GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

February 25, 2013

Congressional Requesters

Subject: *High-Containment Laboratories: Assessment of the Nation's Need Is Missing*

High-containment laboratories, biosafety level (BSL)-3 and BSL-4 laboratories, are used to (1) develop medical and veterinary countermeasures against biological agents and (2) research the risks these agents pose to human health, animal health, the food supply, and the U.S. economy. In 2009 we reported on the expansion of these laboratories, which began in the 1990s and accelerated after the 2001 anthrax attack.[1] We found that although this expansion was occurring, no single federal agency was responsible for assessing overall laboratory needs.[2] Instead, departments and agencies only assessed laboratory needs that were within the scope of their respective missions. We therefore determined that a national strategy for oversight, including periodic assessments of the nation's need for these laboratories, was called for. We also found that the absence of national standards for laboratory design, construction, commissioning, operations, and maintenance raised concerns and increased the risk of laboratory accidents.

Our 2009 report made two recommendations to the National Security Advisor, located in the Executive Office of the President (EOP), to address these weaknesses.[3] Specifically, we recommended that the National Security Advisor identify a single entity, charged with periodic government-wide strategic evaluation of high-containment laboratories, that will (1) determine (a) the number, location, and mission of the laboratories needed to effectively meet national goals to counter biothreats; (b) the existing capacity within the United States; (c) the aggregate risks associated with the laboratories' expansion; and (d) 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.

---

[1]GAO, *High-Containment Laboratories: National Strategy for Oversight Is Needed,* GAO-09-574 (Washington, D.C.: Sept. 21, 2009). High-containment laboratories include biosafety level (BSL)-3, animal biosafety level (ABSL)-3 laboratories, and BSL-4 laboratories that study agents that have the potential for respiratory transmission and that may cause serious and potentially lethal infections. See also the related GAO products section at the end of this report for a list of reports that represent the body of GAO work on high-containment laboratories.

[2]In 2009 we reported that there were over 240 entities with at least 1,362 BSL-3 laboratories in the United States registered with the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services, and Animal and Plant Health Inspection Service in the Department of Agriculture, under the Federal Select Agent Program. In 2010, 1,495 laboratories were registered with the CDC as cited in Jocelyn Kaiser, "Taking Stock of the Biodefense Boom," *Science*, vol. 333, (Sept. 2, 2011). But this is only an incomplete estimate of the total number of all high-containment laboratories in the United States since there are an undetermined number of laboratories that do not work with select agents.

[3]The National Security Advisor is the head of the National Security Staff.

This report addresses the following questions:

1. What actions have been taken to implement the recommendations made in our 2009 report?

2. To what extent is action still needed concerning (1) an assessment of the nation's need for high-containment laboratories, including their numbers, functions, and research priorities and (2) the development of any national standards for designing, constructing, commissioning, maintaining, and operating high-containment laboratories?

To assess implementation of our 2009 report recommendations, we interviewed officials of the National Security Staff (NSS). We also reviewed documents for evidence of any current assessments of the nation's need, including research priorities and capacity for all high-containment laboratories, and evidence of national standards. To determine if action is still needed, we compared that evidence with the conditions GAO reported on in 2009: no assessment of national capacity to meet national goals and no national standards. The continued absence of such assessment and national standards would be reasons for further action. We interviewed officials in the Office of Science and Technology Policy (OSTP) in the EOP and reviewed documents they identified, as well as others we subsequently identified, including those from the National Academy of Sciences (see enc. I for a complete list of documents reviewed).

We conducted our work from February 2010 through December 2012 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.

Actions Not Yet Taken to Implement GAO's 2009 Recommendations

In accordance with our normal procedures, we sought comments on a draft of our 2009 report, which included our recommendations to the National Security Advisor, from the EOP. However, the EOP did not provide comments on the draft of the report. Subsequent to the report's issuance, a designated representative of the NSS stated that "The NSS has considered the recommendations of the GAO regarding designating a single entity charged with periodic governmentwide strategic evaluation of high-containment laboratories and has determined that it is not in the best interests of U.S. national security to allocate resources in that way." The designated representative of the NSS also did not tell us of any action taken on the recommendations.[4] Subsequently, we asked the NSS, among other things, what criteria the NSS used to determine that designating a single entity was not in the best interests of national security to allocate resources that way. The NSS did not further discuss

[4]We reviewed the President's National Security Strategy (2010); the National Strategy for Countering Biological Threats (November 2009), authored by the National Security Council; Executive Order 13546: Optimizing the Security of Biological Select Agents and Toxins in the United States (2010); and the President's Memorandum on Scientific Integrity (March 2009) and OSTP's subsequent guidance on it and found no evidence of such actions.

its decision making on this issue, but instead suggested that we direct any additional questions concerning high-containment laboratory oversight to the OSTP.

Accordingly, we contacted the OSTP to further discuss our recommendations.[5] In October 2011 and September 2012, OSTP officials told us that while they did not agree with all parts of our recommendations, they were willing to engage us in discussions on how best, from their perspective, to address the 2009 report findings and implement our recommendations. The OSTP initially interpreted our first recommendation as creation of a single entity to conduct strategic evaluations, but we clarified that we were not specifying whether the entity would be conducting or coordinating periodic evaluations of, and the development of national standards for, high-containment laboratories. OSTP officials did not agree that a single entity should be charged with government-wide strategic evaluation of high-containment laboratories. Such an assessment was considered to be unnecessarily broad and cumbersome. However, they did support periodic, government-wide assessments of national biodefense research and development needs, including whether appropriate resources—including high-containment laboratories—meet those research and development needs. According to OSTP officials, they had taken some steps to examine the need for national standards for designing, constructing, commissioning, maintaining, and operating high-containment laboratories.

Full Assessment of Nation's Need for High-Containment Laboratories and Standards Remains

Three years after our 2009 report, a comprehensive assessment of the nation's need for high-containment laboratories, including research priorities and capacity, is still unavailable. In particular, no national entity or working group has published an assessment of the nation's need that cuts across all agencies, universities, and the private sector. Further, there still are no national standards for designing, constructing, commissioning, and operating high-containment laboratories, including provisions for long-term maintenance.

The Nation's Need for High-Containment Laboratories Is Still Unknown

There is still no one agency or group that knows the nation's need for all U.S. high-containment laboratories, including the research priorities and the capacity, number and location, to address priorities. This deficiency may be more critical today than 3 years ago because current budget constraints make prioritization essential. Since the publication of our report in 2009, the number of high-containment laboratories has increased. Although modern high-containment technologies (for example, high-efficiency particulate air [HEPA] filtration) in conjunction with laboratory design have been effective in reducing the level of risk, there is nevertheless some degree of risk associated with design, construction, operations, and maintenance of high-containment laboratories. This was realized following a Centers for Disease Control and Prevention (CDC) power failure incident in Atlanta, Georgia, where no biological agent was released but that showed the difficulties in maintaining biological containment, and a leaky pipe incident in Pirbright, United Kingdom,

[5]Specifically, the OSTP mission is to help coordinate science and technology policy across the government; build partnerships among federal, state, and local governments and the private sector; and develop policies related to science and technology activity. OSTP also coordinates governmentwide policy regarding the biosafety, biosecurity, and biocontainment of high-containment laboratories.

that failed to maintain biological containment.[6] Increasing the number of laboratories also increases the aggregate national risk.

In addition, the current budget constraints may already have affected our national capacity to address certain research priorities. For example, according to a 2012 National Academy of Sciences report, a critical need exists for giving priority to a modern animal biosafety level-4 (ABSL-4) laboratory with large-animal capacity.[7] Such a laboratory would be able to safely research, develop, and test vaccines for catastrophic foreign animal diseases, such as foot-and-mouth disease, and high-risk zoonotic diseases with the potential to severely harm human health. The Department of Homeland Security had stated that its proposed new National Bio- and Agro-Defense Facility laboratory, estimated to cost $1.14 billion to construct, would address that research priority. However, faced with the nation's current budget constraints, achieving that research priority could be in doubt.

No National Standards for Designing, Constructing, Commissioning, Operating, and Maintaining High-Containment Laboratories

We found a continued lack of national standards for the design, construction, commissioning, and operation of high-containment laboratories. These laboratories are expensive to build, operate, and maintain. As we noted in our 2009 report, in the absence of national standards, it is likely that there may be variations resulting from local requirements, but without an underpinning set of standards to ensure safe operations. In the absence of some fundamental criteria, each laboratory can be designed, constructed, and maintained according to local requirements. This will make it difficult to be able to assess and guarantee safety, as we noted in our 2009 report. For example, while investigating a power outage incident in its recently constructed BSL-4 laboratory, the CDC later determined that, some time earlier, a critical grounding cable buried in the ground outside the building had been cut by construction workers digging at an adjacent site. The cutting of the grounding cable, which had hitherto gone unnoticed by CDC facility managers, compromised the electrical system of the facility that housed the BSL-4 laboratory. Given that grounding cables were cut, it is apparent that the building's integrity as it related to adjacent construction was not adequately supervised. CDC officials stated in 2009 that standard procedures under local building codes did not require monitoring of the integrity of the new BSL-4 facility's electrical grounding. This incident highlighted the risks inherent in relying on local building codes to ensure the safety of high-containment laboratories, as there are no building codes and testing procedures specifically for those laboratories.

The Biosafety in Microbiological and Biomedical Laboratories document, often referred to as the BMBL, provides guidance on design, construction, and operations; however, that guidance does not equate to standards that should be adhered to or ways to determine if such standards have been achieved.[8] National standards are valuable not only in relation to

[6]See GAO-09-574 for more information on this incident.

[7]National Research Council, Committee on an Analysis of the Requirements and Alternatives for Foreign Animal and Zoonotic Disease Research and Diagnostic Laboratory Capabilities, *Meeting Critical Laboratory Needs for Animal Agriculture: Examination of Three Options* (Washington, D.C.: National Academies Press, 2012).

[8]Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. (Atlanta, Ga.: December 2009, http://www.cdc.gov/biosafety/publications/bmbl5 (accessed Feb. 19, 2013).

new laboratory construction but also for periodic upgrades. Therefore, national standards would contribute to ensuring that all high-containment laboratories meet minimum acceptable standards. Such standards need not be a constraining "one-size fits all" model, but can inform as to levels of performance to be achieved.

Conclusion

As we demonstrated in our 2009 report, assessment of the nation's need for high-containment laboratories, including research priorities and capacity, is essential. The absence of such an assessment hampers planning for existing and future research priorities and capacity of high-containment laboratories. The OSTP is in a position to assess this need, as well as determine whether and where overlap and gaps exist.[9] OSTP officials are also in a position to coordinate agency efforts, directly or through the efforts of working groups, across the government.

In addition, the cost of building and maintaining high-containment laboratories, combined with the current lack of national standards and the uncertainty about the number of high-containment laboratories needed to address priorities, exposes the nation to risk.

Therefore, the recommendations in our 2009 report are still valid. Modern high-containment technologies have been effective in reducing the level of risk. Nevertheless with the absence of national standards for design, construction, operation, and maintenance of high-containment laboratories, risk remains. Increasing the number of laboratories necessarily increases the aggregate national risk. In view of the inaction to date by the National Security Advisor on our previous recommendations and the potential for the OSTP to take action in its place, we are redirecting our recommendations to the OSTP.

Recommendations for Executive Action

We recommend that the OSTP ensure that periodic assessments of national biodefense research and development needs are conducted. These assessments would include whether appropriate resources, in particular, high containment laboratories, exist to meet those needs. We also recommend that the OSTP examine the need to establish national standards relating to designing, constructing, commissioning, maintaining, and operating high-containment laboratories.

Agency Comments and Our Evaluations

We obtained written comments on a draft of our report from the EOP's OSTP, which are reprinted in enclosure II. OSTP concurred with our recommendations.

OSTP also stated that biodefense research, development, testing and evaluation are crucial to the long-term health and wellness of our population, animals, plants, the environment, and our economy. We agree. In its agency letter OSTP noted four separate actions taken by this administration in support of these efforts, see enclosure II. These actions focus on the

[9]GAO has reported on overlap and duplication in various programs. GAO, *2012 Annual Report*: *Opportunities to Reduce Duplication, Overlap and Fragmentation, Achieve Savings, and Enhance Revenue,* GAO-12-342SP, (Washington, D.C.:Feb. 28, 2012).

work conducted in high-containment laboratories and the agents worked with in these laboratories as opposed to the laboratories themselves. OSTP officials also provided technical comments, which have been addressed in the body of our report as appropriate.

There are two areas in which OSTP disagreed with GAO in its technical comments.

First, OSTP disagreed that there has been an expansion of high-containment laboratories. As there is no reliable source of the total number of high-containment laboratories in the United States, we used the number of high-containment laboratories registered with one federal program, the Federal Select Agent Program, to estimate the number of all high-containment laboratories (see footnote 2). The number of registered high-containment laboratories (BSL-3 and BSL-4) has increased from 1,362 in 2008 to 1,495 in 2010.[10] Even this estimate is an incomplete picture of all the high-containment laboratories, but it is based on the most-credible source.

Second, OSTP also disagreed with our assessment of the increased overall risk associated with the expansion of high-containment laboratories. Officials did not agree that there was an increased risk. Our assessment is based on probability theory, and we make no assumptions about the magnitude (size or extent) of the increase. The risk associated with any single laboratory is non-zero, for example, as laboratory accidents happen. Even where the newer safety controls reduce the risk of an accident for any individual laboratory, and even if the number of accidents at any laboratory is small, when the number of units (laboratories) increases, each laboratory's risk adds to the overall risk of an accident happening nationwide. As laboratories operate independently, the risk is not increased for each laboratory. The risk at each laboratory leads to an overall increased risk with expansion.

As agreed with your office, unless you publically announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Executive Office of the President (EOP) and other interested parties. In addition, this report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff has any questions about this report, please contact me at (202) 512-2700 or kingsburyn@gao.gov. Key contributors to this report were Sushil Sharma, Ph.D., Dr.PH, Assistant Director; Amy Bowser, Penny Pickett, Laurel Rabin, and Elaine Vaurio.

Nancy Kingsbury, Ph.D.
Managing Director
Applied Research and Methods

---

[10]In 2004 the number of laboratories registered with that program was 415, as we noted in GAO-09-574.

List of Requesters

The Honorable Fred Upton
Chairman
The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

The Honorable Joe Barton
House of Representatives

The Honorable Michael Burgess
House of Representatives

The Honorable Greg Walden
House of Representatives

Enclosure I: Documents Reviewed to Identify Actions on GAO's 2009 Recommendations

This is a list of documents we reviewed for evidence of (1) a current assessment of the nation's need, including research priorities and capacity, for all high-containment laboratories and (2) national standards on designing, constructing, commissioning, operating, and maintaining high-containment laboratories.

Centers for Disease Control and Prevention and Association of Public Health Laboratories. "Guidelines for Biosafety Laboratory Competency," *Morbidity and Mortality Weekly Report.* suppl., vol. 60 (April 15, 2011).

Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. Atlanta, Georgia: December 2009. HHS pub. no. (CDC) 21-1112. http://www.cdc.gov/biosafety/publications/bmbl5 (accessed Feb. 19, 2013).

Executive Order No.13546, 75 Fed. Reg. 39,439 (July 8, 2012). Optimizing the Security of Biological Select Agents and Toxins in the United States (July 8, 2012).

National Academy of Sciences and National Research Council, Committee on Anticipating Biosecurity Challenges of the Global Expansion of High-Containment Laboratories. *Biosecurity Challenges of the Global Expansion of High-Containment Laboratories*. Washington, D.C.: National Academies Press, 2012.

National Institutes of Health. *NIH Guidelines for Research Involving Recombinant DNA Molecules,* Washington, D.C.: October 2011.

National Research Council. Committee on an Analysis of the Requirements and Alternatives for Foreign Animal and Zoonotic Disease Research and Diagnostic Laboratory Capabilities. *Meeting Critical Laboratory Needs for Animal Agriculture: Examination of Three Options,* Washington, D.C.: National Academies Press, 2012.

S3: Science, Safety, and Security. www.phe.gov/S3. The Office of Science and Technology Policy's (OSTP) description of the website: "The U.S. Government has developed a new website entitled, S3: Science, Safety, and Security to address biosafety, biosecurity, biocontainment, and biorisk management. The goal of the website is to promote transparency and broader awareness about the evolving nature of biological agents that can be hazardous, and how to handle and use these agents safely and securely. This S3 website will allow the U.S. Government to share policies and best practices relating to biological risk management. The resources provided on the website include information for laboratory personnel who work with potentially hazardous biological agents, their supervisors, the management personnel of the institutions in which they work, policymakers, and the public. The S3 website will be updated and expanded to include more U.S. Government resources and information."

Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight. *Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight.* Washington, D.C.: July 2009. http://www.phe.gov/preparedness/legal/boards/biosafetytaskforce/Pages/default.aspx. (Accessed Feb. 19, 2013).

Enclosure II: Comments from the OSTP

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

January 25, 2013

Dr. Nancy Kingsbury
Managing Director, Applied Research and Methods
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Dr. Kingsbury:

Thank you for the opportunity to review and comment on the GAO's draft report, "High-Containment Laboratories: Assessing the Nation's Need" (GAO-13-466R).

We agree with the final recommendations in the draft report as crafted. However, we did find some errors in the text of the draft, which we have addressed in the enclosed technical report.

Biodefense research, development, testing, and evaluation are crucial to the long term health and wellness of our population, animals, plants, the environment, and our economy. The Administration is proud of the actions it has taken in support of these important endeavors, including:

- In November, 2009, the National Security Council published the *National Strategy for Countering Biological Threats*, which articulates priorities for domestic and international efforts to counter biological threats. Implementation of this Strategy across the Federal government has strengthened our ability to counter biological threats while reducing duplication across government programs.
- In July, 2010, the Administration released Executive Order (E.O.) 13546, *Optimizing Security of Biological Select Agents and Toxins in the United States*, which led to the publication of new Select Agent Regulations in October, 2012[1] that articulate requirements for improved security measures for laboratories and personnel handling biological agents and toxins that pose the greatest health risk to plants, animals, and humans.
- In July, 2011, the National Science and Technology Council Committee on Homeland and National Security chartered the Subcommittee on Biological Defense Research and Development (BDRD), to coordinate and collaborate on defensive research, development, testing, and evaluation addressing biological threats to national security.
- In May, 2012, the BDRD chartered an Interagency Biorisk Management Working Group to coordinate mechanisms for strengthening research laboratory biorisk management (biosafety, biocontainment, and biosecurity) and for promoting outreach and education programs that inform scientists, biosafety professionals, and the public on biorisk management.

1 http://www.selectagents.gov/resources/CDC%20Select%20Agent%20Biennial%20Review%20Final%20Rule%2010%2005%202012.pdf

We look forward to continuing our efforts in this domain and working with you in the future.

Sincerely,

Patricia Falcone

Patricia Falcone, PhD
Associate Director for National Security and
International Affairs

Enclosure

Related GAO Products

Homeland Security: Actions Needed to Improve Response to Potential Terrorist Attacks and Natural Disasters Affecting Food and Agriculture. GAO-11-652. Washington, D.C.: August 19, 2011.

Biological Laboratories: Design and Implementation Considerations for Safety Reporting Systems. GAO-10-850. Washington, D.C.: September 10, 2010.

High-Containment Laboratories: National Strategy for Oversight Is Needed. GAO-09-1045T. Washington, D.C.: September 22, 2009.

High-Containment Laboratories: National Strategy for Oversight Is Needed. GAO-09-1036T. Washington, D.C.: September 22, 2009.

High-Containment Laboratories: National Strategy for Oversight Is Needed. GAO-09-574. Washington, D.C.: September 21, 2009.

Biological Research: Observations on DHS's Analyses Concerning Whether FMD Research Can Be Done as Safely on the Mainland as on Plum Island. GAO-09-747. Washington, D.C.: July 30, 2009.

Biosafety Laboratories: BSL-4 Laboratories Improved Perimeter Security Despite Limited Action by CDC. GAO-09-851. Washington, D.C.: July 7, 2009.

Plum Island Animal Disease Center: DHS Has Made Significant Progress Implementing Security Recommendations, but Several Recommendations Remain Open. GAO-08-306R. Washington, D.C.: December 17, 2007.

Biosafety Laboratories: Perimeter Security Assessment of the Nation's Five BSL-4 Laboratories. GAO-08-1092. Washington, D.C.: September 17, 2008.

High-Containment Biosafety Laboratories: DHS Lacks Evidence to Conclude That Foot-and-Mouth Disease Research Can Be Done Safely on the U.S. Mainland. GAO-08-821T. Washington, D.C.: May 22, 2008.

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.: October 4, 2007.

Biological Research Laboratories: Issues Associated with the Expansion of Laboratories Funded by the National Institute of Allergy and Infectious Diseases. GAO-07-333R. Washington, D.C.: February 22, 2007.

Homeland Security: Management and Coordination Problems Increase the Vulnerability of U.S. Agriculture to Foreign Pests and Disease. GAO-06-644. Washington, D.C.: May 19, 2006.

Plum Island Animal Disease Center: DHS and USDA Are Successfully Coordinating Current Work, but Long-Term Plans Are Being Assessed. GAO-06-132. Washington, D.C.: December 19, 2005.

Homeland Security: Much Is Being Done to Protect Agriculture from a Terrorist Attack, but Important Challenges Remain. GAO-05-214. Washington, D.C.: March 8, 2005.

Combating Bioterrorism: Actions Needed to Improve Security at Plum Island Animal Disease Center. GAO-03-847. Washington, D.C.: September 19, 2003.

Homeland Security: CDC's Oversight of the Select Agent Program. GAO-03-315R. Washington, D.C.: November 22, 2002.

(460612)