

Environmental Health and Safety Manual (EHS)

EHS 112: Biosafety Policy Governing the Possession, Use, and Transfer of Biological Agents and Toxins of Biological Origin

Effective: 7/8/2003

Revised: 3/1/2016

Purpose

To ensure that activities involving biological agents and toxins of biological origin are conducted safely and in accordance with applicable federal regulations, state laws, and university policies.

Background

ASU has instituted and maintains a biosafety program for the possession, use, transfer and storage of biological agents and toxins of biological origin for personnel who may be exposed to these materials during the performance of their duties. The biosafety program is designed to promote and achieve regulatory compliance and provide a means for personnel to be better informed about and protected from biological agents and toxins of biological origin.

Sources

7 *Code of Federal Regulations* § 331

9 *Code of Federal Regulations* § 121

18 *United States Codes* § 175b (United States Patriot Act)

29 *Code of Federal Regulations* § 1910.1030

42 *Code of Federal Regulations* §§ 72-73, 1003

49 *Code of Federal Regulations* §§ 171-180

United States Department of Agriculture Animal Welfare Act

Public Act 107-188, H.R.3448

Centers for Disease Control and National Institutes of Health, *"Biosafety in Microbiological and Biomedical Laboratories"*

National Institutes of Health, *"Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules"*

Arizona Administrative Code, Article 14, Biohazardous Medical Waste and Discarded

Drugs Arizona State University Biosafety Manual

Applicability

ASU academic, research, and other operations involved in the possession, use, transfer, or storage of biological agents or toxins of biological origin. This applies to activities involving:

1. select agents and toxins regulated by the Centers for Disease Control and United States Department of Agriculture Select Agent Program*
2. recombinant or synthetic nucleic acid molecules (including experiments that are specifically exempt under the National Institutes of Health's "Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules"
3. bacterial, viral, fungal, parasitic, or other potentially infectious agents
4. experimentally infected animals and those naturally harboring zoonotic infectious agents
5. human blood, cell lines, or other materials of human origin
6. toxins of biological origin
and
7. infectious waste.

*The list of select agents and toxins in the select agent regulations is available at <http://www.selectagents.gov/SelectAgentsandToxinsList.html>

Policy

Responsibilities of the Institutional Biosafety Committee

The Institutional Biosafety Committee reviews and approves university operations and facilities involving, or proposed to be involved in, work with biological agents and toxins of biological origin. The Institutional Biosafety Committee is appointed by and responsible to the senior vice president for Research or designee and recommends actions necessary to maintain and/or improve biosafety.

Responsibilities of the Institutional Biosafety Committee include the following:

1. overseeing the registration process for biological agents and toxins of biological origin
2. reviewing and approving research activities involving biological agents or toxins of biological origin as required by federal regulations, state laws, and university policy
3. implementing and promoting procedures supporting the safe use of biological agents or toxins of biological origin and the elimination or reduction of exposure to those materials

and
4. advising biosafety practices related to the use of experimentally infected laboratory animals or plants

Responsibilities of Environmental Health and Safety

Environmental Health and Safety provides resources and support to ensure a safe and healthful working environment. The Responsible Official and Biosafety Officer positions both reside with Environmental Health and Safety.

Responsible Official

The Responsible Official is appointed by the President of the University and is federally mandated to be responsible for activities involving select agents and toxins in accordance with 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73.

The Responsible Official is responsible for the following:

1. developing and implementing safety, security, and emergency response plans for the select agent and toxins program
2. approving personnel to have access to select agents and toxins
3. providing or making available appropriate training for safety, security, and emergency response for select agents and toxins

4. transferring select agents and toxins only to registered personnel
5. providing immediate notice of any theft, loss, or release of a select agent and toxins
6. ensuring laboratory facilities properly contain and dispose of select agents and toxins
7. maintaining complete records related to select agents and toxins
8. reporting the identification of a select agent or toxin as a result of diagnosis, verification, or proficiency testing
9. submitting changes in the registration information by promptly notifying, in writing, the Centers for Disease Control or United States Department of Agriculture
10. conducting regular inspections, at least annually, of the rooms where select agents or toxins are stored or used to ensure compliance with all procedures and protocols and document deficiencies

and

11. providing copies of inspection reports to personnel working with select agents or toxins

Biosafety Officer

The University Biosafety Officer is federally mandated to be responsible for activities involving recombinant and synthetic nucleic acids, large-scale biological research, and high containment facilities in accordance with the National Institutes of Health's "Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" and 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73.

The Biosafety Officer is responsible for the following:

1. developing and maintaining the university's biosafety program
2. reviewing and approving registration for research disclosures involving biological agents or toxins of biological origin in coordination with the Institutional Biosafety Committee
3. consulting with researchers on issues of biosafety and the safe use of biological agents and toxins of biological origin in the facility or on the grounds
4. developing protocols and procedures for biosafety
5. advising researchers on proper infectious waste disposal practices
6. providing oversight of the Arizona State University *Exposure Control Plan for Bloodborne Pathogens*
7. offering biosafety and biosafety training for personnel with potential exposures to biological agents or toxins of biological origin
8. conducting annual biosafety audits to determine compliance status

and

9. promoting regulatory compliance and a safe work environment

Responsibilities of Departments and Units

Deans, Directors, and Chairs

Deans, directors, and chairs of colleges, departments, and other units have the responsibility to ensure the biosafety of people, animals, and the environment within their jurisdiction. Departments and units must identify personnel who use and/or may be exposed to biological agents or toxins of biological origin and ensure that these personnel are provided the necessary protections required when working with these materials.

Principal Investigators

Principal Investigators overseeing activities involving biological agents or toxins of biological origin are responsible for ensuring the health and safety of those working with those materials. The Principal Investigator completes and submits registration forms for all activities involving the use of biological agents or toxins of biological origin and develops

biosafety-specific standard operating procedures appropriate for the biological agents or toxins of biological origin being used.

The Principal Investigators are responsible for the following:

1. ensuring that proper training and instruction are provided for personnel in safe practices and protocols, including, at a minimum, training in aseptic techniques, biology of the organism(s) being used, and emergency procedures
 2. ensuring that personnel receive any necessary medical surveillance
 3. ensuring that biosafety cabinets and other laboratory equipment is certified as required
 4. ensuring that personal protective equipment is provided and used
 5. ensuring that personnel are in compliance with applicable federal regulations, state laws, and university policy
- and
6. requiring personnel to report all thefts, security incidents, accidents, spills, or contamination incidents to the Biosafety Officer and their supervisor

Responsibilities of Employees

Personnel who use biological agents or toxins of biological origins are responsible for the following:

1. participating in appropriate training and instruction
 2. being familiar with the biological agents and toxins of biological origin being used and the potential risks associated with exposure
 3. following all biosafety standard operating procedures and comply with all applicable federal regulations, state law, and university policy
 4. participating in medical surveillance and personal suitability assessments as required
- and
5. reporting all thefts, security incidents, accidents, spills, or contamination incidents to the Biosafety Officer and their supervisor

Procedures

The procedures for the registration of activities with biological agents or toxins of biological origin are available in the Institution of Biosafety Committee's [Policies and Procedures Manual](#). The procedures for activities involving biological agents or toxins of biological origin are available in the ASU [Biological Safety Manual](#).

Cross-Reference

For more information, see:

1. [EHS 101](#), "Bloodborne Pathogens and Needlestick Prevention"
2. [EHS 103](#), "Hazard Communication Program"
3. [EHS 105](#), "Personal Protective Equipment"
4. [EHS 108](#), "Environmental Health and Safety Training"
5. [EHS 205](#), "Storage of Hazardous Chemicals"

and

6. [EHS 403](#), "Chemical Release Emergency Response"

See also the *Police Department Policies and Procedures Manual*— [PDP 104-01](#), "Laboratory Emergencies"