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Report to Congressional Requesters

March 2016

HIGH-CONTAINMENT LABORATORIES

Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety

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GAO-16-305

GAO Highlights

Highlights of GAO-16-305, a report to congressional requesters

March 2016

HIGH-CONTAINMENT LABORATORIES

Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety

Why GAO Did This Study

Safety lapses at federal high-containment laboratories in 2014 and 2015 raised concerns about federal departments' oversight of these laboratories. These laboratories work with hazardous biological agents to develop measures to protect public and animal health and the food supply against these agents. GAO was asked to review oversight at federal high-containment laboratories.

This report examines (1) the extent to which federal agencies have comprehensive and up-to-date policies for managing biological agents in these laboratories, (2) how they oversee laboratories, and (3) the extent to which HHS and DOD have implemented recommendations from laboratory safety reviews. GAO assessed policies and oversight activities at 8 departments and their 15 component agencies that own and operate high-containment laboratories against federal internal control standards and program management leading practices, reviewed plans for implementing laboratory safety recommendations, and interviewed federal officials.

What GAO Recommends

GAO is making 33 recommendations, including that departments develop and update policies to include missing elements, ensure that oversight activity results are reported to senior officials, and develop plans with time frames for implementing safety recommendations. Six departments generally agreed with all recommendations; two departments stated that no further action was needed for some of them. As discussed in the report, GAO maintains that these actions are needed.

View GAO-16-305. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov or John Neumann at (202) 512-3841 or neumannj@gao.gov.

What GAO Found

Most of the 8 departments and 15 agencies that GAO reviewed had policies that were not comprehensive, and some departments and agencies had policies that were not up to date. Specifically, policies at 5 departments and 9 agencies were not comprehensive because they did not contain all six elements that GAO identified as key for managing biological agents in high-containment laboratories. These elements are incident reporting, roles and responsibilities, training, inventory control, inspections, and requiring adherence to or referencing leading laboratory safety guidance. Three of the 8 departments and 5 of the 15 agencies did not have policies. In addition, as of December 2015, 2 departments and 5 agencies did not have up-to-date policies. Comprehensive policies that contain all six key elements and that are reviewed and updated regularly would help departments reduce the risk of mismanaging hazardous biological agents and ensure that their policies convey consistent requirements for oversight, reflect current guidance, and address emerging threats.

The departments and agencies GAO reviewed were primarily using inspections to oversee their high-containment laboratories, but some of them were not routinely reporting inspection results, laboratory incidents, and other oversight activities, such as trend analyses, to senior officials. Specifically, 3 of the 8 departments and 13 of the 14 agencies that were operating high-containment laboratories at the time of GAO's review conducted routine laboratory inspections. Of those departments and agencies that routinely inspected laboratories, 1 department and 5 agencies did not conduct trend analyses of inspection results; senior officials at 5 departments and 8 agencies did not routinely receive inspection results; and senior officials at 4 departments did not routinely receive incident reports. These departments and agencies typically did not report this information because there was no requirement for them to do so. Routinely analyzing inspection results and incident reports and sending this information to senior officials—consistent with federal internal control standards for monitoring—would help them identify laboratory safety trends, determine whether safety lapses reflect systemic issues, and make necessary improvements.

The Department of Health and Human Services (HHS) and Department of Defense (DOD) had a number of serious laboratory safety lapses in 2014 and 2015 and were making progress in implementing recommendations from the reviews of these lapses. As of November 2015, HHS agencies—the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA)—reported implementing 91 and 6 recommendations, respectively, and were taking steps to implement others, and the National Institutes of Health (NIH) reported implementing all of its recommendations. DOD reported implementing one recommendation from its review and was taking steps to implement others. HHS and DOD have developed plans to track implementation of these recommendations, but CDC's, DOD's, and Army's plans lacked some implementation time frames. Plans that include time frames are consistent with federal internal control standards and leading practices for program management and would give HHS and DOD better assurance that they can implement these recommendations in a timely manner and assess their progress in doing so.

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Abbreviations

APHIS	Animal and Plant Health Inspection Service
BMBL	*Biosafety in Microbiological and Biomedical Laboratories*
BSL	biosafety level
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

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
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Congressional Requesters

The United States faces current and emerging threats to public and animal health, the food supply, and the economy from the release of hazardous biological agents. Such agents may include *Bacillus anthracis*, the bacterium that causes anthrax; Variola virus, the virus that causes smallpox; and other naturally-occurring or emerging infectious disease agents, such as highly pathogenic influenza viruses that cause influenza in humans and animals.[1] To address these threats, federal departments own and operate laboratories to identify the characteristics of these agents and develop countermeasures to mitigate or prevent illness or death.[2] 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 report.[3]

In 2014 and 2015, two federal departments reported multiple lapses in laboratory safety that could have exposed personnel and other individuals to hazardous biological agents. For example, within the Department of Health and Human Services (HHS), the Centers for Disease Control and

[1]According to the Centers for Disease Control and Prevention (CDC), an emerging infectious disease is a disease whose incidence in humans has increased in the past two decades or threatens to increase in the near future.

[2]Researchers in these laboratories may also be at risk of accidental exposure to the hazardous biological agents with which they work.

[3]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. The designations of animal BSL-3 and 4 are used for laboratories that work with animals infected with indigenous or exotic agents. The term BSL-3 Agriculture is used to describe laboratories where studies are conducted on agents of high consequence to agriculture employing large or loose-housed animals. For the purposes of this report, we are using the term high-containment laboratories to refer to all laboratories at designated safety levels 3 and 4, regardless of whether they are animal, agriculture, or human health laboratories.

Prevention (CDC) reported an incident in June 2014 that had the potential to expose laboratory personnel to live anthrax bacteria, and in July 2014, boxes containing decades-old vials of smallpox—some of which contained live virus—and other hazardous biological agents were found in a storage space of a Food and Drug Administration (FDA) laboratory on the National Institutes of Health (NIH) campus. In May 2015, the Department of Defense (DOD) reported safety lapses at one of its high-containment laboratories stemming from inadequate procedures to fully inactivate anthrax that resulted in DOD shipping live anthrax to other laboratories.[4]

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 NIH.[5] 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. In addition, certain hazardous biological agents and toxins are subject to specific rules and regulations. 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.[6]

[4]For the purposes of this report, 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 and diagnostic development.

[5]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). In addition to the BMBL, certain laboratory research on biological agents is subject to additional NIH oversight. See Department of Health and Human Services, National Institutes of Health, *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (Bethesda, Md.: November 2013).

[6]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.

The 2014 and 2015 safety lapses illustrated multiple breakdowns in compliance with established policies and inadequate oversight, as well as scientific gaps in effective procedures to inactivate hazardous biological agents. These safety lapses raised questions about how federal departments and agencies manage hazardous biological agents at their high-containment laboratories, and led to several federal government reviews of laboratory programs.

- **White House review.** In August 2014, the White House urged all federal departments and agencies that possess, use, or transfer select agents and toxins to conduct a "safety stand-down" to inventory their laboratories and also established a federal review to identify needed improvements to biosafety and biosecurity practices.[7] In October 2015, the White House issued a report on the results of this review that included recommendations for enhancing biosafety and biosecurity for those entities that conduct research using select agents and toxins.[8] In addition, the report stated that while its findings were specific to select agents and toxins, they should also be applied to any biological agent that could pose a serious threat to public health or agriculture.

- **HHS reviews.** In 2014 and 2015, HHS's component agency, CDC, conducted reviews of the July 2014 anthrax safety lapse and other individual laboratory safety lapses. CDC also conducted a review of its laboratory safety program and convened an external advisory

[7]The White House, "Enhancing Biosafety and Biosecurity in the United States," (Washington, D.C.: Aug. 18, 2014).

[8]The White House, "Next Steps to Enhance Biosafety and Biosecurity in the United States," (Washington, D.C.: Oct. 29, 2015). The White House recommendations highlighted the need for a transparent U.S. laboratory system and called for identifying an approach to determine the appropriate number of high-containment laboratories that conduct work on select agents and toxins, along with improved incident reporting and accountability and inventory management and control. If carried out, the White House's call for identifying an approach to determine the appropriate number of select agent-registered high-containment laboratories will, in part, effectively implement our 2009 recommendation that the National Security Advisor, in consultation with relevant department secretaries, identify a single entity charged with periodic government-wide strategic evaluation of high-containment laboratories to determine the number, location, and mission of the laboratories needed to effectively meet national goals to counter hazardous biological agents. GAO, *High-Containment Laboratories: National Strategy for Oversight Is Needed*, GAO-09-574 (Washington, D.C.: Sept. 21, 2009). We did not examine the status of efforts to implement the White House's recommendations in this review.

group that also conducted reviews of CDC's, FDA's, and NIH's laboratory safety programs. CDC and the external advisory group issued reports on the results of these reviews, which included recommendations to improve the agencies' laboratory biosafety programs.

- **DOD review.** In May 2015, DOD convened a committee to conduct a comprehensive review of procedures, processes, and protocols in place for inactivating live anthrax spores across Army and Navy laboratories and issued a report on its results in July 2015, which included recommendations to enhance laboratory protocols and safety.

Congress has also examined the management of hazardous biological agents in high-containment laboratories.[9]

You asked us to examine federal protocols and oversight for the biosafety and biosecurity of hazardous biological agents. This report 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 laboratory safety reviews that are intended to improve their management of hazardous biological agents in high-containment laboratories.

As you requested, we also provide further information in appendix I on FDA's and NIH's oversight mechanisms in place specifically during the 2014 smallpox safety incident.

To determine the extent to which federal departments and agencies had comprehensive and up-to-date policies for managing hazardous biological

[9]*Review of CDC Anthrax Lab Incident*, Before the Subcomm. on Oversight and Investigations, H. Comm. on Energy and Commerce, 113th Cong. (2014), and *Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax*, Before the Subcomm. on Oversight and Investigations, H. Comm. on Energy and Commerce, 114th Cong. (2015).

agents in high-containment laboratories, we identified the 8 federal departments and their 15 component agencies that owned and operated all of the government's high-containment laboratories (BSL-3, BSL-4, or both).[10] We obtained their policies that were generally related to biosafety and biosecurity in high-containment laboratories between February 2015 and December 2015. We assessed whether these policies specifically addressed the management of hazardous biological agents and applied to high-containment laboratories, and we excluded policies that we determined were not specific to managing hazardous biological agents in high-containment laboratories.[11] To examine whether these policies were comprehensive, we first identified six elements that are key for the management of high-containment laboratories and are consistent with federal standards for internal control—specifically the standards for control environment, control activities, monitoring, and information and communications.[12] These six key elements were also identified as areas of concern in the safety lapses of 2014 and 2015 and are identified in the

[10]These federal departments and their component agencies are DOD and its departments of the Army, Navy, and Air Force; HHS and its CDC, FDA, and 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; Environmental Protection Agency (EPA) and its Office of Pesticide Programs; and United States Department of Agriculture (USDA) and its Animal and Plant Health Inspection Service (APHIS), Agricultural Research Service, and Food Safety and Inspection Service. Federal departments have various terms for their component agencies. For example, DOI refers to its agencies as "bureaus." For the purposes of this report, we refer to the departments' components as "agencies."

[11]For example, some departments and agencies provided policies for broad occupational safety and health programs or policies for employees to obtain identification badges to enter federal facilities. We excluded these, and similar policies, because they were not specific to managing biological agents in high-containment laboratories.

[12]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. Federal internal control standards for control environment and control activities state that management is responsible for developing the detailed policies, procedures, and practices to fit their agency's operations and call for appropriate lines of reporting. The control standard for monitoring calls for assessing the quality of performance over time. The control standard for information and communications calls for information to be communicated to management within a time frame that enables them to carry out their responsibilities.

BMBL—the leading biosafety guidance—as important for management oversight of biosafety and biosecurity at high-containment laboratories. We then assessed whether all six key elements were contained in either department-level policy or in each of a department's component agencies' policies. (For more information about the six key policy elements, their description, and the sources we used to identify them, see app. II.) To determine whether departments' and agencies' policies were up to date, we evaluated whether their policies had been updated according to their own written requirements for reviewing and updating policies. We also interviewed officials from each of the 8 departments and 15 agencies to obtain additional information about department and agency policies.

To determine how federal departments and agencies oversee the management of hazardous biological agents in high-containment laboratories, we reviewed available department and component agency documents that outlined requirements and processes related to oversight activities, and interviewed department and agency officials to obtain information on their oversight activities in practice as of December 2015.[13] We excluded DOE's Office of Science from this part of our review, as the agency has not operated its laboratory at a high-containment level since 2006, which reduced the number of agencies for which we reviewed oversight activities to 14.[14] We compared departments' and agencies' oversight activities with the federal internal control standard for monitoring, as well as with department and agency policies.[15] Generally, we considered the oversight activities to be in accordance with internal controls if either a department or each of its component agencies conducted the activities. We conducted site visits to three department and component agency locations with BSL-3 and BSL-4 laboratories to observe laboratory and oversight activities in practice. In determining which locations to visit, we considered (1) the number of laboratories

[13]This report examines the overall oversight activities conducted by the 8 departments and 15 agencies in our review for their high-containment laboratories regardless of their select agent registration status and does not examine these departments' and agencies' compliance with select agent regulations.

[14]According to officials from DOE's Office of Science, although there are no immediate plans to conduct BSL-3 work at its laboratory, the agency plans to maintain BSL-3 capability at this laboratory should the need to work with hazardous biological agents arise in the future.

[15]GAO/AIMD-00-21.3.1 and GAO-14-704G. The internal control standard for monitoring calls for agencies to assess the quality of performance over time and ensure that the findings of audits and other reviews are promptly resolved.

owned by each department and component agency, (2) the type of laboratory (human or animal), and (3) whether more than one department operates laboratories at the same site. Based on these factors, we selected three locations for our site visits—CDC laboratories in Atlanta, Georgia; United States Department of Agriculture (USDA) laboratories in Ames, Iowa; and the National Interagency Biodefense Campus (laboratories of DOD's departments of the Army and Navy, USDA's Agricultural Research Service, CDC, Department of Homeland Security, and NIH) at Ft. Detrick in Frederick, Maryland.

To determine the extent to which HHS and DOD have implemented recommendations from laboratory safety reviews, we reviewed HHS component agency—CDC, FDA, and NIH—and DOD reports and after-action assessments from their reviews of the 2014 and 2015 safety lapses to identify any recommendations intended to improve or enhance their management of hazardous biological agents in high-containment laboratories. We obtained and analyzed CDC, FDA, NIH, and DOD plans for addressing and implementing these recommendations to determine whether HHS and DOD had made progress in implementing recommendations and whether the plans contained time frames for implementing them as of November 2015 for HHS and December 2015 for DOD (the date of the most recent information available for each department). We compared agency plans to the federal internal control standards for control activities and monitoring and with leading practices identified in the Project Management Institute's *The Standard for Program Management*—which calls for the development of timelines and milestones as program management leading practices—to determine whether federal agencies have appropriate controls in place to oversee the implementation of the recommendations.[16]

To provide information on the oversight mechanisms in place at HHS component agencies, FDA and NIH, during the 2014 smallpox incident described in appendix I, we obtained and reviewed FDA and NIH laboratory inspection checklists and protocols in place during the smallpox incident and any changes made to these checklists and protocols as a result of the incident. We interviewed NIH officials to assess whether and how NIH inspectors used results of prior inspections to inform current and future inspections and communicated inspection

[16]See GAO/AIMD-00-21.3.1 and GAO-14-704G and the Project Management Institute, *The Standard for Program Management*, 3rd ed. (Newton Square, Pa.: 2013).

results to FDA, including the discovery of vials containing smallpox and other select agents. We also interviewed FDA and NIH officials to obtain information on how the agencies coordinated with each other to identify and resolve deficiencies in inspection and inventory management protocols and made any changes to address these deficiencies.

We conducted this performance audit from February 2015 to March 2016 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.

Background

Federal Roles and Responsibilities

Many federal departments and agencies own and operate high-containment laboratories in the United States and abroad. See table 1 for the research responsibilities of these departments' and agencies' high-containment laboratories.

Table 1: Research Responsibilities of Federal Department and Agency High-Containment Laboratories

Department / Agency	Research responsibilities of high-containment laboratories
DHS	Conducts research to support bioforensic operations and biological threat characterization and foreign animal disease diagnostics and vaccine development.
DOD	
Air Force Army Navy	Conducts and supports research on detection, identification, and characterization of biological threats that pose risks to servicemembers and the development of medical countermeasures for those threats.
DOE	
National Nuclear Security Administration	Conducts research to develop detection and response systems to improve preparedness for a biological attack.
Office of Science	Conducts experiments with hazardous biological agents, such as human, animal, or plant viruses and toxins, to understand basic biological, chemical, and physical processes.
DOI	
Fish and Wildlife Service	Conducts testing of evidence to assist with law enforcement investigations of crimes against wildlife.

Department Agency	Research responsibilities of high-containment laboratories
U.S. Geological Survey	Conducts diagnostic investigations of wildlife deaths, research to characterize emerging and other priority wildlife pathogens, susceptibility testing of terrestrial and aquatic wildlife for emerging and invasive pathogens, and offers disease consultation services to external partners.
EPA	
Office of Pesticide Programs	Conducts applied research on methods used to evaluate the efficacy of public health antimicrobial products.
HHS	
CDC	Conducts research to detect, identify, and characterize hazardous biological agents of public health importance.
FDA	Conducts research to support the evaluation and regulation of medical, food, and tobacco products, including testing the safety, toxicity, and efficacy of human and animal drug products.
NIH	Conducts internal biomedical research, in addition to providing funding to external partners to conduct biomedical research.
USDA	
APHIS	Conducts diagnostic testing for domestic and foreign animal diseases and plant pests and diseases.
Agricultural Research Service	Conducts basic and applied research on high-priority livestock diseases, among other diseases.
Food Safety and Inspection Service	Conducts diagnostic testing to identify potential foodborne hazards, estimate risk to human health, and respond to threats to the food supply.
VA	
Veterans Health Administration	Conducts diagnostic testing and research on health issues at its VA medical center laboratories.

Legend

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-16-305

As part of their oversight responsibilities under the federal select agent program, CDC and the Animal and Plant Health Inspection Service (APHIS) regulate facilities—including conducting inspections and other activities—that possess, use, or transfer biological select agents and

toxins, which have the potential to pose a severe threat to public, animal, or plant health or to animal or plant products.[17]

Laboratory Safety Lapses and Reviews

In addition to the 2014 anthrax and smallpox safety lapses at CDC and NIH, respectively, CDC and DOD reported other laboratory safety lapses. Specifically, CDC reported two other incidents in 2014 that had the potential to expose laboratory personnel to highly pathogenic avian influenza and live Ebola virus. In July 2014, CDC also reported that at least four additional safety lapses had occurred at its high-containment laboratories in the past 10 years, all of which were the result of improperly inactivated hazardous biological agents. (See app. III for a timeline of the CDC safety lapses and federal assessments of these lapses.) During its investigation of the May 2015 anthrax safety lapse, DOD confirmed that safety lapses at one of its high-containment laboratories as a result of improper inactivation of hazardous biological agents had occurred for as many as 10 years prior to the discovery of improper anthrax inactivation in 2015.

HHS and DOD have conducted reviews of the 2014 and 2015 safety lapses identified at their laboratories that contained recommendations to enhance or improve policies and oversight, in addition to other agency activities.

HHS Laboratory Safety Reviews

In 2014 and 2015, HHS conducted reviews of its laboratory safety programs at CDC, NIH, and FDA.

- **CDC after-action assessments.** CDC conducted after-action assessments of the individual anthrax, avian influenza, and Ebola safety lapses and issued reports on these assessments, all three of

[17]CDC and APHIS were delegated authority by their respective department secretaries to regulate the use, possession, and transfer of select agents. As part of that oversight, CDC and APHIS maintain a list of select agents and toxins, which they must review and update at least every 2 years. Generally, entities (including federal agencies and private institutions) and individuals that possess, use, or transfer these select agents must register with CDC or APHIS and must renew their registration every 3 years. CDC or APHIS conducts an on-site inspection before issuing a new certificate of registration or renewing an existing registration. 42 C.F.R. §§ 73.7(f) & 73.18(b); 9 C.F.R. §§ 121.7(f) & 121.18(b); 7 C.F.R. §§ 331.7(f) & 331.18(b) (2015). CDC and APHIS may also conduct interim inspections, such as annual inspections, to assess compliance with select agent regulations.

which contained a total of 42 recommendations to address the July 2014, August 2014, and February 2015 respective findings.[18]

- **CDC internal workgroup review.** In October 2014, an internal workgroup established by CDC issued a report from its review of the 2014 safety lapses and CDC's laboratory safety program, which contained 96 recommendations to address its findings.
- **CDC external advisory group review.** CDC also convened an external advisory group to review the agency's laboratory safety program, and the advisory group issued its report, which contained 19 recommendations to address its findings in January 2015.
- **NIH and FDA laboratory reviews.** CDC's external advisory group also conducted reviews of NIH's and FDA's laboratory safety programs. In April 2015, the advisory group issued its report on NIH, which contained 10 recommendations, and in July 2015, the advisory group issued its report on FDA, which contained 27 recommendations to address its findings.

DOD Laboratory Safety Review

In May 2015, DOD convened a committee to conduct a comprehensive review of procedures, processes, and protocols for inactivating live anthrax spores across Army and Navy laboratories.[19] The committee issued a report on the results of its review containing 22 recommendations to address its findings in July 2015.[20] In September 2015, DOD issued a memo directing all department laboratories working with select agents and toxins to conduct an immediate safety review and report on their results within 10 days. DOD did not issue any recommendations as a result of this review but has established a workgroup to study the results of the review and potentially develop additional recommendations in the future.

[18]APHIS's select agent office also conducted reviews of the select agent laboratories involved in each of the safety lapses and issued reports containing recommendations to address its findings for each incident.

[19]According to officials, DOD did not include Air Force in its review because its high-containment laboratory does not conduct anthrax inactivation.

[20]Department of Defense, *Review Committee Report: Inadvertent Shipment of Live Bacillus anthracis Spores by DoD* (Washington, D.C.: July 13, 2015).

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—that is, policies did not contain all of the six elements that we identified as key for managing these laboratories. In addition, some departments and agencies did not have up-to-date policies.

Most Department and Agency Policies Were Not Comprehensive and Did Not Contain All Six Key Elements for Managing High-Containment Laboratories

Most of the departments and agencies we reviewed had policies for managing hazardous biological agents in high-containment laboratories, but those policies were not comprehensive—that is, they lacked some of the six elements that we identified as key for managing these laboratories. These key policy elements are

1. incident reporting—establishing appropriate lines of reporting for incidents involving hazardous biological agents, including the type of incident, to whom to report, and when;
2. roles and responsibilities—defining roles and responsibilities of department, agency, or laboratory personnel;
3. training—establishing training for personnel handling hazardous biological agents;
4. inventory control—requiring an inventory of all hazardous biological agents;
5. inspections—ongoing monitoring in the course of normal laboratory operations; and
6. BMBL—requiring adherence to, or referencing, the BMBL.

For each of the 8 departments and 15 component agencies we reviewed, we examined department- or agency-level policies for laboratory management to determine whether they contained these six key elements. We considered a department's policies to be comprehensive if requirements for all six key elements existed in department-level policies or in agency-level policies for each of the department's component

agencies. In addition, 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.

Our review found that most departments and agencies had policies for managing hazardous biological agents in high-containment laboratories—at either the department level, the agency level, or in the case of DOD, EPA, and USDA, both. Five of the 8 departments had department-level policies, and 10 of the 15 agencies had agency-level policies.[21] These department and agency policies contained at least one of the key elements. One department, DOI, did not have laboratory management policies at either the department or agency level. Table 2 shows the extent to which the 8 departments and 15 agencies we reviewed had policies that contained each of the six key elements as of December 2015.

Table 2: Summary of Six Elements Key for Managing Hazardous Biological Agents in High-Containment Laboratories Contained 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	–	–	–	–	–	–	-

[21]The 5 departments with department-level policies are DHS, DOD, DOE, EPA, and USDA. The 10 agencies with agency-level policies are 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 VA's Veterans Health Administration.

Department Agency	Incident reporting	Roles and responsibilities	Training	Inventory control	Inspections	BMBL	Key elements (count)
U.S. Geological Survey	–	–	–	–	–	–	-
EPA	●	●	●	○	●	○	4
Office of Pesticide Programs	○	●	●	○	○	○	2
HHS	–	–	–	–	–	–	-
CDC	○[b]	●	◐	●	◐	●	3
FDA	○	●	●	●	●	●	5
NIH	●	●	●	●	●	●	6
USDA	○	●	●	●	●	●	5
APHIS	○	●	●	○	○	○	2
Agricultural Research Service	●	●	●	○	●	●	5
Food Safety and Inspection Service[a]	–	–	–	–	–	–	-
VA	–	–	–	–	–	–	-
Veterans Health Administration	○	●	●	◐[c]	●	●	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-16-305

[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]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 found that department and agency policies were not comprehensive because they either did not contain all six key elements or were not applicable to all of a department's or agency's high-containment laboratories.

- **DHS.** We did not consider DHS's policies to be comprehensive because department-level policies did not contain all six key policy elements and did not apply to all of the department's high-containment laboratories. Specifically, DHS's policies contained requirements for inventory control but only for the department's select agent-registered laboratories. At the time of this review, all of DHS's high-containment laboratories were registered with the select agent program. However, should the registration status of these laboratories change, or should DHS open new, nonregistered high-containment laboratories in the future, they would not be covered by department policy.

- **DOD.** We did not consider DOD's policies to be comprehensive because policies containing some key elements applied only to DOD's select agent-registered laboratories. Furthermore, DOD's component agencies (Air Force, Army, and Navy) had policies that contained one to five of the key policy elements, but the policies were missing other elements or applied only to the agencies' select agent-registered laboratories. For example, DOD's and its component agencies' policies contained requirements for inventory control but only for their select agent-registered laboratories, and Air Force's and Navy's policies contained requirements for training and inspections only for their select agent-registered laboratories. The department has high-containment laboratories that are not registered with the select agent program but conduct research on other potentially hazardous biological agents to which these policies would not apply, according to officials.

- **DOE.** We did not consider DOE's policies to be comprehensive because department-level policies did not contain all six key policy elements. Specifically, we found that DOE's policies did not contain requirements for laboratory inspections. Furthermore, DOE's component agencies—National Nuclear Security Administration and

Office of Science—did not have agency-level policies for managing hazardous biological agents in their high-containment laboratories.[22]

- **DOI.** We did not consider DOI's policies to be comprehensive because, as previously stated, DOI did not have policies for managing biological agents in its high-containment laboratories at either the department or agency level.

- **EPA.** We did not consider EPA's policies to be comprehensive because they did not contain all six key policy elements. Specifically, we found that EPA's policies did not contain requirements for inventory control or reference the BMBL. Furthermore, the Office of Pesticide Programs' policies did not contain four of the six key policy elements, including requirements for inventory control and referencing the BMBL.

- **HHS.** We did not consider HHS's policies to be comprehensive because HHS did not have department-level policies, and two of its three component agencies did not have all six key elements in their agency-level policies. Specifically, CDC's policies contained three of the six key policy elements, but policies that contained the requirements for training and inspections applied only to the agency's select agent-registered laboratories. We also found that CDC's and FDA's policies did not contain requirements for incident reporting to senior department officials. In contrast, we considered NIH's policies for laboratory management to be comprehensive because the agency's policies contained all six key elements, including reporting incidents to senior department officials.

- **USDA.** We did not consider USDA's policies to be comprehensive because they did not contain all six key policy elements, and two of its three component agencies did not have all six key elements in their policies or did not have agency policies. Specifically, USDA's policies did not contain requirements for reporting laboratory incidents to senior department officials, including the types of incidents that should be reported, to whom, and when. In addition, APHIS's policies did not contain requirements to report laboratory incidents to senior

[22]According to officials, DOE's Office of Science had one laboratory that was capable of operating at BSL-3 but was not operating as a high-containment laboratory as of December 2015. However, officials told us that the laboratory could become operational as a high-containment laboratory, if needed.

department officials, and Food Safety and Inspection Service did not have agency policies for managing biological agents in high-containment laboratories. 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.

- **VA.** VA did not have department-level policies for managing biological agents in high-containment laboratories. Furthermore, we did not consider VA's Veterans Health Administration policies to be comprehensive because the agency had requirements for all six key elements in agency-level policies for its high-containment research laboratories but lacked requirements for incident reporting in policies for its high-containment clinical laboratory, and requirements for inventory control applied only to select agents for this laboratory.[23]

Department and agency officials we spoke to provided multiple reasons why they do not have policies that contain all six of the key elements. DOI officials told us that the department defers to its component agencies to set appropriate policies for the agencies' biosafety programs, and the agencies delegate this responsibility to subject-matter experts at the laboratories. Officials at USDA, which did not have department-level policies that contained the key element of incident reporting, told us that the department delegates responsibility for policy development, including any requirements contained in these policies, to its component agencies. In addition, officials at DOE and USDA's Agricultural Research Service generally noted that responsibility for policy development, including any requirements contained in these policies, is delegated to their laboratories.

In addition, some departments and agencies did not address all six key elements in policy but told us that they may conduct certain oversight activities, such as inspections and incident reporting, even when requirements for these activities are not specified in policy. For example,

[23]According to officials, VA's Veterans Health Administration had one clinical laboratory that was capable of operating at BSL-3 but was not currently operating as a high-containment laboratory, as of December 2015. However, Veteran's Health Administration officials told us that the laboratory could become operational as a high-containment laboratory as needed, such as during a public health emergency.

DOE's policies did not contain requirements for departmental inspections, and its National Nuclear Security Administration did not have agency-level policies. However, National Nuclear Security Administration officials told us that the agency conducts inspections of its high-containment laboratories on a regular basis in conjunction with laboratory personnel. Additionally, CDC's policies did not contain requirements for incident reporting, but the agency has taken related actions. Specifically, CDC distributed incident reporting procedures and a risk assessment flow chart for reporting potential incidents in its select agent and infectious disease laboratories to agency personnel in a July 2015 memorandum. Officials also stated that these requirements are available on the agency's internal laboratory safety website.

The lack of department- and component agency-level policies that contain all six elements we identified as key for managing biological agents in high-containment laboratories may hinder effective oversight of the laboratories and conflicts with federal internal control standards. According to federal internal control standards, agencies should have control activities in place to ensure that management's directives, such as policies and procedures for managing their programs, are carried out.[24] These standards also state that information should be recorded and communicated to management and other responsible officials in a form and within a time frame that enables them to carry out their internal control and other responsibilities. Developing comprehensive policies that contain requirements for all six key elements and apply to all high-containment laboratories would help departments and agencies reduce the risk of mismanaging hazardous biological agents by ensuring that policies convey consistent requirements for oversight, reflect current biosafety and biosecurity guidance, and address emerging threats and needed improvements. In addition, developing policies that contain these key elements for those departments and agencies with laboratories that are capable of operating as high-containment laboratories during public health or other emergencies would help departments and agencies ensure that they set policy expectations in advance of emergency response activities. Furthermore, policies for incident reporting that specify the type of incidents to report, to whom to report, and when would help ensure that senior department officials are consistently made aware of serious laboratory safety incidents at their high-containment laboratories.

[24]GAO/AIMD-00-21.3.1 and GAO-14-704G.

Some Departments and Agencies Do Not Have Up-to-Date Policies for Managing Hazardous Biological Agents in High-Containment Laboratories

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.[25] 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.

We found that most departments and agencies had general requirements and time frames for reviewing and updating their policies or their policies included specific expiration or recertification dates. However, other departments and agencies lacked either general requirements and time frames for reviewing and updating policies or specific policy expiration or recertification dates; these departments and agencies—DHS, EPA, HHS's FDA, and USDA's APHIS—review their policies on an as-needed basis, according to officials. We considered each department and each of its agencies separately and assessed their policies according to their own review schedules. We considered a department's or agency's policies to be up to date if they had been reviewed within general department or agency review time frames or before the policy's specific expiration or recertification date. See table 3 for the status of department and agency policies for managing high-containment laboratories as of December 2015.

[25]As shown in table 3, DOI, HHS, and VA did not have department-level policies for managing biological agents in high-containment laboratories at the time of our review. In addition, five component agencies—DOE's National Nuclear Security Administration and Office of Science, DOI's Fish and Wildlife Service and U.S. Geological Survey, and USDA's Food Safety and Inspection Service—did not have agency-level policies.

Table 3: Status of Department and Agency Policies for Managing High-Containment Laboratories, as of December 2015

Department / Agency	Status of policies
DHS[a]	?
DOD	●
Air Force	◒
Army	◒
Navy	●
DOE	◒
National Nuclear Security Administration	–
Office of Science	–
DOI	–
Fish and Wildlife Service	–
U.S. Geological Survey	–
EPA[a]	?
Office of Pesticide Programs[a]	●
HHS	–
CDC	●
FDA[a]	●
NIH	◒
USDA	○
APHIS[a]	?
Agricultural Research Service	○
Food Safety and Inspection Service	–
VA	–
Veterans Health Administration	◒

Legend:

? Unable to determine—department or agency did not have documented review time frames and policies did not include specific expiration or recertification dates.

● All policies were up to date.

◒ Not all policies were up to date.

○ No policies were up to date.

– Department or agency did not have policies.

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-16-305

[a]The department or component agency reviews policies on an as-needed basis.

Of the three departments with specified review time frames for their policies (DOD, DOE, and USDA), we found that only DOD had reviewed and updated all department-level policies according to DOD review time frames, as of December 2015. Of the seven agencies with specified review time frames for their policies—DOD's Air Force, Army, and Navy; HHS's CDC and NIH; USDA's Agricultural Research Service; and VA's Veterans Health Administration—only Navy and CDC had reviewed and updated all agency-level policies according to their review time frames, as of December 2015.[26] In addition, for the two departments and three agencies that review policies on an as-needed basis—DHS, EPA and its Office of Pesticide Programs, HHS's FDA, and USDA's APHIS—we determined that EPA's Office of Pesticide Programs and FDA also had up-to-date policies. We considered these agencies' policies to be up to date because the agencies made them effective in 2015. We were unable to determine whether DHS, EPA, and APHIS have up-to-date policies because they did not have documented review time frames and their policies did not include specific expiration or recertification dates. For example, DHS's two policies, *Biosafety* and *Select Agent and Toxin Security*, are each dated March 2007 and did not appear to have been updated since then. According to DHS officials, the department has reviewed these policies periodically since 2007 and has begun to update them, but officials did not provide a completion date. EPA officials told us that, in calendar year 2016, they expect to finalize new requirements for updating safety, health, and sustainability policy orders at least every 3 years. In addition, APHIS officials told us that they review their policies on an as-needed basis whenever changes to regulations occur.

[26]For the purposes of this section of the report, we looked only at whether existing policies were up to date. Five component agencies—DOE's National Nuclear Security Administration and Office of Science, DOI's Fish and Wildlife Service and U.S. Geological Survey, and USDA's Food Safety and Inspection service—did not have any agency-level policies for managing biological agents in high-containment laboratories.

Some of the other departments we reviewed also were reviewing their policies as of December 2015. For example, DOD's policies, *Safeguarding Biological Select Agents and Toxins* and *Minimum Security Standards for Safeguarding Biological Select Agents and Toxins*, were up to date at the time of our review, but DOD officials told us that DOD is reviewing them following an office reorganization and revisions to select agent regulations.[27] In this case, we found that DOD's review has resulted in its component agencies waiting to update their policies until after the department has completed its reviews and updates. For example, Army's policy *Biological Surety*, dated July 2008, states that it is to be updated every 3 years, and, therefore, we considered it to be not up to date. Army officials told us that the Army was currently reviewing the policy. However, because the Army policy implements DOD policy, Army officials said that the service would complete its review after DOD's revised policy was finalized. In addition, VA's Veterans Health Administration is also reviewing its policies, but officials were unable to tell us when they would be finalized. Officials told us that hiring freezes and staff vacancies have affected the agency's ability to update its policies according to their recertification dates.

Federal internal control standards state that agencies should accurately document internal control activities, such as reviews and updates of their policies.[28] Regular reviews and any needed updates would help departments and agencies ensure that their policies are current and address any new emerging threats, improved scientific understanding of hazardous biological agents, and lessons learned from reviews of safety lapses at high-containment laboratories.

[27]According to DOD officials, the review will streamline *Safeguarding Biological Select Agents and Toxins* and *Minimum Security Standards for Safeguarding Biological Select Agents and Toxins* into one policy document.

[28]GAO/AIMD-00-21.3.1 and GAO-14-704G.

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

Departments and agencies were using inspections as the primary activity to oversee the management of hazardous biological agents in high-containment laboratories. However, some departments and agencies did not routinely report the results of these inspections and other oversight activities to senior department or agency officials.

Departments and Agencies Use Inspections as the Primary Activity to Oversee the Management of Hazardous Biological Agents in High-Containment Laboratories

We found that as of December 2015, the 8 departments and 14 agencies we reviewed were using inspections or audits as the primary activity to oversee the management of hazardous biological agents in high-containment laboratories, and some department and agencies were also using additional oversight activities.[29] Additional oversight activities included reviewing training records and verifying laboratories' inventory of hazardous biological agents, both of which may occur as part of inspection or audit activities. Some departments and agencies were also analyzing safety data—including inspection results and incident reports—to identify trends or recurring issues in laboratory safety or security. See table 4 for an overview of department and agency activities for overseeing the management of hazardous biological agents in high-containment laboratories as of December 2015.

[29]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 4: 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:

✓ Department or agency conducted activity.
— Department or agency 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-16-305

[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.

Inspections. We found that 3 of the 8 departments and 13 of the 14 agencies with currently operating high-containment laboratories inspected or audited their high-containment laboratories on a routine basis. Inspections help departments and agencies determine whether laboratory personnel are following policies for managing hazardous biological agents, as well as identify any deficiencies or areas for improvement. For example, according to agency officials, CDC conducted annual inspections of its high-containment laboratories that consisted of walkthroughs of laboratory spaces, surveys of laboratory personnel, and reviews of the safety procedures outlined in laboratory biosafety manuals. Officials from the remaining agency—USDA's APHIS—told us that the agency's inspections have not occurred on a routine basis because the frequency of the inspections has depended in part on the availability of travel funds. APHIS officials initially told us that the agency planned to formalize its laboratory inspection process, and in February 2016, officials reported that APHIS had established a regular inspection schedule.

For the five departments that did not conduct routine inspections of their high-containment laboratories, we found that their component agencies conducted these routine inspections. DOD had policies that required laboratory inspections but delegated responsibility for conducting these inspections to its agencies (Air Force, Army, Navy), all of which conducted regular inspections. DOE, DOI, HHS, and VA did not have policies explicitly requiring laboratory inspections. Rather, these four departments left responsibility for conducting inspections to the discretion of their component agencies, all of which conducted routine inspections.[30]

[30]These component agencies were DOE's National Nuclear Security Administration; DOI's Fish and Wildlife Service and U.S. Geological Survey; HHS's CDC, FDA, and NIH; and VA's Veterans Health Administration.

DOE and DOI officials told us that the departments may include audits of their high-containment laboratories as part of broader reviews of programs under which laboratories reside, in addition to any laboratory inspections their agencies conduct. For example, DOE officials told us that the department may audit any safety and health program when the need arises, separate from the routine inspections conducted by its component agency. DOE officials said that, as of December 2015, the department was auditing all of its laboratories that conduct biological research, including the high-containment laboratory operated by DOE's National Nuclear Security Administration. Additionally, DOI officials told us that the department's triennial evaluations of its component agencies could include spot-checks of their high-containment laboratories; however, officials said that DOI's triennial evaluations conducted to date have not included any laboratory spot-checks.

Review of training records. We found that 1 of the 8 departments and 13 of the 14 agencies routinely reviewed training records to monitor whether personnel were completing laboratory training intended to reinforce policies for managing hazardous biological agents. These departments and agencies typically reviewed training records during inspections. However, officials with one agency—HHS's FDA—told us that this review occurred outside of inspections; details related to training compliance were included in a certified annual report prepared by each of the agency's centers and submitted to FDA's designated safety and health official. Officials with another agency—DOI's Fish and Wildlife Service—said that the agency verified training records before it allowed personnel to work in its high-containment laboratory. In contrast, officials from one agency—USDA's APHIS—told us that they could use USDA's electronic training system—through which APHIS makes training, including laboratory training, available to all APHIS personnel—to monitor whether personnel were completing this training. However, we could not determine whether APHIS was doing so, and USDA officials told us that the department did not track the completion of laboratory training taken by APHIS personnel. The lack of oversight for laboratory training is inconsistent with federal internal control standards that state that management should establish and operate activities to monitor the internal control system.[31] APHIS officials said that laboratory supervisors have been responsible for assigning and tracking laboratory training, and facility biosafety officers may have access to training documentation.

[31]GAO/AIMD-00-21.3.1 and GAO-14-704G.

However, APHIS officials told us that the agency intends to include a review of training records as part of the formal laboratory inspections that the agency is planning.

Inventory verification. We found that 3 of the 8 departments and all 14 agencies had mechanisms in place to routinely verify the accuracy of laboratories' biological inventories. These departments and agencies verified inventory using mechanisms such as spot-checks of inventory during laboratory inspections or by requiring laboratories to annually verify their inventory. For example, NIH conducted spot-checks of biological inventory as part of its annual inspection process and quarterly inventories of stored select agents. FDA and Navy required senior laboratory supervisors to submit annual certifications verifying that inventory is current and accurate. Officials from 1 of these 3 departments—DOD—and 5 of these 14 agencies—HHS's CDC, FDA, and NIH; EPA's Office of Pesticide Programs; and USDA's Food Safety and Inspection Service—told us that the departments and agencies have taken steps to strengthen inventory management controls to better oversee their inventories of hazardous biological agents. However, DOD and 3 of the 5 component agencies—HHS's CDC and FDA and USDA's Food Safety and Inspection Service—had not fully implemented their systems for these controls as of December 2015. For example, in March 2015, CDC launched a new, centralized electronic specimen management system to inventory hazardous biological agents in all of its infectious disease laboratories. However, CDC had not made the new system available to all of its laboratories; officials said that the agency expects to do so within the next 2 years. See table 5 for the steps these departments and component agencies have taken to strengthen inventory management controls and their progress toward completing these steps.

Table 5: Steps Taken by Certain Departments and Agencies to Strengthen Inventory Management Controls, as of December 2015

Department Agency	Activity	Complete
DOD	DOD is working with Air Force, Army, and Navy laboratories to establish a database that will centralize the select agent inventory of all DOD laboratories into one system.[a] Officials expect to finalize an implementation schedule for this system by the end of 2015.	N
EPA		
Office of Pesticide Programs	In January 2015, the Office of Pesticide Programs transitioned to a bar-coded inventory system to manage its hazardous biological agents.	Y
	In July 2015, the office revised the standard operating procedure that provides guidance for establishing the receipt, expiration dates, and disposal of biological inventory used in the laboratory.	Y
	In August 2015, the office instituted quarterly management reviews of its biological inventory.	Y
HHS		
CDC	In February 2015, CDC developed a new procedure for scientists separating from the agency to account for any biological specimens they may have been researching.	Y
	In March 2015, CDC launched a centralized electronic system to manage inventory of hazardous biological agents in all of CDCs infectious disease laboratories, with plans to roll the system out to all of the agency's laboratories within 2 years.	N
FDA	In October 2015, FDA introduced an electronic inventory control and management system to track the agency's radiological, chemical, and biological materials but does not plan to fully implement this system until the first quarter of fiscal year 2017.	N
NIH	As of March 2015, NIH implemented a revision to its safety audit inspection checklists that include documentation of inventory spot-checks during annual laboratory audits.	Y
	In September 2014, NIH established a database to record all hazardous biological agents in long-term storage at the agency as a supplement to its existing database for biological agents in active use by research staff.	Y
USDA		
Food Safety and Inspection Service	Food Safety and Inspection Service assigned staff to lead an initiative for all agency laboratories to have an electronic system in place for select agent inventory by September 2016 and an electronic system in place for all biological inventory by September 2017.	N

Legend

CDC Centers for Disease Control and Prevention
DOD Department of Defense
FDA Food and Drug Administration
HHS Department of Health and Human Services
NIH National Institutes of Health
USDA United States Department of Agriculture

Source: GAO analysis of department and agency information | GAO-16-305

[a]Officials said that the department has no plans to implement a similar system for its non-select agent biological inventory that would still require at least biosafety level 3 containment.

Trend analysis. We found that 2 departments and 10 agencies conducted analyses of inspection results or incident reports to identify potential trends that may highlight recurring laboratory safety or security issues.[32] For example, DHS officials said that the department analyzed each laboratory inspection and incident report to identify recurring issues that needed to be addressed, determine that the necessary corrective actions had been implemented, and ensure lessons learned were disseminated to laboratory personnel. NIH officials told us that the agency collected and analyzed accident and injury data to identify potential trends and conducted annual analyses of audit results to identify the most common deficiencies. Additionally, officials from USDA's APHIS and Agricultural Research Service said that the agencies investigated all incidents and accidents with the goal of identifying causal factors in order to prevent recurrence. The Agricultural Research Service communicated lessons learned from these investigations broadly throughout the agency, including through discussions of incidents during monthly teleconferences with laboratory personnel to discuss issues related to biosafety and safety, health, and environmental management; presentations at agency conferences; and, more recently, through agency safety bulletins.

Federal internal control standards state that management should assess the quality of performance over time and ensure that the findings of audits and other reviews are promptly resolved.[33] Of the departments and agencies that conducted laboratory inspections, officials from one department—USDA—and five agencies—DOD's Army and Navy, DOI's Fish and Wildlife Service and U.S. Geological Survey, and EPA's Office of Pesticide Programs—said the department and agencies did not conduct any trend analyses of the results. USDA officials said that although the department conducted inspections, it provided the results to its component agencies for any additional analysis and did not conduct further analysis of the results. Army officials told us that the agency conducted trend analysis of incident reports, though the agency did not perform any trend analysis of inspection results, as the agency's assumption had been that the laboratories would review inspection results to identify systemic findings that would require remediation. Army

[32]DOD officials told us that the recent anthrax incident prompted the department to collect information on other safety incidents at Air Force, Army, and Navy laboratories. After completing its review of the anthrax incident, DOD intends to review these past safety incidents to identify potential trends and determine whether the department needs to address them.

[33]GAO/AIMD-00-21.3.1 and GAO-14-704G.

officials said that the agency intends to start publishing a report that will identify recurring issues, trends, lessons learned, and best practices, but did not say when the agency would begin to publish such a report. Officials from DOI's Fish and Wildlife Service told us that inspections of the agency's one high-containment laboratory identified too few findings to perform any trend analyses, while U.S. Geological Survey officials said that the agency did not conduct formal analyses of laboratory inspection results as they have not historically identified any recurring gaps or issues. However, U.S. Geological Survey officials told us that based on our review, the agency had identified the lack of any trend analyses of inspection results as a potential gap and were developing a process to analyze inspection results. Officials from EPA's Office of Pesticide Programs said that laboratory personnel reviewed the results of each inspection, but neither the personnel nor the agency conducted formal analyses of the results. Officials said that there was little data in the inspection reports to analyze, and any issues identified during an inspection were usually corrected on the spot and did not recur in subsequent inspections. Routinely conducting such analyses would allow these departments and agencies to identify trends in laboratory safety and security data and determine whether individual lapses are isolated incidents or whether they suggest more systemic problems in their laboratories' management of hazardous biological agents.

Some Departments and Agencies Do Not Routinely Report the Results of Inspections and Other Oversight Activities to Senior Officials

As of December 2015, senior officials at 5 departments and 8 agencies did not routinely receive the results of inspections, and senior officials at 4 departments did not routinely receive reports of laboratory safety or security incidents occurring at agency laboratories.

Department and agency inspection results. Although 3 departments and all 14 agencies inspected their high-containment laboratories, they did not always report the results of these inspections to senior department or agency officials.[34] Specifically, of the 3 departments that conducted inspections—DHS, EPA, and USDA—we found that only DHS routinely reported the results of these inspections to senior department officials.[35]

[34]For the purposes of this report, "senior officials" refers to department and agency senior executive leadership.

[35]Officials from EPA and USDA told us that the results of their departments' inspections of high-containment laboratories were reported to senior agency officials but not to senior department officials.

Four agencies—DOD's Air Force, DOI's Fish and Wildlife Service, EPA's Office of Pesticide Programs, and USDA's Agricultural Research Service—said that they routinely reported inspection results to senior agency officials but not to senior department officials. Eight agencies—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—did not routinely report the results of internal inspections to either senior agency or senior department officials.[36] Only DOE's National Nuclear Security Administration and VA's Veteran's Health Administration routinely reported inspection results to both senior agency and senior department officials. For those departments and agencies that delegated responsibility for inspections to lower-level offices, these offices may not report the results of these inspections to senior officials because the department or agency does not require them to do so. For example, DOD officials told us that the department did not require its Army, Navy, or Air Force high-containment laboratories that are not registered with the select agent program to report the results of any agency inspections to DOD and has no plans to implement such a requirement. Navy officials said that laboratory personnel made the results of inspections available to senior agency officials upon request but did not proactively report these results to them. FDA's centers, which are located below the agency level, were responsible for conducting laboratory inspections, but according to FDA officials, the centers did not share the results of these inspections with senior agency officials.[37] According to CDC officials, the office that conducted inspections of the agency's laboratories provided the results of those inspections to the laboratory supervisor only. However, CDC officials said that following the realignment of key laboratory safety functions to a newly-created laboratory safety oversight office, laboratories will report the results of inspections to senior agency officials beginning in January 2016.

[36]Officials from DOD's Army, DOI's U.S. Geological Survey, HHS's NIH, and USDA's APHIS and Food Safety and Inspection Service told us the agencies reported the results of inspections on an as-needed basis, such as when the inspection identified significant issues at the laboratory.

[37]FDA officials said that the agency is exploring creating an ongoing oversight role for the agency's Laboratory Safety Practices and Policies Workgroup, which it established to conduct its laboratory sweeps for the White House's August 2014 safety stand-down. Possible oversight roles for the workgroup could include reviewing internal laboratory inspection results and conducting its own reviews of FDA's select agent-registered laboratories. However, FDA officials were unable to tell us when it would make a decision regarding the workgroup's oversight role.

Select agent program inspection results. For those departments and agencies that operated laboratories registered with and inspected by the select agent program, only DHS and DOE's National Nuclear Security Administration routinely reported the results of these inspections to senior department and agency officials. Officials from three agencies—DOI's U.S. Geological Survey, HHS's FDA, and USDA's Food Safety and Inspection Service—told us that the results of select agent inspections had not been routinely reported to senior department or agency officials because there was no requirement for laboratory personnel to do so. However, officials from DOI's U.S. Geological Survey said that the agency reported inspection results to senior department and agency officials on an as-needed basis, such as when there were significant issues identified during the inspection. Similarly, officials from USDA's Food Safety and Inspection Service said that its laboratory reported select agent inspection results to senior agency officials on an as-needed basis but did not report results to senior department officials because the department did not require or request its agencies to report the results of select agent inspections to it. FDA officials said that the agency did not require or expect its laboratory personnel to submit select agent inspection reports to senior agency officials, and HHS officials neither received nor requested the results.

DOD's Air Force, Army, and Navy laboratories routinely reported the results of select agent inspections to senior department officials, but not all of its agencies also reported the results to senior agency officials. DOD officials told us that, following the May 2015 anthrax incident, the department began to require Air Force, Army, and Navy laboratories to routinely report the results of select agent inspections to senior department officials. However, only Air Force laboratories routinely reported these results to senior agency officials, and Army and Navy laboratories did not. Navy officials said that laboratory personnel did not report the results of select agent inspections to senior agency officials, but inspection results would be made available up the chain of command if requested. Army officials said that the agency's laboratories reported results of select agent inspections to senior agency officials on an as-needed basis, such as when there were significant issues identified during the inspection.

Officials from five 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. However, they did not report the results to senior department officials, either because the department did not require the reporting of select agent inspection results to department

officials or because of an expectation that providing the results of such inspections should be limited to those officials with a “need-to-know” basis. For example, officials from CDC and NIH told us that HHS neither received nor requested the results of select agent inspections. As previously noted, USDA officials said that the department did not require or request its agencies to report the results of select agent inspections of its registered laboratories. Officials from EPA’s Office of Pesticide Programs said that synopses of the results of any select agent inspections were included in the laboratory division’s weekly report to senior agency officials; however, officials said that inspection results were not provided to senior EPA officials because of sensitivity requirements imposed by the select agent program. We found that other departments and agencies did not cite sensitivity requirements as a reason for not reporting the results of select agent inspections to senior officials, and these departments and agencies had mechanisms in place specifically to share this information with senior officials. For example, DHS has a memorandum of understanding with CDC’s and APHIS’s select agent offices, through which the results of these inspections were provided to department officials with primary laboratory oversight responsibilities. DHS officials told us that the DHS office that conducted joint select agent inspections then briefed senior DHS officials, such as the department’s chief of staff, on the results of the inspection, any corrective actions taken, and the implementation of any lessons learned. Senior department officials, such as a department administrator, his or her deputy, or chief of staff, by virtue of their stature and rank within a department should understand the requirements and responsibilities for safeguarding sensitive department information.

Laboratory incidents. 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. As noted previously, 2 of these departments—DOI and HHS—did not have any department policies for managing hazardous biological agents, or, in the case of USDA, departmental policies did not contain requirements for incident reporting. HHS officials told us that, while it did not require its agencies to report every laboratory incident, the agencies would report major incidents to the department. However, HHS did not have a formal

definition of what it considers to be major incidents.[38] USDA officials said that incidents were reported through supervisory channels to senior agency officials, who would inform senior department officials as necessary; officials agreed that there was no written guidance or directive on incident reporting at the department level and that documentation of this requirement could be stronger. Additionally, only one of USDA's agencies—Agricultural Research Service—told us that the agency routinely reported laboratory incidents to senior department officials. DOI officials said that all accidents and illnesses were reported through a dedicated DOI system, but also told us there was no guarantee that senior officials would receive notice of laboratory incidents through this system because the determination of whether an incident should be flagged for attention by senior officials depended on the judgment of the staff monitoring the system. Instead, officials said that it was likely that department officials would hear of high-containment laboratory incidents through informal channels.[39] DOD had department-level policies that contained requirements for laboratory personnel to report incidents to their respective senior agency (Air Force, Army, and Navy) officials, but these policies required that only serious mishaps be reported to senior DOD safety officials.[40] DOD officials said that a pending update to its biosecurity policy will require laboratories to report all incidents involving select agents to the DOD office with primary responsibility for oversight of the department's select agent laboratories, but this requirement will not apply to the department's high-containment laboratories that are not registered with the select agent program.

[38]Officials told us that in October 2015, HHS established a biosafety and biosecurity council composed of representatives from CDC, FDA, NIH, and other HHS agencies and offices. The council is intended to promote interagency coordination and facilitate sharing of best practices for biosafety and biosecurity matters. According to officials, the council is also considering developing a notification system for laboratory incidents.

[39]Officials from DOI's U.S. Geological Survey told us that the agency had a formal process in place to notify senior agency and department officials of safety or security incidents that occur in a high-containment laboratory. Specifically, such incidents would be reported from the laboratory, through U.S. Geological Survey's headquarters, to DOI senior management. U.S. Geological Survey officials also told us the agency was finalizing an incident reporting policy that documents this process, with an anticipated completion date of no later than January 2016.

[40]According to DOD policy, a serious mishap would include an accident that results in death, permanent total disability, hospitalization for inpatient care of three or more individuals, damage equal to or greater than $2 million, or destroyed aircraft.

Federal internal control standards call for information to be communicated to senior management and others within the entity who need it and in a form and within a time frame that enables them to carry out their responsibilities.[41] Routinely reporting inspection results and laboratory incidents to senior officials, as well as regularly analyzing this information—consistent with federal internal control standards for monitoring—would help these officials identify trends in laboratory safety and determine whether safety lapses reflect systemic issues. Reporting laboratory incidents to senior department officials, regardless of the severity, is especially important, as even near misses or potential exposures may highlight laboratory deficiencies that, if not addressed, could lead to more serious problems that could put the safety or security of laboratory personnel and the general public at risk. Additionally, the analysis of reported inspection results and laboratory incidents would help senior officials take appropriate measures to improve the management of hazardous biological agents in their high-containment laboratories, help ensure the safety and security of personnel working in these laboratories, and could be used to assure Congress and the American people that federal officials are working to protect the safety and security of laboratory personnel and of the general public.

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

HHS and DOD were making progress in implementing recommendations intended to help them strengthen their policies and oversight for managing their high-containment laboratories, among other safety activities, from the laboratory safety reviews they conducted after the 2014 and 2015 safety lapses. However, HHS and DOD had not developed specific time frames for implementing some recommendations.

[41] GAO/AIMD-00-21.3.1 and GAO-14-704G.

HHS and DOD Have Made Progress in Implementing Recommendations from Laboratory Safety Reviews

HHS component agencies have made varying progress in implementing recommendations from their laboratory safety reviews, as of November 2015 (the date of the most recent information available). CDC reported implementing a total of 91 recommendations from 209 recommendations made across all of its internal and external reviews. FDA reported implementing 6 of 30 recommendations from its external laboratory safety review and taking steps to implement others, and NIH reported implementing 9 of 10 recommendations from the external laboratory safety review of that agency.[42] NIH officials said the agency did not plan to implement the remaining recommendation because it believed that current agency processes adequately addressed the advisory group's concerns. Table 6 lists the number of recommendations included in the various HHS laboratory safety reviews and the number of recommendations that CDC, FDA, and NIH reported as implemented, as of November 2015.

Table 6: Implementation Status of Recommendations from 2014 and 2015 Reviews of the Department of Health and Human Services (HHS) Laboratory Safety Programs by Component Agency, as of November 2015

Review	Number of recommendations made	Number of implemented recommendations
Centers for Disease Control and Prevention (CDC)		
January 2015 external advisory group report	19	10
February 2015 after-action assessment of the Ebola safety incident	8	8
October 2014 internal workgroup report	148[a]	43
August 2014 after-action assessment of the avian influenza safety incident	26	23
July 2014 after-action assessment of the anthrax safety incident	8	7
Food and Drug Administration (FDA)		
July 2015 external advisory group report	30[b]	6
National Institutes of Health (NIH)		
April 2015 external advisory group report	10	9[c]

Source: GAO summary of HHS data. | GAO-16-305

[a]The internal workgroup made 96 recommendations to CDC, some of which included multiple actions or activities. For those recommendations, CDC counted the individual actions and activities as separate recommendations.

[42]The agencies were reporting their progress to HHS in monthly status updates.

[b]The advisory group made 27 explicit recommendations to FDA. Officials told us that the agency identified three additional, unnumbered recommendations in the text of the group's findings.

[c]NIH considered all recommendations to be implemented. Agency officials told us that NIH is not implementing one of the advisory group's recommendations because officials believe the agency's current processes adequately address the advisory group's concerns.

As of December 2015 (the date of the most recent information available), we found that DOD reported implementing one recommendation from its July 2015 report on the anthrax safety lapse and was taking steps to implement the remaining 21 recommendations. DOD convened a committee to review the May 2015 anthrax incident, which issued a report in July 2015 containing 19 recommendations in three overarching areas—quality assurance, scientific peer review, and program management for inactivation and viability testing of anthrax bacteria—and 3 broad recommendations related to laboratory procedures for select agents and toxins, chains of command, and budgets. For example, DOD's July 2015 report on the anthrax incident found that laboratory practices across the department were inconsistent and recommended that DOD review its laboratory chains of command and pursue consistent safety practices. In the same month, DOD issued a departmental memorandum assigning responsibility for implementing the committee's recommendations to DOD senior offices and the Secretary of the Army, including for the Secretary to develop an implementation plan. The memo also tasked DOD and Army with additional activities, such as reviewing and revising as necessary DOD's biosafety and biosecurity policies and ensuring their consistent application across DOD laboratories and assessing the optimal distribution of research, development, and production of medical countermeasures at DOD's biological and chemical laboratories. As of December 2015, Army reported implementing the recommendation to review laboratory missions and chains of command and provide appropriate policy and organizational recommendations to ensure consistent application of biosafety and biosecurity across all of its laboratories. Army also reported developing recommendations of proposed alternatives to the distribution of medical countermeasure research, development, and production across all of its agencies' laboratories. DOD has not fully implemented any of the 19 quality assurance, peer review, or program management recommendations but has convened DOD and Army workgroups that are taking steps to do so. For example, for the quality assurance recommendation to standardize anthrax inactivation procedures across all DOD laboratories, DOD has developed a scientific study plan, which was undergoing final review at the time of this report, and anticipates beginning those studies in February 2016.

DOD was also taking other steps generally to address weaknesses in laboratory safety that were not outlined in its July 2015 report or in its implementation plan. We previously reported on DOD's preliminary progress in addressing weaknesses in the management of its high-containment laboratories and found that DOD had begun revising some policies, such as its select agent security policy, to address these weaknesses prior to the July 2015 review but had not finalized them prior to the May 2015 anthrax safety lapse.[43] According to officials, DOD plans to finalize its select agent security policy by the end of 2015. However, DOD officials told us that the department plans to make further revisions to this policy as a result of the anthrax safety lapse after the first set of revisions are finalized, but DOD did not know when it would finalize these subsequent changes.

Some actions taken by HHS's component agencies and DOD to address laboratory safety review recommendations—such as FDA's implementation of an electronic inventory system capable of tracking the agency's radiological, chemical, and biological material—address oversight activities for management of high-containment laboratories that we identified previously in this report. Other recommendations, such as for CDC to establish an agency-wide standardized safety curriculum, address other gaps in departments' and agencies' laboratory management. Table 7 provides additional information on HHS's and DOD's safety reviews and examples of the resulting recommendations from these reviews.

[43]GAO, *High-Containment Laboratories: Preliminary Observations on Federal Efforts to Address Weaknesses Exposed by Recent Safety Lapses*, GAO-15-792T (Washington, D.C.: July 28, 2015).

Table 7: Examples of Recommendations from the 2014 and 2015 Reviews of the Department of Health and Human Services (HHS) and Department of Defense (DOD) Laboratory Safety Programs

Review	Recommendation areas	Example of recommendations from laboratory safety reviews
HHS laboratory safety reviews[a]		
Centers for Disease Control and Prevention (CDC) January 2015 external advisory group report	To address the findings in its report, the external advisory group made recommendations in 7 areas, including areas of particular relevance to our review: leadership, training, and accountability. Some of the advisory group's findings and recommendations echoed the findings and recommendations from CDC's October 2014 internal workgroup report, such as those recommendations in the areas of leadership and training.	Establish a CDC brand and communicate, from the top down, a "CDC Way" that is the performance of responsible science practiced in a consistently safe manner. As part of this effort, better mechanisms should be established for sharing information about safety incidents across CDC to promote transparency at all levels.
		Establish a standardized, agency-wide laboratory safety curriculum.
CDC October 2014 internal workgroup report	As a result of its review, the advisory group found weaknesses in six functional areas, including areas of particular relevance to our review: leadership, staffing, and organizational structure; policy, authority, and enforcement; and training and education. To address its findings, the internal workgroup made recommendations in 31 areas to improve safety and CDC's management of its laboratories—including areas such as exercising authority and providing leadership for laboratory science and safety, establishing and enforcing agency safety policies, and leading and monitoring world-class training. The recommendations were targeted to specific CDC offices and divisions, and 14 recommendations included multiple actions or activities.	Establish and implement a laboratory safety strategic plan that (1) defines tangible safety and quality objectives; (2) focuses on high quality, sustainable safety initiatives; and (3) ensures implementation and sustainability of new safety and quality initiatives.
		Improve data management systems including those for training and competency records, equipment maintenance and monitoring, and specimen inventory, and make systems electronic, integrated, user-friendly, flexible, fast, and accessible.
Food and Drug Administration (FDA) July 2015 external advisory group report	To address the findings in its July 2015 report on FDA's laboratory safety program, the external advisory group made recommendations to the agency in areas such as laboratory safety leadership, inventory management, training, and communication.	Establish a single electronic biological inventory system throughout the agency.
		Increase the visibility of signs and phone numbers that people can use to call with any safety concerns.
National Institutes of Health (NIH) April 2015 external advisory group report	To address the findings in its April 2015 report on NIH's laboratory safety program, the external advisory group made recommendations in areas such as governance and staff recognition, responsibilities and processes for conducting risk assessments, and competency testing and documentation.	Develop a laboratory safety survey tool to accurately gauge areas for improvement in laboratory and research safety programs currently and over time.
		Establish regular opportunities and mechanisms to improve communications between laboratory managers across NIH.
DOD laboratory safety review		

Review	Recommendation areas	Example of recommendations from laboratory safety reviews
DOD July 2015 committee report	To address its findings, the committee made detailed recommendations in three areas: (1) enhancement of quality assurance, (2) more extensive scientific peer review processes, and (3) improvements in program management for anthrax inactivation and validation testing. In addition to these recommendations, the committee also recommended that DOD review all laboratory procedures for select agents and that Army, Navy, and the Office of the Secretary of Defense review their chains of command and pursue consistent safety practices.[b]	Army, Navy, and Office of the Secretary of Defense should review the chain of command and pursue consistent safety practices.
		In the area of quality assurance, establish and manage an environmental surface sampling program and develop procedures for laboratories to document, investigate, and report contamination found outside primary containment areas during environmental sampling. The procedures, at a minimum, should include notification protocols, including notification of the safety manager of that location, results and follow-up actions taken.

Source: GAO summary of HHS and DOD information. | GAO-16-305

[a]We excluded from this table the three after-action assessments of laboratory safety incidents (anthrax, Ebola, and avian influenza) that CDC conducted during this period because many of these recommendations were specific to the individual laboratories in which the incidents occurred.

[b]In July 2015, DOD issued a departmental memorandum assigning responsibility for implementing the committee's recommendations to the Under Secretary of Defense for Acquisition, Technology, and Logistics and the Secretary of the Army. The memo also tasked Army with additional activities, such as assessing the optimal distribution of research and development at DOD's biological and chemical laboratories. Army, as directed by DOD, developed implementation plans in August 2015 to address the internal committee's recommendations in its May 2015 report and additional activities included in the July 2015 memorandum.

HHS and DOD Planning Documents Lack Some Time Frames for Implementing Recommendations from Laboratory Safety Reviews

HHS and DOD have developed planning documents to track and manage implementation of the recommendations from laboratory reviews, but CDC's, DOD's, and Army's planning documents lack some time frames for implementing these recommendations. CDC and DOD officials told us that they plan to address all of the recommendations from the safety reviews. CDC has developed time frames for implementing open recommendations from the January 2015 external advisory group report and CDC's July 2014 anthrax, August 2014 avian influenza, and February 2015 Ebola after-action assessments but has not developed time frames for implementing the recommendations from the agency's October 2014 internal working group report. DOD's and Army's implementation plans for the recommendations made in the July 2015 report include time frames for the three overarching areas in which the internal workgroup made recommendations—quality assurance, scientific peer review, and program management for inactivation and viability testing of anthrax bacteria—as well as for the additional tasks assigned to DOD and Army, such as reviewing and revising as necessary DOD's biosafety and biosecurity policies. However, the DOD and Army implementation plans and other planning documents do not include time frames for each of the

detailed 19 recommendations in the three areas. DOD officials told us that the Army workgroup is responsible for overseeing the implementation of only some of the 19 recommendations, while senior DOD workgroups are responsible for overseeing the implementation of the remaining recommendations. Officials also said that DOD is unable to establish time frames for certain recommendations because their completion is dependent upon the success of the research into inactivation and related procedures called for in them. However, some of the 19 recommendations do not require the completion of research studies. For example, one quality assurance recommendation calls for DOD to establish an environmental surface sampling program to establish written laboratory procedures to document, investigate, and report contamination found outside of primary containment areas. Another recommendation, in the area of program management for anthrax inactivation, calls for DOD to establish an oversight group to ensure effective and persistent implementation of corrective actions by actively engaging in tracking standards, processes, and procedures throughout department laboratories.

CDC's, DOD's, and Army's lack of implementation plans with time frames for all recommendations is inconsistent with federal internal control standards for monitoring that state that departments and agencies should establish policies and procedures for ensuring that the findings of audits and other reviews are promptly resolved.[44] These standards also state that managers should promptly evaluate findings from audits and other reviews and determine proper actions in response to those findings and subsequent recommendations. In addition, the Project Management Institute's *The Standard for Program Management* calls for development of timelines and milestones as a leading practice to ensure organizational activities are completed.[45] Developing plans that include specific time frames would provide CDC, DOD, and Army with assurance that they can implement recommendations and associated activities in a timely manner to fully address weaknesses identified during safety reviews and determine whether they are making progress, including identifying any potential barriers to implementation.

[44]GAO/AIMD-00-21.3.1 and GAO-14-704G.

[45]See Project Management Institute, *The Standard for Program Management*, 3rd ed. (Newton Square, Pa.: 2013).

Conclusions

The safety lapses of 2014 and 2015 continue to raise questions about the adequacy of federal policies for managing hazardous biological agents in high-containment laboratories and department and agency oversight activities, including appropriate levels of senior management involvement. Given the threat that hazardous biological agents pose to public and animal health and the U.S. economy, federal departments and agencies need to strengthen oversight of their high-containment laboratories. To that end, federal reviews—including those by HHS, DOD, and the White House—have made recommendations intended to strengthen federal and national oversight. These recommendations are an important step in addressing the weaknesses identified in the 2014 and 2015 safety lapses.

Nonetheless, we continued to find certain deficiencies in departments' and agencies' internal controls for the management of their high-containment laboratories, as well as opportunities for improvement. Most of the 8 departments and 15 agencies we reviewed had policies for management of their high-containment laboratories, but the policies were not comprehensive because they lacked key safety elements or did not apply to all high-containment laboratories. In addition, most departments and agencies have not kept their policies up to date, so that the most recent safety guidance, protocols, or improvements may not be incorporated into department or agency management practices. Moreover, departments and agencies used inspections as their primary activity to oversee their laboratories' handling of hazardous biological agents, but inspection findings and necessary corrective actions were not routinely transmitted to senior officials, who could use them to identify trends and ensure that improvements to the management of biosafety and biosecurity are implemented across all of their high-containment laboratories. In the absence of up-to-date policies for managing these agents that include all six of the key elements we identified, routine oversight of laboratories' compliance with these policies through regular inspections, and analysis of safety data to identify trends, departments and agencies cannot assure the safety of laboratory personnel and the public, and help prevent the loss, theft, or misuse of hazardous biological agents. Furthermore, absent routine reporting of the results of inspections and trend analyses, senior department and agency officials are hindered in their ability to recognize when individual safety lapses that appear to be isolated incidents point to systemic weaknesses and thus to identify needed improvements and corrective actions.

In addition, although HHS and DOD are making progress in implementing the recommendations to improve their laboratory safety programs resulting from reviews of the 2014 and 2015 safety lapses, they have not developed time frames for all of these recommendations. Without

implementation plans that include time frames, their ability to gauge performance and track progress toward implementing these important improvements will be hampered.

Recommendations for Executive Action

To ensure that federal departments and agencies have comprehensive and up-to-date policies and stronger oversight mechanisms in place for managing hazardous biological agents in high-containment laboratories and are fully addressing weaknesses identified after laboratory safety lapses, we are making the following 33 recommendations.

We recommend that the Secretary of Agriculture

- revise existing department policies for managing hazardous biological agents in high-containment laboratories to contain specific requirements for reporting laboratory incidents to senior department officials, including the types of incidents that should be reported, to whom, and when, or direct the Administrator of the Food Safety and Inspection Service to develop agency policies that contain these requirements;
- review and update outdated department policies for managing hazardous biological agents in high-containment laboratories and direct the Administrators of APHIS and Agricultural Research Service to update their policies and, in the case of APHIS, establish a regular review schedule;
- routinely analyze results of the department's laboratory inspections and incident reports to identify potential trends that may highlight recurring laboratory safety or security issues and share lessons learned with laboratory personnel;
- require routine reporting of the results of department, agency, and select agent laboratory inspections to senior department officials; and
- require routine reporting of incidents at agency laboratories to senior department officials.

We recommend that the Secretary of Defense

- revise existing department policies for managing hazardous biological agents in high-containment laboratories to contain

specific requirements for inventory control for all of DOD's high-containment laboratories, not just for its select agent-registered laboratories, or direct the Secretaries of the Air Force, Army, and Navy to revise their existing, respective policies to contain these requirements;

- direct the Secretaries of the Air Force and Army to review and update their respective outdated policies for managing hazardous biological agents in high-containment laboratories;
- routinely analyze agencies' inspection results and incident reports to identify potential trends that may highlight recurring laboratory safety or security issues and share lessons learned with laboratory personnel, or direct the Secretaries of the Army and Navy to do so;
- require routine reporting of the results of Air Force, Army, and Navy inspections of non-select agent registered laboratories to senior department officials;
- require routine reporting of laboratory incidents at Air Force, Army, and Navy non-select agent registered laboratories to senior department officials;
- direct the Secretaries of the Army and Navy to require reporting of agency and select agent laboratory inspection results to senior agency officials; and
- develop time frames for the 19 specific recommendations from the July 2015 review, or direct the Secretary of the Army to do so.

We recommend that the Secretary of Energy

- revise existing department policies for managing hazardous biological agents in high-containment laboratories to contain specific requirements for inspections, or direct the Administrator of the National Nuclear Security Administration and the Director of the Office of Science to develop agency policies that contain this requirement; and
- review and update its outdated policies for managing hazardous biological agents in high-containment laboratories.

We recommend that the Administrator of EPA

- revise existing EPA policies for managing hazardous biological agents in high-containment laboratories to contain specific requirements for inventory control, or direct the Director of the Office of Pesticide Programs to incorporate this requirement into its policy;

- review and update EPA's outdated policies for managing hazardous biological agents in high-containment laboratories and establish a regular schedule for reviewing and updating EPA and Office of Pesticide Programs policies; and

- require routine reporting of the results of department, agency, and select agent laboratory inspections to senior department officials.

We recommend that the Secretary of Health and Human Services

- develop department policies for managing hazardous biological agents in high-containment laboratories that contain specific requirements for reporting laboratory incidents to senior department officials, including the types of incidents that should be reported, to whom, and when, or direct the Director of CDC and the Commissioner of FDA to incorporate these requirements into their respective policies;

- develop department policies for managing hazardous biological agents in high-containment laboratories that contain specific requirements for training and inspections for all high-containment component agency laboratories and not just for their select-agent-registered laboratories; or direct the Director of CDC to provide these requirements in agency policies;

- direct the Director of NIH to review and update the agency's outdated policies for managing hazardous biological agents in high-containment laboratories;

- direct the Commissioner of FDA to establish a regular schedule for reviewing and updating agency policies for managing hazardous biological agents in high-containment laboratories;

- require routine reporting of the results of agency and select agent laboratory inspections to senior department officials;

- direct the Director of NIH and the Commissioner of FDA to require routine reporting of the results of agency laboratory inspections—and in the case of FDA, require routine reporting of select agent inspection results—to senior agency officials;

- require routine reporting of incidents at CDC, FDA, and NIH laboratories to senior department officials; and

- direct the Director of CDC to develop time frames for the recommendations from the internal workgroup review.

We recommend that the Secretary of Homeland Security

- revise existing policies for managing hazardous biological agents in high-containment laboratories to contain specific requirements for inventory control that would apply to all high-containment laboratories, not just select agent-registered laboratories; and

- review and update its outdated policies for managing high-containment laboratories and establish a regular schedule for reviewing and updating these policies.

We recommend that the Secretary of the Interior

- develop department policies, or direct the Directors of Fish and Wildlife Service and U.S. Geological Survey to develop agency policies for managing hazardous biological agents in high-containment laboratories that contain specific requirements for reporting laboratory incidents to senior department officials—including the types of incidents that should be reported, to whom, and when—and specific requirements for roles and responsibilities, training, inventory control, and inspections;

- routinely analyze the results of the agency's laboratory inspections and incident reports to identify potential trends that may highlight recurring laboratory safety or security issues and share lessons learned with laboratory personnel, or direct the Directors of Fish and Wildlife Service and U.S. Geological Survey to do so;

- require routine reporting of the results of agency and select agent inspections to senior department officials; and

- direct the Director of the U.S. Geological Survey to require routine reporting of the results of agency and select agent laboratory inspections to senior agency officials.

We recommend that the Secretary of Veterans Affairs

- develop department policies for managing hazardous biological agents in high-containment laboratories that contain specific requirements for reporting laboratory incidents to senior department officials—including the types of incidents that should be reported, to whom, and when—and requirements for inventory control for all of its high-containment laboratories, including its select agent-registered clinical laboratory, or direct the Under Secretary of Health to incorporate these requirements into its policies; and

- direct the Under Secretary of Health to review and update outdated agency policies for managing hazardous biological agents in high-containment laboratories.

Agency Comments and Our Evaluation

We sent draft copies of this report to the eight departments in our review. Written responses from these departments are reprinted in appendixes IV through XI. Of the eight departments to which we made recommendations, six (DHS, DOD, DOI, HHS, USDA, and VA) generally agreed with all of our recommendations for them. The remaining two departments (DOE and EPA) did not believe that further action was needed to respond to some of the recommendations directed to them. In addition, DHS provided clarifying information, HHS provided additional information on its laboratory oversight activities, and USDA and VA provided information regarding specific actions they have taken or plan on taking to address portions of our recommendations. In cases in which departments also provided technical comments, we incorporated them as appropriate.

DOE disagreed that further action was needed for our recommendation to incorporate requirements for inspections into its department or agency policies. DOE stated that its current policies, including departmental orders and regulations, provide it with the authority to conduct inspections of both department and contractor laboratories as the department deems necessary and appropriate and take action in cases of noncompliance. However, the DOE orders are for overarching department oversight, and we believe that the language DOE cited in the policies, orders, and regulations is broad. This language may allow for DOE and its

components to conduct inspections, but it does not provide specific requirements for inspection frequency; nor is the order specific to managing biological agents in high-containment laboratories. As we state in the report, inspections help departments and agencies determine whether laboratory personnel are following policies for managing hazardous biological agents, as well as identify any deficiencies or areas for improvement. Therefore, we maintain that DOE should incorporate more specific requirements for laboratory inspections—for example, how often they should be conducted and processes for managing their results and resolving any deficiencies identified during these inspections—into DOE policies or regulations for managing high-containment laboratories.

EPA disagreed that further action was needed for our recommendations to include specific requirements for inventory control and to review and update policies for managing hazardous biological agents in high-containment laboratories. EPA believes it has current policies that comply with these recommendations and provided us with additional information to support its belief. We updated our analysis to include the Office of Pesticide Programs policy that EPA provided. This policy contains requirements for two of the elements we identified as key in our review—roles and responsibilities and training. Accordingly, we revised our recommendation to EPA to reflect this information. We determined that the other policies EPA provided were laboratory-level policies, procedures, or protocols and, hence, did not provide department or agency-level requirements for managing hazardous biological agents in all high-containment laboratories within EPA or the Office of Pesticide Programs. In addition, EPA reported that its inventory control policy requirement was complete given the Office of Pesticide Programs' inventory control program. However, EPA was silent on any plans to incorporate inventory control requirements into EPA or Office of Pesticide Programs policy. We maintain that EPA should incorporate the missing inventory control element into overarching, up-to-date EPA or Office of Pesticide Programs policies to document key requirements in order to demonstrate support for laboratory safety from senior EPA or Office of Pesticide Programs officials.

In response to our draft recommendation to revise existing policies to include requirements for inspections and inventory control, DHS provided clarifying information to show that its policies contained requirements for inspections. We updated our analysis to reflect this information and revised our recommendation to DHS accordingly.

In its written response, HHS provided additional information about the goals and responsibilities of its intradepartmental biosafety and

biosecurity council, which HHS established in October 2015. HHS reported that the council will work with CDC, FDA, and NIH to determine appropriate criteria and procedures for reporting incidents to HHS, as well as assess whether department-wide incident reporting policies could be modeled on agency policies. In addition, HHS stated that the council will work with CDC to determine appropriate criteria and procedures for reporting inspection results to HHS, and FDA plans to submit inspection findings annually to HHS as part of the regulatory compliance and assurance program the agency plans to establish. However, HHS was silent on whether it will require NIH to report the results of its laboratory inspections to senior agency officials, and the results of select agent inspections to senior department officials; as we found in the report, NIH's current practice is to notify only senior agency officials of select agent inspections and their results. We maintain that the reporting of all inspection results to senior agency and department officials is important, especially in light of the HHS biosafety and biosecurity council's planned efforts to coordinate and improve biosafety and biosecurity standards and activities across the department and its plans for CDC and FDA to share inspection results routinely with HHS. HHS also provided us with an updated report on the progress CDC has made in implementing the recommendations from its internal workgroup review as of the beginning of February 2016.

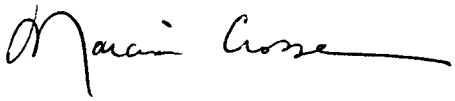
In response to our draft recommendation that USDA revise existing department policies to contain specific requirements for reporting laboratory incidents to senior department officials or direct the Administrator of APHIS to do so, APHIS provided its updated biosafety policy, issued February 2016, which contains the incident reporting key element and the other five elements that we identified as key for laboratory management. Accordingly, we revised our recommendation to USDA. In response to the recommendation for USDA to direct the Administrator of the Food Safety and Inspection Service to incorporate requirements for incident reporting into its policies if the department does not, USDA stated that because the Food Safety and Inspection Service's high-containment laboratory was registered with the select agent program, it was therefore required by the select agent regulations to have policies at the laboratory level. However, USDA was silent on its plans to incorporate requirements for incident reporting into either department or Food Safety and Inspection Service policy. We maintain that it is important for the department to document key requirements in overarching department or agency policies in order to demonstrate support for laboratory safety from senior department officials. USDA also provided information on the steps APHIS is taking that address our other recommendations, such as routinely reporting the results of laboratory

inspections and incidents to senior department officials. However, USDA was silent on steps it is taking for three of our recommendations—for the department to routinely analyze laboratory inspections and incident reports to identify potential trends across the department, require routine reporting of the results of laboratory inspections to senior department officials, and require routine reporting of laboratory incidents to senior department officials. We reiterate that USDA should implement these recommendations that are intended to establish and strengthen consistent department oversight of laboratory safety across all USDA agencies.

In response to our recommendation to update Veterans Health Administration policies, VA reported that the Veterans Health Administration updated its agency-level policy for management of its clinical laboratories in January 2016 and shared a copy of the updated policy with us. However, VA did not provide further information on when the Veterans Health Administration plans to finalize agency policies for its research laboratories. We believe that the Veterans Health Administration should also update its outdated policies for its research laboratories in a timely manner.

As agreed with your offices, unless you publicly 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 to the Secretaries of Agriculture, Defense, Energy, Health and Human Services, Homeland Security, Interior, and Veterans Affairs; and the Administrator of EPA. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions concerning this report, please contact Marcia Crosse, Director, Health Care at (202) 512-7114 or crossem@gao.gov or John Neumann, Director, Natural Resources and Environment at (202) 512-3841 or neumannj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix XII.



Marcia Crosse
Director, Health Care

John Neumann
Director, Natural Resources and Environment

List of Requesters

The Honorable Fred Upton
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

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

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

Appendix I: Department of Health and Human Services Laboratory Oversight during the 2014 Smallpox Safety Incident

In July 2014, decades-old vials of smallpox, some of which contained live virus, were found in a storage space of a former Food and Drug Administration (FDA) laboratory on the National Institutes of Health (NIH) campus, within the Department of Health and Human Services. FDA and NIH had gaps in their inspection and inventory management protocols, which resulted in the vials of smallpox remaining undiscovered. Neither NIH nor FDA claimed responsibility for the boxes; therefore, neither agency looked in the unlabeled boxes in which the vials of smallpox were stored until FDA was cleaning out its inventory in preparation for a move to its new location at FDA headquarters. During the period when FDA was leasing laboratory facilities from NIH, NIH and FDA officials told us that NIH was responsible for conducting inspections of FDA-leased laboratories and their associated spaces, including the cold storage room where the smallpox vials were found in unlabeled cardboard boxes. However, the NIH inspection checklists did not require inspectors to review the types of containers laboratory personnel used to store their inventory of hazardous biological agents, nor were inspectors required to check the contents of materials in the cold storage room. NIH officials told us that the agency did not have responsibility for the contents of any boxes stored in the FDA-leased cold storage spaces. Further, NIH officials told us that the agency notes the presence of cardboard in storage from a safety perspective only, such as when cardboard on the floor represents a tripping hazard or wet cardboard represents a mold hazard.[1] FDA officials told us that FDA's laboratory personnel were responsible for their own hazardous biological agents but did not claim responsibility for the boxes in which the vials were discovered because they were not being used in active research.

NIH and FDA have taken steps to address gaps in their inspection and inventory management protocols in response to the discovery of smallpox vials in 2014. Specifically, the FDA center that had responsibility for the leased NIH cold storage space developed three new procedures for handling inventory in common rooms, cold rooms, and shared freezer spaces, all of which require personnel to look at all contents of boxes and storage compartments in these rooms. In addition, NIH conducted a sweep of its laboratories to identify any select agents stored in them and revised its inspection checklist, effective as of April 2015, to more clearly state when cardboard in cold storage rooms presents a safety hazard.

[1]According to NIH officials, inspections did not identify as a safety concern any cardboard boxes used for storage or identify the contents of storage boxes.

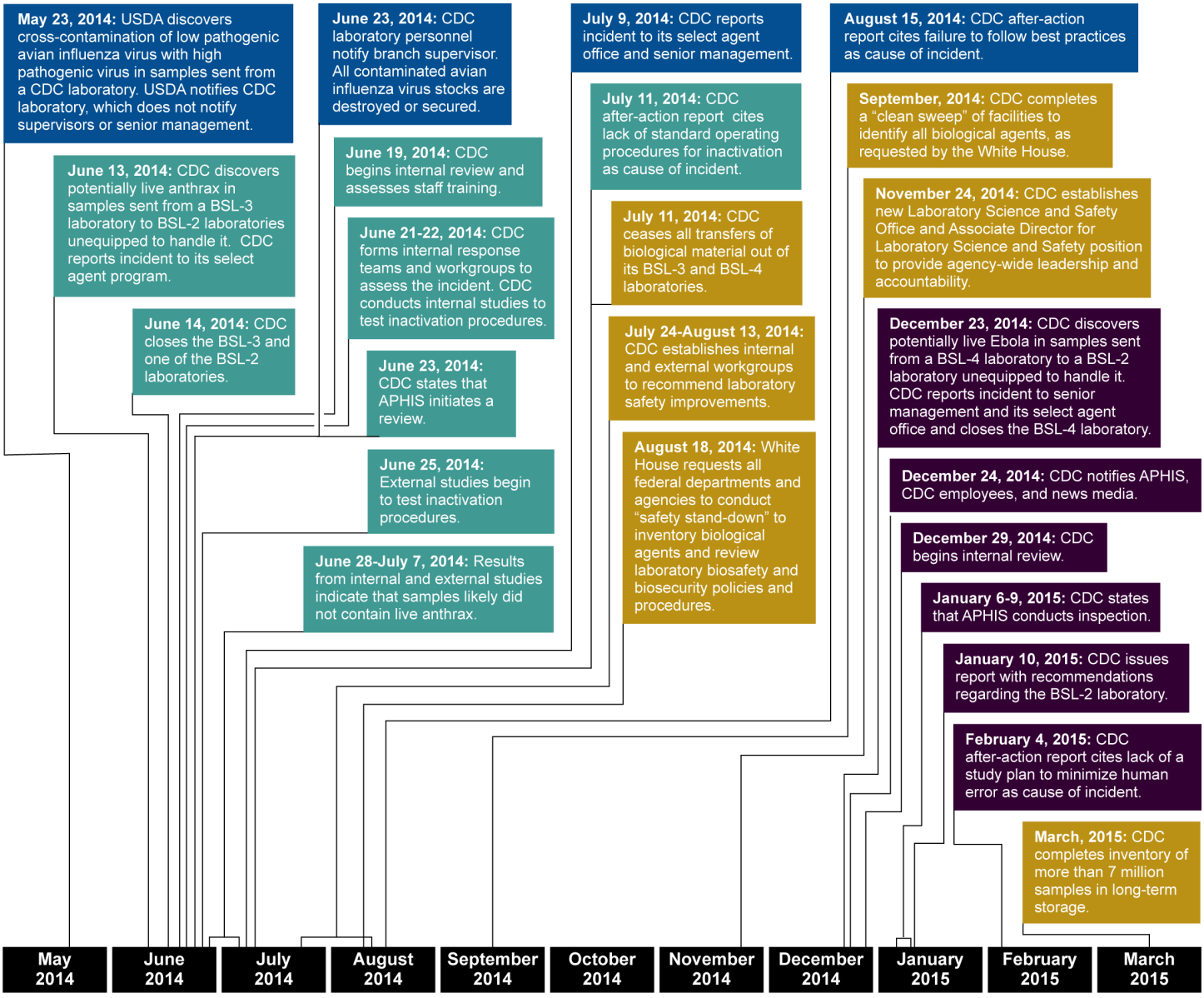
Appendix II: Description and Sources of the Six Policy Elements That Are Key for Managing High-Containment Laboratories

Key element	Description	Source
Incident reporting	Policies establish appropriate lines of reporting for incidents involving hazardous biological agents in high-containment laboratories within their organizational structure that include the timely notification of laboratory and program officials, institution management, and any relevant regulatory or public authorities. We assessed whether policies contained incident reporting requirements and, specifically (1) what laboratory incidents should be reported, (2) to whom reports should be sent, and (3) time frames for reporting. We determined that policies addressed the key element, incident reporting, if at least one department or agency policy contained the three pieces of information.	GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999); GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014); 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); Centers for Disease Control and Prevention, *Report on the Inadvertent Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1* (Atlanta, Ga.: Aug. 15, 2014).
Roles and responsibilities	Policies clearly define key areas of authority and responsibility for operating activities, including a designated individual for reviewing and approving laboratory safety protocols, practices, and procedures. *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) identifies positions such as the laboratory director, a biological safety officer, and an institutional biosafety committee. We determined that policies contained the key element, roles and responsibilities, if they provided a specific role for the review and approval of standard operating procedures or biosafety plans for high-containment laboratories.	GAO/AIMD-00-21.3.1; GAO-14-704G; Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*; Centers for Disease Control and Prevention, *Report on the Inadvertent Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1*; Centers for Disease Control and Prevention, *Report on the Potential Exposure to Anthrax* (Atlanta, Ga.: July 11, 2014); Department of Defense, *Review Committee Report: Inadvertent Shipment of Live Bacillus anthracis Spores by DoD* (Washington, D.C.: July 13, 2015).
Training	Policies identify appropriate knowledge and skills needed for various jobs, including potential hazards, and provide needed training, including the practices and techniques required to handle hazardous biological agents safely, as well as candid and constructive counseling and performance appraisals. We determined that policies contained the key element, training, if they included requirements for training specific to the hazards and safety concerns of hazardous biological agents in high-containment laboratories.	GAO/AIMD-00-21.3.1; GAO-14-704G; Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*; Centers for Disease Control and Prevention, *Report on the Inadvertent Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1*.

Key element	Description	Source
Inventory control	Policies establish physical control to secure and safeguard vulnerable assets, including inventories. The BMBL suggests procedures to track the inventory, storage, use, transfer and destruction of hazardous biological materials and assets when no longer needed. We determined that policies contained the key element, inventory control, if they included requirements for an inventory of all hazardous biological agents, including, but not limited to, those identified by the select agent program.	GAO/AIMD-00-21.3.1; GAO-14-704G; Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*; The White House, *Enhancing Biosafety and Biosecurity in the United States* (Washington, D.C.: Aug. 18, 2014); The White House, *Next Steps to Enhance Biosafety and Biosecurity in the United States* (Washington, D.C.: Oct. 29, 2015).
Inspections	Policies establish ongoing monitoring in the course of normal laboratory operations. Evaluations may take the form of self-assessments as well as review of control design. We determined that policies contained the key element, inspections, if they included requirements for a self-administered inspection, which could be in addition to inspections conducted for the select agent program as applicable.	GAO/AIMD-00-21.3.1; GAO-14-704G; Department of Health and Human Services, *Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight* (Washington, D.C.: July 2009); Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*; The White House, *Next Steps to Enhance Biosafety and Biosecurity in the United States*.
Biosafety in Microbiological and Biomedical Laboratories	Policies address the widely-accepted leading guidance on the principles and practices of biosafety and biosecurity in biological laboratories, including practices for training, inventory control, and inspections. We determined that policies contained the key element, BMBL, if they included a statement specifically requiring adherence to the laboratory procedures outlined in the BMBL or listed the BMBL as a reference or authority.	Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*; Department of Health and Human Services, *Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight*.

Source: GAO analysis of source documents. | GAO-16-305

Appendix III: Timeline of Recent Centers for Disease Control and Prevention Safety Lapses and Related Federal Assessments



Source: GAO analysis of CDC documents. | GAO-16-305

Abbreviations:

APHIS	Animal and Plant Health Inspection Service
BSL	biosafety level
CDC	Centers for Disease Control and Prevention
USDA	United States Department of Agriculture

Appendix IV: Comments from the Department of Agriculture

USDA

United States Department of Agriculture

Office of the Secretary
Washington D.C. 20250

FEB 23 2016

Ms. Marcia Crosse
Director, Health Care
and
Mr. John Neumann
Director, Natural Resources and Environment
Government Accountability Office
441 G Street NW
Washington, DC 20548
Dear Ms. Crosse and Mr. Neumann:

Thank you for providing the United States Department of Agriculture (USDA) the opportunity to comment on the Government Accountability Office's (GAO) Draft Report "High Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety" (16-305). We have addressed the five Recommendations made to the Secretary of Agriculture, as it relates to your review performed of three of our agencies, the Animal and Plant Health Inspection Service (APHIS); Agricultural Research Service (ARS); and the Food Safety and Inspection Service (FSIS).

To ensure that federal departments and agencies have comprehensive and up-to-date policies and stronger oversight mechanisms in place for managing hazardous biological agents in high-containment laboratories and are fully addressing weaknesses identified after laboratory safety incidents, GAO recommends that the Secretary of Agriculture:

Recommendation (1)
Revise existing department policies for managing hazardous biological agents in high-containment laboratories to contain specific requirement for reporting of laboratory incidents to senior department officials, including the types of incidents that should be reported, to whom, and when, or direct the Administrators of APHIS and the Food Safety and Inspection Service to develop respective agency policies that contain these requirements.

USDA generally agrees with this Recommendation. At the time of the GAO review, APHIS was in the process of finalizing Section 2 titled "Biological Safety Program," of the APHIS Safety and Health Manual. On February 5, 2016, APHIS implemented the newly approved Section 2. Chapter 12, within Section 2, is titled "Occupational Exposures, Incident Reporting, and Emergency Plans," and details the types of incidents that need to be reported and the reporting timeframes. These incidents may include: accidental or deliberate release from primary containment; employee exposure; injury, illness, or infection resulting from exposure to biological materials; incidents involving select agents or toxins; biosafety related regulatory inspection, notification, or visit; and theft, loss or release into the environment of hazardous biological materials or toxins. It also states in Chapter 12 that once incidents are reported to the APHIS Biosafety Program Manager, these incidents are reported from the APHIS Marketing and Regulatory Programs-Business Services (MRP-BS) Leadership upward to USDA Departmental officials through the APHIS Administrator, or his designee, in a timely manner.

USDA is concerned how GAO represents FSIS in Table 2 and in Table 3. In reviewing these Tables 2 and 3, we believe the information in the tables could be taken out of context in that it shows that FSIS does not have policies and procedures associated with its high-containment laboratory. To the contrary, FSIS' high-containment laboratory, as a select-agent registered lab, is required by the Federal Select Agent Program to have entity policies and procedures that must be reviewed and updated annually. Thus, FSIS does have policies and procedures associated with its high-containment laboratory. For Table 2, USDA wants the following additional information added to Footnote A "Select agent-registered labs are required by the Federal Select Agent Program to have these key elements addressed in entity policies and procedures." For Table 3, USDA wants a Footnote B added for FSIS that reads "FSIS' high-containment laboratory, as a select agent-registered lab, is required by the Federal Select Agent Program to have entity policies and procedures that must be reviewed and updated annually."

GAO Recommendation (2)

Review and update outdated department policies for managing hazardous biological agents in high-containment laboratories and direct the Administrators of APHIS and Agricultural Research Service to update their policies and, in the case of APHIS, establish a regular review schedule.

USDA Response

USDA agrees with this Recommendation. APHIS' policies and directives for managing hazardous biological agents in high-containment laboratories will be reviewed every 3-5 years, or sooner if changes in regulations and/or external guidance occur. USDA departmental policies will state how often such policies and directives will need to be reviewed. In addition, ARS' has completed a draft version of its Policy and Procedure on Institutional Biological Safety Committees. ARS' Policy and Procedure on Institutional Biological Safety Committees is now undergoing final executive review and approval; and once approved and signed, will be issued as a formal ARS Policy.

GAO Recommendation (3)

Routinely analyze results of the department's laboratory inspections and incident reports to identify potential trends that may highlight recurring laboratory safety or security issues, and share lessons learned with laboratory personnel.

USDA Response

USDA agrees with this Recommendation. APHIS investigates and analyzes all incidents and accidents with the goal of identifying causal factors in order to prevent recurrence. APHIS communicates lessons learned from these investigations with laboratory personnel to include topics highlighting laboratory safety or security issues, among any other topics. APHIS' Biosafety/Biocontainment Managers and Safety and Health Staff also participate along with Agricultural Research Service (ARS) colleagues in ARS-led monthly teleconferences on biosafety. The National APHIS Safety and Health Council, comprised of management and non-management representatives from various agency programs as well as agency safety and health professionals, meets annually with the APHIS Safety and Health Program Managers, where incident trends are discussed. Additionally, two of the APHIS Safety Council representatives meet with the APHIS Administrator quarterly. The APHIS Administrator and the Designated Agency Safety and Health Officer (DASHO) have been spearheading a culture of safety initiatives. Lastly, APHIS employees who have positively contributed to the agency's safety and health initiatives are recognized at the annual APHIS Safety and Health Awards.

GAO Recommendation (4)

Require routine reporting of the results of department, agency, and select agent laboratory inspections to senior department officials.

USDA Response

USDA agrees with this Recommendation. APHIS' policy on routine reporting of laboratory inspection results is contained in Chapter 2, Section 2: Biological Safety Program of the APHIS Safety and Health Manual. Chapter 2 cites that "Copies of evaluations or inspections results will be provided to the Facility Leadership, the APHIS Biosafety Program Manager, and the APHIS Designated Agency Safety and Health Official (DASHO)."

In addition, the APHIS Agricultural Select Agent Services (AgSAS), which is part of the Federal Select Agent Program, will reach out to USDA Departments and Agencies (D/A) with registered laboratories to identify senior departmental points of contact at each D/A to receive select agent inspection reports. AgSAS will update existing Memoranda of Understandings (MOU) accordingly or will develop new MOUs where none exist.

GAO Recommendation (5)

Require routine reporting of incidents at agency laboratories to senior department officials.

USDA Response

USDA agrees with this Recommendation. APHIS' Incident reporting policy is contained in Chapter 12 of Section 2, of the "Safety and Health Manual," and cites that once incidents are reported to the APHIS Biosafety Program Manager, these incidents are subsequently reported to APHIS' MRP-BS Leadership upward to Departmental Officials through the APHIS Administrator, or his designee, in a timely manner.

In closing, thank you for your review of our high-containment laboratories. If you have any questions or if there is any further information we can provide, please feel free to reach us.

Edward Avalos
Under Secretary
Marketing and Regulatory Programs

Appendix V: Comments from the Department of Defense

ASSISTANT SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

FEB 12 2016

NUCLEAR, CHEMICAL, AND BIOLOGICAL DEFENSE PROGRAMS

Ms. Marcia Crosse, Director, Health Care
Mr. John Neumann, Director, Natural Resources & Environment
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Crosse and Mr. Neumann,

This is the Department of Defense (DoD) response to the Government Accountability Office (GAO) Draft Report GAO-16-305, "HIGH-CONTAINMENT LABORATORIES: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety," dated January 13, 2016 (GAO Code 291264).

The Department appreciates the opportunity to review the draft report and concurs with the recommendations of the GAO. The Department is actively reviewing and assessing its policies and standards related to biosafety and biosecurity for Biological Select Agents and Toxins (BSAT) and non-BSAT materials. We will ensure that GAO's recommendations are carefully considered and appropriately captured in policy revisions and in the development of associated guidance.

If you need additional information, please do not hesitate to call me at 703-697-1771. My point of contact for this effort is Ms. June Sellers, Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense at 571-256-0855 or june.k.sellers.civ@mail.mil.

Sincerely,

Arthur T. Hopkins
Principal Deputy
Performing the Duties of the ASD(NCB)

Enclosure:
As stated

GAO DRAFT REPORT DATED JANUARY 13, 2016
GAO-16-305 (GAO CODE 291264)

"HIGH-CONTAINMENT LABORATORIES: COMPREHENSIVE AND UP-TO-DATE POLICIES AND STRONGER OVERSIGHT MECHANISMS NEEDED TO IMPROVE SAFETY"

DEPARTMENT OF DEFENSE COMMENTS TO THE GAO RECOMMENDATION

RECOMMENDATION 1: The GAO recommends that the Secretary of Defense revise existing department policies for managing hazardous biological agents in high-containment laboratories to contain specific requirements for inventory control for all of DOD's high-containment laboratories, not just for its select agent-registered laboratories, or direct the Secretaries of Air Force, Army, and Navy to revise their existing, respective policies to contain these requirements.

DoD RESPONSE: The DoD concurs with this recommendation. The DoD believes that specific inventory control is required for Biological Select Agents and Toxins (BSAT) and inactivated BSAT. We are currently evaluating policies and standards related to exempt bacterial strains, non-infectious agents, and non-BSAT infectious agents. The DoD has initiated an update to Department of Defense Manual (DoDM) 6055.18-M, Safety Standards for Microbiology and Biomedical Laboratories. As part of this effort, DoD will analyze expanding the inventory control requirement across the DoD lab enterprise, to include registered and non-registered labs. Additionally, DoD is awaiting the recommendations of the National Science and Technology Council's Fast Track Action Committee Task Force; the task force is charged with making proposals on whether, and how, the Federal Government should regulate biosafety of non-select agents.

RECOMMENDATION 2: The GAO recommends that the Secretary of Defense direct the Secretaries of the Air Force and Army to review and update their respective outdated policies for managing hazardous biological agents in high-containment laboratories.

DoD RESPONSE: The DoD concurs with this recommendation. The DoD initiated an update to DoDM 6055.18-M, Safety Standards for Microbiology and Biomedical Laboratories, and the Services will continue the process with their derivative policies and standards. Additionally, the revised DoD Instruction (DoDI) 5210.88, Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT), was published on January 19, 2016. DoDI 5210.88 provides overarching policy that will guide the Services in updating their related policies.

RECOMMENDATION 3: The GAO recommends that the Secretary of Defense routinely analyze agencies' inspection results and incident reports, to identify potential trends that may highlight recurring laboratory safety or security issues, and share lessons learned with laboratory personnel, or direct the Secretaries of the Army and Navy to do so.

DoD RESPONSE: The DoD concurs with this recommendation. The DoD will work to develop a requirement to routinely analyze inspection trends and incident reports to identify recurring issues in safety, security, or administration and include it in future policy for safeguarding BSAT.

RECOMMENDATION 4: The GAO recommends that the Secretary of Defense require routine reporting of the results of Air Force, Army, and Navy inspections of non-select agent registered laboratories to senior department officials.

DoD RESPONSE: The DoD concurs with this recommendation. The DoD will add such a reporting requirement for non-BSAT inspections and incidents in the revision of the DoDM 6055.18-M, Safety Standards for Microbiology and Biomedical Laboratories, and derivative Service regulations.

RECOMMENDATION 5: The GAO recommends that the Secretary of Defense require routine reporting of laboratory incidents at Air Force, Army, and Navy non-select agent laboratories to senior department officials.

DoD RESPONSE: The DoD concurs with this recommendation and will add a routine reporting requirement for non-BSAT incidents in the revision of the DoDM 6055.18-M, Safety Standards for Microbiology and Biomedical Laboratories, and all derivative Service regulations.

RECOMMENDATION 6: The GAO recommends that the Secretary of Defense direct the Secretaries of the Army and Navy to require reporting of agency and select agent laboratory inspection results to senior agency officials.

DoD RESPONSE: The DoD concurs with this recommendation and will add a routine reporting requirement for non-BSAT inspections in the revision of the DoDM 6055.18-M, Safety Standards for Microbiology and Biomedical Laboratories, and all derivative Service regulations. This requirement will also be added to the next revision of DoDI 5210.88, Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT).

RECOMMENDATION 7: The GAO recommends that the Secretary of Defense develop timeframes for the 19 specific recommendations from the July 2015 review, or direct the Secretary of the Army to do so.

DoD RESPONSE: The DoD concurs with this recommendation and will develop timeframes for the completion of specific recommendations.

2

Appendix VI: Comments from the Department of Energy

Department of Energy
Washington, DC 20585

February 18, 2016

Mr. John Neumann
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, NW
Room 2T23A
Washington, DC 20548

Dear Mr. Neumann:

The Department of Energy (DOE) has completed its review of the Government Accountability Office (GAO) draft report, GAO-16-305, *HIGH-CONTAINMENT LABORATORIES: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety.* This letter provides DOE's response with respect to the "Recommendations for Executive Action" in the draft report that are directed to DOE.

Recommendation 1: [GAO recommends] that the Secretary of Energy revise existing Department policies for managing hazardous biological agents in high-containment laboratories to contain specific requirements for inspections, or direct the Administrator of the National Nuclear Security Administration and the Director of the Office of Science to develop agency policies that contain this requirement.

Management Response:

DOE recognizes the significance of safety lapses experienced at non-DOE federal high-containment laboratories in 2014 and 2015 and acknowledges the importance of having appropriate oversight and inspection requirements for managing hazardous biological agents. The Department has a robust system of policies, orders, and regulations in place, which provide for oversight and inspection of facilities to address all potential hazards, including biohazards. As described below in the response to Recommendation 2, while the Department is in the process of revising DOE Policy 434.1A, *Conduct and Approval of Select Agent and Toxin Work at Department of Energy Sites*, to highlight the need for appropriate oversight of biological facilities within the framework of existing DOE regulations and directives, the Department does not believe that an additional policy statement is necessary.

As the GAO report points out, 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. With respect to BSL-4, DOE policy is articulated in DOE Policy 434.1A, *Conduct and Approval of Select Agent and Toxin Work at Department of Energy Sites*. This Policy states that "[t]he Department will not authorize any biosafety level (BSL)-4 activities at LABS or allow BSL-4 operations to be conducted at DOE facilities or on DOE sites."

As noted in the GAO report, the Office of Science currently has one laboratory that is capable of, but is not currently operating at BSL-3. This laboratory could become operational as a high-

containment laboratory if needed. In addition, DOE recognizes that there may be opportunities to build or modify other laboratory facilities to operate as BSL-3 facilities in the future. With respect to BSL-3 facilities, DOE Policy 434.1A states that "BSL-3 labs will follow current DOE procedures and policy. If necessary, DOE will establish additional specific guidance to ensure safe construction and operation of BSL-3 LABS."

DOE Policy 226.1B, *Department of Energy Oversight Policy*, establishes the Department's "expectations for the implementation of a comprehensive and robust oversight process that enables the Department's mission to be accomplished effectively and efficiently while maintaining the highest standard of performance for safety and security." The scope of this Policy encompasses operational aspects of environment, safety and health; safeguards and security; cyber security; and emergency management. DOE Order 226.1B, *Implementation of Department of Energy Oversight Policy*, requires DOE to "[e]valuate contractor and DOE programs and management systems, including site assurance systems, for effectiveness of performance (including compliance with requirements). Such evaluations must be based on the results of operational awareness activities; assessments of facilities, operations, and programs; and assessments of the contractor's assurance system."

Oversight, including inspections, is further captured in departmental policy through DOE Policy 450.4A, *Integrated Safety Management Policy*. DOE Policy 450.4A specifies that "work be conducted safely and efficiently and in a manner that ensures protection of workers, the public, and the environment." This Policy goes further, noting that "[t]he ultimate responsibility and accountability for ensuring adequate protection of the workers, the public, and the environment from the operation of DOE facilities rests with DOE line management. The Department will meet this responsibility by:

- Establishing functions and clear lines of responsibilities, authorities, and appropriate accountabilities;
- Measuring safety management performance, with special emphasis on work related to high consequence activities[] by evaluating incident reports; using environment, safety, and health performance measures; and assessing performance; and
- Holding itself, and its contractors, accountable at all organizational levels for safety performance through codified safety regulations, contract clauses, DOE directives, and the use of contractual and regulatory enforcement tools.

DOE Order 450.2, *Integrated Safety Management*, requires DOE line management to "oversee compliance" and "assess contractor performance against established performance measures." Inspections, as identified in GAO's review, would clearly fall within the framework of this order and the policies and orders previously noted.

In addition, title 10, Code of Federal Regulations (CFR), Part 851, *Worker Safety and Health Program*, requires contractors to provide a place of employment that is free from recognized hazards and ensure that work is performed in accordance with a DOE-approved worker safety and health program. Moreover, 10 CFR Part 851, Appendix A, Section 7, *Biological Safety*, requires contractors with applicable functional areas to establish and implement a biological safety program that meets the requirements of this section. Under 10 CFR Part 851, DOE has

the authority to conduct such investigations and inspections as DOE deems necessary and appropriate and take enforcement actions to ensure contractor compliance with Part 851.

Recommendation 2: [GAO recommends] that the Secretary of Energy review and update its outdated policies for managing hazardous biological agents in high-containment laboratories.

Management Response:

DOE is currently revising DOE Policy 434.1A, *Conduct and Approval of Select Agent and Toxin Work at Department of Energy Sites*, and will highlight the need for appropriate oversight of biological facilities within the framework of existing DOE regulations and directives, including 10 CFR Part 851, DOE Policy 226.1B, DOE Policy 450.4A, DOE Order 226.1B, and DOE Order 450.2. The revised Policy will also contain an updated list of references, which address biological safety and security.

The Office of Environment, Health, Safety and Security is revising this Policy in cooperation with the National Nuclear Security Administration and the Office of Science, as well as other program offices, to appropriately articulate our safety approach to managing hazardous biological agents.

Estimated Completion Date: September 30, 2016.

If you have any questions about our planned actions and improvement initiatives, please contact me at (202) 586-5175.

Sincerely,

MB Moury

Matthew B. Moury
Associate Under Secretary for
Environment, Health, Safety and Security

Appendix VII: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

FEB 12 2016

Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Crosse:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety" (GAO-16-305).*

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: HIGH-CONTAINMENT LABORATORIES: COMPREHENSIVE AND UP-TO-DATE POLICIES AND STRONGER OVERSIGHT MECHANISMS NEEDED TO IMPROVE SAFETY (GAO-16-305)

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

HHS is committed to ensuring that high containment laboratories operate safely and securely while conducting research, diagnostics, and response activities critical to enhancing and protecting the public health.

In October 2015, the Department established the HHS Biosafety and Biosecurity Coordinating Council, on behalf of the Secretary, to provide a high-level and formal mechanism to coordinate and collaborate on biosafety and biosecurity issues across the Department. This body is chaired by the Office of the Assistant Secretary for Preparedness and Response and includes senior-level participation of the Immediate Office of the Secretary, Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and the National Institutes of Health (NIH). The Council has already been working to address issues raised in this report and the accompanying recommendations, and will continue to do so.

The Council will advise the Secretary and senior leadership of the Department on biosafety and biosecurity matters; foster coordination and collaboration among HHS Operating and Staff Divisions; recommend Department-wide policy; facilitate the sharing of best practices related to training and other biosafety and biosecurity matters; facilitate consistent messaging related to biosafety and biosecurity issues; and build upon existing activities and authorities within the Department. The Council is not intended to assume direct responsibilities over the management or execution of individual agencies' biosafety and biosecurity programs or incident management of events.

Among other responsibilities, the Council has been tasked with the following responsibilities:

- Develop a framework to coordinate and improve biosafety and biosecurity standards and activities across the Department to include identification of key actions to enhance biosafety and biosecurity; progress on such actions; and opportunities to further enhance biosafety and biosecurity;
- Serve as the Department-level coordinating point of contact for biosafety and biosecurity matters with the Executive Office of the President, other federal departments and agencies, and other stakeholders;
- Coordinate implementation of U.S. Government-wide recommendations on biosafety and biosecurity practices resulting from parallel federal and non-federal reviews (Federal Experts Security Advisory Panel [FESAP] and Fast Track Action Committee on Select Agent Regulations [FTAC-SAR] recommendations); and
- Coordinate development of a system for increased transparency related to notification of key laboratory incidents.

In addition to actions taken by HHS at the departmental level to strengthen biosafety and biosecurity, HHS has also been collaborating with federal partners to improve and strengthen

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: HIGH-CONTAINMENT LABORATORIES: COMPREHENSIVE AND UP-TO-DATE POLICIES AND STRONGER OVERSIGHT MECHANISMS NEEDED TO IMPROVE SAFETY (GAO-16-305)

biosafety and biosecurity. On October 29, 2015, the United States Government (USG) released two sets of recommendations, one from the FESAP (http://www.phe.gov/s3/Documents/fesap.pdf) and another from the FTAC-SAR (http://www.phe.gov/s3/Documents/ftac-sar.pdf). Both groups were co-chaired by HHS. These recommendations are key elements of progress toward strengthening the government's biosafety and biosecurity practices and the oversight system. The recommendations of both groups are complementary and will help further ensure that life science efforts that benefit the global community in countering biological threats are carried out safely and securely.

The USG expects that implementing the FESAP and FTAC-SAR recommended actions will strengthen biosafety and biosecurity practices and oversight activities and has developed a plan (http://www.phe.gov/s3/Documents/fesap-ftac-ip.pdf) to do so. The plan includes concrete actions to optimize biosafety and biosecurity policies and practices, as well as oversight. Steps are currently being taken to enhance the culture of responsibility; strengthen oversight; promote outreach and education; conduct applied biosafety research; develop an incident reporting system; enhance material accountability and inspection processes; and update regulations and guidance.

In addition to the aforementioned efforts, HHS is collaborating with other federal partners to support implementation of efforts to strengthen biosafety and biosecurity including incident reporting, training, and inspections. By sharing best practices and leveraging USG-wide work on biosafety and biosecurity, the Department will continue to improve the operation of high containment laboratories while supporting their vital mission.

GAO Recommendation

GAO recommends the Secretary of HHS develop department policies for managing hazardous biological agents in high-containment laboratories that contain specific requirements for reporting laboratory incidents to senior department officials, including the types of incidents that should be reported, to whom, and when, or direct the Director of the CDC and the Commissioner of the FDA to incorporate these requirements into their respective policies.

HHS Response

HHS concurs with this recommendation and efforts are already underway to implement it. As noted in this report, CDC's Associate Director for Laboratory Science and Safety (ADLSS) distributed a memorandum in July 2015 to agency laboratory staff and leadership outlining the agency's expectations around reporting laboratory-related incidents, issues, and concerns. The memorandum clearly stated that "CDC requires reporting of all incidents," and it was accompanied by a risk assessment tool and flow chart which described the procedures for reporting all incidents to the ADLSS. These materials were updated in November 2015, based on feedback from laboratory staff and leadership and to clarify issues raised. FDA's Director for Laboratory Science and Safety (DLSS) is currently working closely with FDA's safety officers to develop a comprehensive reporting mechanism to capture Laboratory Accidents, Incidents, Near-Misses, and Laboratory Acquired Infections. This new reporting mechanism will be

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GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: HIGH-CONTAINMENT LABORATORIES: COMPREHENSIVE AND UP-TO-DATE POLICIES AND STRONGER OVERSIGHT MECHANISMS NEEDED TO IMPROVE SAFETY (GAO-16-305)

implemented very shortly requiring the agency to report all events to the DLSS. The Office of the ADLSS (OADLSS) from CDC and DLSS (ODLSS) from FDA will incorporate these reporting requirements into official CDC and FDA-wide policy and will work with the HHS Biosafety and Biosecurity Coordinating Council to determine appropriate criteria and procedures for reporting incidents to HHS as well as to assess the applicability of these policies to an HHS-wide approach.

GAO Recommendation
GAO recommends the Secretary of HHS develop department policies for managing hazardous biological agents in high-containment laboratories that contain specific requirements for training and inspections for all high-containment component agency laboratories and not just for their select-agent-registered laboratories; or direct the Director of the CDC to provide these requirements in agency policies.

HHS Response
HHS concurs with this recommendation. CDC health and safety staff conduct safety inspections of all CDC laboratories annually. CDC has additional inspection and training requirements for select agent laboratories. CDC is updating its existing training policy to include more comprehensive training requirements for laboratory staff.

GAO Recommendation
GAO recommends the Secretary of HHS direct the Director of NIH to review and update the agency's outdated policies for managing hazardous biological agents in high-containment laboratories.

HHS Response
HHS concurs with this recommendation. NIH already has an established practice in place to review all agency policies in a five-year life cycle and while NIH's policies are reviewed every five years, that length of time is the maximum between reviews; the agency can also revise its policies more frequently, if warranted.

NIH has reviewed the policies listed below that are related to managing hazardous biological agents as part of the regular life cycle. At the time of this GAO engagement, Manual Chapter 1340 – Occupational Safety and Health Management was being reviewed and revised. This was the only policy that had not been reviewed within the five-year review period.

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GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: HIGH-CONTAINMENT LABORATORIES: COMPREHENSIVE AND UP-TO-DATE POLICIES AND STRONGER OVERSIGHT MECHANISMS NEEDED TO IMPROVE SAFETY (GAO-16-305)

Manual chapter (MC) Number and Title	Date Issued	Next Policy Revision Due (5-year requirement)
MC 1340 – *NIH Occupational Safety and Health Management Program*	February 2016 (Anticipated)	February 2021 (Anticipated)
MC 3035 – *Working Safely With Potentially Hazardous Biological Materials*	7/31/2015	7/31/2020
MC 3037 – *NIH Biological Surety Program*	7/31/2015	7/31/2020
MC 1405 – *NIH Physical Access Control*	9/24/2015	9/24/2020

GAO Recommendation
GAO recommends the Secretary of HHS direct the Commissioner of FDA to establish a regular schedule for reviewing and updating agency policies for managing hazardous biological agents in high-containment laboratories.

HHS Response
HHS concurs with this recommendation. FDA has recently established a new Office of Laboratory Science and Safety to oversee all of FDA's laboratory science and safety needs. On an annual basis, this office will review and update agency policies for managing hazardous biological agents in high-containment laboratories.

GAO Recommendation
GAO recommends the Secretary of HHS require routine reporting of the results of agency and select agent laboratory inspections to senior department officials.

HHS Response
HHS concurs with this recommendation. Efforts have already been undertaken to implement this recommendation. At CDC, as part of a recently completed reorganization and realignment of laboratory safety functions into the OADLSS, the results of inspections will be reported to CDC's ADLSS. CDC will work with the HHS Biosafety and Biosecurity Coordinating Council to determine appropriate criteria and procedures for reporting inspection results to HHS. Further, FDA's Office of Laboratory Science and Safety is planning to establish a program for regulatory compliance and assurance across the FDA. As part of this program, all FDA laboratories working with hazardous biological agents and toxins will be subject to an annual inspection for compliance to agency policies and applicable rules and regulations relating to the management of hazardous biological agents in high-containment laboratories. On an annual basis, a summary of the inspection findings along with the select agent inspection reports conducted by CDC and USDA, will be shared through the Office of Laboratory Science and Safety with senior FDA officials and the HHS Biosafety and Biosecurity Coordinating Council.

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GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: HIGH-CONTAINMENT LABORATORIES: COMPREHENSIVE AND UP-TO-DATE POLICIES AND STRONGER OVERSIGHT MECHANISMS NEEDED TO IMPROVE SAFETY (GAO-16-305)

GAO Recommendation
GAO recommends the Secretary of HHS direct the Director of NIH and the Commissioner of FDA to require routine reporting of the results of agency laboratory inspection – and in the case of FDA, require routine reporting of select agent inspection results – to senior agency officials.

HHS Response
HHS concurs with this recommendation. As outlined in the response to the previous recommendation, such efforts are already underway at FDA. In regard to NIH, it has been and is currently the practice at NIH that the Associate Director of Research Services, Office of the Director (OD), is routinely notified of planned select agent inspections and select agent inspection results. This individual is also the Designated Agency Safety and Health Official for NIH.

GAO Recommendation
GAO recommends the Secretary of HHS require routine reporting of incidents at CDC, FDA, and NIH laboratories to senior department officials.

HHS Response
HHS concurs with this recommendation. As stated above, the HHS Biosafety and Biosecurity Coordinating Council has been tasked with coordinating the development of a system for increased transparency related to notification of key laboratory incidents. CDC, FDA, and NIH are committed to continue working with the Council to determine appropriate criteria and procedures for reporting incidents to senior department officials. Further, as noted by GAO in this report, NIH does currently have an established policy regarding reporting incidents to senior Department officials. FDA is currently in the process of updating its policies and reporting form to capture laboratory incidents, accidents, and near-misses. Incidents and accidents will be shared with the agency leadership on a monthly basis whereas near misses will be used to support lessons learned and, as needed, implementation of improved safety measures. Incidents and accidents that are deemed serious will be shared with the Department leadership through the Office of the Commissioner as the event unfolds.

GAO Recommendation
GAO recommends the Secretary of HHS direct the Director of CDC to develop time frames for the recommendations from the internal workgroup review.

HHS Response
HHS concurs with this recommendation. CDC's OADLSS is working to establish time frames for initiating, completing, and/or moving forward towards addressing remaining outstanding recommendations from CDC's internal Laboratory Safety Improvement Workgroup's (LSIW) 2014 review of CDC laboratory safety practices. CDC has initiated efforts to address almost all of the LSIW recommendations. CDC and its external Laboratory Safety Workgroup members have noted that addressing some areas will be an ongoing activity and that CDC expects to continue implementing improvements into the future.

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Appendix VIII: Comments from the Department of Homeland Security

U.S. Department of Homeland Security
Washington, DC 20528

Homeland Security

February 16, 2016

Ms. Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Mr. John Neumann
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Re: Draft Report GAO-16-305, "HIGH-CONTAINMENT LABORATORIES: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety"

Dear Ms. Crosse and Mr. Neumann:

Thank you for the opportunity to comment on this draft report. The U.S. Department of Homeland Security (DHS) appreciates the U.S. Government Accountability Office's (GAO's) work in planning and conducting its review and issuing this report.

The Department is pleased to note GAO's positive recognition of DHS's ongoing oversight activities for the management of biological select agents and toxins (BSAT) in high-containment laboratories. As noted in the draft report, these activities include routine inspections; inventory audits and verifications; and training records reviews. DHS is also pleased GAO highlighted that DHS routinely reported inspection results to senior department officials.

DHS's Science and Technology Directorate's (S&T) Compliance Assurance Program Office (CAPO) has maintained a robust Department-level compliance assurance program for laboratory biosafety and security since 2007. CAPO's program provides centralized, ongoing oversight for the management of BSAT at the Department's two biocontainment laboratories, the National Biodefense Analysis and Countermeasures Center (NBACC) and the Plum Island Animal Disease Center (PIADC). CAPO also provides compliance

oversight for DHS-sponsored activities involving BSAT at non-government high-containment laboratories.

CAPO has coordinated these oversight efforts with the appropriate regulatory authorities, to include joint inspections with the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT), and the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Agency (APHIS) Agricultural Select Agent Services (AgSAS) since the inception of the program. In 2011, CAPO formalized this coordination through a Memorandum of Understanding with the CDC and the USDA APHIS, under which CAPO routinely conducts joint inspections of the NBACC, PIADC, and other high/maximum-containment laboratories carrying out work for DHS involving BSAT.

The draft report contained two recommendations for DHS with which the Department concurs. Specifically, GAO recommended that the Secretary of Homeland Security:

Recommendation 1: Revise existing policies for managing hazardous biological agents in high-containment laboratories to contain specific requirements for inventory control that would apply to all high-containment laboratories, not just select agent-registered laboratories.

Response: Concur. As noted in the draft report, current DHS policies already contain inventory control requirements for DHS's two high- and maximum-containment laboratories, both of which are registered with the Select Agent Program. At present, DHS has no other high- or maximum-containment laboratories. DHS's S&T CAPO will, however, amend the current policies to include language requiring inventory control measures for managing hazardous biological agents in high-containment laboratories, regardless of select agent registration status. CAPO has already initiated a comprehensive review and revision of these policies. Estimated Completion Date (ECD): September 30, 2016.

Recommendation 2: Review and update policies for managing high-containment laboratories, and establish a regular schedule for reviewing and updating these policies.

Response: Concur. DHS's S&T CAPO began the review process for both policy directives (i.e., MD-066-02, *Biosafety*, and MD-026-03, *Select Agent and Toxin Security*) before this audit was initiated. CAPO understands the importance of regularly scheduled reviews and will recommend to senior DHS leadership that existing policies be amended to require mandatory review on a recurring schedule, then update related policies as directed by leadership. ECD: October 31, 2016.

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Again, thank you for the opportunity to comment on this draft report. Technical comments were previously provided under separate cover. Please contact me if you have any questions. We look forward to working with you in the future.

Sincerely,

Jim H. Crumpacker, CIA, CFE
Director
Departmental GAO-OIG Liaison Office

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Appendix IX: Comments from the Department of the Interior

United States Department of the Interior

OFFICE OF THE SECRETARY
Washington, DC 20240

FEB 12 2016

Ms. Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Crosse:

Thank you for providing the U.S. Department of the Interior (DOI) the opportunity to review and comment on the draft Government Accountability Office (GAO) Report entitled *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety* (GAO-16-305). We appreciate GAO's review of the oversight at Federal high-containment laboratories. The GAO concluded that updated comprehensive policy and procedures would help Federal agencies reduce the risk of mismanaging hazardous biological agents by conveying consistent requirements for oversight.

The GAO issued four recommendations to the DOI in response to its overall findings. We generally agree with the findings and concur with the recommendations and offer the following responses.

To address the recommendations, the Secretary of the Interior will direct the Directors of Fish and Wildlife Service (FWS) and the U.S. Geological Survey (USGS) to develop bureau policies for reporting laboratory incidents to senior Department officials, including the types of incidents that should be reported, to whom, and when, and specific requirements for roles and responsibilities, training, inventory control, and inspections. The DOI created a Biosafety Working Group (BWG) with representation from the Office of Emergency Management (OEM), Office of Law Enforcement and Security (OLES), Office of Occupational Safety and Health (OSH), FWS, and USGS.

The DOI BWG is currently developing an automated process enabling the DOI to routinely analyze the results of the agency's laboratory inspections and incident reports and identify potential trends that may highlight recurring laboratory safety or security issues. The DOI BWG will also develop a process for sharing the information gleaned from the analysis, including lessons learned with laboratory personnel in a timely manner. The USGS is modifying and expanding its existing policies for reporting safety and security incidents to include routine reporting of all agency and select agent laboratory inspection results to senior Department and USGS officials.

Following is a technical comment for your consideration when finalizing the report.

Page 8, Table 1, FWS line - The FWS has one lab that falls within the scope of the GAO review. It is a forensics lab that handles evidence of a criminal nature. This lab has no select agents, does not conduct research on emerging pathogens or handle samples for zoologic purposes.

If you have any questions, or need additional information, please contact me.

Sincerely,

Kristen J. Sarri
Principal Deputy Assistant Secretary
Policy, Management and Budget

Appendix X: Comments from the Department of Veterans Affairs

DEPARTMENT OF VETERANS AFFAIRS
Washington DC 20420

February 22, 2016

Ms. Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Crosse:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, ***"HIGH-CONTAINMENT LABORATORIES: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety"*** (GAO-16-305). VA agrees with GAO's conclusions and concurs with GAO's recommendations to the Department.

The enclosure specifically addresses GAO's recommendations in the draft report and provides an action plan, and provides technical comments to the draft report.

VA appreciates the opportunity to comment on your draft report.

Sincerely,

Robert D. Snyder
Interim Chief of Staff

Enclosure

Enclosure

Department of Veterans Affairs (VA) Response to
Government Accountability Office (GAO) Draft Report
"HIGH-CONTAINMENT LABORATORIES: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety"
(GAO-16-305)

GAO Recommendation: GAO recommends the Secretary of Veterans Affairs:

Recommendation 1: Develop department policies for managing hazardous biological agents in high-containment laboratories that contain specific requirements for reporting laboratory incidents to senior department officials – including the types of incidents that should be reported, to whom, and when – and requirements for inventory control of all of its high-containment laboratories, including its select agent-registered clinical laboratory, or direct the Administrator of the Veterans Health Administration to incorporate these requirements into its policies.

VA Comment: Concur. The Department of Veterans Affairs (VA) agrees that setting policy expectations in advance of emergency response activities which may require activation of VA's high containment laboratory facilities is essential for VA and national preparedness. Presently, VA has local facility policies but will develop a national policy in the event that there is an emergency activation of high containment laboratories. This policy will include specific requirements for reporting laboratory incidents during emergency activation to senior officials – including the types of incidents that should be reported, to whom, and when – and requirements for inventory control. Target Completion Date: March 2018.

Recommendation 2: Direct the Administrator of the Veterans Health Administration to review and update agency policies for managing hazardous biological agents in high-containment laboratories.

VA Comment: Concur. The Veterans Health Administration has reviewed the most recently published handbook titled Pathology and Laboratory Medicine Service Procedures 1106.1, which is dated January 29, 2016 and has concluded this version contains the required sections as indicated within the report on management of hazardous biological agents. Please see Attachment A.

Appendix XI : Comments from the Environmental Protection Agency

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 12 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. John Neumann
Director
Natural Resources and Environment
U.S. Government Accountability Office
Washington, DC 20548

Dear Mr. Neumann:

Thank you for the opportunity to review and comment on the Government Accountability Office's Draft Report entitled, "High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety," dated January 13, 2016; Project No. GAO-16-305.

The GAO stated as its objectives for this evaluation to answer the following questions:

1. Examine the extent to which federal agencies have comprehensive and up-to-date policies for managing biological agents in these laboratories.
2. Examine how agencies oversee laboratories.
3. Examine the extent to which HHS and DOD have implemented recommendations from safety reviews.

Of the 33 recommendations in the GAO report, three recommendations were directed at the U.S. Environmental Protection Agency. The EPA appreciates the GAO's effort in evaluating the policy, procedures and oversight mechanisms to improve safety at the EPA's Office of Chemical Safety and Pollution Prevention/Office of Pesticide Programs' Microbiology Laboratory. The EPA believes the OCSPP/OPP laboratory is currently in compliance with the first two EPA recommendations made by the GAO, which include: (1) specific requirements for inventory control and (2) review and update of policies for managing hazardous biological agents in high-containment laboratories. Additional information is provided in this response for the GAO's consideration to determine the OCSPP's compliance with these requirements. The EPA is in agreement with the third recommendation to require routine reporting of the results of department, agency, and select agent laboratory inspections to senior department officials. In addition, the EPA would like the GAO to reconsider the scoring provided on Table 2 for the OCSPP/OPP laboratory for the reasons noted below under "Policies, Procedures and Oversight at the Lab."

1

Internet Address (URL) • http://www.epa.gov
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Background

The primary focus of the OCSPP/OPP Microbiology Laboratory is the standardization of existing test methods, and the development and validation of methods for new uses and emerging pathogens for antimicrobial products with public health claims (*i.e.*, products used to kill or suppress the growth of pathogenic microorganisms on inanimate objects and surfaces). A variety of pathogens including bacteria, viruses, *Mycobacterium*, *Clostridium difficile,* and biofilms are of interest. The laboratory is instrumental in advancing the science of antimicrobial product testing and provides technical expertise to standard-setting organizations and various agency stakeholder groups. The laboratory also supports other agency offices on Homeland Security initiatives and is registered with the CDC/USDA Select Agent Program. Technical workshops, training, and multi-laboratory collaborative studies are key priorities for the OCSPP/OPP Microbiology Laboratory as well.

For clarification purposes, the OCSPP/OPP Microbiology Laboratory does not conduct "high containment" work on a regular basis. While the OCSPP/OPP lab is the only EPA laboratory with the physical attributes necessary for high containment work, the only high containment (BSL-3) work anticipated for the laboratory is for preparedness purposes should there be a national or regional emergency involving *Bacillus anthracis*. The work at the OCSPP/OPP Microbiology Laboratory under normal operations involves only microorganisms categorized as Biosafety Level 1 and 2.

Policies, Procedures and Oversight at the Lab

In Table 2 of the Draft Report, the GAO appears to indicate that the OCSPP/OPP is deficient in all six key elements under consideration. The OCSPP/OPP does not agree that this is the case, and Attachment 1 provides citations to the OCSPP/OPP's policies corresponding to each of the six key elements outlined by the GAO. Accordingly, we respectfully request that the GAO revisit its assessment of the OCSPP/OPP's deficiencies. The OCSPP/OPP provided several of the documents noted in Attachment 1 to the GAO between March and August 2015, and we are concerned that the documents may have been overlooked. Two of the documents cited in Attachment 1, the Occupant Emergency Plan and the Standard Operating Procedure for laboratory training, are also attached.

The OCSPP/OPP and the Environmental Science Center facility (which houses the OPP laboratories) have long standing policies and procedures with respect to the six elements. While the information is presented as the general policies for the laboratory and the facility, the OCSPP/OPP laboratory is also registered under the Select Agent Program. The laboratory would not have met the requirements by the CDC and the USDA for a Tier 1 agent without meeting several of the key elements noted by that GAO in Table 2 of the Draft Report – particularly adherence to the Biosafety in Microbiological and Biomedical Laboratories manual, staff training, and biological inventory control. In addition, it is noted in the Draft Report that the OCSPP/OPP made significant progress in automating its inventory control system but received a "department or agency does not have policies" ranking in that key element. As noted in the attached documents, graded policies and procedures are followed from generally applicable (for the ESC), then specific to the laboratory (OPP), and then specific to the high containment microbe (*Bacillus anthracis*).

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The EPA Response to GAO's Recommendations

Listed below are the GAO's recommendations, followed by the EPA's efforts to implement each recommendation or arguments why the EPA disagrees with the recommendations and what the agency plans to do instead.

1. Revise existing department policies for managing hazardous biological agents in high containment laboratories to contain specific requirements for inventory control, or direct the Director of the Office of Pesticide Programs to develop agency policies that contain this requirement.

   The EPA agrees and the OCSPP/OPP already has taken strong steps to strengthen and automate the biological inventory control system at the laboratory. The GAO acknowledged these steps as being complete in Table 5. The OPP maintains an automated inventory of all microbes used by the laboratory and will continue to do so in the future. The inventory system is fully functional and is used on daily basis to track and monitor biological materials used by the laboratory. The inventory is inspected on a quarterly basis. Since the OCSPP/OPP laboratory is the only EPA high containment lab, we believe and the GAO acknowledges, that OPP's requirement for inventory control is complete.

2. Review and update policies for managing hazardous biological agents in high containment laboratories, and establish a regular schedule for reviewing and updating these policies.

   The EPA agrees that a regular schedule for updating and reviewing these policies is important and is currently being done at the agency. The policies and procedures for the ESC (the facility that houses the OCSPP/OPP Microbiology Laboratory), and the procedures and policies for operations of the laboratory, are reviewed and updated on a regular basis, consistent with EPA policy for these types of documents (biosafety plans, laboratory operational plans etc.). Facility-related documents are updated on a bi-yearly basis and operational documents are updated annually. Please refer to the documents noted in Attachment 1.

3. Require routine reporting of the results of department, agency and select agent laboratory inspection to senior department officials.

   The EPA agrees with this recommendation and the OCSPP/OPP laboratory will notify senior officials within three weeks of any inspection findings that relate to the OCSPP/OPP Microbiology Laboratory.

Overall, we are pleased that the Draft Report recognizes EPA's continuing efforts to improve the policies, oversight and management of our laboratory.

Sincerely,

James J. Jones
Assistant Administrator

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Attachments:
1 - Citation of Documents That Illustrate the OCSPP/OPP's Compliance with the Six Elements Identified by the GAO
2 - Suggested Technical Corrections

cc: The EPA GAO Liaison Team

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Appendix XII: GAO Contacts and Staff Acknowledgments

GAO Contacts

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Staff Acknowledgments

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Related GAO Products

High-Containment Laboratories: Preliminary Observations on Federal Efforts to Address Weaknesses Exposed by Recent Safety Lapses. GAO-15-792T. Washington, D.C.: July 28, 2015.

Chemical and Biological Defense: Designated Entity Needed to Identify, Align, and Manage DOD's Infrastructure. GAO-15-257. Washington, D.C.: June 25, 2015.

High-Containment Laboratories: Recent Incidents of Biosafety Lapses. GAO-14-785T. Washington, D.C.: July 16, 2014.

High-Containment Laboratories: Assessment of the Nation's Need Is Missing. GAO-13-466R. Washington, D.C.: February 25, 2013.

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-09-574. Washington, D.C.: September 21, 2009.

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