U.S. Department of Agriculture

Office of Inspector General
Southeast Region

Audit Report

Animal and Plant Health Inspection Service Evaluation of the Implementation of the Select Agent or Toxin Regulations Phase II

Report No. 33601-3-AT
January 2006

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250

January 17, 2006

REPLY TO
ATTN OF: 33601-3-At

TO: W. Ron DeHaven
Administrator
Animal and Plant Health Inspection Service

ATTN: William J. Hudnall
Deputy Administrator for Marketing Regulatory Program
Business Services

FROM: Robert W. Young /S/
Assistant Inspector General
for Audit

SUBJECT: Evaluation of the Implementation of the Select Agent or Toxin Regulations (Phase II)

This report presents the results of the subject audit. Your response to the report, dated December 2, 2005, is included as exhibit A, with excerpts and the Office of Inspector General's (OIG) position incorporated into the Findings and Recommendations section of the report.

Based on your response, we have reached management decisions on Recommendations 2, 3, and 10. To achieve management decisions on Recommendations 1, 4, 5, 6, 7, 8, 9, 11, 12, and 13, we need additional corrective actions as outlined in the OIG Position section of the report, following each recommendation.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned and the timeframes for implementation of those recommendations for which management decisions have not yet been reached. Please note that the regulation requires that management decisions be reached on all recommendations within a maximum of 6 months from report issuance.

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

Executive Summary

Animal and Plant Health Inspection Service Evaluation of the Implementation of the Select Agent or Toxin Regulations Phase II, Audit Report No. 33601-3-At

Results in Brief

After the events of September 11, 2001, the Government has taken a number of steps to strengthen homeland security. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188, signed June 12, 2002), 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.[1] 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 U.S. Department of Agriculture.

The objective of the audit was to evaluate APHIS' implementation of regulations governing the possession, use, and transfer of biological agents and toxins. The audit was conducted in two phases. In Phase I (Audit No. 33601-2-At), we evaluated the agency's overall implementation of the regulations governing the possession, use, and transfer of biological agents and toxins. In Phase II, we made field visits to locations where select agents or toxins are used or stored to determine whether controls are in place and functioning as designed by examining registered entities' compliance with the regulations. This report presents the results of Phase II of our review.

We found that APHIS' oversight and enforcement of regulations regarding the security over select agents or toxins needed strengthening. As we reported in Phase I of our review, [2] the agency had not fully implemented controls for enforcing safeguard and security measures to prevent access to dangerous biological agents and toxins, as required by legislation. During our fieldwork in Phase II, we found that APHIS had not ensured that entities were: fully complying with regulations regarding security plans; restricting access to select agents or toxins; training individuals authorized to possess, use, or transfer select agents or toxins; and maintaining current and accurate inventories. These weaknesses occurred because APHIS had not performed timely or adequate reviews to ensure that security measures were implemented in accordance with the regulatory requirements. As we reported in Phase I, APHIS initially

[1] House of Representatives Conference Report No. 107-481, dated May 21, 2002.
[2] Audit Report No. 33601-2-At, issued June 23, 2005.

reviewed registration applications only to ensure that a security plan was submitted before granting provisional registrations. The agency did not determine the adequacy of the plans. In Phase I, we also reported that APHIS' inspections of the entities were not thorough enough to determine whether security was adequate. As a result, select agents or toxins were vulnerable to potential theft or misuse.

We found that APHIS had not updated its list of individuals authorized to access select agents or toxins. On October 8, 2004, APHIS provided us a current list of approved individuals granted access to select agents or toxins (authorized list). However, we found that the APHIS list did not always agree with the lists maintained by the registered entities. We found that 5 of the 10 entities reviewed had lists that were different from APHIS'. The differences occurred because (1) APHIS did not update the lists when notified by the entities that certain individuals no longer had access to the select agents or toxins or (2) the entities did not notify APHIS of individuals no longer having access. As a result, APHIS does not have accurate information to use in monitoring registered entities' compliance with requirements for restricting access to the select agents.

APHIS had not adequately safeguarded sensitive security and personal information pertaining to individuals authorized access to possess, use, or transfer select agents or toxins. We identified two instances where information regarding authorized individuals was provided to the wrong registered entity. This occurred because of human error, which we attributed in part to the fact that APHIS had not developed a national database of registered entities. This database should contain critical information including the names of individuals authorized to access select agents at the particular entity.[3] Until the national database is developed, APHIS will have to continue to rely on a mix of manual records and computerized spreadsheets maintained separately while administering the select agent program. In addition, APHIS had not established internal controls, in the form of policies and procedures, to prevent such occurrences. As a result, there is a greater risk that sensitive information is inadvertently disclosed in violation of the Act.

For our Phase I review, we reported that APHIS granted provisional registrations to entities without determining whether their security plans provided adequate safeguard and security measures. During our site visits in Phase II, we found that none of the 10 entities we reviewed had fully complied with the regulations. We selected 10 entities registered with APHIS, and performed site visits to test the entities' compliance with the regulations and to determine whether security controls were adequate and functioning. We found that security plans (1) were not based on site-specific risk assessments as required, (2) did not address critical requirements in the

[3] This condition was identified in our Phase I report (Audit No. 33601-2-At).

regulations, and (3) were not performance tested or reviewed and updated annually by the registered entities.

Registered entities we visited expressed concerns regarding APHIS oversight, including inadequate guidance to implement the select agent rules, untimely review and response to required submissions, and insufficient timeframes for responding to APHIS inquires. Inadequate guidance and untimely reviews of security plans may have contributed to some of the deficiencies we identified. However, we noted that, in many cases, deficiencies were due to the entities not following regulatory requirements. Even though each had been inspected by APHIS for compliance with the regulations prior to our review, we identified a number of security deficiencies at the sites visited.[4] We found that registered entities:

1. did not adequately restrict access to select agents or toxins as required by the regulations;

2. did not maintain adequate inventories of select agents; and

3. did not maintain adequate documentation concerning Biocontainment or Biosafety and Security training.

For our Phase I review, we reported that APHIS had not established policies and procedures to ensure that inspections of the registering entities' security measures were consistent and thorough. Inspections performed by APHIS did not provide clear documentation concerning the nature or extent of deficiencies, and did not always conclude as to whether security measures implemented by the registered entities were adequate. We also reported that although some inspections revealed deficiencies, APHIS did not always notify the registered entities of the results of the inspections and address, in writing, the nature of the deficiencies or the requirements for followup.

Because the Act requires APHIS and the Center for Disease Control (CDC) to develop and implement procedures to share responsibilities for inspecting entities that handle overlap agents, we met with officials from the Health and Human Services (HHS) Office of Inspector General (OIG) to coordinate our recommendations. The HHS-OIG conducted reviews of entities registered with CDC and identified issues similar to those identified during our reviews of entities registered with APHIS.

Recommendations in Brief

We are recommending that APHIS re-inspect registered entities to ensure compliance with regulations regarding the security over select agents. The inspections should be done using formal written procedures to ensure consistent and thorough reviews. In developing policies and procedures for

[4] Deficiencies were discussed with responsible officials at entities visited.

reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to:

- ensure registered entities base their security plans on a site-specific risk analysis;
- verify that the entities' security plans have thoroughly addressed all critical areas identified by the regulations;
- verify that entities are conducting and documenting annual performance tests of their security plans, and are updating plans based on the results of the performance tests, drills, or exercises;
- compare its list of authorized individuals with the names of individuals having access to areas with select agents;
- identify and examine all areas where select agents are used or stored to ensure that access to those areas are properly secured;
- verify that the entities have established and implemented inventory controls and perform tests to see that inventories are accurate and up to date; and
- verify that the entities have provided annual training, including required security training, to all individuals authorized to access select agents, and have documented the training as required.

We are also recommending that APHIS develop and implement written policies and procedures to ensure authorized lists are accurately and promptly updated. The procedures should include periodically disseminating the lists to registered entities and requiring the entities to verify APHIS' records, and either provide corrections or attest to the accuracy of the list. Additionally, we are recommending that APHIS develop and implement internal controls designed to prevent the release of sensitive security information associated with registered entities.

Agency Response

APHIS provided a written response to the official draft report on December 2, 2005. We have incorporated applicable portions of the response into the Findings and Recommendations section of this report. The agency response is included as exhibit A.

OIG Position

Based on your response, we have reached management decisions on Recommendations 2, 3, and 10. To achieve management decisions on Recommendations 1, 4, 5, 6, 7, 8, 9, 11, 12, and 13, we need additional corrective actions as outlined in the OIG Position section of the report, following each recommendation.

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Background and Objectives

Background

Plant and animal biological agents and toxins are considered "select" agents if they appear on a list prepared by the U.S. Department of Agriculture (USDA), and published in the *Federal Register* in accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) (the Act). The Agricultural Bioterrorism Protection Act of 2002[5] provides for the regulation of those agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products.

The Act also provides for the regulation of biological agents and toxins listed as dangerous by the Department of Health and Human Services (HHS). Where both HHS and USDA list the same agents, known as overlap agents, the Act provides for interagency coordination between the two departments. The Centers for Disease Control and Prevention (CDC) has responsibility for enforcing the Act on behalf of HHS; the Animal and Plant Health Inspection Service (APHIS) has responsibility for enforcing the Act on behalf of USDA.

The Act also required USDA's Secretary to establish:

- safety requirements for select agents, ensuring that appropriate skills exist to handle the agents and that proper laboratory facilities are available to contain and dispose of them;

- security requirements to prevent access to select agents for use in domestic or international terrorism or for any other criminal purpose; and

- requirements to protect animal and plant health, and animal and plant products in the event of a transfer of a select agent.

The Act requires all persons in possession of any select biological agent or toxin, including those select agents listed by CDC, to notify CDC or the Secretary of Agriculture of such possession. APHIS published the first list of select agents or toxins as an interim rule in the *Federal Register* in August 2002. The notification forms were due to APHIS no later than October 11, 2002.

APHIS published the final list of select agents or toxins on December 13, 2002. The list of plant agents appeared in 7 *Code of Federal Regulations* (CFR) 331 and the list of overlap and animal agents appeared in 9 CFR 121.

[5] 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."

Both regulations established safety, security, and transfer requirements for the select agents.

The Act required that APHIS publish an interim final rule for carrying out the safeguard and security measures within 180 days of passage of Public Law 107-188. The interim final rule, published on December 13, 2002, provided the regulations that registered entities were required to follow at the time of our site visits. The interim final rule became effective on February 11, 2003. Our review included an examination of the entities' compliance with the interim final rule. On March 18, 2005, APHIS adopted as a final rule, with changes, the interim final rule. The final rule promulgated regulations that became effective on April 18, 2005. The final rule provided clarification for issues such as inventory control requirements for select agents, and state that additional guidance will be forthcoming for issues such as security required for select agents or toxins.

One other requirement set forth by the Act (and repeated as regulation in the *Federal Register*) was that all entities possessing, using, or transferring select agents must register with the appropriate regulatory agency, APHIS or CDC. Entities with overlap agents could register with either agency. As part of the registration process, the entities' responsible official (RO), the alternate RO, the entity, and—where applicable—the individual who owns or controls the entity must undergo a security risk assessment by the Criminal Justice Information Services (CJIS) Division of the Federal Bureau of Investigation (FBI). Moreover, those individuals identified by an entity as having a legitimate need to handle or use select biological agents or toxins must undergo a security risk assessment by the CJIS Division.

To minimize the disruption of research and educational projects that were underway as of the effective date of the regulations (February 11, 2003), APHIS and CDC established a phase-in period that gave individuals and entities until November 12, 2003, to reach full compliance with the regulations. The phase-in dates were as follows:

- By March 12, 2003, the RO was to submit the registration application package to the regulatory agency. The official was also to transmit to the Attorney General the names of the RO, the entity, and the individual who owned the entity.

- By April 11, 2003, the RO was to submit to the Attorney General the names of all the individuals with the entity that had a legitimate need to use the select agents.

- By June 12, 2003, the RO was to submit to APHIS the security section of the entity's security plan.

- By September 12, 2003, the RO was to implement the security section of the entity's Biocontainment/Biosafety and Security Plan and provide security training in accordance with regulations.

- By November 12, 2003, the registration application process was to be complete and the entity in full compliance.

Objectives

The primary objective of this audit was to evaluate APHIS' implementation of regulations governing the possession, use, and transfer of biological agents and toxins. For this phase, we conducted field visits to locations where select agents or toxins are used or stored to determine whether established controls are functioning as designed by examining registered entities' compliance with the regulations, as well as assess APHIS' oversight of the entities.

Findings and Recommendations

Section 1: APHIS Controls Over the Select Agent Program

Finding 1 — APHIS Did Not Ensure That Registered Entities Had Developed and Implemented Adequate Security Measures

APHIS had not ensured that entities were fully complying with regulations regarding the development and implementation of security plans; restricting access to select agents or toxins; training for individuals authorized to possess, use, or transfer select agents or toxins; and maintaining accurate inventories. This occurred because APHIS had not performed adequate or timely reviews to ensure that security measures were implemented in accordance with the regulatory requirements. As we reported in Phase I, APHIS initially reviewed registration applications only to ensure that a security plan was submitted before granting provisional registrations. The agency did not determine the adequacy of the plans. In Phase I, we also reported that APHIS' inspections of the entities were not thorough enough to determine whether security was adequate. As a result, select agents or toxins were vulnerable to potential theft or misuse.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, was enacted to enhance controls over dangerous biological agents and toxins. Title II, subtitle B of the Act,[6] addressed the lack of authority for the Secretary of Agriculture, under legislation effective at that time, to regulate possession of biological agents and toxins that pose a severe threat to plant or animal health. The Act requires the Secretary to both establish and enforce safeguard and security measures to prevent access to select agents. On December 13, 2002, APHIS published an interim final rule setting forth the regulations for possessing, using, and transferring select agents. The regulations addressed standards and procedures that registered entities must follow to safeguard and secure the select agents.

For our Phase I review, we reported that APHIS granted provisional registrations to entities without determining whether their security plans provided adequate safeguard and security measures. During our site visits in Phase II, we found that none of the 10 entities we reviewed had fully complied with the regulations. We selected 10 of 75 entities registered with APHIS, and performed site visits to test the entities' compliance with the regulations and to determine whether security controls were adequate and functioning. We found that security plans (1) were not based on site-specific risk assessments as required, (2) did not address critical areas required by the regulations, and (3) were not performance tested or reviewed and updated annually by the registered entities (see Finding 4).

[6] Also known as "The Agricultural Bioterrorism Protection Act of 2002."

APHIS had not performed timely reviews of security plans to determine whether the plans were sufficient and had not timely followed up with the entities to address any deficiencies. This occurred because APHIS officials believed that the regulations intention to "minimize disruption of research" took precedence over the need to fully comply with the regulations. Therefore, APHIS only reviewed the initial registration applications to determine if a security plan was submitted. APHIS did not perform more thorough reviews until several months after the initial registrations, at that time identifying significant deficiencies in the plans. For example, one entity submitted an initial registration package on March 12, 2003. The entity submitted its Biosafety and Security Plan in a subsequent submission on May 27, 2003.[7] On September 29, 2004, nearly 16 months after the registration was submitted, APHIS sent a letter to the entity with 56 action-items or items needing clarification and 8 recommendations. Thirty-three of the 56 action items and 4 of the 8 recommendations related to the Biosafety and Security Plan. The remaining items and recommendations were related to the initial registration package. The APHIS letter provided the entity 10 business days to respond. However, the entity was not able to provide their response until November 19, 2004. During our site visit in December 2004, we identified significant deficiencies in the security plans, such as the lack of procedures to report and remove suspicious persons, and the lack of procedures for reporting and investigating unintentional and/or inappropriate release of select agents.

Registered entities we visited expressed concerns regarding APHIS oversight, including inadequate guidance to implement the select agent rules, untimely review and response to required submissions, and insufficient timeframes for responding to APHIS inquires. Inadequate guidance and untimely reviews of security plans may have contributed to some of the deficiencies we identified. However, we noted that, in many cases, deficiencies were due to the entities not following regulatory requirements. Even though each had been inspected by APHIS for compliance with the regulations prior to our review, we identified a number of security deficiencies at the sites visited. We found that registered entities:

1. did not adequately restrict access to select agents or toxins as required by the regulations (Finding 5);

2. did not maintain adequate inventories of select agents (Finding 6); and

3. did not maintain adequate documentation concerning Biocontainment or Biosafety and Security training (Finding 7).

For our Phase I review, we reported that APHIS had not established policies and procedures to ensure that inspections of the registering entities' security

[7] In 9 CFR §121.0(d), the RO was required to submit the security section of the Biosafety and Security Plan by June 12, 2003.

measures were consistent and thorough. Inspections performed by APHIS did not provide clear documentation concerning the nature or extent of deficiencies, and did not always conclude as to whether security measures implemented by the registered entities were adequate. We also reported that although some inspections revealed deficiencies, APHIS did not always notify the registered entities of the results of the inspections and address, in writing, the nature of the deficiencies or the requirements for followup.

Subsequent to our site visits, final regulations were issued on March 18, 2005. The final regulations provide additional guidance to entities to help ensure that the provisions of the Act and applicable regulations are fully implemented. For example, the final regulations provide clarification for issues such as inventory control requirements for select agents, and state that additional guidance will be forthcoming for issues such as security required for select agents or toxins. In addition, APHIS and CDC are working with interagency groups and security experts to draft a document that will provide additional guidance about the security required for select agents or toxins. Even though the guidance was to be available in spring 2005, it was not completed as of August 12, 2005.

In the Phase I report, we recommended that APHIS establish formal procedures for performing security inspections at the registered entities in order to ensure that the inspections are consistent and thorough, and that documented and supportable conclusions are made concerning the adequacy of security measures. We concluded that the issues identified during our site visits in Phase II confirm the need for thorough and consistent inspections as recommended in the Phase I report. Because of the noncompliance issues we identified in Findings 4 through 7, we are recommending that APHIS re-inspect the registered entities. Re-inspections of entities' security plans and procedures should be done using formal procedures established to ensure consistent and thorough reviews (as recommended in Phase I, Audit No. 33601-2-At). The inspections should also ensure that conclusions are drawn regarding whether security is adequate, and corrective action plans should be developed and followup performed to ensure deficiencies are corrected.

Recommendation 1

Re-inspect registered entities to ensure compliance with regulations regarding the security over select agents. The inspections should be done using formal written procedures to ensure consistent and thorough reviews. In our Phase I report we recommended that formal procedures be developed.

Agency Response. In its December 2, 2005, response, APHIS stated:

> Per direction from the Office of Management and Budget, APHIS must coordinate entity inspection policy with * * * CDC. To date, CDC has not agreed to total re-inspection of all current registrants. Also, good regulatory policy and resource constraints dictate that we adopt a risk based re-inspection policy. APHIS will re-inspect a registered entity upon submission of either an amendment, which includes the use of an agent or activity of higher risk and/or work in a new area. Also, APHIS will re-inspect entities when evidence suggests there is a compliance issue or when an entity has requested amendments that results in a "higher risk" level of activity. This will be effective immediately. In the event that there are no compliance issues or registration amendments, we will re-inspect each no less than every * * * [2] to * * * [3] years consistent with the registration schedule. This combination of risk-based and regularly scheduled re-inspection plan would provide sufficient security and result in most entities being re-inspected within the next * * * [2] years. All re-inspections will be conducted under formal procedures.

OIG Position. We cannot accept management decision for this recommendation. The Secretary of Agriculture is required to establish and enforce security measures to prevent access to select agents. Our review at 10 registered entities identified several compliance issues that were not identified during inspections performed prior to our visits to the registered entities. APHIS inspections, if performed in a consistent and through manner, should provide primary evidence for determining if adequate security has been implemented at the registered entities. Without such inspections, the agency would not have the means to gather sufficient evidence that would "suggest there is a compliance issue" at a specific registered entity. Therefore, APHIS should re-inspect registered entities using formal written procedures to provide for consistent and thorough inspections and to gather sufficient evidence to conclude whether adequate security measures have been implemented. We agree that in performing the re-inspections, a risk-based strategy would be prudent so that entities possessing select agents with a higher level of risk would be re-inspected first. In order to reach management decision for this recommendation, please provide a plan for re-inspecting APHIS registered entities using formal procedures and the timeframes for completing the re-inspections.

Finding 2 APHIS Had Not Kept Up-to-date Data Pertaining to Individuals Who Have Access to Select Agents or Toxins

APHIS had not updated its list of individuals authorized to access select agents or toxins. On October 8, 2004, APHIS provided us a current list of approved individuals granted access to select agents or toxins (authorized list). However, we found that the APHIS list did not always agree with the lists maintained by the registered entities. We found that APHIS had not updated the list for 5 of the 10 entities we reviewed. This occurred because (1) APHIS did not update the lists when notified by the entities that certain individuals no longer had access to the select agents or toxins or (2) the entities did not notify APHIS of individuals no longer having access. We found that APHIS had not developed written policies and procedures for accurately and promptly updating authorized lists subsequent to entity requests that individuals needing access be added to the list or that the access status for individuals no longer needing access be changed from active to inactive. As a result, APHIS does not have accurate information to use in monitoring registered entities' compliance with requirements for restricting access to the select agents.

The Act[8] states that APHIS regulations shall include provisions to ensure that registered entities provide access to select agents or toxins to only those individuals whom the RO determines have a legitimate need to handle or use such agents and toxins. In accordance with requirements of the Act, APHIS' regulations[9] state that, for each individual identified by the RO as having a legitimate need to handle or use select agents, the RO must submit the individual's name and identifying information to APHIS[10] and the U.S. Attorney General. The U.S. Attorney General then determines whether the person is a "restricted person" as defined in the Act.[11] Once the determination is made, APHIS is notified, and in-turn, notifies the registered entity of whether access is granted or denied. The legislation and regulations further provide that the names of individuals having access to select agents be submitted to the U.S. Attorney General for review at least every 5 years. APHIS is responsible for notifying the RO if an individual is granted full or limited access, or denied access, to biological agents or toxins, and will notify the individual if he/she is denied access or granted only limited access to such agents or toxins.[12] APHIS regulations state that the RO must immediately notify the agency when access is terminated and the reasons for termination.[13]

[8] Section 212(e)(2) and (3) of Public Law 107-188.
[9] APHIS regulations 7 CFR 331.10(d) and 9 CFR 121.11(d)
[10] For overlap agents, names can either be submitted to APHIS or CDC.
[11] Restricted persons are defined by the Act as individuals within certain categories as defined by various *United States Code* citations. These categories include people who have committed certain crimes, people who have known ties to domestic or international terrorist organizations, and persons determined to be an agent of a foreign power.
[12] APHIS regulations 7 CFR 331.10(g) and 9 CFR 121.11(g), issued December 13, 2002.
[13] APHIS regulations 7 CFR 331.10(k) and 9 CFR 121.11(l).

APHIS maintains (on an electronic spreadsheet) the listing of individuals that have been approved or denied access to select agents or toxins. In confirming the accuracy of the spreadsheet with the list maintained by the 10 entities visited,[14] we found that the agency's spreadsheet provided to us on October 8, 2004, was not up to date for 5 of the 10 entities.

- At one entity, we compared the list provided by APHIS (dated October 2004) to a listing provided by the registered entity dated June 2004. We found that seven individuals shown as active on APHIS' list were not included on the entity's list. The RO told us that periodic reports were sent to APHIS updating the entity's authorized list with individuals either being added or deleted from the list. For one of the individuals on the list, we were given a letter to APHIS dated June 3, 2004, telling the agency to remove the person from their active list. The entity neither had documentation showing that the other six inactive individuals had been reported to APHIS, nor had documentation giving the reasons access was terminated. We were told by entity officials that access was terminated for the individuals because they were no longer working with the agents because of transfers to other positions within the entity or they had taken jobs with other entities.

- At another entity, we found inaccuracies and out-of-date data when we compared the access list prepared and maintained by the entity and the list APHIS provided the entity subsequent to requested modifications. We found discrepancies in identification numbers, employee status (active/inactive), and names. For example, the institution submitted documentation to APHIS to remove an individual from the authorized list in August 2004. APHIS acknowledged the request during the same month. However, APHIS' November 2004 list, showed the individual as current with unrestricted access. Entity officials stated that errors appearing on the authorized list from APHIS were common. Based on our evaluation, we concluded that APHIS is not reviewing or maintaining adequate controls over the authorized list.

Although it is the responsibility of the RO to ensure only APHIS approved individuals are granted access to select agents or toxins, it is incumbent upon APHIS to promptly and accurately update the list based on requested changes from the registered entities. Registered entities seek to add individuals to the list or to show individuals inactive once access to the select agents is terminated. Since we identified instances where APHIS had not adequately updated the authorized lists subsequent to requested changes

[14] Site visits were performed in November and December 2004.

(additions/deletions), we concluded that APHIS' controls over the authorized lists do not lend assurance that the list is adequately updated to reflect the most current information presented to APHIS by the registered entities. By not ensuring accurate and up-to-date lists of approved individuals, APHIS cannot assure the public that access is restricted to approved individuals and that select agents or toxins are secure and adequately safeguarded from theft and/or unauthorized use.

Recommendation 2

Develop and implement written policies and procedures to ensure authorized lists are accurately and promptly updated. The procedures should include requiring the entities to verify APHIS records, and either provide corrections or attest to the accuracy of the list.

Agency Response. In its December 2, 2005, response, APHIS stated:

> APHIS agrees with this recommendation. The National Select Agent Registry (NSAR) will become functional by December 30, 2006. The NSAR will contain all of the information found on the registration application documents, which include all of the authorized individuals. The * * * RO and the alternate responsible official (ARO) will have access to this system in order to update and verify the accuracy of the data. APHIS will request programming modifications that will allow notices to be sent out quarterly to entities that require verification of their section 4B. This will be completed by December 30, 2006.

OIG Position. We accept management decision for this recommendation.

Finding 3 — APHIS Had Not Properly Safeguarded Sensitive Data Regarding Individuals Authorized to Possess, Use, and Transfer Select Agents or Toxins

APHIS had not adequately safeguarded sensitive security and personal information pertaining to individuals authorized to possess, use, or transfer select agents or toxins. We identified two instances where information regarding authorized individuals was provided to the wrong registered entity. This occurred because of human error, which we attributed in part to the fact that APHIS had not developed a national database of registered entities containing critical information including the names of individuals authorized

to access select agents at the particular entity.[15] Until the national database is developed, APHIS will have to continue to rely on a mix of manual records and computerized spreadsheets maintained separately while administering the select agent program. Also, APHIS had not established internal controls, in the form of policies and procedures, to prevent such occurrences. As a result, there is a greater risk that sensitive information is inadvertently disclosed in violation of the Act.

According to the Act, USDA (among other agencies) shall not disclose information that identifies the select agent or toxin possessed, used, or transferred by a specific person or "discloses the identity or location of a specific person."[16]

We identified two instances where APHIS provided personal and security information to the wrong registered entities. This occurred because of human error. Currently information regarding security clearances for individuals is maintained on an electronic spreadsheet, separate from hardcopy files maintained for each registered entity. The data has not been incorporated into a single database of registered entities. In our Phase I report, we reported that APHIS had not developed a national database of registered entities, as required by the Act. The purpose of the database is to facilitate the identification of the agents and their location, as well as their source. In our Phase I report, we concluded that the absence of the database diminishes APHIS' ability to effectively monitor compliance with safety and security requirements. During our Phase II review, we concluded that the absence of the database contributed toward APHIS erroneously providing sensitive information to the wrong entities. If the information had been maintained as part of a comprehensive and organized database, the likelihood of this type of error could have been reduced.

In Phase I, we also reported that, because APHIS had not designated a single RO for the select agent program, the agency had not issued instructions or procedures for implementing the Act. The absence of agency policies and procedures weakens APHIS' ability to ensure applicable laws and regulations are followed. Internal control comprises plans, methods, procedures, and actions to meet objectives such as ensuring compliance with applicable laws and regulations.[17] For Phase II, we concluded that the establishment of an adequate system of internal controls could have prevented the two violations of the Act we identified during our site visits.

- On November 15, 2004, APHIS mistakenly faxed a list of all of the people approved for access (the authorized list) at a non-profit research hospital along with their identification numbers, which are

[15] This condition was identified in our Phase I report (Audit No. 33601-2-At).
[16] Public Law 107-188, June 12, 2002, section 212, (h) (1) (A).
[17] "Standards for Internal Control in the Federal Government," published by the General Accountability Office in November 1999.

used by the FBI for background checks to one of the academic institutions in our sample. Two of the academic institution's employees that were to be added to the list of employees approved to work with select agents or toxins were included on the erroneously faxed list from the research hospital. The following day, APHIS faxed a new list with only the academic institution's approved individuals, including the two newly approved employees.

- Also on November 15, 2004, APHIS mistakenly faxed one page listing individuals for another institution. The list was a printout of APHIS' electronic spreadsheet, and included the individuals' names, identification numbers, other personal information, and the access and security status of the individuals (i.e., restricted or unrestricted access). The academic entity's officials told us that they informed APHIS officials of the mistake and were told to return the list.

Recommendation 3

Develop and implement internal controls designed to prevent the release of sensitive security information associated with registered entities.

Agency Response. In its December 2, 2005, response, APHIS stated:

> APHIS agrees with this response. The NSAR will prevent accidental release of another entity's information. For those entities that are not using the NSAR to register or amend their application, a protocol will be developed that requires second party verification of any sensitive information that is sent to an entity. This protocol will be developed by March 30, 2006.

OIG Position. We accept management decision for this recommendation.

During this phase of our audit, we also made field visits to 10 registered entities where select agents or toxins are used or stored to examine registered entities' compliance with the regulations. The purpose of the visits was to determine whether APHIS had adequate controls to ensure compliance with the regulations. We identified compliance issues including:

1. Biosafety/Biocontainment and Security Plans did not comply with regulatory requirements;
2. Registered entities did not adequately restrict access to select agents or toxins as required by the regulations;
3. Registered entities did not maintain adequate documentation concerning Biocontainment/Biosafety and Security training; and
4. Registered entities did not maintain adequate inventories of select agents.

Even though APHIS inspected 9 of the 10 registered entities and CDC had inspected the other entity prior to our field visits, the conditions we noted were seldom identified by the inspections. For Phase I of our review, we reported that APHIS had not established policies and procedures to ensure that inspections of the registering entities' security measures were consistent and thorough, and that APHIS inspections were not sufficiently documented to show whether registered entities had implemented adequate safeguard and security measures. We also reported that inspections performed by APHIS did not provide clear documentation concerning the nature or extent of deficiencies, and did not always conclude as to whether security measures implemented by the registered entities were adequate.

We concluded that more thorough inspections would help APHIS better identify and address compliance issues at the registered entities. Therefore, several of our recommendations in Finding Nos. 4 through 7 address ways of improving the inspection process. Because the Act requires APHIS and CDC to develop and implement procedures to share responsibilities for inspecting entities that handle overlap agents, we met with officials from the HHS-Office of Inspector General (OIG) to coordinate our recommendations. HHS-OIG conducted reviews of entities registered with CDC and identified issues with inspections similar to those identified during our reviews of entities registered with APHIS.

Finding 4 Biosafety/Biocontainment and Security Plans Did Not Comply With Regulatory Requirements

During our site visits, we noted a number of deficiencies regarding the entities' security plans. We found that security plans (1) were not based on site-specific risk assessments as required, (2) did not address critical requirements required by the regulations, and (3) were not performance tested or reviewed and updated annually. Registered entities in our sample gave various reasons for deficiencies in their plans, including the lack of sufficient guidance from APHIS. Based on the results of our site visits and the deficiencies we found in the security plans, we concluded that APHIS had not provided the entities with timely feedback on the sufficiency of the plans, and had not provided sufficient guidance for completing the plans in accordance with the regulations. Because of the deficiencies in the plans, there is reduced assurance that security measures at registered entities are adequate to mitigate risks of unauthorized access to the agents or toxins.

The Act requires that USDA establish and enforce safety procedures for select agents or toxins, including appropriate skills to handle agents and toxins, and proper laboratory facilities to contain and dispose of agents and toxins. In addition, the Act requires that USDA establish and enforce safeguard and security measures to prevent access to select agents or toxins for use in domestic or international terrorism or for any other criminal purpose. Pursuant to section 212(e)(1) of the Act, the safeguard and security requirements must be commensurate with the risk posed by the agent or toxin. As a condition of registration, the RO must develop and implement a Biocontainment/Biosafety[18] and Security Plan. The plans must contain sufficient information and documentation to describe the biosafety and containment procedures, and the security systems and procedures.

As we reported in our Phase I report (Audit No. 33601-2-At), APHIS granted provisional registrations to entities without determining whether their security plans provided adequate safeguard and security measures. Regulations allowed for provisional registration if an entity could show by November 12, 2003, that the entity had provided the Attorney General with all of the documentation required to conduct security risk assessments and had otherwise met all of the requirements of the regulations. However, APHIS officials stated that the regulation's intention to "minimize disruption of research" took precedence over the need to fully comply with security requirements by the deadline. Consequently, APHIS reviewed registration applications only to ensure a security plan had been submitted, not that it met the requirements of the regulations. As a result, the agency had not taken

[18] APHIS regulation 7 CFR 331.11 requires a biocontainment plan for plant pathogens. APHIS regulation 9 CFR 121.12 requires a biosafety plan for animal and overlap agents and toxins.

sufficient action to ensure that registered entities have implemented adequate safeguard and security measures to comply with the legislation and regulations.

In promulgating the interim final rule, APHIS concluded that because different agents and toxins pose differing degrees of risk, depending on factors such as their escape potential and availability of a suitable habitat (for plant-related agents) and transmission and effect of exposure to the agent or toxin (for overlap and animal agents or toxins), it would be counterproductive to attempt to prepare a detailed list of prescriptive requirements for entities (i.e., a ‘‘one size fits all’’ design standard). Instead, APHIS established a set of performance standards to be addressed while considering the degree to which they were appropriate to the risks presented by a particular agent or toxin, given its intended use and the location of the entity. Therefore, risk assessments were crucial to the development of security plans sufficient to mitigate vulnerabilities and fully address the established performance standards. We found that 7 of the 10 entities did not base their security plans on site-specific risk assessments.

To address the performance standards and comply with the regulations, entities' Biocontainment/Biosafety and Security Plans must describe critical requirements such as, inventory control procedures, personnel suitability for those individuals with access to select agents or toxins, physical security, as well as other areas. We found that 7 of the 10 entities lacked documented policies and procedures for critical requirements identified in the regulations.

Finally, to ensure that the plans continue to meet the entities' containment and security needs, APHIS requires that the plans be reviewed, performance tested, and updated annually. The plans must also be reviewed and revised, as necessary, after any incident. We found that 4 of the 10 entities either did not performance test the security plans or did not annually review and update their plans.

The final rule, issued on March 18, 2005, stated that APHIS and CDC were working with interagency groups and security experts to draft a document to provide additional guidance about the security required for select agents or toxins. Even though the guidance was to be available in spring 2005, it was not completed as of August 12, 2005. The 5th edition of the “Biosafety in Microbiological and Biomedical Laboratories”, which is under development, will provide additional guidance on laboratory security.

Security Plans Were Not Based on Site-Specific Risk Assessments

We found that 7 of the 10 entities we reviewed did not base their security plans on site-specific risk assessments. APHIS regulations[19] require that entities' security systems and procedures must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the threat posed by the agent or toxin. The regulations state that a site-specific risk assessment should involve a threat assessment and risk analysis in which threats are defined, vulnerabilities examined, and risks associated with those vulnerabilities are identified. The interim final rule required that security systems and procedures must be tailored to address site-specific characteristics and requirements, ongoing programs, and operational needs and must mitigate the risks identified by the assessments. The following are examples of the deficiencies we found.

- One registered entity based its security systems and procedures on security measures in place prior to September 11, 2001. The entity's officials claimed that lack of guidance from APHIS regarding specific requirements for site-specific risk assessments and the costs of having a risk assessment performed by an outside consultant were barriers to completing a formalized risk assessment. APHIS' inspection checklist prepared October 2003 showed that the entity's security plan was based on a site-specific risk assessment.

- At another entity for which a site-specific risk assessment was not prepared, we found that the security plan described physical security measures that included guarded entrance gates and perimeter fencing. However, the facility did not have these security measures. The plan actually describes security features at another of the entity's facilities. The entity had used the plan from another facility, had not performed a site-specific risk assessment for that location, and had not addressed the vulnerabilities at that particular site. APHIS has prepared two inspection checklists, including one in October 2003 and one in December 2003. The October 2003 checklist indicated that the security plan was based on a site-specific risk assessment, and the December 2003 checklist indicated that the risk assessment was not site specific.

- The RO at one entity said that the entity had not had the resources to perform a site-specific risk assessment. He said that the entity was just starting an assessment at the time of our audit. During our visit to this entity, we found that vials of Exotic Newcastle Disease were stored in a freezer in an area with unrestricted access. The location of the freezer was not identified in the entity's security plans, and there

[19] Title 7 CFR 331.11(a)(2) and 9 CFR 121.12(a)(2), issued December 13, 2002.

was no determination of the risk associated with storing the select agent in an area that was accessible to unauthorized individuals. APHIS' inspection checklist prepared in October 2003 showed that the entity's security plan was based on a site-specific risk assessment.

APHIS' interim rule dated December 13, 2002, stated that risk assessments should include a threat assessment and risk analysis in which threats are defined, vulnerabilities examined, and risks associated with those vulnerabilities are identified. It also stated that the security systems and procedures must be tailored to address site-specific characteristics and requirements and must mitigate risks identified by the risk assessments. However, APHIS' final rule issued on March 18, 2005, deleted these requirements and substituted the requirement that the security plan be designed according to a site-specific risk assessment and provide graded protection in accordance with the risk of the select agent or toxin, given its intended use.

Even though we agree that the site-specific risk assessments should provide protection in accordance with the risk of the select agent or toxin, we believe that the risk assessments should not only take into account the "intended use" of the biological agent, but should address vulnerabilities associated with the potential unintended use, such as the consequences of terrorists acquiring a particular agent and using it as a weapon. This would be in line with the intent of the Act. The Act gave the Secretary of Agriculture authority to regulate the possession of biological agents that, through acts of bioterrorism, could have a devastating impact on the domestic agricultural economy.[20] In addition, the Act specifically requires the establishment and enforcement of safeguard and security measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose. Therefore, APHIS should ensure that entities conduct risk assessments that adequately address vulnerabilities and mitigate risks of unauthorized individuals accessing and acquiring select agents for use in terrorism.

Security Plans Did Not Address Critical Requirements in the Regulations

During field visits we found that security plans for 7 of the 10 registered entities' lacked documented policies and procedures for critical requirements identified in the regulations. To address the performance standards and comply with the regulations, the Biocontainment/Biosafety and Security Plans must describe inventory control procedures, personnel suitability for those individuals with access to select agents or toxins, physical security, and cyber security. The plan must also contain provisions for securing the area (e.g., card access, key pads, locks) and protocols for changing access

[20] House of Representatives Conference Report No. 107-481, dated May 21, 2002.

numbers or locks following staff changes; procedures for loss or compromise of keys, passwords, combinations, etc.; procedures for reporting suspicious persons or activities, loss or theft of select agents or toxins, release of select agents or toxins, or alteration of inventory records; provisions for the control of access to containers where select agents or toxins are stored; provisions for routine cleaning, maintenance, and repairs; and procedures for reporting and removing unauthorized persons. We observed the following.

- One entity claimed that a staff vacancy resulted in elements of the security plan not being developed. The RO stated that the biosafety officer who was responsible for conducting the risk assessment had resigned and the position had remained vacant for over a year. The entity's plan lacked procedures for reporting incidents, such as releases of select agents, and security breaches. The plan also did not contain security training procedures. A September 23, 2004, letter from APHIS also recommended that the entity develop a sign-in/out log for after-hour and weekend activity employees; expand card-key access controls to all select agent areas; develop restricted access policy and procedures support units, such as maintenance and custodial staff; and to complete comprehensive incident response plans for the select agents. In contrast to the September 2004 letter, an APHIS inspection checklist prepared in October 2003 showed that the entity's security plan contained all the critical elements required.

- At another entity, we found that critical requirements were missing from the security plans, including procedures for (1) notifying APHIS and CDC when individuals' access was terminated, (2) changing access numbers or locks when staff left, (3) addressing the loss or compromise of keys or combinations, (4) reporting suspicious activities, and (5) removing unauthorized individuals from select agent or toxin areas. APHIS' inspection checklist prepared in October 2003 showed that the entity's security plan contained all the critical elements required.

Security Plans Were Not Performance Tested or Reviewed and Updated as Required

We found that 4 of the 10 entities either did not performance test the security plans or did not annually review and update their plans. Regulations require that Biocontainment/Biosafety and Security Plans must be reviewed, performance tested, and updated annually. The plan must also be reviewed and revised, as necessary, after any incident. The following examples are some of the conditions noted for entities that did not performance test or did not annually review and update plans.

- One entity had not updated the security plan annually as required by regulation. The last update of the plan was the version submitted on June 2003. APHIS' security checklist prepared in October 2003 showed that the security plan had not been tested or updated. However, the RO stated that the plan had not been updated because they thought it was adequate since they had not received any feedback from APHIS. However, during the time of our site visit, the entity received a letter from APHIS, dated November 15, 2004, noting a number of deficiencies in the plan and recommending sign-in/out procedures and protocols be developed for after-hours activities, electronic monitoring and access controls be installed in select agent activity areas, locks be installed in specified laboratory rooms, and the number of individuals having access to the select agent activity areas be verified (noting that a substantial number of people appear to have access to some areas).

- At another institution, the assistant RO stated that they periodically checked entryways and prohibited areas to ensure that doors were locked. However, there were no procedures to review and evaluate other procedures in the security plan. APHIS' security checklist prepared in October 2003 did not include any deficiencies regarding testing and updating security plans.

The final regulations published on March 18, 2005, require that drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after an incident. APHIS will need to ensure that these new requirements are included in the registered entities' procedures and determine that the procedures have been implemented when APHIS inspections are performed.

Recommendation 4

Provide registered entities specific guidance for performing risk assessments, including instructions for performing site-specific risk analyses. APHIS' guidance should provide advice on how to perform threat assessments and identify vulnerabilities, and suggest security measures that could help to mitigate risks.

Agency Response. In its December 2, 2005, response, APHIS stated:

> APHIS agrees with this recommendation. CDC has requested that APHIS participate in a meeting on March 6 - 8, 2006, in order to provide better guidance to entities in the following areas: agent specific risk/threat assessment; IT and records security; risk mitigation and screening of individuals; and

> compliance issues and tools. The meeting, as currently planned, will include security specialists from the federal and state governments. Using the materials generated from this meeting, APHIS (and CDC) will provide guidance to entities on risk assessment by December 1, 2006. Finalization is dependent on receiving concurrence from CDC.

OIG Position. We cannot accept management decision for this recommendation. Although the planned meeting with CDC should be helpful in establishing guidance to entities for establishing security procedures, the response addressed "agent specific risk/threat assessments" rather than site-specific risk assessments. We found that 7 of 10 entities we visited did not perform site-specific risk assessments to address the physical characteristics of the areas where the select agents were used or stored. In order to reach management decision, please indicate whether the guidance will include instructions on performing risk assessments based on the physical characteristics of each site (e.g., laboratories and storage areas) housing select agents. Also, we cannot accept management decision for corrective action that is contingent upon receiving concurrence from CDC. In this circumstance, the recommendation must remain open until a detailed time-phased corrective action plan has been developed.

Recommendation 5

In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to ensure registered entities base their security plans on a site-specific risk analysis. Site specific risk analyses should be examined to ensure that entities perform threat assessments that address its vulnerabilities. APHIS should also ensure that security plans are developed that will mitigate the risks identified and help to prevent unauthorized individuals from accessing and acquiring select agents or toxins for use in terrorism. APHIS' inspection reports should conclude whether entities' security plans were based on the results of site-specific risk analyses performed in accordance with the guidance issued.

Agency Response. In its December 2, 2005, response, APHIS stated:

> APHIS agrees with this recommendation. In response to Recommendation 4, APHIS is working with CDC to provide guidance to entities regarding the risk assessment process. Based on these guidance documents, improved guidance for inspectors will be documented in the CDC/APHIS Operational Plan. This will be completed by December 1, 2006. Finalization is dependent upon receiving concurrence from CDC.

OIG Position. We cannot accept management decision for this recommendation. Although the response states that APHIS agrees with the recommendation, it does not specifically address whether APHIS will include steps in the inspections to (1) ensure that registered entities base security plans on site-specific risk analysis, (2) ensure that registered entities perform threat assessments that address vulnerabilities, (3) ensure that security plans developed by registered entities provide measures to mitigate risks identified in risk assessments, and (4) conclude whether registered entities' security plans were based on the results of site-specific risk analysis performed in accordance with the guidance issued. Also, we cannot accept management decision for corrective action that is contingent upon receiving concurrence from CDC. In this circumstance, the recommendation must remain open until a detailed time-phased corrective action plan has been developed.

Recommendation 6

In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to verify that the entities' security plans have thoroughly addressed all critical areas identified by the regulations. APHIS' inspection reports should conclude whether each critical area was adequately addressed.

Agency Response. In its December 2, 2005, response, APHIS stated:

> APHIS agrees with this recommendation. A check list will be developed by June 30, 2006, that the APHIS Security Specialist will use when each entity is reviewed.

OIG Position. We cannot accept management decision for this recommendation. Although the response states that APHIS agrees with the recommendation, it does not specifically address whether APHIS will include steps in the inspections to verify that entities' security plans have thoroughly addressed all critical areas identified by the regulations. In addition, security plans should be reviewed during APHIS inspections to ensure that the plans being used by the entity contain all critical areas required by regulations.

Recommendation 7

In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to verify that that entities are conducting and documenting annual performance tests of their security plans, and are updating plans based on the results of the performance tests, drills, or exercises. APHIS' inspection reports should conclude whether annual performance tests were performed and whether their results were appropriately utilized in updating security plans.

Agency Response. In its December 2, 2005, response, APHIS stated:

> APHIS agrees with this recommendation. To provide better guidance to inspectors, APHIS and CDC will document operational procedures for review of annual drills and exercises conducted by an entity. These procedures will be finalized by September 30, 2006. Finalization is dependent upon receiving concurrence from CDC.

OIG Position. We cannot accept management decision for this recommendation. Although the response states that APHIS agrees with the recommendation, it does not specifically address whether APHIS will include steps in the inspections to verify that entities are conducting and documenting annual performance tests of their security plans and updating the plans based on the results of the tests. Also, we cannot accept management decision for corrective action that is contingent upon receiving concurrence from CDC. In this circumstance, the recommendation must remain open until a detailed time-phased corrective action plan has been developed.

Finding 5 — Registered Entities Did Not Adequately Restrict Access to Select Agents or Toxins As Required by the Regulations

During our site visits, we found that 6 of the 10 entities' did not adequately restrict access to select agents. This occurred because three entities did not provide APHIS the names of all individuals so they could be cleared by Department of Justice for access to the select agents, and three entities did not implement adequate controls for restricting access to areas where select agents were stored or used. At one of the three entities that did not provide APHIS the names of all persons having access to the select agents, an unauthorized individual was allowed to perform experiments with the select agent. By not adequately restricting access to select agents, these entities increased the risk that select agents could be acquired and used in domestic or international terrorism.

The Act requires that the regulations include provisions to ensure that the registered entities provide access to select agents or toxins to only those individuals that have a legitimate need to handle or use such agents or toxins. APHIS regulations 7 CFR 331.10(a) and 9 CFR 121.11(a) provide that an individual may not have access to select biological agents or toxins unless approved by APHIS or, for overlap agents, APHIS or CDC. Regulations require the RO to ensure that only approved individuals within the entity have access to select agents or toxins. In addition, the RO must request such access for only those individuals who have a legitimate need to handle or use

select agents or toxins, and who have the appropriate training and skills to handle such agents or toxins.

The following are examples where registered entities were not adequately restricting access to select agents.

- At one entity, two unauthorized individuals were granted access to a laboratory with select agents, and one of the two individuals was given direct access to the select agent, without approval from the RO, and without clearance by the Attorney General. The RO was not aware that unauthorized individuals were given access to the laboratory. The principal investigator[21] was aware of the situation and approved their access without clearance from the RO. One individual was allowed to conduct experiments using Brucella abortus.[22] APHIS' inspection checklist prepared in August 2004 did not cite any deficiencies regarding access to the select agents.

- At another entity, we found that two individuals having access to sensitive information (i.e., locations of select agents, individuals granted access to the agents, security procedures) had not been reviewed by the Attorney General. APHIS' interim final rule issued December 13, 2002, did not require the RO to submit the names of individuals having access to sensitive information for clearance by APHIS and the Attorney General. During our site visit in November 2004, we discussed our concerns with the entity that the individuals had access to information that could allow them to gain access to the select agents. The entity agreed, and submitted the names to APHIS. The final regulations published on March 18, 2005, added that an individual is deemed to have access if he/she has the ability to gain possession of a select agent or toxin. We also found that four of the entity's employees still had access to the laboratory where select agents are used even though they no longer had a legitimate need to access that area. This occurred because the entity did not have controls in place to properly monitor electronic card authorization, removal, and verification (periodic review of the access log). As a result, the university has reduced assurance that dangerous biological agents and toxins, retained for research or held in culture repositories, are secure from unauthorized use or loss.

- During our visit to one facility, we found that 62 vials and 15 tissue cultures of Exotic Newcastle Disease[23] were stored in a long-term storage freezer in the basement. The freezer was locked with a

[21] The principal investigator is the researcher in charge of the particular research project.
[22] Brucella abortus is a contagious disease affecting cattle and bison. It is an overlap agent that also affects humans.
[23] According to an APHIS fact sheet dated January 2003, Exotic Newcastle Disease is probably one of the most infectious diseases in poultry. It is a fatal viral disease affecting all species of birds.

common padlock. The select agent was stored in an area that had not been identified on the entity's security plans, and was not in a secure area. The basement storage room was not locked during the day, and was accessible by many individuals who had not been approved to access select agents. The researcher stated that the vials had been moved to the storage area because they were not needed and were to be destroyed. The freezer had not been accessed in 2 to 3 months prior to our visit. Because of our inquiries concerning security over the select agent, the RO took action to destroy all but 15 vials of the agent, which were to be transferred to another registered entity. APHIS' inspection checklist prepared in August 2004 did not cite any deficiencies regarding access to the select agents. There was nothing in the inspection documentation to indicate whether this freezer had been identified and examined during the August 2004 visit by APHIS.

- Although one registered entity maintained a visitor's logbook of access to areas housing select agents, many of the logs were missing critical data, such as the date of the visit, time of the visit, or the signature of the visitor's escort. No one, such as a security guard, was monitoring the entries in the access logbook. Therefore, visitors accompanying authorized individuals may be gaining access into labs containing select agents or toxins without the knowledge of institution officials. We reviewed 476 recorded visits in the logbook and found that 27 were missing the date, 16 were missing time in and/or the time out, and 38 were missing an escort signature. Institution officials agreed that the visitor logs should be complete and up to date, but they stated that they were not overly concerned because an authorized individual must escort any visitor and only authorized individuals would have a key to enter the restricted areas. However, without a complete and accurate logbook, there is no accountability that only authorized individuals accompanied all visitors to the lab. During multiple APHIS inspections in October 2003, APHIS cited several deficiencies relating to restricting access such as the lack of security guards or employees present to control access into the facility. However, the inspection checklist showed that the entity had adequate controls regarding visitors. There was no indication that APHIS examined entries in the visitor's logbook during the inspection.

- At one entity, we were informed that the access logbook for periods prior to January 2004 was missing. The entity had reported to APHIS possession of the select agents (Mycoplasma capricolum and Mycoplasma mycoides)[24] in July 2002. The two researchers with access to the agent had transferred to another entity that was not registered to possess select agents. The laboratory manager had also

[24] Mycoplasma capricolum causes contagious caprine pleuropneumonia in goats and Mycoplasma mycoides causes contagious bovine pleuropneumonia in cattle, both highly infectious diseases.

transferred to another position at the same entity and no longer had access to the select agent. Prior to their transfer, one of the two researchers reported to the RO an unexplained discrepancy in the inventory records. The records were adjusted to reduce the select agent inventory by two vials. In a report to the RO, one of the former researchers wrote that the discrepancy was unexplained, but concluded that it was probably a clerical error since other such discrepancies had occurred. The report also concluded that there was limited access to the select agents and it was "extremely unlikely that someone could locate or procure these select agents surreptitiously." The researcher's report stated that they did not consider the discrepancy "to be of any concern regarding a breach of security." The missing access logbook covered the period during which the discrepancy was noted, as well as another 10 months after the report was submitted to the RO. APHIS relied on an inspection performed by CDC in March 2003 even though the report did not make clear which laboratories were inspected and what was contained in those laboratories. There was no evidence that this storage area had been examined and no similar issued identified by CDC.

Recommendation 8

In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to compare its list of authorized individuals with the names of individuals having access to areas with select agents. This would include an examination of log books or other documented entries, as well as questioning researchers concerning which individuals can access the area. Inspectors should also examine the completeness and accuracy of access log books. Inspection reports should state whether security measures are adequate to restrict access to select agents only to authorized individuals.

Agency Response. In its December 2, 2005, response, APHIS stated:

> APHIS agrees with this recommendation. To provide better guidance to inspectors, APHIS and CDC will document operational procedures that improve methods for verification of access controls used by the entity. These procedures will be finalized by September 30, 2006. Finalization is dependent upon receiving concurrence from CDC.

OIG Position. We cannot accept management decision for this recommendation. Although the response states that APHIS agrees with the recommendation, it does not specifically address whether APHIS will include steps in the inspections to compare its list of authorized individuals with the names of individuals having access to areas with select agents by examining

log books or interviewing researchers concerning access to the areas. The response also does not address whether APHIS' inspections would include an examination of log books or other documented entries to examine the completeness and accuracy of access records. In addition, we cannot accept management decision for corrective action that is contingent upon receiving concurrence from CDC. In this circumstance, the recommendation must remain open until a detailed time-phased corrective action plan has been developed.

Recommendation 9

In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to identify and examine all areas where select agents are used or stored to ensure that access to those areas are properly secured. Inspection reports should specifically identify all areas containing select agents, state whether the areas are identified in the security plan and included in the site-specific risk assessments, and conclude as to whether security for each area is adequate.

Agency Response. In its December 2, 2005, response, APHIS stated:

> APHIS agrees with this recommendation. To provide better guidance to inspectors, APHIS and CDC will document operational procedures for this phase of the inspection in the CDC/APHIS Operational Plan. These procedures will be finalized by September 30, 2006. Finalization is dependent upon receiving concurrence from CDC.

OIG Position. We cannot accept management decision for this recommendation. Although the response states that APHIS agrees with the recommendation, it does not specifically address whether APHIS will include steps in the inspections to identify and examine all areas where select agents are used or stored to ensure that the areas are properly secured. The response also does not address whether the inspection reports will identify all areas having select agents, state whether the areas are identified in the security plan and included in the site-specific risk assessment, and conclude as to whether security is adequate for each area. In addition, we cannot accept management decision for corrective action that is contingent upon receiving concurrence from CDC. In this circumstance, the recommendation must remain open until a detailed time-phased corrective action plan has been developed.

Recommendation 10

APHIS should conduct an investigation into the missing access logbook at the affected entity and, based on the outcome, make a determination as to the appropriateness of the entity's registration status.

Agency Response. In its December 2, 2005, response, APHIS stated:

> APHIS agrees with this recommendation and will request that APHIS' Investigative and Enforcement Services staff conduct an investigation of this finding and submit its findings to the Associate Administrator by March 1, 2006.

OIG Position. We accept management decision for this recommendation.

Finding 6 Registered Entities Did Not Maintain Adequate Inventories of Select Agents

We found that 3 of the 10 registered entities in our sample did not adequately account for their inventories of select agents or toxins. This occurred because entity officials at one registered entity had not required researchers to keep track of select agent or toxin usage, and because of inaccurate inventory recordkeeping. Even though the entities were inspected by APHIS or CDC prior to our site visits, the inspection checklists did not identify the inventory deficiencies. As a result, without adequate accountability of select agent or toxin inventories, select agents may be lost or used for unauthorized purposes.

APHIS regulations[25] provided that the RO must maintain complete records of information necessary to give an accounting of all of the activities related to select agents. Such records must include accurate and current inventory records (including source and characterization data). We noted the following.

- One registered entity did not have inventory controls in place to track select agents. The current researcher maintained short hand records of the agents or toxins on hand and in use. This occurred because the researchers have not been required to maintain these records in the past and the entity had not developed and implemented an inventory system in compliance with current regulations. A detailed inventory system did not exist in recent years. As a result, there is no way to confirm exact amounts of each agent on hand at any given time to determine if there has been an incident of theft or loss. Additionally, the entity cannot readily provide an accounting of all current and past activities involving the agents they have been handling and storing. APHIS' inspection checklist prepared in October 2003 showed that the entity had a systematic approach to maintain a current, comprehensive system to track select agents.

[25] Title 7 CFR 331.14 and 9 CFR 121.15, issued December 13, 2002.

- At one entity, we found a repository containing 152 vials of biological material of which 31 vials were identified as select agents (26 vials were Mycoplasma capricolum and 5 were Mycoplasma mycoides); 20 vials as a non-select agent; and 101 vials for which the RO could not determine whether the biological material was or was not a select agent. We questioned the RO about the vials and she stated that they were part of a large repository that the registered entity had intended to ship to another entity. However, the other entity was not registered and the vials remained in storage. The RO stated that they were not sure what the other vials are so they are treating them as if they were select agents even though some of them may not be. Currently, these vials are stored in a freezer. We were told that the inventory had not been used since it was acquired. APHIS relied on an inspection performed by CDC in March 2003 even though the report did not make clear which laboratories were inspected and what was contained in those laboratories. There were no inventory deficiencies reported for this storage area.

- At another entity, we selected a sample of 10 entries in the inventory log. We traced the entries to the associated vials of select agent in the storage freezer. The researcher could not locate two vials. We were later told by the RO that the two missing vials were incorrectly recorded in the inventory since one was not a select agent and the other was incorrectly identified because inventory log numbers were transposed when the entry was made in the log. The RO acknowledged that the accounting for select agents needed to be improved. In response to the finding, the entity drafted a procedure to better account for select agents, which was awaiting approval and implementation. APHIS' inspection checklist prepared in October 2003 did not indicate any deficiencies regarding inventories.

APHIS amended the regulations to require the maintenance of an accurate, current inventory for each toxin held and for each select agent held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials). The final regulations also provide more information about the types of information that must be included in the inventory records for each select agent or toxin. Under the new regulations, an inventory for a select agent must include the name and characteristics of the agent, the quantity acquired from another entity, where stored, when moved from storage and by whom, purpose of use, transfer records, etc., while an inventory for a toxin must include the name and characteristics of the toxin, the quantity acquired from another entity, the initial and current quantity, where stored, when moved from storage and by whom, transfer records, etc.

Recommendation 11

In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to verify that the entities have established and implemented inventory controls and perform procedures to ensure that inventory records are accurate and up to date.

Agency Response. In its December 2, 2005, response, APHIS stated:

> APHIS agrees with this recommendation. To provide better guidance to inspectors, APHIS and CDC will document operational procedures for this phase of the inspection in the CDC/APHIS Operational Plan. These procedures will be finalized by September 30, 2006. Finalization is dependent upon receiving concurrence from CDC.

OIG Position. We cannot accept management decision for this recommendation. Although the response states that APHIS agrees with the recommendation, it does not specifically address whether APHIS will include steps in the inspections to verify that the entities have established and implemented inventory controls and whether inspectors whether inspectors will perform procedures to ensure that inventory records are accurate and up to date. Also, we cannot accept management decision for corrective action that is contingent upon receiving concurrence from CDC. In this circumstance, the recommendation must remain open until a detailed time-phased corrective action plan has been developed.

Recommendation 12

For the entity with 152 vials of biological material (31 select agents, 20 non-select agents, and 101 unidentified agents), APHIS should conduct an investigation into the discrepancies, and work with the entity to determine whether the vials should be destroyed or transferred to another registered entity.

Agency Response. In its December 2, 2005, response, APHIS stated:

> APHIS agrees with this recommendation and has investigated this finding. The entity was storing unknown agents as "select agents." The select agent regulations do not prevent this. Thus, no violation of the regulations have occurred.

OIG Position. We cannot accept management decision for this recommendation. Although the response states that APHIS agrees with the recommendation and has investigated this issue, it does not specifically state whether APHIS and the registered entity have worked together to determine

the disposition of the vials. In order to reach management decision for this recommendation, please provide information on what steps have been taken or are being taken to destroy or transfer the vials of select agents.

Finding 7 — Registered Entities Did Not Maintain Adequate Documentation Concerning Biocontainment/Biosafety and Security Training

We found that 6 of the 10 entities had not documented Biocontainment/Biosafety and Security training as required, and 2 of the 6 entities did not provide the required training for all individuals having access to the select agents or toxins. APHIS regulations require that entities provide safety/containment and security training[26] and that records of the training be complete and up to date.[27] We found that the ROs were not fully aware of the requirements related to annual staff training specified in the regulations and did not recognize the need to document the limited training that was provided. APHIS had not provided guidance on what constitutes appropriate training and the need for accurate training records. As a result, although staff may have the educational and work experience backgrounds needed to perform the basic technical requirements of operating a biological laboratory, there is no assurance that they have received training on current technological changes or procedural requirements concerning biocontainment, biosafety and security procedures regarding select agents or toxins. Without such training, not only is the safety and security of individuals working with the select agents or toxins at risk, but also the select agents or toxins may be vulnerable to misuse or mishandling.

According to the regulations[28], the RO must provide appropriate training in containment and security procedures to all individuals with access to select agents or toxins. Training must be provided to an individual at the time the individual is assigned to work with a select agent or toxin, and refresher training provided annually. The RO must maintain complete, up-to-date records of information necessary to give an accounting of all of the activities related to select agents or toxins listed, including training records for the individuals having access to the pathogens.[29]

The following are examples of our observations regarding security training.

- At one entity, there was insufficient documentation to show that individuals were provided the proper training. Because of the large number of individuals having access to the select agents or toxins, we

[26] APHIS regulations 7 CFR §331.12 and 9 CFR §121.13, issued December 13, 2002.
[27] APHIS regulations 7 CFR §331.14(a)(3) and 9 CFR §121.15(a)(3), issued December 13, 2002.
[28] APHIS regulations 7 CFR 331.12 and 9 CFR 121.13.
[29] APHIS regulations 7 CFR 331.14 and 9 CFR 121.15.

were not able to confirm during our site visit, that everyone had the required training. In response to our inquiries, the RO developed a checklist to be used to track future training. At the time of our visit, the checklist had not been incorporated into the entity's standard operating procedures. APHIS performed multiple inspections at this registered entity in October 2003, and from October to December 2004. Checklists prepared during these inspections all showed that training was properly documented.

- At another entity, the initial training was not documented, and the entity was not providing annual refresher training as required. The entity's biosafety officer stated that the researchers were required to read the laboratory safety plan when they were initially assigned to work with any biological agents or toxins. There was no specific training for containment or security procedures aside from the requirement that individuals with access to select agents or toxins read policies and directives in the security plan. There was no process to confirm that the individuals had read the required procedures or had otherwise been informed about its provisions relating to containment and security procedures. APHIS' inspection checklist prepared in August 2004 showed that annual security awareness training was provided to all employees and that the training was properly documented.

We noted that regulations do not define what "appropriate training" would represent, and according to one entity's RO, APHIS has not provided any specific guidance on what would meet the requirement of "appropriate training". APHIS had not issued any guidance regarding training, other than the regulations. We concluded that training and documentation of training is not being provided consistent treatment at the registered entities we visited. It is the responsibility of the RO at each registered entity to ensure that individuals who handle or use select agents or toxins have the appropriate training and skills.

Final regulations published on March 18, 2005, state that a record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of training, a description of the training provided, and the means used to verify that the employee understood the training.

Recommendation 13

In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to verify that the entities have provided annual training, including required security

training, to all individuals authorized to access select agents, and have documented the training as required.

Agency Response. In its December 2, 2005, response, APHIS stated:

> APHIS agrees with this recommendation. To provide better guidance to inspectors, APHIS and CDC will document operational procedures for this phase of the inspection in the CDC/APHIS Operational Plan. These procedures will be finalized by September 30, 2006. Finalization is dependent upon receiving concurrence from CDC.

OIG Position. We cannot accept management decision for this recommendation. Although the response states that APHIS agrees with the recommendation, it does not specifically address whether APHIS will include steps in the inspections to verify that entities have provided annual training, including required security training, to all individuals having access to select agents. Also, the response does not state whether inspectors will determine if the training has been documented as required by the regulations. In addition, we cannot accept management decision for corrective action that is contingent upon receiving concurrence from CDC. In this circumstance, the recommendation must remain open until a detailed time-phased corrective action plan has been developed.

Scope and Methodology

This report presents the results of the second phase of our audit work to determine how effectively APHIS has implemented the select agent program. During the second phase of the audit, we examined registered entities' compliance with the select agent regulations and assessed APHIS' oversight of the entities. Our fieldwork was conducted at the APHIS Headquarters in Riverdale, Maryland, and at 10 judgmentally selected laboratories. The period of review was calendar year 2003 through current operations. Fieldwork was conducted during the period October 2004 through April 2005.

To accomplish our audit objectives for this second phase, we performed the following audit procedures. At APHIS Headquarters in Riverdale, Maryland, we examined select agent registration files and registered entities' biocontainment (plants)/biosafety (animals) and security plans in order to judgmentally select 10 registered entities for review. Our selection criteria included knowledge gleaned from Phase I of this audit, as well as previous audits, select agents or toxins possessed by the registered entities, geographic considerations and type of entity (e.g., commercial, non-profit, etc.). Included in our sample of 10 registered entities were 5 academic institutions; 2 commercial companies; 1 Federal laboratory; 1 State diagnostic laboratory; and, 1 non-profit research hospital. At each selected registered entity, we performed the following steps.

- Interviewed the ROs and alternate ROs to gain an understanding of each entities implementation of the select agents or toxins regulations, as well as compliance with the regulations.

- Evaluated registered entities' biocontainment (plants)/biosafety (animals) and security plan (Plan). We examined each plan for compliance with regulatory requirements including procedures for –

  - inventory control;
  - physical security;
  - personnel security and suitability;
  - accountability for select agents or toxins;
  - security training;
  - transfer of select agents or toxins;
  - response to emergencies; and
  - reporting incidents, injuries, and breaches.

- Evaluated the entities' procedures for restricting access to select agents or toxins.

- Evaluated physical security measures in place for each laboratory where select agents or toxins were stored and/or used.

- Evaluated the entities' and laboratories' inventory control procedures.

- Evaluated the entities' policies and procedures for transferring select agents or toxins.

- Evaluated the entities' policies and procedures to notify APHIS or CDC in the event of theft, loss, or release of select agents or toxins.

- Assessed the accuracy, adequacy and completeness of the records required to be kept by each RO, including –

    - Biocontainment/Biosafety and Security Plan;
    - A current list of all individuals with access to select agents or toxins;
    - Accurate and current inventory records (including select agent or toxin source and characteristic data);
    - Permits and transfer documents issued by APHIS;
    - Security records (e.g., transactions from access control systems, visitor logs); and
    - Biosafety, containment, and security incident reports.

We conducted this audit in accordance with generally accepted government auditing standards.

USDA

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United States Department of Agriculture

Animal and Plant Health Inspection Service

Marketing & Regulatory Programs Business Services

Riverdale, MD 20737

TO: Robert W. Young
Assistant Inspector General for Audit

FROM: W. Ron DeHaven
Administrator

SUBJECT: APHIS Response to OIG Report, "Evaluation of the Implementation of the Select Agent or Toxin Regulations (Phase II) (33601-3-AT)

Thank you for the opportunity for the Animal and Plant Health Inspection Service (APHIS) to comment on this report. We have listed each OIG recommendation and our response.

Recommendation No. 1: Re-inspect registered entities to ensure compliance with regulations regarding the security over select agents. The inspections should be done using formal written procedures to ensure consistent and thorough reviews. In our Phase I report we recommended that formal procedures be developed.

APHIS Response

Per direction from the Office of Management and Budget, APHIS must coordinate entity inspection policy with the Centers for Disease Control (CDC). To date, CDC has not agreed to total reinspection of all current registrants. Also, good regulatory policy and resource constraints dictate that we adopt a risk based reinspection policy. APHIS will reinspect a registered entity upon submission of either an amendment, which includes the use of an agent or activity of higher risk and/or work in a new area. Also, APHIS will reinspect entities when evidence suggests there is a compliance issue or when an entity has requested amendments that results in a "higher risk" level of activity. This will be effective immediately. In the event that there are no compliance issues or registration amendments, we will reinspect each no less than every two to three years consistent with the registration schedule. This combination of risk-based and regularly scheduled reinspection plan would provide sufficient security and result in most entities being reinspected within the next two years. All reinspections will be conducted under formal procedures.

Recommendation No. 2: Develop and implement written policies and procedures to ensure authorized lists are accurately and promptly updated. The procedures should

include requiring the entities to verify APHIS records, and either provide corrections or attest to the accuracy of the list.

APHIS Response

APHIS agrees with this recommendation. The National Select Agent Registry (NSAR) will become functional by December 30, 2006. The NSAR will contain all of the information found on the registration application documents, which include all of the authorized individuals. The Responsible Official (RO) and the Alternate Responsible Official (ARO) will have access to this system in order to update and verify the accuracy of the data. APHIS will request programming modifications that will allow notices to be sent out quarterly to entities that require verification of their Section 4B. This will be completed by December 30, 2006.

Recommendation No. 3: Develop and implement internal controls designed to prevent the release of sensitive security information associated with registered entities.

APHIS Response

APHIS agrees with this response. The NSAR will prevent accidental release of another entity's information. For those entities that are not using the NSAR to register or amend their application, a protocol will be developed that requires second party verification of any sensitive information that is sent to an entity. This protocol will be developed by March 30, 2006.

Recommendation No. 4: Provide registered entities specific guidance for performing risk assessments, including instructions for performing site-specific risk analyses. APHIS' guidance should provide advice on how to perform threat assessments and identify vulnerabilities, and suggest security measures that could help mitigate risks.

APHIS Response

APHIS agrees with this recommendation. CDC has requested that APHIS participate in a meeting on March 6-8, 2006 in order to provide better guidance to entities in the following areas: agent specific risk/threat assessment; IT and records security; risk mitigation and screening of individuals; and compliance issues and tools. The meeting, as currently planned, will include security specialists from the federal and state governments. Using the materials generated from this meeting, APHIS (and CDC) will provide guidance to entities on risk assessment by December 1, 2006. Finalization is dependent on receiving concurrence from CDC.

Recommendation No. 5: In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to ensure registered entities base security plans on a site-specific risk analysis. Site

specific risk analyses should be examined to ensure that entities perform threat assessments that address its vulnerabilities. APHIS should also ensure that security plans are developed that will mitigate the risks identified and help prevent unauthorized individuals from accessing and acquiring select agents or toxins for use in terrorism. APHIS' inspection reports should conclude whether entities' security plans were based on the results of site-specific risk analyses performed in accordance with the guidance issued.

APHIS Response

APHIS agrees with this recommendation. In response to recommendation No. 4, APHIS is working with CDC to provide guidance to entities regarding the risk assessment process. Based on these guidance documents, improved guidance for inspectors will be documented in the CDC/APHIS Operational Plan. This will be completed by December 1, 2006. Finalization is dependent upon receiving concurrence from CDC.

Recommendation No. 6: In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to verify that entities' security plans have thoroughly addressed all critical areas identified by the regulations. APHIS' inspection reports should include whether each critical area was adequately addressed.

APHIS Response

APHIS agrees with this recommendation. A check list will be developed by June 30, 2006 that the APHIS Security Specialist will use when each entity is reviewed.

Recommendation No. 7: In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to verify that entities are conducting and documenting annual performance tests of their security plans, and are updating plans based on the results of the performance tests, drills, or exercises. APHIS' inspection reports should conclude whether their results were appropriately utilized in updating security plans.

APHIS Response

APHIS agrees with this recommendation. To provide better guidance to inspectors, APHIS and CDC will document operational procedures for review of annual drills and exercises conducted by an entity. These procedures will be finalized by September 30, 2006. Finalization is dependent upon receiving concurrence from CDC.

Recommendation No. 8: In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to compare its list of authorized individuals with the names of the individuals having

access to areas with select agents. This would include an examination of the log books or other documented entries, as well as questioning researchers concerning with individuals can access the area. Inspectors should also examine the completeness and accuracy of access log books. Inspection reports should state whether security measures are adequate to restrict access to select agents only to authorized individuals.

APHIS Response:

APHIS agrees with this recommendation. To provide better guidance to inspectors, APHIS and CDC will document operational procedures that improve methods for verification of access controls used by the entity. These procedures will be finalized by September 30, 2006. Finalization is dependent upon receiving concurrence from CDC.

Recommendation No. 9: In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to identify and examine all areas where select agents are used or stored to ensure that access to those areas are properly secured. Inspection reports should specifically identify all areas containing select agents, state whether the areas are identified in the security plan and included in the site-specific risk assessments, and conclude as to whether security for each area is adequate.

APHIS Response:

APHIS agrees with this recommendation. To provide better guidance to inspectors, APHIS and CDC will document operational procedures for this phase of the inspection in the CDC/APHIS Operational Plan. These procedures will be finalized by September 30, 2006. Finalization is dependent upon receiving concurrence from CDC.

Recommendation No. 10: APHIS should conduct an investigation into the missing access logbook at the affected entity and, based on the outcome, make a determination as to the appropriateness of the entity's registration status.

APHIS Response: APHIS agrees with this recommendation and will request that APHIS' Investigative and Enforcement Services staff conduct an investigation of this finding and submit its findings to the Associate Administrator by March 1, 2006.

Recommendation No. 11: In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to verify that the entities have established and implemented inventory controls and perform procedures to ensure that inventory records are accurate and up to date.

APHIS Response:

APHIS agrees with this recommendation. To provide better guidance to inspectors, APHIS and CDC will document operational procedures for this phase of the inspection in the CDC/APHIS Operational Plan. These procedures will be finalized by September 30, 2006. Finalization is dependent upon receiving concurrence from CDC.

Recommendation No. 12: For the entity with 152 vials of biological material (31 select agents, 20 non-select agents, and 101 unidentified agents), APHIS should conduct an investigation into the discrepancies, and work with the entity to determine whether the vials should be destroyed or transferred to another registered entity.

APHIS Response:

APHIS agrees with this recommendation and has investigated this finding. The entity was storing unknown agents as "select agents." The select agent regulations do not prevent this. Thus, no violation of the regulations have occurred.

Recommendation No. 13: In developing policies and procedures for reviewing and inspecting entities' compliance with the regulations, APHIS should include steps to verify that entities have provided annual training, including required security training, to all individuals authorized to access select agents, and have documented the training as required.

APHIS Response:

APHIS agrees with this recommendation. To provide better guidance to inspectors, APHIS and CDC will document operational procedures for this phase of the inspection in the CDC/APHIS Operational Plan. These procedures will be finalized by September 30, 2006. Finalization is dependent upon receiving concurrence from CDC.

Informational copies of this report have been distributed to:

Administrator, APHIS (9)
ATTN: Agency Liaison Officer
Government Accountability Office (1)
Office of Management and Budget (1)
Office of the Chief Financial Officer (1)
Director, Planning and Accountability Division