

DEPARTMENTAL REGULATION		Number: 4400-007
SUBJECT: Biological Safety Program	DATE: May 19, 2006	
	OPI: Office of Human Capital Management	

1 PURPOSE

This regulation establishes the Department of Agriculture's (USDA) Biological Safety policy and program responsibilities. It provides general Occupational Safety and Health Administration's (OSHA) requirements for USDA facilities that use and or handle biohazardous agents.

2 POLICY

All known biohazardous agents and their toxins housed and or studied at USDA facilities will be identified, and hazard information concerning their effect on humans and the environment will be communicated to affected employees. USDA will comply with all applicable federal, state and local laws governing the use, storage, transport, and disposal of potentially hazardous biological agents. Additional USDA safety and security requirements can be found in:

DM 9610-001, USDA Security Policies and Procedures for Biosafety Level-3 Facilities, dated August 2002.

DM 9610-002, USDA Security Policies and Procedures for Laboratories and Technical Facilities (Excluding Biosafety Level-3 Facilities), dated April 2003.

3 CANCELLATION

Safety and Health Manual-Biological Safety Policy dated October 15, 1998, is hereby superseded by this Departmental Regulation.

4 DEFINITIONS

- a Biohazardous Agent. Any biological agent or organism, and or its toxin, extracted or intended for research that is known or suspected to cause human or vertebrate animal disease by direct or deliberate exposure. This includes microorganisms such as viruses, bacteria, fungi, and protozoa and their toxic metabolites, which exhibit human and animal risks by direct or environmental contact.

Nucleic acids such as deoxyribonucleic acid (DNA) derived from pathogenic organisms, human oncogenes, and transformed cell lines are considered biohazardous agents as well. Select agents listed under Title 42 Code of Federal Regulation (CFR) Part 72 Appendix A, are also considered biohazardous agents. Commercial reference kits or samples are not included.

- b Facility. Any location where USDA conducts chemical or biological manipulations and procedures. These procedures are not part of a production process, nor in any way simulate a production process. Protective laboratory practices and equipment are available and in common use to minimize potential employee exposure to biohazardous agents.

5 AUTHORITIES

- a Hazard Communication, 29 CFR 1910.1200, dated 1986.
- b Occupational Exposure to Hazardous Chemicals in the Laboratory, 29 CFR 1910.1450.
- c Title 42 CFR Part 73, Possession, Use, Transfer of Select Agents and Toxins, October 2005.
- d Title 7 CFR 331 and 9 CFR Part 121, Agricultural Bioterrorism Protection Act of 2002: Possession, Use, Transfer of Select Agents and Toxins, October 2005.
- e Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and the National Institute of Health, latest edition.
- f DM 5600-1, Environmental Pollution Prevention, Control, and Abatement Manual, dated December 2002, as amended.

- g DM 9610-001, USDA Security Policies and Procedures for Biosafety Level-3 Facilities, dated August 2000.
- h DM 9610-002, USDA Security Policies and Procedures for Laboratories and Technical Facilities (Excluding Biosafety Level-3 Facilities), dated April 2003.
- i OSHA Blood-borne Pathogen Standard, 29 CFR 1910.1030.

6 RESPONSIBILITIES

a USDA Biological Safety Committee will:

- (1) Consist of representatives from USDA agencies that employ workers for the purpose of handling, or have employees that are potentially exposed to, biohazardous agents as part of their official duties. Technical and specialized advisors; e.g., Medical Officer, Office of the General Counsel and Hazardous Waste Management Group, will participate on the Biological Safety Committee as needed.
- (2) Provide a forum for the development of general policies regarding biological safety.
- (3) Serve as a resource for all USDA locations on biological safety-related issues.
- (4) Assist Biological Safety Program Managers in monitoring mission area or agency compliance with applicable standards, regulations, and policies.
- (5) Disseminate information on biohazardous agents and accepted workplace practices and procedures.

b The Assistant Secretary for Administration (ASA) will:

- (1) Advise the Secretary of Agriculture, mission area or agency heads, and staff officials in planning, developing and implementing policies, programs, and systems to manage biological safety programs.
- (2) Oversee the operations and effectiveness of the Biological Safety Committee.

- c The Director of the Office of Human Capital Management (OHCM) will:
- (1) Advise the ASA, agency, and staff officials in planning, developing and implementing policies and programs, and overseeing the Biological Safety Program.
 - (2) Provide and interpret Departmental policies and standards for the Biological Safety Program.
- d The Director, Quality of Work Life Division (QWLD) will:
- (1) Provide administrative support to the Biological Safety Committee.
 - (2) Monitor Biological Safety Program activities within USDA.
 - (3) Provide agency officials with technical assistance and consultative services, through the Biological Safety Committee, for bio-safety issues.
- e Agency Heads of Agencies Using Biological Material will:
- (1) Implement a Biological Safety Program consistent with law, applicable regulation, and policy.
 - (2) Designate a Biological Safety Program Coordinator having training or experience in the use or management of biological materials. This designee will also serve as a representative to the Biological Safety Committee.
 - (3) At a minimum, conduct annual reviews of biohazardous facilities and material handling procedures and practices.
- f Employees will:
- (1) Stay informed about hazardous biological agents in their work areas.
 - (2) Adhere to written policies, safe workplace practices and procedures, and use all protective equipment required for safe job performance.
 - (3) Plan and conduct operations in accordance with recognized biological safety procedures and practices.

- (4) Inform their supervisor of incidents, accidents, and near misses, as well as conditions or work practices and procedures they believe to be potentially hazardous to their safety and health or the environment.
- (5) Attend biological safety training provided by the agency.

7 PROGRAM ADMINISTRATION

a Biohazard Control Plan:

- (1) Communication of biological hazard information to affected personnel is to be accomplished by means of a site-specific, written Biohazard Control Plan. The Biohazard Control Plan must specify how personnel working with such hazards within USDA facilities will be protected from exposure. This plan can be incorporated into existing worker protection plans such as the Chemical Hygiene Plan (Laboratory Safety) or Hazard Communication Plan mandated by the Occupational Safety and Health Administration. All workers and ancillary personnel engaged in the use of biohazardous agents within USDA facilities must adhere to these guidelines.
- (2) The written plan must include provisions for identifying and accounting for all biohazardous agents and their toxins within the facility via a biohazard inventory, for safe handling and disposal of hazardous biological agents and their toxins and for worker information and training. It must also designate a responsible individual as a safety monitor for plan implementation and effectiveness.

b Biohazard Inventory:

Facilities that handle, maintain or store known biohazardous agents and/or toxins must maintain an accurate inventory of such agents. Commercial reference or analytical tests are not inventory-required. However, if the analysis of the sample results in the isolation of a pure culture pathogen (disease causing) organism, and this culture is to be stored at the facility, it must be listed on the inventory. The culture is not inventory-required if the standard operating procedure of the laboratory is to sterilize and dispose of the isolate and sample upon completion of the analysis.

c Safe Handling, Inspection and Disposal:

The written plan must:

- (1) Identify the required personal protective equipment (e.g., protective gloves, goggles), engineering controls (e.g., biological safety cabinets, chemical hoods) and any administrative controls to be followed when working with biohazardous agents at the facility.
- (2) Clearly identify where biohazardous agents and toxins are located. All such locations must display appropriate warning signs to alert employees and visitors to potential biological hazards. Local emergency response personnel should be made aware of locations where known biohazardous agents are maintained at the facility.
- (3) Identify workplace disinfectant procedures employees will follow to ensure work areas are decontaminated after exposure to biohazardous agents. Workers should conduct daily inspections of their workspaces when handling biohazardous agents.
- (4) Provide for periodic inspection of biohazardous storage and workspaces. Facilities that maintain stock cultures of biohazardous agents must ensure that these are properly stored in a manner to restrict access by unauthorized personnel and to ensure total accountability at all times. The frequency of inspections should be dictated by the type, amount, and hazard characteristics of stored cultures. At a minimum, two full-scale facility inspections per year are required. Inspection records must be maintained as long as cited deficiencies exist and the materials included in the inspection are stored at the facility. Completed corrective action inspection records must be maintained a minimum of three years upon the corrective action completion date.
- (5) Outline proper decontamination and disposal procedures for biological agents, biological material and equipment used at the facility. Cultures containing biohazardous agents not directly related to the work being performed must be disposed of by acceptable practices. (Note: Some working materials, when contaminated, must be handled as medical waste). Facilities that are required to maintain such cultures, due to unavailability or unique characteristics of the culture, must document the reason for maintaining culture(s) in the facility biohazard Control Plan.

Respective state, or local jurisdiction disposal requirements must be also included in the plan.

- (6) Indicate how the facility will comply with requirements of Title 42 CFR Part 73, Possession, Use, Transfer of Select Agents and Toxins. Agencies that ship, transfer or receive biological agents, listed in Title 42 CFR, Part 73 must consult with their agency's Biological Safety Program Coordinator to determine to what degree this regulation regulates their activities.

d Information and Training:

Facilities must provide affected employees with information and training on known biohazardous agents in their work area.

Employee Information will Include:

- (1) The location and availability of the written Biohazard Control Plan and the biohazardous agent inventory.
- (2) All operations or activities in their work area where known biohazardous agents are present and any "conditions for use" or other work requirements at those locations; e.g., vaccinations or medical monitoring.
- (3) Methods and observations that can detect the presence or release of a biohazardous agent in the work area or to the environment (e.g., air sampling or surface testing).
- (4) Information on the physiological effects associated with exposure to the biohazardous agents in the facility's inventory.
- (5) Measures employees can take to protect themselves and the environment from biohazardous agents. These include appropriate work practices and procedures, use of mechanical controls, emergency response procedures, personal protective clothing and safety equipment to be used when working with such agents.

Employee Training:

- (1) May take the form of individual instruction, group seminars, audiovisual presentations, handout material or any other format that communicates safe handling and hazard awareness to the employee.

- (2) Will be provided at the time of an employee's initial assignment to a work area where known biohazardous agents are present, and prior to an assignment involving new exposure situations. Employees will receive periodic refresher information and training as new information becomes available. Employees will be encouraged to ask questions on unfamiliar topics. All training must be documented.

8 INQUIRIES

Direct all inquiries to the Office of Human Capital Management, Quality of Work Life Division, Room 3021 South Building, Washington, D.C. 20250, telephone number (202) 720-8248.

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