Inspection Checklist for Agent-Specific Storage Only Biosafety (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.	ASFv and CSFv: The entity plan describes that liquid effluents originating from the laboratory are collected and heat or chemically treated for sterility prior to exiting the facility or entering a public sewage 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 written policy for ASFv prohibits laboratory staff and visitors from having contact with susceptible species for a minimum of 4 days after the last possible contact with the ASF virus.	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 written policy for CSFv prohibits laboratory staff and visitors from having contact with susceptible species for a minimum of 5 days after the last possible contact with the CSF virus.	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).	Employees and visitors read the policy, and acknowledge, by signature, their agreement to comply with that policy. Employees and visitors must sign annually.	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.	ASFv and CSFv: The entity plan describes a practice that when leaving the laboratory, employees shower out at the non-containment/containment boundary. If the boundary is accessed via a common corridor, the plan describes how unintentional contamination will be prevented and containment maintained.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	The entity has implemented a personal quarantine or restriction policy. The policy prohibits laboratory staff and visitors from having contact with susceptible avian species for a minimum of 5 days after the last possible contact with the AIV virus. If there is no quarantine/restriction, then the entity is to provide a risk assessment to justify.	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.	AIV: The entity plan describes a practice that when leaving the laboratory, employees shower out at the non-containment/containment boundary. If the boundary is accessed via a common corridor, the plan describes how unintentional contamination will be prevented and containment 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 entity has implemented a personal quarantine or restriction policy. The policy prohibits laboratory staff and visitors from having contact with susceptible avian species for a minimum of 5 days after the last possible contact with the NDV virus. If there is no quarantine/restriction, then the entity is to provide a risk assessment to justify.	o No o Yes o N/A	
12(b)	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).	The entity has received WOAH and FAO endorsement for the holding of rinderpest virus-containing materials, in-vitro handling and/or in-vivo handling of rinderpest virus-containing materials.	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.	Rinderpest: The entity plan outlines a procedure where street clothes and personal effects are to be removed in a locker room or clean changing area. Laboratory specific clothing and PPE are donned prior to entering the laboratory area. At the room-level a gown-in protocol is described where there is an anteroom located between an inner, potentially contaminated changing area (dirty change area), and an outer clean changing area to eliminate the possibility of cross-contamination from dirty to clean clothing.	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.	Rinderpest: The entity plan describes a procedure that on exiting at the room level, all PPE and laboratory specific clothing is removed and hand washing capability available in the dirty change area. On exiting the research area (containment/ non-containment barrier), all PPE and clothing are removed, and each individual takes a full body shower. The shower exiting containment is located between an inner, potentially contaminated changing area and the outer clean changing area to eliminate the possibility of cross contamination from dirty to clean clothing.	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 all rinderpest virus-containing materials (excluding carcasses) are autoclaved for sterility/ inactivation prior to leaving containment space and are incinerated for final disposal.	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).	All rinderpest virus-containing materials (excluding carcasses) are autoclaved for sterility/ inactivation prior to leaving containment space and are incinerated for final disposal.	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).	Rinderpest: An interlocking, double door autoclave with a bioseal is installed around the face forming an airtight seal with the barrier wall and permitting the outer door to be opened only after cycle completion. The autoclave should be situated such that it will allow maintenance to occur in a convenient manner from outside of containment.	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 a process for autoclaving where, if the destruction cycle for inactivation/destruction of rinderpest virus-containing material has not been used in the past seven days, it should be run on this cycle at least 24 hours prior to any scheduled rinderpest virus-containing material destruction.	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 an autoclave to be used for inactivation/destruction of rinderpest virus-containing material has not been used on this destruction cycle in the past seven days, it should be run on this cycle at least 24 hours prior to destroying any rinderpest virus-containing material.	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).	Annual reports of rinderpest virus containing-material are submitted to the WOAH by November of each year.	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).	Confirm implementation of a written personal quarantine or restriction policy that prohibits personnel from having contact with susceptible species (e.g., cloven-hoofed animals) for a minimum of 4 days after the last possible contact with Rinderpest virus.	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 a process where rinderpest virus and rinderpest virus-containing material are stored in leak-resistant containers in a separate or dedicated biosecure area, apart from non-rinderpest virus samples or materials.	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).	Rinderpest virus and rinderpest virus-containing material are stored in leak-resistant containers in a separate or dedicated biosecure area, apart from non-rinderpest virus samples or materials.	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 procedures where rinderpest virus or rinderpest virus-containing materials that are to be removed from the laboratory room must be placed in a non-breakable, sealed primary container and then enclosed in a non-breakable, sealed secondary container. The sealed container must be transferred through a dunk tank, pass-thru chamber, or comparable surface decontamination method prior to movement to 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).	Rinderpest virus or rinderpest virus-containing materials that are to be removed from the laboratory room must be placed in a non-breakable, sealed primary container and then enclosed in a non-breakable, sealed secondary container. The sealed container must be transferred through a dunk tank, pass-thru chamber, or comparable surface decontamination method prior to movement to the non-containment side.	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.	Rinderpest: The entity plan describes that liquid effluents originating from the laboratory (e.g., sinks, floor drains, autoclaves, etc.), and including shower areas, are collected and heat or chemically treated for sterility prior to being discharged into the public domain.	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).	Rinderpest: A biological validation is performed on the sterilization system at least once every 12 months.	o No o Yes o N/A	