

Inspection Checklist for Biosafety: BSL-4/ ABSL-4 Annual Verification Policy (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).	HVAC operational verification is performed and documented prior to initial operation of the BSL-4/ABSL-4 containment areas (suit and cabinet), annually, and after major changes 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).	☐ 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).	The tested failure conditions for verification of HVAC performance include: Mechanical failure of the supply and exhaust fans systems and the ability to transition to the redundant fan without airflow reversals from the BSL-4/ABSL-4 laboratory (suit and cabinet) that escapes the containment boundary.	☐ 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).	The tested failure conditions for verification of HVAC performance include: Transfer to an automatically activated backup power supply and the ability to transition from normal power to the automatically activated backup, emergency power supply without airflow reversal from the BSL-4/ABSL-4 laboratory (suit and cabinet) that escapes the containment boundary.	☐ 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).	The tested failure conditions for verification of HVAC performance include: Return from emergency power status to normal power status and the ability to transition from automatically activated backup, emergency power to normal power without positive pressurization events from the BSL-4/ABSL-4 containment areas (suit and cabinet) to non-containment areas.	☐ 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).	HVAC operation is verified and documented after major changes have been made to the HVAC system, including replacement or repairs of exhaust and supply fans serving the BSL-4/ABSL-4 containment areas.	☐ No ☐ Yes ☐ 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).	HVAC operation is verified and documented after major changes have been made to the HVAC system, including BAS logic programming changes.	☐ 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).	HVAC operation is verified and documented after major changes have been made to the HVAC system, including structural changes to the BSL-4/ABSL-4 containment areas.	☐ 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).	HVAC operation is verified and documented after major changes have been made to the HVAC system, including addition or removal of hard-ducted biological safety cabinets (BSCs), Class III BSCs, or decontamination systems.	☐ 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).	HVAC operation is verified and documented after major changes have been made to the HVAC system, including events that compromise the containment envelope.	☐ 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).	HVAC operation is verified and documented after resolving major problems noted with, the HVAC system, including recurring failures of the HVAC system.	☐ 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).	HVAC operation is verified and documented after resolving major problems noted with, the HVAC system, including observation or evidence that HVAC alarms are not working properly.	☐ 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).	HVAC operation is verified and documented after major changes have been made to the HVAC system, including replacement, repairs, or modifications of HVAC control system(s) that serve BSL-4/ABSL-4 containment areas.	☐ 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).	HVAC operation is verified and documented after major changes have been made to the HVAC system, including replacement, repairs, or modifications of ductwork valves or dampers that serve BSL-4/ABSL-4 containment areas.	☐ 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).	HVAC operation is verified and documented after resolving major problems noted with, the HVAC system, including observation or evidence that BSCs with an HVAC connection (hard duct or thimble) are not working as designed.	☐ 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).	HVAC operation is verified and documented after resolving major problems noted with, the HVAC system, including supply or exhaust interlocking system failures.	☐ No ☐ Yes ☐ 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-4 or ABSL-4 laboratory and at least annually: Recalibration of components that monitor containment parameters (e.g., differential pressure gauges, pressure transducers, BAS).	☐ 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).	The entity performs and documents initially for a BSL-4 or ABSL-4 laboratory and at least annually: Verification of BAS-programmed alarm communication.	☐ 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).	The entity performs and documents initially for a BSL-4 or ABSL-4 laboratory and at least annually: Confirmation that decontamination systems are operating as designed, including verification that system operational parameters have not changed from biologically validated conditions.	☐ 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).	The entity performs and documents initially for a BSL-4 or ABSL-4 laboratory and at least annually: Confirmation that decontamination systems are operating as designed, including biological validation is performed at least annually or more often, if required by institutional policy and/or risk assessment.	☐ 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).	The entity performs and documents initially for a BSL-4 or ABSL-4 laboratory and at least annually: Confirmation that decontamination systems are operating as designed, including certification testing of associated high-efficiency particulate air (HEPA) filters, when applicable (e.g., operating vent, pressure relief vent, chamber effluent/vent).	☐ 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).	The entity performs and documents initially for a BSL-4 or ABSL-4 laboratory and at least annually: Confirmation that decontamination systems, including system failure and emergency communication systems, are operating as designed (e.g., alarms, leak detection).	☐ 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).	The entity performs and documents initially for a BSL-4 or ABSL-4 laboratory and at least annually: Confirmation that decontamination systems are operating as designed, including verifying appropriate filter media is selected and maintained (e.g., HEPA, polytetrafluoroethylene [PTFE]).	☐ No ☐ Yes ☐ 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-4 or ABSL-4 laboratory and at least annually: Confirmation that decontamination systems are operating as designed, including implementation of risk-based preventative maintenance for other equipment that is critical to containment components (e.g., cook tanks, etc.).	☐ 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).	The entity performs and documents initially for a BSL-4 or ABSL-4 laboratory and at least annually: Verification of laboratory HVAC, plumbing vent line, and decontamination system filters by appropriate means and appropriate acceptance criteria to ensure integrity.	☐ 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).	The entity performs and documents initially for a BSL-4 or ABSL-4 laboratory and at least annually: Assessment of breathing air quality for both main and backup breathing air supply.	☐ 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).	The entity performs and documents initially for a BSL-4 or ABSL-4 laboratory and at least annually: Certification of biological safety cabinets.	☐ 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).	The entity performs and documents initially for a BSL-4 or ABSL-4 laboratory and at least annually: Verification of primary containment integrity with component replacement if defective.	☐ 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).	The entity performs and documents initially for a BSL-4 or ABSL-4 laboratory and at least annually: Confirmation that all alarms have been checked and are functioning according to approved design specifications.	☐ 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).	The entity performs and documents on an ongoing, routine basis: Surveillance and implementation of routine maintenance programs and backup power systems for HVAC supply and exhaust fans, main and backup breathing air systems, and decontamination systems.	☐ 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).	The entity performs and documents on an ongoing, routine basis: Surveillance of containment envelope for penetrations, cracks, breaks, and performance or related repairs.	☐ No ☐ Yes ☐ 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 on an ongoing, routine basis: Surveillance and verification of secondary containment envelope integrity.	☐ 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).	The entity performs and documents on an ongoing, routine basis: Confirmation and testing of critical interlocks and manual overrides (e.g., between exhaust fans and air handling units, between laboratory exhaust fan airflows and supply airflows, and between mechanical and electronic door interlocks)	☐ No ☐ Yes ☐ N/A	