

Inspection Checklist for General Biocontainment Laboratories (7 CFR 331; 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 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. | <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 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. | <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 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. | <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 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. | Validated inactivation procedures have been developed for select agents or toxins intended for inactivation and future use outside of registered areas, at a lower biocontainment level, or with less stringent PPE and biocontainment practices. | <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 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. | <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 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. | <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 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. | <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 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. | <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 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. | <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 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). | <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 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. | <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 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. | <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 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. | <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 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. | <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 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. | Hand washing or "Shower out" is conducted prior to leaving laboratory. | <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 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 | <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 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. | 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 | |

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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 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 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: spill procedures | <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 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 | <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 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 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 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. | Entity conducts work with recombinant/synthetic organisms propagated >10L quantities and complies with guidelines specified by the NIH Large Scale checklist(s). | <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 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 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(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 the following FSAP guidance; http://www.selectagents.gov/guidance-wastetreatment.html . | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A | |

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| 12(a)(1) | <p>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.</p> | <p>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.</p> | <ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A | |
| 12(a)(2) | <p>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.</p> | <p>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.</p> | <ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A | |

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| 12(a)(3) | An individual or entity required to register under this part must develop and implement a written 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A | |
| 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | Decontamination systems have been appropriately validated annually. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | 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). | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 placed in locations where with minimal susceptibility to airflow disruptions (e.g., away from doors, away from supply air ducts). | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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), 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 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 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 | |
| 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 certifier verifies negative pressure/ventilation rate is appropriate. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 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 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | 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 are water resistant (walls, floors and ceilings). Penetrations in floors, walls, and ceiling surfaces are sealed. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 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 | |
| 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; | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 safety practices are employed for inventory audits. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 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 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 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 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 changing / disposing of / decontaminating PPE are sufficient. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | 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 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | 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(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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 implemented for laboratory equipment decontamination. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A | |

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| 12(b) | The biocontainment and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). | Entity conducts work with recombinant/synthetic organisms propagated >10L quantities and complies with guidelines specified by the NIH Large Scale checklist(s). | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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.) | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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 \geq 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 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | All biological safety cabinets have been certified annually. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | 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 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. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | Laboratory HVAC HEPA filters, if present, have been certified annually. | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | 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 . | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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) | <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> 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). | <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 biocontainment 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 biocontainment 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 | |

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| 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> | <p><input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A</p> | |