Biosafety Laboratories: Isolating Dangerous Biological Agents in an Enclosed Facility

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Executive Summary

A biosafety laboratory is a life-sciences laboratory where pathogens, ranging from mildly infectious to lethal, are handled. Such laboratories are equipped with engineering and administrative controls to "ensure that pathogenic microbes are safely contained."[1] These controls include the assessment of the hazard level of the pathogen(s) for the assignment of its biosafety level and the associated microbiological practices, safety equipment, and laboratory facility necessary to isolate a pathogen and handle it safely.[2]

Hazard Levels

Pathogens are assigned a biosafety level according to the severity of their hazard. These correspond to the level of biocontainment precautions required to isolate that pathogen in an enclosed facility. The levels of containment range from the lowest biosafety level 1 (BSL-1) to the highest at level 4 (BSL-4). In the United States, the Centers for Disease Control and Prevention (CDC) have specified these levels.[3] In the European Union, the same biosafety levels are defined in a directive.[4]

The hazard level of a pathogen is assessed by determining the degree of hazard it presents:[5]

- Low risk hazards (BSL-1) are well characterized agents not known to cause disease in healthy adult humans. An example is non-pathogenic E. Coli.
- Moderate risk hazards (BSL-2) are agents which cause human disease of moderate hazard. Examples are Hepatitis A/B/C.
- High risk hazards (BSL-3) are agents that cause disease of moderate to high hazard that have serious or potentially lethal consequences, but for which treatments exist. An example is Mycobacterium tuberculosis.
- Very high hazards (BSL-4) are agents which cause severe to fatal disease in humans, for which vaccines or other treatments are not available. An example is the Ebola virus. Such pathogens are limited to government research facilities or institutions associated with such research and therefore, are very rarely encountered.

Standard Microbiological Practices

These practices include the administration of basic principles of biosafety and laboratory practices and techniques, as well as engineering controls such as safety equipment, facility design and construction and other considerations determined by the biosafety level of the hazard being controlled.[6] These considerations include:

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- Access to the laboratory: For low risk hazards, access does not have to be restricted, but higher hazards require doors to be closed or locked to prevent public or untrained personnel access.
- Biohazard signage: For low hazard risks, biohazard signage is not required, whereas it is required for higher hazard risks.
- Biohazard solid waste decontamination: For low risk hazards, biowastes can be managed by a biomedical waste vendor, whereas for higher risk hazards, biowastes require steam sterilization before vendor disposal.
- Biohazardous liquids decontamination: For low risk hazards, a 10% bleach solution can be added in the liquid and allowed to decontaminate over a period of time (typically 30 minutes), whereas high hazard liquids require steam sterilization.
- Eating, drinking, application of cosmetics or contact lenses: For low and moderate risk hazards, this can be permitted in clean areas separate from the laboratory, whereas for high risk hazards, it is not permitted anywhere in the facility. Contact lens use in laboratories should be strictly prohibited.
- Contaminated sharps: For all hazard types, develop and implement safe handling practices consistent with Universal Precautions under Federal or statutory OSHA's Bloodborne Pathogens standard.
- Decontamination of work surfaces: This should be conducted daily and following spills.
- Pipetting: Mechanical device pipetting only; no mouth pipetting.
- Biohazardous waste material storage: This should be stored in double red biohazard bags with biohazard labels on the top and side. Biohazardous waste must be under direct control of the laboratory until it is placed in a suitable storage area.
- Handwashing: This is required after working with potentially hazardous materials and before leaving the laboratory.
- Training: Laboratory supervisors must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures and exposure evaluation procedures.
- Medical surveillance: For low risk hazards, this is recommended where personal health status may result in increased susceptibility to infection, or inability to receive vaccinations or prophylactic interventions. For higher risk hazards, laboratory personnel must be provided with medical surveillance and offered appropriate immunizations.
- Equipment: It must be cleaned of residues and tagged as such by designated safety and health personnel before repair, maintenance, or removal from laboratory.

Additionally, biosafety laboratories may implement special practices known as "enhanced precautions."[7] This is most common when a moderate risk hazard pathogen presents potentially infectious exposure due to its use in processes which might aerosolize the pathogen. In these situations, standard microbiological processes for high risk hazard pathogens can be implemented under a specialized plan. Aerosol generating processes can include: centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers with high internal pressures, inoculating animals intranasally and harvesting tissues from animals or embryonate eggs.

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Safety Equipment

Biosafety laboratories use a range of safety equipment including personal protective equipment, rated biosafety cabinets,[8] accessory safety devices for lab equipment such as centrifuges, pneumatic vacuum filter lines and other considerations determined by the biosafety level of the hazard being controlled. These considerations include:

- Rated biosafety cabinets: A Class 1 cabinet is suitable for low risk hazards, whereas a Class 2 cabinet is required for all moderate risk hazards generating aerosols. A Class 2 cabinet is required for all high risk hazard types.
- Sealed rotors or safety cups for centrifuging: While not required for low risk hazards, they are required for high concentrations or volumes of moderate risk hazard agents, and required for all high risk hazards.
- Lab coats: They are recommended for low risk hazards, and required for higher risk hazards. For high risk hazard agents, a solid front disposable gown is recommended.
- Gloves: They are required for all risk hazards. Latex-free alternative glove materials should be provided.
- Eye protection: In the form of safety glasses or goggles, is required for all risk hazards.
- Sleeve protectors: They are not required for low and moderate risk hazards, but they are required for high risk hazards.
- Vacuum lines: For sample filtering processes, these should be equipped with HEPA filtration.

Facilities Considerations

Construction and contents of biosafety laboratories feature engineering controls and equipment such as ventilation, doors, handwashing facilities, autoclaves and other considerations determined by the biosafety level of the hazard being controlled.[9] These considerations include:

- Ventilation should be negative pressure. No recirculation or exhaust air to other areas of the building is permitted.[10]
- Handwashing facilities are required. For high risk hazards, facilities should be equipped with foot, elbow and/or electronic operation.
- Autoclaves are required in high risk hazard laboratories.
- Eyewash stations are recommended for low risk hazards based on the nature of chemicals involved. They are required for higher risk hazards regardless of chemical use.
- Doors are required on all laboratories. For moderate hazards, doors should be self-closing and have locks. For high risk hazards, a series of two self-closing doors with an anteroom in between is required. Electronic security access is recommended.
- Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
- General laboratory design should allow the facility to be easily cleaned and decontaminated. Carpets and rugs should be prohibited.

Conclusion

Physical isolation of dangerous infectious agents is dependent upon the safety awareness and practices of laboratory staff, the availability and proper use of safety equipment and the design of the laboratory or facility. Containment is achieved through the combination of these and the scrupulous adherence to good laboratory or facility practices. Poor practices can override the protection provided by equipment and facility design and place personnel in jeopardy. This may lead to claims under workers compensation and/or general liability. Organizations using these practices should regularly review and improve their practices and documents - with an eye toward continual reduction of the risks involved in working with infectious agents and other hazardous laboratory materials.

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[6] Ibid 2, pp 30-44
[7] Ibid 6
[8] Ibid 2, pp 290-323
[9] Ibid 6
[10] ANSI/AIHA Z9.5-2002, Laboratory Ventilation, August 29, 2002, Chapter 5