

Inspection Checklist for General Biosafety (7 CFR 331, 9 CFR 121, 42 CFR 73; BMBL 5th 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 entity has developed a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 biosafety plan contains sufficient information on biosafety and containment procedures for animals or plants accidentally exposed to or infected with a select agent.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Appropriate spatial/temporal separation requirements have been developed and implemented, such that the biosafety plan is commensurate with the risk of select agents to limit the unintentional contamination of non-select agents and inactivated materials with viable select agents, when applicable.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Appropriate biosafety and containment procedures have been developed and implemented when any registered area is used as a 'swing space,' such that the biosafety plan is commensurate with the risk of BSAT given its intended use.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Manipulation of BSAT is handled in primary containment devices and work on the open bench top is not permitted.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	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).	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Sign with biohazard symbol is posted at entrance of areas containing BSAT and includes information on responsible personnel and contact numbers.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Procedures for entry and exit of areas containing BSAT are appropriate.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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.	Appropriate PPE worn during handling and/or manipulation of BSAT.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Appropriate glove practices used when BSAT is handled or area has not been decontaminated.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	PPE selection is based upon risk of the select agent or toxin and is appropriate for the work performed.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Disposable PPE and/or protective clothing worn when handling BSAT is removed and not worn outside of the laboratory.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Eye and face protection is disposed of with biohazardous waste, or decontaminated prior to reuse.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Hand washing or “shower out” is conducted prior to leaving laboratory.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Appropriate procedures have been developed and implemented for the use of sharps.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Equipment that may produce infectious aerosols of BSAT is contained in primary barrier devices that exhaust air through HEPA filters or their equivalent. HEPA filters should be tested and/or replaced at least annually	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Entity has developed and implemented appropriate biosafety and containment procedures for BSAT aerosol experiments.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Appropriate procedures implemented for: laboratory equipment decontamination.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Appropriate procedures implemented for: laboratory space decontamination.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Appropriate procedures implemented for: spill procedures.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Appropriate procedures implemented for: waste transport.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	Appropriate procedures implemented for: waste decontamination.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 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).	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<p>Appropriate procedures have been developed and implemented for use of centrifuges with BSAT. If no, describe below:</p> <ul style="list-style-type: none"> • Sealed rotor/safety cups bioseals (O-rings) damaged or not intact. • Rotor not equipped with a bioseal. • Sealed rotor, but cannot be moved to primary containment device w/o opening rotor lid. • Centrifuge without sealed containment rotor/cover is operated outside of primary barrier devices with HEPA filters or their equivalent. • Safety cups not available, or other. 	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<p>Appropriate procedures have been developed and implemented for use of centrifuges with BSAT. (safety cups with o-rings, opening in BSC, etc.)</p>	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<p>The method(s) for BSAT waste treatment is available in the registered space. If not, entity complies with the following FSAP guidance; http://www.selectagents.gov/guidance-wastetreatment.html.</p>	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(a)(1)	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.	<p>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.</p>	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

Section	Regulation Text	Observation	Status	Comments
12(a)(2)	The biosafety plan must include the following provisions: 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.	The biosafety plan includes the following provisions: 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(a)(3)	The biosafety plan must include 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(a)(4)	The biosafety plan must include the following provisions: Procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.	The biosafety plan includes the following provisions: Procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 have been appropriately validated annually.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	Flexible film isolator(s) have annual leak-testing of the exhaust HEPA filter(s).	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	Inspector smoke test(s) of BSC(s) and/or CFH(s) verify containment.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 entrance of areas containing BSAT and includes procedures required for entry and exit and agent information, per entity policy.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If registered areas contain Class II Type A1 or A2 biosafety cabinet(s) that are thimble connected to the building exhaust system, inward airflow is verified at the thimble connection.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If registered areas contain Class II Type B biosafety cabinet(s), the BSC(s) pass certification.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If registered areas contain Class II Type B biosafety cabinet(s), certifier included a test of the internal cabinet supply fan interlock.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If any registered area contains Class III biosafety cabinet(s): the condition of gloves is acceptable.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If any registered area contains Class III biosafety cabinet(s): the cabinet is appropriately certified.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If any registered area contains Class III biosafety cabinet(s): HEPA filter (supply and exhaust) leak tests passed.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If any registered area contains Class III biosafety cabinet(s): A successful cabinet integrity test is conducted if the BSC is new.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If any registered area contains Class III biosafety cabinet(s): A successful cabinet integrity test is conducted if the BSC was moved.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If any registered area contains Class III biosafety cabinet(s): A successful cabinet integrity test is conducted if the BSC panels have been removed for maintenance.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If any registered area contains Class III biosafety cabinet(s): the certifier verifies negative pressure/ventilation rate is appropriate.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If any registered area contains Class III biosafety cabinet(s): the certifier verifies all alarms and interlocks which are present are working as intended.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	Area containing BSAT has self-closing doors.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 interior surfaces (walls, floors and ceilings) are water resistant.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If installed or required: HEPA filters on laboratory exhaust are certified annually.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If installed or required: HEPA housing has isolation dampers for gas decontamination or bag-in-bag-out.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	Entity completed and documented Initial and Annual reverification of BSL-3/ABSL-3 facilities.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	Vacuum lines or vacuum pumps are protected with HEPA filters or their equivalent. These must be replaced as needed.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 posted at entrance of areas containing BSAT. Includes procedures required for entry and exit, information on responsible personnel and contact numbers and agent information per entity policy.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If present, BSC(s) and/or CFH(s) are certified annually.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 spatial/temporal separation requirements have been developed and implemented, such that the biosafety plan is commensurate with the risk of select agents to limit the unintentional contamination of non-select agents and inactivated materials with viable select agents, when applicable.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 biosafety and containment procedures have been developed and implemented when any registered area is used as a 'swing space,' such that the biosafety plan is commensurate with the risk of BSAT given its intended use.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	Manipulation of BSAT is handled in primary containment devices and work on the open bench top is not permitted.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	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).	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

Section	Regulation Text	Observation	Status	Comments
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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	PPE selection is based upon risk of the select agent or toxin and is appropriate for the work performed.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	Hand washing or "shower out" is conducted prior to leaving laboratory.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 procedures have been developed and implemented for the use of sharps.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	Equipment that may produce infectious aerosols of BSAT is contained in primary barrier devices that exhaust air through HEPA filters or their equivalent. HEPA filters should be tested and/or replaced at least annually	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

Section	Regulation Text	Observation	Status	Comments
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 implemented appropriate biosafety and containment procedures for BSAT aerosol experiments.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 implemented appropriate procedures implemented for laboratory equipment decontamination.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 implemented appropriate procedures for laboratory space decontamination	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 spills	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	<p>Appropriate procedures have been developed and implemented for use of centrifuges with BSAT.</p> <p>If no, describe below:</p> <ul style="list-style-type: none"> • Sealed rotor/safety cups bioseals (O-rings) damaged or not intact. • Rotor not equipped with a bioseal. • Sealed rotor, but cannot be moved to primary containment device w/o opening rotor lid. • Centrifuge without sealed containment rotor/cover is operated outside of primary barrier devices with HEPA filters or their equivalent. • Safety cups not available, or other. 	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	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).	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	If BSAT quantities in use represent an increased risk (e.g., large scale >10 L select agents; large amount ≥ 1g select toxins), the biosafety plan(s) and risk assessments appropriately consider these risks.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	No indication that BSAT inactivation procedures have failed and resulted in removal of BSAT from registered areas.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	All biological safety cabinets have been certified annually.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	Any registered area contains Class III biosafety cabinet(s). If yes, condition of gloves is acceptable and cabinet appropriately certified.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 procedures have been developed and implemented for use of centrifuges with BSAT. (safety cups with o-rings, opening in BSC, etc.)	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 HVAC HEPA filters, if present, have been certified annually.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 the following FSAP guidance; https://www.selectagents.gov/policystatement_effluent.html	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

Section	Regulation Text	Observation	Status	Comments
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).	Work surfaces are decontaminated at least once a day and immediately after any spill of viable material.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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).	Spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the Institutional Biosafety Committee and NIH Office of Science Policy.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

Section	Regulation Text	Observation	Status	Comments
12(e)	<p>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.</p>	<p>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.</p>	<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A 	