RECORD VERSION

STATEMENT BY
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IN SUPPORT OF THE
EXECUTIVE AGENT RESPONSIBLE OFFICIAL
FOR THE DEPARTMENT OF DEFENSE
BIOLOGICAL SELECT AGENTS AND TOXINS BIOSAFETY PROGRAM

BEFORE THE

HOUSE ENERGY AND COMMERCE
OVERSIGHT AND INVESTIGATIONS SUBCOMMITTEE
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BIORESEARCH LABS AND INACTIVATION OF DANGEROUS PATHOGENS

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COMMITTEE ON HOUSE ENERGY AND COMMERCE

Chairman Murphy, Ranking Member DeGette, Distinguished Members of the Subcommittee, thank you for this opportunity to brief you on the Department of Defense's (DoD) and the Army's actions since the last hearing on April 20, 2016. The DoD has accomplished several actions and is in the process of completing several additional near term changes to address the development and implementation of oversight policy and procedures for the safe handling and transfer of Biological Select Agents and Toxins (BSAT) among DoD laboratories and affiliated institutions.

Following the May 2015 reporting of the incomplete inactivation and shipments of *Bacillus anthracis* (anthrax) spores by an Army laboratory, the DoD implemented a moratorium on anthrax production, handling, testing, and shipment. The Army also issued a similar moratorium on all BSAT. The DoD instituted an immediate realignment of authorities and oversight for BSAT activities. By direction of the Deputy Secretary of Defense, the Secretary of the Army is designated the Executive Agent (EA) for the DoD BSAT Biosafety Program. By the direction of the Secretary of the Army, The Surgeon General of the Army 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 to the Secretary of the Army.

As the Commanding General of the U.S. Army Medical Research and Materiel Command, I also support The Surgeon General of the Army, the DoD EA RO for BSAT. In this support role, I oversee the management for harmonization of BSAT policy, technical review, and inspection guidelines across DoD.

Background

In April 2016, my predecessor, Major General (MG) Lein testified before this committee describing the Army and the DoD's response to the improper inactivation and shipping of anthrax spores by an Army laboratory. MG Lein explained that the DoD and other government agencies store, study, and ship BSAT materials for research, development, testing and evaluation of medical and physical countermeasures to biological and bioterrorism threats. MG Lein noted that it is DoD's goal to develop a system that incorporates the fundamentals of quality policies and systems. We believe that the systems under development will provide for the necessary checks and balances to prevent future challenges.

Today, I will briefly describe several of the actions accomplished since April and also describe our anticipated plans for future validation procedures, oversight and implementation of governance policies for biosafety. I also look forward to working with the other federal agencies as they develop new national standards for oversight of dangerous pathogens and high-containment laboratories participating in the Select Agent Program.

Recent Actions

The EA RO created the BSAT Biosafety Program Office (BBPO). The BBPO will advise the EA RO for the DoD BSAT Biosafety Program on biosafety for all matters that pertain to risk associated with BSAT operations, provide oversight of DoD BSAT laboratory biosafety operations, serve as a unified DoD interface with regulatory agencies, ensure standardization of safety elements of procedures used in DoD BSAT

laboratories, and identify best practices to enhance biosafety across the full spectrum of DoD BSAT operations.

As of July this year, the Life Science Division production facility, from which the inadvertent live Anthrax shipments were sent, was reassigned from Dugway Proving Ground and placed under the U.S. Army Edgewood Chemical Biological Center. This transfer provides a chain of command which has a robust, BSAT experienced staff, assigned under the Research Development and Engineering Command and the Army Materiel Command.

A BSAT Biosafety and Scientific Review Panel (BSRP) was established. On an as needed basis, minimum two times per year, the BSAT-BSRP will review and assess biosafety concerns associated with currently established and new procedures conducted at DoD BSAT laboratories, review and assess scientific evidence that supports mitigation of the biosafety concerns identified, and provide recommendations to the EA RO for BSAT Biosafety Programs on their acceptability for continued use or initiation of use to enhance biosafety across DoD BSAT programs. This panel is also intended to serve in an advisory capacity to the EA RO on any matters that pertain to biosafety associated with BSAT-related research.

As per direction of the Deputy Secretary of Defense, a credentialed biosafety professional was designated to advise the executive agent and is a member of the BBPO staff.

A joint DoD inspection team was established by the Department of Army Inspector General. This joint inspection team will ensure that all DoD BSAT laboratories are inspected to a common standard and best practices identified by the BBPO are

uniformly implemented. The team will report and provide findings to laboratory leadership, to the Service responsible official, to the EA RO, and the Secretary of Defense Office of Primary Responsibility for biosecurity. They will also obtain inspection results from both the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service and provide the results to the EA RO.

Army Directive 2016-24

Most recently, on July 25, 2016, the Secretary of the Army signed Army Directive 2016-24, the "Department of Defense Biological Select Agent and Toxins Biosafety Program." This directive establishes policy and assigns several responsibilities to applicable DoD, Service, and Army activities with the oversight and governance of the DoD BSAT Biosafety Program delegated to The Surgeon General of the Army. It applies to any DoD activity that provides oversight to use, produce, store, handle, transport, transfer, or destroy BSAT. Applicable provisions of this directive will also be incorporated into contracts which provide for DoD to prohibit transfer of inactivated BSAT and derivatives of BSAT beyond the initial customer receiving the material and an annual inquiry by DoD until the material is consumed or destroyed.

This new Army Directive and the requirements stated in the U.S. Department of Health and Human Services publication, "Biosafety in Microbiological and Biomedical Laboratories" apply to all DoD activities and facilities in which BSAT are used, produced, stored, handled, transported, transferred, or destroyed. Army Directive 2016-24 has mandatory procedures and guidance, as well as preferred and acceptable methods of accomplishment.

The Army Directive removes the previous Secretary of the Army moratorium. The Deputy Secretary of Defense July 2015 moratorium on the production, handling, testing, and shipment of inactivated anthrax will remain in effect, until rescinded. The Federal Select Agent Program issued an updated policy statement for work with *Bacillus anthracis* spores and DoD laboratories will comply with the updated guidance.

GAO-16-642

The DoD appreciated the opportunity to review the draft report dated June 8, 2016, and had no comments. We value the analysis provided by the Government Accountability Office (GAO); their observations will inform efforts of the DoD Biological Select Agents and Toxins Biosafety Program and improve oversight. Similar to the new GAO-16-642 recommendations, the DoD is addressing our BSAT oversight of inactivation documentation, improving guidance for development and validation of inactivation protocols, and developing consistent enforcement of investigations and referrals. We look forward to coordinating and cooperating with the U.S. Department of Health and Human Services and the U.S. Department of Agriculture as they respond to the GAO recommendations.

Way Ahead

Several initiatives are intended to enhance harmonization and standardization of practices and procedures across the DoD network of laboratories. These initiatives include development of a joint Service inspection team, the review process previously described for all BSAT protocols and procedures, and the establishment of unified oversight for biosafety and biosecurity to enhance composite risk management for BSAT operations.

The Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense initiated studies to better define conditions for inactivation and viability testing of BSAT. Current studies are focused on the causative agent for anthrax, *Bacillus anthracis*. An irradiation inactivation study on *Bacillus anthracis* is under way and is scheduled for completion in October 2016. Additional studies, based on what is learned from the initial study, are planned for fiscal year 2017.

The BSRP will primarily focus on conducting critical review of all DoD BSAT protocols and procedures and will identify scientific gaps related to safety to focus future research initiatives. Through this process, we will gain assurance that all procedures are properly validated and/or verified. This panel is an intra-governmental committee made up of DoD Biosafety Officers and scientists along with similar representation from the CDC and the U.S. Department of Agriculture.

Working with the Assistant Secretary of the Army (Acquisition, Logistics & Technology), we anticipate development of a Defense Business System that will integrate information from current BSAT management databases and provide additional capabilities for tracking inactivated BSAT and products derived from BSAT. Capturing critical information from a Bio-Risk Quality Management System is also planned for development. Completion of the Defense Business System development is anticipated by September 2017.

In conclusion, the DoD realigned activities, developed policy and implemented procedural steps to create systems of checks and balances to improve the efficiency, oversight, and governance of BSAT biosafety programs. The DoD will continue to improve and develop standardized procedures. The DoD looks forward to coordinating

with other federal agencies to develop and implement national Select Agent Program oversight guidance for high containment laboratories and the handling of dangerous pathogens.