

Notes:

1. To be added to existing WUSM FMD Design Standards as new Section 2.03
2. WUSM FMD Design Standards Section 2.02, "Basic Laboratory Design Features", to be revised to only include BSL-1 and BSL-2 design features.

2.03 – BSL3 Design Guidelines**Introduction and Basis of Design:**

The following BSL-3 Design Guidelines are intended to assist the Washington University School of Medicine (WUSM) and its stakeholders with programming and design of new Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) facilities. The previous WUSM laboratory Design Guidelines combined BSL-2, BSL-3 and ABSL-3 into one category of high hazard. During a review of those Guidelines it was recommended to separate those project types and isolate the very specialized requirements for BSL-3 and ABSL-3 environments. These Guidelines were developed specifically for the requirements of high containment facilities, for both laboratory and animal facilities.

These Guidelines are based on input from several sources, including the following:

- Biosafety in Microbiological and Biomedical Laboratories, 5th Edition
- NIH Design Requirements Manual (DRM), 2008;
- USDA ARS Facility Design Standards, 2012;
- WUSM FMD Design Standards, 2008;
- Guide for the Care and Use of Laboratory Animals, 8th Edition;
- Industry Standards and Best Practices.

The information contained herein is only one element of the process required to develop the appropriate design and engineering systems for A/BSL-3 containment facilities. The operational protocols and procedures are a critical component of the development of the design and must be included in the final evaluations. Principal Investigators, Administrators, and Biosafety Professionals must be involved in conducting "risk assessments", preparing and documenting the operational procedures, and providing input into selecting the appropriate engineering controls required to mitigate the risks.

These Design Guidelines are intended to provide design teams with the tools and information needed to complete future A/BSL-3 facilities at WUSM, and therefore attempt to cover all the options that could be considered for these types of spaces. Even though a broad range of requirements are listed, architectural and engineered systems should not be selected where they are not needed (i.e. *"one size does not fit all"*). The final selection of these systems should be based on the specific risks associated with a given body of research; however, WUSM may choose to include engineering controls that may not be required by a given type of research, but may be included to provide the School with the ability to adapt to future research requirements and/or promote community outreach and engagement.

It is not the intent of these Guidelines to require the retro-active upgrades to the existing A/BSL-3 spaces, but to provide guidance going forward with new facilities. However, any issues identified in existing spaces that impact the safe operation of these facilities which may result in harming the health and well-being of faculty, staff, students, visitors or the environment should be addressed accordingly.

PART 1 – GENERAL

- A. Biosafety Level 3 (BSL3) laboratories and animal facilities (ABSL3) are those in which activities are conducted with infectious material that may cause serious disease through inhalation, there is an increased risk of personnel exposure via aerosol generating manipulations, and/or the Institutional Biological and Chemical Safety Committee (IBC) or Biosafety Officer (BSO) has determined the activities warrant the use of high containment facilities and practices.
- B. All new laboratory facility projects, laboratory usage, and agents to be used will be evaluated by the University Environmental Health & Safety (EH&SEH&S) group in conjunction with oversight by the IBC and a thorough Risk Assessment.
- C. All manipulations of infectious agents within BSL3 and ABSL3 facilities shall be conducted within biosafety cabinets (BSC's) or other appropriate primary containment equipment/devices.
- D. Consideration for decontamination of surfaces, equipment, and the facility itself should take into account the infectious agent in use, required contact time of decontamination agent, and material compatibilities, as well as any other factors deemed appropriate by the risk assessment. Any decontamination process should be evaluated and verified by EH&S on a project-specific basis.
- E. All critical equipment shall be tied to the building automation system (BAS) to allow for constant monitoring and alarming. Critical equipment may include air-handling units, exhaust fans, differential pressure monitors, terminal units, -80 degree C freezers, IVC Racks, walk-in cold rooms, incubators, or other devices deemed necessary to maintain the safe and secure operation of the BSL3 laboratory.

PART 2 – Basic BSL3 and ABSL3 Design Features

Directives: Requirements with respect to best practice within a university laboratory, based on nationally accepted biosafety guidelines and standards, issued by the EH&S.

- A. BSL3 entry must only be through two interlocking (mechanical or procedural), self-closing doors. Methods for restricting access to only those individuals with demonstrated need, proper clearance, and training must be in place. Notices should be posted outside the first door to notify potential entrants of the hazards contained within and measures they must take to protect themselves.

Guideline: CDC/NIH BMBL; BSL3 Best Practices

Regulation (for Select Agent use only): 42 CFR Part 73, 9 CFR Part 121, 7 CFR Part 331

Justification: The risk of potential exposure in high containment spaces and the regulatory requirements for access to Select Agent spaces require that only those individuals with demonstrated need and proper preparation be allowed access to high containment spaces. Interlocking double-door access is necessary to ensure that, at no time, is the interior of the laboratory exposed to any common area.

- B. The interior surfaces of the A/BSL3 laboratory shall be impervious to water and resistant to chemical disinfectants intended for use in the space.
 - a. Walls and ceilings shall be high impact, water resistant gypsum board or CMU with epoxy paint coating or FRP. All penetrations should be sealed airtight.
 - b. Floors should be epoxy with integral cove base in ABSL3 rooms or welded sheet vinyl with integral cove in BSL3 rooms.
 - c. Doors should be chemical resistant coated metal.

Guideline: CDC/NIH BMBL; BSL3 Best Practices

Justification: Due to the highly pathogenic nature of the microorganisms frequently encountered in BSL3 laboratories, the efficacy of disinfection and decontamination procedures must be ensured without compromising the integrity of the facility. Surfaces that absorb water or degrade in the presence of chemical disinfectants are not suitable for an environment that will be repeatedly exposed to both. Sealed surfaces and floor coving are recommended to reduce the number

of cracks or crevices that may harbor microorganisms during application of a disinfectant or decontaminant.

- C. Bench tops and other work surfaces such as the work space inside a Biosafety Cabinet (BSC) shall be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

Guideline: CDC/NIH BMBL; BSL3 Best Practices

Justification: Activities within a BSL3 laboratory can involve concurrent use of chemical solvents such as formaldehyde, phenol, and ethanol as well as corrosives or other reactive chemicals. The laboratory bench or BSC work surface must be resistant to the chemical actions of these substances as well as disinfectants used to inactivate the organisms under study. Wooden or other porous or combustible bench tops are not appropriate because even finished wooden surfaces can absorb liquids or ignite in the event of a fire. Fiberglass is inappropriate since it can degrade in the presence of some chemicals; it also produces toxic smoke if burned.

- D. Laboratory furniture shall be sturdy and not upholstered with absorbent materials. Space shall be left between benches, cabinets, and equipment to allow access for cleaning/decontamination and maintenance.

Guideline: CDC/NIH BMBL; BSL3 Best Practices

Justification: Laboratory furniture must not be absorbent so that it may be decontaminated effectively. Space must be left between furniture to allow for cleaning and maintenance of devices as required (i.e. biosafety cabinets).

- E. Any windows in the BSL3 laboratory shall be permanently sealed.

Guideline: CDC/NIH BMBL; BSL3 Best Practices

Justification: To maintain proper pressure differential and directional airflow, to prevent egress of aerosols, particularly during space decontamination, to the surrounding spaces or environment, and to assist with pest control.

- F. BSL3 spaces located on a building exterior wall should have a positively pressurized interstitial space between the occupied areas and the exterior wall. The depth of the interstitial space should allow adequate access to MEP equipment and maintenance of the exterior wall.

Guideline: BSL3 Best Practices

Justification: To prevent the intrusion of exterior moisture and contaminants.

- G. Any penetrations into the laboratory should be avoided or minimized; however, when required (i.e. for ductwork, electrical conduits, sprinkler piping, gas piping, etc.), they should be fully sealed (or sealable) with particular consideration of decontamination processes.

Guideline: CDC/NIH BMBL; BSL3 Best Practices

Justification: To maintain proper pressure differential and directional airflow and to prevent egress of aerosols, particularly during space decontamination, to the surrounding spaces or environment.

- H. An appropriate method for solid waste decontamination, which has been selected and validated based on the Risk Assessment and EH&S input, must be available (i.e. autoclave) within the facility and if possible, within the BSL3 laboratory suite/space.

For select agent laboratories, autoclave is required and should be appropriately sized, pass through from the laboratory to the anteroom. Certain select agents may require additional waste decontamination processes, such as effluent decontamination systems.

Guideline: CDC/NIH BMBL; BSL3 Best Practices

Regulation (for Select Agent use only): 42 CFR Part 73, 9 CFR Part 121, 7 CFR Part 331

Justification: Effective waste management and disposal ensures proper decontamination of infectious and contaminated material to mitigate potential releases and exposures to personnel, community, or the environment.

PART 3 – BSL3 and ABSL3 Heating, Ventilation, and Air Conditioning (HVAC) System Features

- A. The room shall have a fully ducted mechanically generated ventilation system. All supply air to the suite shall be 100% outside air. All air from the suite shall be 100% exhausted via dedicated exhaust with no recirculation to other building areas. Exhaust air should be dispersed away from occupied areas and from building intake locations.

Guideline: CDC/NIH BMBL; BSL3 Best Practices

Justification: Recirculated air is not permitted to eliminate any possibility of potentially contaminated air entering other building spaces such as in the event of a failure in one of the containment systems.

- B. There shall be no positive pressure exhaust ductwork in occupied spaces, including mechanical rooms. Any pre-existing conditions that do not meet this requirement should be mitigated appropriately (i.e. mechanically sealed ductwork, relocate fan to the roof, etc.)

Guideline: CDC/NIH BMBL; BSL3 Best Practices

Justification: Positive pressure ductwork inside occupied spaces is not permitted to eliminate any possibility of potentially contaminated air entering building spaces in the event of a breach or failure in the ductwork.

- C. The laboratories shall have inward directional airflow and have a negative pressure (0.05" water column, but no less than 0.03") in relation to areas such as corridors or any adjacent spaces. This is to be controlled by volumetric offset (preferably between 100-150 cfm), but monitored by pressure differential, unless dictated otherwise by a regulatory agency (i.e. USDA) wherein fast-acting valves with interval differential pressure switches (or equivalent) will be used.

Guideline: NIH Design Requirements Manual; BSL3 Best Practices

Regulation (for Select Agent use only): 42 CFR Part 73, 9 CFR Part 121, 7 CFR Part 331

Justification: Negative air pressure between rooms produces the directional airflow necessary to contain potentially contaminated aerosols, 0.05" WG is typically within the operating range of most HVAC components and sensors and provides containment during common events such as doors opening and personnel ingress/egress.

- D. Exhausted air from BSL3 laboratories should be HEPA-filtered locally, prior to leaving the room.

Directive: EH&S, BMBL, the Guide for the Care and Use of Laboratory Animals, and Regulation (for Select Agent use only): 42 CFR Part 73, 9 CFR Part 121, 7 CFR Part 331

Justification: Enhanced engineering controls, such as HEPA-filtered exhaust, are necessary to prepare the space for the potential need in future research. Providing HEPA-filtered exhaust (or the capability to do so, e.g. installing HEPA filter housings but not using HEPA filters until required) affords greater flexibility and adaptability of the BSL3 laboratory spaces.

- E. The ventilation system shall utilize pressure independent airflow control valves. Each room shall have a dedicated supply and exhaust valve. Airflow control valves shall be designed for passive control with fixed airflow offset. Supply air valve shall track the exhaust air valve to maintain negative pressure. Each room shall have an independent controller, unless dictated otherwise by a regulatory agency (i.e. USDA) wherein fast-acting valves with interval differential pressure switches (or equivalent) will be used.

Guideline: CDC/NIH BMBL; BSL3 Best Practices

Justification: To maintain directional airflow under failure scenarios, control valves must be in place to compensate for changing system pressures. With airflow offset control, doors must be designed to allow air to flow into room to maintain directional airflow. As an option, if doors are too tight barometric damper in door or wall of room can be provided.

- F. Autoclaves exhaust canopies shall be provided over both sides of double door pass through autoclaves.

Guideline: BSL3 Best Practices

Justification: Steam and heat shall be removed at the source. The amount of heat and steam produced by an autoclave can undo the air balance in a room or disrupt airflow by changing convection currents, and compromise containment.

- G. Laboratory and equipment storage should not block fire sprinkler heads and should be placed at a minimum distance of 18” or otherwise specified by applicable fire code, whichever distance is shorter.

Directive: City and County Fire and Building Code

Guideline: BSL3 Best Practices

Justification: Many supply diffusers and room exhaust grilles are located along laboratory walls. High storage of boxes may impede the circulation of air and hinder the functionality of air supply and exhaust.

- H. Sound control from mechanical systems relative to the laboratory space shall be maintained below room criteria (RC) of 45 dB.

Directive: DCM and OSHA Action Level

Guideline: BSL3 Best Practices

Justification: Noise levels above room criteria (RC) 45 dB interfere with voice communication and increase the risk of accidents within the laboratory.

- I. All energy recovery devices in the exhaust airstream must be kept downstream of the HEPA filter. Energy recovery devices that have any potential for cross-contamination (i.e. energy recovery wheels) are not permitted.

Directive: BSL3 Best Practices

Justification: Energy Conservation

- J. A mechanism with a magnahelic or electronic gauge must be installed at the entry to BSL3 spaces to provide personnel with a visual means to verify directional airflow.

Guideline: CDC/NIH BMBL, BSL3 Best Practices

Justification: Indicates proper functioning of laboratory ventilation system.

- K. Audible and visual alarms shall be placed in the lab suite to alert the users of airflow disruption. Audible and visual alarms must be programmable to facilitate the type of research being conducted in the space. WUSM Division of Comparative Medicine (DCM) or governing body shall be consulted in the design and installation

of alarm system notification devices since careful consideration is necessary so as not to negatively impact research activities (i.e. animal welfare in ABSL3 spaces).

Guideline: CDC/NIH BMBL, BSL3 Best Practices, Guide for the Care and Use of Laboratory Animals

Justification: Users must be aware of directional airflow disruptions so that aerosol generating procedures are not performed without the protection provided by directional airflow in the laboratory.

- L. Locate all equipment requiring access and maintenance outside the containment zone. (In extreme circumstance, equipment that is required to be installed above ceilings in containment zone must be provided with a fully gasketed access panel; the number of access panels shall be minimized).

Directive: BSL3 Best Practices

Justification: Safety precautions for maintenance personnel.

- M. Bioseal dampers *must* be provided in supply and exhaust duct to each room . Damper shall be capable of bubble tight shut-off at minimum 10" wc and be provided with either manual or automatic actuator. The damper in the supply shall be automatic but the damper in the exhaust may be manual.

Guideline: BSL3 Best Practices

Justification: In the event of a loss of exhaust, these are installed to prevent the BSL3 from going into positive pressure mode. And, also aids in decontamination of individual laboratories to be able to isolate airflows. Dampers shall be located outside of containment zone.

- N. Supply ductwork to the bioseal shall at minimum be galvanized construction. Supply ductwork should be fully-welded stainless steel construction from the bioseal damper to the air device.

Guideline: BSL3 Best Practices

Justification: Minimize any leakage in ductwork to containment zone and for safety precautions of maintenance personnel.

- O. Exhaust ductwork from the room to the bioseal damper shall be fully-welded, stainless steel construction. Ductwork from the bioseal damper to the exhaust fan

shall maintain the stainless steel construction. Ductwork exposed to the outside elements shall be wrapped, covered or of stainless steel construction.

Guideline: BSL3 Best Practices

Justification: Minimize any leakage in ductwork from containment zone and for safety precautions of maintenance personnel.

- P. Supply airflow shall be the greater of the following:
- i. Calculated airflow required to meet room load calculation results with end users temperature and humidity requirements.
 - ii. Minimum 8 air changes per hour for laboratories.
 - iii. Minimum 12 to 15 air changes per hour for animal holding rooms.

Guideline: BSL3 Best Practices

Justification: Maintain proper air changes in laboratories.

- Q. Diffusers and grilles shall be one piece aluminum construction (or otherwise specified based on selected space decontamination method) or have fully welded back pans.

Guideline: BSL3 Best Practices

Justification: Minimize leakage from containment zone into ceiling cavity.

- R. For HEPA filter installation, the system shall contain the following components in order of airflow:
1. Automatic bioseal damper on supply side (as described above)
 2. Decontamination port for decontamination of HEPA unit
 3. Inlet transition from round bioseal damper to rectangular HEPA module
 4. Bag-in, bag-out 30% pre-filter with sufficient access and clearance to change the unit (Optional)
 5. Bag-in, bag-out, knife-edge, gel-seal or gasketed HEPA filter with sufficient access and clearance to change the unit
 6. HEPA filter test section for verification of integrity of installed HEPA filter
 7. Outlet transition from rectangular HEPA module to round bioseal damper
 8. Decontamination port for decontamination of HEPA unit
 9. Manual bioseal damper on exhaust side (as described above)

10. HEPA filter module shall be of fully welded stainless steel construction.
11. Sloped-roof style shall be used if HEPA filter module is housed outdoors.
12. Double wall insulated unit shall be used if located outdoors

Guideline: CDC/NIH BMBL, BSL3 Best Practices

Justification: Proper operation and control of the room during shut down events.

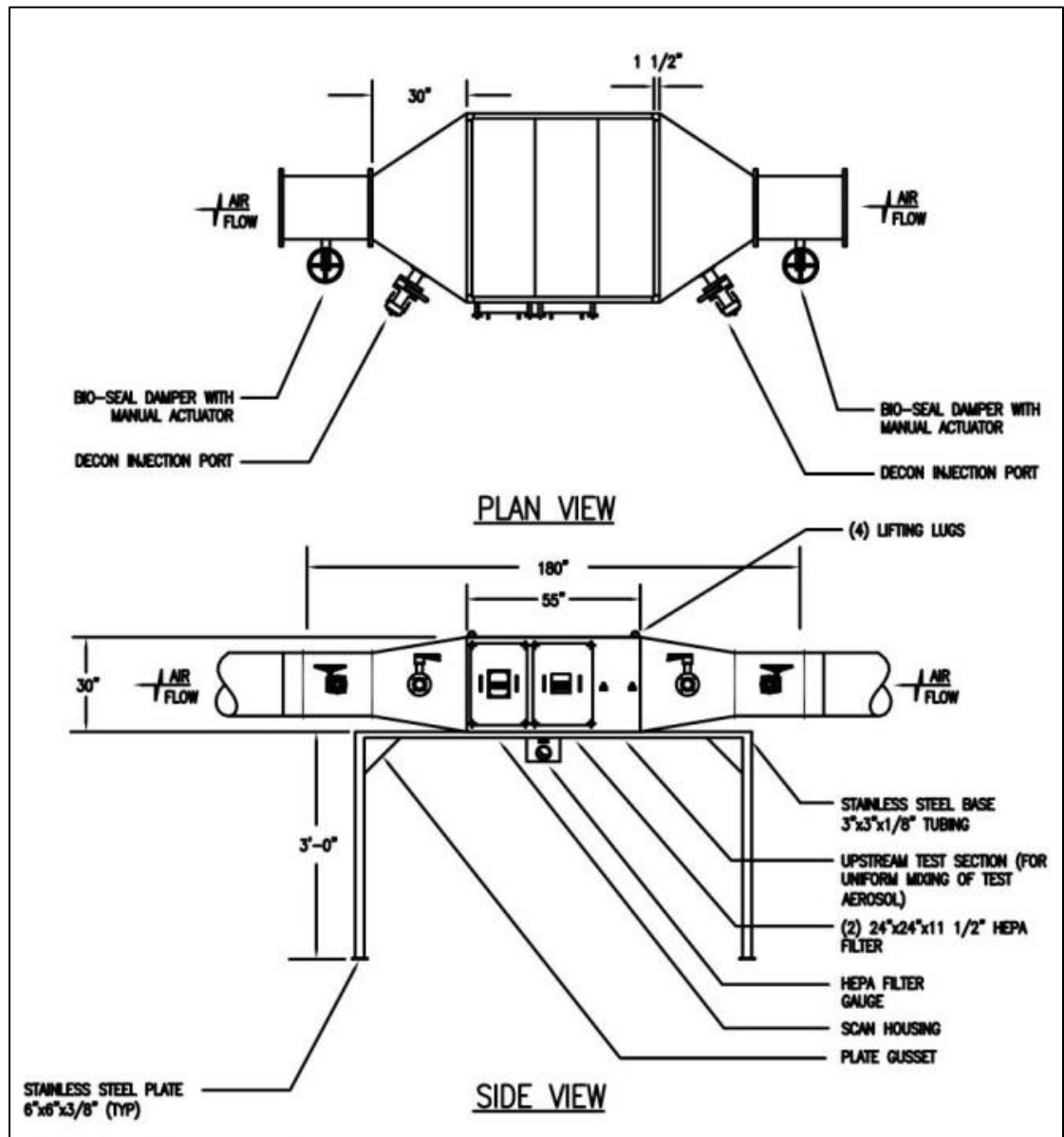


Figure 1. Example 24" x 48" HEPA Exhaust Housing

- S. Dedicated BSL3 exhaust fans shall be provided in an N+1 configuration, where "N" is the number of components to handle the airflow. Both the primary and

redundant fan shall operate simultaneously at reduced speed to maintain directional airflow. Upon a failure of one fan the remaining fan(s) shall ramp up to full speed.

Guideline: BSL3 Best Practices

Justification: To ensure near 100% reliability of the exhaust system per Guide requirements.

- T. Where dedicated supply air handling units are deemed necessary by the risk assessment or regulatory requirement (for ABSL3), they should be provided in an N+1 configuration, where “N” is the number of components to handle the load. The redundant air handling unit shall automatically start upon failure of the primary air handling unit.

Guideline: ABSL3 Best Practices

Justification: Minimize down time of system. To meet the Guide requirements.

- U. Dedicated A/BSL3 supply air handling units shall be hard wire interlocked with exhaust fans to prevent reversal of airflow. Upon a loss of exhaust fans the air handling units fans shall automatically be shut down.

Guideline: A/BSL3 Best Practices

Justification: No reversal of airflow.

- V. The A/BSL3 facility basis of design, WUSM commissioning/re-commissioning protocols, operational parameters, and procedures must be verified and documented prior to operation. Operational parameters must be re-verified and documented at least annually.

Guideline: CDC/NIH BMBL; A/BSL3 Best Practices

Justification: Ensure system operates as designed in a safe and reliable manner.

PART 4– BSL3 and ABSL3 Plumbing System Features

- A. Emergency showers that are located within the suite shall not have an associated floor drain nearby. Showers required by regulation may/may not require shower water to be contained in a holding tank for later decontamination).

Guideline: BSL3 Best Practices

Justification: All contaminated liquids are required to be decontaminated prior to disposal.

- B. If there is a central vacuum system, two in-line hydrophobic (water-resistant) HEPA filters must be placed near each use point. Filters must be installed to permit in-place decontamination and replacement. Liquid disinfectant traps are required. Local filters are to be provided by the end user on the suction side of the pump. All vacuum exhaust shall be outside the building. If a system filter is used, a way for decontamination of the house vacuum lines shall be incorporated.

Guideline: CDC/NIH BMBL; BSL3 Best Practices

Justification: Safety precautions of maintenance personnel.

- I. Hands-free (i.e. foot operated, wrist/elbow operated, electronic sensor, etc.) hand washing sinks should be available prior to exiting the BSL3 laboratory area (i.e. within the anteroom after doffing lab-specific personal protective equipment).

Guideline: CDC/NIH BMBL; BSL3 Best Practices

Justification: Numerous pathogenic organisms can be transferred by hand contact to mucous membranes or other surfaces in the laboratory. It is extremely important to wash hands often and before leaving the laboratory. For the latter reason, the sink shall be located close to the egress.

- C. An eyewash station shall be readily available.

Standard: ANSI Z358.1

Justification: Numerous microorganisms are infectious if exposed to the mucous membranes around the eye. Therefore, eyes shall be flushed thoroughly after splashes and exposures to the eyes.

- D. Atmospheric contained drain system typically services sink and floor drains. Regulations require that drain traps are always filled with water or suitable liquid disinfectant. Traps within this system should have extra depth, a total of 2" WG greater than maximum static pressure generated by HVAC supply or exhaust, to prevent trap from being cleared in event of HVAC/exhaust system malfunction. Drain vents should be HEPA filtered.

Standard: CDC/NIH BMBL

Justification: Safety precautions for maintenance personnel.

PART 5 – BSL3 and ABSL3 Fire Protection System Features

- A. Gasketed sprinkler heads with sealed housing shall be used to maintain the airtight construction of the ceiling system. Gasket material shall be compatible with the decontamination agent to be used. Sprinkler heads shall have a protective enclosure to prevent accidental impact.

Guidelines: BSL3 Best Practices

Justification: To maintain the integrity of the containment barrier and prevent air leakage.

PART 6 – BSL3 and ABSL3 Lighting System Requirements

- A. All recessed lighting shall be gasketed at the ceiling penetration. Gasket material shall be compatible with the decontamination agent to be used.

Guidelines: NIH DRM, Guide for the Care and Use of Laboratory Animals, BMBL, BSL3 best practices.

Justification: To maintain the integrity of the containment barrier and prevent air leakage.

- B. Light fixture material shall be stainless or aluminum as required to withstand the decontamination chemicals. Fixtures shall be surface mounted or recessed, fully sealed, enclosed, gasketed and UL Listed for damp locations. Lenses shall be acrylic prismatic.

Guidelines: NIH DRM, Guide for the Care and Use of Laboratory Animals, BMBL, BSL3 best practices.

Justification: To maintain the integrity of the containment barrier and prevent air leakage.

- C. For areas where there is high water usage (i.e. laboratory animal housing), light switches shall be weatherproof, corrosion resistant, stainless steel cover with a sealed rubber gasket.

Guidelines: NIH DRM, Guide for the Care and Use of Laboratory Animals.

Justification: To eliminate electrical hazards.

PART 7 – BSL3 and ABSL3 Power System Requirements

- A. Emergency power shall be utilized on the following equipment as a minimum:
1. Dedicated supply and/or exhaust fans and controls serving the BSL3 suite
 2. All monitoring equipment and controls, both for any lab equipment and HVAC equipment
 3. Specialized equipment designated by the end user

Guidelines: NIH DRM, Guide for the Care and Use of Laboratory Animals, BSL3 best practices.

Justification: In the event of power failure, an alternative or emergency power source should be available to maintain critical services and support functions in animal rooms, operating suites and essential areas.

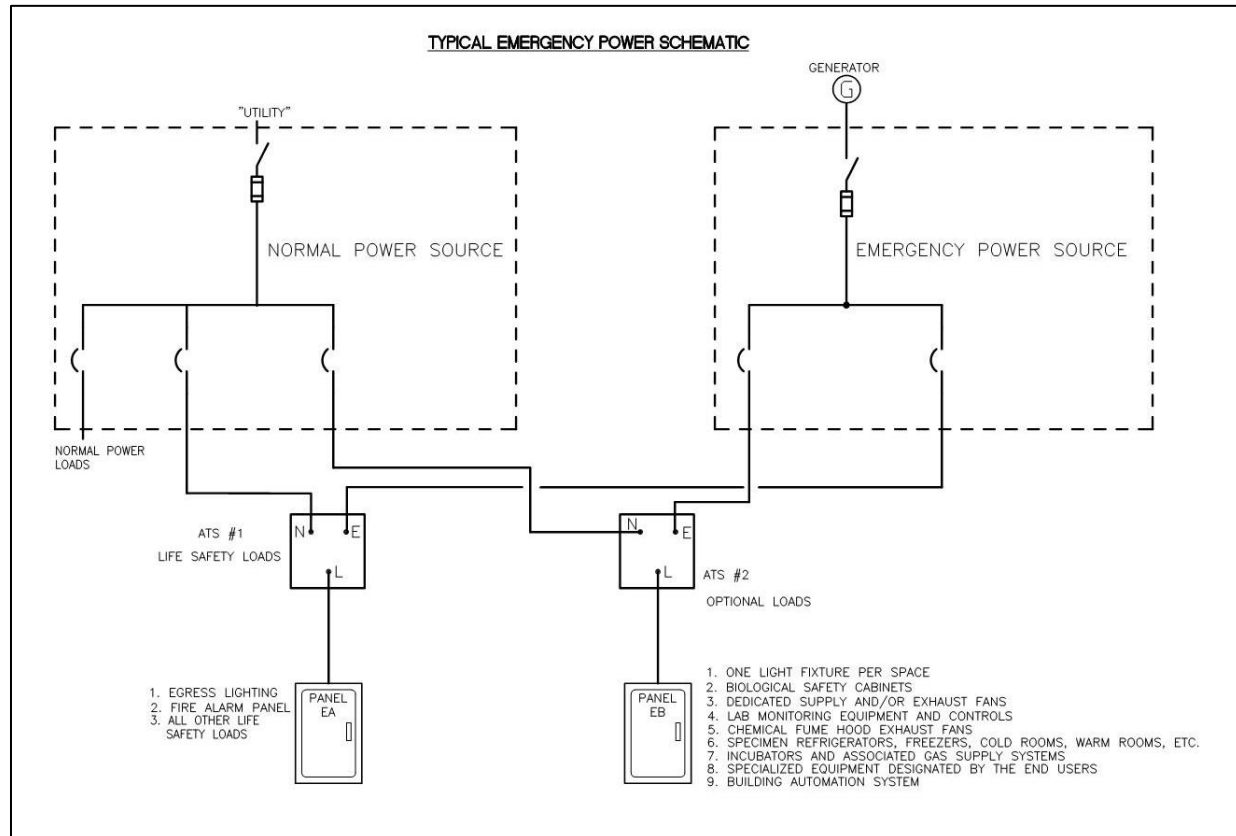


Figure 2. Example Emergency Power Schematic

- B. All backboxes shall be cast metal, water-tight, gasketed, and have a threaded hub.
All conduit penetrations shall be sealed.

Guidelines: NIH DRM, BSL3 best practices.

Justification: To maintain the integrity of the containment barrier and prevent air leakage.

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- C. All conduits shall be sealed airtight internally at the containment boundary.

Guidelines: NIH DRM, BSL3 best practices.

Justification: To maintain the integrity of the containment barrier and prevent air leakage. To facilitate pest control.

- D. Receptacles shall be corrosion and moisture-resistant with a neoprene gasket and stainless steel cover as a minimum.

Guidelines: NIH DRM, Guide for the Care and Use of Laboratory Animals, BSL3 best practices.

Justification: To maintain the integrity of the containment barrier and prevent air leakage.

PART 8 - EXECUTION

END OF SECTION