SECTION 2.5

Biocontainment Facility Planning and Programming

2.5.1. General

This section delineates requirements for planning and programming biosafety level three (BSL-3) research laboratories and animal biosafety level three (ABSL-3) animal research facilities, referred to collectively as biocontainment facilities. The BSL-3 and ABSL-3 classifications are categorized by the NIH/CDC Biosafety Microbiological and Biomedical Laboratories (BMBL) as work that involves infectious agents which may cause serious or potentially lethal disease as a result of exposure by inhalation route.

Requirements listed in Sections 2.1 (research laboratory planning and programming) and 2.3 (animal research facility planning and programming) also apply.

BSL-3 enhancements for research involving agricultural agents (BSL-3 Ag) in which the physical space comprises the primary containment barrier are not included in this section.

Planning and Programming Team: Stakeholders who must be actively involved in the planning process have been previously identified, but the degree of involvement is critically important due to the inherent risks involved in the study of infectious and sometimes lethal agents. Early and active participation of the entire group during the planning and programming phase is essential to identify potential design impacts of factors related to occupational health, safety and security.

Risk Assessment: The design of BSL-3 and ABSL-3 facilities can vary widely depending on agents to be used, types of research and procedures, quantities of agents, animal species caging types, and other risk factors. Planning and programming must therefore be guided by a risk assessment that identifies the degree to which risk factors may be mitigated by building design and engineering controls, standard operating procedures (SOPs), or both. Requirements identified herein are typical for NIH biocontainment facilities, but additional measures may be required if prescribed by the risk assessment.

2.5.2 Master Planning

Master planning issues that may be impacted by construction of a biocontainment facility include minimum setbacks and security requirements that may be required for blast protection, intrusion protection, and protection of exterior elements critical to the operation of the biocontainment facility (e.g. emergency generators, supply air intake, loading docks, etc). The dispersion of exhaust air shall be considered relative to surrounding facilities and supply air intakes. Planning of these features shall be guided by threat-risk and biological risk assessments.

2.5.3 Programming
The core of the typical biocontainment facility program consists of infectious disease laboratories and/or animal holding and procedure rooms located within a secure biocontainment zone that is environmentally isolated from other areas using airlocks and engineering controls to ensure inward directional airflow, facilitate ingress and egress SOPs and support decontamination procedures. Manipulation and handling of infectious agents within the biocontainment zone is performed mostly within containment devices such as biosafety cabinets. Hence, the physical barrier constructed around the biocontainment zone is typically considered to be secondary containment. The core biocontainment zone may be supported by transitional areas, decontamination facilities, and an array of support facilities that often eclipses the size of the actual biocontainment area.

Programming the types, sizes and relationships among these areas requires a full understanding of physical requirements, engineering controls and SOPs required to use, access, and maintain the facility.

### 2.5.3.1 Project Parameters

Special considerations for biocontainment facilities include:

- **Risk Assessments:** Biological risk assessment and physical threat/risk assessment must be provided to the project team to help guide development of SOPs and the design of the facility.

- **Special Studies:** It must be determined early in the project planning phase which types of special studies and consultants will be required to establish the criteria related to safety and security of the facility. Typical studies or assessments may include: building information modeling, computational fluid dynamics simulations for laboratory ventilation, chemical use analysis, and environmental assessment. The project team must establish and document the limitations that each of these criteria will impose on the design.

- **Community relations:** Health and safety concerns of neighboring entities outside of the immediate stakeholder group may need to be solicited and addressed to ensure that all perspectives are considered, information is accurately disseminated, and two-way communication is established to facilitate community and regulatory acceptance of the project. A community relations plan including a timeline for communication with elected officials, community leaders, citizen groups and institutional leadership should be included in the overall schedule.

- **Infrastructure:** Separate, dedicated or segregated infrastructure is required for HVAC systems and other utilities serving biocontainment facilities. Extensive space may be required to house these systems.  

- **Standard Operating Procedures:** SOPs have an interdependent relationship with facility design and must be outlined early in the planning process. Detailed SOPs for operation and maintenance of the facility may not be fully developed during early project phases,
or may be modified as the project progresses. Ongoing documentation of SOPs that affect design must be included in the project narrative and reconfirmed by the project team during latter phases.

f. **Regulatory Requirements:** Additional regulations may impact the design of the facility if select agents and/or agricultural agents are to be used. [LINK].

g. **Budget:** The cost of biocontainment facility construction is often 2-3 times higher than conventional BSL-2 laboratories and animal facilities. Budgets developed during the programming phase must identify total project cost and include allowances for low net-to-gross ratios, infrastructure improvements, enhanced security requirements, special containment and decontamination equipment, high performance finishes, special studies, etc. Benchmarking the cost of similar recently constructed facilities is encouraged.

### 2.5.3.2 Data Collection

A supplementary user questionnaire shall be completed for biocontainment projects focusing on SOPs that impact facility design. [LINK TO BIOCONTAINMENT QUESTIONNAIRE]. Specific information required to design the facility will include:

a. **Containment zone entry and exit procedures:**
   - Procedures for entering and exiting containment
   - Anticipated volume of staff working within the containment zone
   - PPE: PPE Requirements, locations for storing, donning and removal of PPR, PPE decontamination methodology, location for PAPR recharging (if required)
   - Use and location of hand wash sinks
   - Current or future SOPs for showering, if required
   - Separate of men’s and women’s gowning / shower facilities, if required
   - Communication requirements during the entering/exiting process
   - Transfer of large equipment in and out of containment

b. **Security and biosecurity requirements:** Define security requirements including threat protection, access control, CCTV monitoring, and biometrics for each zone within the biocontainment facility. Identify where infectious agents will be stored, and what security provisions are required for storage areas and freezers. Identify requirements for secure communication system or data network.

c. **Waste decontamination:** Define methods for decontamination, transport and disposal of liquid and solid waste. Establish likely waste volume and minimum autoclave chamber sizes.
d. **General Decontamination**: Identify the method(s) of space and equipment decontamination. Identify how and where large equipment will be decontaminated. Identify typical time periods required for decontamination. Define elements of the HVAC and other utility systems that may require decontamination. Verify corrosive properties of decontaminants to be used. If gas or vapor decontamination is required, verify types of equipment and/or systems to be used in this process.

e. **Facility shutdown requirements**: Identify SOPs for facility shutdown. Determine if zoning is required to enable partial shutdowns.

f. **Cage Processing**: Identify animal caging types (isolators, ventilated caging, conventional caging). Identify requirements for in-place and/or centralized decontamination of caging. Identify throughput requirements for caging decontamination as well as minimum chamber sizes if caging is autoclaved. Identify need and methodology for decontamination of wastewater if room wash down is required.

g. **Animal Procedures**: Identify how infected animals will be transported within the containment area. Identify the need for dedicated procedure spaces connected directly to holding rooms vs. shared procedure rooms. Identify special procedure requirements (e.g., aerobiology, isolation, etc.).

h. **Carcass disposal**: Identify volume and methodology of carcass decontamination and disposal.

i. **Agent transport and storage requirements**: Identify how infectious agents will be transported to and from the facility. Identify how agents will be transported within non-contained and public corridors.

j. **Facility maintenance**: Identify utility components serving the containment area that will require service access. Identify methodology for servicing components that may become contaminated.

k. **Emergency procedures**: Identify procedures for emergency egress and shutdown. Coordinate emergency procedures with local fire and rescue, police and health officials.

### 2.5.3.3 Data Recordation

Comply with section 2.1.2.3, and submit the following information:

a. Include special studies in the project manual.

Exception: Distribution of the Threat Risk analysis and other information pertaining to security and biological risk shall be limited to personnel designated by the Project Officer.
b. Include a list of SOPs for each type of procedure that may affect design in the project manual. Where possible, list the detailed SOP.

2.5.4 Biocontainment Planning

2.5.4.1 Location Considerations

Consideration for the location of a biocontainment facility may be impacted by several factors.

a. The ability to buffer the facility from surrounding functions to enhance safety and security as required by security classification.

b. Adjacency to facilities that support the project (administrative, laboratory, animal facilities, logistical facilities)

c. Compatibility with neighboring functions

d. Proximity to mechanical areas, utility shafts, and/or interstitial floors available for placement and routing of dedicated utility services

Biocontainment facilities should be located within secure areas isolated from public areas of a building. Adjacency to interstitial floors or other mechanical service zones is highly recommended so that utilities can be safely accessed and maintained without entering into containment areas, and to minimize exhaust duct runs to HEPA filter caisson location.

2.5.4.2 Space Requirements

Biocontainment facilities are typically less efficient than their BSL-2 and ABSL-2 counterparts due space required to house and access redundant, dedicated utility systems. Net-to-gross ratios are typically less than 50%, as illustrated in the following diagram.

Net-To-Gross Space Efficiency

BSL-2 55%-60%

BSL-3 35%-45%
The amount of space within the containment zone used for working directly with active biological agents is typically less than 45% of the overall net program area, and less than 20% of the total gross area of the facility.

### 2.5.4.3 Functional Relationships

Functional relationships for buildings containing biocontainment facilities are similar to those of conventional laboratory and animal research facilities except that additional consideration is required for buffering and isolating containment areas. Primary zones include:

- Personnel Zone
- Laboratory Zone
- Animal Zone
- Containment Zone
- Logistic Zone.

The following diagram illustrates typical relationships among primary building zones:

Organizational structure may vary depending on the biocontainment program. Additional factors that should be considered include:
a. ABSL-2 / ABSL-3 Proximity: A close connection between ABSL-3 areas and the conventional animal research facility greatly facilitates shared use of cage processing and other ARF support facilities that usually serve all animal holding areas. This is illustrated in the attached diagram:

Satellite ABSL-3 suites are also feasible provided that proper SOPS are in place for decontaminating cages and waste prior to transport out of the suite.

b. BSL-3 / ABSL-3 Proximity: Connection between ABSL-3 areas and BSL-3 labs may also be desired to facilitate movement of active agents and infected materials between lab and holding areas. This is particularly important with highly pathogenic agents that may present additional risk or operational complexity to package and transport out of the biocontainment barrier.

2.5.4.4 Circulation

Movement of staff, materials, equipment and waste in and out of the containment zone requires the use of air locks and/or anterooms to meet BMBL requirements for passage through a series of two self-closing, lockable doors. This requirement also facilitates engineering controls that enable cascading airflow into the containment zone. There are many design variations that address this requirement. Factors that must be considered include:

a. Through-put: Airlocks must be designed to accommodate the volume of staff using the facility. This includes both normal transit as well as emergency egress scenarios. Factors affecting throughput include time required to don and remove PPE, time and facilities required for decontamination prior to exiting (PPE spray-down, shower-out, privacy issues).

b. PPE: Requirements for PPE including disposable materials as well as laundered materials, positive air pressure respirators (PAPRs) PAPR recharging stations, lockers, waste bins, etc.

c. Showers: Risk assessment may require the use of pass-through showers in the exiting sequence for highly pathogenic or agricultural agents. When not required, consideration may be given to the addition of showers for future flexibility.
d. Decontamination: Airlocks and anterooms may be used for surface decontamination or coupled with autoclaves or fumigation chambers used for decontaminating materials removed from the containment zone. If this is the case, space required to house and service equipment and store load carts must also be considered.

e. Equipment Transport: A pathway for transit of large equipment used within the containment zone such as freezers, biosafety cabinets, etc. must be defined. The airlock used for this purpose should be sized to accommodate the largest equipment item to facilitate decontamination prior to removal.

f. Security: Biometric access control is recommended (required?) for entry into the containment area.

Examples of containment area airlock arrangements are illustrated below.

2.5.4.5 Flexibility

The type of construction and intensity of infrastructure required in biocontainment facilities is inherently inflexible from the standpoint of partition changes and repurposing. However, there are still opportunities to plan for flexibility.

a. Compartmented Design: The hazardous nature of work performed in containment labs is not usually suited to large, open-bay configurations. Compartmentalization into multiple self-contained one or two module suites has several advantages:
• Work with different infectious agents may be incompatible due to the need for different SOPs for use, storage, personal protection, decontamination, vaccines and training. If a single suite is used, the most restrictive SOPs may apply regardless of agent in use.

• Partial shutdown of a single compartmented suite for repairs or decontamination does not necessarily require shutdown of the entire containment zone provided that utility systems are similarly compartmented to allow for isolation of each suite.

• Security protocols may differ among agents, requiring selective use of staff, forced entry protection, and enhanced surveillance or biosecurity measures. This is more easily addressed in compartmentalized suites.

• Use of multiple suites with dedicated holding and procedure rooms within the ABSL-3 containment zone can enhance flexibility for similar reasons as laboratory compartmentalization.

b. Flexible Casework Systems: Mobile casework systems are particularly useful in containment applications because they are generally more easily decontaminated and can be rearranged without utilizing outside contractors. This is applicable to other fixed elements that can be “plugged in” versus “hard wired” including equipment, task lighting, etc.

c. Decontamination: Use of large, centralized decontamination equipment versus smaller equipment localized within each suite should be evaluated. The capability of decontaminating material before it leaves the suite may simplify SOPs and enhance safety. This is typically impractical in ABSL-3 facilities where large volumes of contaminated caging and cage racks require large autoclave and/or fumigation chambers. When this is the case, SOPs for moving contaminated or partially decontaminated materials must be fully understood to ensure that the physical layout supports the proposed SOPs.

2.5.4.6 Biocontainment Utility Systems:

Dedicated Systems: Utility systems serving containment zones shall be segregated from systems serving other areas of the building to minimize the risk of cross-contamination. <LINK>

Maintenance Access: Utility system components that require maintenance access or adjustment shall be located outside of the containment zone. Where possible, an interstitial mezzanine should be considered above the containment zone.

Compartmentalization: If partial shutdown of the containment zone is a design criterion, utility systems configuration must be coordinated with the space compartmentalization strategy. This is particularly important for HEPA filtration zones. Consideration should be given to the use of redundant or dual HEPA filter caissons to facilitate filter testing and replacement without suspension of containment zone operations in areas that must remain operational during partial suite shutdowns, such as shared corridors.
Decontamination: Methodologies for decontaminating utility system components exposed to the containment environment must be considered.

Directional Airflow: BMBL requirements for directional airflow into the containment zone through two doors require coordination between the architect and mechanical engineer to insure that entering and exiting SOPs are fully coordinated with the air lock layout, modes of operation and engineering controls. Within the containment zone, there are further requirements for directional airflow among rooms and suites to ensure that air moves towards the most contaminated areas, and to protect research from potential cross-contamination. An airflow diagram illustrating directional airflow at each doorway is required to communicate intent among architects, engineers, and users.

2.5.5 Additional Planning Considerations

2.5.2.1 Decontamination

Planning must identify proposed methodologies for decontamination for waste, material, carcasses, equipment and room surfaces.

is recommended that the decontamination occur at the containment barrier to minimize risk associated with transporting potentially contaminated materials out of the containment zone; however, materials that are bagged and surface decontaminated may be fully sterilized outside of containment if allowed by the risk assessment.

Autoclaves are most commonly used for decontaminating waste and material. Tissue digesters may be used for decontamination and disposal of animal carcasses. The location of both autoclaves and tissue digesters must be coordinated with SOPs for waste decontamination and disposal. A pass-through unit from containment to an anteroom outside of the containment barrier eliminates the need for transport of contaminated material outside of containment; however, it may require the use of multiple units for compartmented suites. If shared equipment is used, a location within the security perimeter is recommended and procedures for surface decontamination and transport of contaminated material to the autoclave or digester must be identified.

Surface decontamination with chemical disinfectants or fumigation with gas or vapor are most commonly used for decontaminating large equipment and room surfaces. Each decontamination methodology has design implications and limitations regarding chemical resistance of finishes, location of decontamination equipment, distribution of the disinfecting agent, cycle time and efficacy that must be considered so that physical features and finishes can be designed to support the proposed procedures.

2.5.5.2 Security

Security features shall be planned to respond to the threat-risk assessment as determined by the NIH Security and Emergency Response Services or the jurisdiction having authority in locations outside of the NIH campus. Security considerations for the containment zone and the building housing the biocontainment facility shall include:

- Vehicular and/or personnel exclusion zones for the building site
• Blast protection
• Access control, security guard station, forced entry protection and CCTV surveillance for the building
• Biometric access control, forced entry protection and CCTV surveillance for the containment zone
• Biosecurity requirements for select agent storage
• Security for communications and data associated with the biocontainment facility and research.
• Security for planning and design documentation associated with the facility.

2.5.5.3 Specialty Areas

Aerobiology: ABSL-3 facilities typically require a specially equipped procedure room used for infecting animals via inhalation of aerosolized agents. This equipment is typically housed in a dedicated room and shared by all suites within the containment zone. Depending on the animal species and type of inhalation (nose only, whole body, etc) equipment required to support this procedure may range from a biosafety cabinet to an exhausting class III glove box. Procedure rooms housing this high-risk operation may also require pass-through shower. Planning considerations must account for the space required for specialized equipment and personnel involved in the procedure as well as the methodology of transporting infected animals to and from the aerobiology suite.

Imaging: Imaging equipment used in biocontainment facilities is typically housed in a dedicated suite with anteroom, and shared by all suites within the containment zone. Where possible, equipment control rooms should be located outside of containment. Imaging equipment must be capable of withstanding decontamination without voiding manufacturer warranties. The method of transporting infected animals to and from the imaging suite must be planned.

Large Animal Facilities: Large animal research may utilize caging that must be cleaned in place or fumigated prior to transport to cage wash areas. If open caging is used, the holding room will become the primary containment barrier and additional enhancements may be required. The holding rooms may also require cleaning with hoses between studies, after decontamination. Planning must include methodology for capturing and decontaminating effluent generated by this process, as well as SOPs for transport of both infected and uninfected large animals.

Insectaries: Insects are a common vector for transport of infectious diseases. ABSL-3 insectaries require special design considerations compliant with the Arthropod Containment Guidelines published by the American Society of Tropical Medicine and Hygiene to insure that infected insects are contained within the suite. Risks associated with conducting research involving insects within a containment facility housing potential host animals must be addressed by the risk assessment.

2.3.4 Planning and Programming Deliverables

Refer to Sections 2.1.4 and 2.3.4 for predesign deliverable requirements. Additions to this list are as follows:
• Biocontainment questionnaire <LINK>

• SOP descriptions for items listed in section 2.5.3.2

• Airflow diagram for the containment zone

• Through-put assumptions and calculations validating that decontamination equipment is properly sized

• Special studies listed in section 2.5.3.1

Containment Zone Service Areas: Utility rooms and interstitial areas serving containment areas shall be provided with access control. Utility areas located above the containment zone should be designed with solid floors and waterproof finish systems to prevent fluid leaks from migrating into the containment zone. Penetrations through the floor shall be protected by raised curbs or sleeves. <MOVE TO DESIGN SECTION>
Biocontainment Facility Questionnaire <UNEDITED DRAFT>

Risk Assessment considerations – Biological Agent/Environment/Host. Link to 2.8 xx for CFR – select agent

Practices and procedures

• Waste decontamination procedures
• Daily decontamination of work surfaces
• Decontamination of equipment
• Intercommunication devices – this is important and often overlooked.

Administrative Controls

• Access controls
• Lab-specific training and biosafety manual

Safety Equipment (Primary Barrier)

• BSC (for all agent manipulations) Class II or Class III
• Glove Box
• Aerosol-containaining versions of equipment (centrifuges, cell sorters)
• Leak-proof containers used for agent transport within lab
• PPE
  o Solid-front gowns or coveralls
  o Respirators
  o

Facility Design and Construction (Secondary Barrier)

• Fire alarm system must be visual and/or audible to staff in extensive PPE
• Separate bulding or isolated zone – lab must be separated from areas that are open to unrestricted traffic flow within the bldg..

• Security systems shall be used to control access to the laboratory

• Double-door entry (doors must be self closing and be interlocked). Space between the two sets of doors can be used as an anteroom.

• Anteroom - transition from lower risk to higher risk space e.g gowining, gloves, etc. ?)

• Sink with hands-free operation

• Ceilings shall be constructed, sealed, and finished in the same manner as walls.

• All penetrations & openings seal-able

• An eyewash station must be readily available in the laboratory.

• Windows sealed

• (autoclave) in facility

• Vacuum line protection (?)

• Ability by Lab perosonel to veify direction of ai flow by means of visual monitoring device at lab entry. Audible alarm to alert personnel (?)

HVAC

- Directional inward airflow

- Single-pass, no recirculation

- HEPA filtration, if necessary

- Method to verify airflow direction

- Control system to prevent pressurization

- DPM

BSCs

Containment enclosures for aerosol-generating equipment.
BSL3 Enhancements – needs input from HVAC

- Dress in, shower out
- Autoclave in lab (?)
- Containment of piped services
- Liquid effluent decontamination Fumigation (?)

REFER TO 2.7.3 – BOTH SHOULD MATCH

DRM Program Questionnaire for Containment BSL-3 Research Laboratory and Animal Research Facility

The purpose of this questionnaire is to obtain information from the customer that is necessary to produce the Program of Requirements (POR).

1. Where is the proposed facility located?
2. How many mice, rats, rabbits, guinea pigs, etc. are held at one time (maximum)?
3. How many of each of the above are specific pathogen-free (SPF), viral antibody-free (VAF), conventional, etc.?
4. How many animals and what type are maintained in Biocontainment Level 3 at one time?
5. What forms of barriers or sequestration are currently being used?
6. Equipment Maintenance – What needs maintenance, and interval (yearly or otherwise). Items to consider: light bulbs, equipment w/in BSL3, facility systems.
7. This may generate the need to segregate the BSL3 zones independently one from another so that one suite can be shut down.
8. What agents will be used in this facility? List all (if possible)
9. What pathogens will be used in this facility? List all (if possible)
10. What is the method of decontamination used for daily work and others.
11. Means of decontamination of large equipment.

12. What type of PPE will be used?
   a. Disposable or re-usable? *(verify terminology)*
   b. Battery powered or electrical outlet for charging
   c. Will PPE connect to any umbilical?
   d. Dimensions needed for PPE to determine storage and disposal requirements.

13. Storage (for PPE and other items) mobile or fixed?

14. Anteroom – consider storage, consider bench, shower-in / shower-out protocols, lockers, unisex or two different anterooms, accessibility, handwashing sink, anteroom is not an airlock, how lab SOP will impact space.

15. Central locker/gown-in/gown-out area.

16. ADD PICTURES – URI – LESSONS LEARNED CONF. AND EAGLESTON PICTURES – NEETHA

17. Location within building – not near elevator or may cause vibration or air fluctuation in lab.

18. Security – type used to control access

19. Intercommunication devices used by personnel within the suite.

20. BSC must be ducted.

21. Benchtop or working surfaces

22. Mobile casework (easier to clean/decon)

23. Incubators, centrifuge, freezer

24. Windows (vision panels)

25. Eyewash station

26. Access to autoclave from the clean side

27. Waste disposal and material waste decon