

Inspection Checklist for Storage Only Biosafety (9 CFR 121, BMBL 6th Edition)**Entity Name:****Inspection Date:****Building/Rooms:****Inspectors:****When information is entered in this form, the form is to be considered "Sensitive Select Agent Information."**

Section	Regulation Text	Observation	Status	Comments
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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	The entity has developed a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use.	☐ No ☐ Yes ☐ N/A	
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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	The biosafety plan contains sufficient information and documentation to describe all biosafety and containment procedures for the entity's approved BSAT work and storage. Additional SOPs containing information required for the plan to fully describe all biosafety and containment procedures are referenced.	☐ No ☐ Yes ☐ N/A	
12(a)(1)	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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested. The biosafety plan must include the following provisions: 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.	The biosafety plan includes 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.	☐ No ☐ Yes ☐ N/A	

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12(a)(3)	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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested. The biosafety plan includes the following provisions: 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.	The biosafety plan includes the following provisions: 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.	☐ No ☐ Yes ☐ N/A	
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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	☐ No ☐ Yes ☐ N/A	

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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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Personnel are enrolled in an appropriate respiratory protection program commensurate with the risk of BSAT given its intended use. Personnel receive fit tests/training annually (if applicable).	☐ No ☐ Yes ☐ N/A	
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).	The biosafety and containment procedures are sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	☐ No ☐ Yes ☐ N/A	
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.	For Tier 1 entities, the biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins.	☐ No ☐ Yes ☐ N/A	
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.	For Tier 1 entities, individuals with access to Tier 1 select agents and toxins are enrolled in the occupational health program.	☐ No ☐ Yes ☐ N/A	
12(e)	The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. 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.	The biosafety plan(s) and any referenced SOPs are reviewed annually and revised as necessary.	☐ No ☐ Yes ☐ N/A	
12(e)	The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. 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.	Drills or exercises are conducted at least annually to test and evaluate the effectiveness of the biosafety plan(s). The plan(s) are reviewed and revised, as necessary, after any drill or exercise and after any incident.	☐ No ☐ Yes ☐ N/A	

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12(e)	The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. 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.	Drill or exercise documentation includes 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.	☐ No ☐ Yes ☐ N/A	
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).	BSC(s), CFH(s) is certified annually, and/or flexible film isolator(s) have annual leak-testing of the exhaust HEPA filter(s).	☐ No ☐ Yes ☐ N/A	
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).	Laboratory has a sink and an eyewash station.	☐ No ☐ Yes ☐ N/A	
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).	Sign with biohazard symbol is posted at the entrance of areas containing BSAT and includes: the laboratory's Biosafety Level, the supervisor's or other responsible personnel's name and telephone number, PPE requirements, general occupational health requirements, and required procedures for entering and exiting the laboratory. Agent information is posted in accordance with entity institutional policy.	☐ No ☐ Yes ☐ N/A	
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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate biosafety and containment procedures have been developed and implemented for entry and exit of areas containing BSAT.	☐ No ☐ Yes ☐ N/A	

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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).	Procedures for entry and exit of areas containing BSAT are appropriate.	☐ No ☐ Yes ☐ N/A	
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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate biosafety and containment procedures have been developed and implemented for PPE worn during handling and/or manipulation of BSAT.	☐ No ☐ Yes ☐ N/A	
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).	Appropriate PPE worn during handling and/or manipulation of BSAT.	☐ No ☐ Yes ☐ N/A	
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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate biosafety and containment procedures have been developed and implemented for glove practices used when BSAT is handled or area has not been decontaminated.	☐ No ☐ Yes ☐ N/A	
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).	Appropriate glove practices used when BSAT is handled or area has not been decontaminated.	☐ No ☐ Yes ☐ N/A	

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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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate biosafety and containment procedures have been developed and implemented for the wearing of disposable PPE and/or protective clothing when handling BSAT and the removal of PPE and/or protective clothing, which must not be worn outside the laboratory.	☐ No ☐ Yes ☐ N/A	
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).	Disposable PPE and/or protective clothing worn when handling BSAT is removed and not worn outside of the laboratory.	☐ No ☐ Yes ☐ N/A	
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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate biosafety and containment procedures have been developed and implemented for the disposal of eye and face protection with biohazardous waste, or decontamination prior to reuse.	☐ No ☐ Yes ☐ N/A	
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).	Eye and face protection is disposed of with biohazardous waste, or decontaminated prior to reuse.	☐ No ☐ Yes ☐ N/A	
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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate biosafety and containment procedures have been developed and implemented for hand washing or "shower out" prior to leaving the laboratory.	☐ No ☐ Yes ☐ N/A	

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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).	Hand washing or “shower out” is conducted prior to leaving laboratory.	☐ No ☐ Yes ☐ N/A	
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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate biosafety and containment procedures have been developed and implemented for waste transport.	☐ No ☐ Yes ☐ N/A	
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).	Entity implemented appropriate procedures for waste transport.	☐ No ☐ Yes ☐ N/A	
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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate biosafety and containment procedures have been developed and implemented for waste decontamination.	☐ No ☐ Yes ☐ N/A	
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).	Entity implemented appropriate procedures for waste decontamination.	☐ No ☐ Yes ☐ N/A	

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12(b)	The biocontainment 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).	Entity implemented appropriate procedures for laboratory space decontamination.	☐ No ☐ Yes ☐ N/A	
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).	Decontamination systems (autoclave, room decontamination systems, digesters, liquid effluent systems, etc.) have been confirmed to be operating correctly by annual revalidation.	☐ No ☐ Yes ☐ N/A	
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).	The method(s) for BSAT waste treatment is available in the registered space. If not, entity complies with FSAP guidance in the Biosafety/Biocontainment Plan Guidance document, available at https://www.selectagents.gov/compliance/guidance/biosafety/index.htm .	☐ No ☐ Yes ☐ N/A	
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).	Entity has developed and posted appropriate procedures for spills.	☐ No ☐ Yes ☐ N/A	

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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 select agent or toxin, given its intended use. 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. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate biosafety and containment procedures have been developed and implemented for the removal of biological materials that require BSL-4 containment from the BSL-4 facility. Biological materials that require BSL-4 containment are placed in a durable, leak-proof sealed primary container and then enclosed in a non-breakable, sealed secondary container prior to removal from the BSL-4 facility. These materials are transferred through a disinfectant dunk tank, fumigation chamber, or decontamination shower. Once removed, the primary container is not to be opened outside BSL-4 containment unless a validated inactivation method is used (e.g., gamma irradiation). The inactivation method is documented in-house with viability testing data to support the method.	☐ No ☐ Yes ☐ N/A	
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).	Biological materials that require BSL-4 containment are placed in a durable, leak-proof sealed primary container and then enclosed in a non-breakable, sealed secondary container prior to removal from the BSL-4 facility. These materials are transferred through a disinfectant dunk tank, fumigation chamber, or decontamination shower. Once removed, the primary container is not to be opened outside BSL-4 containment unless a validated inactivation method is used (e.g., gamma irradiation). The inactivation method is documented in-house with viability testing data to support the method.	☐ No ☐ Yes ☐ N/A	