

Biosafety Manual





Environmental Health and Safety

Revised 2012

First edition, January 2000
Iowa State University | Ames, Iowa

IOWA STATE UNIVERSITY

Environmental Health and Safety Statement

Iowa State University strives to be a model for environmental, health and safety excellence in teaching, research, extension, and the management of its facilities. In pursuit of this goal, appropriate policies and procedures must be developed and followed to ensure this community operates in an environment free from recognized hazards. Faculty, staff and students are responsible for compliance with established policies and are encouraged to enculturate practices that ensure safety, protect health and minimize the institution's impact on the environment.

As an institution of higher learning, Iowa State University

- fosters an understanding of and a responsibility for the environment;
- encourages individuals to be knowledgeable about environmental, health and safety issues that affect their discipline;
- shares examples of superior environmental health and safety performance with peer institutions, the State of Iowa and the local community.

As a responsible steward of facilities and the environment, Iowa State University

- strives to provide and maintain safe working environments that minimize the risk of injury or illness to employees, students and the public;
- continuously improves operations, with the goal of meeting or exceeding required and applicable environmental, health and safety regulations, rules, policies, or voluntary standards;
- employs innovative strategies of waste minimization and pollution prevention to reduce the use of toxic substances, promote reuse, and encourage the purchase of renewable, recyclable and recycled materials.

The intent of this statement is to promote environmental stewardship, protect health, and encourage safe work practices within the Iowa State University community. The cooperative efforts of the campus community to remain mindful of these goals will ensure that Iowa State University continues to be a great place to live, work and learn.



Dr. Steven Leath
President

University Nondiscrimination Statement

Iowa State University does not discriminate on the basis of race, color, age, religion, national origin, sexual orientation, gender identity, sex, marital status, disability, or status as a U.S. veteran. Inquiries can be directed to the Director of Equal Opportunity and Diversity, 3280 Beardshear Hall, (515) 294-7612.

DIRECTORY OF SERVICE AND EMERGENCY PROVIDERS

**Emergency - fire, police ambulance
911**

**Environmental Health and Safety
294-5359**

**Ames Laboratory Environment, Safety, Health and Assurance
294-2153**

**Occupational Medicine
294-2056**

**Thielen Student Health Center
294-5801**

**McFarland Clinic Occupational Medicine Department
239-4496**

**Mary Greeley Medical Center (emergency room)
239-2155 or 911**

**Department of Public Safety
294-4428**

A. INTRODUCTION

Definition of Biohazardous Materials

Biohazardous materials are those materials of biological origin that could potentially cause harm to humans, domestic or wild animals or plants. Examples include recombinant DNA; transgenic animals or plants; human, animal or plant pathogens; biological toxins (such as tetanus toxin); human blood and certain human body fluids; and human or primate cell cultures.

Purpose

The purpose of the Iowa State University Biosafety Program is to assist in protecting faculty, staff and students minimize exposure to biohazardous materials, to prevent the release of biohazardous materials that may harm humans, animals, plants or the environment and to protect the integrity of experimental materials.

To better fulfill these goals, biosafety staff members serve on the Institutional Biosafety Committee (IBC) and the Institutional Animal Care and Use Committee (IACUC), manage the Bloodborne Pathogen Exposure Control Plan, and conduct exposure assessments for the Occupational Medicine Program. Environmental Health and Safety (EH&S) biosafety staff also:

- coordinate the certification of biosafety cabinets.
- advise staff, faculty, and students who work with biohazardous materials about applicable regulatory guidelines.
- assist researchers in determining appropriate practices and facilities for biocontainment and proper biohazardous waste disposal methods.
- oversee proper disposal of biohazardous waste.
- provide assistance with obtaining regulatory permits and shipping biohazardous materials.
- oversight of Select Agents & Toxins program.

The university's Biosafety Manual outlines appropriate practices, university policies and regulatory requirements for working safely with biohazardous materials. For a comprehensive overview of the core requirements that must be followed in all laboratories at Iowa State, please see the [Laboratory Safety Manual](#).

Responsibilities //////////////////////////////////////////////////////////////////

Iowa State University

The president of Iowa State University is ultimately responsible for all environmental health and safety issues. This responsibility is exercised through the normal lines of authority within the university by delegating the charge for ensuring safe work practices and adherence to established policies and guidelines to the executive vice president, provost, vice-presidents, deans, directors, department chairs, principal investigators, supervisors and, ultimately, each employee.

Environmental Health and Safety

EH&S is responsible for the development and oversight of proper management practices for all biohazardous materials at Iowa State University, including developing and implementing policies for Iowa State University. EH&S is also responsible for ensuring that affected departments are aware of the university policies and regulatory guidelines regarding the proper use of biohazardous materials.

Supervisors

Principal Investigators (PIs), instructors and supervisors are primarily responsible for ensuring that the policies and guidelines established in this manual are strictly followed by all personnel under their jurisdiction, including collaborating researchers.

Personnel

Individuals who work with biohazardous materials have a responsibility to follow the guidelines presented in this manual and to consult with their supervisors regarding the safe handling and proper disposal of specific biohazardous materials used in their work area.

Pregnant women, individuals who are immunocompromised or have other health conditions are advised to consult the Material Safety Data Sheets (MSDS) for all hazardous chemicals, radioactive materials and pathogenic organisms in their environment in order to determine if any risks exist. They should also consult with their supervisor, Occupational Medicine or their physician of choice concerning potential risks and how to manage those risks.

Institutional Biosafety Committee

The IBC is appointed by the Office of the Vice President of Research and Economic Development and serves as the review committee in all matters involving **recombinant DNA** studies, as required by the National Institutes of Health's (NIH) **Guidelines for Research Involving Recombinant DNA Molecules**. The IBC is responsible for reviewing the biological safety and public health programs at Iowa State, including oversight of any use of human, animal or plant pathogens or biological toxins, administration of experimental biological products (vaccines, sera, etc.) to animals and field releases of plant pests or genetically engineered organisms. The IBC also makes policy recommendations to the Office of the Vice President for Research and Economic Development to ensure compliance with federal, state and local regulations and guidelines. The IBC has the authority to require operational changes to ensure compliance with required conditions.

B. RECOMBINANT DNA, HUMAN, ANIMAL AND PLANT PATHOGENS, BIOLOGICAL TOXINS: IBC

The IBC must approve any teaching or research project that involves:

- Recombinant DNA, including transgenic animals or plants.
- Human, animal or plant pathogens (such as bacteria, viruses, fungi, prions or parasites).
- Toxins of biological origin (such as tetanus toxin or aflatoxin).
- Administration of experimental biological products to animals.
- Field releases of plant pests or genetically modified organisms.

The IBC is administered by the Office for Responsible Research. The IBC was established under the NIH Guidelines, and its authority is derived from federal regulations and from the Iowa State University Office of the Executive Vice President and Provost. The IBC is appointed by the Vice President for Research and Economic Development, as one of the standing committees of the university. The committee serves as campus authority in all matters involving recombinant DNA studies as required by the Federal Register, May 7, 1986, vol.51, #88, pages 16958-16985, and subsequent guidelines which supersede earlier versions. The committee also reviews projects involving other hazardous biological materials.

Compliance with the NIH Guidelines is important to promote the safe conduct of research involving recombinant DNA. Compliance with the NIH Guidelines is mandatory as a condition of receiving NIH funding. Institutions that fail to comply risk suspension, limitation, or termination of financial assistance for non-compliant NIH projects and risk NIH funding for other recombinant DNA research at the Institution. It is also possible the institution would have to obtain prior NIH approval for any recombinant DNA projects.

The IBC is composed of several experts including bacteriologists, entomologist, plant pathologist, diagnostic laboratory virologist, biosafety officer, laboratory technician, zoonotic disease expert, public health expert, and two non-institutional members.

Additional Resources:

NIH Guidelines For Research Involving Recombinant DNA Molecules

- ◇ Federal requirements for all recombinant DNA
- ◇ Guidelines for Institutional Biosafety Committees

Recombinant DNA Molecules-NIH Guidelines Training

C. MEDICAL SURVEILLANCE

The **Occupational Medicine Program** provides medical surveillance for all personnel who are exposed to identified or regulated hazardous materials or conditions. Examples include human pathogens, tissues and cell lines as well as radiological, chemical and physical hazards requiring medical surveillance.

Workplace exposure to human blood, tissues, cell lines and other potentially infectious materials (OPIM), as defined by the OSHA Bloodborne Pathogen Standard (29 CFR1910.1030), requires medical surveillance and annual Bloodborne Pathogen Exposure Control Training. Iowa State University's written bloodborne pathogen exposure control plan is the **Bloodborne Pathogens Manual**.

Hazard Inventory //////////////////////////////////////////////////////////////////

Personnel must complete a **Hazard Inventory Form** prior to working with any hazardous materials or conditions. Information from the Hazard Inventory Form will be used by EH&S or Ames Laboratory Environment, Safety, Health and Assurance (EHS&A) and the Occupational Medicine staff to determine if a vaccination is necessary, if a pre-exposure serum sample must be drawn or other medical surveillance is required.

Vaccinations and Testing //////////////////////////////////////////////////////////////////

Personnel who work with human pathogens must be given the option of being vaccinated, provided a vaccine is available, and informed of the risks associated with the vaccine. Personnel working with human blood, tissues, cell lines or OPIM must be offered the Hepatitis B vaccination. High-risk personnel, such as health care workers, must also be offered a titer test two months after the final Hepatitis B vaccine dose. Personnel whose job duties potentially expose them to tuberculosis must be offered routine testing to monitor exposure. Vaccinations and tuberculosis testing will be administered by the Occupational Medicine office and billed to the appropriate PI or department.

Affected personnel choosing to receive a vaccination will need to schedule an appointment with Occupational Medicine (294-2056). They should bring a completed Intramural Purchase Order form with them to their appointment.

Affected personnel choosing not to receive a vaccination must complete the Decline to Vaccinate portion of the Consent or Decline of Vaccination Form. The department supervisor must ensure that the completed and signed decline form is placed in the individual's department personnel file.

Information about specific vaccines and exposure tests commonly given to Iowa State personnel can be found on the Centers for Disease Control and Prevention (CDC) website.

The following are vaccines and procedures offered by Occupational Medicine:

- **Hepatitis A**

- Hepatitis B
- Influenza, inactivated vaccine
- Influenza, live intranasal vaccine
- Rabies
- Tetanus/Diphtheria
- Tuberculosis testing

Exposure to Biohazardous Materials

Before working with human pathogens, blood, tissues and cell lines or OPIM, all applicable safety information, such as the MSDS for a specific pathogen, must be reviewed and documented. Human pathogen MSDSs can be obtained at the [Public Health Agency of Canada](#). Familiarity with exposure routes, symptoms and treatment methods will provide better preparation in the event of exposure to the human pathogens, blood, tissues and cell lines or OPIM.

If exposure to human pathogens, blood, tissue and cell lines or OPIM occurs or is suspected to have occurred while at work, appropriate medical treatment must be sought immediately.

During regular university work hours (M-F, between 8:00 AM and 5:00 PM):

- McFarland Clinic Occupational Medicine department must be notified immediately so that necessary appropriate prophylactic treatment can be started as soon as possible. Any relevant safety information about the exposure, such as an MSDS, should also be taken to McFarland Clinic Occupational Medicine department.

After hours (between 5:00 PM and 8:00 AM) and on weekends:

- If the exposure requires immediate prophylactic treatment, affected personnel should go to the Emergency Room at Mary Greeley Medical Center. Any relevant safety information about the exposure, such as an MSDS, should also be taken to the Emergency Room at Mary Greeley Medical Center. The incident must also be reported to EH&S as soon as possible.
- If the exposure does not require immediate prophylactic treatment, the McFarland Clinic Occupational Medicine department should be contacted as soon as it opens, so that necessary prophylactic treatment can be started as soon as possible.

All accidents and injuries occurring in the course of employment must be reported to the individual's supervisor, even if no medical attention is required:

- The supervisor is responsible for completing a First Report of Injury Form within 24 hours of being notified of the incident. The form can be completed by logging into [AccessPlus](#) and clicking the Employee tab.
- The supervisor should also complete the [Accident Investigation Form](#) as soon as possible to accurately record the events surrounding the incident. Accident investigations should be completed and the forms sent to EH&S at 2809 Daley Drive or emailed to the [web administrator](#) within seven business days of the incident.

Additional Resources:

[OSHA Bloodborne Pathogen Standard \(29 CFR1910.1030\)](#)

[Bloodborne Pathogens Manual](#)

[CDC](#)

[Public Health Agency of Canada, Office of Laboratory Security](#)

D. BIOSAFETY PRACTICES AND PROCEDURES

Work Practices (First Line Of Defense)//////

Safe work practices are the most critical part of preventing exposure when working with biohazardous materials. The best laboratory and safety equipment available cannot provide protection unless personnel use good work practices and have adequate training. Biosafety levels have been developed by the CDC [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#) and NIH to ensure that proper practices, procedures and facilities are employed for work with biological materials that are hazardous to humans.

Laboratory Biosafety Level Criteria//////

The four biosafety levels provide guidelines to ensure an appropriate amount of protection for laboratory users and the environment based on biological risk. Biological risk is related to the infectious agent used, the pathogenicity of the agent and the mode of transmission. A wide variety of requirements for both physical containment and procedural details come with increasing levels of protection.

- BSL-1 facilities and practices are required for work with “defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans.”
- BSL-2 facilities and practices are required for work with “indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity.”
- BSL-3 facilities and practices are required for work with “indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection.
- BSL-4 facilities and practices are required for work with “dangerous and exotic agents that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy.”

BIOSAFETY LEVELS - THE SHORT VERSION

(adapted from BMBL with Iowa State University policies incorporated)

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard microbiological practices	Refer to Iowa State University policy on minimum personal protective equipment (PPE) for labs: lab coats, gloves, eye and/or face protection	Open bench top Sink required
2	Associated with human disease Hazard: percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: Limited access Biohazard warning signs “Sharps” precautions Biosafety manual defining any needed Waste decontamination or medical surveillance policies	Primary barriers: Class I or II Biosafety Cabinets (BSCs) or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials PPE: lab coat, gloves, eye and/or face protection	BSL-1 plus: Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practice plus: Controlled access Decontamination of all wastes Decontamination of lab clothing before laundering Baseline serum	Primary barriers: Class I or II BSCs or other physical containment devices used for all open manipulations of agents PPE: protective lab clothing, gloves, respiratory, eye and/or face protection	BSL-2 plus: Physical separation from access corridors Self-closing, double door access Exhausted air not recirculated Negative airflow into laboratory
4	Materials requiring BSL-4 facilities and practices are not used at Iowa State University.	Materials requiring BSL-4 facilities and practices are not used at Iowa State University.	Materials requiring BSL-4 facilities and practices are not used at Iowa State University.	Materials requiring BSL-4 facilities and practices are not used at Iowa State University.

Reference: *BMBL, 5th Edition and NIH Guidelines*

*Animal biosafety levels describe similar levels for containment facilities and practices necessary when vertebrate animals are infected with human pathogens (ABSL-1, ABSL-2, ABSL-3, ABSL-4).

Plant biosafety levels describe similar levels for greenhouse containment facilities and practices necessary for recombinant plants and plants infected with plant pathogens or plant pests (BL1-P, BL2-P, BL3-P, BL4-P).

Most laboratories on campus qualify as BSL-1 or BSL-2. One BSL-3 laboratory is operational as of December 2004 and more are being planned.

The following lists summarize the minimum criteria for laboratories operating at biosafety levels 1-3. These criteria are detailed in the current edition of the BMBL, a joint publication of the CDC and NIH.

Biosafety Level 1 (BSL-1) Minimum Criteria

- Personnel are trained in analytical methods, standard operating procedures (SOPs), spill response, potential hazards, and applicable safety training.
- Access to the laboratory is limited or restricted at the discretion of the laboratory director when work with cultures or specimens is in progress.
- Laboratory walls, floors and ceilings are designed to be easily cleaned.
- Bench tops are impervious to water and resistant to heat, acids, bases, and solvents.
- Laboratory furniture is appropriate for use and easily accessible for cleaning.
- Laboratory windows are fitted with insect screens.
- Laboratory is outfitted with a hand-washing sink with soap and towels.
- Appropriate PPE is used in the laboratory (for example lab coats, safety glasses/goggles, closed-toe shoes and gloves).
- Personnel wash their hands after they handle viable material, after removing gloves or before leaving the room.
- Eating, drinking, smoking, applying cosmetics, handling contact lenses, and storing food for human consumption are prohibited in the laboratory.
- Mouth pipetting is prohibited. Mechanical devices are used for pipetting.
- Policy is in place for safe handling of sharps.
- Procedures are in place to minimize splashes and the creation of aerosols.
- Work surfaces are decontaminated with an appropriate disinfectant at least once a day and after a spill of viable material.
- Cultures, stocks and regulated waste are decontaminated by an acceptable method before disposal.
- Proper biological waste labeling is in place for off-site decontamination.
- Appropriate biohazard containers are used for containment of biohazardous waste.
- Autoclave validation is performed monthly.
- Laboratory has a rodent and pest control program in place.

Biosafety Level 2 (BSL-2) Minimum Criteria

- BSL-1 safety practices are followed.
- Personnel have been assessed to determine if experimental work poses any special risks to the individual.
- Personnel have been trained in the specific hazards associated with pathogenic agents in accordance with SOPs and protocols.
- A list of trained and qualified personnel is available for inspection.
- A biohazard sign indicating the required biosafety level, required PPE, exit procedures, required immunizations, and the PI's name and phone number is posted at the laboratory entrance during work with human pathogens.
- Laboratory personnel have received appropriate immunizations if available.
- Laboratory personnel have submitted a baseline serum sample when appropriate.
- A biosafety manual and/or SOPs are written to incorporate specific biosafety precautions pertinent to the laboratory.

- Training on the Iowa State University **Biosafety Manual** and SOPs is completed at least annually by the PI.
- Procedures for handling a spill or accident, including required follow-up and documentation, are in place and posted.
- Only animals or plants associated with current studies are present in the laboratory.
- Currently certified biosafety cabinets are used for processes that generate aerosols and for handling large volumes of human pathogen materials.
- Biosafety cabinets are in an area away from traffic and drafts.
- Centrifuges having sealed cups are used to contain aerosols.
- Personnel wear safety glasses, goggles or a face shield during operations posing potential for splashes or aerosols.
- Protective clothing (such as lab coats) is kept inside the laboratory.
- Appropriate gloves are worn when handling materials hazardous to humans.
- Doors are lockable for facilities housing BSL-2 and higher agents.
- An eyewash station is located within the laboratory.
- Illumination is adequate for all activities, avoiding reflections and glare that could affect vision.
- Vacuum lines are protected with liquid disinfectant traps.

Biosafety Level 3 (BSL-3) Minimum Criteria

- BSL-2 safety practices are followed.
- Laboratory is accessed by a double door access zone with self-closing doors and sealed penetrations.
- Laboratory doors remain closed at all times.
- Every consideration has been given to the physical construction of the BSL-3 laboratory (for example sealed penetrations, smooth walls, sealed joints and coved bases).
- Depending on the biohazardous materials used or special handling conditions, HEPA (High Efficiency Particulate Air) filtration may be required for air exiting the room to the outdoors.
- Directional airflow, flowing from clean areas to contaminated areas, is provided.
- All experimental manipulations are done inside a biosafety cabinet (primary containment).
- Every consideration is given to alternative forms of needles or glassware to prevent sharps injuries.
- Equipment exposed to BSL-3 agents is decontaminated before any repair, service or disposal.
- Protective clothing consists of solid-front gowns, scrub suits or coveralls.
- Respiratory and face protection is used when in rooms containing infected animals.
- A hands-free sink with soap and towels is available for use near the exit door.
- If present, all windows are closed and sealed.
- All cultures, stocks, biological waste, gloves, gowns and other contaminated articles are decontaminated in the laboratory.
- Vacuum lines are protected with liquid disinfectant traps and HEPA filters.
- All procedures for the facility design and operation are documented.
- Documentation exists providing evidence that the design and construction have met specific operational parameters before use.
- The BSL-3 laboratory is assessed at least annually to document that the operational parameters are still within specifications.

Biosafety Level 4 (BSL-4)

Use of materials requiring BSL-4 facilities and practices must be conducted within a certified BSL4 facility.

Additional Resources:

U.S. Department of Agriculture (USDA) Regulations for Animals and Animal Products (9 CFR 001-199)

- ◇ Import/transport permits are issued by the Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) branch
- ◇ Quick reference and applications for import and interstate transport permits are available at the USDA Import-Export Directory for USDA-APHIS Veterinary Services

USDA Agricultural Bioterrorism Protection Act of 2002: Possession, Use and Transfer of Biological Agents and Toxins (9 CFR 121)

- ◇ Registration program for possession and transfer of pathogens or biological toxins defined as USDA VS Select Agents

Biosafety in Microbiological and Biomedical Laboratories (BMBL)

- ◇ Guidelines for human pathogen use published by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). Fifth edition

U.S. Public Health Service (USPHS) Foreign Quarantine (42 CFR 71) and Etiologic Agents, Hosts, and Vectors (Part 71.54) Regulations

- ◇ CDC Importation Permits for Etiologic Agents

CDC Possession, Use and Transfer of Select Agents and Toxins (42 CFR 72-73, 42 CFR 1003)

- ◇ Registration program for possession and transfer of pathogens or biological toxins defined as Department of Health and Human Services (DHHS) Select Agents

Infectious Agent MSDSs from Public Health Agency of Canada

- ◇ Quick safety references for pathogenic microorganisms in an MSDS format from Health Canada's Laboratory Centre for Disease Control

Laboratory Decommissioning

When a laboratory is shut down, decommissioned, or transferred to another researcher or purpose, established procedures must be strictly followed. The [Laboratory Checkout/Decommission Checklist](#) that may be used for this purpose. If assistance is required, please call EH&S, 294-5359.

Training and Education

Anyone planning to use biohazardous materials must be adequately trained before beginning the work. Annual laboratory-specific training is also required to be conducted and documented by the supervisor to ensure continued safety. Information communicated in the laboratory-specific training must include:

- A discussion of the Iowa State University Biosafety Manual and how it applies to activities conducted in specific work areas.
- An explanation of the health hazards and signs and symptoms of exposure to biohazardous materials used in specific work areas.
- A description of actions personnel can take to protect themselves from exposure, such as special work practices, use of safety equipment, vaccinations, emergency procedures, etc.

- Lab specific training is required to be updated annually for personnel working in Select Agent registered laboratories.

EH&S offers a variety of biosafety and other safety-related on-line and classroom training courses. Visit the EH&S online [Learning Center](#) for more information or to register for classes.

Signs and Labeling

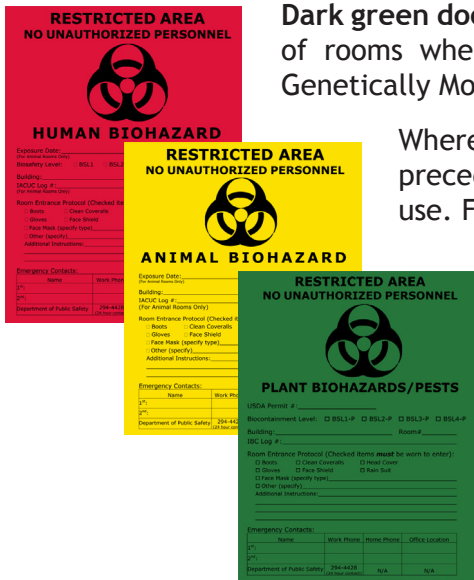
Anyone entering areas where biohazardous materials are used must be aware of the potential hazards. Specific door signs for this purpose are provided by EH&S; call 294-5359.

Red door signs indicating human biohazards must be posted at the entrance of rooms where microorganisms or biological toxins known to cause disease in humans are used. This includes microorganisms classified as Biosafety Level 2 (BSL-2) or greater and human blood, tissues, cell lines or OPIM. Red or orange biohazard labels must be placed on containers and storage units (refrigerators, freezers, incubators, waste containers, etc.) used for microorganisms or biological toxins causing disease in humans, or human blood, tissues, cell lines or OPIM. Contaminated equipment and biohazardous waste must be labeled in the same manner.

Yellow door signs indicating animal biohazards must be posted at the entrance of rooms where strict animal pathogens are used.

Dark green door signs indicating plant biohazards must be posted at the entrance of rooms where strict plant pathogens or pests are used, or where certain Genetically Modified (GM) plants are grown or processed.

Where multiple biohazards are present, human hazards generally take precedence over animal and plant hazards when choosing which sign to use. For EH&S assistance and to obtain correct signs, call 294-5359.



Security

Some level of security is warranted for all laboratories, based on the risks present and regulatory requirements. Each laboratory should conduct a risk assessment to determine appropriate security measures. Some examples of security measures include locked buildings, locked laboratories, locked storage units, limiting distribution of brass keys, proximity cards or key codes and personnel background checks. For detailed information on biohazardous materials security requirements, refer to Section H in this manual.

Personal Protective Equipment

Appropriate PPE is chosen by considering the potential routes of exposure that need to be protected to prevent exposure and infection. It is essential that PPE be removed before leaving the room where biohazardous materials are used. PPE must never be taken home. It should be disposed of or decontaminated in the work area where it is used. Please refer to the [Laboratory Safety Manual](#) for more information regarding PPE.

Lab Coats and Uniforms

Lab coats, scrub suits, gowns and closed-toe shoes prevent biohazardous materials from reaching skin, and more importantly, any cuts, dermatitis, etc. that may be present. They prevent biohazardous materials from contaminating street clothing. They also prevent the normal flora present on the skin from contaminating laboratory cultures.

- ◇ At minimum, a long-sleeved lab coat worn over clothing and closed-toe shoes must be worn in any laboratory. Long sleeves minimize contamination of skin and street clothes and reduce shedding of microorganisms from the skin. Closed-toe shoes protect the feet from spills and injuries from dropped sharps.
- ◇ Lab coats must remain in the laboratory when personnel leave the laboratory. This keeps any contamination in the laboratory instead of spreading it to other work areas or homes.
- ◇ PPE that is sent for commercial laundering, such as lab coats, must be properly contained and labeled. A proper label must have the name of the biological agent of potential exposure, type of decontamination used, and the date when it was last used.
- ◇ Elastic-cuffed lab coats help prevent spills that can be caused by catching a loose cuff on laboratory equipment. When working with biohazardous materials inside a biosafety cabinet, elastic cuffs or double gloving (second pair over cuff) prevent contaminated air from being blown up the lab coat sleeve onto clothing.

Gloves

Gloves prevent exposure of the skin, and any cuts, dermatitis, etc. that may be present, to biohazardous materials.

- ◇ Both latex and nitrile disposable gloves will prevent exposure to microorganisms. However, nitrile gloves must be worn when handling chemicals, since latex provides little to no protection from chemical exposure. EH&S, or ESH&A for Ames Laboratory personnel, can provide assistance with choosing appropriate gloves.
- ◇ For the best protection, the cuffs of the gloves should overlap the lower sleeves of the lab coat.
- ◇ Disposable gloves must not be reused. They are designed for disposal after one use or if exposed to a chemical (they offer limited chemical protection). Utility gloves, such as rubber dishwashing gloves, may be disinfected for re-use if they do not show signs of wear or degradation.
- ◇ For information concerning the chemical resistance of the different types of gloves, access the [Ansell Chemical Resistance Guide](#).
- ◇ EH&S can provide assistance with finding an alternative for personnel with allergic reactions to gloves (most common with latex) and/or the powder they contain.



Eye and Face Protection

Eye and face protection prevent splashes into the eyes, nose and mouth (mucous membrane exposure), and onto the skin.

- ◇ Goggles or safety glasses must be worn when working with laboratory hazards.
- ◇ Prescription safety glasses are available through [Central Stores](#).
- ◇ Face shields should be used for full face protection.
- ◇ N-95 masks provide some splash protection for the mouth and nose.

Respirators

Respirators prevent the inhalation of aerosolized microorganisms (inhalation exposure) when safety equipment designed to contain infectious aerosols, such as a biosafety cabinet, is not available.

- ◇ EH&S can assist in determining if a respirator is needed and which type, call 294-5359.
- ◇ Personnel who are required to use dust masks or other types of respirators for personal

protection must participate in annual respirator training and fit testing. Medical approval to wear respiratory protection is required before training and fit-testing can occur. For more information contact EH&S at 294-5359.

The PI or laboratory supervisor is responsible for conducting hazard assessments, training and coordinating the use of PPE. Completion of a hazard assessment or standard operating procedure may allow individual laboratory PPE requirements to be determined and justified by PIs or laboratory supervisors. Document PPE selection on a standard operating procedure developed for the experiment or laboratory operation.

Laboratory Practice and Technique//////

Workplace-acquired infections are rare. In order for infection and disease to occur, there must be an adequate number of organisms to cause disease (infectious dose) and a route of entry into the body. Knowing how infectious organisms are transmitted and what their infectious doses are can help in evaluating risk and avoiding infection. Information about the organism(s) must be gathered prior to commencing work with them. Good starting points for safety information about human pathogens are infectious agent MSDSs and the current edition of the **BMBL**.



Infectious agents are transmitted through one or more of these routes of exposure:

- Sharps injuries (needlesticks, cuts with contaminated broken glass, etc.; also known as parenteral exposure).
- Inhalation of aerosols (microscopic solid or liquid particles small enough to remain dispersed and suspended in air about 5 micrometers or less in diameter) for long periods.
- Ingestion (oral-fecal routes of contamination are a common source of infection; handwashing is imperative).
- Mucous membrane exposure (including the eyes, inside of the mouth and nose and the genitals).

Using work practices that block routes of exposure can prevent workplace infection. Good microbiological techniques must always be used in the laboratory:

- Wearing appropriate PPE blocks potential routes of exposure.
- Eating, drinking, smoking, chewing tobacco, applying cosmetics, or storing food in laboratories is strictly prohibited. Potentially contaminated hands must be kept away from the mouth, eyes and non-intact skin.
- Hands must be washed frequently, even after wearing gloves, and scrubbed vigorously with soap and water for a full 30 seconds (as long as it takes to sing “Happy Birthday” or the “Iowa State Fight Song”). The physical removal of organisms from the skin is just as important as using a disinfectant.
- Work surfaces and equipment must be decontaminated immediately after using biohazardous materials.

More specific suggestions for common laboratory procedures used with biohazardous materials follow. Each prevents biohazardous materials from entering the body through common exposure routes.

Pipetting

The greatest risks with pipetting are the creation of aerosols and splashing. Micropipettors may also create aerosols.

- ◇ Mouth pipetting is prohibited. Mechanical pipetting aids must be used instead.
- ◇ All biohazardous materials must be pipetted in a biosafety cabinet if possible.
- ◇ Cotton-plugged pipettes should be used. Cotton-plugged micropipette tips are also available.
- ◇ Biohazardous materials must never be forcibly discharged from pipettes. “To deliver” (TD) pipettes must be used instead of pipettes requiring blowout.
- ◇ To avoid splashing, biohazardous material should be dispensed from a pipette or micropipettor by allowing it to run down the receiving container wall.
- ◇ After using pipettes, they should be placed horizontally in a pan filled with enough liquid disinfectant to completely cover them. Allow adequate disinfection time before disposal of pipettes.
- ◇ Plastic micropipette tips and pipettes are sharp and should be disposed of in a puncture-resistant container after decontamination.
- ◇ When working in a biosafety cabinet, all waste and/or disinfecting containers must be kept inside the cabinet while they are being used.
- ◇ Use proper PPE: eye protection, gloves, lab coat, etc.



Centrifugation

The greatest risk with centrifugation is the creation of aerosols.

- ◇ Leaks can be prevented by not overfilling centrifuge tubes. The outsides of the tubes should be wiped with disinfectant after they are filled and sealed.
- ◇ Sealed tubes, O-ring sealed rotors or O-ring sealed safety buckets must be used. To avoid spills from broken tubes, the tubes, lids, O-rings, buckets and rotors should be inspected for damage before each use.
- ◇ Ensure that rotors are balanced before centrifugation.
- ◇ Rotors and centrifuge tubes must be opened inside a biosafety cabinet. If a biosafety cabinet is not available, a minimum of 10 minutes settling time must be allowed before opening.
- ◇ Use proper PPE: eye protection, gloves, lab coat, etc.

Using Needles, Syringes and Other Sharps

The greatest risks when using sharps are accidental injections and the creation of aerosols.

- ◇ Needles and syringes may only be used when there is no reasonable alternative. Safety needles and syringes must be used in these instances.
- ◇ Sharps must be kept away from fingers as much as possible. Sharps must never be bent, sheared, or recapped. Needles should never be removed from syringes after use. If a contaminated needle must be recapped or removed from its syringe, a mechanical device, such as a forceps, must be used.
- ◇ Air bubbles should be minimized when filling syringes.
- ◇ A pad moistened with disinfectant must be placed over the tip of a needle when expelling air. Work must be performed in a biosafety cabinet whenever possible.
- ◇ An appropriate sharps container must be kept close to the work area to avoid walking around with contaminated sharps. Care must be taken not to overfill sharps containers. They are

considered full when they are 2/3 filled. The [Sharps and Biohazardous Waste Procedure](#) details proper disposal methods.

- ◇ Use proper PPE: eye protection, gloves, lab coat, etc.

Blending, Grinding, Sonicating, Lyophilizing, and Freezing

The greatest risk when using any of these devices is the creation of aerosols.

- ◇ Blenders, grinders, sonicators, lyophilizers, etc. must be operated in a biosafety cabinet whenever possible. Shields or covers must be used whenever possible to minimize aerosols and splatters.
- ◇ Safety blenders should be used. Safety blenders are designed to prevent leakage from the bottom of the blender jar and to withstand sterilization by autoclaving. They also provide a cooling jacket to avoid biological inactivation.
- ◇ Avoiding glass blender jars prevents breakage. If a glass jar must be used, it must be covered with a polypropylene jar to contain the glass in case of breakage.
- ◇ A towel moistened with disinfectant must be placed over the top of the blender while operating. This practice can be adapted to grinders and sonicators as well.
- ◇ Aerosols must be allowed to settle for five minutes before opening the blender jar (or grinder or sonicator container).
- ◇ Lyophilizer vacuum pump exhaust must be filtered through HEPA filters or vented into a biosafety cabinet.
- ◇ Polypropylene tubes should be used in place of glass ampoules for storing biohazardous material in liquid nitrogen. Ampoules can explode, causing eye injuries and exposure to the biohazardous material.
- ◇ Use proper PPE: eye protection, gloves, lab coat, etc.

Open Flames

When sterilizing inoculating loops in an open flame, aerosols which may contain viable microorganisms, can be created. Open flames are also an obvious fire hazard.

- ◇ A shielded electric incinerator or hot bead sterilizer should be used instead of an open flame.
- ◇ Disposable plastic loops and needles are also excellent alternatives.
- ◇ Open flames should not be used in biosafety cabinets because they disrupt the laminar airflow and may be a fire hazard.

Flow Cytometry

Flow cytometers operate under pressure, generating aerosols. When flow cytometry is used to study known or potentially biohazardous materials, such as unfixed human or primate cells or known pathogens, operators may be at risk of exposure to aerosolized materials. When possible, all biological samples should be fixed (for example, with formalin) before being run through the flow cytometer.

When performing flow cytometry on known or potentially biohazardous materials cannot be avoided, the following guidelines must be followed to prevent personal exposure.

- ◇ Flow cytometry must be conducted in a laboratory meeting BSL-2 criteria at minimum.
- ◇ Flow cytometry must be conducted in either a certified chemical fume hood, certified biosafety cabinet or other approved negative exhaust ventilation system.
- ◇ Personnel must wear proper personal protective equipment, including gloves, a lab coat and eye protection.

- ◇ The catch basin should have an appropriate disinfectant added when the unit is in use.
- ◇ The flow cytometer and lab bench must be cleaned and disinfected after each use.

Refer also to [Wiley Cytometry Guidelines](#) for additional references regarding flow cytometry biosafety. Note the article [Biosafety Guidelines for Sorting of Unfixed Cells](#).

Evaluating Laboratory Safety

- The Laboratory Safety Survey includes criteria for work with infectious agents (from the current edition of Biosafety in Microbiological and Biomedical Laboratories, BMBL) and for work with recombinant DNA (from the NIH Guidelines for Research Involving Recombinant DNA Molecules). [Laboratory Safety Survey](#) should be completed annually to help ensure that good laboratory safety practices are being used.
- Use the Laboratory Biosafety Level Criteria in the current edition of the BMBL to evaluate whether the facility meets requirements for the organisms and/or toxins used there.

Animal Handling

Animals on Campus

The spread of infectious agents between animal populations or between animals and humans can be prevented by adhering to basic guidelines. Laboratory Animal Resources requires the following wherever animals are housed or used on campus:

- ◇ Footbaths must be used (if provided) when entering and leaving animal rooms.
- ◇ All animal room doors must remain closed at all times, except when entering and exiting the room.
- ◇ Disposable gloves must be worn when handling animals, bedding or soiled cages.
- ◇ Disposable or washable outer garments (such as lab coats, gowns, coveralls) protect personal clothing from contamination when working with animals.
- ◇ Eating, drinking, smoking, applying cosmetics, and handling contact lenses in animal rooms or procedure rooms is prohibited.
- ◇ Hand contact with the nose, eyes or mouth is strongly discouraged when working with animals.
- ◇ Hands must be washed with soap and water immediately after handling any animals or animal equipment, and before leaving the animal facility or laboratory.
- ◇ Extra caution must be taken with needles or other sharp equipment used with animals. Needles shall remain capped until ready to use, then be promptly and properly discarded. Above all do not recap needles. The [Sharps and Biohazardous Waste Procedure](#) details proper disposal procedures and sharps alternatives.
- ◇ Handling only those animal species for which proper handling training has been provided can prevent injury.
- ◇ Any bites or other wounds must be washed immediately with soap and water and appropriate medical attention sought. All accidents and injuries occurring at work or in the course of employment must be reported to the individual's supervisor, even if no medical attention is required:
- ◇ Unauthorized persons are prohibited from entering animal rooms. Additional requirements may be specified for certain research studies.



Animals in the Field

Fieldwork involving wild animals requires adapting the basic animal infection control guidelines to the particular situation in the field. Wild animals potentially transmit many diseases, including rabies, Hantavirus Pulmonary Syndrome, Leptospirosis, West Nile Virus infection, Salmonellosis, Tularemia and plague.

- ◇ Personnel working in areas where they are likely to be exposed to wild rodents or their nesting areas must follow the [Guidelines for Experiments with Wild Rodents](#).
- ◇ Rabies vaccinations must be offered to all personnel who may be exposed to wild animals.
- ◇ Field work may also involve exposure to disease-transmitting insects and arthropods. Take appropriate precautions to prevent exposure to diseases, such as West Nile Virus infection or Lyme Disease, carried by insect and arthropod vectors.



Arthropod Research

Some blood-sucking arthropod species can serve as vectors of infectious human pathogens. A competent arthropod vector (i.e., one that supports the development and transmission of a pathogen) that is infected with the infectious stage of a pathogen has potential to transmit that pathogen if an opportunity to feed on a host arises. As a result, it is critical to have guidelines in place to protect laboratory personnel, the campus community, and the general public from the risk associated with coming into contact with infected vector arthropods.

The American Society of Tropical Medicine and Hygiene drafted the “[Arthropod Containment Guidelines](#)”. These guidelines describe facilities, specific handling practices, and safety equipment for containment of arthropods of public health importance. The arthropods include, but are not limited to insects (Diptera - mosquitoes, tsetse flies, black flies, sand flies, midges; Hemiptera - reduvids; Anoplura - lice; Siphonaptera - fleas), and Arachnids (Ascari - ticks, mites). Typically containment is necessary for mobile stages (larvae/nymphs, adults) of the arthropod lifecycle, but in certain vector-pathogen combinations, even eggs must be considered under these containment guidelines.

Arthropod Containment Levels

When arthropods covered in these guidelines are used, safe work practices, trained personnel, and appropriate facilities must be employed to ensure that personnel and the environment are protected from inadvertent release of the arthropod. The “Arthropod Containment Guidelines” give requirements for standard practices, special practices, safety equipment (primary barriers), and facilities (secondary barriers). The IBC has the final authority to determine if the correct level of containment has been indicated on the protocol.

The following is an explanation of each containment level:

- ◇ ACL-1 is suitable for work with uninfected arthropod vectors or arthropods infected with a non-pathogen. This group would also include arthropods that are native to the region where work is being done, regardless of whether there is an active vector borne disease transmission in the area, and non-native arthropods that if escape, would become inviable or only be able



to establish temporarily in an area. This category would also include arthropods used for educational purposes.

- ◇ ACL-2 is suitable for work with arthropods infected with BSL-2 agents or suspected of being infected with such agents. Uninfected arthropods that have been genetically modified are also placed in this category. This category builds on ACL-1 practices and is more stringent in the physical containment, disposal and facility design. Access is also more restricted than in ACL-1.
- ◇ ACL-3 is suitable for work with arthropods infected with BSL-3 agents associated with human disease. This category builds upon ACL-2 requirements and it is more stringent on access and more emphasis is put on the microbiological containment to determine which practices and facilities are appropriate for arthropods in this containment level.
- ◇ ACL-4 is suitable for work with the most dangerous pathogen-infected arthropods. These arthropods are infected with pathogens capable of causing life threatening disease.

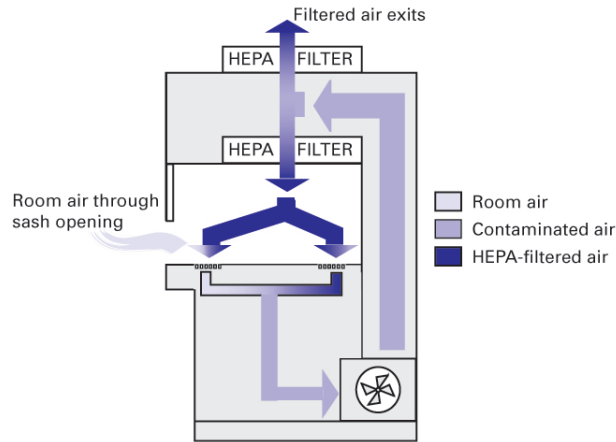
The following table is a summary of general characteristics of the arthropod containment levels. For more specific criteria reference the Arthropod Containment Guide mentioned above.

General Characteristics of the Arthropod Containment Levels

Arthropod Containment Level	1	2	3	4
Infection Status	Uninfected OR Infected with non-pathogen	Up to BSL-2	Up to BSL-3	BSL-4
Practices	ACL-1 standard arthropod handling practices	ACL-1 plus more rigorous disposal, signage and limited access	ACL-2 plus highly restricted access, training and record-keeping	ACL-3 plus enhanced access restriction, extensive training, and full isolation
Primary Barriers	Species-appropriate containers	Species-appropriate containers	Escape-proof arthropod containers, glove boxes, BSC	Escape-proof arthropod containers handled in cabinet or suit laboratory
Secondary Barriers		Separated from laboratories, double doors (2), sealed electrical/plumbing openings. Breeding containers and harborages minimized	BSL-3	BSL-4

Open Flames in a BSC

Open flames, such as Bunsen burners, should never be used in a BSC. Open flames inside of a BSC disrupt the airflow, compromising protection of both the worker and the material being handled. Open flames are extremely dangerous around flammable materials, such as ethanol, which is often found in a BSC. Electric incinerators or sterile disposable instruments are excellent alternatives.



Decontamination and Ultraviolet Lights in a BSC

The BSC work area must always be cleaned and disinfected thoroughly before and after each use, using a chemical disinfectant such as an iodophor. Iodophors (Wescodyne) can be purchased through [Central Stores](#). Be sure to allow adequate disinfection time for the disinfectant used. 70% alcohol evaporates too quickly to be effective and fumes can build up in the biosafety cabinet, creating an explosion hazard. If you use bleach as a disinfectant, be sure to follow by wiping with sterile water, as bleach will corrode the stainless steel of the biosafety cabinet. EH&S does not recommend the use of ultraviolet (UV) lights in a biosafety cabinet because of their ineffectiveness and safety risk. UV light has very little power to penetrate, even through a dust particle, so the UV light is not a method that should be used for primary decontamination. Note that UV lights lose effectiveness over time. **Warning:** Be sure the UV light is turned off before beginning work. Exposure to UV light for a prolonged period will cause skin, corneal and/or retinal burns. Newer BSCs have safeguards to prevent personnel from being exposed to UV light; however, some older models may not have these safeguards. For most consistent contamination control and safe operation, biosafety cabinets should be run 24 hours a day, 7 days a week.

Annual Certification Testing

To ensure that BSCs are providing necessary protection to workers and the environment, a contracted qualified servicing company provides annual certification testing for all BSCs on campus that are used to contain biological hazards. Testing is done according to the internationally accepted standards of National Sanitation Foundation (NSF) International. Each BSC should have a label displaying the date it was last certified (see example at right).

Moving or Repairs

Filter changes and repairs must be done by the contracted qualified servicing company. This company will also be responsible for filter disposal.

BSCs must be recertified whenever they are moved or have the filters changed. EH&S can arrange testing and repairs upon request.

BioCon Lab Safety Division
Test Certification

Unit Type: _____
Test Spec's: _____
Test Date: _____
Next Test Date: _____
Results: PASS FAIL
Contact: _____
Phone: _____
Signed: _____
Phone No: 1-877-380-0552

Purchasing and Installing a New BSC

If plans exist for the purchase of a new BSC, EH&S must be notified to provide assistance in choosing the appropriate BSC and for ensuring that the BSC is put on the annual certification testing schedule.

The following purchasing and installation guidelines must be followed.

- ◇ The BSC must be certified by an NSF certified technician according to NSF Standard 49/2002. Work with any materials classified as requiring BSL-2 or higher containment will not be permitted in a BSC that does not pass certification testing for containment.
- ◇ EH&S must verify that the BSC type (Class II Type A1, Class II Type B2, etc.) is appropriate for the work to be done.
- ◇ Any outlets inside the work area of the BSC should be ground fault circuit protected (GFCI) outlets.
- ◇ Installation of BSCs must allow access to both supply and exhaust filters for annual certification testing and filter changes.
- ◇ The top of the BSC must be far enough below the ceiling (at least 18 inches) to allow field testing of exhaust flow according to NSF Standard 49/2002.
- ◇ Any connections to exhaust duct work must allow access for field testing of exhaust flow according to NSF Standard 49/2002.
- ◇ If the BSC is a Class II Type A2, the connection to the exhaust must be a thimble connection and not a gas-tight connection.

Additional details about choosing appropriate BSCs and their proper use are published by the CDC in a booklet titled Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets.

Additional Resources:

NSF Standard 49/2002 for the Evaluation of Class II (Laminar Flow) Biological Safety Cabinets

- ◇ Information on the NSF Biohazard Cabinetry Program, which sets the criteria for standard methods by which biosafety cabinets are to be tested in order to be certified

Facility Design (Secondary Containment)////

Laboratories intended for work with biohazardous materials are designed to contain those materials in the laboratory so that they cannot cause harm to the general public or the environment. If a laboratory is to be used for work with recombinant DNA, human, animal or plant pathogens, or biological toxins, it must meet certain federal criteria regarding appropriate containment facilities for the specific work to be done. The level of work that a laboratory is qualified to do is referred to as the biosafety level. There are four defined biosafety levels, BSL-1, BSL-2, BSL-3 and BSL-4, for work with human pathogens. Materials requiring BSL-4 facilities and practices are not used at Iowa State University. The BMBL describes the criteria for the different biosafety levels in detail. The NIH Guidelines for Research Involving Recombinant DNA Molecules describes additional criteria for work with recombinant DNA. A brief overview of biosafety level criteria is given in Section D. of this manual.

The IBC and regulatory agencies require that work with animal or plant pathogens be conducted with comparable biocontainment facilities and biosafety practices.

E. DISPOSAL AND DISINFECTION OF BIOHAZARDOUS MATERIALS

University Policies

The [Sharps and Biohazardous Waste Procedure](#) specifies proper procedures for treatment and disposal of biohazardous waste, according to applicable federal, state and local laws as well as university policies. The [Sharps and Biohazardous Waste Disposal Flow Chart](#) may be posted near waste handling areas in the laboratory for quick reference.

Supplies

Most supplies for decontaminating biohazardous waste, such as autoclavable biohazard waste bags, sharps containers and labels, may be purchased through Central Stores. The biosafety staff of EH&S can provide assistance with finding supplies for special disposal needs.

What If I Do Not Have Waste Handling Facilities?

As described in the [First Aid Guidelines](#), if facilities for decontaminating biohazardous waste, such as autoclaves, are not available in a given work area, arrangements can be made with EH&S for disposal. Call 294-5359 to arrange pick-up of your contaminated waste.

Autoclaves

Elements Required for Effective Autoclave Use

Autoclaves must be properly used to effectively sterilize their contents. Autoclave use for microbiological media preparation requires various time and temperature settings for sterilization. Individual trials should be done to determine the proper loading and time settings to determine adequate sterilization.

Autoclaving biohazardous waste must take into account the volume of waste and the ability of steam to penetrate the load. Minimum autoclave cycle time for biohazardous waste is 45 minutes at 121°C. The following elements all contribute to autoclave effectiveness.

- ◇ Temperature: Unless specifically instructed by media manufacturers' directions, autoclave chamber temperature should be at least 121°C (250°F).
- ◇ Time: Autoclave cycle time will vary according to the contents of the autoclave. If media is to be prepared, then the manufacturers' instructions should be followed. Adequate autoclaving time for biohazardous waste is a minimum of 45 minutes, measured after the temperature of the material being sterilized reaches 121°C and 15 PSI pressure. The tighter the autoclave is packed, the longer it will take to reach 121°C in the center of the load. It is important to

assure that the material you are autoclaving is properly inactivated.

- ◇ Contact: Steam saturation of the load is essential for effective decontamination. Air pockets or insufficient steam supply will prevent adequate contact. To ensure adequate steam contact, leave autoclave bags partially open during autoclaving to allow steam to penetrate into the bag. Add a small amount of water inside the bag to help ensure heat transfer to the items being decontaminated (do not add water if it will cause biohazardous materials to splash out of the bag).
- ◇ Containers: Use leak-proof containers for items to be autoclaved. Wherever possible, all considerations should be given to non-glass containers. Plastics such as polypropylene, polypropylene copolymer or fluoropolymer products are capable of being autoclaved repeatedly. Place non-borosilicate glass bottles in a tray of water to help prevent heat shock. Place plastic bags inside a secondary container in the autoclave in case liquids leak out. Plastic or stainless steel containers are appropriate secondary containers. Make sure plastic bags and pans are autoclavable, to avoid having to clean up melted plastic.
- ◇ Indicators: Tape indicators can only verify that the autoclave has reached normal operating temperatures for decontamination. Most chemical indicators change color after being exposed to 121°C, but cannot measure the length of time spent at 121°C. Biological indicators (*Geobacillus stearothermophilus* spore strips or spore suspension) and certain chemical indicators (such as Sterigage) verify that the autoclave reached adequate temperature for a long enough time to kill microorganisms.
- ◇ Use autoclave tape on all bags of biohazardous waste. Before autoclaving bags of biohazardous waste, place an “X” with autoclave indicator tape over the biohazard symbol. Autoclave tape can also be used to indicate if media or equipment has been autoclaved.
- ◇ Once a month, use a biological indicator (*Geobacillus stearothermophilus* spore strips or spore suspension). Bury the indicator in the center of the load to validate adequate steam penetration. Document the biological indicator results in a log book or other suitable form. For more information about the ISU autoclave bioindicator program, contact EH&S at 294-5359.

Autoclave Safety

Autoclaves use saturated steam under high pressure to achieve sterilizing temperatures. Proper use is important to ensure operator safety. Prevent injuries when using the autoclave by observing the following rules:

- ◇ Wear heat resistant gloves, eye protection, closed-toe shoes and a lab coat, especially when unloading the autoclave.
- ◇ Prevent steam burns and shattered glassware by making sure that the pressure in the autoclave chamber is zero before opening the door at the end of a cycle. Slowly open the autoclave door and allow any residual steam to escape gradually.
- ◇ Allow items to cool for at least 10 minutes before removing them from the autoclave. Be careful with glass containers that contain liquids. Superheating is a condition that occurs often in autoclaves. Superheating occurs when liquids are at a temperature above their normal boiling point but do not appear to be boiling. In situations where personnel are in a hurry removing flasks or bottles from the autoclave, these superheated containers can explode or boil over.
- ◇ Never put sealed containers in an autoclave. They can explode. Large bottles with narrow necks may boil over violently if filled too full of liquid.
- ◇ Never put solvents, volatile or corrosive chemicals (such as phenol, chloroform, bleach, formalin, fixed tissues, etc.), or radioactive materials in an autoclave. Call EH&S at 294-5359 if you have questions about proper disposal of these materials.

Pressure Vessel Monitoring

Autoclaves are classified as pressure vessels. Iowa Code requires that all autoclaves meet the American Society of Mechanical Engineers (ASME) Code and must be identified with a metal plate, which is permanently affixed to the vessel. Autoclaves with an internal capacity greater than 5 cubic feet are subject to Department of Labor inspection and certification. Manufacturers of pressure vessels have been following the ASME standards and affixing the plates where required since 1909.

Autoclaves used at Iowa State University must meet the following criteria:

- ◇ All new autoclaves and pressure vessels must have ASME identification plates on them in order to be used or installed at any location.
- ◇ Autoclaves and pressure vessels without the ASME identification plate may continue to be used at their installed location as long as they are in good condition and are inspected for safety at least annually (automatically scheduled each year). They can never be unhooked and installed at a different location.

Inspect your autoclave components regularly. Do not operate an autoclave until it has been properly repaired. Repair or service of autoclaves on campus can be requested by calling Facilities Planning and Management at 294-5100 unless the autoclave is under a special service contract. In this case, the service provider must be contacted.

Chemical Disinfectants ////////////////

Items that cannot be autoclaved can generally be decontaminated using a chemical disinfectant. Choosing the appropriate chemical disinfectant depends on the surface or item needing decontamination, as well as the particular organism requiring inactivation.

Choosing a Chemical Disinfectant

When choosing a chemical disinfectant, the MSDS of the Public Health Agency of Canada (if available) for the agent needing inactivation, the categories of disinfectants listed in this section and the disinfectant product label must be reviewed.

Note: Be sure to wear eye protection when using any chemical disinfectant.

Personnel in the process of choosing a disinfectant must also keep the following considerations in mind:

- ◇ How effective is the disinfectant for the particular application?
 - ✦ What is the organism requiring inactivation? (Different disinfectants are more effective against different types of organisms.)
 - ✦ How many of the organisms are present? (The more organisms present, the more disinfectant required and/or the longer the application time will be.)
- ◇ What needs decontamination? (The disinfectant must be compatible with the item to be decontaminated.)
 - ✦ Work surfaces (for example, metal, tile, plastic, wood, concrete)
 - ✦ Glassware
 - ✦ Equipment (such as biosafety cabinet, surgical tools, cages)
 - ✦ Liquids for disposal
- ◇ Does organic matter inactivate the disinfectant? (Proteins in organic matter can inactivate or slow down the activity of certain disinfectants, such as bleach.)
- ◇ What is the shelf life of the disinfectant?
- ◇ How hazardous is the disinfectant? Refer to the MSDS and the product label for this

information.

- ✘ Is the disinfectant an eye, skin or respiratory irritant? (If yes, proper PPE is required during use.)
- ✘ Is the disinfectant toxic (by skin absorption, ingestion or inhalation)? (If yes, proper PPE is required during use.)
- ✘ Is the disinfectant corrosive to equipment or work surfaces?
- ✘ Does the disinfectant leave a residue?

Types of Chemical Disinfectants

The following are outlines of the basic properties and examples of the most common categories of chemical disinfectants, including alcohols, chlorine compounds, liquid formaldehyde, glutaraldehyde, iodophors, peracetic acid, phenolic compounds and quaternary ammonium compounds. Adequate contact time is very important to ensure complete disinfection. Contact time varies with the type of material being disinfected.

- ◇ Alcohols (for example, ethanol, isopropanol)
 - ✘ These are most effective against lipophilic viruses, less effective against non-lipid viruses and ineffective against bacterial spores.
 - ✘ Optimal disinfection is attained by using 70% ethanol for 15 minutes.
 - ✘ These types of disinfectants evaporate quickly, so sufficient contact time may be difficult to achieve. Concentrations above 70% are less effective because of increased evaporation rate.
- ◇ Chlorine compounds (for example, household bleach - 5.25% sodium hypochlorite)
 - ✘ Chlorine compounds are effective against vegetative bacteria and most viruses in solutions of 50-500 ppm available chlorine. Bacterial spores require concentrations of 2,500 ppm with extended exposure time. Prions require 20,000 ppm with extended exposure time.
 - ✘ A 5,000-ppm available chlorine solution is preferred for general use because excess organic materials inactivate chlorine compounds. This concentration of solution is made by diluting household bleach 1:10 with water. Shelf life for diluted bleach is approximately 24 hours, if kept in a clear container.
 - ✘ Air and light inactivate diluted solutions, so solutions must be freshly made in order to maintain adequate available chlorine concentrations. These solutions should be stored in an airtight, opaque container out of the light. Shelf life is approximately seven days. Otherwise, make up a new solution every day.
 - ✘ Strong oxidizers are very corrosive to metal surfaces, as well as to the skin, eyes and respiratory tract.
- ◇ Formalin
 - ✘ These disinfectants are effective against vegetative bacteria, spores and viruses.
 - ✘ Effective concentration is a 5-8% solution of formalin (formaldehyde in water; made by diluting a 37% solution).
 - ✘ Formaldehyde is a suspected human carcinogen and can cause respiratory problems at very low concentrations. Inhalation limits are 2 ppm for 15 minutes, 0.75 ppm for 8 hours of exposure.
 - ✘ Formaldehyde has an irritating odor and is a sensitizer, so a potential exists for developing allergic reactions.
- ◇ Glutaraldehyde mixtures (for example, Cidex, Sporicidin and 3M Glutarex)
 - ✘ Glutaraldehyde mixtures are effective against vegetative bacteria, spores and viruses

- (more so than formaldehyde).
- ✘ Effective concentration is 2%.
- ✘ Chemically related to formaldehyde, vapors are irritating to the eyes, nasal passages and upper respiratory tract.
- ◇ Iodophors - organically bound iodine compounds (for example, Wescodyne diluted 1:10 is a popular hand washing disinfectant)
 - ✘ These are effective against vegetative bacteria and viruses, but not against bacterial spores.
 - ✘ Effective concentration is 75-150 ppm.
 - ✘ Iodophors are relatively nontoxic to humans, so they are often used as general disinfectants in antiseptics and surgical soaps.
 - ✘ These disinfectants have built-in indicators: if the solution is brown or yellow, it is active. Sodium thiosulfate solution can be used to readily inactivate iodophors and remove iodophor stains.
- ◇ Peracetic acid - used most commonly to sterilize gnotobiotic animal-holding chambers and equipment
 - ✘ Peracetic acid is effective against bacteria, viruses, fungi, and bacterial spores. It is very powerful and fast-acting.
 - ✘ Effective concentration is 2% in water, or 0.08% solution in 10-20% ethanol. The ethanol solution has fewer adverse properties than the 2% solution in water.
 - ✘ Peracetic acid is received as a 40% concentrated solution, which can explode if contaminated with heavy metals or reducing agents, or if rapidly heated. It is also flammable and must be refrigerated. It is a potent respiratory irritant and requires a respirator for use. Peracetic acid is corrosive to metal surfaces.
 - ✘ Diluted solution degrades rapidly, so it must be freshly prepared for use.
- ◇ Phenolic compounds (for example, Amphyl, Vesphene II) - commonly used for disinfecting contaminated walls, floors and bench tops
 - ✘ Phenolic compounds are effective against vegetative bacteria, including mycobacterium tuberculosis, fungi and lipophilic viruses. They are not effective against spores and non-lipid viruses.
 - ✘ Effective concentrations are 0.5-2.0%.
 - ✘ Phenolic compounds produce an unpleasant odor and are toxic.
 - ✘ These are irritants to the eyes, skin, respiratory tract, and gastric tract.
- ◇ Quaternary Ammonium compounds - cationic detergent (surfactant) with strong surface activity, commonly referred to as "Quats"
 - ✘ Quats are effective against fungi, Gram-positive bacteria and lipophilic viruses, but less effective against Gram-negative bacteria. They are ineffective against hydrophilic viruses or bacterial spores. Quats mixed with phenolics are very effective disinfectants, as well as cleaners.
 - ✘ Usual effective concentration is 1:750.
 - ✘ These are relatively nontoxic and acceptable as a general disinfectant, such as for decontaminating food equipment or for general cleaning.
 - ✘ Quats are easily inactivated by organic materials, anionic detergents (soaps), or salts of metals found in hard water.

Procedures For Inactivation and Safety Containment of Toxins

For more information on procedures for inactivation and safety containment of toxins please refer to the [presentation](#) by Dr. Robert W. Wannemacher from the U.S. Army Medical Research Institute of Infectious Disease.

Refer also to the current BMBL for additional Guidelines for Working with Toxins of Biological Origin.

Prion Inactivation and Biocontainment Procedures

USDA Recommendations for Inactivation of Prions Affecting Livestock

- ◇ Porous load autoclaving at 134°C-138°C at 30 psi for 18 minutes holding time at temperature (does not include warm-up and cool-down). (Please note that this practice is consistent with USDA requirements for prions affecting animals, but not BMBL recommendations for prions affecting humans.)
- ◇ Soak ground samples in 40% household bleach (5.25% sodium hypochlorite) to provide 20,000 ppm available chlorine (prepared freshly at time of use). Soak for minimum of 1 hour at 20°C.
- ◇ Non-disposable instruments should be soaked in 40% household bleach for 1 hour, then rinsed with water and autoclaved at 134°C for 1 hour.
- ◇ Wash all surfaces with 40% household bleach, soaking for 60 minutes, then rinse with water. Note: Some surfaces are prone to corrosion from prolonged exposure to these chemicals, so rinsing is very important.

BMBL Recommendations for Inactivation of Prions Affecting Humans

- ◇ Autoclave at 132°C for 4.5 hours (does not include warm-up and cool-down).
- ◇ 1N NaOH or household bleach (>2% free chlorine or 50% household bleach), final concentration.
- ◇ Carefully package contaminated materials and incinerate at >1,500°C.
- ◇ Non-disposable instruments should be soaked in 2N NaOH for 1 hour or 1N NaOH for 2 hours, then rinsed with water and autoclaved at 134°C for 1 hour.
- ◇ Wash all surfaces with 1N NaOH, followed by soaking with 1N HCl for 60 minutes, then rinse with water. Note: Some surfaces are prone to corrosion from prolonged exposure to these chemicals, so rinsing is very important.

Precautions in Using NaOH or Sodium Hypochlorite Solutions in Autoclaves

NaOH spills or gas may damage the autoclave if proper containers are not used. The use of containers with a rim and lid designed for condensation to collect and drip back into the pan is recommended. Persons who use this procedure should be cautious in handling hot NaOH solution (post-autoclave) and in avoiding potential exposure to gaseous NaOH, exercise caution during all sterilization steps, and allow the autoclave, instruments, and solutions to cool down before removal.

Biocontainment and Working Procedures

- ◇ Utilize a Class II biosafety cabinet for all manipulations of samples.
- ◇ Utilize personal protective equipment, including nitrile gloves, lab coat and eye protection.
- ◇ Use disposable instruments (scalpels, pipettes, etc.) when possible.

Refer also to the current edition of BMBL for additional information and recommendations regarding work with prions.

Additional Resources:

U.S. Environmental Protection Agency (EPA) Hospital/Medical/Infectious Waste Incinerators Regulations (40 CFR 62)

- ◇ Emissions requirements for hospital, medical and infectious waste incinerators
- ◇ Iowa State University Sharps and Biohazardous Waste Policy

F. BIOHAZARD SPILL CLEAN-UP

The following protocol is generic, and is intended for use with microorganisms classified as BSL-2 or lower. The correct protocol for any situation depends on the specific biohazardous material used, quantity of material spilled, and location of the spill. Questions about spill clean-up or the use of organisms classified as BSL-3 should be directed to EH&S biosafety staff; call 294-5359.

If a biohazardous spill also includes radioactive material, the clean-up protocol may need to be modified. For these situations, contact the Radiation Safety Officer at 294-5359 during the regular workday. The Department of Public Safety should be contacted at 294-4428 for spill clean-up questions after hours.

Biohazard Spill Kit //////////////////////////////////////////////////////////////////

Each laboratory using biohazardous materials (i.e. recombinant DNA, synthetic molecules, animal pathogens, human pathogens, and plant pathogens) must have appropriate equipment and supplies on hand for managing spills and accidents involving biohazardous materials. Permanent equipment should include a safety shower, eyewash and a hand-washing sink and supplies. A Biohazard Spill Kit should be available in the areas where work is being conducted with biohazardous materials. The supplies available in a Biohazard Spill Kit should include, but are not limited to:

- a copy of the following biohazard spill clean-up protocol
- nitrile disposable gloves (8 mil)(check for holes or deterioration; replace box of nitrile gloves every two years)
- lab coat(s) or gowns
- goggles or safety glasses with side shields
- face masks
- disposable shoe covers (booties)
- absorbent material, such as absorbent paper towels, granular absorbent material, etc. (a disposable or cleanable scoop will be needed for granular absorbent)
- all-purpose disinfectant, such as normal household bleach (freshly diluted 1:10) or an iodophor (such as Wescodyne) or a quaternary ammonia preparation (such as EndBac II)
- autoclavable bucket for diluting disinfectant (this can be used to store the kit contents when not in use)
- something disposable or easily disinfected such as tongs, forceps, manila folders, etc. for picking up broken glass, other contaminated sharps, or contaminated absorbent material
- biohazard sharps waste container(s)
- autoclavable biohazard waste bags
- biohazard spill warning signs

All non-disposable items should either be autoclavable or compatible with the disinfectant to be used. Most of the listed items, as well as other biohazard spill control items, are available at Central Stores, and often are contained within various commercially available biohazard spill control kits.



Biohazard Spill/Response //////////////////////////////////////////////////////////////////

1. Biohazardous spill outside laboratory:
 - ◇ Evacuate the immediate area for at least 30 minutes to allow any potential aerosols to settle. If outdoors, personnel should remain upwind from the spill, if at all possible.
 - ◇ The Iowa State University Department of Public Safety (DPS) is available to assist in evacuation perimeter control. Laboratory personnel should secure the site while someone else is sent for help.
2. Biohazardous spill within laboratory:
 - ◇ Outside of a BSC: the laboratory must be evacuated for at least 30 minutes to allow any potential aerosols to settle. It is the responsibility of the last person out to ensure that all doors have been closed.
 - ◇ Within a centrifuge: the centrifuge should be closed as soon as the spill is noticed. Wait 30 minutes to allow aerosol to settle before opening to clean and disinfect.
 - ◇ Within a BSC: the BSC must remain running. Inform EH&S of spill.
3. Any potentially contaminated clothing must be removed and placed in a biohazard waste bag for decontamination.
4. Hands and any other contaminated skin must be washed thoroughly with soap and water.
5. Everyone not needed for spill clean up must be cautioned to stay away from the spill area until clean up has occurred. Signs may be posted if necessary.
 - ◇ Any personnel present during the incident should remain on site and not go home. They may be asked to provide information about what occurred.
 - ◇ EH&S and DPS are available to assist with spills that occur outside a laboratory. If at all possible, laboratory personnel should appoint someone to call so they may remain and secure the site.
 - ◇ Depending on the size of the spill, a contractor may need to be hired to clean up the spill. EH&S will serve an advisory role.
6. While cleaning up the spill, appropriate PPE must be worn. At minimum, nitrile gloves, eye protection and a lab coat must be worn. A face shield or mask (splash protection) is advised for spills greater than ~10 ml outside a BSC, or any spill inside a centrifuge. If there is a potential for aerosolization of the spilled material, use a respirator (see the EH&S **Respiratory Protection**

Manual).

7. Any sharp, contaminated objects must be removed from the spill area using mechanical means, never with hands.
8. Paper towels must be placed on the spilled material and disinfectant poured carefully around the edges of the spill, with care taken to avoid splashing. Working from the outside of the spill toward the center avoids spreading the contamination. Place discarded paper towels into a biohazard bag for disposal.
 - ◇ Note: Alcohol is not recommended as a disinfectant for large spills, especially inside a BSC, because large amounts of alcohol pose an explosion hazard and small amounts evaporate too quickly to ensure disinfection.
9. If the spill is inside a centrifuge, the rotor and its contents should be moved to a BSC, if possible. The external surfaces should be decontaminated prior to moving to the BSC.
10. If the spill is inside a BSC, the spill tray underneath the work area and the trough below the air intake grill must be cleaned as well as the work area itself. These are likely to be contaminated when the spill is large. The cabinet should be left running for at least 10 minutes before resuming use.
11. After initial clean up, paper towels must again be placed on the spill area, flooded with disinfectant, and left to soak for at least 15 minutes or according to manufacturer's instruction. Adequate contact time is important to ensure complete decontamination.
12. A final wipe-down should be done with clean paper towels soaked with disinfectant. Laboratory personnel should be sure to disinfect any equipment, walls or other areas likely to have been splashed by the spill.
13. If radioactive material is involved in the spill, also wash the surface with detergent according to [radioactive spill guidelines](#).
14. All contaminated waste must be [disposed of properly](#).
15. Hands must be washed thoroughly with soap and water.

G. TRANSPORTING AND SHIPPING BIOHAZARDOUS MATERIALS

On-Campus Transport of Biohazardous Materials

Any biohazardous materials transported between laboratories or buildings on campus must be contained,

USDA-APHIS-Plant Protection and Quarantine

(permits for the import and interstate transport of plant materials, plant pests, plant pathogens and soils)

USDA-APHIS Biotechnology Regulatory Services

(permits and notifications for the import and interstate movement of Genetically Modified Plants, Plant Pests or Plant Pathogens)

USDA-APHIS Veterinary Services

(permits for the import and interstate transport of pathogens of livestock and poultry, and anything biological derived from or exposed to pathogens of livestock and poultry)

as they would be in the laboratory, to prevent release of the materials into the environment. Refer to the [Guidelines for Transport of Infectious Materials by Non-Commercial Routes](#) for detailed procedures. Transport containers must be labeled with the biohazard symbol and the identity of the material inside.

For example, to transport a rack of test tubes containing serum samples from pigs infected with *Salmonella* spp. from a laboratory in Science II to a laboratory in Molecular Biology:

- The tubes must be capped and placed inside a sealed, puncture-resistant, unbreakable secondary container with a biohazard label indicating *Salmonella* spp. The secondary container must contain the samples in case the person carrying the container drops it. Adequate absorbent material must be placed between the two containers in case of spills.

Transport of any material subject to a USDA permit can be performed only in accordance with the permit conditions. For example, a researcher has a permit to work with a porcine virus in growth chambers in a Veterinary Medicine laboratory. This virus cannot be transported to another laboratory on campus without the written permission of the USDA. These guidelines also apply to plant pathogens.

Transport of GM plant, or GM plant pests must be in accordance with USDA regulations in 7 CFR 340.8 and labeling must be according to 7 CFR 340.7.

Transport of any Select Agents between laboratories or buildings on campus also requires that records be kept of the amount and locations. The Select Agent regulations are described below.

Off-Campus Transport of Biohazardous Materials by Commercial Carriers

All off-campus transport of biohazardous materials by commercial carriers must comply with federal and state shipping and permitting requirements, as described in the following sections. Off-campus includes across town to a collaborative research facility, out of town within the state, out of state in the United States, and out of the country.

Permit Requirements

Special federal permits may be required for importing, exporting and/or transporting human pathogens, animal pathogens, animals or animal products, plant pathogens or plant pests, and plants or plant products. Permit requirements should be verified well in advance of needing the material in question, because some permits can take 60-180 days to receive. The biosafety staff can provide assistance with any questions about shipping and/or required permits for biological materials. For assistance in determining the need for a permit, see the EH&S website or call 294-5359.

Animals, Plants, Introduction of Genetically Modified Organisms

The USDA, through its Animal and Plant Health Inspection Service (APHIS), regulates transport of materials that could potentially harm U.S. agricultural products, such as livestock or crops. For this reason, APHIS permits may be required for import, export and/or transport of animal or plant pathogens, soil samples, insects, import or export of animals, animal products, plants or plant products, or transport or introduction of genetically modified organisms into the environment. The information contained on the following APHIS websites and the biosafety staff can help determine if a permit is required and assist with the application process.

Special packaging may also be required for shipping regulated materials. The Packaging and Paperwork Requirements information, listed later in this section, provides details.

Human Pathogens or Biological Toxins

The Department of Health and Human Services, through the CDC, regulates the import and transport of biological materials that could cause illness in humans. These regulated biological materials include pathogenic bacteria or viruses, toxins from biological sources (for example, tetanus toxin, aflatoxin, etc.), blood or tissues capable of containing pathogens transmissible to humans and certain animals, and insects that may harbor disease-causing organisms. The information contained on the CDC website and biosafety staff can help determine if a permit is required and assist with the application process.

CDC Importation Permits for Etiologic Agents

Special packaging may also be required for shipping these materials. See the Packaging and Paperwork Requirements information, listed later in this section, for details.

Select Agents (SAs)

As of February 2003, the CDC and USDA federal regulations regarding Select Agents (42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 121) supersede any previous regulations. Entities that export, import, transport or possess SAs, which include certain viruses, bacteria, Rickettsia, fungi, prions and biological toxins, are now required to apply for and receive registration with the appropriate

federal agency before possession occurs. Substantial criminal penalties apply to both individuals and organizations that do not comply with the regulatory requirements.

Separate paperwork must not only be completed for each laboratory on campus that plans to possess any of the SAs covered by these regulations, but also for each SA used. The paperwork consists of an extensive application packet requiring renewal every three years. Registered laboratories are subject to inspection by outside agencies. The CDC and USDA websites and the Biosafety Officer (294-5359) can help determine whether the SA rules apply to specific projects and whether registration is required.

Each individual working with SAs must also obtain clearance to do so, by having a Bioterrorism Security Risk Assessment conducted by the FBI.

Additional Resources:

[CDC Select Agent Program](#)

[USDA Agricultural Select Agent Program](#)

Packaging and Paperwork Requirements

Any product that is or contains a hazardous material must be transported according to the requirements outlined in the Department of Transportation's (DOT) Hazardous Materials Regulations, 49 CFR parts 100-185 and the International Air Transport Association (IATA) Dangerous Goods Regulations. This includes hazardous biological agents. To comply with DOT regulations, all hazardous materials must be properly classified, packaged, documented and handled by trained personnel. If the regulatory requirements for hazardous materials shipments are not met, citations and fines may be levied and shipping privileges suspended. The regulations also require Hazardous Materials Shipping Training for personnel involved in the transportation of hazardous materials.

When it is necessary to ship a hazardous material, the following procedures must be followed:

- ◇ Required training must be completed. EH&S provides this training in both online and classroom formats.
- ◇ Required permit(s) must be obtained and hazard information collected regarding the product to be shipped.
- ◇ Proper classification must be determined.
- ◇ Approved packaging must be obtained.
- ◇ The product must be packaged under the direction of EH&S and according to any package instructions.
- ◇ EH&S will generate documentation.
- ◇ Package inspection takes place at Postal and Parcel Services. Documentation to accompany the package to Postal and Parcel is faxed to the shipper upon request.
- ◇ The [Hazardous Materials Shipping Guide](#) provides more detailed information, including lists of packaging suppliers and commercial carriers.

Off-Campus Transport of Biohazardous Materials by Non-Commercial Routes

All off-campus transport of biohazardous materials by non-commercial routes must comply with the Guidelines for Transport of Infectious Materials by Non-Commercial Routes. Iowa State University personnel may transport biohazardous materials by non-commercial routes only in university vehicles. Personal vehicles may not be used due to insurance coverage limitations.

- ◇ Transport by non-commercial routes may only be done within the state of Iowa.
- ◇ Some materials may never be transported via non-commercial routes. These materials are listed in the above mentioned guidelines.

Additional Resources:

USDA Import-Export Regulations (9 CFR 300-399)

- ◇ Import/export permits issued by the APHIS Plant Protection and Quarantine (PPQ) branch
- ◇ For export of plant materials, plant pests, plant pathogens, or soil samples, check with EH&S for permit requirements or to determine whether a phytosanitary certificate is needed prior to shipping

USDA Introduction of Genetically Engineered Organisms (GMO) Regulations (7 CFR 340.0-340.9)

- ◇ Biotechnology transport, introduction and import permits issued by the APHIS Biotechnology Regulatory Services branch; information on labeling and packaging of GMO materials prior to shipping
- ◇ Field testing of Genetically Modified Plants (7 CFR 340.0-340.9 &FR11337-11441)

USDA Agricultural Bioterrorism Protection Act of 2002; Possession, Use and Transfer of Biological Agents and Toxins (7 CFR 331)

- ◇ Registration program for possession and transfer of pathogens or biological toxins defined as USDA PPQ Select Agents

U.S. Department of Transportation (DOT) Hazardous Materials Regulations (49 CFR 100-185)

- ◇ Federal requirements for transport of hazardous materials
- ◇ FAA Guidelines/Regulations

Iowa State University Shipping Policies

International Civil Aviation Organization (ICAO) Technical Instructions on the Safe Transport of Dangerous Goods by Air

- ◇ International requirements for air transport of hazardous materials
- ◇ Purchasing information available online

International Air Transport Association (IATA) Dangerous Goods Regulations

- ◇ Manual for international air transport of hazardous materials, based on the ICAO's Technical Instructions on the Safe Transport of Dangerous Goods by Air
- ◇ Purchasing information available online

H. BIOLOGICAL MATERIAL INVENTORY AND BIOHAZARDOUS MATERIALS SECURITY

Bioinventory //////////////////////////////////////////////////////////////////

As outlined in Iowa State Policy, biological materials that are used or stored must be inventoried annually and a copy shared with EH&S.

The **Biological Materials Inventory** serves as a confidential, off-site record to help select university personnel (e.g., Department of Public Safety, emergency responders, EH&S) prepare necessary reports and to determine the risks that are present in research laboratories on campus in case of an emergency or accident. Federal regulations, along with public concern over security of biohazardous materials, make it necessary for the university to maintain an up-to-date inventory of biological agents and biological toxins. The inventory will enable university-wide compliance with federal regulations and guidelines.

Biosecurity //////////////////////////////////////////////////////////////////

Although most microbiology laboratories contain a variety of dangerous biological, chemical and radioactive materials, these materials serve as necessary tools and have rarely been used to intentionally injure anyone. In recent years, however, concern has increased regarding the potential use of certain biological, chemical and radioactive materials by terrorists. In response to these concerns, the CDC has developed guidelines to address laboratory security issues in the current edition of **BMBL**.

All laboratory personnel are responsible for:

- controlling access to areas where hazardous materials are used and stored
- knowing who is in the laboratory
- knowing what materials are brought into the laboratory
- knowing what materials are removed from the laboratory

Federal laws that became effective in 2003 mandate specific security measures for all laboratories possessing Select Agents. The university Biological Research Security Plan reflects these requirements.

If you currently possess or plan to possess any Select Agents, contact EH&S at 294-5359 for specific security requirements.

Similarities and Differences Between Biosafety and Biosecurity Practices

BIOSAFETY

Protecting workers, the public and the environment from unintentional exposure to biohazardous materials

Examples of biosafety:

- Personal Protective Equipment
- Training/knowledge
- Safe practices, such as safe sharps usage, minimizing splashes, handwashing
- Biosafety cabinets
- Autoclaves
- Disinfectants
- Laboratory design/ventilation
- Hazard awareness signage
- Medical surveillance (Occupational Medicine)
- Vaccinations
- Proper transport of materials

BIOSECURITY

Preventing theft and intentional misuse of biohazardous materials

Examples of biosecurity:

- Fences
- Guards
- Locked buildings
- Security cameras
- Locked doors/monitored card access
- Challenging unknown visitors
- Locked storage units
- Documented inventories
- Coded labeling of materials
- Security risk assessment of personnel
- Registration/permits