



SONOMA STATE UNIVERSITY

Biosafety Manual

Department of Environmental Health & Safety
November 2021 Version 0

Table of Contents

1.0	INTRODUCTION	1-1
1.1	Purpose.....	1-1
1.2	Scope.....	1-1
1.3	Reference.....	1-1
2.0	ROLES & RESPONSIBILITIES	2-1
2.1	Environmental Health & Safety Department (EH&S)	2-1
2.2	Deans, Departments Chairs (or designee).....	2-1
2.3	Faculty/Principal Investigator.....	2-1
2.4	Staff, Student Assistants and Student Researchers	2-1
2.5	Biosafety Committee	2-1
3.0	BIOSAFETY LEVEL CRITERIA	3-1
3.1	Biosafety Level 1 (BSL-1).....	3-1
3.2	Biosafety Level 2 (BSL-2).....	3-1
4.0	STANDARD MICROBIAL PRACTICES AT SSU	4-1
4.1	Microbial Practices for Biosafety Level 2	4-1
5.0	FACILITY SPECIFIC REQUIREMENTS	5-1
5.1	BSL-1	5-1
5.2	BSL-2	5-1
6.0	SAFETY EQUIPMENT	6-1
6.1	Biological Safety Cabinets.....	6-1
6.2	Personal Protective Equipment (PPE).....	6-1
7.0	HANDLING AND CONTAINMENT	7-1
7.1	Biosafety Level 1	7-1
7.2	Biosafety Level 2	7-1
7.3	Animal Biosafety.....	7-2
7.4	Bloodborne Pathogens (BBP).....	7-2
7.5	Hazard Communication	7-2
7.6	Training	7-3
7.7	Disposal of Biological Waste	7-4
8.0	EMERGENCY PROCEDURES	8-1
9.0	APPROVAL PROCESS FOR BIOSAFETY LABORATORY	9-1
9.1	Approval for a BSL-1 with require the following:	9-1
9.2	Approval for a BSL \geq 2 will require the following:	9-1
10.0	REPORTING PROBLEMS	10-1
11.0	RECORD KEEPING	11-1

Appendix A: Biosafety Level Summary Chart

RECORD OF REVISIONS

Version	By	Date	Description of Revision
0	CG	11/2021	Initial document
-	-	-	-

Legend:

CG: Christy Gorman, Safety Program Manager

DEFINITIONS

Biohazard: an agent of biological origin that has the capacity to produce deleterious effects on humans, i.e. microorganisms, toxins, and allergens derived from those organisms; and allergens and toxins derived from higher plants and animals.

Biohazardous waste: is technically a subset of medical waste as defined in the Medical Waste Management Act (California Health and Safety Code; see sections 117690 & 117700 for more precise definitions). For SSU's purposes, biohazardous waste is any of the following:

1. Waste generated or produced as a result of:
 - a. Diagnosis, treatment, or immunization of human beings or animals
 - b. Research pertaining to activities in above
 - c. Regulated waste from trauma scenes
2. Laboratory waste including the following:
 - a. Human or animal specimen cultures from medical and pathology laboratories
 - b. Culture and stocks of infections agents (human or animal pathogens) from research and industrial laboratories
 - c. Wastes from the production of bacteria, viruses, or the use of spores, discarded live and attenuated vaccines used in human health care or research, discarded animal vaccines, including only Brucellosis, Contagious Ecthyma, and other animal vaccines, as identified by the department, and culture dishes and devices used to transfer, inoculate, and mix cultures.
 - d. Waste containing any microbiologic specimens.
3. Human surgery specimens or tissues suspected of being contaminated with infections agents
4. Animal parts, tissues, fluids, or carcasses suspected by the attending veterinarian of being contaminated with infectious agents known to be contagious to humans
5. Waste containing recognizable fluid blood, fluid blood products, containers of fluid blood, or equipment containing blood that is fluid or blood from animals known to be infected with diseases which are highly communicable to humans
6. Waste contaminated with excretion, exudate, or secretions from humans or animals under isolation to prevent infection
7. Waste from human surgery or tissues fixed in formaldehyde or contaminated with chemotherapeutic agents
8. Pharmaceutical waste
9. Biohazardous sharps waste to include home-generated sharps, but also includes sharps generated from above activities including anything that can produce a sharp protuberances or acute rigid corners (e.g. Glass/plastic pipettes, needles from syringes scalpels, broken glass, glass vials, microscope slides, etc.)

Biohazardous waste is **NOT**:

- Waste generated in food processing or biotechnology that does not contain an infectious agent, or an agent capable of causing an infection that is highly communicable.

- Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans or a highly communicable disease.
- Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomit, unless it contains visible or recognizable fluid blood.
- Waste which is not biohazardous, such as paper towels, paper products, articles containing non-fluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.
- Hazardous waste, radioactive waste, or household waste.
- Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch unless otherwise specified in law.

Biosafety: the application of safety precautions that reduce a laboratorian's risk of exposure to a potentially infectious microbe and limit contamination of the work environment and, ultimately, the community.

Biosafety Levels: are the levels of safety from exposure to infectious agents. There are four biosafety levels. Each level has specific controls required for containment of dangerous biological agents in an enclosed facility. The primary risks that determine levels of containment are infectivity, severity of disease, transmissibility, and the nature of the work conducted. Each biosafety level has its own specific containment controls that are required for practices/techniques, safety equipment, and laboratory facility construction. Sonoma State University does not conduct research activities beyond a BSL-2. All four levels of biosafety are summarized in Appendix A.

- Biosafety Level 1: work with microorganisms not known to cause disease in healthy human adults and of minimal potential hazard to personnel and the environment under ordinary conditions of use.
- Biosafety Level 2: work with microorganisms of moderate potential hazard to personnel and the environment.

Biosafety Officer (BSO): responsible for planning and implementation of the campus Biosafety Program with the purpose to ensure the health and safety of all personnel working with biohazardous agents.

Bloodborne Pathogens: pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBP), hepatitis C virus (HVC) and human immunodeficiency virus (HIV). For information on the campus Bloodborne Pathogen program, please go to the EHS website: <http://ehs.sonoma.edu/health-and-safety/bloodborne-pathogens>

Containment: a method of managing infectious agents in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory personnel, other persons and the outside environment to potentially hazardous agents.

- Primary containment: involves the protection of personnel in the immediate laboratory environment from exposure to infectious agents, and is provided by good microbiological technique, the use of proper safety equipment and appropriate vaccines.

- Secondary containment: refers to the protection of the environment external to the laboratory from exposure to infectious materials and is provided by a combination of facility design and operational practices.

Infectious agent: a type of microorganism, bacteria, mold, parasite or virus, including, but not limited to, organisms managed as Biosafety Level II-IV by the CDC that normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings.

Medical Waste: any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the federal Resource Conservation and Recovery Act of 1976 (Public Law 94-580), as amended;

1. Sharps and trace chemotherapy wastes generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals
2. Waste generated in autopsy or necropsy; waste generated in research pertaining to the production or testing of microbiologicals
3. Waste generated in research using human or animal pathogens
4. Sharps and laboratory waste that poses a potential risk of infection to humans generated in the inoculation of animals in commercial farming operations
5. Waste generated from the consolidation of home-generated sharps including personally generated waste such as syringe waste generated by persons who self-administer insulin for diabetic
6. Waste generated in the cleanup of trauma scenes.

For information on the campus Medical Waste program, please go the EHS website: <http://ehs.sonoma.edu/environmental-management/medical-waste-management>

Select Agents: pathogens and biological toxins which have been declared by the U.S. Department of Health and Human Services or by the U.S. Department of Agriculture to have the "potential to pose a severe threat to public health and safety." The Centers for Disease Control administers the Select Agent Program, which regulates the laboratories which may possess, use, or transfer select agents within the United States. A list of these materials can be found at: <http://www.selectagents.gov/select%20agents%20and%20Toxins%20list.html>

Standard Microbiological Practices: consists of aseptic techniques and other good microbiological practices, which are not uniformly defined, but are necessary, to prevent contamination of the laboratory with the agents being handled, and contamination of the work with agents from the environment.

Sharps: any device having acute rigid corners, edges, or protuberances capable of cutting or piercing, including, but not limited to, all of the following: any object used with infectious material that can be reasonably anticipated to penetrate the skin or any other part of the body, and to result in an exposure incident, including, but not limited to, needles, scalpels, lancets, broken glass, and broken capillary tubes. Sharps waste includes:

- Hypodermic needles with or without syringes
- Syringes contaminated with biohazardous waste

- Broken glass, such as Pasteur pipettes
- Blood vials contaminated with biohazardous waste
- Any contaminated trauma scene waste capable of cutting or piercing

Universal Precautions: a method of infection control by treating all human blood and certain human body fluids as infectious for HIV, HBV, HCV, and other bloodborne pathogens.

1.0 INTRODUCTION

This program is designed to protect faculty, staff, students, and the community from potential health hazards stemming from the use of infectious agents in various laboratory settings.

1.1 Purpose

To establish and maintain an effective Biosafety Program to protect faculty, staff, students, and the community from potential health hazards. This program is intended to provide the combination of standard and special microbiological practices for work with infectious agents in various laboratory settings. The requirements of this program apply to all university members engaged in the laboratory use of infectious agents.

Current campus facilities at Sonoma State University do not support work at any level higher than BSL-2. The requirements contained herein only apply to BSL-1 and BSL-2.

1.2 Scope

The program applies to all research, clinical and teaching activities conducted by SSU faculty, staff, students, contract employees and other personnel working at locations where SSU has management control of biohazardous materials. This program will ensure compliance with pertinent governmental and institutional guidelines, regulations and policies.

1.3 Regulations, Standards, Guidelines, and Other University Plans

- Bloodborne Pathogens, [Title 8 California Code of Regulations, Section 5193](#)
- [Biosafety in Microbiological and Biomedical Laboratories](#) Sixth Edition, 2009, U. S. Dept. of Health and Human Services, Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH).
- The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, [NIH Guidelines](#)
- The Association of Biosafety and Biosecurity, [ABSA International](#)
- Medical Waste Management Act, [California Health and Safety Code Sections 117600- 118360](#).
- Select Agents Program [National Select Agents Registry](#)

The Biosafety Program will work in concert with other Plans and Programs implemented by the University, including:

- Hazard Communication Program
- Respiratory Protection Program
- Bloodborne Pathogen Program (Exposure Control Plan)
- Emergency Response/Evacuation Procedures
- Chemical Hygiene Plan
- Institute for Animal Care and Use Committee (IACUC)

2.0 ROLES & RESPONSIBILITIES

2.1 Environmental Health & Safety Department (EH&S)

Environmental, Health & Safety (EH&S) and the EH&S Biosafety Officer (BSO) are responsible for developing, communicating, implementing, providing program information and training, and conduct annual inspections and reporting results to department management for this program campus wide.

2.2 Deans, Departments Chairs (or designee)

Deans, Departments Chairs (or designee) are responsible for communicating, promoting and enforcing the policy and the program guidelines in areas under their control. They will work with EH&S to identify biohazardous activities under their authority that fall under the purview of this program.

2.3 Faculty/Principal Investigator

Faculty/Principal Investigators are responsible for complying with the policy and program guidelines and for ensuring that staff and students working under their supervision are appropriately trained in the biohazards that are present in the work area and perform all work under the proper biosafety containment levels as required by this program. Additional responsibilities include:

- Submit a protocol to BSC for review/approval of any BSL 2
- Perform research and instruction
- Ensure students/research personnel are trained and training is documented
- Ensure accident forms are completed
- Routinely review protocols and provide changes to BSC

2.4 Staff, Student Assistants and Student Researchers

Staff, Student Assistants and Student Researchers are required to follow all training for biohazards present in areas in which they work or enter, and for working in the proper biosafety containment levels outlined in this program. They are responsible for informing others in the area of these requirements and reporting unsafe conditions to their supervisor, or EH&S.

2.5 Biosafety Committee

A Biosafety Committee (BSC) shall be formed to review projects involving biological agents. The BSC shall be comprised, at a minimum, of a Biology Dept. Faculty member familiar with BSL's and working with biological agents, a Lab Technician and a Manager from EH&S.

- The committee shall meet at a minimum, annually, or more frequently depending on the number of projects or changes to existing research.
- The BSC shall be a faculty-led committee per NIH guidelines.
- Changes, modifications or new research involving infectious agents, changes must be submitted to the BSC Chair and approved by the committee prior to their

implementation. The committee will focus and discuss the changes and any effect they may have on personnel safety or laboratory practices.

- The BSC must keep sign-in sheet of attendance to the meetings as well as agendas and minutes. The custodian of the records will reside with the EH&S Dept.
- The BSC shall conduct an inspection of all BSLs annually.
- In the event of a laboratory accident or accidental exposure, the BSC shall conduct an investigation with a focus on root cause analysis and lessons learned.
- Other duties include:
 - Conduct BSL inspections and risk assessments
 - Develops & approves BSC protocols and policies
 - Recommends/requires appropriate corrective measures to BSL's

3.0 BIOSAFETY LEVEL CRITERIA

The following guidelines from the CDC publication, Biosafety in Microbiological and Biomedical Laboratories (BMBL), will be used by all laboratory personnel, the BSO, and the BSC to determine the proper practices, safety equipment and facilities applicable to the hazards present. SSU does not conduct any research above the level of BSL-2. See Appendix A for complete Biosafety Level Summary chart.

3.1 Biosafety Level 1 (BSL-1)

BSL-1 practices, safety equipment and facility design and construction are appropriate for undergraduate and secondary educational training and teaching laboratories and for other laboratories in which work is done with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans.

3.2 Biosafety Level 2 (BSL-2)

BSL-2 practices, equipment and facility design and construction are applicable to clinical, diagnostic, teaching and other facilities in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity.

4.0 Standard Microbial Practices at SSU

Following are standard microbiological practices that apply to all biosafety levels. These practices are common sense principals that protect personnel, the experiment, and the environment. They include the following:

- Access to the laboratory will be limited or restricted when experiments or work with cultures and specimens is in progress.
- Biological agents are not to be transported between laboratories on campus. Work must be performed at the designated BSL. Exceptions must be vetted through the Biosafety Committee.
- Decontaminate work surfaces after use, after any spill of viable materials, and at least once per day.
- Eating, drinking, smoking, applying cosmetics, handling contact lenses and storing food are prohibited in work areas. Food must be stored in cabinets or refrigerators solely designated for this purpose and should be located outside the work area.
- Use mechanical pipetting devices; mouth pipetting is prohibited.
- Restrict the use of needles and syringes to those procedures for which there are no alternatives; use needles, syringes, and other “sharps” carefully to avoid self-inoculation; and dispose of “sharps” in leak and puncture resistant containers. Ensure container is properly labeled.
- Procedures for the safe handling of sharps are instituted.
- Wash hands after handling cultures or animals, after removing gloves, and before leaving the room.
- Carefully perform all procedures to minimize the creation of aerosols and splashes.
- Long pants and closed-toed shoes are required in all BSL’s.
- Protective eyewear should be worn for activities and procedures in which splashes are anticipated.
- Laboratory coats or gowns are required.
- Wear lab coat, gloves and safety glasses to prevent contamination from the infectious material, and remove protective equipment prior to leaving the lab area.

4.1 Microbial Practices for Biosafety Level 2

In addition to the standard microbial practices listed above, the following practices shall be followed when working with or around biosafety level 2 agents/materials:

- Safety cabinets or other appropriate combinations of personal protective equipment and physical containment devices (centrifuge safety cups, sealed centrifuge rotors, containment caging for animals) should be used for the following:
 - Procedures with a high potential for creating infectious aerosols.
 - Procedures using high concentrations or large volumes of infectious agents.
 - Handle all liquid and solid waste as though infectious.

- Decontaminate work surfaces on completion of work, or at the end of the day, and after any spill or splash of viable material with disinfectants that are effective against the agents of concern.
- Dispose of all biohazardous waste in accordance with applicable regulations.
- Wash hands after handling any biohazardous material and before leaving the laboratory.
- Take special care to avoid skin contamination with infectious material; gloves should be worn when skin contact with infectious materials is unavoidable.
- Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps.

5.0 Facility Specific Requirements

The biosafety levels range from BSL-1 to BSL-4. Each biosafety level builds on the control of the level before it. Every microbiology laboratory, regardless of biosafety level follows standard microbiological practices. Sonoma State University does not conduct research activities beyond a BSL-2.

5.1 BSL-1

If you work in a lab designated a BSL-1, the microbes there are not known to consistently cause disease in healthy adults and present minimal potential hazard to laboratorians and the environment. An example of a microbe that is typically worked with at a BSL-1 is a nonpathogenic strain of *E. coli*.

5.1.1 Laboratory practices

- Standard microbiological practices are followed
- Work can be performed on an open lab bench or table.

5.1.2 Safety equipment

- Personal Protective Equipment (PPE) consists of lab coats, gloves, and eye protection to be worn as needed.

5.1.3 Facility construction

- A sink must be available for hand washing
- The lab should have doors to separate the working space with the rest of the facility.

5.2 BSL-2

BSL-2 builds upon BSL-1. If you work in a lab designated a BSL-2, the microbes there pose moderate hazards to laboratorians and the environment. The microbes are typically indigenous and associated with diseases of varying severity. An example of a microbe that is typically worked with at a BSL-2 laboratory is *Staphylococcus aureus*.

In addition to BSL-1 considerations, BSL-2 laboratories have the following containment requirements:

5.2.1 Laboratory practices

- Access to the laboratory is restricted when work is being conducted.

5.2.2 Safety equipment

- Appropriate PPE is worn, including lab coats and gloves. Eye protection and face shields can also be worn as needed.
- All procedures that can cause infection from aerosols or splashes are performed within a biological safety cabinet (BSC).
- An autoclave or an alternative method of decontamination is available for proper disposals.

5.2.3 Facility construction

- The laboratory has self-closing doors.
- A sink and eyewash are readily available.

6.0 Safety Equipment

The risk of exposure of laboratory personnel can be minimized by the use of carefully selected safety equipment. This safety equipment should effectively isolate the worker from the toxic or infectious material being processed.

6.1 Biological Safety Cabinets

Biological safety cabinets are used extensively to prevent the escape of aerosols and droplets and to protect materials from airborne contamination. The types used at Sonoma State University are Class II biological safety cabinets, which provide protection to the worker, the environment and the products. Both the supply and the exhaust air are HEPA-filtered. These cabinets are partial containment devices, which if used in conjunction with good laboratory practices, can dramatically reduce the risk of exposure to infectious aerosols and droplets.

Although biological safety cabinets with HEPA filters protect operators from exposure to particulates, including bacteria, viruses, and so forth, they do not absorb chemical vapors or gases. For this reason, biological safety cabinets with recirculating airflow (Class II biological safety cabinets) cannot be used for protection against gases and vapors, as there is the potential for buildup of hazardous concentrations within the cabinet.

Biological safety cabinet systems are tested and certified annually to ensure they are functioning properly.

6.2 Personal Protective Equipment (PPE)

There may be hazards that require specialized personal protective equipment in addition to safety glasses, laboratory gowns, and gloves. For example, a procedure that presents a splash hazard may require the use of a mask and a face shield to provide adequate protection.

7.0 Handling and Containment

The handling of all biological materials will employ the Principles for Good Microbiological Practice, as the base for all biosafety levels. In addition, the following requirements will also be employed:

7.1 Biosafety Level 1

- The guidelines of this Biosafety Program must be enforced by the PI or lab supervisor for his or her lab spaces and personnel (staff and students).
- To prevent contamination while working with potentially hazardous biological material; personnel must wear appropriate personal protective equipment (PPE); gloves, closed toe shoes, and safety glasses, and remove them when leaving the work area.
- Universal Precautions must be followed. These precautions were designed for working with bloodborne pathogens and are required for work with any Biosafety Level 2 and higher infectious agents. In addition, it is an excellent system to employ while working with any biological material.
- When work is being conducted all work surfaces must be decontaminated with approved sanitizers once per day after work is complete and after any spill of viable material.
- Eating, drinking and applying cosmetics are not permitted in labs. Food must be stored in cabinets or refrigerators designated for this purpose and must be located outside the work area.
- Hand washing should occur after handling viable materials and animals and before leaving the lab.
- Biological materials must be transported in labeled, leak-proof containers. In addition, infectious material must be placed in a red biohazard bag.

7.2 Biosafety Level 2

This includes all of BSL-1 requirements above plus:

- Access must be limited to authorized individuals in areas where experiments with infectious agents are in progress.
- A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include:
 - the laboratory's biosafety level
 - the supervisor's name (or other responsible personnel) and telephone number
 - the required procedures for entering and exiting the laboratory
- Clearly label areas in which infectious agents are used or stored and, using the biohazard symbol, designate specific areas or equipment where those materials are routinely used or stored.
- Individuals working with known infectious agents must be provided with medical surveillance and offered appropriate immunizations when applicable.

- Laboratory supervisors must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
- Incidents involving potential exposure must be reported immediately to the PI and Biosafety Officer/EH&S.
- All procedures involving the manipulation of infectious materials that may generate an infectious aerosol or splashes should be conducted within a certified biological safety cabinet (BSC) or other physical containment devices. These may include pipetting, centrifuging, grinding, blending, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting tissue from animals or eggs.
- Personal protective equipment (PPE) must be worn at the level determined by the Laboratory Hazard Assessment.

NOTE: Current campus facilities do not support work at any level higher than BSL-2. Any projected work at a higher level is not permitted.

7.3 Animal Biosafety

Laboratory animal facilities are a special type of laboratory. As a general principle, the biosafety level (facilities, practices, and operational requirements) recommended for working with infectious agents in vivo and in vitro are comparable. In the animal room, the activities of the animals themselves can present unique hazards not found in standard microbiological laboratories. Animals may generate aerosols, may bite and scratch, and they may be infected with a zoonotic agent.

Allergens are associated with lab animal materials, including fur, skin, dander, saliva, urine, and feces. The concentration of allergens can vary significantly by species, sex, and age of the animal (for example, males, older males, and the C57BL/6J strain all produce greater amounts of mouse urinary proteins). Workers can be exposed through inhalation of airborne particles, skin contact, and contact with facial mucous membranes. Basic allergen containment should be employed where applicable.

7.4 Bloodborne Pathogens (BBP)

Bloodborne pathogens are pathogenic microorganisms that are transmitted via human blood and cause disease in humans. They include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV). All work with human-derived blood, body fluids, tissues or primary human cell lines where the presence of an infectious agent may be unknown will be performed using BSL-2 containment procedures. More information on the campus Bloodborne Pathogen program can be found on the EHS website: <http://ehs.sonoma.edu/health-and-safety/bloodborne-pathogens>

7.5 Hazard Communication

7.5.1 Signs

Signs shall be posted at the entrance to all BSL-2 or higher work areas which shall bear:

- Name of the infectious agent(s).
- International symbol for biohazard in fluorescent orange-red.
- Special requirements for entering the area.
- Name and telephone number of the laboratory PI (or other responsible person).

7.5.2 Warning labels

Warning labels shall be affixed to: containers of infectious waste; refrigerators and freezers containing blood and other potentially infectious materials; and other containers used to store or transport blood or other potentially infectious materials. Labels shall have the international biohazard symbol. The labels shall be fluorescent orange or orange-red with lettering or symbols in a contrasting color. The labels shall either be an integral part of the container or shall be tightly affixed to the container by adhesive to prevent their loss or removal.

7.6 Training

The goal of the biosafety training is to ensure that all individuals potentially at risk are adequately informed about the hazards in the laboratory, their risks, and what to do if an accident occurs.

Individual supervisors and PIs, in consultation with EH&S, shall ensure that all students and employees with potential for occupational exposure are trained in:

- The proper techniques for handling and disposal of biohazardous materials.
- PIs and supervisors must ensure that students and employees are trained in and demonstrate proficiency in standard microbiological practices and in operations specific to the laboratory in question before being allowed to work with biohazards.
- Specific training on the warning signs and symptoms of infection with the biohazard being used shall be included.
- If applicable, training should also include aspects of the Bloodborne Pathogen program that would directly affect their specific laboratory work.
- Emergency procedures for spills and personnel contamination as outlined in this program.
- Emergency procedures for injuries or accidents involving laboratory personnel.

Every faculty, staff and student working in a laboratory should know the location and proper use of personal protective equipment and basic emergency response procedures.

Training shall be provided when faculty, staff and students are initially assigned to a laboratory where biological hazards are present and also prior to assignments involving new materials or work procedures.

Completion of the following training, at a minimum, available on CSU Learn:

- Laboratory-specific procedures, policies and practices (provided by the PI)

- CSU IBC Compliance Training
- CSU Laboratory Safety Fundamentals
- Bloodborne Pathogen Training

7.7 Disposal of Biological Waste

7.7.1 Laboratory cultures

Laboratory cultures include the biological agents that contains or has been in contact with infectious agents, potentially infectious materials or recombinant or synthetic nucleic acids, (cells cultures, plants, algae, or other living entity) from research laboratories, wastes from their production, and culture dishes and devices used to culture, transfer, inoculate, and mix cultures.

- All biologically active materials must be inactivated by autoclaving, ultraviolet (UV) light, germicidal agent, or any other proven effective method before disposal into the regular trash. All waste must be rendered “environmentally neutral” before placing in the regular trash.
- All inactivated biological waste that is contained in bags that have a biohazard symbol MUST be placed in an opaque bag (no biohazard symbol or red bag should be visible) before disposal into the regular trash.
- Unless otherwise established, inactivated waste will be taken directly to the regular trash bins by the user.

7.7.2 Animal Waste

- Vertebrates or fish must be placed in clear plastic bags and frozen, when possible, and arranged as disposal as pathological waste.
- Invertebrates must be placed in tightly closed plastic bags and taken directly to dumpsters outside the building.
- Preserved animals and animal parts must be placed in plastic bags and EH&S consulted for disposal. Any animal carcass or animal parts which have been preserved in formaldehyde or any other preservative must have as much of the preservatives decanted from the carcass as possible and be drained completely of any fluids before they can be placed in any container for disposal. Please note: the decanted preservative is hazardous waste and will be placed in a labeled waste container. Notify EH&S for pickup of the pathological and hazardous waste collected from the preserved specimens.

7.7.3 Medical Waste

Medical Waste must be placed in red (labeled) “biohazard” bags and arranged for pickup. For information on the campus Medical Waste Management Program, go the EHS website: <http://ehs.sonoma.edu/environmental-management/medical-waste-management>

7.7.4 Sharps needle waste

Sharps needle waste must be placed in red (labeled) “biohazard” plastic sharps container. For more information on sharps needle waste, consult the campus Medical Waste Management Program on the EHS website:

<http://ehs.sonoma.edu/environmental-management/medical-waste-management>

7.7.5 Mixed Waste

Mixed Waste is waste that has different categories of waste, such as biological waste mixed with chemicals or radioactive material. Use the following hierarchy to categorize the waste.

- If biohazardous and radioactive:
 - Inactivate the biohazard, if possible (use procedures approved by the Radiation Safety Officer which restrict further contamination). Classify as radioactive and treated accordingly.
 - See campus Radiation Safety manual for treatment of radioactive materials.
- If chemically hazardous and biohazardous:
 - Classify as chemically hazardous and treat accordingly.
 - Call Chemical Hygiene Officer/EH&S for specific instructions.
- If biohazardous, chemically hazardous and radioactive:
 - Classify as radioactive and treat accordingly.
- If chemically hazardous and radioactive (no biohazards present):
 - Contact Radiation Safety Officer/EH&S for specific treatment or pickup for those radioactive materials and chemicals.

7.7.6 Miscellaneous Biological Waste

- Animal blood and body fluids -- fresh, uninfected, untreated body fluids (USDA Grade, for example) must be disposed of in the laboratory drain (sanitary sewer), with copious amounts of water.
- Human or animal urine – dispose of in the toilet or the laboratory drain with copious amounts of water; rinse the sink thoroughly with a 0.1% bleach solution.
- Human cheek cells collected on swabs – dispose of in normal trash.

7.7.7 Autoclave Use for Biological Waste

An autoclave uses high pressure saturated steam to sterilize equipment and supplies and is highly effective for inactivating biohazardous materials. Consult the Medical Waste Management Program for guidelines to safely sterilize biological waste. Inactivation of biological waste must follow the standard operating procedures for autoclave sterilization and calibration listed in the Medical Waste Management Program. Autoclaves must be maintained as per manufacturers' suggested procedures by qualified personnel.

- Solid Waste
 - Waste must be in an autoclave bag, with at least 200 ml of liquid.
 - Bag must be vented to allow proper steam penetration.
 - Bag should have a temperature indicator (e.g., autoclave tape).
 - Bag must be placed in a metal pan to catch any leakage.
 - Waste must be autoclaved for at least 45 minutes on LIQUID setting.

- Temperature must reach and be maintained at 250°F (121°C) and pressure must be maintained at 15 lbs. for the entire autoclave time.
- Place autoclaved waste into regular trash bags and, after the waste has cooled, take directly to outside dumpsters.
- Liquid Waste
 - Place containers of liquid waste in trays to collect any spilled material.
 - Autoclave for 45 minutes on LIQUID setting.
 - Dispose of liquid in lab sinks.
 - Strain out any solid material, place in plastic bags and dispose as regular trash.

8.0 Emergency Procedures

Appropriate emergency procedural documents must be available in all areas where biohazardous work occurs. In the event of any spill or contamination, immediately notify the PI or instructor and the Biosafety Officer/EH&S as soon as possible for follow-up.

8.1.1 BSL-1 Spills

Usually a “just clean it up” approach is most appropriate. Administrative follow-up is not required unless the spill involves personal injury, or a spill of recombinant DNA in a publicly accessible area such as a corridor.

1. Cover spill with paper towels.
2. Carefully pour disinfectant onto the paper towels, starting at the periphery and working inward toward the center. Allow sufficient contact time for disinfectant.
3. If sharps are involved do not use hands to pick up; rather, use forceps or a brush and dustpan.
4. Transfer to appropriate waste container.
5. If spill involves personal injury, report to supervisor immediately.
6. If spill is a recombinant DNA spill of more than 500 mL or the spill is in a publicly accessible area such as a corridor, notify the BSO immediately.

8.1.2 BSL-2 Spills

The spill response depends upon location and volume.

- Spills inside the biosafety cabinet (BSC) are considered “contained”.
- Spills outside the BSC are of much greater concern since there is a risk of exposure to an infectious agent via aerosols or possible skin exposure via a splash.
- Categories of spills also are subdivided into “minor” and “major.”
- “Minor spills” are somewhat arbitrarily defined as spills of 10 ml or less, where there is little chance that a splash could get out of control before it could be contained with absorbent material.
- “Major spills” are anything over 10 ml, where there is a risk that the liquid is not easily contained.
- Special considerations are required for centrifuge accidents, biohazard spills involving radioactivity (decontaminate first, then clean up as for radioactive spills), and biohazards with toxic chemicals.
- Labs working with biological toxins must have standard operating procedures (SOPs) for decontamination of those agents.

8.1.3 Spills containing recombinant or synthetic nucleic acid molecules

Spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the:

- Biosafety Committee or Biosafety Officer (BSO) and;
- NIH OSP- reports to NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov; (301) 496-9838. Additional contact information is also available on the [OSP website](#);
- Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

8.1.4 Composition of a Basic Spill Kit

Microbiological and biomedical research laboratories should prepare and maintain a biological spill kit. A spill kit is an essential safety item for labs working with microbiological agents classified at BSL-2 or higher and for groups working with large volumes (more than 1 liter) of BSL-1 material. A basic spill kit should include:

- Concentrated household bleach
- A spray bottle for making 10 percent bleach solutions
- Forceps, autoclavable broom and dust pan, or other mechanical device for handling sharps
- Paper towels or other suitable absorbent
- Biohazard autoclave bags for the collection of contaminated spill clean-up items
- Utility gloves and medical examination gloves
- Face protection (eye wear and mask, or full-face shield)

8.1.5 Personnel Contamination

1. Remove contaminated clothing
2. Wash the exposed area with soap and rinse with water for 15 minutes. Use a safety shower or eyewash as necessary.
3. Obtain medical evaluation and treatment if appropriate.
4. Any sharps or puncture wound, animal bite, or contamination by BSL-2 or higher must be subject to medical evaluation followed by notification to the Biosafety Officer and PI or supervisor.

8.1.6 Research Related Illness

A research related illness may be suspected if an illness develops with symptoms of those for the biological agent being studied.

- Steps:
 1. For treatment/counseling go to Health Center (student or student assistant), or Emergency Room.
 2. Notify supervisor.
 3. Supervisor notifies Biosafety Officer or EH&S within 48 hours for follow-up and reporting to appropriate entities.

9.0 APPROVAL PROCESS FOR BIOSAFETY LABORATORY

9.1 Approval for a BSL-1 will require the following:

- Submit a summary of the research to be conducted. Include the procedures that will be utilized for the work to be conducted.
- Submit a Project Hazard Assessment (PHA) for the hazards that may potentially be present in the laboratory and how to mitigate the potential risks.
- Establish emergency procedures in the event of a spill or incident.
- All personnel working in the laboratory have signed the PHA training sheet acknowledging lab specific training.
- Must pass the BSL inspection.

9.2 Approval for a BSL \geq 2 will require the following:

- Submit a summary of the biological research to be conducted. Include the procedures/policies that will be utilized for the work to be conducted.
- Submit a Project Hazard Assessment (PHA) for the hazards that may potentially be present in the laboratory and how to mitigate the potential risks.
- Establish emergency procedures in the event of a spill or personnel accident/incident.
- All personnel working in the laboratory have signed the PHA training sheet acknowledging lab specific training.
- The BSC approves of your project.
- Must successfully pass the BSL inspection.
- All equipment has been calibrated and functioning properly.
- All chemicals are properly labeled and an inventory has been completed.
- All training has been completed and documented.

10.0 Reporting Problems

Researchers are required to report to the BSC and the BSO any significant problems pertaining to the execution and implementation of biohazard-containment practices and procedures, violations of the NIH Guidelines, and all significant research-related accidents and illnesses. Serious problems or events – such as those resulting in serious injury or death – must be reported to the BSO immediately whenever possible or at least within 48 hours from the onset of the incident. Other, non-serious incidents must be reported within five business days.

11.0 Record Keeping

Proper records shall be prepared and maintained to document all policies, procedures, PHA's, inspection records, BBP Exposure Control Plans and training activities. Departments must keep all training records for a period of at least three years plus current year.

Appendix A: Biosafety Level Summary Chart

Biosafety Level Summary Chart

BSL Level	Agents	Practices & Techniques	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to cause disease in healthy adults.	Standard Microbiological Practices	None: primary containment provided by adherence to standard laboratory practices during open bench operations.	Open bench top and sink
2	Agents associated with: - Human disease - Hazards include skin absorption, ingestion, mucous membrane exposure	BSL-1 plus: - Limited access - Biohazard warning signs - Sharps precautions - Waste decontamination - Medical surveillance	- Primary containment = Class II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials - PPE: laboratory coats; gloves; face protection, as needed	Basic 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 waste - Decontamination of lab clothing before laundering - Baseline serum	- Primary containment = Class II or III BSCs or other physical containment devices used for all open manipulations of agents. - PPE: protective lab clothing; gloves; respiratory protection as needed	BSL 2 plus: - Physical separation from access corridors - Self-closing, double-door access - Exhausted air not recirculated - Negative airflow into laboratory
4*	- Dangerous/exotic agents which post high individual risk of aerosol-transmitted laboratory infections that are frequently fatal, for which there are no vaccines or treatments - Agents with a close or identical antigenic relationship to an agent requiring BSL-4 until data are available to redesignate the level - Related agents with unknown risk of transmission	BSL-3 practices plus: - Clothing change before entering - Shower on exit - All material decontaminated on exit from facility	Primary barriers: All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air supplied, positive pressure suit	BSL-3 plus: - Separate building or isolated zone - Dedicated supply and exhaust, vacuum, and decontamination systems - Other requirements outlined in the text

****All work using BSL-3 and BSL-4 materials is currently not permitted at SSU facilities***