

## Inspection Checklist for BSL-2 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
<b>CFR: Section 12(a)</b>	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.				
<b>CFR: Section 12(a)</b>	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.				
<b>CFR: Section 12(a)</b>	The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.				
<b>CFR: Section 12(a)(1)</b>	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.				

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<b>CFR: Section 12(a)(2)</b>	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.				
<b>CFR: Section 12(a)(3)</b>	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.				
<b>CFR: Section 12(a)(4)</b>	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.				
<b>CFR: Section 12(b)</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).				
<b>CFR: Section 12 (c)(1)</b>	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 <a href="http://www.selectagents.gov/">http://www.selectagents.gov/</a> . In developing a biocontainment plan, an individual or entity should consider the following: (1) Containment Facilities and Safeguards for Exotic Plant Pathogens and Pests (Robert P. Kahn and S.B.Mathur eds., 1999); and (2) A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes (Patricia L. Traynor ed., 2001).				
<b>CFR: Section 12(d)</b>	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.				

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<b>CFR: Section 12(e)</b>	The plan must be reviewed annually and revised as necessary.				
<b>CFR: Section 12(e)</b>	Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan.				
<b>CFR: Section 12(e)</b>	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.				
<b>CFR: Section 12(e)</b>	The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.				
<b>42 CFR 73: Section 13 (a)</b>	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.				
<b>42 CFR 73: Section 13 (a)</b>	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.				
<b>9 CFR 121: Section 13(a)</b>	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:				

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A		Standard Microbiological Practices			
BMBL: A1	The laboratory supervisor must enforce the institutional policies that control access to the laboratory.				
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	<b>Precautions, including those listed below, must always be taken with sharp items. These include:</b>				
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.				

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<b>BMBL: A5-d</b>	Plasticware should be substituted for glassware whenever possible.				
<b>BMBL: A6</b>	Perform all procedures to minimize the creation of splashes and/or aerosols.				
<b>BMBL: A7</b>	Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.				
<b>BMBL: A8</b>	Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method.				
<b>BMBL: A8</b>	<b>Depending on where the decontamination will be performed, the following methods should be used prior to transport:</b>				
<b>BMBL: A8-a</b>	Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.				
<b>BMBL: A8-b</b>	Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.				
<b>BMBL: A9</b>	A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. 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.				
<b>BMBL: A9</b>	Agent information should be posted in accordance with the institutional policy.				
<b>BMBL: A10</b>	An effective integrated pest management program is required. See Appendix G of BMBL.				
<b>BMBL: A11</b>	The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur.				

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<b>BMBL: A11</b>	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.				
<b>B</b>	<b>Special Practices</b>				
<b>BMBL: B1</b>	All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.				
<b>BMBL: B2</b>	Laboratory personnel must be provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory.				
<b>BMBL: B3</b>	Each institution should consider the need for collection and storage of serum samples from at-risk personnel.				
<b>BMBL: B4</b>	A laboratory-specific biosafety manual must be prepared and adopted as policy.				
<b>BMBL: B4</b>	The biosafety manual must be available and accessible.				
<b>BMBL: B5</b>	The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.				
<b>BMBL: B6</b>	Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.				
<b>BMBL: B7</b>	Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.				
<b>BMBL: B7-a</b>	Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.				

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<b>BMBL: B7-b</b>	Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.				
<b>BMBL: B8</b>	Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety safety manual. All such incidents must be reported to the laboratory supervisor.				
<b>BMBL: B8</b>	Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.				
<b>BMBL: B9</b>	Animals and plants not associated with the work being performed must not be permitted in the laboratory.				
<b>BMBL: B10</b>	All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.				
<b>C</b>	<b>Safety Equipment (Primary Barriers and Personal Protective Equipment)</b>				
<b>BMBL: C1</b>	Properly maintained BSCs (preferably Class II), other appropriate personal protective equipment, or other physical containment devices must be used whenever:				
<b>BMBL: C1-a</b>	Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.				
<b>BMBL: C1-b</b>	High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.				
<b>BMBL: C2</b>	Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials.				
<b>BMBL: C2</b>	Remove protective clothing before leaving for non-laboratory areas (e.g., cafeteria, library, and administrative offices).				

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<b>BMBL: C2</b>	Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that laboratory clothing not be taken home.				
<b>BMBL: C3</b>	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 when the microorganisms must be handled outside the BSC or containment device.				
<b>BMBL: C3</b>	Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse.				
<b>BMBL: C3</b>	Persons who wear contact lenses in laboratories should also wear eye protection.				
<b>BMBL: C4</b>	Gloves must be worn to protect hands from exposure to hazardous materials.				
<b>BMBL: C4</b>	Glove selection should be based on an appropriate risk assessment.				
<b>BMBL: C4</b>	Alternatives to latex gloves should be available.				
<b>BMBL: C4</b>	Gloves must not be worn outside the laboratory.				
<b>In addition, BSL-2 laboratory workers should:</b>					
<b>BMBL: C4-a</b>	Change gloves when contaminated, integrity has been compromised, or when otherwise necessary.				
<b>BMBL: C4-b</b>	Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.				
<b>BMBL: C4-c</b>	Do not wash or reuse disposable gloves.				



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<b>BMBL: C4-c</b>	Dispose of used gloves with other contaminated laboratory waste.				
<b>BMBL: C4-c</b>	Hand washing protocols must be rigorously followed.				
<b>BMBL: C5</b>	Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.				
<b>D</b>	<b>Laboratory Facilities (Secondary Barriers)</b>				
<b>BMBL: D1</b>	Laboratory doors should be self-closing and have locks in accordance with the institutional policies.				
<b>BMBL: D2</b>	Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.				
<b>BMBL: D3</b>	The laboratory should be designed so that it can be easily cleaned and decontaminated.				
<b>BMBL: D3</b>	Carpets and rugs in laboratories are not permitted.				
<b>BMBL: D4</b>	Laboratory furniture must be capable of supporting anticipated loads and uses.				
<b>BMBL: D4</b>	Spaces between benches, cabinets, and equipment should be accessible for cleaning.				
<b>BMBL: D4-a</b>	Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.				
<b>BMBL: D4-b</b>	Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.				

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<b>BMBL: D5</b>	Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they must be fitted with screens.				
<b>BMBL: D6</b>	BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations.				
<b>BMBL: D6</b>	BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.				
<b>BMBL: D7</b>	Vacuum lines should be protected with liquid disinfectant traps.				
<b>BMBL: D8</b>	An eyewash station must be readily available.				
<b>BMBL: D9</b>	There are no specific requirements on ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.				
<b>BMBL: D10</b>	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 manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection.				
<b>BMBL: D10</b>	Provisions to assure proper safety cabinet performance and air system operation must be verified.				
<b>BMBL: D11</b>	A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).				

Comments continued:

Inspector summary and comments:

Lead inspector:

Date:

Other inspectors present:

Date:

Lead inspector signature: \_\_\_\_\_

Date: \_\_\_\_\_