

# GAO Highlights

Highlights of [GAO-18-422](#), a report to congressional committees

## 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](mailto:KirchbaumJ@gao.gov).

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## BIOLOGICAL SELECT AGENTS AND TOXINS

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

## 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.

United States Government Accountability Office