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

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ON MEDICAL LAB SAFETY

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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 reviews, current actions and future directions to address the development and implementation of valid oversight policy and procedures for the safe handling and transfer of Biological Select Agents and Toxins (BSAT) including, *Bacillus anthracis* spores ("anthrax"), among laboratories and institutions.

The previous incomplete understanding of the science for deactivation, varying DoD protocols for the inactivation of anthrax spores, the failure of procedural checks and balances to certify the killing of all live agent, sub-standard laboratory practices and lack of oversight that allowed for the inadvertent shipments of samples containing live anthrax spores from the Dugway Proving Ground to other facilities was not acceptable. The DoD and the US Army are cooperating and coordinating with other federal agencies including with the proponents of BSAT policy, the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (of the Department of Agriculture), to jointly develop common government policies and procedures to account for the safe use and shipment of BSAT materials across all applicable institutions and specifically those under the command and control of the DoD.

I am here as the Commanding General of the US Army Medical Research and Materiel Command and in support of The Surgeon General of the Army as the DoD Executive Agent Responsible Official (EARO) for BSAT. In this role, I am responsible for harmonization of BSAT policy, technical review, and inspection guidelines across DoD. Today, I will briefly describe why we work with BSAT material, detail several of

the actions that have been taken, ongoing developments, and the plan for future validation procedures, oversight and implementation that have been in progress since May 22, 2015 when we first learned of the anthrax shipment incidents.

Why BSAT?

The public may ask "Why do the various government agencies store, study and ship BSAT materials among various institutions?'" The short answer is because bioterrorism is a serious threat to the US military, our civilian population, and to our allies. The DoD regularly ships inactivated biological materials for research, development, testing and evaluation to industry and academia (on behalf of US Government entities), and other Foreign laboratories of our allies for the development and testing of medical and physical countermeasures to biological threats such as sensors for anthrax. Biological Select Agents and Toxins are designated by the Department of Health and Human Services, CDC/Division of Select Agents and Toxins and the Department of Agriculture, Animal and Plant Health Inspection Services/Agriculture Select Agent Services. They determine which agents 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 present a severe threat to plant health or to plant products.

The DoD has eight institutions working with BSAT: US Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD; Naval Medical Research Center, Fort Detrick, MD; Edgewood Chemical and Biological Center (ECBC), Aberdeen Proving Ground, MD; Chemical, Biological and Radiological Defense Division, Naval Surface

Warfare Center, Dahlgren Division, Dahlgren, VA; Air Force 711th Human Performance Wing, Wright Patterson AFB, OH; the Life Sciences Division (LSD), West Desert Test Center (WTDC), Dugway Proving Ground (DPG), UT; and two overseas Navy laboratories: Naval Medical Research Unit (NAMRU)-3 (Cairo, Egypt) and NAMRU-6 (Lima, Peru).

Actions taken

Since the May 2015 notification from the CDC of the discovery of an inadvertent shipment of live anthrax from the LSD at DPG, the DoD has directed comprehensive reviews and inspections of the entire BSAT program. The DoD has done a critical reorganization of oversight responsibilities and implemented new policies and procedures which will be detailed in this statement. As an initial safety step, on July 23, 2015 the Deputy Secretary of Defense instituted a moratorium on BSAT processes and shipments. This action was taken to allow for a thorough investigation and review of the potential problems and to ensure safety of laboratory workers and other personnel.

Many additional steps have been taken starting with the Deputy Secretary of Defense designating the Secretary of the Army as the Executive Agent for the DoD BSAT Biosafety Program. The Director of the Army Staff conducted a full accountability of DPG, including the Chain of Command. Additionally, the Secretary of the Army directed the establishment of the Army Biosafety Task Force (BSTF) to lead the development of recommendations and implement the changes necessary to ensure the long-term safety and security of DoD BSAT programs. A summary of these two critical reviews follows.

Army Regulation 15-6 Investigation

In December 2015, the Investigating Officer for the Army Regulation (AR) 15-6 Investigation Team finalized the "AR 15-6 Investigation Report-Individual and Institutional Accountability for the Shipment of Viable *Bacillus anthracis* from Dugway Proving Ground" which concluded that "The inadvertent shipment of viable *Bacillus anthracis* is a serious breach of regulations, but did not pose a risk to public health." A copy of this report has previously been made available to the Committee.

The preponderance of evidence supports the AR 15-6 finding that no individual or institution was directly responsible for the unauthorized shipment of low concentrations of viable anthrax. Over the years, significant safeguards effectively ensured that the inadvertent shipments were not a threat. However, several findings related to scientific, institutional, and individual failures may have been contributing factors. The report included several recommendations: four specific scientific, several institutional, and the recommendation for twelve individuals to be held accountable for their failures to take action in response to mishaps, failure to execute oversight and ensure compliance with protocols and regulation, and failure to exercise care in performance of duties. For the accountability, all personnel actions as a consequence of the AR 15-6 are currently being addressed at the appropriate level of the chain of command.

I will discuss actions being taken to implement the AR 15-6 recommendations as I present information from the Biosafety Task Force and the development of the BSAT

Biosafety Program Office (BBPO) that will serve to provide continuity to future execution of oversight by the EARO.

Army BSTF

I am pleased to describe the progress of the Army BSTF and the four lines of improvement it has addressed with the completion of its work in January 2016. This Task Force reviewed the recommendations made by the DoD Review Committee and accompanying direction from the Office of the Secretary of Defense and developed implementing tasks and guidance in the form of an Army Directive to ensure the long-term safety and security of BSAT programs. The Army Directive is currently in staffing for Secretary of the Army approval. The Task Force capitalized on the best subject matter experts inside and outside the DoD to adopt science-based policies and proven management procedures for the military Services to operate in a safe and secure manner for the foreseeable future. The four working group specific lines of improvement described above are shown below:

1. Anthrax inactivation studies. This task is the development of a peer reviewed protocol for the inactivation and viability testing of anthrax that incorporates quality assurance. This recommendation was accepted by the Acting Secretary of the Army to approve the draft anthrax inactivation and viability testing Standing Operating Procedure pending the completion of scientific research being performed by ECBC. We have already started the inactivation initiative and a 90- day review will be submitted in May 2016. Emphasis is on validating inactivation and viability testing for a standardized

spore production. The results of this initiative should also answer the concerns raised in the AR 15-6 investigation concerning the potential healing process as well.

2. Understand and Manage Customer Requirements. The Army Joint Program Executive Office Critical Reagents Program has been eliminated and a new program, the Defense Biological Products Assurance Office, has been created to address DoD and non-DoD BSAT needs. Shipments of BSAT materials from the LSD at DPG have ceased. Enhanced tracking systems are being developed to ensure increased accountability and traceability of DoD BSAT material. This initiative involves two tasks, one to identify and develop a centralized Information Technology (IT) system to track and maintain records of material transfers and a second task to develop processes and implement policy to evaluate and approve/disapprove customer requirements to provide BSAT or an appropriate alternative. The first task was approved by the Acting Secretary of the Army and will provide end-to-end tracking, record keeping, and internal movements of BSAT, BSAT derived, and exempt materials. Integration of databases is under development to avoid duplication and provide leadership with visibility. The second task provides for an evaluation of the need for BSAT, BSAT derived, or BSAT exempt material by non-DoD entities, by the EARO.

3. Governance. This BSTF working group had three sub-working groups and made determinations on five important tasks. The first task was to make a recommendation as to who should serve as the Responsible Official to carry out the Army's Executive Agent (EA) responsibilities for the DoD BSAT Biosafety Program. The Secretary of the Army designated the Army Surgeon General, as the Responsible Official to act on his behalf for all EA responsibilities for the DoD BSAT Biosafety

Program. The second task was to establish a standing BSAT biosafety and review anthrax panel which would be subordinate to the lead agent and available to review scientific protocols and procedures; review waiver requests, and provide biosafety and scientific guidance to the EARO. In December 2015, the Acting Secretary of the Army accepted the recommendations of the BSTF and approved the stand-up of the BSAT Biosafety and Scientific Review Panel (BSRP). Five BSRP meetings have already taken place for waiver reviews, and a May 24-25, 2016 meeting is set to initiate the review process for organizational Standing Operating Procedures that involve BSAT. The third task was to develop a strategy to streamline DoD BSAT safety and security policy. The Acting Secretary of the Army approved the strategy to streamline BSAT safety and security policy to eliminate the Army's use of the term "biosurety", and fast track revision and consolidate AR 50-1 (*Biological Surety*). The fourth task was to develop a harmonized inspection regime that balanced oversight and inspection burden. The Acting Secretary of the Army approved the recommendation for an inspection regime conducted by a single DoD joint service inspection team under the supervision of the Department of the Army Inspector General in coordination with the EARO. The fifth and final task was developing the necessary supporting materials to assist the designated Responsible Official to execute this mission and quickly implement the necessary measures in order for the Army to begin serving effectively as the EA. Additional documents for Army Directives and a BSTF final report are in staffing at this time.

4. Organization and Distribution of Research and Production. The first task was to develop recommendations of proposed alternatives to the laboratory missions,

distribution of research, development, and production activities. The Acting Secretary of the Army approved the recommendation to forward the BSTF Research, Development and Acquisition Distribution Study to the Office of the Secretary of Defense with an endorsement that additional study is required, while acknowledging the limitations of the study and the Services' concerns. The second task, to review laboratory missions and chains of command and provide appropriate policy and organizational recommendations to ensure consistent application of biosafety and biosecurity policies across all laboratories was approved by the Secretary of the Army for the reassignment of WDTC-LSD to ECBC under the Research, Development and Engineering Command. A Memorandum of Agreement and General Order is in staffing for transfer in July 2016.

Other Reviews

The DoD Inspector General (DoDIG) also provided a report for comment with very similar findings and similar recommendations to track results, ensure regular inspections, coordinate external reviews, develop standard training, issue guidance for technical and scientific reviews, and to develop site specific security. The DoD agrees with the DoDIG's findings and recommendations and will act on those in conjunction with other recommended actions.

The Department has also received seven recommendations from the Government Accountability Office (GAO) draft report GAO-16-305, "HIGH-CONTAINMENT LABORATORIES: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety," dated January 13, 2016 (GAO Code 291264). The DoD appreciated the opportunity to review the draft report

and concurred with the recommendations of the GAO. We will ensure that the GAO's recommendations are carefully considered and appropriately captured in policy revisions and in the development of associated guidance.

Way ahead

As we look toward the future, we anticipate that within one year, the Inactivation study will be completed, the BBPO office will be at full operating capability, processes and procedures for all BSAT entities will be in review by the BSAT-BSRP, and the integrated IT solution will be implemented.

In conclusion, DoD's goal is to develop a system that incorporates the fundamentals of quality policies and systems. Establishing strong and robust processes that are continually evaluated and improved upon is our best defense against potential human accidental or management lapses. We believe the DoD systems being developed will provide for the necessary checks and balances to prevent or minimize the impacts of future accidental human and procedural missteps. Quality procedures do not stand alone as they must be incorporated along with personnel training, evaluation and encouragement followed by review, oversight, documentation and reporting in order to have a whole systematic approach to manage the successful and safe performance of BSAT personnel and institutions. Finally, it is imperative we partner with other federal and private organizations to ensure transparency of this critical program and ensure the safety of the US and confidence in the responsible execution of this critical program for the DoD.