United States Government Accountability Office

Report to Congressional Committees

September 2018

BIOLOGICAL SELECT AGENTS AND TOXINS

Actions Needed to Improve Management of DOD's Biosafety and Biosecurity Program

GAO-18-422

GAO Highlights

Highlights of GAO-18-422, a report to congressional committees

September 2018

BIOLOGICAL SELECT AGENTS AND TOXINS

Actions Needed to Improve Management of DOD's Biosafety and Biosecurity Program

Why GAO Did This Study

In May 2015, DOD discovered that one of its laboratories (formerly called the Life Sciences Division) at Dugway Proving Ground, Utah, had inadvertently made 575 shipments of live *Bacillus anthracis*—the bacterium that causes anthrax—to 194 laboratories and contractors worldwide from 2004 through 2015. A December 2015 investigation by the Army determined that there was insufficient evidence to establish a single point of failure and made recommendations for improving safety and security at DOD laboratories that handle BSAT.

The NDAA for Fiscal Year 2017 included a provision for GAO to review DOD's actions to address the Army's recommendations. GAO assessed the extent to which (1) DOD has implemented recommendations from the Army's 2015 investigation report, (2) the Army has implemented the BSAT Biosafety and Biosecurity Program and developed a strategy and implementation plan, (3) the Army's biological T&E mission is independent from its biological R&D mission, and (4) DOD has carried out a required study and evaluation. GAO reviewed DOD documents and key actions in response to the Army's recommendations and conducted site visits to DOD's BSAT laboratories.

What GAO Recommends

GAO recommends that DOD develop an approach to assess the effectiveness of the recommendations, a strategy and implementation plan for its BSAT Biosafety and Biosecurity Program, measures to ensure independence, and time frames to complete a study. DOD concurred with all four of GAO's recommendations.

View GAO-18-422. For more information, contact Joseph Kirschbaum at (202) 512-9971 or KirchbaumJ@gao.gov.

What GAO Found

The Department of Defense (DOD) has made progress by taking a number of actions to address the 35 recommendations from the Army's 2015 investigation report on the inadvertent shipments of live *Bacillus anthracis* (anthrax). However, DOD has not yet developed an approach to measure the effectiveness of these actions. As of March 2018, DOD reports 18 recommendations as having been implemented and 17 as having actions under way to implement them. These actions are part of a broader effort to improve biosafety, biosecurity, and overall program management. For example, in March 2016, DOD established the Biological Select Agents and Toxins (BSAT) Biorisk Program Office to assist in overseeing the BSAT Biosafety and Biosecurity Program and implementation of the recommendations. Measuring the effectiveness of each implemented recommendation would help better determine if the actions taken are working, if there are unintended consequences, or if further action is necessary.

The Secretary of the Army, as DOD's Executive Agent, has implemented a BSAT Biosafety and Biosecurity Program to improve management, coordination, safety, and quality assurance for the DOD BSAT enterprise. However, DOD has not developed a strategy and implementation plan for managing the program. Without a strategy and implementation plan, Dugway Proving Ground, Utah, and DOD's laboratory facilities that currently produce and handle BSAT may be unclear about DOD's strategy to harmonize BSAT operations to ensure safety, security, and standardization of procedures throughout DOD's BSAT enterprise.

The Army has not fully institutionalized measures to ensure that its biological test and evaluation (T&E) mission remains independent from its biological research and development (R&D) mission so that its T&E procedures are objective and reliable. In April 2016, the Army directed the transfer of the operational T&E mission from West Desert Test Center-Life Sciences Division at Dugway Proving Ground, Utah, to Edgewood Chemical Biological Center, Maryland. The Army issued a memorandum of agreement between the two entities to lay out roles and responsibilities for test processes and procedures. However, the memorandum does not distinguish T&E from R&D mission requirements, and does not contain guidelines to mitigate risks associated with potential conflicts of interest between the R&D and T&E missions. Without these measures, there is a potential risk to the independence of the T&E mission.

The National Defense Authorization Act (NDAA) for Fiscal Year 2017 required DOD to report by February 1, 2017, on the feasibility of consolidating BSAT facilities within a unified command, partnering with industry for the production of BSAT in lieu of maintaining such capabilities within the Army, and whether such operations should be transferred to another government or commercial laboratory. DOD has not completed this required study and evaluation of its BSAT infrastructure which, when complete, will affect the future infrastructure of the BSAT Biosafety and Biosecurity Program. Further, DOD officials have no estimated time frames for when DOD will complete the study and evaluation. Without time frames for completing the study and evaluation, DOD is unable to provide decision makers with key information on its infrastructure requirements.

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Abbreviations

ABSA	The Association for Biosafety and Biosecurity (ABSA) International
AgSAS	Agriculture Select Agent Services
APHIS	Animal and Plant Health Inspection Service
ATEC	Army Test and Evaluation Command
BBPO	BSAT Biorisk Program Office
BSAT	biological select agents and toxins
BSL	biological safety level
BSRP	BSAT Biorisk and Scientific Review Panel
CBDP	Chemical and Biological Defense Program
CDC	Centers for Disease Control and Prevention
DBPAO	Defense Biological Product Assurance Office
DOD	Department of Defense
DPG-LSD	Dugway Proving Ground-Life Sciences Division
DSAT	Division of Select Agents and Toxins
EARO	Executive Agent Responsible Official
ECBC	Edgewood Chemical Biological Center
FSAP	Federal Select Agent Program
HHS	Department of Health and Human Services
ISO	International Organization for Standardization
NDAA	National Defense Authorization Act
QMS	Quality Management System
R&D	research and development
RDECOM	Research, Development and Engineering Command
T&E	test and evaluation
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USDA	U.S. Department of Agriculture
WDTC-LSD	West Desert Test Center-Life Sciences Division
WMD	weapons of mass destruction

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

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Congressional Committees

Safety lapses involving hazardous pathogens have occurred at some of the 276 government, private, and academic laboratories in the United States that conduct research on biological select agents and toxins (BSAT). Such agents may cause serious or lethal infection in humans, animals, or plants. BSAT materials, such as the Ebola virus and *Bacillus anthracis*—the bacterium that causes anthrax—have been determined to have the potential to pose a severe threat to public health and safety. Laboratories conduct research on BSAT for a variety of reasons, including identifying their characteristics and developing vaccines and other measures to help diagnose, prevent, or treat exposure to or infection by these agents. Safety lapses involving hazardous pathogens have occurred in the past at some of the Department of Defense (DOD) laboratories that handle BSAT to conduct research on medical and physical countermeasures to protect the warfighter from biological threats. Such incidents raise concerns about whether oversight of biosafety and biosecurity in these laboratories is effective.

In May 2015, DOD discovered that one of its laboratories—formerly called the Life Sciences Division—at Dugway Proving Ground, Utah, had inadvertently shipped incompletely inactivated (i.e., live) *Bacillus anthracis* to 194 laboratories and contractors worldwide over the course of 12 years.[1] In response to this discovery, the Deputy Secretary of Defense ordered an immediate 30-day review in May 2015 that resulted in a moratorium on the production, handling, testing, and shipment of inactivated *Bacillus anthracis*. The Deputy Secretary of Defense subsequently directed a more detailed review by the Army.[2] In December 2015, the Army issued an investigation report on its findings which, among other things, determined that although the inadvertent shipment of

[1]Section 73.1 of title 42 of the Code of Federal Regulations defines validated inactivation as a procedure, whose efficacy is confirmed by data generated from a viability testing protocol, to render a select agent non-viable, but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

[2]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).

incompletely inactivated *Bacillus anthracis* was a serious breach of regulations and raised biosecurity concerns, it did not pose a public health risk. The investigation also determined that there was insufficient evidence to establish a single failure as the cause for the inadvertent shipments of incompletely inactivated *Bacillus anthracis*. However, the report cited scientific and institutional issues and said that senior management at Dugway Proving Ground had contributed to "a culture of complacency, resulting in laboratory personnel not always following rules, regulations, and procedures."[3] The Army's 2015 investigation report resulted in recommendations to the Army to improve scientific knowledge gaps on irradiation and viability testing processes, address institutional concerns to reduce the risk of future mishaps involving biological material, and address individual accountability for the failures that contributed to the inadvertent shipment of incompletely inactivated *Bacillus anthracis*.

DOD's Chemical and Biological Defense Program (CBDP) leads the department's efforts to protect military personnel, particularly the warfighter, against a wide range of threats, including biological threats. The CBDP Enterprise is comprised of 26 DOD organizations that determine warfighter requirements, provide science and technology expertise, conduct research and development and test and evaluation on capabilities needed to protect the warfighter, and provide oversight. In fiscal year 2017, according to DOD officials, CBDP received about $1.2 billion to support research, development, testing, and evaluation, and procurement efforts. For fiscal year 2018, CBDP received nearly $1.4 billion. The Army supports CBDP, and the Secretary of the Army is the Executive Agent for the BSAT Biosafety and Biosecurity Program.[4]

[3]Army, AR 15-6 Investigation Report, *Individual and Institutional Accountability for the Shipment* of *Viable Bacillus anthracis from Dugway Proving Ground* (Dec. 17, 2015). We did not evaluate the quality of this Army report describing the Army's Dugway investigation and findings.

[4]According to DOD Directive 5101.1, *DOD Executive Agent*, DOD Executive Agent designations are conferred when no existing means to accomplish department objectives exists, DOD resources need to be focused on a specific area or areas of responsibility in order to minimize duplication or redundancy, or such designation is required by law, executive order, or government-wide regulation. Further, within the scope of assigned responsibilities and functions, the authority of the DOD Executive Agent takes precedence over the authority of other DOD component officials performing related or collateral joint or multicomponent support responsibilities and functions. Department of Defense Directive 5101.1, *DOD Executive Agent* (Sept. 3, 2002) (incorporating change 1, May 9, 2003).

Since 2007, we have testified and reported on issues associated with high-containment laboratories that handle BSAT and have recommended improvements for federal oversight and enhancements to biosafety and biosecurity.[5] Our most recent testimonies and reports have addressed the effectiveness of the current federal approach to overseeing select agents and issues related to the inactivation of pathogens in high-containment laboratories.[6] For example, in our July 2015 testimony before the House Energy and Commerce Subcommittee on Oversight and Investigations, we noted that DOD had begun to track biosafety and biosecurity incidents at the senior department level, which it had not done prior to the May 2015 incident at Dugway Proving Ground in which incompletely inactivated *Bacillus anthracis* was inadvertently shipped to other laboratories and contractors worldwide.[7]

In March 2016, we issued a report that made recommendations to various federal departments and agencies with responsibility for managing BSAT in high-containment laboratories. Some of these recommendations were addressed to DOD.[8] The department concurred with the

[5]Laboratories that handle pathogens are classified into four biological safety levels (BSL) based on the risk imposed by the pathogens. Laboratories classified as BSL-1 or 2 are suitable for work involving pathogens that pose minimal to moderate hazard to laboratory personnel and the environment. High-containment laboratories—BSL-3 and 4 for the purpose of this report—are designed with additional safety measures to protect those working with dangerous pathogens that may cause serious and potentially lethal infection. Each level of containment describes the laboratory practices, safety equipment, and facility safeguards for the level of risk associated with handling particular pathogens. BSL-3 laboratories work with indigenous or exotic pathogens with known potential for airborne transmission or pathogens that may cause serious and potentially lethal infections, such as severe acute respiratory syndrome-coronavirus. BSL-4 laboratories work with exotic pathogens—such as Ebola virus—that pose a high individual risk of life-threatening disease by airborne transmission and for which treatment may not be available.

[6]See GAO, *High Containment Laboratories: Coordinated Efforts Needed to Further Strengthen Oversight of Select Agents*, GAO-18-197T (Washington, D.C.: Nov. 2, 2017); GAO, *High Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens*, GAO-18-145 (Washington, D.C.: Oct. 19, 2017); GAO, *High Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk*, GAO-16-642 (Washington, D.C.: Aug. 30, 2016); and GAO, *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety*, GAO-16-305 (Washington, D.C.: Mar. 21, 2016).

[7]GAO, *High-Containment Laboratories: Preliminary Observations on Federal Efforts to Address Weaknesses Exposed by Recent Safety Lapses*, GAO-15-792T (Washington, D.C.: July 28, 2015).

[8]GAO-16-305.

recommendations on improving oversight mechanisms of high-containment laboratories. In implementing those recommendations, DOD reported in 2016 that it was taking actions, such as revising existing department policies for managing hazardous biological agents in high-containment laboratories; analyzing inspection trends and incident reports to identify recurring issues in safety, security, or administration; requiring routine reporting results from laboratories that are not registered to handle select agents and laboratory incidents; and developing implementation time frames for the recommendations from a July 2015 DOD review of the incident at Dugway Proving Ground.

Section 218 of the National Defense Authorization Act (NDAA) for Fiscal Year 2017 included a provision for us to review DOD's actions to address findings and recommendations of the Army's December 2015 investigation report regarding the inadvertent shipment of incompletely inactivated *Bacillus anthracis* from Dugway Proving Ground, Utah. It also included a provision for us to review DOD's efforts to implement quality control and assurance measures for the department's BSAT Biosafety and Biosecurity Program, among other things.[9] This report discusses the extent to which (1) DOD has implemented the recommendations from the Army's 2015 investigation report and has developed an approach to measure the effectiveness of actions taken to address the recommendations, (2) the Army has implemented the BSAT Biosafety and Biosecurity Program and developed a strategy and implementation plan, (3) the Army has developed measures to ensure that its biological test and evaluation mission remains independent from its biological research and development mission, and (4) DOD has carried out a study and evaluation in compliance with the requirements of section 218, subsection (d), of the NDAA for Fiscal Year 2017.

For objective one, we reviewed key policy, guidance, and other documents, including the recommendations from the Army's 2015 investigation report, and assessed the actions that DOD took from May 2015 through May 2018 to address those recommendations.[10] In addition, we reviewed the *Standards for Internal Control in the Federal Government* and DOD Instruction 5010.40, *Managers' Internal Control*

[9]Pub. L. No. 114-328, § 218 (2016).

[10]We did not independently assess whether each recommendation and DOD's subsequent actions address the problems reported in the Army's 2015 investigation report.

Program Procedures, to identify criteria for communicating quality information and performing monitoring and reporting activities.[11]

For objective two, we obtained and reviewed documentation from DOD officials on current policies, procedures, and directives identifying oversight and governance authorities involved in supporting DOD's BSAT Biosafety and Biosecurity Program. We compared the actions of the Army to leading practices for strategic planning and the recommendations from the Army's 2015 investigation report.[12] We interviewed DOD officials from the military services to identify their strategies and efforts in supporting DOD's plans to effectively manage DOD's BSAT Biosafety and Biosecurity Program. We also interviewed cognizant officials to identify any biosafety and biosecurity improvements that have been made to DOD laboratories that possess, use, or transfer biological select agents and toxins made since the 2015 incident at Dugway Proving Ground. In addition, we conducted site visits to all six DOD BSAT laboratories, five of which currently are responsible for handling BSAT.[13] We also conducted voluntary facilitated group discussions with small, self-selected groups of laboratory staff at each of these facilities to obtain their views on the effect of the incident at Dugway Proving Ground on covered facilities and on DOD's subsequent corrective actions.[14]

For objective three, we reviewed and compared an Army regulation on test and evaluation to an Army general order that directed the reassignment of the West Desert Test Center – Life Sciences Division at

[11]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014), and Department of Defense Instruction 5010.40, *Managers' Internal Control Program Procedures* (May 30, 2013).

[12]For guidance and examples on leading practices for sound strategic planning, see GPRA Modernization Act of 2010, Pub. L. No. 111-352, 124 Stat. 3866-3884 (Jan. 4, 2011), *Homeland Security: Agriculture Inspection Program Has Made Some Improvements, but Management Challenges Persist*, GAO-12-885 (Washington, D.C.: Sept. 27, 2012), and *Environmental Justice: EPA Needs to Take Additional Actions to Help Ensure Effective Implementation*, GAO-12-77 (Washington, D.C.: Oct. 6, 2011).

[13]We conducted site visits to six DOD laboratories: (1) BioTesting Division, Dugway Proving Ground, Utah; (2) Edgewood Chemical Biological Center, Aberdeen Proving Ground, Maryland; (3) U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Maryland; (4) Naval Medical Research Center, Fort Detrick, Maryland; (5) Chemical, Biological, and Radiological Defense Division, Naval Surface Warfare Center-Dahlgren Division, Dahlgren, Virginia; and (6) 711th Human Performance Wing, Wright-Patterson Air Force Base, Ohio.

[14]"Covered facilities" refers to any DOD facility that produces BSAT.

Dugway Proving Ground, Utah, to the U.S. Army Materiel Command Research, Development and Engineering Command – U.S. Army Edgewood Chemical Biological Center at Aberdeen Proving Ground, Maryland.[15] We also compared that Army regulation to an Army directive that provided guidelines for the transfer of the Life Sciences Division (now known as the BioTesting Division) from Army Test and Evaluation Command to Army Research, Development and Engineering Command's Edgewood Chemical Biological Center.[16] We conducted interviews with senior staff at the BioTesting Division, the West Desert Test Center, and Edgewood Chemical Biological Center to determine what procedures are in place to ensure that the BioTesting Division's test and evaluation activities are not being influenced by Edgewood Chemical Biological Center's research and development efforts.

For objective four, we compared the relevant requirements from the NDAA for Fiscal Year 2017 contained in section 218, subsection (d), with DOD's April 2017 report to the congressional defense committees, to determine whether the report included all of the required elements.[17] Specifically, DOD is required to evaluate (1) the feasibility of consolidating covered facilities within a unified command to minimize risk, (2) opportunities to partner with industry on the production of BSAT and related services in lieu of maintaining such capabilities within the Army, and (3) whether BSAT operations should be transferred to another laboratory that may be better suited to execute production for non-DOD customers. We also reviewed our prior reports that evaluated federal oversight of high-containment laboratories and DOD's management of infrastructure within the CBDP Enterprise, and we toured all six DOD BSAT laboratory facilities to observe the current physical space—both operational and under construction—for handling and testing BSAT. More detailed information on our scope and methodology can be found in appendix I of this report.

[15]Army Regulation 73-1, *Test and Evaluation: Test and Evaluation Policy* (Nov. 16, 2016) and Army General Order 2016-04, *Transfer of the West Desert Test Center-Life Sciences Division* (Apr. 15, 2016).

[16]AR 73-1 and Army Directive 2016-24, *Department of Defense Biological Select Agent and Toxins Biosafety Program* (July 25, 2016).

[17]DOD, *Report to Congressional Defense Committees in Response to the National Defense Authorization Act for Fiscal Year 2017, Improved Biosafety for Handling of Select Agents and Toxins* (Apr. 10, 2017); and Pub. L. No. 114-328, § 218 (2016).

We conducted this performance audit from May 2017 to September 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Biodefense Roles and Responsibilities

Multiple federal departments and agencies—including DOD—have responsibilities as part of their missions to assess the threat of biological agents and carry out key biodefense roles as delineated in Homeland Security Presidential Directive 10, *Biodefense for the 21st Century, and the National Strategy for Countering Biological Threats*.[18] Since the 2001 anthrax incident, in which powdered *Bacillus anthracis* spores were deliberately put into letters that were mailed through the U.S. postal system that resulted in five deaths, the federal government has experienced growth and proliferation of research programs to protect public health and agriculture in the event of a natural emergency, man-made biological incident, or act of biological terrorism.[19] DOD laboratories that handle and research deadly pathogens are important components of the U.S. biodefense infrastructure that supports such biological research programs.

The Federal Select Agent Program

Select agent research is subject to federal oversight and regulations and is guided by the principles and practices of biosafety and biosecurity. The Federal Select Agent Program was established to regulate the possession, use, and transfer of BSAT, in response to security concerns following bioterrorism attacks in the 1990s and early 2000s. The Federal Select Agent Program is jointly managed by the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins,

[18]Homeland Security Presidential Directive 10, *Biodefense for the 21st Century* (Apr. 28, 2004); and National Security Council, *National Strategy for Countering Biological Threats* (Nov. 23, 2009).

[19]In 2001, powdered *Bacillus anthracis* spores were deliberately put into letters that were mailed through the U.S. postal system. Twenty-two people, including 12 mail handlers, contracted anthrax, and 5 of these 22 people died.

within the Department of Health and Human Services (HHS), and the Animal and Plant Health Inspection Service (APHIS), Agriculture Select Agent Services, within the Department of Agriculture (USDA).[20] These two agencies jointly regulate and oversee laboratories in the United States that are registered to work with BSAT. The Federal Select Agent Program also conducts inspections of registered entities for compliance with the select agent regulations.[21]

DOD's Designated Infrastructure Manager for CBDP, Including BSAT

CBDP was established to develop defense capabilities to protect the warfighter from current and emerging chemical and biological threats.[22] The CBDP Enterprise's mission is to enable the warfighter to deter, prevent, protect against, mitigate, respond to, and recover from chemical, biological, radiological, and nuclear threats and effects as part of a layered, integrated defense. The CBDP Enterprise conducts research and develops defenses against chemical threats—such as cyanide and mustard gases—and biological threats—such as anthrax and Ebola—and tests and evaluates capabilities and products to protect military forces from them. We reported in June 2015 on the need for DOD to designate an entity to identify, align, and manage its chemical and biological defense infrastructure, which includes its BSAT-related infrastructure.[23] We found that CBDP had not fully identified the infrastructure capabilities required to address threats, had not planned to identify potential duplication without considering information from existing federal studies, and had not updated its guidance and planning process to include specific responsibilities and time frames for risk assessments. As a result, we recommended, among other things, that DOD

[20]Part 331 of title 7 of the Code of Federal Regulations covers the Animal Plant and Health Inspection Service for plants. Part 121 of title 9 of the Code of Federal Regulations covers the Animal Plant and Health Inspection Service for animals. Part 73 of title 42 of the Code of Federal Regulations covers the Centers for Disease Control and Prevention regulations for public health.

[21]As of March 2018, 66 biological agents and toxins have been designated as "select agents and toxins" that are subject to specific types of safeguards and oversight. As of December 2016, there were 276 government, private, and academic laboratories registered with the Federal Select Agent Program to possess, use, or transfer BSAT.

[22]*See* National Defense Authorization Act for Fiscal Year 1994, Pub. L. No. 103-160, §§ 1701, 1703 (1993) (codified in relevant part at 50 U.S.C. §§ 1522, 1523).

[23]GAO, *Chemical and Biological Defense: Designated Entity Needed to Identify, Align, and Manage DOD's Infrastructure*, GAO-15-257 (Washington, D.C.: June 25, 2015).

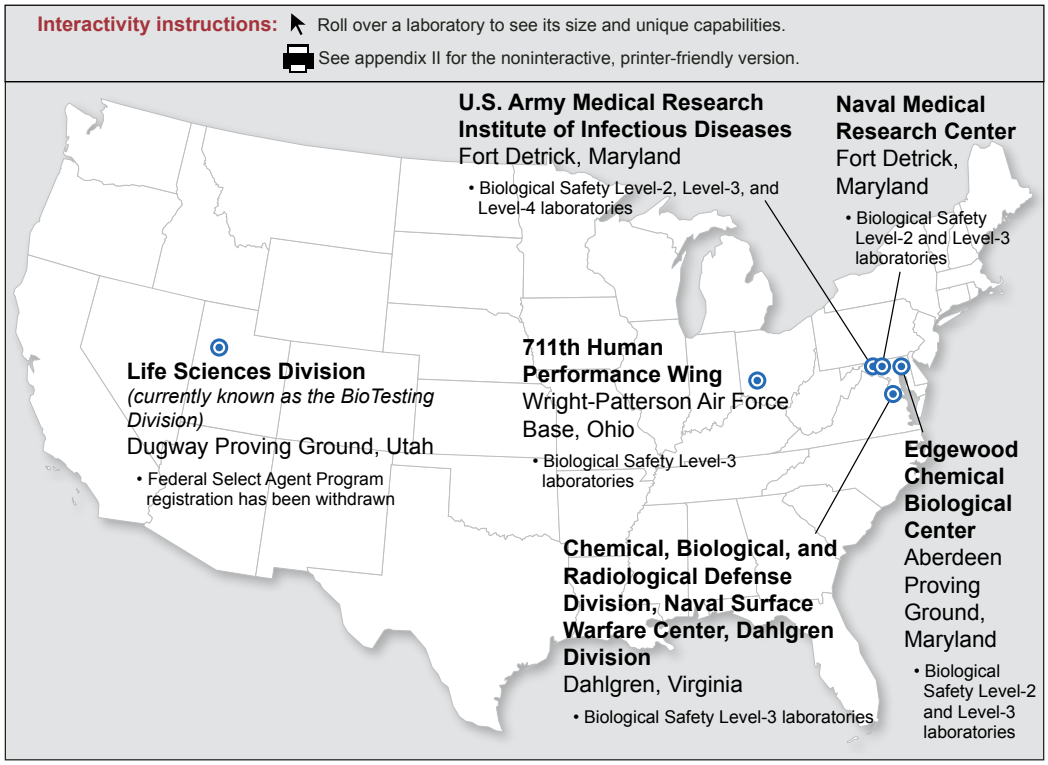
- identify and designate an entity within the CBDP Enterprise with the responsibility and authority to lead the effort to ensure achievement of infrastructure goals, and
- establish time lines and milestones for achieving the goals it has identified for chemical and biological infrastructure, including the Program Analysis and Integration Office's 2008 recommendation that the CBDP Enterprise identify its required infrastructure capabilities.

DOD concurred with all of our recommendations. In response to our recommendations, DOD, among other things, designated an infrastructure manager for CBDP and is implementing a three-phase process to identify and define the roles and responsibilities of the position by the end of 2018.[24]

As part of its BSAT infrastructure, DOD currently has five covered facilities that contain various laboratories across the military services that possess and handle BSAT. Each of these facilities currently is registered with the Federal Select Agent Program to possess BSAT in the United States. A sixth DOD facility, the BioTesting Division at Dugway Proving Ground, Utah, is working to regain its certification as a covered facility (see fig. 1).

[24]GAO, *Chemical and Biological Defense: DOD Has Identified an Infrastructure Manager and Is Developing the Position's Roles and Responsibilities*, GAO-17-522R (Washington, D.C.: July 7, 2017).

Figure 1: Size[a] and Unique Capabilities[b] of Facilities Included in the Department of Defense's Biological Select Agents and Toxins Biosafety and Biosecurity Program as of March 2018



Source: GAO analysis of Department of Defense information. | GAO-18-422

[a]Laboratory size is based upon the following: 1-4 labs or suites (small), 5-14 labs or suites (medium), and 15 or more labs or suites (large). From, Department of Defense, Office of the Under Secretary of Defense For Acquisition, Technology, and Logistics, *Report of the Defense Science Board Task Force on Department of Defense Biological Safety and Security Program*, (Washington D.C.: May 2009).

[b]Unless otherwise noted, the six laboratories confirmed or provided us with a narrative description of the unique capabilities of each laboratory.

DOD officials said that other DOD facilities, in addition to these six, are registered with the Federal Select Agent Program to handle BSAT in an emergency outbreak situation. However, according to DOD officials, they do not currently possess BSAT. CBDP officials stated that DOD used to have more facilities that possessed and handled BSAT, but as a result of prior base realignment and closure activities, the department has consolidated its BSAT laboratory capabilities within the six facilities highlighted in figure 1, based on the unique capabilities and missions performed by each facility to support the warfighter. One of these unique capabilities, for example, is the Whole System Live Agent Test Chamber located at the BioTesting Division at Dugway Proving Ground, Utah, a one-of-a-kind chamber designed and constructed primarily for biological agent aerosol testing. For more information on the unique capabilities DOD has identified for each of the DOD laboratories that handle BSAT, scroll over figure 1 to see an interactive display of information on each facility or see appendix II for static images of this information.

BSAT Policies and Guidance

DOD and the military services have issued a number of policies and guidance aimed at ensuring safety and security for BSAT materials and establishing standards for the handling of BSAT within DOD facilities. In particular, DOD issued Instruction 5210.88, *Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT)*, which established security standards for safeguarding BSAT materials and identified roles and responsibilities for BSAT biosecurity. These include oversight responsibilities for the BSAT security program, which is led by the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs.[25] Oversight responsibilities include establishing security standards for safeguarding BSAT, coordinating with the Federal Select Agent Program, and establishing and maintaining a database of all BSAT at DOD covered facilities.

In response to DOD Instruction 5210.88, each of the military services has received waivers or issued separate policies for securing BSAT materials. The Army has been granted a waiver to its existing policies that are inconsistent with DOD Instruction 5210.88 and, according to Army officials, is in the process of updating its policies to align with the DOD instruction. According to Navy officials, the Navy has been granted

[25]Department of Defense Instruction 5210.88, *Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT)* (Jan. 19, 2016) (incorporating change 1, Oct. 6, 2017).

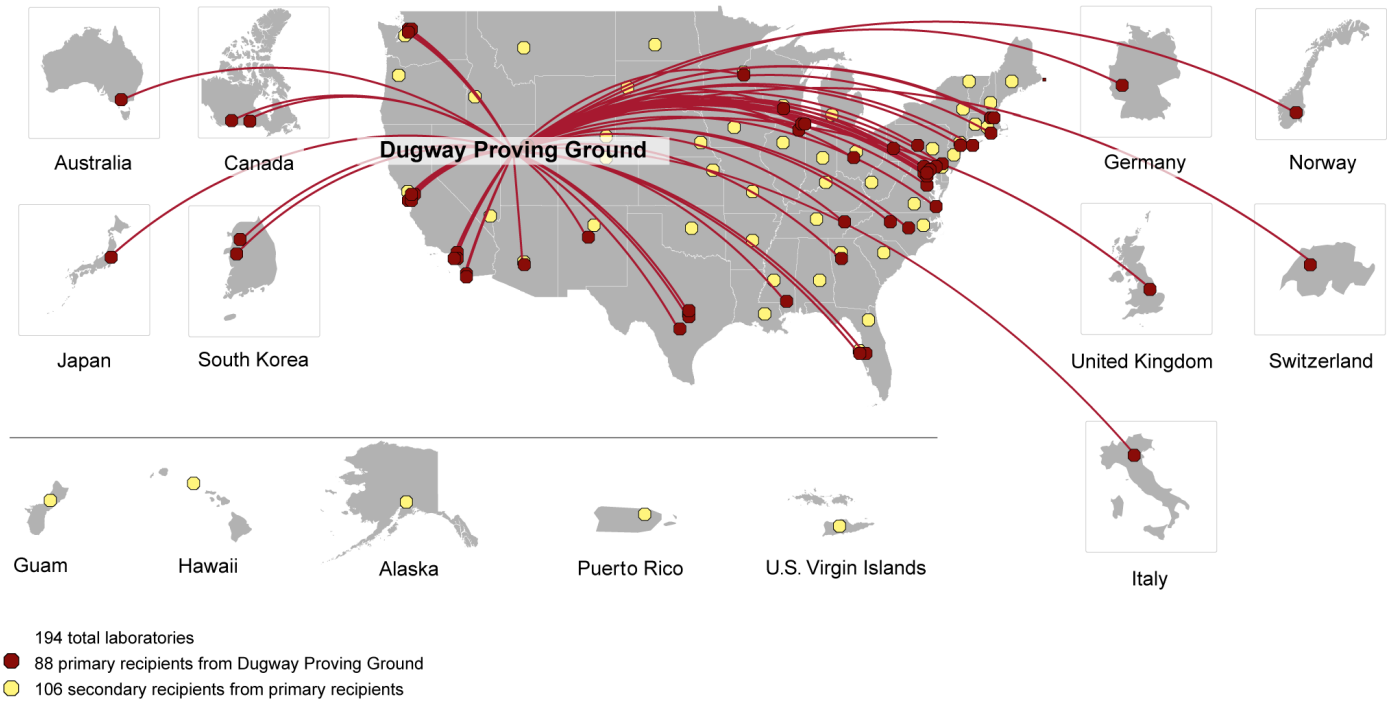
waivers while it is updating existing policies that do not currently align with DOD Instruction 5210.88. The Air Force has issued policies directing alignment with the DOD instruction. Further, a national strategy and a number of executive orders and presidential directives have been issued addressing a range of concerns, such as biological defense and safety and security for handling BSAT.[26] For example, in 2010 the President issued an executive order directing federal agencies to harmonize their policies and guidance on BSAT to align them with the select agent regulations in order to mitigate any conflicting direction and promote research and innovation.

The Army's Investigation into the May 2015 Dugway Incident

In May 2015, DOD discovered that the Life Sciences Division—currently known as the BioTesting Division—at Dugway Proving Ground, Utah, had inadvertently made 575 shipments from 2004 through 2015 of incompletely inactivated *Bacillus anthracis*—the bacterium that causes anthrax—to 194 laboratories and contractors worldwide (see fig. 2 for locations).

[26] *See* National Security Council, *National Strategy for Countering Biological Threats* (Nov. 23, 2009); Exec. Order No. 13486, *Strengthening Laboratory Biosecurity in the United States*, 74 Fed. Reg. 2289 (Jan. 9, 2009); Exec. Order No. 13546, *Optimizing the Security of Biological Select Agents and Toxins in the United States*, 75 Fed. Reg. 39437 (July 2, 2010); Homeland Security Presidential Directive 10, *Biodefense for the 21st Century* (Apr. 28, 2004); and Presidential Policy Directive 2, *Implementation of the "National Strategy for Countering Biological Threats"* (Dec. 2, 2009).

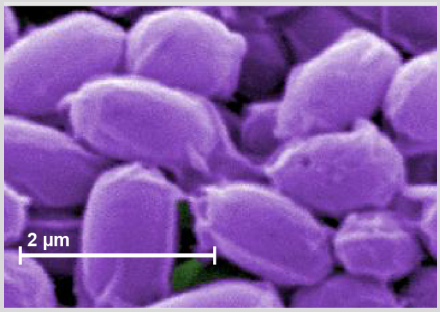
Figure 2: Sites around the World that Received Viable Bacillus anthracis (Anthrax) Samples from Dugway Proving Ground That Were Incompletely Inactivated (i.e., Live), from 2004-2015



Source: GAO analysis of information from the Department of Defense and Centers for Disease Control and Prevention. | GAO-18-422

Overview of Anthrax

The photograph shows enlarged *Bacillus anthracis* spores under a microscope.



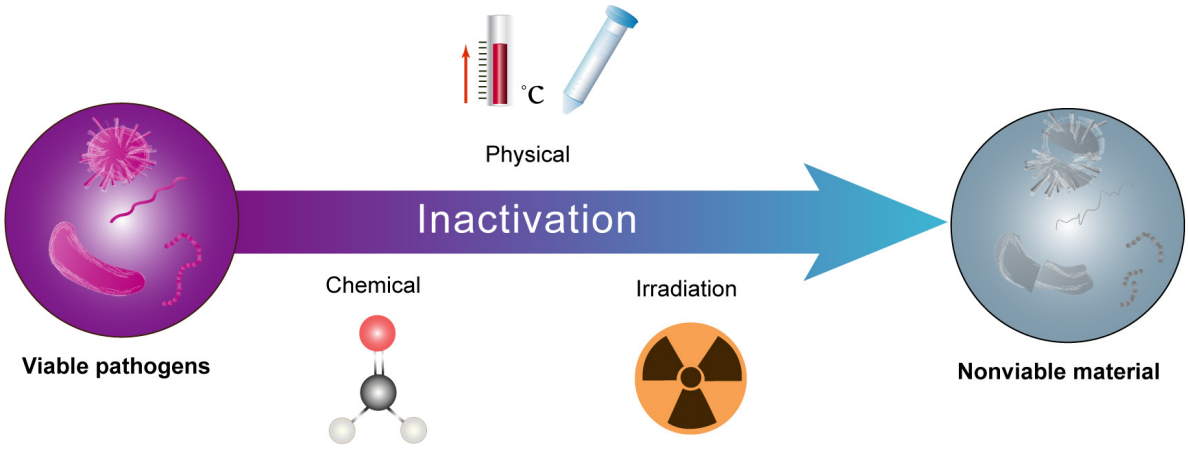
Anthrax is a serious infectious disease caused by the pathogen known as *Bacillus anthracis*. This pathogen occurs naturally in soil and commonly affects domestic and wild animals around the world. It can survive in the environment for decades. Contact with *Bacillus anthracis* can cause severe illness in both humans and animals. The bacteria can multiply, spread out in the body, produce toxins (poisons), and cause severe illness. Humans can be infected by breathing in spores, eating food or drinking water that is contaminated with spores, or getting spores in a cut or scrape in the skin. It is very uncommon for people in the United States to become sick with anthrax.

Because *Bacillus anthracis* is both infectious and exceptionally resilient, it is ideally suited for potential adversaries' biological weapons programs. Therefore, Department of Defense (DOD) biodefense officials believe that it is critical for the department to have a strong countermeasures program to protect the warfighter against this dangerous pathogen.

Source: GAO analysis of information from DOD and the Centers for Disease Control and Prevention. Photo: Courtesy of Centers for Disease Control and Prevention (Laura Rose). | GAO-18-422

Laboratory officials at Dugway Proving Ground believed that the samples of *Bacillus anthracis* (see sidebar) they were shipping had been inactivated—that the hazardous effects of the pathogen had been destroyed, while the pathogen retained characteristics of interest for research purposes. DOD was inactivating samples to support research on the detection, identification, and characterization of biological threats (see fig. 3).

Figure 3: Methods to Inactivate Pathogens



Source: GAO. | GAO-18-422

Note: Researchers use various methods to inactivate pathogens, which they select depending on the type of pathogen to be inactivated and the intended use of the inactivated material. The frequency with which inactivation is performed in high-containment laboratories varies significantly. Some researchers conduct inactivation on a daily or weekly basis and others only a few times each year. Pathogens can be inactivated using physical, irradiation, and chemical methods. Each of these methods has advantages and disadvantages. (See GAO-16-642 for a full description of selected inactivation methods used in high-containment laboratories.)

In the wake of the May 2015 incident at Dugway Proving Ground, the Army took a number of actions to safeguard personnel and BSAT materials and investigate the cause of the inadvertent shipments of incompletely inactivated *Bacillus anthracis* from Dugway Proving Ground. For example, in September 2015, the Secretary of the Army directed reviews at all Army laboratories working with *Bacillus anthracis* and other deadly pathogens and expanded the Deputy Secretary of Defense's moratorium relating to *Bacillus anthracis*. Specifically, the expanded moratorium temporarily prohibited certain facilities that were involved in the inactivation of *Bacillus anthracis* from producing, handling, testing, and shipping BSAT, except as required for inactivation and viability testing.

In August 2015, the Army established a Biosafety Task Force to lead efforts to identify changes necessary to ensure the biosafety and biosecurity of BSAT, in response to direction from the Deputy Secretary of Defense. The Biosafety Task Force operated from August 2015 through December 2015 and consisted of four working groups and associated sub-working groups that were charged with studying (1) the inactivation of *Bacillus anthracis*, (2) end-user requirements for BSAT

materials, (3) the chain of command for DOD's BSAT Biosafety Program, and (4) the organization and distribution of research and production of BSAT. In December 2015, the Army completed its investigation into the incident at Dugway Proving Ground and issued a report that made 39 recommendations, including recommendations for adverse personnel actions.[27] In July 2017, the Deputy Secretary of Defense approved the rescission of the moratorium on the production, handling, testing, and shipment of inactivated *Bacillus anthracis*. Subsequently, in August 2017, the Army lifted the moratorium on inactivated *Bacillus anthracis* and directed DOD covered facilities to act in compliance with Federal Select Agent Program policy on inactivation of *Bacillus anthracis*.

DOD Continues to Implement Recommendations from the Army's 2015 Investigation Report but Has Not Developed an Approach for Assessing the Effectiveness of Its Actions

DOD Is Making Progress Addressing the Recommendations from the Army's 2015 Investigation Report

As of March 2018, DOD reported having implemented 18 of 35 recommendations in the Army's 2015 investigation report. DOD reported that it has actions under way to implement the remaining 17 recommendations. The Secretary of the Army, as Executive Agent for DOD's BSAT Biosafety and Biosecurity Program, is responsible for implementing the recommendations from the 2015 investigation report. Since 2015, the Army has taken multiple types of actions—including

[27]For the purposes of this report, we addressed the implementation status of 35 of the 39 recommendations contained in the Army's 2015 investigation report. We did not report on the 4 recommendations in the Army's 2015 investigation report that pertain to individual accountability. The status information on the recommendations was conducted by DOD officials at GAO's request.

operational, administrative, and personnel actions—to implement the recommendations from the report.

We asked DOD to characterize the relative priority of the recommendations and describe those actions that have been taken or are under way. DOD reported that

- 12 recommendations were considered “high” priority, 7 of these being assessed as implemented and 5 as in progress,
- 18 recommendations were considered “moderate” priority, 10 of these being assessed as implemented and 8 as in progress, and
- 5 recommendations were considered “low” priority, 1 being assessed as implemented and 4 as in progress.

Appendix III shows the implementation status of the 35 recommendations from the Army’s 2015 investigation report that we reviewed.

Rather than focus exclusively on the recommendations from the Army’s 2015 investigation report, the BSAT Biorisk Program Office (BBPO) incorporated actions to implement the 2015 recommendations into broader Army efforts to improve biosafety, biosecurity, and overall program management. Appendix IV describes BBPO’s roles and responsibilities. For example, Army Directive 2016-24, *Department of Defense Biological Select Agent and Toxins Biosafety Program*, incorporates some of the recommendations from the Army’s 2015 investigation report, such as establishing a mentorship program for laboratory staff and others who work with BSAT, as well as directing studies into the science of inactivation of *Bacillus anthracis*. In addition, the Army has developed implementation guidance to carry out Army Directive 2016-24, which provides clarification on the directive and on the reporting requirements to the BBPO and Executive Agent Responsible Official (hereafter referred to as the EARO) in support of the NDAA for Fiscal Year 2017.

BBPO officials told us that recommendations from the Army’s 2015 investigation report that are not incorporated in the directive have been or are being addressed through a combination of establishing working groups and, at one time, through a General Officers Steering Committee. This committee monitored implementation through updates to the EARO and the Director of the Army Staff. For example, BBPO officials told us that, from 2016 to 2017, quarterly meetings between the General Officers Steering Committee and the Director of the Army Staff were used to

discuss the status of requirements in Army Directive 2016-24. These quarterly meetings also provided status updates on target completion dates for the Army's 2015 investigation report recommendations that were incorporated in the directive. We found that the quarterly information briefs included information on the status and time frames for implementing recommendations that were incorporated into the Army directive.

BBPO Has Not Yet Developed an Approach to Measure the Effectiveness of Actions Taken to Address Recommendations

In carrying out broader biosafety efforts and implementing recommendations from the Army's 2015 investigation report as well as recommendations from other entities, BBPO has established processes to track the status of actions that it has taken and monitor time lines for completion by responsible DOD organizations. This helps BBPO understand what actions have been taken and where they fit into a larger plan to improve biosafety at specific facilities and organizations and across the DOD BSAT enterprise.

According to *Standards for Internal Control in the Federal Government*, an internal control provides reasonable assurance that the objectives of an entity will be achieved, including the use of ongoing monitoring, evaluations, or a combination of the two to obtain reasonable assurance of the operating effectiveness of the entity's internal controls over the assigned process.[28] It also states that managers should identify, analyze, and respond to risks. Such evaluations and risk assessments are necessary to help officials understand whether the actions they have taken—or will take—address the situations that prompted the original recommendations.

We found that BBPO's approach to planning for and executing actions to implement the 2015 Army recommendations and other recommendations fulfills the monitoring element of the internal control standards. BBPO has not, however, systematically carried out the evaluation element. Based on our review of DOD documentation, such as the quarterly information briefs on status of recommendations, and on subsequent interviews with BBPO officials, we found that BBPO has not developed an approach to assess the effectiveness of each implemented recommendation in achieving its intended purpose. According to DOD officials, BBPO has been focused on implementing not only the recommendations from the

[28]GAO-14-704G.

2015 Army investigation report but also its broader efforts for the DOD BSAT Biosafety and Biosecurity Program and has not yet formalized an approach to evaluating the effectiveness of actions taken to address the recommendations from the 2015 Army investigation report.

There are many ways to assess effectiveness that could assist BBPO in improving its implementation processes. One approach we found related to DOD's implementation of recommendations for the defense nuclear enterprise provides an example that may be useful. In 2017, we reported on DOD's process to monitor progress and identify risks while implementing recommendations within the defense nuclear enterprise—a community that, like chemical and biological defense, operates in a low-probability, high-risk environment.[29] In that report, we noted that DOD's Office of Cost Assessment and Program Evaluation had developed a tracking tool that applied a systematic approach for stating the underlying problem, identifying and overseeing offices of responsibility, implementation actions, milestones, and metrics to measure the effectiveness of the actions taken toward implementing each of the recommendations to support the defense nuclear enterprise. We also found that identifying risks can help an agency to track and measure the completion of tasks over time. This example incorporates both the monitoring and evaluation elements of internal control that we discussed earlier. Measuring the effectiveness of each implemented recommendation would help bolster BBPO's existing efforts. It would also help BBPO to better determine whether the actions taken are working, whether there are unintended consequences, or if further action is necessary.

[29]GAO, *Defense Nuclear Enterprise: Processes to Monitor Progress on Implementing Recommendations and Managing Risks Could be Improved*, GAO-18-144 (Washington, D.C.: Oct. 5, 2017).

The Army Has Implemented a BSAT Biosafety and Biosecurity Program but Does Not Have a Completed Strategy and Implementation Plan

The BSAT Biosafety and Biosecurity Program Is a Broad Effort to Improve Management, Coordination, Safety, and Quality Assurance

In response to the 2015 incident at Dugway Proving Ground and various subsequent DOD and external reviews of management, operational, coordination, safety, and quality assurance incidents between 2004 and 2015, DOD has initiated a broad range of efforts to address these types of incidents and to improve DOD's BSAT enterprise. The designation of the Army as the DOD Executive Agent for the DOD Biosafety and Biosecurity Program is one example of DOD's efforts to improve management. Prior to 2015, there was no centralized oversight authority for DOD's BSAT enterprise. The Secretary of the Army's designation as the Executive Agent and subsequent delegation of this authority to The Army Surgeon General has, according to BBPO and laboratory officials, resulted in improved coordination and communication across DOD and with the Federal Select Agent Program. According to these same officials, BBPO also has contributed to improved communication between DOD laboratories by establishing working groups and is developing a process for approving standard operating procedures for working with BSAT across the CBDP Enterprise.

DOD has made key safety improvements by taking a number of actions to address the incident at Dugway Proving Ground and the recommendations from the Army's 2015 investigation report. These key safety improvements include (1) establishing a DOD Executive Agent and a support office to provide oversight, (2) implementing improved quality control and assurance standards at its covered facilities, (3) developing a new quality management system, (4) conducting additional scientific studies on BSAT inactivation, and (5) taking multiple actions to address requirements associated with Army Directive 2016-24 and the Army's 2015 investigation report. Appendix V provides detailed information on the key safety improvements DOD has completed in response to the

incident at Dugway Proving Ground and the recommendations from the Army's investigation report.

According to BBPO officials, in addition to implementing improved quality control and assurance standards at covered facilities, they also have established a quality control and assurance working group to address and track implementation of the recommendations in accordance with the Army's Implementation Guidance for Army Directive 2016-24 and to implement the quality control and assurance measures from section 218 of the NDAA for Fiscal Year 2017. Further, the EARO has established a BSAT Biorisk and Scientific Review Panel to review and assess biosafety and biosecurity concerns associated with new and existing procedures conducted at DOD BSAT laboratories and to provide recommendations to the EARO on their acceptability for use to enhance biosafety and biosecurity across the DOD BSAT programs.[30]

To provide additional insights into DOD's actions to make safety improvements and to better understand the effects of those actions on laboratory staff and operations following the 2015 incident at Dugway Proving Ground, we conducted facilitated discussions with a non-generalizable sample of supervisory and non-supervisory staff at the six DOD laboratories that handled BSAT. We used these facilitated discussions to obtain the views of those laboratory staff who have and will be implementing key biosafety and biosecurity actions from multiple sources. Appendix VI presents selected comments, organized by key themes, from laboratory staff at DOD facilities that handle BSAT in response to actions taken by DOD following the 2015 incident at Dugway Proving Ground. We heard a broad range of views on the effects of the Dugway incidents as well as the effects of subsequent actions to improve the BSAT Biosafety and Biosecurity Program. For example, some individuals were concerned about the effect of administrative requirements on the efficiency of their work, while others believed that the organizational changes made by the Army have improved communication and coordination. We did not validate any of the views expressed to us, but they may be of value to BBPO and officials throughout the BSAT enterprise in considering both how their program efforts are perceived and how best to carry them out.

[30]Department of the Army, Office of the Surgeon General Memorandum, *Charter Document for Biological Select Agents and Toxins Biorisk and Scientific Review Panel* (Aug. 17, 2017).

BBPO Has Not Completed a Strategy and Implementation Plan to Assist the Program in the Long Term

BBPO has begun to develop a draft concept plan to establish roles and responsibilities for the BSAT Biosafety and Biosecurity Program. However, we found that BBPO has not developed a strategy or implementation plan for the long term. BBPO's draft concept plan identified manpower and funding requirements for the BSAT Biorisk Program Office but did not go further in laying out a strategy and implementation plan. According to BBPO officials, BBPO currently is relying on DOD Instruction 5210.88 as overarching guidance for managing BSAT biosecurity operations and bringing DOD into compliance with Executive Order 13546, *Optimizing the Security of Biological Select Agents and Toxins in the United States*, and select agent regulations.[31] BBPO also relies on DOD Manual 6055.18-M for managing DOD BSAT biosafety operations.[32] In addition, DOD is in the process of drafting an overarching directive for the combined DOD BSAT Biosafety and Biosecurity Program that will be based on DOD Instruction 5210.88 and DOD Manual 6055.18-M. According to BBPO officials, BBPO plans to develop a multi-service policy to consolidate biosafety and biosecurity initiatives for combined biorisk management and replace Army Directive 2016-24 once the Army has fully implemented its directive. While efforts to develop the draft concept plan and overarching guidance are important, BBPO has not identified long-term goals, objectives, external factors that can affect goals, use of metrics to gauge progress, an evaluation plan for monitoring goals and objectives, and an overall time frame for completion of a strategy and implementation plan.

According to Office of Management and Budget Circular (OMB) A-11, in addition to fulfilling the requirements of the GPRA Modernization Act of 2010, strategic planning serves a number of important management functions related to achieving an agency's mission.[33] For example, strategic planning is a valuable tool for communicating a vision for the

[31]DOD Instruction 5210.88; Exec. Order No.13546, *Optimizing the Security of Biological Select Agents and Toxins in the United States*, 75 Fed. Reg. 39437 (July 2, 2010).

[32]Department of Defense Manual 6055.18-M, *Safety Standards for Microbiological and Biomedical Laboratories* (May 11, 2010).

[33]OMB, Circular No. A-11, *Preparation, Submission, and Execution of the Budget* (Washington, D.C., Executive Office of the President, July 2017).We previously have found that requirements under the Government Performance and Results Act for strategic planning can also serve as leading practices for strategic planning at lower levels within federal agencies, such as planning for individual programs. See Pub. L. No. 111-352, 124 Stat. 3866-3884 (2011), GAO-12-885 and GAO-12-77.

future and should include goals and objectives that align with resources and guide decision making to accomplish priorities and improve outcomes. An overall strategy would also help to prioritize funding; accomplish priorities to improve outcomes; and coordinate biosafety and biosecurity protocols, practices, and procedures to achieve harmonization across the military services and the DOD BSAT enterprise. To accomplish these things, a strategy and implementation plan can include such things as long-term goals, objectives, external factors that can affect goals, use of metrics to gauge progress, and a time frame for completion.

BBPO officials acknowledged that they need a strategy and implementation plan for the BSAT Biosafety and Biosecurity Program. They said that once they complete the concept plan, they will develop a strategy that will include specific goals and tasks to support programmatic efforts. They explained that they have not been able to develop a strategy and implementation plan because BBPO still is organizing the office and carrying out its other responsibilities while working toward obtaining stakeholder support for the program.

As DOD completes a concept plan for the program and turns its attention to a strategy and implementation plan for the program over the long term, BBPO has an opportunity to incorporate the following key elements typically found in such strategies and implementation plans and specified in OMB guidance: long-term goals, objectives, external factors that can affect goals, use of metrics to gauge progress, evaluation of the plan to monitor goals and objectives, and an overall time frame for completion of the strategy and implementation plan. Without a strategy and implementation plan, Dugway Proving Ground and DOD's currently covered facilities may not be able to determine how to inform DOD's long-term planning efforts. In addition, components of the DOD BSAT enterprise may remain unclear about the department's strategy to harmonize BSAT operations to ensure safety, security, and standardization of procedures throughout DOD's BSAT enterprise. A strategy and implementation plan could also help ensure unity of command among the military services to employ department-wide policies and procedures for managing the biosafety and biosecurity of BSAT. They also could help DOD to identify the capabilities necessary to support laboratory improvements, mitigate biological mishaps similar to the 2015 incident at Dugway Proving Ground, and allocate resources that support the BSAT enterprise.

The Army Has Not Fully Institutionalized Measures to Ensure the Independence of Edgewood Chemical Biological Center's Test and Evaluation Mission

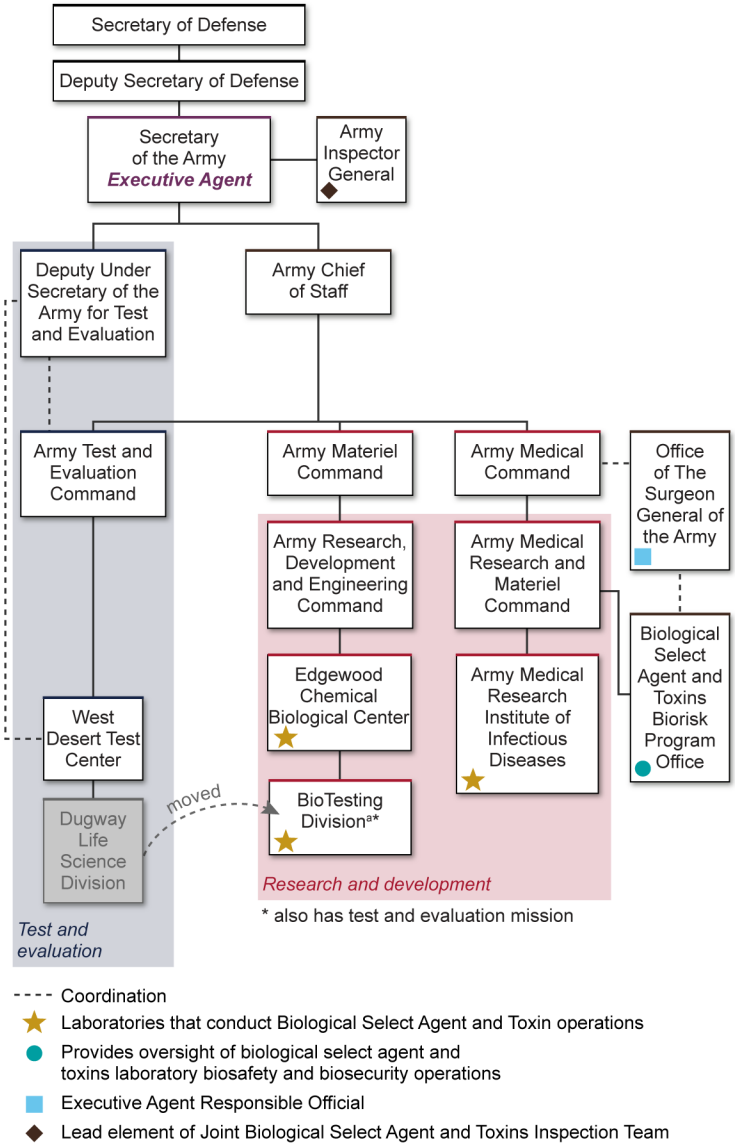
The Army has not fully institutionalized measures to ensure that its biological test and evaluation mission remains independent from its biological research and development mission at Edgewood Chemical Biological Center. This is important for preventing undue influence of test and evaluation procedures on research and development procedures, and vice versa. In April 2016, the Army issued General Order 2016-04 in response to a recommendation from the Army's Biosafety Task Force, which directed the transfer of the West Desert Test Center – Life Sciences Division at Dugway Proving Ground, Utah, and its reassignment to the U.S. Army Materiel Command-Research, Development and Engineering Command – U.S. Army Edgewood Chemical Biological Center at Aberdeen Proving Ground, Maryland.[34] This transfer took place in July 2016, and the former Life Sciences Division was subsequently renamed the BioTesting Division. Edgewood Chemical Biological Center's traditional mission primarily is focused on research and development, while the West Desert Test Center's traditional mission is focused on test and evaluation.

DOD subsequently reported to the congressional defense committees on April 10, 2017, that it had realigned the BioTesting Division in order to place it under staff with more experience in handling BSAT.[35] According to the CBDP's 2017 Annual Report to Congress, the realignment of the BioTesting Division will enable tracking, reporting, and meeting of audit requirements within an approved framework for managing governance, risks, and compliance. Figure 4 illustrates the transfer of command and control of the BioTesting Division.

[34]AGO 2016-04.

[35]DOD, *Report to Congressional Defense Committees in Response to the National Defense Authorization Act for Fiscal Year 2017, Improved Biosafety for Handling of Select Agents and Toxins* (Apr. 10, 2017). The physical and intellectual infrastructure of the BioTesting Division will remain at Dugway Proving Ground, Utah.

Figure 4: Transfer of Command and Control of the BioTesting Division from the West Desert Test Center to Edgewood Chemical Biological Center as of March 2018



Source: GAO analysis of Department of Defense (DOD) information. | GAO-18-422

[a]The BioTesting Division mission command was transferred and reassigned to Edgewood Chemical Biological Center.

Officials at Edgewood Chemical Biological Center identified a number of steps they have taken and plan to take to address concerns related to potential conflict of interest, including the following:

- In June 2016, the Army Test and Evaluation Command and Army Research, Development and Engineering Command signed a memorandum of agreement addressing reassignment of the BioTesting Division that lays out roles and responsibilities for test processes and procedures between the two entities.[36] The memorandum also notes that the Research, Development and Engineering Command will develop a mitigation strategy for conflicts of interest when Edgewood Chemical Biological Center is the developer and the BioTesting Division is the tester.
- In November 2017, Edgewood Chemical Biological Center elevated the BioTesting Division from a branch to a division to raise its visibility and alleviate concerns about independence between the test and evaluation functions and the research and development functions of Edgewood Chemical Biological Center.

However, as of March 2018, the Army has not institutionalized measures, such as policies, standard operating procedures, protocols, and roles and responsibilities to ensure independence between the biological research and development mission and the test and evaluation mission. Specifically, the Army has not provided any measures beyond the memorandum of agreement that acknowledged the potential for conflict of interest, such as the conditions under which one or more officials—even without intent—exercises undue influence of test and evaluation mission procedures on research and development procedures. The Army also recognizes the need for a mitigation strategy—to ensure independence between the biological research and development function and the test and evaluation function that takes the transfer of command and control into account. The memorandum of agreement does not contain, for example, criteria that distinguish the mission requirements for operational test and evaluation for the BioTesting Division from the mission requirements for research and development, and risk management guidelines to mitigate risks associated with potential conflicts of interest between the Edgewood Chemical Biological Center research and

[36]*Memorandum of Agreement Between the U.S. Army Test and Evaluation Command (ATEC) and the U.S. Army Research, Development and Engineering Command (RDECOM) regarding Reassignment of West Desert Test Center – Life Sciences Division (WDTC-LSD) from ATEC to RDECOM* (June 23, 2016).

development mission and the BioTesting Division's test and evaluation mission.

Army officials explained that a mitigation strategy has not been developed—and that there is no time frame for developing such a strategy—because there is no testing of BSAT materials under way at the BioTesting Division, since its BSAT registration has been withdrawn. According to Army officials, this condition could last for at least 1 to 2 years. While a mitigation strategy to prevent potential conflict of interest is envisioned by the memorandum of agreement, Edgewood Chemical Biological Center officials currently are focused on re-registering the BioTesting Division with the Federal Select Agent Program and bringing it back up to full operational capability. A senior official at Edgewood Chemical Biological Center acknowledged that the risk to independence between Edgewood Chemical Biological Center and the BioTesting Division is an issue that remains unresolved and there are currently no measures in place to prevent potential conflict of interest.

According to Army Regulation 73-1, *Test and Evaluation: Test and Evaluation Policy*, independence is important to ensure that the decision maker is provided with, for example, unbiased, objective advice about the status of the development of a system.[37] In addition, as we have reported, independence between research and development functions and test and evaluation functions is key to the effectiveness of operational test and evaluation.[38] We have reported long-standing conflicts between the research and development mission and the test and evaluation mission when there is a lack of independence, including (1) how many and what types of tests to conduct; (2) when testing should occur; (3) what data to collect, how to collect it, and how best to analyze it; and (4) what conclusions are supportable given the analysis and the limitations of the test program.[39]

One example where the Army considered a potential conflict of interest was between the Army Test and Evaluation Command's chemical test and evaluation mission and Edgewood Chemical Biological Center's chemical research and development mission. Specifically, Army Directive

[37]AR 73-1.

[38]GAO, *Test and Evaluation: Impact of DOD's Office of the Director of Operational Test and Evaluation,* GAO/NSIAD-98-22 (Washington, D.C., Oct. 24, 1997).

[39]GAO/NSIAD-98-22.

2016-24 directed the Army Test and Evaluation Command to conduct a separate evaluation to determine whether to transfer the "remaining elements," that is, the chemical mission, from West Desert Test Center to Edgewood Chemical Biological Center. Officials from the Army Test and Evaluation Command stated that after developing alternative courses of action, they decided—in contrast to their decision on the biological mission—to keep the chemical mission under the Army Test and Evaluation Command rather than transferring it to the Edgewood Chemical Biological Center. According to officials at the Army Test and Evaluation Command, the transfer of operational command and control of their chemical mission could create an independence issue by placing the chemical test and evaluation function within the same command as the research and development function.[40] The chemical mission represents a major operational command and control element of the Army Test and Evaluation Command.

Without measures in place to preserve independence—such as criteria that establish mission requirements for operational test and evaluation for the BioTesting Division or risk management guidelines—there is a potential risk to the independence of the testing and evaluation mission conducted by the BioTesting Division. For example, the BioTesting Division might be compelled to prioritize the testing of Edgewood Chemical Biological Center products over those of other DOD and non-DOD customers. Officials in the Army Test and Evaluation Command stated that the transfer of the biological test and evaluation mission may increase the complexity of the evaluation mission by requiring additional coordination. Furthermore, the BioTesting Division's procedures on particular efforts could be influenced, resulting in test and evaluation that may not be objective or reliable. Without developing measures to prevent conflicts of interest, the Army will not have reasonable assurance of the independence of the BioTesting Division's test and evaluation mission.

[40]Army Test and Evaluation Command traditionally has been responsible for planning, integrating, and conducting experiments, developmental testing, independent operational testing, and independent evaluations and assessments using chemical and biological materials, among other things, to provide essential information to acquisition decision makers and commanders.

DOD Has Not Completed the Study and Evaluation Required by the NDAA for Fiscal Year 2017 to Determine Specific Infrastructure Needs for the BSAT Program

DOD has not completed its BSAT infrastructure study to determine its infrastructure needs, as required by the NDAA for Fiscal Year 2017. DOD was to report to the congressional defense committees by February 1, 2017, among other things, on the results of its study to evaluate (1) the feasibility of consolidating covered facilities within a unified command to minimize risk, (2) opportunities to partner with industry for the production of BSAT and related services in lieu of maintaining such capabilities within the Army, and (3) whether operations under the BSAT production program should be transferred to another government or commercial laboratory that might be better suited to produce BSAT for non-DOD customers. Moreover, *Standards for Internal Control in the Federal Government* provides specific guidance to federal agencies on how to communicate clearly defined objectives that are to be achieved—including time frames for completing those objectives—and to inform decision makers in a timely manner.[41]

DOD provided a report to the congressional defense committees on April 10, 2017, stating that the department is still identifying its BSAT infrastructure requirements.[42] However, as of March 2018, CBDP officials acknowledged that these study efforts are still ongoing and that there are no estimated time frames for completing any of them. DOD officials stated that they are focusing on identifying enterprise-wide infrastructure for CBDP, of which BSAT infrastructure is just one part. Officials explained that they have prioritized their efforts to first address the recommendations from our 2015 report, which included calling for DOD to designate an entity to take responsibility for CBDP Enterprise infrastructure.[43] CBDP officials stated that when they established the infrastructure manager position, they decided to study CBDP Enterprise infrastructure from a “clean slate” and leverage lessons learned from previous studies. According to DOD officials, this information will be used to identify any capability gaps, right-size the CBDP Enterprise infrastructure, and support DOD’s final report to Congress regarding BSAT infrastructure.

[41]GAO-14-704G.

[42]DOD, *Report to Congressional Defense Committees in Response to National Defense Authorization Act for Fiscal Year 2017*, April 10, 2017.

[43]GAO-15-257.

Regarding DOD's first required task—to study the feasibility of consolidating covered facilities within a unified command to minimize risk—DOD officials stated that study efforts are ongoing and highlighted initial consolidation actions the department has taken. Specifically, DOD officials stated that (1) DOD had established the Secretary of the Army as Executive Agent to further consolidate command oversight of DOD's BSAT Biosafety and Biosecurity Program and (2) the Army had transferred the command and control of the BioTesting Division from the Army Test and Evaluation Command to Edgewood Chemical Biological Center, as previously discussed.

Regarding DOD's second required task, DOD officials stated that the Army and DOD have not yet begun any specific studies on opportunities to partner with industry to produce BSAT and related services as an alternative to maintaining these capabilities within the Army. CBDP officials stated that they continually look for opportunities to partner with industry on production. CBDP officials told us that they plan to determine if there are opportunities to partner with industry after the CBDP Enterprise-wide study effort is completed. In the meantime, officials highlighted that the Army's Defense Biological Product Assurance Office within the Joint Program Executive Office for Chemical and Biological Defense—formerly known as the Critical Reagents Program—has taken action to study its office's BSAT-related commercial product line, which has resulted in the office divesting itself of inactivated BSAT materials.[44]

Regarding the third required task, the NDAA for Fiscal Year 2017 required DOD to study whether BSAT production operations should be transferred to another government or commercial laboratory that might be better suited to produce BSAT for non-DOD customers. DOD reported that it has taken steps to support a future decision on this issue and, according to DOD officials, once it has completed the CBDP Enterprise-wide study of infrastructure capabilities and capacity, it will determine whether the BSAT community needs to transfer any part of its production to another entity. With regard to the production of BSAT for non-DOD customers, Army officials stated that when the BioTesting Division at Dugway Proving Ground becomes fully operational and re-registers with the Federal Select Agent Program in fiscal year 2019, it will no longer be

[44]The Critical Reagents Program was established in 1998 and its mission included serving as the principal resource for biological reference materials, reagents, and assays to meet the needs of DOD and its partners. In 2016, the Critical Reagents Program was replaced with the Defense Biological Product Assurance Office.

producing and shipping BSAT to non-DOD customers. The Army took steps to address the issue prior to the NDAA for Fiscal Year 2017. Specifically, in August 2015, the Army established a Biosafety Task Force working group that examined, among other things, DOD's covered facilities and options for locations for producing BSAT. Subsequently, in February 2016, the Army recommended that additional analysis be conducted before any decision is made to change the current BSAT laboratory infrastructure. Appendix VII shows what DOD has reported and completed in response to the requirements in the NDAA for Fiscal Year 2017.

The NDAA for Fiscal Year 2017 is not the first time that DOD has been directed to review its BSAT infrastructure. Biosafety, biosecurity, and biodefense issues have been long-standing concerns for the nation. We found that the federal government—including DOD—has spent over a decade studying biosafety and biosecurity issues, including BSAT infrastructure. DOD has contributed to and is continuing to support a number of federal efforts regarding size, safety, security, and oversight of high-containment laboratories across the United States, including the efforts of the Federal Experts Security Advisory Panel and Fast Track Action Committee to examine the size and scope of laboratories working with BSAT across the United States. Appendix VIII describes and provides a summary of selected federal panels, task forces, and working groups that have examined biosafety, biosecurity and biodefense issues since 2004. (Our prior reports related to these matters are included in Related GAO Products at the end of this report.)

According to CBDP officials, once CBDP gathers information on the capacity and needs of its enterprise-wide infrastructure and determines where there are capability gaps, it anticipates providing a report to the congressional defense committees. These officials said that the report will provide information on whether DOD should consolidate or transfer infrastructure and opportunities to partner with industry on BSAT. The EARO has periodically met with congressional authorizers, according to BBPO officials, to provide programmatic updates on the DOD BSAT Biosafety and Biosecurity Program. However, CBDP officials stated that they have not provided an update to the congressional defense committees on the results of the study efforts since they issued their preliminary report on April 10, 2017. In addition, CBDP officials told us that they do not have an estimated time frame for when they will be able to provide the final report on the results of the study of BSAT infrastructure. DOD has reported that its mandated study efforts on BSAT-related infrastructure still are ongoing because DOD is focused first

on identifying CBDP Enterprise-wide infrastructure and has no estimated time frames for completing the mandated study. Unless DOD establishes time frames for finalizing its study, decision makers will not have reasonable assurance that DOD is taking the necessary steps in a timely manner to provide the required BSAT infrastructure CBDP needs to support the warfighter.

Conclusions

The inadvertent shipments of incompletely inactivated *Bacillus anthracis* from Dugway Proving Ground, according to the Army's 2015 investigation report, constituted serious breaches of regulations and raised biosafety and biosecurity concerns. Since then, DOD has taken steps to improve biosafety and biosecurity and made significant progress in addressing the recommendations from the Army's investigation report. The department currently has an opportunity to take several additional management actions that, if implemented fully, will help it capitalize on the progress that it has made. Addressing the gap in assessing how effectively the recommendations and actions taken address the original condition and contributing factors they were intended to resolve would bolster the Army's long-term efforts. The Army could incorporate such an approach into its existing processes to monitor the implementation of recommendations from the Army's 2015 investigation report.

The Army clearly has a concept in mind for the BSAT Biosafety and Biosecurity Program. However, that concept does not constitute a strategy and implementation plan that identifies specific long-term goals, objectives, external factors that can affect goals, and tasks to support programmatic efforts through the use of metrics to gauge progress; milestones; an evaluation of the plan; and an overall time frame for completion. Without a strategy and implementation plan, the Army may not be able to harmonize BSAT operations to ensure safety, security, and standardization of procedures throughout DOD's BSAT enterprise.

The Army recognizes that the transfer of operational command and control of the BioTesting Division from West Desert Test Center at Dugway Proving Ground, Utah, to Edgewood Chemical Biological Center at Aberdeen Proving Ground, Maryland, could result in unintended consequences, such as a potential risk to the independence of the testing and evaluation mission. However, although Army officials said they intend to develop a strategy to mitigate this risk, there is no time frame for doing so, because there is no testing under way at the BioTesting Division and there will be none for at least 1 to 2 years. This hiatus in testing should not preclude Army efforts to develop a mitigation strategy. Without

measures in place to prevent or mitigate a risk to independence, the transfer of operational command and control could ultimately compromise the quality of future technologies used by the warfighter.

Finally, DOD is focusing on identifying the enterprise-wide infrastructure necessary for CBDP. However, it has not yet determined time frames for completion of the study required by the NDAA for Fiscal Year 2017 related to consolidation of command, transfer of BSAT production responsibilities, and opportunities to partner with industry for the production of BSAT. Without time frames for reporting on the final results of this study, DOD is unable to provide decision makers with key information needed to determine infrastructure requirements for the BSAT program and contribute to federal-level efforts to determine the appropriate number of high-containment laboratories in the United States.

Recommendations for Executive Action

We are making the following four recommendations to the Department of Defense:

The Secretary of the Army should ensure that The Surgeon General of the Army, as the EARO for DOD's BSAT Biosafety and Biosecurity Program, incorporates into existing processes an approach for assessing how effectively the recommendations from the Army's 2015 investigation report address the original condition and contributing factors that they were intended to resolve. (Recommendation 1)

The Secretary of the Army should ensure that The Surgeon General of the Army, as the EARO for DOD's BSAT Biosafety and Biosecurity Program, develops a strategy and implementation plan for the DOD BSAT Biosafety and Biosecurity Program that includes long-term goals, objectives, external factors that can affect goals, use of metrics to gauge progress, an evaluation plan for monitoring goals and objectives, and a time frame for completion. (Recommendation 2)

The Secretary of the Army should ensure that the Commander of Army Materiel Command establishes measures to prevent the potential risk to independence posed by transferring operational command and control of the BioTesting Division from West Desert Test Center to the Edgewood Chemical Biological Center. Such measures could include, for example, criteria that establish mission requirements for operational test and evaluation for the BioTesting Division, in accordance with DOD and Army regulations, and risk management guidelines to mitigate risks associated with potential conflicts of interest between the Edgewood Chemical

Biological Center research and development mission and the BioTesting Division's test and evaluation mission. (Recommendation 3)

The Secretary of Defense should ensure that the Deputy Assistant Secretary of Defense for Chemical and Biological Defense establishes time frames to complete the study and its evaluations required by the NDAA for Fiscal Year 2017, Section 218(d), regarding the feasibility of consolidating covered facilities within a unified command, opportunities to partner with other industry for the production of BSAT, and transfer of BSAT production responsibilities. (Recommendation 4)

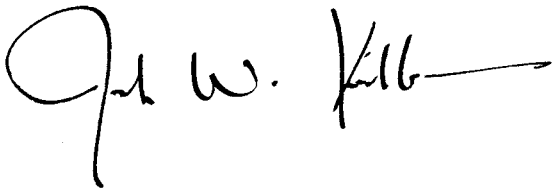
Agency Comments and Our Evaluation

In written comments on a draft of this report, DOD concurred with all four of our recommendations, discussed actions it is taking and plans to take to implement them, and provided target dates for completing implementation of these actions. The full text of DOD's written comments are reprinted in appendix IX. DOD also provided us with several technical comments, which we incorporated in the report, as appropriate. We believe these actions, if fully implemented, will address our recommendations.

USDA and HHS did not provide formal agency comments on a draft of this report, but provided us with a technical comment, which we incorporated in the report, as appropriate.

We are sending copies of this report to the congressional defense committees as well as other appropriate congressional committees; the Secretaries of Defense, Agriculture, and Health and Human Services; the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs; the Deputy Assistant Secretary of Defense for Chemical and Biological Defense; the Department of Defense Inspector General; the Secretaries of the Army, the Air Force, and the Navy and the Commandant of the Marine Corps; the Directors, Centers for Disease Control and Prevention and Animal and Plant Health Inspection Service; and other cognizant officials, as appropriate. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions concerning this report, please contact Joseph Kirschbaum at (202) 512-9971 or KirschbaumJ@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix X.



Joseph W. Kirschbaum
Director, Defense Capabilities and Management

List of Committees

The Honorable James M. Inhofe
Chairman
The Honorable Jack Reed
Ranking Member
Committee on Armed Services
United States Senate

The Honorable Richard Shelby
Chairman
The Honorable Richard Durbin
Ranking Member
Subcommittee on Defense
Committee on Appropriations
United States Senate

The Honorable Mac Thornberry
Chairman
The Honorable Adam Smith
Ranking Member
Committee on Armed Services
House of Representatives

The Honorable Kay Granger
Chairwoman
The Honorable Peter J. Visclosky
Ranking Member
Subcommittee on Defense
Committee on Appropriations
House of Representatives

Appendix I: Objectives, Scope, and Methodology

The National Defense Authorization Act (NDAA) for Fiscal Year 2017 included a provision for us to report on the Department of Defense's (DOD) actions to address findings and recommendations of the Army's December 2015 investigation report (hereafter, the Army's 2015 investigation report) regarding the inadvertent shipment of incompletely inactivated *Bacillus anthracis* from Dugway Proving Ground, Utah.[1] It also included a provision for us to report on DOD's efforts to implement quality control and assurance measures for the department's Biological Select Agents and Toxins (BSAT) Biosafety and Biosecurity Program, among other things.[2] This report discusses the extent to which (1) DOD has implemented the recommendations from the Army's 2015 investigation report and has developed an approach to measure the effectiveness of actions taken to address the recommendations, (2) the Army has implemented the BSAT Biosafety and Biosecurity Program and developed a strategy and implementation plan, (3) the Army has developed measures to ensure that its biological test and evaluation mission remains independent under its biological research and development mission, and (4) DOD has carried out a study and evaluation in compliance with the requirements contained in section 218, subsection (d), of the NDAA for Fiscal Year 2017.

To determine how DOD has implemented the recommendations from the Army's 2015 investigation report and has developed an approach to measure the effectiveness of actions taken to address the recommendations, we reviewed the Army's 2015 investigation report recommendations and assessed the subsequent actions that DOD had taken to address those recommendations. To determine whether specific recommendations have been addressed, we analyzed guidance that DOD and the Army issued to instruct department and military service activities on roles and responsibilities and implementation efforts to support DOD's BSAT Biosafety and Biosecurity Program, such as DOD Instruction 5210.88, *Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT)*; Army Directive 2016-24, *Department of Defense Biological Select Agent and Toxins Biosafety Program*; and

[1]Army, AR 15-6 Investigation Report, *Individual and Institutional Accountability for the Shipment of Viable Bacillus anthracis from Dugway Proving Ground* (Dec. 17, 2015).

[2]Pub. L. No. 114-328 § 218 (2016).

Implementation Guidance for Army Directive 2016-24.[3] We also analyzed supporting documentation from DOD officials to demonstrate how those specific recommendations were addressed.[4]

As of March 2018, DOD had designated a priority level and had updated the completion status of its implementation for each of the 35 of 39 recommendations from the Army's 2015 investigation report that we reviewed. This update and priority level designation was conducted at our request. We also asked that DOD provide us with milestones and risk assessments associated with the implementation of the recommendations from the Army's investigation report. However, DOD was unable to provide this information. (We did not review the 4 recommendations in the investigation report that pertain to individual accountability.) We interviewed cognizant DOD and military service officials to obtain their perspectives on efforts to address the recommendations in response to the 2015 incident at Dugway Proving Ground. In addition, we reviewed *Standards for Internal Control in the Federal Government* and DOD Instruction 5010.40, *Managers' Internal Control Program Procedures* to identify criteria for communicating quality information and performing monitoring and reporting activities.[5]

To determine the extent to which the Army has implemented the BSAT Biosafety and Biosecurity Program and developed a strategy and implementation plan, we obtained documentation from DOD officials on current policies, procedures, and directives identifying oversight and governance authorities involved in supporting DOD's BSAT Biosafety and Biosecurity Program. Also, we obtained examples of working groups responsible for developing quality control and assurance guidance and standard operating procedures for working with BSAT in DOD

[3]Department of Defense Instruction 5210.88, *Security Standards for Safeguarding Biological Select Agents and Toxins* (BSAT) (Jan. 19, 2016) (incorporating change 1, Oct. 6, 2017); Army Directive 2016-24, *Department of Defense Biological Select Agent and Toxins Biosafety Program* (Jul. 25, 2016); and Department of the Army, Office of The Surgeon General Memorandum, *Implementation Guidance for Army Directive 2016-24* (Sep. 16, 2017).

[4]GAO did not independently assess whether each recommendation and DOD's subsequent actions addressed the problems reported in the Army's 2015 investigation report.

[5]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014), and Department of Defense Instruction 5010.40, *Managers' Internal Control Program Procedures* (May 30, 2013).

laboratories and across the Chemical and Biological Defense Program (CBPD) Enterprise. In addition, we compared the actions of the BSAT Biorisk Program Office (BBPO), such as developing the draft *Department of Defense Biological Select Agents and Toxins Biorisk Program Office Concept Plan*, to leading practices for sound management identified in the GPRA Modernization Act of 2010, and the Army's 2015 investigation report recommendations.[6] Further, we interviewed DOD officials from the military services to determine their strategies and efforts in supporting DOD's plans to effectively manage DOD's BSAT Biosafety and Biosecurity Program. We also interviewed cognizant officials to determine any biosafety and biosecurity improvements made since the 2015 incident at Dugway Proving Ground.

We toured all six DOD BSAT laboratory facilities, five of which currently are responsible for handling BSAT, to observe the current physical space—both operational and under construction—for handling and testing BSAT. These site visits were conducted at the (1) BioTesting Division, Dugway Proving Ground, Utah; (2) Edgewood Chemical Biological Center, Aberdeen Proving Ground, Maryland; (3) U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Maryland; (4) Naval Medical Research Center, Fort Detrick, Maryland; (5) Chemical, Biological, and Radiological Defense Division, Naval Surface Warfare Center – Dahlgren Division, Dahlgren, Virginia; and (6) 711th Human Performance Wing, Wright – Patterson Air Force Base, Ohio.

We also conducted facilitated discussions between September 2017 and November 2017 with groups of laboratory non-supervisory staff at each of the six DOD BSAT laboratories—five of which currently are responsible for handling BSAT—to obtain their views of the effects of the 2015 discovery at Dugway Proving Ground and the subsequent investigation and management actions to respond to identified problems. Generally, discussion groups are designed to obtain in-depth testimonial information about participants' views, opinions, and/or experiences on specific issues, which cannot be easily obtained from single interviews. In preparation for each discussion group, we asked the leadership at each of the six DOD laboratories to distribute our e-mail inviting all laboratory staff to participate in an on-site discussion group. These small groups consisted of self-selected volunteers, and were not random samples of research

[6]BSAT Biorisk Program Office, *Department of Defense Biological Select Agents and Toxins Biorisk Program Office Concept Plan* (draft). Pub. L. No. 111-352, 124 Stat. 3866-3884 (Jan. 4, 2011).

staff at each of these laboratories. The number of non-supervisory laboratory staff participants in each group ranged from 3 to 17 and totaled 44 participants.

A GAO team member facilitated each discussion group, using a structured discussion guide with open-ended questions. The team did not record the discussions. Instead, multiple GAO team members took notes of the discussion, without ascribing comments to specific individuals.

We later summarized the information collected for each discussion group and identified recurring themes. We did not design these discussion groups to provide results that were generalizable to the whole research staff at each laboratory. Laboratory staff who did not participate in these discussion groups may have different opinions and observations from those who participated in our discussion groups. Moreover, while we designed our discussion method to encourage participants to offer whatever comments they wished, we cannot assume that participants mentioned all of the effects that may have influenced their laboratory activities since 2015.

We also reviewed our prior work on the management of hazardous biological agents in high-containment laboratories at federal departments and agencies, including DOD. A list of related GAO products on high-containment laboratories is included in the Related GAO Products pages at the end of this report.

To examine the extent to which DOD has developed measures to ensure that the BioTesting Division's test and evaluation mission remains independent from the research and development mission that resides at Edgewood Chemical Biological Center, we reviewed and compared Army Regulation 73-1 on testing and evaluation to Army General Order 2016-04, which first directed the transfer of the Life Sciences Division—later renamed the BioTesting Division—from the Army Test and Evaluation Command to Edgewood Chemical Biological Center.[7] We also compared AR 73-1 to Army Directive 2016-24, *Department of Defense Biological Select Agent and Toxins Biosafety Program*, which provided

[7]Army Regulation 73-1, *Test and Evaluation: Test and Evaluation Policy* (Nov. 16, 2016), and Army General Order 2016-04, *Transfer of the West Desert Test Center-Life Sciences Division* (Apr. 15, 2016).

additional guidelines for this transfer.[8] We also reviewed the memorandum of agreement between the Army Test and Evaluation Command and the Army Research, Development and Engineering Command to assess plans, roles, and responsibilities for transfer and reassignment of the BioTesting Division from the West Desert Test Center to the Edgewood Chemical Biological Center.[9] We also conducted interviews with senior staff at the BioTesting Division, the West Desert Test Center, and the Edgewood Chemical Biological Center to determine what procedures are in place to ensure that the BioTesting Division's test and evaluation activities are not being influenced by the Edgewood Chemical Biological Center's research and development efforts.

To examine the extent to which DOD has carried out a study and evaluation in compliance with the requirements contained in section 218, subsection (d), of the NDAA for Fiscal Year 2017, we compared the relevant requirements from the NDAA for Fiscal Year 2017 with DOD's April 10, 2017, report to the congressional defense committees to determine whether the report included all of the required elements concerning consolidation, transfer, and opportunities to partner with industry on the production of BSAT.[10] We also obtained—through interviews with agency and written responses—the status of DOD's efforts to address NDAA for Fiscal Year 2017 concerning infrastructure requirements for the BSAT program and enterprise-wide infrastructure for CBDP. We reviewed the *Standards for Internal Control in the Federal Government* to identify criteria providing guidance to federal agencies to communicate clearly defined objectives that are to be achieved, including time frames for completing those objectives and informing decision makers.[11]

[8]AR 73-1 and Army Directive 2016-24, *Department of Defense Biological Select Agent and Toxins Biosafety Program* (July 25, 2016).

[9]*Memorandum of Agreement Between the U.S. Army Test and Evaluation Command (ATEC) and the U.S. Army Research, Development and Engineering Command (RDECOM) regarding Reassignment of West Desert Test Center* – Life *Sciences Division (WDTC-LSD) from ATEC to RDECOM* (June 23, 2016).

[10]Department of Defense, *Report to Congressional Defense Committees in Response to the National Defense Authorization Act for Fiscal Year 2017, Improved Biosafety for Handling of Select Agents and Toxins* (Apr. 10, 2017); and Pub. L. No. 114-328, § 218 (2016).

[11]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014).

Information used in our analysis primarily covers the period from May 2015 through July 2018 and the information is the most recent available. We included budget information from fiscal year 2016 to fiscal year 2018. To conduct our work, we obtained documentation and interviewed cognizant officials from DOD organizations, offices, and military commands responsible for funding, managing, and overseeing the production, handling, testing, and shipment of BSAT; the Departments of Health and Human Services (HHS) and Agriculture (USDA) agencies that manage the Federal Select Agent Program, which jointly regulate and oversee covered entities in the United States that are registered to possess, use, and transfer BSAT; and all six DOD BSAT laboratories, five of which currently are responsible for handling BSAT. See below for a complete list of organizations and agencies.

Department of Defense

- Office of the Under Secretary of Defense for Acquisition and Sustainment
  - Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs
    - Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense
      - Chemical and Biological Defense Program
- Office of the Inspector General
- Military services
  - Department of the Army
    - Office of the Assistant Secretary of the Army for Acquisition, Logistics and Technology
      - Joint Program Executive Office for Chemical and Biological Defense, Aberdeen Proving Ground, Maryland
        - Defense Biological Product Assurance Office, Ft. Detrick, Maryland
    - U.S. Army Materiel Command, Redstone Arsenal, Alabama
      - U.S. Army Research, Development and Engineering Command, Aberdeen Proving Ground, Maryland
        - U.S. Army Edgewood Chemical Biological Center, Aberdeen Proving Ground, Maryland

            - U.S. Army Edgewood Chemical Biological Center, BioTesting Division, Dugway Proving Ground, Utah
    - U.S. Army Test and Evaluation Command, Aberdeen Proving Ground, Maryland
        - U.S. Army Test and Evaluation Command, West Desert Test Center, Dugway Proving Ground, Utah
    - U.S. Army Medical Command, San Antonio, Texas
        - U.S. Army Medical Research and Materiel Command, Ft. Detrick, Maryland
            - Executive Agent Responsible Official, Ft. Detrick, Maryland
            - Biological Select Agents and Toxins Biorisk Program Office, Ft. Detrick, Maryland
            - U.S. Army Medical Research Institute of Infectious Diseases, Ft. Detrick, Maryland
    - Department of the Army Office of the Inspector General
- Department of the Navy
    - U.S. Navy Bureau of Medicine and Surgery, Falls Church, Virginia
        - Naval Medical Research Center, U.S. Army Forest Glen Annex, Silver Spring, Maryland
        - Naval Medical Research Center, Ft. Detrick, Maryland
    - Naval Sea Systems Command, Washington, DC
        - Naval Surface Warfare Center – Dahlgren Division, Dahlgren, Virginia
- Department of the Air Force
    - Office of Strategic Deterrence and Nuclear Integration
        - 711th Human Performance Wing, Wright – Patterson Air Force Base, Ohio

Department of Agriculture

- Animal and Plant Health Inspection Service, Riverdale, Maryland

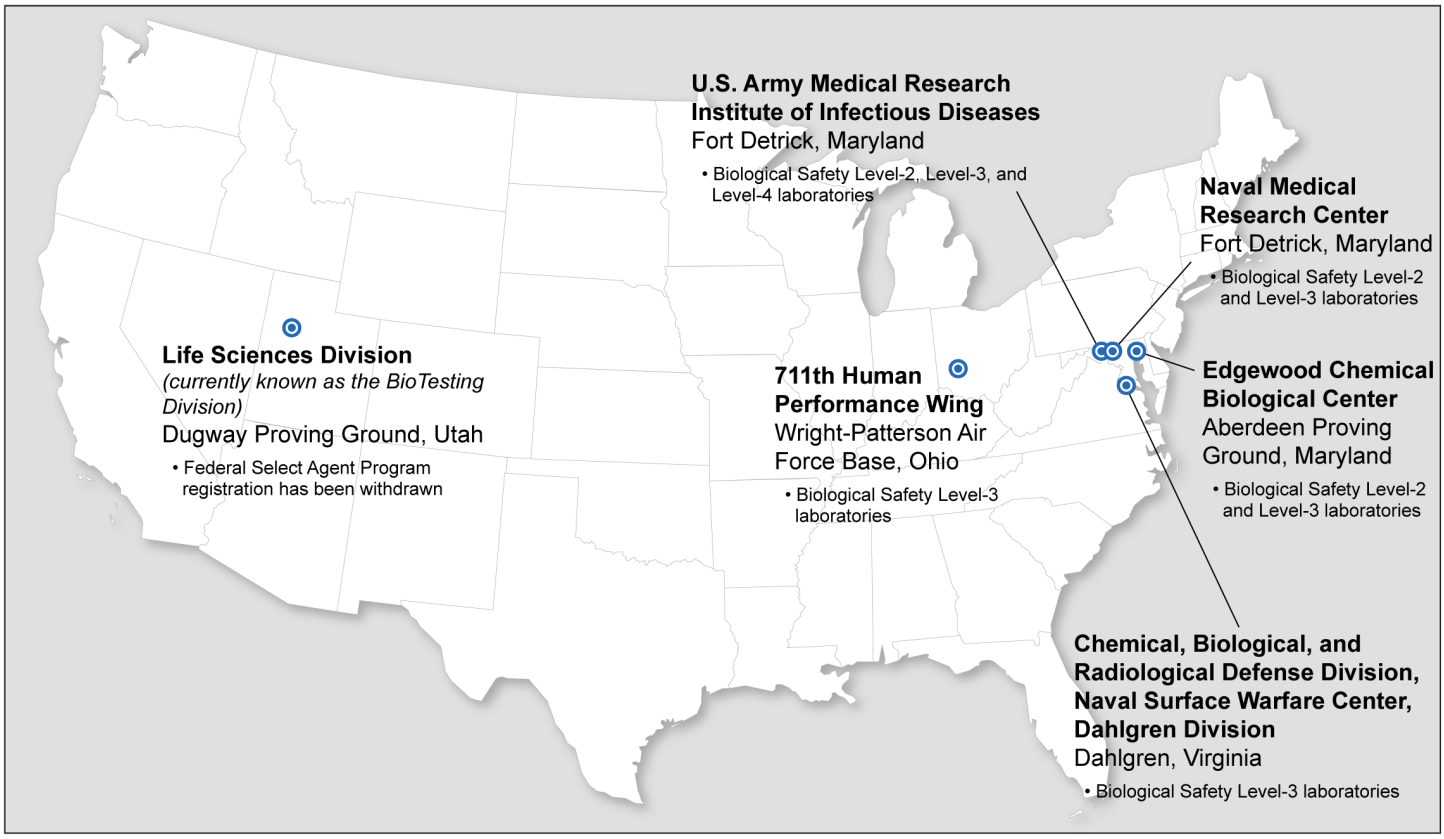
Department of Health and Human Services

- Centers for Disease Control and Prevention, Atlanta, Georgia

We conducted this performance audit from May 2017 to September 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Static Images and Information for Map of Department of Defense Biological Select Agents and Toxins Laboratories

Figure 5: Facilities Included in the Department of Defense's Biological Select Agents and Toxins Biosafety and Biosecurity Program as of March 2018



Source: GAO analysis of Department of Defense information. | GAO-18-422

Table 1: Unique Capabilities of Department of Defense Laboratories That Handle Biological Selected Agents and Toxins as of March 2018

Department of Defense (DOD) Biological Select Agents and Toxins (BSAT) Laboratories	Size of Laboratory[a]	Unique Capabilities[b]
Army		
Edgewood Chemical Biological Center (ECBC), Aberdeen Proving Ground, Maryland	Medium	ECBC fosters research, development, testing, and application of technologies for protecting warfighters, first responders, and the nation from chemical and biological warfare agents. ECBC currently is developing better ways to remotely detect these chemical and biological materials and technologies to counter everything from homemade explosives to biological aerosols to traditional and non-traditional chemical hazards.
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland	Large	USAMRIID's mission is to provide leading edge medical capabilities to deter and defend against current and emerging biological threat agents. USAMRIID has the largest BSAT program within DOD and is committed to protecting U.S. Armed Forces from biological threats worldwide by conducting a range of efforts in the research and development of medical countermeasures and other technologies to prevent or mitigate the health effects of biological agents and emerging diseases.
Life Sciences Division (currently known as the BioTesting Division), Dugway Proving Ground, Utah	Medium	ECBC BioTesting Division, Dugway Proving Ground's primary mission is to support the Chemical Biological Defense Program through test and evaluation of biological systems, methodologies, and any associated need that requires biological capabilities. ECBC Dugway possesses the Whole System Live Agent Test Chamber, a high capacity, one-of-a-kind biological agent aerosol containment chamber designed and constructed primarily for biological warfare agent aerosol-detection system testing.
Navy		
Chemical, Biological, Radiological Defense Division, Naval Surface Warfare Center – Dahlgren Division (NSWCDD), Dahlgren, Virginia	Small	The Chemical, Biological, Radiological Defense Division at NSWCDD provides full-spectrum life cycle support for chemical, biological, and radiological detection, protection, decontamination, and modeling and simulation systems. This mission includes shipboard, fixed-site, and expeditionary chemical, biological, and radiological defense applications. NSWCDD maintains the only Navy Biological Safety Level-3 laboratory devoted to non-medical chemical, biological, and radiological defense applications, and is a leader in chemical and biological decontamination research, centering on the decontamination of *Bacillus anthracis*.
Naval Medical Research Center, Fort Detrick, Maryland	Medium	The Biological Defense Research Directorate at the Naval Medical Research Center serves as a national resource providing testing and analysis for the presence of potential biological hazards. The researchers are considered leaders in the field of detection, including hand-held assays, molecular diagnostics, and confirmatory analysis.
Air Force		
711th Human Performance Wing, Wright – Patterson Air Force Base, Ohio	Small	The 711th Human Performance Wing conducts research on technologies for the rapid detection of chemical, biological, and radiological events; hyperbaric medical research; and light, durable intensive care capabilities for aeromedical evacuation. It also has the nation's only Radiological Assessment Teams available for 24/7 deployment.

Source: GAO analysis of DOD information. | GAO-18-422

[a]Laboratory size is based upon the following: 1-4 laboratories or suites (small), 5-14 laboratories or suites (medium), and 15 or more laboratories or suites (large). See Department of Defense, Office of the Under Secretary of Defense For Acquisition, Technology, and Logistics, Report of the Defense Science Board Task Force on Department of Defense Biological Safety and Security Program, (Washington D.C.: May 2009).

[b]Unless otherwise noted, each of the six laboratories confirmed or provided us with a narrative description of its unique capabilities.

Figure 6: Laboratory Personnel Conducting Biological Defense Research in the Biological Safety Level-3 Laboratory at Edgewood Chemical Biological Center, Aberdeen Proving Ground, Maryland

Source: Edgewood Chemical Biological Center, Aberdeen Proving Ground, Maryland (provided March 27, 2018). | GAO-18-422

Note: Figure 6 shows two laboratory personnel conducting biological defense research in the Biological Safety Level-3 laboratory at Edgewood Chemical Biological Center at Aberdeen Proving Ground, Maryland. For their safety and protection, the researchers wear powered air purifying respirators while working in biological safety cabinets.

Figure 7: Researcher Conducting Operations in a Biological Safety Level-4 Laboratory at the U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Maryland

Source: U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Maryland (provided on March 28, 2018). | GAO-18-422

Note: Figure 7 shows a researcher in a Biological Safety Level-4 laboratory at the U.S. Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland. The researcher is loading an ultracentrifuge.

Figure 8: Researchers Preparing Particle Analyzer for Calibration in the Whole System Live Agent Test Chamber at the BioTesting Division, Dugway Proving Ground, Utah

Source: BioTesting Division, Edgewood Chemical Biological Center, Dugway Proving Ground, Utah (provided March 27, 2018). | GAO-18-422

Note: Figure 8 shows two laboratory researchers preparing an inert particulate non-biological aerosol test in the BioTesting Division's Whole System Live Agent Test Chamber at Dugway Proving Ground, Utah. The unique 7,000 cubic foot stainless steel test chamber will test biological detectors designed to warn the warfighter of airborne biological weapons.

Figure 9: Demonstration of Countermeasure Wash Down System on the USS *Ronald Reagan* Aircraft Carrier

Source: U.S. Navy photo by Mass Communication Specialist 3rd Class Kyle Carlstrom (Released March 23, 2011). | GAO-18-422

Note: Figure 9 shows the aircraft carrier USS *Ronald Reagan* conducting a countermeasure wash down to decontaminate the flight deck while the ship is operating off the coast of Japan. Sailors scrubbed the external surfaces on the flight deck and island superstructure to remove potential radiation contamination. The USS *Ronald Reagan* was providing humanitarian assistance as directed.

Appendix III: Actions Taken to Implement Recommendations from the Army's 2015 Investigation Report as of March 2018

The National Defense Authorization Act for Fiscal Year 2017 contained a provision for us to review the actions taken by the Department of Defense (DOD) to address the findings and recommendations of the Army's 2015 investigation report regarding the incident at Dugway Proving Ground, including any actions taken to address the culture of complacency in the biological select agents and toxins (BSAT) program that was identified in the report.[1]

As of March 2018, DOD had designated a priority level and had updated the completion status of its implementation for each of the 35 of 39 recommendations from the Army's 2015 investigation report that we reviewed. This update and priority level designation was conducted at GAO's request. We also asked that DOD provide us with milestones and risk assessments associated with the implementation of the recommendations from the Army's investigation report. However, DOD was unable to provide this information. We did not review the 4 recommendations in the investigation report that pertain to individual accountability. Of the 35 recommendations, DOD officials identified 12 as high priority, 18 as moderate priority, and 5 as low priority. DOD officials also provided us with an update of the completion status for implementation of each of the recommendations. Of those 35 recommendations, DOD officials indicated that 18 had been completed and 17 were in progress. (We did not independently assess whether each recommendation and DOD's subsequent actions addressed the problems identified in the Army's report.) Table 2 lists the 35 recommendations (tasks) by category, the priority assigned to each recommendation by DOD, the reported actions DOD has taken to address them, and the completion status DOD has reported for each as of March 2018.

[1]Pub. L. No. 114-328, § 218 (2016); Army, AR 15-6 Investigation Report, *Individual and Institutional Accountability for the Shipment of Viable Bacillus anthracis from Dugway Proving Ground* (Dec. 17, 2015).

Table 2: Actions Taken to Implement Recommendations from the Army's 2015 Investigation Report, Priority, and Completion Status Reported by the Department of Defense as of March 2018

Recommendation from the Army's 2015 Investigation Report[a] and Priority Assigned by the Department of Defense (DOD)	Actions Taken to Address Recommendation and Completion Status as Reported by DOD
Scientific	
1. Collaborate with DOD and Centers for Disease Control and Prevention (CDC) to revise current policy and regulations, including 42 Code of Federal Regulation part 73, to define "Non-Viable Select Agents" and to determine how to demonstrate non-viability of a select agent. Furthermore, DOD and CDC should consider allowing exempted amounts (below an infectious dose) of material to be treated as non-viable select agent and consider eliminating or re-categorizing inactivated biological select agents and toxins (BSAT) to account for the fact that it is not possible to verify that material has been inactivated with 100 percent certainty. **[High]**	Army Directive 2016-24 directs the Executive Agent Responsible Official (EARO) to collaborate with policy makers at all levels on formulation and revision of policy. Department of Defense Directive (DODD) 5101.XXE (Draft) designates the EARO as the single point of contact for collaboration with CDC on behalf of DOD. The BSAT Biorisk Program Office (BBPO) has established a working relationship with the Federal Select Agent Program (FSAP). BBPO and EARO periodically meet with FSAP on regulatory interpretation and any areas of concern. BBPO also has an active role in the Federal Experts Security Advisory Panel and associated working groups and participates in the Executive Order 13546 quarterly calls along with CDC and the Animal and Plant Health Inspection Service (APHIS). The recommendation to consider allowing exempted amounts below an infectious dose would be in conflict with federal law and would create biosecurity vulnerabilities. This has been discussed with the FSAP and is an ongoing effort. **[Complete]**
2. Conduct studies to evaluate factors that could affect *Bacillus anthracis* spore resistance to gamma irradiation. A variety of factors can affect resistance to gamma irradiation including: (1) the strain of *Bacillus anthracis*, (2) the concentration of spores in the solution being irradiated, (3) the total number of spores being irradiated, and (4) the purity of the spore solution being irradiated. Carefully controlled studies using varying doses of gamma irradiation should be conducted to evaluate each of these factors as well as the potential confounding effects of multiple factors. The desired outcome would be the development of kill curves for selected strains and spore concentrations of *Bacillus anthracis* under controlled conditions that could be replicated by production facilities. **[High]**	The Deputy Secretary of Defense, in a July 23, 2015 memo, directed the Office of the Under Secretary of Defense for Acquisition, Technology and Logistics to fund and conduct studies to address these issues and work with CDC to establish standards for irradiation. This was further documented in Army Directive 2016-24 (sections II.1.e, II.1.k, III.3.a, and III.6) and in the implementation plan for Army Directive 2016-24 (section 6). The study directed by the Deputy Secretary of Defense is complete and was published in *Applied and Environmental Microbiology* in June 2018. The publication is entitled "A Standard Method to Inactivate *Bacillus anthracis* Spores to Sterility Using Irradiation." The study was conducted by a DOD-wide consortium and outlines the thorough investigation of the production processes for inactivated B. anthracis spores. This effort establishes a baseline validated protocol that can inform future validation efforts with additional variables. BBPO also has established a Scientific Gaps in Biorisk Research Program (hereafter referred to the scientific gaps program). This program, funded by DOD, is intended to close scientific gaps in knowledge to facilitate validation of protocols or procedures or provide critical information to support developing a validated protocol or procedure in viability testing, inactivation procedures, BSAT derivatives, pathogen destruction/decontamination/sterilization procedures, risk determination/characterization, environmental sampling/monitoring, or quality system development. Since its inception, the scientific gaps program has funded three additional research proposals, and it is securing funding mechanisms to fund more proposed studies. Funded projects are tracked through required quarterly reports and detailed written updates of milestone accomplishments. **[Complete]**

Scientific		
3.	Conduct studies to evaluate the potential for gamma irradiated spores to heal. For growth to be detected during viability testing, dormant spores (that were not actually killed during irradiation) must germinate first in order to begin growing. The triggers that allow for this transition are not clearly understood; however, there is evidence that suggests that time, variance in temperature, salt content, air pressure and nutrients dramatically affect germination and growth rates of spores. There is also evidence that the introduction of a catalyst could spur the onset of germination within a damaged germinating spore. The catalyst could be any number of potential factors including, but not limited to the following: time, incubation temperature, a freeze thaw cycle, or the introduction of growth media. **[High]**	The study outlined in the response to recommendation 2 also addressed the potential of injured spores to heal. **[Complete]**
4.	Conduct studies to evaluate factors that could affect viability testing of irradiated *Bacillus anthracis* spores. Key to the establishment of an effective *Bacillus anthracis* irradiation program is the establishment of a validated means of assessing the viability of the irradiated spores. In order to ensure that irradiated spores have truly been killed, conditions should be provided that optimizes the opportunity for growth. Factors to evaluate under viability testing include: length of time spores are incubated in broth and on plates, types of growth media used for incubation in broth and on plates (tryptic soy agar, brain heart infusion agar, nutrient broth, etc.), temperature(s) for incubation in broth and on plates, and the portion of the irradiated sample that should be used for viability testing. **[High]**	The study outlined in the response to recommendation 2 addressed these concerns. This study established the required baseline information; however, additional variables regarding viability testing need to be evaluated. These studies will be submitted to the scientific gaps program for funding. **[In progress]**

Institutional at United States Army	
5. Unity of Command/ Consolidation of Facilities by appointing an Executive Agent with oversight over the laboratories at Dugway Proving Ground – Life Sciences Division (DPG – LSD), Edgewood Chemical Biological Center (ECBC), and U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) as well as any other entity working with BSAT administered by the Department of the Army. **[High]**	The Secretary of the Army was designated by the Deputy Secretary of Defense as the Executive Agent for Biosafety in a July 23, 2015, memorandum and as the Executive Agent for Biosecurity in a January 3, 2017, memorandum. The Secretary of the Army delegated authority to The Surgeon General of the Army in October 26, 2015, and March 31, 2017, memorandums. The Surgeon General delegated authority to the Commanding General, U.S. Army Medical Research and Materiel Command, in memorandums from the Department of the Army Surgeon General on December 9, 2016, and May 30, 2017. The roles and responsibilities of the Executive Agent are delineated in DODD 5101.XXE. (Draft DOD Instruction 5210.88, as amended in October 2017, also addresses the role of the Executive Agent.) Army Directive 2016-24 (paragraphs 1.3.a and b) further defines the role of the Executive Agent. **[Complete]**
6. The Executive Agent should study consolidation of the laboratories involved in working with BSAT in order to leverage unity of command and minimize risk.[b] **[High]**	The Secretary of Defense has designated the Deputy Assistant Secretary of Defense for Chemical and Biological Defense as the Infrastructure Manager with the responsibility to ensure that infrastructure is adequate to support the Chemical and Biological Defense Program (CBDP) mission to protect the warfighter (CBDP Infrastructure Manager Designation). The EARO/BBPO participates in infrastructure meetings. The Biosafety Task Force Working Group 4 also addressed this question prior to the National Defense Authorization Act (NDAA) for Fiscal Year 2017 publication. CBDP has not undertaken a study specifically designed to address the feasibility of consolidating covered facilities as defined in the Sec. 218 of the NDAA for Fiscal Year 2017. Instead, its efforts have focused on addressing recommendations from GAO-15-257, which included designating an entity to lead the effort to identify required infrastructure. In his role as the Infrastructure Manager, the Deputy Assistant Secretary of Defense for Chemical and Biological Defense is leading the effort to identify core competencies (physical and intellectual) required to support the program. A core competency study of the DOD Service Laboratories, led by the Defense Threat Reduction Agency, Chemical and Biological Technologies Department, was completed in June 2017. This study identified 46 core competencies that are vital to the CBDP science and technology mission. The critical core competencies related to the DOD BSAT Program reside at Naval Surface Warfare Center – Dahlgren Division, USAMRIID, and ECBC (including the BioTesting Division at Dugway Proving Ground). After the report was published, the Defense Threat Reduction Agency, Chemical Biological Technologies Department, recognized the critical support provided by the Naval Medical Research Center to the Defense Health Program, which was not mentioned in the report. The Air Force Research Laboratory at Wright – Patterson Air Force Base also was not addressed in this report, because its BSAT capabilities were not yet active. The CBDP community is working to document the competencies associated with these laboratories for inclusion in the overall infrastructure management effort. **[In progress]**
Institutional at United States Army	
7. The Executive Agent could assist in the development of common policies related to laboratory practices, cross fertilization of lessons learned/best practices, and increased communication between colleagues and between organizations. **[Moderate]**	BBPO holds quarterly BSAT Biorisk and Scientific Review Panel (BSRP) meetings, semi-annual stakeholders meetings, Responsible Official, and Biosafety Officer council meetings. It sponsors the attendance of Responsible Officials, Biosafety Officers, and research personnel at professional organization meetings such as The Association for Biosafety and Biosecurity (ABSA) International, and continuously provides opportunity for cross-talk between organizations. The EARO is continually assessing the need for and value of developing common policies related to laboratory practices. For practices shared by the enterprise, such as the Environmental Sampling Program, BBPO is developing policies to ensure harmonization. This is an ongoing effort. **[Complete]**

Institutional at United States Army	
8. The Army should consider working with CDC to create policy that addresses how correspondence between CDC and Army biological laboratories is delivered to the chain of command. Currently, communications occur between CDC representatives and the Responsible Officials at each individual laboratory, so reporting of significant events that may require action by senior leaders is not required or guaranteed by existing policy. **[Moderate]**	Army Directive 2016-24 and DODD 5101.XXE (Draft) establish the requirement for the EARO to serve as the focal point for communications with CDC. BBPO has negotiated a memorandum of understanding with CDC and APHIS that inserts BBPO and the EARO in the communication chain between CDC, APHIS, and the laboratories without hampering their ability to provide oversight to the laboratories. Routine communication is occurring between BBPO and CDC and APHIS, and the BBPO is serving as the DOD advocate for the laboratories with CDC and APHIS regulators. BBPO also continuously engages with FSAP about concerns raised from its regulated community. BBPO is being granted read-only access to the electronic FSAP database for its BSAT registered entities, which will allow for further oversight of status and communication of DOD BSAT-registered laboratories with FSAP. It is important to note that FSAP standard operating procedure is to communicate directly with its approved Responsible Officials at each entity. BBPO will continue to work with the FSAP to enhance communication with entity leadership and recognize Command and Control authority within DOD entities. **[In progress]**
9. The Army should study whether opportunities exist to reduce risk by partnering with industry for the production and services of BSAT in lieu of maintaining this capability internal to the Army.[c] **[Low]**	The Joint Program Executive Office was tasked through the Army Task Force to conduct this study and has provided information relative to their findings in a business case analysis. In short, DOD takes every opportunity to partner with industry and academia (per DODD 5160.05E) but there are instances where the unique nature of the DOD mission makes it important to retain BSAT production and research capabilities in house. Partnering with industry is a large part of the overall CBDP, and any opportunity to partner is continually explored. **[In progress]**
10. The Army should consider removing the Critical Reagents Program operations from DPG – LSD and realign it under another laboratory (whether government or commercial) that may be better suited to execute production for external customers. **[Moderate]**	Edgewood Chemical Biological Center – BioTesting Division (ECBC–BTD) (formerly known as DPG – LSD) is not currently registered with CDC for work with BSAT and, therefore, is not providing products for the Defense Biological Product Assurance Office (DBPAO). Although the ECBC-BTD is expected to regain its registration around April 2019, it is not expected to resume a production role in support of DBPAO. Army Directive 2016-24 disestablished the Critical Reagents Program along with any policies or procedures formerly associated with the program. The Joint Program Executive Office has conducted a business case analysis that completely changes the future of the operation, no longer known as the Critical Reagents Program but now known as DBPAO. After extensive customer surveys, the program is now focusing on providing surrogates for work in this area rather than the inactivated products previously being used. It is believed that use of surrogates will meet the need of at least 90 percent of the DBPAO customers. **[Complete]**

Institutional at United States Army	
11. The Army should execute a mobile training team, comprised of Ph.D.-level microbiologists from ECBC, USAMRIID, NMRC, and CDC, to travel to DPG – LSD to initiate a complete review of laboratory practices and procedures at DPG – LSD. The main goal of the mobile training team should be to improve laboratory processes and procedures by sharing commonly accepted practices as they apply to production facilities. **[Moderate]**	As a result of the anthrax incident in 2015, the Army made the decision to move command and control of DPG – LSD to ECBC per AGO 2016-04. ECBC has sent multiple people to Dugway Proving Ground to review the laboratory and its procedures. The individuals that have gone to Dugway Proving Ground have a variety of skill sets that cover all aspects of laboratory processes. For scientific activities, ECBC has sent multiple researchers from the ECBC BioSciences Division. The researchers have discussed laboratory procedures and this area represents part of the culture transition between the two groups. ECBC also has a Biosafety Committee that is comprised of members throughout the organization (scientists, engineers, and risk/safety) as well as external participants (e.g., Kirk Health Clinic). Each standard operating procedure is briefed to this committee to evaluate potential risks and regulatory requirements prior to staffing a standard operating procedure. The Risk Management Team and the scientists at Dugway Proving Ground are included in these meetings either in person or via video teleconferences. Individuals from Office of Safety and Human Capital, which has risk, safety and security elements, also are frequently onsite at Dugway Proving Ground. ECBC has leveraged video teleconferences for meetings between site visits. All standard operating procedures were reinitiated to conform to the safety and risk reviews used by ECBC. The required Biosafety Level-1 and Biosafety Level-2 standard operating procedures have completed the process. Biosafety Level-3 standard operating procedures will be staffed for signature within ECBC and sent to BBPO and BSRP for review once ECBC – BioTesting Division has received a registration from the FSAP. The ECBC Responsible Official maintains a reoccurring trip schedule to the Lothar Salomon Life Sciences Test Facility at Dugway Proving Ground. Part of the effort is the continued inspection of the Building 2029 laboratory as it is modernized and to help prepare for resubmission of the Form 1 for re-registration with the FSAP in order to resume operations. These efforts include inspecting the layout of the laboratory and how it will function moving forward. In addition, laboratory processes and procedures are being shared across all DOD laboratories through newly created forums including the BSRP, the Responsible Official and Biosafety Officer councils, and stakeholder meetings. **[Complete]**

Institutional at United States Army	
12. Establish programs wherein all Army laboratories exchange personnel to facilitate collaboration and development of best practices. The expectation is that cross-pollination of knowledge, experience, and best practices will occur, allowing for the intellectual development of associated personnel, as well as the advancement of science. Furthermore, it will create a culture among the labs that will allow for better communication and collaboration. **[Moderate]**	BBPO has developed Biosafety Level-3 and Biosafety Level-4 mentorship programs with input from all laboratories. In addition, laboratory processes and procedures are being shared across all DOD laboratories through newly created forums including the BSRP, established in a charter document, and Responsible Official and Biosafety Officer councils and stakeholder meetings. The BSRP, as part of a requirement specified in Army Directive 2016-24, has been meeting quarterly to (1) review and assess biosafety and biosecurity concerns associated with currently established and new procedures conducted at DOD BSAT laboratories, (2) review and assess scientific evidence that supports mitigation of the biosafety and biosecurity concerns identified, and (3) provide recommendations to the EARO on its acceptability for continued use or initiation of use to enhance biosafety and biosecurity across DOD BSAT programs. This committee also serves in an advisory capacity to the EARO on any matters that pertain to biosafety and biosecurity associated with BSAT-related research. The BSRP is comprised of one biosafety officer or designee (military or DOD federal employee), one Responsible Official or designee (military or DOD federal employee), and one scientist (military or DOD federal employee) from each contiguous United States DOD facility with a mission involving storage and work with BSAT, as well as the Program Manager or Gatekeeper for the Laboratory Response Network from each of the services. In addition to convening to review and assess biosafety and biosecurity concerns associated with currently established and new procedures conducted at DOD BSAT laboratories, the BSRP also is serving as a formalized review panel of research proposals for projects designed to fill scientific research gaps in BSAT biosafety and biosecurity. This process is facilitating cross-talk among DOD laboratory scientists and further opportunities for collaboration. **[Complete]**
13. Review conference and symposium attendance policy for biological research personnel. Conferences and symposia are critical information exchange venues for this community, and are key opportunities to promote professional education and collaboration with commercial industry. **[Low]**	Conference and symposium attendance policy is initiated by the Secretary of Defense and further implemented through each service's chain of command. This policy is periodically reviewed and updated using the chain of command. In accordance with Army Directive 2016-24, BBPO provides funding for each laboratory to send biosafety, biosecurity, and research personnel to the ABSA International conference. DOD organizations are encouraged to send research scientists to professional meetings, conferences, and symposia. Several of these additional opportunities are also funded by BBPO. **[Complete]**
14. Implement a formal mentorship program to ensure that personnel engaged in work with all aspects of BSAT, to include laboratory technicians, safety personnel, regulatory oversight personnel, and inspectors, are adequately trained. The mentorship process should include an annual side-by-side, in-person peer review. **[Moderate]**	As required by Army Directive 2016-24, and the NDAA for Fiscal Year 2017, BBPO developed DOD Biosafety Level-2/3, Animal Biosafety Level-2/3, Biosafety Level-4, and Animal Biosafety Level-4 mentorship programs with input from all laboratories. BBPO also is engaged in monthly meetings with the Department of the Army Inspector General to continue to develop and strengthen regulatory oversight and shape inspector training and knowledge development. **[Complete]**
15. Leverage existing incentive programs to attract and retain highly qualified scientists to Dugway Proving Ground (DPG). **[Low]**	ECBC has hired multiple external candidates to positions at ECBC – BTD. To date, none have required any of the existing Army incentive programs to fill posted positions. Each Command is responsible for ensuring they are able to hire and retain the best qualified scientists in DOD laboratories. **[In progress]**

16. Work with CDC to enhance the effectiveness of joint inspections. The following five critical areas should be considered: (1) Frequency of Inspections. Synchronize the various inspections (Federal Agencies, Army, and Command) to ensure adequate overall inspection frequency. (2) Notification of Inspections. Implement unannounced inspections. (3) Scope of Inspections. Review the scope of inspections to include production standards and protocol process reviews. Appoint a scientific protocol review audit team to review the validity of inactivation and viability testing protocols. Current inspections primarily focus on compliance and conformance related matters—not technical matters. This recommendation is aligned with the recommendations of the DOD Review Committee Report. (4) Composition of Inspection Teams. Ensure inspection teams are comprised of subject matter experts with operational experience and familiar with the current scientific data and standards in the areas to be inspected. Each team should include microbiologists and credentialed biosafety professionals with experience in working with BSAT. Command representatives should review inspection reports for Army-wide implications. These issues should be submitted to the Office of the Director of Army Safety to be presented to the Department of the Army Biological Safety and Health Council in order to update Army policy. The council serves as the peer review forum for discussion of lessons learned and recommendations for policy development. (5) Department of the Army Inspector General Reviews. Convert the Army Biological Surety Inspections, which are required by AR 50-1, to be a mix of non-rated and rated reviews that focus on systemic, non-scientific issues such as security, accountability, personnel reliability, equipment maintenance, emergency response, medical services, and external support issues. Rated reviews hinder open dialog, honesty about deficiencies, and the overall effectiveness of the reviews. Furthermore, it creates the perception that the inspected organization is trying to avoid failing at all costs. **[High]**	The EARO and CDC and APHIS have entered into a memorandum of understanding that discusses joint inspections. A lot of work has been done in this area and joint inspection teams currently include subject matter experts from all services. Inspections are also conducted at the same time as CDC Division of Select Agents and Toxins (CDC – DSAT)/APHIS – Agriculture Select Agent Services (APHIS – AgSAS) inspections. The Department of the Army Inspector General leads the joint inspection team and coordinates with CDC – DSAT/APHIS – AgSAS team on scheduling. The Department of the Army Inspector General also coordinates with CDC – DSAT/APHIS – AgSAS team on the scope of inspections, ensuring that there is no duplication of effort in what is being inspected or in findings reported. CDC – DSAT/APHIS – AgSAS has incorporated unannounced inspections into their program to ensure this task is accomplished. BBPO is engaged in monthly meetings with the Department of the Army Inspector General to continue to develop and strengthen regulatory oversight, and to determine how to address the five critical areas in this recommendation. Discussions with Department of the Army Inspector General are underway to develop process-based evaluations and unrated reviews, off-cycle with DSAT/AgSAS compliance inspections. **[In progress]**

Institutional United States Army Test and Evaluation Command	
17. Investigate whether complacency is widespread throughout Dugway Proving Ground. **[High]**	ECBC has not conducted a formal investigation. ECBC has reinitiated and reestablished all processes for the personnel transferred to Research, Development and Engineering Command (RDECOM)/ECBC. These activities include: (1) Established two separate chains of command onsite at the Lothar Salomon Life Sciences Test Facility at Dugway Proving Ground. The laboratory personnel report through the BioTesting Division Chief to the Director of Research and Technology Directorate. The Dugway Proving Ground Risk Management Team, which employs the safety and security personnel, report to the ECBC Risk Management Branch. The Risk Management Branch reports to the Director of the Office of Safety and Human Capital, which directly reports to the ECBC Director. (2) Requested and received a withdrawal of the select agent registration by FSAP. Registration will be reestablished with new standard operating procedures that are reviewed by ECBC's Biosafety Committee, ECBC's management, and the BSRP. (3) Hiring new managers to provide the required culture change. (4) Rewriting and staffing all standard operating procedures through ECBC's Biosafety Committee and management team to evaluate risk, risk mitigation, and concurrence by ECBC leadership. (5) Site visits by ECBC Leadership to Dugway Proving Ground and visits to Aberdeen Proving Ground by personnel located at Dugway Proving Ground. (6) Establishing a quality management system (QMS) for the ECBC – BioTesting Division. Since the publication of reports associated with the anthrax incident of 2015, all commands (not just Dugway Proving Ground) are attuned to the issue of complacency in the laboratories. Several of the newly instituted programs are causing scientists and risk personnel to look more deeply at existing protocols, questioning their currency and validity for the project at hand. One such program is the BSRP, designed so that peer review of critical protocols brings to light problems that may have been buried in routine. The EARO is periodically visiting all DOD BSAT-registered laboratories to emphasize and reinforce the urgency of ensuring that DOD BSAT Biosafety and Biosecurity measures have ownership at the bench level of operations, that everyone is a safety and security officer, and that safety and security are perceived as an obligation associated with the privilege of working with BSAT and facilitating overall mission success. The EARO also is conducting town-hall meetings at every entity to receive feedback directly from the laboratory staff and provide replies to questions of concern and clarification. BBPO is conducting staff assistance visits at all BSAT entities. This allows open conversations about ongoing problems, sharing of best practices seen at other sites, etc. The Department of the Army Inspector General, CDC – DSAT, and Animal and Plant Health Inspection Service inspections are focusing more on how scientific operations are conducted and the people that are conducting them and less on the bureaucratic details of forms and paperwork. This meshes well with DOD's intent to foster the concept of risk-based decision making with risks managed as close to the hazards as possible. These are all ongoing efforts. **[In Progress]**

Institutional United States Army Test and Evaluation Command	
18. Assess and ensure that all personnel assigned to biosafety, biosurety, and scientific positions are qualified. **[Moderate]**	All personnel remaining after the transfer of command to ECBC were reviewed. All of the position descriptions were evaluated and updated to reflect current duties. As part of the decommissioning process with FSAP, only five members are currently enrolled in the Biological Personnel Responsibility Program. ECBC anticipates having 25 individuals enrolled in the biological Personnel Responsibility Program when the Federal Select Agent registration is reestablished. Personnel Responsibility Program members are continuously monitored. Current risk management personnel assigned to the roles of biosafety and surety positions have been assessed and are qualified to hold those positions. DOD Manual 6055.18-M contains the requirements for a biosafety officer and the assigned person meets and exceeds those requirements. DOD Instruction 5210.88 and DOD Manual 6055-18-M require that only personnel who are qualified and meet requirements for the position, occupy these positions within DOD. DOD Mentorship Programs will enhance and continuously assess personnel qualifications for scientific positions within DOD BSAT laboratories. This is an ongoing effort. **[Complete]**
19. Ensure all mishaps are internally investigated and that responsible parties are held accountable if appropriate. **[High]**	ECBC – BioTesting Division safety investigations will be conducted as mishaps arise and these investigations will assess root cause but are not fault-finding. Incidents requiring administrative/putative personnel actions would follow Army Regulation 15-6, Procedures for Administrative Investigations and Boards of Officers. Current safety and security policies contained in DOD Instruction 5210.88 and DOD Manual 6055.18-M require reporting and investigation of mishaps. Department of the Army Inspector General and CDC – DSAT and APHIS – AgSAS review past mishaps and note when appropriate actions are not taken. The Army Directive 2016-24, Implementation Plan establishes the guidelines for laboratory reporting to the EARO/BBPO. All mishaps requiring Form-3 reporting to DSAT must also be reported to BBPO. **[Complete]**

Institutional United States Army Test and Evaluation Command	
20. Review Army Regulation 702-11, Army Quality Program (Feb. 25, 2014), and determine whether Army Test and Evaluation Command (ATEC), Dugway Proving Ground (DPG), and DPG – LSD are in compliance with this regulation as it relates to the production of *Bacillus anthracis* and other biological materials. **[Moderate]**	The BioTesting Division Quality Manager and Deputy Quality Manager received appointments after training in root cause analysis and internal audits. The BioTesting Division Quality Policy was developed and approved for use. The quality managers have developed a QMS modeled on International Organization for Standardization (ISO) 17025, which is the international standard for laboratories and certification organizations. The Quality Control laboratories currently are being established under the QMS. In December 2017, the ECBC Quality Office performed an internal gap analysis to the ISO 17025 standard, which meets the guiding principles of the Army Quality Program (Army Regulation 702-11). Comments from that audit currently are being addressed. Once comments have been addressed, the BioTesting Division must operate under the new QMS for 4 to 6 months. At this point, the ECBC Quality Office will perform an internal audit to the ISO 17025 standard. Any corrective actions issued during the internal audit will need to be addressed, and a management review performed prior to a formal external audit. Certification for compliance with ISO 17025 will be the final outcome of the external audit. Certification is renewed annually. Army Directive 2016-24, Section 10 b, requires DBPAO, formally known as the Critical Reagent Program, to "cease DBPAO production at Dugway Proving Ground". However, the ECBC – BioTesting Division will continue to produce materials to support programs of record and will maintain its operational readiness as a Major Range and Test Facility Base. Any material produced by the ECBC – BioTesting Division has to follow the requirements set by the BBPO. (See the Army Directive 2016-24, Implementation Guidance (Sept. 16, 2017).) BBPO recognizes that standardizing a quality management program across all DOD laboratories is important and has expanded the scope of this AR 15-6 finding accordingly. BBPO is developing a QMS program for implementation in all DOD BSAT laboratories. The ECBC – BioTesting Division will be held to the same quality standards as other laboratories. **[Complete]**
Institutional Dugway Proving Ground–Life Sciences Division	
21. Resource and ensure external oversight of a full-time Quality Assurance/Quality Control Manager position. **[Moderate]**	The ECBC – BioTesting Division appointed an on-site Quality Manager and Deputy Quality manager after each received training in root cause analysis and internal audits. The ECBC Quality Office was resourced to provide oversight of newly appointed BioTesting Division quality managers by a veteran ECBC Quality Manager and Quality Control specialist experienced in implementing a QMS that conformed to ISO 17025. The oversight personnel mentored the BioTesting Division Quality Managers and assisted them in development of the QMS documentation. In December 2017, the ECBC Quality Office performed an internal gap analysis to ensure conformance with ISO 17025. The audit team found that the documentation and processes in place supporting BioTesting Division's QMS met the requirements of ISO 17025. The next step was to implement the QMS and conduct an internal audit within 4 to 6 months to assess BioTesting Division's degree of conformance to ISO 17025, to be followed by a management review of BioTesting Division's QMS. Future events will continue to develop the quality program and identify other processes such as virus growth and referee equipment that will be incorporated into the quality program. The BBPO is the external oversight element, providing centralized oversight of the program through the QMS and developing it with input from the laboratories. The Deputy Director for Biosecurity in BBPO is designated to perform the functions of a Quality Control Manager. **[Complete]**
22. Execute and enforce the existing environmental sampling/inspection program. **[Moderate]**	The BBPO formed a Quality Assurance working group and is drafting an environmental sampling program for implementation in all DOD BSAT laboratories, along with programs to address all other NDAA for Fiscal Year 2017 recommendations. **[In progress]**

Institutional Dugway Proving Ground–Life Sciences Division	
23. Develop and enforce production procedures that prohibit operations where live select agents are used in the same laboratory where viability testing is conducted. **[Moderate]**	The BBPO has established a Quality Assurance working group, and the working group currently is establishing requirements as part of a BSAT Laboratory Cross Contamination Control Program. **[In progress]**
24. Prohibit production work on multiple organisms or multiple strains of one organism within the same biosafety cabinet. **[Moderate]**	The BBPO has established a Quality Assurance working group (per the Biological Select Agents and Toxins Laboratory Cross Contamination Control Program) and the working group currently is establishing requirements. **[In progress]**
25. Develop the existing video surveillance program and use the video as a tool to improve laboratory practices in accordance with regulatory requirements. Ensure that closed circuit television cameras are placed in locations that are conducive to the proper monitoring of safety, security, and general laboratory practices within the laboratories, including inside the biosafety cabinets. **[Low]**	There is no regulatory requirement for video surveillance, although most laboratories do have some form of video surveillance in place. Where cameras are in place, each laboratory has responsibility for using them to enhance safety and/or security of their program. Recommendations for use are being established by the Quality Assurance working group, referenced previously in GAO-17-522R, in accordance with Army Directive 2016-24**. [In progress]**
26. Implement formal, recurring data reviews of Critical Reagents Program processes in an effort to identify trends and issues before they affect end products. **[Moderate]**	The BBPO is developing an enterprise-wide quality assurance program to implement this recommendation. This effort will be facilitated by development of a Defense Business System mandated by Army Directive 2016-24. The BBPO is developing a QMS to assess quality and reliability of all BSAT-related products and trends will be evaluated. Army Directive 2016-24, Section 10 b, requires the DBPAO, which was formally known as the Critical Reagent Program, to "cease DBPAO production at Dugway Proving Ground." **[In progress]**
27. Establish validated protocols for Critical Reagents Program production processes to ensure that process deviations are adequately vetted prior to implementation. **[Moderate]**	Validated protocols and procedures are now required by the Federal Select Agent Regulations for all BSAT-related products. Army Directive 2016-24 and the Army Directive 2016-24, Implementation Plan, address validation of protocols and procedures in the Quality and Reliability section. BBPO is developing an enterprise-wide quality assurance program to implement this recommendation, along with the efforts already established by the BSRP. Army Directive 2016-24, Section 10 b, requires DBPAO, which was formally known as the Critical Reagent Program, to "cease DBPAO production at Dugway Proving Ground." **[In progress]**
28. Enforce maintenance and calibration procedures and schedules for all Critical Reagents Program tools and equipment. When necessary, contract with vendors to ensure that repairs are adequate and thorough. **[Moderate]**	Army Directive 2016-24, Section 10 b, requires DBPAO, which was formally known as the Critical Reagent Program, to "cease DBPAO production at Dugway Proving Ground." However, ECBC continues portions of this requirement since the ECBC – BioTesting Division and Risk Management Office are Major Ranges and Test Facility Bases. Parts of this requirement will also be implemented in the ISO 17025. The BBPO is developing an enterprise-wide quality assurance program to implement this recommendation. Parameters are being developed by the Quality Assurance working group, and will be monitored through the QMS. **[In progress]**

Institutional Dugway Proving Ground–Life Sciences Division	
29. Develop and enforce maintenance procedures and schedules for irradiators. **[Moderate]**	The Radiation Safety Officer will assist BioTesting management with the contract requirements for ensuring that the irradiators are part of a scheduled maintenance procedure. The irradiators are currently part of ATEC/West Desert Test Center. Transfer to ECBC – BioTesting Division is expected to be completed after all outstanding questions are resolved with the Nuclear Regulatory Commission. BBPO is developing an enterprise-wide quality assurance program to implement this recommendation, and this will be monitored through the QMS. This program will expand the maintenance program to all critical systems and equipment. The DOD study that established data for validation of an irradiation protocol noted variations in irradiator performance as well as techniques to mitigate variability. The study's findings will be incorporated into a validated procedure. A publication from this study is under peer review, as mentioned above. **[In progress]**
30. Ensure that all standard operating procedures and work instructions governing operations at DPG – LSD are nested as appropriate and subjected to a uniform review and approval process. Notify the chain of command and request approval from the Director of DPG – LSD prior to implementing any deviations from standard operating procedures. **[High]**	A collaborative research project was completed by the Deputy Secretary of Defense, who directed the Under Secretary of Defense for Acquisition, Technology, and Logistics to develop inactivation and viability testing protocols for biological agents. As mentioned above, the final publication currently is under peer review. The BSRP also has been meeting quarterly to review and assess biosafety and biosecurity concerns associated with currently established and new procedures conducted at DOD BSAT laboratories, review and assess scientific evidence that supports mitigation of the biosafety and biosecurity concerns identified, and provide recommendations to the EARO on their acceptability for continued use or initiation of use to enhance biosafety and biosecurity across DOD BSAT programs. This committee also serves in an advisory capacity to the EARO on any matters that pertain to biosafety and biosecurity associated with BSAT-related research. The BSRP is comprised of one biosafety officer or designee (military or DOD federal employee), one Responsible Official or designee (military or DOD federal employee), and one scientist (military or DOD federal employee) from each contiguous United States DOD facility with a mission involving storage and work with BSAT, as well as the Program Manager or Gatekeeper for the Laboratory Response Network from each of the services. The BSRP requires re-review whenever changes to approved procedures are made. This is an ongoing effort and ECBC – BioTesting Division (formerly the DPG – LSD) protocols and procedures will be evaluated as that entity is brought back on line for BSAT operations. **[Complete]**
31. Ensure that the irradiator source decay curves are consulted, in conjunction with the readings from the dosimeters, when calculating required time for irradiating a sample. Any issues with the irradiator should immediately be brought to the attention of the Radiation Safety Officer, the Radiation Safety Committee and the (DPG – LSD) Director. All individuals operating irradiation equipment should receive documented comprehensive training on the equipment. **[High]**	A collaborative research project was completed by the Deputy Secretary of Defense, who directed the Under Secretary of Defense for Acquisition, Technology, and Logistics (see response for Recommendation 2) to develop inactivation and viability testing protocols for biological agents. The study noted variations in irradiator performance as well as techniques to mitigate concerns associated with variability. These findings will be incorporated into a validated procedure. Irradiator maintenance and calibration will also be monitored as part of the QMS. **[In progress]**

Institutional Dugway Proving Ground–Life Sciences Division	
32. Revise the death certificate process to restrict the modification of certificates after all reviewers have signed the document. Train the signatories on their respective responsibilities to establish a better understanding of their responsibilities and the importance of a critical review of the certificate. Amend the certificate to accurately reflect the protocol and work instructions. Also consider reverting to the "inactivation certificate" title. **[Moderate]**	FSAP published guidance, which all DOD BSAT-registered laboratories are required to follow, regarding use of the terms certificates of inactivation or certificates of non-viability as well as review and approval of the certificates. Any material produced by the ECBC – BioTesting Division must follow the requirements set out by the FSAP and BBPO. Army Directive 2016-24 Implementation Guidance dated September 16, 2017, details these requirements. **[Complete]**
33. Personnel Qualification. Assess and ensure that all personnel assigned to biosafety, biosurety, and scientific positions are qualified and fully vetted by the Biological Personnel Reliability Program, as appropriate. **[Moderate]**	ECBC currently has five employees in the Personnel Responsibility Program located at Dugway Proving Ground. These positions are continuously monitored. In the future, ECBC expects 25 Personnel Responsibility Program employees to be registered at the Lothar Salomon Life Sciences Test Facility as part of the reestablishment of the FSAP registration. DOD Instruction 5210.88 and DOD Manual 6055.18-M require that only personnel who are qualified and specific requirements for the position occupy these positions within DOD. The Mentorship Programs will enhance and continuously assess personnel qualifications for scientific positions within DOD BSAT laboratories. This is an ongoing effort. **[Complete]**
34. Mishap Investigation and Reporting. Ensure all mishaps are investigated and appropriately reported and that responsible parties are held accountable, as appropriate. **[High]**	ECBC has multiple guidance documents in place to address this requirement. The Biosafety Manual covers the current ECBC – BioTesting Division operations. Once the BSAT registration is reestablished, an Incident Response Plan also will exist. These documents are reviewed annually and are inspected by CDC and the Department of the Army Inspector General as part of the joint inspection program. Current safety and security policies, per DOD Instruction 5210.88 and DOD Manual 6055.18-M, require reporting and investigation of mishaps. Department of the Army Inspector General and CDC – DSAT and APHIS – AgSAS inspections review past mishaps and note when appropriate actions are not taken. Reference 4 establishes the guidelines for laboratory reporting to EARO/BBPO. All mishaps requiring Form-3 reporting to the DSAT must also be reported to BBPO. **[Complete]**
35. Hiring Incentives. Leverage existing Army incentive programs to attract and retain highly qualified scientists. **[Low]`**	ECBC has hired multiple personnel to positions at Dugway Proving Ground. To date, none required any of the existing Army incentive programs to fill posted positions. Each command is responsible for ensuring they are able to hire and retain the best qualified scientists in DOD laboratories. Although Army Directive 2016-24 made this a requirement for DPG – LSD, it is applicable to all commands and all laboratories. **[In progress]**

Source: GAO analysis of DOD reported information. | GAO-18-422

Note: GAO did not independently assess whether each recommendation and DOD's subsequent actions address the problems reported in the Army's 2015 investigation report.

[a]Army AR 15-6 Investigation Report, *Individual and Institutional Accountability for the Shipment of Viable Bacillus anthracis from Dugway Proving Ground* (Dec. 17, 2015). For the purposes of this report, we addressed the implementation status of 35 of the 39 recommendations contained in the Army's 2015 investigation report. We did not report on the 4 recommendations in the Army's 2015 Investigation Report that pertain to individual accountability.

[b]This provision of the AR 15-6 Investigation Report was not contained in the Army Directive 2016-24, *Department of Defense Biological Select Agent and Toxins Biosafety Program*. However, the NDAA for Fiscal Year 2017, section 218, subsection (d) did require DOD to conduct this study and report to

the defense congressional committees by February 1, 2017. DOD provided a report as required on April 10, 2017, that noted DOD is continuing to study this issue, among others.

[c]This provision of the AR 15-6 Investigation Report was not contained in the Army Directive 2016-24, *Department of Defense Biological Select Agent and Toxins Biosafety Program*. However, the NDAA for Fiscal Year 2017, section 218, subsection (d) did require DOD to conduct this study and report to the defense congressional committees by February 1, 2017. DOD provided a report as required on April 10, 2017, that noted DOD is continuing to study this issue, among others.

Appendix IV: Delegation of Authority for the Biological Select Agents and Toxins Biosafety and Biosecurity Program

The Deputy Secretary of Defense designated the Secretary of the Army on July 23, 2015, as the Executive Agent for the Department of Defense's (DOD) Biological Select Agents and Toxins (BSAT) Biosafety Program. According to DOD Instruction 5210.88, the Secretary of the Army is responsible for performing technical reviews and conducting inspections, and harmonizing protocols and procedures across DOD laboratories that handle BSAT.[1]

DOD used a sequential delegation of authority to establish leadership roles and responsibilities initially for the DOD BSAT Biosafety Program and subsequently for the DOD BSAT Biosecurity Program. First, on October 26, 2015, the Secretary of the Army designated The Surgeon General of the Army as the Executive Agent Responsible Official (EARO) for the DOD BSAT Biosafety Program to consolidate oversight of BSAT biosafety operations across the department. Second, on December 9, 2016, The Surgeon General of the Army further delegated EARO authority to the Commanding General, U.S. Army Medical Research and Materiel Command, for the DOD BSAT Biosafety Program. Third, on January 3, 2017, the Deputy Secretary of Defense designated the Secretary of the Army as the DOD Executive Agent for the BSAT Biosecurity Program. Fourth, on March 31, 2017, the Secretary of the Army further designated The Surgeon General of the Army as the EARO for the DOD BSAT Biosecurity Program. Finally, on May 30, 2017, The Surgeon General of the Army delegated EARO responsibility for the DOD BSAT Biosecurity Program to the Commanding General, U.S. Army Medical Research and Materiel Command.

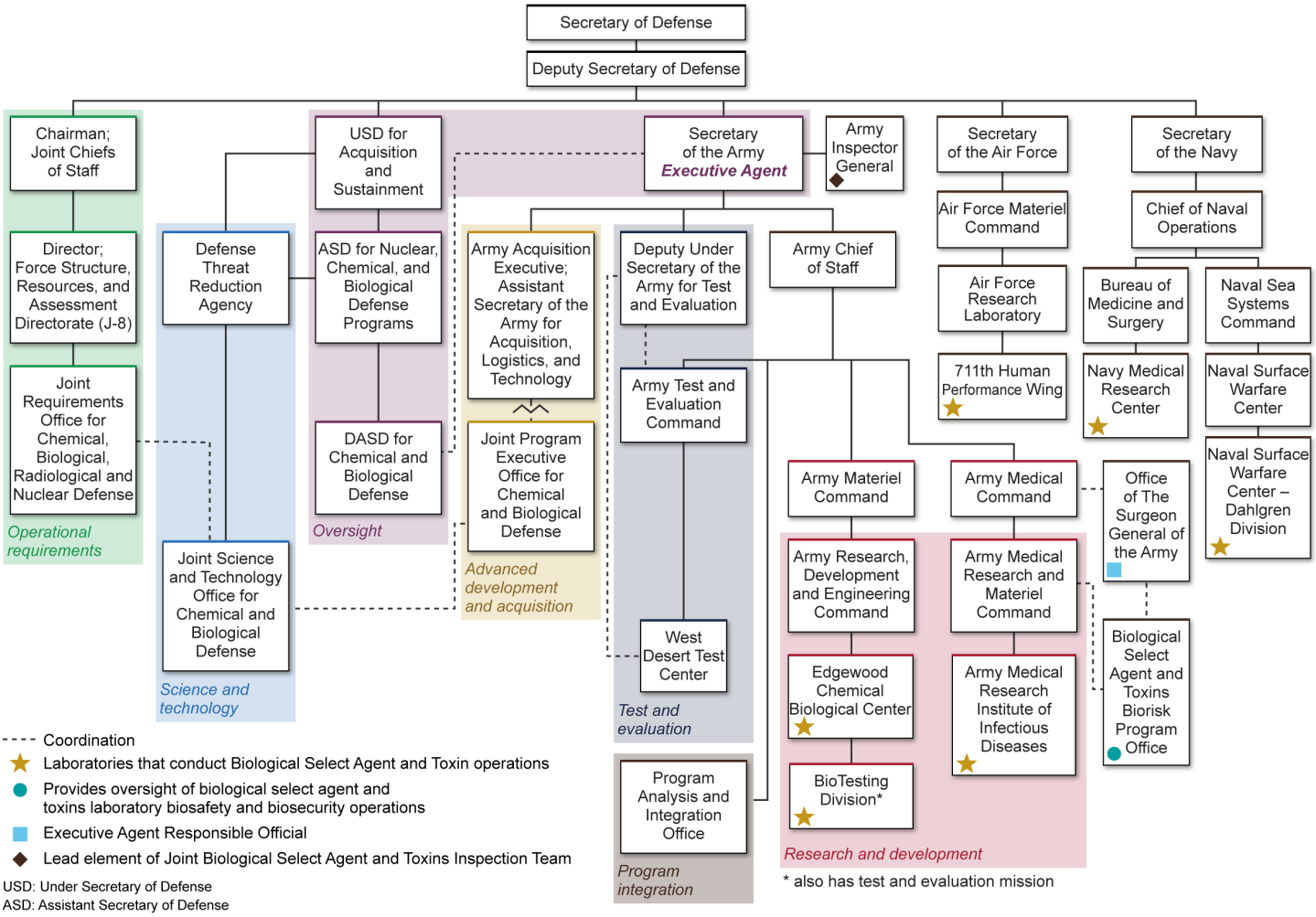
Army Directive 2016-24, *Department of Defense Biological Select Agent and Toxins Biosafety Program*, directs The Surgeon General of the Army to coordinate with the Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense for requirements and resources—including force structure, manpower, and infrastructure—and to prioritize resources for research requirements to advance the field of BSAT biosafety.[2] Figure 10 shows the alignment and organization of offices

[1]Department of Defense Instruction 5210.88, *Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT)* (Jan. 19, 2016) (incorporating change 1, Oct. 6, 2017).

[2]Army Directive 2016-24, *Department of Defense Biological Select Agent and Toxins Biosafety Program* (July 25, 2016).

within DOD and the military services that are responsible for carrying out and supporting the Chemical and Biological Defense Program Enterprise.

Figure 10: Department of Defense and Military Service Offices Responsible for the Chemical and Biological Defense Program Enterprise as of March 2018



USD: Under Secretary of Defense
ASD: Assistant Secretary of Defense
DASD: Deputy Assistant Secretary of Defense

Source: GAO analysis of Department of Defense (DOD) information. | GAO-18-422

According to BSAT Biorisk Program Office (BBPO) officials, BBPO was established in March 2016 to support the EARO in its oversight of DOD's BSAT Biosafety and Biosecurity Program and implementation of tasks and recommendations in Army Directive 2016-24. BBPO manages a scientific review panel, inspection of DOD laboratories, harmonization of

DOD's BSAT-related regulations and procedures, and coordination of interaction and information with the Federal Select Agent Program. BBPO also is responsible for establishing a system to track and manage BSAT and BSAT-related products across DOD, providing oversight for laboratory biosafety, and advancing BSAT-related scientific research to address knowledge gaps. According to DOD officials, in fiscal year 2016, BBPO received approximately $805,000 for operation costs; in fiscal year 2017, BBPO received approximately $2 million. In addition, in fiscal year 2018, BBPO received approximately $2 million.

As part of BBPO's oversight responsibilities, it acts as a single point of contact for coordinating with the Federal Select Agent Program. In June 2017, the EARO and the directors of the Centers for Disease Control and Prevention, Division of Select Agents and Toxins, and the Animal and Plant Health Inspection Service (APHIS), Agriculture Select Agent Services, on behalf of the Federal Select Agent Program, executed a memorandum of understanding that articulates agency responsibilities. This memorandum includes (1) oversight coordination, (2) Centers for Disease Control and Prevention and APHIS notifying DOD BSAT Biosafety and Biosecurity Programs of any referrals of a DOD-registered entity to the Department of Health and Human Services Office of Inspector General that may involve compliance violations with select agent regulations, and (3) facilitating coordinated inspections. For example, according to BBPO officials, BBPO receives every inspection report and reviews it for DOD-wide implications.

The Army has established a joint service inspection program that is led by the Department of the Army Inspector General.[3] That office, according to BBPO officials, has worked closely with the Federal Select Agent Program in coordination with BBPO to enhance the effectiveness of joint inspections and unannounced or short-notice inspections. According to an Army official, the Department of the Army Inspector General coordinates with the other military services' Inspectors General, who identify subject matter experts with operational experience to serve on every joint service inspection team.

[3]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), directed that the Secretary of the Army, as the Executive Agent for the DOD BSAT Biosafety Program, shall be responsible for the inspection of biosafety protocols and procedures in DOD laboratories that handle BSAT. Army Directive 2016-24 subsequently established roles and responsibilities for the DOD joint inspection program.

In addition, BBPO officials told us that, as part of its oversight and coordination responsibilities, the office established the BSAT Biorisk and Scientific Review Panel, which was formally chartered in August 2017. This panel is charged with convening at least twice a year to review and assess biosafety, biosecurity, and technical concerns associated with currently established and new procedures conducted at DOD BSAT laboratories. The panel will review and assess scientific evidence that supports the mitigation of biosafety risks and provide recommendations to the EARO on approval of new or existing laboratory procedures. It also serves in an advisory capacity to the EARO on any matters that pertain to biosafety and biosecurity associated with BSAT-related research.

Appendix V: The Department of Defense Has Made Key Safety Improvements by Implementing Recommendations

The Department of Defense (DOD) has made key safety improvements by taking a number of actions to address the incident at Dugway Proving Ground and the recommendations from the Army's 2015 investigation report.[1] Key safety improvements include (1) establishing a DOD Executive Agent and a support office to provide oversight, (2) implementing improved quality control and assurance standards at its covered facilities, (3) developing a new quality management system, (4) conducting additional scientific studies on biological select agents and toxin (BSAT) inactivation, and (5) taking multiple actions to address Army Directive 2016-24 and the Army's 2015 investigation report.[2] These safety improvements are discussed below in more detail.

DOD Has Established an Executive Agent for DOD's BSAT Biosafety and Biosecurity Program

One of the key safety improvements DOD took in response to the incident at Dugway Proving Ground was to establish an Executive Agent for the BSAT Biosafety and Biosecurity Program (see appendix IV). Specifically, at the direction of the Deputy Secretary of Defense, the Secretary of the Army was designated in July 2015 as the Executive Agent for DOD's BSAT Biosafety Program, and subsequently in January 2017 as the Executive Agent for the DOD BSAT Biosecurity Program. In October 2015, the Secretary of the Army further designated The Surgeon General of the Army as the Executive Agent Responsible Official for the DOD BSAT Biosafety Program to consolidate oversight of BSAT biosafety operations across the department. The Secretary of the Army, as outlined in DOD Instruction 5210.88, is responsible for performing technical reviews, conducting inspections, and harmonizing protocols and procedures across DOD laboratories that handle BSAT.[3]

[1]Army, AR 15-6 Investigation Report, *Individual and Institutional Accountability for the Shipment of Viable Bacillus anthracis from Dugway Proving Ground* (Dec. 17, 2015).

[2]Army Directive 2016-24, *Department of Defense Biological Select Agent and Toxins Biosafety Program* (July 25, 2016).

[3]Department of Defense Instruction 5210.88, *Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT)* (Jan. 19, 2016) (incorporating change 1, Oct. 6, 2017).

DOD Has Improved Quality Control and Assurance at Dugway Proving Ground and Currently Covered Facilities

Another key safety improvement DOD took in response to the incident at Dugway Proving Ground was to improve quality control and assurance at Dugway and other DOD facilities that currently handle BSAT. The Army's 2015 investigation report made several recommendations to the Army to enhance and improve quality control and assurance at Dugway Proving Ground. These included (1) establishing a quality control and assurance manager, (2) carrying out an environmental sampling and inspection program, and (3) developing and enhancing the video surveillance program. BSAT Biorisk Program Office (BBPO) officials explained that the DOD BSAT laboratories had some quality control and assurance measures in place prior to the National Defense Authorization Act (NDAA) for Fiscal Year 2017.

The quality control and assurance recommendations from the Army's 2015 investigation report, which initially applied only to Dugway Proving Ground, were subsequently enacted in section 218 of the NDAA for Fiscal Year 2017 to apply to all DOD covered facilities.[4] These requirements include:

1. designation of an external manager to oversee quality assurance and quality control;
2. environmental sampling and inspections;
3. production procedures that prohibit operations where live BSAT are used in the same laboratory where viability testing is conducted;
4. production procedures that prohibit work on multiple organisms or multiple strains of one organism within the same biosafety cabinet;
5. a video surveillance program that uses video monitoring as a tool to improve laboratory practices in accordance with regulatory requirements;
6. formal, recurring data reviews of production in an effort to identify trends and nonconformance issues before such issues affect end products;
7. validated protocols for production processes to ensure that process deviations are adequately vetted prior to implementation; and

[4]The BioTesting Division at Dugway Proving Ground currently is not one of DOD's covered facilities, because it is not producing BSAT, since its registration for possession, use, and transfer of BSAT was withdrawn.

8. maintenance and calibration procedures and schedules for all tools, equipment, and irradiators.

BBPO officials told us that, in response to the requirements in the NDAA for Fiscal Year 2017, they are developing a department-wide quality control and assurance program for the BSAT community. BBPO also developed several policies that address the measures mandated by the NDAA for Fiscal Year 2017. These policies address setting minimum requirements for (1) monitoring environmental quality, (2) performing maintenance on laboratory equipment, and (3) controlling laboratory cross-contamination between organisms or strains within the same biological safety cabinet and between live and inactivated BSAT.[5]

DOD officials said that some NDAA for Fiscal Year 2017 requirements do not necessarily apply to every laboratory. According to DOD officials, some of these requirements are no longer relevant as a result of certain events, such as the inadvertent shipment of incompletely inactivated anthrax from the BioTesting Division at Dugway Proving Ground that currently is not handling BSAT. Furthermore, some of the requirements need further clarification. For example, the NDAA for Fiscal Year 2017 required DOD covered facilities to implement quality control and quality assurance measures, including a video surveillance program that uses video monitoring, in accordance with regulatory requirements. (In providing technical comments on a draft of this report, both the Department of Health and Human Services' Centers for Disease Control and Prevention and Department of Agriculture's Animal and Plant Health Inspection Service—which jointly manage the Federal Select Agent Program—said that select agent regulations do not require development and utilization of a video surveillance program.)

The Army's 2015 investigation report also recommended the development and utilization of a video surveillance program in accordance with Federal Select Agent Program regulatory requirements. DOD officials stated that there is no such requirement in federal select agent regulations and, therefore, to implement a video surveillance program would result in laboratories having an unfunded requirement for maintenance costs. According to a BBPO official, DOD officials reached out to congressional staff to obtain clarification on implementing this requirement and, according to these officials, were advised to "interpret

[5]Biological safety cabinets are the primary means of containment developed for working safely with infectious microorganisms.

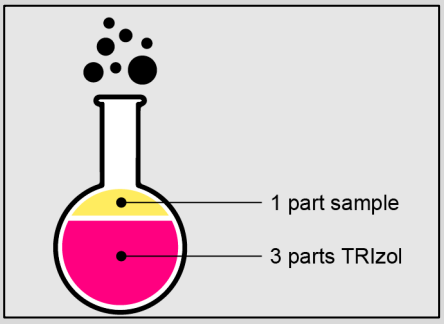
the requirement as appropriate." DOD officials stated that because the federal select agent regulations do not require video surveillance, DOD is not obligated to implement a video surveillance program in accordance with the provision in the NDAA for Fiscal Year 2017. Army Regulation 190-17 for the BSAT security program, however, already includes a requirement that all Army Biosafety Level-3 and 4 laboratories have operational closed-circuit television cameras installed and positioned so that all areas of the research room can be viewed.[6] In response to the NDAA for Fiscal Year 2017 and its requirement to implement a video surveillance program, BBPO officials stated that recommendations for the use of video surveillance are being established by the Quality Assurance Working Group that supports BBPO for all laboratories in each of the military services that handle BSAT.

[6]Army Regulation 190-17, *Biological Select Agents and Toxins Security Program* (Sep. 3, 2009).

DOD is Developing a New Quality Management System

Example of a Potential Quality Control and Assurance Procedure at the Department of Defense (DOD)

DOD's future quality management system will include critical control points for helping to prevent personnel from making mistakes while conducting scientific procedures. For example, a certain procedure for extracting genetic information from pathogens that also inactivates pathogens uses a chemical mixture called TRIzol. The quality management system will include a critical control point for this procedure in the form of achieving a ratio of pathogen sample to the amount of TRIzol. In this new system, the scientist or laboratory technician may be required to enter the amount into the new system to show that the ratio is correct to inactivate the pathogen.



Source: GAO analysis of DOD information. | GAO-18-422

DOD officials report that, to enhance quality control and assurance at Dugway Proving Ground and across DOD's currently covered facilities, the Joint Program Executive Office for Chemical and Biological Defense, on behalf of BBPO, is in the process of developing a new quality management system known as the Joint Interagency Biorisk System. The system would centralize information on DOD's BSAT Biosafety and Biosecurity Program, such as operational and governance documentation. For example, the system would gather applicable quality assurance-related information from Dugway Proving Ground and DOD's currently covered facilities to provide BBPO with the ability to track inventory and shipment of BSAT materials and ensure that approvals and waivers for exceptions to laboratory protocols are made at the appropriate level, among other things. DOD currently is identifying the critical control points that would be built into the Joint Interagency Biosafety System to ensure quality throughout the BSAT handling, production, storage, containment, shipment, destruction, and inactivation processes. According to officials from BBPO, DOD's future quality management system will include critical control points to help personnel prevent mistakes while conducting scientific procedures (see sidebar for additional information).

DOD Has Conducted Studies on Inactivating Pathogens and Is Continuing Its Research

In response to the results of DOD's July 2015 30-day review, the Deputy Secretary of Defense directed the Under Secretary of Defense for Acquisition, Technology and Logistics to develop a plan for research related to the development of standardized irradiation and viability testing protocols.[7] The Army's subsequent 2015 investigation report also identified specific actions the Secretary of the Army should consider taking, including directing additional research to address existing gaps in scientific knowledge regarding the inactivation of BSAT.

Chemical and Biological Defense Program officials said that they are developing a validated method for inactivating *Bacillus anthracis* spores using irradiation to improve safety. DOD reported completion of the first phase of the study for developing a validated method with scientists from three DOD laboratories, using a weakened strain of *Bacillus anthracis*.[8] The second phase of the *Bacillus anthracis* inactivation study was completed in October 2017, according to Army officials, using a potentially lethal strain of *Bacillus anthracis*. In April 2018, DOD officials stated that as a result of the first two phases of this study, they have received approval from peer reviewers to publish their study results, which will recommend these results as a validated inactivation method. The next step will be to analyze the data from these studies to determine whether additional studies are needed to answer further questions about factors that may affect testing for the presence of live pathogens.[9]

[7]Section 901 of the NDAA for Fiscal Year 2017 eliminated the position of the Under Secretary of Defense for Acquisition, Technology and Logistics and established an Under Secretary of Defense for Research and Engineering and an Under Secretary of Defense for Acquisition and Sustainment. Oversight responsibilities for Chemical and Biological Defense Program (CBDP), which previously were assigned to the Under Secretary of Defense for Acquisition, Technology and Logistics, have been transferred to the Under Secretary of Defense for Acquisition and Sustainment. *See* Pub. L. No. 114-328, § 901 (2016); Deputy Secretary of Defense Memorandum, *Implementation Guidance for the Establishment of the Office of the Under Secretary of Defense for Research and Engineering and the Office of the Under Secretary of Defense for Acquisition and Sustainment* (Jan. 31, 2018).

[8]The three facilities participating in the study are Edgewood Chemical Biological Center, U.S. Army Medical Research Institute of Infectious Diseases, and Naval Surface Warfare Center-Dahlgren Division.

[9]In response to inactivation issues, the Federal Select Agent Program updated regulations and guidance which now define inactivation and provide information on how to conduct inactivation. 82 Fed. Reg. 6278-6294; *see also* 42 C.F.R. § 73.1 (2018); *see also* Centers for Disease Control and Prevention, *Guidance on the Inactivation or Removal of Select Agents and Toxins for Future Use* (August 2017).

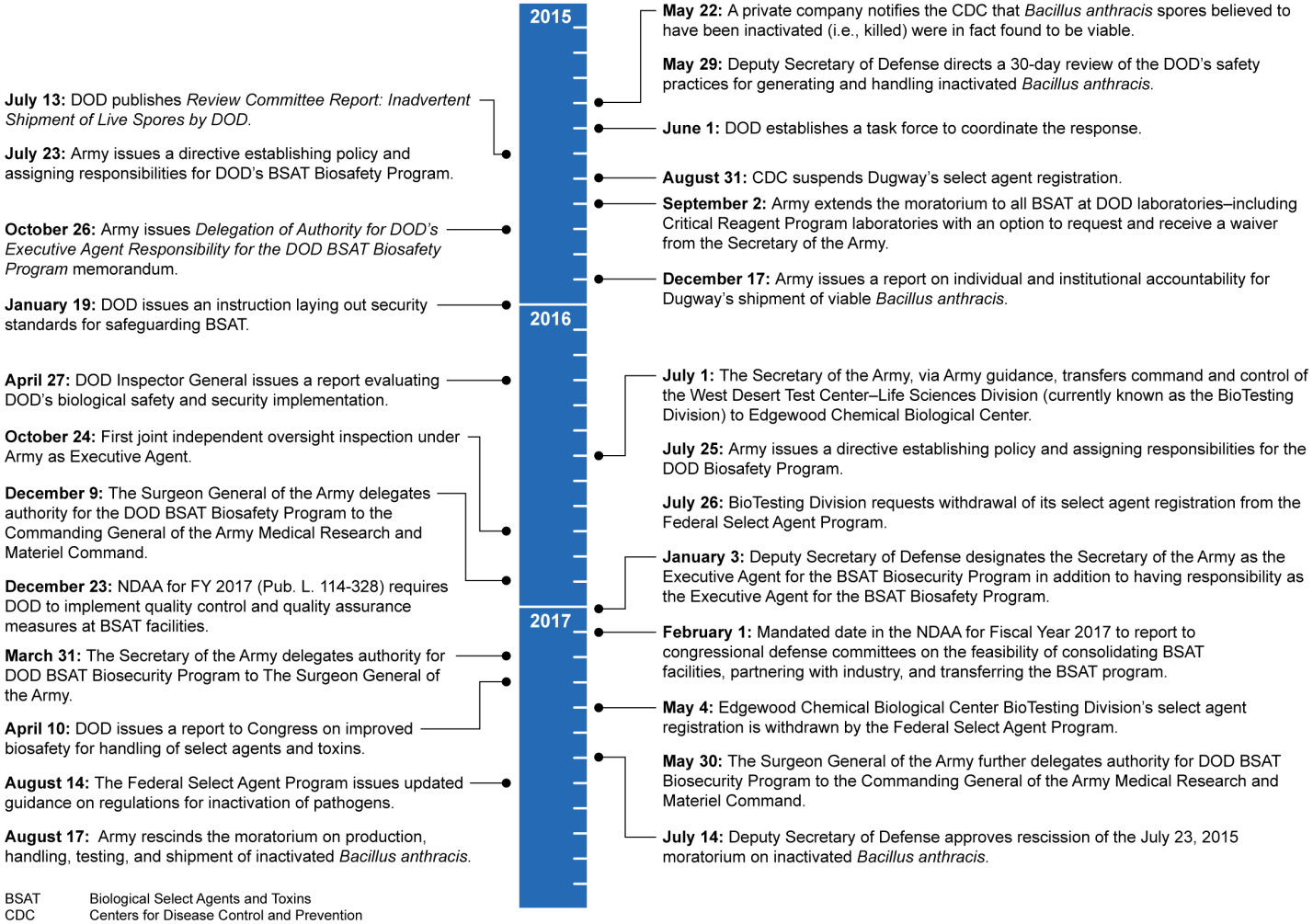
The Army Has Taken Multiple Types of Actions at Dugway Proving Ground to Implement Recommendations from the Army's 2015 Investigation Report

Since 2015, the Army also has taken multiple types of actions specifically at Dugway Proving Ground—including operational, administrative, and personnel actions—to implement the recommendations from the Army's 2015 investigation report. The report made several recommendations for improvements at the BioTesting Division at Dugway Proving Ground. The Army's subsequent Directive 2016-24 assigned responsibility for implementing some of these recommendations and called for additional actions, including reassigning command and control of the division to the Army's Edgewood Chemical Biological Center at Aberdeen Proving Ground, Maryland. According to DOD officials, as part of this action, a new management team was established at the BioTesting Division that includes new managers responsible for quality control and assurance. In addition to hiring personnel, the BioTesting Division established training programs for all laboratory staff, including training sessions on biological safety, for which participants received certification after completing coursework.

In response to the 2015 incident at Dugway Proving Ground, the Centers for Disease Control and Prevention suspended Dugway Proving Ground's BioTesting Division's certificate of registration in accordance with federal select agent regulations in August 2015.[10] In May 2017, DOD's request for withdrawal of the laboratory's registration was approved and remaining BSAT in its possession was either transferred or destroyed. DOD officials explained that the withdrawal of the BioTesting Division's registration has allowed the division time to implement recommendations, modernize and make repairs to laboratories, and retrain personnel without the added burden of continuous inspections. Officials from the BioTesting Division stated that they are in the process of re-registering with the Federal Select Agent Program and are taking a phased approach in anticipation of reaching full operational status in fiscal year 2019. Figure 11 is a timeline of selected actions DOD has taken.

[10] 42 C.F.R. § 73.8 (2018).

Figure 11: Selected Actions Taken by the Department of Defense Following the Inadvertent Shipment of Live Bacillus anthracis (Anthrax) from Dugway Proving Ground from 2015 through 2017



BSAT Biological Select Agents and Toxins
CDC Centers for Disease Control and Prevention
DOD Department of Defense
NDAA National Defense Authorization Act

Source: GAO analysis of documents from Congress, DOD, U.S. Department of Agriculture, and CDC. | GAO-18-422

Because BBPO is focused on broader issues and not just the Army's 2015 investigation report recommendations, BBPO officials have also compiled and consolidated recommendations and actions from multiple reports, including the Army's 2015 investigation report, the DOD Review Committee Report, a DOD Inspector General report, and the NDAA for

Fiscal Year 2017.[11] BBPO officials explained that they developed tasks to operationalize the recommendations and acknowledged that BBPO and the now-terminated General Officers Steering Committee had not yet developed a standardized definition for recommendations deemed complete. BBPO officials told us they consider all of these recommendations to be part of their broader DOD biosafety efforts.

[11]Army, AR 15-6 Investigation Report, *Individual and Institutional Accountability for the Shipment of Viable Bacillus anthracis from Dugway Proving Ground* (Dec. 17, 2015); DOD, *Review Committee Report: Inadvertent Shipment of Live Bacillus anthracis Spores by DOD* (July 13, 2015); DOD Office of the Inspector General, *Evaluation of DOD Biological Safety and Security Implementation* (April 27, 2016); and Pub. L. No. 114-328, § 218 (2016).

Appendix VI: Key Themes and Selected Comments from Staff at Department of Defense BSAT Facilities

As part of our review, we conducted facilitated discussions between September 2017 and November 2017 using a self-selected sample of supervisory and non-supervisory staff at six Department of Defense (DOD) laboratories, five of which currently handle biological select agents and toxins (BSAT). The purpose of the discussions was to better understand the effects of DOD actions on laboratory staff and operations following the 2015 discovery that staff at Dugway Proving Ground had incompletely inactivated *Bacillus anthracis* and subsequently shipped live anthrax to multiple locations. The intent was to obtain the views of those laboratory staff who have and will be implementing recommendations from multiple reports. Using a protocol we developed, one of our analysts facilitated each discussion group by asking a similar set of questions about effects of the DOD response to the 2015 incident at Dugway Proving Ground. Our analysts documented laboratory staffs' comments as closely as possible to the original language used by participants. During subsequent reviews and sorting (coding) of the participants comments, we found that four key themes emerged. Within each of the four themes, our analysts also identified related sub-themes.

For the purposes of selecting individual comments as shown in table 3 below, our analysts considered several factors including clarity and relevance to our study's objectives. Our self-selected convenience sample of laboratory staff provided comments describing the various effects of the 2015 anthrax incident on laboratory staff and operations. We did not verify the factual basis of the laboratory staff comments. Moreover, the comments that we have identified cannot be generalized to all DOD laboratory staff at the six facilities we visited. Table 3 lists the key theme, sub-theme, and selected comments made by laboratory staff during our facilitated discussion groups at each of the six DOD covered laboratories, five of which currently handle BSAT.

Table 3: Selected Comments by Laboratory Staff during Facilitated Discussion Groups from September through December 2017

Key Themes	Sub-themes	Selected Comments by Laboratory Staff
Safety and Risk		
	Safety and Risk	• There is an unwillingness to accept risk. Zero percent risk is not possible when working with biological select agents and toxins (BSAT). The only way to get 0 percent risk when working in a laboratory is not to do any work. At the division level, they are afraid to make decisions. The logic seems to be that you cannot make mistakes if you are not doing research. • Adding new safety procedures is not always helpful and has created redundancies. New safety procedures can also contribute to complacency because people start to rely more on the procedure than professional judgement. • In terms of the culture of complacency concern, I could see how older labs may have that issue (as it develops over time), but we do not have that issue and have always been hyper vigilant and sensitive to safety concerns. The culture at our lab is such that if someone says we need to stop work for safety reasons then we would do it. A big piece of mitigating cultural complacency is having reporting standards. We also have mishap reporting procedures that can be done anonymously so that management is not controlling the reporting. • I feel like the reaction (to the Dugway incident) was overblown and overly harsh. The incident could have been characterized differently. There were gaps in science in terms of the amount of gamma irradiation it takes to achieve zero growth of *Bacillus anthracis* spore. However, before the incident no one was looking into this topic. • At the division level, they are afraid to make decisions. The logic seems to be that you cannot make mistakes if you are not doing research. For example, the Department of Defense wants to exceed what is required in Centers for Disease Control and Prevention guideline, which is not necessary. Also, we are getting dinged on administrative matters that are not safety related. • We felt like the laboratory staff was getting blamed for what someone else did at another base.
Business		
	Cost	• From a resources and regulatory standpoint, validation procedures and costs have increased dramatically. Validation is much more time intensive than pre-2015 before the Dugway incident.
	Funding	• Since Dugway shut down, we are losing work due to the moratorium on inactivated BSAT amounting to around several million dollars in funding.
	Competition	• We are losing capability, in general, while a private competitor is trying to obtain capability.

Key Themes	Sub-themes	Selected Comments by Laboratory Staff
Productivity		
	Administrative Process	• Staff is not getting clear guidance and said it was “death by red tape” and that they were “more afraid of the paperwork than the pathogens.” • For one project that was in collaboration with a university, it took 9 months to get a waiver for the moratorium up to and signed by the Commanding General, U.S. Army Medical Research and Materiel Command. As a result of the approval process taking so long, the project was terminated and we no longer work with that client. • The biggest impact was the shutdown of production work involving inactivated spores so now we have to use live agents, which is actually more dangerous.
	Hiring and Retention	• Edgewood Chemical Biological Center has generated hiring actions and there have been several promotions since it has taken over command and control of the BioTesting Division.
	Shipping	• Also, we are impacted because everyone was getting out of the shipping business and no one will ship inactivated BSAT any longer. FedEx used to ship but now it has to go through military transport. The shipping process is now very expensive and much more complicated. FedEx won’t ship BSAT but they will ship other non-inactivated substances which doesn’t make any sense. • Shipping inactivated BSAT has become a problem. We can no longer use FedEx to ship inactivated material. But it’s ridiculous because the Centers for Disease Control and Prevention can call something a clinical sample and get around this.
Quality of Work		
	Research Quality	• The whole research community has suffered from the lack of inactivated agent production at Dugway Proving Ground. As a result, there has been a movement away from BSAT and toward surrogates to avoid the consequences of inadvertent release. Surrogates may not work for every target and may not work as intended, so surrogates are not a solution for every project.
	Collaboration	• Before there was a lot of stove pipping across the biological safety laboratories and there was the perception that you shouldn’t talk to other laboratories because they could “steal your business.” The creation of the Executive Agent Responsible Official has worked to solve that issue. For example, best practices are shared across laboratories as well as risk assessments and capabilities.
	Communication	• A positive impact of the Dugway incident is that we are sharing best practices across the military service labs. The communication chain across the labs is better, not as isolated. There’s more transparency.

Source: Comments from laboratory staff during GAO’s facilitated discussions at Department of Defense facilities that handle biological select agents and toxins. | GAO-18-422

Appendix VII: Department of Defense Reported Responses to Tasks Required by the NDAA for Fiscal Year 2017

The Department of Defense (DOD) issued a report to the defense congressional committees on April 10, 2017, in response to section 218 of the National Defense Authorization Act (NDAA) for Fiscal Year 2017. As of March 2018, DOD officials stated that the tasks required by the NDAA for Fiscal Year 2017 to study the consolidation of commands, opportunities to partner with industry for the production of biological select agents and toxins (BSAT), and the transfer of BSAT production responsibilities are still ongoing. Table 4 shows the status of DOD's efforts to respond to the tasks required by the NDAA for Fiscal Year 2017.

Table 4: Department of Defense's Reported Responses to Tasks Required by the National Defense Authorization Act for Fiscal Year 2017

Task Required of the Department of Defense (DOD) by the National Defense Authorization Act for Fiscal Year 2017	What DOD Reported It Has Done to Meet the Requirements
Study the feasibility of consolidating covered facilities within a unified command to minimize risk.	In April 2017, DOD reported that it had undertaken a number of assessments to support a future decision on this issue. As of March 2018, Chemical and Biological Defense Program (CBDP) officials stated that DOD has prioritized its current study efforts more broadly on identifying infrastructure requirements to support the entire CBDP Enterprise—of which DOD's biological select agents and toxins (BSAT) infrastructure is just one part. • In August 2015, the Army established a Biosafety Task Force that set up four working groups to develop recommendations and implement changes necessary to ensure the long-term safety and security of BSAT programs. The fourth working group developed a study in December 2015 that initially examined the infrastructure of DOD BSAT facilities, among other things. Part of the role of the working group was to examine alternatives and options for DOD's BSAT community on the optimal distribution of research, development, and production activities. However, because the scope of the working group's study was limited, the Army recommended in February 2016 that additional analysis and study be undertaken before any decision was made to adjust the current BSAT laboratory framework. • In April 2016, the Deputy Assistant Secretary of Defense for Chemical and Biological Defense directed three assessments to examine (1) laboratory overhead costs; (2) the composition and disposition of the Army research, development, testing, and evaluation enterprise; and (3) the core competencies and military service-specific capabilities of the laboratories. • In June 2017, the Defense Threat Reduction Agency completed a study of the core competencies of DOD laboratories that are required to support CBDP's science and technology mission. Officials acknowledged that this study included only five of the six DOD BSAT laboratories, since BSAT laboratory capabilities at the Air Force facility were not yet operational at the time of the review. • DOD officials also identified another study that DOD had under way to review the optimization of the CBDP infrastructure, and which included only three of the six DOD BSAT laboratories due to limited funding. DOD officials estimate that this study will be completed by March 2018.

Task Required of the Department of Defense (DOD) by the National Defense Authorization Act for Fiscal Year 2017	What DOD Reported It Has Done to Meet the Requirements
Study opportunities to partner with industry for the production of BSAT and related services in lieu of maintaining such capabilities within the Department of the Army.	• DOD reported that it has undertaken a number of steps to support a future decision on this issue. DOD officials reiterated that once they complete the CBDP Enterprise-wide study of infrastructure capabilities and capacity, they will then be able to identify any additional opportunities to partner with industry while continuing to look for safe ways to conduct business within the BSAT community. • In August 2015, the Biosafety Task Force's second working group was tasked with examining and managing end-user requirements for BSAT, which could stem from both internal and external partner needs. As noted by the Army, many federal partners, private sector laboratories, and DOD components depend on DOD's ability to provide inactivated BSAT materials to support their capabilities for national security and public safety missions. The working group developed recommendations to the Army, including the development of a centralized system for tracking and maintaining records for transfers of BSAT materials and draft policy language for developing a process to evaluate and approve end-user requirements to provide BSAT or an appropriate alternative to incorporate in an Army directive. • In July 2016, the Army issued a directive for the BSAT Biosafety Program which, among other things, requires The Surgeon General of the Army, as the Executive Agent Responsible Official, to coordinate and collaborate with partners, including industry partners, and provide oversight and governance for the production, distribution, tracking, and evaluation of end-user requirements for BSAT materials. • In April 2017, DOD reported that the Defense Biological Product Assurance Office (DBPAO) within the Joint Program Executive Office for Chemical and Biological Defense—formerly known as the Critical Reagents Program—released two Requests for Information to inform DBPAO's evaluation of the most efficient mechanism to support product development. Specifically, DBPAO contracted for the development of a business case analysis to assess its current business model for production, handling, storage, and distribution of BSAT. • In March 2017, the contractor issued a report on the results of the analysis and recommendations, including a recommendation that DBPAO stop offering inactivated BSAT materials as part of its commercial offerings. The business case analysis also recommended that, among other things, DOD undertake an enterprise-wide analysis of the production, handling, storage, distribution, tracking, and disposition of BSAT-related materials. • In July 2017, the Joint Program Executive Office for Chemical and Biological Defense issued an Acquisition Decision Memorandum[a] approving the selected recommendation for DBPAO to divest all BSAT and non-BSAT inactivated organisms from its portfolio. Officials within the Joint Program Executive Office for Chemical and Biological Defense explained that their decision to divest DBPAO of BSAT allows them to focus on offering their clients safer surrogate alternatives and that clients can now go directly to the military laboratories for any BSAT-related materials they may require.

Task Required of the Department of Defense (DOD) by the National Defense Authorization Act for Fiscal Year 2017	What DOD Reported It Has Done to Meet the Requirements
Study whether operations under the BSAT production program should be transferred to another government or commercial laboratory that may be better suited to execute production for non-Department of Defense customers.	DOD reported that it has undertaken a number of steps to support a future decision on this issue. DOD officials reiterated that once they complete the CBDP Enterprise-wide study of infrastructure capabilities and capacity, they can work to determine whether the BSAT community in particular needs to transfer any part of its production to another entity. • For example, DOD is participating in a government-wide, three-phase assessment that will inform a Federal Experts Security Advisory Panel on the appropriate number of federally funded high-containment laboratories required to possess, use, or transfer BSAT. DOD's participation in the panel will help inform leadership of the critical infrastructure and requirements for DOD BSAT and BSAT-related production operations for both unique DOD and non-DOD customer requirements. DOD officials stated that they have provided information on DOD BSAT infrastructure to the panel and that in November 2017 the panel issued a report determining that DOD's BSAT infrastructure was adequate. However, the panel's 2017 report was based on survey information collected from the military agencies operating DOD's BSAT laboratories, and panelists noted a number of concerns, including that some DOD laboratories may have space that is not fully utilized and the appearance of duplication of research areas in the mission statements of the agencies' laboratories. For this reason, the panel recommended, among other things, that DOD continue to review planned and ongoing research efforts across the BSAT enterprise to minimize any duplication of effort. • DOD's April 10, 2017, report to the congressional defense committees also referred to the business case analysis conducted on behalf of DBPAO and the Biosafety Task Force's fourth working group, which assessed the optimal distribution of research, development, and production activities at the laboratories.

Source: GAO analysis of information provided by DOD. | GAO-18-422

[a]An Acquisition Decision Memorandum is defined as a memorandum signed by the milestone decision authority that documents decisions made as a result of a milestone decision review or other decision or program review.

Appendix VIII: Summary of Selected Federal Panels, Task Forces, and Working Groups Examining Biodefense-Related Issues

Biosafety, biosecurity, and biodefense issues have been a long-standing concern for the nation. The federal government has been examining biosafety, biosecurity, and biodefense issues for over a decade through many voluntary and federally mandated commissions, task forces, and federal panels and working groups. These issues have been reviewed from a variety of perspectives—scientific, regulatory, academic, health, national defense, and homeland security. Table 5 provides a summary of some key recommendations and observations to address biosafety, biosecurity, and biodefense issues and related topics. The Department of Defense (DOD) participated in many of these efforts, some of which are ongoing, including the National Science Advisory Board for Biosecurity and the Federal Experts Security Advisory Panel. Observations represent comments made by individual participants and do not represent organizational recommendations.

Table 5: Summary of Key Recommendations and Observations from Selected Federal Panels, Task Forces, and Working Groups Examining Biosafety, Biosecurity, and Biodefense Issues between 2004 and Present

National Science Advisory Board for Biosecurity (NSABB) (2004 – Present)
Report(s) Issued: • *Addressing Biosecurity Concerns Related to the Synthesis of Select Agents* (2006) • *Proposed Framework for the Oversight of Dual Use Life Sciences Research* (2007) • *Strategic Plan for Outreach and Education on Dual Use Research Issues* (2008) • *Enhancing Personnel Reliability among Individuals with Access to Select Agents* (2009) • *Enhancing Responsible Science: Development of Codes of Conduct for Dual Use Research* (2010) • *Addressing Biosecurity Concerns Related to Synthetic Biology* (2010) • *Strategies to Educate Amateur Biologists and Scientists in Non-life Science Disciplines About Dual Use Research in the Life Sciences (*2011) • *Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility* (2011) • *Framework for Conducting Risk and Benefit Assessments of Gain-of-Function Research* (2015) • *Recommendations for the Evaluation and Oversight of Proposed Gain-of-Function Research* (2016)
Purpose: To provide advice, guidance, and leadership regarding biosecurity oversight of dual use research—biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security.

National Science Advisory Board for Biosecurity (NSABB) (2004 – Present)

Key Recommendations/Observations:

1. The Departments of Health and Human Services and Agriculture should collaboratively develop and disseminate harmonized guidance concerning the select agent regulations with respect to synthetically-derived DNA (deoxyribonucleic acid). (2006)
2. The U.S. government should charge relevant federal agencies, in consultation with outside experts, to develop a process to be used by providers of synthetic DNA for determining the sequences for which to screen. (2006)
3. The U.S. government should foster an international dialogue and collaboration with the goal of developing and implementing universal standards and preferred practices for screening DNA sequences and related matters. (2006)
4. The U.S. government should examine the language and implementation of current biosafety guidelines to ensure that such guidelines and regulations provide adequate guidance for working with synthetically derived DNA and are understood by all those working in areas addressed by the guidelines. (2006)
5. The U.S. government should convene a group of experts from the scientific community to conduct an open and in-depth examination of the select agent classification system to determine if it is possible to reconcile current controls for select agents with the anticipated scientific advances enabled by synthetic genomes. (2006)
6. The current security risk assessment process should be strengthened by identifying potential weaknesses and gaps in the information gathering process, and adjusting the procedures as necessary. (2009)
7. The culture of responsibility and accountability should be enhanced at institutions that conduct select agent research. (2009)
8. The list of select agents and toxins should be reduced or stratified. (2009)
9. When considering a candidate for a position with access to biological select agents and toxins (BSAT), potential employers should explore aspects of the individual's prior work performance that directly relate to issues of reliability. (2011)
10. All institutions conducting BSAT research are recommended to perform a thorough risk assessment of all laboratory protocols involving BSAT prior to the initiation of the protocol or planned research and on an ongoing basis throughout the lifespan of the research project, as appropriate. (2011)

Commission on the Prevention of Weapons of Mass Destruction (WMD), Proliferation, and Terrorism (2007 - 2008)

Report(s) Issued:

World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism (2008)

Purpose: To assess, within 180 days, any and all of the nation's activities, initiatives, and programs to prevent weapons of mass destruction proliferation and terrorism, and provide recommendations to address these threats.

Key Recommendations/Observations:

1. The United States should undertake a series of mutually reinforcing domestic measures to prevent bioterrorism:
   a. conduct a comprehensive review of the domestic program to secure dangerous pathogens,
   b. develop a national strategy for advancing bio-forensic capabilities,
   c. tighten government oversight of high-containment laboratories,
   d. promote a culture of security awareness in the life sciences community, and
   e. enhance the nation's capabilities for rapid response to prevent biological attacks from inflicting mass casualties.
2. The United States must build a national security workforce for the 21st century, including meeting requirements in the National Security Professional Development Implementation Plan to recruit, train, and retain sufficient national security professionals, including at the U.S. national laboratories.

Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight (2007 – 2009)

Report(s) Issued:

Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight (2009)

Purpose: To propose options and recommendations to improve biosafety and biocontainment oversight of research activities at high and maximum containment laboratories given concerns with their growth in numbers.

Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight (2007 – 2009)

Key Recommendations/Observations:

1. Identify or establish a federal entity to coordinate biosafety and biocontainment oversight activities, and to ensure comprehensive and effective federal oversight for all high and maximum containment research facilities and activities in all sectors.
2. Develop a registry of all high- and maximum-containment facilities in the United States.
3. Require that all institutions conducting high- and maximum-containment research designate (1) a senior official with the appropriate knowledge, authority, and accountability who is responsible for institutional compliance with biosafety and biocontainment regulations and guidelines and (2) a credentialed biosafety professional who is responsible for oversight of biosafety and biocontainment programs.
4. Require that, at all institutions conducting high- or maximum-containment research, an appropriately constituted review body performs a thorough risk assessment of all laboratory protocols potentially requiring high or maximum containment.
5. Mandate compliance with federal biosafety and biocontainment guidelines for all high- and maximum-containment research institutions in all sectors.
6. Establish national, position-specific training standards and core competencies in biosafety and biocontainment for all research, managerial, and support personnel at high- and maximum-containment research laboratories in all sectors.
7. Establish a new voluntary, non-punitive incident-reporting system for high- and maximum-containment research laboratories that would ensure the protection of sensitive and private information, as necessary.
8. Develop comprehensive biocontainment guidelines comparable to those of the Biosafety in *Microbiological and Biomedical Laboratories* guidelines to cover research, including high- and maximum-containment research, on plant, livestock, and other agriculturally significant pests and pathogens.
9. Require that all institutions with high- or maximum-containment laboratories ensure proper installation of and preventive and ongoing maintenance programs for biosafety and biocontainment infrastructure and equipment.
10. Develop a mechanism for sharing information and best practices about infrastructure and equipment design, operations, and maintenance among all high- and maximum-containment research facilities.

Defense Science Board Task Force on Department of Defense Biological Safety and Security Program (2008 - 2009)

Report(s) Issued:

Report of the Defense Science Board Task Force on Department of Defense Biological Safety and Security Program (2009)

Purpose: To examine the biological safety, security, and personnel reliability programs of DOD's biological laboratories and compare them with other similar operations in academia, industry, and the federal government.

Key Recommendations/Observations:

1. Conduct cyber red-team reviews of the computer systems at the U.S. Army Medical Research Institute of Infectious Diseases and other DOD laboratories.
2. Make changes to procedures used to monitor activities in DOD laboratories to improve effectiveness without introducing significantly obtrusive measures that are unwarranted by the threat, including retaining video records of laboratory surveillance for a minimum of 1 year.
3. Maintain the use of the Biological Personnel Reliability Program tailored to biodefense work and balance risk from a malevolent insider against the detriment to the laboratory mission, including automated suitability checks.
4. Provide resources for an independent DOD inspection team.
5. Engage with other organizations concerned with biosafety and biosecurity include developing consistency among compliance inspection programs.
6. Review the use of the two-person rule for shipments of BSAT and investigate the potential of tamper-resistant shipment containers.
7. All U.S. DOD bio-containment facilities and their immediate senior commands should develop a risk communication plan and public relations plan to provide for emergency response.

Working Group on Strengthening the Biosecurity of the United States (2009)

Report(s) Issued:

Report of the Working Group on Strengthening the Biosecurity of the United States (2009)

Purpose: As directed by Executive Order No. 13486, Strengthening Laboratory Biosecurity in the United States (Jan. 9, 2009), review and evaluate the efficiency and effectiveness of existing laws, regulations, guidance, and practices relating to physical, facility, and personnel security and assurance at federal and non-federal facilities that possess, manage, research, handle, store, or transport BSAT.

Key Recommendations/Observations:

1. Task the Federal Select Agent Program to develop standard security risk assessment methodology for use at all BSAT facilities.
2. Identify or establish a federal entity to coordinate biosecurity oversight activities, and to ensure comprehensive and effective federal oversight for all select agent research facilities and activities.
3. Develop coordinated training and oversight programs for inspectors from various U.S. government agencies and offices with oversight responsibilities.
4. Provide guidance for and require entities to conduct comprehensive BSAT program reviews and facility inspections.
5. Provide comprehensive guidance on inventory management and recordkeeping requirements, approaches, and templates.
6. Establish a working group that will investigate and establish guidance and training on suitability criteria, above and beyond restricted and potential prohibited categories.
7. Assess the feasibility of a registry or repository containing derogatory information reported by Responsible Officials that can be used, in combination with results of the security risk assessment, for determining whether an individual should be granted BSAT access.
8. Identify a federal agency that will (1) develop guidelines for vetting foreign nationals that require BSAT access and (2) screen foreign nationals according to these newly established criteria.
9. Develop minimum physical security standards based on the risk of the agent or toxin and characteristics of facilities and type of work being done.
10. Task the Transportation Security Administration, in partnership with other U.S. government agencies, to conduct a risk assessment to determine the risk posed by air and ground transportation of BSAT.

Federal Experts Security Advisory Panel (2010 – Present)

Report(s) Issued:

- *Recommendations Concerning the Select Agent Program* (2010)
- *Report of the Federal Experts Security Advisory Panel* (2014)
- *Summary of Findings and Recommendations of the Federal Security Advisory Panel on the Biennial Review of the Select Agents and Toxins List* (2016)
- *An Approach to Determine the Appropriate Number of High-Containment Laboratories: Phase I* (2017)

Purpose: To make recommendations regarding the biosecurity measures of the national Federal Select Agent Program, and evaluate approaches to enhance biosafety and biosecurity in the United States.

Federal Experts Security Advisory Panel (2010 – Present)

Key Recommendations/Observations:

1. Enhance and clarify the security risk assessment process to better assess disqualifiers and vet foreign nationals. (2010)
2. Provide guidance on pre-access suitability assessments of personnel to assist the entity in identifying qualities of suitability for being granted access to BSAT. (2010)
3. Federal partners involved in BSAT security should develop a government-furnished risk management tool for all entities to use as part of their site-specific risk assessment. (2010)
4. Create and strengthen a culture that emphasizes biosafety, laboratory biosecurity, and responsible conduct in the life sciences. (2014)
5. Require all research institutions conducting BSAT research to have an appropriate organizational and governance structure to ensure compliance with biosafety, biocontainment, and laboratory biosecurity regulations and guidelines. (2014)
6. Require that an appropriately constituted and qualified review entity validate local policies, laboratory protocols, and mitigation plans involving inactivation, sterilization, or decontamination of biohazardous materials at research institutions. (2014)
7. Establish a new voluntary, anonymous, and non-punitive incident reporting system for research laboratories that would ensure the protection of sensitive and private information, as necessary. (2014)
8. Carry out a three-phase process to determine the appropriate number of federally funded high-containment U.S. laboratories required to possess, use, or transfer BSAT. (2014)
9. Multiple panelists observed that some DOD laboratories may have high-containment space that is not being fully utilized. DOD should further explore collaborative opportunities with other departments and agencies for work that could be supported at DOD facilities. (2017)
10. Panelists noted the appearance of duplication of research areas in the stated missions of DOD laboratories as they support the diverse missions set by their respective services. To minimize duplication of effort, DOD should continue to review planned and ongoing research efforts across the enterprise. (2017)
11. DOD should engage with other departments and agencies that conduct classified select agent research, and re-evaluate DOD's ability to use contractor laboratories or other established service laboratories, and the assumption that classified research can only be accomplished at DOD-owned facilities. (2017)
12. Multiple panelists pointed out that DOD's planning assumptions appear to be relatively short term (up to 5 years) while a large biocontainment facility project may take a decade or more to complete. It may be beneficial for DOD to consider a longer-term deliberation process for high-containment space needs. (2017)

Blue Ribbon Study Panel on Biodefense (2014 – 2015)

Report(s) Issued:

A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts (2015)

Purpose: To assess gaps and provide recommendations to improve U.S. biodefense.

Key Recommendations/Observations:

1. Establish a Biodefense Coordination Council at the White House led by the Vice President.
2. Develop, implement, and update a comprehensive national biodefense strategy.
3. Prioritize and align investments in medical countermeasures among all federal stakeholders.
4. Establish a national environmental decontamination and remediation capacity.
5. Implement an integrated national biosurveillance capability.
6. Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.
7. Develop and implement a Medical Countermeasure Response Framework.
8. Harden pathogen and advanced biotechnology information from cyber-attacks.
9. Implement military-civilian collaboration for biodefense.
10. Review and overhaul the Federal Select Agent Program.

Fast Track Action Committee on Select Agents Regulation (2014 – 2015)

Report(s) Issued:

Fast Track Action Committee Report: Recommendations on the Select Agent Regulations Based on Broad Stakeholder Engagement (2015)

Purpose: To review the impact that the select agent regulations have had on science, technology, and national security in the United States.

Key Recommendations/Observations:

1. Develop a formal mechanism for issuing, publicizing, and accepting requests for interpretations of the select agent regulations.
2. Develop an approach to improve the consistency of the inspection process across inspectors, inspecting agencies, and inspected sites.
3. Create an expert panel or federal advisory committee to serve as an external group that could share best practices or make recommendations to the Federal Select Agent Program.
4. Establish international engagement to explore harmonization of pathogen security standards and ensure understanding of the rationale for, and implementation of, the select agent regulation—equivalent standards by collaborating foreign governments.
5. Provide better training and guidance for customs inspectors who process BSAT shipments.
6. Consider creating exemptions from certain security regulations for laboratories that retain certain select agents only for the purposes of positive control material availability and quality assurance procedures.
7. Explore the feasibility of establishing a common interface for institutions with respect to personnel vetting and personnel reliability for people with access to chemical, biological, and radiological materials of security concern.
8. Explore the feasibility of adopting a risk-based approach to managing the safety and security oversight of BSAT.

Fast Track Action Committee on Biosafety and Biosecurity (2016 – 2017)

Report(s) Issued:

Fast Track Action Committee Report: Biosafety and Biosecurity (2017)

Purpose: To consider whether and how (1) to bring all U.S. bioscience institutions—or at least all those operating at or above Biosafety Level-3—under federal biosafety regulation and (2) the federal government could adopt a risk-based approach to managing the safety and security oversight of BSAT that did not depend on designating specific agents and toxins.

Key Recommendations/Observations:

1. Consider modifying the scope and extent of Institutional Biosafety Committee activities in order to promote biosafety.
2. Consider pursuing mandatory or voluntary accreditation or peer review of biosafety/biocontainment programs.

Source: GAO review of reports from federal panels and working groups. | GAO-18-422

Appendix IX: Comments from the Department of Defense

ASSISTANT SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

NUCLEAR, CHEMICAL, AND
BIOLOGICAL DEFENSE PROGRAMS

JUL 30 2018

Mr. Joseph W. Kirschbaum
Director, Defense Capabilities and Management
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Kirschbaum:

This is the Department of Defense (DoD) response to the Government Accountability Office (GAO) Draft Report, GAO-18-422, "BIOLOGICAL SELECT AGENTS AND TOXINS: Actions Needed to Improve Management of DOD's Biosafety and Biosecurity Program" dated July 9, 2018 (GAO Code 102093). Detailed comments on the report recommendations are enclosed.

Sincerely,

Guy B. Roberts

Enclosure:
As stated

GAO DRAFT REPORT DATED JULY 9, 2018
GAO-18-422 (GAO CODE 102093)

"BIOLOGICAL SELECT AGENTS AND TOXINS: ACTIONS NEEDED TO IMPROVE MANAGEMENT OF DOD'S BIOSAFETY AND BIOSECURITY PROGRAM"

DEPARTMENT OF DEFENSE COMMENTS TO THE GAO RECOMMENDATION

RECOMMENDATION 1: The GAO recommends that the Secretary of Army should ensure that The Surgeon General of the Army, as the Executive Agent Responsible Official (EARO) for DOD's biological select agents and toxins (BSAT) Biosafety and Biosecurity Program, incorporate into existing processes an approach for assessing how effectively the recommendations from the Army's 2015 investigation report address the original condition and contributing factors that they were intended to resolve.

DoD RESPONSE: The DoD concurs with this recommendation. The DoD has taken steps to implement recommendations from multiple investigation reports and the 2017 National Defense Authorization Act (NDAA) and has a systematic approach to track them through to completion. The DoD will incorporate into existing processes an approach for assessing how effectively the recommendations from the Army's 2015 investigation report address the original condition and contributing factors they intended to resolve. Recommendations that are no longer considered the best option to resolve the original condition will be identified and alternative solutions developed. The DoD monitors effectiveness of the solutions through requirements defined in the Army Directive 2016-24 and its implementation guide; established working groups and councils; and the Joint Inspection Program. The DoD leadership monitors implementation of solutions through EARO and Director of the Army Staff (DAS) updates. Our target date for completing implementation of these actions is September 1, 2019.

RECOMMENDATION 2: The GAO recommends that the Secretary of Army should ensure that The Surgeon General of the Army, as the EARO for DOD's BSAT Biosafety and Biosecurity Program, develops a strategy and implementation plan for the DOD BSAT Biosafety and Biosecurity Program that includes long-term goals, objectives, external factors that can affect goals, use of metrics to gauge progress, an evaluation plan for monitoring goals and objectives, and a time frame for completion.

DoD RESPONSE: The DoD concurs with this recommendation. Though the DoD BSAT Biorisk Program Office (BBPO) has not finalized the strategic plan, the Army Directive Implementation Guide issued by the EARO links guidance with the updated Select Agent Regulations. The Army Directive and Army Directive Implementation Guide establish a near-term strategy. When all elements of the Army Directive are implemented, the BBPO will establish a working group to transition the near-term strategy into a multi-Service document incorporating a long-term vision and strategy. This multi-Service document will codify biosafety and biosecurity initiatives for composite biorisk management. The BBPO will develop

a strategy and implementation plan for the BSAT Biosafety and Biosecurity Programs that includes long-term goals; objectives; external factors that can affect goals; use of metrics to gauge progress; an evaluation plan for monitoring goals and objectives; and a timeframe for completion. Our target date for completing these actions is September 1, 2019.

RECOMMENDATION 3: The GAO recommends that the Secretary of Army should ensure that the Commander of Army Materiel Command establishes measures to prevent the potential risk to independence posed by transferring operational command and control of the BioTesting Division from West Desert Test Center to the Edgewood Chemical Biological Center. Such measures could include, for example, criteria that establish mission requirements for operational test and evaluation for the BioTesting Division, in accordance with DOD and Army regulations, and risk management guidelines to mitigate risks associated with potential conflicts of interest between the Edgewood Chemical Biological Center research and development mission and the BioTesting Division's test and evaluation mission.

DoD RESPONSE: The DoD concurs with this recommendation. The Edgewood Chemical Biological Center (ECBC) is moving operational control of the BioTesting Division from its Research and Test Directorate to the Program Integration Directorate. In addition to previously established guidelines to mitigate potential conflicts of interest, this realignment will ensure the testing division is separated from the group performing the research and development mission at ECBC. The target date for completing the realignment is October 1, 2018.

RECOMMENDATION 4: The GAO recommends that the Secretary of Defense should ensure that the Deputy Assistant Secretary of Defense for Chemical and Biological Defense establishes time frames to complete the study and its evaluations required by the NDAA for Fiscal Year 2017, Section 218(d), regarding the feasibility of consolidating covered facilities within a unified command, opportunities to partner with other industry for the production of BSAT, and transfer of BSAT production responsibilities.

DoD RESPONSE: The DoD concurs with this recommendation. DoD designated an infrastructure manager for the Chemical and Biological Defense Program (CBDP) and initiated an infrastructure management program for the enterprise in accordance with a 2015 GAO recommendation. DoD is currently assessing physical and intellectual infrastructure needs to identify any potential capability gaps or redundancies across the CBDP Enterprise and to support any realignment decisions. DoD expects to provide a final response to Congress on this issue by the end of Fiscal Year 19.

Appendix X: GAO Contact and GAO Acknowledgments

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Staff Acknowledgments

In addition to the contact name above, GAO staff who made key contributions on this report include Mark A. Pross (Assistant Director); Latrealle Lee (Analyst-in-Charge); Amy Bowser; Patricia Farrell Donahue, Ph.D.; Alexandra Gonzalez; Ashley Grant, Ph.D.; Matthew Jacobs; Joanne Landesman; Amie Lesser; Amber Lopez Roberts; Timothy M. Persons, Ph.D.; Bethann Ritter Snyder, and Lillian Yob.

Glossary

assay: A quantitative or qualitative procedure for detecting the presence, estimating the concentration, and/or determining the biological activity of a macromolecule (e.g., an antibody or antigen, molecule, ion, cell, pathogen, etc.). Assays are based on measurable parameters that allow differentiation between sample and control.

biodefense: Prevention, protection against, and mitigations for biological threats that could have catastrophic consequences to the nation.

biological agent: Microorganism (or derived toxin) that causes disease in humans, animals, or plants.

biological weapon: A harmful biological agent used as a weapon to cause death or disease usually on a large scale.

biorisk management: The effective management of risks posed by working with infectious agents and toxins in laboratories; it includes a range of practices and procedures to ensure the biosecurity, biosafety, and biocontainment of those infectious agents and toxins.

biosafety: The combination of practices, procedures, and equipment that protect laboratory workers, the public, and the environment from the infectious agents and toxins used in the laboratory.

biosecurity: The measures taken to protect infectious agents and toxins from loss, theft, or misuse.

biotechnology: The manipulation of living organisms or their components to produce useful usually commercial products.

biological select agents and toxins certified personnel: Personnel certified and cleared to work with biological select agents and toxins.

covered facility: Any facility of the Department of Defense that produces biological select agents and toxins.

decontamination: The removal or count reduction of contaminating pathogens present on an object.

Federal Select Agent Program: A regulatory program established to regulate the possession, use, and transfer of biological select agents and toxins.

high-containment laboratory: Biosafety level (BSL)-3 or 4 facilities in which studies are conducted on a variety of dangerous pathogens and toxins.

inactivation: A procedure to render pathogens as non-toxic while retaining characteristics of interest for future use.

irradiation: A process by which radiation (e.g., ultraviolet light, gamma rays, and X-rays) is used.

nonviable: A pathogen that is no longer capable of growing, replicating, infecting, or causing disease.

protocol: A detailed plan for a scientific procedure.

select agent: A biological agent or toxin that (1) potentially poses a severe threat to public health and safety, animal or plant health, or animal or plant products and (2) is regulated by select agent rules for possession, use, and transfer (7 C.F.R. Part 331 (2018), 9 C.F.R. Part 121 (2018), and 42 C.F.R. Part 73 (2018)).

toxin: The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes (1) any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism or (2) any poisonous isomer or biological product, homolog, or derivative of such a substance.

ultracentrifuge: A high-speed centrifuge able to separate colloidal and other small particles and used especially in determining the sizes of such particles or the molecular weights of large molecules.

validation: For the purpose of inactivation methods, the method must be scientifically sound and produce consistent results each time it is used such that the expected result can be ensured. Methods of validation may include (1) use of the exact conditions of a commonly accepted method that has been validated, (2) a published method with adherence to the exact published conditions, or (3) for in-house methods, validation testing should include the specific conditions used and appropriate controls (from the Federal Select Agent Program).

validated inactivation procedure: A procedure to render a select agent non-viable but which allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use. The efficacy of the procedure is confirmed by demonstrating the material is free of all viable select agents.

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