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Design Requirements Manual
The formulae for building state of the art biomedical research facilities.

'Design Requirements Manual (DRM) News to Use' is a monthly ORF publication featuring salient technical information that should be applied to the design of NIH biomedical research laboratories and animal facilities. NIH Project Officers, A/E's and other consultants to the NIH, who develop intramural, extramural and American Recovery and Reinvestment Act (ARRA) projects will benefit from 'News to Use'. Please address questions or comments to: shawm@mail.nih.gov

# BSL-3 Planning Part 1: The Barrier

The BMBL states that Biosafety level 3 practices, safety equipment and facility design and construction are applicable to…facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection.[1]

The first step in planning a BSL-3 facility is defining the barriers that are fundamental to the safety and function of the facility. Barriers are required to contain the infectious agents and protect the people who are working directly with them. Barriers also protect occupants in the building outside of the BSL-3 laboratory and people and animals in the larger community. Barrier protection is accomplished as a two-layer approach, consisting of primary and secondary barriers.

**Primary Barriers** are items within the BSL-3 laboratory which isolate and contain the infectious agents, and physically separate them from the personnel manipulating them. The use and function of primary barriers are determined by a laboratory's standard operating procedures (SOPs), risk assessment based on the agents to be used and the activities to be performed. It is important that the SOPs be established early in the planning process, and that the design professionals have access to them, so that the equipment and procedures associated with primary barriers can be understood and accommodated in the design. Primary barriers include:

1) Biological safety cabinet (BSC): BSC uses directional air flow and HEPA filtration to contain infectious material within the cabinet enclosure and protect the user. BSCs are available in a range of sizes and types, and must be selected to meet the requirements of the particular lab.[2] BSCs must be placed with adequate clearance to ensure their optimal operation.[3] All manipulation of infectious agents should occur in a BSC.

2) Lab containers (including centrifuge cups and waste containers): When out of the BSC, lab containers encapsulate the infectious material and prevent spills and aerosolization.

3) Personnel protective equipment (PPE): PPE requirements depend on the specific (SOPs) of a lab, but generally include gloves, gowns and shoe covers, and may include eye or face protection, hair covers, respirators and other items.

**Secondary Barriers** consist of the physical enclosure of the BSL-3 laboratory. The secondary barrier protects people and animals outside of the BSL-3 laboratory from agents that are inside of the lab, but outside of the primary barriers. Secondary barriers include:

1) Architectural Enclosure: The perimeter walls, floor, ceiling, doors, windows and other elements that surround and contain the BSL-3 lab must be constructed, finished and sealed sufficiently to prevent leakage and infiltration. Windows must be sealed, and entrances and exits must be minimized. Required entrances and exits must be configured in vestibules with interlocking doors and directional airflow to maintain the integrity of the barrier.

2) Heating, Ventilation and Air Conditioning (HVAC) Systems: The HVAC systems treat, control and exhaust the air in the BSL-3 lab, and ultimately releases the filtered air to the atmosphere. The HVAC system must be configured to prevent the release of unfiltered air and maintain directional airflow (generally from the least-hazardous to the most-hazardous areas), during normal operation, emergency and failure scenarios.

3) Waste Treatment: Waste must be sterilized as it exits the BSL-3 laboratory. Most waste is autoclaved. Liquid sterilized autoclaved waste may discharge through the sanitary or general BSL-2 lab waste. Effluent decontamination systems are only required where approved risk assessment validates the need. PPE, equipment and all other materials leaving the BSL-3 lab must be considered potentially hazardous waste and handled and treated accordingly.

The barriers dictate the general functional layout of the lab (see Figure 1: BSL-3 Barriers). Entry is from a low hazard area (generally a BSL-2 laboratory) through the secondary barrier at a vestibule. The laboratory is arranged so that people and processes proceed to increasingly hazardous areas, with the BSC s and other primary barrier components at the end of the process. The process is reversed, from the most hazardous to the least hazardous, for exiting.

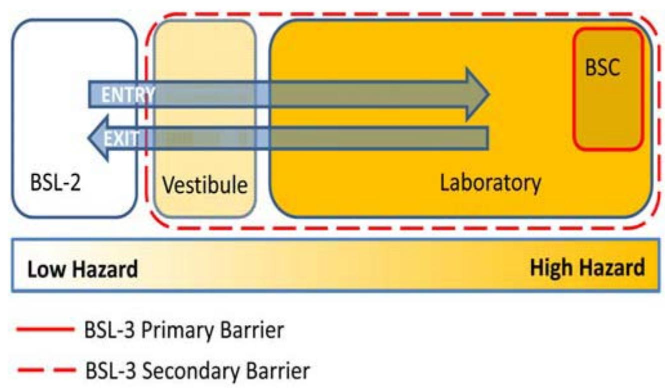


**Figure 1: BSL-3 Barriers**

References:

[1]Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, December 2009
[2]Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, BMBL, Appendix A
[3]BSC Placement Requirements for All New Buildings and Renovations, NIH DRM 2008, Appendix I

Further details on this month's topic are available on the DRM website
http://orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/Pages/DesignRequirementsManualpdf.aspx
DRM Chapter 2, Section 2-5 BSL3 Containment Laboratories at the BSL3 Level