Inspection Checklist for BSL-4 Laboratories (7 CFR 331; 9 CFR 121; 42 CFR 73; BMBL 5th Edition)

Entity Name:
Inspection Date:
Street Address:
City, State, Zip:
RO:
ARO(s):

Lead Inspector:
Other Inspectors:

Building/Room(s):

PI(s):

HHS Agents:

Overlap Agents:

USDA Agents:

When information is entered in this form, the form is to be considered Sensitive Select Agent Information.

Entity Name:		**Inspection Date:**			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
CFR: Section 12(a)	An individual or entity required to register under this part must develop and implement a written biosafety (biocontainment) plan that is commensurate with the risk of the select agent or toxin, given its intended use.	☐	☐	☐	
CFR: Section 12(a)	The biosafety (biocontainment) plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent.	☐	☐	☐	
CFR: Section 12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	☐	☐	☐	
CFR: Section 12 (c)(1)	In developing a biosafety plan, an individual or entity should consider: The CDC/NIH publication, Biosafety in Microbiological and Biomedical Laboratories. This document is available on the National Select Agent Registry website at http://www.selectagents.gov/.	☐	☐	☐	
CFR: Section 12(d)	The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
CFR: Section 12(e)	The plan must be reviewed annually and revised as necessary.	☐	☐	☐	
CFR: Section 12(e)	Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan.	☐	☐	☐	
CFR: Section 12(e)	The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.	☐	☐	☐	
42 CFR 73: Section 13 (a)	An individual or entity may not conduct or possess products (i.e., select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from, a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary.	☐	☐	☐	
42 CFR 73: Section 13 (a)	In addition, an individual or entity may not conduct or possess products (i.e., select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from, a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary, after consultation with Administrator.	☐	☐	☐	
9 CFR 121: Section13(a)	An individual or entity may not conduct or possess products (i.e., select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator:	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
A					
BMBL: A1	The laboratory supervisor must enforce the institutional policies that control access to the laboratory.	☐	☐	☐	
BMBL: A2	Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas.	☐	☐	☐	
BMBL: A2	Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.	☐	☐	☐	
BMBL: A3	Mechanical pipetting devices must be used.	☐	☐	☐	
BMBL: A4	Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented.	☐	☐	☐	
BMBL: A5	**Precautions, including those listed below, must be taken with any sharp items. These include:**				
BMBL: A5-a	Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps.	☐	☐	☐	
BMBL: A5-a	Plasticware should be substituted for glassware whenever possible.	☐	☐	☐	
BMBL: A5-b	Use of needles and syringes or other sharp instruments should be restricted in the laboratory, except when there is no practical alternative.	☐	☐	☐	
BMBL: A5-c	Used needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal or decontamination.	☐	☐	☐	
BMBL: A5-c	Used disposable needles must be carefully placed in puncture-resistant containers used for sharps disposal, located as close to the point of use as possible.	☐	☐	☐	
BMBL: A5-d	Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: A6	Perform all procedures to minimize the creation of splashes and/ or aerosols.	☐	☐	☐	
BMBL: A7	Decontaminate work surfaces with appropriate disinfectant after completion of work and after any spill or splash of potentially infectious material.	☐	☐	☐	
BMBL: A8	Decontaminate all wastes before removal from the laboratory by an effective and validated method.	☐	☐	☐	
BMBL: A9	A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present.	☐	☐	☐	
BMBL: A9	Posted information must include the laboratory's biosafety level, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory.	☐	☐	☐	
BMBL: A9	Agent information should be posted in accordance with the institutional policy.	☐	☐	☐	
BMBL: A10	An effective integrated pest management program is required. See Appendix G of BMBL.	☐	☐	☐	
BMBL: A11	The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures.	☐	☐	☐	
BMBL: A11	Personnel must receive annual updates or additional training when procedural or policy changes occur.	☐	☐	☐	
BMBL: A11	Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
B					
BMBL: B1	All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements in accordance with institutional policies.	☐	☐	☐	
BMBL: B1	Only persons whose presence in the facility or individual laboratory rooms is required for scientific or support purposes should be authorized to enter.	☐	☐	☐	
BMBL: B1	Entry into the facility must be limited by means of secure, locked doors.	☐	☐	☐	
BMBL: B1	A logbook, or other means of documenting the date and time of all persons entering and leaving the laboratory must be maintained.	☐	☐	☐	
BMBL: B1	While the laboratory is operational, personnel must enter and exit the laboratory through the clothing change and shower rooms except during emergencies.	☐	☐	☐	
BMBL: B1	All personal clothing must be removed in the outer clothing change room.	☐	☐	☐	
BMBL: B1	Laboratory clothing, including undergarments, pants, shirts, jumpsuits, shoes, and gloves, must be used by all personnel entering the laboratory.	☐	☐	☐	
BMBL: B1	All persons leaving the laboratory must take a personal body shower. Used laboratory clothing must not be removed from the inner change room through the personal shower. These items must be treated as contaminated materials and decontaminated before laundering.	☐	☐	☐	
BMBL: B1	After the laboratory has been completely decontaminated, necessary staff may enter and exit without following the clothing change and shower requirements described above.	☐	☐	☐	
BMBL: B2	Laboratory personnel and support staff must be provided appropriate occupational medical service including medical surveillance and available immunizations for agents handled or potentially present in the laboratory.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: B2	A system must be established for reporting and documenting laboratory accidents, exposures, employee absenteeism and for the medical surveillance of potential laboratory-associated illnesses. An essential adjunct to such an occupational medical services system is the availability of a facility for the isolation and medical care of personnel with potential or known laboratory-acquired infections.	☐	☐	☐	
BMBL: B3	Each institution must establish policies and procedures describing the collection and storage of serum samples from at-risk personnel.	☐	☐	☐	
BMBL: B4	A laboratory-specific biosafety manual must be prepared. The biosafety manual must be available, accessible, and followed.	☐	☐	☐	
BMBL: B5-a	The laboratory supervisor is responsible for ensuring that laboratory personnel: Demonstrate high proficiency in standard and special microbiological practices, and techniques for working with agents requiring BSL-4 containment.	☐	☐	☐	
BMBL: B5-b	The laboratory supervisor is responsible for ensuring that laboratory personnel: Receive appropriate training in the practices and operations specific to the laboratory facility.	☐	☐	☐	
BMBL: B5-c	The laboratory supervisor is responsible for ensuring that laboratory personnel: Receive annual updates or additional training when procedural or policy changes occur.	☐	☐	☐	
BMBL: B6	Removal of biological materials that are to remain in a viable or intact state from the laboratory must be transferred to a non-breakable, sealed primary container and then enclosed in a non-breakable, sealed secondary container.	☐	☐	☐	
BMBL: B6	These materials must be transferred through a disinfectant dunk tank, fumigation chamber, or decontamination shower.	☐	☐	☐	
BMBL: B6	Once removed, packaged viable material must not be opened outside BSL-4 containment unless inactivated by a validated method.	☐	☐	☐	
BMBL: B7	Laboratory equipment must be routinely decontaminated, as well as after spills, splashes, or other potential contamination.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: B7-a	Spills involving infectious materials must be contained, decontaminated, and cleaned up by appropriate professional staff, or others properly trained and equipped to work with infectious material.	☐	☐	☐	
BMBL: B7-a	A spill procedure must be developed and posted within the laboratory.	☐	☐	☐	
BMBL: B7-b	Equipment must be decontaminated using an effective and validated method before repair, maintenance, or removal from the laboratory.	☐	☐	☐	
BMBL: B7-b	The interior of the Class III cabinet as well as all contaminated plenums, fans and filters must be decontaminated using a validated gaseous or vapor method.	☐	☐	☐	
BMBL: B7-c	Equipment or material that might be damaged by high temperatures or steam must be decontaminated using an effective and validated procedure such as a gaseous or vapor method in an airlock or chamber designed for this purpose.	☐	☐	☐	
BMBL: B8	Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety manual.	☐	☐	☐	
BMBL: B8	All incidents must be reported to the laboratory supervisor, institutional management and appropriate laboratory personnel as defined in the laboratory biosafety manual.	☐	☐	☐	
BMBL: B8	Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.	☐	☐	☐	
BMBL: B9	Animals and plants not associated with the work being performed must not be permitted in the laboratory.	☐	☐	☐	
BMBL: B10	Supplies and materials that are not brought into the BSL-4 laboratory through the change room, must be brought in through a previously decontaminated double-door autoclave, fumigation chamber, or airlock.	☐	☐	☐	
BMBL: B10	After securing the outer doors, personnel within the laboratory retrieve the materials by opening the interior doors of the autoclave, fumigation chamber, or airlock.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: B10	These doors must be secured after materials are brought into the facility.	☐	☐	☐	
BMBL: B10	The doors of the autoclave are interlocked in a manner that prevents opening of the outer door unless the autoclave has been operated through a decontamination cycle.	☐	☐	☐	
BMBL: B10	The doors of a fumigation chamber must be secured in a manner that prevents opening of the outer door unless the fumigation chamber has been operated through a fumigation cycle.	☐	☐	☐	
BMBL: B10	Only necessary equipment and supplies should be stored inside the BSL-4 laboratory.	☐	☐	☐	
BMBL: B10	All equipment and supplies taken inside the laboratory must be decontaminated before removal from the facility.	☐	☐	☐	
BMBL: B11	Daily inspections of essential containment and life support systems must be completed and documented before laboratory work is initiated to ensure that the laboratory is operating according to established parameters.	☐	☐	☐	
BMBL: B12	Practical and effective protocols for emergency situations must be established.	☐	☐	☐	
BMBL: B12	These protocols must include plans for medical emergencies, facility malfunctions, fires, escape of animals within the laboratory, and other potential emergencies.	☐	☐	☐	
BMBL: B12	Training in emergency response procedures must be provided to emergency response personnel and other responsible staff according to institutional policies.	☐	☐	☐	
C					
BMBL: C(A)	**Cabinet Laboratory**	☐	☐	☐	
BMBL: C(A)1	All manipulations of infectious materials within the facility must be conducted in the Class III biological safety cabinet.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: C(A)1	Double-door, pass through autoclaves must be provided for decontaminating materials passing out of the Class III BSC(s).	☐	☐	☐	
BMBL: C(A)1	The autoclave doors must be interlocked so that only one can be opened at any time and be automatically controlled so that the outside door to the autoclave can only be opened after the decontamination cycle has been completed.	☐	☐	☐	
BMBL: C(A)1	The Class III cabinet must also have a pass-through dunk tank, fumigation chamber, or equivalent decontamination method so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the cabinet.	☐	☐	☐	
BMBL: C(A)1	Containment must be maintained at all times.	☐	☐	☐	
BMBL: C(A)1	The Class III cabinet must have a HEPA filter on the supply air intake and two HEPA filters in series on the exhaust outlet of the unit.	☐	☐	☐	
BMBL: C(A)1	There must be gas tight dampers on the supply and exhaust ducts of the cabinet to permit gas or vapor decontamination of the unit.	☐	☐	☐	
BMBL: C(A)1	Ports for injection of test medium must be present on all HEPA filter housings.	☐	☐	☐	
BMBL: C(A)1	The interior of the Class III cabinet must be constructed with smooth finishes that can be easily cleaned and decontaminated.	☐	☐	☐	
BMBL: C(A)1	All sharp edges on cabinet finishes must be eliminated to reduce the potential for cuts and tears of gloves.	☐	☐	☐	
BMBL: C(A)1	Equipment to be placed in the Class III cabinet should also be free of sharp edges or other surfaces that may damage or puncture the cabinet gloves.	☐	☐	☐	
BMBL: C(A)1	Class III cabinet gloves must be inspected for leaks periodically and changed if necessary.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: C(A)1	Gloves should be replaced annually during cabinet recertification.	☐	☐	☐	
BMBL: C(A)1	The cabinet should be designed to permit maintenance and repairs of cabinet mechanical systems (refrigeration, incubators, centrifuges, etc.) to be performed from the exterior of the cabinet whenever possible.	☐	☐	☐	
BMBL: C(A)1	Manipulation of high concentrations or large volumes of infectious agents within the Class III cabinet should be performed using physical containment devices inside the cabinet whenever practical.	☐	☐	☐	
BMBL: C(A)1	Such materials should be centrifuged inside the cabinet using sealed rotor heads or centrifuge safety cups.	☐	☐	☐	
BMBL: C(A)1	The Class III cabinet must be certified at least annually.	☐	☐	☐	
BMBL: C(A)2	Protective laboratory clothing with a solid-front such as tie-back or wraparound gowns, scrub suits, or coveralls must be worn by workers when in the laboratory.	☐	☐	☐	
BMBL: C(A)2	No personal clothing, jewelry, or other items except eyeglasses should be taken past the personal shower area.	☐	☐	☐	
BMBL: C(A)2	All protective clothing must be removed in the dirty side change room before showering.	☐	☐	☐	
BMBL: C(A)2	Reusable clothing must be autoclaved before being laundered.	☐	☐	☐	
BMBL: C(A)3	Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.	☐	☐	☐	
BMBL: C(A)3	Prescription eyeglasses must be decontaminated before removal through the personal body shower.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: C(A)4	Gloves must be worn to protect against breaks or tears in the cabinet gloves.	☐	☐	☐	
BMBL: C(A)4	Gloves must not be worn outside the laboratory.	☐	☐	☐	
BMBL: C(A)4	Alternatives to latex gloves should be available.	☐	☐	☐	
BMBL: C(A)4	Do not wash or reuse disposable gloves.	☐	☐	☐	
BMBL: C(A)4	Dispose of used gloves with other contaminated laboratory waste.	☐	☐	☐	
BMBL: C(B)	**Suit Laboratory**				
BMBL: C(B)1	All procedures must be conducted by personnel wearing a one-piece positive pressure suit ventilated with a life support system.	☐	☐	☐	
BMBL: C(B)1	All manipulations of infectious agents must be performed within a BSC or other primary barrier system.	☐	☐	☐	
BMBL: C(B)1	Equipment that may produce aerosols must be contained in devices that exhaust air through HEPA filtration before being discharged into the laboratory.	☐	☐	☐	
BMBL: C(B)1	These HEPA filters should be tested annually and replaced as needed.	☐	☐	☐	
BMBL: C(B)1	HEPA filtered exhaust air from a Class II BSC can be safely re-circulated into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's specifications.	☐	☐	☐	
BMBL: C(B)2	Protective laboratory clothing such as scrub suits must be worn by workers before entering the room used for donning positive pressure suits.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: C(B)2	All protective clothing must be removed in the dirty side change room before entering the personal shower.	☐	☐	☐	
BMBL: C(B)2	Reusable laboratory clothing must be autoclaved before being laundered.	☐	☐	☐	
BMBL: C(B)3	Inner gloves must be worn to protect against break or tears in the outer suit gloves.	☐	☐	☐	
BMBL: C(B)3	Disposable gloves must not be worn outside the change area.	☐	☐	☐	
BMBL: C(B)3	Alternatives to latex gloves should be available.	☐	☐	☐	
BMBL: C(B)3	Do not wash or reuse disposable gloves.	☐	☐	☐	
BMBL: C(B)3	Inner gloves must be removed and discarded in the inner change room prior to personal shower.	☐	☐	☐	
BMBL: C(B)3	Dispose of used gloves with other contaminated waste.	☐	☐	☐	
BMBL: C(B)4	Decontamination of outer suit gloves is performed during operations to remove gross contamination and minimize further contamination of the laboratory.	☐	☐	☐	
D					
BMBL: There are two models for Biosafety Level 4 laboratories: (A) the Cabinet Laboratory where all handling of the agent is performed in a Class III Biological Safety Cabinet, and (B) the Suit Laboratory where personnel wear a protective suit. Biosafety Level-4 laboratories may be based on either model or a combination of both models in the same facility. If a combination is used, each type must meet all the requirements identified for that type.					
BMBL: D(A)	**Cabinet Laboratory**				
BMBL: D(A)1	The BSL-4 cabinet laboratory consists of either a separate building or a clearly demarcated and isolated zone within a building.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D(A)1	Laboratory doors must have locks in accordance with the institutional policies.	☐	☐	☐	
BMBL: D(A)1	Rooms in the facility must be arranged to ensure sequential passage through an inner (dirty) changing area, a personal shower and an outer (clean) change room prior to exiting the room(s) containing the Class III BSC(s).	☐	☐	☐	
BMBL: D(A)1	An automatically activated emergency power source must be provided at a minimum for the laboratory exhaust system, life support systems, alarms, lighting, entry and exit controls, BSCs, and door gaskets.	☐	☐	☐	
BMBL: D(A)1	Monitoring and control systems for air supply, exhaust, life support, alarms, entry and exit, and security systems should be on an uninterrupted power supply (UPS).	☐	☐	☐	
BMBL: D(A)1	A double-door autoclave, dunk tank, fumigation chamber, or ventilated anteroom/airlock must be provided at the containment barrier for the passage of materials, supplies, or equipment.	☐	☐	☐	
BMBL: D(A)2	A hands-free sink must be provided near the door of the cabinet room(s) and the inner change room.	☐	☐	☐	
BMBL: D(A)2	A sink must be provided in the outer change room.	☐	☐	☐	
BMBL: D(A)2	All sinks in the room(s) containing the Class III BSC and the inner (dirty) change room must be connected to the wastewater decontamination system.	☐	☐	☐	
BMBL: D(A)3	Walls, floors, and ceilings of the laboratory must be constructed to form a sealed internal shell to facilitate fumigation and prohibit animal and insect intrusion.	☐	☐	☐	
BMBL: D(A)3	The internal surfaces of this shell must be resistant to liquids and chemicals used for cleaning and decontamination of the area.	☐	☐	☐	
BMBL: D(A)3	Floors must be monolithic, sealed and coved.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D(A)3	All penetrations in the internal shell of the laboratory and inner change room must be sealed.	☐	☐	☐	
BMBL: D(A)3	Openings around doors into the cabinet room and inner change room must be minimized and capable of being sealed to facilitate decontamination.	☐	☐	☐	
BMBL: D(A)3	Drains in the laboratory floor (if present) must be connected directly to the liquid waste decontamination system.	☐	☐	☐	
BMBL: D(A)3	Services, plumbing or otherwise that penetrate the laboratory walls, floors, ceiling, plumbing or otherwise, must ensure that no backflow from the laboratory occurs.	☐	☐	☐	
BMBL: D(A)3	These penetrations must be fitted with two (in series) backflow prevention devices. Consideration should be given to locating these devices outside of containment.	☐	☐	☐	
BMBL: D(A)3	Atmospheric venting systems must be provided with two HEPA filters in series and be sealed up to the second filter.	☐	☐	☐	
BMBL: D(A)3	Decontamination of the entire cabinet must be performed using a validated gaseous or vapor method when there have been significant changes in cabinet usage, before major renovations or maintenance shut downs, and in other situations, as determined by risk assessment.	☐	☐	☐	
BMBL: D(A)3	Selection of the appropriate materials and methods used for decontamination must be based on the risk assessment of the biological agents in use.	☐	☐	☐	
BMBL: D(A)4	Laboratory furniture must be of simple construction, capable of supporting anticipated loading and uses.	☐	☐	☐	
BMBL: D(A)4	Spaces between benches, cabinets, and equipment must be accessible for cleaning and decontamination.	☐	☐	☐	
BMBL: D(A)4	Chairs and other furniture should be covered with a non-porous material that can be easily decontaminated.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D(A)5	Windows must be break-resistant and sealed.	☐	☐	☐	
BMBL: D(A)6	If Class II BSCs are needed in the cabinet laboratory, they must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations.	☐	☐	☐	
BMBL: D(A)6	Class II cabinets should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.	☐	☐	☐	
BMBL: D(A)7	Central vacuum systems are not recommended. If, however, there is a central vacuum system, it must not serve areas outside the cabinet room.	☐	☐	☐	
BMBL: D(A)7	Two in-line HEPA filters must be placed near each use point.	☐	☐	☐	
BMBL: D(A)7	Filters must be installed to permit in-place decontamination and replacement.	☐	☐	☐	
BMBL: D(A)8	An eyewash station must be readily available in the laboratory.	☐	☐	☐	
BMBL: D(A)9	A dedicated non-recirculating ventilation system is provided.	☐	☐	☐	
BMBL: D(A)9	Only laboratories with the same HVAC requirements (i.e., other BSL-4 labs, ABSL-4, BSL-3 Ag labs) may share ventilation systems if each individual laboratory system is isolated by gas tight dampers and HEPA filters.	☐	☐	☐	
BMBL: D(A)9	The supply and exhaust components of the ventilation system must be designed to maintain the laboratory at negative pressure to surrounding areas and provide differential pressure/directional airflow between adjacent areas within the laboratory.	☐	☐	☐	
BMBL: D(A)9	Redundant supply fans are recommended. Redundant exhaust fans are required.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D(A)9	Supply and exhaust fans must be interlocked to prevent positive pressurization of the laboratory.	☐	☐	☐	
BMBL: D(A)9	The ventilation system must be monitored and alarmed to indicate malfunction or deviation from design parameters.	☐	☐	☐	
BMBL: D(A)9	A visual monitoring device must be installed near the clean change room so proper differential pressures within the laboratory may be verified prior to entry.	☐	☐	☐	
BMBL: D(A)9	Supply air to and exhaust air from the cabinet room, inner change room, and fumigation/decontamination chambers must pass through HEPA filter(s).	☐	☐	☐	
BMBL: D(A)9	The air exhaust discharge must be located away from occupied spaces and building air intakes.	☐	☐	☐	
BMBL: D(A)9	All HEPA filters should be located as near as practicable to the cabinet or laboratory in order to minimize the length of potentially contaminated ductwork.	☐	☐	☐	
BMBL: D(A)9	All HEPA filters must to be tested and certified annually.	☐	☐	☐	
BMBL: D(A)9	The HEPA filter housings should be designed to allow for in situ decontamination and validation of the filter prior to removal.	☐	☐	☐	
BMBL: D(A)9	The design of the HEPA filter housing must have gas-tight isolation dampers; decontamination ports; and ability to scan each filter assembly for leaks.	☐	☐	☐	
BMBL: D(A)10	HEPA filtered exhaust air from a Class II BSC can be safely re-circulated into the laboratory environment if the cabinet is tested and certified at least annually and operated according to the manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or a direct (hard) connection.	☐	☐	☐	
BMBL: D(A)10	Provisions to assure proper safety cabinet performance and air system operation must be verified.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D(A)10	Class III BSCs must be directly and independently exhausted through two HEPA filters in series.	☐	☐	☐	
BMBL: D(A)10	Supply air must be provided in such a manner that prevents positive pressurization of the cabinet.	☐	☐	☐	
BMBL: D(A)11	Pass through dunk tanks, fumigation chambers, or equivalent decontamination methods must be provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the cabinet room(s).	☐	☐	☐	
BMBL: D(A)11	Access to the exit side of the pass-through shall be limited to those individuals authorized to be in the BSL-4 laboratory.	☐	☐	☐	
BMBL: D(A)12	Liquid effluents from cabinet room sinks, floor drains, autoclave chambers, and other sources within the cabinet room must be decontaminated by a proven method, preferably heat treatment, before being discharged to the sanitary sewer.	☐	☐	☐	
BMBL: D(A)12	Decontamination of all liquid wastes must be documented.	☐	☐	☐	
BMBL: D(A)12	The decontamination process for liquid wastes must be validated physically and biologically.	☐	☐	☐	
BMBL: D(A)12	Biological validation must be performed annually or more often if required by institutional policy.	☐	☐	☐	
BMBL: D(A)12	Effluents from showers and toilets may be discharged to the sanitary sewer without treatment.	☐	☐	☐	
BMBL: D(A)13	A double-door, pass through autoclave(s) must be provided for decontaminating materials passing out of the cabinet laboratory.	☐	☐	☐	
BMBL: D(A)13	Autoclaves that open outside of the laboratory must be sealed to the primary wall.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D(A)13	This bioseal must be durable and airtight.	☐	☐	☐	
BMBL: D(A)13	Positioning the bioseal so that the equipment can be accessed and maintained from outside the laboratory is strongly recommended.	☐	☐	☐	
BMBL: D(A)13	The autoclave doors must be interlocked so that only one can be opened at any time and be automatically controlled so that the outside door to the autoclave can only be opened after the decontamination cycle has been completed.	☐	☐	☐	
BMBL: D(A)13	Gas and liquid discharge from the autoclave chamber must be decontaminated.	☐	☐	☐	
BMBL: D(A)13	When feasible, autoclave decontamination processes should be designed so that over-pressurization cannot release unfiltered air or steam exposed to infectious material to the environment.	☐	☐	☐	
BMBL: D(A)14	The BSL-4 facility design parameters and operational procedures must be documented.	☐	☐	☐	
BMBL: D(A)14	The facility must be tested to verify that the design and operational parameters have been met prior to operation.	☐	☐	☐	
BMBL: D(A)14	Facilities must also be re-verified annually.	☐	☐	☐	
BMBL: D(A)14	Verification criteria should be modified as necessary by operational experience.	☐	☐	☐	
BMBL: D(A)15	Appropriate communication systems must be provided between the laboratory and the outside (e.g., voice, fax, and computer).	☐	☐	☐	
BMBL: D(A)15	Provisions for emergency communication and access/egress must be considered.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D(B)	**Suit Laboratory**				
BMBL: D(B)1	The BSL-4 suit laboratory consists of either a separate building or a clearly demarcated and isolated zone within a building.	☐	☐	☐	
BMBL: D(B)1	Laboratory doors must have locks in accordance with the institutional policies.	☐	☐	☐	
BMBL: D(B)1	Rooms in the facility must be arranged to ensure exit by sequential passage through the chemical shower, inner (dirty) change room, personal shower, and outer (clean) changing area.	☐	☐	☐	
BMBL: D(B)1	Entry into the BSL-4 laboratory must be through an airlock fitted with airtight doors.	☐	☐	☐	
BMBL: D(B)1	Personnel who enter this area must wear a positive pressure suit with HEPA filtered breathing air.	☐	☐	☐	
BMBL: D(B)1	The breathing air systems must have redundant compressors, failure alarms and emergency backup.	☐	☐	☐	
BMBL: D(B)1	A chemical shower must be provided to decontaminate the surface of the positive pressure suit before the worker leaves the laboratory.	☐	☐	☐	
BMBL: D(B)1	In the event of an emergency exit or failure of chemical shower system a method for decontaminating positive pressure suits, such as a gravity fed supply of chemical disinfectant, is needed.	☐	☐	☐	
BMBL: D(B)1	An automatically activated emergency power source must be provided at a minimum for the laboratory exhaust system, life support systems, alarms, lighting, entry and exit controls, BSCs, and door gaskets.	☐	☐	☐	
BMBL: D(B)1	Monitoring and control systems for air supply, exhaust, life support, alarms, entry and exit, and security systems should be on a UPS.	☐	☐	☐	
BMBL: D(B)1	A double-door autoclave, dunk tank, or fumigation chamber must be provided at the containment barrier for the passage of materials, supplies, or equipment.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D(B)2	Sinks inside the suit laboratory should be placed near procedure areas and contain traps and be connected to the wastewater decontamination system.	☐	☐	☐	
BMBL: D(B)3	Walls, floors, and ceilings of the laboratory must be constructed to form a sealed internal shell to facilitate fumigation and prohibit animal and insect intrusion.	☐	☐	☐	
BMBL: D(B)3	The internal surfaces of this shell must be resistant to liquids and chemicals used for cleaning and decontamination of the area.	☐	☐	☐	
BMBL: D(B)3	Floors must be monolithic, sealed and coved.	☐	☐	☐	
BMBL: D(B)3	All penetrations in the internal shell of the laboratory, suit storage room and the inner change room must be sealed.	☐	☐	☐	
BMBL: D(B)3	Drains if present, in the laboratory floor must be connected directly to the liquid waste decontamination system.	☐	☐	☐	
BMBL: D(B)3	Sewer vents and other service lines must be protected by two HEPA filters in series and have protection against insect and animal intrusion.	☐	☐	☐	
BMBL: D(B)3	Services, plumbing or otherwise that penetrate the laboratory walls, floors, ceiling, plumbing or otherwise, must ensure that no backflow from the laboratory occurs. These penetrations must be fitted with two (in series) backflow prevention devices.	☐	☐	☐	
BMBL: D(B)3	Consideration should be given to locating these devices outside of containment.	☐	☐	☐	
BMBL: D(B)3	Atmospheric venting systems must be provided with two HEPA filters in series and be sealed up to the second filter.	☐	☐	☐	
BMBL: D(B)3	Decontamination of the entire laboratory must be performed using a validated gaseous or vapor method when there have been significant changes in laboratory usage, before major renovations or maintenance shut downs, and in other situations, as determined by risk assessment.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D(B)4	Laboratory furniture must be of simple construction, capable of supporting anticipated loading and uses.	☐	☐	☐	
BMBL: D(B)4	Sharp edges and corners should be avoided.	☐	☐	☐	
BMBL: D(B)4	Spaces between benches, cabinets, and equipment must be accessible for cleaning and decontamination.	☐	☐	☐	
BMBL: D(B)4	Chairs and other furniture should be covered with a non-porous material that can be easily decontaminated.	☐	☐	☐	
BMBL: D(B)5	Windows must be break-resistant and sealed.	☐	☐	☐	
BMBL: D(B)6	BSCs and other primary containment barrier systems must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations.	☐	☐	☐	
BMBL: D(B)6	BSCs should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.	☐	☐	☐	
BMBL: D(B)7	Central vacuum systems are not recommended. If, however, there is a central vacuum system, it must not serve areas outside the BSL-4 laboratory.	☐	☐	☐	
BMBL: D(B)7	Two inline HEPA filters must be placed near each use point.	☐	☐	☐	
BMBL: D(B)7	Filters must be installed to permit in-place decontamination and replacement.	☐	☐	☐	
BMBL: D(B)8	An eyewash station must be readily available in the laboratory area for use during maintenance and repair activities.	☐	☐	☐	
BMBL: D(B)9	A dedicated non-recirculating ventilation system is provided.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D(B)9	Only laboratories with the same HVAC requirements (i.e., other BSL-4 labs, ABSL-4, BSL-3 Ag labs) may share ventilation systems if each individual laboratory system is isolated by gas tight dampers and HEPA filters.	☐	☐	☐	
BMBL: D(B)9	The supply and exhaust components of the ventilation system must be designed to maintain the laboratory at negative pressure to surrounding areas and provide differential pressure/directional airflow between adjacent areas within the laboratory.	☐	☐	☐	
BMBL: D(B)9	Redundant supply fans are recommended. Redundant exhaust fans are required.	☐	☐	☐	
BMBL: D(B)9	Supply and exhaust fans must be interlocked to prevent positive pressurization of the laboratory.	☐	☐	☐	
BMBL: D(B)9	The ventilation system must be monitored and alarmed to indicate malfunction or deviation from design parameters.	☐	☐	☐	
BMBL: D(B)9	A visual monitoring device must be installed near the clean change room so proper differential pressures within the laboratory may be verified.	☐	☐	☐	
BMBL: D(B)9	Supply air to the laboratory, including the decontamination shower, must pass through a HEPA filter.	☐	☐	☐	
BMBL: D(B)9	All exhaust air from the suit laboratory, decontamination shower and fumigation or decontamination chambers must pass through two HEPA filters, in series, before discharge to the outside.	☐	☐	☐	
BMBL: D(B)9	The exhaust air discharge must be located away from occupied spaces and air intakes.	☐	☐	☐	
BMBL: D(B)9	All HEPA filters must be located as near as practicable to the laboratory in order to minimize the length of potentially contaminated ductwork.	☐	☐	☐	
BMBL: D(B)9	All HEPA filters must be tested and certified annually.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D(B)9	The HEPA filter housings should be designed to allow for in situ decontamination and validation of the filter prior to removal.	☐	☐	☐	
BMBL: D(B)9	The design of the HEPA filter housing must have gas-tight isolation dampers; decontamination ports; and ability to scan each filter assembly for leaks.	☐	☐	☐	
BMBL: D(B)10	HEPA filtered exhaust air from a Class II BSC can be safely re-circulated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to the manufacturer's recommendations. Biological safety cabinets can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or a direct (hard) connection.	☐	☐	☐	
BMBL: D(B)10	Provisions to assure proper safety cabinet performance and air system operation must be verified.	☐	☐	☐	
BMBL: D(B)11	Pass through dunk tanks, fumigation chambers, or equivalent decontamination methods must be provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the BSL-4 laboratory.	☐	☐	☐	
BMBL: D(B)11	Access to the exit side of the pass-through shall be limited to those individuals authorized to be in the BSL-4 laboratory.	☐	☐	☐	
BMBL: D(B)12	Liquid effluents from chemical showers, sinks, floor drains, autoclave chambers, and other sources within the laboratory must be decontaminated by a proven method, preferably heat treatment, before being discharged to the sanitary sewer.	☐	☐	☐	
BMBL: D(B)12	Decontamination of all liquid wastes must be documented.	☐	☐	☐	
BMBL: D(B)12	The decontamination process for liquid wastes must be validated physically and biologically.	☐	☐	☐	
BMBL: D(B)12	Biological validation must be performed annually or more often if required by institutional policy.	☐	☐	☐	
BMBL: D(B)12	Effluents from personal body showers and toilets may be discharged to the sanitary sewer without treatment.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D(B)13	A double-door, pass through autoclave(s) must be provided for decontaminating materials passing out of the cabinet laboratory.	☐	☐	☐	
BMBL: D(B)13	Autoclaves that open outside of the laboratory must be sealed to the primary wall.	☐	☐	☐	
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BMBL: D(B)13	Gas and liquid discharge from the autoclave chamber must be decontaminated.	☐	☐	☐	
BMBL: D(B)13	When feasible, autoclave decontamination processes should be designed so that over-pressurization cannot release unfiltered air or steam exposed to infectious material to the environment.	☐	☐	☐	
BMBL: D(B)14	The BSL-4 facility design parameters and operational procedures must be documented.	☐	☐	☐	
BMBL: D(B)14	The facility must be tested to verify that the design and operational parameters have been met prior to operation.	☐	☐	☐	
BMBL: D(B)14	Facilities must also be re-verified annually.	☐	☐	☐	
BMBL: D(B)14	Verification criteria should be modified as necessary by operational experience.	☐	☐	☐	

Comments continued:

Inspector summary and comments:

Lead inspector: Date:

Other inspectors present: Date:

Lead inspector signature: _____ Date: _____

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