Weber State University

Biosafety Program

WEBER STATE UNIVERSITY
Environmental Health & Safety

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INTRODUCTION

Purpose

The purpose of the Weber State University (WSU) Biosafety Program is to assist in protecting personnel; minimize exposure to biohazardous materials, prevent the release of biohazardous materials that may harm humans, animals, plants, or the environment, and protect the integrity of experimental materials. The WSU Biosafety Program is intended to be a resource for information, guidelines and procedures that will enable safe research and learning environments and to eliminate, or reduce, the potential for exposure to biohazards.

Scope

Biosafety encompasses the knowledge, techniques, equipment and facilities necessary to prevent or minimize an exposure to, or release of, a biohazard. The information presented here also reflects the requirements and guidelines of federal and state regulations, information about safe work practices, safety equipment and personal protective equipment. It is intended that the Principal Investigator, Laboratory Instructors, and supervisory personnel will supplement this information with instruction and guidance regarding specific practices and procedures unique to the work being done by those in their laboratories.

The Biosafety Program fulfills these goals, with the Environmental Health and Safety (EHS) staff members providing support for the Institutional Biosafety Committee (IBC), the Institutional Animal Care and Use Committee (IACUC), managing the Bloodborne Pathogens Exposure Control Plan, and consulting on exposure assessments with Human Resources. The Biosafety Program outlines appropriate practices, university policies, and regulatory requirements for working safely with biohazardous materials.

Definitions

Biohazardous Materials: Materials of biological origin that could potentially cause harm to humans, domestic or wild animals, or plants. Examples include recombinant or synthetic nucleic acid molecules, 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.

Recombinant and Synthetic Nucleic Acid Molecules:

In the context of the *NIH Guidelines*, recombinant and synthetic nucleic acids are defined as:

- molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
- nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
- molecules that result from the replication of those described above.

Roles and Responsibilities

Weber State University

The president of Weber State University is ultimately responsible for all environmental, health, and safety issues at the institution. 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 provost, deans, directors, Environmental Health and Safety, department chairs, principal investigators, supervisors, lab instructors, and, ultimately, each individual.

Environmental Health and Safety

Environmental Health and Safety is responsible for the development and oversight of proper management practices for all biohazardous materials at WSU, including developing and implementing procedures for WSU. Environmental Health and Safety is also responsible for ensuring that affected departments are aware of the university policies and regulatory guidelines regarding the proper use of biohazardous materials.

Biosafety Officer (BSO)

The BSO for the university is provided by the EHS Office to assist with coordination and guidance in the development and implementation of the Institutional Biosafety Program. The BSO's duties include, but are not limited to:

- Regularly inspects departments working with biohazardous materials to ensure compliance with the Biosafety Program.
- Reporting to the IBC and the specific college of any significant problems, violations of the NIH guidelines, and any significant research-related accidents or illnesses.
- Developing emergency plans for handling accidental spills and personnel contamination, and investigating laboratory accidents involving recombinant DNA (rDNA) research.
- Providing technical advice to principal investigators (PIs), and the IBC on laboratory safety procedures.
- Coordinates and documents the certification and annual inspections of biosafety cabinets.
- Advises personnel who work with biohazardous materials about applicable regulatory guidelines.
- Assists researchers in determining and ensuring appropriate practices and facilities for biocontainment and proper biohazardous waste disposal and temporary storage methods.
- Aids with obtaining regulatory permits, shipments of biohazardous materials, and documents biosafety levels allowable per the Centers for Disease Control and Prevention (CDC) guidelines.

Institutional Biosafety Committee (IBC)

The IBC serves to provide resources to university employees and supervisors for the safe handling of biohazardous materials. In addition, the IBC serves as a review committee for all recombinant or synthetic nucleic acid molecules studies, as required by the National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines). The IBC is responsible for reviewing the biological safety and r/DNA research at WSU, and approves those research projects that conform to the NIH guidelines. This review shall include:

- An independent assessment of the containment levels required by the NIH guidelines for the proposed research.
- Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in r/DNA research.
- Notifying the PI of the results of the committee's review.
- Reviewing both ongoing and proposed r/DNA research conducted at WSU to ensure compliance with the NIH guidelines.
- Adopting emergency plans concerning spills, personnel contamination, or potential releases resulting from r/DNA research.
- Reporting any significant problems or violations of the NIH guidelines and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/Office of Biotechnology Activities (OBA) within 30 days.

- Establishing subcommittees, or ad hoc committees, as necessary to carry out its overall responsibilities.

The IBC is comprised of at least five members who collectively have experience and expertise in r/DNA technology. Two members are not affiliated with the university (apart from their membership on the IBC) and represent the interest of the surrounding community with respect to health and protection of the environment. The BSO also serves on the IBC. The IBC has the authority to require operational changes to ensure compliance with required conditions.

Deans, Directors, Department Chairs, and Administrators

Department, College, and University administrators are responsible for informing new employees of the Biosafety Program. They are to aid in obtaining the resources required to comply with proper procedures and reduce exposure to biohazards.

Principal Investigators (PIs), Instructors, and Supervisors

Laboratory instructors and supervisors are primarily responsible for ensuring that the procedures and guidelines established in this manual are strictly followed by all personnel under their jurisdiction, including collaborating researchers. For the purpose of the WSU Biosafety Program, personnel are identified as any individuals working with biohazardous materials. This may include employees, students, and volunteers.

Individuals employed by the university 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.

Individuals who are pregnant, immunocompromised, or have other health conditions are advised to consult the safety data sheets (SDS) for all hazardous chemicals, radioactive materials, and pathogenic organisms in their workplace environment in order to determine if any risks exist. They should also consult with their supervisor, or their physician of choice concerning potential risks and how to manage those risks.

POLICIES

RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES; HUMAN, ANIMAL, AND PLANT PATHOGENS; AND BIOLOGICAL TOXINS

The Institutional Biosafety Committee (IBC) approves IBC-applicable research projects that involve:
• Recombinant or synthetic nucleic acid molecules, 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 established under the NIH guidelines. Compliance with the NIH Guidelines is important to promote the safe conduct of research involving recombinant or synthetic nucleic acid molecules. 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 or synthetic nucleic acid molecules research at the institution. It is also possible the institution would have to obtain prior NIH approval for recombinant or synthetic nucleic acid molecules projects.

Initiation and Authorization

The PI must complete the rDNA Registration Form (Appendix A) when their research involves the introduction of recombinant or synthetic nucleic acid molecules into organisms, cells, or viruses. Submit this form at ehs@weber.edu. The IBC will review the registration form and perform a thorough risk assessment. The IBC's decision and recommendations will be relayed to the PI.

Renewal

Authorization for projects involving the use of r/DNA, infectious agents or biological toxins must be renewed every three years or if there are any significant changes in research or processes. A reauthorization form will be sent to the PI sixty days before the authorization anniversary date.

MEDICAL SURVEILLANCE

Workplace exposure to human pathogens, 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 Pathogens Exposure Control Training. Weber State University has a written Bloodborne Pathogens Exposure Control Plan available to employees (Appendix B). Weber State University Human Resources provides medical surveillance for all employees who are exposed to identified or regulated risks.

Vaccinations and Testing

Employees who work with human blood must be given the option of being vaccinated, provided a vaccine is available, and informed of the risks associated with the vaccine. High-risk personnel, such as health care workers, must also be offered a titer test two months after the final hepatitis B vaccine dose. Hepatitis B vaccinations will be administered by WorkMed and billed to the appropriate PI or department. Affected personnel choosing to receive a vaccination must schedule an appointment with WorkMed (801) 387-6150. Affected personnel choosing not to receive a vaccination must complete the Decline to be Immunized portion of the Hepatitis B Vaccination Form (Appendix C). The department supervisor must ensure that the completed and signed decline form is placed in the individual's department personnel file and a copy sent to Human Resources.

Exposure to Biohazardous Materials

Before working with human pathogens, blood, tissues, cell lines, or OPIM, all applicable safety information, such as the Pathogen Safety Data Sheets (PSDS) for a specific pathogen, must be reviewed and documented. PSDSs are available at the Public Health Agency of Canada (https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html). Familiarity with exposure routes, symptoms, and treatment methods will provide better preparation in the event of exposure to the human pathogens, blood, tissues, cell lines, or OPIM.

If exposure to human pathogens, blood, tissue, cell lines, or OPIM occurs or is suspected of having occurred while at work, appropriate medical treatment must be sought immediately. More information can be found in the Bloodborne Pathogens (BBP) Exposure Control Plan or at https://www.weber.edu/EHS/postexposure.html.

Employee Work-Related Injuries, Illnesses and Exposures

All work-related injuries, illnesses, or exposures must be reported to the employee's supervisor, even when medical attention is not required or is refused by the employee. More information can be found at https://www.weber.edu/HumanResources/workerscomp.html.

Other near miss incidents (something that could have resulted in injury but did not) or anything else you think may be a safety hazard in the work setting should be reported following https://survey123.arcgis.com/share/68349d34a32b4fd4afce988d6c824b2b.

Student Accidents and Injuries

Students not employed by WSU who are exposed or injured in the classroom or laboratory should seek medical attention as necessary.

All accidents and injuries sustained by WSU students while in academic classes or events sponsored by the university must be reported to Risk Management by the student and a university representative.

Any bloodborne exposure sustained while off site in a clinical setting will be handled using the procedures of the medical facility.

Although student safety is administratively separate from employee safety, the most directly responsible party (lab instructor, research mentor, etc.) should direct the student to the appropriate safety procedures for the situation, referring to the emergency contact sheet found in each lab.

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.

Laboratory Biosafety Level Criteria

The four biosafety levels (BSL) provide guidelines to ensure appropriate 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 comes with increasing levels of protection. The Biosafety in Microbiological and Biomedical Laboratories (BMBL), published by CDC and NIH, lists proper practices, procedures, and facilities for each biosafety level. Weber State University currently allows only BSL-1 and BSL-2 work, as defined below.

- BSL-1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment.
- BSL-2 builds upon BSL-1. BSL-2 is suitable for work involving agents associated with human disease that pose moderate hazards to personnel and the environment.
- BSL-3 is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure.
- BSL- 4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments, or a related agent with unknown risk of transmission.

Training and Education

Anyone planning to use biohazardous materials must be adequately trained before beginning work. Annual laboratory-specific training is 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 *WSU Biosafety Program* 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.

Signs and Labeling

Anyone entering areas where rDNA and biohazardous materials are used must be aware of the potential hazards. Biohazard signs should be posted on doors to rooms where microorganisms, rDNA or biological toxins known to cause disease in humans are used, such as microorganisms classified as Biosafety Level 2 or greater. Red or orange biohazard labels should be placed on containers and storage units (refrigerators, freezers, incubators, waste containers, etc.) used for microorganisms, rDNA or biological toxins causing human disease. Contaminated equipment must be labeled as well. Animal biohazard signs should be posted where strict non-human animal pathogens are used.

Security

Some level of security is warranted for all laboratories, based on the existing risks 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 keys, proximity cards or key codes, video monitoring, and personnel background checks.

Personal Protective Equipment (PPE)

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. Personal Protective Equipment must never be taken home. Personal Protective Equipment shall be removed in a manner that minimizes personal contamination, and should be disposed of or decontaminated in the work area where it is used.

Lab Coats and Closed Toe Shoes

Lab coats, scrub suits, gowns, and closed toe shoes prevent biohazardous materials from reaching the 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 working with biohazardous materials. 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 on the lab coat in the laboratory instead of spreading it to other work areas or homes.

- Personal Protective Equipment 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 to the skin and any cuts, dermatitis, etc. that may be present, in 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. Environmental Health and Safety personnel can aid with choosing appropriate gloves.
- For best protection, the cuffs of the gloves should overlap the lower sleeves of the lab coat.
- Consider the need for bite and/or scratch resistant gloves.
- 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). Dispose of used gloves with other contaminated laboratory waste. Utility gloves, such as rubber dishwashing gloves, may be disinfected for re-use if they do not show signs of wear or degradation.
- Change gloves when contaminated, when glove integrity is compromised, or when otherwise necessary.
- Environmental Health and Safety can help with finding an alternative for personnel with allergic reactions to gloves (most common with latex) and/or the powder they contain.
- Thick cloth gloves for handling hot or cold items should be worn when appropriate, but should be free from exposure to biohazards or autoclaved after use.

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.
- Face shields should be used for full-face protection.

Respirators

Respirators prevent the inhalation of aerosolized microorganisms (inhalation exposure) when safety equipment designed to contain infectious aerosols, such as a biosafety cabinet, is unavailable. Respirators also reduce the inhalation of animal allergens when primary containment of animals is not possible or practical.

- Environmental Health and Safety can assist in determining if a respirator is needed and which type.
- Respirator training and fit-testing are required for certain respirators. The Respiratory Protection Program provides details.
- The PI or laboratory supervisor is responsible for conducting hazard assessments, training, and coordinating PPE use. Completing a hazard assessment in association with a standard operating procedure allows 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

Personnel can be infected with organisms they come in contact with in the workplace. In order for infection 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 the infectious doses can help in evaluating risk and avoiding infection. Information about the organism(s) must be gathered prior to starting work with them. Safety information about pathogens can be obtained through PSDSs and the *BMBL*.

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

- Sharps (parenteral) injuries (needlesticks, cuts with contaminated broken glass, etc.).
- Inhalation of aerosols (microscopic solid or liquid particles (5 micrometers or less) dispersed or suspended in air).
- Ingestion (oral-fecal routes of contamination are a common source of infection; hand-washing 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 skincare products, 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. The physical removal of organisms from the skin is just as important as using a disinfectant.
- Work surfaces and equipment must be decontaminated after using biohazardous materials.

Evaluating Laboratory Safety

The Laboratory Safety Survey includes criteria for work with infectious agents (from the current edition of the Biosafety Microbiological and Biomedical Laboratories- *BMBL* *https://www.weber.edu/wsuimages/EHS/pdfs/Biosafety-Labroratories.pdf* and work with recombinant or synthetic nucleic acid molecules (from the National Institute of Health- NIH guidelines https://www.weber.edu/wsuimages/EHS/pdfs/NIH-Guidelines.pdf). A Laboratory Safety Survey should be completed by laboratory personnel annually to help ensure that good laboratory safety practices are being used. Weber State University Laboratory Safety Survey can be found in Appendix D.

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. Weber State University requires the following precautions wherever animals are housed or used on campus:

- Shoe covers must be worn, when specified, upon entering an animal room.
- 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, and coveralls) protect personal clothing from contamination when working with animals.

- Eating, drinking, smoking, applying cosmetics or skincare products, 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 and promptly and properly discarded. Above all, do not recap needles. Needles and uncapped syringes with needles should be disposed of directly into the sharps container.
- Injury can be prevented by handling only those animal species for which proper handling training has been provided.
- 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.
- Other near miss incidents (something that could have resulted in injury but did not) or anything else you think may be a safety hazard in the work setting should be reported following https://survey123.arcgis.com/share/68349d34a32b4fd4afce988d6c824b2b.Unauthorized persons are prohibited from entering animal rooms. Additional requirements may be specified for certain research studies. High Efficiency Particulate Air (HEPA) filters must be changed every 5 years (per manufacturer's standards) on animal cage racks that house animals infected with an organism that is worked with at BSL-2 or tested to make sure they are functioning correctly.

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. The PI or laboratory supervisor is responsible for conducting hazard assessments for working in the field. Completion of a hazard assessment in association with a standard operating procedure allows individual research requirements to be determined and justified by PIs or laboratory supervisors.

Cell and Tissue Culture

Cell and tissue cultures may contain pathogenic organisms. It is prudent to consider all cell lines to be potentially infectious. Most cell and tissue cultures can be safely manipulated using BSL-2 practices and containment.

- All primary and immortalized human or other primate cell lines or tissue cultures must be handled using BSL-2 practices and containment.
- Personnel handling human cell and tissue cultures must participate in the Bloodborne Pathogens Exposure Control Program.
- If any cell or tissue cultures are known or suspected to contain a specific pathogen or oncogenic virus, appropriate biosafety practices for handling that virus must be used when working with the cell or tissue culture.

BSL-1 practices and containment may be used for cell lines that meet all of the following criteria. Cells must:

- Not be of human or other primate origin.
- Be confirmed not to contain human or other primate pathogens, including viruses, pathogenic bacteria, mycoplasma, or fungi.
- Be well-established, such as those purchased from biological storehouses

Safety Equipment (Primary Containment)

Primary containment equipment is designed to reduce or eliminate exposure to biohazardous materials. Biosafety cabinets (BSC) serve as the primary containment for biohazardous materials in the laboratory. Other types of primary containment equipment include sealed centrifuge cups and special airtight enclosures designed to contain specific laboratory equipment (such as Sonicators) that are likely to produce aerosols of biohazardous materials.

Biosafety Cabinets (BSC)

Biosafety cabinets are designed to protect personnel, the products being handled, and the environment from particulate hazards, such as infectious microorganisms. Biosafety cabinets use uniform vertical laminar airflow to create a barrier to airborne particulates. Biosafety cabinets utilize (HEPA) filters to clean both the air entering the work area and the air exhausted to the environment.

A BSC is not a chemical fume hood. Chemical fume hoods are designed to protect personnel by removing chemical vapors and aerosols from the work area. The HEPA filter removes airborne particles from the air, but does not remove chemical fumes. Only BSCs that are exhausted via duct work are appropriate for use with small amounts of toxic volatile chemicals. Always use a fume hood when working with large amounts of toxic volatile chemicals.

For more detailed information on BSC types and uses, see BMBL Appendix A, “Primary Containment for Biohazards: Selection, Installation, and Use of Biological Safety Cabinets.”

Biosafety Cabinet Use

Biosafety cabinets should be used when conducting lab procedures with biohazardous materials that may produce aerosols or when you are working with large amounts of infectious materials. A BSC must also be used for all manipulation of airborne-transmitted human pathogens, such as SARS-CoV-2 and influenza virus.

Open Flames in a BSC

Open flames, such as Bunsen burners, should never be used in a BSC. Open flames inside a BSC disrupt the airflow, compromising protection of the worker and the material being handled. Open flames are extremely dangerous around flammable materials, such as ethanol, which is often used 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. 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 BSC, 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. Ultraviolet (UV) lights are not to be used as a primary decontamination of BSC because of their ineffectiveness and safety risk. 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 the 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.

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. Biosafety cabinets must be recertified whenever they are moved, repaired, or have the filters changed.

Purchasing and Installing a New BSC

If plans exist for the purchase of a new BSC, EHS must be notified to aid in choosing the appropriate BSC and for ensuring that the BSC is put on the annual certification testing schedule.
The purchasing and installation guidelines must be followed.

- The BSC must be certified by an NSF accredited technician according to NSF/ANSI 49 Standard. 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.
- Environmental Health and Safety must verify that the BSC type (Class II Type A2, 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/ANSI 49-2019.

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 or synthetic nucleic acid molecules, 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 for work with human pathogens: BSL-1, BSL-2, BSL-3, and BSL-4. Materials requiring BSL-4 and BSL-3 facilities and practices are not currently used at WSU. The BMBL describes the criteria for the different biosafety levels in detail. The BMBL-Appendix A, “Primary Containment for Biohazards: Selection, Installation, and Use of Biological Safety Cabinets.” describes additional criteria for work with recombinant or synthetic nucleic acid molecules. A brief overview of biosafety level criteria is given in Biosafety Practices and Procedures 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.

Table 1: Summary of Laboratory Biosafety Levels (BSLs)

BSL	Agents	Special Practices[a]	Primary Barrier and PPE	Facilities (Secondary Barriers)
1	Well-characterized agents not known to consistently cause disease in immunocompetent adult humans and present minimal potential hazard to laboratory personnel and the environment.	Standard microbiological practices	No primary barriers required; protective laboratory clothing; protective face, eyewear, as needed	Laboratory doors; sink for handwashing; laboratory bench; windows fitted with screens; lighting adequate for all activities
2	Agents associated with human disease and pose moderate hazards to personnel and the environment	Limited access; occupational medical services including medical evaluation, surveillance, and treatment, as appropriate; all procedures that may generate an aerosol or splash conducted in a BSC; decontamination process needed for laboratory equipment	BSCs or other primary containment device used for manipulations of agents that may cause splashes or aerosols; protective laboratory clothing; other PPE, including respiratory protection, as needed	Self-closing doors; sink located near exit; windows sealed or fitted with screens; autoclave available
3	Indigenous or exotic agents; may cause serious or potentially lethal disease through the inhalation route of exposure	Access limited to those with need to enter; viable material removed from laboratory in primary and secondary containers; opened only in BSL-3 or ABSL-3 laboratories; all procedures with infectious materials performed in a BSC	BSCs for all procedures with viable agents; solid front gowns, scrubs, or coveralls; two pairs of gloves, when appropriate; protective eyewear, respiratory protection, as needed	Physical separation from access corridors; access through two consecutive self-closing doors; hands-free sink near exit; windows are sealed; ducted air ventilation system with negative airflow into laboratory; autoclave available, preferably in laboratory
4	Dangerous and exotic agents that pose high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that are frequently fatal, for which there are no vaccines or treatments; and related agents with unknown risk of transmission	Clothing change before entry; daily inspections of essential containment and life support systems; all wastes decontaminated prior to removal from laboratory; shower on exit	BSCs for all procedures with viable agents; solid front gowns, scrubs, or coveralls; gloves; full-body, air-supplied, positive-pressure suit	Entry sequence; entry through airlock with airtight doors; walls, floors, ceilings form sealed internal shell; dedicated, non-recirculating ventilation system required; double-door, pass-through autoclave required

a. Each successive BSL contains the recommendations of the preceding level(s)

BMBL Section IV Table 1

DISPOSAL AND DISINFECTION OF BIOHAZARDOUS MATERIALS

The rDNA and Biohazardous Waste Disposal Guide (Appendix E) specify proper procedures for the treatment and disposal of biohazardous waste, according to applicable federal, state, and local laws as well as university policies.

Supplies

Most supplies for decontaminating biohazardous waste, such as autoclavable biohazard waste bags, sharps containers, disinfectants, and labels, may be purchased through Science Stores. The biosafety officer, with the EHS Office can help with finding supplies for special disposal needs.

What If I Do Not Have Waste Handling Facilities?

If facilities for decontaminating biohazardous waste, such as autoclaves, are not available in a given work area, arrangements can be made with the EHS Office for disposal. Submit a request online for pick-up https://docs.google.com/forms/d/e/1FAIpQLSepCXoJQ8k-kauO5kHkMaqU6vvqrwauYs_YUHUwuNnWs8Wd_g/viewform 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. Ensure you follow the manufacturer's direction.

Autoclaving biohazardous waste must consider 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.
- 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 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.

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 often occurs 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 hurry to remove 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.

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, review the PSDS of the Public Health Agency of Canada (if available) https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html for the agent needing inactivation, the categories of disinfectants listed in this section and the disinfectant product label.

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 SDS 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 [hand sanitizer], isopropanol [rubbing alcohol])
  - 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 irritation 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%. Once activated, glutaraldehyde solutions are biocidal for 14 to 30 days, depending on the formulation.
  - 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, Lysol, Amphyl, Vesphene II) – commonly used for disinfecting contaminated walls, floors and bench tops
  - Phenolic compounds are effective against vegetative bacteria, including M*ycobacterium 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.

BIOHAZARD AND rDNA SPILL CLEAN UP

The following protocol is generic and is intended for use with microorganisms worked with at 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. All spills in the laboratory should be reported immediately to the supervisor in charge of the lab.

If a biohazardous spill also includes radioactive material, the cleanup protocol may need to be modified. For these situations, contact the Radiation Safety Officer (RSO) at (801) 626-7982 during the regular workday. If the RSO is unavailable, the Department of Public Safety should be contacted at (801) 626-6460. After hours contact 911 for biohazardous spills that include radioactive materials.

Biohazard Spill Kit

Each laboratory using biohazardous materials (recombinant or synthetic nucleic acid molecules, 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. 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 Biological Spill Cleanup Procedures
- Nitrile disposable gloves (8 mil) (check for holes or deterioration; replace boxes of nitrile gloves every two years)
- Lab coats 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), 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 Science Stores. There are also various commercially available biohazard spill-control kits.

Biohazard Spill Response Procedure

1. Biohazardous spill outside laboratory
    a. 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 possible.
    b. The Weber State University Department of Public Safety (DPS) is available to assist in evacuation and perimeter control. Laboratory personnel should secure the site while someone else is sent for help.

2. Biohazardous spill within laboratory
    a. 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.
    b. Within a centrifuge: the centrifuge should be closed as soon as the spill is noticed. Wait 30 minutes to allow aerosols to settle before opening to clean and disinfect.
    c. Within a BSC: cover the spill with absorbent, apply disinfectant, allow 15 minutes contact time (BSC remains running), and then proceed with clean-up.
    d. Inform EHS of spill if you require assistance with clean-up.
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.
    a. Any personnel present during the incident should remain on site and not go home until released. They may be asked to provide information about what occurred.
    b. Depending on the size of the spill, a contractor may need to be hired to clean up the spill. Environmental Health and Safety 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 or face mask (see the WSU Respiratory Protection Program).
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.
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.
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 the 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.

TRANSPORTING AND SHIPPING BIOHAZARDOUS MATERIALS

On Campus Transport of rDNA and Biohazardous Materials

Any biohazardous materials transported between laboratories or buildings on campus must be contained, as they would be in the laboratory, to prevent release of the materials into the environment. Transport containers must be labeled with the biohazard symbol and the identity of the material inside.

- The tubes must be capped and placed inside a sealed, puncture resistant, unbreakable secondary container with a biohazard label indicating BSL-2. 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.

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 officer can aid with any questions about shipping and/or required permits for biological materials.

Animals, Plants, Introduction of Genetically Modified Organisms

The United States Department of Agriculture (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 to import and/or transport animal or plant pathogens, soil samples, insects, import of animals, animal products, plants or plant products, or transport or introduction of genetically modified organisms into the environment.

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 U.S. Department of Health and Human Services (HHS), 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 guidance from the biosafety officer 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. For details, see the Packaging and Paperwork Requirements information, listed later in this section.

Select Agents and Toxins

Entities that export, import, transport, or possess Select Agents (SAs), which include certain viruses, bacteria, *Rickettsia*, fungi, 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.

Packaging and Paperwork Requirements

Any product that is or contains a material determined by the United States Department of Transportation (DOT) to be hazardous when shipped in commerce must be transported according to the requirements outlined in the 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 permit(s) must be obtained and hazard information collected regarding the product(s) to be shipped.
- Proper classification must be determined.
- Approved packaging must be obtained.
- The product must be packaged under the direction of EHS and according to any package instructions.
- Environmental Health and Safety will generate documentation.
- Package and paperwork may be delivered to the carrier directly.
- For additional information on Shipping Hazardous Materials go to: https://www.transportation.gov/check-the-box/getting-started-with-hazmat

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

Consult with EHS for all off-campus transport of biohazardous materials by non-commercial routes. Weber State University personnel may transport biohazardous materials by noncommercial routes only in university vehicles. Personal vehicles may not be used.

- Some materials may never be transported via non-commercial routes. These materials are listed in the above-mentioned guidelines.

BIOLOGICAL MATERIAL INVENTORY AND BIOHAZARDOUS MATERIALS SECURITY

Biological Materials Inventory

Biological materials that are used or stored must be inventoried annually and made available upon request from EHS. The Biological Materials Inventory serves as a confidential, off-site record to help select university personnel, (DPS, emergency responders, EHS) 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 materials. 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 mandate specific security measures for all laboratories possessing Select Agents.

If you currently possess or plan to possess any Select Agents, contact EHS at (801) 626-7783 for specific security requirements.

APPENDIX A rDNA Registration Form

APPENDIX B Bloodborne Pathogen Exposure Control Plan

APPENDIX C Hepatitis B Vaccination Form

APPENDIX D WSU Laboratory Safety Survey

APPENDIX E rDNA and Biohazardous Waste Disposal Guide