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HIGH-CONTAINMENT LABORATORIES

National Strategy for Oversight Is Needed

GAO Accountability • Integrity • Reliability

Highlights

Highlights of GAO-09-574, a report to congressional requesters

Why GAO Did This Study

U.S. laboratories working with dangerous biological pathogens (commonly referred to as high-containment laboratories) have proliferated in recent years. As a result, the public is concerned about the oversight of these laboratories. The deliberate or accidental release of biological pathogens can have disastrous consequences.

GAO was asked to determine (1) to what extent, and in what areas, the number of high-containment laboratories has increased in the United States, (2) which federal agency is responsible for tracking this expansion and determining the associated aggregate risks, and (3) lessons learned from highly publicized incidents at these laboratories and actions taken by the regulatory agencies.

To carry out its work, GAO surveyed and interviewed federal agency officials, (including relevant intelligence community officials), consulted with experts in microbiology, reviewed literature, conducted site visits, and analyzed incidents at high-containment laboratories.

What GAO Recommends

GAO is recommending that (1) the National Security Advisor name an entity charged with government-wide strategic evaluation of high-containment laboratories and (2) the Secretaries of Health and Human Services and Agriculture address specific oversight issues regarding high-containment laboratories. The Secretaries of Health and Human Services and Agriculture agreed with our recommendations relevant to them.

View GAO-09-574 or key components. For more information, contact Nancy Kingsbury at (202) 512-2700 or kingsburyn@gao.gov.

What GAO Found

The recent expansion of high-containment laboratories in the United States began in response to the need to develop medical countermeasures after the anthrax attacks in 2001. Understandably, the expansion initially lacked a clear, governmentwide coordinated strategy. In that emergency situation, the expansion was based on individual agency perceptions of the capacity their high-containment labs required as well as the availability of congressionally approved funding. Decisions to fund the construction of high-containment labs were made by multiple federal agencies in multiple budget cycles. Federal and state agencies, academia, and the private sector considered their individual requirements, but an assessment of national needs was lacking. Even now, after more than 7 years, GAO was unable to find any projections based on a governmentwide strategic evaluation of future capacity requirements set in light of existing capacity; the numbers, location, and mission of the laboratories needed to effectively counter biothreats; and national public health goals. Such information is needed to ensure that the United States will have facilities in the right place with the right specifications.

Furthermore, since no single agency is in charge of the expansion, no one is determining the aggregate risks associated with this expansion. As a consequence, no federal agency can determine whether high-containment laboratory capacity may now meet or exceed the national need or is at a level that can be operated safely. If an agency were tasked, or a mechanism were established, with the purpose of overseeing the expansion of high-containment laboratories, it could develop a strategic plan to (1) ensure that the numbers and capabilities of potentially dangerous high-containment laboratories are no greater than necessary, (2) balance the risks and benefits of expanding such laboratories, and (3) determine the type of oversight needed.

Four highly publicized incidents in high-containment laboratories, as well as evidence in scientific literature, demonstrate that (1) while laboratory accidents are rare, they do occur, primarily due to human error or systems (management and technical operations) failure, including the failure of safety equipment and procedures, (2) insiders can pose a risk, and (3) it is difficult to control inventories of biological agents with currently available technologies. Taken as a whole, these incidents demonstrate failures of systems and procedures meant to maintain biosafety and biosecurity in high-containment laboratories. For example, they revealed the failure to comply with regulatory requirements, safety measures that were not commensurate with the level of risk to public health posed by laboratory workers and pathogens in the laboratories, and the failure to fund ongoing facility maintenance and monitor the operational effectiveness of laboratory physical infrastructure.

Oversight plays a critical role in improving biosafety and ensuring that high-containment laboratories comply with regulations. However, some aspects of the current oversight programs provided by the Departments of Health and Human Services and Agriculture are dependent upon entities monitoring themselves and reporting incidents to federal regulators. Since 2001, personnel reliability programs have been established to counter insider risks, but their cost, effectiveness, and impact has not been evaluated.