UNIVERSITY OF MIAMI

OFFICE of ENVIRONMENTAL HEALTH & SAFETY

BIOSAFETY MANUAL

University of Miami

An overview of the safety expectations and guidelines to be observed for biological research conducted at the University of Miami.

Biosafety
Environmental Health & Safety

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Introduction

The University of Miami Biosafety Manual is maintained and enforced by the Biosafety Team, part of the Office of Environmental Health & Safety (EHS). The biosafety manual aims to establish the expectations for biological lab safety based on regulations and best research practices applicable to biological research here at the University of Miami. Guidance and policy supporting hygienic practices is paramount in establishing a strong safety culture in both (1) preventing exposures in the lab and (2) in representing the standards that are expected for individuals representing this prestigious university. The history of laboratory-associated infections in particular has been well documented and includes several thousands of individuals, with well over a hundred documented cases resulting in fatalities.

Given the broad nature of the varying types of biological-related research conducted at UM, there will inevitably be topics that may not be covered in depth. This document is not meant to cover every laboratory procedure, as Principal Investigators and subject matter experts in the individual laboratories shall establish standard operating procedures for their work and create an individual laboratory biological hygiene plan, otherwise referred to as a "site specific biosafety manual". This biological hygiene plan is not to be confused with the chemical hygiene plan, which is meant for chemical hazards. EHS Biosafety will provide clarification and guidance as needed. Further, the team welcomes collaboration, suggestions and feedback, and strives to provide resources of the highest quality to all of our research stakeholders.

Establishing a culture of safety is built on broad stakeholder inclusion and collaboration, and the responsibility of all University faculty, staff and students. Assessing and managing risk in laboratories should be a routine task and integral to your daily laboratory operations. Our laboratories throughout the U vary from room to room, therefore laboratories identifying potential hazards is essential to creating safe guidelines, within the scope of this biosafety manual and other relevant University policies and local, state and federal regulations.

Basics of Biosafety

Biosafety in Microbiological and Biomedical Laboratories (BMBL)

The BMBL has been the cornerstone of biosafety practice in the United States since its initial release in 1984. It serves as a foundation for biosafety policy and best practices across the country at institutions of all sizes. In that vein, while the policies and recommendations in this manual are rooted in a number notable safety manuals, government regulations, and guidelines overseeing the research industry, the BMBL is the anchor of any biosafety policy and is an excellent reference for anyone seeking additional guidance beyond the UM Biosafety Manual. It can be accessed through the CDC's website below.

- Biosafety in Microbiological and Biomedical Laboratories (BMBL)

Risk Groups

The Risk Group (RG) of an agent is an important factor to be considered during the biosafety risk assessment process. Biological agents and toxins are assigned to a RG level based on their estimated ability to cause disease in healthy human adults and spread within the community. Briefly, there are four levels. Level 1 agents generally don't have the capacity to infect humans. Level 2 agents generally can infect humans, though are treatable. Level 3 agents are usually major human pathogens, though treatment and therapeutics are generally available. Level 4 agents are major human pathogens where treatment or therapeutics are generally not available. Level 4 agents can also be a significant community risk should they escape the laboratory. In conducting a risk assessment however, considering the RG is only the first step and the RG alone is not sufficient for determining the appropriate biosafety level for working with a specific agent.

Biosafety Levels

The four primary Biosafety Levels (BSLs) for laboratories described in Section IV of BMBL consist of combinations of facility design features and safety equipment (primary and secondary barriers), facility practices and procedures, and personal protective equipment. Selection of the appropriate combinations to safely conduct the work should be based upon a comprehensive facility-specific biosafety risk assessment that documents the properties of the biological agents and toxins to be used, potential host characteristics, potential routes of infection, and the laboratory work practices and procedures conducted or anticipated to be used in the future. Recommended BSLs for the biological agents and toxins in Section VIII of BMBL represent suggested practices for work with an agent or toxin using standard protocols. Not all biological agents and toxins capable of causing disease in humans are included in Section VIII.

When working with well-defined organisms, identification of the appropriate biosafety controls should be based on the comprehensive biosafety risk assessment. However, when information is available to suggest that virulence, pathogenicity, antibiotic resistance patterns, vaccine and treatment availability, or other factors are significantly altered, an adjustment to the stringency of biosafety controls may be needed. For example, handling large volumes or high concentrations of a biological agent or toxin may require additional practices outlined in Sections IV and V of BMBL. Similarly, procedures that produce large amounts of aerosols may also require additional biosafety controls to reduce the likelihood of exposures to personnel and the unintentional release of a biological agent or toxin in the surrounding community or the environment. Furthermore, vaccines should not necessarily be considered non-pathogenic simply because they are vaccine strains.

It is important to note that the four Biosafety Levels described below are not to be confused and equated with agent Risk Groups as described in the previous section.

Biosafety Level 1 (BSL-1)

Biosafety Level 1 (BSL-1) is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans and that present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open benchtops using standard microbiological practices. Special containment equipment or facility design is not generally required but may be used as determined by appropriate risk assessment. Laboratory personnel receive specific training in the procedures conducted in the laboratory and are supervised by a scientist with training in microbiology or a related science.

Standard Microbiological Practices for BSL-1

The following standard practices, safety equipment, and facility specifications are recommended for BSL-1.

1. The laboratory supervisor enforces the institutional policies that control safety in and access to the laboratory.
2. The laboratory supervisor ensures that laboratory personnel receive appropriate training regarding their duties, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization) and that appropriate records are maintained. Personnel receive annual updates and additional training when equipment, procedures, or policies change. All persons entering the facility are advised of the potential hazards, are instructed on the appropriate safeguards, and read and follow instructions on practices and procedures. An institutional policy regarding visitor training, occupational health requirements, and safety communication is considered.
3. Personal health status may affect an individual's susceptibility to infection and ability to receive available immunizations or prophylactic interventions. Therefore, all personnel, and particularly those of reproductive age and/or those having conditions that may predispose them to increased risk for infection (e.g., organ transplant, medical immunosuppressive agents), are provided information regarding immune competence and susceptibility to infectious agents. Individuals having such conditions are encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.
4. A safety manual specific to the facility is prepared or adopted in consultation with the facility director and appropriate safety professionals. The safety manual is available, accessible, and periodically reviewed and updated, as necessary.
    a. The safety manual contains sufficient information to describe the biosafety and containment procedures for the organisms and biological materials in use, appropriate agent-specific decontamination methods, and the work performed.
    b. The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, and other potential emergencies. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies.

5. A sign is posted at the entrance to the laboratory when infectious materials are present. Posted information includes: the laboratory's Biosafety Level, the supervisor's or other responsible personnel's name and telephone number, PPE requirements, general occupational health requirements (e.g., immunizations, respiratory protection), and required procedures for entering and exiting the laboratory. Agent information is posted in accordance with the institutional policy.
6. Long hair is restrained so that it cannot contact hands, specimens, containers, or equipment.
7. Gloves are worn to protect hands from exposure to hazardous materials.
    a. Glove selection is based on an appropriate risk assessment.
    b. Gloves are not worn outside the laboratory.
    c. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
    d. Do not wash or reuse disposable gloves, and dispose of used gloves with other contaminated laboratory waste.
8. Gloves and other PPE are removed in a manner that minimizes personal contamination and transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or manipulated.
9. Persons wash their hands after working with potentially hazardous materials and before leaving the laboratory.
10. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in laboratory areas. Food is stored outside the laboratory area.
11. Mouth pipetting is prohibited. Mechanical pipetting devices are used.
12. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware are developed, implemented, and followed; policies are consistent with applicable state, federal, and local requirements. Whenever practical, laboratory supervisors adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions are always taken with sharp items. These include:
    a. Plasticware is substituted for glassware whenever possible.
    b. Use of needles and syringes or other sharp instruments is limited in the laboratory and is restricted to situations where there is no alternative (e.g., parenteral injection, blood collection, or aspiration of fluids from laboratory animals or diaphragm bottles). Active or passive needle-based safety devices are to be used whenever possible.
        i. Uncapping of needles is performed in such a manner to reduce the potential for recoil causing an accidental needlestick.
        ii. Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
        iii. If absolutely necessary to remove a needle from a syringe (e.g., to prevent lysing blood cells) or recap a needle (e.g., loading syringes in one room and injecting animals in another), a hands-free device or comparable safety procedure must be used (e.g., a needle remover on a sharps container, the use of forceps to hold the cap when recapping a needle).
        iv. Used, disposable needles and syringes are carefully placed in puncture-resistant containers used for sharps disposal immediately after use. The sharps disposal container is located as close to the point of use as possible.

    c. Non-disposable sharps are placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
    d. Broken glassware is not handled directly. Instead, it is removed using a brush and dustpan, tongs, or forceps.
13. Perform all procedures to minimize the creation of splashes and/or aerosols.
14. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant. Spills involving infectious materials are contained, decontaminated, and cleaned up by staff who are properly trained and equipped to work with infectious material. A spill procedure is developed and posted within the laboratory.
15. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method, consistent with applicable institutional, local, and state requirements. Depending on where the decontamination will be performed, the following methods are used prior to transport:
    a. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container and secured for transport. For infectious materials, the outer surface of the container is disinfected prior to moving materials and the transport container has a universal biohazard label.
    b. Materials to be removed from the facility for decontamination are packed in accordance with applicable local, state, and federal regulations.
16. An effective integrated pest management program is implemented.
17. Animals and plants not associated with the work being performed are not permitted in the laboratory.

Special Practices

None required.

Safety Equipment (Primary Barriers and Personal Protective Equipment)

1. Special containment devices or equipment, such as biosafety cabinets BSCs), are not generally required.
2. Protective laboratory coats, gowns, or uniforms are worn to prevent contamination of personal clothing.
3. Protective eyewear is worn by personnel when conducting procedures that have the potential to create splashes and sprays of microorganisms or other hazardous materials. Eye protection and face protection are disposed of with other contaminated laboratory waste or decontaminated after use.
4. In circumstances where research animals are present in the laboratory, the risk assessment considers appropriate eye, face, and respiratory protection, as well as potential animal allergens.

Laboratory Facilities (Secondary Barriers)

1. Laboratories have doors for access control.
2. Laboratories have a sink for handwashing.
3. An eyewash station is readily available.
4. The laboratory is designed so that it can be easily cleaned.
    a. Carpets and rugs in laboratories are not appropriate.
    b. Spaces between benches, cabinets, and equipment are accessible for cleaning.

5. Laboratory furniture can support anticipated loads and uses.
    a. Benchtops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
    b. Chairs used in laboratory work are covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
6. Laboratory windows that open to the exterior are fitted with screens.
7. Illumination is adequate for all activities and avoids reflections and glare that could impede vision.

Biosafety Level 2 (BSL-2)

Biosafety Level 2 (BSL-2) builds upon BSL-1. BSL-2 is suitable for work with agents associated with human disease and pose moderate hazards to personnel and the environment. BSL-2 differs from BSL-1 primarily because: 1) laboratory personnel receive specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

Standard Microbiological Practices for BSL-2

The following standard and special practices, safety equipment, and facility specifications are recommended for BSL-2.

1. The laboratory supervisor enforces the institutional policies that control safety in and access to the laboratory.
2. The laboratory supervisor ensures that laboratory personnel receive appropriate training regarding their duties, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization) and that appropriate records are maintained. Personnel receive annual updates and additional training when equipment, procedures, or policies change. All persons entering the facility are advised of the potential hazards, are instructed on the appropriate safeguards, and read and follow instructions on practices and procedures. An institutional policy regarding visitor training, occupational health requirements, and safety communication is considered.
3. Personal health status may affect an individual's susceptibility to infection and ability to receive available immunizations or prophylactic interventions. Therefore, all personnel, and particularly those of reproductive age and/or those having conditions that may predispose them to increased risk for infection (e.g., organ transplant, medical immunosuppressive agents), are provided information regarding immune competence and susceptibility to infectious agents. Individuals having such conditions are encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.
4. A safety manual specific to the facility is prepared or adopted in consultation with the facility director and appropriate safety professionals. The safety manual is available, accessible, and periodically reviewed and updated as necessary.
    a. The safety manual contains sufficient information to describe the biosafety and containment procedures for the organisms and biological materials in use, appropriate agent-specific decontamination methods, and the work performed.

    b. The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, and other potential emergencies. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies.
5. A sign incorporating the universal biohazard symbol is posted at the entrance to the laboratory when infectious materials are present. Posted information includes: the laboratory's Biosafety Level, the supervisor's or other responsible personnel's name and telephone number, PPE requirements, general occupational health requirements (e.g., immunizations, respiratory protection), and required procedures for entering and exiting the laboratory. Agent information is posted in accordance with the institutional policy.
6. Long hair is restrained so that it cannot contact hands, specimens, containers, or equipment.
7. Gloves are worn to protect hands from exposure to hazardous materials.
    a. Glove selection is based on an appropriate risk assessment.
    b. Gloves are not worn outside the laboratory.
    c. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
    d. Do not wash or reuse disposable gloves, and dispose of used gloves with other contaminated laboratory waste.
8. Gloves and other PPE are removed in a manner that minimizes personal contamination and transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or manipulated.
9. Persons wash their hands after working with potentially hazardous materials and before leaving the laboratory.
10. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in laboratory areas. Food is stored outside the laboratory area.
11. Mouth pipetting is prohibited. Mechanical pipetting devices are used.
12. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware are developed, implemented, and followed; policies are consistent with applicable state, federal, and local requirements. Whenever practical, laboratory supervisors adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions are always taken with sharp items. These include:
    a. Plasticware is substituted for glassware whenever possible.
    b. Use of needles and syringes or other sharp instruments is limited in the laboratory and is restricted to situations where there is no alternative (e.g., parenteral injection, blood collection, or aspiration of fluids from laboratory animals or diaphragm bottles). Active or passive needle-based safety devices are to be used whenever possible.
        i. Uncapping of needles is performed in such a manner to reduce the potential for recoil causing an accidental needlestick.
        ii. Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
        iii. If absolutely necessary to remove a needle from a syringe (e.g., to prevent lysing blood cells) or recap a needle (e.g., loading syringes in one room and injecting animals in another), a hands-free device or comparable safety procedure must be

used (e.g., a needle remover on a sharps container, the use of forceps to hold the cap when recapping a needle).

iv. Used, disposable needles and syringes are carefully placed in puncture-resistant containers used for sharps disposal immediately after use. The sharps disposal container is located as close to the point of use as possible.

v. Non-disposable sharps are placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

vi. Broken glassware is not handled directly. Instead, it is removed using a brush and dustpan, tongs, or forceps.

13. Perform all procedures to minimize the creation of splashes and/or aerosols.
14. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant. Spills involving infectious materials are contained, decontaminated, and cleaned up by staff who are properly trained and equipped to work with infectious material. A spill procedure is developed and posted within the laboratory.
15. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method, consistent with applicable institutional, local, and state requirements. Depending on where the decontamination will be performed, the following methods are used prior to transport:
    a. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container and secured for transport. For infectious materials, the outer surface of the container is disinfected prior to moving materials and the transport container has a universal biohazard label.
    b. Materials to be removed from the facility for decontamination are packed in accordance with applicable local, state, and federal regulations.
16. An effective integrated pest management program is implemented.
17. Animals and plants not associated with the work being performed are not permitted in the laboratory.

Special Practices

1. Access to the laboratory is controlled when work is being conducted.
2. The laboratory supervisor is responsible for ensuring that laboratory personnel demonstrate proficiency in standard microbiological practices and techniques for working with agents requiring BSL-2 containment.
3. Laboratory personnel are provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory.
4. Properly maintained BSCs or other physical containment devices are used, when possible, whenever:
    a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
    b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotors or centrifuge safety cups with loading

and unloading of the rotors and centrifuge safety cups in the BSC or another containment device.

c. If it is not possible to perform a procedure within a BSC or other physical containment device, a combination of appropriate personal protective equipment and administrative controls are used, based on a risk assessment.

5. Laboratory equipment is decontaminated routinely; after spills, splashes, or other potential contamination; and before repair, maintenance, or removal from the laboratory.
6. A method for decontaminating all laboratory waste is available (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).
7. Incidents that may result in exposure to infectious materials are immediately evaluated per institutional policies. All such incidents are reported to the laboratory supervisor and any other personnel designated by the institution. Appropriate records are maintained.

Safety Equipment (Primary Barriers and Personal Protective Equipment)

1. Protective laboratory coats, gowns, or uniforms designated for laboratory use are worn while working with hazardous materials and removed before leaving for non-laboratory areas (e.g., cafeteria, library, and administrative offices). Protective clothing is disposed of appropriately or deposited for laundering by the institution. Laboratory clothing is not taken home.
2. Eye protection and face protection (e.g., safety glasses, goggles, mask, face shield or other splatter guard) are used for manipulations or activities that may result in splashes or sprays of infectious or other hazardous materials. Eye protection and face protection are disposed of with other contaminated laboratory waste or decontaminated after use.
3. The risk assessment considers whether respiratory protection is needed for the work with hazardous materials. If needed, relevant staff are enrolled in a properly constituted respiratory protection program.
4. In circumstances where research animals are present in the laboratory, the risk assessment considers appropriate eye, face, and respiratory protection, as well as potential animal allergens.

Laboratory Facilities (Secondary Barriers)

1. Laboratory doors are self-closing and have locks in accordance with the institutional policies.
2. Laboratories have a sink for handwashing. It should be located near the exit door.
3. An eyewash station is readily available in the laboratory.
4. The laboratory is designed so that it can be easily cleaned.
    a. Carpets and rugs in laboratories are not appropriate.
    b. Spaces between benches, cabinets, and equipment are accessible for cleaning.
5. Laboratory furniture can support anticipated loads and uses.
    a. Benchtops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
    b. Chairs used in laboratory work are covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
6. Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they are fitted with screens.
7. Illumination is adequate for all activities and avoids reflections and glare that could impede vision.

8. Vacuum lines in use are protected with liquid disinfectant traps and in-line HEPA filters or their equivalent. Filters are replaced, as needed, or are on a replacement schedule determined by a risk assessment.
9. There are no specific requirements for ventilation systems. However, the planning of new facilities considers mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.
10. BSCs and other primary containment barrier systems are installed and operated in a manner to ensure their effectiveness.
    a. BSCs are installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs are located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.
    b. BSCs can be connected to the laboratory exhaust system by either a canopy connection (Class IIA only) or directly exhausted to the outside through a hard connection (Class IIB, IIC, or III). Class IIA or IIC BSC exhaust can be safely recirculated back into the laboratory environment if no volatile toxic chemicals are used in the cabinet.
    c. BSCs are certified at least annually to ensure correct performance.

Biosafety Level 3 and Biosafety Level 4

At this revision of the Biosafety Manual, no Biosafety Level 3 or 4 work is being conducted at the University of Miami. There are no BSL-3 or BSL-4 facilities on the research campuses. Therefore, no BSL-3 or BSL-4 work is permitted onsite. Should there be a desire to work at a higher BSL then what is available, contact the Office of the Vice Provost for Scholarship and Research to explore the possibility of conducting the research.

Animal Biosafety Levels

Four primary Biosafety Levels are also described for activities involving hazardous biological agent and toxin work conducted with animals. These four combinations of facility design and construction, safety equipment, and practices and procedures are designated Animal Biosafety Levels (ABSL) 1, 2, 3, and 4, and provide increasing levels of protection to personnel, the surrounding community, and the environment.

This guidance is provided for the use of experimentally infected animals housed in indoor research facilities (e.g., vivarium research facilities) and applies to the maintenance of laboratory animals that may naturally harbor zoonotic infectious agents. In both instances, institutional management provides facilities, staff, and established practices that reasonably ensure appropriate levels of environmental quality, safety, security, and care for the laboratory animal.1 Laboratory animal facilities are to be considered a special type of laboratory. As a general principle, the Biosafety Level (e.g., facilities, practices, and operational requirements) recommended for working with infectious agents in vivo and in vitro are comparable.

The animal room can present unique concerns. Animals may generate aerosols, may bite and scratch, and/or may be infected with a zoonotic agent. The application of the Animal Biosafety Levels (ABSL) is determined by a protocol-driven risk assessment.

Facilities for laboratory animals used in studies of infectious or non-infectious disease should be physically separate from other activities, such as animal production, quarantine, clinical laboratories,

and from facilities providing patient care. Traffic flow that will minimize the risk of cross-contamination should be incorporated into the facility.

Animal Biosafety Level 1 (ABSL-1)

Animal Biosafety Level 1 (ABSL-1) is suitable for animal work involving well-characterized agents that are not known to consistently cause disease in immunocompetent adult humans and present minimal potential hazard to personnel and the environment.

Special containment equipment or facility design may be required as determined by risk assessment. See Section II for additional information on the Biological Risk Assessment.

Personnel receive specific training in animal facility procedures and are supervised by an individual with adequate knowledge of potential hazards and experimental animal procedures.

Standard Microbiological Practices for ABSL-1

The following standard practices, safety equipment, and facility specifications are recommended for ABSL-1.

1. The animal facility director establishes and enforces policies, procedures, and protocols for biosafety, biosecurity, and emergencies within the animal facility.
2. Access to the animal room is limited. Only those persons required for experimental, husbandry, or support purposes are authorized to enter the facility.
3. Each institution ensures that worker safety and health concerns are addressed as part of the animal protocol review process. Consideration is given to specific biohazards unique to the animal species and protocol in use. Prior to beginning a study, animal protocols are reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) as well as the Institutional Biosafety Committee (IBC), as appropriate.
4. The supervisor ensures that animal care, facility, and support personnel receive appropriate training regarding their duties, animal husbandry procedures, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization). Personnel receive annual updates and additional training when equipment, procedures, or policies change. Records are maintained for all hazard evaluations, training sessions, and staff attendance. All persons, including facility equipment personnel, service workers, and visitors, are advised of the potential hazards (e.g., naturally acquired or research pathogens, allergens); are instructed on the appropriate safeguards; and read and follow instructions on practices and procedures. An institutional policy regarding visitor training, occupational health requirements, and safety communication is considered.
5. Personal health status may affect an individual's susceptibility to infection or ability to receive available immunizations or prophylactic interventions. Therefore, all personnel, and particularly those of reproductive age and/or those having conditions that may predispose them to increased risk for infection (e.g., organ transplant, medical immunosuppressive agents), are provided information regarding immune competence and susceptibility to infectious agents. Individuals having such conditions are encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance. Facility supervisors ensure that medical staff are informed of potential occupational hazards within the animal facility, to include those associated with research, animal husbandry duties, animal care, and manipulations.

6. Appropriate occupational medical services are in place, as determined by risk assessment.
    a. An animal allergy prevention program is part of the medical surveillance.
    b. Personnel using respirators for animal allergy prevention are enrolled in an appropriately constituted respiratory protection program.
7. A safety manual specific to the facility is prepared or adopted in consultation with the facility director and appropriate safety professionals. The safety manual is available, accessible, and periodically reviewed and updated, as necessary.
    a. The safety manual contains sufficient information to describe the biosafety and containment procedures for the experimental animals, organisms, and biological materials in use, appropriate agent-specific decontamination methods, and the work performed.
    b. The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, escape of animals within the animal facility, and other potential emergencies. A plan for the disposition of animals during emergency situations is included. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies.
8. A sign is posted at the entrance to the animal room when infectious agents are present. Posted information includes: the room's Animal Biosafety Level, the supervisor's or other responsible personnel's name and telephone number, PPE requirements, general occupational health requirements (e.g., immunizations, respiratory protection), and required procedures for entering and exiting the animal room. Agent information is posted in accordance with the institutional policy.
9. Long hair is restrained so that it cannot contact hands, animals, specimens, containers, or equipment.
10. Gloves are worn to protect hands from exposure to hazardous materials and when handling animals.
    a. Glove selection is based on an appropriate risk assessment.8–12
    b. Consider the need for bite and/or scratch-resistant gloves.
    c. Gloves worn inside the animal facility are not worn outside the animal facility.
    d. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
    e. Do not wash or reuse disposable gloves, and dispose of used gloves with other contaminated animal facility waste.
11. Gloves and other PPE are removed in a manner that minimizes personal contamination and transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or manipulated.
12. Persons wash their hands after handling animals and before leaving the areas where infectious materials and/or animals are housed or manipulated.
13. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in animal areas.
14. Mouth pipetting is prohibited. Mechanical pipetting devices are used.
15. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware are developed, implemented, and followed; policies are consistent with applicable state, federal, and local requirements.13 Whenever practical, supervisors adopt improved engineering and work practice controls that reduce the risk of sharps injuries. Precautions are always taken with sharp items. These include:

a. Plasticware is substituted for glassware whenever possible.
b. Use of needles and syringes or other sharp instruments is limited in the animal facility and is restricted to situations where there is no alternative (e.g., parenteral injection, blood collection, or aspiration of fluids from laboratory animals or diaphragm bottles). Active or passive needle-based safety devices are used whenever possible.
    i. Uncapping of needles is performed in such a manner to reduce the potential for recoil causing an accidental needlestick.
    ii. Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
    iii. If absolutely necessary to remove a needle from a syringe (e.g., to prevent lysing blood cells) or recap a needle (e.g., loading syringes in one room and injecting animals in another), a hands-free device or comparable safety procedure must be used (e.g., a needle remover on a sharps container, or the use of forceps to hold the cap when recapping a needle).
    iv. Used, disposable needles and syringes are carefully placed in puncture-resistant containers used for sharps disposal immediately after use. The sharps disposal container is located as close to the point of use as possible.
c. Non-disposable sharps (e.g., necropsy instruments such as forceps, pins, reusable scalpels) are placed in a hard-walled container for transport to a processing area for decontamination.
d. Broken glassware is not handled directly. Instead, it is removed using a brush and dustpan, tongs, or forceps.

16. Procedures are carefully performed to minimize the creation of aerosols or splatters of infectious materials and waste.
17. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant. Spills involving infectious materials are contained, decontaminated, and cleaned up by staff who are properly trained and equipped to work with infectious material. A spill procedure is developed and posted within the animal facility.
18. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method, consistent with applicable institutional, local and state requirements. Depending on where the decontamination will be performed, the following methods are used prior to transport:
    a. Materials to be decontaminated outside of the immediate animal room are placed in a durable, leak-proof container and secured for transport. For infectious materials, the outer surface of the container is disinfected prior to moving materials and the transport container has a universal biohazard label.
    b. Materials to be removed from the facility for decontamination are packed in accordance with applicable local, state, and federal regulations.
19. An effective integrated pest management program is required.
20. Animals and plants not associated with the work being performed are not permitted in the areas where infectious materials and/or animals are housed or manipulated.

Special Practices

None required.

Safety Equipment (Primary Barriers and Personal Protective Equipment)

1. Specialized devices or equipment for restraint or containment may be required as determined by appropriate risk assessment.
2. Laboratory coats, gowns, or uniforms are the minimum recommended to prevent contamination of personal clothing. Protective outer clothing is not worn outside areas where infectious materials and/or animals are housed or manipulated. Gowns and uniforms are not worn outside the animal facility.
3. Eye protection and face protection (e.g., safety glasses, goggles, mask, face shield, or other splatter guard) are used for manipulations or activities that may result in splashes or sprays of infectious or other hazardous materials. Eye protection and face protection are disposed of with other contaminated facility waste or decontaminated after use.
4. Persons having contact with NHPs assess the risk of mucous membrane exposure and wear protective equipment (e.g., face shield, surgical mask, goggles), as appropriate.
5. Additional PPE is considered for persons working with large animals.

Animal Facilities (Secondary Barriers)

1. ABSL-1 facilities should be separated from the general traffic patterns of the building and restricted as appropriate. Consider placing animal areas away from exterior walls of buildings to minimize the impact from the outside environment temperatures.
    a. External facility doors are self-closing and self-locking.
    b. Access to the animal facility is restricted.
    c. Doors to areas where infectious materials and/or animals are housed open inward, are self-closing, are kept closed when experimental animals are present, and never propped open. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically.
2. The animal facility has a sink for handwashing.
    a. Emergency eyewash and shower are readily available, easily accessible, and appropriately maintained.
    b. Sink traps are filled with water and/or appropriate disinfectant to prevent the migration of vermin and gases.
    c. If open floor drains are provided, the traps are filled with water and/ or appropriate disinfectant or sealed to prevent the migration of vermin and gases.
3. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (e.g., walls, floors, ceilings) are water-resistant.
    a. Floors are slip-resistant, impervious to liquids, and resistant to chemicals. Floors with drains are sloped toward drains to facilitate cleaning.
    b. It is recommended that penetrations in floors, walls, and ceilings be sealed, including openings around ducts, doors, doorframes, outlets, and switch plates to facilitate pest control and proper cleaning.
    c. Internal facility fixtures, such as light features, air ducts, and utility pipes, are designed and installed to minimize horizontal surface areas to facilitate cleaning and minimize the accumulation of debris or fomites.

    d. External windows are not recommended; if present, they are resistant to breakage. Where possible, windows are sealed. If the animal facility has windows that open, they are fitted with fly screens.
    e. Illumination is adequate for all activities and avoids reflections and glare that could impede vision.
4. Furniture can support anticipated loads and uses.
    a. Benchtops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
    b. Chairs used in animal areas are covered with a non-porous material that can be easily cleaned and decontaminated with an appropriate disinfectant and sealed to prevent harboring of insects/vermin.
    c. Equipment and furnishings are carefully evaluated to minimize exposure of personnel to pinch points and sharp edges and corners.
5. Ventilation is provided in accordance with the Guide for the Care and Use of Laboratory Animals.
    a. Ventilation system design considers the heat and high moisture load produced during the cleaning of animal rooms and the cage wash process.
6. Cages are washed manually or preferably in a mechanical cage washer. The mechanical cage washers have a final rinse temperature of at least 180°F. If manual cage washing is utilized, ensure that appropriate disinfectants are selected.

Animal Biosafety Level 2 (ABSL-2)

Animal Biosafety Level 2 (ABSL-2) builds upon the practices, procedures, containment equipment, and facility requirements of ABSL-1. ABSL-2 is suitable for work involving laboratory animals infected with agents associated with human disease and posing a moderate hazard to personnel and the environment. It also addresses hazards from ingestion and from percutaneous and mucous membrane exposure.

ABSL-2 requires that, in addition to the requirements for ABSL-1, a BSC or other physical containment equipment is used when procedures involve the manipulation of infectious materials or where aerosols or splashes may be created.

Appropriate PPE is worn to reduce exposure to infectious agents, animals, and contaminated equipment. An appropriate occupational health program is in place, as determined by risk assessment.

Standard Microbiological Practices for ABSL-2

The following standard and special practices, safety equipment, and facility specifications are recommended for ABSL-2.

1. The animal facility director establishes and enforces policies, procedures, and protocols for biosafety, biosecurity, and emergencies within the animal facility.
2. Access to the animal room is limited. Only those persons required for experimental, husbandry, or support purposes are authorized to enter the facility.
3. Each institution ensures that worker safety and health concerns are addressed as part of the animal protocol review process. Consideration is given to specific biohazards unique to the animal species and protocol in use. Prior to beginning a study, animal protocols are also reviewed and approved by

the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biosafety Committee (IBC), or equivalent resource, as appropriate.

4. The supervisor ensures that animal care, facility, and support personnel receive appropriate training regarding their duties, animal husbandry procedures, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization). Personnel receive annual updates and additional training when equipment, procedures, or policies change. Records are maintained for all hazard evaluations, training sessions, and staff attendance. All persons, including facility equipment personnel, service workers, and visitors, are advised of the potential hazards (e.g., naturally acquired or research pathogens, allergens); are instructed on the appropriate safeguards; and read and follow instructions on practices and procedures. An institutional policy regarding visitor training, occupational health requirements, and safety communication is considered.
5. Personal health status may affect an individual's susceptibility to infection and ability to receive available immunizations or prophylactic interventions. Therefore, all personnel, and particularly those of reproductive age and/or those having conditions that may predispose them to increased risk for infection (e.g., organ transplant, medical immunosuppressive agents), are provided information regarding immune competence and susceptibility to infectious agents. Individuals having such conditions are encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance. Facility supervisors ensure that medical staff are informed of potential occupational hazards within the animal facility, to include those associated with research, animal husbandry duties, animal care, and manipulations.
6. Appropriate occupational medical services are in place, as determined by risk assessment.
    a. An animal allergy prevention program is part of the medical surveillance.
    b. Personnel using respirators for animal allergy prevention are enrolled in an appropriately constituted respiratory protection program.
7. A safety manual specific to the facility is prepared or adopted in consultation with the facility director and appropriate safety professionals. The safety manual is available, accessible, and periodically reviewed and updated as necessary.
    a. The safety manual contains sufficient information to describe the biosafety and containment procedures for the experimental animals, organisms, biological materials in use, and the work performed.
    b. The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, escape of animals within the animal facility, and other potential emergencies. A plan for the disposition of animals during emergency situations is included. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies.
8. A sign is posted at the entrance to the animal room when infectious agents are present. Posted information includes: the universal biohazard symbol, the room's Animal Biosafety Level, the supervisor's or other responsible personnel's name and telephone number, PPE requirements, general occupational health requirements (e.g., immunization, respiratory protection), and required procedures for entering and exiting the animal room. Agent information is posted in accordance with the institutional policy.

9. Long hair is restrained so that it cannot contact hands, animals, specimens, containers, or equipment.
10. Gloves are worn to protect hands from exposure to hazardous materials and when handling animals.
    a. Glove selection is based on an appropriate risk assessment.
    b. Consider the need for bite and/or scratch-resistant gloves.
    c. Gloves worn inside the animal facility are not worn outside the animal facility.
    d. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
    e. Do not wash or reuse disposable gloves, and dispose of used gloves with other contaminated animal facility waste.
11. Gloves and other PPE are removed in a manner that minimizes personal contamination and transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or manipulated.
12. Persons wash their hands after handling animals and before leaving the areas where infectious materials and/or animals are housed or manipulated.
13. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in animal areas.
14. Mouth pipetting is prohibited. Mechanical pipetting devices are used.
15. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware are developed, implemented, and followed; policies are consistent with applicable state, federal, and local requirements. Whenever practical, supervisors adopt improved engineering and work practice controls that reduce the risk of sharps injuries. Precautions are always taken with sharp items. These include:
    a. Plasticware is substituted for glassware whenever possible.
    b. Use of needles and syringes or other sharp instruments is limited in the animal facility and is restricted to situations where there is no alternative (e.g., parenteral injection, blood collection, or aspiration of fluids from laboratory animals or diaphragm bottles). Active or passive needle-based safety devices are to be used whenever possible.
        i. Uncapping of needles is performed in such a manner to reduce the potential for recoil causing an accidental needlestick.
        ii. Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
        iii. If absolutely necessary to remove a needle from a syringe (e.g., to prevent lysing blood cells) or recap a needle (e.g., loading syringes in one room and injecting animals in another), a hands-free device or comparable safety procedure must be used (e.g., a needle remover on a sharps container, or the use of forceps to hold the cap when recapping a needle).
        iv. Used, disposable needles and syringes are carefully placed in puncture-resistant containers used for sharps disposal immediately after use. The sharps disposal container is located as close to the point of use as possible.
    c. Non-disposable sharps (e.g., necropsy instruments such as forceps, pins, reusable scalpels) are placed in a hard-walled container for transport to a processing area for decontamination.

    d. Broken glassware is not handled directly. Instead, it is removed using a brush and dustpan, tongs, or forceps.
16. Procedures are carefully performed to minimize the creation of aerosols or splatters of infectious materials and waste.
17. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant. Decontaminate all potentially infectious materials before transport or disposal using an effective method. Spills involving infectious materials are contained, decontaminated, and cleaned up by staff who are properly trained and equipped to work with infectious material. A spill procedure is developed and posted within the animal facility.
18. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method, consistent with applicable institutional, local and state requirements. Depending on where the decontamination will be performed, the following methods are used prior to transport:
    a. Materials to be decontaminated outside of the immediate animal room are placed in a durable, leak-proof container and secured for transport. For infectious materials, the outer surface of the container is disinfected prior to moving materials and the transport container has a universal biohazard label.
    b. Materials to be removed from the facility for decontamination are packed in accordance with applicable local, state, and federal regulations.
19. An effective integrated pest management program is required.
20. Animals and plants not associated with the work being performed are not permitted in the areas where infectious materials and/or animals are housed or manipulated.

Special Practices

1. Animal care staff are provided information on signs and symptoms of disease, receive occupational medical services including medical evaluation, surveillance, and treatment, as appropriate, and are offered available immunizations for agents handled or potentially present in the facility.
2. All procedures involving the manipulation of infectious materials that may generate an aerosol are conducted within a BSC or other physical containment device, when possible. If it is not possible to perform a procedure within a BSC or other physical containment device, a combination of appropriate personal protective equipment, administrative and/or engineering controls (e.g., downdraft table) are used, based on a risk assessment.
    a. Restraint devices and practices that reduce the risk of exposure during animal manipulations (e.g., physical restraint, chemical restraint) are used whenever possible.
    b. Equipment, cages, and racks are handled in a manner that minimizes contamination of other areas. Cages are decontaminated prior to washing.
3. Develop and implement an appropriate decontamination program in compliance with applicable institutional, local, and state requirements.
    a. Equipment is decontaminated before repair, maintenance, or removal from the animal facility. A method for decontaminating routine husbandry equipment and sensitive electronic or medical equipment is identified and implemented.
    b. Decontamination of an entire animal room is considered when there has been gross contamination of the space, significant changes in usage, and for major renovations or

maintenance shutdowns. Selection of the appropriate materials and methods used to decontaminate the animal room is based on the risk assessment.

c. Decontamination processes are verified on a routine basis.

4. Incidents that may result in exposure to infectious materials are immediately evaluated per institutional policies. All such incidents are reported to the animal facility supervisor and any other personnel designated by the institution. Appropriate records are maintained.

Safety Equipment (Primary Barriers and Personal Protective Equipment)

1. Properly maintained BSCs and other physical containment devices or equipment are used whenever conducting procedures with a potential for creating aerosols, splashes, or other potential exposures to hazardous materials. These include the necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, and intranasal inoculation of animals. A risk assessment dictates the type of other physical containment devices used when BSCs may not be suitable.
    a. When indicated by risk assessment, animals are housed in primary biosafety containment equipment appropriate for the animal species, such as solid wall and bottom cages covered with micro-isolator lids or other equivalent primary containment systems for larger animals.
    b. If used, actively ventilated caging systems are designed to contain microorganisms. Exhaust plenums for these systems are sealed. Safety mechanisms are in place to prevent the cage and exhaust plenums from becoming positively pressurized if the exhaust fan fails. The system is also alarmed to indicate operational malfunctions. Exhaust HEPA filters and filter housings are certified annually.
2. Protective clothing, such as gowns, uniforms, scrubs, or laboratory coats, and other PPE are worn while in the areas where infectious materials and/or animals are housed or manipulated.
    a. Scrubs and uniforms are removed before leaving the animal facility.
    b. Reusable clothing is appropriately contained and decontaminated before being laundered. Animal facility and protective clothing is never taken home.
    c. Disposable PPE and other contaminated waste are appropriately contained and decontaminated prior to disposal.
3. Eye protection and face protection (e.g., safety glasses, goggles, mask, face shield, or other splatter guard) are used for manipulations or activities that may result in splashes or sprays from infectious or other hazardous materials when the animal or microorganisms is handled outside the BSC or another containment device. Eye protection and face protection are disposed of with other contaminated facility waste or decontaminated after use.
4. Persons having contact with NHPs assess the risk of mucous membrane exposure and wear protective equipment (e.g., face shield, surgical mask, goggles), as appropriate.
5. Additional PPE is considered for persons working with large animals.
6. Based on the pathogen and work performed, respiratory protection may be considered for staff enrolled in a properly constituted respiratory protection program.

Animal Facilities (Secondary Barriers)

1. ABSL-2 facilities should be separated from the general traffic patterns of the building and restricted, as appropriate. Consider placing animal areas away from exterior walls of buildings to minimize the impact from the outside environment temperatures.
    a. External facility doors are self-closing and self-locking.

    b. Access to the animal facility is restricted.
    c. Doors to areas where infectious materials and/or animals are housed open inward, are self-closing, are kept closed when experimental animals are present, and are never to be propped open. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically.
2. A handwashing sink is located at the exit of the areas where infectious materials and/or animals are housed or manipulated. Additional sinks for handwashing are located in other appropriate locations within the facility. If the animal facility has segregated areas where infectious materials and/or animals are housed or manipulated, a sink is also available for handwashing at the exit from each segregated area.
    a. Emergency eyewash and shower are readily available, easily accessible, and appropriately maintained.
    b. Sink traps are filled with water and/or appropriate disinfectant to prevent the migration of vermin and gases.
    c. If open floor drains are provided, the traps are filled with water and/or appropriate disinfectant or sealed to prevent the migration of vermin and gases.
3. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (e.g., walls, floors, and ceilings) are water-resistant.
    a. Floors are slip-resistant, impervious to liquids, and resistant to chemicals. Floors with drains are sloped toward drains to facilitate cleaning.
    b. Penetrations in floors, walls, and ceiling surfaces are sealed, including openings around ducts, doors, doorframes, outlets, and switch plates to facilitate pest control and proper cleaning.
    c. Internal facility fixtures, such as light features, air ducts, and utility pipes, are designed and installed to minimize horizontal surface areas to facilitate cleaning and minimize the accumulation of debris or fomites.
    d. External windows are not recommended; if present, they are sealed and resistant to breakage.
    e. Illumination is adequate for all activities and avoids reflections and glare that could impede vision.
4. Furniture is minimized and can support anticipated loads and uses.
    a. Benchtops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
    b. Chairs used in animal areas are covered with a non-porous material that can be easily cleaned and decontaminated with an appropriate disinfectant and sealed to prevent harboring of insects/vermin.
    c. Equipment and furnishings are carefully evaluated to minimize exposure of personnel to pinch points and sharp edges and corners.
5. Ventilation is provided in accordance with the Guide for the Care and Use of Laboratory Animals.
    a. Ventilation system design considers the heat and high moisture load produced during the cleaning of animal rooms and the cage wash process.
    b. The direction of airflow into the animal facility is inward; animal rooms maintain inward directional airflow compared to adjoining hallways.
    c. A ducted exhaust air ventilation system is provided.

    d. Exhaust air is discharged to the outside without being recirculated to other rooms.
6. Mechanical cage washers have a final rinse temperature of at least 180°F. The cage wash area is designed to accommodate the use of high-pressure spray systems, humidity, strong chemical disinfectants, and 180°F water temperatures during the cage/equipment cleaning process.
7. BSCs and other primary containment barrier systems are installed and operated in a manner to ensure their effectiveness.
    a. BSCs are installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs are located away from doors, windows that can be opened, heavily traveled areas, and other possible airflow disruptions.
    b. BSCs can be connected to the animal facility exhaust system by either a canopy connection (Class IIA only) or directly exhausted to the outside through a hard connection (Class IIB, IIC, or III). Class IIA or IIC BSC exhaust can be safely recirculated back into the animal facility environment if no volatile toxic chemicals are used in the cabinet.
    c. BSCs are certified at least annually to ensure correct performance.
8. Vacuum lines in use are protected with liquid disinfectant traps and in-line HEPA filters or their equivalent. Filters are replaced, as needed, or on a replacement schedule determined by a risk assessment.
9. If an autoclave is present in an animal facility, it's used to facilitate the sterilization of reusable equipment and not used for the decontamination of infectious materials and waste. A validated alternative process (e.g., alkaline digestion, incineration) may be used for decontamination and disposal of carcasses.

Animal Biosafety Level 3 and Animal Biosafety Level 4

At this revision of the Biosafety Manual, no Animal Biosafety Level 3 or 4 work is being conducted at the University of Miami. There are no ABSL-3 or ABSL-4 facilities on the research campuses. Therefore, no BSL-3 or BSL-4 work is permitted onsite. Should there be a desire to work at a higher BSL then what is available, contact the Office of the Vice Provost for Scholarship and Research to explore the possibility of conducting the research.

Clinical Biosafety

Most contemporary medical decision-making utilizes the result(s) of at least one diagnostic test conducted in a clinical laboratory as a part of evidence-based care. Clinical laboratories are one of the first lines of public health defense because they detect and report epidemiologically important organisms and identify emerging patterns of antimicrobial resistance. The safe, effective operation of clinical laboratories is critical for both the care of individual patients and the health of laboratory professionals, the community, and the environment.

In 2016, following the U.S. Ebola crisis, the U.S. Clinical Laboratory Improvement Advisory Committee (CLIAC) recognized "the matter of biosafety in clinical laboratories as an urgent unmet national need." In particular, CLIAC indicated the need for concise, understandable guidance to help enable clinical laboratories to assess and mitigate risks when the identity of the infectious agent is unknown or unconfirmed.

Clinical laboratories routinely work with unknown specimens and specimens that have the potential to be infected with multiple pathogens; as such, the occupational risks in a clinical laboratory environment differ from those of a research or teaching laboratory. Most public and animal health clinical

laboratories use Biosafety Level 2 (BSL-2) facility, engineering, and biosafety practices. Clinical diagnostic laboratory personnel may not know what infectious agent or other hazard(s) exist in the specimen they handle and process. The OSHA BBP Standard (29 CFR Section 1910.1030) applies to all occupational exposure to human blood or other potentially infectious materials and directs the creation and implementation of a written Exposure Control Plan to eliminate or minimize employee exposure. Details on what is required in the Exposure Control Plan is provided in the following subsection. Existing guidance (e.g., CDC, MMWR, BMBL) states that most clinical laboratories function as BSL-2 facilities with workers following Standard Precautions and BSL-2 practices. As such, concerns such as PPE requirements, handling agents and bodily fluids, cleaning spills, and disposal of contaminated materials should be followed as outlined in the BSL-2 lab practices mentioned earlier in this document. Risk assessment however will be the backbone in evaluating the risks that arise from agent and lab hazards, taking into account the adequacy of existing controls, prioritizing those risks, and deciding if the risks are acceptable.

Exposure Control Plan

The Exposure Control Plan must comply with OSHA's Bloodborne Pathogens Standard, 29CFR§1910.1030. The plan is designed to eliminate or minimize occupational exposure of employees to bloodborne pathogens and other potentially infectious materials.

The Exposure Control Plan includes mandated implementation of exposure determination and risk assessment, training, notification of employees' rights, Standard Precautions (formerly known as Universal Precautions), engineering controls, personal protective equipment, and medical surveillance. For specific information regarding laboratory compliance with the Exposure Control Plan, contact EHS. The Hepatitis B Virus (HBV) is the major infectious occupational hazard in the health-care industry. Despite the similarities in the modes of transmission, the risk of HBV infection in the health-care environment far exceeds that for other viruses of great concern, such as the Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV). All chemicals used to inactivate these viruses must be tuberculocidal and EPA approved.

Recombinant Therapeutics

The use of recombinant therapeutics in clinical research often, but not always, requires the introduction of new viruses into the patient. These viruses are commonly referred to as “viral vectors”, as the purpose of the virus is to deliver genetic material into the cell. While these viral vectors fall outside the consideration of typical bloodborne pathogens, their properties and thus risk to the personnel administering the vector will vary virus to virus. As with any clinical research laboratory, observe standard precautions and review the laboratory biological hygiene plan for additional guidance on agent risks and any special standard operating procedures (SOP) that may be required for handling patient specimens. All specimen manipulations of this nature should be considered BSL-2 minimum and all clinical work involving recombinant therapeutics requires IBC review and approval.

Plant Biosafety

Plants are an important research tool used to learn more about basic life processes and to help answer questions in agriculture, health and the environment. Plant research generally does not pose a risk to human health but can pose a hazard to other plants and the environment. Research involving plant diseases, plant pests, or genetically modified plants requires containment from the natural environment and from agricultural crops and markets.

Plant containment is intended to prevent any potential release of a genetically modified plant or associated organism. The movement, use, possession or release of exotic or potentially harmful plant-associated arthropods, biological control agents, plant pests, plant pathogens, noxious weeds and invasive plants are regulated by local, state, and federal agencies.

Aquatics Biosafety

The risks in aquatic research can vary far beyond the scope of traditional biosafety, including electrical hazards, physical hazards, and, as is the case with most all biological research, chemical hazards. The research itself often goes beyond the confines of a traditional lab and may introduce field hazards as well, such as heat exposure. A holistic safety culture must assess all of these varied risks in these research environments, with traditional biosafety playing a vital part in the culture of safety.

Biosecurity

In recent years, with the passing of federal legislation regulating the possession, use, and transfer of biological Select Agents and Toxins with high adverse public health and/or agricultural consequences (DHHS, USDA APHIS Select Agents), a much greater emphasis has been placed in the emerging field of biosecurity. Biosecurity and Select Agent issues are covered in detail in Section VI and Appendix F of BMBL. While biosafety focuses on the protection of personnel, the surrounding community, and the environment from the unintentional release of hazardous biological agents and toxins, the field of laboratory biosecurity is focused on the prevention of the theft, loss, and misuse of hazardous biological agents and toxins, equipment, and/or valuable information by an individual(s) for malicious use. Nonetheless, a successful containment strategy must incorporate aspects of both biosafety and laboratory biosecurity to adequately address the risks present at the facility.

Other Common Bio-Related Hazards

Chemicals

Virtually all biological research is possible only with the application of various chemicals. While some of the base standards for safety requirements outlined herein may seem in excess of what may strictly be needed for risk group 1 agents, these standards were developed holistically in consideration of this fact that chemicals are ubiquitously found in biological research facilities. Note that expectations outlined in this manual are the general standard for research, but those standards will naturally shift depending on individual lab, procedures employed, and risk assessment. Please consult the EHS Laboratory Safety Manual for more guidance on the subject of chemical hazards.

Field Research

The varied challenges of field research have to be assessed on a case-by-case basis using risk assessment and considering the chosen environment, the nature of the work, and the potential risks existing outside the scope of a traditional biosafety program. At UM, field research is assessed using the Field Research Hazard Assessment Form and is administered through the IACUC or IBC offices, depending on the nature of the work.

Risk Assessment and Risk Mitigation

Risk assessment is the process by which the consequences of an exposure to an agent are weighed against the likelihood of an exposure is to occur while performing a task in an experiment. Events that are likely to occur and have a severe consequence will require a greater amount of risk mitigation to

ensure that task can be performed safely as compared to tasks that are unlikely to occur and/or have benign risks from exposure. The Biosafety Office conducts risk assessments of new research and during protocol review. However, best practice would dictate that labs conduct routine risk assessment of the procedures ongoing in a lab. Researchers would be well served to conduct risk assessments daily for routine operations within the lab to ensure safety is always observed and practiced.

There are 4 methods for risk mitigation in a lab to ensure safety is observed. The hierarchy of controls dictates that some methods of risk mitigation are more effective than other methods. In descending order, the methods for risk mitigation in order of effectiveness are: engineering controls, administrative controls, work practice controls, and personal protective equipment.

Engineering Controls

Engineering controls are the physical and technological aspects in laboratory design that are often part of the lab design itself. However, devices brought into the lab solely for the purpose of making a task less risky also serve as forms of engineering controls.

Primary Containment

Primary barrier or primary containment is defined as physical containment measure(s) placed directly at the level of the hazard. Safety equipment such as biological safety cabinets (BSCs), enclosed containers, and other biosafety controls are designed to protect personnel, the surrounding community, and the environment from possible exposure to hazardous biological agents and toxins. Primary barriers can function to either provide containment (e.g., BSCs) or direct personal protection from the hazardous biological agents and toxins used. The BSC is the standard device used to provide containment of hazardous biological agents and toxins when conducting microbiological activities. Three primary types of BSCs (Class I, II, III) are used in laboratory facilities and selection of the appropriate BSC should be based on the risks identified for each respective laboratory.

Additional primary containment devices may include sealed containers (e.g., sealed rotors and centrifuge safety cups). These enclosed containers are designed to contain aerosols, droplets, and leakage of hazardous biological agents and toxins that may result during certain activities (e.g., centrifugation). Sealed containers provide containment for transfers between laboratories within a facility, between facilities, and depending upon risk assessment, within a laboratory. Selection of the appropriate primary containment device should be based on the risks identified for those activities likely to produce aerosols, droplets, or result in potential leakage of hazardous biological agents and toxins. Note that in some cases, such as when working with large animals, secondary barriers may become primary barriers. This lack of traditional primary barriers (e.g., BSC) can lead to additional risks to personnel, the surrounding community, and the environment. In these cases, the facility becomes the primary barrier and personnel must rely on administrative and personal protective equipment to reduce the risk of exposure. This type of facility may require additional engineering controls and precautions (e.g., HEPA filtration on the exhaust air) to mitigate the risks posed to personnel, the surrounding community, and the environment.

Biological Safety Cabinets

Biosafety cabinets come in a variety of classes and types, and offer different types of protections based on the need of the research. Class I cabinets protect the user and the environment around the user, but not the product. Class II cabinets protect the user, the environment around the user, and the product by using laminar airflow. Class II Type A2 cabinets are the most commonly represented biosafety cabinet in UM research labs. Class III cabinets feature an airtight glove box design, where the enclosed bench is leak-tight to ensure that there is no pathway of exposure to biohazards sealed inside. Biosafety cabinets must be certified on an annual basis or anytime a cabinet is relocated to another space. As cabinets are used for work with hazardous materials, they must be professional decontaminated prior to the movement of the unit out of the laboratory.

Working in a Biological Safety Cabinet

In addition to the high efficiency particulate air (HEPA) filters that remove particles of 0.3 µm with at least 99.97% efficiency, the protection provided by a BSC is also dependent upon an undisrupted,

directional airflow within the cabinet. Disruptions to the airflow resulting from inappropriate work practices or laboratory design can marginalize the operation of the BSC and put the user at risk. For this reason, the BSC should be located away from doorways, high traffic areas and other locations in the laboratory where equipment or the movement of people may generate air currents that disturb air flow in the cabinet.

Preparing for work in the BSC

1. Before starting work in the BSC, review all procedures that will be used; identify the necessary equipment and materials that will be needed and develop a plan for safe and efficient work.
2. If the cabinet is not running, turn on the blower and fluorescent lights and turn off the UV light if it is on.
3. Verify that the BSC is operating correctly:
    a. Check the instrument display/gauges for operational status.
    b. Check the intake and exhaust grills for obstructions.
    c. Check that the sash is in the appropriate position.
    d. Check for the inward flow of air at the face of the BSC by holding a tissue near the bottom edge of the sash.
4. Wipe down the interior surfaces of the cabinet with an appropriate disinfectant such as 70% ethanol, WEX-CIDE, a 1:100 dilution of household bleach (0.05% sodium hypochlorite) or another suitable disinfectant. Note that bleach, although an excellent and inexpensive disinfectant, will react with stainless steel surfaces of the hood and must be followed with a rinse of sterile water or 70% ethanol.
5. Load the cabinet with materials that will be needed for the procedure, wiping their surfaces with 70% ethanol to minimize the introduction of contaminants into the BSC. Position the materials near the back of the hood and organize them in a manner that will allow for the separation of clean and contaminated items during your work in the hood. Only materials needed for immediate work should be place in the cabinet. Extra supplies (gloves, culture flasks/plates should be stored outside the cabinet).
6. Define a work area 4 to 5 inches behind the front grill of the hood. This area may be covered with a plastic-backed absorbent liner to minimize the effects of splatter and aerosol generation and to facilitate clean-up in the event of a spill. The liner may be moistened with an appropriate disinfectant to promote aseptic conditions within the cabinet.
7. Before beginning your work, allow the hood to run for a minimum of 5 minutes to purge any airborne contaminates from the work area.

Working in the BSC

1. Wear appropriate personal protective equipment (PPE). At a minimum, a lab coat with close-fitting sleeves and gloves should be worn. Because it is appropriate to wash your hands after removing gloves, double-gloving is a good option if you anticipate the need for glove changes during your work or in the event of a spill a double pair of gloves adds an additional layer of personal protection.
2. Proper aseptic technique is essential. The BSC will prevent aerosol contamination but will not prevent contact transfer resulting from poor technique.

3. Avoid rapid, sweeping movements of the arms into or out of the cabinet. Move items into our out of the cabinet slowly and perpendicular to the face of the cabinet to minimize disturbance to the protective curtain of air.
4. Do not block the air flow in the BSC by resting your arms or placing discarded wrappers, procedure notes or other materials on the grill at the front of the BSC.
5. Organize your work to maintain a separation of clean materials from materials that have become contaminated during use.
6. Provide a container(s) within the BSC for the collection of contaminated waste and other materials. Repeated movement out of the hood to discard pipettes or other waste materials can disrupt airflow in the cabinet and marginalize the protection to both the individual working at the BSC and to the cultures that are being manipulated.
    a. Low profile, horizontal containers are preferable to vertical containers as they are less obstructive to airflow in the cabinet.
    b. Contaminated items that will not be reused may be placed into small biohazard bag or a similar container.
    c. If chemical disinfection will be used for the decontamination of reusable items an appropriate disinfectant should be poured into the discard container prior to use.
7. Alternatively.
    d. If contaminated materials will be sterilized by autoclaving add enough water to the discard pan to ensure that sufficient steam is generated during autoclaving.
8. Do not work with open flames or other heat sources. These generate heated convection currents that may disrupt the smooth flow of air in the hood and may also damage the hood's HEPA filters.

Completion of work in the BSC

1. Discard all waste materials generated by your work into appropriate containers inside the BSC. Close or cover all open containers.
2. Allow the cabinet to run for 3 to 5 minutes with no activity.
3. Disinfect the surfaces of all materials, equipment and containers that will be removed from the BSC, to minimize subsequent contamination in the laboratory.
4. Remove contaminated gloves and dispose of them appropriately
5. After putting on a clean pair of gloves, remove all materials for the BSC.
6. Wipe down all interior surfaces of the BSC with an appropriate disinfectant.
7. If the BSC is not scheduled for subsequent use, turn off the fluorescent light and cabinet blower. BSCs are designed for 24 hour operation, but in the interest of energy conservation it should be shut down when it will not be used for an extended period of time.
8. Turn on the UV light if the cabinet is equipped and if appropriate.

Laminar Flow Hoods (Clean Benches)

Laminar Flow Hoods, also called Clean Benches, use a HEPA filter to blow sterile air across a work surface. By design, clean benches protect products only. They do not provide protection for users or the environment. Consequently, only non-hazardous materials may be allowed to be used in a clean bench. However, similar to BSCs, they must still be certified on an annual basis by a certified vendor.

Chemical Fume Hoods

Please consult the EHS Laboratory Safety Manual for a more comprehensive review of Chemical Fume Hoods (CFHs). Worthy of note, chemical fume hoods differentiate themselves from the aforementioned hoods by design in that they do not use HEPA filters, they do not contain hazards, and they protect the user only. Similar to BSCs, CFHs must be inspected annually by EHS to ensure that hoods are running within specification.

Secondary Containment

The design and construction of the laboratory facility provide a means of secondary containment of hazardous biological agents and toxins. The secondary barriers, together with other biosafety controls, help provide protection of personnel, the surrounding community, and the environment from possible exposure to hazardous biological agents and toxins.

Lab Facility Design

When the risk of infection by aerosol or droplet exposure is present, higher levels of secondary containment and multiple primary barriers may be used in combination with other controls to minimize the risk of exposure to personnel and the unintentional release into the surrounding community or the environment. Such design features may include, but are not limited to the following:

- Ventilation strategies to ensure containment of the hazards;
- Effluent decontamination systems; and
- Specialized building/suite/laboratory configurations, including:
    - Controlled access zones to support the separation of the laboratory from office and public spaces;
    - Anterooms; and
    - Airlocks.

While some of these aforementioned airflow design features can provide specially designed engineering controls in the management of aerosolized laboratory hazards, at lower biosafety levels simply keeping doors closed can provide many similar benefits in theory. Keeping doors closed helps prevent aerosols from leaking out of lab spaces out into hallway and shared spaces, and if building ventilation is designed as such, it can help maintain directional airflow from hallway settings into laboratory spaces.

Work Practice Controls

Work practice controls are procedures lab researchers can observe to help ensure a higher degree of safety in the laboratory. This can include routine hand washing, routine surface decontamination, strategic sharps bin placement in the lab, careful liquid culture manipulation to minimize potential aerosol creation, and a careful sharps management plan.

Biohazardous Waste Collection

Liquid Cultures

Liquid cultures are to be decontaminated by the lab using an appropriate disinfectant and disposed of as a hazardous chemical through EHS HazMat. If bleach is used as the disinfectant of choice, add household bleach (at least 5% sodium hypochlorite) to the container of liquid waste so that the final volume of the solution is 10% bleach. Mix gently and allow a minimum of 30 minutes contact time before discarding into the sanitary sewer. Longer contact times may be required for some infectious agents. Contact EHS Biosafety for additional guidance.

Solid Biohazardous Waste

Solid waste including culture plates, flasks and other disposable materials containing or contaminated with regulated waste materials such gloves, or materials used for cleaning/absorbing spills of blood or other biological liquids shall be collected in a biohazardous waste container. This container shall be prominently labeled for biohazardous waste collection and equipped with a lid to minimize exposure to discarded waste material. This waste must be disposed of as biohazardous waste and cannot be decontaminated for disposal by the lab via autoclave.

Disposable Sharps

Sharps, such as needles, syringes, scalpels, and intravenous tubing with needles attached, must be properly disposed of when work with them has finished. Sharps may also include glass microscope slides, Pasteur pipettes, microtome blades, capillary tubes and any other items that are contaminated with infectious or potentially infectious biological materials and are capable of causing puncture wounds or lacerations if handled improperly. This working definition of sharps is not limited to those items that are specifically used in medical or biological procedures and includes sharps generated from all other uses, with the exception sharps that are contaminated with hazardous, toxic or radioactive chemicals,.

Guidelines for the disposal of sharps:

1. Never discard needles or other disposable sharp instruments into the regular trash or into bags containing hazardous waste.
2. Never leave unprotected sharps lying on benchtops or in drawers/trays.
3. Immediately discard all used sharps directly into puncture-resistant containers that are specifically designed / designated for the collection of sharps.
4. Sharps containers used for the collection of needles, syringes and/or scalpels shall be dated when they are put into use.
5. Pasteur pipettes and other disposable glass items that are not contaminated with potentially infectious materials may be discarded into broken glass containers.

6. Disposable syringes with needles shall be discarded as a unit. If the needle must be removed, use the integrated device for needle removal found on most sharps containers or use other mechanical means.
7. Used needles and other contaminated sharps shall not be bent, broken, cut, recapped, re-sheathed or otherwise manipulated by hand. If any of the actions described above are required by a specific procedure, it should be done using a mechanical device such as pliers or hemostats.
8. Do not over-fill sharps containers. They must be closed and sealed when they are approximately 3/4 full.
9. If the outside of a filled sharps container is contaminated, the surface of the container should be chemically disinfected prior to being removed from the laboratory.
10. Sharps containers used for the collection of discarded needles, syringes and scalpels cannot be put into the trash, even if decontaminated.

Disinfection/Decontamination

Labs should adopt routine decontamination practices that involve decontamination at the end of experiments, prior to the initiation of new experiments, and at anytime when an overt loss of containment occurs.

Personal Protective Equipment

Personal protective equipment (PPE) helps protect the user's body from injury from a variety of sources (e.g., physical, electrical, heat, noise, chemical) or potential exposure to biological hazards and airborne particulate matter. PPE includes gloves, coats, gowns, shoe covers, closed-toe laboratory footwear, respirators, face shields, safety glasses, goggles, or ear plugs. PPE is usually used in combination with other biosafety controls (e.g., BSCs, centrifuge safety cups, and small animal caging systems) that contain the hazardous biological agents and toxins, animals, or materials being handled. In situations where a BSC cannot be used, PPE may become the primary barrier between personnel and the hazardous biological agents and toxins. Examples include fieldwork, resource-limited settings, certain animal studies, animal necropsy, and activities relating to operations, maintenance, service, or support of the laboratory facility. Selection of the appropriate PPE should be based on the risks identified for each respective laboratory.

Lab Clothing

Personal attire while in the laboratory plays a major role in determining the level of risk of exposure to hazardous agents. Appropriate clothing provides an extra layer of protection against spills and splashes. Appropriate clothing covers the torso, legs, and feet. Therefore, the following practices should be adopted by the lab:

- Ships and tops must cover the upper torso. Cropped shirts, plunging necklines, spaghetti straps, or ripped shirts are prohibited.
- Pants should be long enough to cover the wearer to the ankle. Ripped jeans, shorts, capris, short skirts, and long skirts are prohibited.
- Shoes should be completely enclosed, covering the instep of the foot. Shoes with open toes, open back, open weave, or with holes are prohibited. Sandals, Crocs, Mary Janes, Birkenstocks, and flip flops are all prohibited in the lab. Leather is the preferred material for lab shoes, as these can be wiped clean.

Additional considerations for everyday wear include:

- Clothing that accommodates lab coat use. Loose or flowing tops with wide/bell sleeves; outerwear s/a coats or shawls that make it difficult to don a lab coat. Wearing this type of clothing makes it difficult/uncomfortable to wear a lab coat: The wearer may be tempted to do without the lab coat. Loose sleeves may also be dragged across the bench becoming contaminated and are a hazard around rotating equipment and open flames
- Hair must be kept away from the eyes. Long hair must be tied back. Hair longer than 6 inches from the nape of the neck must also pinned up (Use of hair nets or hats is acceptable) Hair must not impede vision, come in contact with the work, or open flames. Hair can impede vision. Long hair can fall onto the lab bench/come in contact with chemicals or biologicals. Long hair is also a hazard around rotating equipment and open flames such as Bunsen burners or alcohol burners.
- Ties and scarves that do not hang loose outside the lab coat Neckwear such as ties and scarves that hang loose Dangling neckwear may come in contact with chemicals, biologicals or open flames. These also are a hazard around rotating equipment.
- Baseball caps and other headgear as long as they are kept far enough back on the head so that vision is not impaired and also do not interfere with protective eyewear. Caps worn low over the

eyes so as to impede vision. Avoiding accidents means staying aware of one's surroundings at all times. Unimpeded visual observation is key in this regard.

- Use of iPods, MP3 players, or other electronic devices with head-phones is not allowed in laboratories and is highly discouraged in laboratory buildings. Laboratorians must be aware of their surroundings at all times which includes being able to hear alarms, sirens, run away reactions, and other people calling for help.
- Choose clothing made of natural fibers, especially cotton whenever possible Natural fibers are more fire resistant than synthetic fibers
- Avoid wearing pantyhose Fire and some chemicals may cause the nylon to melt to the skin increasing risk of serious injury
- Keep a change of clothes, including shoes, in a desk drawer After an exposure, the victim will not be allowed to re-don contaminated clothing and will need something to wear home.

PPE Standards

Personal protective equipment being critical to the safety of the research must be carefully selected and employed by the lab to mitigate risks in the lab that cannot be engineered out or planned around. PPE should be selected based on its compatibility with the hazards used in the lab and the processes employed in the research. Typical PPE can include safety glasses, goggles, face shields, gloves, lab coats, aprons, ear plugs, respirators, booties, surgical masks, among many others. While there is no universal standard for all labs to adhere to, most standard biological labs will likely use at a minimum a combination of:

- Safety Glasses: safety glasses must be donned before entering any wet bench area, including cell culture labs. This applies to lab visitors, maintenance and custodial workers, as well as staff and students. Safety glasses must meet the ANSI Z87.1 standard for impact resistance and have side shields for splash protection. Goggles may be required for certain processes where safety glasses are deemed inadequate. Safety glasses must be worn over prescription glasses, as regular prescription glasses do not provide adequate protection. Prescription safety glasses are a viable alternative for individuals who are interested.
- Lab Coats: Lab coats should be donned before handling biological materials. They should cover the wearer to the knees. Lab coats of a poly-cotton blend are acceptable, however labs where open flames are used should use coats made of 100% cotton or flame-resistant materials.
- Gloves: Glove selection must be based on the materials being used in the lab. Work dealing with only biological samples or live animals may use powder free latex gloves. However, any procedures involving the use of chemicals may be better suited with the use of nitrile exam gloves. Most chemically resistant gloves however are combustible: keep hands well away from unprotected flames or other high temperature heat sources. Before using, check gloves for physical damage, such as tears or pin holes. It may be advisable when removing gloves that have been used in working with infectious substances to disinfect the glove first to ensure hands or wrists are not incidentally touched during the removal process.

Administrative Controls

Administrative controls are a method of risk mitigation in which specialized safety committees or professional safety expertise can provide additional assessment of work procedures and suggest safer alternatives. This often includes the observance and enrollment into the University's Occupational Health Program, which can dictate vaccinations for lab staff appropriate to the risks of the research or additional medical monitoring, as needed.

Bio-Related Safety Committees

- IBC: The Institutional Biosafety Committee reviews all research comprised of recombinant or synthetic nucleic acid molecules.
- IACUC: The Institutional Animal Care & Use Committee reviews all research involving the use of animals.
- IRB: The Institutional Review Board reviews all research involving the use of live human research participants, or work that may involve materials from such participants that has not been adequately de-identified.
- IRE: The Intuitional Review Entity reviews research in accordance with US government law requiring specific oversight for life science research that could be used for dual purposes, with the potential to serve a beneficial purpose or a nefarious purpose.
- Biological Registration: At UM, all labs conducting any degree of biological research must register their research with a Biological Registration and a supporting hygiene plan.

Hygiene Plan

The biological hygiene plan serves to provide a brief risk assessment for the hazards worked with in the lab as well as detail some of the SOPs that will be critical for that research. The sections of the hygiene plan include:

1. Administration: provides an overview of the administrative details about the lab, including listing information about both the PI, the lab manager, and biosafety cabinets in use by the lab.
2. Training Requirements for Lab: this section will indicate what safety trainings will be required by the members of the lab by selecting the sections that are relevant to your research.
3. Hazard Communication: briefly outlines the types of biohazards worked with in the lab and how those materials are essential for accomplishing the aims of the lab.
4. Risk Assessment: these questions aim to clarify the risks that are inherent in the lab based on the materials used in the lab, and how those risks are being considered and mitigated by the lab.
5. Hygiene Plan: this section lists a variety of commonly used standard operating procedures broken down by category. Check the boxes for SOPs that are used by the lab. Part F is for listing additional SOPs that are specific to the research project and/or are critical to safety in the lab. For example, if the lab must recap needles, the special considerations to do this safely must be outlined and reviewed by EHS.
6. Select Agents Assessment: this section screens for materials that may be considered select agents. Review the list of organisms and select those that apply to the research, or select "NONE" if your lab does not work with any of these materials. Note that working with strains of select agents that are exempt from the Federal Select Agent Program should be detailed in section 3, hazard communication, specifically noting strains that would make use of the agent exempt from the list.

7. Dual Use Research of Concern (DURC) Assessment: This section screens for materials that could be considered dual use research. Review the materials in section 7.1 and the types of experiments in section 7.2 and check the boxes accordingly as they relate to your research. Materials meeting criteria from both categories may likely be considered dual use research of concern (DURC), although this screening process will be sent to the IRE for further review. Note that only checking a box from 1 question may still require IRE review. Checking "NONE" under both questions likewise may still require IRE review at the discretion of the IRE.
8. Acknowledgement and E-Signature: Safety is ultimately the responsibility of the PI. This section is for the PI to acknowledge and confirm their understanding of this responsibility.

Lab Inspections

All biological facilities must be inspected by EHS on an annual basis to ensure compliance with relevant biological regulations and best practices. Supporting documentation, including the annual checklist, can be found on the EHS Biosafety website.

Training Overview

Individuals working in laboratories shall be provided with laboratory specific training that is appropriate for their duties and responsibilities in the lab. Training must be completed prior to beginning work in the lab and refreshed according to each training's own requirements. For biological research, training may include:

- All biological researchers must complete:
    - One general biological safety course and refreshed every 3 years.
    - Bloodborne pathogens safety course and refreshed annually, per OSHA requirements.
    - Laboratory safety training course and refreshed every 3 years.
- All biological researchers working on research involving recombinant/synthetic nucleic acid molecules must complete:
    - Recombinant DNA training course and refreshed every 3 years.
- All lab personnel involved in the shipment of biological specimens or preparation of specimens for the purpose of shipping must complete:
    - Shipping of dangerous goods training and refreshed every 2 years.
    - Shipping of biological materials, completed once.
- Additional trainings may be available or may become required or may be created on demand. Such trainings will be listed and outlined on the EHS Biosafety website.
    - Transportation / Shipping of Biological Materials.

The shipping of dangerous goods is regulated by various entities, including International Air Transport Association (IATA), US Department of Transportation (DOT), and the Federal Aviation Administration (FAA). Regulated dangerous goods includes chemicals, biohazards, preservatives of biological materials (ex: dry ice), radioactive materials, and batteries.

University of Miami (UM) personnel must adhere to all shipping regulations, as penalties for improper shipping can include fines for you, fines for the university, as well as criminal charges. All UM personnel intending to ship must complete the Shipping of Dangerous Goods training, as a first step in the shipping process. This training must be maintained biennially. If you are shipping biological materials of any

kind, including benign materials such as DNA or proteins, you must also complete the Shipping of Biological Materials training.

Occupational Health Program

Employee Health oversees the Occupational Health Program. To enroll, researchers must complete the OHP enrollment form and complete all required pre-requisites. Upon completion, Employee Health will conduct a risk assessment based on the responses submitted and provides appropriate medical recommendations. Laboratory researchers must complete these recommendations for enrollment into the program.

Emergency Response

Biological Spill Response

The consequences of a spill may be minimized by covering the laboratory bench or work surface with a plastic baked absorbent liner, when working with hazardous or potentially hazardous organisms or biological materials,

A spill kit containing the following items must be available in the laboratory:

1. an appropriate disinfectant solution (such as 10% dilution of household bleach),
2. a package of paper towels,
3. gloves,
4. autoclave bags,
5. sharps container, and
6. forceps to pick up broken glass.

Preventing and minimizing personal exposure takes priority. If a biological spill is beyond your capacity to safely clean up:

1. Notify others working in the laboratory and evacuate immediately.
2. Close the laboratory door to restrict access to the spill area.
3. If you or other individuals are exposed, immediately remove contaminated protective equipment and clothing and wash affected areas with soap and water and rinse for up to 15 minutes.
4. Seek assistance by notifying EHS Biosafety.
5. If medical follow-up is warranted, it should be sought immediately.

Biological spills are classified based on whether they're major or minor, and whether they're in a biosafety cabinet or outside of one in the lab. A biosafety cabinet (BSC) makes spill cleanup easier, as the BSC works to contain aerosols that were generated during the spill. A biohazard spill is either major or minor based on:

- Major Spill: A spill event that requires EHS emergency response assistance to be handled safely.
- Minor Spill: A spill event that can be handled safely without EHS emergency response assistance.

Spills in the lab

Major Spills in the Lab

1. Avoid inhaling airborne materials while quickly leaving the room. Notify others to leave the room and close the door.
2. Post a sign on the door indicating the nature and time of the spill.
3. Remove contaminated clothing/PPE.
4. Wash all exposed skin with soap and warm water.
5. Call EHS (305-243-3400).
6. EHS to arrange clean-up.

Minor Spills In the Lab

1. Avoid inhaling airborne materials while quickly leaving the room. Notify others to leave the room and close the door.
2. Post a sign on the door indicating the nature and time of the spill.
3. Remove contaminated clothing/PPE.
4. Wash all exposed skin with soap and warm water.
5. Wait 30 minutes to allow aerosols to settle before entering the spill area for cleaning.
6. Don appropriate PPE.
7. Cover spill areas with absorbent material.
8. Pour liquid disinfectant onto the absorbent material from the outside of the spill area, moving towards the center. Allow for appropriate contact time.
9. Collect absorbent material and dispose of as biohazard waste.
10. Spray work surfaces, cabinets and equipment surrounding the spill area with appropriate disinfectant solution and allow for appropriate contact time before wiping up the areas with absorbent materials.
11. Remove PPE and wash hands.
12. Notify users that spill cleanup is complete.

Biosafety Cabinet Spills

Spills in a Biological Safety Cabinet

Leave the Biological Safety Cabinet turned on!

During the cleanup of spills, gloves should be changed whenever they become contaminated, after the work surface is decontaminated and before placing a new absorbent liner in the cabinet. Unless working with a double pair of gloves, hands should be washed whenever gloves are changed.

Small Spills that occur while working in the BSC should be handled immediately to avoid subsequent spread of the contaminating material. Large Spills that result in liquids flowing across the work surface or through the front or rear grills require more extensive decontamination. If material was spilled though the cabinet's grills, the work surface must be removed after it is decontaminated to allow access and cleaning of the drain pan or lower plenum. If assistance is needed, please reach out to EHS Biosafety, or consult with a professional vendor.

Minor Spills Inside the Biosafety Cabinet

1. Keep the BSC on.
2. Change PPE.
3. Cover spill area with absorbent material.
4. Pour liquid disinfectant onto the absorbent material from the outside of the spill area, moving in.
5. Allow for appropriate contact time.
6. Collect spill material and dispose of as biohazard waste.
7. Spray/wipe walls, work surfaces, and equipment with disinfectant solution and allow for appropriate contact time before wiping up residue.
8. Decontaminate grill pans if applicable.

9. Dispose of all spill clean-up materials as biohazard waste.
10. Allow for the BSC to run for at least 10 minutes after cleanup and before resuming work.
11. Notify users that spill cleanup is complete.

Major Spills Inside the Biosafety Cabinet

1. Keep the BSC on.
2. Close the sash of the BSC.
3. Attend to injured or contaminated persons.
4. Alert personnel in the area of the spill and post a sign on the BSC sash that indicates the nature and the time of the spill.
5. Call EHS (305-243-3400).
6. EHS to arrange clean-up.

Exposure Response

In the event that you have an exposure to biological/infectious material, do the following IMMEDIATELY:

- Ocular (Eye) Exposure
  - Hold eyelids open and wash both eyes at your nearest eyewash station for 15 Minutes
- Full Body Exposure
  - Remove contaminated clothing and wash entire body at your nearest safety shower for 15 Minutes
- Needlestick Injury / Hand or Arm Exposure
  - Wash area of exposure with soap and warm water while rubbing at the site of exposure for 15 Minutes

While you are washing or after you finish washing, call Employee Health (305-243-3400) so that EHS personnel can assist in emergency response and provide guidance on next steps.

Eyewashes must be checked for adequate response and to clear the water lines on a weekly basis. If the lab is unsure whether this weekly threshold is being met by a 3rd party, or is unable to verify it with documentation, it is the responsibility of the lab to conduct this check on a weekly basis. Safety showers are required to be tested less frequently, and are generally checked by facilities or EHS. Eyewashes and safety showers must be clear and free of objects blocking their use at all times.

Reporting & Investigation

All incidents regardless of their severity must be reported to Employee Health. EHS Biosafety will conduct an investigation on all reported exposures and may require corrective actions to be carried out by the lab depending on the nature of the incident. Near misses may be reported directly to EHS Biosafety to trigger an investigation, response, and institution of corrective actions for the lab, if necessary.

Resources

Biosafety Contacts

Biosafety General Contact Information

- E-mail: biosafety@miami.edu
- Office Number: 305-243-3269
- IRB Review Box: BSO_Review@miami.edu

Biosafety Manager

- Shane Gillooly
  - E-mail: Sxg1519@med.miami.edu
  - Office: 305-243-3269
  - Cell: 786-797-0387

Biosafety Specialist

- Melanie Peapell
  - E-mail: MPeapell@med.miami.edu
  - Office: 305-243-3269
  - Cell: 305-389-9931

Websites

Environmental Health & Safety Biosafety

- https://ehs.miami.edu/biosafety

Environmental Health & Safety

- https://ehs.miami.edu/

Biosafety in Microbiological and Biomedical Laboratories (BMBL)

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition

- https://www.cdc.gov/labs/BMBL.html