USDA

United States Department of Agriculture
Office of Inspector General

Follow Up on APHIS' Implementation of the Select Agent or Toxin Regulations

Audit Report 33701-0001-AT

November 2012

United States Department of Agriculture
Office of Inspector General
Washington, D.C. 20250

DATE: November 6, 2012

AUDIT NUMBER: 33701-0001-AT

TO: Kevin Shea
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ATTN: Joanne L. Munno
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FROM: Gil H. Harden
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SUBJECT: Follow Up on APHIS' Implementation of the Select Agent or Toxin Regulations

This report presents the results of the subject audit. Your written response to the official draft, dated September 28, 2012, is included in its entirety at the end of the report. Excerpts from your response and the Office of Inspector General's (OIG) position are incorporated in the relevant Findings and Recommendations sections of the report. Based on your responses, we were able to accept management decision on Recommendations 4, 6, and 12. However, we are unable to accept management decision on Recommendations 1, 2, 3, 5, 7, 8, 9, 10, and 11. Documentation or action needed to reach management decision for these recommendations is described under the relevant OIG Position sections.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days, describing the corrective actions taken or planned, and timeframes for implementing the recommendations for which management decisions have not been reached. Please note that the regulation requires management decision to be reached on all recommendations within 6 months from report issuance, and final action to be taken within 1 year of each management decision to prevent being listed in the Department's annual Performance and Accountability Report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions.

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Follow Up on APHIS' Implementation of the Select Agent or Toxin Regulations

Executive Summary

After the events of September 11, 2001, the Government took a number of steps to strengthen homeland security. *The Public Health Security and Bioterrorism Preparedness and Response Act of 2002*[1] (Public Law 107-188, signed June 12, 2002 (hereafter referred to as "the Act")) included provisions for enhancing controls over dangerous biological agents and toxins. The Act addressed the lack of authority for the Secretary of Agriculture to regulate possession of biological agents that, through acts of bioterrorism, could have a devastating impact on the domestic agricultural economy. With passage of the Act, the Secretary of Agriculture was required to promulgate regulations to provide for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of select agents or toxins, including security measures and controls to limit access to only those individuals that have a legitimate need to handle or use such agents or toxins. The Animal and Plant Health Inspection Service (APHIS) was delegated authority to administer the regulations for the Department of Agriculture.

In prior audits of APHIS' select agent program,[2] we found that APHIS had not established a consistent and thorough inspection structure. In response to our recommendations, APHIS established controls to ensure registered entities complied with security regulations, including enhancing its reviews of entity security plans. In addition, APHIS enhanced its inspection process by requiring inspectors to observe security procedures to verify compliance with the security plan and determine whether entities' controls were in accordance with program regulations. The primary objective of this audit was to follow up on our prior audits and assess whether APHIS' new controls are effectively ensuring that registered entities comply with regulations governing the possession, use, and transfer of select agents. We selected 7 of 59 entities that were registered to possess or use select agents to assess their compliance with select agent regulations and determine whether APHIS was effectively overseeing the select agent program at these entities.

Although APHIS has made progress in establishing controls over the select agent program since our last audit, we found that APHIS needs to strengthen its internal controls over the critical program areas related to monitoring the movement of select agents to alternate facilities, controlling access to select agents, ensuring that individuals handling select agents have up-to-date security clearances, and ensuring that responsible officials (RO) are adequately trained. Our audit discovered deficiencies in these critical areas because APHIS did not always (1) ensure effective monitoring of ongoing activities, (2) fully address identified risks, or (3) ensure effective communication within the select agent program. We found deficiencies where

[1] Title II, Subtitle B of *the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* is cited as *the Agricultural Bioterrorism Protection Act of 2002*.

[2] *APHIS Evaluation of the Implementation of the Select Agent or Toxin Regulations, Phase I* (Audit Report 33601-0002-AT, dated June 23, 2005) and *APHIS Evaluation of the Implementation of the Select Agent or Toxin Regulations, Phase II* (Audit Report 33601-0003-AT, dated January 17, 2006).

inspector training and procedures performed did not always ensure that monitoring inspections identified program vulnerabilities. APHIS did not have adequate controls to ensure that legislatively required Department of Justice security risk assessments (SRA) for individuals possessing or using select agents were up-to-date. Finally, APHIS' lack of effective internal and external communication resulted in violations going undetected, such as (1) the transfer of select agents causing anthrax (*Bacillus anthracis*)[3] and the plague (*Yersinia pestis*)[4] to an unregistered facility and (2) access granted to personnel with expired security risk assessments to areas containing select agents at four of the seven entities we reviewed. These communication breakdowns increased the risk that select agents could be accessed by unauthorized personnel and potentially misused.

Finally, at five of the seven entities ROs or alternate ROs did not have documentation of their required biosafety or biocontainment and security training. APHIS did not require ROs or alternate ROs to have specific training related to their select agent program oversight responsibilities. Without appropriate training, ROs or alternate ROs could be providing incorrect or incomplete information to their employees, thus heightening the risk to the health of persons, plants, or animals. Additionally, all seven entities that we reviewed either did not ensure that all employees received the required training or did not maintain complete training records for their employees.

Recommendation Summary

To strengthen internal controls for monitoring program activities, addressing identified risks, and effectively communicating information about the select agent program, we recommend that APHIS revise inspection procedures to include steps for sampling and reviewing access logs; establish agency security policies and procedures for handling requests from registered entities to transfer select agents, under special circumstances; provide guidance to its registered entities to clarify the restricted access requirements; notify each registered entity to clarify that the RO must ensure that SRA renewals are timely, prior to expiration; and develop and conduct training for all ROs and alternate ROs that provides the knowledge necessary to effectively oversee the select agent program.

Agency Response

In its September 28, 2012, response to the official draft report, APHIS agreed with 3 of the 12 recommendations. Although APHIS did not agree with two of the recommendations, it proposed corrective actions that address the concerns identified by the Office of Inspector General (OIG). Excerpts from the response and OIG's position have been incorporated into the relevant sections of the report. The written response is included in its entirety at the end of the report.

[3] *Bacillus anthracis* is the bacterium that causes anthrax. It is considered one of the most serious bioterrorism threats.
[4] *Yersinia pestis* is the bacterium that causes the plague. It is considered one of the most serious bioterrorism threats.

OIG Position

The agency in their response expressed concerns that certain language in the report was unduly alarming and suggested that it should be revised or removed from the audit report. In considering management concerns, we revised certain language in the report. Further, we accept APHIS' management decision for Recommendations 4, 6, and 12, however for recommendations 1, 2, 3, 5, 7, 8, 9, 10, and 11, we were unable to reach management decision. We have provided our comments and a description of actions needed to reach management decision for each of these recommendations in the OIG Position section of the report.

Background and Objectives

Background

Biological agents and toxins that pose a severe risk to plant and animal health or to animal and plant products, such as bovine spongiform encephalopathy (BSE),[5] are regulated by the Department of Agriculture (USDA) as "select agents or toxins" (hereafter referred to as "select agents"). *The Agricultural Bioterrorism Protection Act of 2002*[6] (hereafter referred to as "the Act") gives the USDA authority to designate certain plant and animal biological agents and toxins as select agents by listing them in the *Federal Register* on a biennial basis.

The Act also requires that the Secretary of Health and Human Services (HHS) establish and maintain a list of select agents that have the potential to pose a severe threat to public health and safety (public health being focused on humans instead of plants and animals). Where HHS and USDA list some of the same agents, known as overlap agents,[7] the two departments coordinate.[8] In USDA, the Animal and Plant Health Inspection Service (APHIS) enforces the Act, while in HHS, the Centers for Disease Control and Prevention (CDC) enforces the Act. Further, the Act requires that a national database be established to identify the names of persons, location, and identification of the select agents that are possessed, used, or transferred by the registered entities. To accomplish this, CDC established and APHIS uses the National Select Agent Registry (NSAR) database.

APHIS and CDC regulate select agents by establishing and enforcing:

- Safety procedures for the transfer of listed agents, including measures to ensure proper training and appropriate skills to handle select agents, and proper laboratory facilities to contain and dispose of select agents;
- Security measures to prevent access to select agents for use in domestic or international terrorism or for any other criminal purpose; and
- Procedures to protect public safety, animal and plant health, as well as animal and plant products, in the event of a transfer or potential transfer of select agents in violation of the established safety procedures or established safeguards and security measures.

All entities that possess, use, or transfer these select agents must register with the appropriate regulatory agency, APHIS or CDC, depending on the type of select agents the entity possesses. Entities with overlap agents may choose to register with either APHIS or CDC, but registration

[5] BSE, widely referred to as "mad cow disease," is a chronic degenerative disease affecting the central nervous system of cattle. All infected cattle die. There is neither any treatment nor a vaccine to prevent the disease.
[6] Title II, Subtitle B of *the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* is cited as *the Agricultural Bioterrorism Protection Act of 2002*.
[7] Overlap agents are those agents that may affect both animal and human health.
[8] For select agents that are designated as overlap agents, CDC and APHIS are to coordinate to minimize conflicts between regulations and program activities and administrative burdens, subject to regulation by both APHIS and CDC.

with both agencies is not required. Currently,[9] 50 entities—including government agencies, academic institutions, corporations, associations, and other legal entities—are registered with APHIS to possess, use, and transfer select agents. An entity may have multiple facilities under its purview; however, each facility is, by itself, a separate registered entity. Registered entities are defined as facilities at one physical location (such as a room, a building, or a group of buildings) where the responsible official (RO) will be able to perform all the responsibilities of the Select Agent Program.[10]

Each entity must designate a RO who is responsible for day-to-day program administration and compliance. The entity may also designate one or more alternate ROs, who may act in the absence of the RO. As part of the registration process, the entities' RO, the alternate RO, the entity, and the individual who owns or controls the entity,[11] must undergo a security risk assessment (SRA) by the Criminal Justice Information Service (CJIS) Division of the Department of Justice.[12] Moreover, all individuals who handle or use select agents must undergo an SRA by the CJIS Division.

A Federal working group[13] established to identify and remedy potential gaps in biosecurity recommended that individuals who handle select agents undergo a renewed SRA every 3 years, as opposed to the previous timeline of every 5 years.[14] APHIS and CDC accepted this recommendation and, as of June 1, 2011, began requiring individuals to have their SRA renewed every 3 years.

When an entity registers with APHIS, it submits a site-specific security plan detailing the physical security of the select agents and the laboratories that house them.[15] In addition, the entity submits biosafety, biocontainment,[16] and incident response plans.[17] APHIS performs a

[9] As of May 2012.
[10] Registration is location specific; therefore, APHIS would classify a single corporation that owns three different facilities at distant locations handling select agents as three separate entities.
[11] Owning or controlling individuals undergo an SRA when applicable.
[12] The SRA is the method used by the CJIS to evaluate an individual's suitability to access select agents. Specifically, to determine whether the individual meets any of the statutory restrictors that would restrict them to access to select agents.
[13] The working group includes the Secretaries of Defense, HHS, State, Agriculture, Transportation, and Homeland Security, or their designees.
[14] Executive Order 13486, *Strengthening Laboratory Biosecurity in the United States*, January 2009, established the working group.
[15] 7 *Code of Federal Regulations* (CFR) 331.11(c)(d) and 9 CFR 121.11(c)(d) require that the security plan contain, among other things, provisions for securing the area (e.g., card access, locks); provisions for controlling access to the select agents; provisions for routine cleaning, maintenance, and repairs; provisions for ensuring that all individuals with access understand and comply with the security procedures; and allow access only to individuals with access approval from APHIS.
[16] 7 CFR 331.12(a)(b) and 9 CFR 121.12(a)(b) require the entity to develop and implement biosafety and/or biocontaiment plans detailing the procedures to ensure biosafety and containment. The procedures must be sufficient to contain the select agent (e.g., physical structure and features of the entity, and operational and procedural safeguards).
[17] 7 CFR 331.14(a)(b) and 9 CFR 121.14(a)(b) require the entity to develop and implement an incident response plan that details the entity's response procedures for events such as theft, loss, or release of select agents; security breaches; severe weather and other natural disasters; suspicious packages; and emergencies such as fire, gas leak, power outage, etc.

detailed review of the security, biosafety, biocontainment, and incident response plans and inspects the entity's facility and laboratories where select agents will be used or stored. After the initial registration is approved, APHIS performs a detailed inspection every 3 years as part of its registration renewal process. It follows up with annual compliance reviews that target certain issues, such as annual recordkeeping requirements, requirements to conduct drills and exercises, and accuracy of inventory records, based on the history or concerns with the entity. Compliance inspections are normally unannounced, and are designed to close the gap between the 3-year inspection cycles.

APHIS has 10 staff from Veterinary Services and 5 staff from Plant Protection and Quarantine (PPQ) assigned to the select agent program. Four veterinary medical officers are primarily responsible for overseeing registered entities. The PPQ director is responsible for overseeing entities that possess only plant-related select agents.

In July 2010, the President issued an executive order creating a tiered approach to classifying select agents, identifying a subset of select agents as Tier 1 agents, which are those with the greatest risk "of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence."[18] For Tier 1 agents, APHIS must revise its regulations to establish security standards specific to those agents. APHIS published the proposed list of Tier 1 agents on October 3, 2011. The executive order also created the Federal Experts Security Advisory Panel (FESAP) to make recommendations regarding biosecurity measures for the select agent program. FESAP's recommendations will be addressed during the next round of regulation revisions and FESAP will remain active through 2014.

Our 2005 review of the select agent program identified significant issues with APHIS' implementation of controls to prevent unauthorized access to select agents.[19] For example, APHIS had not established policies and procedures to ensure consistent and thorough security inspections. Our subsequent review of the program in 2006 confirmed the initial findings.[20] Since our 2006 review, APHIS has implemented several changes to program operations in response to issues identified in prior audits, including implementing a national database of select agents, training those conducting inspections, and creating a series of checklists for conducting inspections.[21]

Objective

The objective of this audit was to follow up on our prior audits and assess whether APHIS' new controls were effectively ensuring that registered entities comply with regulations governing the possession, use, and transfer of select agents.

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[18] Executive Order 13546, *Optimizing the Security of Biological Select Agents and Toxins in the United States*, Section 4, July 2, 2010.

[19] APHIS *Evaluation of the Implementation of the Select Agent or Toxin Regulations*, *Phase I* (33601-0002-AT, June 23, 2005).

[20] APHIS *Evaluation of the Implementation of the Select Agent or Toxin Regulations, Phase II* (33601-0003-AT, January 17, 2006).

[21] Management decision was achieved and the agency has stated that it completed final action on all previous audit recommendations for our 2005 and 2006 reviews.

Section 1: APHIS Oversight

Finding 1: APHIS Needs to Strengthen Controls Over Critical Areas in the Select Agent Program

APHIS needs to strengthen the internal controls related to moving select agents to alternate facilities, controlling access to select agents, ensuring that individuals handling select agents have up-to-date security clearances, and ensuring that ROs are adequately trained. These internal control deficiencies occurred because APHIS did not always (1) ensure effective monitoring of ongoing activities, (2) fully address identified risks, or (3) ensure effective communication within the select agent program. As a result, there is increased risk of the misuse of select agents and the potential for serious security violations going undetected.

The *Office of Management and Budget Circular A-123,* "Management's Responsibility for Internal Control," states that management has a fundamental responsibility to develop and maintain effective internal control. The Government Accountability Office Standards for Internal Control in the Federal Government[22] established five goals for internal controls. The first goal calls for Government agencies to establish a control environment that sets a "positive and supportive attitude toward internal control and conscientious management." These goals also include monitoring program activities; addressing identified risks; effectively communicating information; establishing policies, procedures, techniques, and mechanisms that enforce management's directions.

Since our prior audits, APHIS has improved its program administration. Previously, we found that APHIS had not established a consistent and thorough inspection structure. In response to our recommendations, APHIS established controls to ensure entities complied with security regulations, including enhancing its reviews of entity security plans. In addition, APHIS enhanced its inspection process by requiring inspectors to observe security procedures to verify compliance with the security plan and determine whether entities' controls accord with program regulations. While APHIS has made progress, the executive and regulatory authorities continue to emphasize enhancing security over select agents. In July 2010, an executive order[23] instructed APHIS and CDC to increase coordination, security, and oversight for agents and toxins with the highest risk, such as those causing anthrax (*Bacillus anthracis)*[24] and the plague (*Yersinia pestis)*.[25] We determined that continued efforts are needed to strengthen APHIS' internal control environment in the areas of monitoring, risk assessment, and communication to further enhance security for these and other high risk pathogens.

[22] GAO/AIMD-00-21.3.1, *Standards for Internal Control in the Federal Government*, dated November 1999, and OMB Circular A-123, *Management's Responsibility for Internal Control*, dated December 2004.
[23] Executive Order 13546, *Optimizing the Security of Biological Select Agents and Toxins in the United States*, July 2, 2010.
[24] *Bacillus anthracis* is the bacterium that causes anthrax. It is considered one of the most serious bioterrorism threats.
[25] *Yersinia pestis* is the bacterium that causes the plague. It is considered one of the most serious bioterrorism threats.

Monitoring Ongoing Activities

APHIS has established monitoring procedures and security checklists and conducted inspector training to determine whether the programs' legislative requirements are met. However, we found that the inspector training and procedures performed did not always ensure that monitoring inspections identified program vulnerabilities. We found that APHIS' inspection procedures for monitoring registered entities did not include specific steps to review access logs to ensure that only authorized individuals were allowed access to areas with select agents. The inspection procedures also did not include steps to identify individuals whose SRAs had expired. Finally, the inspection procedures did not include steps to ensure consistency in reviewing whether entities were complying with training requirements.

For instance, while legislation clearly identifies unauthorized access to select agents as a major risk, APHIS' checklist/procedures for inspecting physical security did not require its inspectors to check entities' access logs to ensure that unauthorized individuals are not allowed in areas where select agents are stored or used. The security review checklist directs inspectors to determine whether entities "allow access only to individuals with access approval from the HHS secretary or APHIS administrator." APHIS' training material for inspectors addresses onsite observations of individuals accessing areas where select agents are stored or used during the inspection, but it does not instruct inspectors to include an examination of previous log book entries or other documented entries, such as electronic keycard access records. Three of seven entities reviewed allowed unauthorized access into areas where select agents were used or stored (see Finding 3). However, APHIS' inspections did not identify these conditions because inspection procedures did not include steps to review access logs or access privileges.[26] APHIS officials told us that methods for access log reviews should have been covered during the inspectors' training and that the issue should be emphasized in future training. We concluded that inspection checklists should also include steps to review access logs and access privileges.

APHIS' inspections also did not identify other deficiencies, such as individuals with expired SRAs having access to select agents (see Finding 4), and entities that did not perform required security training or adequately document it (see Finding 5). In regard to expired SRAs, the APHIS inspection guidance does not include steps to identify individuals with expired SRAs. As for training deficiencies, officials said that their intent was for inspectors to review all training records for a given period. However, the inspection guidance does not specify this requirement, nor does it instruct inspectors how to assess training records.[27] The checklist also does not require inspectors to document the time period covered by records reviewed during their inspection. Without documentation of the time period, APHIS is hampered in tracking and evaluating registered entities' progress in correcting identified inspection deficiencies. Also, in the event of a security incident, APHIS would be unable to definitively state whether an inspection covered a particular time period.

[26] Access privilege is the ability to gain access to areas where select agents are used or stored. For example, individuals who have been granted keycard access to areas where select agents are used or stored have access privileges.

[27] The inspection checklist states that training records should include the names, dates, descriptions, and means used to verify employees understood the training. The checklist does not indicate how many records should be reviewed or what constitutes adequate documentation of employee understanding.

Fully Addressing Identified Risks

One of the most significant risks in the select agent program is that an individual might gain access to a select agent and deliberately misuse it in a terrorist act.[28] A key control to mitigate this risk is included in the original legislation creating the select agent program, and requires that individuals seeking to possess or use select agents must, by law, be vetted by the Department of Justice. This requirement and process is to ensure that restricted persons are not allowed to work with select agents. Every 3 years the SRA for an individual must be renewed. We found that APHIS was not ensuring that registered entities were keeping up-to-date SRAs for individuals possessing or using select agents. Even though entities' ROs are required to ensure that the SRAs are up-to-date, APHIS was unaware that SRAs were being allowed to expire, due to inaccurate information contained in the NSAR database.[29] During our review at 7 registered entities, we found that SRA approval for 11 individuals at 4 entities lapsed for periods of time ranging from 14 to 478 days (see Finding 4).

APHIS does not have an effective automated system to track the SRA renewals. Instead, the agency manually compares information from the CJIS database, maintained by the Department of Justice, to data that were manually entered into the NSAR database. This manual process is more prone to errors because it relies on both manual input and comparison of data. An APHIS official told us that it is the RO's responsibility to ensure that all individuals with access to select agents have an approved SRA. However, APHIS has the responsibility to monitor the program and ensure that the registered entities are complying with select agent laws and regulations.

Effective Communication within the Select Agent Program

APHIS' lack of effective internal and external communication resulted in violations going undetected, such as the transfer of select agents to an unregistered facility and access granted to unauthorized personnel to areas containing select agents, due to expired security clearances. These communication breakdowns increased the risk that select agents could be released, misused, or diverted for terrorism. We found APHIS permitted transfers of select agents to unregistered entities due, in part, to the lack of communication about the entity's known security plan deficiencies. This occurred when the APHIS Plant Protection and Quarantine (PPQ) official approving the transfer did not communicate with the APHIS veterinary medical officer, who was responsible for overseeing the entity before signing the transfer approval document (see Finding 2).

[28] In a November 2, 2010, report, *Recommendations Concerning the Select Agent Program* (revised 12/20/2010 and 1/10/2011), the FESAP recommended enhancing the SRA process for the select agent program to better assess circumstances that would disqualify an individual from accessing or using select agents. In its *Report of the Working Group on Strengthening the Biosecurity of the United States*, dated October 1, 2009, a Federal working group; which includes the Secretaries of Defense, HHS, State, Agriculture, Transportation, and Homeland Security, or their designees; found that restricting select agent access to only those who have passed an SRA is critical for strengthening the United States' biosecurity. The group recommended that those with access to select agents should meet high standards of reliability, which would prevent misuse by individuals with "nefarious intent."

[29] NSAR is the database that APHIS and CDC use to input data regarding the select agent program; it includes the information about individuals that are authorized to use select agents.

We also found that SRAs were not up-to-date at four of the entities because the entities' ROs expected APHIS to provide them notification when the renewals were due. However, the renewal notifications were not always timely sent by APHIS because the errors and omissions in its list prevented APHIS from timely identifying individuals whose SRAs were expiring (see Finding 4).

Communication that provides accurate and reliable information is essential to ensure that those tasked with administering the select agent program at all levels understand their responsibilities and to ensure that decisions and actions affecting the program provide the best means of preventing unnecessary risks.

As noted in Finding 2, the branch chief of select agents for PPQ approved the transfer of the select agents to an unregistered entity, and not the veterinary medical officer assigned responsibility for the entity.[30] The branch chief obtained CDC's concurrence on the transfer, which was required because *Bacillus anthracis* (anthrax) is an overlap agent that affects both humans and animals and *Yersinia pestis* (plague) is a CDC select agent that may affect human health. Although the assigned veterinary medical officer had identified 27 deficiencies in the security and incident response plans (i.e., the incident response plan did not address how the facility would respond to events such as explosions, gas leaks, power outages, bomb threats, and suspicious packages), at the time the transfer was approved, the branch chief and CDC approved the transfer to the facility because they believed the facility was safe and secure for storing the select agents. However, the unregistered entity did not address these issues until several months after the transfer took place.

In Finding 4, an issue involved incorrect external communication provided to registered entities, which caused confusion regarding the responsibilities for monitoring and updating SRAs. We found that SRAs for all authorized persons were not up-to-date at four of the entities because APHIS was inconsistent in sending renewal notifications and did not adequately describe entity responsibilities in guidance posted on its website. APHIS and CDC maintain a NSAR website that provides information to registered entities to help them manage their select agents. Up until May 2011, under the frequently asked questions section, the site stated that APHIS or CDC will provide the RO with a list of individuals who need renewed SRAs. However, according to the program legislation, entities hold the responsibility for ensuring that SRAs are current—not APHIS. This web posting led ROs to believe that they did not need to take actions to monitor their employees' SRAs, because APHIS would do that for them. Since APHIS does not have an effective system for monitoring SRA expirations itself, the notices that it sent to ROs were often unreliable, compounding the problem.

An APHIS official told us that it is ultimately the entity's responsibility to ensure that all individuals with access to select agents have an approved SRA. In May 2011, APHIS revised its webpage to include a note stating that, "It is the [RO's] responsibility to ensure all individuals listed on the entity's registration are SRA approved." However, we believe that this clarification

[30] Within APHIS' select agent program, there are four veterinary medical officers, each of whom is assigned responsibility for overseeing designated registered entities possessing and using select agents affecting animals. For entities possessing only select agents affecting plants, the branch chief of select agents for PPQ would have oversight responsibility.

does not ensure that all registered entities are fully aware of their responsibilities. Many entities may not know that the site has been corrected and, since APHIS is still sending out notices, they may continue to believe that APHIS is tracking SRAs for them.

In summary, since our last audit, APHIS has established monitoring procedures and security checklists and conducted inspector training, which were all designed to ensure legislative requirements are met. However, the agency needs to improve ongoing monitoring procedures to ensure that access and movement of select agents is done in a secure environment. APHIS also needs to establish controls to ensure program risks are mitigated by monitoring whether security risk assessments are performed as required. Finally, the agency needs to provide for good communication throughout APHIS and with registered entities to ensure that decisions and actions affecting the program provide the best means of preventing unnecessary risks.

Recommendation 1

Revise inspection procedures to include steps for sampling and reviewing access logs, access privileges, and electronic entry records (if available) to ensure entities are adhering to restricted access requirements, including log book documentation requirements.

Agency Response

In its September 28, 2012, response APHIS stated:

> APHIS does not concur with the recommendation. APHIS' current inspection procedures include sampling and reviewing access logs, access privileges, and electronic entry records during renewal inspections as well as annual compliance reviews. Select agent inspector training provided by APHIS specifically addresses the process to examine records and to compare those examinations with the list of authorized personnel. However, APHIS will review the inspection checklists to determine if more specificity is necessary. This review will be completed by December 3, 2012.

OIG Position

We are unable to reach management decision for this recommendation. In its response, APHIS did not provide evidence to support that its inspection procedures included sampling and reviewing access logs, access privileges, and electronic entry records. APHIS did not provide evidence showing that its inspector training specifically addressed the process to examine those records and compare those examinations with the list of authorized personnel. During our audit, we identified instances where unauthorized individuals were provided access, but such instances were not detected during APHIS' inspections. APHIS's inspection checklists, which had been provided to OIG during the audit, did not provide specific procedures for reviewing access logs, privileges, or electronic entry records. Additionally, the inspector training material provided to OIG stated that inspectors should observe individuals entering secure areas, but did not instruct the inspectors to examine previous log book entries or other documented entries such as electronic keycard access records. To reach management decision, APHIS should include steps for sampling and reviewing access logs, access privileges, and electronic entry records in its

checklists to ensure that entities are adhering to restricted access requirements, including requirements for log book documentation.

Recommendation 2

Revise the checklists and guidance used by inspectors to include (1) steps to identify evidence of required training, including what documents are needed to verify an individual's understanding of the training, and (2) the scope of an inspector's training documentation review to identify the period of time for which training records were reviewed.

Agency Response

In its September 28, 2012, response APHIS stated:

> APHIS does not concur with the recommendation. Select agent inspector training provided by APHIS specifically addresses the process to examine an entity's records to ensure that the training requirements are fulfilled. APHIS inspectors review training records typically from the date of the last inspection forward by both APHIS and *** CDC on-site inspectors. APHIS will review the inspection checklists to determine if more specificity is necessary. This review will be completed by December 3, 2012.

OIG Position

We are unable to reach management decision for this recommendation. During our audit, we identified deficiencies in the training records maintained at each of the seven entities we visited. Further, the training materials provided to OIG during the audit did not identify the scope of review performed or what documents the inspectors reviewed to verify that individuals understood the training. To reach management decision, APHIS should (1) revise its inspection checklist to record the scope of the review to identify the period of time for which training records were reviewed, and (2) revise the guidance used by inspectors to identify what documents are necessary to verify an individual's understanding of training; or provide details of how its training specifically addresses the process to examine an entity's records, including identifying what documents are required to be reviewed by inspectors to verify an individual's understanding of the training, to ensure that they training requirements are fulfilled.

Recommendation 3

Develop and implement procedures to ensure that all affected parties receive communication of relevant information regarding significant decisions, such as the approval of a transfer of a select agent, before such determinations are made.

Agency Response

In its September 28, 2012, response APHIS stated:

> APHIS does not concur with this recommendation. APHIS has a Standard Operating Procedure [SOP] for transfers, titled "Procedure for Processing Request to Transfer Select Agents and Toxins, APHIS/CDC Form 2," which was approved January 16, 2011. This document addresses how requests for transfers are communicated within APHIS and CDC. Part of the transfer process includes reviewing whether APHIS movement permits are valid for the recipient and sender of the select agent. If the transfer includes a CDC-only select agent or toxin, CDC must approve the request. In the transfer case cited in the OIG report, all procedures were followed correctly.

OIG Position

We are unable to reach management decision for this recommendation. The SOP cited states that if the recipient entity is not registered to possess the select agent, do not approve the transfer. In the case cited by OIG, the recipient entity did not possess a certificate of registration. Further, the SOP cited addresses communications between APHIS and CDC, not communications that occur internally within APHIS, where we cited the discrepancy. To reach management decision, APHIS should develop and implement procedures to ensure that all affected parties (both within APHIS and outside of APHIS) receive communication of relevant information regarding significant decisions, such as the approval of a transfer of a select agent, before such a determination is made.

Recommendation 4

Notify each registered entity to clarify that its RO must ensure that SRA renewals are done timely and not allowed to expire.

Agency Response

In its September 28, 2012, response APHIS stated:

> APHIS does not concur with the recommendation. APHIS notifies the *** RO of the *** SRA expiration dates as a courtesy, and it is the ROs' responsibility to ensure that SRAs are renewed on time. However, the Federal Select Agent Program (FSAP) will develop a guidance document for ROs which will remind ROs that it is their responsibility to see that employee SRAs are renewed in a timely fashion. This document will be completed by December 3, 2012.

OIG Position

Although APHIS does not agree with this recommendation, its proposed corrective action to develop guidance for ROs to remind them of their responsibility to see that SRAs are renewed timely is sufficient to reach management decision. Therefore, we accept management decision for this recommendation.

Section 2: Registered Entity Compliance Issues

Finding 2: APHIS Allowed Transfers of Select Agents to Unregistered Entities Without Approved Security Plans

APHIS permitted select agent transfers to two unregistered entities that had either not yet been inspected or where inspections had revealed deficiencies in the entity's security or incident response plans.[31] In both cases, a registered entity was relocating to a new facility that was not yet approved for the select agent program. APHIS officials explained that this occurred because the registration process for an entity can at times be lengthy if the entity has areas in the facility that are not yet complete and APHIS did not foresee circumstances where select agents might need to be transferred to a new facility owned by a registered entity before the new facility became fully registered. Therefore, APHIS had not established written policies and procedures to identify under what special circumstances, such as relocating to a new facility or temporarily transferring select agents to another location that is not registered while the entity makes emergency repairs to existing facilities, an unregistered entity may be allowed to store select agents. Because APHIS did not have assurance that the new facilities met safety and security requirements, the risk of theft, loss, or release of select agents increased.

Program regulations state that select agents may only be transferred to registered individuals or entities.[32] In order to transfer select agents, the entity receiving the agents must submit a request form providing the names and quantities of the select agents or toxins being transferred, as well as the sender's name, address, and telephone number. APHIS evaluates the request and determines whether it will allow the transfer.

APHIS authorized two entities to transfer their inventories—which included *Bacillus anthracis*, *Yersinia pestis*, and BSE—to unregistered facilities that had submitted security and incident response plans, but had not yet received approval for the plans. We did note that in both cases, APHIS authorized only the storage of select agents in the unregistered facilities, but not their use.

In the first case, APHIS had identified 27 issues in the entity's incident response and security plans that needed correction. For instance, the incident response plan did not address how the facility would respond to events such as explosions, gas leaks, power outages, bomb threats, and suspicious packages.[33] However, APHIS did not communicate these deficiencies to the entity

[31] An entity (corporation, university, or other) may have multiple facilities under its purview; however, each facility is, by itself, a separate registered entity.
[32] 7 CFR 331.16, 9 CFR 121.16, and 42 CFR 73.16.
[33] Regulations require that entities have an incident response plan in place that describes an entity's response procedures for events such as bomb threats, suspicious packages, and emergencies – such as fires, gas leaks, explosions, and power outages.

until 2 months after the select agents were transferred.[34] The entity eventually resolved the issues, and APHIS approved the registration 7 months after the agents were transferred there.[35]

In the second case, the entity's RO requested, on November 26, 2008, that APHIS allow the transfer of BSE to the new facility prior to registration because the lease at the old facility was expiring at the end of 2008. APHIS approved the transfer on December 2, 2008—but had yet to perform the inspection of the new facility. Additionally, APHIS did not require the entity to complete a transfer request form. Given the risks that select agents pose to human, animal, and plant health, APHIS should take steps to ensure the transfers are made only to entities that have met the safety and security requirements established in the regulations.

Overall, APHIS does not have written policies and procedures in place to allow the transfer of select agents under special circumstances. In the two cases we found, APHIS required one entity to submit a transfer request form, while instructing the other entity that a transfer request form was not required. This illustrates the need for written, formal guidance on the subject. APHIS officials acknowledged the need for policies covering select agent transfers made under special circumstances. To address this issue, we understand that APHIS is working with the CDC to develop formal procedures to allow either a temporary registration or a partial registration, such as authorizing an entity only to store a select agent in a designated room.

Recommendation 5

Establish policies and procedures for handling requests from registered entities to transfer select agents, under special circumstances, such as when an entity must relocate to facilities that are not registered with the select agent program.

Agency Response

In its September 28, 2012, response APHIS stated:

> APHIS concurs with this recommendation. The FSAP will develop a section of the registration form for entities to register for storage only. FSAP will also develop guidance for inspectors and entities on the requirements for such facilities. These actions will be completed and implemented by September 30, 2013.

OIG Position

We are unable to reach management decision for this recommendation. Although we agree with APHIS' proposal to develop a section of the registration form for entities to register for storage only and develop guidance for inspectors and entities on the requirements for such facilities, APHIS does not explain how this proposal relates to the transfer of select agents, under special circumstances, to an unregistered facility. To reach management decision, APHIS needs to

[34] The entity transferred the select agents and toxins to the new facility on February 27, 2008; however, APHIS did not notify the entity of the deficiencies until April 17, 2008.
[35] APHIS authorized the transfer of the select agents on February 19, 2008; however, it approved the registration of the new facility on September 22, 2008.

explain how the registration for storage only relates to the transfer of select agents, under special circumstances, to an unregistered facility and how the guidance being developed for inspectors and entities relates to the process.

Finding 3: Entities Did Not Adhere to Access Security Requirements

Three of the seven entities we reviewed allowed unauthorized individuals unescorted access to areas registered for use or storage of select agents. In addition, one of these three entities did not maintain a logbook identifying names of unauthorized individuals who accessed areas containing select agents. This occurred because entities believed that these individuals did not have access to select agents because APHIS' guidance did not clearly define what is meant by "access" to select agents, leading entities to interpret the guidance contrary to APHIS' intent.[36] Although the unauthorized access instances we found did not involve direct access to select agents, the lack of compliance with access security requirements increases the risk that unauthorized individuals could acquire access and potentially misuse select agents.

Individuals accessing select agents must undergo an SRA and be approved by APHIS (hereafter referred to as "SRA approval").[37] Anyone without SRA approval is considered unauthorized,[38] and may not access select agents.[39] Registered entities must also maintain information about all entries into areas containing select agents, including the names, names of escorts (if applicable), and the dates and times of entry.[40]

In one case, a company that was registered to work with select agents such as *Bacillus anthracis* and *Yersinia pestis*, allowed an unauthorized individual keycard access to a lab space registered for select agent use. The person in question was a scientist who worked in the same facility, but did not have SRA approval. As a result, the unauthorized scientist could enter the space registered for select agent use at any time.[41] Facility officials said that select agents were not in use in the registered area when the scientist entered, and therefore they did not think this was a violation of regulations. However, this policy contradicts the company's security plan, which states that only SRA-approved persons would have unescorted access to areas where select agents are used or stored. As a result of our finding, APHIS officials conducted a review of the company and determined that it was in violation of regulations.

The two other entities in question gave maintenance workers who were not SRA approved unescorted access to areas registered for select agent use. In one case, a company, which works with highly pathogenic avian influenza,[42] allowed maintenance workers key card access to the registered area while the facility was temporarily shut down for maintenance. The RO at the company stated that, since the facility was shut down and select agents were not in use, he did not believe that the individuals had access to select agents. However, the company's security

[36] APHIS officials stated their intent was that no unauthorized individuals (individuals without an approved SRA) should be allowed into any area registered for select agent use—regardless of whether the agents were present or not—unless such access is granted for a specific purpose and documented in an APHIS-approved security plan.
[37] 7 CFR 331.10(a) and (b) and 9 CFR 121.10(a) and (b).
[38] APHIS/CDC Guidance, *Select Agents and Toxins: Security Information Document*, dated March 8, 2007.
[39] 7 CFR 331.10(a) and 9 CFR 121.10(a).
[40] 7 CFR 331.17(a)(4) and 9 CFR 121.17(a)(4).
[41] An entity must identify specific areas where select agents will be used or stored. This may include only one room of a facility, several rooms, an entire building, or multiple buildings. As such, we use the term "registered area" to identify those area(s) in which the entity is approved to use or store select agents.
[42] Highly pathogenic *avian influenza*, also called "bird flu," is a virus that infects birds and can affect humans. It is highly contagious among birds and can result in high mortality rates among birds, especially chickens and turkeys.

plan stated that maintenance would be performed by SRA-approved individuals or unapproved individuals would be escorted. As such, the company was not complying with its own security plan.

Additionally, the entity maintained a sign-in book at the front door of the facility to document visitors; however, the book did not identify who accessed areas where select agents were used or stored, when such access occurred, or the name of that person's escort. The staff of the facility did not view this as noncompliance with regulations because they used electronic access records to document entry into areas containing select agents. However, this system does not capture when individuals without keycard access accompany individuals into areas where select agents are used. Thus, the company did not comply with select agent regulations which require a registered entity to maintain documentation that includes the name, name of escort (if applicable), date, and time of entry for all entries into spaces containing select agents.

In the second case, the company, which works with BSE, sought and received APHIS' approval to allow unescorted access by maintenance workers. However, the company did not revise its security plan to identify that it would allow unescorted access by workers who did not have SRA approval, nor to identify the additional security measures that would be implemented during the time such access was permitted. In addition, APHIS did not require the company to revise its security plan to reflect that it would allow access by these unauthorized individuals or identify what additional security measures would be implemented. The revised security plans should have reflected the circumstances under which access could occur and the additional security measures that would be in place during that time, such as removing all select agents from the area, decontaminating the area before access was granted, and restricting access to other areas registered for select agent use or storage.

In these two latter cases, an APHIS official acknowledged that the security plans should have been revised prior to allowing unescorted access by maintenance personnel. However, since there were no select agents present when the maintenance was performed and the one company had sought permission to allow unescorted individuals in the registered area, the risk relating to this access was minimal. Although one company sought APHIS' approval for unescorted maintenance (for painting) in a September 24, 2010, letter, APHIS' September 27, 2010, response approving the request did not inquire as to what maintenance procedures were included in the company's security plans or attempt to determine whether a change was needed in the company's security plan to address future maintenance needs.

These first two cases occurred because companies did not believe that the individuals had access to select agents because APHIS had not clearly defined what is meant by "access" to select agents. The regulations state that an individual has access if the individual has possession of the select agent or the "ability to gain possession" of a select agent. However, the term "ability to gain possession" is not defined. Therefore, the entities in the first two cases believed that, as long as select agents were not in use or stored in the registered area when unauthorized individuals entered, it was acceptable to allow access. However, because select agents may be brought into the registered space at any time, individuals with keycard access to these areas could potentially have access to select agents.

APHIS officials stated that their intent was that no unauthorized individuals should be allowed into any area registered for select agent use—regardless of whether the select agents were present or not—unless such access was granted for a specific purpose and documented in an APHIS-approved security plan.

Generally, we found that registered entities are not always following their approved security plans when permitting access to areas where select agents are used or stored, even though these plans were appropriately designed to comply with regulations in prohibiting access to areas where select agents were used and/or stored. To ensure that registered entities understand their responsibilities, fully comply with access requirements, and adequately secure select agents, APHIS should clarify its guidance. APHIS officials agreed that they could issue guidance to clarify access requirements.

Recommendation 6

Provide guidance to registered entities that clarifies the restricted access requirements for select agent registered space. Specifically, the guidance should (1) clearly define "access" and the meaning of "ability to gain possession," and (2) clarify whether access is prohibited to all areas registered for select agent use, storage, and transfer, and include examples of appropriate and inappropriate access control scenarios.

Agency Response

In its September 28, 2012, response APHIS stated:

> APHIS concurs with this recommendation. APHIS will clarify "access" and "ability to gain possession" in its security plan guidance document and escort policy guidance document. These documents will be revised by June 28, 2013.

OIG Position

We accept management decision for this recommendation.

Recommendation 7

Ensure that the company, which allowed the scientist who was not SRA approved, restricts access to that individual or obtains appropriate approvals to allow that individual to have access to select agent registered space.

Agency Response

In its September 28, 2012, response APHIS stated:

> Shortly after OIG advised us of this incident, APHIS sent an inspection team, that also included APHIS Investigative and Enforcement Services, to review the incident.

APHIS subsequently issued a letter of warning to the entity on February 3, 2012. The entity has assured APHIS in writing that the individual no longer has access to the registered space.

OIG Position

We are unable to accept management decision for this recommendation. In the recommendation we ask that APHIS ensure that the entity has either restricted that individual's access or obtained approval to allow the individual to have access to the registered space. While we appreciate APHIS' actions in investigating the matter promptly, APHIS has not ensured that the individual no longer has access to the registered space. To reach management decision, APHIS needs to verify that the individual no longer has access to the registered space.

Recommendation 8

Require the company that allowed unapproved maintenance workers keycard access for select agent areas to revise its security plan to reflect how it provides access to registered areas for conducting maintenance activities.

Agency Response

In its September 28, 2012, response APHIS stated:

> APHIS does not concur with the recommendation. In Title 9 of the *Code of Federal Regulations* (CFR) section 121.11(c) and 7 CFR 331.11(c), the select agent regulations state that entities must specify in their security plan provisions for controlling access to select agents and toxins and provisions for routine cleaning, maintenance, and repairs. In the specific instance cited above, the entity had removed select agents from the registered area; therefore, the maintenance workers did not have access to select agents. The entity's security plan properly identifies procedures for access and escort of non-SRA personnel in areas where there is the potential for access to select agents. Therefore, changes are not needed to the entity's security plan.

OIG Position

We are unable to reach management decision for this recommendation. The regulations cited by APHIS above are comprised of two distinct requirementsthe security plan must: (1) contain procedures for the control of access to select agents and toxins and (2) contain provisions for routine cleaning, maintenance, and repairs. We agree that the entity's security plan included both these elements. However, the entity was not conducting its cleaning, maintenance, and repairs in accordance with its written security plan. Because operating in a manner that is incongruent with its written security plan could give rise to additional security and safety risks, the security plan should be revised to reflect how the entity actually conducts its maintenance, cleaning, and repairs. This will allow APHIS to ensure that appropriate controls are in place to ensure the security of the select agents and safety of those performing the cleaning, maintenance,

and repairs. To reach management decision, APHIS needs to require the company in question to revise its security plan to reflect how it performs it cleaning, maintenance, and repair activities.

Recommendation 9

Determine whether the company that sought permission to allow unescorted access by unapproved maintenance workers continues to engage in the practice of allowing unescorted access. If so, require the company to revise its security plan to include a provision to allow unescorted maintenance workers and describe the types of additional security measures to be implemented when unescorted persons are present.

Agency Response

In its September 28, 2012, response APHIS stated:

> APHIS does not concur with this Recommendation. Regulations in 9 CFR 121.11(c) and 7 CFR 331.11(c) state that entities must specify in their security plan provisions for controlling access to select agents and toxins and provisions for routine cleaning, maintenance, and repairs. In the specific instance cited above, the entity had removed select agents from the registered area; therefore, the maintenance workers did not have access to select agents. The entity's security plan properly identifies the procedures for access and escort of non-SRA personnel in areas where there is the potential for access to select agent regulations. Therefore, changes are not needed to the entity's security plan.

OIG Position

We are unable to reach management decision for this recommendation. The regulations cited by APHIS are comprised of two distinct requirements; the security plan must (1) contain procedures for the control of access to select agents and toxins and (2) contain provisions for routine cleaning, maintenance, and repairs. We agree that the entity's security plan included both these elements. However, the entity was not following the procedures in its written security plan. To reach management decision, APHIS needs to determine whether the entity is now following its written security plan. If not, the entity should be required to revise its security plan to reflect actual procedures for cleaning, maintenance, and repairs.

Finding 4: Persons with Access to Select Agents Did Not Possess Updated SRAs

Four of the seven entities we reviewed allowed individuals with expired SRAs continued access to select agents. Individuals identified by an entity as having a legitimate need to handle or use select agents must undergo an SRA by CJIS and may not access select agents unless approved. SRAs are valid for a maximum of 5 years.[43] While Federal regulations place the ultimate responsibility with the entity,[44] we found entity officials were not tracking when individual SRAs expired. Entity officials told us that they relied on APHIS to notify them that SRA renewals were needed. An APHIS official stated that the agency only provided the notices as a courtesy and expected entities to ensure that SRAs were timely renewed, even in the absence of notification from APHIS. However, as we discuss in Finding 1, APHIS' expectation of the entities was unclear, in that APHIS' procedures stated that it would notify the entity's RO when renewals were needed.

APHIS officials stated that the tracking process to identify expiring SRAs requires staff to manually compare information from two separate systems to create the list of expiring SRAs. Because this is a manual process, there is a higher risk of errors and omissions. In fact, we found the notifications APHIS provided to the ROs were not always accurate or timely. We identified a total of 11 SRA approvals that were not renewed or cancelled for time periods ranging from 14 to 478 days (see exhibit A for detail of lapses). We discovered this by obtaining the entities' lists of persons approved for select agent access, and then reviewing the date when each person's SRA was set to expire. Once their SRA expired, 10 of these individuals continued to have access to select agents for periods between 14 to 302 days before their SRA was successfully renewed. The other person continued to have access from the time his approval expired until 19 days later when he retired. However, the RO at this entity did not notify APHIS of the access termination until 478 days after the SRA had expired.

Because of the potential for a change in an individual's classification to a restricted category after being approved for access to select agents, an SRA must be renewed periodically to ensure that a person can still safely possess, use, and transfer select agents.[45] For instance, the SRA process restricts access for an individual convicted in any court of a crime punishable by a prison term exceeding 1 year, or an individual who has been committed to a mental institution. For the period of our review, SRA approval was valid for a maximum of 5 years,[46] after which the SRA must be renewed.[47] When an entity terminates a person's access to select agents, the RO must notify APHIS immediately and provide the reasons for termination.[48] If SRAs are not renewed in a timely manner and individuals continue to have access to select agents, it increases the risk that the select agents could be intentionally misused or diverted for unauthorized purposes.

[43] 7 CFR 331.10(g) and 9 CFR 121.10(g). Effective June 1, 2011, APHIS revised the maximum period of time for which an SRA is valid to 3 years.
[44] 7 CFR 331.10(a) and 7 CFR 331.9(a)(4); 9 CFR 121.10(a) and 9 CFR 121.9(a)(4); and 42 CFR 73.10(a) and 42 CFR 73.9(a)(4).
[45] *Report of the Working Group on Strengthening the Biosecurity of the United States*, dated October 1, 2009.
[46] Effective June 1, 2011, APHIS and CDC require that SRAs must be renewed every 3 years, instead of every 5 years.
[47] 7 CFR 331.10(h), 9 CFR 121.10(i), and 42 CFR 73.10(i).
[48] 7 CFR 331.10(i), 9 CFR 121.10(j), and 42 CFR 73.10(j).

SRAs are a key security measure for the select agent program. APHIS must create a reliable list to serve as the foundation of its SRA approval monitoring efforts. APHIS must also ensure that ROs accurately track their employees' SRA approvals and timely renew them before they expire. We understand APHIS is now working to automate its list compilation process to ensure accuracy, as well as more timely notification to the ROs.

Recommendation 10

Develop and implement policies and procedures for monitoring ROs to ensure the ROs are seeking timely renewals or terminations of individuals' SRAs.

Agency Response

In its September 28, 2012, response APHIS stated:

> APHIS does not concur with the recommendation. APHIS will analyze the discrepancies provided by OIG to determine the reasons for possible lapses in individual's SRAs. If needed, we will develop processes to address these lapses. The analysis will be completed by December 3, 2012.

OIG Position

We are unable to accept management decision for this recommendation. Because APHIS is responsible to ensure that entities are complying with program requirements, the agency needs to monitor the ROs to ensure that they are renewing or terminating each individual's SRA, as appropriate. To reach management decision, APHIS needs to develop and implement policies and procedures for monitoring ROs to ensure that the ROs are seeking timely reviews or terminations of individuals' SRAs.

Finding 5: Responsible Officials and Employees Lacked Required Biosafety and Security Training

Five of the seven entities' ROs or alternate ROs did not have documentation of their required biosafety or biocontainment and security training. ROs and alternate ROs serve as select agent regulations experts in their respective entities, and often train their staff in safety and security measures. Although APHIS requires all individuals with access to select agents, including the RO and alternate RO, to have annual training on biosafety and security, APHIS did not require ROs or alternate ROs to have specific training related to their select agent program oversight responsibilities. The ROs and alternate ROs did not always comply with the select agent regulations in the maintenance of required training documentation to evidence training provided. Further, without appropriate training, ROs or alternate ROs could be providing incorrect or incomplete information to their employees. Additionally, all seven entities either did not ensure that all employees received the required annual training, or did not maintain complete training records for their employees, including evidence that the employees understood the training received. In 2 cases, entities did not provide training to all 58 individuals for 1 year. If training is not routinely conducted or is not understood, individuals working with select agents could develop critical knowledge gaps. These lapses in program training heighten the risk that individuals could hurt themselves or damage public, plant, or animal health if they mishandle a select agent or inadvertently cause a security breach.

Entities must provide biosafety or biocontainment and security training to each SRA-approved person before he/she can gain access to select agents, and refresher training annually thereafter.[49] Entities must also maintain records, including the date and description of the training, as well as the means used to verify that the individual understood the training (such as a quiz or test).[50] These records must be maintained for 3 years.[51]

Responsible Officials' Training

At five of the seven entities we visited, the RO or alternate RO did not document that they received or understood the required training in biosafety or biocontainment and security. They stated that APHIS had not provided guidance as to how ROs and alternate ROs were to meet the training requirements or how they were to document their training when they served as the subject matter expert and provided the training to other staff. Further, we noted that APHIS has not required any specific training for the ROs or alternate ROs to ensure that those responsible for implementing and overseeing the select agent programs at the registered entities have the knowledge necessary to effectively oversee the program. During our audit, we noted certain issues, which highlighted the need for training specifically focused on ensuring that ROs and alternate ROs are aware of select agent program requirements. For example, as we discussed in Finding 3, not all ROs clearly understood that only individuals with an SRA approval may have access to areas where select agents are used or stored. Additionally, as we discussed in Finding 4, ROs were relying on APHIS to notify them when an individual's SRA was due to expire, instead of monitoring that themselves and ensuring timely renewals. Without appropriate

[49] 7 CFR 331.15, 9 CFR 121.15, and 42 CFR 73.15.
[50] APHIS/CDC Guidance, *Select Agents and Toxins, Security Information Document*, March 8, 2007.
[51] 7 CFR 331.17(c), 9 CFR 121.17(c), and 42 CFR 73.17(c).

training, ROs could be providing incorrect or incomplete information to their employees, thus heightening the risk to the health of persons, plants, or animals.

APHIS acknowledged that it has not issued specific training requirements for ROs. However, on October 3, 2011, APHIS issued a proposed rule that will require ROs to possess appropriate training or expertise to ensure that the entity they oversee meets the requirements of the regulations. In addition, APHIS officials stated that, as a result of our concerns, they have discussed developing training specifically for ROs to ensure that ROs are knowledgeable of select agent program requirements, but, due to other priorities, they have yet to develop the training.

Training Other Authorized Persons

All seven entities did not maintain complete training records for all approved individuals or ensure that all individuals received the required training. For example, 2 entities did not provide the required annual training to any of the 58 persons registered to work with select agents for 1 of the 3 years that we reviewed. For one of these cases, the RO stated that he did not know why training was not provided because he was not the RO during that year. At the other, the RO stated that, instead of providing formal training, the staff read the standard operating procedures; however, this did not include a procedure to ensure that the person receiving the training understood the training, which is part of the training requirements.

Generally, where entities did not have complete records to document the required training, it was because they had not retained the required records. In one instance where the entity did not maintain records for the 3-year period required by APHIS regulations, the RO stated that it was because the entity's computer system purged the training records after 12 months. At another entity where they did not require all SRA-approved individuals to attend training, the RO said that the three SRA-approved individuals that did not receive training did not routinely access select agents, or were escorted when they were in the presence of select agents. However, APHIS regulations require that all individuals, whether SRA-approved or not, receive training prior to entering areas where select agents are used or stored.

Recommendation 11

Develop and conduct training for all ROs and alternate ROs that provides the information necessary to effectively oversee the select agent program. The session should provide a method of assessing that ROs and alternate ROs understood the training.

Agency Response

In its September 28, 2012, response APHIS stated:

> APHIS does not concur with this Recommendation. The FSAP held workshops on RO duties and responsibilities on November 16, 2011; May 10, 2011; June 15, 2010; August 12, 2009; and December 9, 2008. We will hold another workshop for ROs on November 16, 2012. A training requirement for ROs and alternate ROs was included in the

proposed rule published in December 2011, titled "Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Amendments to the Select Agent and Toxin Regulations." The public comments we received did not support such a requirement. However, FSAP will develop a guidance document that describes RO responsibilities; this will be completed by December 3, 2012.

OIG Position

We are unable to reach management decision for this recommendation. Although the workshops for ROs are beneficial, as would be a guidance document, they do not provide the same level of assurance that the ROs and alternate ROs are adequately knowledgeable of select agent regulations as would specific training, especially when the training is accompanied by a method for assessing that the ROs and alternate ROs understood the training. We reviewed the 65 public comments related to the proposed rule on Regulations.gov and found that 2 of the 65 comments favored "mandatory" periodic training of personnel working with and responsible for biosafety and biosecurity. To reach management decision, APHIS should develop and conduct training for all ROs and alternate ROs to provide the information necessary to effectively oversee the select agent program. This training should include a method of assessing the ROs and alternate ROs understanding of the training.

Recommendation 12

Provide guidance to each RO re-emphasizing the requirement that biosafety and security training must be provided to and documented for all authorized individuals with access to select agents. The guidance should state that documentation of the training must include the name of the attendee, a description of the training, date of the training, and the means used to verify that the employee understood the training. The guidance should also state that these records must be maintained for 3 years.

Agency Response

In its September 28, 2012, response APHIS stated:

> APHIS does not concur with this Recommendation. The current regulations in 9 CFR 121.15(c) and 7 CFR 331.15(c) already require that documentation of the training include the name of the attendee, a description of the training, date of the training, and the means used to verify that the employee understood the training. The 3-year records retention is also a requirement in 9 CFR 121.17(c) and 7 CFR 331.17(c). We will re-emphasize the training requirements in the RO guidance document that will be finalized by December 3, 2012. (This guidance document is the same document mentioned in Recommendations 4 and 11.) These requirements will also be specified in the security guidance document that will be developed by December 3, 2012.

OIG Position

Although APHIS does not agree with this recommendation, its proposed corrective action to re-emphasize the training requirements in the RO guidance document is sufficient to reach management decision. We accept management decision for this recommendation.

Scope and Methodology

This is our follow up audit to Phases I and II of APHIS' implementation of the select agent program to determine whether APHIS' new controls are effectively ensuring that registered entities are complying with governing regulations.[52] We examined registered entities' compliance with the select agent regulations and assessed APHIS' oversight of the entities from March 2010 through January 2012.

We conducted fieldwork at APHIS Headquarters in Riverdale, Maryland, and at seven judgmentally selected registered entities,[53] reviewing program operations from calendar year 2007 through January 2012. We judgmentally selected 7 entities from the universe of 59 registered entities[54] that were registered as of May 2010 for review, based on knowledge from previous audits, the types of select agents possessed by entities, geographic considerations, and entity type (e.g., commercial, non-profit, etc.). We used a judgmental sample so that we could review entities with a variety of select agents and security measures. Our sample of seven consisted of one academic institution, two commercial entities, two Federal entities, one State entity, and one privately-held entity. Because we did not use a statistical sample, we cannot project our results to the universe of registered entities.

To accomplish our audit objectives, we performed the following steps at APHIS headquarters:

- Reviewed corrective actions implemented as a result of our prior audits.
- Interviewed APHIS officials from both Veterinary Services and PPQ to determine what roles Veterinary Services and PPQ have in the select agent program.
- Interviewed personnel from APHIS' Investigative and Enforcement Services to determine what role Investigative and Enforcement Services has in the select agent program.
- Interviewed APHIS officials to determine agency procedures for coordinating with the CDC for activities, such as entity registration and certification, inspection, and enforcement activities.
- Interviewed APHIS officials to determine registration, renewal, and amendment policies; inspection types; transfer policies; and theft, loss, and release policies.

[52] *APHIS Evaluation of the Implementation of the Select Agent or Toxin Regulations, Phase I* (33601-0002-AT, June 23, 2005) and *APHIS Evaluation of the Implementation of the Select Agent or Toxin Regulations, Phase II* (33601-0003-AT, January 17, 2006).

[53] Our sample included 10 judgmentally selected entities, but due to budget constraints, 3 of the selected entities were eliminated from the review.

[54] The 59 registered entities consisted of 8 Federal governmental entities, 7 State governmental entities, 21 academic institutions, 21 commercial entities, and 2 private entities. As of May 2012, the number of registered entities had declined to 50 because some entities withdrew from the Select Agent Program, while others are now registered under CDC's Select Agent Program, due to a change in the select agents they process.

- Examined registration files and security, biocontainment, biosafety, and incident response plans for the seven selected entities.

At the seven selected entities, we performed the following steps:

- Interviewed the ROs and alternate ROs to gain an understanding of each entity's implementation of select agent program regulations, as well as compliance with the regulations.
- Evaluated security, biocontainment, biosafety, and incident response plans. We examined each plan to ensure it included procedures for inventory control; physical security; personnel security and suitability; accountability for select agents; security training; transfer of select agents; response to emergencies; and reporting incidents, injuries, and breaches.
- Evaluated the entities' policies and procedures for restricting access to select agents, inventory control, transferring select agents, and notifying APHIS in the event of a theft, loss, or release.
- Evaluated physical security measures in place for each laboratory where select agents were stored and/or used.
- Assessed the accuracy, adequacy, and completeness of the records required by each RO including:
    - security, biocontainment/biosafety, and incident response plans;
    - site-specific risk assessments;
    - training records;
    - authorized individuals;
    - security records (e.g., transactions from access control systems, visitor logs, etc.);
    - inventory records (including select agent source and characteristic data); and
    - transfer documents issued by APHIS or CDC.

We conducted this audit 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 audit findings and conclusions based on our audit objectives. We believe that the evidence we obtained provide a reasonable basis for our findings and conclusions based on our audit objectives.

Exhibit A: Summary of SRA Renewal Deficiencies

Exhibit A identifies the number of days that elapsed between the date that the individual's SRA expired and the date that the individual's SRA was renewed, or the date that the individual's name was submitted to APHIS to be removed from the list of approved users of select agents. The first column identifies the entity at which this was observed; the second column identifies the employee sample number; the third column provides the date the SRA expired; the fourth column identifies the date the individual's SRA was renewed and/or was removed from the list of authorized users of select agents; and the fifth and final column identifies the number of days that elapsed between the SRA expiration and SRA renewal (or removal from list of authorized users).

Entity	Individual with Expired SRA	SRA Expiration Date	Approval (A)/ Removal (R) Date	Days Lapsed
Entity 1	Employee 1	03/22/2010	08/20/2010 (A)	151
Entity 1	Employee 7	06/22/2010	09/20/2010 (A)	110
Entity 1	Employee 26	11/02/2010	11/16/2010 (A)	14
Entity 1	Employee 29	12/17/2009	08/20/2010 (A)	246
Entity 3	Employee 8	05/12/2010	09/22/2010 (A)	133
Entity 3	Employee 68	05/11/2010	09/23/2010 (A)	135
Entity 4	Employee 5	03/29/2011	04/13/2011 (A)	15
Entity 5	Employee 1	12/15/2008	04/07/2010 (R)	478
Entity 5	Employee 3	12/16/2008	10/01/2009 (A)	289
Entity 5	Employee 5	12/08/2008	09/18/2009 (A)	284
Entity 5	Employee 19	03/08/2009	01/04/2010 (A)	302

Note: Employee 1 of entity 5 was shown as an authorized user from the time his approval expired, until entity 5 requested that he be removed from the APHIS list of authorized users. Officials of the entity stated that the employee retired January 3, 2009, 19 days after his approval expired. However, the entity did not request APHIS to remove the individual from the list of authorized users until April 7, 2010.

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Abbreviations

APHIS	Animal and Plant Health Inspection Service
BSE	Bovine Spongiform Encephalopathy
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CJIS	Criminal Justice Information Service
FESAP	Federal Experts Security Advisory Panel
HHS	Health and Human Services
NSAR	National Select Agent Registry
PPQ	Plant Protection and Quarantine
RO	Responsible Official
SRA	Security Risk Assessment
USDA	Department of Agriculture

USDA'S
ANIMAL AND PLANT HEALTH
INSPECTION SERVICE'S
RESPONSE TO AUDIT REPORT

United States Department of Agriculture

Animal and Plant Health Inspection Service

Washington, DC 20250

MEMORANDUM

TO: Gil H. Harden September 28, 2012
Assistant Inspector General
For Audit

FROM: Kevin Shea /s/
Acting Administrator

SUBJECT: Animal and Plant Health Inspection Service's Response and Request for Management Decisions on the Office of Inspector General (OIG) Report, "Follow-Up on on Animal and Plant Health Inspection Service's Implementation of the Select Agent or Toxin Regulations" (33701-01-AT)

Thank you for the opportunity for the Animal and Plant Health Inspection Service (APHIS) to comment on this report.

APHIS is committed to protecting the health of animals and plants and their products through the effective management and implementation of the select agent and toxin regulations. In its report, OIG stated that its findings resulted in "potentially dangerous violations going undetected" or "jeopardizing the health of persons, plants or animals." We believe none of the findings uncovered dangerous violations that jeopardized the health of persons, plants, or animals. We believe that such language is unduly alarming and suggest that it should be revised or removed from the audit report.

We have addressed each Recommendation. In the majority of the Recommendations, we already have polices and/or procedures in effect that address the Recommendations. In other instances, we have included our planned corrective actions and the timeframes for implementing these actions.

Recommendation 1

Revise inspection procedures to include steps for sampling and reviewing access logs, access privileges, and electronic entry records (if available) to ensure entities are adhering to restricted access requirements, including log book documentation requirements.

APHIS Response: APHIS does not concur with this Recommendation. APHIS' current inspection procedures include sampling and reviewing access logs, access privileges, and electronic entry records during renewal inspections as well as annual

compliance reviews. Select agent inspector training provided by APHIS specifically addresses the process to examine records and to compare those examinations with the list of authorized personnel. However, APHIS will review the inspection checklists to determine if more specificity is necessary. This review will be completed by December 3, 2012.

Recommendation 2

Revise the checklists and guidance used by inspectors to include (1) steps to identify evidence of required training, including what documents are needed to verify an individual's understanding of the training, and (2) the scope of an inspector's training documentation review to identify the period of time for which training records were reviewed.

APHIS Response: APHIS does not concur with this Recommendation. Select agent inspector training provided by APHIS specifically addresses the process to examine the entity's records to ensure that the training requirements are fulfilled. APHIS inspectors review training records typically from the date of the last inspection forward by both APHIS and Centers for Disease Control and Prevention (CDC) on-site inspectors. APHIS will review the inspection checklists to determine if more specificity is necessary. This review will be completed by December 3, 2012.

Recommendation 3

Develop and implement procedures to ensure that all affected parties receive communication of relevant information regarding significant decisions, such as the approval of a transfer of a select agent, before such determinations are made.

APHIS Response: APHIS does not concur with this Recommendation. APHIS has a Standard Operating Procedure for transfers, titled "Procedure for Processing Request to Transfer Select Agents and Toxins, APHIS/CDC Form 2," which was approved January 16, 2011. This document addresses how requests for transfers are communicated within APHIS and CDC. Part of the transfer process includes reviewing whether APHIS movement permits are valid for the recipient and sender of the select agent. If the transfer includes a CDC-only select agent or toxin, CDC must approve the request. In the transfer case cited in the OIG report, all procedures were followed correctly.

Recommendation 4

Notify each registered entity to clarify that its RO must ensure that SRA renewals are done timely and not allowed to expire.

APHIS Response: APHIS does not concur with this Recommendation. APHIS notifies the Responsible Official (RO) of the security risk assessment (SRA) expiration dates as a courtesy, and it is the ROs' responsibility to ensure that SRAs

are renewed on time. However, the Federal Select Agent Program (FSAP) will develop a guidance document for ROs which will remind ROs that it is their responsibility to see that employee SRAs are renewed in a timely fashion. This document will be completed by December 3, 2012.

Recommendation 5

Establish policies and procedures for handling requests from registered entities to transfer select agents, under special circumstances, such as when an entity must relocate, to facilities that are not registered with the select agent program.

APHIS Response: APHIS concurs with this Recommendation. The FSAP will develop a section of the registration form for entities to register for storage only. FSAP will also develop guidance for inspectors and entities on the requirements for such facilities. These actions will be completed and implemented by September 30, 2013.

Recommendation 6

Provide guidance to registered entities that clarifies the restricted access requirements for select agent registered space. Specifically, the guidance should (1) clearly define "access" and the meaning of "ability to gain possession" and (2) clarify whether access is prohibited to all areas registered for select agent use, storage, and transfer, and include examples of appropriate and inappropriate access control scenarios.

APHIS Response: APHIS concurs with this Recommendation. APHIS will clarify "access" and "ability to gain possession" in its security plan guidance document and escort policy guidance document. These documents will be revised by June 28, 2013.

Recommendation 7

Ensure that the company that allowed the scientist who was not SRA approved, restricts access to that individual or obtains appropriate approvals to allow that individual to have access to select agent registered space.

APHIS Response: Shortly after OIG advised us of this incident, APHIS sent an inspection team, that also included APHIS Investigative and Enforcement Services, to review the incident. APHIS subsequently issued a letter of warning to the entity on February 3, 2012. The entity has assured APHIS in writing that the individual no longer has access to the registered space.

Recommendation 8

Require the company that allowed unapproved maintenance workers keycard access for select agent areas to revise its security plan to reflect how it provides access to registered areas for conducting maintenance activities.

APHIS Response: APHIS does not concur with this Recommendation. In Title 9 of the *Code of Federal Regulations* (CFR) section 121.11(c) and 7 CFR 331.11(c), the select agent regulations state that entities must specify in their security plan provisions for controlling access to select agents and toxins and provisions for routine cleaning, maintenance, and repairs. In the specific instance cited above, the entity had removed select agents from the registered area; therefore, the maintenance workers did not have access to select agents. The entity's security plan properly identifies the procedures for access and escort of non-SRA personnel in areas where there is the potential for access to select agent regulations. Therefore, changes are not needed to the entity's security plan.

Recommendation 9

Determine whether the company that sought permission to allow unescorted access by unapproved maintenance workers continues to engage in the practice of allowing unescorted access. If so, require the company to revise its security plan to include a provision to allow unescorted maintenance workers and describe the types of additional security measures to be implemented when unescorted persons are present.

APHIS Response: APHIS does not concur with this Recommendation. Regulations in 9 CFR 121.11(c) and 7 CFR 331.11(c) state that entities must specify in their security plan provisions for controlling access to select agents and toxins and provisions for routine cleaning, maintenance, and repairs. In the specific instance cited above, the entity had removed select agents from the registered area; therefore, the maintenance workers did not have access to select agents. The entity's security plan properly identifies the procedures for access and escort of non-SRA personnel in areas where there is the potential for access to select agent regulations. Therefore, changes are not needed to the entity's security plan.

Recommendation 10

Develop and implement policies and procedures for monitoring ROs to ensure the ROs are seeking timely renewals or terminations of individuals' SRAs.

APHIS Response: APHIS does not concur with the Recommendation. APHIS will analyze the discrepancies provided by OIG to determine the reasons for possible lapses in individuals' SRAs. If needed, we will develop processes to address these lapses. The analysis will be completed by December 3, 2012.

Recommendation 11

Develop and conduct training for all ROs and alternate ROs that provides the information necessary to effectively oversee the select agent program. The session should provide a method of assessing that ROs and alternate ROs understood the training.

APHIS Response: APHIS does not concur with this Recommendation. The FSAP held workshops on RO duties and responsibilities on November 16, 2011; May 10, 2011; June 15, 2010; August 12, 2009; and December 9, 2008. We will hold another workshop for ROs on November 16, 2012. A training requirement for ROs and alternate ROs was included in the proposed rule published in December 2011, titled "Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Amendments to the Select Agent and Toxin Regulations." The public comments we received did not support such a requirement. However, FSAP will develop guidance document that describes RO responsibilities; this will be completed by December 3, 2012.

Recommendation 12

Provide guidance to each RO re-emphasizing the requirement that biosafety and security training must be provided to and documented for all authorized individuals with access to select agents. The guidance should state that documentation of the training must include the name of the attendee, a description of the training, date of the training, and the means used to verify that the employee understood the training. The guidance should also state that these records must be maintained for 3 years.

APHIS Response: APHIS does not concur with this Recommendation. The current regulations in 9 CFR 121.15(c) and 7 CFR 331.15(c) already require that documentation of the training include the name of the attendee, a description of the training, date of the training, and the means used to verify that the employee understood the training. The 3-year records retention is also a requirement in 9 CFR 121.17(c) and 7 CFR 331.17(c). We will re-emphasize the training requirements in the RO guidance document that will be finalized by December 3, 2012. (This guidance document is the same document mentioned in Recommendations 4 and 11.) These requirements will also be specified in the security guidance document that will be developed by December 3, 2012.

Informational copies of this report have been distributed to:

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