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Biosafety Level 3 Laboratory Certification Requirements

By;

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Introduction

Biosafety Level 3 (BSL-3/ABSL-3) containment laboratories for animals and research are the most difficult containment level facilities to design and operate. They 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, or fan motors) 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 (engineering controls, personal protective equipment, building and system integrity, standard operating procedures (SOPs) and administrative controls such as documentation and record retention systems). 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 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.

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.

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.

National Institutes of Health

Biosafety Level 3 Laboratory Certification Requirements

During the course of developing the certification criteria for a specific building, DOHS or the appropriate Division Technical Resources (DTR) authority may request an alternative to the design requirements 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 certification requirements but meets the intent and provides the level of containment required for the designated use of the facility.

The following is a list of critical areas to inspect or validate that testing has been completed prior to BSL-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.

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
 - Review architectural and mechanical drawings to ensure design intent is being met
 - 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 lab procedures

2. Inspect and Evaluate
 - Finishes, penetrations & caulking integrity for architectural elements such as doors, around the ceilings, 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

National Institutes of Health

Biosafety Level 3 Laboratory Certification Requirements

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 labs in relation to BSL-2 support labs, offices and break rooms, elevators, loading docks, etc. for effects on laboratory pressurization and airflow. This includes operational condition of doors.
 - Presence of an anteroom w/ or w/o a shower
 - Storage provided for donning clean protective clothing and safety equipment (e.g. Powered Air Purifying Respirators)
 - 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 lab director
 - Special requirements such as required use of PPEs, 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

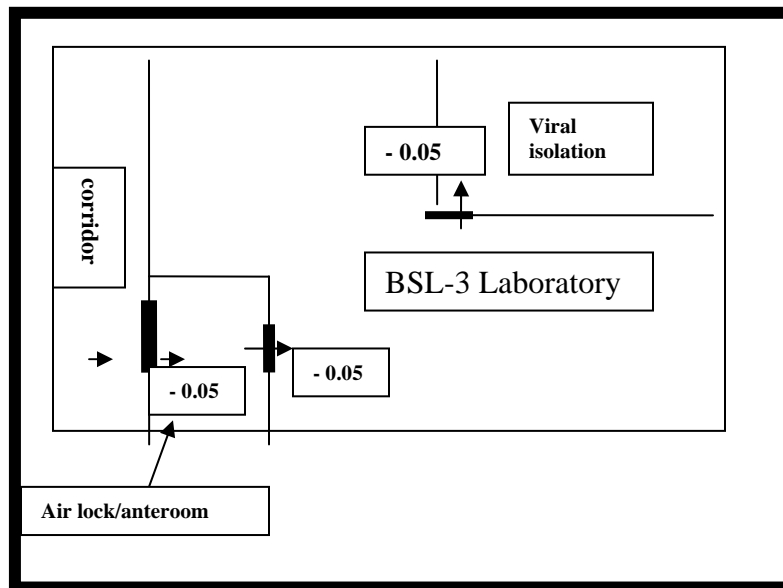
II. Validation of Engineering Controls

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 air flow
3. Measure directional air flow, pressure relationships, air changes and record data

National Institutes of Health Biosafety Level 3 Laboratory Certification Requirements

- Directional air flow must be established from clean areas into contaminated areas. In the event that multiple containment zones exist within a laboratory or laboratory suite, sequentially more negative pressure differentials must be established so 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. In no case should the differential be less than -0.03 in. WG (-7.6 Pa) when the door is closed.

Example:



** Figure Provided For Illustration Purposes Only **

- 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:
 - Normal operations → emergency power
 - Emergency power → 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 return 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

Ensure that laboratories are maintained at negative pressure with respect to less contaminated areas.

National Institutes of Health

Biosafety Level 3 Laboratory Certification Requirements

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 biological safety cabinets 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
 - 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
 - Interlocks required
 - Check operability
 - Open and close doors in all possible sequences
 - Ensure that delay set points are tight enough to preclude inadvertent over ride of interlock
9. Test all alarms
 - HVAC Failure Alarm
 - Availability of air flow alarms showing if the room has gone positive under normal conditions or if door is open for greater than 20 seconds.
 - Availability of a visual indication for personnel to be aware if the room is under positive or negative pressure prior to entering into the lab
 - Review fire alarm annual documentation
 - Review security alarm annual documentation

National Institutes of Health

Biosafety Level 3 Laboratory Certification Requirements

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
- Is all aerosol-producing equipment exhausted by certified HEPA filtration devices?
 - 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
- Measure supply and exhaust air volumes using a device calibrated annually
- Calculate ACR; monitor trends
- In no case should the ACR be less than 6/hr for labs and 10/hr for animal facilities

12. Review biological safety cabinet (BSC) certification data including serial number validation

- 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
 - Decon and challenge ports
 - Scanning access

13. Validate MEP

- Inspect for adequate illumination
- Verify that circuit breakers are outside of containment
- Backflow prevention for lab water system
- Sinks and drains properly marked
- 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.

National Institutes of Health

Biosafety Level 3 Laboratory Certification Requirements

- Validate provision for dedicated vacuum pump, if present
- Inspect effluent decontamination system, if present

14. Validate autoclave availability, operations and bioseal integrity

- Test interlocks
- Confirm cycle –test load
- Visually inspect bioseal
- Smoke test bioseal
- Validate maintenance of sterilization temp. of 121 degrees for 60 minutes.
- Autoclave-out capability directly from the BSL-3 facility in new facilities
- In older facilities where autoclave-out may not be available, an autoclave must be available near the BSL-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

III. Review SOPs

1. Autoclave & Decontamination

- To decontaminate materials before removing them from the biosafety cabinet
- If an autoclave is available near but outside the BSL-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 PPEs
- Assess procedures for decon 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

National Institutes of Health

Biosafety Level 3 Laboratory Certification Requirements

2. Safety SOPs

- Identification of responsible official for BSL-3 facility
- Certification of all personnel working within containment and process used to certify them
- Use, storage and disposal of Personal Protective Equipment
- Documented limited personnel access to facility
- Procedures for maintenance to enter facility
- Hand washing procedures are in place
- 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 are in place
- Training program is in place and documentation available for training and refresher courses of all personnel allowed in the BSL-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 standard operating procedures
- 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), if appropriate

- Blood/ Serum Storage
- 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 agents or materials are used or stored

4. Biohazardous Materials Use Authorization (e.g., Human Pathogen Registration, Recombinant DNA Registration, Select Agent, etc.)

- Current BUA
- 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 A

NIH BSL-3 Certification Checklist

Date: _____ **Contact:** _____

Building: _____ **Telephone:** _____

Room #: _____ **Inspector:** _____

Initial (I): * **Determination must be made as to requirement for initial and / or annual validation**

Annual (A):

A/I

I. Administrative Controls

NOTES

1	Review and Assess Background materials					
A.	SOPs for document retention, maintenance and lab procedures	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A		
B.	Commissioning Report	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A		
C.	Architectural and mechanical drawings to ensure design intent is being met	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A		
D.	Biosafety policies and procedures (SOPs) for the laboratory (facility) including training of occupants and maintenance staff	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A		
E.	Hazardous (infectious) waste management procedures	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A		
F.	Integrated pest management program	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A		
G.	Administrative and engineering procedures to determine if they meet the needs of the program	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A		
H.	Laboratory accident response protocols	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A		
I.	Decontamination procedures for appropriateness with respect to the protocols being conducted or anticipated	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A		

Attachment A NIH BSL-3 Certification Checklist

NOTES

2	Inspect, & Evaluate Architectural Features for Maintenance, Operations (Finishes, penetrations & caulking integrity such as doors, around the ceilings, lighting fixtures, electrical devices, etc. within containment to meet requirements for:						
	A.	Clean-ability of all surfaces including furniture		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	B.	Smoothness of all surfaces		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	C.	Sealed seams and penetrations		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	D.	Monolithic, slip resistant floors		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	E.	Surface impermeability to liquids		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	F.	Resistance of surfaces to chemicals (organic solvents, acids, alkalis,), disinfectants and moderate heat		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	G.	Gas tightness for decontamination		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	H.	Pest management requirements		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	I.	Non-operable windows		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	J.	Bioseals		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
3	Inspection of room layout, placement of equipment and equipment condition						
4	Autoclave verification testing procedures ; inspect logs						
5	Access control and exit procedures						
6	Evaluate availability of:						
	A.	Emergency equipment		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	B.	Emergency two way communication system		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	

Attachment A NIH BSL-3 Certification Checklist

NOTES

	C.	System provided for electronic transfer of information to outside of containment		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	D.	Emergency lighting		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	E.	Working fire extinguisher		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	F.	Chemical spill kit within containment		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
7	Evaluate redundancy requirements (e.g. air handling units exhaust fans, decontamination system components)			<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
8	Assess location of BSL-3 labs in relation to BSL-2 support labs, offices, break rooms, elevators, loading docks, etc. for effects on laboratory pressurization and airflow. This includes operational condition of doors.			<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
9	Presence of an anteroom w/ or w/o a shower						
	A.	Storage provided for donning clean protective clothing and safety equipment (e.g., PAPR)		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
	B.	Hands-free sink located near exit of laboratory		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
10	Office location outside of containment			<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
11	Inspect signage and visual documentation for proper posting:						
	A.	Biohazard sign		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
	B.	List of agents used		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
	C.	Names and telephone number for lab director		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
	D.	Special requirements such as required use of PPEs, personnel immunizations, etc.		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
	E.	Review list of all mechanical controls and their locations		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
	F.	Review start up and shut down procedures in case of emergency		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
12	Evaluate maintenance frequency and review maintenance logs						

Attachment A NIH BSL-3 Certification Checklist

NOTES

A.	Autoclaves		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
B.	BSC filters		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
C.	Centrifuges		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
D.	Door / equipment locks		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
E.	HVAC balancing		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
F.	HVAC belts		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
G.	HVAC Motors / Sheaves		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
H.	Lights		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
I.	Plumbing		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	

II. Validation of Engineering Controls

13	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)		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
14	Ensure single pass air flow		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
15	Measure directional air flow, pressure relationships, air changes and record data		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
16	Ensure directional air flow is established from clean areas into contaminated areas.					

Attachment A NIH BSL-3 Certification Checklist

NOTES

	A.	If multiple containment zones exist within a laboratory or laboratory suite, ensure that sequentially more negative pressure differentials are established so that the more contaminated spaces are maintained at a negative pressure with respect to less contaminated areas.		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	B.	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		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
17	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:						
	A.	Normal operations -> emergency power		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	B.	Emergency power -> normal operations		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	C.	Loss of supply fans (individual and in combination)		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	D.	Loss of exhaust fans (individual and in combination)		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
18	Building automation system maintains operational set points during all scenarios and return to normal operations						
19	Upon reboot BAS must retain operational set points						
20	If an uninterrupted power supply (UPS) is installed, verify						
21	Assess if UPS is operational		I+A	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
22	Provide UPS for BAS						
23	Assess HVAC equipment condition. Visually inspect the following:						
	A.	Belts	I	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	B.	Belt guards	I	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	

Attachment A NIH BSL-3 Certification Checklist

NOTES

	C.	Wiring	I	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	D.	Duct supports and connections		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	E.	Guide wires (if applicable)		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	F.	Dilution air dampers (if applicable)		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	G.	Bearings (high pitched squealing)		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	H.	Ductwork system workmanship, damage, etc.		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
24	Ensure that motor operating temperatures are maintained within equipment specifications			<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
25	Ensure that interlock between supply and exhaust is operational			<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
26	Verify correct placement of biological safety cabinets with respect to supply and exhaust diffusers, doors and traffic patterns			<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
27	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			<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
28	Perform smoke tests to demonstrate directional airflow						
	A.	Doors		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	B.	Vents		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	C.	Windows		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	D.	Autoclave		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	E.	Other vented areas		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
29	Inspect and challenge door interlock systems and automatic door closers						
	A.	Door closers are required		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	

Attachment A NIH BSL-3 Certification Checklist

NOTES

	B.	Ensure that doors automatically close and latch		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	C.	Interlocks required		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	D.	Check operability		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
30	Open and close doors in all possible sequences			<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
31	Ensure that delay set points are tight enough to preclude inadvertent over ride of interlock			<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
32	Test all alarms						
	A.	HVAC Failure Alarm		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	B.	Availability of air flow alarms showing if the room has gone positive under normal conditions or if door is open for greater than 20 seconds		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	C.	Availability of a visual indication for personnel to be aware if the room is under positive or negative pressure prior to entering into the lab		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	D.	Review fire alarm annual documentation		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	E.	Review security alarm annual documentation		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
33	Discharge exhaust assessment (as a measure of performance)			<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
34	Inspect rooftop landscape for re-entrainment opportunities						
	A.	Min. 25 ft. from intake, 40 ft from boiler stacks, 15 ft from plumbing stacks		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
35	Laboratory exhaust stacks - minimum 3m height above highest point on roof			<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
36	Check exhaust stack locations and discharge velocities			<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
37	Exhaust velocity = 15-20 m/s or 3000-4000 fpm			<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	

Attachment A NIH BSL-3 Certification Checklist

NOTES

38	All aerosol-producing equipment exhausted by certified HEPA filtration devices		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
39	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		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
40	Ensure that discharge of local exhaust ventilation (LEV) devices is removed from air intakes to prevent re-entrainment		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
41	Consider local conditions (e.g., HEPA filters on exhaust)		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
42	Verification of air change rates (ACR) in containment spaces					
A.	ACR is determined during design based on sensible and latent heat loads contaminants and odors that require containment space usage		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
B.	Measure supply and exhaust air volumes using a device calibrated annually		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
C.	Calculate ACR; monitor trends		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
D.	In no case should the ACR be less than 6/hr for labs and 10/hr for animal facilities		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
43	Review biological safety cabinet (BSC) certification data including serial number validation					
A.	BSCs must be on an annual certification schedule		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
B.	Verify that BSCs are located away from doors and vents		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
C.	Verify that installation of BSC is correct for cabinet type		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
D.	Inspect HEPA filter installations		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
E.	Review certification documentation for all exhaust HVAC HEPA installations		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
F.	Verify that HEPA filters are on portable vacuum systems at point of use and at the barrier		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	

Attachment A NIH BSL-3 Certification Checklist

NOTES

44	Visually inspect					
	A.	Isolation valves for decon		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	B.	Decon and challenge ports		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	C.	Scanning access		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
45	Validate MEP					
	A.	Inspect for adequate illumination		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	B.	Verify that circuit breakers are outside of containment		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	C.	Backflow prevention for lab water system		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	D.	Sinks and drains properly marked		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	E.	Availability of emergency power for critical systems		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	F.	Availability of hands free emergency eyewash		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	G.	Availability of emergency shower		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	H.	Caulking and sealing requirements for electrical devices such as conduits, boxes, lights, etc.		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	I.	Validate provision for dedicated vacuum pump		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	J.	Inspect effluent decontamination system, if present		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
46	Validate autoclave availability, operations and bioseal integrity					
	A.	Test interlocks		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	B.	Confirm cycle – test load		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	C.	Visually inspect bioseal		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A
	D.	Smoke test bioseal		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A

Attachment A NIH BSL-3 Certification Checklist

NOTES

E.	Validate maintenance of sterilization temp. of 121 degrees for 60 minutes		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
F.	Autoclave-out capability directly from the BSL-3 facility in new facilities		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
G.	In older facilities if autoclave-out is not available, an autoclave must be available near the BSL-3 facility so that containment of biohazardous waste is maintained.		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
H.	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		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	

III. Review SOPs

47	Autoclave & Decontamination					
A.	To decontaminate materials before removing them from the biosafety cabinet		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
B.	If an autoclave is available near but outside the BSL-3 facility, ensure adequate decontamination procedures in place for wet and dry biohazardous materials that leave the facility		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
C.	Assess the travel route to nearest autoclave avoid public corridors		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
D.	Assess procedures for use of and disposal of PPEs		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
E.	Assess procedures for decon of equipment that leaves the facility for repair or discontinuation of use		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
F.	Review storage and transport of biohazardous materials		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	

Attachment A NIH BSL-3 Certification Checklist

NOTES

	G.	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	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	H.	Validate schedule and frequency of changing HVAC filters on vacuum lines	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
48	Safety SOPs					
	A.	Identification of responsible official for BSL-3 facility	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	B.	Certification of all personnel working within containment and process used to certify them	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	C.	Use, storage and disposal of Personal Protective Equipment (PPE)	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	D.	Documented limited personnel access to facility	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	E.	Procedures for maintenance to enter facility	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	F.	Hand washing procedures	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	G.	Use of mechanical pipetting devices; NO mouth pipetting	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	H.	Use of sharps prohibited unless absolutely required and then use should be managed by protocol	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	I.	Procedures to minimize production of aerosols	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	J.	Decontamination procedures	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	K.	Training program and documentation available for training and refresher courses of all personnel allowed in the BSL-3 facility	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	L.	Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	M.	A biosafety manual specific to the laboratory has been prepared and adopted	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	N.	Biosafety precautions are incorporated into standard operating procedures	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	

Attachment A NIH BSL-3 Certification Checklist

NOTES

	O.	If animals are housed under ABSL-3 conditions, all animal specific regulations and biosafety procedures are followed		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
49	Occupational Health Monitoring (Policy and records of implementation), if appropriate						
	A.	Blood/ Serum Storage		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	B.	Vaccinations		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	C.	High-risk (immune suppressed, pregnant, etc.) individuals		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	D.	Health screening		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	E.	Annual updates of Exposure Control Plan to include documentation of all locations where BSL-3 agents or materials are used or stored		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
50	Biohazardous Materials Use Authorization (e.g., Human Pathogen Registration, Recombinant DNA Registration, Select Agent, etc.)						
	A.	Current BUA		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	B.	Symptomology page		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	
	C.	Procedures for how samples are received		<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	

Attachment B

Equivalency Request Procedure for BSL-3 Lab Certification

1.0 Purpose

This procedure defines the steps for requesting, reviewing and resolving equivalency requests for a BSL-3 Lab 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, providing 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 the Division of Occupational Health and Safety (DOHS) and the Division of Technical Recourses (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 Procedures

- 4.1 The NIH Accredited Certifying Agent identifies a need for an alternative to the certification requirements and fills out the Equivalency Request Form.
- 4.2 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.

- 4.3 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.
- 4.4 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.
- 4.5 The NIH Equivalency Coordinator reads and logs the request and forwards it to the discipline appropriate reviewer(s).
- 4.6 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.
- 4.7 The NIH Equivalency Coordinator logs the response and returns the form complete with the reviewer's response back to the NIH Accredited Certifying Agent.
- 4.8 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
- Biosafety Level-3 Certification Requirements
- Biosafety Level-3 Certification Checklist

6.0 Records

- Equivalency Request

REQUEST FOR EQUIVALENCY

Equivalency Tracking Number:

_____	To:	_____	_____
Drawing Reference:		NIH Equivalency Coordinator	Phone
_____	From:	_____	_____
Detail Number:		NIH Accredited Certification Agent	Date
_____		_____	_____
Spec. Section Reference:		Contact	Phone Fax
_____		_____	_____
Paragraph # in NIH Design Requirements:		Equivalency Subject	
Campus	On	Off	New Construction Yes No
Type e.g. lab, animal, office, BSL level			

Project Title _____	Estimated Construction Cost ____
Building Number _____	Project Percent Completed ____
Location _____	Other _____

Describe Equivalency. State specifically how it deviates from the design requirements, how it improves the existing condition and the advantage to implementing. Provide hard copy supporting documents as necessary to Equivalency Coordinator: (Use additional Sheet if necessary)

Provide recommendation of discipline or disciplines to review Equivalency; i.e. mechanical, electrical, architect, civil, structural, fire protection or other:

For NIH Use Only

- Approve Equivalency Request
- Deny Equivalency Request

Director
Div. of Occupational Safety and Health

Director
Div. of Technical Resources