

Biosafety for Laboratory Workers

PROGRAM OVERVIEW

This program has been developed to:

- protect all laboratory personnel from exposure to biological agents that have the potential to cause disease in humans
- prevent environmental contamination
- protect experimental materials
- specify the company policies, procedures, and requirements for safe handling and use of biological agents
- ensure compliance with applicable federal, state, and local regulations/guidelines

Scope

This program addresses all biological agents that are known to, or suspected to, cause disease in humans. This manual does not include policies and procedures addressing biological agents that cause animal or plant death/diseases.

Target Audience

This program applies to all personnel working in company laboratories. This may include:

- regular employees
- temporary or contract employees
- interns
- other individuals working in the environment

Work areas this program may apply to include:

- laboratories / facilities
- health service / clinic facilities
- animal care facilities
- agricultural research operations
- experimental center operations

If you are unsure whether or not your work area must comply with the requirements of this program, please contact the Company Safety Officer.

RESPONSIBLE PARTIES

Directors/Department Heads

Directors/Department Heads shall assume overall responsibility for ensuring their respective departments comply with the requirements of this program.

Directors/Department Heads shall:

- be familiar with the requirements of this program

- ensure that Investigators / Researchers / Supervisors are aware of the requirements of this program
- mandate laboratory participation
- ensure all abandoned hazardous materials remaining within facilities are promptly disposed of or placed in the company's hazardous materials surplus program

Safety Officer

This position shall be the responsibility of the Operations Department. The Safety Officer shall:

- assist laboratory personnel in identifying hazardous operations, establishing safe work practices, and selecting protective equipment and other exposure controls
- develop and maintain the written guidelines and procedures for safe work practices
- develop training programs
- coordinate with the Operations Department to arrange for personal exposure monitoring and respiratory protection
- act as liaison between the company and all federal, state, and local entities regarding biological safety in laboratories
- maintain company's registration with the CDC
- report any suspicious use of a biological agent to the CDC and/or state health department
- conduct periodic inspections of laboratories using biological agents
- consult with laboratory personnel to evaluate and correct deficiencies in the laboratory
- investigate and report to the principal investigator and/or other laboratory supervisors any significant problems with equipment, facilities, and/or safe work practices and procedures
- remain knowledgeable of regulatory and legal requirements associated with biological agents

Principal Investigators and Researchers

Principal Investigators and Researchers shall assume responsibility for the daily operations of a laboratory or group of laboratories. Principal Investigators and Researchers shall:

- read this program and be familiar with its requirements
- ensure all laboratory work is conducted in accordance with this program and all applicable federal, state, and local regulations / guidelines regarding biological safety in laboratories
- select the appropriate control practices for handling hazardous substances
- prepare procedures for response to accidents / incidents involving hazardous substances
- prepare lab-specific policies and procedures
- ensure that laboratory employees are properly trained on the hazards and how to handle hazardous substances in the laboratory
- maintain training documentation
- ensure that safety equipment is properly maintained
- work with the Safety Officer to correct any laboratory deficiencies
- ensure all abandoned hazardous materials remaining within laboratories under their supervision are promptly disposed of or placed in the company's hazardous materials surplus program
- conduct regular self-audits

- complete all necessary reports for any accident / incident involving biological agents, bloodborne pathogens, radioactive material, or chemicals and submit it to the Safety Officer for review

Laboratory Employees

Laboratory employees have a responsibility to:

- read this document and be familiar with its requirements
- wear and properly maintain any personal protective equipment necessary to perform each assigned task
- use engineering controls and safety equipment properly
- follow good personal and laboratory hygiene practices
- participate in all required training
- read, understand, and sign off on laboratory-specific procedures
- inform their supervisor if any deficiencies are noted in the laboratory facility, equipment, and procedures
- ensure all excess hazardous materials used for research under their supervision is promptly disposed of or placed in the company's hazardous materials surplus program
- report to their supervisor any accident that results in injury or exposure to a hazardous substance
- know all emergency procedures

BIOHAZARD IDENTIFICATION

Types of Biohazards

The company, through its research, has the potential to house a number of different types of biological agents that are associated with specific types of hazards.

Type of Agent	Associated Hazard(s)
Microorganisms and their toxins (bacteria, fungi, viruses and their products)	Infection, exposure, or allergic reaction
Prions (proteinaceous infectious particles lacking nucleic acids)	Neurodegenerative diseases (e.g., Creutzfeldt-Jakob disease)
Vertebrate animals and their protein allergens (urine, feces, hair, saliva, and dander)	Zoonotic diseases, allergic reactions
Invertebrate animals <ul style="list-style-type: none"> • arthropods (crustaceans, arachnids, insects) • parasites (protozoa, flatworms, roundworms) 	Bites or stings resulting in skin inflammation, systemic intoxication, transmission of infectious agents (i.e., arboviruses), or allergic reaction
Higher plants and their	Dermatitis from skin contact or rhinitis or asthma

allergens/toxins	from inhalation
Lower plants (lichens, liverworts, and ferns)	Allergic reactions; systemic infections; skin inflammation

Potentially Hazardous Workplaces

Some workplaces may be identified as areas where the potential for exposure to biological agents is high, where controls are difficult to implement or not readily available, or where hazard recognition may be low.

If you are unsure whether or not your work area must comply with the requirements of this program, please contact the Safety Officer.

ADMINISTRATIVE CONTROLS

Risk Assessment

- Risk assessments provide lab research personnel with information needed to protect laboratory workers, individuals not in the immediate work area, and the surrounding environment. This assessment will also determine what procedures, safety equipment, and facility design are required for work with the agent in question.
- Prior to any research work with biological agents, a risk assessment must be completed and included documentation purposes. The risk assessment is the cornerstone of any successful safety program.
- The principal investigator, researcher, or lab director/supervisor is responsible for assessing risks in order to set the biosafety level for the work to be done. This may be done in close collaboration with Operations Department to ensure compliance with established guidelines and regulations.

Biosafety Manual

- Each lab or group of labs under the guidance of a single principal investigator, researcher, or lab director / supervisor must have access to this manual.
- The principal investigator, researcher, or lab director / supervisor is responsible for ensuring that lab-specific policies and procedures are developed and inserted into this manual.
- Each lab worker should be familiar with the manual's location and contents.

Signs and Labeling

- All access doors to labs or animal rooms where biologicals are present must be posted with biohazard information in addition to the emergency contact information required by OSHA's Lab Safety Standard. This information must include:
 - the universal biohazard symbol which is red/orange in color with black lettering (Figure 1)
 - name of the agent(s) present in the lab
 - required biosafety level for working with these agents
 - required immunizations for entering room

- personal protective equipment that must be worn in room
- special procedures for exiting the lab
- name and telephone number of the Principal Investigator, other responsible person(s), and Operations Department emergency personnel
- The OSHA Bloodborne Pathogens Standard requires labels to be placed on items that may be contaminated by bloodborne pathogens. This may include:
 - equipment (e.g., refrigerators, freezers, and incubators)
 - shipping containers
 - primary and secondary agent containers
 - regulated medical waste containers
 - sharps containers



Figure 1. Biohazard Symbol

Inspections

- Operations Department will inspect all company operated labs annually to ensure compliance with local, state, and federal regulations/guidelines. This includes the use of adequate facilities and proper maintenance of these facilities.
- Interviews of laboratory personnel may be conducted during inspections to ensure lab personnel are aware of proper laboratory and emergency protocols and that they are informed of the properties of the organisms with which they are working.
- In addition to Operations Department inspections, each lab must routinely inspect their own lab(s) for deficiencies. Inspection worksheets used by Operations Department are not exhaustive but may help you focus your efforts.

Training/Education

- Training is required for all employees and personnel working in laboratories or animal rooms where biological agents are in use.
- The Lab Safety and Bloodborne Pathogens Programs also require training for all personnel handling hazardous chemicals and/or human blood or body fluids in the laboratory.
- It is the responsibility of the Principal Investigator, lab director, or animal facility director to ensure that adequate instruction is provided.
- Training should include, at a minimum, the following topics:
 - Principles of biosafety
 - Hazards in the lab (biological, chemical, and radiological)
 - Acceptable laboratory and animal practices
 - Personal protective equipment requirements
 - Proper use of ... (specific equipment used in the lab)
 - Signs and labeling requirements
 - How to decontaminate, disinfect, and sterilize
 - Proper waste handling, packaging, and disposal
 - Packaging/shipping etiologic agents

- Emergency procedures
 - Material safety data sheets and how to use them
- Documentation of training forms should be kept current in the lab-specific section and for three years after an individual's termination of employment.

Medical Surveillance

- Vaccines (if available for the agent in question) must be offered to all clearly identified "at-risk" personnel. This cost is borne by Operations Department.
- Hepatitis B vaccinations must be offered to all personnel identified as "at-risk" for exposure to blood borne pathogens. This cost is borne by Operations Department.
- Routine titer checks are provided for individuals working with BSL3 organisms, if such tests are available. This cost is borne by Operations Department.
- Medical exams will be provided for individuals following an exposure incident to blood, potentially infectious material, or to a specific agent. This cost is borne by Operations Department.
- A medical surveillance program will be provided for those personnel having "substantial animal contact."
- It is the responsibility of the Principal Investigator, researcher, lab director/supervisor, or animal facility director to identify "at-risk" personnel and personnel with "substantial animal contact." This must be communicated to Operations Department.
- The Administrative Office manages the coordination of vaccinations and medical exams.

Pest Management

- Each lab must ensure that pests, such as flies and cockroaches which may become vectors of disease, are managed and do not compromise the research environment. Even the presence of innocuous insects can contribute to the perception of unsanitary conditions.
- Each principal investigator is responsible for developing an integrated pest management program. The program should be communicated to all lab workers and included in Part B of this manual.

ENGINEERING CONTROLS

Facility Design

- All laboratories must be able to contain the specific agent(s) in use.
- Assessment of risk, to determine facility design requirements, is the responsibility of the principal investigator, researcher, or laboratory director/supervisor.

Biological Safety Cabinets

General Requirements

- Biosafety cabinets (BSCs) are used to provide primary containment in the laboratory when using potentially infectious agents and can be used to manipulate sterile cultures.
- BSCs should be used in BSL2 or BSL3 projects if:
 - aerosol-generating procedures are conducted
 - a high concentration of infectious agents are used

- if large volumes of infectious agents are used
- Chemicals should never be used in amounts that would exceed the lower explosion limits of the compound.
- The similarities and differences in protection offered by the various classes of biosafety cabinets are listed in Table 2. It is important that the correct cabinet is selected and used for the agent to be handled.
- Horizontal / vertical laminar flow "clean benches" are not BSCs. They discharge HEPA-filtered air across the work surface and toward the user. These devices only provide product protection and should never be used when handling cell culture materials and drug formulations, or when manipulating potentially infectious materials. In addition, no chemicals should be used in this type of apparatus.

Table 2. Type of protection provided by BSC class

Biological Risk Assessed	Protection Provided			BSC Class
	Personal	Product	Environmental	
BSL 1-3	Yes	No	Yes	I
BSL 1-3	Yes	Yes	Yes	II (A1, B1, B2, B3)
BSL 4	Yes	Yes	Yes	III (B1, B2)

Certification of the BSC

- BSCs should be certified:
 - at installation
 - whenever moved
 - after a filter change
 - at least annually
- Currently, an outside vendor performs certification of BSCs (and laminar flow hoods). Contact the Safety Officer to obtain vendor contact information.
- Certification costs are the responsibility of the department budget.

Location of the BSC

- The BSC should be located away from:
 - the entry since people walking by can cause a disturbance in the air curtain
 - any window, air supply registers, or laboratory equipment that creates air movement (e.g., centrifuges, vacuum pumps)
 - other chemical fume hoods and BSCs
- Whenever possible, a 12-inch clearance should be provided behind and on each side of the cabinet to allow easy access for maintenance and to ensure air return to the lab is not hindered.
- A 12- to 14-inch clearance above the cabinet may be required to provide for accurate air velocity measurement across the exhaust filter surface.

Preparing for Work in the BSC

- Prepare a written checklist of materials necessary for a particular activity and place them in the BSC. This will help minimize the number of arm movement disruptions across the air barrier.

- Adjust stool height so that your face is above the front opening.
- Do not block the front grille with research notes, discarded plastic wrappers, pipetting devices, etc.
- Only materials required for the immediate work should be placed in the BSC.
- The blower should be run at least 3-5 minutes before beginning work to allow the cabinet to "purge".
- Delay manipulation of materials for approximately one minute after placing hands/arms inside the cabinet to allow aerosols to settle.
- The interior surfaces of the cabinet should be wiped with 70% ethanol (EtOH), a 1:100 dilution of household bleach (i.e., 0.05% sodium hypochlorite), or other disinfectant prior to beginning work in the cabinet. When bleach is used, a second wiping with sterile water is needed to remove the residual chlorine, which may eventually corrode the stainless steel. Wiping with non-sterile water may recontaminate the surfaces. Bleach should be mixed daily.
- The surfaces of all materials and containers placed into the cabinet should be wiped with 70% EtOH to reduce the introduction of contaminants.

Material Placement Inside the BSC

- Plastic-backed absorbent toweling can be placed on the work surface to facilitate routine cleanup. Make sure it doesn't cover the front or rear grille openings.
- All materials should be placed as far back in the cabinet as practical.
- Aerosol-generating equipment (e.g., vortex mixers, tabletop centrifuges) should be placed toward the rear of the cabinet.
- Materials should be placed in a "clean to dirty" work flow layout.
- Bulky items (e.g., biohazard bags, discard pipette trays, suction collection flasks) should be placed to one side of the interior of the cabinet.
- Autoclave bags should not be taped to the outside of the cabinet.
- Upright pipette collection containers should not be used in the cabinet nor placed on the floor outside the cabinet. Only horizontal pipette discard trays with an appropriate chemical disinfectant should be used in the cabinet.
- Potentially contaminated materials should not be brought out of the cabinet unless decontaminated.

Operations Within the BSC

- Always use techniques that reduce splatter and aerosols.
- Keep clean materials at least 12 inches away from aerosol-generating activities to help minimize the potential for cross-contamination.
- General work flow should be from clean to contaminated areas.
- To reduce the chance of cross-contamination:
 - open tubes or bottles should not be held in a vertical position
 - petri dishes/tissue culture plate lids should be held directly over the open sterile surface to minimize direct impaction from downward air flow
 - bottle or tube caps should not be placed on the toweling
 - items should be recapped or covered as soon as possible
- Open flames should not be used in the BSC. When deemed absolutely necessary, touch-plate microburners equipped with a pilot light to provide a flame on demand may be used. The burner must be turned off when not in use.
- Small electric "furnaces" are available for decontaminating bacteriological loops and needles and are preferable to an open flame.
- Aspirator bottles or suction flasks should be connected to an overflow collection flask (i.e., trap) containing disinfectant and to an in-line HEPA filter.
- When a chemical means of decontamination is used, contaminated items should be placed in a discard pan containing disinfectant with a minimum of splatter. They should be allowed contact time per manufacturer's instructions.

- When an autoclave is used for decontamination, contaminated items should be placed into an autoclave bag or discard tray before removal.

Chemical Fume Hoods

General Information

- Fume hoods are designed to maximize capture of chemical vapors and fumes and move them away from the worker and exhaust them from the building.
- A chemical fume hood must be used if the experiment requires work with more than minute amounts of volatile toxic chemicals and radionuclides.

Certification of the Fume Hood

- Chemical fume hoods are certified by Operations Department personnel:
 - following installation of a new hood
 - following any maintenance performed by the Facilities Department
 - during Operations Department annual laboratory inspections
- When a fume hood is tested, it will either pass or fail.
- A hood that has passed will bear the Hood Certification sticker which will indicate the testing date, tester name, and average face velocity.
- The hood will also bear arrows that should be aligned to ensure proper velocity during operation.
- A hood that has failed will bear a bright orange sticker that states the hood is out of order, the date it failed, and the problem noted. Any hood bearing an orange sticker should not be used for work with chemicals. You are not assured protection from the vapors.

Fume Hood Repair

- If the hood has been tagged out by Operations Department or is malfunctioning, the laboratory manager should be notified. The lab manager should contact the Facilities Department to make a work order request.
- Before the Facilities Department performs any maintenance, all containers must be either capped or physically removed from the fume hood.
- For problems with roof exhaust fans or motors, all chemicals must be capped.
- For problems within the hood itself, all containers and equipment must be removed to another location.
- Once the hood has been serviced, Operations Department will be notified by Facilities Department to recertify it. Operations Department will remove the orange sticker if the hood passes.
- Off-site facilities will be handled differently. Contact the Company Safety Officer, to determine the best method of maintenance.

Location of the Fume Hood

- All fume hoods should be located away from:
 - passageways
 - drafts
 - air diffusers
 - doors
- Fume hoods should be located in the rear of the laboratory to minimize the trapping of occupants in the event of a fire or accident.

Proper Use of the Fume Hood

Many factors can compromise the efficiency of the hood operation. The following should always be considered when using a hood:

- Position the fume hood sash so that work is performed by extending the arms, keeping the glass between the worker and the chemical source.
- Avoid opening and closing the sash rapidly, and avoid swift arm and body movements in front of or inside the hood.
- Place chemicals at least six inches behind the sash in order to reduce chemical concentrations in the breathing zone.
- Place equipment as far back as possible without blocking the bottom baffle.
- Separate and elevate each instrument by using blocks or racks so that air can flow easily around all apparatus.
- Do not remove side panels or the airfoils in order to maintain the hood's integrity.
- Do not use large pieces of equipment in the hood in order to prevent dead spaces in the airflow.
- Do not use the hood to store chemicals or waste.
- Keep clutter to a minimum inside the hood in order to maintain proper airflow.
- Keep the hood closed when not used.
- Cap all chemicals not in use.

Eyewash Stations and Safety Showers

- Suitable eyewash facilities and deluge showers must be available to all laboratories containing chemicals.
- Access to eyewash and safety showers must be within 10 unobstructed seconds of the work area.
- The Company Safety Officer must be contacted before the purchase and/or installation of any eyewash or deluge shower to ensure that they meet the [ANSI](#) standard Z3581-1998.

Safety Centrifuges and Blenders

- Safety centrifuges/blenders are enclosed containers designed to prevent aerosols from being released during centrifugation or homogenization of infectious materials. **These must be used for handling infectious agents that may be transmitted by aerosols.**
- Because the primary containers used in a centrifuge may be subject to extremely high stresses, careful attention must be paid to the quality of the seal.

Personal Protective Equipment

- Personal protective equipment (PPE) may include items such as:
 - gloves
 - lab coats
 - gowns
 - shoe covers
 - boots
 - respirators
 - face shields
 - safety glasses
 - goggles
- PPE is used in combination with biological safety cabinets and other devices that contain the agents, animals, or materials being handled.