Inspection Checklist for ABSL-4 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.	Each institution ensures that worker safety and health concerns are addressed as part of the animal protocol review process. Consideration is given to specific biohazards unique to the animal species and protocol in use. Prior to beginning a study, animal protocols are also reviewed and approved by the IACUC and IBC, or equivalent resources, as appropriate.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Restraint devices and practices that reduce the risk of exposure during animal manipulations must be used where practicable (e.g., physical restraint devices, chemical restraint medications, mesh or Kevlar gloves, etc.).	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	In ABSL-4 suit labs, infected animals are housed in a primary containment system. Primary containment systems include: actively ventilated caging systems; open cages placed in ventilated enclosures; solid wall and bottom cages covered with micro-isolator lids and opened in laminar flow hoods or HEPA-filtered downdraft tables; or other equivalent primary containment systems.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Entity operates ACL-4 laboratory and complies with containment standards outlined in the arthropod containment guidelines.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Needles, syringes, and other sharp instruments are limited for use in the ABSL-4 laboratory to situations where there is no alternative, such as parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.	o No o Yes o 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 waste, including animal tissues, carcasses, and contaminated or presumptively contaminated bedding, is decontaminated by an effective and validated method prior to removal from the ABSL-4 laboratory.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Equipment is routinely decontaminated and is decontaminated before repair, maintenance, or removal from the animal facility. Equipment (e.g., sensitive electronic, medical, or routine husbandry equipment) or material that might be damaged by high temperatures or steam is decontaminated using an effective and verified procedure such as a gaseous or vapor method in a sealable airlock or chamber designed for this purpose.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	In ABSL-4 cabinet labs, all manipulations of infectious animals and materials within the laboratory must be conducted in a Class III BSC.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	In ABSL-4 suit labs, all procedures involving the manipulation of infectious materials or infected animals are conducted within a BSC or other physical containment devices.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Equipment that may produce aerosols is used within primary containment devices that exhaust air through HEPA filtration before being discharged into the animal room or facility exhaust system. These HEPA filters are tested annually and replaced as needed.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Rooms in the ABSL-4 facility must be arranged to ensure sequential passage through an inner (dirty) change area, personal shower, and outer (clean) change room upon exit.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Hands-free sinks inside ABSL-4 suit facilities are placed near procedure areas. For ABSL-4 cabinet labs, a hands-free sink is provided near the door from the cabinet room to the inner change rooms. A sink is provided in the outer change room.	o No o Yes o 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 supply and exhaust components of the ventilation system must be designed to maintain the ABSL-4 laboratory at negative pressure to surrounding areas and provide differential pressure/directional airflow between adjacent areas within the laboratory.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	NHPs may be housed in open cages within a dedicated animal holding room that serves as the primary barrier and in which all personnel are required to wear one-piece positive pressure suits. A room serving as a primary barrier must be air-tight and capable of being decontaminated using fumigation.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If NHPs are contained in a dedicated animal holding room serving as the primary barrier, access to the animal holding room from service corridors outside of the BSL-4 containment space shall require passage through two sets of doors, and the innermost door must be an air pressure resistant (APR) door.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If NHPs are contained in a dedicated animal holding room serving as the primary barrier, APR doors providing direct ingress from the exterior service corridor shall be fitted with appropriate and redundant lock-out mechanisms to prevent access when the animal holding room is contaminated and in use. There should be more than one mechanism to ensure that this primary barrier door cannot be opened when the animal room is contaminated and the APR door shall not serve as an emergency exit from the BSL-4 laboratory. The APR door shall be appropriately tested to demonstrate that in the closed, locked-out mode, the door provides an air-tight barrier proven by pressure decay testing or other equivalent method.	o No o Yes o 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 NHPs are contained in a dedicated animal holding room serving as the primary barrier, any doors allowing access into a corridor from which there is direct ingress to an animal holding room must be fitted with either an APR door or a non-APR door, provided directional airflow is maintained from the laboratory corridor space into the animal room. For the purpose of fumigation, animal rooms equipped with non-APR doors opening into the adjacent interior corridors shall be considered one space (i.e., areas between air-tight doors shall be fumigated together).	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If NHPs are contained in a dedicated animal holding room serving as the primary barrier, any doors used for access to the service corridor shall be self-closing and of solid construction, designed not to corrode, split or warp.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If NHPs are contained in a dedicated animal holding room serving as the primary barrier, access to the service corridor inside the secondary barrier shall be restricted and strictly controlled when animal rooms are in use. Whenever possible, the secondary barrier doors should be fitted with safety interlock switches designed to prevent it from opening when an animal holding room door (the primary barrier) is opened following room decontamination; if interlock devices cannot be used, specific administrative procedures shall be implemented to control access to the service corridor.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If NHPs are contained in a dedicated animal holding room serving as the primary barrier, the service corridor shall maintain a negative pressure relative to adjoining traffic corridors.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If NHPs are contained in a dedicated animal holding room serving as the primary barrier, prior to fumigation of the animal holding room, cages should be removed for autoclaving or chemical decontamination.	o No o Yes o 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 NHPs are contained in a dedicated animal holding room serving as the primary barrier, caging should be chosen to reduce the amount of animal detritus that can be thrown out of the cage and onto the floor of the animal holding room.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If NHPs are contained in a dedicated animal holding room serving as the primary barrier, the flow of personnel, material, and equipment should be directed in order to minimize the spread of contamination from the animal holding room into adjacent areas of the laboratory.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	If NHPs are contained in a dedicated animal holding room serving as the primary barrier, following animal room decontamination, safeguards involving the use of PPE and appropriate administrative controls shall be implemented for the safe retrieval of biological indicators in order to prevent the spread of infectious agents in the event of a decontamination failure.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	Experiments involving other organisms that require containment levels lower than BL4-N may be conducted in the same area concurrently with experiments requiring BL4-N containment provided that they are conducted in accordance with BL4-N practices.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	The BL4-N laboratory provides a double barrier to prevent the release of recombinant or synthetic nucleic acid molecule containing microorganisms into the environment. Design of the animal facility shall be such that if the barrier of the inner facility is breached, the outer barrier will prevent release into the environment. The animal area shall be separated from all other areas. Passage through two sets of doors shall be the basic requirement for entry into the animal area from access corridors or other contiguous areas.	o No o Yes o 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 necropsy room shall be provided within the BL4-N containment area.	o No o Yes o N/A	