Design Requirements Manual

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'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 2: The Barrier

s outlined in the previous News to Use¹, the first step in planning a BSL-3 facility is defining the barriers that are fundamental to the safety and function of the facility. Primary barriers are the devices that contain the infectious agents; the secondary barrier is the physical enclosure of the laboratory.

The integrity of the secondary barriers must be maintained, which is challenging because of the openings through which people, material, utilities and air must constantly pass. Smooth and quick passage through the barrier is desirable for the efficient operation of the facility; however this must be weighed against procedures that are required to maintain the integrity of the barrier. In all cases, the locations of entry and exit points must be limited, and standard operating procedures (SOPs) must be set and followed.

Exit and entry points can be classified as follows:

Personnel People pass through the secondary barrier at an entry vestibule. The first vestibule door is a security point, with appropriate security devices. The purpose of the vestibule is to create containment via differential pressure, which must be maintained by door interlock mechanism or by SOPs. The differential pressure must be monitored, and there may be an alarm to notify of an unacceptable drop of pressure. The vestibule must have adequate accommodations for donning the appropriate personal protective equipment (PPE). Changing rooms and showers may be provided, in accordance with SOP requirements. In smaller facilities, the entry vestibule may also be used for exiting. In larger facilities unidirectional flow may be required, and separate entry and exit vestibules may be provided.

Equipment An equipment vestibule shall be provided if large equipment or bulk materials are expected to be entering or exiting the facility during operation. Vestibule doors and differential pressure are similar to the personnel vestibule. An equipment vestibule must be large enough to accommodate wipe-down, packaging and other required procedures.

<u>Materials</u> Small quantities of materials may be carried by people through the entry vestibule. Alternately, a pass-through box with interlocked doors may be provided. Large or bulk materials shall pass through an equipment vestibule. All material leaving the facility must be sterilized, and is generally autoclaved. Any material that cannot be autoclaved must be sterilized and packaged following SOPs and exit the facility via the personnel vestibule, pass-through box or equipment vestibule.

<u>Utilities</u> Pipes and conduits penetrations must be sealed to maintain the integrity of the secondary barrier. All items must be anchored to prevent movement, and flanges or escutcheons must be provided and sealed. The interior of conduits and junction boxes must be sealed following DRM requirements² to eliminate open pathways. Penetrations with porous thermal or fire safing insulation are not acceptable unless augmented with flanges or escutcheons and properly sealed.

Air The heating, ventilation and air conditioning (HVAC) systems treat, control and exhaust the air, ultimately releasing the filtered air to the atmosphere. Air devices must be sealed to wall and ceiling surfaces to maintain the secondary barrier, and all exhaust components shall be welded stainless steel to provide an air-tight system up to the point of exhaust, which must be HEPA filtered. The HVAC design, including redundancy and controls, shall maintain directional airflow and pressurization during normal operations, emergency operations and failure scenarios.

Waste All waste, including liquid waste, exiting the facility must be sterilized, usually by autoclaving. Autoclaves must be sized to accommodate the expected quantities, and consideration should be given to providing redundant autoclaves for continuous operation during maintenance. Autoclaves must be installed with manufacturer-provided bioseals forming part of secondary barrier, and configured so that components requiring service and maintenance are outside of the barrier. On the sterilized side a vestibule or room shall be provided so that the autoclaved material is not deposited directly into a corridor. A canopy hood shall be provided to capture steam and heat. Adequate space shall be provided for carts and staging.

Thoughtful planning, along with SOPs, can provide required entry and exit while maintain the integrity of the secondary barrier.

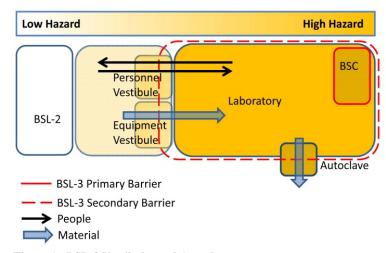


Figure 1: BSL-3 Vestibules and Autoclave

References:

¹February 2014 News to Use,

http://orf.od.nih.gov/POLICIESANDGUIDELINES/Pages/DRM_News_to_Use.aspx

²DRM Sealant Table, Exhibit X4-2-A

http://orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/DRMHTMLver/Chapter4/Pages/Section_4-2_Exterior_Achitectural_Elements.aspx