

Inspection Checklist for ABSL-2 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).	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).	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).	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).	Seams, 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 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).	Direction of airflow into animal facility is inward; animal rooms maintain inward directional airflow compared to adjoining hallways.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If 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	
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 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).	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	

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12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If 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).	Individuals who handle materials and animals containing recombinant or synthetic nucleic acid molecules shall be required to wash their hands before exiting the containment area.	<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).	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).	A double barrier shall be provided to separate male and female animals unless reproductive studies are part of the experiment or other measures are taken to avoid reproductive transmission. Reproductive incapacitation may be used.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> N/A	