United States Government Accountability Office

GAO

Report to Congressional Committees

January 2013

OVERLAP AND DUPLICATION

Federal Inspections of Entities Registered with the Select Agent Program

GAO-13-154

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GAO Accountability * Integrity * Reliability

Highlights

Highlights of GAO-13-154, a report to congressional committees

Why GAO Did This Study

Between 2009 and 2011, there were roughly 374 entities across the United States conducting research with select agents such as anthrax, which have the potential to threaten health and safety. Inspections are one means of ensuring safety and compliance with regulations. However, several federal agencies—CDC, APHIS, DOT, DHS, and DOD—conduct such inspections, creating significant potential for overlap and duplication of effort. In this context, GAO was asked to assess (1) the extent of overlap and potential duplication in federal inspections of select agent entities, (2) the costs of such overlap and effects on laboratory operations, and (3) actions to reduce the costs and negative effects of any overlap. To answer these objectives, GAO analyzed agency data, surveyed entities, held focus groups with lab staff, and interviewed agency officials.

What GAO Recommends

GAO recommends that CDC and APHIS work with DHS and DOD to coordinate inspections and ensure consistent application of inspection standards.

HHS, USDA, DHS, and DOD generally agreed with our recommendations and noted various actions they have already taken, or plan to take, to coordinate inspection efforts.

View GAO-13-154. For more information, contact Nancy Kingsbury at (202) 512-2700 or kingsburyn@gao.gov.

What GAO Found

About 15 percent of entities registered to work with select agents were subject to inspection overlap (multiple federal agencies inspecting within a 2-year period). Entities experiencing overlap tended to be larger ones, with more laboratories, principal investigators, and staff. Although there was overlap between Department of Transportation (DOT) inspections and those of the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS), they were generally not duplicative because specific inspection activities tended to differ, according to GAO's survey of entities experiencing overlap. For example, DOT inspections tended to focus on transportation issues, such as checking hazardous materials and transportation security plans, rather than general biosafety issues. The Department of Homeland Security (DHS) and Department of Defense (DOD) inspections, however, tended to be more duplicative with those of CDC and APHIS. For example, both review the same documents, require safety and security demonstrations, conduct inventory inspections and personnel interviews, and provide corrective action plans. While inspections are important for safety and compliance, there is no value added when federal agencies are expending resources to conduct the same work and, in some cases, reinspecting before entities have had time to respond to findings from a previous inspection.

The costs of overlapping federal inspections and effects on lab operations are difficult to quantify because agencies and entities generally do not track them and some costs are not quantifiable. Although GAO could not quantify the portion of federal and entity costs directly attributable to overlap, it could quantify the costs of inspections in general. According to agency data, the approximate overall federal cost for fiscal years 2010 and 2011 inspections was $2.1 million dollars. On average, the entity costs per inspection were nearly $15,000, and staff time per inspection was 380 hours, according to the GAO survey. While surveyed entities reported that inspections can help correct deficiencies and improve accountability, most reported moderate to significant nonquantifiable costs of inspections due to loss of productivity and delays in research. In addition, according to surveyed entities, overlapping inspections negatively affected lab productivity, staff morale, available time to complete research, and the research schedule. Because many of these entities are federal laboratories or are funded through federal grants, these costs are passed on to the federal government.

Actions to reduce the costs of overlapping and duplicative inspections include better coordination among federal agencies and greater consistency in the application of standards, according to various experts and surveyed entities. CDC has taken actions to better coordinate inspections with other agencies, for example, by increasing the use of joint inspections. But such actions, including joint inspections, do not fully address the negative effects of multiple inspections if agencies apply inconsistent standards and develop separate reports of findings. Well-trained inspectors, who apply consistent standards, are also needed. Collectively, these actions would reduce the negative effects of overlap and duplication and could increase agencies' acceptance of each other's inspection results.

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Abbreviations

ABSA	American Biological Safety Association
APHIS	Animal and Plant Health Inspection Service
ATEC	Army Test and Evaluation Command
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSL	Biosafety Level
CDC	Centers for Disease Control and Prevention
DAIG	Department of the Army, Office of Inspector General
DHS	Department of Homeland Security
DOD	Department of Defense
DOE	Department of Energy
DOJ	Department of Justice
DOT	Department of Transportation
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
MOU	Memorandum of Understanding
NIH	National Institutes of Health
OSHA	Occupational Safety and Health Administration
PHMSA	Pipeline and Hazardous Materials Safety Administration
PPE	personal protective equipment
PRP	personnel reliability program
RO	Responsible Official
SAP	Select Agent Program
SAR	Select Agent Regulations
SAV	Staff Assistance Visits
SMR	Biosurety Management Reviews
UN	United Nations
USDA	United States Department of Agriculture

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

January 31, 2013

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

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

Between fiscal years 2009 and 2011, there were 374 entities registered with the federal Select Agent Program (SAP) that were home to over 1,900 biosafety laboratories in the federal, academic, and private sectors across the United States.[1] These laboratories conduct research with biological agents or toxins, known as "select agents," such as anthrax, which have the potential to severely threaten public health and safety, animal and plant health, and animal and plant products. Consequently, these issues are a key concern of entities and federal agencies conducting, funding, or overseeing select agent work. Inspections are one mechanism for ensuring that entities registered to work with select agents comply with Select Agent Regulations (SAR) for biosafety, biosecurity, and biocontainment. However, there are multiple federal agencies, as

[1]An entity is defined in the Select Agent Regulations (SAR) as any government agency (federal, state, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal body. The number of laboratories at each entity registered with the Centers for Disease Control and Prevention (CDC) or Animal and Plant Health Inspection Service (APHIS) ranges from 1 to 124 laboratories. The term biosafety laboratory refers to biosafety level (BSL)-2, -3, and -4 laboratories, with 4 being the maximum level. In the United States, laboratories working with human, plant, or animal pathogens are classified by the type of agents used; activities being conducted; and the risks those agents pose to laboratory personnel, the environment, and the community. For purposes of this report, we are using the term select agent laboratories to refer to BSL-2, -3, and -4 laboratories that work with select agents.

well as state, local, and professional organizations, that currently inspect these entities, creating the potential for overlap and duplication of effort.

Various federal agencies have the authority to inspect entities that possess, use, or transfer select agents. The Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) and the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) inspect entities under the SAR to ensure compliance with the SAP.[2] In addition, the Department of Transportation's (DOT) Pipeline and Hazardous Materials Safety Administration's (PHMSA), under DOT's Hazardous Materials Regulations, has the authority to regulate the safe and secure transportation of all hazardous materials.[3] Under the SAR, any entity that uses, possesses, or transfers select agents must (1) register with CDC or APHIS and (2) establish and implement plans to ensure the safety and security of its activities.[4] Prior to issuing a certificate of registration, CDC and APHIS may inspect and evaluate the premises and records to ensure compliance with the SAR. In addition, CDC and APHIS may inspect any site, for compliance and other purposes, where activities regulated by the SAR are conducted. DOT's PHMSA also has the authority to perform inspections pertaining to the transport of biological agents. Other federal agencies also inspect laboratories that work with select agents, including the Department of Defense (DOD) and its Army, Navy, and Air Force Inspector General (IG) offices and the Department of Homeland Security (DHS). DOD inspects to ensure compliance with federal, DOD, and

[2] The Public Health Security and Bioterrorism Response Act of 2002 (Pub. L. No. 107-188, title II, subtitle A,116 Stat. 594 (June 12, 2002)) expanded HHS's authority to regulate biological select agents and toxins to include oversight of all entities that possess, use, and transfer select agents affecting public health and safety. The Agricultural Bioterrorism Protection Act of 2002 granted comparable authority to USDA for select agents posing a threat to plant or animal health or products. (Pub. L. No. 107-188, title II, subtitle B, 116 Stat. 594 (June 12, 2002)). CDC and APHIS were delegated authority by their respective departments to regulate the use, possession and transfer of select agents and thereafter issued nearly identical regulations. (42 C.F.R. part 73 [CDC]; 7 C.F.R. part 331 [APHIS–plant]; 9 C.F.R. part 121 [APHIS–animal]).

[3] 49 C.F.R. parts 171 to 180. Under 49 U.S.C. § 5103, DOT has the primary authority to regulate the safe and secure transportation of all hazardous materials, including infectious materials, shipped in intrastate, interstate, and foreign commerce.

[4] Requirements for security, biosafety and incident response plans are at 49 C.F.R. §§ 73.11, 73.12, and 73.14 [CDC]; 7 C.F.R. §§ 331.11, 331.12, and 331.14 [APHIS–plant]; 9 C.F.R. §§ 121.11, 121.12, and 121.14 [APHIS–animal]).

military service component requirements as well as contract requirements. DHS conducts periodic inspections to ensure compliance with funding requirements of entities for which they have funded research. These inspections, however, also generally cover compliance with the SAR. While DOD and DHS inspections assess compliance with the SAR, these departments do not have authority to regulate all entities possessing, using, or transferring select agents. Rather, these departments issue their own agency regulations and directives that allow them to inspect entities they own or fund (see table 1 for major areas covered in agencies' inspections). In addition to these federal agencies, several others, such as the Occupational Safety and Health Administration (OSHA), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA), may also inspect registered entities for a variety of reasons, such as ensuring employee safety and health or compliance with standards for recombinant DNA research. We did not include them in our review because these inspections generally do not focus on biosafety and biosecurity issues.

Table 1: Major Areas Covered in Agencies' Inspections

Agency	Biosafety	Biosecurity	Biocontainment
CDC[a]	Yes	Yes	Yes
APHIS[a]	Yes	Yes	Yes
DOT[b]	Yes	Yes	No
DHS[c]	Yes	Yes	Yes
DOD[d]	Yes	Yes	Yes

Source: GAO analysis of agency inspection practices.

[a]CDC and APHIS inspect under the SAR.

[b]DOT inspects the shipping and packaging of biological agents under its Hazardous Materials Regulations.

[d]DHS issues its own guidance requiring laboratories it owns or funds to undergo inspections. For example, Management Directive 026-03, *Select Agents and Toxin Security*, Mar. 11, 2007.

[d]DOD issues its own policies and regulations that DOD components, such as the service IGs and various major command and lower service-level organizations use to inspect laboratories owned or funded by DOD. For example, Department of the Army Pamphlet 385-69, *Safety Standards for Microbiological and Biomedical Laboratories* (May 6, 2009) and Army Regulation 385-10, *The Army Safety Program*.

In March 2011, we issued our first annual report to Congress on federal programs, agencies, offices, and initiatives, either within departments or

government-wide, that have duplicative goals or activities.[5] The report highlighted instances of (1) overlap—two or more agencies or programs engaged in similar activities or providing similar services to similar beneficiaries; (2) duplication—two or more agencies or programs engaged in the same activities or providing the same services to the same beneficiaries; and (3) fragmentation—more than one federal agency engaged in similar activities, but not coordinating efforts. The number of federal agencies involved in inspections of select agent entities heightens the potential for overlap and duplication. Moreover, the increasing number of inspections further increases the potential for overlap. From fiscal year 2009 through 2011, CDC, APHIS, DOD, DHS, and DOT collectively conducted over 800 inspections of select agent entities.

In this context, you asked us to assess (1) the extent of overlap and potential duplication in federal agencies' inspections of entities that work with select agents, (2) the costs of overlapping federal inspections and effects on laboratory operations, and (3) actions to reduce the costs and negative effects of overlapping inspections.

To answer these objectives, we interviewed agency officials and reviewed pertinent legislation, regulations, and agency documents. We also analyzed agency information on inspectors' total compensation (salary and benefits), hours spent on inspection activities, the associated travel costs for inspections for fiscal years 2010 and 2011, and inspection data to identify entities that had been inspected by more than one agency in a 2-year period (at any point between fiscal years 2009 and 2011). Using the definition of overlap from our 2011 report, in the context of SAR inspection requirements, we defined overlap as two or more federal agencies inspecting the same entity on separate occasions within a 2-year period.[6] Because CDC and APHIS manage the SAP jointly and

[5]GAO, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue*, GAO-11-318SP (Washington, D.C.: Mar. 1, 2011).

[6]This is a somewhat conservative measure of overlap given the SAR requirements for certification renewal inspections every 3 years and the CDC's and APHIS's policy of inspecting before recertifying. However, because the CDC and APHIS can inspect between renewals, the 2-year time frame also captures overlap that may occur as a result of additional CDC/APHIS inspections within the 3-year period. All jointly conducted inspections were counted as a single inspection in our analysis of overlap. For example, a joint APHIS/DHS inspection or a joint CDC/ DAIG inspection would count as one inspection.

conduct joint inspections, where applicable, we collapse these agencies in reporting on overlap to show where DOT, DHS, or DOD inspections overlapped with either a CDC or APHIS inspection.[7] We developed a detailed list of inspection activities and identified duplication where the two overlapping inspections covered the same activities. From the 374 entities registered to work with select agents between fiscal years 2009 and 2011, we identified entities that had been inspected on separate occasions by more than one agency in a 2-year period. We then conducted a web-based survey of all such entities to collect information on (1) the extent to which there was duplication in specific inspection activities related to the preparation, execution, and closeout phases of the two inspections undergone, (2) the costs and operational effects of inspections, (3) the solutions for mitigating the negative effects of multiple inspections, and (4) the positive and negative aspects of joint inspections. Our survey was sent to the responsible official (RO) of each entity that was subject to overlapping inspections, and we received an 85 percent response rate. To gather preliminary information and develop our survey, we conducted focus groups with about 50 laboratory workers from entities that have experienced federal inspections, including ROs, biosafety officers, principal investigators, and technical staff from federal, academic, and private entities that work with select agents. We interviewed officials with CDC, APHIS, DHS, DOD, and DOT and examined inspection files to understand general and agency-specific inspection activities. We also spoke with professional organizations, such as the American Biological Safety Association (ABSA), the American Society for Microbiology, and experts in the safety of select agent laboratories. We determined that the data we used were sufficiently reliable for our purposes. (See app. I for a more-detailed discussion of our scope and methodology.)

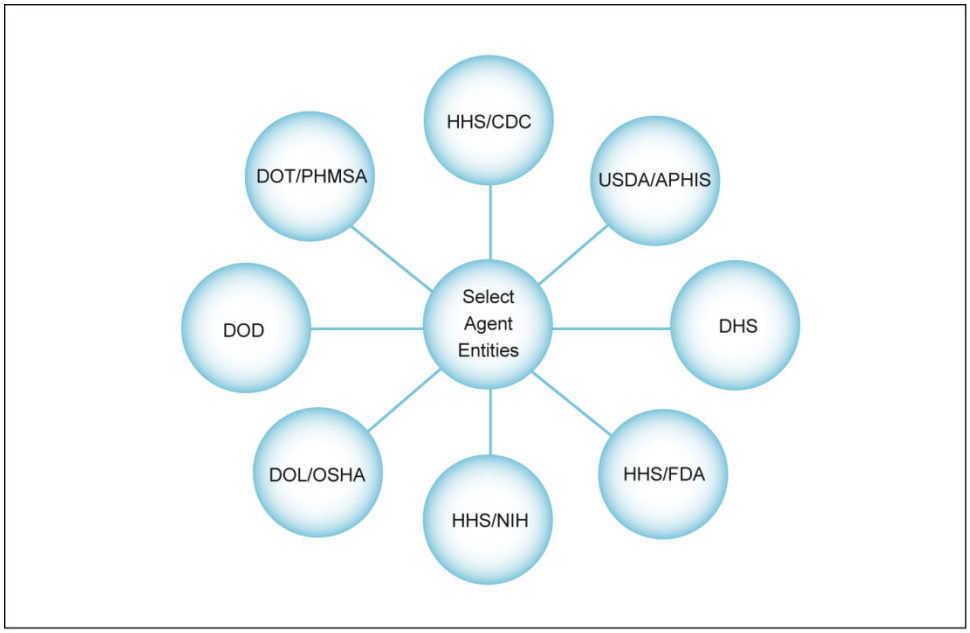
We conducted our work from March 2011 through January 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[7]Consequently, in some summary analyses of overlap, we present CDC/APHIS survey results together.

Background

In 2007, GAO reported on issues associated with the proliferation of biosafety laboratories in the United States. In 2009, we noted that while proliferation of these laboratories was taking place in the federal, academic, and private sectors across the United States, the federal oversight of these laboratories was fragmented—there was not a single federal agency to provide oversight.[8] As a result, numerous federal agencies could be involved in separate and independent inspections of these entities and their associated laboratories. The various agencies that have a role in the oversight of select agent entities and can conduct inspections are shown in figure 1.

Figure 1: Federal Agencies That Inspect Select Agent Entities



Source: GAO.

[8]GAO, *High-Containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, GAO-08-108T (Washington, D.C.: Oct 4, 2007). GAO, *High-Containment Laboratories: National Strategy for Oversight Is Needed*, GAO-09-1036T (Washington, D.C.: Sept 22, 2009).

CDC and APHIS Inspections

CDC and APHIS have regulatory authority to assess compliance with biosafety, biosecurity, and biocontainment requirements. Under the current SAR, entity registration must be renewed every 3 years, and CDC or APHIS may conduct an on-site inspection before the award of a new certificate of registration or the renewal of an existing registration.[9] These inspections generally cover all aspects of the SAR. As a matter of policy, to ensure that the entity is compliant with the SAR, CDC or APHIS inspects the premises and records of applicants, including a review of all required plans, before issuing the initial certificate of registration. In addition, CDC or APHIS may conduct inspections to (1) respond to concerns about an entity's compliance, (2) verify corrections of deficiencies identified through inspections or accomplishment of Performance Improvement Plan goals; or when (3) modifications are made to the entity's registration, (4) a new building or laboratory is added, (5) a higher-risk agent or toxin is added, (6) a change is made in security infrastructure or policy and procedures, (7) a theft, loss, or release incident occurs, or (8) a violation is reported. Any entity where select agents are possessed, used, or transferred must allow CDC and APHIS to inspect, with or without prior notification.[10] In addition to CDC or APHIS inspections, the SAR requires each registered entity to conduct annual self-inspections under the direction of the entity's RO.[11]

DOT Inspections

DOT has the primary authority to regulate the safe and secure transport of all hazardous materials shipped intrastate, interstate, and in foreign commerce. Infectious substances, which include select agents, are regulated as hazardous materials by DOT. DOT regulates select agents in commercial transportation to, from, and within the United States, and its oversight extends to all parts of the hazardous materials transportation system, including classification of materials, packaging, handling, moving, loading, and unloading of hazardous materials shipments in commerce. PHMSA is the component of DOT responsible for this oversight. As its authority is limited to transportation, its focus is on the shipping and

[9]42 C.F.R. §§ 73.7(f) & 73.18(b) (CDC); 9 C.F.R. §§ 121.7(f) & 121.18(b) (APHIS–animal); 7 C.F.R. §§ 331.7(f) & 331.18(b) (APHIS–plant).

[10]42 C.F.R. § 73.18(a) (CDC); 9 C.F.R. § 121.18(a) (APHIS–animal); 7 C.F.R. § 331.18(a) (APHIS–plant).

[11]42 C.F.R. § 73.9(a)(5) (CDC); 9 C.F.R. § 121.9(a)(5) (APHIS–animal); 7 C.F.R. § 331.9(a)(5) (APHIS–plant); 49 U.S.C. § 5103.

packaging aspects of biosafety and biosecurity requirements. Consequently, entities that are active in the transfer of select agents may have their shipping and handling facilities inspected by PHMSA.

DHS and DOD Inspections

DHS and DOD own or fund research at select agent entities, and these entities may undergo additional inspections from these agencies as part of the conditions of funding or based on the safety and security policies of the parent agency. For example, entities that receive funds from DHS to conduct laboratory work involving select agents are subject to on-site compliance reviews and inspections by the DHS Regulatory Compliance Office. In addition, select agent laboratories operated by DOD are subject to inspections by the service IGs and other commands.

DHS

DHS established a regulatory compliance program to facilitate department-wide implementation of and compliance with DHS policies for biosafety, select agent security, and the care and use of animals in research.[12] DHS's select agent research is subject to regulatory oversight by CDC and APHIS. In addition, entities that receive funding from DHS to conduct laboratory work involving select agents are subject to on-site compliance reviews and inspections based on DHS Management Directives.[13] According to DHS, it "conducts significant additional oversight because of unique sensitivities related to biodefense research, as distinct from conventional public health research, and a desire to ensure complete transparency for senior management of the department about all ongoing biodefense efforts." DHS also has responsibility for ensuring biosecurity compliance of DHS funded research under biodefense weapon treaties.

DOD

Through its long-standing Chemical and Biological Defense Program, the DOD supports research on detection, identification, and characterization of biological threats and the development of countermeasures against those threats. DOD research activities take place at numerous facilities,

[12]APHIS Animal Care regulates the care and use of animals under the Animal Welfare Act.

[13]DHS Management Directive 026-03, *Select Agent and Toxin Security* (Mar. 11, 2007); DHS Management Directive 066-02, *Biosafety* (Mar. 11, 2007); DHS Management Directive 026-01, *Care and Use of Animals in Research* (Mar. 11, 2007); and DHS Management Directive 041-01, *Compliance with, and Implementation of, Arms Control Agreements* (Aug. 26, 2005).

including military-owned entities as well as entities in academia and private industry supported by contracts. DOD entities that are registered with CDC or APHIS are required to follow SAR requirements as well as service-specific requirements derived from DOD requirements. DOD-related select agent entities can therefore be subject to inspections from CDC, APHIS, the service IGs, and other commands. Specifically, the Department of the Army Inspector General (DAIG) conducts inspections of five Army and contractor-owned entities, the Navy Medical IG (MEDIG) conducts inspections of two Navy laboratories located in the United States and three overseas, and the Air Force Materiel Command IG conducts inspections of one Air Force select agent facility. In addition to DAIG inspections, Army facilities are also subject to command/program office (PEO) reviews by (1) Army Material Command Surety Management Review Team, (2) Army Test and Evaluation Command (ATEC) Surety Management Review Team, (3) Army Medical Command (MEDCOM) Surety Management Review Team, and (4) Joint Program Office for Chemical and Biological Defense (JPEO-CBD) Surety Management Review Team. The DAIG and command/PEO teams each have a 2-year inspection cycle and stagger the inspections so that each entity is inspected once per year.

Other Federal Agencies Involved in Inspections

Other federal agencies, such as the NIH and USDA's Agriculture Research Service, have their own internal offices that may perform inspections in addition to those performed by CDC or APHIS as part of the SAP. In many cases, these agencies have internal regulations or policies that are more prescriptive than the CDC or APHIS regulations, according to the Trans-Federal Task Force.[14] In addition, as the agency responsible for the general oversight of workplace safety in the United States, OSHA has oversight authority for the safety and health of workers in all workplaces that fall under its jurisdiction, including individuals who work with hazardous biological agents or toxins in high- and maximum-containment research facilities. This includes jurisdiction over the safety

[14]Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight (July 2009).

and health of workers employed by privately owned entities and, under certain circumstances, federal high-containment facilities.[15]

Inspection Activities

Inspection activities are generally conducted in three phases: (1) preparation, (2) execution (the actual inspection), and (3) closeout (postinspection activities). In order to prepare for an inspection, entities conduct a variety of activities, such as responding to requests for documents related to the SAR; reviewing and updating guidance, records, and plans; and checking security and medical certifications of inspectors. In the execution phase, inspection activities include, for example, tours of the facility, document reviews, inventory audits, interviews of laboratory staff, equipment tests, and examinations of physical security and shipping and receiving of select agents. The closeout phase includes activities such as discussing the inspection findings and report, developing corrective action plans, and providing verification of corrective actions. (For a detailed list of inspection activities included in the survey, see app. II.)

Inspections consist of an extensive review of laboratory safety and security. CDC and APHIS use specific checklists, which they developed from the SAR, OSHA regulations, NIH guidelines for recombinant DNA research, and the Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual, to guide their inspections. The BMBL provides guidance for standards of practice for laboratory principles, practices, and procedures. Other inspecting agencies also use the same or similar checklists for their inspections. DOT inspections, for example, are derived from PHMSA's regulations for hazardous materials shipping, packaging, testing, certification, safety and security, and record keeping. The scope of a DOD inspection covers a wide range of functional areas, such as security, safety and occupational health, surety management, emergency response, occupational medical requirements, and transportation.

[15]OSHA may only conduct inspections of federal high-containment facilities if (1) the agency has not established a health and safety committee, (2) half of the committee requests an inspection, or (3) an employee reports an imminent danger situation and the agency has not responded to the employee (29 C.F.R. § 1960.31).

Overlap and Duplication

The number of federal agencies involved in inspections of select agent entities increases the potential for overlap and duplication. Further adding to the potential for overlap is the increase in the number of inspections. These inspections have increased for a variety of reasons, such as heightened security concern in response to the events of September 2001, as well as an increase in select agent research and the number of agencies funding the research. For example, in addition to announced inspections that generally take place with registration certification and renewal, the number of unannounced CDC inspections substantially increased from fewer than 5 in 2006–07 to nearly 80 in 2012, according to estimates from CDC. And while some federal agencies have increased the use of joint inspections, in which two agencies are on-site for an inspection at the same time, it is unclear whether this will address all of the negative aspects of duplication if compliance is still assessed separately.

Some Overlap and Duplication Exist in Inspections of Select Agent Laboratories

About 15 percent of the 374 entities that were registered to work with select agents between fiscal years 2009 and 2011 were subject to inspection overlap. This means that in a 2-year period, these entities were inspected by more than one federal agency for biosafety, biosecurity, and biocontainment compliance.[16] In addition, specific inspection activities were often duplicative, according to our survey of the 55 entities that were subject to overlapping inspections. While the percentage of entities affected by inspection overlap was relatively small, the entities affected tended to be larger ones that work with a greater variety of agents and with more laboratories, principal investigators, and laboratory staff. For example, entities with five or more laboratories are more likely to be subject to overlap than entities with fewer than five laboratories, controlling for biosafety level (BSL) and the number of agents. Similarly, entities working with five or more select agents are more likely to be subject to overlap than entities working with fewer than four select agents, controlling for the number of laboratories and BSL. As a result, the overlap affected roughly a third of all laboratories, principal investigators, and lab staff. Moreover, DOD-owned select agent entities are also subject to inspections from internal inspecting entities. These inspections can overlap with inspections from CDC, APHIS, and the service IGs.

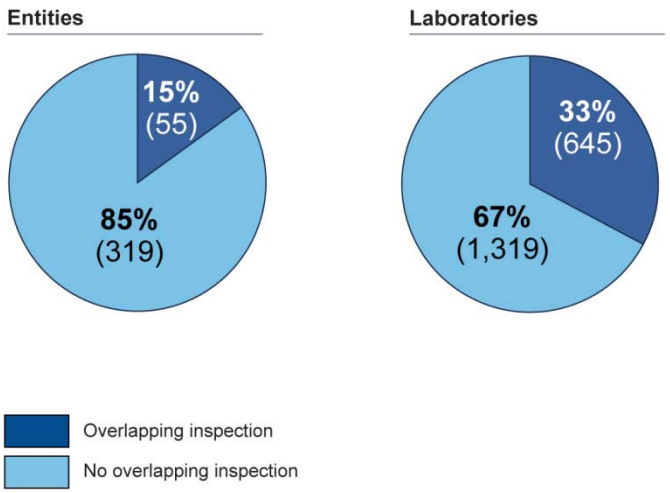
[16]The overlap could have occurred in any 2-year period between October 1, 2009, and July 30, 2011.

Concerning duplication, the entities often prepare the same documents for inspectors to review; conduct the same facility tours, inventory inspections, and personnel interviews; and go through the same exit conference and corrective action plan processes, according to survey results. Inspections conducted by DOT, however, were generally not duplicative of CDC and APHIS inspections because specific inspection activities tended to differ. According to surveyed entities, DOT inspections tended to focus narrowly on transportation issues—such as (1) checking hazardous material and transportation security plans and (2) verifying the labeling, testing, and assembly of United Nations (UN) certified packagings—rather than general biosafety and biosecurity compliance. DHS and DOD's DAIG inspections tended to be more duplicative with those of CDC and APHIS, in that numerous activities were the same across these inspections, according to survey results.

Larger Entities Are More Likely to Experience Overlap in Inspections

Fifty-five, or 15 percent, of entities registered between fiscal years 2009 and 2011 were subject to overlapping inspections. Although the overlap appears to affect only a small portion of registered entities, these entities are home to 645 laboratories—roughly a third of all laboratories involved in select agent work (see fig. 2 for details). On the basis of logistic regression analysis, we found that the likelihood that an entity was subject to overlap in federal inspections depends on the number of laboratories, the highest BSL of its laboratories, and the number of select agents. Specifically, entities with five or more laboratories are more likely to be subject to overlap than entities with fewer than five, controlling for BSL and the number of agents.

Figure 2: Number and Percentage of Entities and Associated Laboratories Experiencing Overlapping Inspections, Fiscal Years 2009 to 2011

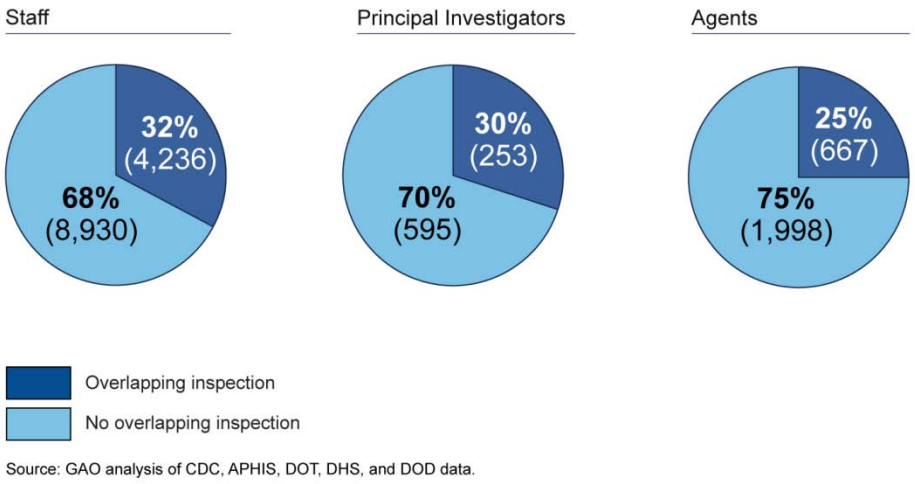


Source: GAO analysis of CDC, APHIS, DOT, DHS, and DOD data.

In addition, entities with at least one BSL-4 lab are more likely to be subject to overlap than entities without a BSL-4 lab, controlling for the number of laboratories and the number of select agents.[17] In addition, entities working with five or more select agents are more likely to be subject to overlap than entities working with fewer than four select agents, controlling for the number of laboratories and BSL. Finally, entities subject to overlap have, on average, more staff and more principal investigators (see fig. 3).

[17]There are only seven entities with a BSL-4 lab in the data.

Figure 3: Number and Percentage of Staff, Principal Investigators, and Agents Affected by Overlapping Inspections, Fiscal Years 2009 to 2011



Source: GAO analysis of CDC, APHIS, DOT, DHS, and DOD data.

Overlap in inspections occurred most frequently between CDC or APHIS and (1) DOT (34 overlapping inspections), (2) DAIG (13 overlapping inspections), and (3) DHS (8 overlapping inspections). Considering only CDC inspections, overlap occurred with 29 DOT inspections, 13 DAIG inspections, and 3 DHS inspections. However, overlapping inspections do not necessarily result in duplication.

DOT Inspections Are Less Duplicative Than DHS and DOD Inspections

While the overlap in inspections occurs most frequently between CDC or APHIS and DOT, these inspections are not necessarily duplicative because the specific inspection activities tend to differ. The activities are likely to differ because the purpose of DOT inspections is narrowly focused on issues and areas related to the transport of select agents, whereas CDC and APHIS inspections are more-broadly focused. While there is less-frequent overlap between CDC or APHIS inspections and those of DHS or DOD, these inspections tend to be more duplicative, in that the inspection activities are similar, according to survey results.

DOT

According to DOT inspection data, DOT's PHSMA conducted 83 inspections of select agent entities between fiscal years 2009 and 2011. DOT coordinates its inspections with CDC and APHIS under a working

Memorandum of Understanding (MOU), which spells out the framework and responsibilities for the exchange and protection of information on transfer of select agents. Under the MOU, CDC and APHIS annually provide DOT with a list of registered entities that have transferred select agents during the 12 preceding months. DOT, in turn, notifies CDC and APHIS of any anticipated inspection of an entity 30 days before the inspection and also provides them with the inspection results. According to DOT officials, they try to coordinate joint inspections whenever possible. After CDC provides a list of scheduled inspections, DOT informs CDC about which inspections it will join. According to DOT officials, where possible, they coordinate joint inspections with CDC because (1) they learn things from each other, (2) with both agencies there at the same time it is more encompassing view of the process, and (3) it brings greater sophistication to inspections. Such coordination appears effective, given survey results of entities that experienced DOT inspections that overlapped with CDC or APHIS inspections. These entities reported little duplication in specific activities in the preparation, execution, and closeout phases of inspections (see table 2). Among the activities that tended to be duplicative were verifying the medical, security, or other credentials of inspectors in the preparation phase; participating in interviews with inspectors in the execution phase; and holding exit conferences with the inspecting agency in the closeout phase. Among the activities that tended to be DOT-specific were checking hazardous materials and transportation security plans and verifying the labeling, testing, and assembly of UN-certified packagings.

Table 2: Number of Duplicative Preparation, Execution, and Closeout Activities: CDC or APHIS and DOT Inspections

	Preparation	Execution	Closeout
Total possible activities	18	9	8
Average	2	3	2
Median	1	3	2
Range	0–7	0–8	0–6

Source: GAO analysis of survey data.

DHS

DHS identified 42 government, university, private, and not-for-profit entities that were receiving DHS funding for work involving select agents. DHS's Regulatory Compliance Office conducted or participated in 19 on-site inspections of 13 of these entities between fiscal years 2009 and 2011. Of those 19 inspections, 8 were joint inspections, including: 5 joint inspections with CDC; 1 joint inspection with APHIS; and 2 joint

inspections with both CDC and APHIS. According to DHS officials, there are numerous reasons for DHS to visit a select agent entity that has also been inspected by CDC or APHIS. These reasons include, for example, CDC or APHIS placing the entity on a Performance Improvement Plan or making substantial recommendations to correct regulatory noncompliance. If it appears that the compliance issues identified by CDC or APHIS could affect the DHS program, DHS may also make a site visit to understand the effect on DHS research and to assist the entity in mitigating the effect through appropriate corrective action.

According to DHS officials, their inspections are fundamentally different from CDC and APHIS inspections. DHS describes its compliance inspections as broader in some ways than those of CDC or APHIS, because they are designed to ensure that DHS-sponsored research activities not only comply with select agent requirements, but with other relevant regulations and guidelines as well. According to DHS officials, CDC and APHIS, as regulatory agencies, conduct more comprehensive inspections at the institutional level. DHS compliance inspections, however, go beyond compliance with select agent regulations to include general biosafety, animal care and use, research protocols and procedures, institutional review and oversight (for example, Institutional Biosafety Committees), and adherence to best practices. Nevertheless, survey responses from entities that experienced DHS inspections that overlapped with CDC or APHIS inspections reported some duplication in specific activities in the preparation, execution, and closeout phases of inspections (see table 3). Among the activities that tended to be duplicative were verifying medical, security, or other credentials of inspectors and arranging staff availability in the preparation phase; participating in interviews with inspectors in the execution phase; and holding exit conferences and developing and implementing corrective action plans in the closeout phase.

Table 3: Number of Duplicative Preparation, Execution, and Closeout Activities: CDC or APHIS and DHS Inspections

	Preparation	Execution	Closeout
Total possible activities	18	9	8
Average	4	5	3
Median	4	6	4
Range	0–13	0–8	0–5

Source: GAO analysis of survey data.

DOD

According to DOD inspection data, the DAIG conducted 16 biosurety inspections of its Army and contractor-owned entities between fiscal years 2009 and 2011, 5 of which were conducted jointly with CDC. Of the 16 DAIG inspections, 13 overlapped with an inspection from another federal agency. The Navy IG conducted one inspection and the Air Force IG conducted two inspections between 2009 and 2011.[18] These inspections did not overlap with an inspection from another federal agency.[19] With respect to specific activities in the preparation, execution, and closeout phases of inspections, entities that experienced DAIG inspections that overlapped with CDC or APHIS inspections also reported substantial duplication in inspection activities (see table 4). Among the inspection activities that tended to be duplicative were arranging staff availability in the preparation phase, holding entry meetings and escorting inspectors in the execution phase, and holding exit conferences in the closeout phase. However, according to DAIG officials, as required by Army directives and regulations, its biosurety inspections are more-comprehensive than CDC and APHIS inspections, covering biosafety, biosecurity, biocontainment, personnel reliability program (PRP), transportation, occupational medical requirements, and emergency response exercises.[20] While DAIG officials acknowledge a level of overlap with CDC and APHIS inspections in terms of verifying compliance with standards, DOD and the Department of the Army have developed specific requirements to implement those standards. In addition, until recently, CDC and APHIS inspections did not look at facility or department-specific requirements such as PRP.[21]

[18]Inspections of United States located entities only.

[19]For entities still registered with the Select Agent Program at the time of our study.

[20]The Army's Biosurety program is a system of control measures designed to provide protection to the local population, workers, and the environment by ensuring that select agent operations are conducted safely, that select agents are secure, and that personnel involved in those operations meet the highest standards of reliability.

[21]HHS and USDA recently (Oct. 5, 2012) published the Select Agent Final Rules, which stipulate that the SAP will now review entities' PRPs.

Table 4: Number of Duplicative Preparation, Execution, and Closeout Activities: CDC or APHIS and DAIG Inspections

	Preparation	Execution	Closeout
Total possible activities	18	9	8
Average	5	7	5
Median	6	8	5
Range	0–13	4–9	1–7

Source: GAO analysis of survey data.

Additional Overlap Can Occur with DOD Internal Inspection Authorities

DOD-related select agent entities are also subject to inspections and reviews from internal organizations, which can overlap with inspections from CDC, APHIS, and the service IGs.[22] For example, in addition to service IG inspections, DOD entities undergo Biosurety Management Reviews (SMR) and Biosurety Staff Assistance Visits (SAV). The SMRs are meant to verify the entity is managing its biosurety program according to standards. They allow the command to see how the surety program is being managed and where there may be deficiencies. According to Army lab officials, however, these inspections tend to be identical to service IG biological surety inspections. SAVs are an opportunity for the command to assist in fixing deficiencies or other lacking areas, and usually take place before another major inspection. SAVs are not biosurety inspections, nor are they required under DOD regulations. However, SAVs tend to be treated similarly to service IG inspections, according to Army lab officials. While SMRs and SAVs may be handled like an inspection with written reports of perceived deficiencies for which the entity makes a formal response and corrections for the identified deficiencies, DOD officials noted that entities may be self-imposing requirements or practices not required by regulation or the inspecting agency. As a result, these internal reviews can represent an additional area of overlap for DOD-owned and DOD-operated entities. For example, as shown in table 5, an Army entity underwent eight inspections or reviews, five of which were for compliance with select agent regulations between fiscal years 2009 and 2011.

[22]Although assessing internal agency duplication by means of survey analysis was outside the scope of our review for these DOD specific entities, we did gather some information about overlap through focus groups and interviews with some affected entities.

Table 5: Inspections and Reviews of One Army Laboratory, Fiscal Years 2009 to 2011

Inspection dates	Inspecting agency	Inspection type
March 2009	ATEC	Biosurety Staff Assistance Visit (SAV)[a]
March–April 2009	DAIG	Biological Surety Inspection
June 2009	DOT	Biological Shipping and Transportation
August 2009	CDC	Verification
May 2010	ATEC	Biosurety Management Review (SMR)
December 2010	ATEC	Biosurety SAV
February–March 2011	ATEC	Biosurety SAV
May 2011	DAIG and CDC	Biological Surety Inspection

Source: DOD

[a]SAVs are not inspections.

According to an official of this particular Army entity, many of the major command reviews and visits use up time and resources, fixing issues that are not value-added, or that are not looked at by other major inspections. In many cases, inspectors are focusing on minor issues, leaving the laboratory open for larger deficiencies on the major inspection. According to the DAIG Chief of Technical Inspections, a major cause of overlapping internal inspections is that there is no single entity within the DOD overseeing or coordinating inspections and that each service validates compliance very differently. The Army requires each major command to have its own internal biosurety team and, because the entities feel they should be prepared for higher-level reviews, the teams conduct inspections in preparation for higher-level inspections. For Army labs, the DAIG inspects an entity every 2 years, an internal command surety team, such as ATEC, conducts an SMR every 2 years (alternating with the DAIG inspection), and SAV reviews may be conducted before any inspection (DOD or otherwise). In an example of an extreme case, an Army select agent laboratory that conducts recombinant DNA research for DHS-funded projects and frequently transfers select agent materials to collaborators could theoretically be inspected by CDC/APHIS, DAIG, NIH, DHS, and DOT all within the same year. This could significantly hinder critical research productivity at the inspected laboratory because of the time dedicated to inspections, according to the report of the Working Group on Strengthening the Biosecurity of the United States. This is somewhat in contrast with inspections of the two Navy and one Air Force entities. For example, while the Navy can perform SAVs prior to inspections, they are not required like Army's SMRs. In addition, rather than conducting its own inspection, the Air Force accepts the CDC

inspection results and adds its own PRP review. This limited coordination among the inspection agencies was noted in the Working Group report.

While Difficult to Quantify, Overlap Adds to the Cost of Inspections and Can Negatively Impact Laboratory Operations

The costs of overlapping federal inspections and effects on lab operations are difficult to quantify because (1) agencies and entities generally do not track the costs or effects of inspections and (2) some costs are not quantifiable. Nevertheless, the costs and effects on lab operations are significant when considering (1) the cost of inspections to federal agencies, (2) both the quantifiable and nonquantifiable costs to the entity, and (3) surveyed entities' perceptions of the negative effects of overlapping inspections on lab operations. Although we could not quantify the portion of federal and entity costs directly attributable to overlap, we could quantify the costs of inspections in general. For example, we estimate that for fiscal years 2010 through August 2011, individual agencies' total inspection costs ranged from approximately $22,400 to over $900,000, according to agency data on the hours spent on inspection activities, inspector compensation (salaries and benefits) per labor hour, and travel. The approximate overall federal cost for fiscal year 2010 and 2011 inspections was over $2.1 million dollars. On average, the entity costs per inspection were nearly $15,000 and 380 hours in staff time, according to our survey. The quantifiable cost of an inspection to a select agent entity depends on the number of laboratories and select agents, the complexity of the entity's mission, its location, and whether it has a history of problems or violations of select agent regulations. In inspections of larger entities, there are higher inspection costs and a greater likelihood for overlap. The costs of overlap are therefore most likely higher as well. Entities also reported moderate to significant nonquantifiable costs of inspections when it comes to loss of productivity and delays in research. While inspections can help entities correct deficiencies, improve inventory management and accountability, and justify the need for resources to improve operations, most surveyed entities reported that overlapping inspections have negative effects on lab operations. According to surveyed entities, overlapping inspections negatively affected lab productivity, staff morale, available time to complete research, and the research schedule. And according to at least one-fifth of surveyed entities, overlapping inspections negatively affected the physical viability of inventory, staff retention, and competitiveness for research funds. Because many of these entities are federal laboratories or are funded through federal grants, these quantifiable and nonquantifiable costs are passed on to the federal government.

While the Cost of Multiple Inspections Is Difficult to Quantify, Data from Inspecting Agencies and Entities Indicate They Are Significant

Obtaining an accurate and complete picture of the costs of multiple inspections is difficult because entities generally do not track the costs of inspections and some of those costs are nonquantifiable. Nonetheless, federal agencies do incur quantifiable costs, including salaries, travel, and training of inspectors, and must purchase inspection equipment and pay staff to engage in inspection activities as opposed to research or other routine activities. Entities may also incur nonquantifiable costs of multiple inspections, such as loss of productivity, delays, and decreased time available to complete research. In addition, because many of these entities are federally owned or funded, some portion of this cost is passed on to the federal government. These costs are affected by the number of inspectors, the time spent on an inspection, and the size of the entity being inspected.[23] The larger the entity—in terms of laboratories, staff, and select agent research—the greater the cost of inspections. Given that inspections cost more for larger entities and overlap occurs more often for larger entities, the cost of overlap is greater than it would be if it were evenly distributed across entities of various sizes.

Federal Inspection Costs

The approximate direct federal cost for fiscal years 2010 and 2011 inspections was over $2.1 million, ranging from approximately $22,400 at DOT to over $900,000 at CDC, according to agency data on the hours spent on inspection activities, inspector compensation (salaries and benefits) per labor hour, and travel. Specifically, APHIS's total labor, travel, and other costs for inspections were $265,792; DOD's costs were $697,744; DOT's costs in 2010 were approximately $22, 444; and CDC's costs were $903,475 (see table 6 for agency inspection costs). DHS estimates their inspection costs at about $250,000 for the 2-year period.[24] Although we did not estimate indirect costs, the federal government also incurs costs from inspections because many select agent entities are either federally owned or funded. Consequently, the costs to entities, described in the sections below, also accrue to the federal government.

[23]In focus group discussions, laboratory workers said that an inspection can last from a few days to 2 weeks.

[24]According to DHS officials, DHS inspections of select agent laboratories are supported under a contract that does not provide breakdowns for labor hours and travel costs specifically associated with inspections. Labor hours for inspection activities are a small subset of the overall labor hours expended under the contract, which supports all DHS compliance-assurance efforts for biosafety, select agent and toxin security, and animal care and use in research.

Table 6: Total Approximate Inspection Costs by Agency, Fiscal Year 2010 to August 2011

Dollars			
Inspecting agency	**2010**	**2011 (up to Aug. 31)**	**Total**
CDC	$617,130	$286,345	**$903,475**
APHIS[a]	173,486	92,396	**265,792**
DOT[b]	22,444	--	**22,444**
DHS	190,000	60,000	**250,000**
DOD	367,490	330,254	**687,744**
Total			**2,129,455**

Source: GAO analysis of CDC, APHIS, DOT,DHS, and DOD data.

[a]APHIS conducts inspections by calendar year coinciding with an entity's renewal of registration.

[b]DOT provided total salary and benefits costs for 2010 inspections but did not provide 2011 data and could not provide specific travel and other costs associated with inspections.

Entity Inspection Costs

The cost of inspections to entities is also difficult to accurately determine because entities generally do not track inspection cost. However, according to focus group participants and entities we surveyed, entities do incur quantifiable and nonquantifiable costs with each inspection, some of which can be significant. Focus group participants and surveyed entities reported quantifiable costs, such as purchasing inspection equipment and salaries for staff involved in preparing for, carrying out, and responding to an inspection. Entities also reported less-easily measured, nonquantifiable costs, such as loss of productivity, delays, and decreased time to complete research, as well as loss of specimen viability from repeated thawing and freezing.

Quantifiable Costs

Staff time and lab resources are required for inspections, and that burden is increased with overlapping inspections. The actual cost of an inspection to a select agent entity will depend on the number of laboratories and select agents, the complexity of the entity's mission, its location, and whether it has a history of problems or violations of select agent regulations. However, because overlap in inspections tends to occur more often for larger entities, the overall costs of overlap for these laboratories are likely higher as well. Entities that experienced an overlapping inspection spent, on average, 380 hours and nearly $15,000 in staff time to engage in a federal inspection, according to survey data on the number of hours spent to prepare for, carry out, and close out inspections and the hourly salaries of laboratory staff involved (see table 7 for average costs across occupational groups). See app. I for an explanation of how we calculated these costs.

Table 7: Average Number of Staff, Labor Hours, and Salary Costs for a Select Agent Inspection, According to Surveyed Entities

Occupation	Average number of staff	Average number of labor hours	Average salary cost (labor hours X average hourly salary) (Dollars)
Responsible official/ alternate responsible official	2	101	$4,987
Principal investigator	4	49	2,356
Owner or controller	1	7	355
Laboratory staff	24	140	4,767
Support staff	17	110	3,201
Total	**48**	**380**	**$14,724**

Source: GAO analysis of survey data.

Much of the time spent on inspections takes place in the preparation phase, according to focus groups of lab staff. For example, staff from Army laboratories noted that there is a period of 3 to 4 months of intense preparation for DAIG inspections and months of follow-up. During the preparation phase, lab staff perform numerous activities, including updating standard operating procedures and other documents and records; verifying inspectors' health records and clearances; turning in unused equipment; holding meetings to prepare for the inspection; checking chemicals and agents in inventory; checking lab equipment; and inspecting, cleaning and painting floors, walls, and desk space. According to some focus group participants, in the weeks preceding an inspection, research is suspended and all staff time is directed toward inspection efforts. Scheduling for inspections can also create conflicts because experiments must be scheduled around the inspection, and key staff must be available during the inspection, regardless of personal plans or schedule.

During the inspection, lab staff are involved in activities that take time and resources. For example, staff conduct safety training for inspectors (how to wear safety suits and respirators and blood-borne pathogen and internal requirement training), issue safety equipment to the inspectors, clear inspectors through security, and provide escorts for inspectors. Safety equipment, such as personal protective equipment (PPE), gowns,

and footies are provided to inspectors at the entities' expense, and these costs increase with larger inspection parties and when there is overlap because the equipment can not be shared or reused.[25] Staff time for escorts can be significant in some cases. For example, Army lab inspection teams can have as many as 20 personnel and stay as long as 2 weeks. According to one Army laboratory, it spent more than 7,305 labor hours in activities related to preparing for, executing, and responding to six inspections during 2009 at a cost of $350,640. During 2010, the laboratory estimated it spent 4,082 hours on these activities for three inspections, at a cost of $195,456.[26] In addition, when joint inspections take place, the size of the inspection team may be too large for some entities to manage. For example, according to one survey respondent, the entity requested DHS and CDC not conduct a joint inspection because the inspection teams are too large to handle at one time. According to another survey respondent, the respondent's laboratory had to arrange for additional personnel to escort large teams of inspectors for multiple inspections. Laboratories also spend time and resources in the closeout phase of the inspection. For example, upper-level staff attend meetings to discuss inspection results, and staff time and effort are required to respond to oral and written findings that may change or be added to even after the completion of the inspection. Of particular concern was that frequent inspections keep lab staff in a constant mode of preparing for the next inspection while responding to the last one, inhibiting their ability to respond to inspection findings and conduct research.

Nonquantifiable Costs

Laboratories also incur nonquantifiable costs from inspections, which can be exacerbated by overlapping inspections. While these costs tend to be small, according to most surveyed entities, for some they can be moderate to significant when it comes to loss of productivity, decreased time available to complete research, and delays (see table 8). Other costs noted by surveyed entities include stress and anxiety for lab staff, contractor and overtime costs, HVAC and equipment testing costs, and loss of focus and manufacturing time.

[25]Select Agent Program (CDC and APHIS) inspectors generally use their own PPE for inspections.

[26]The Army laboratory used a labor rate of $48 per hour to calculate its costs.

Table 8: Nonquantifiable Costs of a Select Agent Inspection, According to Surveyed Entities

	Moderate to Significant Cost	Some Cost	Negligible Cost	Don't know/ Not checked
Q7A. Loss of productivity	18	13	15	1
Q7D. Decreased time to complete research	8	16	22	1
Q7B. Delays in funded research	6	11	28	2
Q7E. Reduced viability of inventory	5	5	35	2
Q7F. Reduced competitiveness for research funding	4	5	35	3
Q7C. Dollars lost in funded research	3	3	35	6
Q7G. Other cost 1	5	1	4	37
Q7H. Other cost 2	1	1	4	41

Source: GAO analysis of survey data.

Focus group participants noted a variety of nonquantifiable costs, such as the loss of productivity, recertifying equipment or bringing it offline for inspection, and loss of agent viability from repeated thawing and freezing of agents. Although only 5 (11 percent) of surveyed entities reported that reduced viability of inventory was a moderate to significant cost, a preliminary study at the Dugway Army Proving Ground on the viability of agent vials that had undergone multiple inspections found reductions in agent viability, with a 100 percent loss of viability in a few cases.[27] While the costs of reduced or lost viability are difficult to determine, a strain that existed in only a single vial would be impossible to replace. Furthermore, loss of agent viability can damage research opportunities and experimental findings.

Focus group participants also noted that multiple inspections reduce an entity's competitiveness for grant money, although most surveyed entities found this a negligible cost. In addition, inspection time must be factored into grant proposals. And because inspections affect the research cycle, the time it takes to complete research and the overall costs of the research increase when entities experience multiple inspections. For example, some participants noted the costs of their entity's grant

[27]Freezing and thawing have been shown to damage the cytoplasmic membrane, cell wall, and DNA. When the cytoplasmic membrane is damaged, low molecular weight materials (such as potassium and magnesium cations [K+, Mg2+], inorganic phosphate, and amino acids) are lost from the cell, and there is an increased penetrability of small molecular weight compounds, such as toxic metals, into the cell. Researchers have attributed cell death and injury to one or both of these processes.

proposals are higher than others' because of the "overhead" costs they must build in for their multiple biosafety and biosecurity inspections. In addition, the time to conduct research is affected when laboratories have to suspend research for inspections. Undergoing multiple inspections exacerbates this problem. Some participants noted that the granting community knows that if laboratories are frequently inspected, the work will not get done by the desired deadlines, affecting the communities' willingness to award grants to these entities.

While Multiple Inspections Can Improve Lab Operations, They Can Also Negatively Impact Lab Operations

Inspections are essential in ensuring biosafety and biosecurity requirements are met and SAR regulations are followed. Most surveyed entities reported that multiple inspections positively affect (1) actions to correct deficiencies, (2) coverage in helping to identify problems, (3) the strength of inventory management and accountability, and (4) justification for additional resources to improve operations. However, many entities also noted multiple inspections negatively affect lab operations. In particular, most surveyed entities reported that multiple inspections negatively affect (1) lab productivity, (2) staff morale, (3) the time to complete research, and (4) the research schedule. While some entities reported negative effects to (1) the physical viability of inventory, (2) staff retention, and (3) staff recruitment, a greater majority of entities reported these issues were unaffected by multiple inspections (see table 9 for effects of multiple inspections).

Table 9: Effects of Multiple inspections, According to Surveyed Entities

	Negative Effect	No Effect	Positive Effect	Don't know/ Not checked
Q9B. Lab productivity	32	12	2	1
Q9H. Staff morale	27	15	3	2
Q9C. Time to complete research	25	18	1	3
Q9D. Research schedule	22	20	1	4
Q9E. Physical viability of inventory	12	31	1	3
Q9F. Staff retention	10	34	0	3
Q9A. Competitiveness for research funding	9	26	4	8
Q9J. Actions to correct deficiencies	8	13	25	1
Q9G. Staff recruitment	6	36	0	5
Q9L. Ability to have specialized inspections in which agencies focus on different areas	4	25	11	2
Q9M. Coverage in helping to identify problems	3	22	20	2
Q9K. Justification for additional resources to improve operations	0	27	18	2
Q9I. Strength of inventory management and accountability	1	25	20	1
Q9N. Other effect	8	7	2	30

Source: GAO analysis of survey data.

Focus group participants also noted some positive aspects of multiple inspections, among them having an "extra set of eyes" or a layer of oversight on laboratory operations to identify areas of need. In addition, inspection report findings, can provide funding justification for resources and staff, validate good laboratory practices, and identify needed quality assurance improvements. However, some focus groups participants also noted that the amount of time spent on inspections slows down the science and that while inspections may help get the laboratory renovated, they do not actually improve the science. Others participants noted that oversight functions in laboratories, such as quality assurance, are growing faster than the research community. Finally, one survey respondent noted that multiple inspections do not allow the laboratory to have the time necessary to implement lessons learned in a meaningful time frame.

A Coordinated Approach with Consistently Applied Standards is Recommended by Earlier Reports and Surveyed Entities

Actions to reduce the costs and negative effects of overlapping and duplicative inspections include better coordination and greater consistency in the application of standards, according to various experts and surveyed entities. Both the HHS-USDA Trans-Federal Task Force and the Executive Order Working Group on Strengthening the Biosecurity of the United States recommended enhancing the coordination of biosafety oversight activities, including inspections. In addition, our earlier work on select agent laboratories recommended a single coordinating agency as a means to improve coordination.[28] Accordingly, CDC and APHIS have taken steps to better coordinate inspections with other agencies, for example, by increasing the use of joint inspections, signing MOUs for sharing inspection information with other agencies, establishing an inspector training program for federal partners, and developing a common "playbook" for inspection of registered entities.[29] Such coordination efforts are important steps in reducing overlap and duplication. However, MOUs and joint inspections may not fully address the negative effects of overlap and duplication if inspectors are still applying standards inconsistently and preparing separate reports of findings. Specifically, according to surveyed entities, standards must be applied more consistently between agencies and from one inspection to another. It is this inconsistent application of standards that exacerbates the negative effects, including costs, of overlapping inspections. According to surveyed entities, the most effective actions for greater consistency in the application of standards include (1) ensuring inspectors are well trained and experienced, (2) establishing a single set of inspection standards that all agencies accept, (3) providing an opportunity to discuss, clarify, and rebut inspection findings, and (4) training inspectors to one set of standards with requirements for noncompliance findings (see table 10). Well-trained inspectors, who are able to apply consistent standards, would reduce the negative effects of overlapping inspections. In particular, they might reduce overlap by allowing federal agencies to accept each other's inspection results. Such a result is facilitated by joint training, according to DOD officials. Without a consistent standard, however, highly trained inspectors would not be effective, according to some surveyed entities. In addition, according to

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

[29]*Resource Manual for Agencies Conducting Site Visits of Entities with Biological Select Agents and Toxins*.

most surveyed entities, a 3-year federal inspection cycle for select agent entities was reasonable.[30] Focus group participants also suggested options for minimizing the potential for overlapping or duplicative inspections and the associated burden, such as having a single inspecting agency whose findings are accepted by all other agencies and improving the knowledge and skills of inspectors.

Table 10: Solutions to the Negative Effects of Multiple Inspections, According to Surveyed Entities

	Effective	Neither	Ineffective	Don't know/ Not checked
Q12G. Ensuring inspectors are well trained/experienced	45	1	1	0
Q12D. Establishing a single set of inspection standards that all agencies accept (in areas where authorities overlap)	42	2	3	0
Q12I. Providing an opportunity to discuss, clarify, and rebut inspection findings	42	4	1	0
Q12F. Training inspectors to one set of standards with requirements for non-compliance findings	40	1	5	1
Q12C. Designating a single agency with inspection authority	33	6	3	5
Q12E. Inspecting to requirements rather than best practices	33	2	9	3
Q12A. Conducting joint inspections	28	8	9	2
Q12H. Training lab staff about the different agency missions and purposes for inspecting	28	9	10	0
Q12B. Establishing an inspection czar (i.e., an individual who directs and coordinates SA inspection programs and strategy)	24	7	7	9
Q12J. Other	5	2	0	5

Source: GAO analysis of survey data.

Reducing the Negative Effects of Multiple Inspections

In addition to scaled responses, surveyed entities provided written suggestions for reducing the negative effects of multiple inspections. While several entities expressed support for a single inspecting agency or joint inspections, others felt that addressing overlap alone would be insufficient when the same agency applies different standards in each inspection. In support of inspections being conducted by a single agency, entities noted that at least the inconsistent application of standards across

[30]The SAR does not define the frequency of inspections. However, to ensure that the entity is in compliance with the SAR, CDC or APHIS inspects the premises and records of applicants, including a review of all required plans, before issuing the initial certificate of registration or 3-year renewal.

agencies and frustration over trying to comply with two different agency regulations would be minimized. Surveyed entities highlighted the inherent conflict that arises when agencies come to different conclusions about an entity's compliance. For example, one noted that because there is no agency "in complete control," entities cannot determine which agency is correct when there is conflict in inspection reports. And a DOD entity wondered about the implication for CDC—which approved the SAP registration—if DAIG recommends the shutdown of a lab. While some thought an independent agency or an inspection czar would be a useful neutral party, others expressed concern that such an entity would just add another level of bureaucracy or require unnecessary new legislation. Because of entities' familiarity with CDC, one noted that they would not want to have a single agency unless it was CDC. However, another noted it was uncertain how useful a single agency with authority to audit would be because there would be a period of mixed messages while each agency has its say. And so far, the entity had not seen government agencies "play well together as a team."

In addition, while some thought joint inspections might address the negative effects of overlap, others thought they would exacerbate the problem because agency coordination—in terms of consistent interpretations and applications of standards—was still a concern.[31] In support of joint inspections, some felt they facilitated agency coordination and reduced duplication. Others noted that joint inspections are a better use of time and resources, reducing disruption and burden. In addition, joint inspections could help bring more uniformity and clarity for the inspection agencies and entities. For example, according to DAIG officials, they have taken steps to address these issues in joint inspections with CDC and APHIS. During joint inspections, the agencies discuss and resolve differences of interpretation so there is one "inspector" face to the inspected facility, and except for major findings, DAIG does not duplicate the findings of the other agency. However, noting recent inspections by two different agencies, one entity reported that having them at the same time would have made the inspection longer and more grueling. Joint inspections also require the entity to provide escorts and enough PPE for everyone entering the facility, a large expense when considering how many PPEs and escorts are needed for

[31]Only 34 percent (16) of surveyed entities had experienced a joint inspection.

some joint inspections.[32] In addition, (1) combined inspections may still result in multiple reports the entity must respond to and (2) having two teams do what a single team can do is still an additional burden on the taxpayer. Nonetheless, the burden that results from inconsistent application of standards could be minimized if agencies (1) conducting joint inspections issued a single report of findings or (2) instead of conducting a separate or joint inspection, accepted each others' inspection findings in lieu of conducting their own inspections.

Training to Consistently Apply Standards Is Needed

Regardless of whether a single agency is responsible or joint inspections are conducted, numerous respondents focused on the need for consistent application of standards by well-trained inspectors. Respondents' concerns focused on the inconsistent application of standards that can occur, not only between agencies, but from one inspection to another. While the problem may be exacerbated by overlapping inspections, the burden results from inconsistency, not overlap per se. For example, one entity noted that the biggest problem with multiple inspections by different agencies is that each has its own agenda, so establishing inspection standards that are accepted by all agencies would have the greatest effect on reducing the negative effects of multiple inspections. Another noted that a common set of requirements and interpretations would significantly reduce variation in compliance assessments. Reflecting on the additional burden to Army laboratories, one entity noted, "Ideally the set of standards that would be accepted would be the same federal standard that all organizations, not only DOD organizations, would be held to. This would not only reduce the burden of multiple inspections but also level the playing field between DOD and academia which would increase collaboration between laboratories." Some noted that this might facilitate sufficient trust for agencies to accept each other's inspection results. If all inspections were based on the same standard, with a checklist to keep them consistent, and all inspectors were trained together and required to use the published standard and checklist, the need for multiple inspections would be decreased or eliminated. Despite the support for greater consistency, some cautioned against the application of a "checklist mentality." For example, one surveyed entity noted that too many inspectors for their select agent program had been

[32]Select Agent Program (CDC and APHIS) inspectors generally use their own PPE for inspections

rigid and unbending, sticking to a checklist rather than common sense. Training can support efforts to consistently apply standards, while still allowing the flexibility for inspectors to have essential discussions with entities to establish rapport, exchange information, and understand why certain procedures and policies are in place in any given facility.

Surveyed entities offered a variety of other suggestions, such as (1) limiting the number of inspectors and days for inspections; (2) streamlining inspections, including the number of inspectors on the team, and coordinating areas of focus within the team to lessen the burden on the laboratories; (3) having an advisory group of ROs to give feedback to the inspection agency, regulatory agency, or GAO; (4) dividing inspection elements among the inspecting agencies, on the basis of their strengths; (5) staffing inspection teams for consistency and historical knowledge; (6) training all inspectors together to help ensure consistent inspections; and (7) giving entities credit for moving in the right direction. While none of the written comments suggested reducing the inspection cycle, almost half of surveyed entities noted that a 3-year federal inspection cycle for select agent laboratories was reasonable. The agencies have taken some steps to address these concerns. For example, after we had initiated our work, CDC and APHIS convened an Interagency Working Group that includes representatives from DHS and DOD, as well as other federal agencies. So that effective oversight can be achieved with minimal disruption, the working group is developing procedures and policies to better coordinate the inspections of entities that are federally owned or funded, improve information sharing between agencies, and implement other activities. For example, the working group has initiated a joint inspection program through which it has, so far, conducted 24 joint inspections. In addition, it has MOUs with DHS and DOD to share inspection data and an inspector-training program to provide the knowledge, skills, and experience to federal agencies to enable them to conduct “internal” inspections of registered entities they own or fund or to conduct joint inspections with CDC or APHIS.

Conclusions

Inspections are important for safety and compliance and can help improve laboratory procedures, infrastructure, and security. However, the value of inspections may be diminished when federal agencies are (1) expending resources to conduct the same or similar work and (2) burdening entities with overlapping or duplicative inspections. While one could argue that more-frequent inspections might be necessary to better ensure safety—in particular for larger entities—there is no apparent value-added when specific inspection activities are duplicative and occur,

in some cases, before entities have had time to respond to findings from a previous inspection. In addition, most surveyed entities reported a federal inspection schedule of once every 3 years was reasonable; more frequent—especially duplicative—inspections waste federal dollars and can negatively affect lab operations. This effect on lab operations also wastes federal dollars because many of the laboratories are federally funded through grants or appropriations. To improve interagency coordination and reduce the potential for overlap and unnecessary duplication, a single coordinating agency could be helpful. Such a coordinating agency need not be responsible for conducting all inspections. Rather, where agencies can demonstrate that they meet SAR standards for their inspections, their inspections could be used in lieu of other agency inspections. Currently, the primary agencies with regulatory authority, CDC and APHIS, have taken steps toward better coordination through the interagency working group. However, CDC and APHIS have not been officially charged with overseeing or coordinating all inspection efforts and the other federal agencies may still inspect an entity regardless of how recently another agency has conducted an inspection. Moreover, consistent application of inspection standards—both across and within the agencies—is needed to reduce the negative effects of multiple inspections on lab operations. Further, cross-agency training efforts could facilitate consistent learning and application of such standards. Agencies could then better target their inspection time and resources, and entities could better prepare for and respond to federal inspections.

Recommendations for Executive Action

In order to eliminate overlapping and potentially duplicative inspections, as well as reduce the burden of such overlap and duplication on select agent entities, we recommend that CDC and APHIS, as the primary agencies with regulatory authority, work with DHS and DOD to (1) coordinate inspections of select agent entities and (2) where possible, use mechanisms such as (a) joint inspections with a single report of findings, (b) acceptance of each other's inspection results rather than independent inspections, and (c) cross-agency training opportunities to ensure consistent application of biosafety, biosecurity, and biocontainment inspection standards.

Agency Comments and Our Evaluation

We provided a draft of this report to HHS, USDA, DOT, DHS, and DOD for review and comment. DOT did not provide any comments. In its written comments, reproduced in appendix III, HHS agreed with our recommendations. HHS noted that DOT, DHS, and DOD have different

authorities than the federal select agent program (SAP), as we had outlined in the background section of this report. HHS stated that it already has a number of activities underway related to reducing overlap and duplication in inspections. Specifically, through the working group for Optimizing the Security of Biological Select Agents and Toxins in the United States, HHS's Federal Select Agent Program has developed procedures and policies to better coordinate inspections of federally owned or funded entities and to improve information sharing between departments and agencies. HHS initiated three programs to accomplish these goals: (1) a joint inspection program, (2) inspection information sharing MOUs, and (3) an inspector training program. HHS has so far conducted 24 joint inspections, signed inspection information sharing MOUs with five agencies, and trained five individuals from DHS and four individuals from DOD. HHS also plans another training session for spring 2013 to educate federal agencies about recent revisions to select agent regulations. HHS also provided technical comments, which we incorporated as appropriate.

In its written comments, reproduced in appendix IV, USDA agreed with our recommendations. Although USDA noted that it did not believe its activities were overlapping with DOD and DHS because of differences in inspection authorities and agency missions, it noted that it had a number of activities underway to reduce overlap and duplication in inspections. Along with CDC—USDA's partner in overseeing the select agent program—USDA noted that it is conducting joint inspections to minimize the number of select agent inspections, signing information sharing MOUs with several agencies to share inspection data, and conducting inspector training programs to provide knowledge, skills, and experience to federal partners. USDA also provided technical comments, which we incorporated as appropriate.

In its written comments, reproduced in appendix V, DHS agreed with our recommendations. DHS notes that its Regulatory Compliance Office collaborates with officials and inspectors at CDC and APHIS to plan joint inspections, share information, and consult on inspection findings in order to reduce the burden on inspected institutions. Specifically, DHS signed an MOU with CDC and APHIS that outlines how the parties will coordinate joint inspections in order to reduce the burden on entities and to facilitate coordination of oversight efforts between the agencies. In line with our recommendations, DHS now accepts the results of inspections conducted jointly with CDC or APHIS instead of conducting independent inspections or generating a DHS-specific report of findings. DHS has also

taken advantage of cross-agency training to ensure consistent application of biosafety, biosecurity, and biocontainment inspection standards.

In its written comments, reproduced in appendix VI, DOD agreed with our recommendations. DOD noted that certain DOD regulations require compliance inspections for areas, such as the personnel reliability program (PRP), that are in addition to the SAR. We recognize some requirements are agency-specific and do not suggest that they be eliminated. We do recommend, however, that the burden on entities be reduced through coordination with other SAR inspection activities. In line with our recommendations, we are encouraged that DOD has several initiatives to coordinate with CDC and APHIS to reduce overlap and duplication of inspections. For example, the Army and Navy have signed information sharing memorandums of agreement and understanding with CDC and APHIS to coordinate inspections of select agent agencies, through which they conducted the first CDC, DOD, and Army joint inspection in spring 2011. Although the Air Force does not have an MOU with CDC or APHIS for its one facility, it accepts the CDC inspection results and performs its own PRP inspection. During joint inspections, DOD notes that it develops an inspection plan with CDC, APHIS, and the entity, and coordinates with the agencies to minimize entries into inspected areas by inspecting an area together. While two separate reports are written, the DAIG notes that it generally does not replicate CDC findings of noncompliance with SAR standards. Findings are discussed to ensure a common understanding of the standards and what was observed, and to delineate between what is required by the SAR, DOD, and DAIG. While DOD notes that it is unclear whether it would or could accept a CDC or APHIS inspection report in lieu of its own inspection, these joint efforts are still new and the issue will evolve with further collaboration. Additionally, DOD is revising its biological and chemical agent security policies in order to harmonize them with the recently revised SAR. DOD also noted other steps it has taken to coordinate oversight efforts though the Working Group, such as developing the charter and implementation plan for the current federal "joint" inspections process, and developing tools, such as the inspector training program and playbook, to administer the joint inspection process. DOD also made some technical comments, which we incorporated as appropriate.

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 Health

and Human Services, Agriculture, Transportation, Homeland Security, and Defense, the appropriate congressional committees, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-2700 or kingsburyn@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 VII.

Nancy Kingsbury, Managing Director
Applied Research and Methods

Appendix I: Scope and Methodology

To assess (1) the extent of overlap and potential duplication in federal agencies' inspections of entities that work with select agents, (2) the costs of overlapping federal inspections and effects on laboratory operations, and (3) actions to reduce the costs and negative effects of overlapping inspections, we interviewed agency officials, reviewed pertinent legislation, regulations, and agency documents. Specifically, we spoke with officials from the Center for Disease Control and Prevention (CDC) Division of Select Agents and Toxins, the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), the Department of Transportation's (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA), the Department of Defense (DOD) military service Inspector General's offices, including the Department of the Army Inspector General (DAIG), Navy Inspector General, and Air Force Inspector General offices. We also spoke with interest groups, such as the American Biological Safety Association (ABSA), and officials at various Army, private, academic, and federal select agent entities.

To assess the extent of overlap and potential duplication in federal agencies' inspections of entities that work with select agents, we (1) identified 374 entities registered to work with select agents between fiscal years 2009 and 2011, (2) analyzed inspection data to identify registered entities that had been inspected by more than one agency on separate occasions in a 2-year period (at any point between fiscal years 2009 and 2011), and (3) surveyed those entities to assess the extent of duplication in inspection activities. In order to operationalize overlap, we relied on our 2011 duplication report, in which we define overlap as multiple agencies or programs having similar goals, engaging in similar activities or strategies to achieve them, or targeting similar beneficiaries.[1] CDC, APHIS, DHS, DOD, and DOT inspections are directed toward a similar goal—assessing biosafety and biosecurity compliance—and are accomplished through a similar strategy, the inspection process. When these inspections targeted the same entities, we counted the inspection as overlapping. Specifically, we analyzed fiscal year 2009 through July 2011 inspection data from CDC, APHIS, DHS, DOD, and DOT, and identified any instances where two different agencies had inspected the same entity on separate occasions within 2 years of each other. We counted joint inspections as a single inspection in our analysis, regardless

[1]GAO, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue,* GAO-11-318SP (Washington D.C.: March 2011).

of the agencies involved. For example, joint APHIS/DHS inspections or CDC/DAIG inspections were counted as one inspection. We chose the 2-year time frame because the Select Agent Regulations (SAR) require certification renewal every 3 years and it is the policy of CDC and APHIS to inspect the entity before recertifying, this represents a somewhat conservative measure of overlap.[2] Because CDC and APHIS manage the Select Agent Program (SAP) jointly and conduct joint inspections, where applicable, we collapse these agencies in reporting on overlap to show where DOT, DHS, or DOD inspections overlapped with either a CDC or APHIS inspection. We also relied on our 2011 report for our definition of duplication—when two or more agencies or programs are engaged in the same activities or provide the same services to the same beneficiaries. The entities experiencing overlap were identified from the population of 374 entities registered with CDC or APHIS at any point in the 3-year period. Some entities register and de-register each year, so the number of entities registered at any point in the 3-year period will differ from a single point-in-time number of registered entities. Using the number of entities registered at any point in the 3-year period, the extent of overlap as we have defined it is 15 percent. To estimate the likelihood that an entity would experience overlap in federal inspections, we developed a logistic regression model, using the following entity characteristics: the number of laboratories, the highest biosafety level (BSL) of laboratories within an entity, and the number of different select agents the entity works with. The model did not include the number of staff or the number of principal investigators, both of which are strongly correlated with the number of laboratories. We chose to include the number of laboratories in

[2]However, because the CDC and APHIS can inspect between renewals, the 2-year time frame also captures overlap that may occur as a result of additional CDC/APHIS inspections within the 3-year period.

the model because it was a stronger predictor of the likelihood, on the basis of the Wald chi-squared test, than these two characteristics.[3]

To assess the extent of duplication in the overlapping inspections, we surveyed the 55 entities that had been inspected by more than one agency in a 2-year period (that is, the population experiencing overlap).[4] The web-based survey of all such entities gathered information on the (1) extent to which there was duplication in specific inspection activities related to the preparation, execution, and close-out phases of the two inspections the entities had undergone, (2) costs and operational effects of inspections, (3) solutions for mitigating the negative effects of multiple inspections, and (4) positive and negative aspects of joint inspections (see app. II for a copy of the survey).The survey was sent to the RO of each entity, and we received an 86 percent response rate, with 47 of the 55 entities responding. To gather preliminary information and develop our survey, we conducted focus groups with about 50 laboratory workers from entities that have experienced federal inspections, including responsible officials, biosafety officers, principal investigators, and technical staff from federal, academic, and private entities that work with select agents. To understand general and agency specific inspection activities, we interviewed inspectors with CDC, APHIS, DHS, DOD service IGs, and DOT and examined inspection files. We also spoke with professional organizations such as the ABSA and the American Society for Microbiology and experts in the safety of select agent laboratories.

[3]The goal of our logistic regression analysis was to model the likelihood that a lab received duplicate inspections. The duplicate inspection was the dependent variable in the analysis (duplicate inspection or not), with three independent variables; the (1) number of laboratories, (2) highest BSL level, and (3) number of different select agents. We did not include the number of staff and the number of principal investigators in the model because these variables were strongly correlated with the number of laboratories and the model only needed one of these three independent variables to explain much of the same variation in the dependent variable. To determine which of the three would be the best to include in the model, we first fit a bivariate logistic model separately for each of these three independent variables. Next, we fit three multivariable models by including the one of these three variables along with the highest BSL level, and the number of different select agents. We then compared the Wald chi-square estimates to determine which of the three was a stronger predictor of the likelihood of duplicate inspections. The number of laboratories was our final choice.

[4]We did not count instances where an entity had been inspected by the same agency more than once in a 2 year time frame as overlapping.

We took several steps to ensure the reliability of survey responses and the analytical process. To ensure the content and wording of the survey were clear, accurate, unbiased, and nonburdensome, we solicited subject-matter expert reviews from affected agencies (CDC, APHIS, DAIG, and PHMSA), an interest group (ABSA), and an internal (GAO) survey expert. We also pretested the survey with lab staff from a variety of laboratories, including an Army lab, an academic lab, a private lab, and a large federal lab. The survey was deployed through the web, and each respondent had a unique user identification and password. To increase the response rate, follow-up e-mail and telephone calls were made to nonrespondents. Once we had reached an 80 percent response rate, we reviewed responses for (1) item nonresponse, (2) obvious errors or outliers in responses, and (3) "no" answers to question 1. We then followed up with respondents, as necessary, to get additional information and clarification. Changes identified through this process were recorded, and appropriate response cleaning was conducted in the analysis. To eliminate data-processing errors, the computer program that generated the survey results was independently verified by an internal SAS expert who was not involved in the engagement.

To assess the costs of overlapping federal inspections and the effects on laboratory operations, we (1) analyzed agency budget data and (2) gathered data from focus groups and our survey of entities on the costs and effects of inspections. Specifically, to assess the costs to the federal government, we requested information on the government and contracted staff involved in inspections and their total compensation (salary and benefits), the number of hours spent on inspection activities, and the associated travel costs for inspections for fiscal years 2010 and 2011. DHS was unable to provide detailed cost data as requested because their inspections of select agent laboratories are provided under a contract that does not identify labor hours, hourly contract rates, salaries, and benefits. But DHS did provide an estimate of the cost of inspections for fiscal years 2010 and 2011. This estimate was based on assumptions about typical staffing levels and costs for the most-common types of inspections, multiplied by the number of inspections conducted in each fiscal year. While DHS believes these estimations include travel costs, they do not include training costs. DOT was not able to provide cost data that include travel, because their system does not distinguish between inspection travel and other travel. As a result, DOT inspection amounts reflect only compensation costs. To assess the reliability of agency data on the costs of inspections, we provided the agencies with a detailed data-collection instrument with specific data requests and precalculated formulas. We reviewed the data for obvious errors, compared these data with cost data

from earlier fiscal years, and followed up with officials to discuss data reliability, significant changes across fiscal years, obvious errors, or omissions. We determined these data were sufficiently reliable for our purposes, which was to provide the approximate aggregate federal costs of inspections for the four agencies.

To assess the costs to entities, we asked surveyed entities to provide labor and cost information about the most recent inspection identified in our overlap analysis (see app. II, question 6, for specific wording). Specifically, we requested data for five occupational groups that tend to be involved in federal inspections, including (1) ROs and Alternate Responsible Officials, (2) Principal Investigators, (3) owners or controllers, (4) laboratory staff, and (5) support staff (security, administrative, maintenance, and information technology). We asked entities to provide the number of staff involved and the total labor hours spent by each occupational group, as well as the average salary for each group. We used these data to develop overall averages of the personnel and labor costs entities experience as a result of inspections by each one of the five federal agencies in our review. For data reliability purposes, we checked for outliers or obvious errors and followed up where such issues were identified. We calculated the average cost of an inspection by dividing the average (yearly) salary by 2080 to get an hourly rate, and then multiplied that by the number of labor hours provided. We also surveyed entities about nonquanitifable costs and the operational effects of multiple inspections and analyzed comments related to costs from our focus groups of lab staff.

To assess actions to reduce the costs and negative effects of overlapping inspections, we interviewed agency officials and interest groups, reviewed key reports addressing the issue, and analyzed comments related to solutions from our focus groups of lab staff. In addition, in our survey, we sought entities' opinions about solutions for overlapping inspections, including their experiences with joint inspections, which have been proposed as a solution for minimizing inspection duplication.

We conducted our work from March 2011 through January 2013 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.

Appendix II: Survey of Select Agent Entities Experiencing Overlapping Inspections

Inspections of Select Agent Registered Entities

U.S. Government Accountability Office

Welcome to the GAO survey on inspections of Select Agent (SA) entities. **To complete this survey, you may consult with others in your lab, as necessary.** Your responses to this web-based survey are essential in order for us to provide complete and accurate information on these issues to Congress.

We will use your responses, together with the responses of other recipients, to develop aggregate statistics, observations, and findings. **The identities of individual respondents will not be disclosed in our final report.**

For questions, contact Jason Fong at fongj@gao.gov or 202-512-xxxx.

If you experience technical problems with this web questionnaire, please contact Rebecca Shea at shear@gao.gov or 202-512-xxxx.

Important! JavaScript must be enabled on your browser in order to use this web questionnaire.

Survey Sections

This survey has 7 main sections covering the following key issues:
1. Inspecting Agencies
2. Inspection Activities:
   a. Preparation
   b. Execution
   c. Close-out/response
3. Quantifiable Costs of Inspections
4. Non-quantifiable Costs of Inspections
5 Effects of Multiple Inspections
6. Solutions
7. Joint Inspections

Click on **"Menu"** to the left of this screen to display a navigation panel that can be used to move from section to section.
Click on the **"Summary"** to the left of this screen to print a copy of the survey.

Abbreviations and Scope

AAALAC Association for Assessment and Accreditation of Laboratory Animal Care
APHIS Department of Agriculture's Animal and Plant Health Inspection Service
BSC Biosafety cabinet
BSO Biosafety Officer
CDC Department Health and Human Services' Centers for Disease Control and Prevention
DAIG Department of the Army's Inspector General
DHS Department of Homeland Security
DOE Department of Energy
DOT Department of Transportation
EPA Environmental Protection Agency
NIH National Institutes of Health
OSHA Occupational Safety and Health Administration
PI Principle investigator
RO Responsible official (CDC designated)
SA Select Agent
UN certified packaging designed/tested in accordance with specifications of the United Nations Committee of Experts on the Transport of Dangerous Goods

Unless otherwise specified, the questions in this survey apply only to inspections for biosafety and biosecurity as required under Select Agent regulations or by those agencies that own or fund your entities' Select Agent research.

Respondent Information

Please check the following information for accuracy. If you need to make changes, please do so in the appropriate editable field(s) below.

Respondent Name

Respondent Title

Respondent email address

Respondent telephone

Inspecting Agencies

1. GAO received inspection data from CDC, APHIS, DHS, DOT, and DAIG, and identified your entity (lab) as one that has been inspected by more than one of these agencies within the past 2 years. Specifically, these data indicate your lab was inspected by the following agencies in the past 2 years: _____ in _____ and _____ in _____.

Is this correct?

- ☐ Yes *(GO TO QUESTION 2)*
- ☐ No
- ☐ Don't know

1a. **If the information above is not correct, please note the necessary corrections in the space below.**

2. States, local governments, accrediting bodies (such as AAALAC and the Joint Commission), military organizations (such as the Medical Command and Army Material Command), and other federal entities such as NIH, OSHA, EPA, and DOE might also inspect SA registered labs.
If your lab was inspected in the past 2 years by any <u>other</u> entities (for SA compliance or other reasons), please provide the name of the inspecting entity and inspection date.

2a. Other inspecting entity and date of inspection:

2b. Other inspecting entity and date of inspection:

2c. Other inspecting entity and date of inspection:

2d. Other inspecting entity and date of inspection:

2e. If you would like to describe any areas of overlap between these "other" inspections and the inspections your lab has received from CDC, APHIS, DAIG, DHS or DOT, please do so in the space below.

Inspection Activities: Preparation

Inspections can be seen as taking place in 3 broad phases--(1) preparation, (2) execution, and (3) closeout/response-- with specific activities occurring in each phase.

3. **Thinking about your lab's inspections by _____in_____and_____in_____, please indicate whether you performed the following preparation activities as part of your routine activities, specifically for each inspection, or not at all.**
Please note: not all listed activities are required as part of routine activities or for inspections.

3a. **Update and/or confirm records related to Select Agents and Toxins are current and accurate (e.g., records for inventory, training, security, biosafety, etc.)**

Q3a1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3a2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3b. **Prepare and send requested documents to inspecting agency (hardcopy or electronic)**

Q3b1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3b2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3c. **Prepare all needed documentation for inspectors to review during visit (hardcopy or electronic)**

Q3c1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3c2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3d. **Revise and update written safety and security plans (e.g., biosafety, incident response plans, cyber, personnel and physical security)**

Q3d1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3d2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3e. **Verify the medical, security, or other credentials of inspectors**

Q3le. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3e2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3f. **Conduct refresher training/briefings to staff on the inspection process and possible questions they may be asked**

Q3f1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3f2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3g. **Arrange for staff (Primary Investigators (PI), Responsible official (RO), Biosafety Officers (BSO), animal handlers, etc.) to be present and available during the inspectors' site visit**

Q3g1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Qfg2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3h. **Schedule/reschedule activities (e.g., animal inoculations, experiments) to take place before or after the inspectors' site visit**

Q3h1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3h2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3i. **Decontaminate and prepare labs (i.e., go from a hot lab to a cold lab)**

Q3i1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3i2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3j. **Check equipment calibration, and operation (e.g., pressure monitors, autoclaves, BSCs, etc.)**

Q3j1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3j2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3k. **Check operation of critical infrastructure and maintenance records/certifications**

Q3k1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3k2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3l. **Ensure entry and exit doors are secure and alarm systems operating properly**

Q3l1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3l2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3m. **Check the operation and condition of personal protection equipment**

Q3m1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3m2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3n. **Verify that UN certified packagings have been properly labeled, tested, and assembled and the personnel trained for the use of these packagings**

Q3n1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3n2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3o. **Check the Hazmat shipping documents were properly prepared, signed and maintained as required**

Q3o1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3o2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3p. **Check Hazmat training records/documents concerning transportation responsibilities are current and available (e.g., general security and safety awareness, function specific)**

Q3o1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3p2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3q. **Check transportation security plans have been updated and trained accordingly**

Q3q1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3q2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

3r. **Other (describe below)**

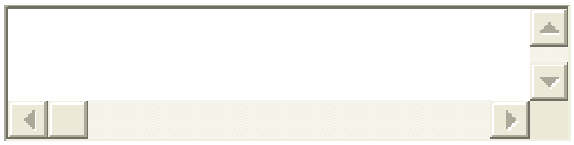
Q3r1. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q3r2. Inspection with _____:

- ☐ Performed as part of routine activities
- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Other--describe



Inspection Activities: Execution

4. **Thinking about your lab's inspections by _____in_____and_____ in_____, please indicate whether you performed the following execution activities specifically for each inspection.**
Please note: not all listed activities are required for all inspections. Participants can include any lab employee (RO, BSO, PI, laboratorians, etc.).

4a. **Hold entry meeting with inspectors**

Q4a1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q4a2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

4b. **Train inspectors on the use of Personal Protective Equipment (PPE)**

Q4b1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q4b2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

4c. **Train inspectors on other issues (e.g., entry/exit, lab hazards, decontamination requirements, emergency procedures, alarm sounds, etc.)**

Q4c1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q4c2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

4d. **Conduct facility tour**

Q4d1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q4d2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

4e. **Escort inspectors during inspection**

Q4e1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q4e2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

4f. **Participate in select agent inventory verification**

Q4f1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q4f2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

4g. **Participate in interviews with inspectors (to answer inspector questions and explain lab procedures and operations)**

Q4g1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q4g2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

4h. **Perform safety or security demonstrations (e.g., emergency response walk-through)**

Q4h1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q4h2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

4i. **Other (describe below)**

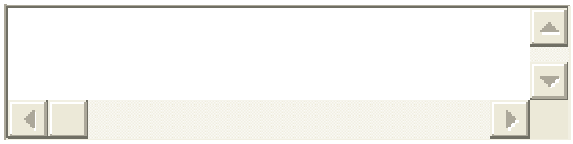
Q4i1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q4i2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Other--describe



Inspection Activities: Close-out/Response

5. **Thinking about your lab's inspections by _____in_____and_____ in_____, please indicate whether you performed the following close-out/response activities specifically for each inspection.**
Please note: not all listed activities are required for all inspections.

5a. **Hold close out/exit conference with inspecting agency (where agency tells the entity the results of the inspection in broad terms)**

Q5a1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q5a2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

5b. **Develop corrective action plan/report based on inspection findings**

Q5b1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q5b2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

5c. **Implement corrective actions**

Q5c1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q5c1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

5d. **Train on new procedures**

Q5d1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q5d2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

5e. **Provide documents to agency to show corrective actions have been taken**

Q5e1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q5e2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

5f. **Undergo limited follow-up inspection by agency to verify corrective actions have been made**

Q5f1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q5f2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

5g. **Bring equipment back online (e.g., HVAC, biosafety cabinets)**

Q5g1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q5g2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

5h. **Other (describe below)**

Q5h1. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Q5h2. Inspection with _____:

- ☐ Performed specifically for this inspection
- ☐ Did not perform
- ☐ Not applicable
- ☐ Don't know

Other--describe

Quantifiable Costs of Inspections

6. **Thinking about your lab's inspection by _____ in _____, and using the list of activities for the preparation, execution, and close-out phases listed above, please provide the following information for each occupational category:**

   (1) total number of personnel involved,
   (2) total labor hours spent, and
   (3) average salary for the occupational category

   Please include only individuals involved in the inspection. If none enter "0"

6a. Responsible Official (RO) and Alternate Responsible Official (ARO)

(1) Number of RO/AROs involved	(2) Labor hours spent	(3) Average salary
		$

6b. Principal Investigators (PI)

(1) Number of PIs involved	(2) Labor hours spent	(3) Average salary
		$

6c. Owner/Controller

(1) Number of owner/controllers involved	(2) Labor hours spent	(3) Average salary
		$

6d. Laboratorians

(1) Number of laboratorians involved	(2) Labor hours spent	(3) Average salary
		$

6e. Support Staff (e.g., IT, Security, Admin, Animal Care, Maintenance, Janitorial)

(1) Number of support staff involved	(2) Labor hours spent	(3) Average salary
		$

Non-quantifiable Costs of Inspections

Labs can incur non-quantifiable costs, such as loss of competitiveness or down-times in research. We are interested in the significance of such costs that are incurred as a result of federal inspections.

7. **In your opinion, how significant a cost, if any, did your lab incur in the following areas as a result of the inspection by _____ in _____?**

	Negligible cost	Some cost	Moderate cost	Significant cost	Don't know
7a. Loss of productivity	☐	☐	☐	☐	☐
7b. Delays in funded research	☐	☐	☐	☐	☐
7c. Dollars lost in funded research	☐	☐	☐	☐	☐
7d. Decreased time to complete research	☐	☐	☐	☐	☐
7e. Reduced viability of inventory	☐	☐	☐	☐	☐
7f. Reduced competitiveness for research funding	☐	☐	☐	☐	☐
7g. Other costs 1 (describe below)	☐	☐	☐	☐	☐
7h. Other costs 2 (describe below)	☐	☐	☐	☐	☐
7i. Other costs 3 (describe below)	☐	☐	☐	☐	☐

Other costs of inspections #1

Other costs of inspections #2

Other costs of inspections #3

8. **If you would like to provide additional information about the costs of inspections, or context for your responses, please do so in the space provided below.**

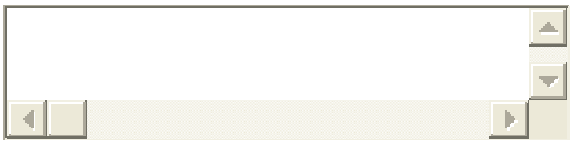
Effects of Multiple Inspections

9. **Thinking about the overall impact of having more than one federal inspection within the past 2 years, has having multiple federal inspections positively or negatively affected your lab operations in the following areas?**

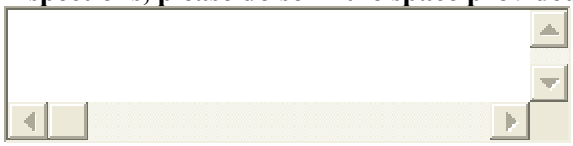
	Significant negative effect	Some negative effect	No effect	Some positive effect	Significant positive effect	Don't know
9a. Competitiveness for research funding	☐	☐	☐	☐	☐	☐
9b. Lab productivity	☐	☐	☐	☐	☐	☐
9c. Time to complete research	☐	☐	☐	☐	☐	☐
9d. Research schedule	☐	☐	☐	☐	☐	☐
9e. Physical viability of inventory (i.e., resilience of the biological sample)	☐	☐	☐	☐	☐	☐
9f. Staff retention	☐	☐	☐	☐	☐	☐
9g. Staff recruitment	☐	☐	☐	☐	☐	☐
9h. Staff morale	☐	☐	☐	☐	☐	☐

	Significant negative effect	Some negative effect	No effect	Some positive effect	Significant positive effect	Don't know
9i. Strength of inventory management and accountability	☐	☐	☐	☐	☐	☐
9j. Actions to correct deficiencies	☐	☐	☐	☐	☐	☐
9k. Justification for additional resources to improve operations	☐	☐	☐	☐	☐	☐
9l. Ability to have specialized inspections in which agencies focus on different areas (e.g., biosafety, security, animal husbandry, SA transport)	☐	☐	☐	☐	☐	☐
9m. "Coverage" in helping to identify problems (i.e., more than one set of "eyes on the problem")	☐	☐	☐	☐	☐	☐
9n. Other effect (describe below)	☐	☐	☐	☐	☐	☐

9o. Other--describe



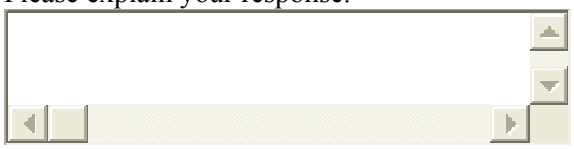
10. **If you would like to provide context for your responses or additional information about the positive or negative effects of multiple federal inspections, please do so in the space provided below.**



11. **In your opinion, what is a reasonable federal inspection cycle for select agent laboratories?**

1. ☐ More than once per year
2. ☐ Once per year
3. ☐ Every other year
4. ☐ Every three years
5. ☐ As needed
6. ☐ Other

11a. Please explain your response.



Solutions

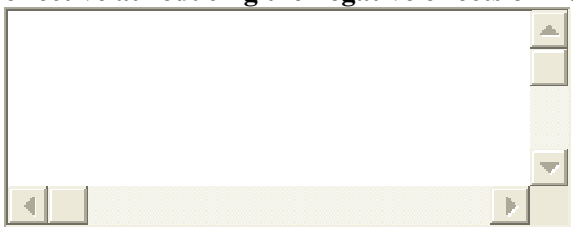
12. **In your opinion, how effective would the following actions be in reducing the negative effects of <u>multiple</u> federal inspections?**

	Very ineffective	Somewhat ineffective	Neither effective nor ineffective	Somewhat effective	Very effective	Don't know
12a. Conducting joint inspections	☐	☐	☐	☐	☐	☐
12b. Establishing an inspection czar (i.e., an individual who directs and coordinates SA inspection programs and strategy)	☐	☐	☐	☐	☐	☐
12c. Designating a single agency with inspection authority	☐	☐	☐	☐	☐	☐
12d. Establishing a single set of inspection standards that all agencies accept (in areas where authorities overlap)	☐	☐	☐	☐	☐	☐
12e. Inspecting to requirements rather than best practices	☐	☐	☐	☐	☐	☐

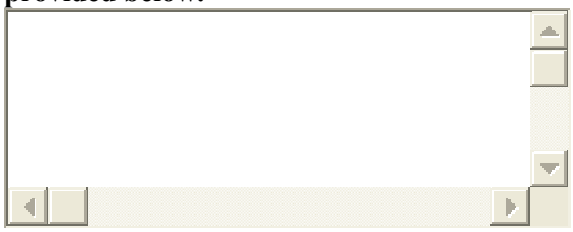
	Very ineffective	Somewhat ineffective	Neither effective nor ineffective	Somewhat effective	Very effective	Don't know
12f. Training inspectors to one set of standards with requirements for non-compliance findings	☐	☐	☐	☐	☐	☐
12g. Ensuring inspectors are well trained/experienced	☐	☐	☐	☐	☐	☐
12h. Training lab staff about the different agency missions and purposes for inspecting	☐	☐	☐	☐	☐	☐
12i. Providing an opportunity to discuss, clarify, and rebut inspection findings	☐	☐	☐	☐	☐	☐
12j. Other (describe)	☐	☐	☐	☐	☐	☐

12k. Other--describe

13. **Please explain why you think the actions above would or would not be effective at reducing the negative effects of multiple federal inspections.**



14. **If you would like to provide additional information about solutions for reducing the costs of multiple inspections, please do so in the space provided below.**

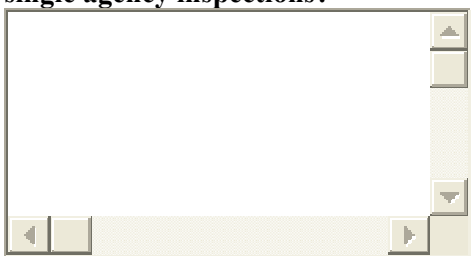


Joint Inspections

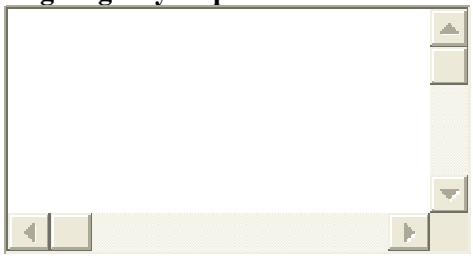
15. **Has your lab received a joint inspection (e.g., CDC/APHIS, CDC/DAIG, CDC/DHS, APHIS/DHS inspect concurrently)?**

1. ○ Yes
2. ○ No *(GO TO QUESTION 16)*
3. ○ Don't know *(GO TO QUESTION 16)*

15a. **If so, what are the positive aspects of joint inspections compared to single agency inspections?**

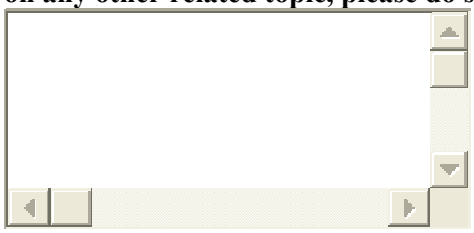


15b. **What are the negative aspects of joint inspections compared to single agency inspections?**



Complete Opinion Survey

16. **If you would like to clarify any of your responses to this survey, or comment on any other related topic, please do so in the space below.**



17. **If you have completed the questions in this survey, please move the check to the "Completed" button below.** ***(Your answers will not be used until you have checked "Completed."***

    1. ○ Completed
    2. ◉ Not completed

Getting a Copy of Your Responses

You may view and print your completed survey by clicking on the Summary link in the menu to the left. When you are done, click on the "Exit" button below to exit the survey and send your responses to GAO.

Thank you for your help.

Appendix III: 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

DEC 12 2012

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

Dear Ms. Kingsbury:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Overlap and Duplication: Federal Inspections of Select Agent Entity Laboratories"(GAO-13-154).

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

Sincerely,

Jim R. Esquea

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, "FEDERAL INSPECTIONS OF ENTITIES REGISTERED WITH THE SELECT AGENT PROGRAM" (GAO-13-154)

The Department appreciates the opportunity to review and comment on this draft report.

GAO Recommendation: In order to eliminate overlapping and potentially duplicative inspections, and reduce the burden of such overlap and duplication on select agent entities, we recommend that the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS), as the primary agencies with regulatory authority, work with the Department of Homeland Security (DHS) and the Department of Defense (DOD) to (1) coordinate inspections of select agent entities, and (2) where possible, use mechanisms—such as joint inspections with a single report of findings, acceptance of each other's inspection results rather than independent inspections, and cross-agency training opportunities—to ensure consistent application of biosafety, biosecurity, and biocontainment inspection standards.

HHS Response: HHS agrees that it is important to reduce the burden of duplicative inspections on entities registered with the Federal Select Agent Program. It should be noted that the Department of Transportation (DOT), DHS, and DOD have different authorities than the Federal Select Agent Program:

- Army - Army Regulation 20-1, Inspector General Activities and Procedures, paragraph 5-5 states: The Department of the Army Inspector General's Technical Inspections Division (SAIG–TI) conducts general, compliance-oriented, technical inspections of chemical, biological, radiological, nuclear, and other technical operations as required by regulations and directing authorities.
- DHS - Title III of the Homeland Security Act of 2002 and DHS Management Directive (MD) 026-03: "Select Agent and Toxin Security". Section 306 of the Homeland Security Act of 2002 establishes that the Secretary, acting through the Under Secretary for Science and Technology, may issue necessary regulations with respect to research, development, demonstration, testing, and evaluation activities of the Department, including the conducting, funding, and reviewing of such activities.
- DOT - Hazardous Materials Regulations (HMR), 49 CFR Parts 100-180, that govern the transportation of hazardous materials by highway, vessel, rail, and air. Under the HMR, select agents and toxins, including their wastes, are regulated as hazardous materials ("UN 2814, Infectious substances, affecting humans," or "UN 2900, Infectious substances, affecting animals").

In accordance with Executive Order 13546 (Optimizing the Security of Biological Select Agents and Toxins in the United States) signed by the President on July 2, 2010, the Federal Select Agent Program convened an Interagency Working Group to execute sections 6(a) and 8 of the Executive Order. This working group, which includes representatives from the Departments of Justice (DOJ), Energy (DOE), DHS, DOD, and the Environmental Protection Agency (EPA), has developed procedures and policies to better coordinate the inspections of entities that are federally owned or federally funded, improve information sharing between departments and agencies, and implement other activities so that effective oversight can be achieved with a minimal disruption of critical biodefense functions.

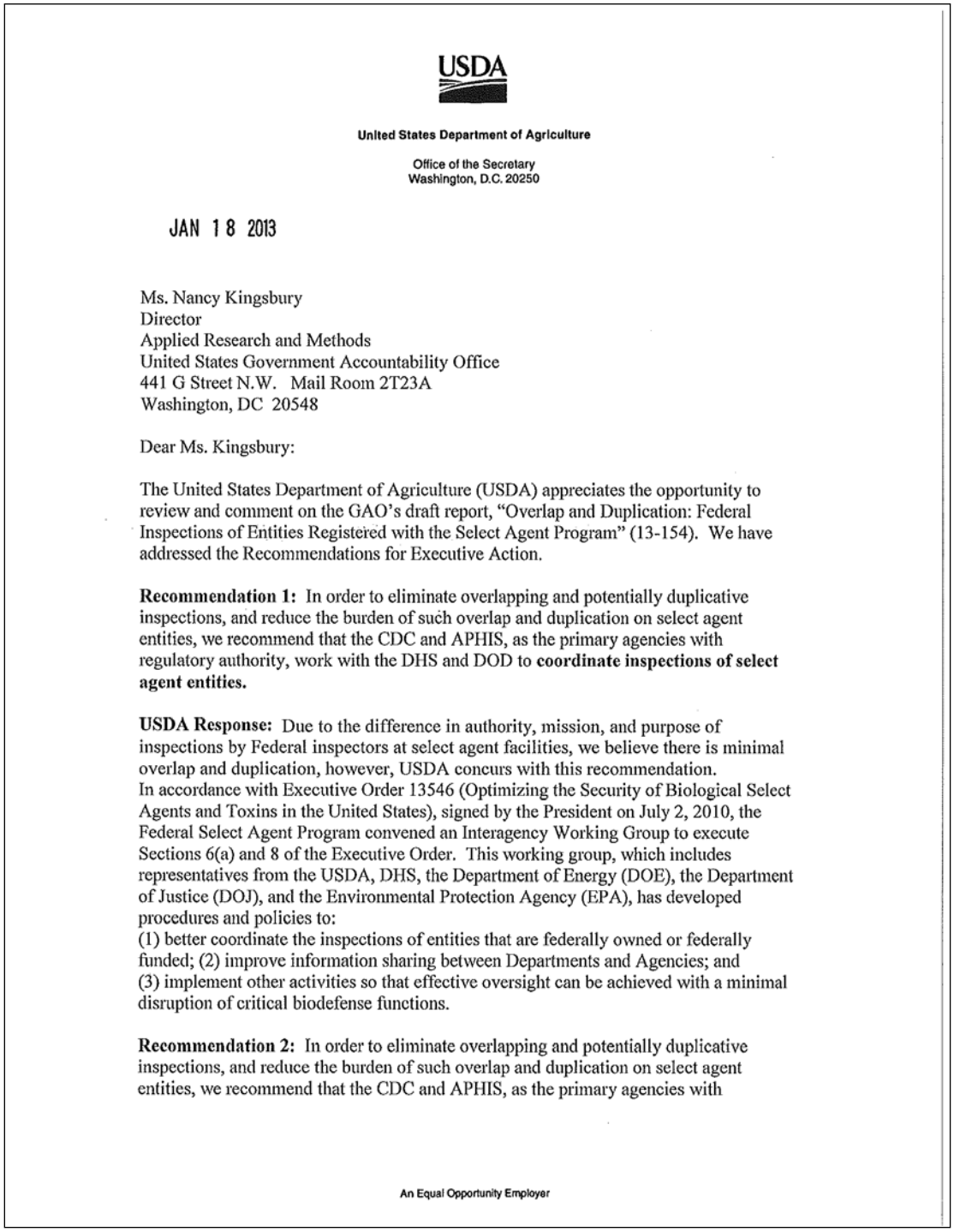
- **Joint inspections:** A joint inspection program has been initiated between the Federal Select Agent Program and other federal agencies that fund or own entities where select

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FEDERAL INSPECTIONS OF ENTITIES REGISTERED WITH THE SELECT AGENT PROGRAM" (GAO-13-154)

agent/toxin work is conducted to minimize the number of select agent inspections that these entities undergo per year. Since the initiation of the joint inspection program, the Federal Select Agent Program has participated in 24 joint inspections.

- **Information sharing:** Memoranda of understanding have been signed between the Federal Select Agent Program and DHS, DOD, EPA, DOE, and Veterans Health Administration to share information, including primarily inspection data.
- **Inspector Training Program:** The Federal Select Agent Program has trained 5 individuals from DHS and 4 individuals from DOD. The goal of the program is to provide the knowledge, skills, and experience to federal partners to enable them to conduct "internal" inspections of registered entities they own or fund, or to conduct joint inspections with the Federal Select Agent Program. The Federal Select Agent Program has planned another training session for spring 2013 to educate our federal partners regarding the recent revisions to the select agent regulations.

Appendix IV: Comments from the Department of Agriculture



USDA

United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

JAN 18 2013

Ms. Nancy Kingsbury
Director
Applied Research and Methods
United States Government Accountability Office
441 G Street N.W. Mail Room 2T23A
Washington, DC 20548

Dear Ms. Kingsbury:

The United States Department of Agriculture (USDA) appreciates the opportunity to review and comment on the GAO's draft report, "Overlap and Duplication: Federal Inspections of Entities Registered with the Select Agent Program" (13-154). We have addressed the Recommendations for Executive Action.

Recommendation 1: In order to eliminate overlapping and potentially duplicative inspections, and reduce the burden of such overlap and duplication on select agent entities, we recommend that the CDC and APHIS, as the primary agencies with regulatory authority, work with the DHS and DOD to **coordinate inspections of select agent entities.**

USDA Response: Due to the difference in authority, mission, and purpose of inspections by Federal inspectors at select agent facilities, we believe there is minimal overlap and duplication, however, USDA concurs with this recommendation.
In accordance with Executive Order 13546 (Optimizing the Security of Biological Select Agents and Toxins in the United States), signed by the President on July 2, 2010, the Federal Select Agent Program convened an Interagency Working Group to execute Sections 6(a) and 8 of the Executive Order. This working group, which includes representatives from the USDA, DHS, the Department of Energy (DOE), the Department of Justice (DOJ), and the Environmental Protection Agency (EPA), has developed procedures and policies to:
(1) better coordinate the inspections of entities that are federally owned or federally funded; (2) improve information sharing between Departments and Agencies; and
(3) implement other activities so that effective oversight can be achieved with a minimal disruption of critical biodefense functions.

Recommendation 2: In order to eliminate overlapping and potentially duplicative inspections, and reduce the burden of such overlap and duplication on select agent entities, we recommend that the CDC and APHIS, as the primary agencies with

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regulatory authority, work with the DHS and DOD to, **where possible, use mechanisms such as joint inspections with a single report of findings, acceptance of each other's inspection results rather than independent inspections, and cross-agency training opportunities to ensure consistent application of biosafety, biosecurity, and biocontainment inspection standards.**

USDA Response: Due to the difference in authority, mission, and purpose of inspections by Federal inspectors at select agent facilities, we believe there is minimal overlap and duplication, however, USDA concurs with this recommendation. The actions discussed below have been taken regarding joint inspections, information sharing, and inspector training.

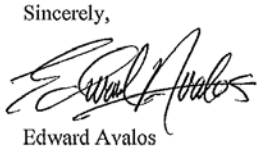
First, a joint inspection program has been initiated between the Federal Select Agent Program and other Federal agencies that fund or own entities where select agent/toxin-related work is conducted, to minimize the number of select agent inspections that these entities undergo per year. Since the initiation of the joint inspection program, the Federal Select Agent Program has participated in 24 joint inspections.

Next, Memoranda of Understandings have been signed between the Federal Select Agent Program and the Department of Defense, DHS, DOE, EPA, and Veterans Affairs (Veterans Health Administration) to share information, including primarily inspection data.

Finally, the Federal Select Agent Program has trained 13 individuals associated with our Federal partners. The goal of the program is to provide the knowledge, skills and experience to Federal partners to enable them to conduct "internal" inspections of registered entities they own or fund, or to conduct joint inspections with the Federal Select Agent Program. The Federal Select Agent Program has planned another training session for spring 2013 to educate our Federal partners regarding the recent revisions to the select agent regulations.

Once again, we appreciate the opportunity to respond to GAO's draft report, "Overlap and Duplication: Federal Inspections of Entities Registered with the Select Agent Program" and hope that our comments will help GAO in the preparation of its final report. If you have any questions, please contact Dr. Freeda Isaac at (301) 851-3368.

Sincerely,



Edward Avalos
Under Secretary
Marketing and Regulatory Programs

Appendix V: Comments from the Department of Homeland Security

U.S. Department of Homeland Security
Washington, D.C. 20528

Homeland Security

December 14, 2012

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

Re: Draft Report GAO-13-154, "OVERLAP AND DUPLICATION: Federal Inspections of Entities Registered With the Select Agent Program"

Dear Ms. Kingsbury:

Thank you for the opportunity to review and 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 progress in coordinating with the Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) and the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) on inspections of registered select agent entities. As highlighted in the report, the DHS Regulatory Compliance Office regularly collaborates with officials and inspectors at CDC and APHIS to plan joint inspections, share information, and consult on inspection findings in order to reduce the burden on inspected institutions.

The draft report contained two recommendations with which DHS agrees. Specifically, GAO recommended that the CDC and APHIS, as primary agencies with regulatory authority, work with the DHS and the Department of Defense to (1) coordinate inspections of select agent entities, and (2) where possible, use mechanisms such as joint inspections with a single report of findings, acceptance of each other's inspection results rather than independent inspections, and cross-agency training opportunities to ensure consistent application of biosafety, biosecurity and biocontainment inspection standards.

DHS currently coordinates with CDC and APHIS on inspections of select agent entities under a Memorandum of Understanding (MOU) between DHS, CDC, and APHIS signed on October 31, 2011. The MOU sets forth how the parties will coordinate joint inspections of registered select agent entities in order to reduce the burden on such entities and to facilitate coordination of oversight efforts between the agencies.

Additionally, DHS currently uses other mechanisms in coordination with CDC and APHIS, including joint inspections for which a DHS-specific report of findings is not generated in order to reduce the burden on the inspected entity. Acceptance of the coordinated parties' inspection results rather than independent inspections and cross-agency trainings are in place to ensure consistent application of biosafety, biosecurity, and biocontainment inspection standards.

Again, thank you for the opportunity to review and comment on this draft report. Please feel free to contact me if you have any questions. We look forward to working with you in the future.

Sincerely,

Jim H. Crumpacker
Director
Departmental GAO-OIG Liaison Office

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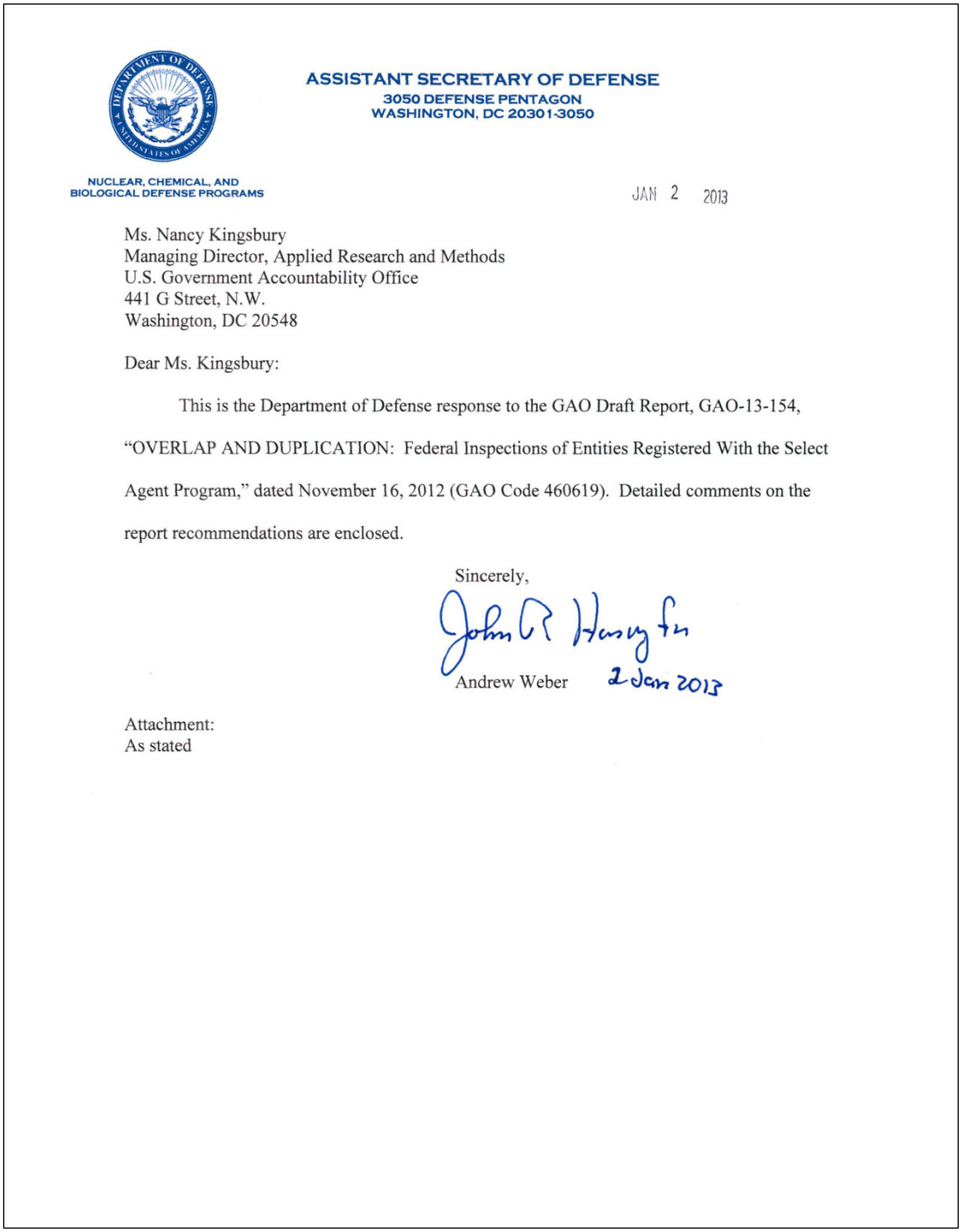
Appendix VI: Comments from the Department of Defense



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

NUCLEAR, CHEMICAL, AND
BIOLOGICAL DEFENSE PROGRAMS

JAN 2 2013

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

Dear Ms. Kingsbury:

This is the Department of Defense response to the GAO Draft Report, GAO-13-154, "OVERLAP AND DUPLICATION: Federal Inspections of Entities Registered With the Select Agent Program," dated November 16, 2012 (GAO Code 460619). Detailed comments on the report recommendations are enclosed.

Sincerely,

John R Hanley for

Andrew Weber 2 Jan 2013

Attachment:
As stated

GAO DRAFT REPORT DATED NOVEMBER 16, 2012
GAO-13-154 (GAO CODE 460619)

"OVERLAP AND DUPLICATION: FEDERAL INSPECTIONS OF ENTITIES REGISTERED WITH THE SELECT AGENT PROGRAM"

DEPARTMENT OF DEFENSE COMMENTS TO THE GAO RECOMMENDATION

RECOMMENDATION 1: The GAO recommends that the Secretary of Defense work together with the Centers for Disease Control and Prevention, the Animal and Plant Health Inspection Service, and the Department of Homeland Security to coordinate inspections of select agent agencies.

DoD RESPONSE: Concur, with comments.

Comments.

While the GAO data was collected from 2009-2011 and analysis was conducted from January 2011-December 2012, the DoD took independent steps to coordinate oversight efforts of biological select agents and toxins.

The Department of Defense (DoD) has been involved, from inception in Fall 2010, in the CDC/APHIS-led Interagency initiative mandated by Executive Order (EO) 13546 (Sections 6(a) and 8) to improve the coordination of federal oversight for Biological Select Agent and Toxin (BSAT) security. The Offices of the Under Secretaries of Defense for Intelligence, and Acquisition, Technology and Logistics, along with the Department of the Army's Inspector General (DAIG), participated in the earliest efforts to develop the Section 6(a)/8 Working Group's charter and implementation plan that guided the development of the current Federal "joint" inspections process. Follow-on initiatives in 2011 to develop the tools (available from the CDC) that are currently used to administer the joint inspection process (inspector training program, inspector playbook, Sharepoint Website, and information sharing agreements) additionally included DoD representation from the Air Force and the Navy. Also, the first CDC-DoD/Army joint inspection under this newly created Interagency process occurred at an Army facility in Spring 2011.

The Army and Navy presently have signed information sharing memoranda of agreement/understanding (MOA/MOU) (enclosed) with CDC/APHIS to coordinate inspections of select agent agencies. The Air Force has elected not to conclude an MOU at this time because they accept the CDC inspections and perform their own personnel reliability program (PRP) inspection of the one BSAT facility that they own.

In June 2012, DoD biological and chemical agent security policy proponency was moved to the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (OASD(NCB)) as part of the Secretary of Defense's initiatives to improve efficiencies and lower costs. Under this transfer of proponency, OASD(NCB) is revising the DoD biological and chemical agent security policies in order to harmonize them (per EO 13546) with the recently Federal Register published (October, 2012) CDC and APHIS revised Select Agent Regulations and associated guidance documents.

RECOMMENDATION 2: The GAO recommends that the Secretary of Defense work together with the Centers for Disease Control and Prevention, the Animal and Plant Health Inspection Service, and the Department of Homeland Security to, where possible, use mechanisms such as joint inspections with a single report of findings, acceptance of each other's inspection results rather than independent inspections, and cross-agency training opportunities to ensure consistent application of biosafety, biosecurity, and biocontainment inspection standards.

DoD RESPONSE: Concur, with comments.

Comments:

1. The GAO analysis was conducted from Jan 2011-Dec 2012 (page 8) and data collected from 2009-2011 (page 7). However, there is no mention of two key issuances that support Federal joint coordination efforts:

> a. The GAO report does not cite the EO 13546 [issued, July 2, 2010, Section 6 – Coordination of Federal Oversight for BSAT Security (a) 1] requiring "a mechanism for coordinated and reciprocal inspection of and harmonized administrative practices for facilities registered with the SAP [Select Agent Program]."
>
> DoD has ongoing initiatives to synchronize/harmonize with the CDC/APHIS-led federal mandate to reduce overlap and duplication of inspections of entities with Select Agents and Toxins (see Recommendation 1, comments).
>
> b. The revised CDC Select Agent Regulations were issued Oct 12, 2012, and include several guidance documents which will further facilitate the harmonization process and joint inspections.

2. The Army MOA and Navy MOU demonstrate the purpose to reduce the burden on registered entities and facilitate the coordination of oversight efforts as suggested in Recommendation 2.

3. Army regulations require the DAIG to conduct compliance inspections approximately every 24 months of those registered facilities that fall under DoD and Army Select Agent

regulations in order to ensure adherence to the technical, health, safety, accountability, security, and reliability standards.

Army regulations require Army Commands, Army Service Component Commands, Direct Reporting Units, and Program Executive Officers that oversee subordinate organizations and activities that fall under Department of the Army (DA) Select Agent requirements (including management of biological surety contracts) to conduct surety management reviews (included in the GAO discussion of inspections) approximately every 24 months to determine the adequacy of unit training, support, guidance provided to its assigned surety organizations, and compliance with applicable regulations.

The CDC and APHIS do not ensure compliance of registered entities with DoD or DA requirements, rather they mandate compliance with CDC and APHIS Code of Federal Regulation requirements.

The DAIG/CDC/APHIS joint inspections are conducted at the same time. Coordination is made with the inspected entity to minimize entries into inspected areas. As an example, a CDC and Army inspector will inspect an area vice DC and Army inspectors conducting two separate inspections. While two separate reports are written, the DAIG does not generally replicate CDC findings of non-compliance with CFR standards.

The ongoing revision of DoD regulations (DoDD 5210.88/DoDI 5210.89) will continue to address inspections that are duplicative (Recommendation 1, comments).

4. Recommendation 2's primary focus is for CDC, APHIS, DoD, and DHS to ensure consistent application of biosafety, biosecurity, and biocontainment inspection standards. The draft report should identify at the time independent development of governing regulations by federal agencies (i.e., DHS, DoD) prior to EO 13546 as a reason for overlap and duplication of inspections since the compilation of the GAO data efforts have been to harmonize the inspection process going forward.

a. The DAIG believes the joint inspection process currently in place between CDC, APHIS, and the DAIG does ensure consistent inspection standards between CDC, APHIS, and DAIG inspectors. A CDC/APHIS/DAIG inspection plan (reference the Army MOA attached) is jointly worked out with the inspected entity, with joint inspection teams formed to look at specific areas. Findings are discussed to ensure a common understanding of the standards and what was observed, and to delineate between CFR, DoD, and DA findings and who will record them in their reports. Any disagreements on CFR requirements are discussed in detail, with deference given to the CDC and APHIS final decisions as the proponents for the Select Agent Programs.

b. As the CDC and APHIS do not inspect for compliance with DoD and DA standards, it is unclear at the present time if the DoD or DA would/could accept a CDC or APHIS inspection report in lieu of a Service inspection as CDC and APHIS do not look at compliance with DoD and DA standards. The joint inspection process is still in its

infancy, and further collaboration and maturation towards overcoming this duplication is required between DoD/DA and CDC/APHIS.

5. The draft GAO report was general, and did not clearly identify the following major areas of inspection for entities registered with the CDC:

(a) BSAT inventory, usage, and transfer of records.
(b) Security Plan (Physical, Personnel, BSAT, etc) and Operations.
(c) Biosafety Program and Mishap records.
(d) Occupational Health Program.
(e) Emergency Management Plan and Operations.
(f) Personnel Reliability Program (now mandatory for all entities with Tier-1agents as of Oct 2012) but has been a part of DoD requirements.
(g) Institutional Biosafety Committee (IBC) Records.

6. The draft GAO report did not consider or report on 'Annual BSL-4 inspections' conducted by the CDC BSL-4 inspection team. These inspections are yet to be harmonized and conducted jointly, in part due to limited personnel permitted in each lab and other safety requirements.

Appendix VII: GAO Contact and Staff Acknowledgments

GAO Contact

Nancy Kingsbury, (202) 512-2700 or kingsburyn@gao.gov

Staff Acknowledgments

In addition to the contact named above, Sushil Sharma, Assistant Director; Rebecca Shea; Jason Fong; Elaine Vaurio; Jim Ashley; and Laurel Rabin made key contributions to this report.