

Inspection Checklist for BSL-4 Core Laboratories (7 CFR 331, 9 CFR 121, 42 CFR 73; BMBL 6th Edition)

Entity Name:

Inspection Date:

Building/Rooms:

Inspectors:

When information is entered in this form, the form is to be considered "Sensitive Select Agent Information."

Section	Regulation Text	Observation	Status	Comments
12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	All persons entering the laboratory must be advised of the potential hazards and meet specific entry requirements in accordance with institutional policies. Only persons whose presence in the facility or individual laboratory rooms is required for scientific or support purposes are authorized to enter.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Laboratory personnel and support staff are provided information on signs and symptoms of disease and receive occupational medical services including medical evaluation, surveillance, and treatment, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory. An essential adjunct to such an occupational medical services system is the availability of a facility for the isolation and medical care of personnel with potential or known laboratory-associated infections. A system is established for reporting and documenting near misses, laboratory accidents, exposures, unanticipated absence due to potential laboratory-associated infection, and for the medical surveillance of potential laboratory-associated illnesses.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	The entity has developed a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	The biosafety plan contains sufficient information and documentation to describe all biosafety and containment procedures for the entity's approved BSAT work and storage. Additional SOPs containing information required for the plan to fully describe all biosafety and containment procedures are referenced.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Biological materials that require BSL-4 containment are placed in a durable, leak-proof sealed primary container and then enclosed in a non-breakable, sealed secondary container prior to removal from the BSL-4 facility. These materials are transferred through a disinfectant dunk tank, fumigation chamber, or decontamination shower. Once removed, the primary container is not to be opened outside BSL-4 containment unless a validated inactivation method is used (e.g., gamma irradiation). The inactivation method is documented in-house with viability testing data to support the method.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	The BSL-4 laboratory may be located in a separate building or a clearly demarcated and isolated zone within a building. Facility access is restricted. Laboratory doors are lockable.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, and other potential emergencies. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Appropriate communication systems must be provided between the laboratory and the outside (e.g., voice, fax, and computer). Provisions for emergency communication and emergency access or egress must be developed and 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 biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	The biosafety plan contains sufficient information on biosafety and containment procedures for animals or plants accidentally exposed to or infected with a select agent.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(a)	An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested.	Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(a)(1)	The hazardous characteristics of each agent or toxin listed on the entity's registration and the biosafety risk associated with laboratory procedures related to the select agent or toxin;	The biosafety plan includes the hazardous characteristics of each agent or toxin listed on the entity's registration and the biosafety risk associated with laboratory procedures related to the select agent or toxin.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(a)(2)	Safeguards in place with associated work practices to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: Personal protective equipment and other safety equipment; containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety containers; and engineering controls and other facility safeguards;	The biosafety plan includes the following provisions: Safeguards in place with associated work practices to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: Personal protective equipment and other safety equipment; containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety containers; and engineering controls and other facility safeguards.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(a)(3)	Written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids (if applicable), laboratory surfaces and equipment, and effluent material	The biosafety plan includes the following provisions: Written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids (if applicable), laboratory surfaces and equipment, and effluent material.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(a)(4)	Procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.	The biosafety plan includes the following provisions: Procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	The biosafety and containment procedures are sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
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).	Precautions must be taken with any sharp items. Broken glassware must not be handled directly; it must be removed using a brush/dustpan, tongs, or forceps. Needle and syringe use should be restricted in the laboratory. Plasticware should be substituted for glassware whenever possible.	<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).	Walls, floors, and ceilings of the laboratory must be constructed to form a sealed internal shell to facilitate fumigation and prohibit animal and insect intrusion. The internal surfaces of this shell must be resistant to chemicals used for cleaning and decontamination of the area. Floors must be monolithic, sealed and coved. All penetrations in the internal shell of the laboratory, suit storage room (for suit labs), and the inner change room must be sealed.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	All persons entering the laboratory must be advised of the potential hazards and meet specific entry requirements in accordance with institutional policies. Only persons whose presence in the facility or individual laboratory rooms is required for scientific or support purposes are authorized to enter.	<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).	Biological materials that require BSL-4 containment are placed in a durable, leak-proof sealed primary container and then enclosed in a non-breakable, sealed secondary container prior to removal from the BSL-4 facility. These materials are transferred through a disinfectant dunk tank, fumigation chamber, or decontamination shower. Once removed, the primary container is not to be opened outside BSL-4 containment unless a validated inactivation method is used (e.g., gamma irradiation). The inactivation method is documented in-house with viability testing data to support the method.	<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).	Daily inspections of essential containment and life support systems are completed and documented before laboratory work is initiated to ensure that the laboratory is operating according to established parameters.	<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).	An automatically activated emergency power source must be provided at a minimum for the laboratory exhaust system, life support systems, alarms, lighting, entry and exit controls, BSCs, and door gaskets. Monitoring and control systems for air supply, exhaust, life support, alarms, entry and exit controls, and security systems should be on an uninterrupted power supply (UPS).	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal. If absolutely necessary to remove a needle from a syringe or recap a needle, a hands-free device or comparable safety procedure must be used. Used, disposable needles and syringes are carefully placed in puncture-resistant containers used for sharps disposal immediately after use. The sharps disposal container is located as close to the point of use as possible.	<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).	Services and plumbing that penetrate the laboratory walls, floors, or ceiling are installed to ensure that no backflow from the laboratory occurs. These penetrations are fitted with two (in series) backflow prevention devices. Consideration is given to locating these devices outside of containment.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	An eyewash station is readily available in the laboratory.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Only necessary equipment and supplies are stored inside the laboratory. All equipment and supplies taken inside the laboratory are decontaminated before removal from the laboratory. Supplies and materials that are not brought into the BSL-4 laboratory through the change room, are brought in through a dunk tank, previously decontaminated double-door autoclave, fumigation chamber, or airlock. After securing the outer doors, personnel within the laboratory retrieve the materials by opening the interior doors of the autoclave, fumigation chamber, or airlock. The inner door is secured after materials are brought into the facility. The outer door of the autoclave or fumigation chamber is not opened until the autoclave, fumigation chamber, or airlock has been operated through a successful decontamination cycle.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	A double-door autoclave, dunk tank, or fumigation chamber must be provided at the containment barrier for the passage of materials, supplies, or equipment in or out of the laboratory.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Atmospheric venting systems must be provided with two HEPA filters in series and be sealed up to the second filter.	<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).	Central vacuum systems are discouraged. If there is a central vacuum system, it does not serve areas outside the BSL-4 suit laboratory or cabinet. Two in-line HEPA filters are placed near each use point and overflow collection is provided while in use. Filters are installed to permit in-place decontamination and replacement. Consideration is made to the provision of two HEPA filters in series as close to the vacuum pump as possible.	<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).	A dedicated, non-recirculating ventilation system is provided. Only laboratories with the same HVAC requirements (i.e., other BSL-4 labs, ABSL-4, BSL-3 Ag labs) may share ventilation systems if gas-tight dampers and HEPA filters isolate each individual laboratory system.	<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 supply and exhaust components of the ventilation system must be designed to maintain the laboratory at negative pressure to surrounding areas and provide differential pressure or directional airflow as appropriate between adjacent areas within the laboratory.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Redundant supply fans are recommended. Redundant exhaust fans are required. Supply and exhaust fans must be interlocked to prevent positive pressurization of the laboratory.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	The ventilation system is monitored and alarmed to indicate malfunction or deviation from design parameters. A visual monitoring device is installed outside of containment so proper differential pressures within the laboratory may be verified prior to entry and during regular checklist procedures. Visual monitoring is also in place within containment.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	All HEPA filters are located as near as practicable to the laboratory to minimize the length of potentially contaminated ductwork. All HEPA filters are tested and certified annually. The HEPA filter housings are designed to allow for in situ decontamination and verification of the validated decontamination process prior to removal. The design of the HEPA filter housing has gas-tight isolation dampers, decontamination ports, and the ability to individually scan each filter in the assembly for leaks.	<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).	HEPA filtered exhaust air from a Class II BSC can be safely re-circulated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to the manufacturer's recommendations. Biological safety cabinets can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or a direct (hard) connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.	<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).	Pass-through dunk tanks, fumigation chambers, or equivalent decontamination methods are provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the BSL-4 laboratory. Access to the exit side of the pass-through is limited to those with authorized to the BSL-4 laboratory.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Liquid effluents from chemical showers, sinks, floor drains, autoclave chambers, and other sources within the laboratory must be decontaminated by a proven method, preferably heat treatment, before being discharged to the sanitary sewer. Effluents from personal body showers and toilets may be discharged to the sanitary sewer without treatment.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Decontamination of all liquid wastes must be documented. The decontamination process for liquid wastes must be validated physically and biologically. Biological validation must be performed annually or more often if required by institutional policy.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	A double-door, pass through autoclave(s) must be provided for decontaminating materials passing out of the BSL-4 laboratory. Autoclaves that open outside of the laboratory must be sealed to the interior wall. This bioseal must be durable, airtight, and capable of expansion and contraction. Positioning the bioseal so that the equipment can be accessed and maintained from outside the laboratory is strongly recommended. The autoclave doors must be interlocked so that only one can be opened at any time and be automatically controlled so that the outside door to the autoclave can only be opened after the decontamination cycle has been completed.	<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).	Gas discharge from the autoclave chamber is HEPA-filtered or is decontaminated. Autoclave decontamination processes are designed so that unfiltered air or steam exposed to infectious material cannot be released to the environment.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	The BSL-4 facility design parameters and operational procedures are documented. The facility is tested to verify that the design and operational parameters have been met prior to operation. Facilities are also be re-tested annually or after significant modification to ensure operational parameters are met. Verification criteria are modified, as necessary, by operational experience.	<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).	After completion of work or after any spill/splash of potentially infectious material, work surfaces are decontaminated with an appropriate disinfectant.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	All waste is decontaminated by an effective and validated method prior to removal from the BSL-4 laboratory.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	While the laboratory is operational, personnel must enter and exit the laboratory through the clothing change and shower rooms except during emergencies. After the laboratory has been completely decontaminated and all infectious agents are secured, necessary staff may enter and exit without following the clothing change and shower requirements.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	All personal clothing must be removed in the outer clothing change room. All persons entering the laboratory must use laboratory clothing, including undergarments, pants, shirts, jumpsuits, shoes, and gloves (as appropriate). All persons leaving the laboratory must take a personal body shower. Used laboratory clothing must not be removed from the inner change room through the personal shower. These items must be treated as contaminated materials and decontaminated before laundering.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Laboratory equipment is routinely decontaminated and is decontaminated after spills, splashes, or other potential contamination and before repair, maintenance, or removal from the laboratory.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Spills involving infectious materials must be contained, decontaminated, and cleaned up by appropriate professional staff, or others properly trained and equipped to work with infectious material. A spill procedure must be developed and posted within the laboratory.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and NIH Office of Science Policy. Written records are prepared and maintained.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Equipment is routinely decontaminated and is decontaminated after spills, splashes, or other potential contamination and before repair, maintenance, or removal from the laboratory. Equipment or material that might be damaged by high temperatures or steam is decontaminated using an effective and verified method, such as a gaseous or vapor method, in an airlock or chamber designed for this purpose.	<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).	Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All incidents must be reported to the laboratory supervisor, institutional management, and appropriate laboratory personnel as defined in the laboratory biosafety manual.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(d)	The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.	For Tier 1 entities, the biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(d)	The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.	For Tier 1 entities, individuals with access to Tier 1 select agents and toxins are enrolled in the occupational health program.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(e)	The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.	The biosafety plan(s) and any referenced SOPs are reviewed annually and revised as necessary.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(e)	The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.	Drills or exercises are conducted at least annually to test and evaluate the effectiveness of the biosafety plan(s). The plan(s) are reviewed and revised, as necessary, after any drill or exercise and after any incident.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
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.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	