

GAO Highlights

Highlights of [GAO-14-785T](#), a testimony before the Subcommittee on Oversight and Inspections, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Recent biosecurity incidents—such as the June 5, 2014, potential exposure of staff in Atlanta laboratories at the Centers for Disease Control and Prevention (CDC) to live spores of a strain of anthrax—highlight the importance of maintaining biosafety and biosecurity protocols at high-containment laboratories. This statement summarizes the results of GAO's past work on the oversight of high-containment laboratories, those designed for handling dangerous pathogens and emerging infectious diseases. Specifically, this statement addresses (1) the need for governmentwide strategic planning for the requirements for high-containment laboratories, including assessment of their risks; (2) the need for national standards for designing, constructing, commissioning, operating, and maintaining such laboratories; and (3) the oversight of biosafety and biosecurity at high-containment laboratories. In addition, it provides GAO's preliminary observations on the potential exposure of CDC staff to anthrax. For this preliminary work, GAO reviewed agency documents, including a report on the potential exposure, and scientific literature; and interviewed CDC officials.

What GAO Recommends

This testimony contains no new recommendations, but GAO has made recommendations in prior reports to responsible agencies.

View [GAO-14-785T](#). For more information, contact Nancy Kingsbury at (202) 512-2700 or kingsburyng@gao.gov.

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HIGH-CONTAINMENT LABORATORIES

Recent Incidents of Biosafety Lapses

What GAO Found

No federal entity is responsible for strategic planning and oversight of high-containment laboratories. Since the 1990s, the number of high-containment laboratories has risen; however, the expansion of high-containment laboratories was not based on a government-wide coordinated strategy. Instead, the expansion was based on the perceptions of individual agencies about the capacity required for their individual missions and the high-containment laboratory activities needed to meet those missions, as well as the availability of congressionally approved funding. Consequent to this mode of expansion, there was no research agenda linking all these agencies, even at the federal level, that would allow for a national needs assessment, strategic plan, or coordinated oversight. As GAO last reported in 2013, after more than 12 years, GAO has not been able to find any detailed projections based on a government-wide strategic evaluation of research requirements based on public health or national security needs. Without this information, there is little assurance of having facilities with the right capacity to meet the nation's needs.

GAO's past work has found a continued lack of national standards for designing, constructing, commissioning, and operating high-containment laboratories. As noted in a 2009 report, the absence of national standards means that the laboratories may vary from place to place because of differences in local building requirements or standards for safe operations. Some guidance exists about designing, constructing, and operating high-containment laboratories. Specifically, the Biosafety in Microbiological and Biomedical Laboratories guidance recommends various design, construction, and operations standards, but GAO's work has found it is not universally followed. The guidance also does not recommend an assessment of whether the suggested design, construction, and operational standards are achieved. As GAO has reported, national standards are valuable not only in relation to new laboratory construction but also in ensuring compliance for periodic upgrades.

No one agency is responsible for determining the aggregate or cumulative risks associated with the continued expansion of high-containment laboratories; according to experts and federal officials GAO interviewed for prior work, the oversight of these laboratories is fragmented and largely self-policing.

On July 11, 2014, the Centers for Disease Control and Prevention (CDC) released a report on the potential exposure to anthrax that described a number of actions that CDC plans to take within its responsibilities to avoid another incident like the one in June. The incident in June was caused when a laboratory scientist inadvertently failed to sterilize plates containing samples of anthrax, derived with a new method, and transferred them to a facility with lower biosecurity protocols. This incident and the inherent risks of biosecurity highlight the need for a national strategy to evaluate the requirements for high-containment laboratories, set and maintain national standards for such laboratories' construction and operation, and maintain a national strategy for the oversight of laboratories that conduct important work on highly infectious pathogens.