

Inspection Checklist for Storage Only (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
Note: Storage areas within laboratories must follow all laboratory procedures for the biosafety level of the laboratory. This checklist is intended for a storage only area such as a warehouse, freezer farm, or a room without access to a biosafety cabinet. The guidelines specified below are for RG-2 and RG-3 agents (as defined in the NIH Guidelines).					
CFR: Section 12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use.				
CFR: Section 12(a)	The biosafety 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(e)	The plan must be reviewed annually and revised as necessary.				

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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.				
CFR: 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.				
CFR: 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					
BMBL: A1	The laboratory supervisor must enforce the institutional policies that control access to the laboratory (storage area).				

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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. <i>Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.</i>				
BMBL: A5	Precautions, including those listed below, must always be taken with sharp items. These include:				
BMBL: A5-d	Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps.				
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	Depending on where the decontamination will be performed, the following methods should be used prior to transport:				
BMBL: A8-a	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	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. 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.				

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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. Personnel must receive annual updates or additional training when procedural or policy changes occur.				
B					
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: B4	A laboratory-specific biosafety manual must be prepared and adopted as policy.				
BMBL: B4	The biosafety manual must be available and accessible upon request.				
BMBL: B6	Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.				
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 safety manual. All such incidents must be reported to the laboratory supervisor.				

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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.				
C					
BMBL: C2	Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials.				
BMBL: C2	Remove protective clothing before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that laboratory clothing not be taken home.				
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 when the microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in laboratories should 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. Alternatives to latex gloves should be available.				
BMBL: C4	Gloves must not be worn outside the laboratory.				
In addition, BSL-2 laboratory workers should:					
BMBL: C4-a	Change gloves when contaminated, integrity has been compromised, or when otherwise necessary.				

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BMBL: C4-b	Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.				
BMBL: C4-c	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.				
D					
BMBL: D6	BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.				
BMBL: D10	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 a direct (hard) connection.				
BMBL: D10	Provisions to assure proper safety cabinet performance and air system operation must be verified.				
BMBL: D11	A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).				
Toxin Storage					
BMBL: Appendix I Training and Laboratory Planning	If toxins are stored in the laboratory, containers should be sealed, labeled and secured to ensure restricted access; refrigerators and other storage containers should be clearly labeled and provide contact information for trained, responsible laboratory staff.				

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BMBL: Appendix I Training and Laboratory Planning	When toxins are in use, the room should be clearly posted: "Toxins in Use - Authorized Personnel Only."				
BMBL: Appendix I Safety Equipment and Containment	Toxin solutions, especially concentrated toxin solutions, should be transported in leak/spill-proof secondary containers.				
BMBL: Appendix I Decontamination and Spills	Depending upon the toxin, contaminated materials and toxin waste solutions can be inactivated by incineration or extensive autoclaving, or by soaking in suitable decontamination solutions (Table 2 of BMBL App I).				
BMBL: Appendix I Decontamination and Spills	Contaminated or potentially contaminated protective clothing and equipment should be decontaminated using suitable chemical methods or autoclaving before removal from the laboratory for disposal, cleaning or repair. If decontamination is impracticable, materials should be disposed of as toxic waste.				
BMBL: Appendix I Decontamination and Spills	In the event of a spill, avoid splashes or generating aerosols during cleanup by covering the spill with paper towels or other disposable, absorbent material. Apply an appropriate decontamination solution to the spill, beginning at the perimeter and working towards the center, and allow sufficient contact time to completely inactivate the toxin (See Table 2 of BMBL App I).				
Laboratories where there is storage of virus isolates or diagnostic materials known to be infected with highly pathogenic Avian influenza virus, virulent Newcastle disease virus, African swine fever virus or Classical swine fever virus also include the following enhancements:					
APHIS/VS Standard: A(1)	Clothing change prior to entering the laboratory and leaving the facility; or				
APHIS/VS Standard: A(2)	Full body Tyvek jumpsuits; or				
APHIS/VS Standard: A(3)	Disposable wrap-around smock, arm covers, shoe covers; and				

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APHIS/VS Standard: A(4)	Confirmation of a written personnel quarantine or restriction policy for visitors and staff. Entities must have, in place, a written policy prohibiting laboratory staff and visitors from having contact with susceptible species for a minimum of 5 days after the last possible contact with the virus. The prohibition on contact with susceptible species includes, but is not limited to, contact with any:				
APHIS/VS Standard: A(4)	(1) pet birds, backyard poultry flocks, birds at county/ state fairs, commercial poultry operations, zoological collections (i.e. zoos), and wild birds (e.g., ducks, geese) for AIV and NDV.				
APHIS/VS Standard: A(4)	(2) pet pigs, hobby farm pigs, swine at county/state fairs, commercial swine operations, zoological collections (exotic swine), and wild pigs for ASFv and CSFv.				
APHIS/VS Standard: A(5)	Laboratories working with these viruses should not be in close proximity to other facilities housing susceptible species.				
APHIS/VS Standard: A(5)	(1) For AIV and NDV, there should be no commercial poultry flocks within 1/2 mile of the facility, or any other avian colonies (e.g. backyard flock, aviary, zoo) within 100 meters of the facility.				
APHIS/VS Standard: A(5)	(2) For ASFv and CSFv, there should be no commercial swine production or any other swine housing (e.g., pet pigs, zoo, petting farm) within 1.5 miles (2.5 Km) of the facility.				
APHIS/VS Standard: A(5)	In lieu of this exclusion zone, entities must specify additional physical biocontainment features of their facility as appropriate to prevent release of these viruses from their facility.				

Comments continued:

Inspector summary and comments:

Lead inspector:

Date:

Other inspectors present:

Date:

Lead inspector signature: _____

Date: _____