Inspection Checklist for BSL-3 Ag Laboratories (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(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 noncontainment 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 access to containment areas should be restricted to authorized personnel. All entry and exit points should be secured with locks or equivalent electronic access systems and protected by alarms that will alert authorities of unauthorized movement into or out of the facility.	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 emergency exit doors are configured to allow safe egress but cannot be used to gain unauthorized access to the facility.	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 pathological incinerators, or other approved means, must be provided for the safe disposal of the large 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	

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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 HVAC system pressure differentials should 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	

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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 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. The alarm system should be compatible with worker safety and animal welfare (i.e., audible without being so loud that animals are startled or stressed, or just visual). Intercom systems should limit the type and number of overhead announcements that can be disruptive and contribute to excessive noise levels.	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 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	

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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 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	
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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 BSCs must be provided and installed where their operations are not adversely affected by air circulation and foot traffic. Class II BSCs use HEPA filters to treat their supply and exhaust air.	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 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	
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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 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. This equipment should be installed with mechanical elements located or accessible outside the ABSL-3Ag facility to facilitate routine maintenance and repairs.	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.	A site-specific risk assessment should be performed to determine the need for a ventilation system that is capable of maintaining directional airflow from low hazard areas to higher hazard areas, and which exhausts directly to the outside.	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 HEPA filters should be located outside of the containment zone to facilitate routine maintenance and validation procedures. They should also be located as close to the ABSL-3Ag facility as possible to minimize the overall length of potentially contaminated ductwork outside the containment zone.	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 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. Whenever possible, deep-seal plumbing traps should be used to prevent potential cross-contamination due to loss of seal, back pressure, or trap siphonage.	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 systems and procedures must be validated using biological indicators, culture of treated waste, or another equivalent process to ensure the selected cycle and operating parameters are appropriate for the agents as well as the types and volumes of waste generated. Operating parameters should be validated for each load type that is treated and periodically verified using an appropriate method.	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 appropriate equipment and supplies should be available inside the ABSL-3Ag facility to decontaminate large animal waste, carcasses, and other contaminated refuse and articles that need to be removed from the containment area. Equipment should include design features that ensure the same level of containment as the primary barrier.	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 a visual indicator that displays real-time pressure differentials should be available outside the containment space to confirm personnel can enter safely.	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. Consideration should be given to locating these devices outside of containment. Atmospheric venting systems must be provided with at least one HEPA filter.	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 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 absense 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	

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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 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-3 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(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).	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 APR doors must be equipped with either pneumatic or mechanical compression seals. Mechanical compression seals should be checked and adjusted at regular intervals to ensure full contact when the seal is engaged. Pneumatic lines that inflate the gaskets on APR doors should be equipped with HEPA filters and check valves.	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 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).	Entrance into the facility is through a series of barriers and/or with procedures that provide a distinct separation between containment and noncontainment 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).	Access to containment areas should be restricted to authorized personnel. All entry and exit points should be secured with locks or equivalent electronic access systems and protected by alarms that will alert authorities of unauthorized movement into or out of the facility.	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).	Emergency exit doors are configured to allow safe egress but cannot be used to gain unauthorized access to the facility.	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).	Waste handling procedures must adhere to the results of a site-specific risk assessment, applicable reuglations, and local policies and procedures. In some cases, a two-step waste process may be indicated. For example, waste can first be autoclaved for removal from the containment facility and then destroyed through incineration (i.e., locally at the facility or through a commercial service). Regulations pertaining to the transport of potentially infected waste must be considered in this process.	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).	Pathological incinerators, or other approved means, must be provided for the safe disposal of the large 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).	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(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(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 should 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(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 should 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).	Air supply and exhaust systems should 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).	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. The alarm system should be compatible with worker safety and animal welfare (i.e., audible without being so loud that animals are startled or stressed, or just visual). Intercom systems should limit the type and number of overhead announcements that can be disruptive and contribute to excessive noise levels.	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	
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).	Parallel HEPA filter units that allow filter changes and scan testing without disrupting facility operation should be considered for maximum flexibility and efficiency. Configuration and operation of parallel units should be carefully evaluated to ensure continuous operation.	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. Collection and decontamination methods should be selected after a site-specific risk assesment. Installation of a central liquid effluent waste collection and decontamination system is the preferred method. Heat decontamination systems must be designed so that the contaminated effluent can be held at specified temperatures, pressures, and times to ensure complete inactivation of all hazardous materials. Systems should operate at a range of temperatures and holding times to economically and efficiently process a wide range of effluents.	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).	At a minimum, effluents from laboratory sinks, BSCs, and floor drains should 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).	Double containment piping systems with annular leak detection capability should be used for plumbing that is buried, concealed, or located outside the containment facility.	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 should be designed with basement access or piping tunnels that allow the facility waste plumbing systems to be inspected.	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	
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	

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).	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).	Only necessary equipment and supplies are recommended to be taken inside the animal facility. Equipment 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. Equipment (i.e., ceiling hoists, wall-mounted drag systems, mobile tilt tables) and strategies to assist with the humane transport of moribund animals and the carcasses of dead animals that are too large for facility staff to move manually should be incorporated into facility design and operations.	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. Due to the high rate of air exchange and room pressure fluctuations that occur with APR door operation in ABSL-3Ag facilities, all ventilated equipment should undergo extensive functional testing during installation and at an increased frequency while in operation to ensure proper placement and operation.	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).	BSCs must be provided and installed where their operations are not adversely affected by air circulation and foot traffic. Class II BSCs use HEPA filters to treat their supply and exhaust air.	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(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 also be re-tested annually or after significant modification to ensure operational parameters are maintained. Verification criteria are modified, as necessary, by operational experience.	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).	Decontamination of personnel exiting the containment zone should involve two separate transitions to ensure maximum environmental protection: the first transition involves exiting the animal room and entering the change room, and 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 even if alternate exit strategies are implemented that do not always require a second shower by personnel.	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 entrance to the ABSL-3Ag containment facility should have a double-door vestibule that separates containment areas from non-containment areas; the doors should be mechanically interlocked to prevent simultaneous opening.	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 cna be performed conveniently.	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).	Decontamination systems used in the ABSL-3Ag include autoclaves, tissue digesters, incinerators, renderers, gaseous decontamination chambers, liquid disinfectant dunk tanks, and similar equipment. Autoclaves, tissue digesters, renderers, and incinerators should be 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 should 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	
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(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 are designed to maintain the ABSL-3Ag facility at negative pressure to surrounding areas and provide differential pressure or directional airflow as appropriate between adjacent areas within the facility.	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. Precautions should be taken if fast-acting dampers are used in closed rooms instead of redundant supply fans because extreme negative pressures can develop that can injure personnel and animals or cause structural damage.	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).	HEPA filters must be installed on return lines of pneumatic systems (e.g., plumbing vents, pneumatic lines for inflatable door seals, vacuum systems). In general, central vacuum systems are discouraged. When a vacuum source is needed, a HEPA filter should be installed near the service cock or point of use. Installation should allow in-place filter decontamination and/or replacement without exposing the local environment to potential contamination.	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 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(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 BSL-3Ag laboratory. Access to the exit side of the pass-through is limited to those with authorized access to the animal facility and with specific clearance, 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).	BSCs can be connected to the animal facility exhaust system by either a canopy connection (Class IIA only) or directly exhausted to the outside through a hard connection (Class IIB, IIC, or III). Cabinet exhaust air passes through two HEPA filters, including the HEPA filter in the BSC, prior to release outside. Class IIA or IIC BSC exhaust can be safety recirculated back into the animal facility environment if no volatile toxic chemicals are used in the cabinet.	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).	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	
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. This equipment should be installed with mechanical elements located or accessible outside the ABSL-3Ag facility to facilitate routine maintenance and repairs.	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 filters should be located outside of the containment zone to facilitate routine maintenance and validation procedures. They should also be located as close to the ABSL-3Ag facility as possible to minimize the overall length of potentially contaminated ductwork outside the containment zone.	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. Whenever possible, deep-seal plumbing traps should be used to prevent potential cross-contamination due to loss of seal, back pressure, or trap siphonage.	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).	Decontamination systems and procedures must be validated using biological indicators, culture of treated waste, or another equivalent process to ensure the selected cycle and operating parameters are appropriate for the agents as well as the types and volumes of waste generated. Operating parameters should be validated for each load type that is treated and periodically verified using an appropriate 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).	Appropriate equipment and supplies should be available inside the ABSL-3Ag facility to decontaminate large animal waste, carcasses, and other contaminated refuse and articles that need to be removed from the containment area. Equipment should include design features that ensure the same level of containment as the primary barrier.	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 should be available outside the containment space to confirm personnel can enter safely.	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 absense 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	

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).	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. Consideration should be given to locating these devices outside of containment. 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).	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-3 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).	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).	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).	APR doors must be equipped with either pneumatic or mechanical compression seals. Mechanical compression seals should be checked and adjusted at regular intervals to ensure full contact when the seal is engaged. Pneumatic lines that inflate the gaskets on APR doors should be equipped with HEPA filters and check valves.	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