SECRETARY OF THE ARMY
WASHINGTON

25 JUL 2016

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Army Directive 2016-24 (Department of Defense Biological Select Agent and Toxins Biosafety Program)

1. References. A complete list of references is at enclosure 1 to the enclosure.

2. Effective immediately, this directive establishes policy and assigns responsibilities for the Department of Defense (DoD) Biological Select Agent and Toxins (BSAT) Biosafety Program.

3. This directive applies to the Regular Army, Army National Guard/Army National Guard of the United States, U.S. Army Reserve, and the U.S. Navy and U.S. Air Force activities that provide oversight to, use, produce, store, handle, transport, transfer, or destroy BSAT. Applicable provisions of this directive will be incorporated into contracts which provide for DoD to maintain responsibility for the BSAT.

4. The Surgeon General is delegated the authority to act on my behalf for all DoD Executive Agent responsibilities, functions, and authorities assigned to the Secretary of the Army. Therefore, The Surgeon General has the authority to implement the DoD BSAT Biosafety Program as set forth in this directive.

5. Effective immediately, the restrictions on the DoD BSAT program imposed on 2 September 2015 (reference w) are rescinded and replaced with the limitations and guidance in this directive.

6. The Surgeon General is the proponent for the policy in this directive and will incorporate these requirements into a new multi-Service publication on BSAT as soon as practicable. This directive is rescinded upon publication of the new multi-Service publication.

Eric K. Fanning

Encl

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SECRETARY OF THE ARMY POLICY
FOR THE DEPARTMENT OF DEFENSE BIOLOGICAL SELECT AGENT AND TOXINS BIOSAFETY PROGRAM

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SECRETARY OF THE ARMY POLICY FOR THE DEPARTMENT OF DEFENSE BIOLOGICAL SELECT AGENT AND TOXINS BIOSAFETY PROGRAM

I. INTRODUCTION

1. **Purpose.** This directive establishes policy and describes the roles, responsibilities, missions, and functions for the Department of Defense (DoD) Biological Select Agent and Toxins (BSAT) Biosafety Program. The overarching purpose of this program is to protect U.S. Government employees who work with BSAT, as well as other individuals and organizations involved with DoD BSAT materials, and to mitigate potential risk to the general public. This directive applies to DoD components and laboratory activities that provide oversight to, use, produce, store, handle, transport, transfer, or destroy BSAT. Applicable provisions of this directive will be incorporated into contracts which provide for DoD to maintain responsibility for BSAT.

2. **References**

a. A complete list of references is at enclosure 1.

b. The requirements stated in the U.S. Department of Health and Human Services publication, “Biosafety in Microbiological and Biomedical Laboratories” (BMBL), and in this directive apply to all DoD activities and facilities in which BSAT are used, produced, stored, handled, transported, transferred, or destroyed.

3. **Provisions**

a. By the direction of the Deputy Secretary of Defense, the Secretary of the Army (SECARMY) is designated the Executive Agent (EA) for the DoD BSAT Biosafety Program. As the DoD EA, the SECARMY is responsible for the technical review, inspection, and harmonization of biosafety protocols and procedures across the DoD laboratories that use, produce, store, handle, transport, transfer, or destroy BSAT.

b. By the direction of the SECARMY, The Surgeon General is designated the Executive Agent Responsible Official (EA RO) for the DoD BSAT Biosafety Program and is delegated the authority to act on the Secretary’s behalf for all DoD EA responsibilities, functions, and authorities the Deputy Secretary of Defense assigned the Secretary.

c. The scope of the DoD BSAT Biosafety Program includes, but is not limited to, the following Army, Navy, and Air Force laboratories:

(1) U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD, which is subordinate to U.S. Army Medical Research and Materiel Command, U.S. Army Medical Command, Joint Base San Antonio-Fort Sam Houston, TX.

(2) Edgewood Chemical and Biological Center (ECBC), Aberdeen Proving Ground, MD, which is subordinate to U.S. Army Research, Development, and Engineering Command, Aberdeen Proving Ground, which is subordinate to Army Materiel Command (AMC), Redstone Arsenal, AL.

(3) Life Science Division, Dugway Proving Ground (DPG), UT, which is subordinate to ECBC, Aberdeen Proving Ground.

(4) Naval Medical Research Center, Fort Detrick, MD, and Naval Medical Research Units Cairo, Egypt, and Lima, Peru, which are subordinate to Navy Medicine West, San Diego, CA, which is subordinate to the Department of the Navy Bureau of Medicine and Surgery, Falls Church, VA.

(5) Chemical, Biological, and Radiological Defense Division, Naval Surface Warfare Center, Dahlgren Division, Dahlgren, VA, which is subordinate to the Naval Surface Warfare Center, Naval Sea Systems Command, Washington Navy Yard, DC.

(6) 711th Human Performance Wing, Wright-Patterson Air Force Base, OH, which is subordinate to the Air Force Research Laboratory, Air Force Materiel Command, Wright-Patterson Air Force Base.

d. Laboratory commanders and directors are best able to identify potential risk through the use of local risk assessments, and they are responsible for promoting cultures of safety and responsibility. The EA RO's oversight and direct liaison will ensure that laboratory commanders and directors are empowered and supported in their operational environment. The ultimate responsibility for the safe and secure receipt, storage, handling, shipment, and transfer of BSAT resides with the laboratory commander or director in accordance with (IAW) the Military Services' and Federal policies and regulations.

e. This directive has mandatory procedures and guidance, as well as preferred and acceptable methods of accomplishment.

f. The words "shall," "will," and "must" are used to state mandatory requirements in this document and the BMBL. Deviation from these provisions requires a risk assessment and approval from leadership at the appropriate risk acceptance authority level in accordance with the provisions of Army Regulation (AR) 385-10 (The Army Safety Program), Department of the Army Pamphlet 385-30 (Risk Management), and similar Service-specific policies.

g. The word “should” in this document and the BMBL indicates an optional or preferred method of accomplishment. Deviation from these methods requires written authorization from the local commander, senior manager, or his or her written designee.

h. The word “may” indicates an acceptable or suggested means of accomplishment.

4. **Background**

a. The Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) develops medical and physical countermeasures to protect the warfighter from chemical and biological threats under the DoD Chemical and Biological Defense Program. In executing this mission, JPEO-CBD is responsible for developing and evaluating detection and diagnostic capability solutions, developing and evaluating the effectiveness of medical and physical protection capability solutions, developing and evaluating medical treatment capabilities, and verifying the accuracy of test and evaluation equipment. Access to valid test materials, including potentially harmful biological materials known as BSAT, is required to successfully perform these activities.

b. BSAT materials are biological agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products.

c. DoD routinely renders BSAT nonviable or nonfunctional through the use of physical or chemical methods. Many Federal partners, private sector laboratories, and DoD components depend on DoD’s ability to provide nonviable or nonfunctional BSAT for national security and public safety missions.

d. DoD conducts microbiological and biomedical activities in developing measures to identify, detect, diagnose, treat, and protect against biological warfare agents. To meet these objectives, BSAT are used when conducting research, development, test, and evaluation activities; sampling and analysis; and clinical tests.

e. The implementation of a structured BSAT Biosafety Program requires clear standards and procedures; clear policies and regulations; peer review; quality control; accountability and oversight; adequate resources and infrastructure; and continuous process improvement. Through these means, employees and members of the public are protected against the hazards associated with BSAT.

f. Critical to the execution of the DoD BSAT Biosafety Program is the collaboration and cooperation of the joint and interagency community working together to ensure the success of the mission through information exchange, scientific and peer review, partnering, training, and education.

g. DoD activities will incorporate the requirement to follow the latest edition of the BMBL into all contracts that entail microbiological and biomedical activities for DoD.

II RESPONSIBILITIES

1. **The Surgeon General.** The Surgeon General will:

a. provide EA oversight and governance of DoD laboratories that use, produce, store, handle, transport, or destroy BSAT on behalf of the SECARMY as the EA RO.

b. develop a governance framework for the DoD BSAT Biosafety Program.

c. maintain, coordinate, and provide oversight for the technical review of DoD standards, protocols, and procedures associated with BSAT and ensure harmonization across DoD laboratories that use, produce, store, handle, transport, transfer, or destroy BSAT, as well as with interagency partners.

d. identify requirements and provide oversight of the inspection regimen to synchronize DoD and interagency inspection activities; assist the Department of the Army Inspector General (DAIG) in maintaining a roster of qualified inspectors to inspect DoD biosafety and biosecurity programs involving BSAT; and remain in constant communication with the DAIG regarding the operation and performance of the DoD BSAT inspection program.

e. coordinate with the Office of the Deputy Assistant Secretary of Defense (Chemical and Biological Defense) for requirements and resources, including force structure, manpower, and infrastructure, and prioritize resources for research requirements to advance the field of BSAT biosafety.

f. establish and execute DoD inter-Service and inter-governmental agreements; promulgate appropriate issuances (charters, memorandums of agreements, and policies) to achieve necessary levels of harmonization; and maintain oversight of program execution to ensure proper coordination and synchronization.

g. provide oversight and governance to the production, distribution, tracking, and evaluation of end-user requirements for BSAT, BSAT-derived, and BSAT-exempt materials in DoD.

h. coordinate and collaborate with the appropriate DoD components and periodically update the SECARMY and the Under Secretary of Defense (Acquisition, Technology and Logistics).

i. coordinate and collaborate with appropriate organizations, including the Office of the Assistant Secretary of Defense for Public Affairs; the Army Office of the Chief, Public Affairs; and DoD laboratories on all public affairs responses and engagements dealing with BSAT biosafety.

j. establish and maintain venues for coordination and collaboration among DoD organizations and agencies and interagency and industry partners that use, produce, store, handle, transport, transfer, or destroy BSAT. Ensure that laboratory commanders or directors, or their designees, meet with the EA RO at least semiannually.

k. establish a BSAT-Biosafety and Scientific Review Panel (BSAT-BSRP) to provide peer-review; assess biosafety concerns and make recommendations associated with new and established procedures at DoD BSAT laboratories; research requirements to advance biosafety, risk management processes, and harmonization with interagency standards; and implement and oversee a BSAT-BSRP governance framework IAW DoD Instruction (DoDI) 5105.18 (DoD Intergovernmental and Intragovernmental Committee Management Program) and AR 15-39 (Department of the Army Intergovernmental and Intragovernmental Committee Management Program) with appropriate authorities and membership.

l. assist the Offices of the Deputy Chief of Staff, G-3/5/7 and the Provost Marshal General in identifying requirements and providing guidance to streamline and revise biosecurity policies and standard operating procedures.

m. assist the Office of the Director of Army Safety and the U.S. Army Combat Readiness Center in identifying requirements and providing guidance to streamline and revise BSAT biosafety policies and standard operating procedures.

n. designate a biosafety officer to serve as a subject matter expert to advise the EA RO.

o. support the new DoD BSAT inspection program by phasing out all internal Office of The Surgeon General- and Medical Command-directed inspections of BSAT facilities to reduce the number of inspections of BSAT facilities, but permit assistance visits to still be conducted if they take place at the request of the laboratory commander or director and the results remain under the laboratory commander’s or director’s control.

p. publish guidance for recommended conference and symposium attendance for biological research personnel that complies with Service travel and conference attendance policies, but recognizes that conferences and symposia are critical information exchange venues for the BSAT community and are key opportunities to promote professional education and collaboration with industry.

q. implement a formal mentorship program for the Department of the Army and maintain oversight of other Service programs to ensure that all personnel who work with BSAT, including laboratory technicians, safety personnel, regulatory oversight personnel, and inspectors, are adequately trained.

r. collaborate with DoD, the Centers for Disease Control and Prevention (CDC), and the Animal and Plant Health Inspection Service (APHIS) on revisions to applicable

policies and regulations, including, but not limited to, Title 42, Code of Federal Regulation (CFR), Part 73, to update definitions of nonviable select agents and determine how to demonstrate the nonviability of a select agent.

s. serve as the DoD focal point, in coordination with the appropriate organization within the Office of the Secretary of Defense (OSD), for interagency coordination with the CDC and APHIS regarding BSAT biosafety.

t. validate and approve shipments of inactivated BSAT or BSAT-derived materials and maintain oversight of third-party conformance testing for products exported outside DoD.

2. **Secretary of the Navy.** The Secretary of the Navy will:

a. provide voting members for the BSAT-BSRP.

b. provide personnel to participate in the joint inspection team to harmonize inspections of laboratories that work with BSAT across DoD, nominate a qualified lead and backup to serve as the Navy team lead for inspections of the Navy's BSAT laboratories, and update personnel as required.

c. provide funding for travel for inspections and training for Navy joint inspection team members.

d. update BSAT safety and security policies IAW DoDI 5210.88 (Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT)), DoD 6055.18-M (Safety Standards for Microbiological and Biomedical Laboratories), and any revisions to those publications.

e. support the DoD BSAT inspection program by phasing out all internal Department of the Navy-directed BSAT inspections of Navy BSAT facilities to reduce the number of inspections of BSAT facilities, but permit assistance visits to still be conducted if they take place at the request of the laboratory commander or director and the results remain under the laboratory commander's or director's control.

f. implement a formal mentorship program and ensure that all Department of the Navy personnel who work with BSAT, including laboratory technicians, safety personnel, regulatory oversight personnel, and inspectors, are adequately trained.

3. **Secretary of the Air Force.** The Secretary of the Air Force will:

a. provide voting members for the BSAT-BSRP.

b. provide personnel to participate in the joint inspection team to harmonize inspections of laboratories that work with BSAT across DoD; nominate a qualified lead

and backup to serve as the Air Force team lead for inspections of the Air Force's BSAT laboratories; and update personnel, as required.

c. provide funding for travel for inspections and training for Air Force joint inspection team members.

d. update BSAT safety and security policies IAW DoDI 5210.88, DoDI 6055.18-M, and any revisions to those publications.

e. support the DoD BSAT inspection program by phasing out all internal Department of the Air Force-directed BSAT inspections of Air Force BSAT facilities to reduce the number of inspections of BSAT facilities, but permit assistance visits to still be conducted if they take place at the request of the laboratory commander or director and the results remain under the laboratory commander's or director's control.

f. implement a formal mentorship program and ensure that all Department of the Air Force personnel who work with BSAT, including laboratory technicians, safety personnel, regulatory oversight personnel, and inspectors, are adequately trained.

4. **Assistant Secretary of the Army (Acquisition, Logistics and Technology).** The Assistant Secretary will:

a. provide support to and remain in close coordination with the Office of The Surgeon General or the designated official for support of the Biosafety Program.

b. oversee the development and sustainment of an information technology/defense business systems capability that all DoD activities and Federal partners operating with BSAT, BSAT-derived, or BSAT-exempt material may access and use, as appropriate, and designate the JPEO-CBD as the functional requirement authority for the above information technology/defense business systems capability. This system will enable the DoD BSAT Biosafety Program to meet enterprise tracking, reporting, and auditability requirements within an approved governance, risk, and compliance framework. Additionally, this system will:

(1) integrate methods and processes to enable authoritative sources within DoD to validate new, incoming requests for BSAT, BSAT-derived, or BSAT-exempt materials; determine the validity of the request; and determine whether a less virulent material could be substituted for the requested item. The EA RO will approve the validation procedure.

(2) establish methods and processes within the business system that ensure auditable accountability, approvals, archiving, and traceability of orders and transfers for all materials, but specifically for BSAT, BSAT-derived, and BSAT-exempt materials. This effort will address an end-to-end process for producing safe materials,

appropriately vetting the customers who receive them, and validating that the customers are using the lowest risk material for their specific application.

(3) provide routine and as needed information regarding inventories and transfers of BSAT, BSAT derivatives, and BSAT-exempt materials held by a government laboratory principal investigator.

c. evaluate and identify DoD, other governmental, and private organizations continuously for sourcing materials to the Defense Biological Product Assurance Office (DBPAO) based on risk and best business case.

d. coordinate the conduct of third-party conformance testing to verify material quality and reliability data and conformance to the EA RO-approved protocols for inactivated and derivatives of BSAT before their shipment outside DoD.

e. explore safer alternatives to substitute BSAT, BSAT derivatives, and BSAT-exempt materials.

5. **Assistant Secretary of the Army (Installations, Energy and Environment).** The Assistant Secretary will:

a. establish, in coordination with the Office of The Surgeon General and the Office of the Director of Army Safety, policy for risk management and training of supervisors and employees in DoD laboratories that manage BSAT materials.

b. establish and synchronize environmental, safety, and occupational health policies for DoD laboratories that use, produce, store, handle, transport, transfer, or destroy BSAT.

c. coordinate with the EA Secretariat for the Chemical Biological Defense Program and the Office of the Deputy Assistant Secretary of Defense (Chemical and Biological Defense) to assist in the prioritization and resourcing of infrastructure requirements for the Chemical and Biological Defense Program.

6. **Army Deputy Chief of Staff, G-3/5/7.** The Deputy Chief of Staff will:

a. support the Army Safety Office and the Office of the Provost Marshal General in updating BSAT safety and security policy IAW DoDI 5210.88, DoD 6055.18-M, and any revisions to those publications.

b. rescind AR 50-1 (Biological Surety) and assist the Office of the Provost Marshal General in incorporating the Personnel Reliability Program requirements from AR 50-1 into AR 190-17 (Biological Select Agents and Toxins Security Program).

c. eliminate the use of the terms “biosurety” and “biological surety” from all future Army publications, doctrine, and training for which the Deputy Chief of Staff, G-3/5/7 is the proponent.

d. lead the staff effort to incorporate the following changes into applicable policies and regulations IAW DoDI 5210.88:

(1) Personnel Reliability Program requirements will apply only to individuals working with Tier 1 BSAT.

(2) DoD laboratories will record inventory and accountability of BSAT directly into the DoD BSAT database.

(3) DoD laboratories will transport BSAT IAW select agent regulations (SAR) (that is, 7 CFR, Part 331; 9 CFR, Part 121; and 42 CFR, Part 73).

7. **The Inspector General.** The DAIG will:

a. establish and maintain a joint DoD inspection team no later than 1 September 2016. The team will be composed of trained subject matter experts from the Army, Air Force, and Navy to harmonize BSAT inspections across DoD.

b. develop a DoD inspection schedule no later than 1 August 2016. Coordinate with the CDC and APHIS to ensure DoD inspections are conducted within 18 months from the date of the last inspection, regardless of whether that inspection was DoD-led or CDC-led with DoD participation, using the appropriate mix of both announced and unannounced inspections and inspections paired with CDC and APHIS inspections.

c. publish a Joint Biosafety Inspection Standard Operating Procedure no later than 30 September 2016 and facilitate training for the inspection team before execution to reduce inconsistencies during inspections.

d. report draft inspection findings to the laboratory commander or director and conduct an immediate outbrief upon completion of an inspection.

e. report and provide outbrief of final inspection findings simultaneously to the inspected Service responsible official, the EA RO for BSAT Biosafety, and the OSD Office of Primary Responsibility for biosecurity.

f. maintain reports of inspections, share common deficiencies across all DoD laboratories, develop a system to monitor deficiencies until corrected, and share lessons learned and best practices in a quarterly report to the EA RO and DoD laboratories.

g. obtain CDC and APHIS inspection results and promptly provide them to the EA RO.

h. develop, implement, and continuously validate a balanced inspection regime that provides equal focus on scientific procedures and laboratory administration.

8. **Provost Marshal General.** The Provost Marshal General will:

a. coordinate with the Deputy Chief of Staff, G-3/5/7 to incorporate the Personnel Reliability Program requirements from AR 50-1 into AR 190-17.

b. incorporate policy changes in DODI 5210.88 into AR 190-17.

c. implement security requirements IAW applicable SARs (for example, 7 CFR, Part 331; 9 CFR, Part 121; or 42 CFR, part 73), including physical security equipment, access and material controls, and serious incident reporting.

d. develop a security requirements baseline; a process for submitting, coordinating, and approving requests for deviations from the security requirements baseline; and a process for submitting, coordinating, and approving requests for waivers from or exceptions to site security requirements that exceed the security requirements baseline.

9. **Director of Army Safety/Commander, Army Combat Readiness Center.** The Director will:

a. incorporate policy changes in DODI 5210.88 into AR 385-10 and synchronize biosafety and biosecurity requirements.

b. update BSAT safety policies IAW DoD 6055.18-M and provide coordination on revisions to DoD 6055.18-M.

c. support The Surgeon General in establishing the BSAT biosafety program and governance framework.

d. support JPEO-CBD in synchronizing biosafety data and information from the Army Safety and Occupational Health Enterprise Information Management System with the DoD BSAT Biosafety Program Defense Business System.

10. **Commander, U.S. Army Materiel Command.** The Commander, AMC will:

a. accept transfer of Western Desert Test Center, Life Sciences Division (WDTC-LSD), DPG, from the Commander, Army Test and Evaluation Command (ATEC) to the Director, ECBC, IAW Department of the Army General Orders No. 2016-04 no later than 1 July 2016. Upon transfer, WDTC-LSD will be referred to as ECBC-LSD.

b. cease DBPAO production at DPG. ECBC-LSD will maintain the ability to produce live and inactivated materiel with BSAT-BSRP-approved standard operating procedures for internal testing and evaluation purposes in support of WDTC.

c. provide oversight and support to facilitate the lifting of the moratorium at ECBC-LSD and the recertification of the laboratory's registration with the CDC.

d. enter into and maintain a memorandum of agreement with the Commander, ATEC for BSAT support at DPG.

e. support the DoD BSAT inspection program by phasing out all internal AMC-directed inspections of ECBC to reduce the number of inspections of BSAT facilities, but permit assistance visits to still be conducted if they take place at the request of the laboratory commander or director and the results remain under the laboratory commander's or director's control.

f. leverage existing incentive programs to attract and retain highly qualified scientists to DPG.

g. ensure compliance with AR 702-11 (Army Quality Program) as it relates to the production of all microbiological organisms before ECBC-LSD resumes operations with BSAT.

h. provide voting members to the BSAT-BSRP and update personnel as required.

11. **Commander, U.S. Army Test and Evaluation Command.** The Commander, ATEC will:

a. transfer WDTC-LSD, DPG, to the Director, ECBC, IAW General Orders No. 2016-04 no later than 1 July 2016. WDTC-LSD will be referred to as ECBC-LSD upon transfer.

b. enter into and maintain a memorandum of agreement with the Commander, AMC for BSAT support at DPG.

c. assess, in coordination with AMC, the costs and benefits of reassigning the remaining elements of the WDTC at DPG and provide any associated recommendations through the chain of command to the SECARMY.

III. EXECUTION

1. Management of the Shipment and Tracking of BSAT, and the Phaseout of Moratoriums

a. Organization. The organization and program known as the Critical Reagents Program is disestablished, and any policies or procedures formerly associated with the program are rescinded. In its place, the JPEO-CBD will establish an office known as the DBPAO. In addition to the acquisition functions it performs, DBPAO will coordinate customer requirements for BSAT, BSAT-derived, and BSAT-exempt materials with DoD suppliers. DBPAO's primary focus will be to exercise system and process oversight of the Defense Business System that will enable the DoD BSAT Biosafety Program to meet end-to-end enterprise tracking, reporting, and auditability requirements within an approved governance, risk, and compliance framework.

b. Coordination. The DBPAO will remain an element of the JPEO-CBD. JPEO-CBD will closely coordinate and collaborate with the EA RO to harmonize policies and procedures of mutual interest.

c. Defense Business System. The Assistant Secretary of the Army (Acquisition, Logistics and Technology) will oversee the development of a Defense Business System that is a Web-based suite of applications, processes, and procedures to meet enterprise tracking, reporting, and auditability requirements. This system will be developed for materials under the oversight of the DBPAO and EA RO within an approved governance, risk, and compliance framework. The system will combine the DoD BSAT database and the JPEO-CBD's online ordering system, the Ordering System for Critical Assays and Reagents (OSCAR).

d. Rescission of Moratorium. Effective immediately, the restrictions imposed on the DBPAO and the DoD BSAT program described in references w and z are rescinded and replaced with the following limitations and guidance:

(1) Inactivated *Bacillus anthracis*. The Deputy Secretary of Defense- and CDC-directed moratoriums on the production, handling, testing, and shipment of inactivated *Bacillus anthracis* remain in effect until rescinded. All EA RO-and CDC-approved waivers remain in effect.

(2) The restrictions the SECARMY imposed on the LSD remain in effect until the CDC restores the LSD's Certificate of Registration for Possession, Use, and Transfer of Select Agents and Toxins and the EA RO approves lifting the restrictions.

(3) Waiver requests for mission-critical requirements will be submitted to the EA RO for approval. The waiver request will document how the applicant will ensure the quality and reliability of the product.

(4) Production, handling, testing, and shipping of inactivated BSAT strains of *Bacillus anthracis*.

(a) Production, handling, and testing of inactivated BSAT must be conducted in BSAT-registered space. Products must be held in BSAT-registered space until

reviewed by the laboratory biosafety officer and responsible official and approved by the laboratory commander or director to ensure the quality and reliability of the product before removal. The laboratory will maintain records from this review for a period not less than 3 years.

(b) All production, handling, and testing must be conducted in accordance with the current authorizations and restrictions the Federal Select Agent Program has established.

(c) Shipping is not authorized until the EA RO has approved standardized procedures for rendering *Bacillus anthracis* nonviable and the CDC has accepted or acknowledged the procedures as adequate.

(d) Shipping is not authorized until the EA RO approves the transfer of BSAT-related material. Quality and reliability data must be endorsed by the laboratory biosafety officer and approved by the laboratory commander or director before submission to the EA RO for review. Third-party conformance testing will be conducted before their shipment outside DoD.

(e) Waiver requests will be submitted to the EA RO for shipping if the applicant provides an approved waiver from the CDC or documents that demonstrate compliance with the most recent CDC guidance for *Bacillus anthracis*. The EA RO will maintain approved waivers from the CDC for a period not less than 3 years.

(5) Production, handling, testing, and shipping of inactivated BSAT and all derivatives of BSAT, except inactivated BSAT strains of *Bacillus anthracis*.

(a) Production, handling, and testing of inactivated BSAT must be conducted in BSAT-registered space. Products must be held in BSAT-registered space until reviewed by the laboratory biosafety officer and responsible official and approved by the laboratory commander or director to ensure the quality and reliability of the product before removal. The laboratory will maintain records from this review for a period not less than 3 years.

(b) Production, handling, and testing of derivatives of BSAT, which are defined as any product that may still contain viable BSAT, must be conducted in BSAT-registered space. Products must be held in BSAT-registered space until reviewed by the laboratory biosafety officer and responsible official and approved by the laboratory commander or director to ensure the quality and reliability of the product before removal. The laboratory will maintain records from this review for a period not less than 3 years.

(c) Attenuated strains of select agents or nonfunctional forms of select toxins that are excluded from the requirements of 7 CFR, sections 331.3(d)–(e); 9 CFR, sections 121.3(d)–(e) and 121.4(d)–(e); and 42 CFR, sections 73.3(d)–(e) and

73.4(d)–(e) will not be transferred within or outside of DoD until the standard operating procedures for their production and testing have been reviewed by the BSAT-BSRP and approved by the EA RO. This will be done when the EA RO has made the determination that the described procedures provide a very high confidence that they deliver a fully characterized product. Characterization of the product must describe the attenuation or loss of function process, cite supportive literature for the process, and provide verification or validation data (if the supportive literature is not specific to the attenuated agent or nonfunctional toxin). The intent is to fully understand and communicate to the recipients and users the characteristics of the products they will receive or handle. If a product cannot be reduced from BSAT status to an attenuated or nonfunctional status, the product will be provided as BSAT with the appropriate risk information, and it will only be provided if the recipient is CDC-registered for that specific BSAT and the product is shipped IAW the approved BSAT packing and shipping requirements set forth in the applicable SAR (7 CFR, Part 331; 9 CFR, Part 121; or 42 CFR, Part 73).

(i) Materials that have been approved for exclusion from the requirements of the SAR as an attenuated strain of a select biological agent or toxin because they do not pose a significant threat to public health and safety, animal and plant health, or animal and plant products may be transferred. After they are approved for exclusion, these materials will be listed on the National Select Agent Registry Web site (http://www.selectagents.gov) and will remain excluded unless they are subject to manipulation that restores or enhances their virulence or toxic activity. Protocols for these materials are also excluded from mandatory BSAT-BSRP review.

(ii) DoD laboratory commanders and directors will forward approved exclusions to the EA RO for filing and sharing with other DoD entities. If a request to exclude an attenuated strain of a select biological agent or toxin is not approved, the material must continue to be treated as BSAT and the BSAT-BSRP must review related protocols.

(d) Shipping is not authorized until approved by the EA RO. Quality and reliability data must be endorsed by the laboratory biosafety officer and approved by the laboratory commander or director before submission to the EA RO for review. Third-party conformance testing will be conducted before shipment outside DoD.

(e) Waiver requests may be submitted to the EA RO if a mission requires the shipping of materials before the BSAT-BSRP reviews the protocols.

e. Third-Party Conformance Testing. The JPEO-CBD will coordinate the conduct of third-party conformance testing. Third-party validation will verify material quality and reliability data and conformance to the EA RO-approved protocols for inactivated and derivatives of BSAT before shipment outside DoD.

f. Inventory and Tracking Requirements. DoD laboratories will record inventory and maintain accountability of BSAT in a centralized business system to be developed,

which will combine the DoD BSAT database and JPEO-CBD's online ordering system, OSCAR. This business system will enable the DoD BSAT Biosafety Program to meet enterprise tracking, reporting, and auditability requirements within an approved governance, risk, and compliance framework. DoD laboratories will transport BSAT IAW DODI 5210.88 and the applicable SAR (7 CFR, Part 331; 9 CFR, Part 121; or 42 CFR, Part 73). Additionally, all materials described in paragraph B of enclosure 2 that are transferred within or between DoD laboratories or to non-DoD customers will be centrally reported and tracked using established procedures and the business system. This system will be in place and operational by 1 August 2016 and will constitute the official system of record for the purposes of 42 CFR, section 73.17 and other regulatory requirements. The following materials will be managed in an approved governance, risk, and compliance framework business system:

(1) Definitions of material classes are in paragraph B of enclosure 2.

(2) Permissible toxin amounts. All select agent toxin amounts held by a principal investigator that are under the aggregate amounts listed in 42 CFR, section 73.3(d)(3).

g. Review of Customer Requests. Before any request for materials from an outside, non-DoD organization or entity is filled, the EA RO, or designee, will review the request to assess the validity of the request and determine whether, if valid, the request can be satisfied with a safer or less dangerous material. This applies to any request, whether it is processed through the DBPAO or not.

h. Forwarding DoD BSAT. All material transfer agreements will prohibit any further transfer of BSAT materials beyond the initial customer receiving the material. Agreements will also require customers to notify the supplier, in writing (in an EA RO- or designee-approved format) when the material has been consumed or destroyed. Until this notification from the customer is received, the original source laboratory of the material will inquire into the status of the material annually.

2. **Command and Control of West Desert Test Center-Life Sciences Division, Dugway Proving Ground, UT**

a. The SECARMY directed the transfer of the WDTC-LSD from ATEC to AMC on 1 July 2016 in General Orders No. 2016-04.

b. AMC and ATEC must submit a memorandum of agreement and supporting Program Objective Memorandum Schedule 8 to the Office of the Army Deputy Chief of Staff, G-37/Force Management to effect this transfer in the Program Objective Memorandum for fiscal years 2019–23.

c. In the alternative, AMC, as the gaining command, may submit a concept plan IAW AR 71-32 (Force Development and Documentation).

d. AMC is authorized to provisionally reorganize the gaining organization, the ECBC, to assume interim command and control of the WDTC-LSD, effective 1 July 2016, pending formal reorganization. No restationing is authorized in conjunction with this action.

e. The Director, ECBC-LSD will provide direct support to ATEC and continue to conduct developmental and operational testing of biological defense systems and medical countermeasure programs for DoD and other Federal Government agencies and microbiological industry clients. The Director, ECBC-LSD may also perform other functions as directed by the Director, ECBC.

f. The Director, ECBC will develop and implement a plan for talent management of laboratory personnel at ECBC and ECBC-LSD that incorporates developmental assignments, incentive programs, and professional development of biological research personnel.

g. The Director, ECBC will provide mobile training teams with doctorate-level microbiologists to assist ECBC-LSD.

3. **Biological Select Agents and Toxins Biosafety and Scientific Review Panel**

a. Under the oversight of the EA RO, the BSAT-BSRP will provide peer review; assess biosafety concerns and make recommendations associated with new and established procedures at DoD BSAT laboratories; and research requirements to advance biosafety, risk management processes, and harmonization with interagency standards.

b. The BSAT-BSRP will also advise the EA RO on any matters that pertain to biosafety associated with related research.

c. The BSAT-BSRP will meet a minimum of two times a year and, as needed, up to four times a year.

d. The BSAT-BSRP will be composed of a biosafety officer (military or DoD civilian) and a scientist (military or DoD civilian) from each DoD facility with a mission involving the use, production, storage, transportation, transfer, or destruction of BSAT, except for the Naval Medical Research Units; the Program Manager or Gatekeeper for Laboratory Response Networks for each of the Services; and two BSAT-experienced scientists and/or biosafety professionals from non-DoD government facilities that are registered by the CDC for work with BSAT. Naval Medical Research Units will only provide scientific representation to the BSAT-BSRP because the Biological Defense Research Directorate-NMRC provides their biosafety officer support.

4. **Inspection Program**

a. A single DoD inspection team, coordinated by the DAIG with the EA RO and the other Services' Inspectors General (IGs), will conduct the DoD BSAT program inspection regime.

b. The inspection team will work to blend inspections across DoD by balancing inspection oversight with the inspection burden placed on the laboratories that work with BSAT material.

c. The inspection team will be composed of trained, multi-Service subject matter experts who retain their Service positions. The DAIG will select inspection team members with the advice of the EA RO and the other Service IGs.

d. The inspection team will work in coordination with the CDC and APHIS to inspect laboratories concurrently when possible.

e. The inspection team lead will be designated by the inspected Service's IG office. The team lead must be a field grade officer or civilian equivalent.

f. The inspection team operates independently of the EA RO and the OSD proponent for biosecurity, but coordinates closely with both to ensure proper policy compliance and assess potential weaknesses in biosafety and biosecurity policies and programs across DoD.

g. Draft inspection findings will be presented to the responsible laboratory commander or director before submission to the EA RO. Final inspection findings will be provided simultaneously to the inspected Service, the EA RO, and the OSD Office of Primary Responsibility for biosecurity.

h. DoD-led inspections of DoD laboratories that manage BSAT will be conducted within 18 months from the date of the last inspection, regardless of whether that inspection was DoD-led, or CDC-led with DoD participation. Increased inspection frequency may occur due to unannounced inspections or other special circumstances.

i. The size and composition of the inspection team will be directly proportional to the size of the program mission or facility inspected.

5. **Revision of Biosafety, Biosecurity, and Biosurety Policy**

a. Revision of biosafety and associated biosecurity policy will occur in three phases:

(1) Phase 1 is the expedited laboratory-level implementation of the requirements in DoDI 5210.88, as the Under Secretary of Defense (Acquisition, Technology and Logistics) directed on 18 February 2016 (reference k). The EA RO will coordinate with

and provide implementing guidance to the laboratories, including requirements for any laboratory requests for exceptions. Phase 1 defers the implementation of the responsibilities assigned to the Services until phase 2.

(2) Phase 2 is Service implementation of DoDI 5210.88. Building on the laboratory-level implementation from phase 1, the Services will expedite the publication of interim guidance to address Service-level responsibilities. One of the objectives of phase 2 is for the Services to identify the implementation guidance needed for the next revision of DoD publications in phase 3. Additionally, the Army will rescind AR 50-1; incorporate the requirements for the Personnel Reliability Program into AR 190-17; and eliminate the use of the terms biosurety and biological surety from all future Army publications, doctrine, and training.

(3) Phase 3 is the recommended revision of DoDI 5210.88 and DoD 6055.18-M to allow direct implementation of these publications by the Services and laboratories without the need for Service publications.

b. In the event DoD is unable to incorporate all Service-required areas, a multi-Service publication may be appropriate or the Services may publish abbreviated Service guidance.

6. **Irradiation Inactivation of *Bacillus anthracis* and Viability Testing**

a. The Director, ECBC will finalize irradiation inactivation and viability testing protocols for *Bacillus anthracis* for EA RO approval and assist the EA RO in ensuring that the most current and peer-reviewed standards are incorporated into subsequent revisions of these protocols.

b. The BSAT BSRP will review and validate the protocols for irradiation inactivation and viability testing.

c. The moratorium on the production, handling, testing, and shipment of inactivated *Bacillus anthracis* for DoD laboratories remains in effect until the EA RO has approved the protocols for irradiation inactivation and viability testing; the CDC has authorized use of the protocols; and the Deputy Secretary of Defense rescinds the moratorium issued on 23 July 2015.

d. Stocks of *Bacillus anthracis* that are inactivated via irradiation and shipped outside of DoD will be assigned a “destroy-by” date to advise entities that store these materials for an extended period of time that they must either dispose of the material or revalidate that the material is nonviable. The assignment of a “destroy-by” date should be based on scientific studies of the effects of storage conditions on the potential for regrowth. In the absence of scientific data to support the “destroy-by” date, the Director, ECBC will determine an appropriate date based on best available evidence, and provide the date to the EA RO for approval.

REFERENCES

a. Possession, Use, and Transfer of Select Agents and Toxins, 7 CFR, Part 331.

b. Possession, Use, and Transfer of Select Agents and Toxins, 9 CFR, Part 121.

c. Select Agents and Toxins, 42 CFR, Part 73.

d. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, HHS Publication No. (CDC) 21-1112, December 2009.

e. DoD Directive 4715.1E (Environment, Safety, and Occupational Health (ESOH)), March 19, 2005.

f. DoD Instruction 5105.18 (DoD Intergovernmental and Intragovernmental Committee Management Program), July 10, 2009, Incorporating Change 1, August 7, 2012.

g. DoD Instruction 5210.88 (Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT)), January 19, 2016.

h. DoD Instruction 6055.01 (DoD Safety and Occupational Health (SOH) Program), October 14, 2014.

i. DoD 6055.18-M (Safety Standards for Microbiological and Biomedical Laboratories), May 11, 2010.

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

k. Memorandum, Under Secretary of Defense (Acquisition, Technology and Logistics), February 18, 2016, subject: Implementation of Department of Defense Instruction 5210.88, “Security Standards for Safeguarding Biological Select Agents and Toxins.”

l. Department of Defense Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* Spores by DoD, July 13, 2015.

m. AR 15-39 (Department of the Army Intergovernmental and Intragovernmental Committee Management Program), 29 May 2015.

n. AR 50-1 (Biological Surety), 28 July 2008.

o. AR 71-32 (Force Development and Documentation), 1 July 2013.

p. AR 190-17 (Biological Select Agents and Toxins Security Program), 3 September 2009.

q. AR 385-10 (Army Safety Program), 27 November 2013.

r. AR 702-11 (Army Quality Program), 25 February 2014.

s. Department of the Army Pamphlet 385-30 (Risk Management), 2 December 2014.

t. Department of the Army General Orders No. 2016-04 (Transfer of the West Desert Test Center–Life Sciences Division), 15 April 2016.

u. Memorandum, Secretary of the Army, 30 Jul 2015, subject: Office of the Secretary of Defense Review Report: Inadvertent Shipment of Live Bacillus anthracis Spores by Department of Defense.

v. Action Memorandum, Secretary of the Army, 13 Aug 2015, subject: Implementation Plan to Address the OSD Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* (Anthrax) Spores by DoD; Findings and Recommendations; Associated Deputy Secretary of Defense Directives; and Related Executive Agent Responsibilities.

w. Memorandum, Secretary of the Army, 2 Sep 2015, subject: Immediate Safety Review and Extension of Moratorium.

x. Memorandum, Secretary of the Army, 26 Oct 2015, subject: Delegation of Authority for Department of Defense (DoD) Executive Agent Responsibility for the DoD Biological Select Agent and Toxin (BSAT) Biosafety Program.

y. Memorandum, Secretary of the Army, 14 Mar 2016, subject: Implementation of Department of Defense Executive Agent Responsibilities for the Department of Defense Biological Select Agents and Toxins Biosafety Program.

z. Memorandum, Assistant Secretary of the Army (Acquisition, Logistics and Technology), 4 Sep 2015, subject: Implementation Guidance.

DEFINITIONS OF MATERIAL CLASSES FOR THE ORDERING SYSTEM FOR CRITICAL ASSAYS AND REAGENTS

A. General Definitions

OSCAR: Ordering System for Critical Assays and Reagents (OSCAR) is a Web-based application that tracks orders of Defense Biological Product Assurance Office (DBPAO) products and transfers of specific Department of Defense (DoD) materials.

Product: Defined as biological materials produced on behalf of the DBPAO that are visible and transferrable through OSCAR to any qualifying program within DoD, a Federal interagency partner, or an academic or private industry partner.

Material: Defined as biological materials held by a Federal laboratory principal investigator that can be transferred at the discretion of the principal investigator through OSCAR, but is not visible to any other OSCAR user.

Primary Transfer: The movement of products or materials from a DoD laboratory that tracks transfers through OSCAR to another laboratory (DoD or otherwise) that may or may not use OSCAR to track transfers.

Secondary Transfer: The movement of DoD products or materials that the primary transfer recipient received via a primary transfer. This definition only applies when the primary transfer recipient does not track transfers through OSCAR, but wants to further distribute the material. All material transfer agreements will prohibit any further transfer of BSAT materials beyond the initial customer receiving the material.

Terminal Recipient: An entity that does not track product or material transfers in OSCAR and therefore is not allowed to redistribute or transfer products or materials that originated from a DoD laboratory subject to these guidelines.

B. Products and Materials Tracked in OSCAR

1. Biological Select Agents and Toxins (BSAT)

a. Biological agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products. Select agents and toxins are identified in 7 CFR, section 331.3; 9 CFR, sections 121.3 and 121.4; and 42 CFR, section 73.3 and 73.4.

b. Tier 1 BSAT are a subset of select agents or toxins designated in the select agent regulations (SAR) (7 CFR Part 331; 9 CFR, Part 121; and 42 CFR, Part 73) as Tier 1 because they present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure,

or public confidence, and pose a severe threat to public health and safety, animal and plant health, or animal and plant products.

2. Select Agent and Toxin Exclusions

a. Products and materials considered to be viable, but excluded from BSAT regulatory requirements: attenuated strains or toxins. An attenuated strain or toxin is a select agent or select toxin that has been genetically modified to alter or remove the virulence genes/toxin so that it loses the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products and has been approved for exclusion from the requirements of the SAR. Spores derived from such strains are also included in this category. Examples are attenuated or modified strains where key amino acid residues in a virulence gene or toxin have been exchanged by substitution, or where part of the gene or its genetic control sequences were deleted or otherwise rendered nonfunctional by molecular biology techniques or by nature. After approved for exclusion, these materials will be listed on the National Select Agent Registry Web site (http://www.selectagents.gov) and will remain excluded unless they are subject to manipulation that restores or enhances their virulence or toxic activity.

b. Products and materials considered to be nonviable select agents and nonfunctional select toxins:

(1) For purposes of the SAR, “nonviable” and “nonfunctional” are similar terms that may be defined as the loss of biological activity. For a select agent, the term “nonviable” means that a select agent is no longer capable of growing, replicating, infecting, or causing disease. For regulated nucleic acids, the term “nonviable” means that the nucleic acids are no longer capable of producing infectious forms of a select virus or expression of a functional select toxin without further genetic manipulation. For a select toxin, the term “nonfunctional” means a toxin is no longer capable of exerting its toxic effect.

(2) Inactivated agents. A select agent that has been 100 percent *inactivated to completion* by chemical or physical (including irradiation) methods so that it loses viability (as determined by a validated protocol that is scientifically sound and produces consistent results), but at the same time retains its properties so that it can be used in diagnostic, detection, or therapeutic applications. Examples: Formalin-fixed animal tissue, heat inactivation, or Gamma (γ) irradiation.

c. Permissible Toxin Amounts. Toxin amounts held by a principal investigator that are under the aggregate amounts listed in 42 CFR, section 73.3(d)(3).

3. Potentially High-Risk Organisms or Viruses Not Currently Considered BSAT. Products or materials determined to have the “potential” to pose a severe threat to public health and safety, animal and plant health, or animal and plant products, as determined by the BSAT-BSRP.

4. Materials Resulting From CDC-Approved “Restricted Experiments”

a. Products resulting from the experiments described in 7 CFR, section 331.13; 9 CFR, section 121.13; 42 CFR section 73.13; or materials resulting from the modification of a non-BSAT strain so that it has the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products.

b. Select agents and toxins that could be genetically modified to have the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products. Example: Transfer of pXO2 to *Bacillus anthracis* Sterne or transfer of pXO1 and pXO2 to *Bacillus anthracis* Sterne or a *B. cereus* strain; enhancement of toxicity of a toxin by genetic mutations; or introduction of anti-microbial resistance genes into select agents.

5. Synthetic viral or gene constructs that are inherently infectious and are immediate precursors to the production of infectious forms of any of the regulated select agent viruses (that is, the nucleic acids that are capable of generating infectious forms of a regulated virus by using host polymerases, but without the need for any additional exogenous factors (proteins, nucleic acids, etc.)).