July 28, 2015

# HIGH-CONTAINMENT LABORATORIES

## Preliminary Observations on Federal Efforts to Address Weaknesses Exposed by Recent Safety Lapses

Highlights of GAO-15-792T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

## Why GAO Did This Study

Recent safety lapses at high-containment laboratories raise questions about how federal departments and agencies manage high-risk biological agents. DOD and CDC both conduct research on high-risk biological agents at their respective laboratories. Biosafety and biosecurity practices in these laboratories are intended to reduce exposure to, and prevent loss, theft, or misuse of, biological agents. CDC regulates the possession, use, and transfer of certain biological agents that pose potentially severe threats to public health under the select agent program.

This statement summarizes (1) preliminary observations from ongoing GAO work on federal laboratories' biosafety and biosecurity policies and practices and (2) GAO's past work on oversight of high-containment laboratories. To conduct ongoing and past work, GAO reviewed documentation and interviewed federal agency officials, including those from DOD and CDC, about policies and procedures for high-containment laboratories; efforts to monitor compliance and evaluate effectiveness of biosafety and biosecurity policies and practices; and the status of federal oversight activities.

## What GAO Recommends

GAO has previously made recommendations to agencies to enhance biosafety and biosecurity. Because this work is preliminary, GAO is making no new recommendations at this time. GAO shared preliminary observations from this statement with DOD and CDC and incorporated comments as appropriate.

View GAO-15-792T. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

## What GAO Found

Recent safety lapses—including shipments of live anthrax bacteria from the Department of Defense (DOD) to U.S. and international laboratories and potential exposures of Centers for Disease Control and Prevention (CDC) laboratory personnel to live anthrax bacteria—have illustrated multiple breakdowns in compliance with established policies and inadequate oversight of high-containment laboratories. In these laboratories, researchers work with potentially high-risk biological agents that may result in serious or lethal infection in humans. Preliminary observations from GAO's ongoing work show that DOD and CDC have begun to address weaknesses in the management of their high-containment laboratories, but their activities have not yet been fully implemented. GAO's ongoing work will include further examination of the status of DOD's and CDC's activities to improve management of high-containment laboratories.

- DOD began taking steps to address weaknesses in its management of high-containment laboratories in 2012 by reviewing and revising biosecurity policies and procedures. According to officials, the revised biosecurity policies will require all DOD laboratories that conduct research with certain high-risk biological agents to submit all inspection reports to senior DOD management, which was not previously required. DOD plans to finalize these policies by September 2015. DOD also plans to make further changes to these policies as a result of its assessment of the May 2015 anthrax incident, after the first set of revisions is finalized. DOD has also begun to track biosafety and biosecurity incidents at the senior department level, such as potential exposures to or misuse of biological agents, which it had not done prior to the May 2015 anthrax incident. DOD officials said the May 2015 incident is the first incident that DOD has tracked at the senior department level.
- CDC also began taking steps to address weaknesses identified in internal and external working group assessments of the June 2014 anthrax incident and other safety incidents but has not yet completed implementing some recommendations intended to improve its laboratory oversight. For example, an internal workgroup recommended that CDC develop agency-wide policies to provide clear and consistent requirements for biosafety for all agency laboratories. In response, CDC developed a specimen transport policy but has not developed other agency-wide policies, such as requirements for laboratory documentation and emergency protocols.

Since 2007, GAO has reported on issues associated with high-containment laboratories and recommended improvements for federal oversight. GAO's prior work recommended the establishment of a single federal entity to (1) conduct government-wide strategic planning for requirements for high-containment laboratories, including assessment of their risks, and (2) develop national standards for designing, constructing, commissioning, operating, and maintaining such laboratories. Federal departments to which GAO's recommendations were addressed agreed with them and have conducted some activities to respond but have not implemented the recommendation to establish a single federal entity with responsibility for oversight of high-containment laboratories.