Inspection Checklist for Biosafety: BSL-3/ ABSL-3 Annual Verification Policy (9 CFR 121, 42 CFR 73, 7 CFR 331- 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).	HVAC operational verification is performed and documented prior to initial operation of the BSL-3/ABSL-3 containment areas to ensure operational parameters are maintained. The HVAC design verification process provides evidence that secondary containment will be maintained during both normal operating conditions and during failure conditions to prevent air-flow reversals into non-containment areas or positive pressurization events (e.g., outside the containment boundary, hallways).	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).	HVAC operation is verified and documented after major changes have been made to, or resolving major problems with, the HVAC 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 entity performs and documents initially for a BSL-3 or ABSL-3 laboratory and at least annually: The means of detecting air flow accurately reflected observed air flow.	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 entity performs and documents initially for a BSL-3 or ABSL-3 laboratory and at least annually: Inward directional airflow was confirmed by observation for 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).	The entity performs and documents initially for a BSL-3 or ABSL-3 laboratory and at least annually: Decontamination systems have been confirmed to be operating correctly.	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 entity performs and documents initially for a BSL-3 or ABSL-3 laboratory and at least annually: Programmed BAS alarms should be verified for proper functioning.	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 entity performs and documents initially for a BSL-3 or ABSL-3 laboratory and at least annually: All alarms (fire, air flow, security, etc.) have been checked and are functioning according to established specifications.	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 entity performs and documents initially for a BSL-3 or ABSL-3 laboratory and at least annually: Laboratory HVAC HEPA filters, if present, have been certified annually.	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 entity performs and documents initially for a BSL-3 or ABSL-3 laboratory and at least annually: Exhaust fan motors have been checked and routine maintenance conducted.	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 entity performs and documents initially for a BSL-3 or ABSL-3 laboratory and at least annually: The laboratory has been checked for unsealed penetrations, cracks, breaks, etc. and these have been repaired if present.	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 entity performs and documents initially for a BSL-3 or ABSL-3 laboratory and at least annually: Biological safety cabinets have been certified annually.	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 entity performs and documents initially for a BSL-3 or ABSL-3 laboratory and at least annually: Seals on centrifuges, Class III cabinets, gloves on Class III cabinets, etc., have been checked and replaced if required.	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 entity performs and documents initially for a BSL-3 or ABSL-3 laboratory and at least annually: Drench showers, eye wash stations, and hands-free sinks have been confirmed to be operating properly.	o No o Yes o N/A	