

# **Inspection Checklist for ABSL-3 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(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).	Emergency shower is available.	<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).	In addition to meeting ABSL-2 requirements, laboratory has two inward-opening self-closing doors.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	In addition to meeting ABSL-2 requirements, laboratory sink is hands-free.	<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).	In addition to meeting ABSL-2 requirements, 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 biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Laboratory has ducted ventilation 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).	In addition to meeting ABSL-2 requirements, animal rooms maintain inward directional airflow compared to adjoining hallways.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If registered area contains Class II type A1 or A2 biosafety cabinet(s) that is canopy-connected (thimble) to the building exhaust system, BSC(s) has an audible and/or visual alarm to indicate insufficient airflow through the canopy.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If registered area contains Class II Type A1 or A2 biosafety cabinet(s) that are thimble connected to the building exhaust system, smoke test(s) verify inward airflow at thimble connection.	<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).	Laboratory and laboratory furniture can be easily decontaminated.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Personnel with access to select agents and toxins are offered appropriate medical surveillance. (For Tier 1 select agents or toxin, entity complies with occupational health program requirements of section 12(d).)	<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).	Sufficient biosafety and containment procedures are developed and implemented for animals or plants intentionally or accidentally exposed to or infected with a select agent agent or toxin.	<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).	Primary containment devices are used for select agent animal work or risk assessments have been conducted for procedures that cannot be conducted under primary 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).	Shared resources (laboratory equipment, cages, racks and/or personnel) used for other animal activities conducted by the entity are handled in a manner that minimizes contamination of other areas. Materials are decontaminated by a validated method prior to reuse and/or personnel adhere to appropriate exit procedures prior to leaving the registered areas.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	There have been no accidental animal select agent exposures or infections.	<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 airflow does not reverse at the containment barrier under failure conditions.	<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).	In addition to meeting ABSL-2 requirements, a visual monitoring device is present to allow verification of directional airflow.	<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).	Research animals are not of a size or with growth requirements that preclude the use of containment for laboratory animals.	<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).	Ventilated caging systems with exhaust HEPA filters are certified annually.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If caging is actively ventilated, there are safety mechanisms in place to prevent the cage and exhaust plenums from becoming positively pressurized if the exhaust fan fails (e.g., a supply/exhaust interlock).	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If caging is actively ventilated, the system is alarmed to indicate operational malfunctions.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If conventional caging is used to house select agent exposed animals, procedures are developed and implemented following an appropriate site-specific risk assessment.	<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).	Smoke testing verifies containment for downdraft tables or other physical containment devices.	<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).	Liquid effluents from downdraft tables are appropriately decontaminated.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Downdraft tables or other physical containment devices operate according to manufacturer's specifications and exhaust air through HEPA filtration (or equivalent) before being discharged into the animal facility. HEPA filters are tested annually and replaced as needed.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	For activities conducted outside of containment devices, risk assessments have been brought back for FSAP management review and verified as sufficient.	<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).	When not possible to conduct procedures inside a BSC or other physical primary containment device, a combination of appropriate PPE, administrative, and/or engineering controls are used based on a risk assessment.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If entity engages in practices to 'grey out' animals that have been exposed to select agents, appropriate procedures are in place and have been reviewed by FSAP biosafety officers.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Disposable PPE (e.g., gowns, lab coats, tyvek suits) and/or protective clothing (e.g., scrubs, uniforms) are worn when infectious materials and/or animals are housed or manipulated, based on risk assessment (describe in comments).	<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).	Protective clothing is removed prior to leaving the animal facility, when applicable.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	To prevent cross contamination, boots, shoe covers, or other protective footwear are used where indicated and disposed of or decontaminated after use.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Molded surgical masks or respirators are worn in rooms containing experimental animals.	<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).	Conventional caging systems may be used provided that all personnel wear appropriate personal protective devices. These protective devices shall include at a minimum wrap-around gowns, head covers, gloves, shoe covers, and respirators. All personnel shall shower on exit from areas where these devices are required.	<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).	When an animal containing recombinant or synthetic nucleic acid molecules or a recombinant or synthetic nucleic acid molecule-derived organism is euthanized or dies, the carcass shall be disposed of to avoid its use as food for human beings or animals unless food use is specifically authorized by an appropriate Federal agency.	<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 work surfaces of containment equipment shall be decontaminated when work with organisms containing recombinant or synthetic nucleic acid molecules is finished. Where feasible, plastic-backed paper toweling shall be used on nonporous work surfaces to facilitate clean-up.	<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 animals shall be euthanized at the end of their experimental usefulness and the carcasses decontaminated before disposal in an approved manner.	<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).	Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated at minimum on a yearly basis with an indicator organism. More frequent validation, based on the amount of use or other safety factors, shall be left to the discretion of the IBC.	<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).	Experiments involving other organisms that require containment levels lower than BL3-N may be conducted in the same area concurrently with experiments requiring BL3-N containment provided that they are conducted in accordance with BL3-N practices.	<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).	Animal holding areas shall be cleaned at least once a day and decontaminated immediately following any spill of viable materials.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Personnel shall be required to shower before exiting the BL3-N area and wearing personal clothing.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If arthropods are used in the experiment or the agent under study can be transmitted by an arthropod, the interior work area shall be appropriately screened (52 mesh). All perimeter joints and openings shall be sealed, and additional arthropod control mechanisms used to minimize arthropod entry and propagation, including appropriate screening, or the equivalent of access doors.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	