Inspection Checklist for ABSL-3 Ag Laboratories (9 CFR 121; 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.	The entity plan describes entrance into the facility is through a series of barriers and/or procedures that provide a distinct separation between containment and non-containment areas. Provisions include removing, disinfecting, and/or disposing of contaminated PPE, footwear, uniforms, and/or 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).	Entrance into the facility is through a series of barriers and/or with procedures that provide a distinct separation between containment and non-containment areas. Provisions include removing, disinfecting, and/or disposing of contaminated PPE, footwear, uniforms, and/or equipment.	o No o Yes o N/A	
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.	The entity plan describes waste handling procedures must adhere to the results of a site-specific risk assessment, applicable regulations, and local policies and procedures.	o No o Yes o 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).	Waste handling procedures must adhere to the results of a site-specific risk assessment, applicable regulations, and local policies and procedures. In some cases, a two-step waste process may be indicated.	o No o Yes o N/A	
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.	The entity plan describes pathological incinerators, or other approved means, must be provided for the safe disposal of the carcasses of infected animals. Redundancy and the use of multiple technologies need to be considered and evaluated.	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).	Pathological incinerators, or other approved means, must be provided for the safe disposal of the carcasses of infected animals. Redundancy and the use of multiple technologies need to be considered and evaluated.	o No o Yes o N/A	
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.	The entity plan describes that ABSL-3Ag facilities are required to have dedicated, single-pass ventilation systems that create and maintain an appropriate inward directional pressure gradient.	o No o Yes o 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).	ABSL-3Ag facilities have dedicated, single-pass ventilation systems that create and maintain an appropriate inward directional pressure gradient.	o No o Yes o N/A	
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.	The entity plan describes that the air supply and exhaust system are independent or isolatable, and provide graded pressure differentials such that inward directional airflow is maintained in containment spaces relative to adjacent non-containment areas in the event of a breach (e.g., opening doors). Pressure differentials are designed such that air moves continuously from low hazard areas to higher hazard areas in the event of a breach.	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 air supply and exhaust system are independent or isolatable, and provide graded pressure differentials such that inward directional airflow is maintained in containment spaces relative to adjacent non-containment areas in the event of a breach (e.g., opening doors). Pressure differentials are designed such that air moves continuously from low hazard areas to higher hazard areas in the event of a breach.	o No o Yes o N/A	
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.	The entity plan describes exhaust air from ABSL-3Ag facilities must pass through ductwork with two HEPA filters installed in series prior to being exhausted outside. Pressure decay testing confirms that HEPA filter frames, housing, and the ductwork between the ABSL-3Ag facility and the HEPA filter are airtight.	o No o Yes o 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).	Exhaust air from ABSL-3Ag facilities must pass through ductwork with two HEPA filters installed in series prior to being exhausted outside. Pressure decay testing confirms that HEPA filter frames, housing, and the ductwork between the ABSL-3Ag facility and the HEPA filter are airtight.	o No o Yes o N/A	
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.	The entity plan describes HVAC system pressure differentials must be designed after a site-specific risk assessment to incorporate engineering features that protect against sustained reversal of directional airflow in the event of a breach of containment (e.g., opening doors).	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 pressure differentials must be designed after a site-specific risk assessment to incorporate engineering features that protect against sustained reversal of directional airflow in the event of a breach of containment (e.g., opening doors).	o No o Yes o N/A	
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.	The entity plan describes air supply and exhaust systems must be interlocked to prevent sustained reversal of directional airflow during HVAC failures or emergencies that can lead to positive pressurization of containment spaces.	o No o Yes o 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).	Air supply and exhaust systems must be interlocked to prevent sustained reversal of directional airflow during HVAC failures or emergencies that can lead to positive pressurization of containment spaces.	o No o Yes o N/A	
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.	The entity plan describes audible or visual alarms are needed that can be heard and/or seen both inside and outside of the containment space to alert staff when pressure differentials are outside the preset range.	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).	Audible or visual alarms are needed that can be heard and/or seen both inside and outside of the containment space to alert staff when pressure differentials are outside the preset range.	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).	HEPA filter housings must be fabricated to allow the filters to be scan tested after installation and decontaminated in place before removal.	o No o Yes o N/A	

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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.	The entity plan describes liquid effluents from ABSL-3Ag containment areas must be collected and decontaminated before disposal into a sanitary sewer.	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).	Liquid effluents from ABSL-3Ag containment areas must be collected and decontaminated before disposal into a sanitary sewer.	o No o Yes o N/A	
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.	The entity plan describes that at a minimum, effluents from laboratory sinks, BSCs, and floor drains must be directed into the waste collection system for decontamination before discharge. A site-specific risk assessment should be performed to: (1) determine if effluent from autoclave chambers, shower rooms, and toilets should be collected and decontaminated, and (2) identify the optimal decontamination method that is required (i.e., validated chemical treatment system or heat liquid waste 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).	At a minimum, effluents from laboratory sinks, BSCs, and floor drains must be directed into the waste collection system for decontamination before discharge. A site-specific risk assessment should be performed to: (1) determine if effluent from autoclave chambers, shower rooms, and toilets should be collected and decontaminated, and (2) identify the optimal decontamination method that is required (i.e., validated chemical treatment system or heat liquid waste decontamination system).	o No o Yes o N/A	

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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.	The entity plan describes facilities are designed with basement access or piping tunnels that allow the facility waste plumbing systems to be inspected. For waste piping that is not readily accessible nor inspected (underground, walls, etc.), double containment piping systems with leak alarms and annular space decontaminating capability must be 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).	Facilities are designed with basement access or piping tunnels that allow the facility waste plumbing systems to be inspected. For waste piping that is not readily accessible nor inspected (underground, walls, etc.), double containment piping systems with leak alarms and annular space decontaminating capability must be present.	o No o Yes o N/A	
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.	The entity plan describes all penetrations in the floor, walls, and ceilings must be sealed and verified to be airtight to prevent cross-contamination and to allow gaseous or vapor phase fumigation within the containment facility without affecting adjacent non-containment space (see specifications in the USDA ARS Facilities Design Standards 242.1M-ARS). This includes openings around ductwork; plumbing fixtures; doorframes; door hardware and gaskets; electrical boxes; and vents.	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 penetrations in the floor, walls, and ceilings must be sealed and verified to be airtight to prevent cross-contamination and to allow gaseous and vapor phase fumigation within the containment facility without affecting adjacent non-containment space (see specifications in the USDA ARS Facilities Design Standards 242.1M-ARS). This includes openings around ductwork; plumbing fixtures; doorframes; door hardware and gaskets; electrical boxes; and vents.	o No o Yes o 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).	Construction materials used in an ABSL-3Ag facility should be appropriate for the intended end use. Walls must be constructed slab-to-slab and must be contiguous with the floor and ceiling.	o No o Yes o N/A	
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.	The entity plan describes decontamination of an entire animal room is considered when there has been gross contamination of the space, significant changes in usage, major renovations, or maintenance shutdowns. Selection of the appropriate materials and methods used to decontaminate the animal room is based on the risk assessment.	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).	Decontamination of an entire animal room is considered when there has been gross contamination of the space, significant changes in usage, major renovations, or maintenance shutdowns. Selection of the appropriate materials and methods used to decontaminate the animal room is based on the risk assessment.	o No o Yes o N/A	
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.	The entity plan describes equipment that enters the facility is decontaminated before repair, maintenance, or removal from the areas where infectious materials and/or animals are housed and manipulated. A method for decontaminating routine husbandry equipment and sensitive electronic or medical equipment is identified and implemented.	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).	Equipment that enters the facility is decontaminated before repair, maintenance, or removal from the areas where infectious materials and/or animals are housed and manipulated. A method for decontaminating routine husbandry equipment and sensitive electronic or medical equipment is identified and implemented.	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).	Necropsy rooms must be equipped and large enough to safely accommodate work on research animals housed in the containment unit.	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 BSCs are installed they must be selected, located, installed, operated, and maintained according to the manufacturer's instructions and standards found in NSF/ANSI 49-2018.	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).	Supply air to a Class III cabinet is HEPA filtered, and the exhaust air must be double filtered (through a cabinet HEPA and then through a HEPA in a dedicated building exhaust system) before being discharged to the atmosphere.	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).	Walls, floors, and ceilings of the ABSL-3Ag facility are constructed to form a sealed internal shell to facilitate fumigation and prohibit animal and insect intrusion. The internal surfaces of this shell must be resistant to liquids and chemicals used for cleaning and decontamination of the area. Floors are monolithic, sealed, and covered. All penetrations into the internal shell of the facility are sealed to create a functional area capable of passing a pressure decay test with a leak rate established by the ARS RPSO. This requirement includes all interior surfaces of all BSL-3Ag spaces, not just the surfaces making up the external containment boundary. Openings around doors into the facility are minimized and capable of being sealed to facilitate decontamination. Exterior windows and vision panels, if required, are breakage resistant and sealed.	o No o Yes o N/A	
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.	The entity plan describes the animal facility design parameters and operational procedures are documented. The facility is tested to verify that the design and operational parameters have been met prior to operation. Facilities are re-tested annually or after significant modification to ensure operational parameters are maintained.	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 animal facility design parameters and operational procedures are documented. The facility is tested to verify that the design and operational parameters have been met prior to operation. Facilities are re-tested annually or after significant modification to ensure operational parameters are maintained.	o No o Yes o N/A	
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.	The entity plan describes decontamination of personnel exiting the containment zone involves two separate transitions to ensure maximum environmental protection. The first transition involves exiting the animal room and entering the change room. The second transition involves exiting the change room and then the containment zone or facility. From a design perspective, ABSL-3Ag facilities must have a personal shower at the containment-non-containment boundary.	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).	Decontamination of personnel exiting the containment zone involves two separate transitions to ensure maximum environmental protection. The first transition involves exiting the animal room and entering the change room. The second transition involves exiting the change room and then the containment zone or facility. From a design perspective, ABSL-3Ag facilities must have a personal shower at the containment-non-containment boundary.	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).	Double-door autoclaves engineered with bioseals are provided to decontaminate laboratory waste passing out of the containment area. The double doors of the autoclave must be interlocked so that the outer door can be opened only after the completion of the sterilizing cycle, and to prevent the simultaneous opening of both doors. All double-door autoclaves are situated through an exterior wall of the containment area, with the autoclave unit forming an air-tight seal with the barrier wall and the bulk of the autoclave situated outside the containment space so that autoclave maintenance can be performed conveniently.	o No o Yes o N/A	
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.	The entity plan describes all decontamination systems used in the ABSL-3Ag, including autoclaves, tissue digesters, incinerators, renderers, gaseous decontamination chambers, liquid disinfectant dunk tanks, and similar equipment. Autoclaves, tissue digesters, renderers, and incinerators are designed or programmed to prevent opening of the outer door until the decontamination cycle is completed and verified to have met program parameters. A site-specific risk assessment must be performed to determine the need for filtration or decontamination of the condensate and/or exhaust from decontamination equipment (e.g., autoclaves).	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).	Autoclaves, tissue digesters, renderers, and incinerators are designed or programmed to prevent opening of the outer door until the decontamination cycle is completed and verified to have met program parameters.	o No o Yes o N/A	
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.	The entity plan describes that a dedicated non-recirculating ventilation system is provided. Only facilities with the same HVAC requirements (i.e., other BSL-4, ABSL-4, BSL-3Ag labs) may share ventilation systems if gas tight dampers and HEPA filters isolate each individual room 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).	A dedicated non-recirculating ventilation system is provided. Only facilities with the same HVAC requirements (i.e., other BSL-4, ABSL-4, BSL-3Ag labs) may share ventilation systems if gas tight dampers and HEPA filters isolate each individual room system.	o No o Yes o N/A	
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.	The entity plan describes redundant exhaust fans must be installed to ensure containment parameters are maintained continuously during equipment maintenance, and redundant supply fans are highly recommended.	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).	Redundant exhaust fans must be installed to ensure containment parameters are maintained continuously during equipment maintenance, and redundant supply fans are highly recommended.	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).	HEPA filters must be installed on return lines of pneumatic systems (e.g., plumbing vents, pneumatic lines for inflatable door seals, vacuum systems).	o No o Yes o N/A	
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.	The entity plan describes services and plumbing that penetrate the laboratory walls, floors, or ceiling must be installed to ensure that no backflow from the laboratory occurs. These penetrations must be fitted with two (in series) backflow prevention devices. Atmospheric venting systems must be provided with at least one HEPA filter.	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).	Services and plumbing that penetrate the laboratory walls, floors, or ceiling must be installed to ensure that no backflow from the laboratory occurs. These penetrations must be fitted with two (in series) backflow prevention devices. Atmospheric venting systems must be provided with at least one HEPA filter.	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).	Decontamination of all liquid effluents is documented. The decontamination process for liquid effluents is validated physically and biologically. Biological validation is performed annually or more often as required by institutional policy.	o No o Yes o N/A	
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.	The entity plan describes that pass-through dunk tanks, fumigation chambers, or equivalent decontamination methods must be provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the ABSL-3Ag 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).	Pass-through dunk tanks, fumigation chambers, or equivalent decontamination methods must be provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the ABSL-3Ag 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).	Pressure test results include records of all portions of the gas tight ductwork and filter systems that may potentially be exposed to contamination: from the rooms to the respective isolation dampers on the upstream side of the supply HEPA filters and on the downstream side of the exhaust HEPA filters.	o No o Yes o N/A	

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.	The entity plan describes the installation of equipment designed with pass-through features that permit contaminated articles to be loaded into an autoclave or sterilizer inside the containment zone and decontaminated before removal on the non-containment side.	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 designed with pass-through features that permit contaminated articles to be loaded into an autoclave or sterilizer inside the containment zone and decontaminated before removal on the non-containment side is installed.	o No o Yes o N/A	
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.	The entity plan describes plumbing traps must be kept filled with liquid disinfectant or capped, and the atmospheric vents associated with these traps must have HEPA filters or their equivalent installed. All HEPA filters are installed to allow in-place decontamination and replacement.	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).	Plumbing traps must be kept filled with liquid disinfectant or capped, and the atmospheric vents associated with these traps must have HEPA filters or their equivalent installed. All HEPA filters are installed to allow in-place decontamination and replacement.	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).	A visual indicator that displays real-time pressure differentials is available outside the containment space to confirm personnel can enter safely.	o No o Yes o N/A	

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.	The entity plan describes supply air must pass through ductwork with either a HEPA filter and/or a fast-acting bioseal (i.e., bubble tight) damper that fails in the closed position to prevent the reverse flow of contaminated air through supply ducts into other containment zones or non-containment areas outside the facility. In the absence of a supply HEPA filter, a robust preventative maintenance program that includes an annual validation process must be implemented to ensure the fast-acting bioseal damper operates as designed to prevent reversal.	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).	Supply air must pass through ductwork with either a HEPA filter and/or a fast-acting bioseal (i.e., bubble tight) damper that fails in the closed position to prevent the reverse flow of contaminated air through supply ducts into other containment zones or non-containment areas outside the facility. In the absence of a supply HEPA filter, a robust preventative maintenance program that includes an annual validation process must be implemented to ensure the fast-acting bioseal damper operates as designed to prevent reversal.	o No o Yes o N/A	
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.	The entity plan describes the room envelope must meet the minimum criteria for a primary containment barrier that is equivalent to performance standards established for secondary barriers in ABSL-3Ag spaces. Each ABSL-3Ag primary containment unit (i.e., room, suite) must be verified to be airtight.	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 room envelope must meet the minimum criteria for a primary containment barrier that is equivalent to performance standards established for secondary barriers in ABSL-3Ag spaces. Each ABSL-3Ag primary containment unit (i.e., room, suite) must be verified to be airtight.	o No o Yes o N/A	

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.	The entity plan describes when two doors are interlocked, at least one of the doors must meet APR specifications, preferably the door that opens into non-containment space (i.e., the door from the facility shower to non-containment space). The APR doors must be equipped with either pneumatic or mechanical compression seals.	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).	When two doors are interlocked, at least one of the doors must meet APR specifications, preferably the door that opens into non-containment space (i.e., the door from the facility shower to non-containment space). The APR doors must be equipped with either pneumatic or mechanical compression seals.	o No o Yes o N/A	
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.	The entity plan describes integral features of all APR doors (e.g., hinges, latches, knobs, locking mechanisms, viewing panels) must be sealed and verified airtight through pressure decay testing.	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).	Integral features of all APR doors (e.g., hinges, latches, knobs, locking mechanisms, viewing panels) must be sealed and verified airtight through pressure decay testing.	o No o Yes o N/A	