFI 10-3901).

2.4. 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 BSAT, shall be screened initially for suitability and reliability in accordance with DoDI 5210.89_AFI 10-3901. All personnel assigned to Air Force BSAT duties will be certified in the BPRP. Personnel will undergo a Single-Scope Background Investigation prior to enrollment in the BPRP, and will be evaluated on a continuing basis as described in DoDI 5210.89_AFI 10-3901.

2.5. 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 BSAT.

2.6. Biosafety Level (BSL) 2, 3, and 4 facilities and laboratories registered by the United States Department of Health and Human Services/Centers for Disease Control and Prevention (HHS/CDC) and/or the United States Department of Agriculture/Animal and

Plant Health Inspection Service (USDA/APHIS) to possess BSAT shall be designated as controlled areas (as defined in attachment 1).

2.7. Visits by foreign nationals shall be processed in accordance with AFI 16-107, *International Personnel Exchange Program (MPEP)*, and AFI 16-201, *Air Force Foreign Disclosure and Technology Transfer Program*. Air Force BSAT shall not employ or assign military, civilian, or contractor personnel who are foreign nationals.

3. Responsibilities and Authorities.

3.1. The Deputy Chief of Staff, Operations, Plans and Requirements (AF/A3/5) will:

3.1.1. Establish Air Force guidance 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.

3.1.2. 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/CDC and/or USDA/APHIS.

3.1.3. In cooperation with The Air Force Surgeon General (AF/SG) and the Secretary of the Air Force Office of Public Affairs (SAF/PA), coordinate public releases of information in accordance with DoDI 5230.29, *Security and Policy Review of DoD Information for Public Release*, and AFI 35-102, *Security and Policy Review Process*.

3.1.4. Ensure guidance for determining the suitability and reliability of military and civilian individuals who have a legitimate need to handle or use BSAT is implemented in a manner consistent with DoD and Air Force policies. AF/A3/5 will consult the Deputy Chief of Staff, Manpower, Personnel, and Services (AF/A1), the AF Judge Advocate General (AF/JA), and the AF General Counsel (SAF/GC) on matters relating to labor and civilian personnel laws and regulations.

3.1.5. 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.

3.2. The Deputy Chief of Staff for Logistics, Installations, and Mission Support (AF/A4/7) will:

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

3.2.2. 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 DoDD 5210.88, 42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121, AFI 31-101 (*Integrated Defense*), DoDI 5210.89, and DoDI 5210.89_AFI 10-3901.

3.3. The Air Force Surgeon General (AF/SG) will:

3.3.1. Provide subject-matter consultation to AF/A3/5 concerning select agent doctrine, policy, and Air Force Medical Service (AFMS) facilities and capabilities.

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

- 3.3.2.1. Implementing Federal, State, DoD, and Air Force select agent requirements.
- 3.3.2.2. Planning and programming for personnel, materiel, and facilities to support BSAT programs.
- 3.3.2.3. Preparing for Air Force BSAT inspection activities.
- 3.3.2.4. Coordinating public releases of information regarding BSAT.
- 3.3.3. 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.
- 3.3.4. Ensure appropriate support is provided by Air Force Medical Treatment Facilities that service Air Force units involved with BSAT activities, as directed in DoDI 5210.89_AFI 10-3901.
- 3.4. The Inspector General of the Air Force (SAF/IG) will ensure considerations for facilities that maintain BSAT are incorporated into existing counterintelligence/force protection programs and vulnerability assessments.
- 3.5. The Assistant Secretary of the Air Force for Acquisition (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 BSAT storage and/or work areas.
- 3.6. The Secretary of the Air Force Office of Public Affairs (SAF/PA) will review and forward, as appropriate, requests for public release of information regarding BSAT to the DoD Office of Security Review in accordance with DoDI 5230.29 and AFI 35-102.
- 3.7. Air Force MAJCOMs that oversee installations/facilities that are registered to possess BSAT will:
 - 3.7.1. Coordinate public releases of information regarding BSAT with AF/A3/5 and SAF/PA.
 - 3.7.2. Establish, in conjunction with affected facilities and AF/A3/5, maximum allowable amounts of toxins and/or any reproducible select agent generated by growth in any liquid or solid media at each facility, to include research and/or test quantities, based on program requirements and the constraints of relevant treaties and/or international agreements.
 - 3.7.3. Act as liaison between unit/base and AF/A3/5 on all issues pertaining to Biosecurity, BPRP, and BSAT. This includes notifying AF/A3/5 of any significant changes to a BSAT program (including, but not limited to, registration of any new BSL 2, 3, or 4 facilities or laboratories containing BSAT).
 - 3.7.4. Ensure that commanders of Air Force installations that have tenant units registered to possess BSAT designate personnel to fulfill the installation-level requirements outlined in DoDI 5210.89_AFI 10-3901.
 - 3.7.5. Provide oversight to the base's/unit's administration of the BPRP.

3.7.6. Ensure BSAT and facilities are registered in accordance with Federal, State, and local regulations, including HHS Inspector General and USDA/APHIS requirements.

3.8. Commanders of Air Force installations that have tenant units registered to possess BSAT will:

3.8.1. Ensure that commanders/directors of units registered to possess BSAT designate personnel to fulfill the unit-level requirements outlined in DoDI 5210.89_AFI 10-3901.

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

3.8.3. 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 DoDD 5210.88, 42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121, AFI 31-101, DoDI 5210.89, and DoDI 5210.89_AFI 10-3901.

3.8.4. Coordinate public releases of information regarding BSAT through their designated MAJCOM Biological Security Program Manager.

MICHAEL B. DONLEY
Secretary of the Air Force

Attachment 1**GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION*****References***

Executive Order 13546, *Optimizing the Security of Biological Select Agents and Toxins in the United States*, July 2, 2010

Public Law 107-56, *Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT Act)*, October 26, 2001

Title 42, Code of Federal Regulations, Part 73, *Select Agents and Toxins*, current edition

Title 7, Code of Federal Regulations, Part 331, *Possession, Use, and Transfer of Select Agents and Toxins*, current edition

Title 9, Code of Federal Regulations, Part 121, *Possession, Use, and Transfer of Select Agents and Toxins*, current edition

DoDD 5210.88, *Safeguarding Biological Select Agents and Toxins*, February 20, 2004

DoDI 5210.89, *Minimum Security Standards for Safeguarding Biological Select Agents and Toxins*, April 18, 2006

DoDI 5230.29, *Security and Policy Review of DoD Information for Public Release*, January 8, 2009

DoDI 5210.89_AFI 10-3901, *Minimum Security Standards for Safeguarding Biological Select Agents and Toxins*, 22 June 2010

AFI 16-107, *Military Personnel Exchange Program (MPEP)*, 2 February 2006

AFI 16-201, *Air Force Foreign Disclosure and Technology Transfer Program*, 1 December 2004

AFI 31-101, *Integrated Defense*, 8 October 2009

AFI 35-102, *Security and Policy Review Process*, 20 October 2009

AFMAN 33-363, *Management of Records*, 1 March 2008

Adopted Forms

Air Force Form 847, *Recommendation for Change of Publication*, 22 September 2009

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 Service

BPRP—Air Force Biological Personnel Reliability Program

BSAT—Biological Select Agents and Toxins

BSL—Biosafety Level

CDC—United States Centers for Disease Control and Prevention

CFR—Code of Federal Regulations

DoD—Department of Defense

DoDD—Department of Defense Directive

DoDI—Department of Defense Instruction

HHS—United States Department of Health and Human Services

MAJCOM—Air Force Major Command

RDS—Records Disposition Schedule

USDA—United States Department of Agriculture

USD(I)—Undersecretary of Defense for Intelligence

Terms

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 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. 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.”

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. It identifies 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 provides a basis for determining antiterrorism measures that can protect personnel and assets from terrorist attacks.