ENVIRONMENTAL HEALTH & SAFETY

BIOSAFETY MANUAL

Cal Poly Pomona

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INTRODUCTION

The Cal Poly Pomona Biosafety Manual is a comprehensive guide designed to enhance safety and health practices in managing potentially hazardous biological materials (e.g., rDNA, animals, and biohazardous agents). It outlines essential practices, procedures, and protocols to minimize or eliminate risks across the university's laboratories and research facilities, ensuring the safety and well-being of students, faculty, staff, and the broader community.

Purpose of the Manual

The primary purpose of this manual is to:

- Provide a framework for implementing and maintaining biosafety standards across the university campus.
- Explain the proper use of safety equipment.
- Ensure compliance with federal, state, and local regulations governing the use of biological agents.
- Minimize or eliminate the risk of exposure to potentially hazardous biological materials.
- Provide guidance on how to complete a Biohazard Use Authorization (BUA).
- Promote a culture of safety that prioritizes the health and well-being of individuals and the environment.

Scope and Applicability

This manual applies to any individual who works, attends, or volunteers at CPP and participates in activities involving the handling, storage, manipulation, and disposal of biological materials. This includes, but is not limited to, research and teaching laboratories, support facilities, and any other areas where biological agents are used or stored. The guidelines within this manual are mandatory for:

- Faculty and research staff.
- Laboratory personnel, such as students, technicians, and visiting scientists.
- Administrative and support staff involved in biosafety oversight.

The practices and procedures outlined in this manual are applicable to all biological agents, including recombinant DNA, pathogens, and potentially infectious materials, across all Biosafety Levels (BSLs).

DEFINITIONS AND KEY TERMS

AUTOCLAVE	A pressurized device designed to use steam under pressure to sterilize biological waste and decontaminate laboratory tools and equipment.
BIOHAZARD	Biological agents or materials that pose a potential risk to human, animal, or environmental health.
BIOLOGICAL AGENTS	Microorganisms, including bacteria, viruses, fungi, prions, and their associated toxins, that can pose a threat to human, animal, or environmental health.
BIOLOGICAL SAFETY CABINET (BSC)	A ventilated cabinet for working safely with materials contaminated with (or potentially contaminated with) pathogens. It provides containment and protection for the user, the environment, and the materials being worked with.
BIOSAFETY LEVEL (BSL)	A specific combination of laboratory practices and techniques, safety equipment, and laboratory facilities designed to minimize the exposure of workers and the environment to infectious agents. BSLs range from 1 to 4, with each level providing a higher degree of containment.
BIOSAFETY OFFICER (BSO)	An individual with the expertise and authority to develop, implement, and manage the university's biosafety program, ensuring compliance with all applicable regulations and guidelines.
CONTAINMENT	Safe methods for managing infectious materials in the laboratory environment where they are being handled or maintained.
DECONTAMINATION	The use of physical or chemical means to remove, inactivate, or destroy harmful microorganisms or infectious materials on a surface or item to the point where they are no longer capable of causing disease.
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)	A committee responsible for reviewing, approving, and overseeing all university activities involving the use of recombinant or synthetic nucleic acid molecules and other biohazards.
PATHOGEN	A microorganism (bacteria, viruses, fungi, or parasites) that can cause disease in humans, animals, or plants.
PERSONAL PROTECTIVE EQUIPMENT (PPE)	Specialized clothing or equipment worn by an individual for protection against infectious materials.
RISK ASSESSMENT	The process of identifying potential hazards and analyzing what could happen if a hazard occurs. A risk assessment for biosafety evaluates the likelihood and consequences of exposure to biohazardous materials.
SHARPS	Objects that can puncture or cut skin and potentially spread infection, such as needles, scalpel blades, and glass slides.

BIOSAFETY GOVERNANCE

The governance of biosafety at Cal Poly Pomona is integral to maintaining a safe and compliant environment for all members of the university community and the surrounding areas. This section outlines the university's commitment to biosafety, describes the roles and responsibilities of key personnel and committees, and summarizes the regulatory framework governing biosafety practices.

Biosafety Policy Statement

Cal Poly Pomona is committed to the highest standards of biosafety in all its activities involving potentially hazardous biological materials. The university recognizes the importance of protecting personnel, the community, and the environment from biological risks. Through adherence to federal and state regulations and the development of university-specific policies, the university strives to maintain a culture of safety, awareness, and responsibility.

Roles and Responsibilities

Institution (EH&S): The Institution shall ensure the following:

- *That the IBC has adequate expertise to evaluate and assess rDNA projects with the use of ad-hoc consultants if necessary.*
- *If human participants are required, NIH Guidelines appendix M must be appropriately completed.*
- *No human participants enroll in any studies involving genetic transfer experiments until IBC and RAC requirements have been met.*
- *File an annual report to the NIH/OBA to include:*
    - *Roster of all IBC members and respective position*
    - *Biographical sketches of all IBC members including community members.*
- *Ensure that no member of the IBC participates in the review or approval of a project in which they are, or expect to be, directly involved or have a financial interest, unless their input is specifically requested to provide information to the IBC.*
- *Establish the procedures that the IBC will follow*
- *Make IBC meetings available to the public when possible and consistent with the protection of privacy and proprietary interests.*
- *Upon request, make available all IBC minutes and any documents submitted to or received from funding agencies (the latter are required to be made public).*

Institutional Biosafety Committee (IBC): The CPP IBC is responsible for the review, approval, and oversight of all university activities that involve the use of recombinant or synthetic nucleic acid molecules and other biohazards. The committee ensures that these activities are conducted within existing Federal and State laws and guidelines that aim to protect the safety of workers, the general public, and the environment. This objective is achieved through careful planning. Specifically, the IBC is required to:

- *Review technical and safety-related aspects of the use of all biological agents.*
- *Develop and maintain policies and procedures for the use of biological agents.*
- *Ensure compliance with State and Federal reporting requirements for research with biological agents.*
- *Maintain records of all committee meetings, inspections, protocols, and training.*

- *Review protocols and facilities upon request and when required periodically as adopted by the committee.*
- *Classify and (if necessary) inspect facilities with respect to appropriate biosafety levels.*
- *Identify members of the IBC to the NIH Office for Biotechnology Activities (OBA) in accordance with NIH guidelines.*
- *Adopt Emergency Plans to cover accidental spills and personnel contamination.*
- *Ensure investigation and reporting of any significant problems with or violations of the NIH and Centers for Disease Control Guidelines (CDC), as specified in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and, in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories.*

Biosafety Officer (BSO): The BSO has the expertise and authority to oversee the development, implementation, and management of the university's biosafety program. This role is responsible for the following tasks:

- *Review the Biohazardous Use Authorizations (BUAs) applications electronically submitted by Principal Investigators (PIs).*
- *Evaluate each BUA for completion and accuracy prior to submitting it for review by IBC members.*
- *Oversee the review and approval process by the IBC.*
- *Develop general policies for biosafety.*
- *Develop and distribute information relevant to biosafety.*
- *Periodic inspections to ensure lab standards are rigorously followed.*
- *Reporting to the IBC and the institution any*
    - *Significant problems*
    - *Violations of NIH Guidelines*
    - *Any Significant Research related accidents or illnesses unless BSO determines a report has already been filed by the PI.*
- *Developing emergency plans for handling*
    - *Accidental Spills,*
    - *Personnel Contamination*
    - *Investigating accidents involving rDNA research*
- *Providing advice on lab security*
- *Providing technical advice and training to PI and IBC on research safety procedures*
- *Submit annual NIH/OBA report*
- *Coordinate with IACUC regarding approval of biohazardous materials in animal research.*
- *Coordinate with IRB regarding approval of the use of biohazards in clinical trials.*
- *Assure compliance with the Federal Select Agent Program and the Dual Use Research of Concern policy.*

Principal Investigators (PIs) and Laboratory Supervisors: PIs and laboratory supervisors are ultimately responsible for all aspects of safety in their laboratories including the adherence to established biosafety practices. This includes but is not limited to the following:

- *PIs must ensure that all laboratory environments under their oversight are safe for work.*
- *Provide comprehensive training and instructions on biosafety practices tailored to the specific needs of the research area.*

- *Develop and prominently display emergency procedures specific to the laboratory's operations. These procedures should include contact information for essential personnel, such as the Lab Manager and Safety Officer, to ensure swift action in case of an emergency.*
- *Maintain strict control over biohazardous materials used within the laboratory in accordance with established guidelines to prevent contamination or exposure.*
- *Assess and document the PPE requirements for each specific procedure conducted within their labs.*
- *Ensure the availability and proper use of PPE necessary for safely working with hazardous materials.*
- *Clearly label all areas, containers, and storage units where biohazardous materials are present to alert personnel of potential risks.*
- *Promptly notify the BSO of any incidents, accidents, or unusual occurrences involving biohazardous materials to facilitate appropriate response measures.*
- *Inform the IBC of any significant personnel changes, adjustments in laboratory design or procedures, plans for relocation, or departure from the university, ensuring that all such changes are reflected in the Biosafety Use Authorization (BUA).*
- *Guarantee that all researchers and laboratory personnel complete the necessary biosafety training programs, including initial orientation and annual refresher courses.*
- *Provide easy access to Safety Data Sheets (SDS) for all hazardous chemicals and materials present in the laboratory, enabling personnel to understand and mitigate associated risks.*
- *Draft and maintain Standard Operating Procedures (SOP) outlining safe work practices for handling biohazardous materials, ensuring these procedures are accessible and understood by all laboratory staff.*
- *Convene regular safety meetings to discuss safety practices, review any incidents, and update the team on new regulations, procedures, or safety equipment.*

Laboratory Personnel: At Cal Poly Pomona, laboratory personnel who work with biohazardous materials under a Principal Investigator play a key role in ensuring a safe research environment. They must follow biosafety protocols closely to reduce risks associated with biohazardous research. The following outlines the specific responsibilities of laboratory personnel within this context:

- *All laboratory personnel must thoroughly read, understand, and comply with the university's safety policies, standards, and the guidelines provided in this Biosafety Manual.*
- *Complete required trainings:*
    - *Engage in EH&S (Environmental Health & Safety) mandated biosafety training programs appropriate for their level of interaction with biohazardous materials.*
    - *Attend additional site-specific safety training sessions conducted by the PI or laboratory manager to ensure familiarity with the particular biosafety practices of their laboratory.*
- *Strictly follow all SOPs and safe handling practices for biohazardous materials.*
- *Actively seek to understand the risks associated with their specific research activities.*
- *Proactively ask for clarifications or guidance on any safety aspects that are unclear or not fully understood.*
- *Know the locations of eyewash stations, safety showers, fire extinguishers, and understand the emergency evacuation routes for the building.*
- *Follow established emergency procedures in the event of an accident or incident involving biohazardous materials.*
- *Report any observed unsafe practices, concerns, or violations of biosafety protocols to the PI or BSO.*
- *Notify the PI or BSO promptly of any accident, incident, or exposure involving infectious agents, chemicals, or recombinant DNA (rDNA) during research.*

REGULATORY COMPLIANCE

Comprehensive regulatory frameworks govern the practices outlined in the Biosafety Manual at California State Polytechnic University, Pomona. Our commitment to these well-established guidelines ensures that we meet or exceed the highest standards for safety in handling biological materials. By aligning our operations with these rigorous standards, we safeguard our community and uphold our commitment to strict legal requirements mandated by state and federal agencies.

Federal Regulations: Compliance with federal regulations, such as those from the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), is mandatory. These regulations include guidelines for working with infectious agents, recombinant DNA, and other potentially hazardous biological materials.

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, NIH OSP
Biosafety in Microbiological and Biomedical Laboratories (BMBL), NIH/CDC
Federal Select Agent Program (FSAP)
Dual Use Research of Concern (DURC)
Department of Transportation (DOT)

California State Regulations: In addition to federal regulations, activities involving biological materials must comply with California state laws and regulations. This includes adherence to guidelines set forth by the California Department of Public Health (CDPH) and other relevant state agencies.

The Bloodborne Pathogens Standard (8CCR Sec. 5193), CalOSHA
The Aerosol Transmissible Diseases Standard (8CCR Sec. 5199), CalOSHA
Medical Waste Management Act of California, January 2017, CDPH-EMB

University Policies: The Cal Poly Pomona Biosafety Manual delineates the requirements and procedures established by the Cal Poly Pomona Biosafety Program and integrates relevant university safety policies and programs within its framework. The Office of Environmental Health & Safety recommends that readers consult the designated authoritative sources for mandated requirements and additional information pertaining to specific safety areas.

Chemical Hygiene Plan: Covers chemical safety and general laboratory practices to enhance safe operations by laboratory personnel and principal investigators.

Exposure Control Plan: The Exposure Control Plan protects employees from bloodborne pathogens like HBV, HCV, and HIV by implementing safe work practices and managing biohazardous waste in compliance with California's Medical Waste Management Program.

Medical Waste Disposal Manual: The manual outlines the comprehensive medical waste disposal program at California State Polytechnic University, Pomona, providing guidelines and protocols for safe and compliant management, containment, and disposal of medical waste generated on campus.

Radiation Safety Manual: Offers procedural guidelines for the safe use of radioactive materials and radiation-producing devices.

Laser Safety Manual: Delineates safe work practices for handling Class 3B and Class 4 lasers, essential for faculty, staff, students, and volunteers involved in non-clinical laser applications.

CPP Injury and Illness Prevention Program: As part of the university's Injury and Illness Prevention Program (IIPP), this policy outlines the safety responsibilities and requirements for all university personnel to maintain a healthy workplace and ensure compliance with safety regulations.

These oversight systems and regulatory guidelines create a robust safety program that protects the well-being of the university community and extends to the broader public. Adhering to these standards is essential for fostering a safety-oriented culture and accountability in all operations involving biological materials.

RISK ASSESSMENT AND BIOSAFETY LEVELS

Risk assessment is the cornerstone of biosafety, providing a systematic process to identify, evaluate, and manage the potential hazards associated with the use of biological agents in research and teaching environments. This section outlines the principles of risk assessment, classification of biological agents, and the determination of appropriate biosafety levels (BSLs) for activities conducted at Cal Poly Pomona.

Principles of Risk Assessment

Risk assessment in biosafety involves identifying biological hazards, evaluating the risks associated with them, and implementing control measures to minimize risks. Key principles include:

- **Identification of Hazards**: This initial step is foundational to the risk assessment process. It involves a thorough examination of the biological agents and materials used within a research project. This examination should include:
    - Sources and Origins: Understanding where and how biological materials are obtained or derived is crucial for assessing potential risks.
    - Characteristics of Biological Agents: Comprehensive understanding of the properties of biological agents, including their pathogenicity, infectious dose, environmental stability, and potential to cause disease in humans, animals, or plants.
    - Genetic Manipulation: Consideration of any genetic modifications that may alter the pathogenicity, host range, or environmental impact of the biological agents.
    - Host Range and Environmental Impact: Assessment of the agents' ability to infect hosts other than humans, including animals and plants, and their potential impact on the environment.
- **Assessment of Exposure Risk**: After identifying the hazards, the next step is to evaluate the risk of exposure. This involves considering:
    - Mode of Transmission: Understanding whether the biological agent is transmitted through air, contact, ingestion, or other routes is critical to assessing exposure risks.
    - Volume and Concentration: The amount and concentration of the biological material used can significantly impact the risk level.
    - Procedures and Manipulations: The specific laboratory techniques and procedures used can affect the likelihood of exposure. Procedures that may produce aerosols or involve sharp instruments carry higher risks.
    - Personnel Competency and Experience: The experience and training of the personnel involved in handling the materials can also impact the risk of exposure.
- **Implementation of Control Measures**: Based on the hazard identification and risk assessment, appropriate control measures must be implemented to manage the identified risks. This includes:

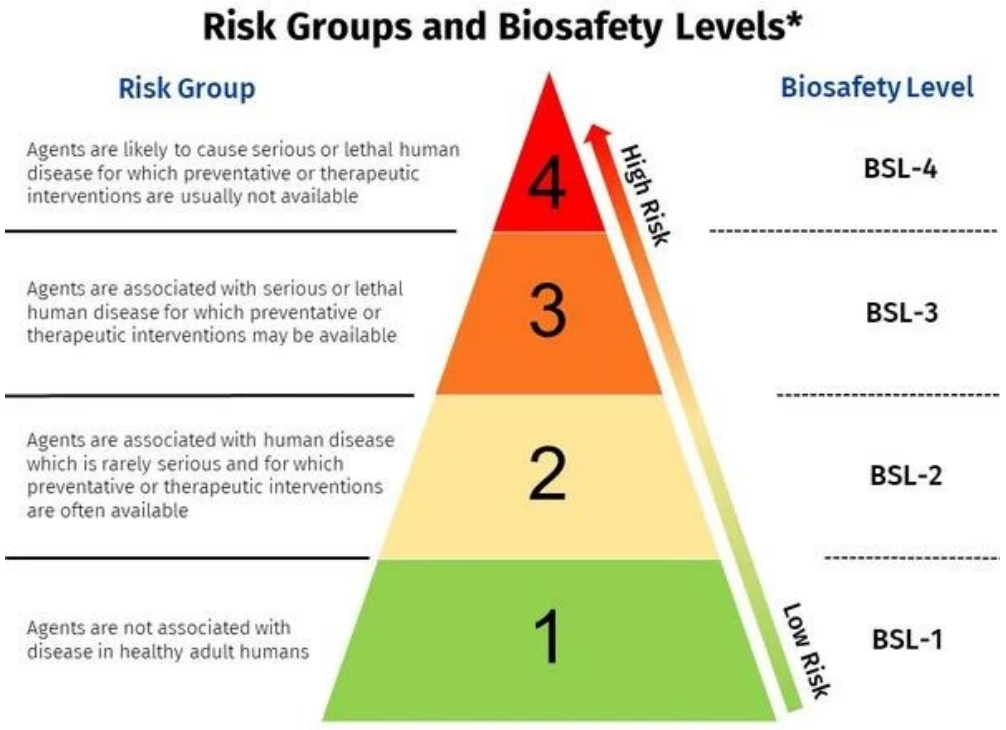
- Containment Practices: Selection of the right level of biological safety containment, ranging from Biosafety Level 1 to 4, depending on the risk assessment.
- Safety Equipment: Use of appropriate personal protective equipment (PPE), such as gloves, lab coats, eye protection, and safety devices like biological safety cabinets.
- Facility Design and Maintenance: Ensuring that the facility design supports containment and that maintenance procedures are in place to keep safety features operational.

- **Review and Adaptation**: Risk assessment is not a one-time task but an ongoing process that requires constant vigilance:
  - Continuous Review: Regularly reevaluate the risk assessment to incorporate new scientific knowledge, feedback from personnel, and observations from daily laboratory operations.
  - Adaptation to Changes: Update risk assessment and control measures in response to changes in research scope, procedures, personnel, or facilities. This might include adopting new containment practices or updating training programs.
  - Learning from Incidents: Analyze any incidents or near-misses to identify lessons learned and incorporate these into future risk assessments.

Following these guidelines helps participants develop a proactive and adaptable risk management strategy that significantly reduces the hazards linked to working with biohazardous materials.

Classification of Biological Agents

Biological agents are classified based on their pathogenicity, infectious dose, mode of transmission, impact on the community, and the availability of effective preventive measures or treatments. The classification into risk groups (RGs) helps inform the level of containment and biosafety measures required:



- Risk Group 1 (RG1): Agents not associated with disease in healthy adult humans.
- Risk Group 2 (RG2): Agents that can cause human disease but whose potential for transmission is limited and for which preventive or therapeutic interventions are often available.
- Risk Group 3 (RG3): Agents that cause serious human disease and present a risk of spreading to the community, but for which interventions are usually available.
- Risk Group 4 (RG4): Agents that cause severe human disease and are likely to spread to the community, with no effective interventions available.

Determining Biosafety Levels

The appropriate Biosafety Level (BSL) for work with a specific agent is determined based on the agent's risk group, the nature of the work conducted, and the laboratory's capability to contain the agent safely. BSLs are a series of protections, categorized from 1 to 4, that increase in stringency as the potential risk of the biological agent increases. These levels dictate the appropriate laboratory practices, safety equipment, and facility design necessary to contain the agent and protect personnel, the public, and the environment.

Overview of Biosafety Levels 1-4:

- BSL-1: Suitable for work with well-characterized agents that are not known to cause disease in healthy humans. It represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended beyond what is normally used for any scientific laboratory.
- BSL-2: Applies to work with agents that present moderate hazards to humans and the environment. It requires enhanced laboratory practices and procedures, safety equipment, and facility design over BSL-1.
- BSL-3: Necessary for work with agents that can cause serious or potentially lethal disease through inhalation. It involves more stringent laboratory practices and safety equipment requirements. BSL-3 facilities also incorporate specific engineering and design features to prevent microorganisms from being released into the environment.
- BSL-4: The highest level of biosafety, for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. BSL-4 requires the most stringent containment conditions.

Laboratory Practices and Techniques

Laboratory practices and techniques are categorized into the different biosafety levels based on the risk associated with the biological agents being handled. Each level builds upon the safety measures of the previous one, incorporating more stringent controls to protect laboratory personnel as well as the external environment.

BSL-1: Basic Microbiological Safety

At the BSL-1 level, standard microbiological practices are employed to manage agents that pose minimal potential hazard to laboratory workers and the environment. These practices include prohibiting mouth pipetting, emphasizing the importance of handwashing after handling viable materials, and the use of minimal personal protective equipment, such as lab coats and gloves, as necessary. The focus at this level is on establishing good hygiene and safe handling techniques to mitigate basic risks.

BSL-2: Enhanced Precautions for Moderate Hazards

BSL-2 encompasses all BSL-1 precautions and introduces additional measures to address agents that pose moderate hazards. This level requires limited access to laboratories, ensuring that only authorized personnel can enter. Biohazard warning signs are displayed to alert individuals to the risks within. Precautions for handling sharps, such as needles and scalpel blades, are emphasized to prevent injuries. Laboratories operate under a biosafety manual tailored to their specific operations, detailing procedures for decontaminating infectious spills. The use of PPE, including lab coats, gloves, and eye protection, becomes mandatory to protect against splashes and other potential exposures.

BSL-3: Stringent Controls for Serious Pathogens

BSL-3 includes all practices from BSL-2 and adds measures for working with agents that can cause serious or potentially lethal diseases through inhalation. Access to these laboratories is strictly controlled, with protocols for decontaminating all waste and laboratory clothing before laundering. Work with infectious materials must be conducted within biological safety cabinets or other physical containment devices to prevent airborne exposure. This level requires rigorous adherence to containment procedures and safety protocols to manage the increased risk.

BSL-4: Maximum Containment for High-Risk Agents

At the BSL-4 level, the highest level of biosafety, all practices from BSL-3 are in place, with additional protocols to manage work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. Entry into these areas requires a change of clothing, and personnel must shower upon exiting. All manipulations of infectious materials are performed in a Class III BSC or by personnel wearing a full-body, air-supplied, positive-pressure suit. This level of containment is designed to provide the maximum possible safety measures to prevent the release of highly contagious or unknown pathogens.

Each biosafety level is tailored to the specific requirements necessary to safely conduct research and handle biological materials at varying degrees of risk. As the level increases, so does the complexity of safety measures, reflecting the heightened risks and the need for more controlled environments to protect both laboratory personnel and the public.

Safety Equipment (Primary Barriers)

- BSL-1: No special containment equipment is required beyond personal protective equipment.
- BSL-2: Use of BSCs for procedures that may generate aerosols or splashes.
- BSL-3: Primary barriers include BSCs or other containment devices for all manipulations of infectious materials.
- BSL-4: Use of Class III BSCs or full-body, air-supplied, positive-pressure suits in combination with BSCs for certain procedures.

Facility Design and Construction (Secondary Barriers)

- BSL-1: Laboratories do not require special design features beyond a sink for handwashing.
- BSL-2: Laboratories should have doors for access control. Windows that open to the exterior are fitted with screens.
- BSL-3: Facilities must have self-closing, double-door access with sealed windows and surfaces that are easily decontaminated. Directional airflow is required to prevent the escape of infectious agents.
- BSL-4: Facilities are either in a separate building or a clearly demarcated and isolated zone within a building. Double-ended autoclaves, shower exits, and specialized ventilation systems to ensure HEPA-filtered air and negative pressure are mandatory features.

Table 2. Summary of Recommended Biosafety Levels for Infectious Agents

BSL	Agents	Practices	Primary Barriers and Safety Equipment	Facilities (Secondary Barriers)
1	Not known to consistently cause diseases in healthy adults	Standard microbiological practices	▪ No primary barriers required. ▪ PPE: laboratory coats and gloves; eye, face protection, as needed	Laboratory bench and sink required
2	▪ Agents associated with human disease ▪ Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: ▪ Limited access ▪ Biohazard warning signs ▪ "Sharps" precautions ▪ Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers: ▪ BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials ▪ PPE: Laboratory coats, gloves, face and eye protection, as needed	BSL-1 plus: ▪ Autoclave available
3	Indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure	BSL-2 practice plus: ▪ Controlled access ▪ Decontamination of all waste ▪ Decontamination of laboratory clothing before laundering	Primary barriers: ▪ BSCs or other physical containment devices used for all open manipulations of agents ▪ PPE: Protective laboratory clothing, gloves, face, eye and respiratory protection, as needed	BSL-2 plus: ▪ Physical separation from access corridors ▪ Self-closing, double-door access ▪ Exhausted air not recirculated ▪ Negative airflow into laboratory ▪ Entry through airlock or anteroom ▪ Hand washing sink near laboratory exit
4	▪ Dangerous/exotic agents which post high individual risk of aerosol-transmitted laboratory infections that are frequently fatal, for which there are no vaccines or treatments ▪ Agents with a close or identical antigenic relationship to an agent requiring BSL-4 until data are available to redesignate the level ▪ Related agents with unknown risk of transmission	BSL-3 practices plus: ▪ Clothing change before entering ▪ Shower on exit ▪ All material decontaminated on exit from facility	Primary barriers: ▪ All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure suit	BSL-3 plus: ▪ Separate building or isolated zone ▪ Dedicated supply and exhaust, vacuum, and decontamination systems ▪ Other requirements outlined in the text

The determination of the appropriate BSL takes into consideration the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and the Biosafety in Microbiological and Biomedical Laboratories (BMBL) standards, ensuring that all research and teaching activities are conducted safely and in compliance with regulatory requirements.

ANIMALS AND ANIMAL BIOSAFETY LEVELS

The use of animals in research presents unique biosafety concerns that must be carefully managed to ensure the health and safety of both the personnel involved and the environment. This section focuses on zoonotic diseases, animal cell lines, and the specific Animal Biosafety Levels (ABSL) that correspond to various risks and containment strategies.

Zoonoses

Zoonotic diseases, which can be transmitted from animals to humans, are a significant concern in animal research. Examples of such agents include the avian influenza virus, rabies, and Leptospira spp. Transmission of these diseases can occur through contact with infected bodily fluids, bites, scratches, or the consumption of contaminated animal products. Measures must be taken to minimize exposure to these risks through personal protective equipment, engineering controls, and strict procedural protocols.

Animal Cell Lines

Animal cell lines are widely used in biomedical research. While most animal cell lines are considered Risk Group 1, implying low risk to healthy adults, cell lines derived from non-human primates require special consideration due to their potential to carry infectious agents. Protocols for handling these materials must adhere to higher biosafety standards to prevent accidental exposure.

Animal Biosafety Levels (ABSL)

Animal Biosafety Levels are designed to provide a graded protection system, similar to the traditional Biosafety Levels used in non-animal laboratory environments. However, ABSLs incorporate additional considerations necessary for safely handling live animals that might be vectors of infectious agents. These levels detail the containment strategies, personal protective equipment requirements, and operational protocols essential to manage and mitigate risks associated with animal research.

ABSL-1: Basic Containment

ABSL-1 represents the lowest level of containment, where the risk associated with the animal work is minimal. This level is appropriate for work involving well-characterized animals that are not known to carry infectious diseases that could harm humans or other animals. Standard animal care practices are maintained, focusing on basic hygiene and minimal PPE requirements, such as gloves and lab coats, to protect against ordinary animal handling hazards. Facilities operating at this level are typically not specialized and do not require significant modifications to accommodate safe research practices.

ABSL-2: Moderate Containment

ABSL-2 is suited for work involving animals that may harbor infectious agents posing moderate risks to humans or other animals. This level includes all practices from ABSL-1 but introduces additional barriers to safety. Facilities at this level are equipped with biohazard warning signs to alert personnel to potential risks. Controlled access systems ensure that only authorized personnel familiar with the specific biohazards are allowed entry. Procedures for decontaminating waste and animal cages are rigorously applied, often involving chemical disinfectants that neutralize potentially infectious agents. The use of

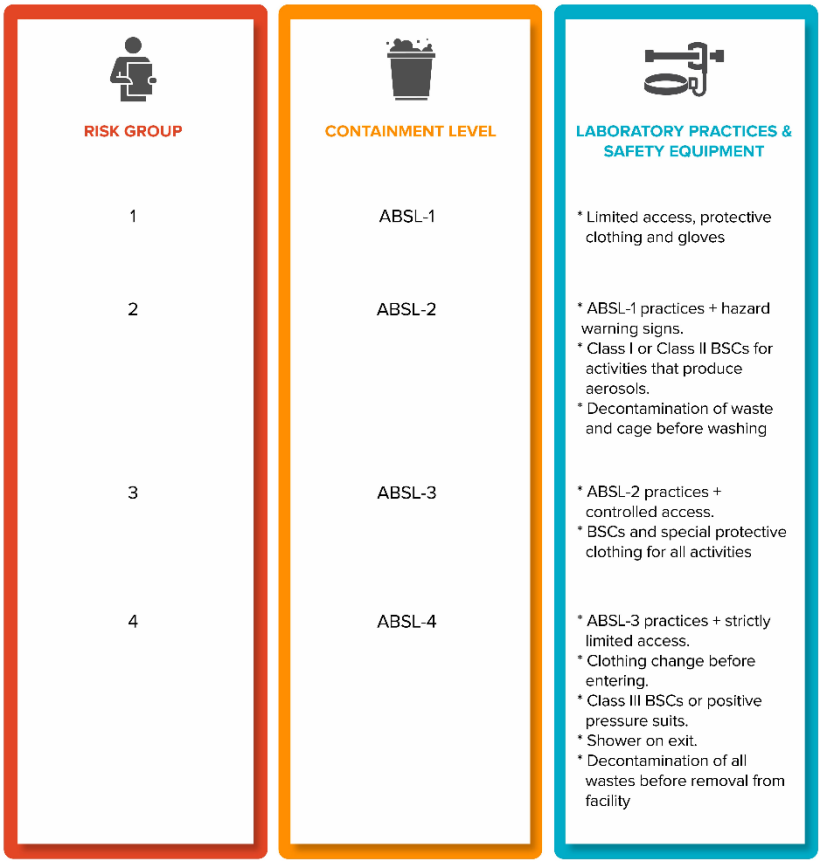
PPE is expanded to include face protection and possibly respirators, depending on the nature of the agents being studied.

ABSL-3: High Containment

ABSL-3 is required for research involving animals infected with agents that can cause serious or potentially lethal diseases, primarily transmitted through inhalation. Facilities at this level are constructed to control all waste output, ensuring that infectious agents cannot escape the controlled environment. Access to ABSL-3 facilities is highly restricted and monitored with secured entries to minimize the risk of accidental exposure. PPE requirements are stringent, including respirators and specialized protective clothing to prevent any contact with infectious particles. Enhanced engineering controls such as specialized ventilation systems that manage airflow to prevent the release of infectious agents are mandatory.

ABSL-4: Maximum Containment

ABSL-4 is the highest level of animal biosafety containment, necessary for work with highly dangerous and exotic agents that have a high risk of aerosol transmission and can cause fatal diseases. Research at this level is conducted in specially designed areas that completely isolate the agent and infected animals from the external environment. Personnel must wear full-body, air-supplied suits that maintain constant positive pressure to prevent pathogen exposure. Facilities are equipped with sophisticated airlocks, shower exits, and waste decontamination systems to ensure that no infectious agent leaves the secure environment. The operational practices at ABSL-4 are the most rigorous and are designed to protect both the personnel and the outside community from the risk of infection.



Containment Measures

Effective containment strategies are crucial in preventing the escape of biohazards from laboratories conducting animal research. These strategies are divided into primary and secondary barriers, each tailored to the specific risks associated with the research being conducted.

Primary Barriers: These include safety cabinets, biological safety cabinets, and enclosed containers, which are designed to provide physical and aerobiological barriers. They prevent airborne pathogens and other hazards from escaping the immediate research environment. Other engineering controls might include sealed centrifuges and closed systems for handling fluids that ensure biohazards remain contained within the equipment.

Secondary Barriers: The design of the facility itself acts as a secondary barrier. This includes the construction of animal rooms with sealed surfaces that are resistant to penetration by liquids and can be easily disinfected. Facilities are also equipped with specialized systems for decontamination, waste handling, and ventilation that ensure hazardous agents do not escape the controlled environment. For example, HEPA filtration systems are commonly used in ventilation to trap infectious particles before the air is expelled from the facility.

Personal Protective Equipment (PPE)

The use of appropriate PPE is mandated for all personnel working in or entering animal research facilities. The type and extent of PPE used are dictated by the level of risk associated with the research.

Protective Clothing: Depending on the level of containment, personnel may be required to wear lab coats, gowns, scrubs, or coveralls. These garments protect the skin and personal clothing from exposure to infectious agents and are selected based on their resistance to penetration by pathogens and cleaning/disinfection capabilities.

Gloves: Gloves are essential for handling animals or materials that may be contaminated. The type of gloves used (e.g., nitrile, latex, or reinforced materials) depends on the nature of the work and the chemicals or biohazards present.

Respiratory Protection: Masks, respirators, or other face coverings are crucial in settings where there is a risk of inhaling infectious agents. The level of respiratory protection ranges from simple surgical masks to more protective respirators, depending on the potential for aerosol generation.

Eye Protection: Safety glasses, goggles, or face shields are required during procedures that risk creating splashes of microorganisms or hazardous chemicals, providing a barrier against exposure to infectious agents.

Training and Competency

Thorough training is critical to ensure that all personnel are aware of the potential hazards and are competent in the necessary safety practices and techniques.

Standard Operating Procedures (SOPs): Comprehensive SOPs address all aspects of animal care, handling of infectious agents, waste disposal, and emergency procedures. Personnel are trained and regularly updated on these procedures to maintain a high standard of safety.

Skill Assessments: Regular assessments of technical skills and procedural competencies are conducted to ensure all animal handlers and researchers are proficient in their roles. These assessments help identify areas where additional training may be required.

Regulatory Compliance

Maintaining compliance with national, state, and institutional regulations governing animal research is essential.

Health Monitoring: Robust health surveillance programs are implemented for both animals and personnel to detect and respond to potential exposure to infectious agents promptly.

Documentation and Record Keeping: Detailed records of animal care, experimental protocols, training logs, and health monitoring results are meticulously maintained. These documents are crucial for audits, compliance checks, and tracking the health status of both animals and personnel.

Emergency Procedures and Incident Response

Established protocols address emergencies such as animal escapes, exposure to infectious agents, and injuries.

Immediate Response Plans: Rapid containment actions are implemented for escaped animals, along with immediate medical response for exposures or injuries, to prevent further incidents and ensure quick control of any situation.

Notification Procedures: A clear reporting protocol ensures that all incidents are promptly communicated to the appropriate institutional safety offices and regulatory bodies.

Post-Incident Assessment: After an incident, a thorough evaluation is conducted to refine animal handling procedures and improve emergency responses, enhancing overall safety and preparedness.

Integration with Institutional Protocols

Institutions conducting animal research must integrate their biosafety protocols with other regulatory requirements and oversight bodies such as the CPP Institutional Animal Care and Use Committee (IACUC). The collaboration ensures that both the biosafety and ethical aspects of animal research are adequately addressed. Anyone who wants to conduct research with animals must get approval from the IACUC. The application can be completed via the ImedRIS online protocol management system:

- https://cpp.imedris.net/

More information regarding the IACUC application process may be found here: https://www.cpp.edu/research/research-compliance/iacuc/protocol.shtml

ARTHROPODS AND ARTHROPOD CONTAINMENT LEVELS (ACLS)

Research on arthropods is focused on diverse aspects of their biology, including fisheries, aquaculture, apiculture and pollination biology, disease and perhaps most prominently, genetics and evolutionary biology. The fruit fly *Drosophila melanogaster* is one of the best-studied animals in laboratories.

The Arthropod Containment Guidelines are a product of the work of the American Committee of Medical Entomology- a subcommittee of the American Society of Tropical Medicine and Hygiene. The guidelines provide a reference for research laboratories to assess the risk and establish protocols for the safe handling of arthropod vectors to human and animal disease agents

ACL-1: Basic Containment

ACL-1 is designated for research involving arthropods that are not known to vector any infectious agents. This level requires basic containment measures and adherence to standard laboratory practices, such as maintaining a clean environment and proper storage of research materials. Facilities used at this level typically include standard insectary rooms with minimal risk of arthropod escape. Personal protective equipment like gloves and lab coats may be used as necessary to handle arthropods safely, but extensive safety measures are not required.

ACL-2: Moderate Risk Containment

ACL-2 is suitable for work involving arthropods that may vector pathogens affecting humans or animals but present a moderate risk. This level requires enhanced containment strategies to prevent escape and protect researchers from exposure. Such strategies include the use of secure containment areas with structures to contain and monitor arthropods effectively, such as fine mesh cages or double-door vestibules. Researchers must use more rigorous safety protocols, including more comprehensive PPE, such as face masks and protective goggles, to prevent direct contact with potentially infectious vectors.

ACL-3: High Risk Containment

ACL-3 is used for research with arthropods known to transmit pathogens that can cause serious or potentially lethal human or animal diseases. This containment level demands stringent safety and containment measures, including sealed facilities with controlled environmental conditions that prevent any form of arthropod escape. Access to these areas is restricted to specially trained personnel only, and procedures are in place for decontaminating equipment and personnel when exiting the facility. Researchers working at this level must employ full-body protective suits and advanced respiratory protection during interactions with live vectors.

ACL-4: Maximum Containment

ACL-4 represents the highest level of containment and is necessary for working with arthropods capable of transmitting agents that pose a high risk of life-threatening disease. Facilities designed for ACL-4 provide the utmost in security and containment, including airlock entry systems, specialized ventilation that filters both incoming and outgoing air, and potentially, multiple barriers to completely prevent the escape of arthropods. These facilities are equipped with state-of-the-art monitoring systems to continuously track environmental conditions and security breaches. Personnel must undergo rigorous

training and follow strict protocols, including using specialized PPE such as pressurized suits and undergoing decontamination showers when exiting research areas.

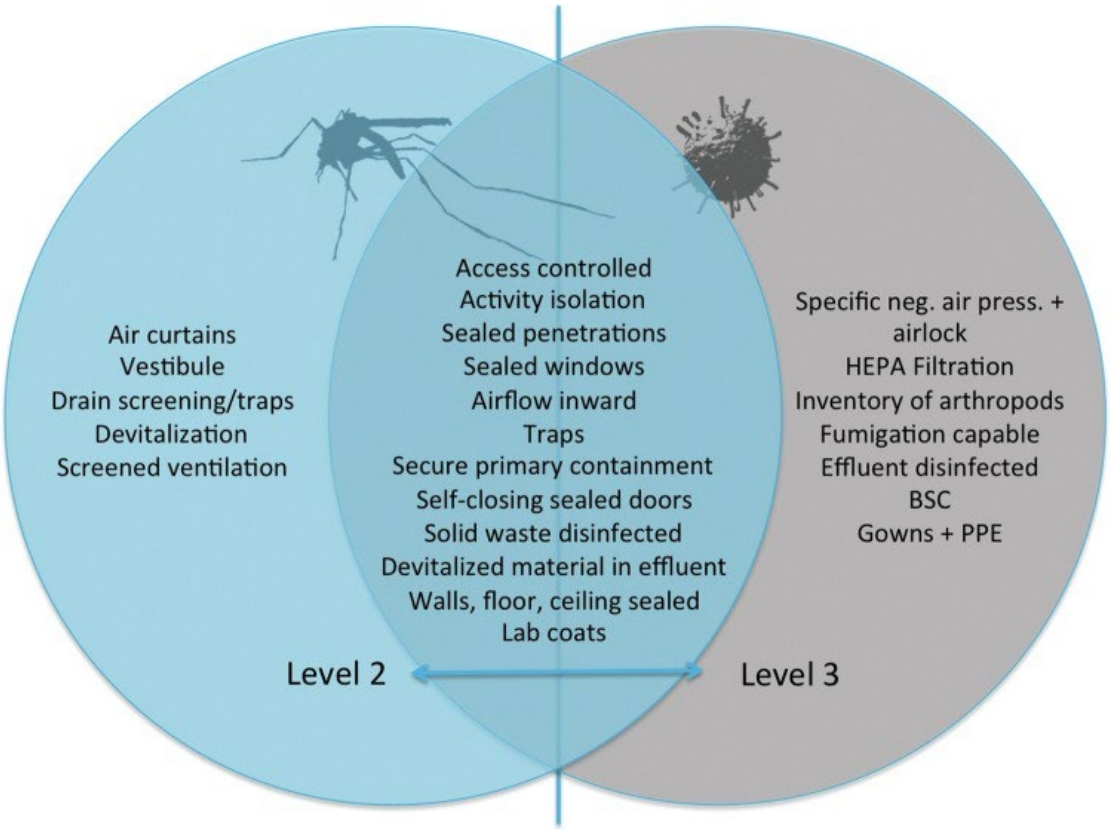
Containment Practices

Effective containment practices are paramount in preventing the unintentional release of potentially hazardous arthropods into the environment and protecting researchers from bites or stings.

Physical Containment: Utilizing secure enclosures such as insectaries or specialized containment rooms equipped with features designed to prevent escape is essential. These features often include double-door entry systems to create airlock effects, sealed windows to prevent any breaches, and controlled ventilation systems equipped with filters to manage both incoming and outgoing air, ensuring that arthropods cannot escape even at a microscopic level.

Personal Protective Equipment (PPE): Proper PPE is crucial and must be worn by all personnel when working with or in the vicinity of potentially hazardous arthropods. This gear might include gloves, lab coats, face shields, and depending on the risk associated with the specific arthropod, respirators or full-body suits to provide additional protection.

Access Controls: Implementing strict access controls ensures that only trained and authorized personnel can enter areas where arthropods are housed. This may involve security measures such as biometric scanners, key card access systems, and surveillance cameras to monitor and control access effectively.



Regulatory Compliance

Adhering to applicable regulations is critical, especially when research involves genetically modified organisms or non-native species:

Permits and Documentation: It's vital to secure all necessary permits for the import, transport, and use of arthropods, particularly for those that are exotic or genetically modified. This compliance includes adhering to local, state, federal, and international regulations which might require detailed risk assessments and mitigation strategies before permits are granted.

Record Keeping: Maintaining comprehensive records is crucial. These records should detail every aspect of arthropod handling from acquisitions and breeding to experiments and disposals. Also, any incidents of escape or unintended releases should be thoroughly documented to assess risks and refine containment strategies.

Training: Providing thorough and ongoing training for all personnel involved in arthropod research is necessary. This training should cover specific handling techniques, safe containment practices, emergency response procedures, and detailed regulatory requirements to ensure compliance and safety.

Emergency Procedures and Incident Response

Clear protocols for emergency situations where containment is breached are essential:

Immediate Response: Immediate actions are required to recapture escaped arthropods or contain the area to prevent further spread. This might include activating secondary containment measures, such as emergency seal-offs for ventilation systems and initiating rapid response teams equipped to handle such incidents.

Notification: Swiftly reporting any breaches is critical. This involves notifying institutional safety officers and relevant regulatory bodies immediately following an incident to ensure an appropriate response can be orchestrated in compliance with legal and safety requirements.

Assessment and Remediation: After an immediate response, a thorough evaluation of the incident's impact is necessary. Implementing measures to prevent future occurrences includes reassessing and potentially redesigning containment measures and reviewing and improving emergency protocols.

PLANT RESEARCH AND BIOSAFETY LEVELS (BL-P)

Research involving genetically engineered plants, plant-associated microbes, and macroorganisms (such as arthropods and nematodes) falls under the NIH Guidelines for Research Involving Recombinant DNA Molecules, which provide standards for safety and compliance.

These guidelines are in place to prevent the accidental transmission of a rDNA-containing plant genome, or the release of rDNA-derived organisms associated with plants into the environment.

PBL-1: Basic Containment

PBL-1 is designated for research involving well-characterized plants that pose no known threat of disease to healthy adult humans or wildlife and are unlikely to impact the environment adversely. This level supports routine scientific work with plants that have a well-documented history of safe use in a controlled environment. Containment measures at this level are minimal, focusing primarily on standard agricultural or horticultural practices without special modifications for containment.

BL1-P includes:

- *All experiments with recombinant or synthetic nucleic acid molecule-containing plants and plant associated microorganisms not covered in Section III-E-2-b or other section of the NIH Guidelines.*

PBL-2: Moderate Risk Containment

PBL-2 is appropriate for work involving plants that present a moderate environmental or health hazard. This includes plants that can interbreed with wild relatives or those whose genetic modifications could confer invasive traits. At this level, measures are enhanced to prevent accidental release, including the control of pollen and seed dispersal through the use of secondary physical barriers such as double-door entryways, air filtration systems, and pollen traps. Researchers are also required to follow stricter decontamination and waste disposal procedures to manage plant residues that may carry transgenes.

BL2-P includes:

- *Experiments involving modification of plants by recombinant or synthetic nucleic acid molecules that are noxious weeds or can interbreed with noxious weeds in the immediate geographic area.* Section III-E-2-b-(1).
- *Experiments in which the introduced DNA represents the complete genome of a non-exotic infectious agent into plants.* Section III-E-2-b-(2).
- *Plants associated with recombinant or synthetic nucleic acid molecule-modified non-exotic microorganisms that have a recognized potential for serious detrimental impact on managed or natural ecosystems.* Section III-E-2-b-(3).
- *Plants associated with recombinant or synthetic nucleic acid molecule-modified exotic microorganisms that have no recognized potential for serious detrimental impact on managed or natural ecosystems.* Section III-E-2-b-(4).
- *Experiments with recombinant or synthetic nucleic acid molecule-modified arthropods or small animals associated with plants, or with arthropods or small animals with recombinant or synthetic*

nucleic acid molecule-modified microorganisms associated with them if the recombinant or synthetic nucleic acid molecule-modified microorganisms have no recognized potential for serious detrimental impact on managed or natural ecosystems. Section III-E-2-b-(5).

PBL-3: High Risk Containment

PBL-3 is required for research with plants that pose serious risks, such as those capable of causing significant harm to sensitive ecosystems, spreading serious diseases to other plants, or impacting animal health. This level deals with plants that could potentially escape containment and establish themselves in the wild, or those that could transfer harmful genes to related species in nearby environments. Facilities at this level are equipped with rigorous containment measures, such as controlled access to greenhouses, use of biological safety cabinets for handling plant material, and strict protocols for sterilizing soil and other growth media. These measures aim to eliminate the dispersal of reproductive or genetic material to the environment.

BL3-P3 includes:

- *Experiments involving most exotic (see* Section V-M*, Footnotes and References of Sections I-IV) infectious agents with recognized potential for serious detrimental impact on managed or natural ecosystems when recombinant or synthetic nucleic acid molecule techniques are associated with whole plants. Section III-D- 5-a.*
- *Experiments involving plants containing cloned genomes of readily transmissible exotic (see* Section V-M*, Footnotes and References of Sections I-IV) infectious agents with recognized potential for serious detrimental effects on managed or natural ecosystems in which there exists the possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation in planta. Section III-D-5-b.*
- *Experiments involving sequences encoding potent vertebrate toxins introduced into plants or associated organisms. Recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of <100 nanograms per kilogram body weight fall under* Section III-B-1*, Experiments Involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms Per Kilogram Body Weight, and require NIH/OBA and Institutional Biosafety Committee approval before initiation. Section III-D-5-d.*
- *Experiments with microbial pathogens of insects or small animals associated with plants if the recombinant or synthetic nucleic acid molecule-modified organism has a recognized potential for serious detrimental impact on managed or natural ecosystems. Section III-D-5-e*

PBL-4: Maximum Containment

PBL-4 represents the highest level of containment and is used for research with plants that pose an extreme risk of causing disease in critical crops or extensive environmental damage. This might include highly pathogenic plants or those engineered with genes that could have catastrophic effects if transferred to other plants or wildlife. Facilities at PBL-4 are highly secure and are designed to completely isolate genetically modified plants from the external environment. These include features such as airlock entries, effluent decontamination systems, and impermeable surfaces. Research at this level is closely monitored under the strictest security protocols to ensure that no genetic material, seeds, or pollen can escape the containment facility.

BL4-P includes:

- *Experiments with a small number of readily transmissible exotic (see* Section V-M*, Footnotes and References of Sections I-IVa) infectious agents, such as the soybean rust fungus (Phakospora pachyrhizi) and maize streak or other viruses in the presence of their specific arthropod vectors, that have the potential of being serious pathogens of major U.S. crops*

Containment Measures

Containment measures are implemented to help manage the risk of escape and unintentional spread of genetically modified or pathogenic plants. These strategies include:

Physical Barriers: The use of structures such as greenhouses, growth chambers, and other secure facilities is important. These facilities are equipped with advanced filtration systems to capture pollen and spores and are built to resist environmental stressors like strong winds and heavy rains, which might otherwise cause breaches. Features like double-door entries, airlock systems, and insect-proof netting enhance the security of these environments, preventing external contamination and the escape of materials.

Security Measures: Implementing controlled access systems ensures that only authorized personnel can enter plant growth areas, minimizing the risk of accidental or intentional dissemination of plant materials. This may include key card access systems, security cameras, and regular audits of access logs to monitor and manage entry.

Waste Management: Appropriate disposal protocols for plant waste are essential to prevent the germination or spread of genetically modified or pathogenic materials. This includes autoclaving plant waste to neutralize seeds and pathogens prior to disposal, utilizing designated biohazard containers, and occasionally resorting to incineration for more resilient materials. Consistent training on waste handling procedures helps maintain adherence to these protocols.

Regulatory Compliance

Adherence to regulatory guidelines is mandatory for maintaining the integrity of plant biosafety in research:

Documentation: Researchers must keep comprehensive records of all plant materials used, including their genetic backgrounds, the source of each plant material, and any genetic modifications. These records should be easily accessible for review and must be updated with every new experiment or batch of plants.

Permits and Approvals: It is important to obtain the required permits for the use and transport of genetically modified plants or plant-associated organisms. This process involves complying with the USDA's Animal and Plant Health Inspection Service (APHIS) regulations, which might necessitate detailed risk assessments and containment strategies before approval can be granted.

Training: All individuals engaged in plant research are required to receive comprehensive training in biosafety protocols. This training covers the safe handling of genetically modified plants, familiarity with containment procedures, and emergency response techniques. It is essential to conduct refresher training sessions annually or whenever new regulations or technologies are introduced.

Emergency Procedures and Incident Response

In the event of an emergency such as a containment breach, the following protocols must be swiftly enacted:

Immediate Containment: Immediate actions include the activation of containment protocols such as closing off ventilation systems to prevent the spread of pollen and securing all exits to contain plant materials within the facility. Emergency kits equipped with PPE, portable barriers, and appropriate disinfectants should be readily accessible to address the breach quickly.

Notification: All incidents of containment breach or accidental release must be reported immediately to institutional safety officers and regulatory bodies. This notification should include a preliminary assessment of the breach, the type of materials potentially released, and initial actions taken.

Remediation: Following containment and notification, a detailed plan for remediation should be implemented. This may involve the removal and safe disposal of contaminated or escaped plant materials, decontamination of the affected areas, and a thorough investigation to determine the cause of the breach. Corrective actions should be developed and implemented to prevent future incidents.

LABORATORY PRACTICES AND TECHNIQUES

Implementing appropriate laboratory practices and techniques is essential for maintaining a safe environment when working with biological agents. This section outlines general laboratory practices, handling and storage of biological agents, decontamination and sterilization techniques, the use of personal protective equipment, and safe use of laboratory equipment.

General Laboratory Practices

Access Control

Controlling access to laboratories is essential for ensuring that only individuals who are trained and authorized can enter areas, particularly those where biohazardous materials are used or stored. This measure prevents unauthorized access that could lead to accidental exposure to hazards or contamination of experiments. Access control can be implemented through physical keys, electronic card systems, or biometric access controls. Moreover, this practice helps in tracking who enters and exits the laboratory, which is important for incident investigation and contact tracing in case of an accident.

Hygiene Practices

Strict hygiene practices are enforced to minimize the risk of contamination and exposure to biohazardous materials. This includes rigorous handwashing protocols that require washing hands before and after handling any biological materials, after removing gloves, and upon exiting the laboratory. Handwashing reduces the transfer of microorganisms and potential biohazards from the laboratory environment to the outside world, protecting both the laboratory personnel and the general public. Additionally, the use of hand sanitizers, though not a replacement for handwashing, can be encouraged for additional safety.

Eating and Drinking Restrictions

The prohibition of eating, drinking, smoking, applying cosmetics, and handling contact lenses within laboratory areas is essential to prevent ingestion or contact exposure to biological agents. These activities can inadvertently lead to the transfer of hazardous materials to the mouth, eyes, or skin, posing a significant health risk. Establishing designated areas away from the laboratory for eating and drinking helps enforce this restriction while ensuring the comfort and well-being of the laboratory personnel.

Labeling and Signage

Proper labeling and signage are key to maintaining a safe laboratory environment. All containers holding biological materials must be clearly labeled with the contents, hazard level, and any required handling precautions. Similarly, areas where biohazards are present and equipment that may come in contact with biohazards should be marked with appropriate biohazard signage to alert personnel to the potential risks. This practice not only aids in the immediate identification of hazards but also helps in the proper management of materials, including their storage, handling, and disposal.

Documentation

Maintaining accurate and detailed records is an indispensable part of laboratory practices. Documentation should cover all training, experiments, procedures, and the use of biohazardous materials, including dates, personnel involved, and specific details of the work conducted. This comprehensive record-keeping supports reproducibility in research, facilitates the tracking of potential contamination or exposure events, and is essential for regulatory compliance and audits. Well-kept records also aid in the ongoing assessment and refinement of safety protocols, contributing to a culture of continuous improvement in laboratory safety.

Handling and Storage of Biological Agents

Containment

The use of appropriate containment devices is critical when handling biohazardous materials to prevent exposure to potentially harmful agents. Biological safety cabinets are among the most effective containment devices, providing a ventilated workspace with filtered air to protect both the user and the environment from aerosolized pathogens. There are different classes of BSCs, each designed for specific types of work and levels of biohazard. For example, Class II BSCs are suitable for most microbiological work with pathogens, offering protection for the user, the product (to prevent contamination), and the environment. Regular maintenance and annual certification of BSCs ensure their proper function and safety efficacy. Training in the correct use of these cabinets is also necessary, as improper usage can negate their protective benefits.

Storage

Biological agents must be stored in well-labeled, durable, ridged, leak-proof containers that clearly indicate the contents and associated biohazards. These containers should be stored at the correct temperature and conditions required for the stability of the material, which may range from room temperature to refrigeration or freezing conditions. Access to stored biohazardous materials should be restricted to authorized personnel only, and an inventory system should be in place to track the location, quantity, and expiration dates of these materials. This system aids in the management of the agents and ensures their proper use and disposal.

Transport

The transport of biological materials, whether within a facility or between locations, requires careful planning to minimize the risk of exposure and spillage. Transport containers should be ridged, leak-proof and capable of securely enclosing the primary container with the biological material. These secondary containers should be prominently marked with the laboratory's name and biohazard symbols on all visible sides, and they must include all required documentation for the materials being transported, such as Safety Data Sheets (SDS) or risk assessments. When transporting materials outside of the laboratory or facility, additional regulations may apply, including those set by governmental and international agencies for the transport of dangerous goods. Personnel involved in the transport of these materials should be trained in proper packaging and handling procedures to ensure their safety and compliance with regulations.

Decontamination and Sterilization Techniques

Chemical Decontamination

Chemical decontamination involves the use of disinfectants to clean surfaces and equipment that have come into contact with biohazardous materials. The effectiveness of this process depends on choosing the appropriate disinfectant for the biological agents being handled. Factors to consider include the disinfectant's spectrum of activity (bactericidal, virucidal, fungicidal, sporicidal), compatibility with the surfaces and materials being disinfected, and any safety considerations for its use. Manufacturer recommendations for dilution, contact time, and application method must be strictly followed to ensure efficacy. For instance, bleach solutions are commonly used for their broad-spectrum disinfecting properties but require careful handling and preparation to specific concentrations. Additionally, the selection of disinfectants should be informed by current guidelines and research, especially in response to emerging pathogens.

Gas and Vapor Decontamination

The most common vaporous and gaseous agents used for laboratory decontamination are formaldehyde gas, vaporous hydrogen peroxide, and gaseous chlorine dioxide. Each of these methods varies in their efficacies in different environmental conditions, cost, ease of use, toxicity, and required exposure times. Careful thought should be given to each chemical agent prior to its use. Contact EH&S if you have any questions and/or need assistance selecting the appropriate disinfectant.

Autoclaving

Autoclaving is a widely used sterilization technique that subjects equipment and waste materials to high-pressure saturated steam at a temperature of at least 121°C (250°F) for a period of 15-20 minutes, depending on the volume. This process is effective against a wide range of microorganisms, including spores, which are among the most resistant forms of life. To ensure the effectiveness of autoclaving, it is crucial to properly prepare items for sterilization, allowing steam to penetrate the material fully. Autoclave bags, containers, and wraps are designed to withstand the temperature and pressure while permitting steam penetration. Regular monitoring of autoclave performance with biological indicators or chemical integrators is necessary to confirm sterilization efficacy. Proper training for personnel in autoclave operation and safety precautions is also essential to prevent accidents and ensure consistent results.

Use of Personal Protective Equipment (PPE)

Selection and Use

The selection of PPE should be guided by a thorough risk assessment that considers the nature of the biological agent, the type of work being conducted, and the potential routes of exposure. This process ensures that the chosen PPE provides adequate protection against the specific hazards present in the laboratory or clinical setting. For example, gloves are necessary for handling biohazardous materials, but the type of glove (latex, nitrile, etc.) may vary depending on the chemical resistance needed. Lab coats or gowns protect the wearer's skin and personal clothing from contamination, while face shields and masks guard against exposure to infectious aerosols and splashes.

Proper training in the correct use of PPE is crucial, including how to don (put on) and doff (take off) PPE in a manner that minimizes the risk of contamination. Personnel must be aware of the limitations of their PPE and the importance of not relying on PPE alone to protect against hazards; rather, it should be used in conjunction with other biosafety measures.

Maintenance

Regular inspection of PPE for signs of wear, damage, or contamination is necessary to determine whether it can be safely reused or should be replaced. Cleaning and decontamination of reusable PPE must be performed according to manufacturer instructions and safety protocols to avoid damaging the material or reducing its protective capabilities. Proper maintenance also involves storing PPE in a clean and accessible location, free from contamination.

Disposal

The disposal or decontamination of PPE contaminated with biohazardous materials must be handled with care to prevent secondary exposure or environmental contamination. Disposable PPE should be placed in designated biohazard waste containers for appropriate disposal. Reusable PPE that can be decontaminated must be processed according to established protocols, which may involve autoclaving, chemical disinfection, or laundering in biohazard-specific facilities.

Safe Use of Laboratory Equipment

Training

Adequate training is the foundation of laboratory safety. Personnel must be thoroughly trained in the safe operation of all laboratory equipment, with particular attention to devices that pose significant risks due to their operation or the materials they handle. For instance, centrifuges can cause injury if improperly balanced or if they fail during operation. Autoclaves, which use high-pressure steam for sterilization, can present burn hazards or pressure-related injuries if not correctly used. Biological safety cabinets require proper technique to maintain the sterile field and protect against biohazard exposure.

Training should be specific to the equipment and the context in which it is used, including an understanding of the potential hazards and the safety features of each device. Refresher training or re-certification at regular intervals ensures that personnel stay up to date on safety protocols and equipment operation. Training completion for all laboratory personnel must be documented to maintain regulatory compliance. The following are general use instructions and information for common laboratory equipment:

Biosafety Cabinets (BSCs)

Biosafety Cabinets are critical in maintaining containment of infectious agents. They are designed to provide a clean work environment and protection for employees working with biological hazards. BSCs must be certified annually to ensure proper airflow and filter integrity. Users should verify that the BSC is operating correctly before each use and follow strict protocols for decontamination after use. BSCs should be operated according to the guidelines set forth by the National Sanitation Foundation (NSF) Standard 49. Use involves:

1. Preparation: Confirm airflow indicators are within the recommended range. Discontinue use if airflow is outside this range.
2. Setup: Turn on the blower and lights at least 10 minutes prior to work. Disinfect the work surface and interior walls with a dilution of household bleach, followed by a 70% ethanol wipe-down.
3. Loading: Load only necessary items, keeping materials at least six inches from the front grill. Place equipment that creates air turbulence at the back of the cabinet.
4. Operation: Segregate contaminated and clean items by working from "Clean to Dirty." Avoid blocking the intake grills and rapid movement of hands or arms.
5. Cleanup: Clean spills immediately according to the laboratory standard operating procedures. After work, wipe down the exterior of all materials with the appropriate disinfectant.

Safety Protocols:

- Do not use flammable or volatile chemicals inside a Type A2 BSC.
- Keep the sash at the recommended height to maintain proper airflow and protection.
- Regularly have the filters checked by a qualified professional and replace them as necessary.

Autoclaves

Autoclaves are used to sterilize biological waste and laboratory instruments that may be contaminated. They use steam under pressure to kill microorganisms and are subject to regular validation to ensure effective sterilization. Users must be trained in the correct loading techniques, which involve not overloading the machine and ensuring that the steam can circulate freely. Safety protocols must be followed to prevent burns, including wearing heat-resistant gloves and allowing for the cooling down of materials after sterilization. Use involves:

1. Preparation: Don appropriate personal protective equipment including a lab coat, heat-resistant gloves, and eye protection. Place items to be autoclaved in the chamber.
2. Settings: Choose the appropriate cycle on the autoclave keypad based on the nature of the load (gravity, liquid, or dry) and set the sterilization temperature to 121°C.
3. Operation: Start the cycle and log the process in the autoclave log. Wait until the pressure and temperature are safe before opening the door.
4. Unloading: Open the door slowly to allow steam to escape, check sterilization indicators, and handle contents carefully, especially liquids.
5. Post-Operation: Place autoclaved biohazardous waste in the appropriate bins and ensure the autoclave door is shut.

Safety Protocols:

- Regularly inspect the autoclave for seal integrity and proper door closure.
- Do not overload the autoclave to prevent uneven sterilization.
- Log each use of the autoclave, noting the operator, date, time, and type of material sterilized.

Centrifuges

Centrifuges are used for isolating and separating suspensions and immiscible liquids. Safety lids or cups must always be used to prevent aerosolization of infectious agents. Before each use, inspect rotors and buckets for signs of stress or cracks. Ensure that all users are trained in the correct balancing techniques and the handling of potentially hazardous materials within the centrifuge. Use Involves:

1. Preparation: Inspect tubes or containers for cracks or flaws before use. Ensure the centrifuge interior is clean and dry.
2. Loading: Use matched sets of tubes, buckets, and other equipment. Balance the contents properly in the rotor.
3. Operation: Secure the centrifuge lid and ensure it is operating normally before leaving. For infectious materials, allow the rotor to stop completely and rest for 10 minutes before opening.
4. Post-Operation: If a spill occurs, use appropriate decontamination and cleanup procedures. Report all accidents immediately.

Safety Protocols:

- Check the rotor and buckets for signs of wear or damage before each use.
- Use only the rotor and accessories recommended by the manufacturer for your specific model.
- Do not open the centrifuge until it has completely stopped.

Vacuum Systems

Vacuum systems, particularly those used in liquid aspiration, must be equipped with HEPA filters or liquid disinfectant traps to prevent the spread of aerosols to the environment. Regular checks are required to ensure that filters and traps are functioning properly and are replaced according to the manufacturer's recommendations.

1. **Setup:** Connect suction flasks to an overflow collection flask containing disinfectant and an in-line HEPA filter to protect the vacuum system.
2. **Operation:** Regularly check the integrity of the system and replace filters as necessary.
3. **Maintenance:** After use, inactivate collected microorganisms with a suitable chemical solution before disposal as non-infectious waste.

Safety Protocols:

- Regularly inspect the vacuum lines and filters for leaks or damage.
- Replace filters as recommended by the manufacturer.
- Do not use the vacuum system for materials that are incompatible with the filters or traps.

Tissue Disruptors and Homogenizers

When using tissue disruptors and homogenizers, procedures should be performed inside a BSC to minimize exposure to hazardous aerosols. Equipment must be thoroughly cleaned and decontaminated after each use. Operators should be trained in the potential risks and the appropriate emergency procedures in case of accidental exposure.

1. Risk Assessment: Assess the risk of generating infectious aerosols when using devices like sonicators, bead beaters, or tissue grinders.
2. Operation: Use appropriate physical containment, such as biosafety cabinets, to prevent exposure. Follow specific device protocols for safe operation.

Safety Protocols:

- Always operate within a BSC when dealing with infectious or hazardous samples.
- Wear appropriate PPE, including gloves and eye protection.
- Ensure that all parts are properly secured, and that the device is not operated beyond its capacity.

Ultraviolet (UV) Lights in BSCs

UV lights are sometimes used within Biological Safety Cabinets (BSCs) for supplemental decontamination but are not reliable as a standalone method. Their effectiveness is limited to surfaces directly exposed to the radiation and may not eliminate all microorganisms.

UV lights must only be used when the BSC is not in operation to prevent user exposure. Regular maintenance, including checks and lamp replacement, is essential. Always pair UV light use with standard cleaning protocols and follow manufacturer guidelines.

Maintenance and Calibration

Regular inspection, maintenance, and calibration of laboratory equipment are critical to ensure that devices function correctly and safely. Equipment malfunction can lead to inaccurate results, loss of experiments, or, in worst-case scenarios, accidents that cause injury or exposure to hazardous materials. For example, a poorly maintained incubator might not maintain the correct temperature, affecting cell culture viability. Similarly, an uncalibrated pipette could lead to errors in experimental assays.

Maintenance schedules should be established according to the manufacturer's recommendations and regulatory guidelines. Records of maintenance and calibration activities should be kept to track equipment history and anticipate future needs. This proactive approach to equipment care helps prevent unexpected failures and extends the life of valuable laboratory instruments.

Emergency Procedures

Laboratories must have clear emergency procedures related to equipment use, addressing potential failures and accidents. This includes knowing how to safely shut down equipment in an emergency, such as cutting power to an electrical device that has malfunctioned or stopping a gas flow to a flame source. Personnel should be trained on specific actions to take in the event of spills, fires, or other accidents involving laboratory devices.

Emergency procedures should be readily accessible, with instructions posted near each piece of equipment or in an easily retrievable format within the laboratory. Regular drills or training sessions can help reinforce these procedures and ensure that personnel react appropriately during an actual emergency.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Personal Protective Equipment (PPE) plays a crucial role in protecting laboratory personnel from exposure to hazardous biological agents. This section covers the types of PPE, their selection and use, and guidelines for maintenance, cleaning, and disposal.

Types of PPE:

Gloves

Gloves are a fundamental component of PPE, serving as a primary barrier to protect hands from coming into contact with hazardous materials, biological agents, and contaminants. The selection of glove material is crucial and should be based on the nature of the hazards involved:

- Latex Gloves are preferred for their high comfort, fit, and tactile sensitivity. However, they may not be suitable for all users due to the potential for allergic reactions.
- Nitrile Gloves offer excellent chemical resistance and are a preferred choice for individuals with latex allergies. They are durable and provide protection against a wide range of chemicals and biohazards.
- Neoprene Gloves are known for their versatility and chemical resistance, including against solvents and harsh chemicals, making them suitable for a variety of laboratory and industrial applications.

Lab Coats and Gowns

Lab coats and gowns offer body protection against spills, splashes, and direct contact with hazardous substances. The choice between different materials reflects the level of protection required:

- Cotton Lab Coats are suitable for general laboratory work where moderate protection is sufficient. They can be laundered and reused but may not provide adequate barrier protection against strong chemicals or infectious agents.
- Disposable Synthetic Gowns are used in environments where there is a high risk of contamination or exposure to infectious materials. These gowns offer superior barrier protection and are discarded after use to prevent cross-contamination.

Face Shields and Safety Goggles

Protecting the face and eyes is crucial in preventing exposure to hazardous substances:

- Face Shields provide full-face protection against splashes, aerosols, and droplets, safeguarding the mucous membranes of the eyes, nose, and mouth. They are commonly used in conjunction with other PPE such as masks or goggles for comprehensive protection.

- Safety Goggles enclose the area around the eyes, offering protection from splashes, dust, and aerosols. They are essential in situations where there is a risk of hazardous materials entering the eyes, which could result in serious injury or infection.

Masks and Respirators

Respiratory protection is vital for preventing the inhalation of infectious agents, hazardous chemicals, and airborne particulates:

- Surgical Masks are designed to protect against large droplets and splashes. They also help to prevent the spread of infectious agents from the wearer to others.
- N95 Respirators offer more advanced protection by filtering out a higher percentage of airborne particles. They are essential in environments with a high risk of airborne transmission of diseases or exposure to fine particulate matter.

Shoe Covers

Shoe covers are used to prevent the spread of contamination from footwear into and out of sensitive areas, such as cleanrooms or laboratories working with infectious agents. They are typically made from disposable materials and are designed to be easily removed before exiting the contaminated area.

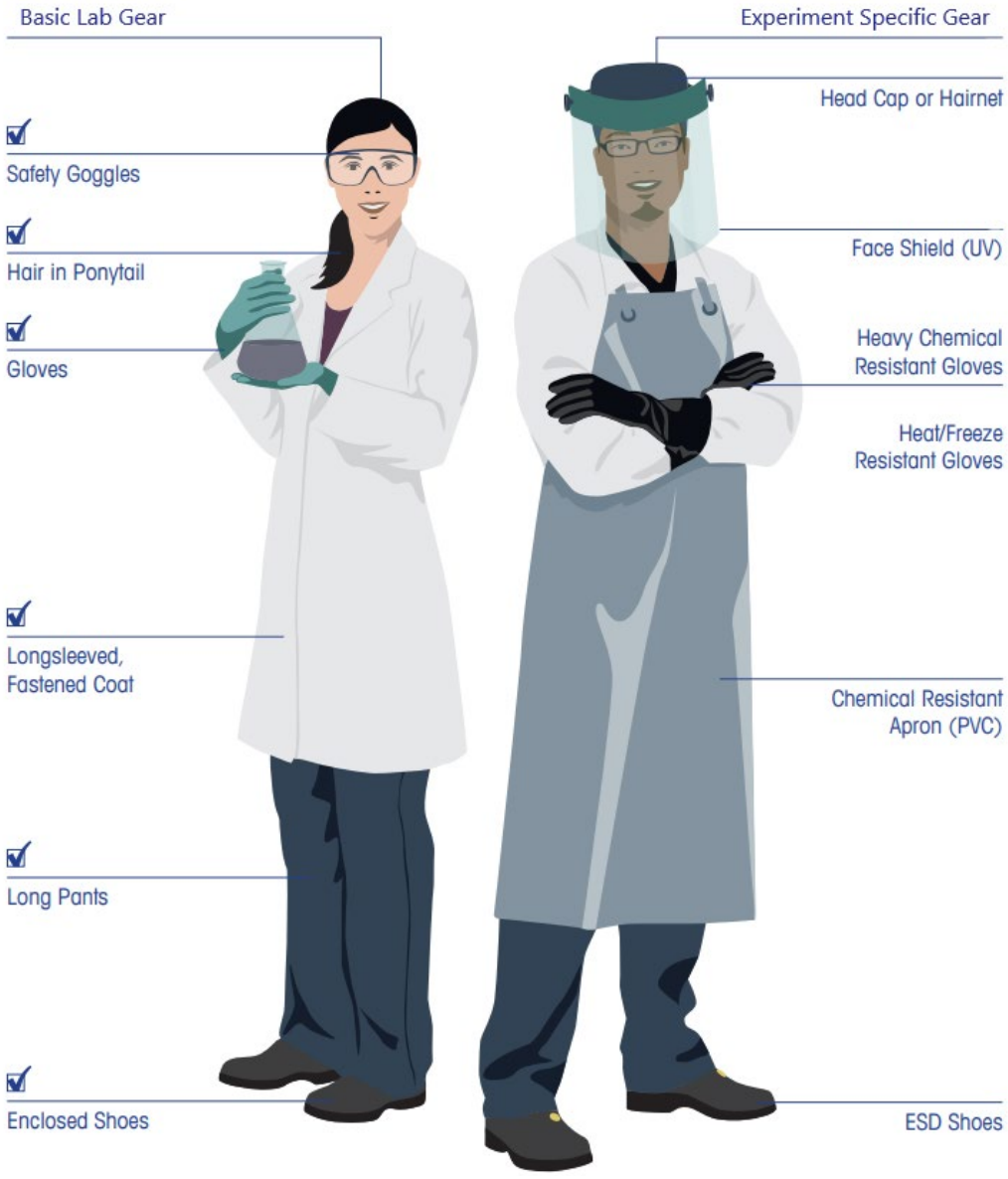
Selection and Use of PPE

A systematic approach to selecting and utilizing PPE not only provides optimal protection but also promotes compliance and comfort among users. Here are some specific steps on how to effectively select and use PPE:

Risk Assessment

A foundational aspect of PPE selection is performing a thorough risk assessment. This involves evaluating the work environment, the activities being performed, the types of biological agents present, and the potential routes of exposure. Risk assessment helps in identifying the specific hazards that personnel may encounter and determines the appropriate level and type of PPE required to mitigate those risks. Factors to consider include:

- Type of Biological Agent: Understanding the virulence, mode of transmission, and potential health effects of the biological agent guides the selection of PPE.
- Procedure Being Performed: Tasks that involve splashing, generation of aerosols, or direct contact with hazardous materials require higher levels of protection.
- Potential Routes of Exposure: Identifying how the agent could enter the body (e.g., inhalation, skin contact, ingestion) informs the choice of protective barriers needed.



Fit and Comfort

The effectiveness of PPE is significantly influenced by its fit and comfort. Ill-fitting PPE can create gaps or allow for slippage, which compromises the barrier against hazards. Furthermore, uncomfortable PPE may discourage proper use, leading to non-compliance and increased risk of exposure. Therefore, it is important to:

- Select PPE that is the right size and design for the individual wearer.
- Consider ergonomic factors and how the PPE will be worn during different tasks.
- Allow for personal adjustments while maintaining protective integrity, where possible.

Training

Comprehensive training is essential for ensuring that personnel know how to correctly use PPE. This includes:

- Donning and Doffing: Demonstrating the proper sequence to put on and remove PPE safely to prevent self-contamination or the spread of contaminants to others.
- Limitations of PPE: Educating users about what their PPE does and does not protect against.
- Care and Maintenance: Providing guidelines on how to inspect, clean, and store reusable PPE, as well as when to dispose of single-use items.

Training should be ongoing to accommodate updates in PPE technology, changes in procedures, and to reinforce correct practices.

Layering

In situations where multiple pieces of PPE are necessary, they must be worn in the correct order to ensure maximum protection and functionality. Proper layering is crucial for:

- Ensuring that the PPE works together as a system without reducing visibility, restricting breathing, or limiting movement in a way that could increase risk.
- Preventing contamination during removal. For example, gloves should typically be the last item donned, and the first item removed to reduce the risk of contaminating other pieces of PPE.

Following these guidelines for the selection and use of PPE ensures that individuals are adequately protected against biological hazards while maintaining the ability to perform their duties effectively and comfortably.

Maintenance, Cleaning, and Disposal

Inspection and Maintenance

Regular and thorough inspection of PPE is essential for identifying signs of wear, damage, or failure that could compromise its protective capabilities. Maintenance routines should be established based on:

- Manufacturer Instructions: Adhering to the manufacturer's guidelines for maintenance ensures that PPE retains its protective properties and complies with regulatory standards.
- Scheduled Inspections: Implementing a regular schedule for inspecting PPE allows for the early detection of potential issues that could affect its functionality.
- Pre-use Checks: Encouraging users to perform quick but thorough checks before each use helps prevent the use of compromised equipment.

Proper maintenance might include procedures such as checking the seals and straps on respirators, inspecting gloves for punctures or tears, and ensuring that protective eyewear remains free of scratches that could impair vision.

Cleaning

Reusable PPE requires regular cleaning and disinfection to remove contaminants and reduce the risk of cross-contamination. Effective cleaning practices include:

- Following Manufacturer Guidelines: Adhering to specific instructions for cleaning and disinfecting PPE without damaging its protective features.
- Selection of Disinfectants: Using disinfectants that are effective against the particular biological agents being handled, ensuring they are compatible with the PPE material.
- Documenting Cleaning Procedures: Keeping records of cleaning schedules and procedures to ensure consistency and accountability.

Special attention should be given to the correct dilution and application of disinfectants and to the drying and storage of PPE after cleaning to prevent damage or the growth of microbial contaminants.

Disposal

The disposal of PPE, particularly single-use items and equipment that can no longer be safely used, is a vital step in preventing contamination and exposure to hazardous materials. Disposal practices should include:

- Biohazard Waste Containers: Designating specific containers for the disposal of contaminated PPE, ensuring they are appropriately labeled and handled according to waste management regulations.
- Decontamination Protocols: For reusable PPE that has become heavily contaminated and cannot be safely cleaned, following strict decontamination procedures before disposal is required to minimize environmental impact and protect waste management personnel.
- Compliance with Regulations: Adhering to local, state, and federal regulations regarding the disposal of biohazardous materials and PPE to ensure environmentally responsible practices.

Adhering to these guidelines for the maintenance, cleaning, and disposal of PPE is fundamental to ensuring the safety of personnel and the broader community. These practices help to maintain the effectiveness of PPE in providing protection against biological hazards, while also supporting public health and environmental sustainability efforts.

BIOLOGICAL WASTE MANAGEMENT

The management of biological waste is an essential aspect of operational safety and environmental compliance at Cal Poly Pomona. This section of the biosafety manual delineates the university's procedures for the appropriate handling, treatment, and disposal of biological waste generated by research, teaching, and diagnostic activities. The guidelines are structured to conform to federal, state, and local regulatory requirements. Following these established protocols is required to maintain a safe and compliant campus environment, minimizing risk to individuals and the surrounding ecosystem.

Types of Biological Waste

Biological waste is categorized based on its form and the specific handling and disposal requirements each type entails:

Solid Biohazardous Waste

Solid biohazardous waste includes a variety of non-sharp items that have been contaminated with biohazardous agents. This category encompasses used personal protective equipment (PPE) such as gloves and gowns, laboratory ware like Petri dishes and test tubes, pipette tips, and other disposable tools that have come into direct contact with biohazardous substances. Solid biohazardous waste must be contained in red biohazard bags that meet ASTM D1922 and D1709 standards for tear and impact resistance, are labeled with the international biohazard symbol, and properly treated before disposal. The aim is to prevent the release of contaminants during handling, transportation, and disposal processes.

- Containment: Place solid biohazardous waste in autoclavable bags within rigid, leak-proof containers to prevent spillage and exposure.
- Treatment: Use an autoclave designated for biohazardous and medical waste treatment to sterilize and kill all biohazardous agents. Autoclaving should be done following the device's operating instructions to ensure complete decontamination.
- Final Disposal: After autoclaving, the treated waste may be placed in a secondary opaque bag and disposed of into the solid waste.

Untreated biohazardous and pathological waste must be taken to a designated medical waste drop-off location. For access details, please contact Environmental Health & Safety (EH&S).

Medical Waste Streams			
Biohazard	**Pathology**	**Trace Chemo**	**Pharmaceutical**
			
Items contaminated with or exposed to human materials or potentially infectious agents that do not contain any other hazards	Recognizable human or animal tissues (fixed or unfixed) Animal carcasses Prion-contaminated materials	**Empty** materials contaminated with chemotherapeutic agents Items that are not empty are discarded as chemical hazardous waste	Prescription or over-the-counter human or veterinary drugs No controlled substances, RCRA-regulated hazards or radioactive materials
44- or 90-gallon (large) red barrels for autoclaving and landfill	20-gallon (small) red barrels labeled for incineration	20-gallon (small) yellow barrels labeled for incineration	Closed containers labeled for incineration are placed upright on the ground at the accumulation site **Do not** place in vendor barrels

Liquid Biohazardous Waste

Liquid biohazardous waste consists of contaminated liquid materials generated during laboratory activities. This includes cultures, stocks, media, and specimens that contain or are suspected of containing viruses, bacteria, parasites, or other pathogenic agents. Handling and disposal of liquid waste necessitate careful containment to prevent spills and leaks, typically requiring inactivation or neutralization of the biohazardous agents through chemical treatment or autoclaving before disposal into the sewage system.

- Decontamination: Treat liquid waste with an appropriate chemical disinfectant to neutralize biohazardous agents. The method of decontamination should be chosen based on the type of biohazard and compatibility with the liquid waste.
- Disposal: Once decontaminated, the liquid waste can be disposed of down the drain. Follow disposal with copious amounts of water to flush the sewage pipes.

Sharps Waste

Sharps waste refers to any objects that are sharp enough to puncture or cut skin, posing a significant risk of injury and infection to handlers. This category includes needles, syringes (with the needle attached), scalpel blades, glass slides, and broken glassware that have been used in the manipulation of biohazardous materials. Given their potential for causing harm, sharps must be disposed of in rigid, puncture-resistant containers that are clearly labeled as biohazardous. These containers are then treated as regulated medical waste and disposed of according to the specific protocols found in the campus Medical Waste Disposal Program to ensure the safety of waste management personnel.

- Collection: Use puncture-resistant containers designed for sharps disposal. These containers should be sealable and labeled with biohazard symbols.
- Safety Precautions: Never attempt to recap, bend, or break needles to avoid accidental needle-stick injuries.
- Treatment and Disposal: Sharps waste must be managed as biohazardous waste. It should be properly contained in approved sharps containers, autoclaved as necessary, and transported to a designated medical waste drop-off location for disposal by a licensed medical waste vendor.

Animal Waste

Animal waste generated from laboratory research includes animal carcasses, body parts, tissues, and bedding that have been exposed to biohazardous agents. The disposal of animal waste requires special consideration due to the potential for large volumes and the need for respectful handling. Typically, animal waste is incinerated in approved facilities to ensure complete destruction of any biohazardous material.

- Disposal: Dispose of animal tissue and carcasses in an approved pathological waste container. Transport the pathological waste container to a designated medical waste disposal location.

Spill Management

The university's comprehensive approach to managing spills of biohazardous materials encompasses preparation, containment, clean-up, waste disposal, and thorough documentation and reporting. This detailed process is designed to address spills efficiently and safely, minimizing potential risks and exposures.

Preparation

Proactive preparation is essential for responding to biohazardous spills efficiently and safely. Each laboratory and facility where biohazardous materials are used must have a spill kit on hand that is easily accessible. The contents of these kits are tailored to address the nature of the biohazardous materials being handled and include:

- Absorbent Materials: Specialized pads or rolls designed to quickly absorb liquid biohazards, reducing the spread of contamination.
- Disinfectant: Broad-spectrum disinfectants that are effective against the biohazards present in the laboratory. The choice of disinfectant should be selected by the types of biohazardous agents used in the lab.
- Personal Protective Equipment (PPE): Gloves, face shields or goggles, lab coats.
- Waste Disposal Bags: Red biohazard bags that meet ASTM D1922 and D1709 standards for tear and impact resistance, are labeled with the international biohazard symbol and designed for the containment and disposal of biohazardous waste, including used PPE and clean-up materials.

Containment

The first step in responding to a spill is to contain it swiftly to prevent further spread of biohazardous materials. Utilize the absorbent materials from the spill kit to encircle the perimeter of the spill, effectively immobilizing the liquid and minimizing the chance of it spreading into uncontaminated areas.

Clean-Up

Before initiating the clean-up process, individuals must don the appropriate PPE (minimum protection: nitrile gloves, splash goggles, and lab coat) to protect against exposure to hazardous materials. The clean-up process involves:

- Applying Disinfectant: Liberally apply a disinfectant to the spill area, beginning at the outer edge and working towards the center. This method helps to ensure that the spill does not spread further during the clean-up process.
- Contact Time: Allow the disinfectant to sit for a sufficient period (typically 15-20 minutes) to ensure effective neutralization of the biohazardous material.

Waste Disposal

Once the spill has been neutralized and cleaned up, all materials used in the clean-up process, including contaminated PPE, must be disposed of as biohazardous waste.

Reporting and Documentation

Reporting and documenting the spill incident are crucial steps in the spill management process. The spill must be reported to the designated laboratory supervisor and biosafety officer, who will initiate any necessary follow-up actions. EH&S and the BSO may be notified via the online Report a Concern Form on the CPP EH&S website. Documentation should include detailed information about the spill, including:

- Nature of the Spill: Type of biohazardous material and volume spilled.
- Response Actions: Steps taken to contain and clean up the spill, including the types of disinfectants and PPE used.
- Exposure or Injuries: Any exposures to individuals or injuries incurred during the spill or clean-up process.

BIOHAZARD USE AUTHORIZATION PROCESS

The Biohazard Use Authorization (BUA) review and approval process ensures that all activities involving potentially hazardous biological materials are conducted in compliance with local, state, and federal regulations. The BUA serves as a control system to safeguard the health of personnel, the public, and the environment by regulating the use, storage, and disposal of biohazards on campus.

Activities and Materials Requiring a BUA

A BUA is mandatory for all research, teaching, and diagnostic activities that involve biohazardous materials, including but not limited to:

- Recombinant DNA and Synthetic Nucleic Acids: Construction and use of recombinant or synthetic nucleic acids, including work with GMOs.
- Infectious Agents: Work involving pathogenic bacteria, viruses, fungi, parasites, or prions.
- Human and Animal Materials: Handling of materials derived from humans or non-human primates, including blood, tissues, and cell lines.
- Biological Toxins: Use of toxins from biological sources that pose a significant health risk.
- Select Agents and Toxins: Activities involving agents and toxins listed under the Federal Select Agent Program.
- Animal Work: Research involving live vertebrates where there is potential exposure to zoonotic agents.

Application and Approval Process

To initiate any project involving biohazardous materials, investigators are required to submit a comprehensive BUA application to the Institutional Biosafety Committee via the Biosafety submission system on the Risk and Safety Solutions Platform (RSS): https://app.riskandsafety.com/

The RSS system may be accessed by logging into the website using your normal campus sign-in credentials. New PI will need to create a Profile in the system for their lab group and complete a Lab Hazard Assessment prior to applying for a BUA. The application must outline the biohazardous work, the protocols for safe handling, and the qualifications of all personnel involved. The IBC reviews each application to ensure the proposed activities meet safety standards and comply with relevant regulations. Approval is granted once the committee is satisfied that all safety measures are appropriately addressed.

If animals are involved in the research project, applications to both the Institutional Animal Care and Use Committee and the Institutional Biosafety Committee can be submitted simultaneously. Nevertheless, the IACUC's final approval is dependent on the IBC's review and approval of the Biohazard Use Authorization.

Research involving recombinant DNA and synthetic nucleic acids must adhere to the *NIH Guidelines for Recombinant and Synthetic Nucleic Acid Research*. Projects with significant implications for human health require comprehensive review by the NIH Director and the Novel and Exceptional Technology and

Research Advisory Committee (NExTRAC), in addition to the local IBC. Furthermore, any research that involves transferring nucleic acids into humans also needs to undergo review by the local Institutional Review Board (IRB).

For more instructions on how to complete the RSS BUA registration and submission process, please contact the campus BSO.

Training Requirements

All personnel listed on a BUA must complete specialized biosafety training before beginning any work with biohazardous materials. This training covers proper handling techniques, emergency procedures, and specific protocols related to the biohazards being used. Additionally, annual refresher training is mandatory to ensure ongoing compliance and to introduce any new safety information or regulatory changes.

Required training typically includes:

- General Biosafety: Covers the fundamental principles of biosafety, including understanding biohazards, risk assessment, and the application of biosafety levels.
- Specific Pathogen Training: Focused education on the pathogens or biohazards the personnel will be working with, including transmission methods, symptoms of exposure, and specific containment strategies.
- Personal Protective Equipment (PPE): Training on the proper selection, use, and disposal of PPE to minimize the risk of exposure to hazardous materials.
- Emergency Response and Incident Reporting: Instruction on how to respond to spills, exposures, and other laboratory emergencies, including the procedures for reporting incidents.
- Laboratory-Specific Protocols: Detailed training on the specific practices, procedures, and equipment used in individual laboratories.
- Waste Management: Education on the proper disposal of biological waste to prevent environmental contamination and exposure.
- Spill Response: Hands-on training in responding to and cleaning up biological spills safely.
- Regulatory Compliance: Information on federal, state, and institutional regulations governing the use of biological materials, including any reporting obligations.

Training programs should be dynamic, updated regularly to reflect changes in regulations, procedures, or findings from incident reviews, and should be repeated periodically to ensure that knowledge and practices remain current.

Here are the online biosafety trainings that should typically be completed by personnel listed on a BUA:

- CSU-Fundamentals of Biosafety (SumTotal)
- CSU-Safe Use of Biological Safety Cabinets (SumTotal)
- Bloodborne Pathogens Awareness (SumTotal)

Record Keeping and Documentation

Training Records: PI and laboratory supervisors must maintain detailed records of all training sessions attended by laboratory personnel, including the dates, topics covered, and names of attendees and trainers. These records should be easily accessible for review by laboratory supervisors, biosafety officers, and regulatory inspectors.

Certification and Assessments: Where applicable, document the completion of training programs with certificates or assessments to demonstrate competence in specific biosafety practices or procedures.

Continuing Education: Keep a log of any additional biosafety training or education completed by personnel, including conferences, workshops, and online courses, to demonstrate ongoing commitment to biosafety education.

BUA Amendment and Renewal

Amendments are required for the following:

- Location changes
- Personnel update
- Addition of new biohazards
- Changes in research scope
- Addition of animal(s) to BUA

BUA amendments must be approved by the IBC before any new work commences. Furthermore, all BUAs must be renewed every 3 years.

Compliance Monitoring

EH&S is responsible for conducting annual inspections of laboratories to ensure compliance with BUA conditions. These inspections help identify potential areas for improvement and focus primarily on engineering controls, administrative controls, and PPE.

The following are biosafety requirements for the laboratory.

1. Biosafety training records must be documented and readily available.
2. Pathogen Data Sheets, BBP Exposure Control Plan (ECP), and Chemical Safety Data Sheets (SDS) must be available for review by lab members.
3. Door signs must be posted on the entrance doors with the following information:
    a. Universal biohazard symbol
    b. The word “Caution”
    c. The overall biosafety level
    d. The PI’s contact information (name, telephone number) in case of emergency
4. Biological hazard warning labels with the universal biohazard must be affixed to laboratory equipment (e.g., freezers, refrigerators, incubators, BSC, centrifuges, biohazard waste containers, and water baths). The labels must be readily visible and used to identify equipment used to store, manipulate, or dispose of infectious materials. In an accident or exposure involving biohazardous materials, immediate reporting to the BSO is crucial for prompt investigation and mitigation.

Deactivation of Authorization

At the completion of a project, principal investigators must notify the IBC to deactivate the BUA. Proper decommissioning includes ensuring that all biohazardous materials are disposed of in accordance with university and regulatory guidelines. In cases of laboratory closure or the departure of the principal investigator, EH&S must be notified to facilitate the safe decommissioning of all biohazardous materials and facilities.

INCIDENT RESPONSE AND EMERGENCY PROCEDURES

A well-prepared response plan is crucial for handling incidents and emergencies in laboratories working with biological materials. This section covers procedures for responding to exposure incidents, biological spills, and other emergencies such as fires and earthquakes.

Exposure Incident Procedures:

1. Immediate Action: In the event of exposure to a biohazardous agent (e.g., splash to the skin, eyes, or mucous membranes, needlestick injury, ingestion, or inhalation), the affected individual should immediately seek to reduce the exposure. This may involve flushing the area with water, removing contaminated clothing, or seeking fresh air.

2. Medical Attention: Seek medical attention as soon as possible. Provide the healthcare provider with detailed information about the biohazard involved, the nature of the exposure, and any safety data sheets available.

3. Notification: Report the incident to the laboratory supervisor, Biosafety Officer, Institutional Biosafety Committee, and Worker's Compensation, as required. Accurate reporting is crucial for the investigation and for preventing future incidents.

4. Documentation: Document the incident thoroughly, including the date, time, persons involved, details of the incident, actions taken, and follow-up required.

Biological Spill Response:

1. Assess the Situation: Quickly assess the spill to determine its extent and potential hazards. Evacuate non-essential personnel from the area.

2. Containment: Contain the spill using absorbent materials to prevent further spread of contamination.

3. Clean-Up: Wearing appropriate PPE, apply a suitable disinfectant, starting from the outer edges of the spill towards the center. Allow adequate contact time for effective disinfection.

4. Waste Disposal: Dispose of clean-up materials and contaminated PPE as biohazardous waste according to the guidelines provided in the "Biological Waste Management" section.

5. Decontamination: Clean and disinfect all equipment and surfaces that may have been contaminated.

6. Report and Review: Report the spill to the Lab Supervisor/PI and the BSO. Review the incident to identify improvements in procedures or training to prevent future occurrences.

Fire, Earthquake, and Other Emergencies

1. Fire: In the event of a fire, follow the RACE protocol - Rescue, Alarm, Contain, and Extinguish/Evacuate. Prioritize personal safety and use fire extinguishers only if trained and it is safe to do so.
2. Earthquake: During an earthquake, Drop, Cover, and Hold On until the shaking stops. Afterward, check for injuries and hazards such as gas leaks or structural damage. Evacuate if necessary, avoiding areas with hazardous materials.
3. General Emergency Procedures: Familiarize yourself with emergency exits, assembly points, and the location of emergency equipment (e.g., fire extinguishers, first aid kits, spill kits). Participate in regular emergency drills and training.
4. Communication: Maintain clear and open communication during any emergency. Use designated emergency contact numbers to report the situation and follow instructions from emergency responders and safety officers.

Preparation, training, and awareness are key to effectively managing incidents and emergencies in a laboratory setting. Regular review and practice of these procedures ensure that all personnel are equipped to respond safely and efficiently to various situations.

MEDICAL SURVEILLANCE

Medical surveillance is a necessary element of an extensive biosafety program, designed to safeguard the health and well-being of laboratory personnel who work with or may be exposed to hazardous biological agents. This section details the components of medical surveillance, which include immunization and health screening programs, monitoring for exposure, and protocols for medical consultation after exposure incidents.

Immunization and Health Screening Programs

- Immunization: Vaccinations are available to protect personnel from infections caused by vaccine-preventable diseases linked to biological agents they might encounter during their work. Potential vaccinations include hepatitis B, tetanus, diphtheria, pertussis, measles, mumps, rubella, and varicella, depending on risk assessments. For any questions or requests regarding vaccination, please contact EH&S.
- Health Screening: Prior to employment or assignment to tasks involving potential exposure to hazardous biological agents, personnel should undergo health screenings to identify any conditions that might increase their risk of infection or complications. Screenings may continue periodically to monitor health status and the effectiveness of the biosafety controls in place.

Exposure Monitoring

- Routine Monitoring: Routine monitoring procedures may be necessary in the lab, based on the type of work being conducted, to identify early signs of occupational illnesses due to biological exposure. Such procedures are determined by assessment and could encompass regular check-ups, blood tests, and other diagnostic tests tailored to the specific agents involved. For any inquiries, please contact EH&S.
- Incident-Related Monitoring: In the event of an exposure incident, immediate and possibly long-term medical monitoring of the affected individual(s) is necessary to identify and treat any resulting infections or illnesses promptly.

Medical Consultation

- Post-Exposure Procedures: Prior to starting work with hazardous biological agents, it is imperative to have established procedures for immediate response and medical consultation in the event of potential exposure. These procedures should clearly outline how to report an exposure incident, assess the exposure risk, and secure necessary post-exposure prophylaxis and medical care. If you have questions about these procedures, please reach out to the Office of Environmental Health and Safety (EH&S).
- Confidentiality: Ensure that all medical consultations and records are kept confidential, in accordance with applicable privacy laws and regulations. Personnel should be informed of their privacy rights and the measures in place to protect their health information.

- Documentation and Follow-up: All exposure incidents, along with the outcomes of medical consultations, treatments administered, and follow-up care, must be documented. This data is essential for assessing the effectiveness of existing biosafety measures and enhancing safety protocols. Any potential exposures should be promptly reported to the Office of Environmental Health and Safety to ensure a thorough investigation and to facilitate recommendations for addressing the root cause.

Reproductive Health Program

- This program outlines the referral process of the reproductive health consult of all individuals (employees, students, and volunteers) on campus from occupational exposure to chemical, biological, radioactive, and other substances that are known or suspected of being capable of posing a hazard to human reproduction.
- The objective of the Reproductive Health Program is to refer the reproductive health individual to the campus occupational clinic for a medical consultation by a licensed medical practitioner.
- EH&S will work with individual and supervisor to conduct a risk assessment and generate a referral for the occupational medical consultation.

APPENDIX A: EMERGENCY CONTACTS

This appendix provides comprehensive contact information for key safety personnel and emergency services at and around Cal Poly Pomona.

Institutional Biosafety Committee (IBC):

- Lance Coey (Committee Chairperson)
- Email: lwcoey@cpp.edu
- Phone: (909) 869-5054

Biosafety Officer (BSO):

- Lance Coey
- Email: lwcoey@cpp.edu
- Phone: (909) 869-5054

Campus Security/Emergency Services:

- CPP University Police
- Email: police@cpp.edu
- Phone: Emergency Dial 9-1-1
- If using a cell phone in an emergency, dial (909) 869-3070

Local Hospital/Emergency Room:

- Pomona Valley Hospital Medical Center
- Address: 1798 N. Garey Avenue, Pomona, Ca 91767
- Phone: (909) 865-9500

Poison Control Center:

- National Capital Poison Center
- Online Help: https://triage.webpoisoncontrol.org/#!/exclusions
- Phone: 1-800-222-1222

Public Health Department:

- Los Angeles County Department of Public Health
- Email: publichealth@ph.lacounty.gov
- Phone: (213) 240-8144

APPENDIX B: FORMS AND TEMPLATES

Incident/Accident Report Form: For documenting any biosafety incidents or accidents that occur, including spills, exposures, or injuries.

- Manager's Report of Injury/Illness Form
- Accident Injury and Illness Investigation Form - Employees
- Accident Injury and Illness Investigation Form - Students
- Report a Safety Concern Online Form

Biosafety Standard Operating Procedures (SOP): Guidelines for safe handling and management of biohazards to prevent exposure and ensure environmental safety.

- Biohazardous Spill Response
- Biosafety Cabinet Use
- Decontamination
- Liquid Medical Waste
- Sharps Medical Waste
- Solid Medical Waste

Laboratory Inspection Checklist: A tool for conducting thorough reviews of laboratory practices and safety compliance.

- BSL1/BSL2 Laboratory Inspection Checklist

Training Record Form:

- Safety Training Documentation Form

Medical Surveillance Form: Used to track health screenings, immunizations, and exposure incidents for individual personnel.

- Exposure Control Plan Employee Certification
- Animal Handler: Risk Assessment Questionnaire Online Form
- Animal Handler: Health History Questionnaire

Other Forms and Templates:

- Universal Safe Work Practices and Hazard Assessment Template
- Safety Training Documentation Form

REFERENCES

The biosafety practices and protocols outlined in this manual are based on a comprehensive review of relevant federal and state regulations, as well as guidelines and standards established by leading health and safety organizations. This section provides a list of key references that have informed the development of the biosafety manual.

Relevant Federal and State Regulations

- Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, and the National Institutes of Health. Provides guidance on the safe handling and containment of infectious microorganisms and hazardous biological materials.

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines): Establishes the framework for the oversight of research involving recombinant or synthetic nucleic acid molecules, including the roles and responsibilities of Institutional Biosafety Committees.

- Occupational Safety and Health Administration (OSHA) Standards for Bloodborne Pathogens (29 CFR 1910.1030): Specifies measures to reduce occupational exposure to bloodborne pathogens and implement appropriate controls.

- Select Agent Regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121): Governs the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public, animal, or plant health.

Guidelines and Standards

- Centers for Disease Control and Prevention (CDC): Offers comprehensive resources on infectious diseases, public health, and biosafety, including guidelines for infection control and laboratory safety.
- National Institutes of Health (NIH): Provides extensive guidance on biosafety considerations for research involving recombinant or synthetic nucleic acid molecules, including risk assessment and management strategies.

- Occupational Safety and Health Administration (OSHA): Publishes standards and guidelines to ensure workplace health and safety, including specific provisions for laboratories and healthcare facilities.

- American Biological Safety Association (ABSA) International: Offers resources, guidelines, and professional development for biosafety and biosecurity professionals, including standards for biosafety level practices and risk assessment.

- World Health Organization (WHO) Laboratory Biosafety Manual, Fourth Edition: Provides a framework for the safe handling of infectious substances and management of biosafety laboratories on a global scale.

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