General Biosafety

Environmental Health & Safety

UMass Chan MEDICAL SCHOOL | UMass Memorial Health

Topics to be Covered

- General Overview
- Risk Assessment
- Biosafety Levels
- Standard Practices
- Principles of Biosafety
- Biosafety Containment
- Biological Safety Cabinets
- Decontamination
- Spill Response
- Proper Waste Disposal
- Shipping Biologicals

Introduction

Biosafety can be defined as a group of practices and procedures designed to provide safe environments for individuals who work with potentially hazardous biological materials in laboratory environments.

- The primary goal of biosafety is to reduce or eliminate exposures to these agents through the use of containment.

General Overview

Scope of Training

- This training is an overview of the Federal guidelines concerning biosafety practices and how these practices are applicable to the research and clinical research laboratories.

General Overview

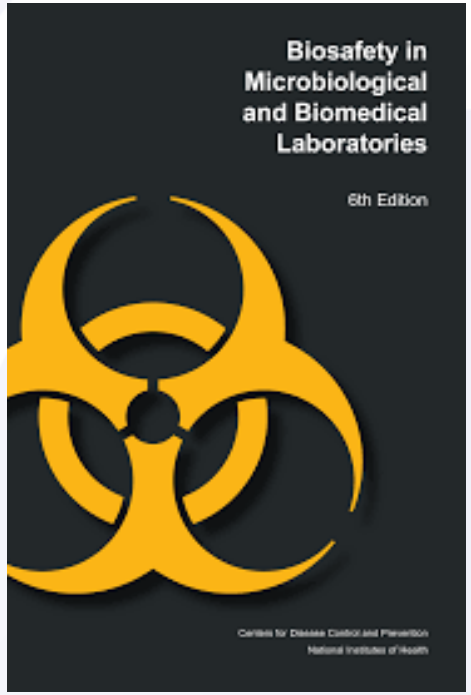
Who Needs this Training?

- All individuals who work with or have access to biohazardous materials

Guidelines/Regulations

Guidelines and regulations that apply to research involving infectious materials:

- **CDC** Biosafety for Microbiological and Biomedical Laboratories, 6th ed.
- **NIH** Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- **OSHA** Bloodborne Pathogen Standard
- Massachusetts Biological Waste Regulations
- CDC/USDA Select Agent Regulations
- US Dept. of Transportation (**DOT**)
- International Air Transport Association (**IATA**) Dangerous Goods Regulations



Common Biological Materials

- **Biological agents**
  - Bacteria, virus, prions, parasites, fungi, etc.
- **Human and Non-Human Primate (NHP) materials**
  - Primary cells, blood, tissues, organs, and cell lines
- **Animals (experimentally inoculated or harboring endemic zoonoses, animals engrafted with human cells, transgenic animals etc.)**
- **Transgenic plants, weeds, plant pathogens**
- **Biological toxins**
- **Recombinant & Synthetic Nucleic Acids (rsNA)**

Risk Assessment

UMass Chan MEDICAL SCHOOL | UMass Memorial Health

Risk Assessment: General

The safe handling of biological agents requires an assessment of the potential hazards associated with all aspects of an experiment including the agent, specific procedures to be performed, lab space and equipment used, and a person's research experience.

Risk Assessment: General

Prior to working with a biological material, a risk assessment should be conducted. At a minimum, the risk assessment should include the following:

- Pathogenicity of the biological material and infectious dose
- Consideration of the outcome of an exposure
- Natural route of exposure
- Other routes of infection (parenteral, airborne, ingestion, etc.)
- Stability of biological material in the environment
- Concentration of biological material and amount to be manipulated

(Continued on next slide)

Risk Assessment: General

- Presence of a suitable host
- Information available from animal studies and reports of laboratory-acquired infections or clinical reports
- How the biological material will be used (concentration, sonication, aerosolization, centrifugation, etc.)
- Any genetic manipulation of the organism that may extend the host range of the agent or alter the agents' sensitivity to known, effective treatment regimens
- Local availability of effective prophylaxis or therapeutic interventions
- Based on this information, the institutional biosafety committee (IBC) will assign a biosafety level to the planned project

Risk Assessment: Limited Information

There are situations when the information is insufficient to perform a risk assessment. For these situations, the following conservative approach should be used:

- Universal Precautions procedures should always be followed, and barrier protections applied (gloves, gowns, eye protection), regardless of the origin of the samples.
- Biosafety level 2 should be the minimum requirement for the handling of specimens.
- Transport of specimens should follow international and/or national rules and regulations.

Risk Assessment: Biological Expression Systems

Biological expression systems consist of vectors and host cells. When conducting a risk assessment, you should consider the following:

1. Whether or not the expression of DNA sequences derived from pathogenic organisms may increase the virulence of the genetically modified organism (GMO);
2. Whether or not the inserted DNA sequences are well characterized; for example, during the preparation of the genomic DNA libraries from pathogenic microorganisms;
3. The potential pharmacological activity of the gene products;
4. Whether or not there is a gene product code for toxins.

Risk Assessment: Genetically Modified Microorganisms (GMO)

Risk assessments for genetically modified microorganisms (GMOs or GMMOs) should consider the characteristics of donor and recipient/host organisms. At a minimum, the following:

- Hazards arising directly from the inserted gene (donor organism)
  - Toxins
  - Cytokines
  - Hormones
  - Gene expression regulators
  - Virulence factors or enhancers
  - Oncogenic gene sequences
  - Antibiotic resistance
  - Allergens

Risk Assessment: Genetically Modified Microorganisms (GMO)

- **Hazard associated with the recipient/host**
  - Susceptibility of the host
  - Pathogenicity of the host strain, including virulence, infectivity, and toxin production
  - Modification of the host range
  - Recipient immune status
  - Consequences of exposure

- **Hazard arising from the alteration of existing pathogenic trails**
  - Is there an increase in infectivity or pathogenicity?
  - Could any disabling mutation within the recipient be overcome as a result of the insertion of the foreign gene?
  - Does the foreign gene encode a pathogenicity determinant from another organism?
  - If the foreign DNA does include a pathogenicity determinant, is it foreseeable that this gene could contribute to the pathogenicity of the GMO?
  - Is treatment available?
  - Will the susceptibility of the GMO to antibiotics or other forms of therapy be affected as a consequence of the genetic modification?
  - Is eradication of the GMO achievable?

Biosafety Levels

UMass Chan MEDICAL SCHOOL | UMass Memorial Health

Biosafety Levels

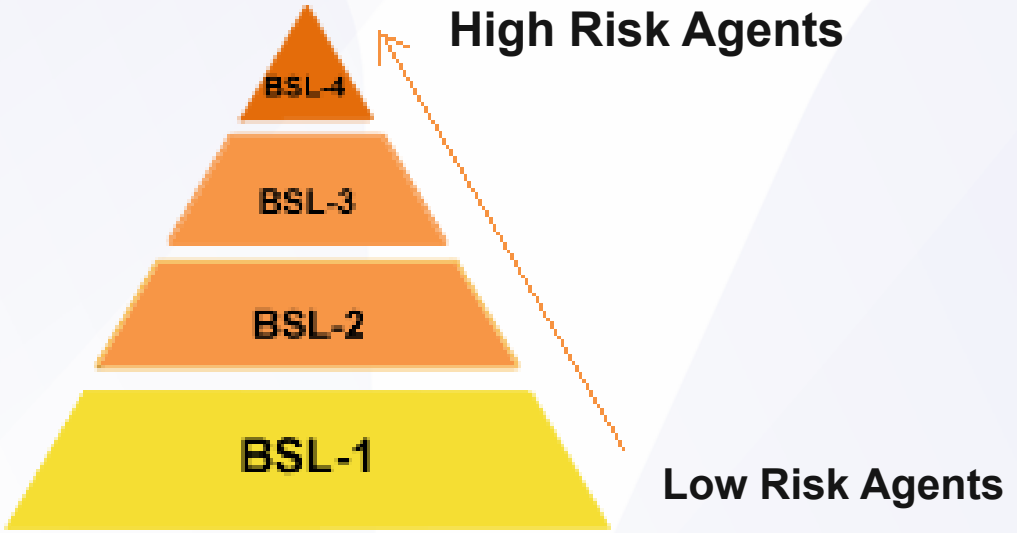
Biosafety Levels (BSLs) consist of combinations of facility design features and safety equipment (primary and secondary barriers), facility practices and procedures, and personal protective equipment.

- Each level has specific controls for containment in order to reduce the risk of exposure to a potentially infectious microbe and limit contamination of the work environment and, ultimately, the community.

Biosafety Levels

Biosafety Levels are assigned from low-risk agents and procedures at BSL-1 to high risk at BSL- 4.

- As risk increases, the biosafety containment level increases.



Biosafety Levels: NIH Risk Groups

The NIH Risk Group of an agent is incorporated into the risk assessment. NIH Risk Groups closely mirror CDC Biosafety Levels with a few exceptions.

Risk Group 1	Risk Group 2	Risk Group 3	Risk Group 4
Agents are not associated with disease in healthy adult humans.	Agents are associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often available.	Agents are associated with serious or lethal human disease for which preventative or therapeutic interventions may be available.	Agents are likely to cause serious or lethal human disease for which preventative or therapeutic interventions are usually not available.

Biosafety Levels: BSL1

The majority of biological research is at biosafety level 1 (BSL1) and biosafety level 2 (BSL2) containment and work practices.

BSL	Agents	Special Practices	Primary Barrier and Personal Protective Equipment	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

Biosafety Levels: BSL2

BSL	Agents	Special Practices	Primary Barrier and Personal Protective Equipment	Facilities (Secondary Barriers)
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

Biosafety Levels: BSL3 and BSL4

BSL	Agents	Special Practices	Primary Barrier and Personal Protective Equipment	Facilities (Secondary Barriers)
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

Biosafety Levels: BSL3 and BSL4

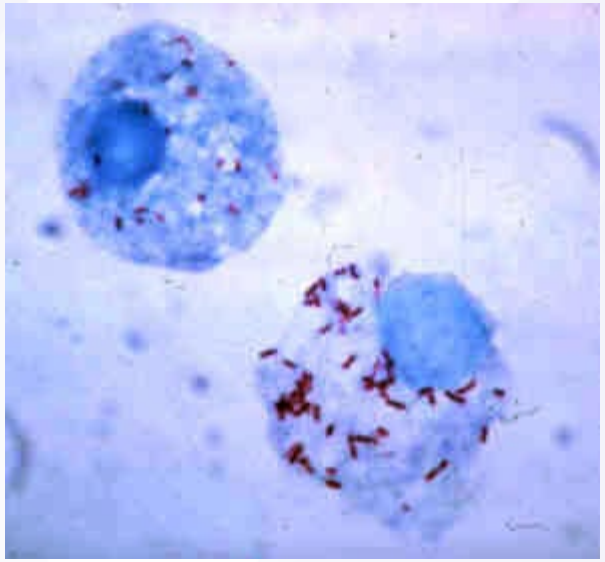
BSL	Agents	Special Practices	Primary Barrier and Personal Protective Equipment	Facilities (Secondary Barriers)
4	Dangerous and exotic agents that pose high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that are frequently fatal, for which there are no vaccines 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;[b] gloves;[b] full-body, air-supplied, positive-pressure suit[c]	Entry sequence; entry through airlock with airtight doors;[c] walls, floors, ceilings form sealed internal shell; dedicated, non-recirculating ventilation system required; double-door, pass-through autoclave required

UMass Chan MEDICAL SCHOOL | UMass Memorial Health

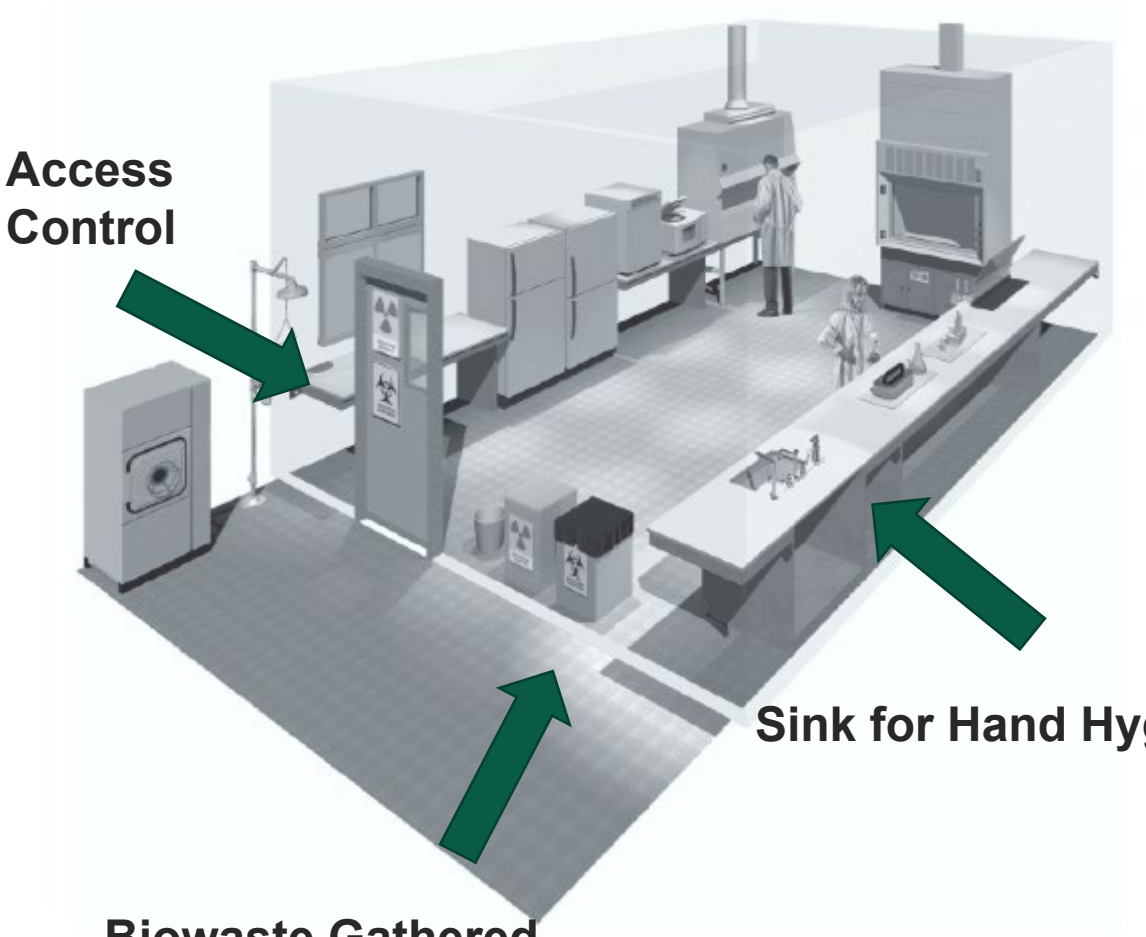
Other Lab Designations: BSL-2+

BSL-2+ (Biosafety Level-2 Enhanced)

- **Although this is not a defined regulatory containment level, it is described as a BSL2 facility with BSL3 practices**
  - All manipulations of agents are performed exclusively in a primary containment device (BSC, sealed centrifuge rotors, etc.)
  - Work surfaces and waste must be decontaminated
  - Additional PPE
  - Additional Administrative Controls
  - Procedures depend on IBC protocol
- Examples of agents used at this level are:
  - HIV, Zika Virus, some work with Lentivirus

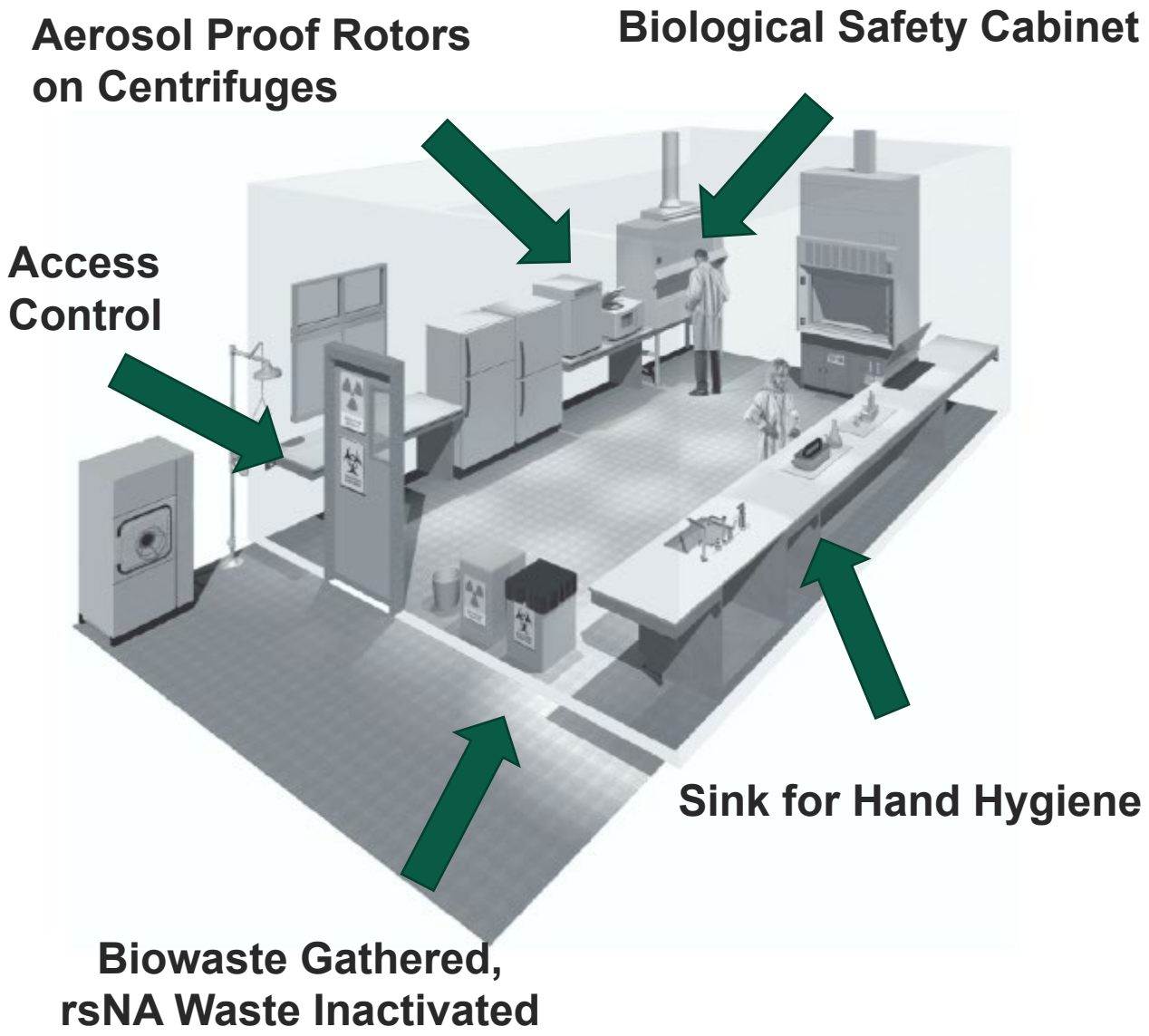


Biosafety Level 1 Laboratory



UMass Chan MEDICAL SCHOOL | UMass Memorial Health

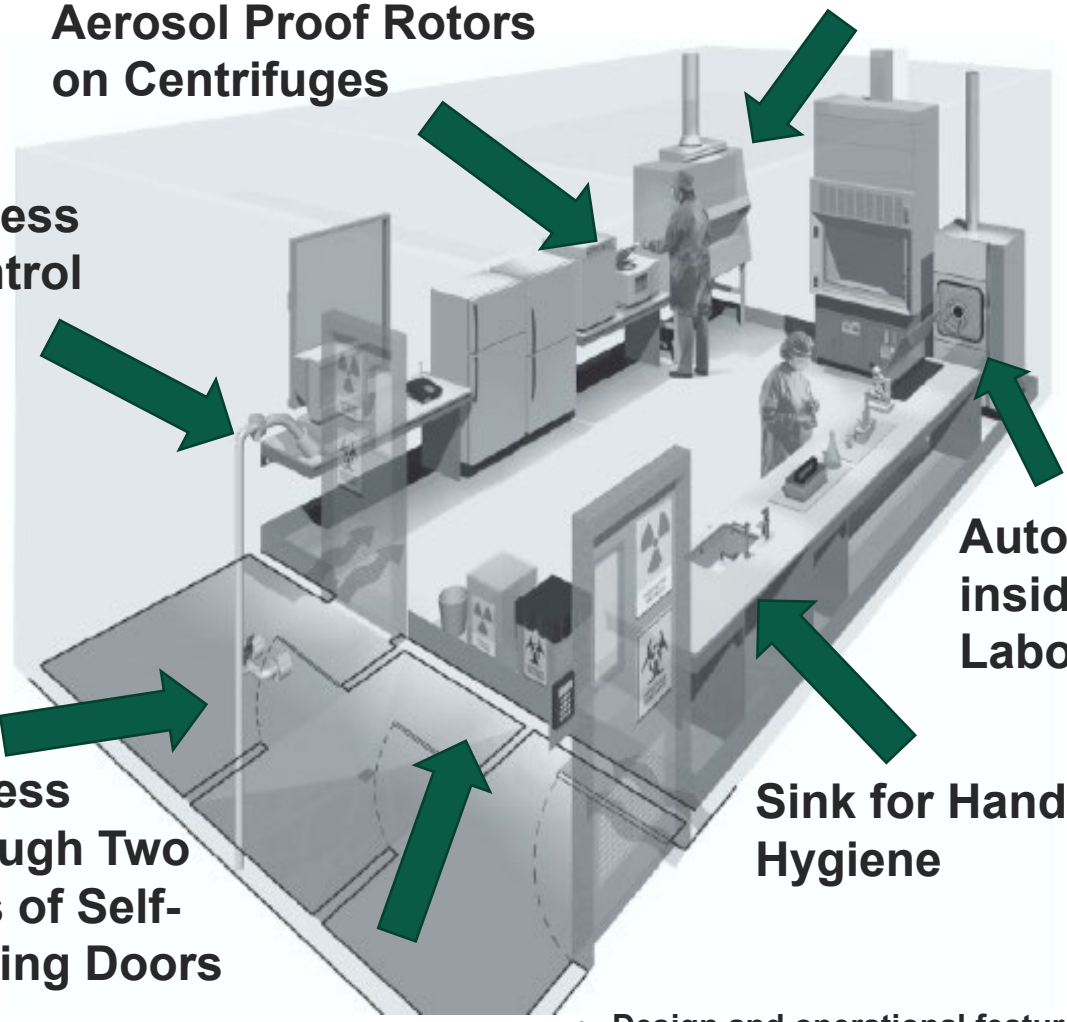
Biosafety Level 2 Laboratory



UMass Chan MEDICAL SCHOOL | UMass Memorial Health

Biosafety Level 3 Laboratory

UMass Chan MEDICAL SCHOOL | UMass Memorial Health



- Design and operational features must be tested and documented yearly
- Seams in walls, floors, ceiling are sealed
- Areas around doors and ventilation openings capable of being sealed for decontamination of the space

Standard Practices

UMass Chan MEDICAL SCHOOL | UMass Memorial Health

Standard Practices: All Biosafety Levels

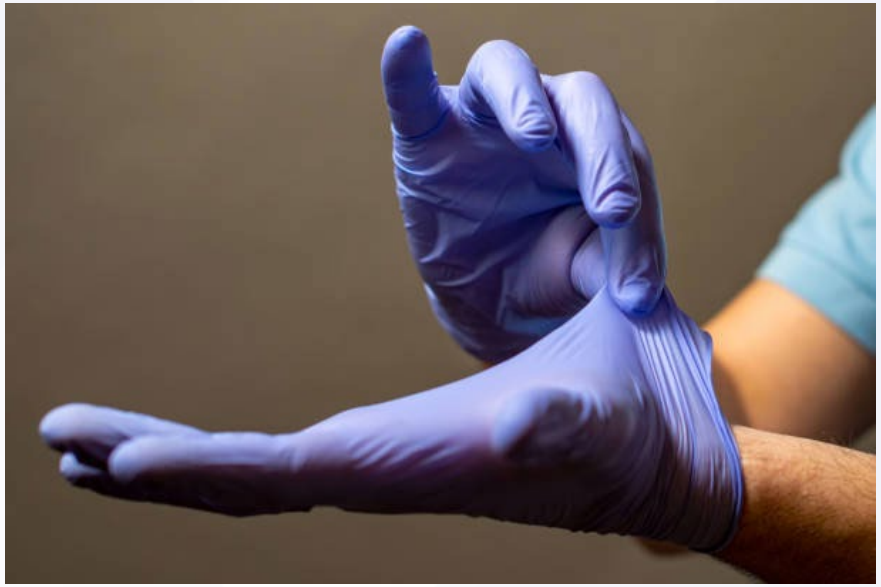
BSL 1	Standard microbiological practices. This includes posting proper lab signage; wearing PPE; washing hands after working with agents; no mouth pipetting; safe sharps disposal; and surface decontamination.
BSL 2	Limited access; occupational medical services including medical evaluation, surveillance, and treatment, as appropriate; all procedures that may generate an aerosol or splash conducted in a BSC; decontamination process needed for laboratory equipment; standard microbiological practices
BSL 3	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; standard microbiological practices
BSL 4	Clothing change before entry; daily inspections of essential containment and life support systems; all wastes decontaminated prior to removal from laboratory; shower on exit; standard microbiological practices

Standard Practices: All Biosafety Levels (Continued)

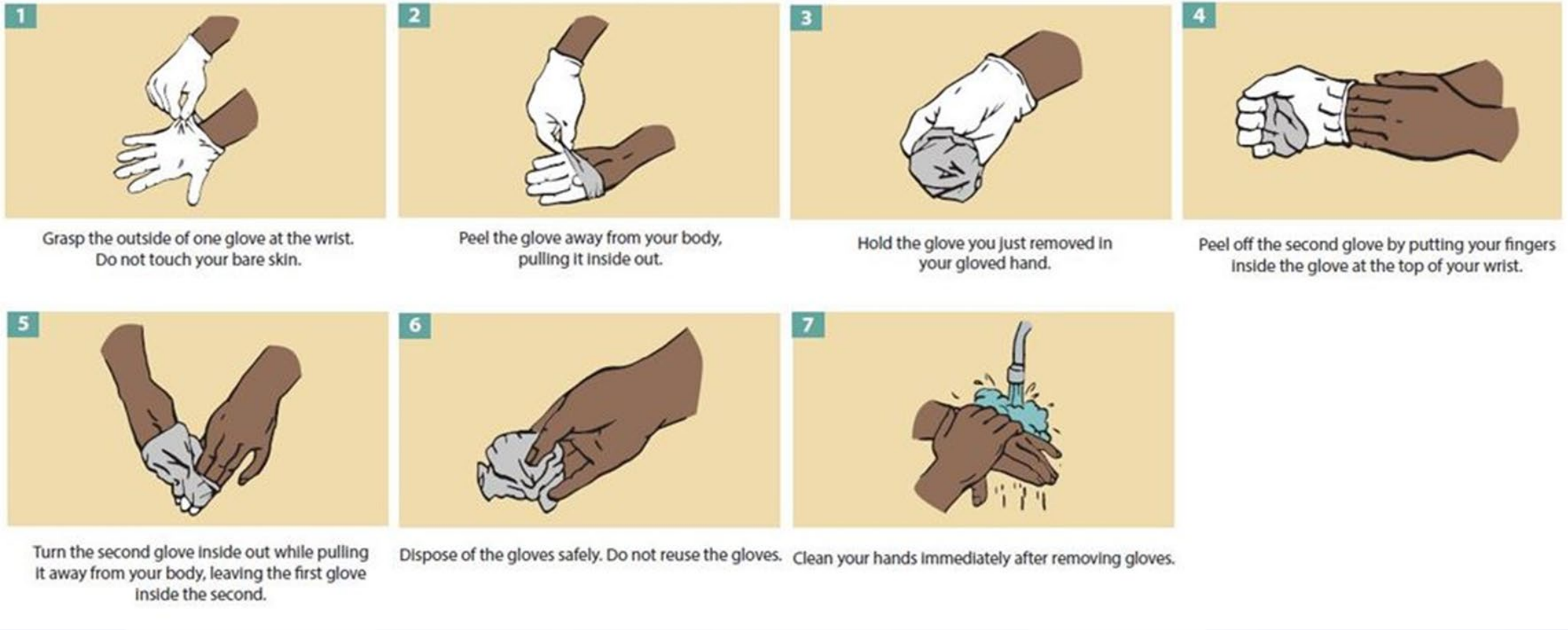
- Limited/Restricted access when work is in progress
- Decontaminate work surfaces before and after use with an effective disinfectant
- Decontaminate waste from all Infectious and potentially infectious materials
- Biohazard signage posted when infectious agents are present or in use
- Training
- PI/lab supervisor must ensure laboratory personnel demonstrate proficiency prior to working in lab

Standard Practices: All Biosafety Levels (Continued)

- Always remove gloves before touching clean surfaces; phone, computers etc.
- Always wash hands with warm water and soap for 10-15 seconds after:
  - Handling any viable material
  - Removing gloves
  - Before leaving lab



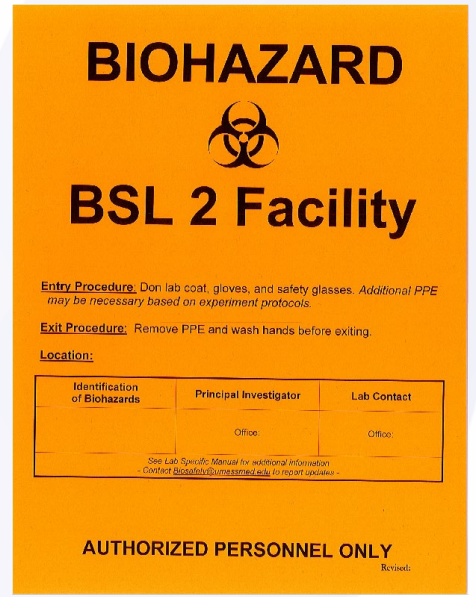
Standard Practices: All Biosafety Levels
Glove Removal



Labeling

Signs indicating the biosafety level of a lab must be posted for BSL-2 labs and higher. Post signage on the lab entrances and any rooms where biological materials are used or stored.

- Biohazard labels must be posted on equipment where BSL-2 materials are used.
  - Refrigerators/Freezers
  - Incubators
  - Centrifuge
  - Storage Containers
  - Waste



UMass Chan MEDICAL SCHOOL | UMass Memorial Health

Sharps

- **Sharps used in research and animal work may cause punctures, lacerations, or cuts. Examples of sharps are:**
  - Hypodermic needles and syringes
  - Pasteur pipettes
  - Serological pipettes *(must be disposed of as sharps)*
  - Scalpel blades
  - Disposable razors
  - Suture needles
  - Sharp edges on metal animal caging

- **Sharps are required to be immediately disposed of within designated, covered, sharps containers. Once the container is three-fourths full, it must be sealed and appropriately discarded.**

Containment

UMass Chan MEDICAL SCHOOL | UMass Memorial Health

Containment

The term containment refers to a series of safe methods for managing infectious agents in the laboratory.

- The purpose of containment is to reduce or eliminate human and environmental exposure to potentially harmful agents.
- The primary principle of biosafety is containment.

Primary and Secondary Containment

There are two levels of biological containment: primary and secondary

- Primary containment protects the laboratory workers and the immediate laboratory environment from exposure to biological agents
  - Achieved through good microbiological technique and the use of safety equipment and personal protective equipment
- Secondary containment protects the environment outside the laboratory
  - Provided by facility design and operational procedures

Primary Containment: Safety Equipment

Primary containment is defined as physical containment measure that is placed directly at the level of the hazard when conducting microbiological activities.

- Examples Safety Equipment Include:
  - BSCs
  - Enclosed containers
  - Centrifuge safety cups

Primary Containment: PPE

Personal protective equipment (PPE) helps protect the user's body from injury or potential exposure to biological hazards and airborne particulates.

- PPE include, but are not limited to:
  - Gloves
  - Laboratory coats (impervious)
  - Face shields/masks
  - Safety glasses with side shields
  - Goggles
  - Hoods
  - Shoe covers
  - Respiratory protection
  - Other task specific PPE

Secondary Containment: Facility Design and Construction

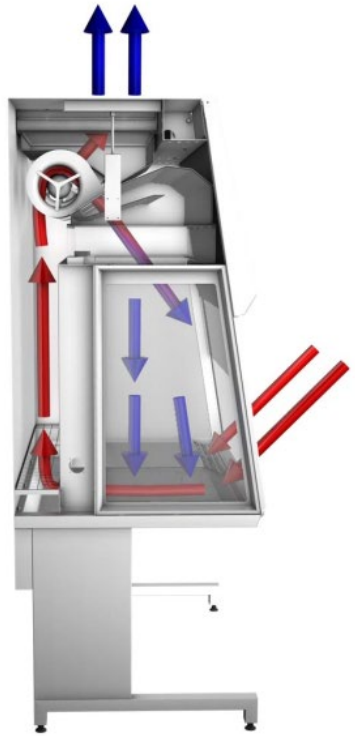
A lab facility's design and construction provide a means of secondary containment of hazardous biological agents and toxins.

- Design features include:
  - Ventilation strategies
  - Effluent decontamination systems
  - Specialized building/suite/laboratory configurations, including:
    - Controlled access zones
    - Anterooms
    - Airlocks

Biological Safety Cabinets

UMass Chan MEDICAL SCHOOL | UMass Memorial Health

Biological Safety Cabinets



Biosafety Cabinets (BSCs) protect you, the environment, and the materials you are using. Contaminated air is passed through a high efficiency particulate air (HEPA) filter and the filtered air is blown onto the work surface or re-circulated out of the cabinet back into the lab.

- Never use toxic or highly volatile chemicals in a biosafety cabinet. Most BSC's re-circulate air back into the room.
- Open flames and heat sources affect the air flow within the cabinet and can compromise the protection offered and the sterility of your work. Open flames / Bunsen burners should not be used in a BSC.

Biological Safety Cabinets

- Three kinds of BSCs: **Class I, II** and **III**
  - **Class I** – Provides personnel and environmental protection but no product protection
  - **Class II** and **Class III** – Provides personnel, environmental, and product protection
- BSCs use high efficiency particulate air (HEPA) filters in their exhaust and/or supply systems.
- HEPA filters are usually composed of a pleated sheet of borosilicate fiber material that has been treated with a wet-strength water-repellant binder. These filters remove particles with an efficiency of 99.97% or greater. **HEPA filters do not trap chemical fumes.**
- Biological safety cabinets must not be confused with laminar flow devices or “clean benches” which direct air towards the operator. The latter devices should never be used for handling infectious, toxic, or sensitizing materials.
- For detailed information on working safely with BSCs, refer to the UMass Chan Medical School Biosafety Manual, or call the Environmental Health & Safety Department (Worcester 508-856-3985; Mattapan 617-474-3004) for assistance.

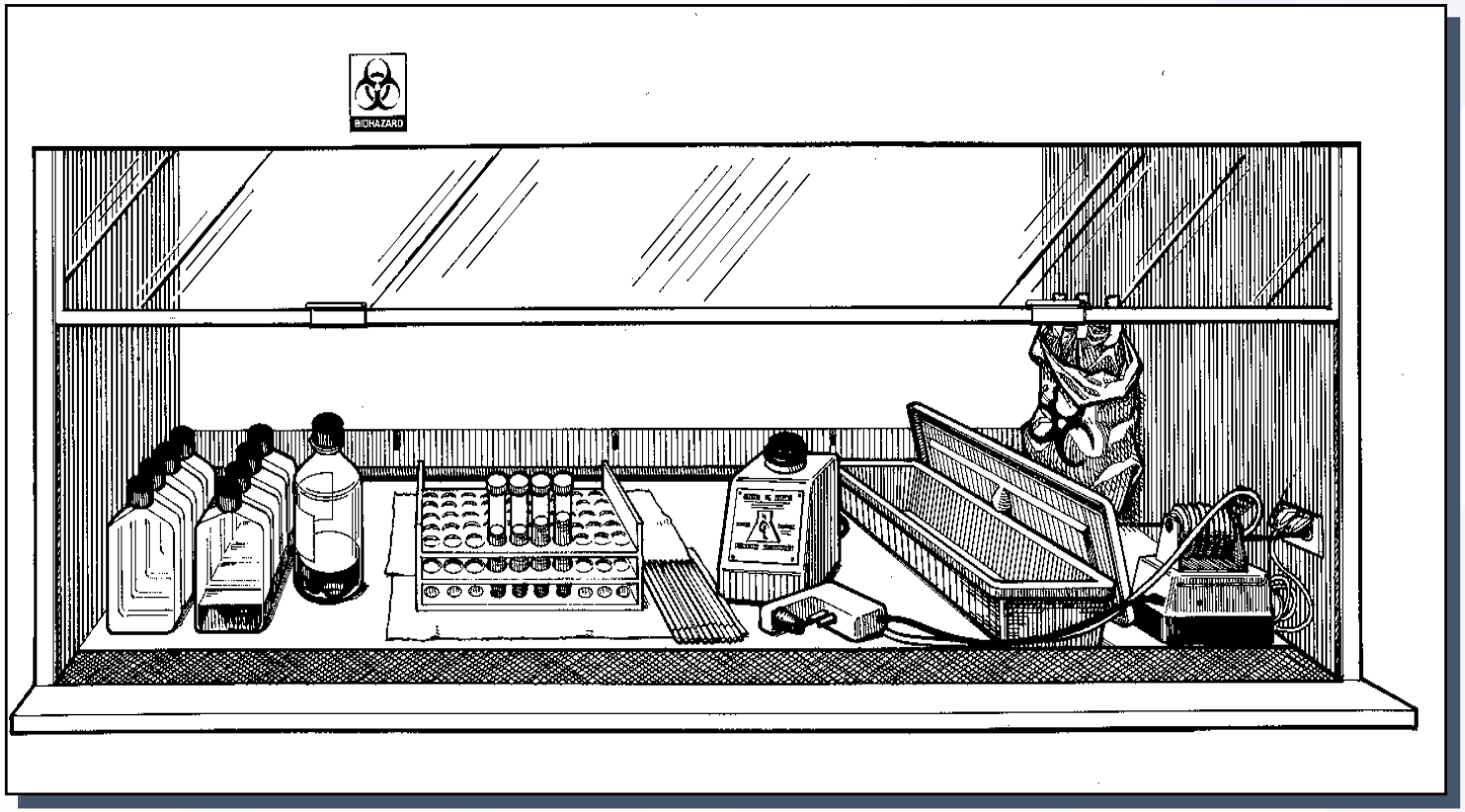
Biological Safety Cabinets

To ensure optimal operation of BSC:

- Annual certification must be performed
- Sash should not be raised above the specified level
- Front grille should be free of clutter to allow proper air intake
- Disinfect surfaces before and after every use
- Clean the pan under the BSC surface at least once a month

Biosafety Cabinet: Set-up

CLEAN → WORKING → DIRTY



Biological Safety Cabinets: Certifications

- BSC's must be tested and certified upon installation or after repair or relocation. BSCs must be certified at a minimum annually. To request service or certification, contact EH&S at x63985.

- EH&S pays for one certification per year, by the contracted vendor during the annual testing. **Certifications outside the annual re-certification period, BSC decontaminations, or repair work are the responsibility of the department.**

- When a BSC fails certification, it must be labeled as OUT OF SERVICE and not be used until repaired. The PI must repair or dispose of BSCs that have failed testing.

Decontamination

UMass Chan MEDICAL SCHOOL | UMass Memorial Health

Decontamination

- Decontamination is an important part of working safely with biological materials to prevent contamination of the laboratory, as well as protecting research materials.
  - Decontaminate work surfaces after completion of work and after any spill or splash.
  - Decontaminate all cultures, stocks, and other potentially contaminated materials before disposal and before removing from the laboratory.

Most disinfectants may not be mixed with other disinfectants or chemicals as they may be incompatible. e.g. Never mix bleach and ammonia or alcohol and bleach together!

Disinfection is NOT the same as Sterilization.

Types of Decontamination

Type	Efficiency Level	Description
Sterilization	High	Physical or chemical procedure that destroys all microbial life, including highly resistant bacterial endospores. Sterilants include autoclaves, ethylene oxide gas, and vaporized hydrogen peroxide.
Disinfection	Intermediate	Eliminates virtually all pathogenic microorganisms, except for bacterial spores, on inanimate objects. Disinfectants include Vesphene, alcohol, Clidox and bleach.
Cleaning	Low	Removes visible soil or organic material by using water, detergent, and some mechanical action such as scrubbing with a gloved hand or brush. Cleaning is often a required step before sterilization or disinfection because it reduces the number of microorganisms on an object.

Decontamination: Liquid Biowaste Disposal

Bleach *OR* autoclave liquid biowaste before sink disposal.

- Add bleach at a 1:10 dilution to liquid biowaste
- Mix well, let sit 20 minutes, dispose
- Do not autoclave any chemicals including bleach
- Do not mix bleach with other disinfectants or chemicals, bleach is an oxidizer and can react violently with other chemicals

Decontamination and Bleach Dilutions

Type of Bleach	Percentage of NaOCl (Sodium Hypochlorite)	Dilution	Preparing Solutions*
Clorox Regular	5.25%	1:9	1 part (vol) bleach: 9 parts (vol) waste
Clorox Ultra	6.0%	1:10	1 part (vol) bleach: 10 parts (vol) waste
Clorox Concentrated	8.25%	1:15	1 part (vol) bleach: 15 parts (vol) waste

*Bleach to biological for disposal or bleach to H_2O for surface decontamination

Spill Response

UMass Chan MEDICAL SCHOOL | UMass Memorial Health

Biological Releases

- **Small Biological Spill**
  - Decontaminate using bleach or other EPA approved decontaminate
- **Larger Biological Spill**
  - Spill that you feel cannot be cleaned safely or requires assistance of EH&S and/or emergency personnel.
  - Immediately leave the area and from an internal phone call x911 or x511 at MassBiologics

Biological Releases

Disinfection with Clorox bleach is extremely effective. Approximately 1:10 dilution of bleach to waste is recommended.

1. Contain spill/release
2. Cover with absorbent/spill pads or paper towels
3. Pour bleach over towels/spill pads to decontaminate
4. Wait 15 minutes
5. Put spill clean up materials into a biohazard waste box
6. Repeat steps 2 - 5
7. Be aware of corrosive nature of bleach

Spill Response: BSL1 or BSL2 Spill

- Biosafety Level 1 (BSL1) agents generally do not cause harm to the healthy worker, but the area must be disinfected to prevent exposure.
- BSL2 agents usually affect employees through exposure to mucous membranes or damaged skin, or injection (needle stick or cut with contaminated material).

Spill Response: BSL1 or BSL2 Spill

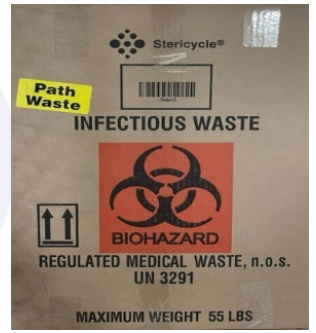
In the event of a BSL1 or BSL2 spill, complete the following procedures:

- Alert people in the immediate area of the spill
- Leave the Biosafety Cabinet turned **ON**
- Wear disposable gloves, lab coat, and safety glasses or goggles
- Pick up sharps and broken glass with tongs or forceps
- Discard the sharps or broken glass into sharps containers **NOTE**: Do not touch sharps, even when wearing gloves
- Cover spill with paper towels or other absorbent materials
- Carefully pour a disinfectant (e.g., freshly prepared 10-25% bleach solution) around the edges of the spill and then into the spill. **AVOID SPLASHING**!
- Wait 20 minutes for disinfectant contact period
- Use paper towels to wipe up the spill, working from the spill's edge toward the center
- Wipe area again with fresh paper towels soaked in disinfectant
- Place paper towels in the double-lined biological waste container

Proper Waste Disposal

UMass Chan MEDICAL SCHOOL | UMass Memorial Health

Laboratory Waste Disposal Simplified



Chemical Sharps Container	Biohazard Sharps Container	Biohazard Box Red Bagged	Radioactive Sharps Containers	Pathological Waste
ALL: ▪ Needles and syringes ▪ Razor blades ▪ Serological pipettes, pipette tips ▪ Pasteur pipettes ▪ Slides and cover slips ▪ Capillary tubes ▪ Broken contaminated glassware **NOTE:** Place sharps contaminated with trace amounts of chemical in sharps container labeled “Chemical Contaminated SHARPS – DO NOT AUTOCLAVE”	ALL: ▪ Needles and syringes ▪ Razor blades ▪ Serological pipettes, pipette tips ▪ Pasteur pipettes ▪ Slides and cover slips ▪ Capillary tubes ▪ Broken contaminated glassware **NOTE:** Full containers will not be removed from the lab if contents are overflowing.	ALL: ▪ Infectious agents ▪ Contaminated paper towels, kimwipes, etc. ▪ Cell cultures ▪ Plastic fly vials ▪ Eppendorph tubes ▪ Contaminated PPE ▪ Unbroken Vials **NOTE**: Packaged in double red bags placed in biohazard boxes, bags tied and top taped and side of box labeled with PI, lab number and building.	ALL RADIOACTIVE: ▪ Needles and syringes ▪ Razor blades ▪ Serological pipettes, pipette tips ▪ Pasteur pipettes ▪ Slides and cover slips ▪ Capillary tubes ▪ Broken contaminated glassware **NOTE:** Radioactive sharps should be in a separate sharp container and per isotope. Should be labeled properly and return to Radiation Safety.	ALL: ▪ Pathological waste ▪ human or animal body parts, organs, tissues, and surgical specimens **NOTE:** Above must be decanted of formaldehyde, formalin, or other preservatives which are packaged **separately** for pickup in containers. • Package as biohazardous box waste, (2 red bags), and place yellow Pathological sticker on box.

For information regarding the disposal of chemical waste contact Environmental Health & Safety at 508-856-3985

Contact Console at 508-856-3292 to reach Environmental Building Services to request empty biohazard waste containers or for the pickup of full containers

Shipping Biologicals

UMass Chan MEDICAL SCHOOL | UMass Memorial Health

Shipping Biologicals: IATA Training

- **International Air Transport Association (IATA) training is required for the labeling, packaging, and shipping of biological agents.**
  - EH&S provides this training via the online platform: Saf-T-Pak
- IATA training covers shipping of Category B biological substances.
  - The training is valid for 2 years following completion and will require refresher training upon the date of expiration
  - Biological substances include infectious agents, patient specimens, biological products, and genetically modified organisms
  - Training also include packing with dry ice
- Each lab is responsible for ensuring a lab representative receives this training.

Shipping Biologicals: Import Permits

THE IMPORTATION AND MOVEMENT OF CERTAIN CATEGORIES OF BIOLOGICAL AGENTS IS TIGHTLY REGULATED BY FEDERAL AGENCIES SUCH AS THE CDC, USDA, APHIS, ETC.

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

USDA

IATA
International Air Transport Association

Failure to comply with regulations when transporting regulated biological materials may result in shipment delays, destruction at the port of entry, refusal of the shipment by carriers, and may be subject to fines and/or criminal penalties

Import Permits:
The CDC Import Permit Program (IPP)

The CDC Import Permit Program, or IPP, regulates the importation of infectious biological materials that could cause disease in humans in order to prevent their introduction and spread into the U.S.

- The program ensures that the importation of these agents is monitored and that facilities receiving permits have appropriate biosafety measures in place to work with the imported agents.
- If you have questions regarding if a permit is required, contact the Biosafety Office or utilize the tool CDC IPP e-Tool

USDA/APHIS Import or Transport Controlled Materials or Organisms or Vectors Permit

Title 9, Chapter 1, Subchapter E, Part 122, Section 122.2 of the Code of Federal Regulations – 'Permits Required' -- mandates that "no organisms or vectors shall be imported into the United States or transported from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia without a permit".

- A list of organisms and vectors that require a USDA/APHIS Import Permit can be found here: https://www.aphis.usda.gov/animal_health/downloads/organisms_and_vectors/vs-regulated-livestock-poultry-pathogens-partial-list.pdf

- VS Form 16-3 "Application for Permit to: Import or Transport Controlled Materials or Organisms or Vectors" is the application form which is submitted to apply for a permit (VS form 16-6A) for Organisms or Vectors. To access ePermits click here: https://www.aphis.usda.gov/aphis/resources/sa_epermits/eauth-epermits

U.S. Fish & Wildlife Services Import/Export

Under FWS, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) regulates the shipment of certain species products to ensure the appropriate level of product protection

- Wildlife/wildlife products imported to and exported from the U.S. must be declared to the U.S. FWS and cleared before release by U.S. Customs and Border Patrol.
  - Declare import or export of fish or wildlife through Form 3-177
- FWS administers permits for the import/export of wildlife/wildlife products
  - FWS Permit Guide

Export Controls and Sanctions

Export controls and trade sanctions are the United States laws that regulate the release and movement of controlled products, software, technology and services from the U.S. to foreign countries in order to protect national security and promote foreign policy objectives under the Export Administration Regulations (EAR).

- The Office of Foreign Assets Control (OFAC) regulates and enforces economic and trade sanctions. Trade sanction programs restrict transactions between the U.S. and certain countries based on U.S. foreign policy and national security goals.

- Additional information can be found at: https://home.treasury.gov/policy-issues/financial-sanctions/faqs/topic/1501

Export License

An export license is a government document that allows export transactions. Export licenses can be issued via the Bureau of Industry and Security (BIS) or the Directorate of Defense Trade Controls (DDTC) depending on the material being exported.

- Refer to the Commerce Control List (CCL) to determine if a license is required by the Department of Commerce based on an item's Export Control Classification Number (EECN).
- Additional information can be found at:
  - https://www.bis.doc.gov/index.php/licensing
  - https://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl
  - https://www.pmddtc.state.gov/ddtc_public?id=ddtc_kb_article_page&sys_id=7110b98edbb8d30044f9ff621f96192d

Hand Carrying Biological Materials

Discouraged

Biological materials must be declared in accordance with the U.S. Customs and Border Patrol if they are being carried via hand carrying or checked baggage through either of the following methods:

- Using CBP Form 6059B
- Oral declaration to a CBP officer
- At an Automated Passport Control kiosk, or
- Global Entry kiosk

- Additional Information: https://www.cbp.gov/trade/basic-import-export/what-you-need-know-importing-biological-materials-united-states

Questions?

Contact:
Biosafety@umassmed.edu

Colleen Driskill, RBP, CBSP
Senior Biosafety Officer, RO

Office: (508) 856-5527 Cell: (774) 670-8053
Environmental Health & Safety
UMass Chan Medical School
55 Lake Avenue North
Worcester, MA 01655

Kris Giaya, MS.
Assistant Biosafety Officer, ARO

Office: (508) 856-3298
Environmental Health & Safety
UMass Chan Medical School
55 Lake Avenue North
Worcester, MA 01655

Mike Pietila, CHMM
EH&S Officer

Office: (617) 474-3004
Environmental Health & Safety
MassBiologics
460 Walk Hill Street
Mattapan, MA 02126

UMass Chan MEDICAL SCHOOL | UMass Memorial Health