Inspection Checklist for Agent Specific- Rinderpest (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(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.	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(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).	Street clothes and personal effects are 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 implemented with 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.	The entity plan describes a procedure that on exiting at the room level, all PPE and laboratory specific clothing are 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	

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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).	On exiting at the room level, all PPE and laboratory specific clothing are 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 outlines a protocol when moving from a laboratory room where there is work with rinderpest virus to another room within the containment space, personnel doff PPE and change their laboratory specific clothing at the level of the laboratory room.	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 moving from a laboratory room where there is work with rinderpest virus to another room within the containment space, personnel doff PPE and change their laboratory specific clothing at the level of the laboratory room.	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).	Reusable laboratory clothing worn in the laboratory room and collected in the dirty change room must be autoclaved before being laundered outside of the 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 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	
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	

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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).	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(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 facility must separate areas housing Rinderpest infected animals from other susceptible livestock or wildlife.	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 laboratory rooms are dedicated for work with rinderpest virus for the duration of the rinderpest virus research project. Only cell cultures and biological materials relevant to rinderpest virus in vitro studies are allowed in the laboratory room and any material that could harbor or maintain viability of rinderpest virus are not brought into the laboratory and then subsequently removed. Experimentation with other agents is not permitted until the room has been decontaminated.	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).	Laboratory rooms are dedicated for work with rinderpest virus for the duration of the rinderpest virus research project. Only cell cultures and biological materials relevant to rinderpest virus in vitro studies are allowed in the laboratory room and any material that could harbor or maintain viability of rinderpest virus are not brought into the laboratory and then subsequently removed. Experimentation with other agents is not permitted until the room has been decontaminated.	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	
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 plans describe 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	

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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).	Laboratory walls are sealed. Openings/ penetrations/ conduits within the room (e.g., electrical, plumbing, access panels, recess eyewashes and other services) are sealed, gasketed or sealable for gas or vapor decontamination.	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).	Suspended ceilings must be sealed to isolate the laboratory room from the interstitial environment. Or, a sealed space is present above the suspended ceiling, and the suspended ceiling is removed for decontamination and room decontamination.	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 liquid effluent originating from the laboratory is collected and heat or chemically treated for sterility prior to exiting the facility or entering the public sewage system. A site-specific risk assessment (including consideration for aerosol work) describes if liquid effluent originating from the shower areas requires collection and heat or chemical treatment for sterility prior to exiting the facility or entering the 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).	Liquid effluent originating from the laboratory is collected and heat or chemically treated for sterility prior to exiting the facility or entering the public sewage system. A site-specific risk assessment (including consideration for aerosol work) describes if liquid effluent originating from the shower areas requires collection and heat or chemical treatment for sterility prior to exiting the facility or entering the 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).	Animal cages are autoclaved or thoroughly decontaminated before removal from the containment area. Animal enclosures, equipment, or materials that might be damaged by high pressures or steam or cannot be moved for sterilization, must be decontaminated using an effective and validated procedure such as gaseous or vapor method in an airlock or chamber designed for this purpose.	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).	A biological validation is performed on the sterilization system at least once every 12 months.	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).	Floor drains must be capped and sealed if there is no central liquid effluent sterilization 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).	Animals used for work with Rinderpest virus are housed in ABSL-3 rooms in sealed ventilated caging systems, or in rooms that comply with ABSL-3Ag standards.	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 supply and exhaust ductwork, between the HEPA filters serving the laboratory rooms (and containment zone), have been subjected to a pressure decay test at commissioning or according to BSL-3/ ABSL-3 Verification 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).	The filter units are fabricated to permit the in-place scan testing of the filters after installation, and to permit filter decontamination 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).	Supply and exhaust systems for the containment zone are equipped with an interlocking system to prevent positive pressurization during HVAC failure.	o No o Yes o N/A	