Inspection Checklist for BSL-3 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(a)	The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	☐	☐	☐	
CFR: Section 12(a)(1)	The biosafety plan must include the hazardous characteristics of each agent or toxin listed on the entity's registration and the biosafety risk associated with laboratory procedures related to the select agent or toxin.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
CFR: Section 12(a)(2)	The biosafety plan must include safeguards in place with associated work practices to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: personal protective equipment and other safety equipment; containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety containers; and engineering controls and other facility safeguards.	☐	☐	☐	
CFR: Section 12(a)(3)	The biosafety plan must include written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids (if applicable), laboratory surfaces and equipment, and effluent material.	☐	☐	☐	
CFR: Section 12(a)(4)	The biosafety plan must include procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.	☐	☐	☐	
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.	☐	☐	☐	
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.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
CFR: Section 12(e)	The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.	☐	☐	☐	
CFR: Section 12(e)	Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.	☐	☐	☐	
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:	☐	☐	☐	
A	**Standard Microbiological Practices**				
BMBL: A1	The laboratory supervisor must enforce the institutional policies that control access to the laboratory.	☐	☐	☐	

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Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: A2	Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.	☐	☐	☐	
BMBL: A3	Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas.	☐	☐	☐	
BMBL: A3	Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.	☐	☐	☐	
BMBL: A4	Mouth pipetting is prohibited; mechanical pipetting devices must be used.	☐	☐	☐	
BMBL: A5	Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented.	☐	☐	☐	
BMBL: A5	Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries.	☐	☐	☐	
BMBL: A5	**Precautions, including those listed below, must always be taken with sharp items. These include:**				
BMBL: A5-a	Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.	☐	☐	☐	
BMBL: A5-b	Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.	☐	☐	☐	
BMBL: A5-c	Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.	☐	☐	☐	
BMBL: A5-d	Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps.	☐	☐	☐	
BMBL: A5-d	Plasticware should be substituted for glassware whenever possible.	☐	☐	☐	

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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 after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.	☐	☐	☐	
BMBL: A8	Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method.	☐	☐	☐	
BMBL: A8	A method for decontaminating all laboratory wastes should be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).	☐	☐	☐	
BMBL: A8-a	Depending on where the decontamination will be performed, the following methods should be used prior to transport: Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.	☐	☐	☐	
BMBL: A8-b	Depending on where the decontamination will be performed, the following methods should be used prior to transport: Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.	☐	☐	☐	
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.	☐	☐	☐	

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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.	☐	☐	☐	
BMBL: A11	Individuals having these conditions should be encouraged to self-identify to the institution?s healthcare provider for appropriate counseling and guidance.	☐	☐	☐	
B	**Special Practices**				
BMBL: B1	All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.	☐	☐	☐	
BMBL: B2	Laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory.	☐	☐	☐	
BMBL: B3	Each institution should consider the need for collection and storage of serum samples from at-risk personnel.	☐	☐	☐	
BMBL: B4	A laboratory-specific biosafety manual must be prepared and adopted as policy.	☐	☐	☐	
BMBL: B4	The biosafety manual must be available and accessible.	☐	☐	☐	
BMBL: B5	The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-3 agents.	☐	☐	☐	
BMBL: B6	Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.	☐	☐	☐	

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BMBL: B7	Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.	☐	☐	☐	
BMBL: B7-a	Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.	☐	☐	☐	
BMBL: B7-b	Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.	☐	☐	☐	
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 such incidents must be reported to the laboratory supervisor.	☐	☐	☐	
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	All procedures involving the manipulation of infectious materials must be conducted within a BSC, or other physical containment devices.	☐	☐	☐	
BMBL: B10	No work with open vessels is conducted on the bench.	☐	☐	☐	
BMBL: B10	When a procedure cannot be performed within a BSC, a combination of personal protective equipment and other containment devices, such as a centrifuge safety cup or sealed rotor, must be used.	☐	☐	☐	
C	**Safety Equipment (Primary Barriers and Personal Protective Equipment)**				
BMBL: C1	All procedures involving the manipulation of infectious materials must be conducted within a BSC (preferably Class II or Class III), or other physical containment devices.	☐	☐	☐	

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Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: C2	Workers in the laboratory wear protective laboratory clothing with a solid-front, such as tie-back or wrap-around gowns, scrub suits, or coveralls.	☐	☐	☐	
BMBL: C2	Protective clothing is not worn outside of the laboratory.	☐	☐	☐	
BMBL: C2	Reusable clothing is decontaminated before being laundered.	☐	☐	☐	
BMBL: C2	Clothing is changed when contaminated.	☐	☐	☐	
BMBL: C3	Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials.	☐	☐	☐	
BMBL: C3	Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse.	☐	☐	☐	
BMBL: C3	Persons who wear contact lenses in laboratories must also wear eye protection.	☐	☐	☐	
BMBL: C4	Gloves must be worn to protect hands from exposure to hazardous materials.	☐	☐	☐	
BMBL: C4	Glove selection should be based on an appropriate risk assessment.	☐	☐	☐	
BMBL: C4	Alternatives to latex gloves should be available.	☐	☐	☐	
BMBL: C4	Gloves must not be worn outside the laboratory.	☐	☐	☐	

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BMBL: C4	**In addition, BSL-3 laboratory workers should:**				
BMBL: C4-a	Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.	☐	☐	☐	
BMBL: C4-a	Wear two pairs of gloves when appropriate.	☐	☐	☐	
BMBL: C4-b	Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.	☐	☐	☐	
BMBL: C4-c	Do not wash or reuse disposable gloves.	☐	☐	☐	
BMBL: C4-c	Dispose of used gloves with other contaminated laboratory waste.	☐	☐	☐	
BMBL: C4-c	Hand washing protocols must be rigorously followed.	☐	☐	☐	
BMBL: C5	Eye, face, and respiratory protection must be used in rooms containing infected animals.	☐	☐	☐	
D	**Laboratory Facilities (Secondary Barriers)**				
BMBL: D1	Laboratory doors must be self closing and have locks in accordance with the institutional policies.	☐	☐	☐	
BMBL: D1	The laboratory must be separated from areas that are open to unrestricted traffic flow within the building.	☐	☐	☐	
BMBL: D1	Laboratory access is restricted.	☐	☐	☐	
BMBL: D1	Access to the laboratory is through two self-closing doors.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D1	A clothing change room (anteroom) may be included in the passageway between the two self-closing doors.	☐	☐	☐	
BMBL: D2	Laboratories must have a sink for hand washing. The sink must be hands-free or automatically operated. It should be located near the exit door.	☐	☐	☐	
BMBL: D2	If the laboratory is segregated into different laboratories, a sink must also be available for hand washing in each zone.	☐	☐	☐	
BMBL: D2	Additional sinks may be required as determined by the risk assessment.	☐	☐	☐	
BMBL: D3	The laboratory must be designed so that it can be easily cleaned and decontaminated.	☐	☐	☐	
BMBL: D3	Carpets and rugs are not permitted.	☐	☐	☐	
BMBL: D3	Seams, floors, walls, and ceiling surfaces should be sealed.	☐	☐	☐	
BMBL: D3	Spaces around doors and ventilation openings should be capable of being sealed to facilitate space decontamination.	☐	☐	☐	
BMBL: D3-a	Floors must be slip resistant, impervious to liquids, and resistant to chemicals.	☐	☐	☐	
BMBL: D3-a	Consideration should be given to the installation of seamless, sealed, resilient or poured floors, with integral cove bases.	☐	☐	☐	
BMBL: D3-b	Walls should be constructed to produce a sealed smooth finish that can be easily cleaned and decontaminated.	☐	☐	☐	
BMBL: D3-c	Ceilings should be constructed, sealed, and finished in the same general manner as walls.	☐	☐	☐	

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Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D3	Decontamination of the entire laboratory should be considered when there has been gross contamination of the space, significant changes in laboratory usage, for major renovations, or maintenance shut downs.	☐	☐	☐	
BMBL: D3	Selection of the appropriate materials and methods used to decontaminate the laboratory must be based on the risk assessment.	☐	☐	☐	
BMBL: D4	Laboratory furniture must be capable of supporting anticipated loads and uses.	☐	☐	☐	
BMBL: D4	Spaces between benches, cabinets, and equipment must be accessible for cleaning.	☐	☐	☐	
BMBL: D4-a	Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.	☐	☐	☐	
BMBL: D4-b	Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.	☐	☐	☐	
BMBL: D5	All windows in the laboratory must be sealed.	☐	☐	☐	
BMBL: D6	BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations.	☐	☐	☐	
BMBL: D6	BSCs should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.	☐	☐	☐	
BMBL: D7	Vacuum lines must be protected with HEPA filters, or their equivalent.	☐	☐	☐	
BMBL: D7	Filters must be replaced as needed.	☐	☐	☐	
BMBL: D7	Liquid disinfectant traps may be required.	☐	☐	☐	

Entity Name:		Inspection Date:			
Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D8	An eyewash station must be readily available in the laboratory.	☐	☐	☐	
BMBL: D9	A ducted air ventilation system is required.	☐	☐	☐	
BMBL: D9	This system must provide sustained directional airflow by drawing air into the laboratory from “clean” areas toward “potentially contaminated” areas.	☐	☐	☐	
BMBL: D9	The laboratory shall be designed such that under failure conditions the airflow will not be reversed.	☐	☐	☐	
BMBL: D9-a	Laboratory personnel must be able to verify directional air flow.	☐	☐	☐	
BMBL: D9-a	A visual monitoring device which confirms directional air flow must be provided at the laboratory entry.	☐	☐	☐	
BMBL: D9-a	Audible alarms should be considered to notify personnel of air flow disruption.	☐	☐	☐	
BMBL: D9-b	The laboratory exhaust air must not re-circulate to any other area of the building.	☐	☐	☐	
BMBL: D9-c	The laboratory building exhaust air should be dispersed away from occupied areas and from building air intake locations or the exhaust air must be HEPA filtered.	☐	☐	☐	
BMBL: D9-d	HEPA filter housings should have gas-tight isolation dampers; decontamination ports; and/or bag-in/bag-out (with appropriate decontamination procedures) capability. The HEPA filter housing should allow for leak testing of each filter and assembly. The filters and the housing should be certified at least annually.	☐	☐	☐	
BMBL: D10	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 recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or a direct (hard) connection.	☐	☐	☐	

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Reference	**Statement**	**Yes**	**No**	**N/A**	**Comments**
BMBL: D10	Provisions to assure proper safety cabinet performance and air system operation must be verified.	☐	☐	☐	
BMBL: D10	BSCs should be certified at least annually to assure correct performance.	☐	☐	☐	
BMBL: D10	Class III BSCs must be directly (hard) connected up through the second exhaust HEPA filter of the cabinet. Supply air must be provided in such a manner that prevents positive pressurization of the cabinet.	☐	☐	☐	
BMBL: D11	A method for decontaminating all laboratory wastes should be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).	☐	☐	☐	
BMBL: D12	Equipment that may produce infectious aerosols must be contained in primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory. These HEPA filters should be tested and/or replaced at least annually.	☐	☐	☐	
BMBL: D13	Facility design consideration should be given to means of decontaminating large pieces of equipment before removal from the laboratory.	☐	☐	☐	
BMBL: D14	Enhanced environmental and personal protection may be required by the agent summary statement, risk assessment, or applicable local, state, or federal regulations. These laboratory enhancements may include, for example, one or more of the following; an anteroom for clean storage of equipment and supplies with dress-in, shower-out capabilities; gas tight dampers to facilitate laboratory isolation; final HEPA filtration of the laboratory exhaust air; laboratory effluent decontamination; and advanced access control devices such as biometrics.	☐	☐	☐	
BMBL: D15	The BSL-3 facility design, operational parameters, and procedures must be verified and documented prior to operation.	☐	☐	☐	
BMBL: D15	Facilities must be re-verified and documented at least annually.	☐	☐	☐	

Comments continued:

Inspector summary and comments:

Lead inspector: Date:

Other inspectors present: Date:

Lead inspector signature: _____ Date: _____

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