

18.0 CHAPTER 18 – BIOSAFETY LEVEL 3 LABORATORIES

This chapter establishes policies, practices and procedures for work requiring Biosafety Level 3 containment. Each laboratory conducting Biosafety Level 3 work must have written laboratory-specific biosafety practices and procedures approved by the IBC prior to commencement of work. It is highly recommended that the practices and procedures set forth here be adopted into the laboratory-specific practices and procedures and implemented as part of required performance of every individual working in the lab.

18.1 General Principles

Biosafety Level 3 work, by definition, involves agents that may cause serious and potentially lethal infection. The primary hazards to personnel working with these agents are autoinoculation, ingestion and inhalation of aerosols. Each person who uses BSL-3 agents must know and understand the concepts of biosafety and the responsibilities of each individual. They must have an in-depth knowledge of the general and laboratory-specific practices, procedures and equipment which form the primary biohazard containment. Therefore, each individual is expected to take an active role in maintaining the containment conditions required for safe conduct of the work. Each person must understand the facility (laboratory) design features that make up the secondary biohazard containment; in addition, participate in the overall maintenance and management of the facility.

18.2 Specific Responsibilities, Practices & Procedures

The following is provided to give guidance in the preparation of laboratory-specific biosafety practices and procedures. This chapter is intended to clarify the responsibilities of the Principal Investigator, all persons who work with Biosafety Level 3 agents and those who work in or enter a Biosafety Level 3 facility. These statements are intended to augment the Biosafety Level 3 (BSL-3) and animal Biosafety Level 3 (ABSL-3) practices and procedures found, and are not intended to limit or reduce those standards of containment.

18.2.1 Responsibilities

A. The PI must ensure that appropriate biosafety practices and procedures are rigorously followed and that the required physical containment features are maintained. If any element of biosafety is considered by the PI to be unachievable, the UCSB Biosafety Officer should be notified immediately. A written report of the problem must be sent to the Biosafety Officer within five working days. The responsibilities of the PI are more completely defined in Chapter 1, *Scope, Policy and Responsibilities*.

B. All persons must conscientiously follow the laboratory-specific biosafety practices and procedures. Responsibilities of laboratory personnel are more completely defined in Chapter 1, *Scope, Policy and Responsibilities*.

C. Failure to follow required behavior may place all workers in the laboratory in jeopardy. Workers should observe and monitor the work practices and procedures of others in the laboratory. A serious or consistent failure to follow these guidelines must be reported to the PI or the UCSB Biosafety Officer. Under no circumstances shall any adverse action be taken against a person for exercising this requirement.

D. The PI must monitor and authorize access of all persons entering the BSL-3 laboratory. Access is limited to those who understand the nature of the biohazard, have adequate laboratory-specific biosafety training and agree to comply with all precautions. Training and agreement to comply must be documented (e.g., in a log or person-specific file). Visitors and maintenance personnel who enter the BSL-3 laboratory must be fully informed of the potential risks, required practices and procedures that they must follow. They must be instructed about the signs and symptoms of any and all biohazardous materials manipulated or stored in the laboratory.

18.2.2 Information

A. Persons who may be at increased risk of acquiring infection or for whom infection might be unusually hazardous (e.g., immunocompromised persons) must be advised of their special risk in terms they understand, and must be strongly discouraged from entering the laboratory. If personnel are allowed to perform research that may put them at an increased risk an Informed Consent document will be required with routine medical surveillance.

B. Biosafety training must be regularly scheduled and presented to all persons who work in or who enter the Biosafety Level 3 laboratory. Comprehensive training must be provided for each new person prior to beginning work. Training continues for all laboratory staff with sessions presented one or more times in any one-month period. Training must focus on biosafety or other health and safety policies, practices and procedures to be followed for this research. Sufficient instruction must be provided to cover the entire gamut of biosafety training at least once each year.

C. Cultures, tissues, etc., sent from a BSL-3 laboratory to another laboratory shall be handled using BSL-3 biosafety practices. All researchers receiving these biohazardous materials must be notified in writing of the risks associated with these materials, and

of the need to handle the materials using BSL-3 practices and procedures. Documentation of biohazardous materials transfers must include the institution, Principal Investigator, date sent, nature and amount of material transferred and the biosafety level required for this work.

18.3.3 Personal Protective Equipment

A. All persons who enter the BSL-3 laboratory must wear all required personal protective equipment as set forth by the Exposure Control Plan established for that specific facility. At a minimum, this includes wraparound gown, gloves and eye protection. Shoe covers, masks, head covers, sleeve protectors and face shields should be added as appropriate. The PI and laboratory staff must enforce this requirement.

B. Any time a frozen storage container (freezer, ultra cold, liquid nitrogen) is opened, eye and face protection (face shield or goggles and a surgical mask) should be worn by persons handling the material. Gases can liquefy or solidify in ultra cold storage; as vials warm, increasing pressure can rupture the containers.

C. Whenever potentially infected animals, tissues or infectious agents are in the Biosafety Level 3 laboratory and not contained in biosafety cabinets, all persons must be provided with (and required to wear) a HEPA-filtered respirator. This respirator provides protection against both liquid and solid aerosols. The respirator must be NIOSH certified and fit tested by EH&S.

D. No person shall leave the Biosafety Level 3 laboratory while wearing clothing designated for wear inside the facility. Distinctive protective clothing (clearly different from protective clothing used in nearby areas) shall be provided to the laboratory staff for their use inside the facility.

E. Lockers must be provided in the anteroom for each person who works in the Animal Biosafety Level 3 facility. No protective clothing used in the ABSL-3 facility may be worn outside the anteroom or ABSL-3 facility, and no street clothes may be worn in the ABSL-3 facility.

18.2.4 Biohazardous Material Waste

All waste (infectious, trash, etc.) from a Biosafety Level 3 facility must be autoclaved by the end of each day and before it leaves the building. Each laboratory must post clear instructions on how Biosafety Level 3 waste will be handled.

Decontamination and Housekeeping

1. Any item removed from the Biosafety Level 3 laboratory but not considered to be waste must be decontaminated before removal, even if there is only a small chance that it is contaminated. Items may be wiped down with a disinfectant or sealed in a bag and autoclaved.
2. Each person will decontaminate their own work surfaces (e.g., benches, sinks, doors, handles, etc.) immediately after each use and immediately after any contamination with viable material.
3. Some disinfectants are much more effective than others and some organisms readily survive some disinfectants. The manufacturer or vendor can provide documentation of a disinfectant's effectiveness against specific organisms. Disinfectants are most effective when used according to the manufacturer's instructions of concentration and contact time. Be sure to keep records that prove the liquid disinfectants are effective. Your laboratory-specific practices and procedures must include detailed instructions on the type of disinfectant, proper mix proportions, contact time required and other information that will ensure effective decontamination of work surfaces. EH&S strongly discourages the use of flammable materials or disinfectants which may create vapors that will have toxic or adverse effects on laboratory staff. Bleach and industrial-grade Lysol are effective for most situations.
4. While it is the ultimate responsibility of the PI, each person who works with BSL-3 materials is individually responsible for maintaining a neat, clean and contamination-free laboratory. Storage of supplies must be in cabinets or on shelves. No boxes or supplies may be stored on the floor. The floors must be cleaned at least weekly and immediately after contamination with any viable material.

Laboratory Maintenance and Repair

1. The PI is responsible for ensuring that the physical components of the laboratory designed to contain the biohazards associated with the research are working properly and properly maintained (e.g., ventilation, filtration, sanitation, security).
2. If the ventilation system or other physical containment component of the laboratory fails, work in the Biosafety Level 3 facility must be halted. Notify Facilities Management and contact the UCSB Biosafety Officer to help determine appropriate action.
3. Repair of the facility or laboratory equipment that requires entry into the BSL-3 laboratory by someone other than the normal laboratory staff must be authorized by the UCSB Biosafety Officer BEFORE work begins.
4. Any time the BSL-3 facility must be closed for maintenance or repair, a laboratory clearance inspection must be performed by the UCSB Biosafety staff before the work may commence. Once clearance is granted, no

further work with biohazardous materials may be conducted until all maintenance and repair work is completed. A thorough inspection of the laboratory must be conducted by the PI or designee to ensure that the laboratory is functioning properly before work with biohazardous materials may recommence.

5. Routine maintenance that affects ventilation, affects containment provided by the facility or requires entry into the lab by non-laboratory staff must be scheduled with EH&S at least two weeks in advance. No maintenance or repair work may begin without prior EH&S authorization. It is expected that EH&S will conduct unannounced inspections during the maintenance.
6. Weekly tests of the required negative pressure for each room in the BSL-3 facility must be performed. (This test can be performed using a strip of tissue held in the opening of door held slightly ajar.) Problems must be reported without delay to Facilities Management and to the UCSB Biosafety Officer. All readings must be logged and kept on file.
7. Special containment systems such as an exhaust HEPA filtration system must be tested and certified to meet National Sanitation Foundation standard 49 no less than annually. These tests must be performed by an approved certification company.
8. The PI must keep a log of all maintenance conducted by non-laboratory staff when the BSL-3 facility has NOT been closed for maintenance. The log must record:
 - Type of work/maintenance completed (with enough detail so those unfamiliar with the work can reconstruct the sequence of work/maintenance events)
 - Date of entry
 - Names of workers
 - Start time
 - Completion time
 - Disinfection technique for contaminated tools
 - Special personal protective equipment required to protect the workers (e.g., boots, heavy gloves, face shield etc.)
 - Work order number
 - Disinfection or other steps taken to protect maintenance workers

18.2.5 Medical Surveillance

Occupational Health Surveillance must be provided for all persons who perform Biosafety Level 3 work. As appropriate, each person must be offered serologic testing when they begin work and at least once a year. The results of this serologic screening must be made available to the IBC upon request. Results may be coded to protect the privacy of the individuals. The IBC may use the results of these tests as a tool to evaluate the effectiveness of the laboratory's biosafety program. It is the expectation of the IBC that no one will acquire a research-related infection as a consequence of the work with biohazardous materials.

18.2.6 Emergencies, Potential Exposures & Spills

The UCSB Biosafety Officer must be immediately notified if a person is known to or suspected of having acquired an infection resulting from work in or around the laboratory.

The Biosafety Officer must be notified immediately if any significant problems, violations of biosafety practice, releases, spills or other laboratory accidents with potential biohazard exposure occur. If there is any doubt, the Biosafety Officer should be notified at 893-8894.