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HIGH-CONTAINMENT LABORATORIES

National Strategy for Oversight Is Needed

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Mr. Chairman and Members of the Subcommittee

We are pleased to be here to discuss our report on a national strategy for high-containment laboratories that deal with dangerous—pathogens also known as biosafety level-3 (BSL-3) laboratories and biosafety level-4 (BSL-4) laboratories—in the United States, which was released yesterday.¹ The number of high-containment laboratories that work with dangerous biological pathogens have proliferated in recent years. In 2007, we reported on several issues associated with the proliferation of high-containment laboratories in the United States, including risks posed by biosafety incidents that have occurred in the past.² The Federal Bureau of Investigation’s allegation in August 2008 that a scientist at the U.S. Army Medical Research Institute of Infectious Diseases was the sole perpetrator of the 2001 anthrax attacks raised additional concerns about the possibility of insider misuse of high-containment laboratory facilities, material, and technology. The public is concerned about these laboratories because the deliberate or accidental release of biological agents can have disastrous consequences by exposing workers and the public to dangerous pathogens. Highly publicized laboratory errors and controversies about where high-containment laboratories should be located have raised questions about whether the governing framework, oversight, and standards for biosafety and biosecurity measures are adequate.³ In this context, you asked us to address the following questions:⁴

1. To what extent, and in what areas, has the number of high-containment laboratories increased in the United States?
2. Which federal agency is responsible for tracking the expansion of high-containment laboratories and determining the associated aggregate risks?

¹GAO, *High-Containment Laboratories: National Strategy for Oversight Is Needed*, [GAO-09-574](#) (Washington, D.C.: Sept. 21, 2009).

²GAO, *High-Containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, [GAO-08-108T](#) (Washington, D.C.: Oct. 4, 2007).

³G.K. Gronvall et. al., “Letter to Senator Edward Kennedy and Senator Richard Burr,” Center for Biosecurity, University of Pittsburgh Medical Center, March 3, 2009.

⁴The request letter contained several questions. In agreement with our requester, we revised the questions as stated.

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3. What lessons can be learned from highly publicized incidents at high-containment laboratories and actions taken by the regulatory agencies?

To answer these questions, we interviewed federal agency officials as well as experts in microbiology, reviewed literature, conducted site visits, and surveyed 12 federal agencies to determine if they have a mission to track high-containment laboratories in the United States. We also interviewed officials from relevant intelligence agencies to determine if they have a mission to determine insider risks in high-containment laboratories. The expert panel that reviewed this report was comprised of scientists with substantive expertise in microbiological and select agent research and the operation of high-containment laboratories.

We conducted our work from September 2005 through June 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The Number of High-Containment Laboratories Is Increasing in Different Sectors throughout the United States

We found that since 2001, the number of BSL-4 and BSL-3 laboratories in the United States has increased, and this expansion has taken place across federal, state, academic, and private sectors and throughout the United States. Federal officials and experts believe that while the number of BSL-4 laboratories in the United States is known, the number of BSL-3 laboratories is unknown. Information about the number, locations, activities, and ownership is available for high-containment laboratories that are registered with the Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins (DSAT) or the United States Department of Agriculture's (USDA) Animal and Plant Health and Inspection Service (APHIS) select agent programs, but not for those outside the program. The recent expansion of high-containment laboratories in the United States began in response to the need to develop medical countermeasures and better risk evaluations 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 requirements relative to the capacity their high-containment labs required as well as the availability of congressionally appropriated 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.

No Federal Agency Has the Mission to Track the Expansion of All High-Containment Laboratories and Regulate Biosafety in the United States

Currently, no executive or legislative mandate directs any federal agency to track the expansion of all high-containment laboratories. Because no federal agency has the mission to track the expansion of BSL-3 and BSL-4 laboratories in the United States, no federal agency knows how many such laboratories exist in the United States. While there is a consensus among federal agency officials and experts that some degree of risk is always associated with high-containment laboratories, no one agency is responsible for determining, or able to determine, the aggregate or cumulative risks associated with the expansion of these high-containment laboratories. 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.

Lessons Learned from Four Incidents Highlight the Risks Inherent in the Expansion of High-Containment Laboratories

Four highly publicized incidents in high-containment laboratories, as well as evidence in the scientific literature, demonstrate that 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. One of the incidents we reviewed involved the allegation that Dr. Bruce Ivins of United States Army Medical Research Institute for Infectious Diseases was the source of the 2001 anthrax attack. This incident highlights two lessons: (1) An ill-intentioned insider can pose a risk not only by passing on confidential information but also by removing dangerous material from a high-containment laboratory, and (2) it is impossible to have completely effective inventory control of biological material with currently available technologies. It is impossible to know the exact number of bacteria or virus in a laboratory's inventory or working stocks at any specific time. At Fort Detrick, ineffective procedures for the control of inventories and the unlimited use of laboratory facilities allegedly allowed Dr. Ivins the opportunity to pursue his own ends. As the number of high-containment laboratories increases, there will be an increase in the pool of scientists with expertise and, thus,

the corresponding risk from insiders may also increase. It has been suggested that personnel reliability programs would mitigate the insider risk. The National Science Advisory Board for Biosecurity reported that there is little evidence that personnel reliability measures are effective or have predictive value in identifying individuals who may pose an insider risk. Finally, continuity of electrical power is vital for the safe functioning of high-containment laboratories, in particular since maintenance of essential pressure differentials using electrically driven fans provides an important barrier for preventing the uncontrolled release of agents. Lapses in electrical power that occurred at a CDC laboratory raise concerns about standards in high-containment laboratory facility design, management of construction, and operations.

Taken as a whole, these incidents demonstrate failures of systems and procedures meant to maintain biosafety 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.

Conclusions

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 HHS 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 programmatic impact have not been evaluated.

In conclusion, proliferation of high-containment laboratories is taking place in all sectors. Furthermore, since no single agency is in charge of the current expansion, no one is determining the associated aggregate risks posed by the expansion. As a consequence, no federal agency can determine whether high-containment laboratory capacity may now be less than, 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 number and capabilities of potentially dangerous high-containment laboratories are no greater or less than necessary, (2) balance the risks and benefits of

expanding such laboratories, and (3) determine the type of oversight needed.

Such an agency or mechanism could analyze the biothreat problems that need to be addressed by additional BSL-3 and -4 laboratories, the scientific and technical capabilities and containment features that such laboratories need to have, how the laboratories should be distributed geographically, and how the activities of the laboratories would be coordinated to achieve intended goals. The agency or mechanism responsible for overseeing the expansion of high-containment laboratories could also be responsible for coordinating with the scientific community to develop guidelines for high-containment laboratory design, construction, and commissioning and training standards for laboratory workers; providing definitions for exposure; developing appropriate inventory control measures; and providing guidance on the most efficient approach to personnel reliability programs.

Overall, the safety record of high-containment laboratories has been good, although a number of weaknesses have become apparent over time. Consequently, along with expansion there needs to be a commensurate development of both operational and oversight procedures to address known deficiencies and, as far as practicable, proactively evaluate future risks.

Laboratory operators, in collaboration with regulators, need to develop and work through potential failure scenarios and use that information to develop and put in place mechanisms to challenge procedures, systems, and equipment to ensure continuing effectiveness.

Recommendations for Executive Action

To address these issues, we recommended that the National Security Advisor, in consultation with the Secretaries of Health and Human Services (HHS), Agriculture (USDA), Defense (DOD), and Homeland Security (DHS); the National Intelligence Council; and other executive departments as deemed appropriate identify a single entity charged with periodic governmentwide strategic evaluation of high-containment laboratories that will (1) determine

- the number, location, and mission of the laboratories needed to effectively meet national goals to counter biothreats,
- the existing capacity within the United States,
- the aggregate risks associated with the laboratories' expansion, and
- the type of oversight needed

and (2) develop, in consultation with the scientific community, national standards for the design, construction, commissioning, and operation of high-containment laboratories, specifically including provisions for long-term maintenance.

We recommended that the Secretaries of HHS and USDA develop (1) a clear definition of exposure to select agents and (2) a mechanism for sharing lessons learned from reported laboratory accidents so that best practices—for other operators of high-containment laboratories—can be identified.

Should the Secretaries consider implementing a personnel reliability program for high-containment laboratories to deal with insider risk, we recommended that they evaluate and document the cost, effectiveness, and programmatic impact of such a program.

Recognizing that biological agent inventories cannot be completely controlled at present, we also recommended that the Secretaries of HHS and USDA review existing inventory control systems and invest in and develop appropriate technologies to minimize the potential for insider misuse of biological agents.

Agency Comments and Our Evaluation

We obtained written comments on a draft of our report from the Secretaries of HHS and USDA. The Executive Office of the President: National Security Council did not provide comments. HHS and USDA concurred with our recommendations that were directed to them.

Mr. Chairman, this concludes my prepared remarks. I would be happy to respond to any questions that you or other members of the subcommittee may have at this time.

Contact and Acknowledgments

If you or your staffs have any questions about this report, please contact me at (202) 512-2700 or kingsburyn@gao.gov or Sushil K. Sharma, Ph.D., Dr.PH, at (202) 512-3460 or sharmas@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Amy Bowser, George Depaoli, Terrell Dorn, Jeff McDermott, Jean McSween, Jack Melling, Ph.D., Corey Scherrer, Linda Sellevaag, and Elaine Vaurio made key contributions to this testimony.

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