

National Institutes of Health Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) Laboratory Certification Requirements and Checklist

By:

**U.S. Department of Health and Human Services (HHS)
National Institutes of Health (NIH)**

**Office For Research Services, Division of Occupational Health and Safety, Biorisk Management Group,
Safety Engineering Activity**

Introduction

Biosafety Level 3 and Animal Biosafety Level 3 (BSL-3/ABSL-3) containment laboratories for animals and research are the most difficult containment level facilities to design and operate. BSL-3/ABSL-3 facilities should be certified for use before initial operation and subsequently on an annual schedule or after a program change, renovation or replacement of critical HVAC/exhaust system components (specifically fans, air valves, Building Automation System (BAS) programming changes) that may affect the operating environment of the laboratory.

Laboratory certification is the systematic review of all safety features and processes associated with the laboratory (administrative controls such as documentation and record retention systems, engineering controls, personal protective equipment, building and system integrity, standard operating procedures [SOPs], operations and maintenance [O&M] schedule and O&M SOPs). This validation assures that all reasonable facility controls and prudent practices are in place to minimize, to the greatest extent possible, the risks associated with laboratory operations and the use of biohazardous materials. Standardization of an initial and annual certification process for BSL-3/ABSL-3 facilities will provide accountability that ensures proper and regular maintenance and demonstrates the use of SOPs that protect human and animal occupants, the environment and the research integrity. Certification is not commissioning. Commissioning is a phase of construction. An endurance period of two to four weeks follows building occupancy. Moveable equipment is moved into the laboratory and supplies are stocked. SOPs are proven and staff is trained. Drills are performed. The commissioning report is received and filed for maintenance use. Facility personnel operate the facility. Upon completion of the endurance period (failure of a building system restarts the endurance period) the certification is performed. In subsequent years, an endurance period is not required and certification follows facility maintenance.

High containment laboratory certification helps ensure that:

- Appropriate site and protocol specific administrative controls and proper engineering controls are being used;
- Personal protective equipment (PPE) is appropriate and undergoes regular inspection to maintain personal safety for the tasks being performed;
- Decontamination systems for waste and other potentially infectious materials, including spill management, has been adequately considered and proper procedures are in place to mitigate environmental and personnel contamination;
- Proper standard operating procedures (SOPs) for general laboratory safety and security, including physical, electrical, biological and chemical control mechanisms are in place; and
- Maintenance is being performed on a regular basis to include staff training for BSL-3/ABSL-3 laboratory maintenance personnel (staff and contractors).

Certification of high containment laboratories will be performed by a team of professionals with experience and credentials in engineering and biosafety/occupational safety and health. DOHS will manage and perform certification of NIH intramural laboratories and other high containment facilities. When appropriate, DOHS may delegate the responsibility for providing certification of a laboratory or

facility to a third party.

As a part of the laboratory certification process, the attached checklist must be completed as a retained record document. Refer to Attachment A. Re-certification of the facility will be performed on an annual basis, as a minimum. A comparison should be made to the baseline established during initial certification. Detailed records of the certification process and test results must be maintained to provide an accurate operations history of the laboratory. When replacing building components, testing should be done and documented for the components conformance to the commissioning report's testing scheme and previous results.

During the course of developing the certification criteria for a specific building, DOHS or the appropriate Office of Research Facilities (ORF), Division of Technical Resources (DTR) authority may request an alternative design requirement to accommodate existing building constraints or site conditions. DOHS may recommend an equivalent design feature that may not conform to the letter of the BSL-3/ABSL-3 certification requirements but meets the intent and provides the level of containment required for the designated use of the facility. A risk assessment should document the acceptance of the alternative.

The following is a list of critical areas to inspect or validate that testing has been completed prior to BSL-3/ABSL-3 laboratory operational start-up. Records shall be retained in the laboratory safety operations file for a predetermined length of time consistent with local health and safety regulations. Participants in the Federal Select Agent Program (FSAP) shall conform to the latest FSAP requirements.

- Primary containment (biosafety cabinet, isolator cages, cell sorter enclosures robotic enclosures, imaging equipment and equipment where agents are stored shook or spun).
- Physical secondary building barrier (laboratory, connecting laboratory corridor, interior laboratory).
- Physical building tertiary barrier (anteroom, change room(s), decontamination room).
- Support areas outside of containment:
 - Autoclave:
 - Bioseal.
 - Room security.
 - Dirty cage wash.
 - Clean cage wash.
 - Animal receiving/quarantine.
 - Waste collection and processing.
 - Mechanical and electrical spaces.
 - Roof top equipment and stack(s).

Basis of BSL-3 Laboratory Certification Checklist

I. Evaluation Of Administrative Controls And Ability To Facilitate Maintenance Operations To Ensure Occupant Safety And Facility Integrity

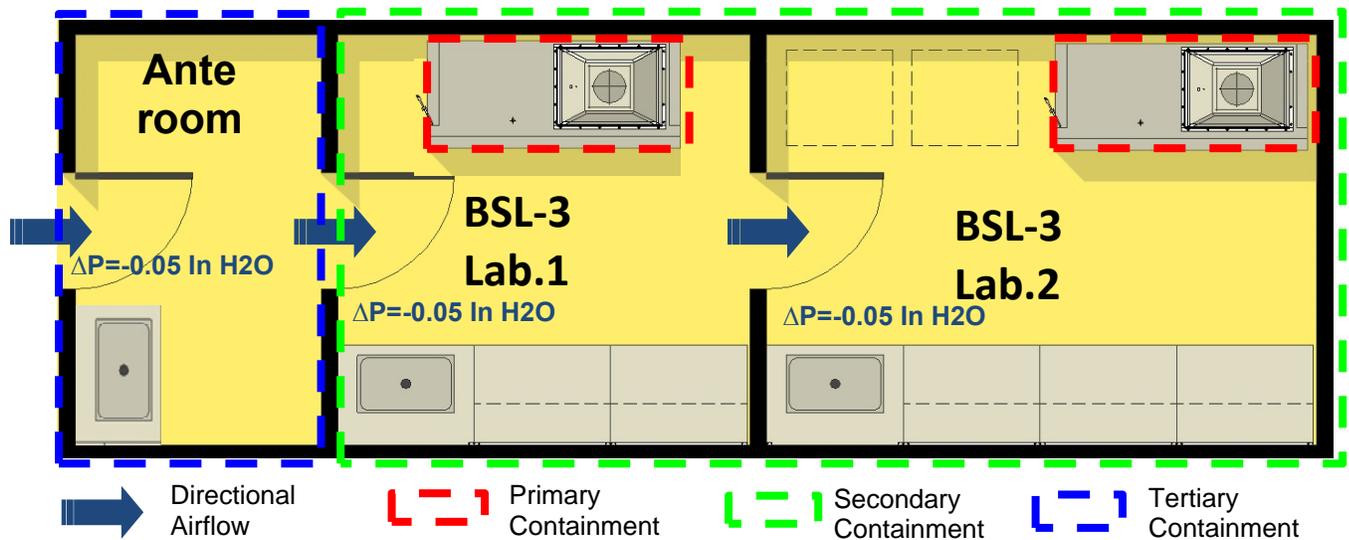
1. Review background materials that affect maintenance operations:
 - Obtain and review Commissioning Report and previous years certification checklists.
 - Review architectural to drawings ensure design intent is being met and physical barriers are identified (secondary and tertiary).
 - Review mechanical drawings to ensure design intent is being met and the pressure gradient is shown on the drawings.
 - Review biosafety policies and procedures (SOPs) for the laboratory (facility) including training of occupants and maintenance staff.
 - Evaluate administrative and engineering procedures to determine if they meet the needs of the program.
 - Review hazardous (infectious) waste management procedures.
 - Assess laboratory accident response protocols.
 - Evaluate decontamination procedures for appropriateness with respect to the protocols being conducted or anticipated.
 - Review integrated pest management program.
 - Review SOPs for document retention, maintenance and laboratory procedures.
 - Review maintenance records for building systems serving the BSL-3/ABSL-3 laboratory.
2. Inspect and evaluate finishes, penetrations and caulking integrity for architectural elements such as doors, around the ceilings, piping penetrations, lighting fixtures, electrical devices, etc. within containment to meet requirements for:
 - Clean-ability of all surfaces including furniture.
 - Smoothness of all surfaces.
 - Sealed seams and penetrations.
 - Monolithic, slip resistant floors.
 - Surface impermeability to liquids.
 - Resistance of surfaces to chemical (organic solvents, acids, alkalis) disinfectants and moderate heat.
 - Gas tightness for decontamination.
 - Pest management requirements.
 - Non-operable windows.
 - Bioseals.
 - Gaps.
 - Exposed screw threads.
 - Exposed insulation.
3. Inspect room layout, placement of equipment and equipment condition:
 - Evaluate autoclave verification testing procedures; inspect logs.
 - Evaluate access control and exit procedures.
 - Evaluate availability of:
 - Emergency equipment.
 - Emergency two way communication system.
 - System provided for electronic transfer of information to outside of containment.
 - Emergency lighting.
 - Working fire extinguisher.
 - Availability of chemical spill kit within containment.

- Evaluate redundancy requirements for particular facility such as air handling units, exhaust fans, decontamination system components (e.g. pumps, HEPA filters).
 - Assess location of BSL-3/ABSL-3 laboratories in relation to BSL-2 support laboratories, offices, restrooms/showers, break rooms, bottled gas rooms, quarantine rooms, food and bedding storage, etc.
 - Assess location of BSL-3/ABSL-3 laboratories in relation to elevators, loading docks, cage washing, shaft ways etc. for effects on laboratory pressurization and airflow. This includes operational condition of doors.
 - Presence of an anteroom.
 - Presence of showers, decontamination rooms etc. as required by risk assessment.
 - Storage provided for donning clean protective clothing and safety equipment (e.g. Powered Air Purifying Respirators PAPR).
 - Hands-free sink located near exit of laboratory.
 - Office location outside of containment.
 - Inspect signage for proper posting.
 - Biohazard sign:
 - Agents used.
 - Names and telephone number for laboratory director.
 - Special requirements such as required use of PPE, personnel access.
 - Review list of all mechanical controls and their locations.
 - Review start up and shut down procedures in case of emergency.
4. Evaluate maintenance frequency and review maintenance logs:
- Autoclaves.
 - BSC filters.
 - Centrifuges.
 - Door/equipment locks.
 - HVAC balancing.
 - HVAC belts.
 - HVAC motors/sheaves.
 - Lights.
 - Plumbing.

II. Validation Of Engineering Controls

1. Validate that extra capacity is present on both supply and exhaust systems and quantify the estimated spare capacity (must document how extra capacity was calculated or estimated).
2. Ensure single pass airflow.
3. Measure directional airflow, pressure relationships, air changes and record data.
4. Directional airflow must be established from clean areas to contaminated areas. In the event that multiple containment zones exist within a laboratory or laboratory suite, sequentially more negative pressure differentials (pressure gradient) must be established that the more contaminated spaces are maintained at a negative pressure with respect to less contaminated areas. Pressure differentials across doorways must be measured using a device calibrated against a primary standard. Ideally, at least -0.05 in WG (-12.5 Pa) should be maintained from clean areas to more contaminated areas. The differential should never be less than -0.03 in. WG (-7.6 Pa) when the door is closed.

** Figure Provided For Illustration Purposes Only **



5. Develop HVAC system and electrical systems failure tests consistent with laboratory design parameters. Perform tests and record data. To verify correct operations these tests should include at a minimum:
 - Baseline.
 - Normal operations to emergency power.
 - Emergency power to normal operations.
 - Loss of supply fans (individual and in combination).
 - Loss of exhaust fans (individual and in combination).
 - Building automation system (BAS) maintains operational set points during all scenarios and returns to normal operations.
 - Upon reboot, BAS must retain operational set points.
 - If an uninterrupted power supply (UPS) is installed, verify operation of relays.
 - Provide UPS for BAS.
 - Assess if UPS is operational.
 - If exhaust static probe has not been certified in the last year then disconnect to simulate a failure.
 - Fans should be restarted after each failure and reach setpoint before the next test.
 - The minimum time for recording data during a test shall be four minutes or when supply and exhaust set point is reached, whichever is the longer period of time.
 - Ensure that laboratories are maintained at negative pressure with respect to less contaminated areas by smoke testing each door when setting data logging equipment.
 - Compare the laboratories' Differential Pressure Meters (DPM) or gauges with a National Institute for Standards and Technology (NIST) certified meter to determine if they are within ten percent (10%) of the certified meter.

6. Assess HVAC equipment condition.
 - Visually inspect:
 - Belts.
 - Belt guards.
 - Wiring.
 - Duct supports and connections.
 - Guide wires (if applicable).
 - Dilution air dampers (if applicable).
 - Bearings (high pitched squealing).
 - Ductwork system workmanship, damage, etc.
 - Ensure that motor operating temperatures are maintained within equipment

- specifications.
 - Ensure that interlock between supply and exhaust is operational.
 - Verify correct placement of biosafety cabinets (BSCs) with respect to supply and exhaust diffusers, doors and traffic patterns.
 - Use smoke at the face of the cabinet to ensure that the air curtain is not being disrupted by supply or exhaust diffusers placed in proximity of the cabinet(s) or opening and closing doors and traffic patterns.
7. Perform smoke tests to demonstrate directional airflow:
- Doors.
 - Vents.
 - Windows (interior and exterior).
 - Autoclave.
 - Other vented areas.
8. Inspect and challenge door interlock systems and automatic door closers:
- Door closers are required.
 - Ensure that doors automatically close and latch from a forty-five degree (45°) and ninety degree (90°) open position.
 - Interlocking doors, autoclave, pass through where installed.
 - Ensure that delay set points are tight enough to preclude inadvertent override of interlock.
9. Test all alarms:
- HVAC failure alarm:
 - Availability of airflow alarms showing if the room has gone positive under normal conditions or if door is open for greater than 30 seconds for BSL-3 laboratories and 45 seconds for ABSL-3 laboratories.
 - Availability of a visual indication for personnel to be aware if the room is under positive or negative pressure prior to entering into the laboratory.
 - Review fire alarm annual documentation.
 - Review security alarm annual documentation.
 - Review who/where the alarms are received and response time.
10. Discharge exhaust assessment (as a measure of performance):
- Inspect rooftop landscape for re-entrainment opportunities.
 - Min. 25 ft. from intake, 40 ft. from boiler stacks, and 15 ft. from plumbing stacks.
 - Laboratory exhaust stacks - minimum 3m height above highest point on roof.
 - Check exhaust stack locations and discharge velocities.
 - Exhaust velocity = 15-20 m/s or 3000-4000 fpm.
 - All aerosol-producing equipment exhausted has annually certified HEPA filtration devices (e.g. autoclaves, plumbing vents etc. when installed).
 - Ensure that continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory.
 - Ensure that discharge of local exhaust ventilation (LEV) devices is removed from air intakes to prevent re-entrainment.
 - Consider local conditions (e.g. HEPA filters on exhaust, dilution air).
11. Verification of air change rates (ACR) in containment spaces:
- ACR is determined during design based on sensible and latent heat loads, contaminants and odors that require containment space usage.
 - Review the annual air balance report or measure supply and exhaust air volumes using a device calibrated annually to verify/calculate ACR monitor trends. In no case should the ACR be less than 6/hr. for laboratories and 10/hr. for animal facilities.

12. Review BSC certification data including serial number validation, which should show the BSC's cabinet location on a floor plan.
 - BSCs must be on an annual certification schedule.
 - Verify that BSCs are located away from doors and vents.
 - Verify that installation of BSC is correct for cabinet type.
 - Inspect HEPA filter installations.
 - Review certification documentation for all exhaust HVAC HEPA installations.
 - Verify that HEPA filters are on portable air vacuum systems at point of use and at the barrier.
 - Visually inspect:
 - Isolation valves for decon (local and HEPA caisson).
 - Decon and challenge ports.
 - Scanning access.

13. Validate MEP:
 - Inspect for adequate illumination.
 - Verify that circuit breakers are outside of containment.
 - Backflow prevention for laboratory water system.
 - Verify sinks faucets are working properly and do not cause aerosol generation.
 - Verify drain traps at bends have not deteriorated from exposure to acids and bases introduced into the drainage system.
 - Availability of emergency power for critical systems.
 - Availability of hands free emergency eyewash.
 - Availability of emergency shower.
 - Caulking and sealing requirements for electrical devices such as conduits, boxes, lights, etc.
 - Validate provision for dedicated vacuum pump, if present.
 - Inspect effluent decontamination system, if present.
 - If there is a central vacuum system, verify that it has a local HEPA filter system with provisions for decontamination.

14. Validate autoclave availability, operations (temperature and maintenance log), bioseal integrity (by visual observation), storage cart for unloading (if available), secure storage room as required by the FSAP and adequate exhaust for steam capture and heat removal atop the autoclave vessel.
 - Test interlocks.
 - Confirm cycle – test load.
 - Visually inspect bioseal.
 - Smoke test bioseal.
 - Validate maintenance of sterilization temperature of one hundred twenty-one degrees (121°) for 60 minutes. In new facilities, autoclave-out capability directly from the BSL-3/ABSL-3 facility. In older facilities where autoclave-out may not be available, an autoclave must be available near the BSL-3/ABSL-3 facility so that containment of biohazardous waste is maintained.
 - Additional environmental protection (e.g. personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) is considered if recommended by the agent summary statement.

III. Review SOPs

1. Autoclave and decontamination:
 - To decontaminate materials before removing them from the BSC.
 - If an autoclave is available near but outside the BSL-3/ABSL-3 facility, ensure adequate decontamination procedures in place for wet and dry biohazardous materials that leave the facility.
 - Assess the travel route to nearest autoclave avoid public corridors.
 - Assess procedures for use of and disposal of PPE.

- Assess procedures for decontamination of equipment that leaves the facility for repair or discontinuation of use.
- Review storage and transport of biohazardous materials.
- Assess type of disinfectant to be used and if it is of adequate strength and type for the biohazardous materials in use in the facility.
- Validate schedule and frequency of changing HVAC filters on vacuum lines.

2. Safety SOPs:

- Identification of Responsible Official for BSL-3/ABSL-3 facility.
- Certification of all personnel working within containment and process used to certify them.
- Use, storage and disposal of PPE.
- Documented limited personnel access to facility.
- Procedures for maintenance to enter facility.
- Hand washing procedures.
- Use of mechanical pipetting devices.
- No mouth pipetting.
- Use of sharps prohibited unless absolutely required and then use should be managed by protocol.
- Procedures in place to minimize production of aerosols.
- Decontamination procedures.
- Training program is in place and documentation available for training and refresher courses of all personnel allowed in the BSL-3/ABSL-3 facility.
- Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel.
- A biosafety manual specific to the laboratory has been prepared and adopted.
- Biosafety precautions are incorporated into SOPs.
- If animals are housed under ABSL-3 conditions, all animal specific regulations and biosafety procedures are followed.

3. Occupational health monitoring (policy and records of implementation):

- Blood/serum storage, if appropriate.
- Vaccinations.
- High-risk (immune suppressed, pregnant, etc.) individuals.
- Health screening.
- Annual updates of Exposure Control Plan to include documentation of all locations where BSL-3/ABSL-3 agents or materials are used or stored.

4. Biohazardous materials use authorization (e.g., human pathogen registration, recombinant DNA registration, select agent, etc.):

- Current biohazardous materials use authorization.
- Symptomology page.
- Procedures for how samples are received.
- Validate that a current Animal Subjects Committee approval is on file (if animals are used in the facility).

Attachment B

Equivalency Request Procedure for BSL-3 Laboratory Certification

1.0 Purpose

This procedure defines the steps for requesting, reviewing and resolving equivalency requests for a BSL-3 Laboratory Certification.

The BSL-3 Requirements are a minimum standard. Prescriptive limitations, when given, such as exact dimensions or quantities, describe a condition that is commonly recognized as a practical standard or NIH requirement for effective operation. The provisions in the requirements are not intended to prohibit the use of alternative systems, methods, or devices that are not specifically outlined in the document, provided that the proposed alternative design is at least equivalent or superior to the requirements set forth with regard to quality, strength, durability, effectiveness, fire resistance, health and safety, and is approved by DOHS and DTR.

During the course of developing the certification criteria for a specific building, the NIH Accredited Certifying Agent may request an alternative to the requirements to accommodate existing building constraints or site conditions. The NIH Accredited Certifying Agent may recommend an equivalent design feature that does not conform to the letter of the BSL-3 certification requirements but meets the intent and provides the level of containment required for the designated use of the facility.

2.0 Applicability

This procedure applies to the NIH Accredited Certifying Agent who provides the facility certification services.

3.0 Responsibilities

Only NIH Accredited Certifying Agents are authorized to apply for an equivalency. This procedure is to be followed whenever a deviation from the certification requirements is deemed necessary.

4.0 Procedure

The NIH Accredited Certifying Agent identifies a need for an alternative to the certification requirements and fills out the Equivalency Request Form.

The NIH Accredited Certifying Agent completes the Equivalency Request form and forwards it to the NIH Equivalency Coordinator. The form must be filled out and routed electronically. The Equivalency request workflow is to be paperless.

All requested Equivalencies within a single discipline shall be submitted as a single package at the same time (e.g., all mechanical in one package; all electrical in one package; etc.). This ensures that all variations to the requirements can be reviewed at one time to preclude conflicts in guidance.

Following submittal of a complete package by the NIH Accredited Certifying Agent to the NIH, the review will take a minimum of 10 working days. Additional time may be necessary depending on the complexity of the request, coordination with other requests, or re-submittal due to incomplete documentation.

The NIH Equivalency Coordinator reads and logs the request and forwards it to the discipline appropriate reviewer(s).

The reviewer approves, disapproves or requests more information and adds notes if necessary in the "NIH Response" block of the Equivalency Request Form and forwards the form to the NIH Equivalency Coordinator.

The NIH Equivalency Coordinator logs the response and returns the form complete with the reviewer's response back to the NIH Accredited Certifying Agent. Equivalencies may also be granted based on an action by a Dispute Resolution Board determined by the NIH as the result of an appeal.

5.0 Relevant Documents

- NIH Design Requirements Manual
- NIH BSL-3/ABSL-3 Certification Requirements and Checklist

6.0 Records

- Equivalency Request

NATIONAL INSTITUTES OF HEALTH
BSL-3/ABSL-3 Laboratory
Certification Checklist
 (Internal use only)

INSTITUTION		BUILDING/ ROOM		BEGINNING SURVEY DATE		END SURVEY DATE	
SURVEYOR(S) NAME (S):	1 _____ 3 _____	BIO SAFETY OFFICER		TELEPHONE		E-MAIL	
	2 _____ 4 _____						

I. Administrative Controls	Certification Periodicity		Meets NIH Requirement			Acceptance Criteria			Recommended Action Plan	Comments/Notes	REF. BMBL
	Initial Year Only	Annually Including Initial Year	YES	NO	N/A	PASS	FAIL	N/A			
A Review and Assess Background Materials											
1. SOPs for document retention: a. Laboratory procedures b. Maintenance procedures c. Maintenance schedule	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✓ Verify that these documents have been reviewed, bear the name of the responsible party who performed the review and that the date for review is within a year.		A.1 A.2 A.3 A.4 A.5 A.6					
2. Review Commissioning Report. Review other commissioning document(s) if the laboratory has had major improvements where recommissioning was required	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓ Verify commissioning document records operating characteristics of all equipment serving the BSL-3 laboratory.		D.15
3. Basis of design, design drawings and specifications to ensure design intent is being met and last issued copies are available to the Biosafety Officer	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓ Verify that users and ventilation test data confirm design intent has been accomplished.		D.15
4. Biosafety policies and procedures (SOPs) for the laboratory (facility) including training of occupants and maintenance staff	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✓ Review policies and procedures to validate relevance to planned research and current research. Confirm training has been completed for new or modified SOPs.		A.11					
5. Hazardous (infectious) waste management procedures	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✓ Verify that the SOPs are being followed from waste generation to final disposal including methodologies for validation of decontamination (i.e. autoclave log etc.)		D.11					
6. Integrated Pest Management Program (IPMP)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✓ Evaluate IPMP using Appendix G of the BMBL 5th Edition. Verify by inspection of laboratory that IPMP is effective.		A.10					
7. Administrative and engineering procedures to determine if they meet the needs of the program	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✓ Verify that where there are engineering controls there are administrative procedures to verify controls are effective. (i.e. A door closer is an engineering control. Personnel verifying that the door closes and latches is an administrative procedure that verifies engineering control is working).		A.1 A.2 A.3 A.4 A.5					
8. BSL-3 Laboratory accident response protocols	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✓ Review SOPs and document review. Provide training on accident response and document training.		B.8					
9. Decontamination procedures for appropriateness with respect to the protocols being conducted or anticipated	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✓ Review SOPs for decontamination to determine their appropriateness for the upcoming year's proposed research.		A.7 A.8 B.7 D.3					
B Assess Containment Laboratory Layout											
1. An automatically activated emergency power source is provided with a minimum capacity for serving the laboratory exhaust system, alarms, lighting, entry and exit controls and BSCs.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✓ Conduct "Pull the Plug" power test. Verify that power transfers and activates all critical equipment and building systems. ✓ Document inspection to include maintenance records for maintenance on emergency generator and automatic transfer switches.		CDC-SAP					
2. Monitoring and control systems for supply, exhaust, alarms, entry and exit, and security systems are supplied through an Uninterruptible Power Supply (UPS).	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓ Test UPS systems serving the BSL-3 laboratory to verify that they are operational. ✓ Review battery replacement schedule for equipment has internal battery backup (i.e. Programmable Logic Controllers, PLCs etc.)		CDC-SAP
3. Windows are break-resistant and sealed.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓ Verify that documentation for break resistant windows as well as any replacement is being retained on file. ✓ Test seals by smoke testing.		CDC-SAP
4. Monolithic, slip resistant floors are coved at the junction of the walls. Floors are free of seam splits, bubbles, dimples, nicks, dents, scratches, blisters or other similar defects that could cause floor failure or capture dirt.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✓ Visually inspect floors and cove bases for defects and defects which capture dirt.		CDC-SAP					
5. An eyewash station is readily available in the BSL-3 Laboratory area for use during an emergency.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✓ Verify that there is a log to document testing, testing weekly. Annually verify for compliance with ANSI Standard Z358.		CDC-SAP					
6. A hands-free sink must be provided near the exit door. If the laboratory is segregated into different laboratories, a sink must also be available for hand washing in each area where agents are handled.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✓ Verify that faucet activation is operational and there are no leaks. Verify that drainage pipe, especially the trap, is not leaking.		CDC-SAP					
7. All BSCs are installed in such a way that airflow disruptions are avoided, (far away from supply and exhaust grilles, doors and heavily traveled laboratory areas).	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✓ Verify by smoke testing.		D.6					
8. Available space for decontamination of large pieces of equipment before removal from the laboratory	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓ Review procedure for decontamination of large equipment to include signage that indicates equipment has been decontaminated.		D.13

National Institutes of Health BSL-3/ABSL-3 Laboratory Certification Checklist is based upon ANSI/ASSE Z9.14 'Standard Testing and Performance Verification Methodologies for Ventilations Systems for Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3)'

NATIONAL INSTITUTES OF HEALTH
BSL-3/ABSL-3 Laboratory
Certification Checklist
 (Internal use only)

I. Administrative Controls														Certification Periodicity		Meets NIH Requirement			Acceptance Criteria			Recommended Action Plan	Comments/Notes	REF. BMBL					
														Initial Year Only	Annually Including Initial Year	YES	NO	N/A	PASS	FAIL	N/A								
B Assess Containment Laboratory Layout (Cont'n)																													
9. Evaluate availability of Emergency Equipment:																													
a. Two-way communication system														<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>													
b. System provided for transfer of information to outside of containment														<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>													
c. Fire extinguisher														<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>													
d. Chemical spill kit within containment														<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>													
e. Emergency shower														<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>													
10. Access Control and Exit Procedures																													
a. Access to the laboratory is through two self-closing doors with locks in accordance with the institutional policies. A clothing change room (anteroom) may be included in the passageway between the two self-closing doors.														<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			A.1 A.9 B.1 D.1 D.9										
b. Prior to entering the space, there is a graphical interface or analog differential pressure gage that allows the users to observe and evaluate the conditions within the space before entering the BSL-3 room (room pressures and alarms as a minimum).														<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			D.14										
c. If infectious agents are being used within the laboratory, a sign incorporating the following information is posted: a) Universal biohazard symbol, b) List of agents used, c) Supervisor's contact information and d) Required procedures for entering and exiting the laboratory.														<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>													
C Inspect and Evaluate Architectural Features for Maintenance and Operations Within Containment to Meet Requirements for:																													
Architectural Features	Cleanability of all surfaces including furniture			Surface impermeability to liquids			Smoothness of all surfaces			Sealed seams, caulking and penetrations			Surfaces are intact and capable of withstanding exposure to chemicals, disinfectants and moderate heat																
	Good	Bad	NA	Good	Bad	NA	Good	Bad	NA	Good	Bad	NA	Good	Bad	NA														
Doors	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>			D.3 D.4										
Bench tops	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Walls/Walls penetrations	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Ceiling/Ceiling penetrations	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Floors and covebase (if applicable)	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Shelving	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Drawers	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Animal cages	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Switches	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Windows/windows frames	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Exposed utilities (piping, conduits or ductwork)	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Try containment devices (i.e. BSC's /Gloveboxes)	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Furniture	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Tables	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Electrical outlets	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Hardware	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Access panels	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Communication ports	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Light fixtures	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													
Diffusers and grills	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>													

NATIONAL INSTITUTES OF HEALTH
BSL-3/ABSL-3 Laboratory
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I. Administrative Controls		Certification Periodicity		Meets NIH Requirement			Acceptance Criteria			Recommended Action Plan	Comments/Notes	REF. BMBL
		Initial Year Only	Annually Including Initial Year	YES	NO	N/A	PASS	FAIL	N/A			
D	Evaluate Maintenance Frequency and Review Maintenance Records/Contracts											
	1. Preventive maintenance program and records	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Review maintenance program scope. ✓ Review reporting systems to determine ability to document maintenance, and documentation to date including contractor invoices to determine if facility is being maintained. ✓ Also, inspect facility to determine the quality of the maintenance performed and determine if budget and personnel are sufficient to maintain facility. 		B.7					
	2. Autoclaves	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Determine effectiveness of preventive maintenance completed. ✓ Review autoclave service contract. ✓ Review maintenance invoices ✓ Review autoclave log for loads processed to validate time and biological indicator results. 		B.7					
	3. Biological Safety Cabinets / Gloveboxes	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Review certificates. Inspect seismic restraints for cleanability. ✓ Review contract with NSF-49 certifier to determine that they have provided certificates as well as their methodology for certification. 		B.7 AP6-10					
	4. Centrifuges / Shakers	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Review certification data to determine speed, temperature etc. ✓ Verify that all closed cups are free from cracks. Replace damaged cups. 		B.7					
	5. Doors	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Inspect door closer for hydraulic seal leak, door's condition and general operation ✓ Evaluate sweep and latch times to determine if their timing pose an injury risk to personnel and verify emergency exit releases are operational. 		B.7 AP Table C-10					
	6. HVAC Testing and Air Balance Report (TAB)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Confirm that the actual airflow values are equal or exceed the design airflow values. ✓ Review the TAB report to determine that the laboratory rooms have a minimum of six (6) air changes per hour. 		B.7					
	7. Lights	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Measure lighting levels ✓ Acceptance criteria being laboratories and laboratory support areas 800-1075 Lux (75 – 100 Foot-candles). 		B.7					
	8. Plumbing	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Verify that all sinks are operational and safety devices (i.e. vacuum breakers and backflow preventers) are operational. 		B.7					
	9. Emergency generator (under load conditions)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Verify that all emergency systems (i.e. BSC, lighting, alarms BAS etc.) necessary to continue operations are operable. ✓ Review monthly and annual load test reports of emergency generator. ✓ Review maintenance reports on emergency generator and automatic transfer switches to determine level of maintenance and reliability. 		B.7					
	10. HEPA filter maintenance program	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Confirm that contract for HEPA exhaust system caisson certification to include methodology for certification is available ✓ Review test report provided by certifier and retain documentation on file. 		B.7					
	11. Biosecurity systems	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Coordinate with security forces the testing of physical security devices to verify that they are operational. 		B.7					
	12. Reduced pressure zone backflow preventers (RPZs)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Verify that maintenance is being accomplished on the industrial water supply which provides water service to the BSL-3 laboratories. 		B.7					
	13. UPS systems	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Verify that there is a battery replacement schedule for equipment with internal back-up batteries. ✓ Test critical systems computers (Building Automation System (BAS) server, Programmable Logic Controllers, -80° Freezers etc.) are operational. 		B.7					
	14. Fire alarm systems	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Document that a fire alarm drill was conducted within the past year. 		B.7					
	15. Building Automation System and components	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Verify that there is a log which shows access to the BAS server's program and changes made to the program. 		B.7					
	16. Zero leakage valves and/or dampers	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Visually observe that zero leakage valves/dampers close when commanded and do not leak. 		B.7					
	17. HVAC Belts	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Verify preventive maintenance is documented. ✓ Visually inspect belts for damage and tightness. Check RPM of belt and compare with set point. 		B.7					
	19. HVAC Motor / Sheaves / Bearings	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Verify preventive maintenance is documented. ✓ Check temperature of Motor / Sheaves / Bearings for a comparative temperature m measurement using a thermal imaging camera. Check for vibration and noise. 		B.7					
	20. Backflow prevention valves for lab water system	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> ✓ Check maintenance log for backflow preventer maintenance. Verify that a field test has been performed. ✓ Review commissioning report to verify proper installation. 		B.7					

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		Initial Year Only	Annually Including Initial Year	YES	NO	N/A	PASS	FAIL	N/A																	
A. Discharge Exhaust Assessment	1. Exhaust Stacks									<ul style="list-style-type: none"> ✓ Determine compliance by either direct measurement of the velocity of the discharge exhaust or by calculation. ✓ Either record data collected or document calculations. 	D.9															
	a. Minimum 7.6 m (25 ft) from intake, 12.2 m (40 ft) from boiler stacks and 4.6 m (15 ft) from plumbing stacks	■	□	□	□	□	□	□	□																	
	b. Minimum 3 m (approx. 10 ft) height above highest point on roof	■	□	□	□	□	□	□	□																	
	2. Discharge velocities greater than 15 m/s (3000 FPM)	■	□	□	□	□	□	□	□																	
B. Doors	1. Door closers are required for all doors and are working properly (all doors automatically close and latch).	□	■	□	□	□	□	□	□	<ul style="list-style-type: none"> ✓ Test all doors to verify that they close and latch from 90° and 45° open positions. 	D.1															
	2. If interlocks are required, check operability in the rooms where these doors are present, (test all possible sequences and verify delay set points).	□	■	□	□	□	□	□	□	<ul style="list-style-type: none"> ✓ Document that the interlocked doors are operational and the doors cannot be opened simultaneously. 																
C. Evaluate Redundancy Requirements	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%;">System</th> <th style="width: 33%;">Component</th> <th style="width: 33%;">Number</th> </tr> </thead> <tbody> <tr> <td>1</td> <td></td> <td></td> </tr> <tr> <td>2</td> <td></td> <td></td> </tr> </tbody> </table>			System	Component	Number	1			2									<ul style="list-style-type: none"> ✓ Obtain information from commissioning report. ✓ Inspect equipment maintenance logs to determine if maintenance is being performed on a regular basis. 	D.9						
	System	Component	Number																							
	1																									
2																										
			■	□	□	□	□	□	□																	
			■	□	□	□	□	□	□																	
D. Validate that Extra Capacity is Present on Both Supply and Exhaust Systems and Quantify the Estimated Spare Capacity (must Document how Extra Capacity was Calculated or Estimated)	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">HVAC System</th> <th style="width: 10%;">No</th> <th style="width: 15%;">Total Design Capacity (cfm)</th> <th style="width: 15%;">Total Current Capacity (cfm)</th> <th style="width: 15%;">Spare Capacity %</th> </tr> </thead> <tbody> <tr> <td>1 No of Air Handler Units</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>2 No of Exhaust fans</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>					HVAC System	No	Total Design Capacity (cfm)	Total Current Capacity (cfm)	Spare Capacity %	1 No of Air Handler Units					2 No of Exhaust fans									<ul style="list-style-type: none"> ✓ From the commissioning report make a determination as to spare capacity. 	D.9
	HVAC System	No	Total Design Capacity (cfm)	Total Current Capacity (cfm)	Spare Capacity %																					
	1 No of Air Handler Units																									
2 No of Exhaust fans																										
					■	□	□	□	□																	
					■	□	□	□	□																	
E. Ensure that directional airflow (where applicable) and proper pressure relationships are established from less potential contaminated areas into more potential contaminated areas:	1. System has been designed as a single pass airflow.	■	□	□	□	□	□	□	□	<ul style="list-style-type: none"> ✓ Using NIST calibrated meters, initially and annually measure, log and record: ✓ Air Change Rate (ACH) in laboratory rooms by air balancing ✓ Pressure differentials testing under normal and common failure modes 	D.9															
	2. Measure pressure relationships (by testing and record). Pressure differentials across doorways must be measured using a device calibrated against a primary standard. Ideally, at least -0.05 in WG (-12.5 Pa) should be maintained from clean areas to more contaminated areas. In no case should the differential be less than -0.03 in WG (-7.6 Pa) when the door is closed.	□	■	□	□	□	□	□	□																	
	3. Measure air changes and record data.	□	■	□	□	□	□	□	□																	
	4. If multiple containment zones exist within a laboratory or laboratory suite, then more negative pressure differentials are established so that the more contaminated spaces are maintained at a negative pressure with respect to less contaminated areas.	□	■	□	□	□	□	□	□																	
	5. Review facility maintenance start up and shut down procedures in case of emergency.	□	■	□	□	□	□	□	□																	
F. Develop HVAC system and electrical systems failure tests consistent with laboratory design parameters. Facility Performs Test and Records Data. To verify correct operations these tests should include at a minimum:	1. Normal Operations -> Standby Power																									
	a. Once "Normal Power" has been failed, generator will start up and transfer to emergency power.	□	■	□	□	□	□	□	□	□	<ul style="list-style-type: none"> ✓ If generation of emergency electrical power is not part of the building system, then provide documentation of testing of emergency power system. ✓ Records of power failure(s) and system testing are reviewed annually. ✓ A positive minimum acceptance criteria is +.009 In. of water. ✓ Perform risk assessments for test results which do not meet acceptance criteria using administrative controls, if possible. ✓ If electrical power tests pose a possibility for a destructive test inconsistent with the mission of the organization due to operational requirements, then provide maintenance data and latest test data including any maintenance contracts. ✓ Prior to testing develop written test script. ✓ Acceptance Criteria Minimum Requirements is based on HVAC system configuration and number of air handling units: <ul style="list-style-type: none"> a. Test shall be completed from beginning to end without any interruptions. b. Acceptance is based on data collected, recorded and documented. c. Evaluate data and determine any airflow reversals have exceeded +.009 In.H₂O. If so, perform a risk assessment. d. Any adjustments require repeating test script from the first step. 	D.9 A														
	b. No airflow reversals or excursions of positive pressure from BSL-3 areas are observed during the transfer to standby power. If there is an airflow reversal or a positive excursion from a laboratory then a risk assessment shall be put in place.	□	■	□	□	□	□	□	□	□																
	c. Building Automation System maintains operational set points.	□	■	□	□	□	□	□	□	□																
	2. Standby Power -> Normal Operations																									
	a. Upon return to "Normal Power", the exhaust flow shall maintain normal set points with the supply flow maintaining the pressure differential.	□	■	□	□	□	□	□	□	□																
	b. No airflow reversals or excursions of positive pressure from BSL-3 areas are observed during the transfer to normal power. If there is an airflow reversal or a positive excursion from a laboratory then a risk assessment shall be put in place.	□	■	□	□	□	□	□	□	□																
	c. Building Automation System maintains operational set points.	□	■	□	□	□	□	□	□	□																
	3. The Emergency Generator test commissioning report has been submitted, reviewed and approved by the Army Corps of Engineers.																									
		■	□	□	□	□	□	□	□	□																

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G. Loss of Supply and Exhaust Fans (Individual and in Combination):																																																											
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NATIONAL INSTITUTES OF HEALTH
BSL-3/ABSL-3 Laboratory
Certification Checklist
 (Internal use only)

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NATIONAL INSTITUTES OF HEALTH
BSL-3/ABSL-3 Laboratory
Certification Checklist
 (Internal use only)

II Validation of Engineering Controls If condition does not meet requirements, then a risk assessment is required and needs to be documented.		Certification Periodicity		Meets NIH Requirement			Acceptance Criteria			Recommended Action Plan	Comments/Notes	REF. BMBL																			
		Initial Year Only	Annually Including Initial Year	YES	NO	N/A	PASS	FAIL	N/A																						
H	Laboratory Equipment (Cont'n)																														
	6. Laboratory Vacuum System LSTF- Check condition of:											D.7																			
	a. Vacuum pumps	■	□	□	□	□	□	□	□																						
	b. Receiver components																														
	b.1. Vertical type, welded stainless steel material fabrication rated for 1034 kPa pressure, ASME code stamped	□	■	□	□	□	□	□	□																						
	b.2. Safety relief valve	□	■	□	□	□	□	□	□																						
	b.3. Sight glass	□	■	□	□	□	□	□	□																						
	c. System components																														
	c.1. Inlet filter assembly	□	■	□	□	□	□	□	□																						
	c.2. Decon and isolation valve assemblies	□	■	□	□	□	□	□	□																						
	c.3. Intake check valve	□	■	□	□	□	□	□	□																						
c.4. Pump isolation valve	□	■	□	□	□	□	□	□																							
7. Fire Alarms / Alarm Systems LSTF																															
a. The Fire Alarm / Alarm System has been commissioned.	□	■	□	□	□	□	□	□																							
b. The commissioning report and test results have been submitted, reviewed and approved.	□	■	□	□	□	□	□	□																							
c. Extinguishers are inspected annually (if applicable).	□	■	□	□	□	□	□	□																							
d. Annual Fire Alarm Test completed and documented.	□	■	□	□	□	□	□	□																							
8. Roughing Filters on Exhaust Grilles in Animal Spaces (if applicable)										✓ Required for assessment of operation and maintenance																					
a. Verify maintenance of roughing filters per SOP.	□	■	□	□	□	□	□	□																							
9. Autoclave Verification																															
a. Validation reports have been submitted, reviewed and approved	□	■	□	□	□	□	□	□		✓ Review documentation to verify successful biological challenge as per AAMI ST46 - Biological indicator testing showing negative growth after sterilization exposure for autoclave.	A.8 D.11																				
b. Manufacturer has reviewed the installation and submitted a report confirming that the installation has met the recommended installation procedures. (Check documentation.)	□	■	□	□	□	□	□	□																							
c. Autoclave pass through capability directly from the Containment facility.	■	□	□	□	□	□	□	□		✓ Visually inspect bioseal and perform smoke test to verify it is working properly.																					
<table border="1"> <thead> <tr> <th rowspan="2">Autoclave Identification Model</th> <th rowspan="2">Location</th> <th rowspan="2">Serial Number</th> <th rowspan="2">Last Cert Date</th> <th colspan="2">Bioseal integrity has been inspected</th> </tr> <tr> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr> <td>1</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>2</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Autoclave Identification Model	Location	Serial Number	Last Cert Date	Bioseal integrity has been inspected		Yes	No	1						2																
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10. Pressurization Alarms																															
There are visual indications for personnel to be aware if the room is under positive or negative pressure prior to entering into the lab. Availability of airflow alarms showing if the room has gone positive under normal conditions or if any door is open for greater than a recommended 30 seconds but not exceeding 45 seconds. Difference between monitor reading and NIST certified gage does not exceed (±10%).																															
	Monitor Location		ΔP		Monitor Location		ΔP																								
	From	To			From	To																									
1			InH ₂ O	1			InH ₂ O	□	■	□	□	□	□	□	□	□															
2			InH ₂ O	2			InH ₂ O	□	■	□	□	□	□	□	□	□															
3			InH ₂ O	3			InH ₂ O	□	■	□	□	□	□	□	□	□															
4			InH ₂ O	4			InH ₂ O	□	■	□	□	□	□	□	□	□															
5			InH ₂ O	5			InH ₂ O	□	■	□	□	□	□	□	□	□															
6			InH ₂ O	6			InH ₂ O	□	■	□	□	□	□	□	□	□															
7			InH ₂ O	7			InH ₂ O	□	■	□	□	□	□	□	□	□															
8			InH ₂ O	8			InH ₂ O	□	■	□	□	□	□	□	□	□															
9			InH ₂ O	9			InH ₂ O	□	■	□	□	□	□	□	□	□															
10			InH ₂ O	10			InH ₂ O	□	■	□	□	□	□	□	□	□															
<i>If more fields are required please add additional pages</i>																															
11. HEPA Filter Housing																															
	Serial Number / Serviced laboratory	Have HEPA filters been tested and certified within a year?		Decon ports present		Testing ports present		Bubble tight isolation dampers present		Redundant housing available		General condition of HEPA filter caisson																			
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Good	Bad																		
1																															
2																															
3																															