ASU Biological Safety Manual

Environmental Health and Safety

Revised May 21, 2025

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Foreword

The Biological Safety Manual has been adopted by Arizona State University to be a resource for information, guidelines, policies and procedures that will enable safe research and to help eliminate or reduce the potential for exposure to biohazards.

ASU Environmental Health and Safety developed this manual to help ensure compliance with the following federal, state and local regulations and guidance materials:

- 18 United States Code §175b
- 29 Code of Federal Regulations §1910.1030
- 42 Code of Federal Regulations §1003
- 42 Code of Federal Regulations §71.54
- 42 Code of Federal Regulations §73
- 49 Code of Federal Regulations §171–180
- 7 Code of Federal Regulations §331
- 9 Code of Federal Regulations §121
- Arizona Administrative Code, title 18, chapter 13, article 14, Biohazardous Medical Waste and Discarded Drugs.
- Arthropod Containment Guidelines, version 3.2 and addendum one, Containment Practices for Arthropods Modified with Engineered Transgenes Capable of Gene Drive.
- Centers for Disease Control and Prevention and National Institutes of Health, “Biosafety in Microbiological and Biomedical Laboratories, 6th Edition.”
- Department of Health and Human Services, “Guide for the Care and Use of Laboratory Animals, 8th edition.”
- National Institutes of Health, “Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.”
- Public Act 107–188, HR3448
- Public Health Service Policy on Humane Care and Use of Laboratory Animals, National Institutes of Health, 2015.
- United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.
- Local, state, federal and international permitting requirements

The ASU Biosafety Manual compiles suggested work practices, protocols, and systems for working safely at ASU. **The ASU Biosafety Manual should not be the only reference for health and safety concerns**.

It is intended that the principal investigator and supervisory personnel supplement this information with instruction and guidance regarding specific practices and procedures unique to the work being done in their areas by completing a lab-specific biosafety manual and including all relevant documentation available to laboratory users. In addition, EHS is always available to address health and safety concerns. The ASU Biosafety Manual is reviewed annually by EHS and the Institutional Biosafety Committee and was last approved **Dec. 18, 2023**.

Signatures

Mary Turlington-Powell

Mary Turlington-Powell
Director of Biosafety and Biosecurity,
CDC Responsible Official
Environmental Health and Safety
Arizona State University

Suzanne Kennedy

Suzanne Kennedy
Assistant Vice President
Environmental Health and Safety
Arizona State University

Debra Murphy
Debra Murphy (May 27, 2025 10:20 CDT)

Debra Murphy
Director of Research Integrity,
Institutional Official
Knowledge Enterprise Operations
Arizona State University

Bert Jacobs

Bertram Jacobs, Ph.D
Professor, School of Life Sciences
Chair, Institutional Biosafety Committee
Arizona State University

Giorgio Scarpellini
Giorgio Scarpellini (May 30, 2025 08:52 PDT)

Giorgio Scarpellini, M.S.
Institutional Biosafety Officer
Environmental Health and Safety
Arizona State University

Gregory L. Powell

Gregory L. Powell, Ph.D
Animal Biosafety Officer
Environmental Health and Safety
Arizona State University

Introduction

Biosafety encompasses the knowledge, techniques, equipment and facilities necessary to prevent or minimize exposure to or release a biohazard. The mission of the EHS Biosafety team is to ensure a safe and healthy environment for individuals working with biohazards and to protect the community and environment by preventing the release and exposure to biohazards.

The ASU Biosafety Manual is intended to be a resource for information, guidelines, policies and procedures that will enable and encourage safe research and eliminate or reduce the potential for biohazard exposure. The information presented here also reflects the requirements and guidelines of federal and state regulations. The most current version of the biosafety manual will be maintained on the EHS Biosafety and Biosecurity webpage.

The ASU Biosafety Manual applies to all laboratories, research, teaching and support activities that may involve biohazards. Biohazards are microorganisms, toxins or other biological agents that can infect or cause disease in humans, animals or plants. Biohazards may include bacteria, toxins, viruses, fungi, rickettsia, prions, protozoans, parasites, genetically modified organisms, and recombinant or synthetic nucleic acid molecules. In addition, biohazards include human blood, body fluids, tissues and cell lines of human origin.

Materials of animal origin where those animals naturally harbor zoonotic agents are also considered biohazards. Biohazards are often referred to as infectious agents or etiological agents. Specific archaeological samples such as bones, clothing fragments and pottery may also be regarded as biohazards due to their proximity to pathogenic organisms that may persist over time.

All research disclosures must be reviewed and approved by the Institutional Biosafety Committee before beginning work if they involve the use of any of the following:

- Agents that can infect humans, animals or plants and cause disease in them.
- Work with archaeological samples that may lead to the production of aerosols. Examples include bones, clothing fragments and pottery.
- Biohazardous waste
- Environmental or field samples. Examples include water, wastewater, soil and air samples.
- Experimentally infected animals and those naturally harboring zoonotic infectious agents.
- Genetically modified organisms.
- Human cell lines and other materials of human origin.
- Recombinant and synthetic nucleic acid molecules.
- Select agents and toxins
- Transgenic plants and animals

Experiments that may qualify as dual-use research of concern and pathogens of pandemic potential require approval by the IBC and Institutional Review Entity before initiation of any work. Please refer to ASU's Field Research Safety Manual for more information about fieldwork.

ASU must have an occupational health and safety program that addresses potential hazards associated with conducting animal research. The publication by the Institute for Laboratory Animal Research, Occupational Health and Safety in the Care and Use of Research Animals, is most helpful.

Additional safety guidance for working with non-human primates is available in the ILAR publication Occupational Health and Safety in the Care and Use of Nonhuman Primates.

Biosafety oversight

Guidance documents from the National Institutes of Health and the Centers for Disease Control and Prevention form the basis for the biosafety practices included in this manual. There are additional guidance documents and regulations imposed by various funding agencies that individual principal investigators must be aware of and incorporate into a Laboratory-Specific Biosafety Manual.

Biosafety requirements must be followed to ensure the continuation of grant funding from federal agencies and for health and safety purposes.

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules detail procedures and practices for containing and safely conducting various forms of recombinant or synthetic nucleic acid research. The NIH Guidelines include the following:

- Establish the practices, procedures and conditions under which recombinant and synthetic nucleic acid activities must be conducted.
- Mandate establishing an Institutional Biosafety Committee for the review and oversight of biological research.
- Outline roles and responsibilities for biosafety.

All institutions receiving NIH funding for recombinant or synthetic nucleic acid molecule activities, including ASU, must comply with the NIH Guidelines. Researchers at institutions subject to the NIH Guidelines must comply with the requirements even if NIH does not fund the individual project. **Non-compliance with the NIH Guidelines may result in suspension, limitation or termination of financial assistance** for the research project and of NIH funds for other recombinant or synthetic nucleic acid activities at ASU or the requirement for prior NIH approval of any or all recombinant or synthetic nucleic acid projects at ASU.

The CDC and NIH manual, Biosafety in Microbiological and Biomedical Laboratories current edition, describes the appropriate measures and facilities for work with all microbial agents, including bacterial, viral, fungal, parasitic, rickettsial and prion agents, as well as toxins of biological origin.

The requirements described in the Occupational Safety and Health Administration's Bloodborne Pathogens regulation, 29 CFR §1910.1030, apply to work with human blood, tissue, organs, body fluids and cell cultures. Special training, medical surveillance, procedures and equipment that must be in place for protection against bloodborne pathogens, needle sticks and other sharps injuries are described in the ASU Bloodborne Pathogens Exposure Control Plan.

OSHA also regulates handling and disposal of biohazardous waste under the OSHA Bloodborne Pathogens regulation and by state and federal statutes. The procedures for biohazardous waste handling are described in the ASU Biological Waste Handling Procedures.

The requirements for packaging and shipment of biohazards are provided in the Department of Transportation's hazardous materials regulation 49 CFR § 171-180. In addition, permits may be required to ship biological materials. Please refer to the CDC Etiological Agent Import Permit Program, Animal and Plant Health Inspection Service permit program, U.S. Fish and Wildlife Service Permits, Food and Drug Administration Permits and National Park Service Permits for information on specific permit requirements.

In addition, country-specific or state-specific permits may be required.

Contact the EHS Biosafety team for assistance with permits. Information on shipping procedures that comply with these regulations is found in the Shipping and Transportation Methods and Requirements section of this manual.

Specific requirements for handling biological toxins are found in the BMBL and OSHA's Occupational Exposure to Hazardous Chemicals in Laboratories, standard 29 CFR § 1910.1450. Information regarding ASU's radiation safety program is found on the ASU Radiation and Laser Safety webpage.

Roles and responsibilities

The biological safety program at ASU was developed from the university's commitment to address and comply with regulations and recommendations for biosafety and biosecurity, as well as the health and safety of the staff, researchers, community and environment. The Institutional Biosafety Committee and Environmental Health and Safety Department oversee ASU's biosafety program.

Roles and responsibilities for biosafety and biosecurity are included in this section.

Arizona State University

ASU has instituted and maintains a Biosafety program for personnel who may be exposed to biological hazards while performing their duties. The biosafety program is designed to achieve regulatory compliance and to provide a means for employees to be informed about and protected from biohazards. To maintain regulatory compliance and to protect personnel from biohazards, Arizona State University must do the following:

- Appoint a Biological Safety Officer for the institution.
- Ensure appropriate training is provided to research personnel with biohazards or recombinant or synthetic nucleic acid materials.
- Ensure that research conforms to the provisions of the NIH Guidelines.
- Establish an Institutional Biosafety Committee.
- Establish and maintain a health surveillance program for personnel.
- Implement policies for safe biological and recombinant or synthetic nucleic acid research conduct.
- Report any significant problems, violations or research-related accidents or illnesses to the NIH Office of Science Policy within 30 days.

Institutional Biosafety Committee

The committee reviews, approves, and oversees research involving recombinant or synthetic nucleic acid molecules and biohazards in research and teaching activities. Biohazards are microorganisms, toxins or other biological agents that can infect and/or cause disease in humans, animals or plants. Biohazards may include bacteria, biological toxins, viruses, fungi, rickettsia, prions, protozoans, parasites, genetically modified organisms, or r/DNA molecules. In addition, biohazards include human blood, body fluid, tissues and cell lines of human origin. Biohazards are often referred to as infectious agents or etiological agents.

The responsibilities of the Institutional Biosafety Committee include assessing facilities in collaboration with EHS, determining procedures and practices, and training research personnel to ensure compliance with NIH Guidelines and other pertinent guidelines and regulations.

To successfully carry out these responsibilities, the Institutional Biosafety Committee has been appointed to achieve sufficient knowledge and expertise in biomedical research and biosafety. The Institutional Biosafety Committee has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as needed to assure compliance with applicable regulations and guidelines. For more information about the ASU Institutional Biosafety Committee, please visit the Research Compliance webpage.

Biosafety in animal use

Approval by the Institutional Biosafety Committee and the Institutional Animal Care and Use Committee is required for any animal use that may create biohazards for personnel or the environment; use of infectious agents, recombinant or synthetic nucleic acids with animals; or any use of non-human primates and field animals with known zoonotic potential.

However, the animal room can present some unique challenges. In the microbiological laboratory, hazardous conditions are caused by personnel or by the equipment being used. In the animal room, the animals' activities can present additional hazards. Animals may generate aerosols; they may bite and scratch and be infected with a zoonotic agent.

The EHS Biosafety team and the IBC review the use of biohazards in animals.

ASU must have an Occupational Health Program to support the animal research program's academic, research and operational activities. The publication of the Institute of Medicine's book titled Occupational Health and Safety in the Care of Research Animals is a good resource.

Ideally, facilities for laboratory animals used in studies of infectious or noninfectious diseases should be physically separate from other activities such as animal production, quarantine and laboratories. Traffic flow that will minimize the risk of cross-contamination should be considered in the plans.

Environmental Health and Safety and ASU Biological Safety Officer

The responsibilities of Environmental Health and Safety and the Biological Safety Officer include, but are not limited to, the following:

- Advise researchers on proper waste disposal methods based on federal and state regulations.
- Assist researchers in developing plans for preventing and handling accidental spills and personnel contamination.
- Develop, implement and maintain the university's biosafety program to address issues of biosafety and biosecurity.
- Develop, implement and maintain the university's select agents and toxins program.
- Perform and review the required risk assessment to determine the appropriate biosafety level and personal protective equipment for handling recombinant and synthetic nucleic acid molecules or biohazards.
- Investigate laboratory accidents and incidents involving recombinant and synthetic nucleic acid molecules and biohazards.
- Perform periodic inspections to ensure that laboratory standards are rigorously followed.
- Promote regulatory compliance and a safe laboratory environment.
- Provide advice on laboratory security.
- Provide oversight of the ASU Bloodborne Pathogen Exposure Control Plan and conduct training for laboratory personnel with such exposure.
- Provide technical advice to principal investigators and the Institutional Biosafety Committee on research safety procedures.
- Provide safe use and practice training and resources for those working with potential biohazards and laboratory equipment.
- Report to the Institutional Biosafety Committee and the institution any significant problems, violations of the NIH guidelines, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware.

The Biological Safety Officer has the authority to immediately halt research that they deem to be an immediate threat to the safety of personnel, the environment or the community. The Biological Safety Officer must immediately report such an action to the Institutional Biosafety Committee.

ASU Employee Health

ASU Employee Health leads a culture of occupational safety for the ASU community by providing high-quality, cost-efficient healthcare and promoting the health, safety and well-being of ASU employees. The responsibilities of ASU Employee Health include, but are not limited to, the following:

- Provide initial and annual medical reviews of medical questionnaires for individuals in contact with vertebrate animals, allergens, unfixed tissue or bodily fluids.
- Provide occupational medical exposure risk assessments for personnel exposed to biological, chemical, noise, laser and radiological agents.
- Provide pre-employment or post-job offer physical examinations.
- Provide individualized medical consultations and periodic examinations, including screening results.
- Maintain confidential employee health medical records.
- ASU Employee Health administers occupational health services for personnel. Services are under the guidance of the ASU Institutional Animal Care and Use Committee and the ASU Institutional Biosafety Committee.
- Provide immunizations for individuals as required or recommended for potential occupational exposures.
- Provide medical surveillance as required or recommended based on risk assessment.
- Provide medical guidance for post-exposure protocols, the select agent program and recombinant nucleic acid exposures.
- Provide oversight to the ASU Serum Banking program.

Principal investigator

The principal investigator responsible for work conducted with biohazards must be a trained scientist knowledgeable in appropriate laboratory techniques, safety procedures and hazards associated with handling biological materials.

This individual should consult the biosafety team or other health and safety professionals regarding risk assessments. Responsibilities of the principal investigator include the following:

- Accept direct responsibility for the health and safety of those working with animals and biohazardous materials, as well as select agents and toxins.
- Adhere to approved emergency plans for handling accidental spills and personnel contamination.
- Comply with permit and shipping requirements for recombinant or synthetic nucleic acid molecules, genetically modified organisms or biohazards. This includes permits, material transfer agreements, and other international, interstate and intrastate transport documentation.
- Develop specific biosafety standard operating procedures for animals and biohazards used in the laboratory.
- Ensure laboratory personnel's compliance with relevant regulations, guidelines and policies.
- Ensure all appropriate personal protective equipment is provided and used.
- Ensure proper training, including refresher training and instruction for laboratory personnel in safe practices and protocols, including, at a minimum, training in aseptic techniques and characteristics of the material or materials used. Please refer to the ASU Laboratory-Specific Biosafety Training Checklist. These signed documents must always remain readily accessible and produced upon request.
- Ensure the integrity of safety equipment, such as biological safety cabinets; maintain biological containment, such as purity and genotypic and phenotypic characteristics; and ensure correct procedures or conditions are followed to prevent the release of or exposure to recombinant or synthetic nucleic acid molecules, biohazards, select agents or toxins.

- Inform laboratory staff of the Occupational Health and Safety Program, possible symptoms of illness related to materials used, and provisions for any precautionary medical practices advised or required, such as vaccinations or serum collection.
- Propose appropriate microbiological practices and laboratory techniques to be used for the research.
- Provide all laboratory employees with the protocols that describe the potential biohazards and the precautions to be taken. Instruct, train and supervise research personnel in:
    - Aseptic technique
    - Characteristics of the materials used
    - Laboratory practices and techniques required to ensure safety
    - NIH classification of work, if working with r/DNA molecules
    - Procedures for dealing with spills or potential exposures to the agents described in the research
    - Signs and symptoms of exposure to biohazards
- Obtain Institutional Biosafety Committee approval prior to initiating or modifying any research involving the use of recombinant or synthetic nucleic acid molecules or biohazards and maintain that approval through timely submission of annual reviews.
- Immediately report any incidents or problems related to the operation and implementation of containment practices and procedures in writing to the biological safety officer and any other university committees, such as the Institutional Biosafety Committee, Institutional Review Board or Institutional Animal Care and Use Committee, that have reviewed and approved the research activity.
- Supervise laboratory staff to ensure that the required safety practices and techniques are employed. Correct work errors and conditions that may result in accidents, injuries or the release of biohazards.

Principal investigators are also responsible for full compliance with the NIH guidelines during the conduct of recombinant or synthetic nucleic acid research.

- The PI will consult with IBC to determine whether the recombinant or synthetic nucleic acid molecule research is subject to the NIH guidelines.
- Develop specific biosafety standard operating procedures for recombinant or synthetic nucleic acid molecules or biohazards used in the laboratory.
- Obtain Institutional Biosafety Committee approval before initiating recombinant or synthetic nucleic acid molecule research subject to the NIH guidelines.
- Make the initial risk assessment and determination of biological containment levels in accordance with the NIH guidelines when registering research with the IBC.
- Immediately report any problems, violations of the NIH guidelines, or any research-related accidents and illnesses to the Biological Safety Officer, Greenhouse/Animal Facility Director, Institutional Biosafety Committee, NIH Office of Science Policy and other authorities as appropriate.
- Submit any subsequent changes, such as changes in the source of DNA or host-vector system, to the disclosure to the Institutional Biosafety Committee for review and approval or disapproval.

Laboratory personnel

The responsibilities of animal care and laboratory personnel include but are not limited to the following:

- Complete any necessary medical surveillance.
- Follow all laboratory practices, and protocols and comply with all applicable policies, procedures and guidelines.
- Fully comprehend all biohazards and select agents and toxins being used in the lab and the potential risks associated with exposure, as well as fully understand the associated emergency response procedures.
- Obtain necessary and recommended vaccinations or submit declination forms as permitted.

- Participate in appropriate training and instruction to ensure that they are adequately trained and fully understand the instructions. This includes successfully completing refresher courses as applicable.
- Report to the supervisor about thefts, security incidents, accidents, spills or contamination.
- Use all required PPE.

Responsible official

A responsible official is required under the Department of Health and Human Services and USDA Select Agent and Toxin regulations.

The individual's responsibilities can be found in the applicable regulations. Although this list is not intended to be a complete list, critical responsibilities include:

- Allow only approved individuals to have access to select agents or toxins.
- Conduct regular inspections, at least annually, of the laboratory where select agents or toxins are stored or used to ensure compliance with all procedures and protocols of this safety plan. The results of these inspections must be documented, and any deficiencies must be corrected and documented.
- Develop and implement safety, security and emergency response plans.
- Maintain complete records relating to select agents as defined in 42 CFR 73.17.
- Provide appropriate training for safety, security and emergency response.
- Provide immediate notice of any theft, loss or release of a select agent or toxin.
- Verify maintenance of proper laboratory facilities to contain and dispose of select agents and toxins.
- Report the identification of a select agent or toxin because of diagnosis, verification or proficiency testing.
- Submit changes in the registration information by promptly notifying the CDC or Animal and Plant Health Inspection/USDA. This includes modifications to the list of individuals approved to work or access select agents, changes in work locations and changes in protocols or objectives of the studies.
- Transfer select agents or toxins to registered individuals at an approved select agent facility.

The following are RO and primary contacts for the ASU Select Agent Program:

- Mary Turlington-Powell, director of Biosafety and Biosecurity, EHS, RO
- Suzanne Kennedy, assistant vice president, EHS, ARO
- Giorgio Scarpellini, biological safety officer, EHS, ARO
- Amanda Rice, biosafety program director, EHS, ARO
- Gregory Powell, animal biological safety officer, EHS, ARO

Other organizations

Other committees, including the Institutional Review Board, Radiation Safety Committee and the ASU Police Department must consult and coordinate with the Institutional Biosafety Committee and EHS on any proposals under their purview that involve the use of biohazards.

Visitors, vendors and contractors

Contractors must ensure that appropriate personal protective equipment is available for their workers. All visitors, vendors and contractors must:

- Be with a Department of Justice-approved person in areas with select agents or toxins.
- Comply with all security requirements and procedures.
- Use PPE provided for them by the laboratory or animal handling room.

Incident reporting

Reportable incidents and violations

Incidents or problems involving biohazards or recombinant or synthetic nucleic acid molecules must be immediately reported to the biological safety officer. Examples of reportable incidents include, but are not limited to, any exposure, such as a needlestick, splash or contamination due to equipment failure, and any potential exposure to biohazards. An incident may also occur from a containment breach, which may later be determined to be a possible exposure.

It should be noted that waste from recombinant or synthetic nucleic acid molecule research is considered biohazardous, and incidents involving improper disposal of recombinant or synthetic nucleic acid molecules must also be reported. Questions regarding reportable incidents should be directed to the Biological Safety Officer.

Failure by research personnel to follow federal and institutional regulations, guidelines, policies or procedures may require reporting to the appropriate institutional, local, state or federal agencies. Violations may include, but are not limited to, conducting new or ongoing research without proper federal or institutional registration, review, approval or oversight.

Principal investigator responsibilities

The principal investigator and their personnel must report any incident, violation of the NIH Guidelines, or any research-related accidents and illnesses immediately by contacting the biological safety officer. Examples of incidents and violations include:

- Any exposure, overt or potential, in a biological laboratory.
- Any illness that may be caused by the agents used in the laboratory.
- Any incident involving the improper disposal of recombinant or synthetic nucleic acid molecules.
- Overt exposures are defined as exposures that result in direct personnel exposure to biohazards such as injection, spills, splashes or aerosol inhalation.
- Potential exposures are defined as exposures with a high risk of exposing personnel to biohazards, such as spills, containment failure while working with the agent or equipment failure that may produce aerosols.
- Injuries or exposures that require medical assistance must be reported within eight hours. Fatalities must be reported immediately.

Biological safety officer responsibilities

The Biological Safety Officer is required, by the NIH guidelines, to report to the Institutional Biosafety Committee:

- All violations of the NIH guidelines and significant incidents.
- Any significant research-related accidents or illnesses.

Institutional responsibilities

The Institutional Biosafety Committee is required, by the NIH guidelines, to report to the appropriate University official and the NIH Office of Science Policy within 30 days any significant incidents, violations of the NIH Guidelines or any significant research-related accidents and illnesses. The Institutional Biosafety Committee will be responsible for determining any necessary actions.

For example, the Institutional Biosafety Committee may choose to change the frequency of lab inspections or adjust the biosafety level of the disclosure based on the results of the incident. Other Institutional Biosafety Committee reporting requirements to the NIH Office of Science Policy and other agencies include, but are not limited to:

- Lax security, unsafe procedures used in a laboratory setting, improper disposal of recombinant waste.
- Research involving recombinant or synthetic nucleic acid molecules or biohazards without prior Institutional Biosafety Committee approval.
- Significant changes to proposed research risk without prior notification and approval by the Institutional Biosafety Committee.

Some incidents must be reported to the NIH Office of Science Policy expeditiously. Spills or accidents in BSL-2 laboratories involving recombinant or synthetic nucleic acid molecules that result in overt exposure must be reported immediately to the NIH Office of Science Policy.

In addition, spills or accidents involving recombinant or synthetic nucleic acid molecules that occur in high-containment laboratories with BSL-3 or higher and result in overt or potential exposure must also be reported immediately. The Institutional Biosafety Committee will report to the institutional official, who will direct the reporting process to the NIH Office of Science Policy for any incidents described above.

Institutional violations that will be reported to the appropriate college or department head may include, but are not limited to:

- Failure to comply with institutional and federal regulations, guidelines and policies
- Lapses in disclosure approval
- Unsafe work practices

Institutional official responsibilities

Upon receiving a report from the Institutional Biosafety Committee, the Institutional Official will directly report any significant research-related illnesses or accidents that may be hazardous to public health and cooperate with state and local public health departments. In writing, any problems with or violations and non-compliance of the NIH guidelines, or any significant incident, accidents or illnesses related to recombinant or synthetic nucleic molecules, to the NIH Office of Science Policy within 30 days or immediately for overt exposure to a BSL-2 agent or potential/overt exposure to a BSL-3 agent.

Risk Group classifications

According to the CDC and NIH document Biosafety in Microbiological and Biomedical Laboratories, the three primary hazardous characteristics associated with biological agents include the following:

- Availability of preventive measures and effective treatments for the disease.
- Capability of an agent to infect and cause disease in a susceptible human or animal host.
- Virulence of an agent, as measured by the severity of disease.

By considering the disease's transmission route, a standardized methodology was developed to classify biological agents into four different risk groups. **See Table One for more information**. Knowing the risk group of an agent assists researchers and safety professionals determine the appropriate safety protocols to be followed.

Table One: Risk Group classifications

RG-1	RG-2	RG-3	RG-4
Agents not associated with disease in healthy adult humans.	Agents related to human diseases are rarely serious, and for which preventative or therapeutic interventions are often available.	Agents associated with serious or lethal human disease for which preventative or therapeutic interventions may be available — high individual risk but low community risk.	Agents that are likely to cause serious or lethal human disease for which preventative or therapeutic interventions are not usually available — high individual risk and high community risk.

Biological safety levels

CDC and NIH have established four levels of biosafety, based on the degree of hazard associated with a microbial agent, to describe the combination of laboratory practices and techniques, safety equipment and facilities needed to protect against exposure.

The CDC and NIH BMBL outline four different biological safety levels that are appropriate for the operations performed in a laboratory, the documented or suspected routes of transmission of the biological agent and the laboratory function or activity. These four biosafety levels require successively more stringent practices and facilities as work moves from the least restrictive, BSL-1, to work with the highest hazard level of BSL-4.

Biohazard exposure may be prevented or limited by establishing and following the appropriate biosafety level practices and conditions. The requirements for each laboratory biosafety level are in the CDC and NIH BMBL. It is important to note that the four Biosafety Levels described below are not to be confused and equated with Agent Risk Groups as described in the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Review the following for a summary of the four biological safety levels:

- **BSL-1** is required for work involving well-characterized agents that are not known to cause disease in immunocompetent adult humans consistently and that present minimal potential hazards to laboratory personnel and the environment.
- **BSL-2** is required for work involving agents associated with human disease and poses moderate hazards to personnel and the environment.

- **BSL-3** is required for clinical, diagnostic, teaching, research or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure.
- **BSL-4** is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening diseases that are frequently fatal, for which there are no vaccines or treatments, or a related agent with unknown risk of transmission.
    - **Note**: No research with biohazards at BSL-4 is currently permitted in ASU facilities.

ASU requires gloves, a lab coat, eye protection, clothing covering the legs to the ankles, and closed-toe shoes when handling or working with biohazardous materials. PPE varies depending on the biological safety level.

Refer to Table Two for the minimum requirements for each of the three biological safety levels used at ASU.

Table Two: Biological Safety — PPE requirements*		
BSL-1	**BSL-2**	**BSL-3**
Protective laboratory coats, gowns or uniforms are worn to prevent contamination of personal clothing and removed before leaving for non-laboratory areas. Protective clothing is disposed of appropriately or deposited for laundering by the institution. Laboratory clothing is not taken home. **Protective eyewear** is worn when conducting procedures that have the potential to create splashes and sprays of microorganisms or other hazardous materials. Eye and face protection are disposed of with other contaminated laboratory waste or decontaminated after use. **Note**: Prescription glasses are not considered eye protection unless certified as such. **Gloves** must be worn to protect hands from exposure to hazardous materials.	As in BSL-1, plus: **The risk assessment considers whether respiratory protection is needed** for the work with hazardous materials. Relevant staff are enrolled in a properly constituted respiratory protection program if needed. **If research animals are present**, a risk assessment considers appropriate eye, face, and respiratory protection and potential animal allergens.	As in BSL-2, plus: **Protective clothing with a solid front, such as tie-back or wrap-around gowns, scrub suits or coveralls, is worn**. Protective clothing is not worn outside of the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when contaminated. **Gloves, two pairs when appropriate**, must be worn to protect hands from exposure to hazardous materials. **Shoe covers** are considered. **Respiratory protection is considered**. Staff wearing respiratory protection are enrolled in a properly constituted respiratory protection program.

*Safety is improved when PPE is combined with physical containment devices or equipment, such as biological safety cabinets. Additional PPE may be required as determined by risk assessment.

Animal Biological Safety Levels

Like the BSLs, there are four animal biosafety levels. These levels are required for the use of experimentally infected animals housed in indoor research facilities, such as vivaria, and for the maintenance of laboratory animals that may naturally harbor zoonotic infectious agents.

It is the responsibility of institutional management to provide facilities, staff and established practices that reasonably ensure appropriate levels of environmental quality, safety, security and care for laboratory animals. There are unique hazards associated with infected animals that must be understood by personnel who have animal contact.

Animal activity may create aerosols, and bites or scratches can occur. As a general principle, the biosafety level — facilities, practices and operational requirements — recommended for working with infectious agents in vivo and in vitro are comparable, though not always identical.

The four animal biosafety levels provide increasing levels of protection to personnel and to the environment and are recommended as minimal standards for activities involving infected laboratory animals. The four ABSLs describe animal facilities and practices applicable to work with animals infected with agents assigned to Biosafety Levels 1–4, respectively.

Investigators who are inexperienced in conducting these types of experiments should seek help in designing their experiments from individuals who are experienced in this special work.

The following are summaries of the four animal biological safety levels:

- **ABSL-1** is required for work in animals involving well-characterized agents that are not known to cause disease in immunocompetent adult humans and present minimal potential hazards to personnel and the environment.
- **ABSL-2** is required for work involving laboratory animals infected with agents associated with human disease, poses moderate hazards to personnel and the environment, and addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure.
- **ABSL-3** is required for work with laboratory animals infected with indigenous or exotic agents, agents that present a potential for aerosol transmission, and agents causing serious or potentially lethal disease.
- **ABSL-4** is required for work with animals infected with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments, or a related agent with unknown risk of transmission.
    - **Note**: No research with biohazards at BSL-4 is currently permitted in ASU facilities.

ASU requires the use of gloves, lab coat, eye protection, clothing that always covers the legs to the ankles and closed-toed shoes when handling or working with biohazardous materials. PPE varies depending on the biological safety level. Please refer to the following table for minimum requirements for each of the three animal biological safety levels in use at ASU.

Refer to Table Three below for more information.

Table Three: Animal Biological Safety — PPE requirements*		
ABSL-1	**ABSL-2**	**ABSL-3**
Laboratory coats, gowns or uniforms are the minimum recommended to prevent contamination of personal clothing. Protective outer clothing is not worn outside areas where infectious materials and/or animals are housed or manipulated. Gowns and uniforms are not worn outside the animal facility. **Reusable clothing** is appropriately contained and decontaminated before being laundered. Disposable PPE and other contaminated waste are appropriately contained and decontaminated prior to disposal. **Eye protection and face protection like safety glasses, goggles, masks, face shields or other splatter guards** are used for manipulations or activities that may result in splashes or sprays of infectious or other hazardous materials. Eye protection and face protection are disposed of with other contaminated facility waste or decontaminated after use. **Note**: Prescription glasses are not considered eye protection unless certified as such. **Additional PPE** is considered for people working with large animals. **Gloves** are worn to protect hands from exposure to hazardous materials and when handling animals.	As in ABSL-1, plus: **Based on the pathogen and work performed, respiratory protection may be considered** for staff enrolled in a properly constituted respiratory protection program. **People who have contact with NHPs** assess the risk of mucous membrane exposure and wear protective equipment like face shields, surgical masks, and goggles as appropriate.	As in ABSL-2, plus **Disposable PPE such as non-woven, olefin cover-all suits or wrap-around or solid-front gowns are worn** before entering areas where infectious materials and/or animals are housed or manipulated. Front-button, laboratory coats are unsuitable. **Disposable PPE** is removed when leaving the areas where infectious materials and/or animals are housed or manipulated. **All personnel entering areas where infectious materials and/or animals are housed or manipulated wear an appropriate head covering and eye, face and respiratory protection**. Head covering, eye protection, and face protection are disposed of with other contaminated animal facility waste or decontaminated after use. **Procedures may require wearing two pairs of gloves or double gloving**. Change outer gloves when contaminated, glove integrity is compromised, or when otherwise necessary. **To prevent cross-contamination, boots, shoe covers or other protective footwear** are used where indicated and disposed of or decontaminated after use.

*Safety is improved when PPE is used in combination with physical containment devices or equipment, such as biological safety cabinets. Additional PPE may be required as determined by risk assessment.

Arthropod Containment Levels

Like the BSLs and ABSLs, there are four Arthropod Containment Levels — ACL-1 through ACL-4. These containment levels are recommended by the American Society of Tropical Medicine and Hygiene and the American Committee of Medical Entomology for work with uninfected arthropods, those carrying infectious agents and transgenic vector arthropods in laboratory settings.

The Arthropod Containment Guidelines recommend biosafety measures for arthropods of public health importance. Field research sites that involve work with arthropods can be defined by the type of activities, duration, risks to researchers and other factors, but they are not the focus of the ACG document.
It is the responsibility of institutional management to provide facilities, staff and established practices that reasonably ensure appropriate levels of environmental quality, safety, security and care for arthropods. Arthropods present unique containment challenges not encountered with microbial pathogens.

Additional challenges include the lack of specific arthropod containment guidance in the BMBL or the NIH Guidelines. The four Arthropod Containment Levels, ACL-1 through ACL-4, introduce increasingly stringent measures and are like biosafety levels. Like BMBL, each level includes four components: standard practices, special practices, equipment or primary barriers, and facilities or secondary barriers.

The four ACL levels provide increasing levels of protection for personnel and the environment and are recommended as minimum standards for activities involving infected laboratory arthropods. In addition, the ACG document addresses how to prevent escapes when working with arthropods. The ASU IBC will assign the appropriate ACL level for each research project involving genetically modified arthropods or arthropods used in combination with recombinant or synthetic nucleic acids or infectious agents. Arthropod work that does not involve these conditions will be reviewed, and the appropriate ACL level will be assigned by EHS.

The following are summaries of the four arthropod containment levels:

- **ACL-1** is required for work with uninfected arthropod vectors or those infected with a nonpathogenic organism, including:
    - Arthropods are already present in the local geographic region, regardless of whether there is active vector-borne disease transmission in the area.
    - Exotic arthropods that, if they were to escape, would be nonviable or only temporarily established in regions without active vector-borne disease transmission.
- **ACL-2** is required for work with exotic and indigenous arthropods infected with BSL-2 agents associated with animal or human disease or that are reasonably suspected of being infected with such agents, such as those found in diagnostic samples.
- **ACL-3** is required for work with potential or known vectors that are or are likely to be infected with BSL-3 agents associated with the disease. Arthropods that are infected or potentially infected with BSL-3 pathogens may pose an additional hazard if the insectary is in an area where the species is indigenous or if alternative suitable vectors are present, as an escaped arthropod could introduce the pathogen into the local population. In the United States, the Select Agent Rule restricts access to certain pathogens of human or veterinary importance, all classified at BSL-3 or BSL-4. Many of these Select Agents are naturally maintained by arthropods. All possessions and use of these restricted agents must comply with the biosecurity requirements outlined in Title 42 CFR Part 73. Violations are criminal offenses.
- **ACL-4** is required for the most dangerous pathogen-infected arthropods. All the standard practices of ACL-3 should be in place, along with the additional safety precautions listed in the ACG and as specified by the IBC. BSL-4 agents are associated with a high risk of infection from aerosol exposure and cause life-threatening disease. Certain other pathogens, such as those listed as “restricted animal pathogens,” may also require BSL-4 containment if used in vectors. If work with vectors must be performed in a BSL-4 facility, BSL-4 requirements must be strictly followed. As described below, vectors must be safely always contained, possibly by use of specially designed apparatus that is tested and approved before use.

PPE varies depending on the arthropod containment level. **Please refer to Table Four below to learn the minimum requirements for each of the three arthropod containment levels in use at ASU**.

Table Four: Arthropod Containment Levels — PPE requirements		
ACL-1	**ACL-2**	**ACL-3**
Protective white laboratory coats, gowns or uniforms are the minimum recommended to prevent contamination of personal clothing. Protective outer clothing is not worn outside areas where infectious materials and/or animals are housed or manipulated. Gowns and uniforms are not worn outside the insectary. Reusable clothing is appropriately contained and decontaminated before being laundered. Disposable PPE and other contaminated waste are appropriately contained and decontaminated before disposal. **Eye protection and face protection like safety glasses, goggles, masks, face shields or other splatter guards** are used for manipulations or activities that may result in splashes or sprays of infectious or other hazardous materials. Eye protection and face protection are disposed of with other contaminated facility waste or decontaminated after use. **Note**: Prescription glasses are not considered eye protection unless certified as such. **Personal protective equipment is worn as appropriate**, for example, respirators for arthropod-associated allergies, particle masks, and head covers, but local risk assessment and institutional policy may provide exceptions. **Gloves** are worn to protect hands from exposure to hazardous materials and when handling arthropods.	**As in ACL-1, plus**: **Appropriate face or eye and respiratory protection are worn** by all personnel entering the insectary if recommended by the local risk assessment. **Gloves — latex or nitrile — are worn** when handling potentially infected arthropods, blood, and associated equipment and when contact with potentially infectious material is unavoidable. **Other equipment may be required as determined by the local risk assessment**. Homogenization of infected arthropods, for example, may require an appropriate respiratory protective device if the procedure is not performed within a biosafety cabinet or glove box.	**As in ACL-2, plus**: **Changing out of street clothes into scrubs, to be worn under PPE is highly recommended**. Wraparound or solid-front gowns are typically worn over this clothing. Front button laboratory coats alone are unsuitable. Before leaving the insectary, scrub suits are removed and appropriately contained and decontaminated before laundering or disposal. **Gloves — latex or nitrile — are worn** when handling infected arthropods or host animals and associated equipment. Gloves are removed aseptically and are changed frequently. **Boots, shoe covers or other protective footwear and disinfectant foot baths**, with appropriate anti-arthropod measures, are available and used where indicated. Footwear dedicated for use in the ACL-3 facility is highly recommended.

Training for working safely with biohazards

The principal investigators and laboratory supervisor are responsible for providing or arranging for site-specific training for all personnel. In addition, each employee must attend biosafety, lab safety, hazardous waste management and other safety training based upon duties.

Contact ASU EHS or the Biological Safety Officer, Giorgio Scarpellini, biological safety officer, EHS, ARO, for more information on training. All training must be documented annually, and records maintained by the principal investigator or laboratory supervisor.

Please refer to the ASU Laboratory-Specific Training checklist.

Biohazardous research project registration

Each principal investigator is responsible for the preparation of the Institutional Biosafety Committee disclosure for all research and teaching activities involving biological materials, including the assignment of the required Biological Safety Level.

The Institutional Biosafety Committee, in conjunction with the biological safety officer, will review all submitted registration documents; confirm, where applicable, that exempt status is appropriate for certain recombinant or synthetic nucleic acid work; and consider approval for those registration documents that are complete and that provide for safe handling of potential biohazards under the appropriate biosafety level. Registration information is available on the Research Compliance webpage.

Work with biological materials that are not covered by the IBC is registered with EHS. This includes, but is not limited to, work performed within ASU Core Facilities, clinical treatment areas, clinical laboratories, horticultural and agricultural spaces and work with uninfected wild-type animals and arthropods. These spaces are registered with EHS and follow all relevant safety and regulated program enrollments, including periodic biosafety inspections. Email the Biosafety team or EHS for information on registration.

Select agents and toxins

Select agents are certain microorganisms and toxins specifically identified in federal regulations. Select agents also include nucleic acids that encode for any select agent or toxin. Select agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products.

An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. Certain select agent toxins are not regulated as select toxins if the amount under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor does not exceed, at any time, the amounts indicated in the following table.

All orders of these toxins require approval from the Biosafety team and must have documented inventory control procedures.

Work with select agents and toxins requires registration with the Department of Health and Human Services and background verification through the FBI. All work with select agents and toxins at ASU is under the supervision of the responsible official and any alternate responsible officials. Please contact the RO or AROs if you have any questions.

Refer to the table below for more information on select agents and toxins.

Select agents and toxins	Amount
Abrin	1,000 milligrams
Botulinum neurotoxins	1 milligram
Diacetoxyscirpenol	10,000 milligrams
Ricin	1,000 milligrams
Saxitoxin	500 milligrams
Short paralytic alpha conotoxins	100 milligrams
Staphylococcal enterotoxins — subtypes A, B, C, D and E	100 milligrams
T-2 toxin	10,000 milligrams
Tetrodotoxin	500 milligrams

The ASU Biosafety Manual, when used in combination with the Laboratory-Specific Biosafety Manual, is designed to meet the federal requirements of the Department of Health and Human Services Standard, 42 CFR § 73, and the Department of Agriculture Standards, 7 CFR §331 and 9 CFR §121.

Toxins of biological origin

Any biological toxin with a median lethal dose, or LD_{50}, of less than 100 micrograms per kilogram body weight in vertebrates, must be approved by the ASU Institutional Biosafety Committee before beginning research.

Research with recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD_{50} of less than 100 nanograms per kilogram body weight requires preapproval from the National Institutes of Health's Office of Science Policy.

Examples of biological toxins with an LD_{50} of less than 100 nanograms per kilogram include the botulinum toxins, tetanus toxin, diphtheria toxin, and Shigella dysenteriae neurotoxin.

Unfixed tissue and bodily fluids

Any laboratory where work involves the use of and/or exposure to blood, body fluids, or unfixed tissues from humans or animals must be registered. There is the danger of exposure to pathogens — disease-causing microorganisms — that may be found in such materials.

Research with materials of human origin like blood, tissue, organs and cell lines are regulated by the Occupational Safety and Health Administration. Work with this material must follow the ASU Bloodborne Pathogens Exposure Control Plan. In addition, when human blood or tissue donors are involved, the principal investigator must contact ORIA to determine whether a human subject Institutional Review Board application is required.

Research or exposure to unfixed animal tissues, blood or bodily fluids requires registration and oversight under the Occupational Health and Safety Program as part of ASU's IACUC. Participation in the OHSP is required for all faculty, staff, visiting scholars, scientists and students who work directly with or have frequent contact with vertebrate animals, unfixed animal tissues or body fluids.

More information on the OHSP can be found at ASU Employee Health.

Recombinant and synthetic nucleic acid molecules

The NIH regulates the use of recombinant and synthetic nucleic acid molecules, as outlined in the NIH Guidelines. At ASU, this research must be reviewed by the Institutional Biosafety Committee before the work is initiated. Guidelines include registration of the recombinant or synthetic nucleic acid molecules, understanding the classification of the use of work, safe work practices and proper disposal of material, including whole animals, containing recombinant or synthetic nucleic acid molecules. Using more than 10 liters of organisms containing recombinant or synthetic nucleic acid requires special practices and IBC approval.

Environmental samples

Environmental samples, such as water, air, soil or plants, may contain pathogens like bacteria, viruses, and spores that could present a health hazard to people, animals, or the environment. Using appropriate personal protective equipment when collecting environmental samples will reduce exposure to potential pathogens and minimize the transfer of pathogens in the environment. Use care when handling environmental samples, especially if the sample will be enhanced in the laboratory by culturing or other growing mechanisms, including greenhouses.

Techniques used to enhance and/or culture environmental samples should be conducted at BSL-2 or higher levels in an appropriate containment device, such as a biological safety cabinet. If the environmental sample is sterilized or inactivated before experimentation, then the sample may be manipulated in a BSL-1-rated laboratory, as determined by the IBC.

All other environmental samples must be registered with the ASU Institutional Biosafety Committee. Environmental samples that the IBC does not cover are subject to review and approval by EHS and ASU Biosafety. Environmental samples are also subject to USDA APHIS and CDC transit and import permit regulations and additional applicable state permits. Researchers should contact ASU Biosafety for assistance in determining whether permits for obtaining environmental samples are required.

Controlled substances

The Controlled Substances Act — Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 — places all substances regulated by federal law into one of five schedules or categories based on the medicinal value and the potential for abuse. The Drug Enforcement Administration, part of the U.S. Department of Justice, has control and enforcement authority for controlled substances. Many drugs used for medical treatment, anesthesia, analgesia, or euthanasia are considered controlled substances. To legally purchase, store, use, dispense and dispose of these drugs, a DEA license is required. **Table Five lists the five schedules of controlled substances**.

Table Five: DEA-controlled drug schedule

	Potential for abuse	Medical use	Examples
Schedule I	High	None	Heroin, hydromorphinol, marijuana and lysergic acid diethylamide
Schedule II	High	With restrictions	Fentanyl, methadone, oxymorphone and pentobarbital
Schedule III	Less than I or II	Currently accepted for medical use	Euthanasia solutions, nalorphine, buprenorphine and ketamine hydrochloride
Schedule IV	Low		Chloral hydrate, phenobarbital and butorphanol
Schedule V	Lower than IV		Codeine

Investigators who use controlled substances in their laboratory must obtain a researcher DEA license. As an ASU employee, the license is free. Refer to the Office of Research Compliance webpage for information on how to apply for a researcher DEA license and detailed instructions on completing the online application.

Submit the initial application using the DEA registration webpage. Once the online application process has been completed, additional documents that need to be completed will be forwarded to the principal investigator by the DEA. Once the DEA has completed the application process, the DEA license will be mailed to the PI. The entire process takes approximately four to six weeks. The license must be renewed annually.

Once the PI secures a DEA license, they may procure controlled substances independently. Submit a DEA 222 form to order or obtain Schedule I or Schedule II drugs.

All persons possessing controlled drugs must maintain specific records for a minimum period of two years per DEA requirements. Inventories and records of controlled substances listed in Schedules I and II must be maintained separately from all other records maintained by the registrant. Information that must be on file and available for review includes:

1. **Inventory**: After an initial inventory, a new inventory of all controlled substances on hand shall be taken at least once every two years. Each inventory must contain the following information:
    a. Date and time the inventory was taken.
    b. A list of all unopened bottles by drug name, including the drug name, the number of bottles, the drug concentration or unit size like 100mg/mL or 50 mg tablets, and the amount of drug in the bottle such as milliliters, milligrams or tablets. For example, Ketamine, two bottles, 100 mg/mL, 10 mL per bottle.
    c. A list of all opened bottles and, for each bottle, the drug name, the drug concentration or unit size like 100 mg/mL or 50 mg tablets, and the amount of drug in the bottle before opening, such as mL/bottle or tablets/bottle, and the remaining units. For example, Ketamine, 100 mg/mL, originally 10 mL per bottle, 4.5 mL remaining.
2. **Transfer form or controlled drug inventory form**: If you obtain controlled substances through a different DEA-licensee or transfer drugs from your inventory, like for reverse distribution of expired drugs, you must maintain a copy of the Transfer Form for two years.
3. **Controlled Substance Administration Record**: When a controlled substance is administered, its usage must be documented. CSAR forms can be provided to PIs, or the PI can generate their tracking form. However, all needed information must be included. This includes the license holder's name and DEA number, name of the drug, drug schedule number, concentration, starting amount, bottle ID, and bottle lot number. For each use of the bottle, the following needs to be recorded: date, name of the user, the amount used, the amount remaining and the initials of the person entering the information.

Per DEA regulations, expired or unused controlled substances must be disposed of via reverse distribution.

Animal research project registration

Vertebrate animals

Research involving live vertebrate animals and octopuses must be registered and approved by the ASU Institutional Animal Care and Use Committee.

Arthropod research project registration

Arthropod research projects that do not fall under the purview of the IBC or IACUC committees must be registered with ASU Biosafety. ASU Biosafety will conduct a risk assessment to determine the appropriate standard and special practices, equipment, and facilities as outlined in the Arthropod Containment Guidelines published by the American Committee of Medical Entomology, a subcommittee of the American Society of Tropical Medicine and Hygiene.

Email ASU Biosafety for questions or more information.

Field research project registration

Field research projects must be registered with the corresponding institutional committees, IBC, IACUC or IRB, depending on the nature of the research. In addition, trips associated with field research projects may require registration in the ASU travel system. Please refer to the ASU Travel Guidance webpage.

Students participating in field research in international locations must register with the ASU Global Education Office.

The ASU Field Research Safety Manual provides the requirements, policies, guidelines and resources for ASU personnel to conduct field research safely and successfully. The manual enables ASU personnel to minimize risks associated with conducting field research in local, regional, national or international locations.

Email ASU EHS for assistance with field research projects.

Biohazardous waste

At ASU, biohazardous waste is defined according to rules and regulations of the state of Arizona and the National Institutes of Health's Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Biohazardous waste includes, but is not limited to, the following:

- Any solid waste generated in the diagnosis, treatment or immunization of a human being or animal or in any research relating to that diagnosis, treatment or immunization or in the production or testing of biological materials.
- Any genetically altered living organisms, products and all organisms containing recombinant nucleic acids.
- Animal carcasses, body parts and bedding of animals that have been infected with agents that produce or may produce human infection.
- Discarded cultures and stocks generated in the diagnosis, treatment or immunization of a human being or animal or in any research relating to that diagnosis, treatment, or immunization or in the production or testing of biological.
- Discarded products and materials containing blood or blood components.
- Discarded organs and body parts removed during surgery.

- Discarded sharps are used in animal or human patient care, medical research, and clinical laboratories.
    - Examples of sharps include hypodermic needles, syringes, pipettes, pipette tips, scalpel blades, blood vials, needles attached to tubing, broken and unbroken glassware, slides and coverslips.

Animal waste

Wastes unique to the animal facility include animal bedding and animal carcasses. These are generated along with the sharps and other biologically contaminated equipment that must be discarded in all laboratories. All animal waste must be treated before disposal unless an alternative disposal method has been pre-approved by EHS. In most instances, animal waste and/or carcass procedures are summarized below.

- Sharps from an animal facility are disposed of in sharps containers and disposed of according to ABSL-specific procedures. After these ABSL-specific procedures, sharps containers are placed in biohazardous waste barrels for biological waste in an animal facility. All other biologically contaminated materials are also placed in the red barrels. When the biohazardous waste barrel is full, it is the responsibility of the laboratory employees to contact EHS for pick-up. Email ASU EHS and DACT with questions regarding sharps disposal in an animal facility.
- Typically, animal carcasses are bagged, sealed, and stored in refrigerators/freezers in each animal facility until picked up by EHS for incineration. Specific instructions for the disposal of animals can depend upon the designated ABSL level. Email ASU EHS Biosafety and DACT with questions regarding carcass disposal.
- Soiled animal bedding is disposed of according to ABSL-specific procedures but is generally collected into EHS biohazardous waste barrels for disposal. Email ASU EHS Biosafety and DACT with questions regarding animal bedding disposal.

Biohazardous waste handling

Wastes associated with biological research materials must be disposed of in special ways. Examples of potentially hazardous items include:

- All sharps like glass implements, needles, syringes and blades coming from facilities using infectious materials
- Agents of any biosafety level containing recombinant or synthetic nucleic acid molecules
- Animal bedding and animal carcasses
- Archaeological samples like bones, clothing fragments and containers
- Biologically cultured stocks and plates
- Environmental samples like soil, water, plants and sewage
- Genetically modified or transgenic plants and animals
- Human or animal blood, tissues, organs and cell lines
- Any other regulated biohazardous material

For EHS to remove biological waste, the following procedures must be followed:

- Biological solid waste derived from human and animal sources like blood, body fluids, tissues, tumors and human cell lines are hazardous biological wastes and should be placed in an autoclavable biohazard bag. Autoclave the bag at the appropriate time and temperature and put it in a biohazardous waste barrel for removal by EHS.
- Bacteria, viruses and other microorganisms that are known human pathogens should also be chemically inactivated or placed into an autoclavable biohazard bag, autoclaved and put in a biohazardous waste barrel for removal by EHS.

- BSL-1 materials containing recombinant or synthetic nucleic acid must be autoclaved or destroyed with bleach.
- Non-human biological wastes are handled using the same methods as human biological wastes: placed in autoclave bags, autoclaved, and put into biohazardous waste barrels for removal by EHS.
- Sharps and sharp objects such as glass, syringes, disposable pipettes, and pipette tips that may be contaminated with human or non-human biohazards must be placed in a rigid, leak-proof and puncture-resistant container. The container is autoclaved and then placed in a biohazardous waste barrel for removal by EHS. **Note**: Needles and other medical sharps must be collected in sharps containers.
- Other waste, including waste from genetically modified plants and animals and environmental and archaeological samples, are considered biohazardous waste. These wastes should be chemically inactivated or autoclaved and placed in an autoclavable biohazard bag. Autoclave the bag outlined in the Arthropod Containment Guidelines published by the American Committee of Medical Entomology.

When a biohazardous waste barrel or liquid hazardous waste is ready for removal, email EHS to arrange a pick-up or submit a hazardous waste pick-up request.

Laboratory procedures and equipment

Exposure control

The term containment describes safe methods for managing biohazardous and select agents and toxins in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other people and the outside environment to potentially hazardous agents. The three containment elements include laboratory practices and techniques, safety equipment and facility design.

The risk assessment of the work with a specific agent will determine the appropriate combination of these elements. If a principal investigator wishes to work with a biological agent or toxin with a reduction in PPE below the standard defined by this manual for the assigned biosafety level. **Refer to Tables One, Two, and Three above for more information**. A Certificate of Hazard Assessment: Personal Protective Equipment Form must be submitted for review and approved by EHS Biosafety and the IBC. The principal investigator's laboratory-specific biosafety manual must include copies of the health hazard assessments.

Laboratory practice and technique

The most important containment element is strict adherence to standard microbiological practices and techniques. People working with infectious agents or infected materials must know potential hazards. They must be trained and proficient in the practices and techniques required for handling such material safely. The principal investigator of each laboratory is responsible for providing or arranging the appropriate training of personnel and verifying each person's competence. In addition, each principal investigator must develop a laboratory-specific biosafety manual to address the use, handling and disposal of biohazardous material, including select agents and toxins, in the laboratory.

The laboratory-specific biosafety manual must identify specific hazards that will or may be encountered and consider procedures needed to minimize or eliminate risks. Personnel should be advised of special hazards and are expected to follow the required practices and procedures.

Safety equipment: primary barriers

Safety equipment includes biological safety cabinets, enclosed biohazardous containers, and other engineering controls designed to eliminate or minimize exposures to biohazards and toxins. The

biological safety cabinet is the principal device to contain infectious splashes or aerosols generated by many microbiological procedures. Refer to the biological safety cabinet section for more information.

Primary safety barriers may include personal protection equipment, such as gloves, lab coats, safety glasses or goggles, face shields and respirators. PPE is often used with a biological safety cabinet and other containment devices. In some situations where working in a biological safety cabinet is impractical, personal protective equipment may form the primary barrier between the worker and the infectious materials.

ASU policy EHS 105 requires the use of gloves, lab coats and eye protection when handling biohazardous materials.

Facility design: secondary barriers

The facility's design is essential in providing a barrier to protect those working inside and outside the laboratory and to protect people, plants, or animals in the community from biohazards and toxins that may be accidentally released from the laboratory. Facilities must be commensurate with the laboratory's function and the recommended biosafety level for the manipulated agent.

The secondary barriers required will depend on the risk of transmission of specific agents. For example, in working with agents at BSL-2, the exposure risks involve direct contact with the agents or inadvertent contact through contaminated work environments. Recommended secondary barriers in these laboratories include separation of the laboratory work area from public access, hand washing facilities, and availability of a decontamination facility such as an autoclave.

When the risk of infection by exposure to an infectious aerosol is present, higher levels of primary containment and multiple secondary barriers may become necessary to prevent infectious agents from escaping into the environment. Such design features include specialized ventilation systems to ensure directional airflow, High-Efficiency Particulate Air filtration to remove agents from exhaust air, controlled access zones, airlocks as laboratory entrances, or separate modules to isolate the laboratory.

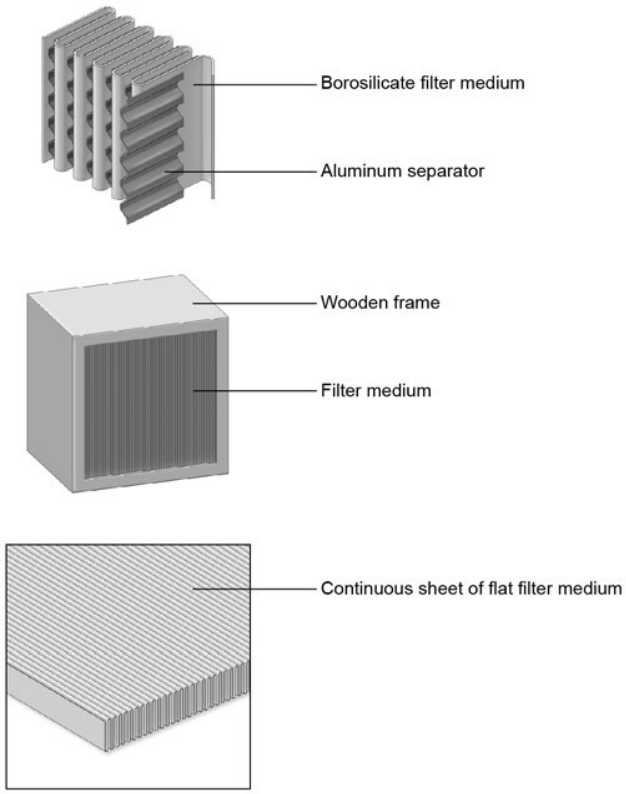
Biological safety cabinets

Biological safety cabinets are classified as Class I, Class II or Class III cabinets. Properly maintained and operated, they effectively contain and capture microbial contaminants and infectious agents using HEPA filters. **Refer to Figure One below for more information**. Biosafety cabinets should not be confused with clean benches that only protect the material being worked with and are unsuitable for work with infectious or toxic material.

Although clean benches or laminar flow hoods, like biological safety cabinets, have HEPA-filtered air, the air flows over the experimental material toward the user rather than being drawn away. Biological safety cabinets should also not be confused with conventional fume hoods that do not filter microorganisms.

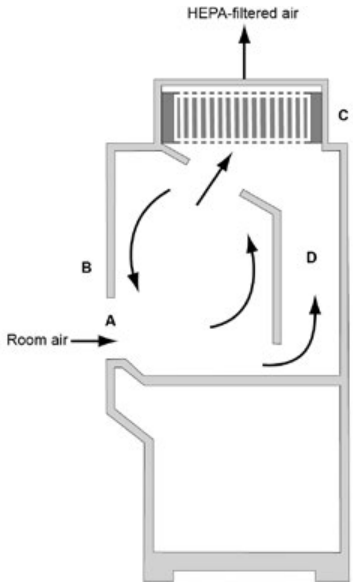
HEPA filters are typically constructed of paper-thin sheets of borosilicate medium, pleated to increase surface area and affixed to a frame. Aluminum or plastic separators are often added for stability.

Figure One: HEPA filters from the Biosafety in Microbiological and Biomedical Laboratories 6th edition.



Class I biological safety cabinets provide personnel and environmental protection, not product protection. **Refer to Figure Two below for more information**.

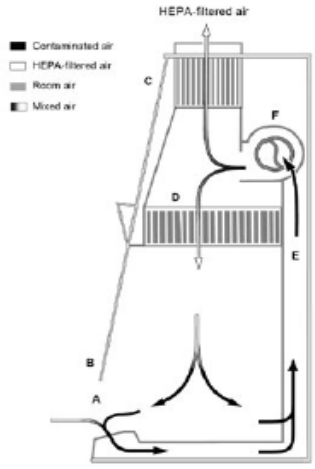
Figure Two: The Class I BSC from Biosafety in Microbiological and Biomedical Laboratories 6th Edition.



Class II biological safety cabinets are the most used biological safety cabinets at ASU for biohazards. These cabinets provide personnel, environmental, and product protection. **Refer to Figure Three below for more information**.

Only those that are hard ducted to exhaust outside and provide a face velocity of 80 to 125 feet per minute should be used when working with volatile chemicals. Additionally, cabinets are not designed to prevent the ignition of volatile flammable chemicals, such as ethanol and isopropanol.

Figure Three: Class II, Type A BSC from Biosafety in Microbiological and Biomedical Laboratories 6th Edition.



Steps for working in a biological safety cabinet

1. Don appropriate PPE, including a laboratory coat, safety glasses and a pair of high-quality nitrile gloves at a minimum.
2. Make sure the biological safety cabinet is certified.
3. Turn on the fluorescent lamp.
4. Turn on the cabinet if it is not left running.
    a. Inspect the air intake grilles for obstructions and foreign material and remove them if necessary.
    b. Ensure the airflow indicator confirms normal airflow.
5. Allow the cabinet to run for at least 15 minutes before use if the cabinet is not running.
6. Disinfect the work surface and exterior of all materials to be placed inside the BSC with an appropriate EPA-registered disinfectant.
7. Place items into the BSC, at least 6 inches from the front grill and approximately two to four inches from the rear grill, without disrupting the airflow.
8. Items used for surface decontamination and cleanup of a small spill should be included inside the BSC. Ensure biohazard waste containers are directly outside the BSC but not attached to the unit, as they can disrupt airflow.
9. Adjust the working height of the stool so that the worker's face is above the front opening.
10. Employ good microbiological practices and work with materials from the clean to the dirty side.
11. Minimize the movement, such as sweeping arms, and reduce the frequency of placing hands or arms into the BSC and taking them out.
12. Upon completion of work, the final surface decontamination of the cabinet must include a wipe-down of the interior surfaces, ensuring the disinfectant is on the surfaces for the manufacturer's recommended contact time. A mechanical means of reaching the back and side walls of the cabinet is highly recommended.

13. Open flames such as Bunsen burners are not permitted in a biological safety cabinet. An open flame creates turbulence that disrupts the supply pattern of HEPA-filtered air and could damage the HEPA filter itself. Non-flame alternatives such as glass bead sterilizers or infrared heating devices may be used. Although these alternative devices don't use an open flame, the heat they generate can still decrease a BSC's effectiveness and compromise the user's safety.
14. The use of ultraviolet light in the BSC is strongly discouraged. UV bulbs in the BSC must be cleaned and checked regularly as dust and debris inhibit effectiveness and degrade over time. Chemical surface disinfection must be the primary means of decontaminating BSC.

Note: Be very careful when using small pieces of materials, such as paper tissues in the hood. These can be blown into the hood and disrupt motor operations. Email EHS with questions or for more information.

Biological safety cabinet certification

Biological safety cabinets provide a partial containment system for safely handling pathogenic microorganisms, environmental samples, and other biohazardous materials. To ensure safety, biological safety cabinets must be used correctly with good microbiological techniques and be in proper mechanical working order. Cabinets must be certified for performance upon installation using the National Sanitation Foundation and American National Standards Institute standard 49.

Certification is a series of performance tests on the biological safety cabinet to confirm that it will provide the user and experimental material with the protection for which it is designed. The airflow, filters, and cabinet integrity are checked to ensure that the cabinet meets minimum performance standards. A list of vendors who provide certification is maintained by EHS Biosafety.

Biological safety cabinets intended for research with biohazards must be certified:

- After they are received and installed but before use with infectious materials
- After filter changes
- After being moved, even if only a few feet
- After a mechanical failure or service repair
- Annually

Biological safety cabinet decontamination using formaldehyde gas, chloride dioxide gas, or other approved method may be provided by an outside vendor and must be done:

- Before any maintenance work requiring disassembly of the air plenum, including the filter replacement
- Before moving the cabinet to a new laboratory
- Before discarding or salvaging

The production of formaldehyde gas is a health concern. Many biological safety cabinets at ASU are not ducted to the outside; therefore, consideration of a temporary cease work order may be implemented, and extreme caution must be used when having the procedure performed.

Decontamination

Decontamination is a process or treatment that renders an instrument or environmental surface safe to handle. A decontamination procedure can be as simple as cleanup with detergent and water or as thorough as sterilization. Sterilization, disinfection and antisepsis are all forms of decontamination.

- **Antisepsis** is the application of a liquid antimicrobial to skin or other living tissue to inhibit or destroy microorganisms. Examples include hand washing with germicidal solutions or swabbing skin with alcohol before an injection.

- **Disinfection** is a chemical or physical treatment that destroys the most resistant vegetative microbes or viruses, but not the spores, in or on inanimate surfaces. Effectiveness is influenced by several factors, including the type and number of organisms, amount of organic matter, the object being disinfected, the disinfectant being used, concentration, temperature, and exposure time.
- **Sterilization** is the use of physical or chemical processes to destroy all viable forms of microbial life, such as bacterial spores.

When to decontaminate

In most ASU laboratories, it is recommended that decontamination be accomplished by steam heat sterilization in an autoclave or by surface application of or placement in a chemical disinfectant solution, such as 1:10 bleach solution or an EPA-registered disinfectant and applied per manufacturer instructions.

All material and equipment contaminated with or containing potential biohazards should be decontaminated:

- At least daily
- Before being washed, stored or discarded
- In the event of spills of biohazards
- Upon completion of procedures involving the use of biohazardous material

Autoclave use

Autoclaving, saturated steam under pressure of approximately 15 pounds per square inch, to achieve a chamber temperature of at least 250˚F for a designated time, is the preferred and most convenient method to rapidly destroy all forms of microbial life. However, to do this, the autoclave process must reach the proper temperature, pressure, and time and prevent the entrapment of air in the bag or container of treated material.

- Material to be sterilized must encounter steam.
- Bags or containers should be left open during the autoclave process or water, ~200 mL, should be added to sealed bags to generate steam.
- Heat indicator tape should be used outside the bag or container with each autoclave load to indicate that sterilization has been completed.
- Autoclave sterility monitoring should be conducted on a regular basis using biological indicators, such as *G. stearothermophilus* spore strips, placed among treated materials and at locations throughout the autoclave. The spores, which are more resistant to heat than most other biological materials, provide validation of general microbial destruction when they are effectively inactivated by autoclave operation, typically 250˚F for 30 minutes.
    - The monitoring of autoclave function via spore testing, certification, maintenance and validation is the responsibility of the laboratory or department.
- Note that the type and frequency of sterility monitoring varies and is based on usage, cycle type, and autoclave type. Email EHS for more information.

The ASU Autoclave Safety Manual provides autoclave information, guidelines, policies and procedures enabling staff using autoclaves to work safely and eliminate or reduce the potential for exposure to hazards or potentially infectious materials. All personnel who use autoclaves at ASU must have successfully completed the Comprehensive Biosafety Tri-University Training and Autoclave Safety Training and received in-person training from their supervisor regarding the safe use and operation of autoclaves.

Chemical disinfectant use

The most practical use of chemical disinfectants is for surface decontamination and, when used in sufficient concentration, as a decontaminant for liquid wastes before final disposal.

Liquids can be disinfected via treatment with a chemical disinfectant that is effective against the biological agents in use.

Refer to Appendix C for additional information on disinfectants.

Decontamination in animal facilities

In ASU animal facilities, decontamination is accomplished using the provided disinfectants applied to surfaces and equipment through the following:

- Chemical sterilant
- Steam heat sterilization in an autoclave, particularly for surgical equipment, bedding and other materials used in the barrier animal facility
- Gas sterilization
- The use of the cage-washing machine

All animal users should be familiar with the safe and proper use of all chemical decontamination materials and equipment they need to use as part of their animal lab responsibilities.

Animal hazards and exposures

Good housekeeping practices and sanitation are essential to reducing the risk of physical hazard injuries. Keeping work surfaces clean and clear of obstructions, waste and other materials is important. All boxes, hoses or bags of bedding material should be routinely removed from the work area. Mop floors and clean work surfaces with the appropriate cleaning and disinfectant solutions. Remember that poor housekeeping is unprofessional and will increase the risk of accidents and injuries.

Animals present a unique risk of hazards and potential biohazardous agent exposures.

Bites and scratches

The risk of animal bites and scratches is associated with handling animals and is best avoided by proper handling techniques and wearing appropriate personal protective equipment. Knowledge of animal behavior and how animals respond to their immediate physical environment is important in reducing the risk of injury to the individual and the animal.

Animals respond to sights, sounds and smells as people do, but they may also hear, smell and react to things people do not detect. For example, if an animal hears a high-pitched sound, it may become frightened and react defensively. Many animals have a flight zone; if approached by another animal or the handler, the affected animal may try to escape. Unsuccessful escape may cause the animal to act aggressively. Of course, inappropriate handling of an animal can cause discomfort, pain, and distress and provoke an animal to bite or scratch.

Animal bites and scratches that cause minor skin damage are sometimes disregarded by animal workers who are unfamiliar with the number of diseases that such injuries can spread. Even minor bites and/or scratches can result in infections and illnesses if they are not adequately treated. Scrapes and injuries from contaminated equipment associated with animal care and housing, such as cages, can be as great a risk as direct animal contact and should be addressed similarly.

Most animals used in research are bred specifically for that purpose and do not have the potential for transmitting the kinds of pathogenic organisms that those in the wild do; however, some illnesses and infections can be passed on from animals to people like zoonoses. These are discussed in more detail later in this document.

With research into animals, biological hazards are of most concern when the animals are naturally infected, like macaques may have B virus or if animals are infected with a bacterium, virus or human cells such as tumorigenic cell lines as part of the experimental work. Under these conditions and when doing field research with wild species, it is critical that appropriate PPE and other appropriate protective measures be used to prevent infection.

The most important step to prevent infection following any bite, scratch or puncture from sharps exposure or mucous membrane exposure is to immediately and thoroughly wash the injury with soap and water. Inform a supervisor and submit an incident report. Contact ASU Employee Health at **602-486-1917** for medical consultation or treatment. Incidents and injuries involving non-human primates must follow the Macaque Injury or Fluid Exposure Emergency Protocol. In addition, everyone working with NHPs must complete the annual B-virus training available through the EHS training platform.

Physical hazards

Sharps such as needles, broken glass, syringes, pipettes, and scalpels are all commonly found in animal facilities and laboratories and present a physical hazard. Use extra care to avoid inadvertent contact and injury. **Sharps injuries** represent a substantial risk of becoming infected, especially when injecting animals with microbial agents or drawing blood.

The animal facility should have puncture-resistant and leak-proof containers for disposal of sharps. To prevent needle sticks, it is critical **to always place used needles directly into the sharps container without recapping or attempting to bend, shear, break or remove the needle from the syringe**.

Animal care operations involve several activities that can cause physical stress when handling and moving heavy loads. Proper lifting techniques can help prevent back and shoulder injuries when moving cages, bags of feed and bedding, equipment, and supplies. Poor physical fitness, obesity, poor posture, smoking, and medical/physical deficiencies are personal factors that may contribute to back pain.

Every attempt should be made to avoid sudden movements and use a two-handed lifting technique when lifting heavy loads. Keep your back straight, feet positioned apart with one slightly ahead of the other, and knees bent as the lift is completed. Reduce loads where possible and get help when lifting awkward loads or those that one person cannot handle safely.

Chemical hazards

Personnel involved in the care and use of research animals must be familiar with the chemical hazards associated with animal care and the laboratory environment. Chemical properties may include flammability, corrosiveness, reactivity or the potential to be explosive. Potentially hazardous chemicals used in animal laboratories include the following:

- **Acids** such as hydrochloric and sulfuric
- **Anesthetics** like isoflurane, tribromoethanol, methane sulfonate, nitrous oxide, urethane and barbiturates.
- **Bases** like sodium hydroxide and quaternary disinfectants
- **Fixatives** like formaldehyde and osmium tetroxide
- **Solvents** like xylene, acetone and dimethyl sulfoxide
- **Sterilants** like peracetic acid, chlorine dioxide, peroxides and glutaraldehyde

Each chemical product should be handled following manufacturer recommendations using PPE, following university guidelines and laboratory training. Safety Data Sheets are available in the animal facility.

Animal allergies

Allergic reactions to animals are among the most common conditions that adversely affect worker health. The estimated prevalence of allergic symptoms among workers exposed to animals is 10–40%. Workers who are continually exposed to animal allergens tend to have progressively more frequent and increasingly severe symptoms, and an estimated 10% develop **asthma**. Hence, all workers must seek to minimize their exposure to animal allergens.

Additionally, once animal allergies develop, the affected worker should minimize any additional allergen exposure to prevent the progression of allergy symptoms. Personnel with questions regarding allergies or allergic symptoms should contact ASU Employee Health.

Allergies are often manifested by nasal symptoms like allergic rhinitis, itchy eyes like allergic conjunctivitis and rashes like contact dermatitis. Symptoms may worsen over time and may lead to acute anaphylaxis in a small number of patients. In **rodents**, the allergen protein is of urinary origin; in rabbits, it is contained in the fur, dander, and, to a lesser degree, the saliva and urine. In **Guinea pigs**, urine is the primary allergen, with dander, fur and saliva contributing.

Exposure to **birds** can cause rhinitis and asthma symptoms. Multiple bird proteins have been identified as allergens and can be found in serum and fecal droppings that contain serum. **Fish** proteins can be an inhalation allergen for those who are sensitized. Proteins in dander, saliva, urine and sweat from **dogs** and **cats** may cause allergic symptoms. Although not common, there are documented cases of individuals developing allergies to **reptile** scales, such as **iguanas** and **lizards**. Allergies to **livestock,** including **horses**, **cattle**, **pigs**, **sheep** and **goats,** are also common, with allergens contained in dander, saliva and, urine and feed in livestock.

Prudent efforts to prevent allergen exposure and reduce the frequency of sensitization in animal workers require strict work practices and consistent use of PPE. Housing animals in filter-top cages, working in well-ventilated areas, and using ventilated hoods for soiled bedding disposal will minimize exposure to animal allergens.

The work area must be maintained clean to prevent inhalation and contact exposure. Procedures that minimize the release of airborne materials, including bedding dust and antibiotic aerosols, and the contamination of hands, arms, body and face should be adopted. Workers should use PPE during each animal contact or allergen exposure. Wearing PPE part-time will not prevent exposure. Wear a facemask or respirator to reduce inhalation and hand-to-face spread of allergens and cover all exposed skin, such as gloves, lab coat, sleeve protectors and hair covers, to prevent allergen contact.

It is also important that once animal procedures are complete, all contaminated PPE and clothing are removed and properly disposed of to prevent repeated exposure while performing subsequent duties. Supervisors or EHS can provide further information and access to approved PPE.

Latex gloves and related allergies

Allergic reactions to natural rubber latex have increased since 1987, when the CDC recommended using universal precautions to protect against potentially infectious materials, bloodborne pathogens and human immunodeficiency viruses. Increased glove demand also resulted in higher allergen levels due to manufacturing process changes. In addition to skin contact with latex allergens, inhalation is another potential route of exposure. Latex proteins and powders used to lubricate the glove’s interior may be released into the air.

In June 1997, the National Institute of Occupational Safety and Health issued the Preventing Allergic Reactions to Latex in the Workplace alert. NIOSH studies indicate that 8–12% of healthcare workers regularly exposed to latex are sensitized, compared to 1–6% of the general population. Latex exposure symptoms include skin rash and inflammation, respiratory irritation, asthma and anaphylaxis. The amount of exposure needed to sensitize an individual to natural rubber latex is unknown, but when exposures are reduced, sensitization decreases.

NIOSH recommends the following actions to reduce exposure to latex:

- If latex gloves must be used, choose reduced-protein, powder-free latex gloves.
- Wash hands with mild soap and water after removing latex gloves.
- Whenever possible, substitute another glove material.

When using antibiotic materials, procedures should be adopted that minimize the release of airborne materials and skin contamination. Of particular concern are releases of penicillin-type or other antibiotics during syringe-loading from multi-dose vials. People with previous exposures and developed sensitivity can quickly go into anaphylaxis after inhaling a mist of antibiotic material. Be sure to handle these materials with caution and according to use directions. Use and caution inserts for each antibiotic are provided in the product packaging and should be read and understood before use. Investigators who are inexperienced in conducting these types of experiments should seek help designing their experiments from individuals experienced in this special work.

Zoonoses

Zoonoses are diseases that can be transmitted between species or, in some instances, by a vector, from animals to humans or humans to animals — the latter is sometimes called reverse zoonosis or anthroponosis. They may be a significant exposure hazard in some laboratories where animals are used for research. Fortunately, many laboratory animal species today are bred to be free of zoonoses that were once more common in these animals. However, there remain zoonotic agents associated with laboratory animals, some of which can be life-threatening.

Field research with wild species also remains a clear source of zoonosis exposure. Prevention of exposure to these animal-related illnesses requires knowledge of the zoonoses related to the animals involved. In the following sections, the zoonotic agents listed for each animal species may be present in the animals being used. If someone is exposed to a bite, scratch, aerosol droplet, mucosal secretion, feces, or urine, there is the potential for infection; a medical evaluation through ASU Employee Health is highly recommended.

Rodents

Modern laboratory mice and rats are bred to exclude all zoonotic agents, including rat-bite fever. Mice received at ASU from foreign countries have been tested during quarantine for many infectious and zoonotic agents. Therefore, unless the laboratory mice and rats are infected as part of the research procedures or exposed to wild mice — those from the natural habitat outside the laboratory — there is limited concern for disease from these research mice. However, there is always concern about secondary infections that can occur with bites and scratches.

Common skin, intestinal, and soil bacteria present in a person, or an animal can infect the scratch or bite wound and cause these secondary infections. Therefore, users should handle all laboratory rodents with care, always cleanse any wound immediately with soap and water for 15 minutes or antiseptic and seek medical evaluation at ASU Employee Health or the nearest emergency medical facility for broken skin.

Wild rodents or laboratory rodents that have been exposed to wild rodents have the potential to carry a variety of zoonotic bacteria and viruses that can be passed on to workers handling them. Tests should always be completed on wild rodents and those from foreign countries when they are received at ASU to

screen for these zoonotic agents. Although this reasonably assures that rodents will be free of zoonotic infections, the screening does not guarantee infection-free rodents.

Therefore, because of the serious consequences of becoming infected, investigators must always follow good personal hygiene and animal handling procedures and use the provided PPE to protect them from exposure. Rodents that have originated from the wild, have had contact with wild rodents, or are from foreign countries could be infected with one or more of the pathogens and are handled at ABSL-2.

Viruses that can cause serious disease in humans include Hantavirus and Lymphocytic Choriomeningitis Virus. Hantavirus is transmitted by inhaling dried rodent feces and urine when such material is raised from disturbed feces, bedding, or nesting material. Transmission can also occur through rodent bites and broken skin or mucous membrane contamination. The infection progresses from flu-like symptoms to respiratory complications and has resulted in death in over 50% of clinical cases, particularly when medical care was not quickly obtained.

It is possible to prevent exposure using PPE, good personal hygiene and properly ventilated handling of waste bedding material. LCMV is transmitted to humans by inhalation, broken skin or mucous membrane exposure to blood, urine, feces and other body secretions from infected mice. The infection results in flu-like symptoms one to three weeks after exposure. More severe symptoms of meningitis and encephalitis can result.

There is a special risk of exposure during pregnancy because the fetus can become infected. Because mice are well-screened and provided from virus-free sources, the potential for exposure in ASU animal facilities is minimal. Proper PPE, such as disposable gloves and lab coats, along with careful hand washing, will further reduce the likelihood of exposure. In addition, DACT conducts tests for LCMV in laboratory-bred mice and rats to ensure these animals remain virus-free.

Gerbils, hamsters and other small rodents

Commercial vendors outbreed small rodents such as gerbils, hamsters, chinchillas and guinea pigs as general models for biomedical research. They are often assured free of infectious pathogens, though an animal can become infectious after it arrives at ASU facilities. Proper care and hygiene, including PPE, should be utilized to protect researchers and animals.

Diseases of zoonotic concern for these rodents include campylobacteriosis, giardiasis, LCMV, sarcoptic mange, Mpox, pasteurellosis, rat bite fever, ringworm and salmonellosis.

Laboratory rabbits

Modern laboratory rabbits contain few infectious pathogens. Of concern are scratches that can be inflicted with their strong hind legs and sharp claws or from bites. Secondary infection with common skin, intestinal, and soil bacteria present on personnel or animals can result, so personnel should always cleanse wounds immediately with soap and water for 15 minutes or antiseptic and seek medical evaluation.

Historically, laboratory rabbits are known to harbor bacteria for human Tularemia or rabbit fever. Although this zoonotic agent remains present in wild rabbit populations, modern laboratory rabbits are free of this bacterium. Other infectious agents capable of causing infection in humans isolated from laboratory rabbits, particularly when group-housed or stressed, include Bordetella bronchiseptica and Pasteurella spp.

Birds

The birds used in research colonies are caught in the wild or acquired from established flocks. Generally, birds are not supplied with disease-free and usually contain several microbial agents, including *Mycobacterium avium*. Of zoonotic concern are highly pathogenic avian influenza and diarrheal bacteria

such as *Salmonella* and *Chlamydia psittaci*, the bacteria that cause psittacosis, which can cause a more severe type of infection.

HPAI, also known as avian or bird flu, is caused by influenza viruses that circulate in wild birds and is known to cause severe disease and high mortality in poultry. HPAI virus infections can cause disease that affects multiple internal organs, with mortality up to 90–100% in chickens, often within 48 hours. However, ducks and other wild birds can be infected without any signs of illness.

Do not handle sick or dead wildlife. If it is necessary to do so or you are within approximately six feet of sick or dead animals, including poultry, wild birds, backyard bird flocks, other animals, animal feces, litter or materials potentially contaminated with HPAI viruses, wear appropriate gloves, safety goggles or safety glasses with a face shield and respirator. The use of respirators requires annual medical evaluation and fit testing. Wash hands with soap and water and change clothing before having contact with domestic poultry or pet birds.

In humans, HPAI viruses have been reported sporadically, with cases ranging from mild illnesses to death, depending on the strain of HPAI. If you believe you may have been exposed to a bird or other animal with HPAI, monitor new respiratory illness symptoms and/or conjunctivitis — eye redness — for 10 days, and consult with ASU Employee Health or a medical professional.

Upon detection, positive identification of HPAI H5N1 must be reported to the ASU CDC responsible official and the ASU Biosafety Team.

Salmonella bacteria is a common contaminant of fecal droppings and eggs. When ingested by humans, this bacterium can potentially cause severe intestinal disease. Use of good personal hygiene measures, including effective and thorough hand washing and proper PPE, such as disposable gloves and lab coat, will greatly reduce the likelihood of infection when handling birds and materials in their environment.

The bacterium *Chlamydia psittaci* is the cause of psittacosis, and it is found most widely in large, imported psittacine birds such as parrots, parakeets, cockatoos, and macaws. Human infection is most often the result of exposure to these imported birds. The risk of exposure from domestic birds is very low; however, it is known that psittacine birds local to Maricopa County have tested positive for *Chlamydia psittaci*. Extra precautions should be taken, and birds should not be presumed negative until confirmed testing.

Because this bacterium is highly infectious, there is some potential that any bird or mammal may be infected. Acute animal infection causes symptoms such as conjunctivitis, difficulty breathing or pneumonia, painful swollen joints or arthritis, and reproductive problems. After the acute infection, those animals that survive enter a period without symptoms, during which stress can cause the animals to shed bacterium. Stress can result from the importation process or birds being handled in their new environment. Humans can be infected when encountering the bird’s body secretions or feces. In humans, the symptoms include fever, headache, muscle pain and chills, and may progress to pneumonia and liver, heart and brain inflammation.

Dogs and cats

Dogs and cats used in research are often acquired from commercial vendors and are considered purpose-bred for biomedical research. Facilities that provide these animals should be regulated by the U.S. Department of Agriculture and accredited by AAALAC International to ensure that the highest possible standards of care are met. However, possible zoonotic infections are still possible even with animals that are certified as clean by any vendor.

Diseases carried by dogs often are not easily ascertained through visual inspection. However, these diseases can cause serious illness in humans. Diseases of zoonotic concern include brucellosis, campylobacteriosis, *Capnocytophaga*, cryptosporidiosis, tapeworms, echinococcosis, giardiasis, hookworms, leptospirosis, MRSA, plague, rabies, ringworm, roundworm, salmonellosis, sarcoptic mange and tickborne diseases.

Cats can carry harmful germs that can cause a variety of illnesses in people, ranging from minor skin infections to serious illnesses. Diseases of zoonotic concern include campylobacteriosis, cat scratch disease, cat tapeworm, cryptosporidiosis, giardiasis, hookworm, MRSA, plague, rabies, ringworm, roundworms, salmonellosis, sporotrichosis, tickborne diseases and toxoplasmosis.

One of the best ways to prevent illness and protect yourself from getting sick is to thoroughly wash your hands after handling, caring for, feeding or cleaning up after dogs or cats.

Fish, corals and amphibians

Fish, corals, and amphibians used in research colonies are mostly wild-caught or raised on commercial farms. These animals often contain parasites and bacteria. Of zoonotic concern are gram-negative bacteria that cause secondary infection of contaminated wounds and breaks in the skin. These bacteria include *Aeromonas*, *Pseudomonas*, *Klebsiella* and *Mycobacteria*. The use of proper PPE, such as disposable gloves, will help prevent contamination of skin surfaces. Likewise, thorough hand washing is very important to further reduce the potential for infection.

Reptiles

Reptiles carry germs that can make handlers sick, most prominently *Salmonella*, located within the digestive tract of healthy reptiles. Infection from *Salmonella* can cause infections, called Salmonellosis, in people who have contact with reptiles and their environments, including the water from terrariums or aquariums where they live. Salmonellosis symptoms include diarrhea, vomiting, fever or abdominal cramps. Infants, elderly people and people with weakened immune systems are more likely than others to develop severe illnesses.

Other diseases of zoonotic concern include *Aeromonas* infection and *mycobacteriosis*. Maintaining good water quality in the home environment, removing any deceased fish that might share the home environment and practicing good hand-washing skills are essential to prevent zoonotic infection.

Additionally, rodents are often used as a source of feed for captive reptiles. These rodents can carry germs that can make people sick, as discussed above. Proper safety precautions should be taken when feeding rodents to reptiles.

Livestock

Livestock animals used in research include cattle, sheep, pigs, goats, llamas, and alpacas.

Diseases of zoonotic concern include anthrax, brucellosis, campylobacteriosis, Orf virus or sore mouth infection, cryptosporidiosis, E. coli, influenza, leptospirosis, listeriosis, MRSA, Q fever or *Coxiella burnetii*, rabies, ringworm, and salmonellosis, among others.

Influenza, such as swine flu, which caused the 2009 pandemic, H1N1 influenza, can spread between pigs and people. Most reported variant flu virus infections in people have occurred following exposure to infected pigs or their various contaminated environments. The main way flu viruses are thought to be spread is when an infected pig or person coughs or sneezes, and droplets containing the virus spread through the air. There is also evidence of transmission by touching something that has the virus on it and then touching your eyes, nose or mouth. Lastly, possible infection can occur when small particles that contain the flu virus are inhaled.

Most swine flu infections have resulted in mild illness in people, but severe illness or death can occur. Those at high risk of developing serious illness include individuals younger than five and older than 65, pregnant women, and people with certain underlying conditions. Personnel working with pigs should use appropriate PPE, such as gloves and a face mask or respirator, as indicated.

To help protect yourself from getting sick, thoroughly wash your hands right after handling farm animals, their supplies, or anything in the areas where they live and roam. The annual seasonal influenza vaccine is recommended for anyone who works with swine.

Non-human primates

Several potentially serious zoonoses are associated with non-human primates. In addition, the strength and unpredictability of NHPs pose dangers to those handling them. It is critical that work with NHPs be done while wearing the appropriate PPE and following well-established, safe protocols and procedures.

B Virus

B Virus is a herpes virus of old-world macaque monkeys. Common macaque monkeys used at ASU include cynomolgus or *Macaca fascicularis* and rhesus or *Macaca mulatta* monkeys. However, all macaques can transmit the virus. In non-human primates, this virus causes symptoms like the human cold sore virus, which includes mouth ulcers during acute infection and long periods of inactivity. Viral activity in monkeys commonly occurs with stress or other diseases and conditions; otherwise, they appear completely healthy while shedding large amounts of active virus in the saliva.

When humans are infected, the virus produces flu-like symptoms that progress to neurological symptoms and can lead to death within 3–14 days. Therefore, it is critical to be familiar with and follow all the established practices and procedures before beginning work with NHPs. The virus will survive on contaminated equipment and human cases have been documented after workers were scratched by soiled equipment or splashed with fluids from NHPs. Fortunately, the virus is susceptible to killing with bleach solutions and other disinfectants used in the animal facility.

All macaques housed at ASU come from sources that provide animals seronegative for the virus. In addition, Arizona law requires that macaques must have negative serology for B virus within 30 days of entry into the state. Because the B virus is fatal in humans if they become infected, all macaques are treated as being potentially infected with the virus should an exposure occur.

ASU Employee Health, EHS and DACT have developed a comprehensive program for NHP workers at ASU that includes the designation of PPE required for each functional area where non-human primates

and potentially contaminated equipment are handled and detailed procedures for medical response and follow-up for injuries associated with NHP care and use.

Tuberculosis

Tuberculosis is caused by bacteria that can be given to and acquired from NHPs. Tuberculosis is transmitted via droplets in the air from infected NHPs and humans. Humans can contract the disease by unprotected exposure to infectious droplets generated by the handling of dirty bedding, the use of high-pressure water sprayers, the coughing of animals with respiratory disease, or contaminated feces of animals with intestinal disease. Likewise, ASU's resident non-human primate colony is susceptible to human tuberculosis, which can be transmitted from infected workers.

The prevention and control measures in place involve bi-annual TB testing of each NHP and the use of PPE that includes respiratory protection. All humans who work with NHPs are tested by ASU Employee Health annually for TB. Required PPE for working with NHPs is listed on postings located in each of the areas of non-human primate activity. It is very important that employees understand and follow these posted requirements.

Measles

Healthy NHPs are susceptible to measles from exposure to humans who are shedding the measles virus. The infection in NHPs is severe and produces rash, fever, malaise, and progressive respiratory distress. There is a vaccine available for use in NHPs. However, all NHP populations should be considered susceptible until proven otherwise. At ASU, all personnel who have contact with NHPs must have adequate vaccinations such as measles, mumps and rubella. There are currently no reliable diagnostic tests to indicate measles infection in NHPs.

Emergency response procedures

ASU has a campus-wide emergency response plan, the ASU Emergency Operations Plan, which complies with 29 CFR 1910.120. Protocols for handling biological emergencies are outlined in the plan. This plan can be summarized by reviewing the ASU Emergency Procedures Flipchart or the ASU Police Department Policies and Procedures Manual.

Principal investigators must be aware of the provisions for emergency procedures and preparedness. Emergency procedures and preparedness must be incorporated into the laboratory-specific biosafety manual and used in the laboratory. Each laboratory should have a written emergency plan specifying the appropriate response to potential emergencies. Accidents and spills of infectious materials will be discussed in Emergency Procedures below. In addition, each principal investigator will submit to EHS the following:

- A completed registration form
- Updated chemical inventory maintained within the Chemical Environmental Management System
- An inventory of biological materials

Exposures to biohazards

In the event of exposure to a biohazard, the following guidelines should be used:

Intact skin

- Remove contaminated clothing. Clothing should not be pulled over the face as contact with the eyes, nose and mouth may occur.

- Vigorously wash contaminated skin for one minute with soap and water. If an emergency shower is necessary, the washing should take 15 minutes.
- Call 911 or seek medical attention at ASU Employee Health.
- Inform the laboratory's principal investigator and/or EHS immediately.

Broken, cut or damaged skin or puncture wound

- Remove contaminated clothing. Clothing should not be pulled over the face as contact with eyes, nose, and mouth may occur.
- Vigorously wash contaminated skin for 10 minutes with soap and water.
- Call 911 or seek medical attention at ASU Employee Health.
- Inform the laboratory's PI and EHS immediately.

Eyes

- Immediately flush your eyes with water for at least 15 minutes, using an eyewash. Hold eyelids away from your eyeball and rotate your eyes so that all surfaces may be washed thoroughly.
- Remove contaminated clothing. Clothing should not be pulled over the face as contact with the eyes, nose and mouth may occur.
- Call 911 or seek medical attention at ASU Employee Health.
- Inform the laboratory's principal investigator and EHS immediately.

Ingestion or inhalation

- Move to fresh air immediately.
- Call 911 or seek medical attention at ASU Employee Health.
- Do not induce vomiting unless advised by a health care provider.
- Inform the laboratory's principal investigator and EHS immediately.

Spills of biohazards, including r/SNA molecules

ASU does not have a centralized biological spill response team. Therefore, each laboratory working with potentially hazardous biological material must be prepared and trained to handle its biological spills. EHS is available for assistance if necessary. Refer to the EHS biological spill webpage for more information about spills involving recombinant or synthetic nucleic acid molecules, blood, microorganisms or other bioresearch materials.

All work on plastic-backed absorbent liners to absorb spills can minimize the consequences of a biohazard spill. The quantities of these materials should be limited so they can be easily contained, cleaned, or destroyed. The ASU Respiratory Protection Program must be followed if respiratory protection is required. All spills must be decontaminated using a disinfectant effective against the material used. Disinfectants should be freshly prepared at the time of clean-up.

A simple spill kit with the following supplies should be available and used by trained personnel:

- Biohazard bag
- Biohazard spill sign
- Disposable lab coat
- Eye protection
- Four pairs of nitrile gloves
- Mini brush and dustpan, or something to scoop spilled materials
- Spray bottle to make a fresh bleach solution
- Tong or forceps to pick up broken glass

Biohazard spill inside a BSC

Follow these guidelines and procedures when a spill occurs inside a BSC:

- Remain calm and secure research samples.
- Alert the other laboratory employees of the spill.
- Leave the cabinet turned on.
- Pick up any pieces of broken glass with forceps or tongs and place them in a sharps container. Never use hands.
- Cover the spill with paper towels.
- Pour an appropriate disinfectant, for example, 1:10 bleach solution, over the paper towels, moving from the outer edges to the middle of the spill.
- Leave the disinfectant for an appropriate contact time for the spilled material.
- Pick up paper towels and discard them into a biohazard container.
- Wipe the spill area with disinfectants again.
- Determine if the spill reached the front or rear grills. If necessary, flood the work surface, drain pans, and catch basins below the work surface with appropriate disinfectants.
- Leave disinfectant for an appropriate contact time for the spilled material.
- Drain the catch basin into a container.
- Lift the front exhaust grill and tray and wipe all surfaces. Ensure that no paper towels or solid debris are blown into the area beneath the grill.
- Depending upon the disinfectant, remove the corrosive residue following standard procedures.
- Dispose of clean-up materials in the biohazard waste container.
- Remove PPE and wash hands after the cleanup procedure.
- Report the spill to the laboratory's PI or lab manager.
- The PI or lab manager will report the spill to EHS.
- Resume work if deemed safe by a supervisor or manager.

Small biohazard spill outside a BSC less than 500 mL

- Remain calm and make note of whether your person has been contaminated.
- Alert other laboratory employees in the area and block off the area.
- Wearing gloves, safety glasses, and a lab coat, secure the spilled container to prevent additional leakage of biohazardous material.
- Pick up any pieces of broken glass with forceps or tongs and place them in a sharps container. Never use hands.
- Cover the spill with paper towels and gently apply appropriate disinfectants, proceeding from the outer edge of the spill to its center. Leave disinfectant for an appropriate contact time for the spilled material.
- Pick up the paper towels and discard them into a biohazard container.
- Wipe the spill area with disinfectant again.
- Remove PPE and wash hands after the cleanup procedure.
- Report the spill to the laboratory's principal investigator or lab manager.
- The principal investigator or lab manager will report the spill to EHS.
- Resume work if deemed safe by a supervisor or manager.

Large biohazard spill outside a BSC greater than 500 mL

Remain calm and notify others in the room to stay out of the spill area to prevent the spread of contamination and leave the room.
Secure the spilled container to prevent additional leakage of biohazardous material.

- Check for contaminated PPE or clothing. Remove contaminated PPE and place it in the biohazard waste. Remove any contaminated clothing, ensuring that clothing is not pulled over the face and leave it in the room for later autoclaving.
- Exit the room.
- Post a sign stating: Do not enter, biohazard spill, contact (name and phone number) for information.
- Block off the area as soon as possible.
- Wash your hands, eyes and exposed skin if needed.
- Notify the PI or supervisor.
- The PI or supervisor will contact EHS immediately.
- Wait 30 minutes before entering the contaminated area to allow for dissipation of aerosols.
- Put on protective clothing such as a lab coat, gloves and, if indicated, respirator, eye protection and shoe covers, and assemble clean-up materials.
- Pick up any broken glass with forceps and place them into a sharps container. Never use hands.
- Cover the spill with paper towels and gently apply disinfectants, proceeding from the outer edge of the spill to its center. Leave disinfectant for an appropriate contact time for the spilled materials.
- If clothing is contaminated, place it in a biohazard bag. Contaminated clothing must be decontaminated before leaving the facility.
- Wipe all the surfaces that may have encountered the spilled material with disinfectants.
- Collect all treated materials and discard them in a biohazard container.
- Wipe the spill area with disinfectant again.
- Remove PPE and wash hands after the cleanup procedure.
- Resume work if deemed safe by a supervisor or manager.

Biohazard spill in a centrifuge

A single centrifuge spill or release can lead to multiple infections in a laboratory. Aerosols are created when fluid escapes from the rotor or cup while the centrifuge operates at high speed. Therefore, the process of opening a centrifuge must be performed slowly.

Unsealed buckets

- If a centrifuge tube breaks while the centrifuge is running, turn off the motor.
- Allow the machine to be at rest for 30 minutes before opening.
- Unplug the centrifuge before initiating clean-up.
- Put on two pairs of nitrile gloves, lab coat and eye protection before proceeding with the cleanup.
- Remove broken tubes and glass fragments using tongs or forceps. Place fragments in a sharps container for autoclaving and disposal as infectious waste.
- Place paper towels over the entire spill area and pour disinfectant over the paper towels. Allow for an appropriate contact time for the disinfectant and materials spilled.
- Remove buckets, trunnions, and rotors and place the pieces in disinfectant for the appropriate contact time or autoclave.
- Unbroken, capped tubes may be wiped down with disinfectants and recovered after the appropriate contact time for the materials spilled, or they may be disposed of as biohazardous waste.
- Remove remaining disinfectant-soaked materials from the centrifuge bowl and discard them as biohazardous waste.
- Wipe down again with disinfectant, wash with water and dry. **Note**: Household bleach is corrosive. Use caution when immersing or having metal components in contact with bleach or sodium hypochlorite for extended periods.
- Remove protective clothing used during cleanup and place it in a biohazard bag for autoclaving. Wash hands after the cleanup procedure.
- Notify the PI, supervisor and EHS.

Sealed buckets: Safety cups

- If breakage of tubes is suspected, remove the sealed bucket or safety cups to a BSC before opening.
- Discard broken tubes in biohazard waste and perform cleanup of the sealed bucket or safety cups inside the BSC.
- Notify the PI, supervisor and EHS if there is a potential for any material to escape the centrifuge.

Reporting exposures

In the event of exposure to biohazardous materials, complete these steps:

- Report to ASU Employee Health or a primary healthcare provider.
- Complete an incident report form and submit it to EHS within 48 hours of the incident.
- Work with the PI, supervisor, biological safety officer and Institutional Biosafety Committee to report the incident to the NIH Office of Science Policy as required by the NIH Guidelines.

Permits

The import, export, transfer or interstate movement of biological materials, animals, plants, arthropods, environmental samples or other materials is strictly regulated by various U.S. federal and international agencies and may require permits or licenses. Some materials may require multiple permits.

Failure to comply with regulations and secure the required permits or licenses when importing, exporting or transporting regulated materials may result in shipment delays or destruction at U.S. ports of entry, refusal of the shipment by carriers, and be subject to fines and/or criminal penalties. The individual or PI is responsible for obtaining and maintaining all permits and ensuring compliance with all permit conditions.

EHS provides compliance support for permits. Submit permits and all subsequent updates to ASU EHS upon receipt of the permit.

CDC Import Permit Program

The CDC Import Permit Program regulates the importation of infectious biological materials that could cause human disease to prevent their introduction and spread into the U.S. The program ensures that these agents' importation is monitored and facilities receiving permits have appropriate biosafety measures to work with the imported agents.

Materials requiring import permits include, but are not limited to:

- Infectious biological agents capable of causing illness in humans
- Materials known or reasonably expected to contain an infectious biological agent
- Vectors of human disease, such as insects or bats

USDA Animal and Plant Health Inspection Service permits

USDA Animal and Plant Health Inspection Service permits are required to import, transit and release regulated animals, animal products, veterinary biologics, plants, plant products, pests, organisms, soil and genetically engineered organisms. Refer to the ASU Office of Research Compliance webpage for more information on importing live animals for research.

Animal and animal products

Includes live animals, semen, embryos and materials derived from animals or exposed to animal-source materials such as animal tissues, blood, cells or cell lines of livestock or poultry origin, RNA and DNA extracts, hormones, enzymes, microorganisms including bacteria, viruses, protozoa and fungi. In addition, animal materials, including dairy products, except butter and cheese, and meat products like meat pies and prepared foods from countries with livestock diseases exotic to the U.S.

- Animal Health Permits application and status
- International Regulations for Animal Product Exports
- Organism and Vectors Guidance and Reporting

Biotechnology Regulatory Services permits

Permits include genetically engineered organisms considered regulated articles. Refer to the USDA BRS permit user guide for more information.

- Biotechnology Permits and Notifications
- Apply for a BRS notification or permit
    - Submit a permit application to APHIS at least 60 days before the first proposed import or interstate movement and at least 120 days before the proposed release into the environment.
    - There is no fee to obtain a BRS permit.

Plants, organisms and soil

- Plant and Plant Product Imports
- Obtain a free Plant and Plant Product Export certificate

Veterinary biologics

Veterinary biologics include vaccines, bacterins, antisera, diagnostic kits and other products of biological origin. Apply for a Veterinary Biologics Permit.

Invasive species in Arizona

Some targeted hungry pests have federal quarantines in some regions of Arizona. Other federal and state quarantines may apply. Arizona has some crops, forests, or urban areas where invasive pests or diseases could survive annually. Species invasive in Arizona may have additional permitting requirements.

U.S. Fish & Wildlife Service permits

The U.S. Fish & Wildlife Service issues permits under various wildlife laws and treaties at different offices at the national, regional and/or wildlife port levels. Generally, all wildlife, including parts and products, imported or exported from the U.S. for any purpose, must be declared and cleared through an authorized wildlife port.

Search for U.S. FWS permits for more information.

Agreements with ASU

In addition to permits, agreements or licenses may be required. Contact the Knowledge Enterprise Research Administration office for more information.

Transfers, packaging and shipping of biological materials

Transfers

Transferring, packing, and shipping select agents and toxins is **highly** regulated. No select agent or toxin shall be transferred, packed or shipped without the express approval from the RO. Please contact the ASU Biological Safety Officer for more information.

For materials that are not select agents, each PI must develop procedures for transferring or shipping from the laboratory. The PI must ensure the following:

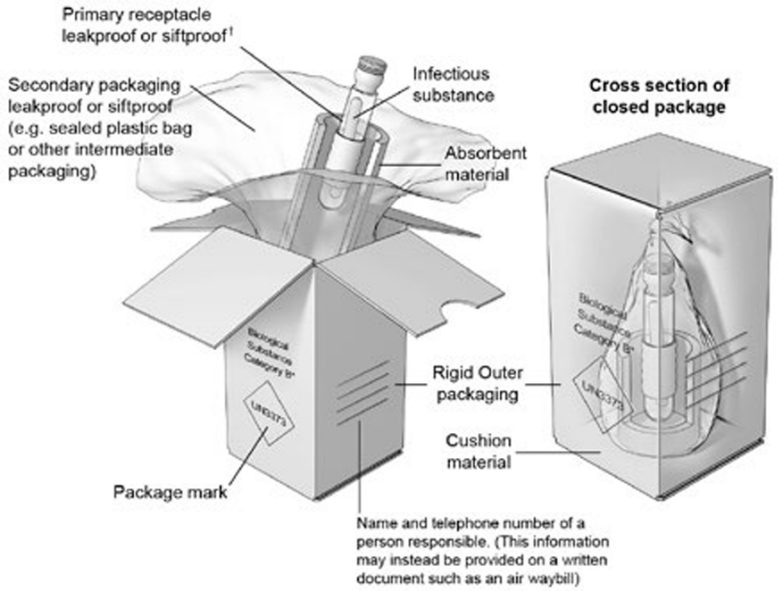
- Personnel who package, handle and ship non-select agents and biohazardous materials, including import and export, are subject to all applicable training. Please refer to ASU policy EHS 406 for more information. The RO must be notified of all select agent transfers, internal or external.
- Standard operating procedures should be in place for all import and export activities.
- Package, label and transport biohazards following all applicable local, federal and international transportation and shipping regulations, including U.S. DOT regulations. Materials that are transported by airline carriers should also comply with packaging and shipping regulations set by the International Air Transport Association. All personnel shipping packages must have current DOT or IATA certifications. Contact EHS at 480-965-1823 for assistance with shipping biological materials.
- Required permits, such as those granted by the U.S. Public Health Service, USDA, FWS, DOT, U.S. Department of Commerce, and IATA, are obtained before biohazards are prepared for transport.
- Avoid hand-carrying biohazards when transferring them to other external facilities. If biohazards are to be hand-carried on common carriers, all applicable packaging, transport and training regulations should be followed.
- Develop and follow a protocol for intra-facility transfer between laboratories on ASU campuses of all biological and biohazards. Contact EHS at 480-965-1823 for assistance.
- Packaging and shipping of biological materials must be completed to ensure the contents will not leak and that the package will arrive in good condition.

Packaging

All biological materials, including diagnostic specimens and biological products that may contain an etiologic or biohazardous agent, must be packaged to withstand leakage of contents, shocks, pressure changes and other conditions possible with ordinary handling and transportation, such as passage through cancelation machines, sorters and conveyors. Contents should not leak to the outside of the shipping container, even if leakage of the primary container occurs.

Specific packaging requirements apply to materials known to contain or reasonably believed to contain certain etiologic agents. For such materials, the procedures outlined in Figure Four apply.

Figure Four: Biohazard packaging diagram from the Biosafety in Microbiological and Biomedical Laboratories 6th Edition.



Packaging volumes

Volumes not exceeding 50 mL

- Place material in a securely enclosed, watertight primary container such as a test tube or vial.
- Enclose this primary container in a secondary, durable, watertight container. Several primary containers may be enclosed in a single secondary container if the total volume of material in all the primary containers enclosed does not exceed 50 mL.
- Place absorbent, non-particulate materials, like paper towels, not sawdust or vermiculite, in the spaces at the top, bottom and sides between the primary and secondary containers. Use enough absorbent material to absorb all the contents of the primary container(s) in case of breakage or leakage.
- Enclose each set of primary and secondary containers in an outer shipping container constructed of corrugated fiberboard, cardboard, wood or other material of equal strength. Do not use bags, envelopes, or similar materials.
- If you package the material with dry ice, refer to the packaging with dry ice section.

Volumes greater than 50 mL

- Follow the requirements for lesser volumes outlined above.
- Place shock-absorbent material at the top, bottom and sides between the secondary and outer shipping containers. This material should equal the amount of absorbent material placed between the primary and secondary containers.
- Ensure single primary containers contain no more than 1000 mL of material; however, two or more primary containers, combined volumes not exceeding 1000 mL, may be placed in a single secondary container. The maximum etiologic agent enclosed within a single outer shipping container must not exceed 4000 mL.

Packaging with dry ice

- If dry ice is used, place it between the secondary and outside containers.
- Place shock absorbent material to prevent the secondary container from becoming loose inside the outer container as the dry ice sublimates.
- Use the DOT dry ice label. Contact EHS at **480-965-1823** for information on shipping guidelines.

Labeling

The outer shipping container of all materials containing etiologic or biohazards being shipped or transported must bear a special label. Please contact EHS for more information about shipping labels.

Shipping and transportation methods and requirements

Contact the ASU responsible official for all shipments containing select agents.

Interfacility transport

All materials being transported within ASU should be packaged to prevent leakage and spills by placing the materials in a sealable bag or container placed within a hard-sided container for transport. The containers should be disinfected before leaving the laboratory. Please be aware that strict federal and state regulations address the transport of hazardous such as biological, chemical and radiological materials on public roads.

Commercial carrier shipments

- All commercial carrier shipments, internationally or domestically, follow the International Air Transport Association dangerous goods regulations. Receipt of shipment notice is not required since the shipment is traceable through the specific carrier.
- Apply appropriate labels to the outer shipping container for packages containing dry ice and/or biohazard, as shown in **Figures Five and Six**.
- Contact the carrier's dangerous goods agent before shipment for additional packaging and labeling requirements.

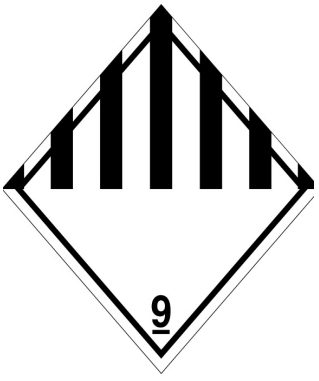


Figure Five: Package containing dry ice.

Figure Six: Package containing a biohazard.

Permits

Import or export permits may be required to ship or receive biological materials. It is up to the PI to ensure all required permits are acquired. Most plant or animal-derived ingredients require a permit. It is better to apply for a permit and receive a letter of no jurisdiction than to have a shipment delayed or rejected for lack of a proper permit.

Food and beverages in the laboratory

To reduce potential exposures and to ensure compliance with prudent laboratory operations, regulations and other best management practices, ASU prohibits the storage and consumption of food and drink in all designated laboratory spaces. The only exception is food and beverages used in research and teaching projects. These materials must be labeled “Not for Human Consumption.”

To prevent potential exposure to hazardous materials:

- Do not eat, drink, smoke, chew gum, apply cosmetics or take medicine in laboratories where hazardous materials are handled or stored.
- Do not store food, beverages, cups or other drinking and eating utensils in areas where hazardous materials are handled or stored.
- Do not use glassware to prepare or consume food or beverages for laboratory operations.
- Do not use laboratory refrigerators, ice chests, cold rooms and ovens for food storage or preparation.
- Do not use laboratory water sources for drinking water.

Note: Food and beverages must never be stored in any laboratory refrigerator where chemicals, biological and radioactive materials are kept unless labeled “Not for Human Consumption.”

Nails and jewelry

Principal Investigators at ASU ensure that laboratory personnel maintain appropriate hand and nail hygiene. Hands should be kept clean and washed frequently, such as after completing work, removing gloves, and leaving the laboratory. Jewelry should be kept to a minimum to prevent puncturing or otherwise compromising protective gloves or limiting dexterity.

The Centers for Disease Control and Prevention, National Institutes of Health and World Health Organization say that nail length should be no longer than 0.25 inch beyond the end of the fingertips. Artificial nails, like nail extensions, nail wraps and nail jewelry, are not recommended when working in the laboratory.

Protective clothing beyond the laboratory

The improper use or lack of protective clothing and equipment in a laboratory can lead to chemical burns, biological exposures or other potential dangers. To help reduce the risk of exposure, personnel in ASU laboratories must wear gloves, safety glasses, lab coats and other PPE. However, wearing PPE and equipment is not recommended in public areas, such as hallways and lounges. This is because contaminated clothing may present a hazard, and the perception of contaminated PPE and equipment in a public area may project a careless image to colleagues and visitors.

Protective gloves should never encounter door handles, elevator buttons, telephones, lavatory faucets, vending machines, bottled water dispensers, ice-making machines or other surfaces outside the laboratory.

Materials should be transported from place to place on a cart, in a clean secondary container or a bottle carrier with secure handles. The materials should be packaged so the outer container can be transported without needing personal protective equipment. When this is not an option, personnel should use a clean, ungloved hand to touch common surfaces and a gloved hand to carry the items, known as the one-glove rule.

Potentially contaminated lab coats and other research clothing should never be worn outside the laboratory.

Laundering laboratory clothing

Laboratory coats, gowns and contaminated clothing or clothing suspected to be contaminated with chemicals or biohazards are never to be taken home or to a public laundry facility. All clothing, laboratory coats, and gowns that are grossly contaminated or used in a spill clean-up must be decontaminated before submitting to any laundry service.

ASU Laboratory Coat Laundry Program

ASU EHS provides a free laboratory coat laundering service to ASU students, faculty and staff in coordination with ASU Mail Services and Mission Linen. Submit your lab coat through your department's designated laundry bin or U.S. mail.

ASU laundry facilities

Laundry facilities exist in a few departments at ASU. Follow departmental procedures for cleaning mild to moderately contaminated clothing. Generally, these facilities are for intra-department use only. Laboratory managers may launder mildly contaminated clothing using departmental laundry facilities where available.

Contaminated clothing shall be washed, at a minimum, following manufacturer recommendations. However, departments are encouraged to launder contaminated clothing in hot water at 160º F or greater. Where departmental facilities are not available, contaminated clothing must be laundered by a professional laundry service.

Professional laundering services

A professional service company may be used if the department cannot wash mild to moderately contaminated clothing. Each laboratory is responsible for determining if the cleaning company is capable and willing to launder the contaminated clothes. Where departmental facilities are not available, contaminated clothing must be laundered by a professional laundry service.

Laboratory managers shall ensure that all laundry sent off-site is containerized in leak-proof bags or boxes marked with the biohazard symbol. They must also advise the vendor that the laundry is contaminated with blood and/or potentially infectious bodily fluids for mildly contaminated textiles.

Laundering of personal clothing

Clothing contaminated with biohazardous material must be autoclaved before laundering at home. Documentation of effective autoclaving must be maintained.

Overtly contaminated clothing

Clothing that is overtly contaminated with chemicals must be disposed of as hazardous waste. Clothing contaminated with radiological material must be disposed of as radiological waste. Clothing contaminated with blood, blood products or other bodily fluids must be removed and placed in leak-proof bags or boxes where it was used. Containers or bags must be marked with the biohazard symbol.

Biosafety inspections

The ASU Biosafety and Biosecurity team conducts regular inspections of laboratories to ensure compliance with the procedures and protocols of this manual. Any significant concerns will be reported to the IBC or other committees required under regulatory reporting requirements.

The biosafety inspection typically includes an evaluation of the autoclave, BSC, microbiological techniques, emergency and safety equipment, storage and handling of biological materials, biohazardous waste management, general housekeeping and review of the laboratory-specific biosafety manual. Refer to the ASU Biosafety and Biosecurity inspection checklists for more information about the biosafety inspection form used by EHS.

EHS will try to schedule biosafety inspections with the PI or their designee. However, if the principal investigator or their designee is unavailable or unresponsive, EHS will proceed with the biosafety inspection. EHS may also conduct unannounced accident investigations. Please be aware that federal, state and local inspectors may also conduct unannounced inspections.

Following the biosafety inspection, a report listing the safety concerns is sent to the PI responsible for the laboratory. The PI is responsible for addressing and documenting corrective actions in the inspection report. Follow-up inspections may be conducted in laboratories with extremely hazardous conditions and/or numerous concerns.

Security

Laboratory security is an integral part of an effective safety program. Follow these steps to ensure a secure working environment:

- Laboratory doors must always be closed and secured when unoccupied.
- Stocks of organisms and hazardous chemicals are stored properly and securely.
- Maintain an accurate record of chemicals, stocks, cultures, project materials, growth media, and other items that support project activities.
- Notify ASU Police if materials are damaged or missing from laboratories.
- Inspect all packages arriving at the laboratory.
- Decontaminate materials and work surfaces after completing work and at least daily.
- Turn off equipment, flames, steam supply and electrical appliances after completing work.
- Ask strangers, someone you do not recognize as a coworker or support staff, to exit the laboratory if they are not authorized to be there. Notify your supervisor and ASU PD of the incident.
- Discuss other security-specific requirements with your supervisor and colleagues.

Working alone

All members of the ASU community working alone who perform or participate in research or activities involving potentially hazardous materials, hazardous equipment, or hazardous processes must meet the requirements of ASU policy EHS 123.

All personnel working alone where potentially hazardous materials, hazardous equipment, or hazardous processes exist shall:

- Ensure that a means to contact emergency response personnel is available when working alone in the laboratory.
- Obtain written permission in an email or letter from the PI or laboratory supervisor to work alone in the laboratory.
- Individuals working alone must contact their supervisor before beginning work and upon completion or other responsible individuals following the working alone plan.

Note: The National Safety Council defines “alone” as someone beyond any other individual’s visual or auditory range for more than a few minutes.

Recordkeeping

The PI must maintain the following records and be prepared to present these at the annual laboratory inspection:

- A current registration for the laboratory spaces in use.
- An accurate, current list of each biological agent or toxin stored in that room, stored in freezers, refrigerators, dehydrated storage or otherwise.
- Training documentation forms
- The current laboratory-specific manual containing safety, security and emergency response plans.
- Copies of field safety plans submitted to the parent department, as applicable.

Appendix A: Definitions

Animals: Any member of the animal kingdom except a human, including an animal product like a mount, rug or other display item composed of the hide, hair, skull, teeth, bones or claws or unfixed tissues.

Arthropods: Any invertebrate animal from the phylum Arthropoda, including, but not limited to, ants, mosquitoes, fruit flies, crustaceans, spiders, scorpions, etc.

Biohazard: Any microorganism including, but not limited to, bacteria, viruses, fungi, rickettsia, protozoa, or prions, infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance or any recombinant and synthetic nucleic acids.

Biological product: A biological prepared and manufactured following regulations that govern the manufacture of vaccines, reagents, etc.

Diagnostic specimen: Any human or animal material, including, but not limited to, excreta, secreta, blood and its components, tissue, tissue fluids, etc., is being shipped for diagnosis.

Etiologic agent: A viable microorganism or its toxin that causes, or may cause human disease

Infectious substance: Any material known or reasonably expected to contain a biohazard.

Interstate shipping: Transporting across state lines within the continental U.S.

Intrastate shipping: Transporting within the state of Arizona.

Recombinant or synthetic nucleic acid (r/sNA) molecules:

- Molecules that are constructed outside living cells by joining natural or synthetic nucleic acid segments to nucleic acid molecules that can replicate in a living cell.
- Nucleic acid molecules that are chemically or by other means synthesized or amplified.
- Synthetic nucleic acid segments are likely to yield a potentially harmful polynucleotide or polypeptide.
- Molecules that result from the replication of those described above.

Responsible official: The individual designated by an institution to act on its behalf for the federal select agent program. This individual must have the authority and control to ensure compliance with the federal select agent program regulations.

Toxin: The toxic material or product of plants, animals, or microorganisms, including, but not limited to, bacteria, viruses, fungi, rickettsia, protozoa, infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

- Any poisonous substance or biological product that may be engineered because of biotechnology produced by a living organism.
- Any poisonous isomer or biological product, homolog or derivative of such a substance.

Vector: Any animal, vertebrate or invertebrate, including arthropods or any noninfectious self-replicating system like plasmids or other molecular vectors or animal products that are known to transfer or can transfer an infectious biological agent.

Appendix B: Acronyms

Acronym	Phrase acronym stands for
AC	Animal care
APHIS	Animal and Plant Health Inspection Service
ASU	Arizona State University
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSC	Biological safety cabinet
BSO	Biological safety officer
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
DACT	Department of Animal Care and Technologies
DEA	Drug Enforcement Administration
EHS	Environmental Health and Safety
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
NHP	Non-human primate
NIH	National Institutes of Health
ORIA	Office of Research Integrity and Assurance
OSHA	Occupational Safety and Health Administration
PI	Principal investigator
PPE	Personal protective equipment
SDS	Safety data sheet
USDA	United States Department of Agriculture

Appendix C: Disinfection tables

Disinfectant activity											
Disinfectants		**Practical requirements**					**Inactivates**				
Type	Category	Use dilution	Contact time (min) lipovirus	Contact time (min) broad spectrum	Temperature (C°)	Relative humidity (%)	Vegetative bacteria	Lipoviruses	Nonlipid viruses	Mycobacteria	Bacterial spores
Liquid	Quaternary ammonia compounds	0.1%-2.0%	10	NE			+	+			
	Phenolic compounds	1.0%-5.0%	10	NE			+	+	B		
	Chlorine compounds	5000 ppm*	10	20			+	+	+	+	+
	Iodophor	25-1600 ppm*	10	30			+	+	+		
	Alcohol, Ethyl	70%-85%	10	30			+	+	B		
	Alcohol, Isopropyl	70%-85%	10	30			+	+	B		
	Formaldehyde	0.2%-8.0%	10	30			+	+	+	+	+
	Glutaraldehyde	2%	10	30			+	+	+	+	+
Gas	Ethylene Oxide	8-23g/ft^3	60	60	37	30	+	+	+	+	+
	Paraformaldehyde	0.3 g/ft^3	60	60	>23	60	+	+	+	+	+

NE=not effective B=Variable results dependent on virus
*=Available halogen (1:100)

Disinfectant characteristics												
Disinfectants		**Important characteristics**										
Type	Category	Effective shelf life >1 week (A)	Corrosive	Flammable	Explosion potential	Residue	Inactivated by organic matter	Compatible for optics (D)	Skin irritant	Eye irritant	Respiratory irritant	Toxic (E)
Liquid	Quaternary ammonia compounds	+					+	+	+	+		+
	Phenolic compounds	+	+			+			+	+		+
	Chlorine compounds		+			+	+		+	+	+	+
	Iodophor	+	+			+	+		+	+		+
	Alcohol, Ethyl	+		+						+		+
	Alcohol, Isopropyl	+		+						+		+
	Formaldehyde	+				+			+	+	+	+
	Glutaraldehyde	+				+		+	+	+	+	+
Gas	Ethylene Oxide	N/A		+(B)	+(B)			+	+	+	+	+
	Paraformaldehyde	N/A		+(C)	+(C)			+	+	+	+	+

N/A=not applicable (A) =Protected from light and air (B) =Neither flammable nor explosive in 90% CO_2 or fluorinated hydrocarbon, the usual form (C) =At concentrations of 7%-73% by volume in air, solid exposure to open flame (D)=Usually compatible but consider interferences from residues and effects on associated materials such as mounting (E)=By skin or mouth, or both. Refer to manufacturer's literature and the SDS

Appendix D: Serum storage procedures

All personnel participating in the Serum Storage Program will be asked to sign the Employee Serum Banking Program Consent/Declination Form available at the ASU Employee Health office.

Personnel must also provide a serum baseline donation as a recommended condition of participation in research if the work involves any of the following:

- Human Immunodeficiency Virus
- Mycobacterium tuberculosis
- Select agents or toxins
- Microorganisms classified as BSL-3 or ABSL-3
- As recommended by the ASU biosafety officer, and/or ASU Employee Health and/or the IBC

PIs or supervisors may also request that serum banking be offered when researching pathogenic, drug-resistant microorganisms or microorganisms classified as BSL-2 and ABSL-2.

Individuals who decline to have a baseline serum sample drawn must sign the Employee Serum Banking Program Consent/Declination Form.

Collection

A serum sample may be collected following exposure, such as percutaneous or mucous membrane exposure to bodily fluid or animal bites to an infectious agent or other biohazardous material, or after work with the particular agent.

Additional serum samples and the baseline sample may be collected if requested by the individual or the supervisor based on a risk assessment or documented occupational exposure.

These samples will not be processed through a clinical laboratory for diagnostic reporting unless there is occupational exposure. A new consent form must be obtained if additional serum is drawn.

Laboratory process

One 7–8.5 mL vial of blood will be obtained via venipuncture at the ASU Employee Health office. Once drawn, the specimen should be left to sit for 30 minutes. Subsequently, the clotted specimen should be centrifuged so that the serum is separated from the cellular elements.

1. 1 mL of serum is pipetted into one cryo vial tube with an O ring on top. This tube should be labeled with a unique identification number rather than the worker's personal information. This identifier will be linked with a log kept by ASU Employee Health that states the worker's name and ASU ID number.

2. The labeled specimen will be placed into an appropriate freezer. ASU Employee Health personnel will place one sample in a -80°C freezer at a designated location.

3. The Serum Sample Log will be completed when entering and removing samples from the -80°C freezer.

4. The serum will be retained by ASU for purposes of this program for 30 years or 10 years after the worker leaves the university.

a. ASU Employee Health will be responsible for compliance with all regulations related to the collection, storage and release of medical information. Any information gained from testing a baseline serum sample will not be used for discrimination purposes or for any reason not addressed in the consent.
b. Specimens will be stored following recommendations of the American College of Clinical Pathologists by ASU Employee Health. The specimens will be stored at -80°C or lower in secure and confidential freezers maintained by DACT. The freezer is stored in a location with a backup emergency generator. Storage of employee serum samples in laboratory freezers is not appropriate.

Storage and retrieval procedures

DACT will do the following:

1. Provide the space for a freezer, including having the freezer on backup power.
2. Permit access to the ASU Employee Health staff for placement of one sample in each freezer
3. Respond to any freezer failures by consolidating the samples into the remaining functional freezer until the failed freezer is functioning normally again.

ASU Employee Health will do the following:

1. Ensure proper serum sample collection procedures are followed.
2. Transfer the sample to the secure -80ºC freezer.
3. Complete the Serum Banking Log.

ASU Employee Health will be permitted to release stored specimens in the following instances and only if appropriate consent has been obtained:

1. In the event of exposure to an infectious or other biohazardous agent. **Note**: As stated above, the worker will be asked to sign a consent form allowing an aliquot of their serum to be released for testing.
2. Public health emergencies. **Note**: The county or state health department may request information from ASU under such circumstances. For public health emergencies, obtaining consent is not legally required.
3. If the worker requests that an aliquot of their serum be released to assist in providing medical care. **Note**: The worker must make a written request in such situations.

Specimens obtained for this program's purposes will become ASU's property. Once the individual has provided the specimen, they will have no access to it unless there is a written request from a medical provider and the worker's signed consent.

Verification

Biosafety and Biosecurity team members will meet with representatives from ASU Employee Health and a representative from DACT to physically verify the serum sample inventory once a year.

Biosafety and Biosecurity team members will provide a report on the status of annual verification to the Assistant Vice President of Environmental Health and Safety, Director of Biosafety and Biosecurity, Associate Director of ASU Employee Health and Director of DACT.

Serum Banking Log

Date	First and last name of the person adding and removing the sample	Time the freezer was opened	Sample ID number	Time freezer closed	Notes