

Inspection Checklist for BSL-4 Suit 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).	All procedures must be conducted by personnel wearing a one-piece positive pressure supplied air suit.	☐ No ☐ Yes ☐ 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 facility must be arranged to ensure exit by sequential passage through the chemical shower, inner (dirty) change room, personal shower, and outer (clean) changing area.	☐ No ☐ Yes ☐ 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).	Entry into the BSL-4 laboratory is through an airlock fitted with airtight doors. Personnel who enter this area wear a positive pressure suit supplied with HEPA-filtered breathing air. The breathing air systems have redundant compressors, failure alarms, and emergency backup capable of supporting all workers within the laboratory to allow the personnel to safely exit the laboratory.	☐ No ☐ Yes ☐ 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 chemical shower must be provided to decontaminate the surface of the positive pressure suit before the worker leaves the laboratory. In the event of an emergency exit or failure of the chemical shower system, a method for decontaminating positive pressure suits, such as a gravity fed supply of chemical disinfectant, is needed.	☐ No ☐ Yes ☐ 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 the suit laboratory are placed near procedure areas.	☐ No ☐ Yes ☐ N/A	

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).	Supply air to the laboratory, including the decontamination shower, must pass through a HEPA filter. All exhaust air from the suit laboratory, decontamination shower and fumigation or decontamination chambers must pass through two HEPA filters, in series, before discharge to the outside. The exhaust air discharge must be located away from occupied spaces and air intakes.	☐ No ☒ Yes ☐ 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 procedures involving the manipulation of infectious agents are conducted within a BSC or other physical containment devices. No work with open vessels is conducted on the open bench.	☐ No ☒ Yes ☐ 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 barrier devices that exhaust air through HEPA filtration before being discharged into the laboratory or facility exhaust system. These HEPA filters are tested annually and replaced as needed.	☐ No ☒ Yes ☐ N/A	