Inspection Checklist for General Biocontainment Laboratories (7 CFR 331; 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 biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	The entity has developed a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use.	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	The biocontainment plan contains sufficient information and documentation to describe all biocontainment and containment procedures for the entity's approved BSAT work and storage. Additional SOPs containing information required for the plan to fully describe all biocontainment and containment procedures are referenced.	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	The biocontainment plan contains sufficient information on biocontainment and containment procedures for animals or plants accidentally exposed to or infected with a select agent.	o No o Yes o N/A	

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12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	The biocontainment plan(s) and referenced SOPs are submitted upon request.	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	The biocontainment plan has been implemented.	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate spatial/temporal separation requirements have been developed and implemented, such that the biocontainment 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.	o No o Yes o N/A	

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12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate biocontainment 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.	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Manipulation of BSAT is handled in primary containment devices and work on the open bench top is not permitted.	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment 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).	o No o Yes o N/A	

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12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Procedures for entry and exit of areas containing BSAT are appropriate.	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate PPE worn during handling and/or manipulation of BSAT.	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate glove practices used when BSAT is handled or area has not been decontaminated.	o No o Yes o N/A	

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12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	PPE selection is based upon risk of the select agent or toxin and is appropriate for the work performed.	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Disposable PPE and/or protective clothing worn when handling BSAT is removed and not worn outside of the laboratory.	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Eye and face protection is disposed of with biohazardous waste, or decontaminated prior to reuse.	o No o Yes o N/A	

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12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate procedures have been developed and implemented for the use of sharps.	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	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	o No o Yes o N/A	

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12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate procedures implemented for: laboratory equipment decontamination	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate procedures implemented for: laboratory space decontamination	o No o Yes o N/A	

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12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate procedures implemented for: waste transport	o No o Yes o N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate procedures implemented for: waste decontamination	o No o Yes o N/A	

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12(a)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested.	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.	o No o Yes o N/A	
12(a)(1)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested. The biocontainment plan must include the following provisions: The hazardous characteristics of each agent or toxin listed on the entity's registration and the biocontainment risk associated with laboratory procedures related to the select agent or toxin.	The biocontainment plan includes the hazardous characteristics of each agent or toxin listed on the entity's registration and the biocontainment risk associated with laboratory procedures related to the select agent or toxin.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
12(a)(2)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested. The biocontainment 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 biocontainment 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.	o No o Yes o N/A	
12(a)(3)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested. The biocontainment 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 biocontainment 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.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
12(a)(4)	An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biocontainment plan must contain sufficient information and documentation to describe the biocontainment 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 biocontainment plan must be submitted for initial registration, renewal of registration, or when requested. The biocontainment 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 biocontainment 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.	o No o Yes o N/A	
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).	The biocontainment 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).	o No o Yes o N/A	
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).	BSC(s) and/or CFH(s) are certified annually.	o No o Yes o N/A	
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).	Flexible film isolator(s) have annual leak-testing of the exhaust HEPA filter(s).	o No o Yes o N/A	
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).	Inspector smoke test(s) of BSC(s) and/or CFH(s) verify containment.	o No o Yes o N/A	
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).	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.	o No o Yes o N/A	
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).	If registered areas contain Class II Type B biosafety cabinet(s), the BSC(s) pass certification.	o No o Yes o 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).	If registered areas contain Class II Type B biosafety cabinet(s),certifier included a test of the internal cabinet supply fan interlock.	o No o Yes o N/A	
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).	If any registered area contains Class III biosafety cabinet(s): , the condition of gloves is acceptable.	o No o Yes o N/A	
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).	If any registered area contains Class III biosafety cabinet(s): , the cabinet is appropriately certified.	o No o Yes o N/A	
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).	If any registered area contains Class III biosafety cabinet(s): HEPA filter (supply and exhaust) leak tests passed.	o No o Yes o N/A	
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).	If any registered area contains Class III biosafety cabinet(s):A successful cabinet integrity test is conducted if the BSC is new.	o No o Yes o N/A	
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).	If any registered area contains Class III biosafety cabinet(s):A successful cabinet integrity test is conducted if the BSC was moved.	o No o Yes o N/A	
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).	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.	o No o Yes o N/A	
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).	If any registered area contains Class III biosafety cabinet(s): the certifer verifies negative pressure/ventilation rate is appropriate.	o No o Yes o N/A	
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).	If any registered area contains Class III biosafety cabinet(s): the certifer verifies all alarms and interlocks which are present are working as intended.	o No o Yes o N/A	
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).	Area containing BSAT has self-closing doors.	o No o Yes o 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).	Laboratory has a sink and an eyewash station.	o No o Yes o 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 are water resistant (walls, floors and ceilings). Penetrations in floors, walls, and ceiling surfaces are sealed.	o No o Yes o N/A	
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).	If installed or required: HEPA filters on laboratory exhaust are certified annually.	o No o Yes o N/A	
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).	If installed or required: HEPA housing has isolation dampers for gas decontamination or bag-in-bag-out.	o No o Yes o N/A	
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 completed and documented Initial and Annual reverification of BSL-3/ABSL-3 facilities in accordance with FSAP policy;	o No o Yes o N/A	
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).	Vacuum lines or vacuum pumps are protected with HEPA filters or their equivalent. These must be replaced as needed.	o No o Yes o N/A	
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).	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.	o No o Yes o N/A	
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).	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.	o No o Yes o N/A	
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).	Appropriate biocontainment 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.	o No o Yes o 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).	Manipulation of BSAT is handled in primary containment devices and work on the open bench top is not permitted.	o No o Yes o N/A	
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).	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).	o No o Yes o N/A	
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).	Procedures for entry and exit of areas containing BSAT are appropriate.	o No o Yes o N/A	
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).	Appropriate PPE worn during handling and/or manipulation of BSAT.	o No o Yes o N/A	
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).	Appropriate glove practices used when BSAT is handled or area has not been decontaminated.	o No o Yes o N/A	
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).	PPE selection is based upon risk of the select agent or toxin and is appropriate for the work performed.	o No o Yes o N/A	
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).	Disposable PPE and/or protective clothing worn when handling BSAT is removed and not worn outside of the laboratory.	o No o Yes o N/A	
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).	Eye and face protection is disposed of with biohazardous waste, or decontaminated prior to reuse.	o No o Yes o N/A	
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).	Hand washing or “Shower out” is conducted prior to leaving laboratory.	o No o Yes o N/A	
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).	Appropriate procedures have been developed and implemented for the use of sharps.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
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).	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	o No o Yes o N/A	
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 has implemented appropriate biosafety and containment procedures for BSAT aerosol experiments.	o No o Yes o N/A	
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 has implemented appropriate procedures for laboratory equipment decontamination.	o No o Yes o N/A	
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 has implemented appropriate procedures for laboratory space decontamination	o No o Yes o N/A	
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 spills	o No o Yes o N/A	
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 waste transport	o No o Yes o N/A	
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 waste decontamination	o No o Yes o N/A	
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).	Appropriate procedures have been developed and implemented for use of centrifuges with BSAT. (safety cups with o-rings, opening in BSC, etc.)	o No o Yes o N/A	
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).	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.	o No o Yes o N/A	
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).	No indication that BSAT inactivation procedures have failed and resulted in removal of BSAT from registered areas.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
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).	Decontamination systems (autoclave, room decontamination systems, digesters, liquid effluent systems, etc.) have been confirmed to be operating correctly by annual revalidation.	o No o Yes o N/A	
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).	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.	o No o Yes o N/A	
12(c)(1)	In developing a biocontainment plan, an individual or entity should consider the following: "Containment Facilities and Safeguards for Exotic Plant Pathogens and Pests" (Robert P. Kahn and S.B. Mathur eds., 1999)	In developing a biocontainment plan, an individual or entity should consider the following: "Containment Facilities and Safeguards for Exotic Plant Pathogens and Pests" (Robert P. Kahn and S.B. Mathur eds., 1999)	o No o Yes o N/A	
12(c)(2)	In developing a biocontainment plan, an individual or entity should consider the following: "A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes" (Patricia L. Traynor ed., 2001).	In developing a biocontainment plan, an individual or entity should consider the following: "A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes" (Patricia L. Traynor ed., 2001).	o No o Yes o 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 biocontainment plan(s) and any referenced SOPs are reviewed annually and revised as necessary.	o No o Yes o 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 biocontainment plan(s). The plan(s) are reviewed and revised, as necessary, after any drill or exercise and after any incident.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
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.	o No o Yes o N/A	