U.S. Department of Agriculture

Office of Inspector General
Southeast Region

Audit Report

Controls Over Biological, Chemical, and Radioactive Materials at Institutions Funded by the U.S. Department of Agriculture

Government-wide Policies are Needed to Establish Security Standards for Federally-Funded Research at Non-Federal Institutions

Report No. 50099-14-At
September 2003

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250

DATE: SEP 29 2003

REPLY TO
ATTN OF: 50099-14-At

SUBJECT: Controls Over Biological, Chemical, and Radioactive Materials at Institutions Funded by the U.S. Department of Agriculture

TO: Jeremy Stump
Acting Director
Homeland Security
Office of the Secretary

Joseph Jen
Under Secretary
Research, Education, and Economics

William Hawks
Under Secretary
Marketing and Regulatory Programs

Mark Rey
Under Secretary
Natural Resources and Environment

John Surina
Acting Assistant Secretary
for Administration

This report presents the results of the subject audit. Your July 18, 2003, response to the draft report is included as exhibit A with excerpts and the Office of Inspector General's position incorporated in the relevant Findings and Recommendations sections of the report.

Based on your response, we have accepted management decision on all recommendations in the report. Follow your internal agency procedures in forwarding final action correspondence to the

Office of the Chief Financial Officer. Final action on the management decisions should be completed within 1 year of the date of this report to preclude being listed in the Secretary's Management Report.

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

Richard D. Long

RICHARD D. LONG
Assistant Inspector General
for Audit

Executive Summary

Controls Over Biological, Chemical, and Radioactive Materials at Institutions Funded by the U.S. Department of Agriculture (Audit Report No. 50099-14-At)

Results in Brief

In its effort to assist the Government in strengthening homeland security since September 11, 2001, the Office of Inspector General (OIG) continues to review those activities of the U.S. Department of Agriculture (USDA) that could be vulnerable to terrorist attacks or could enable terrorists to mount attacks within this country. As part of this effort, we reviewed institutions that receive USDA research funding to conduct research into animal and plant diseases and evaluated the controls these institutions exercise over biological agents and toxins, and chemical and radioactive materials used in their research. In the wrong hands, some of these agents or materials could pose a risk to human health and agricultural production in the United States.

This review follows an audit we performed last year of security at laboratories operated directly by USDA.[1] The deficiencies we noted during that audit occurred because prior to September 11, 2001, managers concentrated on biosafety rather than biosecurity—on ensuring that hazardous materials were not a threat to workers rather than safeguarding the materials against access by unauthorized persons. Since that time, the President has signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The Act requires the Secretary of Agriculture to establish and maintain a list of each biological agent and toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products.[2] To comply with the Act, research laboratories that possess these biological agents and toxins must register them with the Animal and Plant Health Inspection Service (APHIS), the agency designated as responsible for regulating animal and plant pathogens. The Act also requires the Secretary to establish and enforce security standards to prevent these agents and toxins from being used by domestic or international terrorists or by any criminal enterprise. Provisions of the earlier United and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act, known as the USA PATRIOT Act of 2001, require laboratories to ensure that these agents and other hazardous materials are kept out of the hands of illegal aliens or individuals with criminal records.

The objectives of our review were to determine whether the non-Federal research institutions that received USDA funding established adequate security procedures for their laboratories and ensured that biological agents and toxins,

[1] OIG Audit Report No. 50099-13-At, "Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture," dated March 29, 2002.

[2] Biological agents and toxins are classified according to their risk of harming animals or plants—high risk if causing lethal infection, low risk if being relatively benign. Most USDA-funded laboratories use or store moderate or low risk agents. *Bacillus anthracis* (Anthrax) is considered a moderate risk biological agent in its unweaponized form.

and chemical and radioactive materials in the laboratories were secured against unauthorized removal.

We visited 104 laboratories at 11 USDA-funded institutions and determined that although some of the institutions had implemented security standards on their own, there were no consolidated standards, either Federal or institution-wide, that provided guidance on security to the laboratories. Guidance from USDA and other Federal agencies has largely been limited to provisions in the research grant agreements, in which the USDA funding agencies have included safety precautions, grant expenditure requirements, and animal welfare advisories. Furthermore, many institution officials, like their USDA counterparts, concentrated on biosafety rather than biosecurity. Those that manifested a concern with security were generally those whose laboratories had experienced break-ins or domestic terrorist attacks prior to September 11, 2001.

Some direction had been issued by separate Federal agencies, but these agencies were concerned only about their own grants to the institutions or their own jurisdictions. The most complete guidance came from the Nuclear Regulatory Commission, which prescribed strict measures for handling, storing, and securing radioactive materials. Other direction was fragmented among the Environmental Protection Agency, the Occupational Safety and Health Administration, and USDA. We concluded that institution officials, concerned about finances, would implement those measures needed to qualify for the grant money, but would not always provide security commensurate with the risks entailed in possessing the materials.

As a result of fragmented Federal guidance to the institutions, of minimal USDA guidance to the grantees, and of inconsistent institutional guidance to the laboratories, we found deficiencies in inventory controls over biological materials, in physical security at the laboratories, and in access to research areas.

- Institutions had no centralized databases to allow officials to identify the location and risk levels of the biological agents and toxins at their laboratories. We concluded that without such a database, officials cannot adequately determine if the containment and security at the laboratories are commensurate with the risk associated with the agents. Although some laboratories at the institutions did maintain an inventory of their biological agents, not all did, and few of the inventories we reviewed were accurate.

  – We discovered a Centers for Disease Control and Prevention (CDC) select agent at one institution that was kept in an unsecured freezer and for which no risk assessment had been made. The agent, Yersinia pestis, causes bubonic and pneumonic plague and requires strict containment. The freezer that stored this agent had not been

inventoried since 1994, when a box of unidentified pathogens was already noted as missing.

- A laboratory at a second institution claimed to have Actinobacillus pleuropneumoniae[3] stored in its freezer, but it had never inventoried the freezer completely to identify how many vials or containers if any of the pleuropneumoniae pathogen it actually had and how much it ought to have had.

- Institutions had no consistent policies on background checks and on screening employees and visitors.

- Security measures at 20 of the 104 laboratories were not commensurate with the risk associated with the pathogens they housed. These 20 laboratories represented over half of the laboratories in our sample that stored high consequence pathogens. Alarm systems, surveillance cameras, and identification badges were commonly lacking in buildings housing the laboratories, and key-card devices or sign-in sheets were not generally used to record entries to the laboratories.

USDA's responsibility for providing guidance to the laboratories is largely exercised through grant agreements entered into by the Cooperative State Research, Education, and Extension Service (CSREES), and through permits issued to the laboratories by APHIS. The APHIS permits are used to monitor biological agents entering the country and moving between locations within the country. In addition, other agencies such as the Agricultural Research Service (ARS), the Food Safety and Inspection Service (FSIS), and the Forest Service (FS) may provide funding or assistance for research through cooperative agreements with universities and private labs. Neither the grant agreements, the cooperative agreements, or the APHIS permits stipulate any security requirements for the pathogens being transported or used in the laboratory research.[4] APHIS, as directed by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, published security regulations for high consequence biological agents and toxins on December 13, 2002. However, these regulations only apply to the agents and toxins on APHIS' list, not to other harmful pathogens, such as Actinobacillus pleuropneumoniae.

Some of the institutions we visited had established practices that offered good models of security. For the most part, these institutions acted on their own, independently of any State or Federal mandates.

[3] Actinobacillus pleuropneumoniae is a pathogen that causes a severe and often fatal contagious disease in swine.

[4] We recently conducted a review of APHIS' controls over permits used to import biohazardous materials into the United States (Audit No. 33601-4-Ch, issued March 31, 2003).

- Computerized key-cards have been used successfully to deny access to unauthorized persons and monitor the movements in and out of the laboratories of those to whom the cards were issued.

- To enhance control of its chemical inventory, one institution is implementing a system of bar-coding chemicals and tracking them with bar-code readers. This institution also has a central purchasing facility that helped reduce the quantities of hazardous chemicals in the laboratories by ensuring that researchers have had to order only necessary chemicals and by encouraging them to consider less hazardous alternatives.

We are recommending that these practices be incorporated into a Federal standard for security at land grant universities and other entities receiving Federal grant monies. We are also recommending that until Federal standards are promulgated, USDA should share with its grantee institutions those best practices already implemented individually. Some scientists and professional organizations, notably the Experimental Station Committee on Organization and Policy, have recognized a need for greater security and for consistent guidance on implementing security standards throughout the research establishment. Although USDA can put forth its own requirements, it cannot guarantee that the requirements will satisfy the needs of other agencies financing research. Sharing the institutions' current best practices offers one approach to establishing consistent security over hazardous material.

Recommendations In Brief

We are recommending that the issues we raise in this report be elevated to the Department of Homeland Security[5] and to the Executive Office of the President, Homeland Security Council[6], and recommend that a consolidated set of security standards be established with the cooperation of all affected departments, to be implemented by all non-Federal institutions receiving Federal grant monies to engage in laboratory research. We are recommending that these standards call for:

- A centralized database of all biological materials stored at an institution.

- Written procedures concerning background checks and reporting missing pathogens.

[5] The Homeland Security Act of 2000, Public Law 107-296, dated November 25, 2002, established the Department of Homeland Security as an executive department of the United States with the mission of preventing terrorist attacks within the United States, reducing the vulnerability of the Country to terrorism, and minimizing the damage, and assisting in the recovery from terrorist attacks.

[6] Signed by the President on October 29, 2001, President Directive-1 established the Homeland Security Council to ensure coordination of all homeland security-related activities among executive departments and agencies and promote the effective development and implementation of all homeland security policies.

- Risk assessments of laboratories and security upgrades based on the risks assessed.

Until a consolidated set of security standards is in place at the Executive level, we are recommending that USDA be proactive and provide guidance on security to its grantees by sharing with those institutions the Department's own policies on USDA laboratory security, as set forth in the Department Manual, as well as the best practices implemented by the institutions themselves.

Departmental Response

The Department generally agreed with the findings and recommendations in our report. Specifically, the Department agreed that a consolidated set of security standards should apply to all organizations handling various types of biohazardous material. Department officials have begun and plan to continue discussions with the Homeland Security Council regarding biohazardous materials to include those issues identified in our report. The Department has also provided guidance to USDA client organizations that is based on the Department's policy and procedures manual for biosafety level (BSL)-3 laboratories. Additionally, CSREES plans to modify its "Terms and Conditions" for entities receiving USDA funding by February 1, 2004, to incorporate biosecurity provisions.

OIG Position

We agree with the actions taken and planned by the Department in response to the report's recommendations. Therefore, we have accepted management decision on all recommendations and are not requiring any further followup response from the Department or any of the agencies. The Department's written response is included as exhibit A of the report.

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Background and Objectives

Background

The U.S. Department of Agriculture (USDA) provides funding for research of animal and plant diseases at facilities throughout the United States as well as in Canada and other foreign countries. The funding is primarily made available through the Cooperative State Research, Education, and Extension Service (CSREES), which awards grants to institutions based on the quality and direction of the research proposed. Research proposals are submitted by experts in their fields, usually college faculty members, but also researchers affiliated with private laboratories. An applicant whose proposal is awarded a grant is designated the principal investigator of the research. According to CSREES' grants management tracking system, as of September 30, 2002, the agency was administering grants to 15,000 projects undertaken by both public and private institutions. Other agencies such as the Agricultural Research Service (ARS), the Food Safety and Inspection Service (FSIS), and the Forest Service (FS) may provide funding or assistance for research through cooperative agreements.

Institutions engaging in USDA-funded research use any combination of radioactive, chemical, and biological materials in their work. Currently, each of these materials has its own Federal regulatory agency to prescribe the safety precautions the institutions need to take in using and storing the material. The Occupational Safety and Health Administration (OSHA) regulates the use of chemicals in the workplace; the Nuclear Regulatory Commission (NRC) is responsible for regulating nuclear facilities and materials;[7] and the Centers for Disease Control and Prevention (CDC) issues safety regulations for handling and storing biological agents and toxins that are dangerous to workers and the public. USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for regulating animal and plant pathogens that are transported to laboratories from foreign countries or through interstate commerce.

Biological agents and toxins are of concern to both CDC and USDA and are the basic materials of the research. CDC assigns each biological agent and toxin a biosafety level (BSL) that describes the level of containment that must be used to protect researchers from the pathogens. Laboratories that work with agents and toxins that have a low risk of infecting humans are classified as BSL-1 laboratories. Laboratories that work with agents and toxins of moderate risk (e.g., E coli, Salmonella)[8] are classified as BSL-2. Laboratories that use agents and toxins that may cause lethal infections as a result of exposure by inhalation (e.g., Rift Valley fever)[9] are classified as BSL-3. To this BSL-3 classification, USDA has added a subsidiary category. Although CDC classifies Foot and Mouth Disease and other like pathogens as

[7] This includes only materials for civilian use, and does not include materials for military use, those used in nuclear accelerators, and naturally occurring radioactive materials.

[8] These examples were taken from the CDC list of BSL-2 agents.

[9] This example was taken from the CDC list of BSL-3 agents.

BSL-2 agents, USDA classifies this and other plant and animal pathogens that could have major adverse consequences to United States agriculture as BSL-3 agents. Some of these agents are transmitted by means other than inhalation; e.g., by ingestion or arthropod vectors.

The newly passed Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires persons in possession of biological agents and toxins that pose the greatest threat to the public and to the nation's plants and animals to notify CDC and/or APHIS. CDC and APHIS each published a list of agents in these categories. CDC's list, published through regulation 42 Code of Federal Regulations (CFR) part 72, and referred to as the list of "select agents," contains 36 viruses, bacteria, fungi, toxins, and rickettsiae that are lethal to humans. These include Yellow fever, Ebola, and Anthrax. APHIS' list of "high consequence biological agents and toxins" contains 41 biohazardous agents that can destroy plants and animals. These include Foot and Mouth Disease, Bovine Spongiform Encephalopathy (mad cow), and botulism. Persons had until September 10, 2002, to notify CDC and until October 11, 2002, to notify APHIS of any of the listed biological agents and toxins in their possession.

Some pathogens appear on both USDA's list and on CDC's select list (known as "overlap" agents). Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, USDA and CDC's parent organization, the Department of Health and Human Services (HHS), will enter into a memorandum of understanding regarding agents and toxins that both departments are required to regulate. The memorandum of understanding will provide for the development and implementation of the following.

- Single registration system regarding registered persons.
- Shared process of identification to ensure that only authorized persons have access to overlap agents and toxins.
- Coordination of inspections and enforcement.
- Joint regulations.

CDC and APHIS will also coordinate activities to minimize any conflicts between the regulations and activities carried out by each and the administrative burden subject to regulations under each. This coordination will also ensure that the registration information is contained in the national databases for both agencies. Both APHIS and CDC published interim rules in the December 13, 2002, Federal Register to conform to the remaining provisions of the Act.

APHIS also has a responsibility to ensure the public is properly protected against any pathogen in transit that could threaten animal or plant life. Because laboratories obtain their agents from sources both inside and outside the country, pathogens are shipped across borders and across State lines.

APHIS' Plant Protection and Quarantine division administers permits for transporting plant pathogens, and its Veterinary Services division administers permits for organisms affecting animals.

This audit follows a similar review we completed and reported on last year concerning biosecurity at laboratories that are administered entirely by USDA. Our audit report (50099-13-At, dated March 2002) noted concerns about security at these USDA laboratories and especially about the absence of a centralized database that agency managers could use to determine where biological agents were located and what security measures would be appropriate for each location.

We also determined that the emphasis at the USDA laboratories prior to September 11, 2001, was on safety, not security. USDA managers, along with CDC, directed their regulatory messages at ensuring that the biological agents did not endanger laboratory workers. Little emphasis was placed on ensuring that the biological agents were themselves secured against unauthorized possession or use.

After our audit of USDA laboratories, the Department issued Department Manual 9610-1, *USDA Security Policies and Procedures for Biosafety Level-3 Facilities*, dated August 30, 2002. This manual defines USDA requirements to secure USDA-held pathogens at BSL-3 facilities and offers detailed guidance on implementing a biosecurity plan to include physical security of the facilities and access controls to prevent unauthorized persons from entering the laboratories.

Because of the conditions we noted in our review of USDA-administered laboratories, we decided to review security of biological agents and other hazardous material used and stored in non-Federal institutions receiving USDA financial assistance to engage in research. These are largely at land grant universities, which already receive Federal funding for other programs. However, some of the institutions are privately operated, and some are located outside the United States, in Canada and Europe. None of the USDA-funded institutions are subject to the requirements for USDA-administered facilities set forth in Department Manual 9610-1.

Other Federal direction on securing hazardous material comes through CDC and the United and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, known as the USA PATRIOT Act. The USA PATRIOT Act sets forth strict guidelines on who may not be authorized to possess or use biohazardous material. The Act requires laboratories to deny access to illegal aliens, mental defectives, fugitives from justice, and persons with other undesirable pasts. CDC's Appendix F to its manual, *Biosafety in Microbiological and Biomedical Laboratories*, provides guidelines that address security issues for laboratories

using biological agents or toxins capable of causing serious or fatal illness to humans or animals. Government-funded laboratories must comply with the requirements of the USA PATRIOT Act.

Objectives

The objectives of the audit were to evaluate controls and security (commensurate with risk) over biological agents and toxins, and chemical and radioactive materials at universities, colleges, and private labs[10] that receive USDA financial assistance for research. Specifically, we performed work to determine whether institutions (1) established security requirements and guidelines for their laboratories, (2) implemented controls to ensure accountability of hazardous materials and to restrict access to authorized persons, and (3) implemented adequate physical security at laboratories in which hazardous materials were used. We also performed steps to determine whether USDA provided adequate instruction and guidance to its grantee institutions to ensure that all biological agents and toxins, and chemical and radioactive materials used for USDA-funded research were secured against unauthorized use.

Our review was performed during the summer of 2002. We visited 104 laboratories at 11 institutions across the United States. Only one of these institutions was a private laboratory. See the Scope and Methodology section at the end of this report for details concerning our review sample.

[10] Private laboratories are those operated by entities other than the Federal Government or universities; e.g., for-profit, commercial entities.

Findings and Recommendations

Section 1. Institutional Oversight

Institution officials have given inconsistent guidance to their laboratories concerning security over hazardous biological and chemical materials. At the 104 laboratories we visited, some security measures were evident, but these were based largely on safety considerations and were unrelated to the risk that dangerous pathogens could be accessed by potential terrorists, illegal aliens, criminals, or other restricted individuals listed under the USA PATRIOT Act of 2001. In addition, institutions did not always have emergency response plans to prepare for terrorist intrusions at the laboratories. The absence of guidelines was apparent in three critical areas:

- Only 1 of the 11 institutions we visited had a centralized database to maintain an institution-wide summary-level inventory of the biological materials under their administration. Only 1 had a centralized inventory for chemicals. We concluded that without a centralized inventory, the institution cannot adequately assess the security risk associated with each laboratory and determine the appropriate measures needed to guard the materials stored in the laboratories.

- Although some of the institutions may have performed some background checks of research faculty and staff, these checks were limited to the State and local resources available to the institution. Information from national and international sources was not available.

- Six of the institutions had established no formal procedures for reporting missing pathogens.

Institutions had formulated no coherent policy on security because the grants came from multiple sources and adhered to no consolidated Federal standard. Standards that had been developed within USDA for biological materials applied only to USDA laboratories and were not circulated to the institutions as guidance on security issues. Those materials for which security appeared consistent—i.e., radioactive—are strictly regulated by the NRC. Funding for research using biological materials, by contrast, is governed by grant agreements from at least 11 different Federal agencies.

We concluded that the Federal Government should issue one set of standards governing security of hazardous materials. Consequently, we are recommending that the Department elevate this issue to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council.

Finding 1 — Lack of Emphasis on Security at Institutions Receiving USDA Funding for Research Resulted From No Government-wide Standards

Institutions did not exercise consistent security oversight for laboratories under their administration, and the Federal Government has issued no consolidated regulations covering the responsibilities of grant recipients to provide security for their laboratories. Nor had USDA taken any initiative to provide security guidance of its own prior to the time of our review. Although some institutions have implemented their own security measures, many have continued to emphasize employee safety—ensuring that laboratory personnel are protected from hazardous material—rather than laboratory security—ensuring that such materials are not accessible to unauthorized personnel. Without a standard minimum level of security, there is a potential that laboratories could experience unauthorized entries and that the loss or theft of high consequence pathogens could go undetected.

Unlike USDA-controlled laboratories that are subject to USDA regulation, institution laboratories receive funding from a wide spectrum of Government departments and are consequently regulated by no one department. USDA's security policies and procedures, set forth in Department Manual 9610-1,[11] establish security requirements only for USDA-controlled laboratories. However, the measures the manual calls for—inventory controls, incident response plans, facility risk assessments, and personnel suitability—are the basic elements of any security system. USDA could informally circulate these policies and procedures to its grantee institutions as a form of guidance, but it has not done so. At the time of our review, it confined its guidance to the grant agreements, which address only grant expenditure requirements and safety procedures. (Finding 5 in this report explains the limits of USDA's authority as a research funding source and the potential role USDA could play in initiating security standards at federally funded laboratories.) Federal agencies on the whole have left each individual institution to define its own security needs.

We found that eight institutions did not provide detailed security guidance at the institutional level but, like USDA, passed on the responsibility for setting and enforcing safety and security to the individual researcher in charge of each laboratory. Although institutions provided some guidance, this was general in nature, advisory in approach, or simply not enforced. Of the 11 institutions reviewed, 7 provided no security training to laboratory workers or to emergency responders; and 6 had no comprehensive plan for evaluating security needs and upgrading the security devices to protect buildings, laboratories, and storage areas.

[11] *USDA Security Policies and Procedures for Biosafety Level-3 Facilities*, dated August 30, 2002.

Those institutions that had upgraded security at their laboratories had done so in response to previous break-ins or attacks by domestic terrorists and not as a result of the events of September 11, 2001. Domestic terrorists attacked a number of institutions during the 1990's. One institution that experienced such an attack introduced a key-card entry system to limit access to laboratories that housed animals used in research. Although the purpose of the added security was to protect the facilities, the animals, and the individuals working in the laboratories, it had the additional benefit of limiting access to high consequence pathogens located in the facility.

Even though some institutions had taken steps to increase security on their own, they were generally waiting for direction from the Federal Government. At one institution when security was increased, it was done as part of the design of new buildings, not as an upgrade to older facilities. We were told that it was much more cost effective to design security into a new building rather than retrofit an existing one. However, we found that higher risk research did not determine a laboratory's location within a more secure building. Location in a newer building was a function of how well research was funded.

Funding the costs associated with improved security was a major concern at every institution. We were provided with cost estimates on security items ranging from key-carded doors to entirely rebuilt laboratories. Most institutions further noted that they were experiencing reduced funding at the State levels, and that they may have to decide between increasing security and discontinuing research. However, as risks increase (e.g., working with pathogens that have a high potential for use as biological weapons) at the laboratories, costs should become less of a consideration.

Emphasis at the institutions has been on safety rather than security because prior to September 11, 2001, safety was the main concern of Federal regulators, including CDC. The BSL ratings for laboratories using biohazardous material were established by CDC as guides to biosafety and cautions to laboratory managers of the containment equipment required to reduce the danger of exposing workers and others to certain pathogens used in research. Similarly, direction provided by OSHA for hazardous chemicals considered only the danger those chemicals posed to their users.

The security guidance issued at the institutional levels resulted in some useful practices but no overall standard from one institution to the next. At one institution, for example, officials estimated that monetary fines for laboratories violating environmental quality standards had increased compliance with safety requirements by 80 percent and could be adjusted to include security requirements. None of the other 10 institutions levied such fines or performed surprise inspections on which to base the fines. In approaches to emergency planning, two institutions have included the use of local authorities as first

responders to incidents and accidents at the laboratories. One institution formed its own HAZMAT Team that not only serves as the first responder for the institution, but also for the city and county in which it is located. Conversely, two other institutions have given little attention to emergencies and have not trained response teams or informed them of the locations of biohazardous materials on site. Four institutions we visited require authorization from their environmental health and/or safety divisions before the laboratories can handle biohazardous material. The other institutions do not.

One institution took action after the September 11 attacks to conduct a comprehensive inventory of its biohazardous materials. By destroying all pathogens that were not needed, the institution was able to reduce the number of laboratories containing these materials by 40 percent and correspondingly reduced its security risk. Conversely, nine institutions had no institution-wide requirement for an inventory of biological agents.

Although the Federal Government has recently passed statutes identifying the security risks involved with using and storing certain pathogens, regulations have until now only governed the transportation of biological materials. Both CDC and APHIS have required institutions to notify them of their intention to obtain agents pathogenic to humans, animals, and plants. CDC and APHIS are responsible to ensure that the laboratories receiving certain pathogens are equipped to store them safely. Beyond this one piece of Government oversight, there have been no Federal requirements on security of federally-funded laboratories. Only since September 11 have security considerations formed the subject of legislation, notably the USA PATRIOT Act of 2001 and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Prior to these Acts, the bulk of Federal requirements imposed on institutions have been unrelated to security and have appeared only in the separate and distinct conditions laid down in the grant agreements administered by the many Federal agencies awarding the research grants.

Enforceability of the conditions in any agreement comes through the threat to withhold grant funding for that one particular grant, and the numerous Federal agencies funding research grants have made no coordinated effort to inspect laboratories and implement biosecurity requirements. Consequently, grant conditions and enforcement of those conditions are spread across the Government spectrum. Typically, institutions receive Federal research funding from HHS, the National Science Foundation, the Department of Agriculture, the Department of Defense, the Department of Energy, and many other Federal sources.

The chart below illustrates the multiple sources of Federal grant funding at one of the institutions we visited.

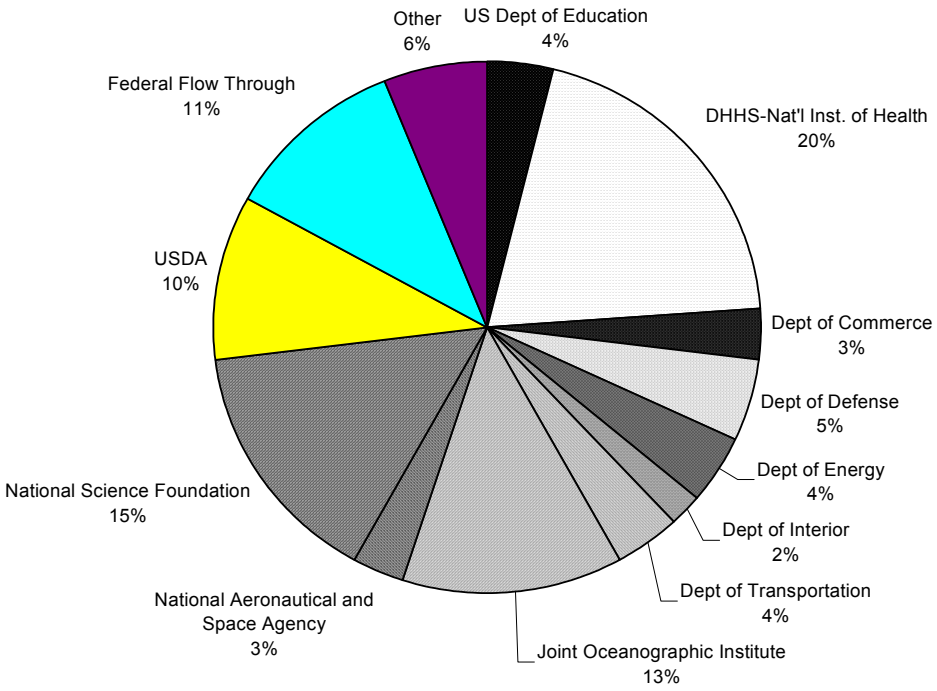

Figure 1: Federal Funding Sources for Research at One Institution Visited.

Each of these Federal departments would have to provide its own security requirements in grant agreements, resulting in a patchwork of requirements that may simply be costly variations of one another. The Government has avoided such duplication of effort in the cases of chemical and radioactive materials. OSHA provides the safety standards for chemicals while Environmental Protection Agency regulates chemical waste, and NRC provides the safety and security standards for radioactive materials. Radioactive materials in particular are subject to strict NRC oversight. To meet NRC requirements, institutions maintained systems to track requests for certain radioactive substances, receipts, inventory, and disposal of the substances. We concluded that Federal standards issued by one agency could result in consistent responses by institutions and produce overall compliance.

Although the institutions we visited did not discuss with each other their security practices, many of these practices could form the basis for Federal standards. The successful use of key-cards to log researchers in at laboratories at one institution has already proven the value of that device. The protocols followed at another institution that required researchers to obtain institutional permits before beginning research could be established as a required control for all Government-funded laboratories.

Officials at many of the institutions we visited indicated that they would welcome the standards. At least one professional organization, the Experiment Station Committee on Organization and Policy, has acknowledged the need for security standards across the spectrum of institutions receiving Federal grants and has recognized the value of Government involvement. Mandates made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and by CDC and APHIS requirements to register the possession of select list biological agents have given the issues of biosecurity at the institutions greater priority than they have had in the past. Further direction from the Government is needed to help the institutions understand what they must do to implement the new mandates and to ensure security measures are consistent with the risks posed by the pathogens possessed.

We concluded that although USDA can impose security standards of its own in its grant agreements (see Finding 5), a more useful method of achieving consistent levels of security by all Government-funded laboratories is through a broader authority. The Department has held preliminary discussions with the Office of Homeland Security and the Office of Science and Technology Policy (OSTP)[12] on the need to go forward with Government-wide security standards for non-Federal laboratories receiving Federal funding. We are therefore recommending that the Department elevate the issue to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council. There, the Department of Homeland Security, the Homeland Security Council, or the OSTP, could, in cooperation with all affected Federal departments, establish and publish a consolidated set of security standards for research institutions.

Recommendation No. 1

Elevate the issues we raise in this report to the Department of Homeland Security and to the Executive Office of the President, Homeland Security Council, with the recommendation that they or OSTP in coordination with CDC, APHIS, and other Federal agencies publish a consolidated set of security standards to be implemented by all institutions working with CDC select agents and toxins and APHIS listed agents and toxins.

Departmental Response. In the July 18, 2003, response, the Acting Director of Homeland Security stated, "We agree that these important issues should be elevated to an appropriate level for governmentwide consideration. We have already begun and will continue discussions with the Homeland Security Council."

OIG Position. We accept management decision for this recommendation.

[12] The OSTP was established by Congress in 1976 to advise the President on science and technology matters and to lead an interagency effort to devise sound policies in cooperation with the private sector, State and local governments, and higher education communities.

Finding 2 Institutions Have Not Established Procedures to Account for Biohazardous Materials and to Restrict Access to Pathogens

Institutions did not have procedures in place to account for biohazardous materials or to ensure that only authorized persons were given access to the pathogens used and stored in the laboratories. Generally, the institutions did not have consolidated databases to allow officials to identify the location and containment level of biological agents or chemicals. Without such a database, the officials could not perform risk assessments as a basis for establishing security needs at the facilities, and they could not track the pathogens that were imported to the laboratories or that were grown by the researchers themselves. The institutions similarly had no formal protocols for reporting missing pathogens.

The institutions also did not always institute background checks of researchers or other employees with access to the laboratories. Although a few of the institutions reviewed some State criminal records, these reviews were limited and did not answer the requirements of the USA PATRIOT Act of 2001, which mandates that research laboratories ensure that access to hazardous materials is denied to illegal aliens, mental defectives, or persons with a criminal past.

Centralized Database

Although many laboratories kept inventories of some sort, institution officials did not establish a centralized repository for the information and could not provide us with a summary-level inventory of high consequence biological agents and toxins or chemicals used or stored on their campuses. Without such a database, managers cannot assess the risks associated with the individual materials and determine if the current containment and security levels are appropriate for each. Many laboratories did not keep up-to-date inventories themselves and consequently could not ensure that the security provided was commensurate with the risk involved.

As a first step toward improving laboratory oversight and assessing the risk of unauthorized intrusion and the biosecurity needed to mitigate that risk, each laboratory must know what biological agents it stores. Institutions should develop a site-specific, written biohazard control plan. The plan should contain provisions for identifying and accounting for all biological agents, toxins, and chemicals within each facility. Laboratories that handle, maintain, or store known biological agents and their toxins must maintain an accurate inventory of such agents.

Such a database would not only strengthen management oversight, it would provide for offsite data storage so data could be retrieved in the event the laboratory is damaged or destroyed. Most importantly, it could provide the

basis for establishing security measures for each of the individual laboratories and for guiding emergency response teams that must enter the laboratories in the event of a contamination.

Reporting Missing Pathogens

The majority of the institutions we reviewed did not have specific written procedures for reporting missing pathogens. All of the institutions had published a manual on handling, storing, and disposing of biological materials, but these manuals were directed toward the safety of the researchers and workers and not toward the security of the pathogens.

Appendix F to CDC's manual, *Biosafety in Microbiological and Biomedical Laboratories*, which became effective May 1999, offers suggestions to laboratories concerning some aspects of biosecurity. The manual suggests that laboratories should have a protocol for reporting incidents such as missing hazardous materials.

Most of the researchers we spoke to believed that they would know immediately if any pathogens on hand and used in research were missing from their laboratories. In general, laboratory workers, including principal investigators, said that if a pathogen were detected as missing, they would call the department responsible for laboratory safety or the institution police.

Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, effective June 2002, now requires laboratories that experience a theft or loss of agents identified on APHIS' list of high consequence biological agents and toxins to promptly notify the Secretary of Agriculture of the theft or loss as well as appropriate Federal, State, and local law enforcement agencies.

Background Checks

We noted that a security background check was not completed for all personnel who had access to CDC and APHIS agents and toxins. Employees had been given access to these materials based on their own affirmations that they were authorized to do the research. Without adequate background checks, the risk that someone may vandalize or destroy ongoing research or laboratory facilities or remove hazardous organisms is increased.

Background checks have become a critical control over access to high consequence biohazardous material in this country. The USA PATRIOT Act disallows the possession of high consequence pathogens by illegal aliens, individuals who have been adjudicated as mentally defective, and individuals with criminal records. Officials at one institution were unaware of any laws or regulations that required it to conduct background checks. They did not

require any checks themselves because the cost to perform them would be substantial, and the institution did not wish to impose on the personal and academic freedom of its research faculty and staff.

Some of the institutions we reviewed performed some form of criminal check on researchers, but these checks were limited to State and local records. Officials at universities and private laboratories are not given access to the Federal and international databases that generally form the sources of Federal background investigations. For example, one institution performed only limited background checks that did not include checking information that would identify illegal aliens. In an attempt to fulfill the requirements of the USA PATRIOT Act, the institution required the researchers to affirm that they were not illegal aliens or wanted as fugitives from justice.

Background checks were also not performed on foreign scientists and foreign students having access to the laboratories. All of the sites we visited had foreign scientists or students working in the laboratories, and most of these visitors have access to biological material. However, none of these sites did background checks on the visitors. Visiting research scientists and other skilled technicians may be allowed access to the facilities (and the biological agents) based on their reputations in their fields or on their prior working experience with facility officials. Subsequent to September 11, Congress authorized the Attorney General to collect information from institutions with respect to foreign students. A proposed rule in the Federal Register[13] makes the use of the Student and Exchange Visitor Information System (SEVIS) mandatory by January 30, 2003.

Background checks were also not performed on non-researchers who are allowed access to buildings and laboratories. Custodial and maintenance staffs routinely perform duties in facilities housing hazardous materials. We noted that only 14 of the 39 laboratories using CDC or APHIS listed agents and toxins limited access to the laboratories by custodial and maintenance workers to hours when other laboratory workers were present. Only 2 of the 11 institutions we reviewed performed limited background checks on the custodians and maintenance employees.

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, any person authorized to possess, use, and transfer listed agents and toxins must be registered with the Secretary of Agriculture. This Act authorizes the Attorney General to use all available electronic databases—criminal, immigration, national security, and others—to identify whether individuals meet the requirements of registration under the Act. Institutions will not be required to perform background checks themselves, but they must implement procedures to ensure that their researchers register in accordance with the Act so that access to hazardous material is denied to individuals

[13] See Proposed Rules 8 CFR part 214.2 published in the May 16, 2002, Federal Register.

restricted under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and USA PATRIOT Act.

We concluded that a consolidated database is needed to provide the universities and other institutions with better monitoring and oversight of biological agents at their facilities and to establish a basis for assessing the security risks at laboratories on their campuses. We also concluded that guidance needs to be issued to the laboratories concerning reporting stolen or missing pathogens and complying with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. In Finding No. 1, we recommended that the issues in this report be elevated to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council. The following recommendations stress issues that we believe should be addressed in a consolidated set of security standards to be implemented by all institutions working with CDC and APHIS listed agents and toxins.

Recommendation No. 2

Recommend to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council, that Federal standards include direction that all Government-funded research institutions compile a summary inventory of the hazardous chemicals and biological agents and toxins located at their facility. The inventory record should be maintained in a secure location where institution officials could readily access it. (NRC requires current inventories for certain radioactive materials.)

Departmental Response. In the July 18, 2003, response, the Acting Director of Homeland Security stated,

> *We concur with the recommendation and observe that the inventory requirements for listed agents and toxins are contained in 7 CFR Part 331, 9 CFR Part 121 (APHIS) "Possession of Biological Agents and Toxins" and 42 CFR Part 73 (CDC) "Interim Final Rule Possession, Use and Transfer of Select Agents and Toxins". We will include these issues in our ongoing discussions with the Homeland Security Council. We believe the control of hazardous chemicals falls outside of USDA's mission area.*

OIG Position. We accept management decision on this recommendation.

Recommendation No. 3

Recommend to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council, that Federal standards include direction that all Government-funded research institutions use the

inventories of biological agents, chemicals, and licensing requirements for NRC licensed radioactive materials to assess the risks associated with these materials and determine the commensurate security level for them.

Departmental Response. In the July 18, 2003, response, the Acting Director of Homeland Security stated, "We concur with the recommendation and observe that many of these requirements are contained in 7 CFR Part 331, 9 CFR Part 121 (APHIS) and 42 CFR Part 73 (CDC). We will include these issues in our ongoing discussions with the Homeland Security Council."

OIG Position. We accept management decision for this recommendation.

Recommendation No. 4

Recommend to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council, that Federal standards include direction that all Government-funded research institutions establish and implement procedures for reporting stolen or missing pathogens in compliance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Departmental Response. In the July 18, 2003, response, the Acting Director of Homeland Security stated, "We concur with this recommendation and believe that these requirements have been implemented via 7 CFR Part 331 (APHIS), 42 CFR Part 73, and 9 CFR Part 121."

OIG Position. We accept management decision for this recommendation.

Recommendation No. 5

Recommend to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council, that Federal standards include a requirement that all Government-funded research institutions have procedures to ensure that appropriate background checks are performed for all individuals having access to CDC and APHIS listed agents and toxins.

Departmental Response. In the July 18, 2003, response, the Acting Director of Homeland Security stated, "We concur with the recommendation and observe that background checks are presently a requirement for all individuals handling listed agents and toxins."

OIG Position. We accept management decision for this recommendation.

The laboratories we visited generally did not have the controls needed to protect biological agents from unauthorized removal. Physical security at the laboratories was unacceptable compared to the risk posed by the pathogens stored in laboratory freezers. Few of the 63 buildings that housed the laboratories we selected had security guards posted or used security cameras or burglar alarms to detect intrusions. Fewer of the campus departments restricted access to the laboratories themselves. Identification badges were generally not required for laboratory workers, and sign-in logs were not used to record visitors' entries. Missing pathogens would not be immediately noticed because physical inventories were seldom performed to account for the contents of each freezer.

Institutions have not until recently implemented security controls because of the longstanding tradition of openness and individual freedom of movement on the American campuses, as well as the emphasis on safety that prevailed before September 11, 2001. Also, researchers noted that they were not required to keep inventories of their biological agents. Without adequate controls over inventories and laboratory access, there is an increased risk that biological agents could be stolen and misused and pose a threat in United States agriculture.

Finding 3 Researchers Working In Institution Laboratories Were Not Adequately Accounting for Their Inventories of Biological Agents

The research staff working in institution laboratories were not adequately accounting for their inventories of biological agents, particularly those agents on the CDC select agent list that pose a serious threat to public health and safety or on the APHIS list of high consequence biological agents and toxins affecting animal and plant health. Researchers did not always keep a detailed inventory of their biological agents stored in their freezers and seldom performed physical inventories. Furthermore, the institutions had not established uniform policies and procedures to ensure the timely disposal of their inventory when researchers responsible for these agents left the institution.

USDA Department Manual 9610-1, which establishes policies for USDA-controlled laboratories, recognizes an acceptable inventory to be a record of current inventory that will serve as a historical record of pathogens used at the facility and that will include experimental samples used for working stocks or experimental purposes and tracked by laboratory records.

The manual requires that USDA-operated facilities[14] maintain three types of accountability records:

1. Summary level inventory records including the agent name, location, responsible person, and contact information;
2. Detailed inventories of repository materials (i.e., stored in freezers) kept at the research laboratory or facility including agents stored, number of vials or containers, biosafety level, storage location, disposition when removed from inventory, and other important information; and
3. Materials accountability for experimental or working samples accurately tracked by laboratory notebooks or electronic means.

The Department Manual also states that a physical review will be performed at least annually and that the methods used during physical review or reconciliation may include counts of entire inventory or statistical sampling or records and repository materials (i.e., a periodic physical inventory).

Forty-three of the laboratories we visited did not maintain detailed inventory records for their biological agents stored in freezers, and only a few conducted periodic physical inventories. Our review disclosed two instances where inventory controls could have established whether biological agents were actually missing or stolen, allowing the Government to prepare for the serious consequences of such a theft.

- At one institution an unlocked freezer contained seven vials of a Category A[15] CDC select agent, Yersinia pestis, which causes bubonic and pneumonic plague. Pneumonic plague is more severe than the bubonic plague, or Black Death, and is an airborne pathogen that infects the victim's lungs, where it produces a frothy, bloody liquid. Pneumonic plague is almost 100-percent fatal within 48 hours of symptom onset.

  The agent was stored in the freezer since 1981 when the principal investigator left the institution. The freezer was not located in a research laboratory but in a preparatory area under the control of a science lecturer who teaches undergraduate courses in molecular biology. Furthermore, in reviewing the inventory record for the freezer, we noted that it did not adequately account for the freezer's contents. It was not a record of working stock (it was dated November 1994 and was the only existing inventory record for the

[14] USDA's Manual 9610-1 does not prescribe requirements for USDA-funded, non-Federal institutions.

[15] Category A denotes the highest priority agents on the CDC select agent list. These agents pose a risk to national security because they (1) can be easily disseminated or transmitted from person to person, (2) result in high mortality rates and have the potential for major public health impact, (3) might cause public panic and social disruption, and (4) require special action for public health preparedness.

freezer), and it did not include everything that was currently stored in the freezer.

According to the inventory record, the freezer contained a total of seven canisters. One canister contained the Yersinia pestis, but the inventory record did not show the number of vials of the pathogen stored in the canister, or the number of vials stored for any of the other agents in the freezer. A second canister was missing a box, but there was no record of the disposition of that box. Also, because the entries on the inventory record were difficult to understand, the custodian could not determine from the record what biological agents were stored in a third canister.

The inventory record also indicated that one of the canisters contained Clostridium perfringens. This is a Category B[16] CDC select agent when it is in the form of epsilon toxin,[17] but the inventory record did not indicate whether it was an epsilon toxin. We also asked a CDC official to review the inventory record, and the official identified another potentially dangerous pathogen (Shigella) that could have been enhanced to become Shigatoxin, a Category B CDC select agent.

The science lecturer, who is the current custodian of the contents of the freezer, said the seven vials of Yersinia pestis were destroyed by autoclaving (i.e., sterilization) on September 25, 2002, after we raised concerns about possession of the dangerous pathogen. The only documentation regarding destruction of the pathogen was a note on the inventory saying, "destroyed", and indicating a date.

After discussions with officials from CDC, APHIS, and CSREES, we prepared a Management Alert, dated November 8, 2002, recommending that CSREES inform the institution to perform an immediate inventory of the freezer, destroy any unneeded pathogens, and properly secure the remaining pathogens. On November 18, 2002, the CSREES Administrator sent a letter to the University expressing concern about the unsecured freezer and recommending that an immediate and comprehensive inventory of the freezer be taken, and that the University determine whether any similar pathogen storage situations exist at the University, and if so, appropriate action should be taken. USDA and CDC officials we spoke with about this situation believed there was a strong possibility that similar conditions existed at a number of other institutions. Therefore we concluded that it would be appropriate for CSREES to

[16] Category B denotes the second highest priority agents on the CDC select list. Category B agents (1) are moderately easy to disseminate, (2) result in moderate morbidity (disease) rates and low mortality rates, and (3) require enhanced disease surveillance.

[17] Epsilon toxin is a potent toxin produced by the bacterium Clostridium perfringens.

send out a letter to all grantee institutions recommending that each identify any similar conditions at their facilities and take appropriate actions.

- At another institution, we noted that there was no beginning inventory for the biological agents present in a freezer where Actinobacillus pleuropneumonia was stored. Actinobacillus pleuropneumonia is a pathogen that causes a severe and often fatal contagious disease in swine. Inventory records of working stock at this laboratory were not kept and periodic inventories were not performed. According to a research assistant, there has never been a complete inventory of the biological agents in the freezer, although a partial inventory had been performed when the freezer and its contents were moved from another building several years ago.

  We also noted that access to the freezer was not controlled. As a result, graduate students could access the freezer at any time to remove agents, and their removal would not be documented or detected.

We concluded that laboratories need to improve controls over their inventories of dangerous biological agents, particularly those on the lists established by CDC and APHIS. To adequately account for these agents, laboratories should be required to maintain accountability records similar to those required for USDA-operated facilities and perform periodic physical inventories, particularly when those laboratories contain agents on the APHIS and CDC lists. Laboratories should also ensure that the person responsible for maintaining the inventory records of working stock is not responsible for performing the periodic physical inventory.

Finally, institutions need to establish uniform policies and procedures for ensuring the disposal of biological agents when researchers responsible for those agents leave the institution. In the long term, inventory controls should be included in Federal standards developed by the Department of Homeland Security, the Homeland Security Council, or OSTP. In the short term, USDA agencies need to establish minimum inventory control requirements for research facilities receiving USDA funds through grant agreements.

Recommendation No. 6

Direct CSREES to issue a letter to all institutions engaged in USDA-funded research suggesting that they immediately (1) identify all freezers at their institutions used to store biological agents; (2) take a complete and thorough inventory of the contents of these freezers; (3) destroy any pathogens identified in the freezers that are no longer needed for valid research purposes or for reference collections and germplasm storage banks, or those that can no

longer be identified; and (4) report to CDC and APHIS any pathogens found in the freezers not already reported.

Departmental Response. In the July 18, 2003, response, the Acting Director of Homeland Security stated,

> *On November 27, 2002, CSREES issued a letter to each Authorized Organizational Representative supported with CSREES funds advising them to take the following appropriate actions:*
>
> - *"Perform a comprehensive inventory of any unsecured area (storage rooms, freezers, etc.) that may contain potentially harmful pathogens that are no longer needed for research or educational purposes including those that cannot be identified.*
> - *Closely review inventory sheets to assure they are up to date and accurate.*
> - *If agents or toxins potentially harmful to humans, animals, or plants are found transfer them to an appropriate bio-containment facility with adequate security, or if they are not currently being used in research dispose of them in an appropriate manner.*
> - *Notify * * * CDC or USDA regarding the possession of any listed agent or toxin retained in your inventories for research or education. You can find the listed agent in the Federal Register (67FR 52383-52389, Docket No. 02-082-1) published August 12, 2002, through the Federal Register Online via GPO Access; http://www.access.gpo.gov/su_docs/aces/aces140.html.*
> - *Maintain full documentation of any destruction of listed agents and toxins and take steps to reconcile your inventory sheets of pathogen storage sites by having them reviewed by someone other than the custodian of the sites."*

OIG Position. We accept management decision for this recommendation.

Recommendation No. 7

Recommend to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council, that Federal standards include a requirement for laboratories to develop inventory control procedures.

Departmental Response. In the July 18, 2003, response, the Acting Director of Homeland Security stated,

> *We concur with the recommendation and observe that these requirements are contained in 7 CFR Part 331, 9 CFR Part 121 (APHIS) and 42 CFR Part 73 (CDC). We will include these issues in our ongoing discussions with the Homeland Security Council. We note that the security standards and guidelines contain an inventory component.*

OIG Position. We accept management decision for this recommendation.

Recommendation No. 8

Recommend to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council, that Federal standards include a requirement that institutions establish uniform policies and procedures for ensuring disposal of biological agents when researchers responsible for those agents leave the institution.

Departmental Response. In the July 18, 2003, response, the Acting Director of Homeland Security stated,

> *We concur with the recommendation and observe that several of these requirements are contained in 7 CFR Part 331, 9 CFR Part 121 (APHIS) and 42 CFR Part 73 (CDC). In addition, we suggest the recommendation be strengthened to state that institutions establish policies to 1) dispose of biological agents when researchers responsible for those agents leave the institution or the agent is no longer needed for a specific program, or 2) confirm their inventory and transfer it to another primary researcher with security and scientific credentials needed to properly store and handle such materials. We will include these issues in our ongoing discussions with the Homeland Security Council.*

OIG Position. We accept management decision for this recommendation.

Finding 4 Physical Security and Access Controls Need To Be Improved at Institution Research Facilities

Institutions did not always provide adequate security for the 63 buildings and 104 interior laboratories where research was being conducted. The institutions had not assessed the security needs of all facilities and had not provided

upgrades for those buildings and laboratories that needed them or imposed controls to restrict access to the laboratories. Of the 104 laboratories visited, 39 laboratories at all 11 institutions used or stored pathogens on the CDC select list or the APHIS list of high consequence pathogens, and 20 laboratories at 10 of the institutions did not have security that we regarded as being commensurate with the risk associated with these pathogens. These conditions existed largely because institutions have had a tradition of openness and individual freedom of movement on their campuses. However, the events of September 11 have raised security awareness in sectors of the research community. Although officials now recognize the potential for unauthorized individuals to enter research laboratories and remove biological agents to commit terrorist acts, institutions were awaiting Federal direction before committing themselves to security upgrades.

At the time of our review there were no Federal regulations requiring institutions to establish security measures at research facilities. CDC and APHIS published regulations in early December 2002, to address security issues. In the interim, CDC suggested some measures in appendix F to its manual, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). These measures were designed for laboratories using biological agents at the BSL-3 or BSL-4 level, but could apply to other laboratories working with high consequence pathogens and toxins. The guidelines instruct officials to control access to areas where biological agents or toxins are used and stored, and to know what materials are being brought into the laboratory and what materials are being taken out.

Fifteen of the 104 laboratories we visited were designated BSL-3 laboratories. Eight of the 15 laboratories used or stored CDC select agents or APHIS high consequence pathogens. An additional 29 BSL-2 and 2 BSL-1 laboratories used or stored CDC select agents and/or APHIS high consequence pathogens. Our reviews made allowances for the fact that these laboratories were not located in Federal facilities but on university campuses, where an inherent amount of openness and accessibility are required.

Physical Security

Appendix F of the BMBL Manual recommends that laboratories be locked at all times and that key-cards or similar devices be used to permit entry. Only 3 of the 11 institutions included in our review used surveillance cameras or intrusion alarms in some of their buildings. Thirty-five of the 39 laboratories with high consequence pathogens did not have key-card access to provide a record of who entered the facilities, particularly after normal business hours. Only 7 of 63 buildings reviewed had key-card access. Examples of the physical security weaknesses include the following.

- Building security. One BSL-2 laboratory at an institution we reviewed, housing research on botulinum toxins, a CDC select agent, was secured with a manual lock and was kept locked during business hours. However, we noted that there were inadequate security measures in the building housing this laboratory. The building remained open 24 hours a day, 7 days a week; did not have video surveillance of the entrance; and did not have key-card access, door alarms, or intrusion detection. Therefore, all of the laboratories within the building were vulnerable to forced or unforced entry and subject to unauthorized removal of hazardous agents.

- Laboratory security: key-card access. Twelve of the 15 laboratories rated BSL-3 did not have key-card access. A system like a computerized key-card that tracks individuals entering laboratories provides a good security measure.

- Laboratory security: door locks and alarm systems. Ninety-four of the laboratories visited had manual locks but laboratory personnel did not always close and lock their doors, and alarm systems were not present on the buildings where laboratories were located. We recognize that laboratories do not always store dangerous pathogens, but security lapses at a low-risk laboratory could impact other areas where dangerous materials are located. For example, at one institution a principal investigator had both BSL-3 and BSL-2 laboratories in the same area. The BSL-3 laboratory contained Brucella species, a CDC select agent that is dangerous to animals and humans. The BSL-2 laboratory contained Bovine herpes virus, an animal pathogen. The BLS-3 laboratory was locked at all times, but the BSL-2 laboratory, which was adjacent to the entry of the BSL-3 laboratory, was open during business hours. Once inside the BSL-2 laboratory, anyone could force open the door to the BSL-3 laboratory and remove hazardous agents without being detected or interrupted because there was no alarm system installed.

Generally, university officials noted that university campuses were sensitive about privacy issues arising from the use of cameras. However, they generally agreed that key-card access systems would improve security at the buildings and laboratories.

Access Controls at Laboratories and Laboratory Buildings

Appendix F of the BMBL Manual recommends that laboratories require workers to wear identification badges, record all entries by workers and visitors, and limit access by visitors and maintenance workers to hours when regular employees are present.

- Access Controls at Laboratories

  Overall, 80 of the 104 laboratories did not require their employees to wear identification badges. A similar number did not require visitors, including vendors and the maintenance staff, to sign-in so that the institution had a record of everyone who entered the laboratories. In many cases, the cleaning staff had access to the laboratories after hours when no one was present. Furthermore, doors to the laboratories were not always kept closed or locked while researchers were working in the laboratories, and the locks on the doors were not changed periodically, particularly after keys were lost or stolen or after the staff experienced a turnover. In addition, we found that the keys to the outer doors and to the freezers inside the laboratories were not adequately controlled.

  Controls over access to 20 of the 39 laboratories with high consequence pathogens were not adequate considering the level of risk associated with the pathogens they contained.

  Institutions were also inconsistent in the access controls they implemented. Two laboratories at one institution reviewed demonstrated the inconsistency.

  – One laboratory, designated BSL-3, had two pathogens (Eastern Equine Encephalitis virus and Yellow fever virus) on the CDC select agent list and two pathogens (Japanese Encephalitis and Bluetongue) on the APHIS list. This laboratory had a single master key to access all of its freezers and kept the key in a highly visible area of the laboratory. Consequently the custodial staff that had access to the laboratory in the evenings when research personnel were not present could have easily taken the key and opened any of the freezers.

  – The second laboratory, designated BSL-2, contained a CDC select agent (Clostridium botulinum) and maintained more stringent access controls. Personnel were restricted to only certain areas of the laboratory through the use of an electronically coded key-card; the custodial staff were not allowed to enter the laboratory at any time; and the CDC select agent was housed in a freezer that was locked at all times. At this particular institution, the need for security was not necessarily based on the type of pathogen used in the laboratory but on the threat from animal and environmental rights groups.

- Access Controls at Buildings That Housed Laboratories

  Laboratories with high consequence pathogens were generally located in shared facilities. For example, some of the buildings where these laboratories were located also had classrooms, administrative and faculty offices, and other public areas. The laboratories were generally located throughout the buildings, making it difficult to control access to them.

  These buildings generally did not contribute to the overall security of the laboratories, particularly those with pathogens on the CDC and APHIS lists. Many of the buildings did not have a receptionist or security guard or sign-in sheet to keep track of the visitors who entered the building. Furthermore, neither visitors, students, faculty, nor staff were required to wear identification badges while in the buildings.

  For example, one building at an institution reviewed housed research laboratories and administrative offices for the Food Safety and Food Science and Technology Departments. This building had four pathogens (Bacillus anthracis, Clostridium botulinum, Shigatoxin, and Staphylococcal entertoxins) on the CDC select agent list in its laboratories. The Food Science and Technology Department had a food science taste test program, during which the general public was invited to food sensory laboratories to participate in the tests and to tour the facilities. The building had eight entrances, only six of which were locked during normal business hours (7:30 a.m. and 5:30 p.m.). Neither a receptionist nor a guard was stationed at the two entrances that were unlocked and identification badges were not required inside the laboratories. During business hours, anyone could enter the building and gain access to the laboratories, and there would be no record of entry. After normal working hours, however, the building used key-card reader doors to restrict and monitor entries.

  Another building at the same institution housed a BSL-3 laboratory for a researcher working with Burkholderia mallei, Burkholderia psuedomallei, and Ralstonia solananacearum, all CDC select agents. The building is 30 yards from the football stadium and, during night games, is open for bathroom use. Although the campus police and the custodial staff generally observe activities in the building during this time, there is no receptionist or guard stationed in the building to ensure that the general public is limited to only authorized areas of the building. Furthermore, there is no receptionist or guard during normal business hours. Visitors are not required to sign-in and identification badges are not worn. After hours, manual keys are used to enter the building and many people have keys. In some cases, the doors remain unlocked.

Laboratory officials have shown an interest in increasing security at their facilities, but funding has been the chief obstacle. Funding for security upgrades has been limited, and outside sources for funds have not been established. Officials at one institution stated that unless there were requirements from the Federal Government, the priority for security upgrades would remain low. Officials at two other institutions told us that while they knew security was a concern, Federal grantor agencies neither required additional security measures nor provided additional funding to pay for improvements.

The Experiment Station Committee on Organization and Policy (ESCOP), a committee of the National Association of State Universities and Land-Grant Colleges, recently recognized the need to improve the level of security over their research facilities. This association has suggested that funding for security upgrades come from new appropriations. Currently Congress is being requested to provide $50 million to increase the level of security at agricultural research facilities on the campuses of land-grant universities.

One institution has taken the initiative to act without additional Federal funding. This institution has formed a compliance team to assess the safety and security of biological agents, hazardous chemicals, and radioactive materials. Once the assessment is completed, the team will determine the minimum physical security standards for each facility and laboratory at the institution and those requirements will become mandatory. We agree with this proactive approach to physical security at all institutions where research is conducted using hazardous materials, and believe that the institutions should conduct similar assessments and immediately implement those measures that can be accomplished with their existing appropriations.

We made recommendations in Findings 1 through 3 of this report regarding the development and implementation of a consolidated set of security standards that should also address vulnerabilities identified in this finding, including (1) requiring institutions to perform risk assessments based on the types of pathogens in the laboratories to determine the appropriate level of security, (2) requiring the institutions to implement accountability records similar to those required for USDA-operated facilities, and (3) requiring institutions to implement procedures for reporting stolen or missing pathogens. Additionally, in Finding 5, we are recommending that CSREES and other USDA agencies provide interim guidance to USDA-funded institutions to address vulnerabilities identified during our review. Therefore, we are not making further recommendations in this finding.

Finding 5 USDA Could Use Current Department Policy as Guidance on Biosecurity for Institutions Working With Animal and Plant Biological Agents and Toxins

During our fieldwork, there were no USDA agencies that provided guidance on laboratory security to grantee or other institutions that work with animal and plant pathogens. Specifically, APHIS has until recently only regulated the transportation of those pathogens, and CSREES has only issued guidance in the form of safety precautions, grant expenditure requirements, and animal welfare advisories. Although biosecurity requirements have recently been published by APHIS for high consequence animal and plant pathogens, these requirements only apply to USDA listed agents and toxins, not other harmful pathogens, such as Actinobacillus pleuropneumoniae. We concluded that CSREES should be proactive on this issue and offer guidance to institutions on all levels of biological and chemical materials. According to officials in the research community, laboratories are currently receptive to such guidance.

We previously conducted an audit of USDA-operated facilities and identified conditions similar to those reported in Sections 1 and 2 of this report. The Department responded to these conditions by issuing Department Manual 9610-1, which set forth policies and procedures to improve security at USDA-operated laboratories. We believe these same policies and procedures could form a basis for raising security awareness at USDA-funded research facilities. CSREES could use Department Manual 9610-1, as well as some of the best methods practiced by USDA-funded laboratories, to help those institutions formulate biosecurity standards of their own until such time as Federal standards are in place.

As previously mentioned, APHIS, CSREES, and other USDA agencies such as ARS, FSIS, and FS have some level of oversight authority over research institutions working with biohazardous material. APHIS is responsible for ensuring that laboratories proposing to work with dangerous animal and plant pathogens are equipped to do so; CSREES is responsible for dispensing funds to the laboratories to carry out the proposed research. Although the Act designates APHIS as the agency to offer technical assistance on pathogen risk levels, CSREES is the primary agency for monitoring research funding at the institutions and for establishing institutional compliance with laws governing the use of research materials and subjects. Consequently, CSREES is better positioned to provide biosecurity guidance to the institutions through the grant agreements that it enters into with the researchers receiving USDA grant funding.

Prior to passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, USDA's responsibilities for providing guidance to research laboratories have been largely exercised through grant agreements entered into by CSREES. The grants are regulated under Title 7 CFR 3016 through 3019 in accordance with Office of Management and Budget (OMB) Circulars Nos. A-102[18] and A-110.[19] In general, the regulations and OMB circulars address requirements for performance and expenditures related to the agreements; they do not address nonfinancial matters such as safety and security. However, as part of the grants management process, CSREES requires all institutions receiving funding for research to be responsible for adhering to applicable laws and research guidelines. These include protecting human subjects, providing humane treatment of animals, and monitoring the use of recombinant DNA. Institutions demonstrate their adherence to these guidelines by signing a statement that the institution agrees to comply with both the intent and procedures of the following:

a. The National Institutes of Health, Department of Health and Human Service's Guidelines for Research Involving Recombinant DNA Molecules;
b. The Animal Welfare Act, and the Federation of Animal Societies, 1999, Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching; and
c. The Federal Policy for Protection of Human Subjects set forth in Title 45 CFR Part 46, and Title 7 CFR 1c.

Ultimately, CSREES may out of necessity add to this list the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. However, APHIS is the agency designated by the Act to regulate animal and plant pathogens. CSREES may encourage the institutions to adopt security standards over biological and chemical materials, but without obtaining approval through the OMB approval process, it has no authority to direct institutions to adopt any standards or to enforce compliance with those standards.

We concluded that CSREES should be proactive and provide the institutions with a suitable departmental guide to biosecurity. APHIS, ARS, FSIS, and FS should also provide the guidance to institutions working with biohazardous material under cooperative agreements with the agencies. Such a guide would be based largely on the policies and procedures established by the Department for its own laboratories. USDA's Department Manual 9610-1 sets forth policies on issues, including the following:

[18] *Uniform Administrative Requirements for Grants and Other Agreements to State and Local Governments.*
[19] *Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals, and Nonprofit Organizations.*

- Handling, storage, shipping, disposal, recordkeeping, and monitoring of pathogens;
- Maintaining accountability records;
- Securing pathogens;
- Ensuring appropriate levels of physical security to protect against unauthorized access, theft, or loss of agents or toxins; and
- Biosecurity incident response plans.

Although the manual's policies and procedures may not always apply to non-Federal facilities, many would. For example:

- USDA requires its facilities to use individuals with wide-ranging expertise—e.g., biological sciences, physical security, etc.—to design physical security systems based on site-specific risk assessments, giving the highest level of protection to items whose loss, theft, or unauthorized use could seriously affect national security. Similar risk assessments could be used effectively by institutions to determine risks at their facilities and laboratories, allowing them to upgrade existing security systems or implement new enhanced systems rather than make changes in response to break-ins or attacks.

- USDA requires any facility that stores or uses high consequence pathogens to maintain a current detailed inventory that (1) serves as a historical record of pathogens used (amount, storage location, disposition, etc.) and (2) provides material accountability of experimental or working samples to be tracked by laboratory records. Similar requirements for institutions and registered persons would help ensure that they can keep track of their CDC and USDA listed agents and toxins in order to properly notify CDC or APHIS when pathogens are stolen or lost.

Other requirements implemented at USDA-operated facilities may not be as easily adapted to non-Federal institutions. For example, USDA requires intrusion detection system alarms to protect certain pathogens, but USDA laboratories typically have more restrictive access. Because institutional facilities that house laboratories are often used for educational as well as research purposes, a greater number of people would have access to the facilities, and the number of intrusion detection systems for multiple areas in the facilities could be costly. Therefore, consideration should be given to the level of risk associated with the agent or toxin before requiring entry alarms.

Security standards for hazardous research materials could also be based on the protections already practiced by some of the institutions. As mentioned previously, the key-card system has proven its value at one institution. Likewise, the practice by another institution of imposing monetary fines on laboratories that violate environmental quality has shown a method of gaining compliance with self-imposed standards. CSREES could survey the institutions receiving USDA funding and share these best practices with other grantees as a way of raising security awareness throughout the research community and of standardizing levels of security in a campus environment. Exhibit B lists some of the policies and procedures we observed and considered to be "best practices" at the USDA-funded institutions we visited.

APHIS and CDC issued new regulations on December 13, 2002, to conform to the remaining provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The regulations, governing high consequence pathogens, include requirements for:

- establishing standards and procedures for possession and use of agents and toxins,
- registering agents and toxins,
- limiting access to appropriate individuals,
- screening for restricted persons,
- establishing notification procedures for theft or loss of agents and toxins,
- developing technical assistance for registered persons, and
- requiring inspections of persons possessing or using agents or toxins.

The Act also allows USDA, through APHIS, to provide technical assistance for improving facility security to persons possessing, using, and transferring the agents and toxins on the USDA list. However, the Department will still need to provide guidance to institutions possessing 1) biological materials that are not on the USDA list and 2) hazardous chemicals.

The new APHIS regulations can provide CSREES with a basis for expanding the requirements for funding that it includes in the grant agreement. In the interim, CSREES should use the Department Manual and the current best practices established by the institutions to lay the groundwork for security standards that will respond to APHIS' requirements and apply to those research materials not covered by APHIS' list. CSREES should also work with APHIS to familiarize itself with the new Department requirements. Also, until Federal security standards are developed, the agency should include those requirements in its grants management process to ensure that grantee institutions comply with the Act, regulations, and guidance set forth by CDC and APHIS regarding security over high consequence agents and toxins.

Recommendation No. 9

Direct CSREES, ARS, FSIS, and FS to use USDA's Department Manual as a basis for providing technical guidance regarding security over USDA listed agents and toxins to funded institutions.

Departmental Response. In the July 18, 2003, response, the Acting Director of Homeland Security stated, "As discussed previously in this response, we have offered and provided such guidance to our client organizations. The agencies listed above are continuing to provide technical guidance when requested."

OIG Position. We accept management decision for this recommendation.

Recommendation No. 10

Direct CSREES to survey grant institutions for their best practices involving security of research facilities and laboratories and to share this survey with all grantees as a basis for establishing biosecurity standards throughout the research community.

Departmental Response. In the July 18, 2003, response, the Acting Director of Homeland Security stated,

> *We do not believe it is prudent at this time for * * * CSREES to survey organizations for their best practices involving security of research facilities and laboratories and to share this survey with all grantees for two reasons. First, CSREES does not have authorization to place an added paperwork burden on the organizations and second, it does not have the expertise to recommend biosecurity standards. Even a catalog of practices might be interpreted by some as recommended practices. As an alternative CSREES believes that the institutions themselves or a third party should undertake such a survey. CSREES began discussions on July 2, 2003, with the National Institution for Agriculture Security, a not for profit corporation recently formed by the Experimental Station Committee on Organization and Policy, relative to its interest in undertaking a survey of security practices. They are still considering such action. CSREES will continue to pursue this option.*

OIG Position. We accept management decision for this recommendation.

Recommendation No. 11

Until Federal security standards have been developed, direct CSREES to incorporate requirements into its policies and grant agreements and processes that institutions receiving USDA research funding should follow all laws, regulations, and guidance regarding biosecurity governed by CDC and APHIS.

Other agencies such as ARS, FSIS, and FS should also be directed to incorporate the requirements into their policies and cooperative agreements.

Departmental Response. In the July 18, 2003, response, the Acting Director of Homeland Security stated, "We concur with this recommendation. Consistent with current laws and regulations, CSREES will modify its Terms and Conditions to include a provision regarding biosecurity by February 1, 2004."

OIG Position. We accept management decision for this recommendation.

We visited 104 laboratories at 11 sites. Of these 104 laboratories, 15 were designated BSL-3 laboratories, 63 were designated BSL-2 laboratories, and 25 were designated BSL-1 laboratories. The remaining laboratory had no BSL designation.

We targeted our sample to those institutions within the United States[20] that were receiving grants from USDA to perform research involving high-risk[21] biohazardous material. To identify these institutions, we reviewed the Current Research Information System (CRIS), maintained by CSREES for the management of USDA grants. This system identifies the grant recipients, identifies the number of grants each recipient received, and provides a summary of the grant research. We searched the grant summaries for the pathogens named in each grant application, giving greatest emphasis to those pathogens that are listed by CDC or USDA as BSL-2 and BSL-3. CRIS listed 93 institutions with grant recipients whose grant abstract referred to these levels of pathogens. Of this number, 59 were land-grant universities and 34 were either non-land-grant universities or private institutions.

From these 93 institutions, we selected 22 based on the quantity of high-risk pathogens identified at each institution and their geographic locations within the United States. Because of the common vulnerabilities we observed among the first 11 institutions, we determined that we had sufficient information to address overall conditions at grantee institutions and discontinued fieldwork to prepare a report. Of these 11 institutions, 10 were land-grant universities, and only 1 was a private institution (very few of the USDA grant recipients in our universe were private institutions studying quantities of sensitive pathogens).

We reviewed 104 laboratories at the 11 institutions selected. According to ESCOP, there are probably over 9,000 laboratories at the land-grant institutions alone.

Our site visits to the institutions and laboratories were made between July and September 2002. This review was conducted in accordance with generally accepted government accounting standards.

In order to complete our objectives, we performed the following steps.

- Reviewed current legislation and regulations concerning security over biological agents and toxins, and chemical and radioactive materials.

- Reviewed institutions' written procedures regarding biological agents and toxins, and chemical and radioactive materials.

[20] Many grant recipients perform research in Canada and Europe. We excluded these recipients from our universe.

[21] We identified "high-risk" pathogens based on those determined to be high risk by CDC or by USDA, according to the biosafety levels.

- Interviewed officials with each of the 11 institutions.

- Inspected security of selected laboratories at the 11 institutions. Interviewed laboratory managers, principal investigators, and other researchers. Performed a manual inventory of the contents of one laboratory freezer.

- Consulted with the CDC concerning requirements for pathogens on their select list.

- Consulted with HHS' Office of Inspector General concerning their current reviews of HHS-funded laboratories at other institutions.

USDA

United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

July 18, 2003

TO: Richard D. Long
Assistant Inspector General for Audit
Office of Inspector General

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

SUBJECT: Draft Audit Report No. 50099-14-At -- Controls Over Biological, Chemical, and Radioactive Materials at Institutions Funded by the U.S. Department of Agriculture

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

The overall recommendation in the executive summary on page v states: *"...[u]ntil a consolidated set of security standards is in place at the Executive level, we are recommending that USDA be proactive and provide guidance on security to its grantees by sharing with those institutions the Department's own policies on USDA laboratory security, as set forth in the Department Manual as well as the best practices implemented by the institutions themselves."*

We agree that a consolidated set of security standards should apply to all organizations handling various types of biohazardous material. In implementing the Agricultural Bioterrorism Protection Act of 2002, the Animal and Plant Health Inspection Service (APHIS) codified security standards (See 7 CFR 331.11 "Possession of Biological Agents and Toxins"). Those standards, for the most part, set basic requirements for those organizations possessing, importing, and transporting select toxins and agents.

We have offered and provided guidance to our client organizations. On December 18, 2002, the Cooperative State Research, Education, and Extension Service (CSREES), the Agricultural Research Service (ARS), the Food Safety and Inspection Service (FSIS) and APHIS held a workshop on security for USDA grantees. The Department's Policy and Procedures Manual for BSL-3 labs was made available to interested parties and is published on the Department's web site at www.usda.gov/ocio/directives/DM/DM9610-001.pdf. In addition, a video of the conference was made and is available to interested parties seeking guidance.

Below is our response to each of the recommendations.

Recommendation No. 1

Elevate the issues to the Department of Homeland Security and to the Executive Office of the President, Homeland Security Council, with the recommendation that they or the Office of Science and Technology Policy (OSTP) in coordination with the Centers for Disease Control and Prevention (CDC), the Animal and Plant Health Inspection Service (APHIS), and other Federal agencies publish a consolidated set of security standards to be implemented by all institutions working with the CDC select agents and toxins and APHIS listed agents and toxins.

We agree that these important issues should be elevated to an appropriate level for government-wide consideration. We have already begun and will continue discussions with the Homeland Security Council.

Recommendation No. 2

Recommend to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council, that Federal standards include directions that all Government-funded research institutions compile a summary inventory of hazardous chemicals and biological agents and toxins located at their facility. The inventory record should be maintained in a secure location where institution officials can readily access it.

We concur with the recommendation and observe that the inventory requirements for listed agents and toxins are contained in 7 CFR Part 331, 9 CFR Part 121 (APHIS) "Possession of Biological Agents and Toxins" and 42 CFR Part 73 (CDC) "Interim Final Rule Possession, Use and Transfer of Select Agents and Toxins". We will include these issues in our ongoing discussions with the Homeland Security Council. We believe the control of hazardous chemicals falls outside of USDA's mission area.

Recommendation No. 3

Recommend to the Department of Homeland Security and the Office of the President, Homeland Security Council, that Federal standards include direction that all Government-funded research institutions use the inventories of biological agents, chemicals, and licensing requirements for radioactive materials to assess the risks associated with these materials and determine the commensurate security level for them.

We concur with the recommendation and observe that many of these requirements are contained in 7 CFR Part 331, 9 CFR Part 121 (APHIS) and 42 CFR Part 73 (CDC). We will include these issues in our ongoing discussions with the Homeland Security Council.

Recommendation No. 4

Recommend to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council, that Federal standards include direction that all Government-funded research institutions establish and implement procedures for reporting stolen or missing

pathogens in compliance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

We concur with this recommendation and believe that these requirements have been implemented via 7 CFR Part 331 (APHIS), 42 CFR Part 73, and 9 CFR Part 121.

Recommendation No. 5

Recommend to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council, that Federal standards include a requirement that all Government-funded research institutions have procedures to ensure that appropriate background checks are performed for all individuals having access to CDC and APHIS listed agents and toxins.

We concur with the recommendation and observe that background checks are presently a requirement for all individuals handling listed agents and toxins.

Recommendation No. 6

Direct the Cooperative State Research, Education, and Extension Service (CSREES) to issue a letter to all institutions engaged in USDA-funded research suggesting that they immediately (1) identify all freezers at their institutions used to store biological agents, (2) take a complete and thorough inventory of the contents of these freezers, (3) destroy any pathogens identified in the freezers that are no longer needed for valid research purposes or can no longer be identified, and (4) report to CDC and APHIS any pathogens found in the freezers not already reported.

On November 27, 2002, CSREES issued a letter to each Authorized Organizational Representative supported with CSREES funds advising them to take the following appropriate action:

- "Perform a comprehensive inventory of any unsecured area (storage rooms, freezers, etc.) that may contain potentially harmful pathogens that are no longer needed for research or educational purposes including those that cannot be identified.
- Closely review inventory sheets to assure they are up to date and accurate.
- If agents or toxins potentially harmful to humans, animals, or plants are found transfer them to an appropriate bio-containment facility with adequate security, or if they are not currently being used in research dispose of them in an appropriate manner.
- Notify the Center for Disease Control (CDC) or USDA regarding the possession of any listed agent or toxin retained in your inventories for research or education. You can find the listed agents in the Federal Register (67FR 52383-52389, Docket No. 02-082-1) published August 12, 2002, through the Federal Register Online via GPO Access;

htpp://www.access.gpo.gov/su_docs/aces/aces140.html.

- Maintain full documentation of any destruction of listed agents and toxins and take steps to reconcile your inventory sheets of pathogen storage sites by having them reviewed by someone other than the custodian of the sites."

Recommendation No. 7

Recommend to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council, that Federal standards include a requirement for laboratories to develop inventory control procedures.

We concur with the recommendation and observe that these requirements are contained in 7 CFR Part 331, 9 CFR Part 121 (APHIS) and 42 CFR Part 73 (CDC). We will include these issues in our ongoing discussions with the Homeland Security Council. We note that the security standards and guidelines contain an inventory component.

Recommendation No. 8

Recommend to the Department of Homeland Security and the Executive Office of the President, Homeland Security Council, that Federal standards include a requirement that institutions establish uniform policies and procedures for ensuring disposal of biological agents when researchers responsible for those agents leave the institution.

We concur with the recommendation and observe that several of these requirements are contained in 7 CFR Part 331, 9 CFR Part 121 (APHIS) and 42 CFR Part 73 (CDC). In addition, we suggest the recommendation be strengthened to state that institutions establish policies to 1) dispose of biological agents when researchers responsible for those agents leave the institution or the agent is no longer needed for a specific program, or 2) confirm their inventory and transfer it to another primary researcher with security and scientific credentials needed to properly store and handle such materials. We will include these issues in our ongoing discussions with the Homeland Security Council.

Recommendation No. 9

Direct CSREES, ARS, FSIS, and FS to use USDA's Department Manual as a basis for providing technical guidance regarding security of USDA listed agents and toxins to funded institutions.

As discussed previously in this response, we have offered and provided such guidance to our client organizations. The agencies listed above are continuing to provide technical guidance when requested.

Recommendation No. 10

Direct CSREES to survey grant institutions for their best practices involving security of research facilities and laboratories and to share this survey with all grantees as a basis for establishing biosecurity standards throughout the research community.

We do not believe it is prudent at this time for the Cooperative State Research, Education, and Extension Service (CSREES) to survey organizations for their best practices involving security of research facilities and laboratories and to share this survey with all grantees for two reasons. First, CSREES does not have authorization to place an added paperwork burden on the organizations and second, it does not have the expertise to recommend biosecurity standards. Even a catalog of practices might be interpreted by some as recommended practices. As an alternative CSREES believes that the institutions themselves or a third party should undertake such a survey. CSREES began discussions on July 2, 2003, with the National Institution for Agricultural Security, a not for profit corporation recently formed by the Experiment Station Committee on Organization and Policy, relative to its interest in undertaking a survey of security practices. They are still considering such action. CSREES will continue to pursue this option.

Recommendation No. 11

Until Federal security standards have been developed, direct CSREES to incorporate requirements into its policies and grant agreements and processes that institutions receiving USDA research funding should follow all laws, regulations, and guidance regarding biosecurity governed by CDC and APHIS. Other agencies such as ARS, FSIS, and FS should also be directed to incorporate the requirements into their policies and cooperative agreements.

We concur with this recommendation. Consistent with current laws and regulations, CSREES will modify its Terms and Conditions to include a provision regarding biosecurity by February 1, 2004.

Exhibit B

Best Practices at Institutions Visited

The following list provides examples of the “best practices” we noted during our site visits. This list is not meant to be all-inclusive, and the practices listed below were not followed at all locations visited. The purpose of the following list is to present some of the policies and procedures we observed and considered to be good practices to help ensure security at the institutions and in the laboratories.

- Centralized summary-level inventory/database identifying all biological materials at the institution
- Coordinating emergency operations plans with local and State authorities and ensuring that hazardous materials in buildings and laboratories can be readily identified off-site in case of emergencies
- Requiring formal "Biological Use Authorizations" under which critical information concerning agents and materials being used, authorized users, training, etc., is gathered and maintained by the university (Research could not begin until the authorizations were approved.)
- Conducting surprise reviews of laboratories to ensure compliance with lab safety/security requirements and issuing fines to researchers who violate the institutions policies and procedures
- Security reviews conducted at research buildings and laboratories performed by university police
- Developing a “Chemical Select List” of hazardous chemicals and requiring approval from the Chemical Safety Officer for purchases of select chemicals
- Centralized purchasing of hazardous chemicals to help reduce the quantities of those chemicals in the laboratories
- Establishment of a protocol for ensuring the proper removal or disposal of biological agents, chemicals, and radioactive materials prior to a laboratory being vacated by a researcher
- Developing and utilizing coding systems to label cultures, stocks, and other inventories of pathogens and tie the inventories to laboratory research notes
- Maintaining inventory sheets for repository stocks of CDC select agents that show the user’s initials, date used, reason for use, and amount remaining for each agent

- The use of computerized key-cards to limit access to authorized personnel only
- The use of sign-in and sign-out sheets to track individuals' accessing the laboratories
- Requiring escorts for all visitors during the full time they are in the research buildings or laboratories

Abbreviations

A

APHIS
Animal and Plant Health Inspection Service 1

ARS
Agricultural Research Service 1

B

BMBL
Biosafety in Microbiological and Biomedical Laboratories 22

BSL
biosafety level 1

C

CDC
Centers for Disease Control and Prevention 1

CFR
Code of Federal Regulations 2

CRIS
Current Research Information System 33

CSREES
Cooperative State Research, Education, and Extension Service 1

E

ESCOP
Experiment Station Committee on Organization and Policy 26

F

FS
Forest Service 1

FSIS
Food Safety and Inspection Service 1

H

HAZMAT
Hazardous Material 8

HHS
Department of Health and Human Services 2

N

NRC
Nuclear Regulatory Commission 1

O

OMB
Office of Management and Budget 28

OSHA
Occupational Safety and Health Administration 1

OSTP
Office of Science and Technology Policy 10