U.S. Department of Agriculture

Office of Inspector General
Southeast Region

Audit Report

Followup Report on the Security of Biological Agents at U.S. Department of Agriculture Laboratories

Report No. 50601-10-AT
March 2004

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250

DATE: March 8, 2004

REPLY TO
ATTN OF: 50601-10-At

SUBJECT: Followup Report on the Security of Biological Agents at U.S. Department of Agriculture Laboratories

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This report presents the results of the subject audit. The Department's February 10, 2004, response to the draft report is included as exhibit A with excerpts and the Office of Inspector General's (OIG) position incorporated into the relevant Findings and Recommendations sections of the report.

Based on your response, we have accepted management decision for Recommendations Nos. 1 and 3. Additional information, as specified in the OIG Position sections, is needed before we can accept management decisions for Recommendations Nos. 2 and 4.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective action taken or planned and the timeframes for implementation for those recommendations for which a management decision has not yet been reached. Please note that the regulation requires a management decision to be reached on all findings and recommendations within a maximum of 6 months from report issuance and final action to be taken within 1 year of each management decision. Follow your internal agency procedures for forwarding final action correspondence to the Office of the Chief Financial Officer.

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

Robert W. Young

ROBERT W. YOUNG
Assistant Inspector General
for Audit

Executive Summary

Followup Report on the Security of Biological Agents at U.S. Department of Agriculture Laboratories (Audit Report No. 50601-10-AT)

Results in Brief

This report follows up a review of the security of biological agents at the U.S. Department of Agriculture (USDA) laboratories presented on March 29, 2002 (Audit Report No. 50099-13-At). Our objectives were to (1) determine whether laboratories and agencies have addressed security, inventory, and access concerns reported in our earlier report and (2) examine the implementation of new policies and procedures regulating inventories and biosecurity controls.

In our March 29, 2002, audit, "Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture," we found inconsistent security for biological agents at USDA laboratories. Out of the 124 laboratories we visited, almost half needed to improve their security measures. For this review, we visited 16 laboratories (at least one from each agency) where we had previously identified deficiencies in the biosecurity areas of physical security, inventory control, and unrestricted access to laboratory areas. Of the 16 laboratories revisited, 4 were biosafety level-3 (BSL) laboratories and 12 were non-BSL-3 (medium- and low-risk) laboratories.

USDA's Office of Procurement and Property Management's (OPPM) security reviews had also discovered many areas needing improvement but funding constraints slowed the progress of remediation. In addition, many laboratories did not inventory their biological agents and those that did often did so inaccurately. Further, we found that the Department did not adequately control access to biological agents. A backlog of security background checks, led to researchers without security clearances gaining access to biological materials. At some laboratories, scientists and researchers not associated with USDA work—some not United States' citizens—had ready access to units where biological agents were stored.

We made 10 recommendations in the prior report to help agencies improve the security of biological agents (see exhibit A). We recommended, for example, that the Department quickly implement policies and procedures established by its task force. The agencies responded that they either have or are instituting controls to bring their laboratories in compliance with the Department's new policies and procedures. Our recent review found that while the Department has issued security policies and procedures for BSL-3 (high-risk) facilities, the agencies have not fully implemented them and the policies and procedures lack key regulatory requirements (see section 2).

We also recommended that the agencies compile a comprehensive list of biological agents and toxins handled or stored at their facilities. The agencies responded immediately and they have obtained inventory listings from all of their facilities.

We advised the agencies to limit access to high-risk or high-consequence biological agents and suggested that the Department determine the security background checks necessary for such access. Significant progress has been made in controlling access to high security laboratory areas and in reducing the backlog of background checks for USDA personnel working with high-consequence pathogens. However, background checks are still not conducted on contractors, foreign and visiting scientists, students, and university personnel. Although lacking security clearances, these personnel often have unlimited access to medium and low risk facilities (see section 3).

Even though we reached an agreement with the Animal and Plant Health Inspection Service (APHIS) for a site-specific recommendation, we still have a concern. We recommended in the prior report that APHIS immediately evaluate the feasibility of continuing research and diagnostic activities at facilities located in a strip mall. The building housing the strip mall is close to other commercial businesses, and it has limited security at the entry and exit points. APHIS officials assured us that all pathogens of consequence had been removed but during this review a laboratory official informed us that the strip mall facility housed a USDA listed agent of high-consequence [Bovine spongiform encephalopathy (BSE)]. We expressed our concerns to agency officials who believed that the BSE slides posed little risk but agreed that the pathogens should not be at the strip mall facility. According to the laboratory director, steps have been taken to prevent the incident from recurring.

Significant progress has been made developing biosecurity policies and procedures for USDA laboratories. The agencies have taken great strides to implement biosecurity policies for BSL-3 laboratories. During the followup audit, many of the laboratories we visited had strengthened their controls and policies governing physical inventory, materials access, and materials accountability.

Examples of progress noted during our limited review include:

- All four BSL-3 laboratories have had a site-specific risk assessment conducted by Sandia National Laboratories. Based on Sandia's recommendations, they are remedying security concerns.

- BSL-3 laboratories have started to implement security system upgrades like fences, new doors and locks, 18-gauge expanded metal fastenings for windows, and proximity card readers.

- There are stricter requirements for employees and visitors, and tighter policies and procedures have been implemented. Only persons having received the appropriate security clearance can have unlimited and unsupervised access to laboratories working with high-consequence pathogens.

- All 16 laboratories have developed inventory lists for biological agents. The four BSL-3 laboratories have requirements in place for what information the inventory records should contain.

- All 16 laboratories have forwarded inventory information for the National Pathogen Inventory (NPI) to their agency headquarters as required.

- Laboratories that possessed or used listed agents and toxins have reported them to APHIS as required.

- No inventory discrepancies were disclosed during our fieldwork at BSL-3 laboratories.

- Based on our interviews with laboratory officials and limited observations, all four BSL-3 laboratories have tightened their security regarding visitors and foreign scientists. All personnel lacking the appropriate clearance are escorted at all times while in high containment areas as required.

We found that all USDA agencies have made a concerted effort to implement biosecurity measures. Although they are working toward complete compliance with the BSL-3 manual, much remains to be done. In particular, key biosecurity measures for accountable records, internal reviews, and cybersecurity systems need improvement. In addition, they must continue to improve their control over access to dangerous pathogens (see section 3). They have, though, done well in reducing the backlog of background checks for personnel with access to biological materials. With more time and more specific guidance from the agencies, we believe that BSL-3 laboratories will come to comply fully with the biosecurity measures in the manual.

Recommendations in Brief

We recommend that:

- APHIS verifies that all HHS and USDA listed agents and toxins have been removed from the strip mall facility.

- Agencies give more specific guidance to BSL-3 laboratories about interpreting and enforcing the biosecurity measures listed in the BSL-3 manual.

- The Department update the BSL-3 manual to include requirements and regulations published subsequent to the manual's issuance.

- Non-BSL-3 laboratories expedite the implementation of the appropriate policies and procedures.

Agency Response

The Department agreed with the findings and recommendations in the report. Specifically, APHIS' officials have verified that listed agents, in particular BSE, were removed from the strip mall facility. APHIS and ARS both agreed to develop internal procedures and provide more guidance to laboratories' officials to comply with the biosecurity measures contained in the Department's BSL-3 manual. The Department is planning to update the BSL-3 manual to include regulatory requirements and to expand coverage to BSL-2 laboratories with select agents and toxins. In addition, the Department will expand its efforts to ensure that laboratories comply with the appropriate departmental manual for security. The Department's response to the draft report is included as exhibit B of the audit report.

OIG Position

We agree with the actions taken and planned by the Department in response to the report's recommendations. We have accepted management decisions on Recommendations Nos. 2 and 4. However, to reach management decision on Recommendations Nos. 1 and 3, the Department needs to provide timeframes for all planned corrective actions. Actions necessary to achieve management decisions are provided in the findings and recommendations section. The report was also revised to clarify the appropriateness of background investigations and national security clearances.

Abbreviations Used in This Report

APHIS	
Animal and Plant Health Inspection Service	1
ARS	
Agricultural Research Service	1
BSE	
Bovine spongiform encephalopathy	5
BSL	
Biosafety Level	2
BSL-3 manual	
USDA Security Policies and Procedures for Biosafety Level-3 Facilities	2
CDC	
Centers for Disease Control and Prevention	1
CFR	
Code of Federal Regulations	1
DA	
Departmental Administration	6
DM	
Departmental Manual	2
FS	
Forest Service	1
FSIS	
Food Safety and Inspection Service	1
HCP	
High Consequence Pathogens	10
HHS	
Department of Health and Human Services	1
ISSP	
Information System Security Plan	9
non-BSL-3 manual	
USDA Security Policies and Procedures for Laboratories and Technical Facilities [Excluding Biosafety Level-3 Facilities]	2
NPI	
National Pathogen Inventory	8
OCIO	
Office of the Chief Information Officer	12
OIG	
Office of Inspector General	5
OPPM	
Office of Procurement and Property Management	2
Public Law 107-188	
Public Health Security and Bioterrorism Preparedness and Response Act of 2002	1

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Background and Objectives

Background

Biological agents and toxins are of concern to both the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS). Those used in USDA research and diagnostics are generally pathogenic (disease-producing) to some degree. Some of these pathogens can harm agricultural crops like citrus canker while others like Avian influenza virus can cause disease or death in animals and humans.

Through its various agencies, USDA performs research or diagnostic work on animal and plant pathogens throughout the United States. The Agricultural Research Service (ARS) operates the largest number of laboratories, 243 at 113 locations, and the Forest Service (FS) operates 77 at 67 locations. Other agencies, such as Animal and Plant Health Inspection Service (APHIS) and Food Safety and Inspection Service (FSIS) have fewer laboratories.

On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). Title II of this law, "Enhancing Controls on Dangerous Biological Agents and Toxins," regulates certain biological agents and toxins researched by USDA and HHS. USDA has been given primary responsibility for ensuring that APHIS implement the provisions of Public Law 107-88 while HHS is responsible for Centers for Disease Control and Prevention's (CDC) compliance.

To comply with the law, APHIS issued regulations [section 7, part 331, and section 9, part 121, of the Code of Federal Regulations (CFR)], dated December 13, 2002, that governs the "Possession, Use and Transfer of Biological Agents and Toxins." These regulations are designed to tighten security at United States laboratories where researchers work with potential bioterror agents. In order not to disrupt research or educational projects involving listed pathogens, the regulations are applied with staggered completion dates, beginning on the effective date of February 11, 2003. By November 12, 2003, every individual and entity possessing, using, or transferring any listed agent or toxin must be in full compliance with the law.

The regulations include a list[1] of each biological agent and each toxin that the Secretary of Agriculture determined has the potential to pose a severe threat to animal or plant health, or to animal or plant products. Section 9 CFR 121.3(b) also contains the listing of overlap agents and toxins[2] that have the potential to pose a severe threat to both human and animal health.

[1] 7 CFR 331.3 for plant pathogens and 9 CFR 121.3 for animal pathogens.
[2] Appears on both the CDC select agent and toxin list (42 CFR 73.4) and USDA listed agents and toxins.

HHS' CDC assigns each biological agent and toxin a biosafety level (BSL) from 1 to 4 that describes the increasing level of containment required to protect researchers from the pathogens. BSL-1 laboratories work with low-risk pathogens. BSL-2 laboratories work with moderate risk agents and toxins like E. coli or Salmonella. BSL-3[3] laboratories work with biological material that can cause lethal infections like Rift Valley Fever. BSL-4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease.

In our March 29, 2002, audit report, "Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture" (Audit Report No. 50099-13-At), we described security flaws at many USDA laboratories. The security measures for almost half of the 124 laboratories we visited needed improvement. Although earlier internal security reviews had discovered deficiencies, funding constraints slowed the progress of remedial action. Also, despite requirements, many laboratories did not inventory their biological agents, and those that did often did so inaccurately.

Further, we found that the Department did not adequately control access to biological agents. At some laboratories, scientists and researchers not associated with USDA work, and some not United States' citizens, had ready access to units that stored biological agents. Due to a backlog of background checks, researchers who had not been granted security clearance were routinely granted access.

The agencies covered in our March 2002 audit replied that they were responding to our recommendations.

The Department has recently issued two manuals on laboratory security designed to prevent unauthorized access to USDA facilities, to curtail theft or property loss, and to deter any other acts that may cause adverse impacts on national security or the health and safety of USDA employees.[4] The Department has also contracted security experts to perform risk assessments on all USDA laboratories. Sandia National Laboratories conducted risk assessments on BSL-3 laboratories and the Office of Procurement and Property Management (OPPM) is coordinating security assessment reviews for non-BSL-3 laboratories.

[3] USDA added a subsidiary category to its BSL-3 classification, BSL-3 Ag, that CDC did not. For the USDA, BSL-3 Ag recognizes plant and animal pathogens that pose major threats to domestic agriculture like Foot and Mouth Disease that CDC classifies as BSL-2.

[4] The Departmental Manual (DM) 9610-1, entitled, USDA Security Policies and Procedures for Biosafety Level-3 Facilities (BSL-3 manual), dated August 20, 2002, covers the security of pathogens held at USDA BSL-3 facilities – the Department's highest risk. A DM, USDA Security Policies and Procedures for Laboratories and Technical Facilities [Excluding Biosafety Level-3 Facilities] (Non-BSL-3 manual), was issued on April 30, 2003, to cover facilities holding lower risk organisms.

Objectives

The objectives of our audit were (1) to revisit a sample of USDA laboratories where we found security, inventory, and access problems presented in our March 29, 2002, report in order to determine whether the agencies and laboratories had made significant corrections and (2) to examine the implementation of new departmental policies and procedures pertaining to inventories and biosecurity controls.

Findings and Recommendations

Section 1. Followup on Recommendations of Prior Audit Report No. 50099-13-AT

During our followup visits, we found all agencies responding to the prior audit's recommendations. In our March 29, 2002, audit, "Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture," we found inconsistent security for biological agents at USDA laboratories. Out of the 124 laboratories we visited, almost half needed to improve their security measures. For this report, we visited 16 laboratories (at least one from each agency) that had previously identified deficiencies in the biosecurity areas of physical security, inventory control, and unrestricted access to laboratory. Of the 16 laboratories, 4 were BSL-3 laboratories and 12 were non-BSL-3 (medium- and low-risk) laboratories.

The initial audit assessed the extent and location of dangerous pathogens, the procedures guarding against accidental or intentional release of these agents, and the adequacy of security measures in place to prevent unauthorized access to and removal of the agents.

In the initial audit, we reported (1) the security of biological agents at USDA laboratories was inconsistent and needed general improvement, (2) the absence of a consolidated database that would allow agency managers to identify the location and risk levels of biological agents, (3) the Department did not adequately control access to biological agents, and (4) the Department needed to institute reporting procedures for instances of unauthorized access.

Finding 1 Status of Implementation

We made 10 recommendations in the initial audit to help agencies improve security over biological agents (see exhibit A). Among them, we recommended that the Department quickly implement policies and procedures established by its task force and that it compile a centralized database of all its biological agents. In August 2002, the Department issued security policies and procedures for BSL-3 facilities but the agencies have not fully implemented them. Also, the policies and procedures lack key regulatory requirements (see section 2). In April 2003, the Department issued security policies and procedures for non-BSL-3 facilities.

The agencies responded that they either have controls in place or are instituting controls to make their laboratories comply with the Department's new policies and procedures.

We also recommended that the agencies compile a comprehensive list of biological agents and toxins handled or stored at their facilities. The agencies acted immediately and they have obtained inventory listings from all of their sites.

We proposed that the agencies limit access to high-risk or biological agents and that the Department establish the security clearance required for personnel to have such access. Significant progress has been made in controlling access to BSL-3 laboratory areas and in reducing the backlog of background checks for USDA personnel working with dangerous pathogens. However, background checks are still not conducted on contractors, foreign and visiting scientists, students, and university personnel that often have unlimited access to non-BSL-3 facilities (see section 3).

Even though we reached an agreement with APHIS for a site-specific recommendation, we still have a concern. We recommended that APHIS should immediately consider the issues posed by continuing research and diagnostic activities at facilities located in a strip mall. The building housing the strip mall is close to other commercial businesses and has limited security at the entry and exit points. In response to our recommendation, APHIS officials assured us that all pathogens of consequence had been removed from the strip mall facility.

During our review, however, a laboratory official informed us that the strip mall facility continued to house pathogens of high consequence. Bovine spongiform encephalopathy (BSE) slides (a USDA listed agent) had been returned to the strip mall site for further work. The laboratory director told us that he was not aware that the slides were sent to the strip mall and he made immediate arrangements to return them to the main facility. We expressed our concerns to agency officials. They stated that the BSE slides posed little risk but agreed that the pathogens should not be at the strip mall facility. The laboratory director stated that personnel have since received training to ensure that this incident does not recur.

Recommendation No. 1

APHIS needs to verify that all HHS and USDA listed agents and toxins have been removed from the strip mall facility and report back to the Office of Inspector General (OIG).

Agency Response. In the February 10, 2004, response, the Director of Homeland Security stated, "* * * APHIS has verified via internal reviews (December 2002 and October 2003) that there are no listed agents at the strip mall site, in particular no * * * (BSE) slides. No discrepancies were found."

OIG Position. We accept management decision on this recommendation.

Section 2. Departmental Policies and Procedures Have Been Issued and Agencies are Working Toward Full Implementation

Significant progress has been made since we issued our prior audit. The Secretary assigned a task force to develop policies and procedures governing biosecurity measures for the Department's laboratories and facilities. The task force drafted standards for the key biosecurity areas of inventory control, physical security, cybersecurity, personnel suitability, and biosecurity incident response.

The Department also took the following actions in order to address biosecurity issues:

- USDA-Departmental Administration (DA) contracted with Sandia National Laboratories to conduct comprehensive reviews of all USDA BSL-3 facilities. USDA's OPPM is coordinating security assessment reviews at non-BSL-3 laboratory facilities.

- Agencies compiled consolidated databases that allow agency managers to identify the extent and location of biological agents and toxins at USDA laboratories. These inventories help managers determine the risks associated with individual materials so they can effect appropriate containment and BSL's.

- On August 30, 2002, the Department issued the BSL-3 manual.

- On December 13, 2002, APHIS published regulations 7 CFR part 331 and 9 CFR part 121 to comply with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

- On April 30, 2003, the Department issued the non-BSL-3 manual.

- The backlog of security clearances has been greatly reduced. Agencies have prioritized personnel needing clearances. USDA-DA designated OPPM to be in charge of the security clearance process.

- Physical access to BSL-3 laboratory areas has been restricted. Agency officials stated that all personnel without the proper clearance are escorted at all times while in high containment areas.

- All BSL-3 laboratories that we visited have developed biosecurity incident response plans detailing the actions required by specific types of incidents.

Finding 2 — Further Progress Needed on the Design and Implementation of Biosecurity Measures in the BSL-3 Manual and BSL-3 Security Measures

The BSL-3 manual establishes a biosecurity program that outlines "individual responsibilities to deter, detect, and respond to any security threat and to ensure that pathogens are not removed illegally from biocontainment facilities." While the BSL-3 manual was only recently issued and we realize that it takes time to implement, the BSL-3 manual needs to be updated to help laboratories adhere to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. In addition, laboratory officials need guidance on implementing certain provisions of the new biosecurity requirements.

Also, agencies may need to offer site-specific guidance about interpreting and enforcing the biosecurity measure requirements listed in the BSL-3 manual. The Department has developed biosecurity policies and procedures for BSL-3 laboratories but we found that biosecurity requirements at BSL-3 laboratories have not been carried out fully because agencies have not completely incorporated the requirements into their own laboratory operational procedures. As a result, USDA laboratories have not implemented key measures designed to help mitigate biosecurity weaknesses.

We found that all agencies have made a concerted effort to address biosecurity measures but much work remains to achieve full compliance. In particular, key biosecurity measures pertaining to accountable records, internal reviews, and cybersecurity systems still need improvement.

Inventory Accountability Records

Our review of four BSL-3 laboratories revealed that only one of the laboratories had inventory records that contained each of the nine database elements required by the BSL-3 manual. Scientists at the BSL-3 laboratories explained that they had difficulty tracking inventories using the nine data elements. Agency officials noted that they were aware of the problem of inconsistent laboratory inventories. They acknowledged that compiling the inventory records with the nine data elements was more difficult than they had originally thought it would be. One difficulty that arose was including the information for the date of change of status. Scientists often remove a small or minuscule amount of a pathogen from the repository inventory to start a new sample. It is extremely difficult to know the pathogen amount to record on the inventory record. Consequently, they lacked precise information to include for the date of change of status.

Additional guidance will need to be given to BSL-3 laboratories to help them comply with the required database format for inventory records.

Section 8a(1) of the BSL-3 manual requires three types of accountability records for the pathogen inventory at BSL-3 laboratories. These three accountability records are (1) a summary inventory at USDA agency headquarters, i.e., National Pathogen Inventory (NPI); (2) a detailed inventory of repository materials to be kept at the facility; and (3) material accountability for experimental or working samples. Section 8a(1)(b) of the BSL-3 manual requires that nine database elements be maintained for the repository materials inventory. Section 8a(1)(b) also requires that "the database will not only serve as a record of current inventory but will also serve as a historical record of pathogen use at the facility."

Inventory Controls

Our fieldwork determined that progress has been made with inventory controls and inventory accountability records. Examples of progress relating to inventory controls include:

- All four BSL-3 laboratories have developed an inventory of their biological agents. The four BSL-3 laboratories have requirements in place for what information the inventory records should contain.

- All four BSL-3 laboratories have sent the required NPI information to their agency headquarters.

- Scientists at all four of the BSL-3 laboratories maintained laboratory notebooks for the experimental or working samples.

- All four BSL-3 laboratories have reported to APHIS the listed agents and toxins that they possess in their facilities.

- No inventory discrepancies were disclosed during our fieldwork at the four BSL-3 laboratories.

While policies have been developed to address inventory, agencies need to interpret the requirements of the BSL-3 manual and to work with individual laboratories in order to develop standard inventory methods. Agencies also need to give more site-specific guidance to BSL-3 laboratory officials in the area of inventory record keeping.

Internal Reviews

An integral component of the biosecurity program is a system of internal reviews. Scientists working with pathogens are responsible for the accuracy of electronic databases and laboratory notebook records. Scientists must

maintain detailed records of information necessary to give a complete accounting of all the activities related to agents or toxins. The laboratory director/responsible official (RO) must perform a physical review of these material accountability records annually. This review must include a reconciliation of inventory records to repository materials. The agency biosafety officer is required to perform random reviews annually to ensure compliance at laboratories.

Section 8a(3) of the BSL-3 manual states that a "* * * physical review will be [conducted] at least annually. * * * The Center Director, Laboratory Director, or equivalent is responsible for ensuring the physical reviews are accomplished. Random reviews shall be conducted on an annual basis by the agency Biosafety Officer to ensure compliance at the locations."

Internal reviews by someone other than the scientists who are working with the pathogens and who are responsible for keeping current inventory records will help to make certain that proper chain of custody procedures are in place. Our review of four BSL-3 laboratories disclosed that the scientists had compiled an inventory list of the biological agents they stored or used. To accomplish this, the scientists reconciled inventory records to repository materials in storage areas. However, the laboratory director, RO, or biosafety officer did not perform a review.

The Department's manual was not clear on the type of reviews required. Some laboratories did not know the types of reviews required. Other laboratories were aware of the type of reviews required but did not know who was supposed to perform them. Some laboratories were not sure if their laboratory biosafety officer or a superordinate agency biosafety officer was to carry out the random review. (The agency biosafety officer should perform the random review.) The agencies need to work with BSL-3 laboratory officials and should offer more specific guidance about how to interpret biosecurity measures relating to internal reviews of inventory.

Cybersecurity Systems

Our review of four BSL-3 laboratories determined that progress has been made with the development of cybersecurity plans. The Department realizes the importance of protecting the biological agents and information about the agents. From that realization have come policies and procedures in the BSL-3 manual relating to cybersecurity systems. Our review found all BSL - 3 laboratories developing cybersecurity plans. Once the "Information System Security Plan" (ISSP) is complete, it will be sent to the laboratories respective agencies for feedback and approval.

Section 10b(1) of the BSL-3 manual states that "each agency shall ensure that all USDA information resources, including USDA information related to

high-consequence pathogens under its purview, are protected in a manner that is consistent with its threats and missions at all times." Section 10b(3) of the BSL-3 manual states "each agency shall plan, budget, allocate, and execute resources sufficient to ensure comprehensive implementation and maintenance of that organization's computer security program." After resources have been allocated, a cybersecurity program plan can be developed. Section 10b(4) of the BSL-3 manual states "each agency shall document its cybersecurity program in an ISSP."

The current cybersecurity systems in place for BSL-3 laboratories do not conform to the requirements of the BSL-3 manual. The BSL-3 manual mandates that the cybersecurity system should only secure the USDA BSL-3 facility. For example, our review determined that two BSL-3 laboratories share a cybersecurity system with outside parties. While these two laboratories are developing their own stand-alone cybersecurity systems, information related to high consequence pathogens (HCP) may not be adequately protected. One of these two laboratories shares a cybersecurity network with the U.S. Army. The laboratory is developing its own ISSP as required by the BSL-3 manual. The other BSL-3 laboratory uses the same cybersecurity network as a university. The research leader for this laboratory stated that the cybersecurity system for the laboratory is limited to what the university provides. He added that the cybersecurity system provided by the university is inadequate but the university has refused to provide more cybersecurity protection.

Requirements for a cybersecurity system have been developed since the Department realized the importance of protecting information relating to HCP's. However, the BSL-3 laboratories have not received adequate resources to implement a cybersecurity plan. BSL-3 laboratories need more specific guidance to help them develop their own systems and to implement the cybersecurity policies in the BSL-3 manual.

Access Controls

Significant progress has been made at the Department level to develop controls, policies, and security over access to BSL-3 laboratory areas. Examples of progress seen during our fieldwork include:

- The four BSL-3 laboratories we visited had tightened their security on visitors and foreign scientists. We were told that all personnel without the appropriate clearance are always escorted when in high containment areas, as required by the manual.

- The time needed to obtain security clearances has been greatly reduced. Now, agencies prioritize the employees who need clearances. Only employees with the authorized clearances have

unrestricted access to BSL-3 laboratory areas. Once USDA personnel have received their security clearances, they can escort visitors, foreign and visiting scientists, students, and contractors, as required.

Section 11a of the BSL-3 manual, sets policy on human reliability requirements for USDA and non-USDA personnel who work in USDA laboratories including collaborators, cooperators, university personnel, and contractors. Section 11a(4) states that "* * * Non-USDA personnel will be escorted at all times by staff members who have a completed background investigation and appropriate facility authorization."

Physical Security

Our fieldwork determined that progress in physical security has been made at BSL-3 laboratories. Security upgrades will help ensure that appropriate levels of protection will exist to prevent or deter against unauthorized access, theft, diversion, or loss of custody of BSL-3 pathogens. Examples of progress noted during our fieldwork at BSL-3 laboratories include:

- All four BSL-3 laboratories had a site-specific risk assessment conducted by Sandia for their facility. All four BSL-3 laboratories are implementing corrective actions based on recommendations from Sandia's assessment.

- Noted improvements were security system upgrades, tighter policies and procedures, and stricter requirements for employees and visitors.

- Some security upgrades seen at the BSL-3 laboratories were fences, new doors and locks; 18-gauge expanded metal fastened on the inside of windows, and proximity card readers.

Recommendation No. 2

Agencies need to provide more specific guidance to BSL-3 laboratories on how to interpret and enforce the biosecurity measures listed in the BSL-3 manual.

For example:

- Site-specific guidance for inventory recordkeeping.

- The type and frequency of internal reviews to be conducted and by whom.

- Site-specific guidance for cybersecurity issues.

Agency Response. In the February 10, 2004, response, the Director of Homeland Security stated,

> ** * * USDA is in the process of reviewing several inventory systems to determine if any would be suitable for general use in ARS laboratories. The question of how to handle the removal of miniscule samples from the repository stocks will require additional study.*
>
> ** * * [ARS] agrees that internal reviews of individual laboratories would improve compliance with the appropriate * * * [DM] for security. It is the intention of ARS to develop procedures for such reviews by April, 2004. These procedures will include both reviews by the Area Office, and unscheduled random reviews by components of ARS Homeland Security and/or NPS. Once the policy is developed, it will be conveyed to the ARS locations.*
>
> *The ARS Office of the Chief Information Officer (OCIO) is actively working with the laboratories to develop cyber security plans. Requirements have already been met for compliance with the Select Agent Rule for those seven locations where it applies. Specific guidance for what material may be placed on the web without violation of Sensitive Security Information will need to come from the Department OCIO. Other ID related Business Recovery Plans, such as Disaster Recovery Plans, IT [information technology] Contingency Plans, and Cyber Incident Response Plans, involve cyber security and are being developed under a Departmental contract with CRI that will provide templates by the end of 2004.*
>
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>
> *APHIS and Sandia Laboratories collaborated on the USDA Biological Reference Standard. This manual is currently in the draft stage. In addition, the APHIS/ARS facility located in*

Ames, Iowa, collaborated with Sandia in the development of a site-specific Security Manual. A similar manual for the Plum Island facility will require coordination with the Department of Homeland Security, and this will commence at their discretion.

OIG Position. We concur with the planned actions of the Department, APHIS, and ARS to provide guidance to BSL-3 laboratories on the implementation of biosecurity measures in the BSL-3 manual. However, in order to reach management decision on this recommendation, the Department needs to provide a timeframe for the selection and implementation of an inventory system suitable for general use in BSL-3 laboratories.

Finding 3 The BSL-3 Manual Lacks Key Regulatory Requirements

We found that with the issuance of new codified regulations, the BSL-3 manual needs to be updated. While much progress has been made with the development and implementation of biosecurity measures for BSL-3 facilities, the BSL-3 manual lacks some key regulatory requirements. The new regulations establish security measures at laboratory facilities that the BSL-3 manual does not address. As a result, agency officials and other users who rely strictly on the BSL-3 manual may omit key biosecurity measures of the regulations that are designed to mitigate biosecurity weaknesses.

Title 7, part 331, and title 9, part 121, of the CFR, both dated December 13, 2002, and effective on February 11, 2003, state that any person possessing, using, or transferring any biological agent or toxin must comply with the detailed regulations mentioned above.

Both titles specify that any person possessing, using, or transferring any biological agent or toxin must have a "Biocontainment/Biosafety and Security Plan." Title 7 CFR part 331.11 and Title 9 CFR part 121.12 make specific references to the BSL-3 manual for guidance on security systems and procedures. Since the CFR refers to the BSL-3 manual, the manual needs to be compatible with the CFR. Updating the BSL-3 manual to include the key regulatory requirements of the CFR will greatly aid laboratories to comply with biosecurity measures.

In addition, the new regulations require that an individual or entity must have a "Biocontainment and Security Plan" (7 CFR 331.11) or a "Biosafety and Security Plan" (9 CFR 121.12). The CFR states "* * * the titles and

provisions of the plans are different because the agents listed under 7 CFR 331.3 do not pose a severe threat to human health and, therefore, it is unnecessary to require that the plant-related plan address personnel safety and health." While the provisions may differ, both ask for security requirements that are commensurate with the risk posed by the agent or toxin. The CFR requires that the security plan "* * * must describe inventory control procedures, personnel suitability for those individuals with access to listed agents or toxins, physical security, and cybersecurity." The regulations also state that APHIS will review the "Biocontainment/Biosafety and Security Plan," as applicable. Finally, to make sure that the plans continue to meet an entity's containment and security needs, it is a requirement that "* * * the plan be reviewed, performance tested, and updated annually. The plan must also be reviewed and revised, as necessary, after any incident."

The new regulations also require that a RO be named. The regulations state that the RO is the individual designated by an entity to act on its behalf. The RO must have the authority and the control to ensure compliance with the regulations. We found that the RO has specific responsibilities, which include, but are not limited to the following:

- Ensuring compliance with regulations.
- Providing laboratory facilities with proper methods to contain, handle, and dispose of agents and toxins.
- Developing and implementing a "Biocontainment/Biosafety and Security Plan."
- Providing appropriate annual training in containment and security procedures for all personnel.
- Notifying APHIS or CDC of termination of toxin and agent users.
- Allowing only approved individuals to have access to listed agents or toxins.
- Providing timely notice of any theft, loss, or release of a biological agent or toxin.
- Maintaining detailed records of information necessary to give a complete accounting of all the activities related to agents or toxins.
- Notifying APHIS or CDC five business days prior to discontinuing or inactivating the possession, use, or transfer of the agent or toxin.

While the biosecurity plan described in the BSL-3 manual has the same biosecurity requirements of the plans described in the CFR, our review found

that the plans mentioned in the CFR have more requirements and more detailed information than the biosecurity plan. For a few examples, we found that the regulations would require that the "Biocontainment/Biosafety and Security Plans" provide for the following:

- Inspection of all packages upon entry and exit.
- Notification to RO's about loss or compromise of keys and passwords, and suspicious persons or activities.
- Permission for unescorted access only to individuals with the appropriate clearance, during authorized hours, and only for job performance.
- Reviewing, performance testing, and updating processes of the security system on an annual basis and after any incident.

The requirements of the new regulations addressing biosecurity conditions are not adequately discussed in the BSL-3 manual. By referring to the BSL-3 manual, the regulations setup the BSL-3 manual as a model for how non-Federal possessors of biological agents and toxins should establish protocols to secure their pathogens. Consequently, the provisions of the BSL-3 manual may be construed as protocols, and therefore should mirror the regulations as much as possible.

The BSL-3 manual asserts that the policies and procedures should be reviewed in five years unless conditions warrant an earlier review. We found that there were no provisions in the BSL-3 manual that adequately address the above regulatory provisions. Consequently, we believe that it is time to update the BSL-3 manual to reflect the provisions in the new regulations. A unified and parallel set of regulations would further aid BSL-3 laboratories in fulfilling all of the biosecurity requirements.

Significant progress has been made with the development of biosecurity policies and procedures for USDA laboratories. The agencies have taken great strides to effect the biosecurity policies for BSL-3 laboratories. However, we found that the new regulations have several biosecurity measures or provisions that the BSL-3 manual does not address. For example, the new regulations require that any individual or entity that possesses, uses, or transfers any agent or toxin must have an APHIS or CDC issued certification of registration and a personnel security risk assessment by the attorney general.

Even though USDA has taken positive steps toward improving security at USDA laboratories, further actions are needed so that appropriate security measures are implemented in accordance with the requirements of the Public Health Security and Bioterrorism Preparedness Response Act of 2002.

Recommendation No. 3

Update the BSL-3 manual to include requirements in regulations published subsequent to the manual's issuance.

Agency Response. In the February 10, 2004, response, the Director of Homeland Security stated, "* * *USDA is planning to revise the Policies and Procedures in May of 2004 to include the appropriate CFRs for selected agents and toxins, and to expand coverage to BSL-2 laboratories with select agents and toxins."

OIG Position. We accept management decision on this recommendation.

Section 3. Non-BSL-3 Laboratories Have Made Progress in Improving Biosecurity Measures; However, Further Improvements are Needed

During our followup review we visited a total of 16 laboratories (4 BSL-3 laboratories and 12 non-BSL-3 laboratories). These laboratories were selected for review because our prior audit disclosed concerns about their physical security, inventory controls, and access supervision. Overall we noted that the 16 laboratories have made progress toward improving biosecurity measures, however further improvements are needed.

Finding 4 USDA Needs to Strengthen Controls Over Security of Biological Agents at its Non-BSL-3 Laboratories

USDA needs to strengthen controls over the security of biological agents at its laboratories—especially non-BSL-3 laboratories. Our followup visits to selected USDA non-BSL-3 laboratories with prior security issues determined that they are strengthening their overall security but they must make additional improvements in the areas of physical security, materials accountability, and access by personnel entering laboratory areas to protect USDA facilities from theft of valuable equipment or intellectual property[5].

Physical Security

Five of the 12 non-BSL-3 laboratories visited must improve physical security. Laboratory doors were still left unlocked and pathogens were kept in unlocked freezers. Several laboratory officials stated that they do not lock doors because they are not required to do so. These physical security issues make the laboratories vulnerable to theft and misuse of USDA assets. In fact, there have been three instances of theft at non-BSL-3 laboratories following the fieldwork for our prior audit. These three laboratories had unresolved security related issues that we had identified during the audit.

Section 9 of the non-BSL-3 manual states, that "* * * a physical security system shall be designed according to risk assessment principles, which will evaluate targets, adversary capabilities, consequences, and vulnerabilities." Qualified individuals who have expertise in physical security should develop the risk assessment. In addition, section 9g states that "* * * physical security systems will be tailored to address site-specific characteristics and requirements, ongoing programs, and operational needs, and to achieve acceptable protection levels using current technology in a cost-effective manner."

[5] Intellectual property – the product or results of scientific experiments.

Five of the 12 non-BSL-3 laboratories visited had not corrected prior physical security problems. Unlocked laboratory doors and pathogens stored in unlocked freezers left laboratories vulnerable, especially laboratories co-located with universities. During their security assessments, OPPM also identified unlocked doors and freezers as vulnerabilities that could lead to the theft of USDA resources. At three laboratories, USDA property was stolen:

- Two laboratories had equipment valued at approximately $159,000 stolen in February 2002. Our review found that laboratory doors were still being left unlocked. OPPM had called attention to the threat of valuable laboratory equipment being stolen due to unlocked and unoccupied laboratories. OPPM recommended locking doors to unoccupied laboratories. Equipment can be just as valuable to a terrorist as biological agents themselves so it should be protected and secured against theft.

- OPPM identified unauthorized access and theft of government property as a threat at one laboratory because of a lack of distinction between authorized and unauthorized personnel. Shared space with universities leaves laboratories vulnerable. The laboratory shares space with a university and although only minor equipment has been stolen to this point (calculators), other USDA assets like equipment valued at approximately $250,000 and pathogens are in jeopardy. Freezers containing pathogens were left unlocked and employees did not wear identification badges. While co-located facilities are not bad situations, having inadequate security measures in place leads to unrestricted access and avoidable vulnerabilities.

We made recommendations in the prior audit to lock doors and freezers at non-BSL-3 laboratories. Security upgrades need to be made at non-BSL-3 laboratories to adequately protect USDA resources. Implementation of the physical security procedures required in the recently published DM for non-BSL-3 facilities should help to prevent theft of USDA property.

Materials Accountability

While progress was observed for inventory and materials accountability controls, there remain weaknesses with inventory controls at non-BSL-3 laboratories. Prior to April 30, 2003, inventory controls were not required for non-BSL-3 facilities. We reported in the prior audit that not all USDA laboratories kept inventories and that those laboratories that had inventories did not keep them current. In addition, not all existing inventories were accurate. While our followup visits found that individual laboratories at non-BSL-3 facilities did keep inventories of biological agents they stored, these inventories were still not kept current.

Section 8a(1) of the non-BSL-3 manual requires laboratories to maintain three types of material accountability records for pathogens. The three accountability records are: (1) a summary inventory at USDA agency headquarters (i.e., National Pathogen Inventory System), (2) a detailed inventory of repository materials to be kept at the facility, and (3) materials accountability for experimental or working stocks. Section 8a(1) of the non-BSL-3 manual states, "The objective of maintaining such records is to ensure that the agency or equivalent is aware which pathogens are present, or have been present in its facilities, to ensure the accountability of scientists for the pathogens they store and use, and to be aware of the final disposition of pathogens, including destruction or shipping to another facility."

In addition, the non-BSL-3 manual makes several references to current inventory records. Section 8a(1)(b) of the manual states, "Each USDA facility that stores or uses any pathogen must maintain a current detailed inventory * * * Each facility will maintain a current master database reflecting the cumulative pathogens of all management units at the facility. The database will not only serve as a record of current inventory but will also serve as a historical record of pathogens used at the facility."

We reported in the prior report that USDA needs a consolidated database to monitor biological agents. We noted that not all laboratories kept inventories and those that had inventories did not keep them current or in some cases accurate. Many of the laboratories we visited during the followup audit had made significant progress toward strengthening controls and policies over inventory materials accountability. Examples of improvement ascertained during this current audit's review for materials accountability include:

- All 12 non-BSL-3 laboratories have developed inventory lists for biological agents.

- All 12 non-BSL-3 laboratories have forwarded inventory information for the NPI to their agency headquarters, as required.

- All non-BSL-3 laboratories that possessed or used listed agents and toxins have reported them to APHIS, as required.

However, we did find inventory discrepancies at several of the non-BSL-3 facilities. Non-BSL-3 laboratories were not updating their records to reflect the current inventory on hand. Examples of inventory discrepancies include:

- One laboratory's inventory listed eight vials of a pathogen but only seven were found in the freezer. The research leader stated that the vial had just been used up and the inventory list had not been updated to reflect the recent use.

- At another facility, inventory items were intentionally left off the list of pathogens sent to the agency. These items were an archived collection that had been passed down from other scientists. The laboratory received clarification from its headquarters and it plans to correct the oversight by sorting through the collection and either entering the samples into the inventory list or destroying them.

- At one laboratory, we found two vials of a pathogen that were in the freezer but the inventory list reported that all vials of the pathogen had been destroyed in 1996. The research leader stated that all of the vials should have been destroyed and he could not explain why the vials were still in the freezer. He had the administrator of the pathogen collection pull up a list of the pathogen on his computer. The database showed that all vials of the pathogen were destroyed in 1996. The vials were immediately destroyed.

Implementation of inventory control procedures required in the recently published DM for non-BSL-3 facilities should help to prevent inventory discrepancies.

Access Controls

Officials did not always restrict access to non-BSL-3 laboratories or to the potentially dangerous biological agents and valuable equipment stored in them. At many non-BSL-3 laboratories, individuals not associated with USDA research and diagnostic activities could enter parts of the laboratories where there were biological agent and equipment. Also, non-USDA personnel who are associated with laboratory activities but should not have access to biological material (e.g., contractors, personnel from universities, and visiting and foreign scientists) continue to have access to pathogen storage areas. With unrestricted access, unauthorized personnel having knowledge of a laboratory's inventory could remove a biological agent or piece of equipment and place it in a terrorist's hands long before the theft was discovered.

Section 11a of the BSL-3 manual, sets policy on human reliability requirements for USDA and non-USDA personnel who work in USDA laboratories including collaborators, cooperators, university personnel, and contractors. Section 11a(4) states that "* * * Non-USDA personnel will be escorted at all times by staff members who have a completed background investigation and appropriate facility authorization."

Examples of access problems noted during our fieldwork include:

- One laboratory leased space to a private firm. The firm's employees had free and unrestricted access to USDA laboratory areas. There

were no policies in place for escorting and restricting access of non-USDA personnel.

- Laboratories share space with universities. OPPM found that sharing space with the university caused a lack of security and that there was no meaningful physical security beyond typical door locks. It is not uncommon for USDA laboratories to share space with outside parties but access is not restricted to only USDA employees for these co-located facilities. Currently there are no guidelines laid out for co-located facilities that require security measures and restricted access to laboratory areas.

- Contractors and foreign scientists still had unescorted and unrestricted access to laboratory areas. At one laboratory, we found that contractors were given proximity cards that allowed them access to the entire facility at any time. A definition of "authorized" and "unauthorized" personnel needs to be formulated so that non-BSL-3 laboratories can limit access to appropriate personnel.

- Contractors, foreign and visiting scientists, students, and university personnel do not undergo background checks. In some instances, these individuals have unrestricted access to laboratory areas. Without an appropriate background investigation, these individuals may pose a serious threat to USDA resources.

We conclude that the Department should implement policies and procedures as soon as possible to establish consistent management of biosecurity activities and to centralize control of laboratory practices for non-BSL-3 laboratories. We also conclude that agencies should review their security procedures for non-BSL-3 laboratories to control access to biological agents and equipment and to make sure that unauthorized removal of biological agents and equipment does not occur.

Recommendation No. 4

Expedite the implementation of the policies and procedures for non-BSL-3 laboratories.

Agency Response. In the February 10, 2004, response, the Director of Homeland Security stated,

> ** * * USDA will expand efforts to ensure that laboratories comply with the appropriate * * * [DM's] for security. The status of APHIS's entire facilities is elevated to that of BSL-3 since those pathogens are present. Physical security is provided by locking laboratories when researchers are not present in those labs. Inventories are maintained and updated*

for bacterial cultures under study. Access is restricted to labs, and visitors are escorted within the facilities. Employees are subject to a standard clearance process used by the agency.

Plant Protection and Quarantine has upgraded the physical security of its Beltsville, Maryland, facility. All visitors are "badged" and escorted throughout restricted areas of the premises.

Physical security assessments at all ARS laboratories have been completed and physical security countermeasures will be implemented as soon as additional financial resources are available. Laboratories will again be reminded to follow basic security procedures such as locking doors and enforcing the wearing of IDs. Public trust risk levels are being determined for all positions at the remainder of the Priority 1 and Priority 2 mission critical facilities. ARS is currently leading the effort to publish a Federal Register Notice to permit USDA to require and conduct the appropriate background investigations on all persons having access to USDA facilities, not just employees.

*The FSIS Field Service and Microbial Outbreaks and Special Projects laboratories use the * * * [non-BSL-3 manual] as a reference for providing appropriate technical guidance at FSIS non-BSL-3 laboratories. After reviewing the requirements of the USDA Policies and Procedures for non-BSL-3 laboratories, FSIS determined that the Standard Operating Procedures, security plans, continuation of operation plans, and emergency plans in effect in the non-BSL-3 Laboratories meet or exceed the requirements set forth in the Policies and Procedures manual.*

OIG Position. We concur with the planned actions of the Department to expedite the implementation of policies and procedures for non-BSL-3 laboratories. However, in order to reach management decision on this recommendation, ARS needs to provide a timeframe for (1) implementation of physical security countermeasures, as appropriate, at ARS laboratories; (2) determination of public trust risk level for all positions at Priority 1 and Priority 2 mission critical facilities; and (3) publication of a Federal Register Notice to permit USDA to require and conduct the appropriate background investigations on all person having access to USDA facilities, not just employees.

Scope and Methodology

In our March 29, 2002, audit, "Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture," we visited 124 laboratories of which almost half needed to improve their security measures. For this report, we conducted the audit by making unannounced visits to 16 laboratories (at least one from each agency) that had previously identified deficiencies in the biosecurity areas of physical security, inventory control, and unrestricted access to laboratory area. Of the 16 laboratories, 4 were BSL-3 laboratories and 12 were non-BSL-3 (medium and low risk) laboratories. All 4 of the BSL-3 laboratories had a security assessment performed by Sandia National Laboratories while 9 of the 12 non-BSL-3 laboratories had a security review performed by OPPM.

Site visits were performed from November 2002 through February 2003.

We performed the audit in accordance with generally accepted government auditing standards. To accomplish our objectives, we used the following audit steps and procedures:

- Reviewed applicable laws, regulations, and guidance concerning biological agents.
- Reviewed the BSL-3 manual, dated August 2002, and the non-BSL-3 manual, dated April 2003.
- Reviewed reports of OPPM site security assessments for selected field facilities.
- Examined reports of Sandia National Laboratories site security reviews for selected field facilities.
- Interviewed laboratory and agency officials responsible for handling, storing, and disposing of biological agents.
- Conducted spot-checks using laboratory inventories of biological agents or toxins to identify discrepancies.

Exhibit A – Recommendations – Audit Report No. 50099-13-At

Recommendation Number	Recommendation
1	Hasten the implementation of the policies and procedures being prepared by the Department's biosecurity task force.
2	Direct all agencies to instruct USDA laboratories to compile a comprehensive list of biological agents handled or stored at their respective facilities and to forward this list to the agency's headquarters for consolidation at the Department level. This inventory record should include all laboratories, by agency, showing the biosafety level for each facility and a current inventory that easily identifies all biological agents. Ensure that the inventory record is secure and readily accessible by managers at the headquarters level. Establish a date for accomplishing these tasks.
3	Based on the inventory of biological agents for each facility, each agency should immediately assess the risk associated with such biological agents and determine the commensurate biosafety and biosecurity level required for such agents.
4	Evaluate the results of security reviews conducted at two of the Department's BSL-3 laboratories (laboratories E and F) and directly implement corrective actions related to security issues. Arrange security reviews for other USDA laboratories beginning with level-3 facilities.
5	Immediately assesses the feasibility of continuing current research and diagnostic activities at the facilities located in the strip mall.
6	Take immediate action to correct the deficiencies at laboratory B, including the problems with inventory of biological agents, containment procedures, and physical security.
7	Propose to the Secretary that one individual at the Department level be responsible for monitoring and reviewing the physical security at USDA laboratories to ensure adequate security.
8	Immediately review security procedures to make certain that access to high consequence biological agents is controlled and limited to authorized purposes. Institute management controls to ensure that unauthorized removal does not occur by restricting access to facilities and laboratories handling or storing such high consequence biological agents to personnel with authorized access and appropriate identification. Track the removal and return of samples of dangerous pathogens.
9	Immediately determine the required background checks and security clearances for personnel who have access to high consequence biological agents, particularly those with access to level-3 laboratories. Establish a protocol for approving authorized access to such materials. Also, work with the Department to reduce the backlog of security clearances.
10	Immediately issue a notice to all laboratory facilities with high consequence biological agents that they must report any improprieties or vandalism involving such materials to the agency's headquarters office, which will in turn notify the Office of Inspector General and the other relevant offices.

United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

February 10, 2004

TO: Robert W. Young
Assistant Inspector General for Audit
Office of Inspector General

FROM: Jeremy Stump
Homeland Security Director
U.S. Department of Agriculture

SUBJECT: OIG Audit Report No. 50601-10-At -- Follow up Report on the Security of Biological Agents at the U.S. Department of Agriculture Laboratories

We wish to comment on items that we believe should be addressed and included as part of the final audit report.

Below is our response to each of the recommendations.

Recommendation No. 1.
Verify that all Health and Human Services (HHS) and USDA listed agents and toxins have been removed from the strip mall facility and report back to OIG.

Departmental Response. APHIS has verified via internal reviews (December 2002 and October 2003) that there are no listed agents at the strip mall site, in particular no Bovine Spongiform Encephalopathy (BSE) slides. No discrepancies were found.

Recommendation No. 2.
Provide more specific guidance to BSL-3 laboratories on how to interpret and enforce the biosecurity measurers listed in the BSL-3 manual.

For example:

- Site-specific guidance for inventory record keeping.
- The type and frequency of internal reviews to be conducted and by whom.
- Site-specific guidance for cyber security issues.

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Departmental Response. USDA is in the process of reviewing several inventory systems to determine if any would be suitable for general use in ARS laboratories. The question of how to handle the removal of miniscule samples from the repository stocks will require additional study.

Agriculture Research Service (ARS) agrees that internal reviews of individual laboratories would improve compliance with the appropriate Departmental Manual for security. It is the intention of ARS to develop procedures for such reviews by April, 2004. These procedures will include both reviews by the Area Office, and unscheduled random reviews by components of ARS Homeland Security and/or NPS. Once the policy is developed, it will be conveyed to the ARS locations.

The ARS Office of the Chief Information Officer (OCIO) is actively working with the laboratories to develop cyber security plans. Requirements have already been met for compliance with the Select Agent Rule for those seven locations where it applies. Specific guidance for what material may be placed on the web without violation of Sensitive Security Information will need to come from the Department OCIO. Other ID related Business Recovery Plans, such as Disaster Recovery Plans, IT Contingency Plans, and Cyber Incident Response Plans, involve cyber security and are being developed under a Departmental contract with CRI that will provide templates by the end of 2004.

The OIG report mentions, in several locations, the need for access controls including security clearances. ARS would like to point out that background investigations for public trust risk positions are not the same as National Security Clearances. Although all persons having access to select agents and toxins are at least moderate public trust risk level and require a limited background investigation, a security clearance is only required if the person is handling classified documents or attending meetings where classified information is discussed.

APHIS and Sandia Laboratories collaborated on the USDA Biological Reference Standard. This manual is currently in the draft stage. In addition, the APHIS/ARS facility located in Ames, Iowa, collaborated with Sandia in the development of a site-specific Security Manual. A similar manual for the Plum Island facility will require coordination with the Department of Homeland Security, and this will commence at their discretion.

Recommendation No. 3.
Update the Policies and Procedures to include requirements in regulations published subsequent to the manual's issuance.

Departmental Response. USDA is planning to revise the Policies and Procedures in May of 2004 to include the appropriate CFRs for select agents and toxins, and to expand coverage to BSL-2 laboratories with select agents and toxins.

Recommendation No. 4.
Expedite the implementation of the policies and procedures for non-BSL-3 laboratories.

Departmental Response. USDA will expand efforts to ensure that laboratories comply with the appropriate Departmental Manuals for security. The status of APHIS's entire facilities is elevated to that of BSL-3 since those pathogens are present. Physical security is provided by locking laboratories when researchers are not present in those labs. Inventories are maintained & updated for bacterial cultures under study. Access is restricted to labs, and visitors are escorted within the facilities. Employees are subject to a standard clearance process used by the agency.

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The FSIS Field Service and Microbial Outbreaks and Special Projects laboratories use the USDA Policies and Procedures Manuel for Laboratories and Technical Facilities (Excluding Biosafety BSL03 Facilities) as a reference for providing appropriate technical guidance at FSIS non-BSL-3 laboratories. After reviewing the requirements of the USDA Policies and Procedures for non-BSL-3 laboratories, FSIS determined that the Standard Operating Procedures, security plans, continuation of operation plans, and emergency plans in effect in the non-BSL-3 Laboratories meet or exceed the requirements set forth in the Policies and Procedures manual.

If you have any questions, please contact Tim Johnson in the Homeland Security Staff at 202-720-3632.