Inspection Checklist for ABSL-4 Laboratories (7 CFR 331, 9 CFR 121, 42 CFR 73; 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 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.	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).	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).	The ABSL-4 facility design parameters and operational procedures must be documented. The facility must be tested to verify that the design and operational parameters have been met prior to operation. Facilities must also be re-verified annually. Verification criteria should be modified as necessary by operational experience.	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).	Infected animals should be housed in a primary containment system (such as open cages placed in ventilated enclosures, solid wall and bottom cages covered with filter bonnets and opened in laminar flow hoods, or other equivalent primary containment systems).	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).	Prior to beginning a study, appropriate policies and procedures for animal welfare during the conduct of research must be developed and approved by the IACUC. The biosafety official, the IBC, and/or other applicable committees are responsible for review of protocols and policies to prevent hazardous exposures to personnel who manipulate and care for animals.	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	
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).	All equipment and supplies taken inside the laboratory must be decontaminated before removal. Consideration should be given to means for decontaminating routine husbandry equipment and sensitive electronic and medical equipment.	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, infected animals should be housed in a primary containment system (such as open cages placed in ventilated enclosures, solid wall and bottom cages covered with filter bonnets and opened in laminar flow hoods, or other equivalent primary containment systems). Personnel wearing a one-piece positive pressure suit ventilated with a life support system must conduct all procedures.	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 manipulations of potentially infectious agents must be performed within a Class II BSC or other primary barrier system. Infected animals should be handled within a primary barrier system, such as a Class II BSC or other equivalent containment system.	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 must be contained in primary barrier devices that exhaust air through HEPA filtration before being discharged into the laboratory. These HEPA filters should be 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).	Sinks inside the ABSL-4 laboratory must be placed near procedure areas, contain traps, and be connected to the wastewater decontamination system.	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 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	

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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, 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	
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	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	

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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, 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	
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	

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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 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	