



Highlights of [GAO-08-108T](#), a testimony before the Subcommittee on Oversight and Investigation, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

In response to the global spread of emerging infectious diseases and the threat of bioterrorism, high-containment biosafety laboratories (BSL)—specifically biosafety level (BSL)-3 and BSL-4—have been proliferating in the United States. These labs—classified by the type of agents used and the risk posed to personnel, the environment, and the community—often contain the most dangerous infectious disease agents, such as Ebola, smallpox, and avian influenza. This testimony addresses (1) the extent to which there has been a proliferation of BSL-3 and BSL-4 labs, (2) federal agencies’ responsibility for tracking this proliferation and determining the associated risks, and (3) the lessons that can be learned from recent incidents at three high-containment biosafety labs. To address these objectives, GAO asked 12 federal agencies involved with high-containment labs about their missions and whether they tracked the number of labs overall. GAO also reviewed documents from these agencies, such as pertinent legislation, regulation, and guidance. Finally, GAO interviewed academic experts in microbiological research.

HIGH-CONTAINMENT BIOSAFETY LABORATORIES

Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States

What GAO Found

A major proliferation of high-containment BSL-3 and BSL-4 labs is taking place in the United States, according to the literature, federal agency officials, and experts. The expansion is taking place across many sectors—federal, academic, state, and private—and all over the United States. Concerning BSL-4 labs, which handle the most dangerous agents, the number of these labs has increased from 5—before the terrorist attacks of 2001—to 15, including at least 1 in planning stage. Information on expansion is available about high-containment labs that are registered with the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture’s (USDA) Select Agent Program, and that are federally funded. However, much less is known about the expansion of labs outside the Select Agent Program, as well as the nonfederally funded labs, including location, activities, and ownership.

No single federal agency, according to 12 agencies’ responses to our survey, has the mission to track the overall number of BSL-3 and BSL-4 labs in the United States. Though several agencies have a need to know, no one agency knows the number and location of these labs in the United States. Consequently, no agency is responsible for determining the risks associated with the proliferation of these labs.

We identified six lessons from three recent incidents: failure to report to CDC exposures to select agents by Texas A&M University (TAMU); power outage at the CDC’s new BSL-4 lab in Atlanta, Georgia; and release of foot-and-mouth disease virus at Pirbright in the United Kingdom. These lessons highlight the importance of (1) identifying and overcoming barriers to reporting in order to enhance biosafety through shared learning from mistakes and to assure the public that accidents are examined and contained; (2) training lab staff in general biosafety, as well as in specific agents being used in the labs to ensure maximum protection; (3) developing mechanisms for informing medical providers about all the agents that lab staff work with to ensure quick diagnosis and effective treatment; (4) addressing confusion over the definition of exposure to aid in the consistency of reporting; (5) ensuring that BSL-4 labs’ safety and security measures are commensurate with the level of risk these labs present; and (6) maintenance of high-containment labs to ensure integrity of physical infrastructure over time.

Summary of Known BSL-4 Labs in the United States by Sector

Sector	Before 1990	1990-2000	2001-Present	Total
Federal government	2	1	6	9
Academic	0	1	3	4
State	0	0	1	1
Private	0	1	0	1
Total	2	3	10	15

Source: GAO analysis based on open source information.

To view the full product, including the scope and methodology, click on [GAO-08-108T](#). For more information, contact Keith Rhodes at (202) 512-6412 or rhodesk@gao.gov.