Description of document:	**US Department of Agriculture (USDA) Audit Report 50099-5-AT, Biological Material and Waste Management by USDA Agencies, March 1997**
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USDA

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

OCT 31 2007

Subject: Log No. 08-00006

This letter responds to your request dated October 6, 2007, under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, sent by e-mail to the Department of Agriculture (USDA), Office of Inspector General (OIG). You requested "a digital copy by email or on CD-ROM of a 1996 audit Report 50099-0005-AT."

After searching OIG records we concluded that the audit report you are seeking was released March 18, 1997. This audit is not available electronically. Enclosed, please find the responsive audit: Audit Report 50099-5-AT, March 1997, "Biological Material and Waste Management by USDA Agencies." A total of 47 pages are being released.

However, certain information has been redacted as it is exempt from release pursuant to FOIA. Specifically, in accordance with 5 U.S.C. § 552(b)(2), an agency is allowed to withhold sensitive information to protect facilities, stockpiles, and other assets from security breaches. Therefore, we have redacted the facilities' names and locations because of the potential harm which release of this information may have on security, national economic security, national pubic health or safety, or any combination thereof.

You have the right to appeal the decision to withhold information by writing to the Inspector General, U.S. Department of Agriculture, 1400 Independence Avenue SW., Jamie L. Whitten Building, Suite 441-E, Washington, D.C. 20250-2308, within 45 days of the date of this letter. The outside of the envelope should be clearly marked, "FOIA APPEAL."

For information about OIG, you may refer to our Web site at www.usda.gov/oig/home.htm. Should you have any questions or need additional information, please feel free to contact me at (202) 720-8112.

Sincerely,

Deirdre MacNeil
FOIA/PA Attorney

Enclosures: Documents

UNITED STATES DEPARTMENT OF AGRICULTURE
BIOLOGICAL MATERIAL AND WASTE MANAGEMENT BY USDA AGENCIES
WASHINGTON, D.C.
AUDIT REPORT NO. 50099-5-At

MARCH 1997

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UNITED STATES DEPARTMENT OF AGRICULTURE
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UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: March 18, 1997

REPLY TO
ATTN OF: 50099-5-At

SUBJECT: Biological Material and Waste Management by USDA Agencies

TO: Pearlie S. Reed
Acting Assistant Secretary for Administration

ATTN: Evelyn Davis
Audit Liaison

This report presents the results of our audit of the U.S. Department of Agriculture's biological material and waste management controls and practices. The Department's response to the recommendations is included as exhibit C with excerpts and the Office of Inspector General's position incorporated into the Findings and Recommendations section of the report.

We have accepted management decisions for Recommendations Nos. 1b, 1c, 1d, and 2a through 2d. Further information as specified in the OIG Position sections is needed before we can accept management decisions for Recommendations Nos. 1a, 1e, and 3.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective action taken or planned and the timeframes for implementation. Please note that the regulation requires a management decision to be reached on all findings and recommendations within a maximum of 6 months from report issuance. Follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended by Department and agency staff to our auditors.

J. R. Ebbitt

JAMES R. EBBITT
Assistant Inspector General
for Audit

EXECUTIVE SUMMARY

UNITED STATES DEPARTMENT OF AGRICULTURE BIOLOGICAL MATERIAL AND WASTE MANAGEMENT BY USDA AGENCIES AUDIT REPORT NO. 50099-5-At

PURPOSE

As part of the Office of Inspector General's ongoing review of employee safety and health and environmental programs within the U.S. Department of Agriculture (USDA), we conducted an audit of the Department's and three agencies' (Agricultural Research Service (ARS), Animal and Plant Health Inspection Service (APHIS), and Food Safety and Inspection Service (FSIS)) biological material and waste management controls and practices. The audit objective was to assess the adequacy of the Department's and agencies' management control systems for ensuring USDA facility compliance with requirements and standards for handling, storage, and disposal of biological material (agents) and waste.

USDA policy defines a biological agent as any microorganism or its by-products that present a potential risk of infection or disease in humans. For audit purposes, biological agent included all pathological, biomedical, biohazardous, toxic, infectious, or medically hazardous agents that pose harm to humans if improperly handled, stored, or disposed.

RESULTS IN BRIEF

Our review determined that risks to employee and public health and the environment were increased because the Department, ARS, APHIS, and FSIS did not have adequate management control systems to ensure that (1) USDA facilities managed biological agents and waste in accordance with Department policy and Federal and State requirements and (2) safety, health, and environmental deficiencies would be prevented or promptly detected.

There are few Federal laws and regulations governing handling, storing, and disposing of biological agents and waste. The Occupational Safety and Health Administration (OSHA) requires that employers provide employees a safe working environment. It regulates chemical hazards in the workplace and requires that employees be informed of all hazards. OSHA has also established regulatory controls for handling human blood and blood products. The Department of Commerce regulates the export of selected human,

animal, and plant pathogens and APHIS controls the import and domestic shipment of all animal pathogens. Based on the threat of terrorism, the Department of Health and Human Services (DHHS) in October 1996, issued regulations to control the acquisition and transfer of certain human pathogens. The Centers for Disease Control and Prevention's and National Institutes of Health's Biosafety in Microbiological and Biomedical Laboratories handbook contains industry standards for handling biological agents.

USDA's hazard communication program, contained in Departmental Regulation (DR) 4400-2, requires that agencies establish controls over biological agents and chemicals. Controls include maintaining inventory records, developing material safety data sheets, and training staff regarding potential exposures.

Although Congress defined hazardous waste as including waste that is potentially infectious to humans, the Environmental Protection Agency has not finalized infectious waste management regulations. Regulation of biological waste has, therefore, been left up to the States. States' regulatory controls vary significantly.

Executive Order 12088 requires agencies of the executive branch to comply with Federal, State, and local environmental standards. Departmental Manual 5600-1 applies the order to USDA program objectives with a goal "to minimize adverse impacts on the quality of the environment." It is the Department's policy to demonstrate initiative and provide leadership in environmental pollution prevention, control, and abatement through the management and operation of its facilities. The Assistant Secretary for Administration provides the policy guidance and oversight to achieve these objectives ensuring that applicable environmental laws and regulations are applied by the individual agencies.

The Department and agencies had not developed biological agent and waste management programs. The Department's and agencies' existing safety and health and hazardous waste management programs did not address biological agents and waste. Biological safety practices were, therefore, primarily a facility responsibility. The Department conducted no routine oversight reviews to assess biosafety or facility compliance with State biological waste requirements. Safety and health inspections required by DR 4400-2 were not conducted timely and standard inspection instruments did not include questions/steps to assess biological safety and waste management practices at agency facilities.

Only ARS had a Biological Safety Officer, but he had no staff, issued no policies, and conducted no oversight reviews.

The absence of adequate management control systems resulted in significant compliance deficiencies at the seven USDA facilities we reviewed (see exhibit B). Due to the serious nature of some deficiencies, we issued four Management Alerts during our review recommending immediate corrective actions. The Department and all

three agencies took prompt action to address the serious deficiencies we reported.

- Five facilities did not maintain adequate control over their biological agent inventories. We identified agents in laboratories that facility management was not aware existed and some agents that were no longer needed. Some of the agents posed a serious threat to human health, the environment, and national security if not properly controlled.

- Four facilities did not comply with OSHA bloodborne pathogen requirements for safely working with human blood and/or blood products. Two of the facilities violated Federal requirements by testing human blood and using the test results for diagnostic purposes without required certification by DHHS.

- Seven facilities did not develop Material Safety Data Sheets for biological agents and did not adequately train staff regarding potential exposure to agents handled and stored at the facilities.

- Six facilities did not maintain written standard operating procedures which incorporated biological safety and health requirements and standards.

All seven USDA facilities were not in compliance with State biological waste disposal requirements. One facility we reviewed was correcting deficiencies found previously by State inspectors and had submitted information to obtain State approval of its waste disposal practices.

USDA facilities routinely handle numerous human pathogens and biological waste. USDA facilities store thousands of biological agents and agent strains. Some agent strains pose a serious threat to employee and public health and the environment if improperly handled, stored, transferred, or disposed. Illicit access to some dangerous agents could threaten national security. Strengthening USDA management control systems is essential to minimizing these risks.

KEY RECOMMENDATIONS

We recommend that the Assistant Secretary for Administration (1) include biosafety in the Department's safety and health program and require that agencies establish biosafety programs and (2) incorporate provisions for biological waste into the Department's waste management policy. The Assistant Secretary should also require agencies to (1) incorporate USDA policy and Federal and State regulatory requirements for biological materials and waste in their written policies, (2) revise inspection instruments to include questions/steps to assess compliance with those requirements, and (3) inspect their facilities more often than annually to ensure compliance.

AGENCY POSITION

On February 25, 1997, the Assistant Secretary for Administration agreed with all recommendations and provided acceptable management decisions for 7 of the 10 recommendations. Before we can accept management decisions for Recommendations Nos. 1a and 1e, we need Management Council approval to fund and establish a departmentwide biological safety program which will include a Biological Safety Committee and Biological Safety Officer. We also need additional information on Recommendation No. 3 as detailed in the applicable Office of Inspector General Position section. The Department's complete written response is included as exhibit C.

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INTRODUCTION

BACKGROUND

There are few Federal laws and regulations governing the handling, storing, and disposing of biological material (agents) and waste. General exposure to biological agents comes under section 5(a)(1) of the Occupational Safety and Health Administration (OSHA) Act of 1970.[1] This section, known as the General Duty Clause, requires employers to provide employees a safe working environment. Executive Order 12196, Occupational Safety and Health Programs for Federal Employees, dated February 26, 1980, and U.S. Department of Agriculture (USDA) Departmental Regulation (DR) 4400-1, Departmental Occupational Safety and Health Management, dated January 6, 1983, also require that places of employment be free from recognized hazards.

Biological Agents

DR 4400-2, Hazard Communication Programs, dated October 14, 1986, defines a "biological agent" as any microorganism or its by-products that present a potential risk of infection or disease in humans. For purposes of this audit, the terms biological material (agents) and waste include all pathological, biomedical, biohazardous, toxic, infectious, or medically hazardous agents and waste that pose a potential risk to humans. DR 4400-2 requires that biological agents be treated the same as hazardous chemicals. For example, each agency and staff office must maintain biological agent inventory records updated annually, develop safety information including Material Safety Data Sheets (MSDS), and provide employees with appropriate training.

Section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132) established requirements on laboratories that domestically receive and transfer infectious agents capable of causing substantial harm to humans and to national security. In October 1996, the Department of Health and Human Services (DHHS) published final regulations to implement the law. In addition, the Department of Commerce (Commerce) regulates the export of selected human pathogens, and OSHA regulates occupational exposure to bloodborne pathogens.

[1] Public Law 91-596, dated December 29, 1970.

Industry standards for handling biological agents are contained in the Centers for Disease Control and Prevention's (CDC) and National Institutes of Health's Biosafety in Microbiological and Biomedical Laboratories (BMBL) handbook. The BMBL establishes four biosafety levels (BSL) for facilities, equipment, and practices depending on biological agents handled at a facility.

BSL-1 practices, safety equipment, and facilities are appropriate for facilities in which work is done with defined microorganisms not known to cause disease in healthy adults.

BSL-2 practices, equipment, and facilities are applicable where work is done with indigenous moderate-risk agents associated with disease of varying severity but not serious and potentially lethal to healthy adults.

BSL-3 practices, equipment, and facilities are applied to work with indigenous or exotic agents with potential for respiratory transmission and may cause serious and potentially lethal infections.

BSL-4 practices, equipment, and facilities are applicable for work with dangerous and exotic agents with a high risk of life-threatening disease for which there is no available vaccine or therapy.

OSHA requires that high hazard work areas (e.g., most laboratories) be inspected for work hazards more frequently than annually and that locations where biological materials are used or stored have biohazard warning labels.

USDA's occupational safety and health management program is administered by the Assistant Secretary for Administration's Safety and Health Management Division (SHMD). The SHMD is responsible for program management including developing departmental policies and procedures and monitoring program compliance. The SHMD also advises the Assistant Secretary as well as agency officials in the planning, development, and implementation of policies, programs, and systems that affect the safety and health of USDA employees.

Biological Waste

Biological waste regulation is primarily a State responsibility. The Federal Resource Conservation and Recovery Act of 1976 required that the Environmental Protection Agency (EPA) establish a "cradle-to grave" management system for solid wastes identified as hazardous. Congress defined hazardous waste as a solid waste, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may (1) cause or significantly contribute to an increase in mortality or an increase in serious illness or (2) pose a substantial present or potential hazard to human health or the environment when

improperly treated, stored, transported, disposed, or otherwise managed. These wastes can be solids, liquids, or gases.

EPA published proposed regulations in 1978 regarding hazardous waste including treatment methods for biological or infectious waste; however, the regulations were not finalized. In response to numerous requests for technical information and guidance on management of biological waste, EPA published the EPA Guide for Infectious Waste Management in May 1986. Waste categories routinely considered infectious include (1) microbiological wastes, such as stocks and cultures of infectious agents, (2) liquid blood and blood products, (3) isolation wastes from patients with communicable diseases, (4) pathological wastes such as body tissues and organs, (5) used "sharps" such as needles, scalpels, and broken glassware, and (6) contaminated animal carcasses, body parts, and bedding.

Although EPA never published final biological waste regulations, most States have regulations governing waste management. However, States' controls vary in definitions and types of waste regulated; categories of waste generators regulated; handling, treatment, and disposal requirements; compliance activities; and enforcement actions taken. Executive Order 12088, Federal Compliance With Pollution Control Standards, dated October 13, 1978, requires Federal agency compliance with these controls.

Departmental Manual (DM) 5600-1, Environmental Pollution Prevention, Control, and Abatement Manual, dated December 9, 1992, provides policies and procedures for USDA's environmental programs including solid and hazardous waste management programs. This manual does not specifically address biological waste; however, it does compel agencies to take leadership in the prevention, control, and abatement of environmental pollution by initiating policies and controls that "minimize adverse impacts on the quality of the environment."

The Assistant Secretary's Hazardous Waste Management unit monitors agency compliance with hazardous materials and waste requirements. Day-to-day management of environmental programs is an agency responsibility.

During the exit conference on December 3, 1996, we were informed that DR 4400-2 had been superseded. SHMD had developed a USDA Safety and Health Manual to consolidate Department directives and guidance. The manual was approved for issuance on November 26, 1996, but as of December 3, 1996, had not been sent to the agencies. Our review of the manual found only one paragraph on biological safety compared to five pages on radiation safety. Important management controls detailed in DR 4400-2 were left out of the manual. These controls included (1) maintenance of biological agent inventories, updated annually, (2) development of agent MSDS' that identify disease symptoms, available treatment, disposal and disinfection methods, and personal protection, and (3) training

employees who may be exposed to agents when initially assigned and whenever a new agent is introduced in the workplace. Also, there was no mention of CDC's BMBL manual, or OSHA's bloodborne pathogen requirements. A biological safety workgroup was proposed by SHMD in June 1996 to review the draft manual and develop USDA policy on biological safety, but it never materialized.

Three USDA agencies routinely work with biological agents: The Agricultural Research Service (ARS), the Animal and Plant Health Inspection Service (APHIS), and the Food Safety and Inspection Service (FSIS).

- ARS is the primary research arm of USDA. ARS employees conduct research with animal and human pathogens and toxins and routinely work with animals exposed to agents that pose a threat to humans. ARS laboratories routinely work with such pathogens as Brucella, Mycobaterium bovis (M. bovis), and Salmonella.

- APHIS is responsible for protecting livestock and poultry from disease and pests. To meet these responsibilities, monitoring and support services are provided. Laboratory services include a wide array of diagnostic procedures. Agents routinely encountered include Leptospira interrogans, M. bovis, Brucella, and Escherichia coli (E. coli) among others. In addition, APHIS manages three animal quarantine centers. It also regulates the import and domestic shipment of animal pathogens.

- FSIS ensures that meat and poultry products are safe and wholesome for human consumption. Meat and poultry samples are routinely collected and forwarded to FSIS laboratories for analysis. Typical pathogens encountered include E. coli, Staphylococcus aureus, Listeria monocytogenes, and Salmonella.

Most of USDA's work with biological agents does not exceed BSL-2 practices, equipment, and facilities. Some USDA facilities such as ARS' and APHIS' [redacted] (b) 2 facility at [redacted] and ARS' [redacted] (b) 2 work with biological agents that require BSL-3 security. USDA does not work with BSL-4 agents.

OBJECTIVES

The objective of the audit was to assess the adequacy of the Department's and agencies' management control systems for ensuring USDA facility compliance with requirements and standards for handling, storage, and disposal of biological material (agents) and waste.

Although USDA control over human pathogens was the primary focus of this audit, many of the same management controls apply to animal and plant pathogens handled and stored in USDA facilities.

SCOPE

The audit was directed at USDA facilities where employees may be exposed to harmful biological agents. We assessed management control systems at the departmental, agency, and facility levels. Management controls assessed included policies and operating procedures pertinent to (1) handling, storage, transfer, and disposal of biological agents, (2) storage and disposal of biological (or hazardous) waste, and (3) employee safety and health programs. We did not assess management controls over biological agents and waste handled by USDA employees outside of USDA facilities.

The audit included reviews at USDA's SHMD and FSIS Headquarter offices in Washington, D.C., ARS Headquarters in Beltsville, Maryland, and an APHIS office in Riverdale, Maryland. We visited six USDA laboratories (the [redacted] laboratory was considered one facility) and one animal quarantine center. (See exhibit A for USDA offices and facilities visited.) We contacted Commerce, DHHS, CDC, and various State officials. We assessed controls in effect and activities during the period August 1995 through August 1996. The audit was conducted in accordance with generally accepted government auditing standards.

METHODOLOGY

To accomplish the audit objectives we

- reviewed Federal and State requirements and guidance governing USDA facilities' handling, storing, transferring, and disposing of biological agents and waste,
- evaluated departmental and agency employee safety and health programs with emphasis on biosafety,
- studied the Department's and agencies' solid and hazardous waste management programs with emphasis on biological waste management,
- assessed departmental and agency organizational controls and policies and procedures for managing biological agents and waste,
- evaluated agency safety and health inspection instruments and reports,
- reviewed agency accident reports and facility employee training records, and

- developed a questionnaire about biological agent and waste management practices and controls and analyzed responses from 71 USDA facilities. These facilities were identified from prior audit work as potentially possessing human pathogens and/or handling infected animals.

Based on questionnaire responses, about 37 USDA facilities (26 ARS, 7 APHIS, and 4 FSIS) may possess human pathogens and/or handle potentially infected animals. Other USDA facilities may dispose of biological waste (e.g., needles and syringes) depending upon State waste definitions. To assess agency controls, we judgmentally selected and reviewed seven facilities that would reflect the number and types of facilities managed by each agency.

USDA controls over hazardous material (chemicals) and associated waste were reported on in September 1992 (Office of Inspector General (OIG) Audit Report No. 50099-28-At).

FINDINGS AND RECOMMENDATIONS

MANAGEMENT CONTROLS OVER BIOLOGICAL AGENTS AND WASTE NEED STRENGTHENING TO REDUCE RISK

USDA's management controls over biological agents and associated waste were not adequate to minimize risks to employees, public health, and the environment. Some biological agents which were routinely handled, stored, transferred, and disposed of by USDA facilities could pose a serious threat to human health and the environment due to the absence of controls. A small number of dangerous biological agents we identified could pose a risk to national security if improperly disposed of or illicitly obtained by persons with ill intent. The Department's and agencies' solid and hazardous waste management programs did not address biological waste.

We identified control deficiencies at all seven USDA facilities visited. Significant deficiencies which needed immediate corrective action were reported to departmental and agency management during our audit and were promptly addressed. Additional actions are needed, however, to establish adequate management control systems at all organizational levels. The deficiencies we found could have been avoided or promptly detected if adequate control systems had been in place.

DEPARTMENT AND AGENCY CONTROLS OVER BIOLOGICAL AGENTS AND WASTE WERE NOT ADEQUATE

FINDING NO. 1

The Department and the three agencies that routinely handle, store, transfer, and dispose of biological agents did not have adequate management controls to ensure compliance with Federal and/or State requirements. USDA had established programs to address facility management of hazardous materials (chemicals) and associated waste but had no biological safety or waste management programs. As a result, agencies did not have comprehensive policies to control biological agents and waste. Significant deficiencies were identified at all seven facilities we visited (see Findings Nos. 2 and 3). The inadequate controls over biological agents and waste increase the risk posed to human health and the environment. According to the CDC, illicit access to some

dangerous biological agents we identified could have adverse consequences on national security.

Departmental Controls - Programs, Policies, and Monitoring

The Department needs to establish programs and comprehensive written policies for managing its biological agents and waste. It also needs to better monitor agency compliance with its policies and Federal and State safety and health and environmental requirements regarding biological agents and waste.

Overall management of the Department's safety and health and environmental programs is the responsibility of USDA's Assistant Secretary for Administration. The Assistant Secretary's SHMD was delegated responsibility for developing policies and monitoring agency compliance with safety and health requirements. The Assistant Secretary's Hazardous Waste Management unit is responsible for monitoring agency compliance with hazardous waste requirements. Responsibility for day-to-day management of the Department's safety and health and environmental programs was delegated to agency heads.

DR 4400-2, Hazard Communication Programs, dated October 14, 1986, provides comprehensive policy for managing chemicals and biological agents. The policy established requirements beyond those required by OSHA. OSHA's requirements only apply to chemicals. USDA policy requires that each agency and staff office inform employees of the potential physical and health hazards that may result from exposure to chemicals and biological agents which are present in the workplace. The regulation requires that biological agents be treated the same as hazardous chemicals. Required controls include (a) maintaining accurate biological agent inventory records, updated annually, (b) developing MSDS' for individual biological agents handled and stored in the workplace that identify disease symptoms, available treatment, disposal and disinfection methods, and personal protection, and (c) training employees who may be exposed to the potential hazards when initially assigned and whenever a new agent is introduced into the workplace.

The Department had no biological safety program. When departmental safety issues arose regarding biological agents, ARS' Biological Safety Officer was consulted. SHMD conducted no reviews of facility biosafety. SHMD received annual safety and health reports from ARS, APHIS, and FSIS, but the reports provided no detailed results of facility inspections and no information regarding biological safety.

USDA's solid and hazardous waste management programs did not address biological waste. DM 5600-1, Environmental Pollution Prevention, Control, and Abatement Manual, dated December 9, 1992, provides objectives, policies, and procedures for managing USDA's various environmental programs and requires agencies to establish solid and hazardous waste management programs. DM 5600-1 primarily restates EPA regulations. The EPA regulations were directed at management of chemical waste and they did not address biological waste. As a

result, the Department's hazardous waste program did not include biological waste requirements. Compliance reviews by the Department's Hazardous Waste Management unit did not address biological waste.

Although day-to-day management of biological agents and waste was an agency responsibility, the Department had responsibility to provide policy guidance and oversee agency activities including ensuring compliance with Federal and State statutory and regulatory requirements and standards.

Agency Controls - Programs, Policies, and Monitoring

ARS, APHIS, and FSIS need to strengthen their programs and policies for managing and monitoring biological agents and waste. Each agency is responsible for (a) operating a safety and health program that complies with all Federal and State regulatory requirements and standards and departmental policies and directives, (b) providing necessary resources to develop and manage the program, (c) ensuring that workplace inspections for hazardous conditions are performed by qualified and properly equipped personnel and include prompt deficiency abatement, and (d) providing appropriate training to all employees. For USDA environmental programs, agency responsibilities include (a) ensuring that all necessary actions are taken for the prevention, control, and abatement of pollution at facilities under agency jurisdiction, (b) complying with all applicable Federal and State pollution regulations and standards, (c) developing improvement plans and providing followup reports to achieve and maintain compliance, and (d) providing adequate funding in agency budgets for compliance.

None of the agencies had biosafety programs, and their solid and hazardous waste management programs did not include biological waste. This was because the Department did not require that agency safety and health and hazardous waste management programs include biological controls. Only ARS had a biosafety officer, but he had no professional staff, developed no written policies and procedures, conducted no routine facility reviews, and received no routine facility reports regarding biosafety. His primary responsibilities were to assess construction projects for biocontainment and act as a consultant when biosafety problems occurred. ARS' safety and health staff was organizationally and functionally separate from ARS' biosafety officer.

All agencies had fulltime staff assigned at the Headquarter's level to develop policies and monitor compliance related to employee safety and health and environmental programs. However, only FSIS conducted routine facility reviews of biosafety and waste management. An FSIS contractor performed the reviews. ARS' and FSIS' safety and health staff duties at the Headquarter's level did not include biosafety or biological waste management. FSIS' safety and health staff was organizationally and functionally separate from staff responsible for laboratory safety.

Day-to-day management of agency safety, health, and environmental programs was generally a facility responsibility. Each facility had full-time or collateral-duty safety officers. Large facilities such as [b2] and [b2] had full-time safety officers and staff. ARS also had full-time safety and health staff located in area offices who were responsible for managing facility safety and health activities. ARS and APHIS required that their laboratories establish safety committees to assist facility management with oversight of operations.

Agency written policies regarding biosafety did not always incorporate Department policy. For example, ARS' Safety, Health, and Environmental Management Program Manual reiterated departmental policy regarding maintenance of biological agent inventories, MSDS', and provision of employee training. APHIS had no similar policies. FSIS' safety manual did not include the requirement for biological agent inventories. ARS had not developed policy implementing OSHA's bloodborne pathogen requirements, although the Department had issued guidance in December 1991.

None of the agencies' safety manuals included policies for authorizing facility receipt and use of new biological agents or transferring agents from facilities (e.g., agents in culture collections). Commerce had strict requirements for export of select human pathogens, and APHIS regulated the import and domestic shipment of animal pathogens. The DHHS recently published proposed regulations to control domestic receipt and transfer of certain dangerous biological agents capable of causing substantial harm to humans and to national security.

ARS' project approval process was its primary control for ensuring the proper handling, storage, and disposal of biological agents used in its facilities. The approval process included reviews of project proposals by peer groups and by agency officials at facility, area, and headquarter levels. ARS area directors certified that proposed projects comply with all applicable requirements. However, safety and health staff or safety committees were not part of the approval process unless proposed research involved genetic research, biological agents requiring BSL-3 or greater containment, or cooperative biomedical research projects involving humans.

Some laboratory facilities had established policy to control the introduction of new biological agents and agent transfers. For example, because of its research and diagnostic work involving exotic (foreign) animal diseases, ARS' and APHIS' [b2] facility had extensive policy covering introduction of new agents on

the [b2] facility and transfer of agents off the [b2] However, the policies were not followed in all cases. (See Finding No. 2.)

OSHA requires that all Federal facilities receive annual safety and health inspections. Facilities with an increased risk of employee accident, injury, or illness due to the nature of the work performed (e.g., laboratories and animal quarantine centers) are to be inspected more frequently.

The three agencies did not effectively monitor compliance with Federal and State requirements and standards for managing biological agents and waste. Review instruments used by the agencies did not address proper handling, storage, and disposal of biological agents and waste. Additionally, ARS and APHIS did not conduct safety and health inspections as frequently as required by OSHA.

ARS and APHIS had developed standard checklists for conducting facilities safety and health inspections. FSIS and some APHIS facilities developed their own inspection instruments. For example, APHIS' National Veterinary Services Laboratories (NVSL) safety and health staff tailored inspection checklists to individual laboratory rooms. None of the inspection checklists we reviewed assessed compliance with DR 4400-2 regarding biological agent inventories, MSDS', or employee training regarding agents. The instruments did not assess compliance with bloodborne pathogen requirements, nor with State requirements for managing and disposal of biological waste.

Of the seven USDA facilities visited, five (two ARS, two APHIS, and one ARS/APHIS) had not received the required number of safety and health inspections in 1994 and 1995 (see exhibit B). For example, in 1994 there were no inspections conducted or documented at the [b2] facility and at [b2] In 1995, one inspection was made at each facility; however, the ARS Administrator specifically requested the two inspections which were directed primarily at management of hazardous chemicals. FSIS required that facility inspections be conducted quarterly. All required inspections were conducted at FSIS' St. Louis, Missouri, laboratory. ARS' Athens, Georgia, laboratory was also inspected on time.

Timely inspections using comprehensive review instruments are essential to effectively assessing and maintaining facility compliance with safety and health and environmental requirements, thus minimizing risks to employee and public health and the environment. Our audit identified serious noncompliance with biosafety and waste requirements (see Findings Nos. 2 and 3) which involved human pathogens and toxins that pose a threat to human health and the environment. Illicit access to some dangerous agents could pose a risk to national security. Animal and plant health could be adversely impacted by some pathogens in USDA facilities if improperly controlled.

RECOMMENDATION NO. 1a

Incorporate into the Department's Safety and Health Management Program, policies and management controls for biological agents, and require agencies to develop control programs. Minimum controls should include biological agent inventory lists (updated annually), MSDS for human pathogens requiring BSL-2 and above containment (according to the BMBL), appropriate employee training, and timely compliance inspections.

Department Response

On February 25, 1997, the Assistant Secretary for Administration concurred with the recommendation. He stated that since the audit, the USDA Safety and Health Manual had been issued which superseded Department safety and health regulations and consolidated all USDA safety and health program requirements. An adhoc Biological Safety Committee has been established to recommend management controls including (1) formation of a permanent Biological Safety Committee, (2) appointment of a Department Biological Safety Officer and one technical support person, and (3) development of broad-based policy which will address the need for agency biological safety policies and recordkeeping, facility inspection, and employee training requirements. Approval of the Department's Management Council will be required to fund and establish an ongoing departmentwide biological safety program.

Action	Date
Forward adhoc committee recommendations to the Management Council	28 MAR 97
Recommend the appointment of a Biological Safety Officer	28 MAR 97
Publish guidelines for control of selected dangerous biological agents	15 APR 97
Establish the USDA Biological Safety Committee	30 MAY 97
Develop a Biological Safety chapter in the USDA Safety and Health Manual	29 AUG 97

OIG Position

The Department's response was positive; however, to reach management decision we need assurance that the proposed biological safety chapter to be incorporated in the USDA Safety and Health Manual will include the minimum controls detailed in the recommendation. Agencies should be required to implement these controls whether or not a departmentwide biological safety program is approved.

RECOMMENDATION NO. 1b

Incorporate into the Department's environmental pollution prevention, control, and abatement policy, management controls for biological waste, and require that agencies implement those controls.

Department Response

The Assistant Secretary for Administration stated on February 25, 1997, that:

> *The Department concurs with this recommendation. Management controls for biological wastes, and the requirement for agency implementation will be in the Biological Safety chapter in the USDA Safety and Health Manual, and cross-referenced in the Department's Environmental Pollution Prevention, Control, and Abatement policy.*

This task will be completed by August 29, 1997.

OIG Position

We agree with the management decision.

RECOMMENDATION NO. 1c

Require that each agency develop and disseminate written policies that (1) incorporate all Department policies and management controls for biological agents, (2) establish controls over the receipt, use, storage, and transfer of high risk biological agents, and (3) reiterate OSHA's bloodborne pathogen requirements and establish controls at the facility level for working with human blood and bloodproducts.

Department Response

On February 25, 1997, the Assistant Secretary for Administration stated that:

> *The Department concurs with this recommendation. Agencies will develop and implement written policies which incorporate Department policies and management controls for biological agents. * * * Policies and management controls for high-risk agents will be incorporated in the USDA Safety and Health Manual. Additional bloodborne pathogen requirements will be incorporated in the Department's Safety and Health Manual.*

These tasks will be accomplished by August 29, 1997.

OIG Position

We agree with the management decision.

RECOMMENDATION NO. 1d

Require that each agency establish controls to ensure the conduct of effective and timely safety and health inspections, and revise inspection requirements and instruments to include facility compliance with departmental and State requirements for handling, storing, transferring, and disposing of biological agents and waste.

Department Response

The Assistant Secretary for Administration stated on February 25, 1997, that:

> *The Department concurs with this recommendation. The Department's new Safety and Health Manual requires that agencies establish management controls to ensure compliance with applicable Department, Federal, and local biological safety requirements. A letter will be sent to agency heads reminding them of these requirements. In addition, specific procedures will be included in the USDA Safety and Health Manual.*

These tasks will be completed by October 17, 1997.

OIG Position

We agree with the management decision.

RECOMMENDATION NO. 1e

Establish a departmental review or monitoring process to ensure that agencies conduct effective and timely facility reviews to assess agency compliance with Federal and State requirements for managing biological agents and waste.

Department Response

The Assistant Secretary for Administration stated on February 25, 1997, that:

> *The Department concurs with this recommendation. The role of the Department's Biological Safety Committee will include the oversight and monitoring of agency compliance with Federal and State requirements for managing biological agents and wastes. The committee will develop review criteria and conduct targeted reviews of USDA agency programs. Agencies will be required to conduct periodic reviews of agency facilities. The committee will require agencies to submit annual reports of program status and accomplishments.*

These tasks will be accomplished by August 31, 1998.

OIG Position

The response was positive; however, creation of a Biological Safety Committee is subject to the Management Council's approval. Also, DR 1720-1 requires that implementation of corrective action must occur within 12 months of report issuance. To reach management decision, we need the Management Council's approval and a revised corrective action date.

FACILITIES DID NOT MAINTAIN ADEQUATE CONTROL OVER THEIR BIOLOGICAL AGENTS

FINDING NO. 2

The seven USDA facilities we reviewed did not comply with requirements for managing their biological agents (see exhibit B). This occurred in part because the Department and/or managing agencies had not (a) established formal biosafety programs, (b) developed comprehensive written policies incorporating appropriate biological agent controls, and (c) effectively monitored to ensure facility compliance (see Finding No. 1). Because facilities did not maintain adequate controls over biological agents, employees and public health and the environment were at risk. Illicit access to some agents in USDA facilities could adversely impact national security.

Agent Inventories

DR 4400-2, Hazard Communication Programs, provides specific policies to reduce potential employee exposure to harmful biological agents. Requirements include biological agent inventory records, updated annually. Facility management's knowledge of biological agents onhand is critical in making decisions regarding employee safety and health, biocontainment, and security.

Five of six laboratories reviewed did not maintain adequate control over their biological agent inventories. Inventory control did not apply to APHIS' animal quarantine center.

ARS - [b2]

The [ ] did not maintain inventory records of all biological materials at the facility. We discovered a microorganism culture collection containing pathogens that the facility's director and the responsible research leader were not aware existed. Research activities such as culturing several pathogens in the collection would have been incompatible with the facility's maximum biosafety level (BSL-2). The collection, which had been inventoried, contained about 80,000 microorganisms which were stored in unlocked refrigerators without biohazard signs. Although we did not review 100 percent of the collection, we identified 18 strains of Bacillus anthraces (anthrax), 3 species of Mycobacterium (including M. tuberculosis), Salmonella typhi (typhoid fever), Vibrio cholerae (cholera), Pseudomonas pseudomallei, and Histoplasma capsulatum (histoplasmosis). Bacillus anthraces, M. tuberculosis, and Histoplasma capsulatum require BSL-3 facilities when working with cultures. The research leader said that these pathogens were not needed and would be destroyed or donated to a recognized repository.

In one walk-in cooler, we observed about 10 test tubes labeled only "Fusarium" and dated May 5, 1978, that were not inventoried. Facility research leaders were unaware of this material and did not know its origin or need.

ARS - [b2]

The [b2] facility was operated as one facility managed by ARS. Although it contained two agencies' laboratories, it was operated as one facility with one director and one safety and health office. The facility is the only place in the United States that legally worked with the Foot and Mouth Disease virus, a serious animal pathogen. It is on an [b2] and access is limited. All work was conducted under BSL-3 or greater containment requirements. At our request, the facility prepared an agent inventory list prior to our visit. Our review

identified about 40 agents in freezers throughout the facility that were not on the inventory list. Most were animal pathogens; however, some were zoonotic (affecting both humans and animals). These included Venezuelan equine encephalomyelitis virus, Rabies virus, and Wesselsbron virus. We found biological agents and potentially infected serums remaining in vacant laboratories that had been seldom used for several years and agents in working laboratories that were no longer needed. The facility had a comprehensive policy that required a registry of all agents to be maintained. It required that new agents be reviewed by safety and health staff before being allowed on the island. Similar controls were specified for transferring agents off the [b2] However, these policies were not always followed.

FSIS - [b2]

The [b2] inventory of biological agents was not complete. We found several vials of Clostridium botulinum (botulism)-type B toxin in an unlocked refrigerator with no biohazard sign as required by OSHA regulations. The toxin had not been inventoried. The facility's microbiologist-in-charge had told us before our discovery that the facility did not have any of this material. The workers in the laboratory where it was located had not received CDC's recommended toxoid inoculations. The maximum biosafety level of the facility (BSL-2) is not compatible with some uses of this toxin. We identified other agents that were not on the inventory list provided by facility management and were outdated. These agents, provided by the American Type Culture Collection, were outdated according to label expiration dates. For example, we found Campylobacter jejuni (gastroenteritis) expired July 1983; Clostridium tetani (tetanus) expired November 1983; and Salmonella typhi (typhoid fever) expired November 1988.

ARS - [b2]

An accurate and complete inventory of biological agents was not maintained. In three of seven laboratory units visited, we found human pathogens that were not shown on the facility's master inventory list. In one research unit, we found various E. coli, various Salmonella species, Shigella, and Proteus species that were not listed. In another unit, we found Listeria cultures that were not listed and were no longer used in the unit's research. In the third unit, we found Vesicular stomatitis virus (New Jersey strain) and a culture collection of Enteroccoccus. The collection had been brought to the unit by a new principal investigator; however, this pathogen was not used in any unit research. The [b2] director was not aware of these pathogens. He agreed that a comprehensive facility inventory should be taken and a needs assessment done.

APHIS - [b2]

The [ ] did not maintain a biological material inventory list. Our review determined that all diagnostic units did not maintain lists as required. For example, we found three freezers in the basement that were not inventoried. In a walk-in cooler, we observed Clostridium tetani (tetanus) dated December 3, 1982, that was not listed. A laboratory employee said that it should be destroyed.

The CDC has expressed serious concerns regarding potential terrorist access to dangerous human pathogens and their threat to human health and national security. In October 1996, DHHS issued regulations regarding acquisition and transfer of certain biological agents. These agents included anthrax, botulism, brucellosis, plague, Q-fever, tularemia, and any agents classified for work at BSL-4. Some of these agents were identified in USDA laboratories during our audit.

Researchers and other scientists routinely accumulate and maintain microorganism collections which they have spent years developing. Often, when researchers transfer, their collections transfer with them, even if the research changes. When scientists retire, their collections may remain at a facility. These collections often contain harmless microorganisms, but some contain dangerous human, animal, and/or plant pathogens. Items in these collections are often shared with other scientists. For example, items in the large collection at ARS' laboratory in [b2] are routinely, upon request, sent to other facilities. Laboratory management was unaware of all items in the [b2] collection. Some items had been in the collection since the 1940's.

ARS Headquarters officials did not have information to identify dangerous pathogens being maintained or used in its laboratories. In addition, neither USDA nor ARS have written policies and procedures regarding access to dangerous pathogens.

In May 1996, we reported to the agencies our concerns about controls over inventories at the laboratories visited. We recommended that the agencies immediately conduct physical inventories at all laboratories which potentially possess dangerous human pathogens, perform needs assessments, and dispose of or store and control access to such agents. We also recommended that the agencies survey their scientists to identify all collections for proper inventory identification, access control, and disposition. All agencies agreed to take immediate action to correct the deficiencies.

Bloodborne Pathogens

OSHA's Title 29, Code of Federal Regulations 1910.1030, Occupational Exposure to Bloodborne Pathogens, effective March 6, 1992, and departmental guidance issued in December 1991, established compliance standards for all occupational exposures to pathogenic

microorganisms that are present in human blood or human body fluids. These pathogenic organisms include, but are not limited to, the Hepatitis-B virus and the human immunodeficiency virus. Other examples of bloodborne pathogens include Brucellosis, Leptospirosis, Arboviral infections, Babesiosis, and Viral Hemorrhagic fever. OSHA requires that written Exposure Control Plans be developed to eliminate or minimize employee exposure, and that employees receive training from qualified personnel regarding risks. Hepatitis-B vaccinations must be made available to all employees who may have occupational exposure, at no cost to the employee. If employees decline vaccinations, a signed statement must be kept on record.

We found that laboratory units at four facilities we reviewed were using or had recently used human blood and/blood serums without complying with OSHA requirements.

ARS - [b2]

[b2] officials told us that human blood or blood products were not used in the facility; however, we identified employees in at least six laboratory units working with or risking exposure to blood without adequate safeguards. [b2] had not specifically identified the employees nor provided training in bloodborne pathogen requirements, as required. Although [b2] officials stated that the employees were offered Hepatitis-B vaccinations, only 3 of the 23 employees received vaccinations. Required records were not maintained to document employees declining vaccinations. Two units tested employee blood for medical surveillance purposes and used the results for diagnosis. NADC officials stated that employee blood testing was conducted because the level of testing done could not be provided by outside laboratories. The laboratory testing violated the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (section 353 of the Public Service Act) by having examined human serums and cultures and reporting the results for diagnostic purposes without required CLIA certification. Facility safety staff or the safety committee had not reviewed the associated research projects. In December 1995, ARS officials were notified regarding this deficiency, and all unauthorized human blood testing was stopped and proper controls were established.

ARS [b2]

One facility laboratory conducting human nutrition research, obtained blood samples from university students. The facility did not have an Exposure Control Plan, unit employees had not been offered Hepatitis-B vaccinations, and required safety training on bloodborne pathogens was not provided. The projects research proposal clearly stated that human blood would be used; however, neither safety and health staff nor the safety committee

reviewed the proposal to assess compliance before the project began.

ARS - [b2] and APHIS - [b2]

One laboratory unit had used blood taken from unit employees in diagnostic tests for Viral Hemorrhagic Disease of Rabbits. Testing for the disease was last conducted in 1994. The facility's Exposure Control Plan covered emergency workers (e.g., fire and security), but did not include laboratory workers. Employees had not been offered Hepatitis-B vaccinations or received proper training. When informed, the acting facility director said that human blood would no longer be used. He said that other nonhuman material may be available for use in detecting the disease.

APHIS [b2]

At the entrance conference, we were told that no human blood was used for any purpose at this facility; however, we determined otherwise. One laboratory unit which conducted diagnostic work for Leptospirosis routinely tested unit employees' blood for medical surveillance purposes. An employee working with the blood had not been offered vaccinations or received proper training. It also was not CLIA certified. The acting facility director was not aware of the testing. He said the testing would cease.

MSDS' and Training

The Department required that facilities develop MSDS' for all biological agents on hand and train staff regarding potential exposure to the agents. [b2] had developed some MSDS' but had not completed them for all agents. The other four laboratories had no MSDS' for the human pathogens on hand. The MSDS requirement did not apply to the animal quarantine center reviewed.

All seven facilities visited had not conducted required training and maintained adequate training records to review. For example, most of the [b2] facility's safety and health training was contracted out. However, the contractor did not maintain records. The only safety training documented by the safety staff for the period October 1993 through May 1996 was hazard communication training in late 1994.

Standard Operating Procedures (SOP)

The most important element of biocontainment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or potentially infected materials must be aware of potential hazards, and must be trained and proficient in the practices and techniques required for safely handling such material. The [b2] manual provides that employees should be advised

of special hazards and required to read and follow established standard practices and procedures. Written SOP's should be developed for laboratory practices and techniques which incorporate biosafety. Our review found that the six laboratory facilities visited either had no SOP's or SOP's did not contain safety information.

RECOMMENDATION NO. 2a

Require that each agency facility (1) maintain an inventory list of biological agents and collections, updated annually and (2) conduct periodic needs assessments on biological agents onhand.

Department Response

The Assistant Secretary for Administration stated on February 25, 1997, that:

> *The Department concurs with this recommendation. Each agency will maintain an inventory list of biological agents, updated annually and conduct periodic needs assessments on current inventory.*

A letter will be sent by August 29, 1997, to agency heads directing that this be done.

OIG Position

We agree with the management decision.

RECOMMENDATION NO. 2b

Require that each agency develop and disseminate written policies and procedures to control the acquisition, transfer, and access to dangerous biological agents and to ensure compliance with established regulatory controls (e.g., DHHS and Commerce regulations) regarding domestic transfers and export and import of agents.

Department Response

On February 25, 1997, the Assistant Secretary for Administration stated that:

> *The Department concurs with this recommendation. Each agency has been requested to determine locations where the Select Agents listed in Appendix A to 42 CFR Part 72 are used to*

determine the quantity and/or prevalence of these agents. Quantities may be deferred until facilities conduct thorough inventories of all biological agents (see Response 2a). The Adhoc Biological Safety Committee has established a sub-committee to evaluate the Department's use of Select Agents, and make recommendations on policies and procedures to ensure compliance with established regulatory controls.

Action	Date
Develop guidelines for controls over the receipt, use, storage, and transfer of Select Agents	4 APR 97
Forward letter to affected USDA Agency Heads with guidance on compliance with 42 CFR Part 72, and require the development of written agency policies and procedures to implement regulatory requirements.	4 APR 97

OIG Position

We agree with the management decision.

RECOMMENDATION NO. 2c

Require that each agency identify all work in USDA facilities involving human blood/blood products and ensure that the work is authorized and OSHA's bloodborne pathogen and DHHS CLIA requirements are met, if appropriate.

Department Response

The Assistant Secretary for Administration stated on February 25, 1997, that:

The Department concurs with this recommendation. Each agency will be requested to determine locations where human blood/blood products are used, and to ensure that the work is authorized; and the OSHA's bloodborne pathogen and DHHS CLIA requirements are met where appropriate. APHIS laboratories no longer work with human blood/blood products.

This will be accomplished by August 29, 1997.

OIG Position

We agree with the management decision.

RECOMMENDATION NO. 2d

Require that all USDA facilities where employees may be potentially exposed to biological agents review and/or develop SOP's that include safety information.

Department Response

On February 25, 1997, the Assistant Secretary for Administration stated that:

> *The Department concurs with this recommendation. The requirement for use of SOP's will be included in the proposed USDA Safety and Health Manual.*

This task will be completed by August 29, 1997.

OIG Position

We agree with the management decision.

FACILITIES DID NOT MAINTAIN ADEQUATE CONTROL OVER THEIR BIOLOGICAL WASTE

FINDING NO. 3

The seven USDA facilities reviewed did not comply with State biological waste requirements. One of the facilities was in violation of State law at the time of our review but had submitted to the State the documents required for compliance. Noncompliance occurred because (1) facility management was not aware of State requirements, (2) the Department's and agencies' hazardous waste programs did not include requirements for biological waste management and, (3) agencies did not have effective monitoring systems which incorporated State requirements and assessed compliance (see Finding No. 1). Violations of State environmental regulations could result in fines, degradation of USDA's and facilities' images in the community, and possible harm to employee and public health and the environment.

Biological waste regulation was primarily a State responsibility. Although Congress defined hazardous waste to include any waste that because of its infectious characteristic, poses a potential threat to human health or the environment when improperly treated, stored, transported, or disposed of, EPA's hazardous waste regulations did not include infectious waste. Instead, it published the EPA Guide for Infectious Waste Management in May 1986, which established standards for handling, storing, and disposing of the waste. Many States adopted portions of the guide into law. State control varies in definition and types of waste and categories of waste generators regulated; handling, treatment, and disposal requirements;

compliance activities; and enforcement actions taken.

USDA facilities were required to follow applicable State requirements. We assessed facility compliance and found that all seven USDA facilities reviewed did not comply.

ARS - [b2]

[b2] violated Georgia biomedical waste requirements by improperly disposing of contaminated poultry carcasses in a landfill and via unpermitted incinerators. Also, [b2] laboratory waste was treated in unpermitted autoclaves before disposal. [b2] law defines biomedical waste, in part, as any solid waste containing contaminated animal carcasses (including body parts) and their bedding. Waste must be treated by incinerating, autoclaving, or by another recognized and approved treatment method to render it noninfectious. Facilities that treat biomedical waste onsite by incineration or autoclave must meet minimum standards and be permitted by the State to operate a treatment facility. In [b2] landfills cannot be used to dispose of biomedical waste.

[b2] in cooperative research projects with the [b2] routinely inoculated poultry with Campylobacter and Salmonella. [ ] maintained the birds and disposed of the carcasses and related waste. All waste was originally incinerated in one of two [ ] unpermitted incinerators. However, the incinerator was shut down and some carcasses were sent to a landfill. [b2] was also in the process of constructing a compost facility for poultry carcasses which was going to be used by [ ] [ ] officials were not aware of the State biomedical waste requirements. Composting is not recognized by [b2] as an approved treatment method for the waste. In August 1996, we informed ARS of the disposal violations and corrective action was promptly taken.

ARS - [b2]

[b2] violated [b2] infectious medical waste requirements by (a) autoclaving laboratory materials and waste without being permitted as a treatment facility, (b) not testing autoclaves monthly and documenting their effectiveness, and (c) improperly disposing of needles and syringes in a landfill. The State requires that these instruments be rendered unrecognizable (e.g., grinding) before disposal or the facility must manifest the waste and transport it by a permitted medical waste hauler. Facility officials stated that they were not aware of the State requirements. Facility management took corrective action after being informed about the deficiencies.

FSIS - [b2]

[b2] was not complying with Illinois' infectious medical waste requirements. The facility did not comply because it disposed

of its waste in a Illinois landfill. Management was unaware that its waste hauler disposed of the waste in Illinois. MTSL was not meeting Illinois requirements for (a) permitting as a treatment facility, (b) testing autoclaves by an approved method and documenting test results, and (c) manifesting disposal of recognizable needles and syringes. FSIS officials said that the deficiencies would be corrected.

APHIS - [b2]

[b2] did not meet [b2] medical waste requirements for disposal of needles and syringes (sharps). The facility used sharps routinely to draw animal blood for testing. Sharps were placed in a 2-liter plastic soda bottle until half full, then filled with cement. Full bottles were disposed of in the dumpster with other household trash. It properly disposed of animal carcasses, bedding, blood, and other waste by incineration. State regulators informed us that [ ] was considered a medical waste generator under State law. We determined that the facility did not (a) dispose of its sharps using a licensed biomedical waste hauler, (b) store used sharps in containers that met State specifications, (c) obtain a permit as a medical waste generator, (d) develop a written operating plan to manage its medical waste, and (e) provide applicable employee training. The facility director said he was not aware of the State requirements but would contact State regulators for direction.

ARS - [b2] and APHIS - [b2]

[b2] did not meet [b2] State infectious waste disposal requirements. The facilities were near each other and shared services. [b2] provided [b2] with safety and health staff and waste disposal services including hauling [b2] incinerator ash to a landfill. Both facilities autoclaved most of their laboratory waste before disposal as household trash. Animal carcasses, bedding, needles and syringes, and similar wastes were incinerated at each facility. According to [b2] regulators, the facilities' incinerator ash was infectious waste. Each facility was required to complete Special Waste Authorization forms and submit them to the State with results of residue testing of their ash. The landfill that received the ash was required to be permitted to accept it. Residue testing and forms were completed almost 1 year before our visit, but had not been sent in. The landfill where the ash had been sent was not permitted. We informed facility management and corrective action was taken. Appropriate data was provided the State, and ash was sent to a permitted landfill in an adjoining county.

ARS - [b2] and APHIS - [b2]

At the time of our review, the [b2] facility was not in compliance with New York regulated medical waste requirements. However, based on the results of a State inspection made in

August 1994, actions had been taken to bring the facility into compliance. Because of its work with exotic animal diseases and its [b2] location, [b2] shared most services including administrative, safety and health staff, and waste treatment and disposal processes. State inspectors had found that the facility's three incinerators had no pollution control devices and had not been permitted for treating regulated medical waste. Also, [b2] waste water treatment facility was not permitted. (A new facility became operational in early 1995.) [b2] management hired an outside firm to complete its permit applications and submit them to the State. A State regulator told us that the State was satisfied with actions taken to date.

Deficiencies occurred primarily because (a) USDA facility management was not aware of State requirements for disposal of biological waste and (b) agencies' safety and health inspections did not include questions/steps to assess compliance with State waste requirements. Also the Department's and agencies' solid and hazardous waste management programs did not include biological waste management. (See Finding No. 1.)

Violations of State environmental requirements could result in fines and degradation of USDA's and facilities' images in the community. Continued noncompliance could pose a serious risk to employees, public health, and the environment.

RECOMMENDATION NO. 3

Require each agency to notify its facilities of deficiencies disclosed by this audit, and direct that facility management determine applicable State requirements and review biological waste management practices (including disposal of sharps) for compliance.

Department Response

On February 25, 1997, the Assistant Secretary for Administration stated that:

> *The Department concurs with this recommendation. Affected facilities will be notified of the deficiencies disclosed by this audit after we have received the final report.*

This will be done by March 28, 1997.

OIG Position

To reach management decision, we also need a planned timeframe for agencies' facility management to identify State biological waste requirements and review their facilities compliance.

EXHIBIT A - USDA OFFICES AND FACILITIES REVIEWED

Agency	Entity	Location
Assistant Secretary	Safety and Health Management Division	Washington, D.C.
ARS	National Program Staff - Biological Safety Officer	Beltsville, Maryland
	[b2]	[b2]
	[b2]	[b2]
	[b2] 1/	[b2]
	[b2]	[b2]
APHIS	Management Services Division - Contracting, Engineering and Safety Branch	Riverdale, Maryland
	[b2] 1/	[b2]
	[b2]	[b2]
	[b2]	[b2]
FSIS	Science and Technology Program	Washington, D.C.
	Personnel Division - Program Evaluation and Safety Branch	Washington, D.C.
	Administrative Services Division - Environmental Management Branch	Washington, D.C.
	[b2]	[b2]

1/ Operated as one facility managed by ARS

EXHIBIT B - BIOLOGICAL AGENT AND WASTE DEFICIENCIES

		COMPLIANCE DEFICIENCIES							
Agency	Facility	Inspection Frequency	Inspection Checklists	Inventory Records	Blood Handling	MSDS'	Training	SOP's	Waste Disposal
ARS	[b2]	X	X	X	X	X	X	X	X
ARS	[b2]	X	X	X	X	X	X	X	X
ARS	[b2]	X	X	X	X	X	X	X	2/
ARS	[b2]		X			X	X		X
APHIS	[b2]	X	X	X	X	X	X	X	2/
APHIS	[b2]	X	X	N/A	N/A	X	X	X	X
APHIS	[b2]	X	3/	X	X	X	X	X	X
FSIS	[b2]		X	X		X	X	X	X

X Deficiencies noted during audit.

1/ Operated as one facility.
2/ Treatment permit applications were submitted, but not approved by the [b2] at review time.
3/ Comprehensive checklists, but did not include questions to assess biological inventory and waste management.

EXHIBIT C - DEPARTMENT RESPONSE TO THE DRAFT REPORT

DEPARTMENT OF AGRICULTURE

OFFICE OF ASSISTANT SECRETARY FOR ADMINISTRATION

WASHINGTON, D. C. 20250-0100

FEB 2 5 1997

TO: Raymond G. Poland
Regional Inspector General for Audit
U.S. Department of Agriculture

FROM: Wardell C. Townsend, Jr
Assistant Secretary for
Administration

SUBJECT: Department's Response to Official Draft Report on Biological Material and Waste Management by USDA Agencies

This is in response to your request for the Department's response to Audit 50099-5-At, Biological Material and Waste Management. Attached are the Department's responses to the recommendations contained in the audit, and planned corrective actions and completion dates.

If you have questions, please contact James A. Stevens, Director, Safety and Health Management Division at (202) 720-8248.

EXHIBIT C - DEPARTMENT RESPONSE TO THE DRAFT REPORT

Background:

As a result of the subject audit, the Department has established an adhoc Biological Safety Committee. The role of this adhoc committee is to develop the required corrective actions and proposed completion dates to address the audit findings. In addition, the adhoc committee considered new Department of Health and Human Services (DHHS) regulations to control the acquisition and transfer of Select Agents.

The enclosed responses were developed by the adhoc committee. It should be noted however, that the planned actions will require considerable resources (i.e., staffing, training, travel and per diem, equipment and supplies, etc.) **These resource needs have not been previously identified.** Therefore, the approval of the Department's Management Council will be required to fund, and establish an on-going, Department-wide, Biological Safety Program. This funding is required to implement the planned corrective actions. If this funding cannot be secured, possibly other less effective corrective actions will have to be developed.

We will advise your office of the status of the Department's Management Council's decisions regarding this program.

Following are the Department's responses to Audit 5009-5-At:

Recommendation No. 1a

Department's Response:

The Department concurs with this recommendation. Since the audit, we have issued a revised Safety and Health Manual which consolidates all safety, health, biological safety, workers' compensation, employee wellness and fitness, drug-testing, HIV/AIDS, and radiation safety program guidance. The new manual supercedes all previously issued safety and health Departmental Regulations. A new separate section of the manual addresses basic program elements required for the Department's biological safety program.

An adhoc Biological Safety Committee has been established to recommend management controls to address the concerns identified in the subject report. The committee's recommendations will be forwarded to the Department's Human Resource Management Council for approval. Most agencies have initiated inventory procedures in response to prior Management Alerts issued by your office. The committee will also recommend the formation of a permanent Biological Safety Committee, and the appointment of a Biological Safety Officer, and one technical support staff person. The committee recommends the development of a broad-based policy which will address the need for agency biological safety policies, record keeping, facility inspection, and employee training.

Proposed Completion Dates:

		Date
1.	Establish an Adhoc Biological Safety Committee	14 JAN 97
2. 3.	Forward Adhoc Committee Recommendations to the Management Council	28 MAR 97
4.	Recommend the appointment of a Biological Safety Officer	28 MAR 97
5.	Publish guidelines for control of selected dangerous biological agents	15 APR 97
6.	Establish the USDA Biological Safety Committee	30 MAY 97
7.	Develop a Biological Safety chapter in the USDA Safety and Health Manual	29 AUG 97

Recommendation No. 1b

Department's Response

The Department concurs with this recommendation. Management controls for biological wastes, and the requirement for agency implementation will be in the Biological Safety chapter in the USDA Safety and Health Manual, and cross-referenced in the Department's Environmental Pollution Prevention, Control, and Abatement policy.

Proposed Completion Date:

		Date
1.	Incorporate policies and procedures for agency implementation of biological waste management and disposal in the Biological Safety chapter in the USDA Safety and Health Manual, and cross-referenced in the Department's Environmental Pollution Prevention, Control, and Abatement policy.	29 AUG 97

Recommendation No. 1c

Department's Response

The Department concurs with this recommendation. Agencies will develop and implement written policies which incorporate Department policies and management controls for biological agents. The adhoc committee has initiated a Department-wide inventory of the Select Agents identified in Appendix A to 42 CFR Part 72. Contact with DHHS officials has also been made to determine applicability of the standard to certain USDA facilities and operations (e.g., food laboratories, grain-handling facilities, etc.) Policies and management controls for high-risk agents will be incorporated in the USDA Safety and Health Manual. Additional Bloodborne Pathogen requirements will be incorporated in the Department's Safety and Health Manual.

Proposed Completion Date:

		Date
1.	Complete Department-wide inventory of Select Agents.	7 MAR 97
2.	Develop guidelines for controls over the receipt, use, storage, and transfer of Select Agents	4 APR 97
3.	Revise the Department's Safety and Health Manual to incorporate bloodborne pathogen policy guidance.	29 AUG 97
4.	Revise the Department's Safety and Health Manual to incorporate policies and procedures to control the receipt, use, storage, and transfer of Select Agents.	29 AUG 97
5.	Request each agency to develop and disseminate written policies that incorporate all Department policies and management controls for biological agents; bloodborne pathogen programs; and control of Select Agents.	29 AUG 97

Recommendation No. 1d

Department's Response

The Department concurs with this recommendation. The Department's new Safety and Health Manual requires that agencies establish management controls to ensure compliance with

applicable Department, Federal, and local biological safety requirements. A letter will be sent to agency heads reminding them of these requirements. In addition, specific procedures will be included in the USDA Safety and Health Manual.

Proposed Completion Date:

		Date
1.	Forward letter to affected USDA agency heads to remind them of their responsibilities to ensure the establishment and implementation of required management controls, and for compliance with policy and regulatory requirements.	17 OCT 97
2.	Incorporate inspection and compliance requirements in the proposed USDA Biological Safety Handbook.	29 AUG 97

Recommendation No. 1e

Department's Response

The Department concurs with this recommendation. The role of the Department's Biological Safety Committee will include the oversight and monitoring of agency compliance with Federal and State requirements for managing biological agents and wastes. The committee will develop review criteria and conduct targeted reviews of USDA agency programs. Agencies will be required to conduct periodic reviews of agency facilities. The committee will require agencies to submit annual reports of program status and accomplishments.

Proposed Completion Date:

		Date
1.	Establish compliance sub-committee.	14 NOV 97
2.	Incorporate inspection and compliance requirements in the proposed USDA Biological Safety Handbook.	20 FEB 98

		Date
3.	The committee will conduct targeted agency facility reviews. Require agencies to conduct periodic facility reviews and to submit annual reports to committee.	31 AUG 98.

Recommendation No. 2a

Department's Response

The Department concurs with this recommendation. Each agency will maintain an inventory list of biological agents, updated annually and conduct periodic needs assessments on current inventory.

Proposed Completion Date:

		Date
1.	Forward letter to affected USDA agency heads to require them to maintain an inventory list of biological agents, updated annually and conduct annual updates and periodic needs assessments on current inventory.	29 AUG 97
2.	Incorporate review of agency inventory lists as part of the required agency and Biological Safety Committee's inspection procedures in the USDA Safety and Health Manual.	31 AUG 98

Recommendation No. 2b

Department Response

The Department concurs with this recommendation. Each agency has been requested to determine locations where the Select Agents listed in Appendix A to 42 CFR Part 72 are used to determine the quantity and/or prevalence of these agents. Quantities may be deferred until facilities conduct thorough inventories of all biological agents (see Response 2a.) The Adhoc Biological Safety Committee has established a sub-committee to evaluate the Department's use of

Select Agents, and make recommendations on policies and procedures to ensure compliance with established regulatory controls.

Proposed Completion Date:

		Date
1.	Establish adhoc sub-committee to evaluate the Department's use of Select Agents, and make recommendations on policies and procedures to ensure compliance with established regulatory controls.	11 FEB 97
2.	Develop guidelines for controls over the receipt, use, storage, and transfer of Select Agents	4 APR 97
3.	Forward letter to affected USDA Agency Heads with guidance on compliance with 42 CFR Part 72, and require the development of written agency policies and procedures to implement regulatory requirements.	4 APR 97

Recommendation No. 2c

Department Response

The Department concurs with this recommendation. Each agency will be requested to determine locations where human blood/blood products are used, and to ensure that the work is authorized; and the OSHA's bloodborne pathogen and DHHS CLIA requirements are met where appropriate. APHIS laboratories no longer work with human blood/blood products.

Proposed Completion Date:

		Date
1.	Forward letter to affected USDA agency heads to require them to identify all work involving human blood/blood products.	29 AUG 97

2. Require agency review of locations where human blood/blood products are used in the Biological Safety Committee's inspection procedures in the USDA Safety and Health Manual. 29 AUG 97

Recommendation No. 2d

Department Response

The Department concurs with this recommendation. The requirement for use of SOP's will be included in the proposed USDA Safety and Healh Manual.

Proposed Completion Date:

	Date
1. Incorporate requirement for the use of SOP's as part of the program requirements of the proposed USDA Biological Safety Handbook.	29 AUG 97

Recommendation No. 3

Department Response

The Department concurs with this recommendation. Affected facilities will be notified of the deficiencies disclosed by this audit after we have received the final report.

Proposed Completion Date:

	Date
1. Notify affected facilities of the deficiencies disclosed by this audit.	28 MAR 97

EXHIBIT C - DEPARTMENT RESPONSE TO THE DRAFT REPORT

General Comments:

1. On page 3 clarification is required in the fourth paragraph by adding the wording "hazardous materials/waste". The sentence should now read "The Assistant Secretary's Hazardous Waste Management unit monitors agency compliance with *hazardous materials/waste* environmental program requirements."

2. Several agencies have already initiated many of the recommendations contained in the report in response to previously issued OIG Management Alerts. We find these alerts to be a very effective tool in highlighting issues which require immediate corrective actions.

3. We recommend that the audit include a statement that "EPA has never promulgated any biological waste regulation."

4. We appreciated the professionalism of your inspectors during this audit. The findings and recommendations contained in the audit report have provided an important analysis of USDA agency program deficiencies.

ABBREVIATIONS

APHIS - Animal and Plant Health Inspection Service
ARS - Agricultural Research Service
[b 2]
BSL - Biosafety Level
CDC - Centers for Disease Control and Prevention
[ ]
COMMERCE - Department of Commerce
DHHS - Department of Health and Human Services
DM - Departmental Manual
DR - Departmental Regulation
E. coli - Escherichia coli
EPA - Environmental Protection Agency
[ ]
FSIS - Food Safety and Inspection Service
M. bovis - Mycobacterium bovis
[ ]
MSDS - Material Safety Data Sheet
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OIG - Office of Inspector General
OSHA - Occupational Safety and Health Administration
[ ]
[ ]
SHMD - Safety and Health Management Division
SOP - Standard Operating Procedures
[b 2]
USDA - U.S. Department of Agriculture