

Safeguarding Select Agents and Toxins

I. Purpose

This Directive and the accompanying Instruction establish the authorities, responsibilities, requirements, and procedures for safeguarding biological select agents and toxins (BSAT) in all activities conducted or sponsored by the Department of Homeland Security (DHS). This Directive implements the requirements for possession, use, and transfer of BSAT set forth in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and established by the Department of Health and Human Services in 42 Code of Federal Regulations (CFR) 73 and U.S. Department of Agriculture in 9 CFR 121 and 7 CFR 331.

II. Scope

This Directive applies to any activities conducted, sponsored, or funded by DHS through a contract, grant, cooperative agreement, other transaction, or other arrangement. Its scope includes all activities involving the possession, use, and/or transfer of BSAT. This includes all such activities conducted at DHS-owned laboratories and at non-DHS research institutions, including subcontractors and sub-awardees.

III. Authorities

- A. Title 6, United States Code (U.S.C.), Section 182, Chapter I, Subchapter III, "Responsibilities and Authorities of the Under Secretary for Science and Technology"
- B. Title 6, U.S.C., Chapter I, Subchapter III, Section 182, "Responsibilities and authorities of the Under Secretary for Science and Technology"
- C. Public Law 107-188, "Public Health Security and Bioterrorism Preparedness and Response Act of 2002"
- D. Public Law 107-56, Section 817 (2) of the "Uniting and Strengthening America By Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA Patriot Act) Act of 2001"
- E. Title 7, CFR, Subtitle B, Chapter III, Part 331, "Possession, Use, and Transfer of Select Agents and Toxins"

F. Title 9, CFR, Chapter I, Subchapter E, Part 121, "Possession, Use, and Transfer of Select Agents and Toxins"

G. Title 42, CFR, Chapter I, Subchapter F, Part 73, "Select Agents and Toxins"

IV. Responsibilities

- A. The **Under Secretary for Science and Technology** is the DHS Senior Responsible Official (SRO) and is responsible for directing, ensuring, and supporting Department-wide implementation of and compliance with this Directive and the accompanying Instruction. This responsibility does not impact the authority and responsibility of a registered research institution's Responsible Official, as established in Authorities D-F in Part III of this Directive.
- B. The **Compliance Assurance Program Manager (CAPM)** serves as the head of the Compliance Assurance Program Office, which is responsible for developing and implementing the Department's BSAT security compliance program.
- C. The **Director of the Office of National Labs** has oversight and management of DHS-owned laboratory operations, infrastructure and construction to support research and compliance, testing and evaluation, and technology development needs.
- D. **Laboratory Directors** manage the daily operation of DHS-owned and/or operated biological laboratories, including designating a Responsible Official who is responsible for ensuring compliance with this Directive, the accompanying Instruction, and all Authorities in Part III.
- E. The **Responsible Official** has the authority and responsibility to act on behalf of the registered entity and ensures compliance with Authorities D-F in Part III of this Directive.
- F. **All DHS Components** are responsible for supporting Department-wide implementation of and compliance with this Directive and the accompanying Instruction.

V. Policy and Requirements

A. **Policy:**

1. DHS is committed to ensuring that DHS facilities and research institutions conducting DHS-sponsored activities involving BSAT adopt and implement rigorous BSAT security, accountability, and oversight measures

to protect DHS personnel and the American public, and to support the DHS mission.

2. The Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS) regulatory requirements for BSAT, as established in Authorities D-F in Part III of this Directive, apply to all BSAT activities conducted, funded, or otherwise sponsored by the Department. In the event of any conflict between those requirements and this Directive, the CDC and APHIS regulations take precedence.

3. DHS has a critical responsibility to ensure that its facilities and its sponsored entities, programs, and activities involving BSAT are in compliance with applicable federal regulatory requirements related to BSAT. The SRO directs and the CAPM leads the Department's efforts to fulfill this responsibility, in coordination with the CDC and APHIS regulatory agencies, but all DHS Components and organizational elements have an obligation to support effective, Department-wide compliance with this Directive and the accompanying Instruction.

B. Requirements:

1. Each facility conducting DHS-sponsored activities involving BSAT designates a Responsible Official who is responsible for ensuring compliance with Authorities D-F in Part III of this Directive.

2. All facilities owned and/or operated by DHS and all research institutions performing DHS-sponsored activities involving BSAT submit the appropriate registration forms and obtain a certificate of registration from CDC or APHIS, as required by Authorities D-F in Part III of this Directive, before possessing, transferring, or receiving BSAT.

3. All personnel at DHS facilities and research institutions that have access to BSAT are screened and approved in accordance with Authorities D-F in Part III of this Directive, provided training and information commensurate with their work and the related risks posed by BSAT, and cleared by the research institution's Responsible Official and other institutional and DHS officials, as applicable, prior to being granted access to BSAT.

4. All DHS facilities and sponsored research institutions implement rigorous safeguards for the storage, use, and transfer of all BSAT to prevent loss, theft, diversion, damage, and unauthorized use. Additionally, appropriate security controls, as established by Authorities D-F in Part III of this Directive, are implemented to prevent unauthorized access.

5. All BSAT samples and holdings are actively monitored and accounted for from receipt or identification through transfer and final disposition, via the employment of stringent inventory management, access control, auditing, and recordkeeping processes, including but not limited to chain-of-control documentation and destruction logs.

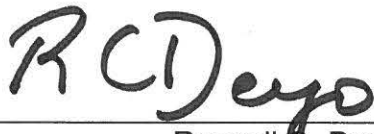
6. Incidents of theft, loss, or release of any BSAT are reported to the CAPM within 72 hours, concurrently with or immediately following reporting of such incidents to either CDC or APHIS, as appropriate and in accordance with Authorities D-F in Part III of this Directive.

7. All incidents of serious or continuing noncompliance with this Directive, the accompanying Instruction, and/or the regulatory requirements of Authorities D-F in Part III of this Directive, involving any DHS Component, facility, and/or sponsored research institution, are reported immediately both to the CAPM within 72 hours, and to the research institution's Responsible Official, as defined in the accompanying Instruction. No action, administrative or disciplinary, may be taken against a person for the act of reporting any such incidents of serious or continuing noncompliance.

All DHS personnel conduct themselves in accordance with the responsibilities set forth in this Directive and the accompanying Instruction, as well as with any subsequently developed and approved policy, procedure, or guidance to ensure appropriate BSAT security, accountability, compliance, and oversight measures for all DHS activities.

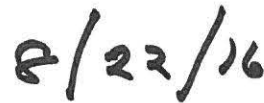
VI. Questions

Please address any questions or concerns regarding this Directive to the Compliance Assurance Program Manager.



Russell C. Deyo

Under Secretary for Management



Date