



## DoD DIRECTIVE 5101.20E

# DoD BIOLOGICAL SELECT AGENTS AND TOXINS (BSAT) BIOSAFETY AND BIOSECURITY PROGRAM

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**Originating Component:** Office of the Under Secretary of Defense for Acquisition and Sustainment

**Effective:** January 25, 2019

**Releasability:** Cleared for public release. Available on the Directives Division Website at <http://www.esd.whs.mil/DD/>.

**Incorporates and Cancels:** Deputy Secretary of Defense Memorandum, "Implementation of the Recommendations in the Comprehensive Review Report: Inadvertent Shipment of Live *Bacillus anthracis* (Anthrax) Spores by Department of Defense," July 23, 2015

Deputy Secretary of Defense Memorandum, "Designation of the Department of Defense Executive Agent for the Biological Select Agents and Toxins Biosecurity Program," January 3, 2017

**Approved by:** David L. Norquist, Performing the Duties of the Deputy Secretary of Defense

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**Purpose:** This issuance:

- Establishes policy and assigns responsibilities for the DoD BSAT Security Program established in DoD Instruction 5210.88 and for meeting the safety standards for microbiological and biomedical laboratories prescribed in DoD 6055.18-M.
- Designates the Secretary of the Army as the DoD Executive Agent (EA) for the DoD BSAT Biosafety and Biosecurity Program, who exercises this authority through the Surgeon General of the Army, in accordance with DoD Directive (DoDD) 5101.1 and assigns the DoD EA responsibilities.

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## **SECTION 1: GENERAL ISSUANCE INFORMATION**

**1.1. APPLICABILITY.** This issuance applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this issuance as the “DoD Components”).

**1.2. POLICY.** It is DoD policy that:

a. The DoD BSAT Biosafety and Biosecurity Program (referred to in this issuance as “the DoD BSAT Biorisk Program”) will directly support the DoD Chemical and Biological Defense Program (CBDP) pursuant to DoDD 5160.05E.

b. Funding requests for the DoD BSAT Biorisk Program Office will be set forth in the DoD budget for each fiscal year as an additional single program element within the separate account already established for the CBDP.

## SECTION 2: RESPONSIBILITIES

### **2.1. UNDER SECRETARY OF DEFENSE FOR ACQUISITION AND SUSTAINMENT (USD(A&S)).** The USD(A&S):

- a. Serves as the Principal Staff Assistant to oversee activities of the DoD EA for the DoD BSAT Biorisk Program, assessing the arrangement periodically in accordance with DoDD 5101.1.
- b. Ensures the DoD BSAT Biorisk Program is added as a line item within the separate CBDP account, which is set forth in the DoD budget for funding requests each fiscal year.
- c. Validates the BSAT Biorisk Program resource levels to ensure that they are consistent with the workload of the Military Services and approve all individual Military Service resource adjustments and staffing authorizations, military and civilian, to the BSAT Biorisk Program.

### **2.2. ASSISTANT SECRETARY OF DEFENSE FOR NUCLEAR, CHEMICAL, AND BIOLOGICAL DEFENSE PROGRAMS (ASD(NCB)).** Under the authority, direction, and control of the USD(A&S) and pursuant to DoDD 5134.08, the ASD(NCB):

- a. Reviews and revises, as necessary, DoD BSAT biosecurity policy, coordinating with the Assistant Secretary of Defense for Sustainment (ASD(S)) to ensure the synchronization of the biosecurity and biosafety policies.
- b. Oversees the DoD Components implementing synchronized BSAT biosecurity policy and ensures this policy is applied consistently across DoD.
- c. Assists the Principal Staff Assistant in providing day-to-day oversight of activities of the DoD EA for the DoD BSAT Biorisk Program.
- d. Ensures sufficient funding is available through the CBDP for managing a comprehensive DoD BSAT Biorisk Program across DoD BSAT-registered laboratories.
- e. Ensures that ASD(NCB) representatives attending interagency meetings on biosafety or biosecurity keep the DoD EA for the DoD BSAT Biorisk Program informed of outcomes.
- f. Coordinates with the DoD EA for the DoD BSAT Biorisk Program for approval or denial of waiver and exception requests regarding DoD biosecurity policy.
- g. Assists the Office of the Under Secretary of Defense for Policy, Defense Technology Security Administration on matters related to export controls for international transfers of items and technology for biosafety and biosecurity.

**2.3. ASD(S).** Under the authority, direction, and control of the USD(A&S), the ASD(S):

- a. Reviews and revises, as necessary, departmental BSAT biosafety policy, coordinating with the ASD(NCB) to ensure the synchronization of the biosecurity and biosafety policies.
- b. Oversees the DoD Components implementing synchronized BSAT biosafety policy and ensures these policies are applied consistently across DoD.
- c. Coordinates with the DoD EA for the DoD BSAT Biorisk Program for approval or denial of waiver and exception requests regarding DoD biosafety policy.

**2.4. DOD COMPONENT HEADS.** The DoD Component heads:

- a. Provide feedback to the DoD EA for the DoD BSAT Biorisk Program on the effectiveness of BSAT biosafety and biosecurity policies, standards, and procedures.
- b. Implement BSAT biosafety and biosecurity policies under the oversight of the DoD EA for the DoD BSAT Biorisk Program.
- c. Support the DoD EA for the DoD BSAT Biorisk Program in determining authorizations for staffing the DoD BSAT Biorisk Program Office.
- d. Provide appropriate representatives to participate in the team of experts established in Section 3 to identify best practices and to review inspection protocols.
- e. Will fully comply with the provisions of the Select Agent Program regulations in accordance with Part 331 of Title 7, Code of Federal Regulations (CFR); Part 121 of Title 9, CFR; and Part 73 of Title 42, CFR, as applicable.

**2.5. SECRETARY OF THE ARMY.** As the DoD EA for the DoD BSAT Biorisk Program, who exercises this authority through the Surgeon General of the Army and in addition to the responsibilities in Paragraph 2.4., the Secretary of the Army:

- a. Has tasking authority of all DoD Components to support DoD EA responsibilities.
- b. In coordination with the ASD(NCB) and the ASD(S), issues regulations and guidance to implement BSAT biosafety and biosecurity policies, standards, and procedures across DoD.
- c. Provides feedback, as requested, through the USD(A&S) to the Deputy Secretary of Defense or his or her designee on the status of the DoD BSAT Biorisk Program.
- d. Provides notice and information to the congressional defense committees in accordance with Section 1528 of Title 50, United States Code (U.S.C.).
- e. Designates a Director for the DoD BSAT Biorisk Program Office to oversee the execution of the responsibilities outlined in Section 3.

f. May approve that the Surgeon General of the Army may further delegate EA responsibilities to a responsible official (general or flag officer or Senior Executive Service level) who will directly oversee the functions of the DoD BSAT Biorisk Program Office.

g. Works with other DoD Components to determine authorizations for staffing the DoD BSAT Biorisk Program Office.

### **SECTION 3: GUIDELINES AND FUNCTIONS FOR THE DoD BSAT BIORISK PROGRAM**

The Director, DoD BSAT Biorisk Program Office, will:

a. Develop a comprehensive BSAT Biorisk Program that follows the guidelines for harmonization as outlined in Executive Order 13546. Specifically, this includes working with the Federal Select Agent Program to create a mechanism for coordinated and reciprocal inspection of DoD BSAT facilities; harmonizing administrative practices for DoD BSAT facilities where possible; ensuring consistent and timely identification and resolution of BSAT compliance issues; and assisting information sharing among DoD BSAT facilities and with other departments and agencies regarding oversight activities.

b. Provide feedback to the DoD EA on the status of the DoD BSAT Biorisk Program, at least semi-annually. Coordinate information for the semi-annual update with the ASD(NCB) and the ASD(S).

c. Maintain an office responsible for executing the DoD BSAT Biorisk Program mission.

d. Establish a government-only scientific peer review panel to conduct an initial technical review, and subsequent periodic reviews, of biosafety protocols and procedures and biosecurity policies and procedures across DoD laboratories that handle BSAT. Implement changes to these protocols, procedures, and policies to enhance their effectiveness. This scientific peer review should include DoD and non-DoD representation whenever possible.

e. Direct a team of experts from across DoD laboratories to periodically identify best practices in BSAT biosafety and biosecurity and recommend appropriate changes to DoD BSAT biosafety and biosecurity policies to the ASD(S) and the ASD(NCB).

f. Develop a comprehensive inspection program that:

(1) Reviews inspection protocols and processes across DoD Components and identifies methods by which they could be further harmonized with the Federal Select Agent Program; presents any changes to the ASD(NCB) and the ASD(S) that would require new or revised policy.

(2) Tracks all internal and external inspection results and reports status of findings, recommendations, and actions taken to address deficiencies and trends to the appropriate DoD manager.

(3) Ensures all personnel included in inspection teams have scientific expertise, experience, and training that is deemed sufficient through coordination between the director and the inspection team lead.

(4) Ensures inspections include a review of site-specific vulnerabilities.

g. Serve as DoD's primary point of contact for and liaison to the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS) for BSAT biosafety and biosecurity matters to ensure departmental priorities or issues are clearly presented, addressed, and resolved. Summary reports of interactions with the CDC and the APHIS will be provided to the ASD(NCB) and the ASD(S).

h. Develop and implement an agreement with the CDC and the APHIS for scheduling inspections of DoD BSAT laboratories that are combined with any inspections required by DoD. This agreement should establish joint inspection criteria and guidance wherever possible.

i. Ensure that policy and procedural changes affecting BSAT laboratories are communicated to those laboratories and supporting personnel appropriately. If BSAT Biorisk Program procedural or policy changes are expected to affect DoD non-BSAT laboratories (e.g., non-BSAT research, environmental, surveillance, or veterinary reference laboratories) they should be informed appropriately.

j. Coordinate with the ASD(S) or the ASD(NCB) to process any request for a waiver to DoD BSAT biosafety or biosecurity policies, respectively.

k. Annually provide the DoD EA budget estimate to CDBP and update periodically through the year with expenditure rates and plans.

l. Designate a credentialed (Registered Biosafety Professional or Certified Biosafety Professional) biological safety officer to execute responsibilities assigned by the director regarding safety of DoD BSAT laboratories.

m. Designate a biological security officer to execute responsibilities assigned by the director regarding security of DoD BSAT laboratories.

n. Designate a quality management officer to execute responsibilities assigned by the director regarding quality control and assurance programs at DoD BSAT laboratories, ensuring they meet requirements in Section 1527 of Title 50, U.S.C.

o. Ensure that biosafety and biosecurity incidents occurring at DoD BSAT laboratories are reported to the appropriate authorities, including reports to meet the requirements in Section 1528 of Title 50, U.S.C.



## GLOSSARY

### G.1. ACRONYMS.

APHIS	Animal and Plant Health Inspection Service
ASD(S)	Assistant Secretary of Defense for Sustainment
ASD(NCB)	Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs
BSAT	biological select agents and toxins
CBDP	Chemical and Biological Defense Program
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
DoDD	DoD directive
EA	Executive Agent
U.S.C.	United States Code
USD(A&S)	Under Secretary of Defense for Acquisition and Sustainment

**G.2. DEFINITIONS.** Unless otherwise noted, these terms and their definitions are for the purpose of this issuance.

**biosafety.** The discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials.

**biosecurity.** The discipline addressing the security of microbiological agents and toxins and the threats posed to human and animal health, the environment, and the economy by deliberate misuse or release.

## **REFERENCES**

- Code of Federal Regulations, Title 7, Part 331
- Code of Federal Regulations, Title 9, Part 121
- Code of Federal Regulations, Title 42, Part 73
- DoD 6055.18-M, “Safety Standards for Microbiological and Biomedical Laboratories,” May 11, 2010, as amended
- DoD Directive 5101.1, “DoD Executive Agent,” September 3, 2002, as amended
- DoD Directive 5134.08, “Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ASD(NCB)), January 14, 2009, as amended
- DoD Directive 5160.05E, “Roles and Responsibilities Associated with the Chemical and Biological Defense Program (CBDP), September 8, 2017, as amended
- DoD Instruction 5210.88, “Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT),” January 19, 2016, as amended
- Executive Order 13546, “Optimizing the Security of Biological Select Agents and Toxins in the United States,” July 2, 2010
- United States Code, Title 50