United States Government Accountability Office

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

For Release on Delivery
Expected at 10:15 a.m. ET
Wednesday, April 20, 2016

HIGH-CONTAINMENT LABORATORIES

Comprehensive and Up-to-Date Policies and Stronger Oversight Needed

Statement of John Neumann, Director,
Natural Resources and Environment

Marcia Crosse, Director, Health Care

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee:

We are pleased to be here today as you examine the oversight and management of biological agents in federal high-containment laboratories. Researchers in high-containment laboratories work with hazardous biological agents that may cause serious or lethal infection in humans and animals. These agents include the bacteria that cause anthrax, the virus that causes smallpox, and highly pathogenic influenza viruses, all of which have the potential to seriously threaten human and animal health and disrupt the U.S. economy. Laboratories that conduct research on hazardous biological agents are assigned one of four biosafety levels (BSL), with those at BSL-3 and BSL-4 referred to as high-containment laboratories for the purposes of this statement.[1] Eight federal departments and 15 agencies—including the Department of Defense (DOD) and the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services (HHS)—own and operate the federal government's high-containment laboratories.[2] These departments and agencies conduct research to identify and characterize biological threats that pose risks to civilians, servicemembers, agriculture, and wildlife; develop detection and response systems to improve preparedness for a biological attack; test

[1]Each level of containment describes the laboratory practices, safety equipment, and facility safeguards for the level of risk associated with handling particular biological agents. BSL-3 laboratories work with indigenous or exotic agents with known potential for airborne transmission or those agents that may cause serious and potentially lethal infections. BSL-4 laboratories work with exotic agents that pose a high individual risk of life-threatening disease by airborne transmission and for which treatment may not be available. Animal and agricultural laboratories have similar safety designations.

[2]The 8 departments and 15 agencies are DOD and its Air Force, Army, and Navy; HHS and its CDC, Food and Drug Administration (FDA), and National Institutes of Health (NIH); Department of Energy (DOE) and its National Nuclear Security Administration and Office of Science; Department of Homeland Security (DHS); Department of the Interior (DOI) and its Fish and Wildlife Service and U.S. Geological Survey; Department of Veterans Affairs (VA) and its Veterans Health Administration; United States Department of Agriculture (USDA) and its Animal and Plant Health Inspection Service (APHIS), Agricultural Research Service, and Food Safety and Inspection Service; and Environmental Protection Agency (EPA) and its Office of Pesticide Programs. Federal departments have various terms for their component agencies. For example, DOI refers to its agencies as "bureaus." For the purposes of this statement, we refer to the departments' components as "agencies."

evidence to assist law enforcement investigations; and conduct diagnostic testing for human and animal diseases, among other activities.

Federal departments' management of hazardous biological agents in their laboratories is primarily guided by the principles and practices of biosafety and biosecurity, as well as federal regulations governing biological select agents and toxins. The principles and practices of biosafety and biosecurity are outlined in the widely-accepted leading guidance for laboratories, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), published in partnership by CDC and National Institutes of Health (NIH).[3] Select agent regulations govern the possession, use, and transfer of certain hazardous biological agents and toxins—designated as select agents and toxins—that have the potential to pose a severe threat to public, animal, or plant health or to animal or plant products.[4] CDC and the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) regulate facilities that possess, use, or transfer biological select agents and toxins, as part of their responsibilities under the select agent program.[5]

In 2014 and 2015, HHS and DOD reported multiple lapses in laboratory safety that could have exposed personnel and other individuals to hazardous biological agents. These lapses also illustrated multiple breakdowns in compliance with established policies and inadequate oversight, as well as scientific gaps in effective procedures to inactivate hazardous biological agents. For example, in 2014, CDC reported several safety lapses, one of which was also a result of inadequate inactivation

[3]Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. (Washington, D.C.: December 2009). Biosafety practices are intended to reduce or eliminate exposure of individuals and the environment to potentially hazardous biological agents. Biosecurity practices are intended to prevent the loss, theft, release, or misuse of hazardous biological agents and research-related information by limiting access to facilities and this information.

[4]For select agent regulations, see 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73 (2015). Research on select agents and toxins may require BSL-3 or BSL-4 containment.

[5]CDC and APHIS were delegated authority by their respective department secretaries to regulate the use, possession, and transfer of select agents. As part of their regulatory responsibilities, CDC and APHIS conduct inspections of facilities that possess, use, or transfer biological select agents and toxins, as well as other activities.

procedures that potentially exposed personnel to live anthrax bacteria. Other safety lapses occurred at CDC and NIH in 2014. In May 2015, DOD announced that it had inadvertently shipped samples containing live anthrax bacteria to laboratories in the United States and overseas as a result of inadequate procedures to fully inactivate the anthrax samples.[6] HHS and DOD convened workgroups and committees to conduct reviews of the 2014 and 2015 safety lapses identified at their laboratories, and these workgroups and committees made recommendations intended to improve policies and oversight, in addition to other activities. One of CDC's workgroups—an external advisory group—also reviewed the laboratory safety programs at the Food and Drug Administration (FDA) and NIH in 2015 and made recommendations to those agencies.

Our testimony today summarizes our March 2016 report, *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety*, which is being released today.[7] Accordingly, this testimony addresses

1. the extent to which federal departments and agencies have comprehensive and up-to-date policies for managing hazardous biological agents in high-containment laboratories,
2. how federal departments and agencies oversee the management of hazardous biological agents in high-containment laboratories, and
3. the extent to which HHS and DOD have implemented recommendations from their laboratory safety reviews.

This testimony also includes a summary of our report recommendations intended to improve oversight and management of high-containment laboratories.

For our report, we examined the laboratory management policies and oversight activities at the 8 departments and 15 component agencies that

[6]For the purposes of this statement, inactivation is defined as a procedure to render hazardous biological agents unable to cause disease but still useful for research purposes, including, for example, vaccine development.

[7]GAO, *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety*, GAO-16-305 (Washington, D.C.: Mar. 21, 2016).

own and operate the federal government's high-containment laboratories. To determine whether policies were comprehensive, we first identified six policy elements that are key for managing high-containment laboratories and are consistent with federal internal control standards.[8] We interviewed department and agency officials about their policies and oversight. We also obtained and reviewed HHS and DOD planning documents for implementing recommendations from their laboratory safety reviews and interviewed officials about their progress in implementing these recommendations. Additional information on our scope and methodology is available in our report. Our work was performed in accordance with generally accepted government auditing standards.

Most Departments and Agencies Have Policies for Managing Hazardous Biological Agents in High-Containment Laboratories That Are Not Comprehensive or Up to Date

Most of the departments and agencies we reviewed did not have comprehensive policies. We considered a department's policies to be comprehensive if requirements for all six elements we identified as key to managing hazardous biological agents in high-containment laboratories existed in department-level policies or in agency-level policies for each of the department's component agencies. The key policy elements are (1) incident reporting, (2) roles and responsibilities, (3) training, (4) inventory control, (5) inspections, and (6) requiring adherence to, or referencing, the BMBL.[9]

Our review found that most of the 8 departments and 15 agencies had policies for managing hazardous biological agents in high-containment laboratories, but those policies were not comprehensive—that is, they did not contain all six elements or were not applicable to all of a department's or agency's high-containment laboratories. Only one agency—HHS's

[8]GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999), and *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014). GAO/AIMD-00-21.3.1 was effective through the end of fiscal year 2015 (Sept. 30, 2015). GAO-14-704G is the 2014 revision of GAO/AIMD-00-21.3.1 and became effective the first day of fiscal year 2016 (Oct. 1, 2015). Internal control is synonymous with management control and comprises the plans, methods, and procedures used to meet missions, goals, and objectives.

[9]For the incident reporting element, if department-level policies did not contain requirements for reporting incidents to senior department officials, our assessment required agency-level policies to do so.

NIH—had policies that included all six key elements, including reporting incidents to senior department officials. Five departments—DOD, Department of Energy (DOE), Department of Homeland Security (DHS), Environmental Protection Agency (EPA), and USDA—had department-level policies. Ten agencies—DOD's Air Force, Army, and Navy; EPA's Office of Pesticide Programs; HHS's CDC, FDA, and NIH; USDA's APHIS and Agricultural Research Service; and Department of Veterans Affairs' (VA) Veterans Health Administration—had agency-level policies. Department of the Interior (DOI) did not have laboratory management policies at either the department or agency level. Table 1 shows the extent to which the departments and agencies had policies that contained each of the six key elements, as of December 2015, based on our analysis.

Table 1: Summary of Six Elements Key for Managing Hazardous Biological Agents in High-Containment Laboratories in Department and Agency Policies, as of December 2015

Department Agency	Incident reporting	Roles and responsibilities	Training	Inventory control	Inspections	BMBL	Key elements (count)
DHS[a]	●	●	●	◐	●	●	5
DOD	●	●	●	◐	●	●	5
Air Force[a]	○	◐	◐	◐	◐	●	1
Army	●	●	●	◐	●	●	5
Navy	◐	◐	◐	◐	◐	●	1
DOE[a]	●	●	●	●	○	●	5
National Nuclear Security Administration	–	–	–	–	–	–	-
Office of Science	–	–	–	–	–	–	-
DOI	–	–	–	–	–	–	-
Fish and Wildlife Service	–	–	–	–	–	–	-
U.S. Geological Survey	–	–	–	–	–	–	-
EPA	●	●	●	○	●	○	4
Office of Pesticide Programs	○	●	●	○	○	○	2
HHS	–	–	–	–	–	–	-

Department / Agency	Incident reporting	Roles and responsibilities	Training	Inventory control	Inspections	BMBL	Key elements (count)
CDC	○[b]	●	◐	●	◐	●	3
FDA	○	●	●	●	●	●	5
NIH	●	●	●	●	●	●	6
USDA	○	●	●	●	●	●	5
APHIS[c]	○	●	●	○	○	○	2
Agricultural Research Service	●	●	●	○	●	●	5
Food Safety and Inspection Service[a]	–	–	–	–	–	–	-
VA	–	–	–	–	–	–	-
Veterans Health Administration	○	●	●	◐[d]	●	●	4

Legend:

● Policies contained requirement for key element for all high-containment laboratories.
◐ Policies contained requirement for key element only for select agent-registered laboratories.
● Policies required adherence to the BMBL or referenced it as guidance.
○ Policies did not contain key element.
– Department or agency did not have policies.

APHIS	Animal and Plant Health Inspection Service
BMBL	*Biosafety in Microbiological and Biomedical Laboratories*
CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
DOD	Department of Defense
DOE	Department of Energy
DOI	Department of the Interior
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
NIH	National Institutes of Health
USDA	United States Department of Agriculture
VA	Department of Veterans Affairs

Source: GAO analysis of department and agency information. | GAO-16-566T

[a]Departments' and agencies' high-containment laboratories are all select agent-registered laboratories, according to officials.

[b]In July 2015, CDC issued a memorandum to agency personnel that included incident reporting procedures and a risk assessment flow chart for reporting potential incidents in its select agent and infectious disease laboratories, and officials stated that these requirements are available on the agency's internal laboratory safety website. However, CDC has not incorporated these requirements into agency-level laboratory safety policies.

[c]At the time of our review, APHIS was in the process of revising and finalizing its agency-level biosafety policy. APHIS finalized this policy in February 2016, after we completed our analysis, and the revised policy contains new requirements for the key elements of incident reporting, inventory control, inspections, and the BMBL.

[d]According to officials from VA's Veterans Health Administration, the agency's BSL-3 capable clinical laboratory is not permitted to store biological inventory.

We also found that some departments and agencies did not have up-to-date policies for managing hazardous biological agents in high-containment laboratories. Some departments and agencies also lacked general requirements and time frames for reviewing and updating their policies or lacked expiration or recertification dates on their policies. Of the 5 departments and 10 agencies that had policies for managing high-containment laboratories, 2 departments and 5 agencies had not updated all of their policies consistent with their internal review schedules, as of December 2015.[10]

Departments and Agencies Use Inspections as Their Primary Oversight Activity, but Results Are Not Routinely Reported to Senior Officials

We found that the 8 departments and 14 agencies in our review were using inspections or audits as the primary activity to oversee the management of hazardous biological agents in high-containment laboratories, as of December 2015.[11] Some department and agencies were also using additional oversight activities, such as verifying laboratories' inventory of hazardous biological agents and analyzing inspection results and incident reports to identify trends or recurring safety issues. Some departments and agencies—including DOD, HHS's CDC and FDA, and USDA's APHIS were taking various steps to strengthen their inventory controls, verify completion of training, and formalize inspection processes. Table 2 provides an overview of department and agency activities for overseeing the management of hazardous biological agents in high-containment laboratories.

[10]Specifically, DOE and USDA had one or more department-level policies that were not up to date. In addition, DOD's Air Force and Army, HHS's NIH, USDA's Agricultural Research Service, and VA's Veterans Health Administration had one or more agency-level policies that were not up to date. DHS, EPA, HHS's FDA, and USDA's APHIS lacked review requirements and time frames or specific policy expiration dates; these departments and agencies review their policies on an as-needed basis.

[11]We excluded DOE's Office of Science from this part of our review because the agency has not operated its laboratory at a high-containment level since 2006; this exclusion reduced the number of agencies for which we reviewed oversight activities from 15 to 14.

Table 2: Department and Agency Activities Used to Oversee the Management of Hazardous Biological Agents in High-Containment Laboratories, as of December 2015

Department Agency	Routine inspections or audits	Training records review	Inventory verification	Trend analysis of inspection results or incident reports
DHS	✓	✓[a]	✓[a]	✓
DOD	—[b]	—	✓[c]	—
Air Force	✓	✓[a]	✓[a]	✓
Army	✓	✓[a]	✓[a]	✓[d]
Navy	✓	✓[a]	✓[a]	—
DOE	—[e]	—	—	—
National Nuclear Security Administration	✓	✓	✓[a]	✓
DOI	—[e]	—	—	—
Fish and Wildlife Service	✓	✓	✓	—
U.S. Geological Survey	✓	✓[a]	✓[a]	—
EPA	✓	—	—	✓
Office of Pesticide Programs	✓	✓	✓	—
HHS	—	—	—	—
CDC	✓	✓[a]	✓	✓
FDA	✓	✓	✓	✓
NIH	✓	✓[a]	✓[a]	✓
USDA	✓[f]	—	✓	—
APHIS	—[g]	—	✓	✓
Agricultural Research Service	✓	✓[a]	✓	✓
Food Safety and Inspection Service	✓	✓[a]	✓	✓
VA	—	—	—	—
Veterans Health Administration	✓	✓[a]	✓[a]	✓
Departments (count)	**3**	**1**	**3**	**2**
Agencies (count)	**13**	**13**	**14**	**10**

Legend:

✓ Conducted activity

— Did not conduct activity

APHIS	Animal and Plant Health Inspection Service
CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
DOD	Department of Defense
DOE	Department of Energy
DOI	Department of the Interior
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
NIH	National Institutes of Health
USDA	United States Department of Agriculture
VA	Department of Veterans Affairs

Source: GAO analysis of department and agency information | GAO-16-566T

[a]This activity was conducted during regular inspections and audits.

[b]The department delegated responsibility for conducting laboratory inspections to its agencies.

[c]The department assessed its inventory of select agents only; officials said the department has no plans to assess the inventory of non-select agents.

[d]The agency conducted trend analyses of incident reports but did not analyze inspection results.

[e]The department did not conduct formal, periodic laboratory inspections but may evaluate some laboratory activities as part of broader reviews of the overall program under which the laboratory resides.

[f]The department's inspections of high-containment laboratories were primarily focused on security-related issues, such as access to the facility, facility security systems, and security operations and administration.

[g]The agency conducted inspections but not on a routine schedule.

Although many of the departments and agencies were conducting internal inspections and other oversight activities, we found that senior officials at 5 departments and 8 agencies did not routinely receive the results of these laboratory inspections, and senior officials at 4 departments did not routinely receive reports of laboratory safety or security incidents that occurred at agency laboratories, as of December 2015. For example, for internal laboratory inspections, 2 departments and 4 agencies reported the results to senior agency officials but not to senior department officials.[12] Eight agencies did not routinely report the results of these inspections to either senior agency or senior department officials.[13] For inspections conducted by the select agent program, we found similar

[12]These 2 departments and 4 agencies are DOD's Air Force, DOI's Fish and Wildlife Service, EPA and its Office of Pesticide Programs, and USDA and its Agricultural Research Service.

[13]These 8 agencies are DOD's Army and Navy; DOI's U.S. Geological Survey; HHS's CDC, FDA, and NIH; and USDA's APHIS and Food Safety and Inspection Service.

variation in departments' and agencies' routine reporting of the results to senior agency and senior department officials.[14] In addition to inspection results, we found that all 14 agencies reported laboratory safety and security incidents to senior officials within their own agencies, but senior officials at 4 departments—DOD, DOI, HHS, and USDA—did not routinely receive reports of any safety and security incidents that occurred at agency laboratories. DOI, HHS, and USDA either did not have any department policies for laboratory management or policies did not contain incident reporting requirements.

HHS and DOD Have Made Some Progress in Implementing Recommendations from Laboratory Safety Reviews, but Have Not Developed Sufficient Implementation Plans

At the time of our review, HHS and DOD were making progress in implementing recommendations from the laboratory safety reviews they conducted after the 2014 and 2015 safety lapses. However, they had not developed specific time frames for implementing some recommendations. Our report provides additional details, including examples of HHS and DOD recommendations; specific numbers of recommendations that CDC, FDA, and NIH had implemented as of November 2015 (the date of the most recent information available); and additional steps DOD was taking to address weaknesses in laboratory safety. Although CDC and DOD officials told us that they plan to address all of the recommendations from the safety reviews, CDC had not developed time frames for implementing the recommendations from the agency's October 2014 internal working group report.[15] DOD's and Army's implementation plans for the recommendations made by the review committee include time frames for the three overarching areas in which the committee made recommendations—quality assurance, scientific peer review, and program management for inactivation and viability testing of anthrax

[14]Of the departments and agencies that operated select agent-registered laboratories, 5 agencies—HHS's CDC and NIH, USDA's Agricultural Research Service and APHIS, and EPA's Office of Pesticide Programs—told us that the agencies routinely reported the results of select agent inspections to senior agency officials but not to senior department officials. Three agencies—DOI's U.S. Geological Survey, HHS's FDA, and USDA's Food Safety and Inspection Service did not routinely report select agent inspection results to either senior agency or senior department officials. DOD's Air Force, Army, and Navy routinely reported the results of select agent inspections to senior department officials, but Army and Navy did not report these results to senior agency officials.

[15]CDC developed time frames for implementing open recommendations from the external advisory group report and CDC's individual after-action assessments of the three 2014 safety lapses.

bacteria—as well as for the additional tasks assigned to DOD and Army. However, the DOD and Army implementation plans and other planning documents do not include time frames for each of the detailed 19 recommendations in these three areas.

Summary of Recommendations to Improve Oversight and Management of High-Containment Laboratories

Our report made 33 specific recommendations intended to help ensure that all 8 federal departments and 15 agencies we reviewed have comprehensive and up-to-date policies and stronger oversight mechanisms for their high-containment laboratories. For example, we recommended that departments and agencies develop and update policies to include missing policy elements and ensure that oversight activity results are reported to senior agency and senior department officials. We also recommended that CDC and DOD develop plans with time frames for implementing recommendations from the reviews of recent safety incidents. Of the 8 departments to which we made recommendations, 6 (DHS, DOD, DOI, HHS, USDA, and VA) generally agreed with all of our recommendations for them. The remaining 2 departments (DOE and EPA) did not believe that further action was needed to respond to some of the recommendations we made to them, but we maintain that recommended actions are needed to assure that the departments have comprehensive and up-to-date policies and adequate oversight. In March 2016, NIH updated its policy in accordance with the recommendation we made to the agency.

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee, this concludes our prepared statement. We would be pleased to respond to any questions that you may have at this time.

GAO Contacts and Staff Acknowledgments

If you or your staff have any questions about this statement, please contact John Neumann, Director, Natural Resources and Environment at (202) 512-3841 or neumannj@gao.gov; or Marcia Crosse, Director, Health Care at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. GAO staff who made key contributions to this testimony are Mary Denigan-Macauley (Assistant Director); Karen Doran (Assistant Director); Nick Bartine; Colleen Corcoran; Shana R. Deitch; Melissa Duong; Holly Hobbs; and Terrance Horner, Jr.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's website (http://www.gao.gov). Each weekday afternoon, GAO posts on its website newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to http://www.gao.gov and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, http://www.gao.gov/ordering.htm.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

Connect with GAO

Connect with GAO on Facebook, Flickr, Twitter, and YouTube.
Subscribe to our RSS Feeds or E-mail Updates.
Listen to our Podcasts and read The Watchblog.
Visit GAO on the web at www.gao.gov.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Website: http://www.gao.gov/fraudnet/fraudnet.htm
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Katherine Siggerud, Managing Director, siggerudk@gao.gov, (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, DC 20548