SAND2014-18897R

Biosecurity management recommendations for rinderpest laboratories

Changes due to eradication

Rinderpest is a virus that can affect cattle and other even toes ungulates; evidence of outbreaks from over 10,000 years ago highlights the potential impact of this virus. During the 18th century, Rinderpest caused huge losses in cattle throughout Europe. Starting in the mid 1900's vaccination efforts seemed feasible and work was initiated to vaccinate large populations of cattle. Walter Plowright received numerous awards for updating the Rinderpest vaccine which many believed would be the key to eradication. Vaccination of the disease lead to a massive drop in outbreaks and the last confirmed case of Rinderpest in Asia was in 2000 and in Africa in 2001.[1] At this point, Rinderpest has been declared eradicated from nature. However, stocks of the virus are still in many laboratories.[2]

Rinderpest was investigated as a biological weapon agent during the Second World War. However, following WWII, rinderpest was not considered a high risk as a biological weapon as there was no direct military advantage. Now, with the concern of the use of biological agents as weapons in acts of terrorism, concern regarding rinderpest has resurfaced. Since the eradication of this virus, cattle populations are highly susceptibility to the virus and the economic impacts would be significant. This paper will discuss the specific nature of the terrorism risks associated with rinderpest; and based upon those risks provide recommendations regarding biosecurity management. The biosecurity management measures will be defined in a manner to align with the CWA 15793: the laboratory biorisk management document.[3]

[1] Lubroth, Juan, Ridding the world of Rinderpest, Food and Agriculture Organization of the United Nations, Italy, 2010
[2] Sample, Ian, Scientists eradicate deadly Rinderpest virus, The Guardian, 2010
[3] ftp://ftp.cenorm.be/PUBLIC/CWAs/wokrshop31/CWA15793.pdf

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Technical Security Risks of Rinderpest

Risk is a function of the likelihood of an occurrence and the consequences of this occurrence. The technical risk analysis used in this report is focused on the risks posed by a malicious release of rinderpest. The methodology used in this analysis is complementary to the methodology used in the BioRAM software tool. The results of this analysis will be used to support the biosecurity management recommendations defined later in this paper.

The BioRAM software tool[4] is not intended to be used to conduct a formal quantitative assessment of absolute risk; rather it is intended to provide a structured analysis for the comparison of the relative biological risks posed in a laboratory setting. These risks include security-related risks—adversaries acquiring and exploiting biological agents with malicious intent—and safety-related risks—accidental releases impacting laboratory workers and/or the environment. Multi-objective decision analysis (MODA) is one of many approaches to structured risk assessment and decision analysis. MODA and its parent process, multi-criteria decision analysis (MCDA), have been identified as scientifically sound methods for decision analysis and have been extensively validated for use in risk analysis.

The likelihood of misuse of rinderpest is driven by two primary attributes: the attractiveness or desire for use of this agent as an agricultural weapon, and the technical feasibility of production and dissemination of the agent. These two objectives are considered preferentially independent and therefore are combined using a weighted additive function: $v(x,y) = k_x v_x(x) + k_y v_y(y)$, where x is the attractiveness of the agent and y technical feasibility of production and dissemination of the agent.

The next sections discuss the two components of the likelihood portion of the model in detail.

Post eradication, the attractiveness of rinderpest has escalated greatly. Prior to complete eradication, rinderpest was an animal health issue and malicious use of this agent was not widely considered. However, post eradication, rinderpest is one of the more attractive biological agents to an adversary with malicious intent. Rinderpest, as it is modeled, is only 10% less attractive than smallpox, but 10% more attractive than either anthrax or FMD for use as a bio/agro terrorism agent.

[4] Caskey, et al, Biosafety Risk Assessment Methodology (BioRAM) Sand # 2010-6487 Albuquerque, NM: Sandia National Laboratories, 2010

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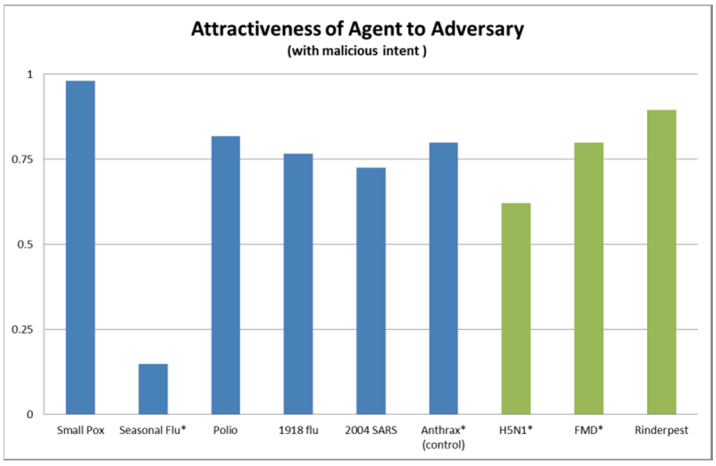

Figure 1: Attractiveness of agents to adversaries

Production of rinderpest would require notable biological skills and equipment. Based upon this, dissemination methods would limited to release in areas were the animals could spread the disease though natural movement (migration or feedlot processes). The disease does spread between animals in close contact. However, the lack of stability as compared to FMD reduces the overall potential for successful dissemination. Based upon these results, production and dissemination of rinderpest is less than that of FMD, but greater than the H5N1 influenza virus.

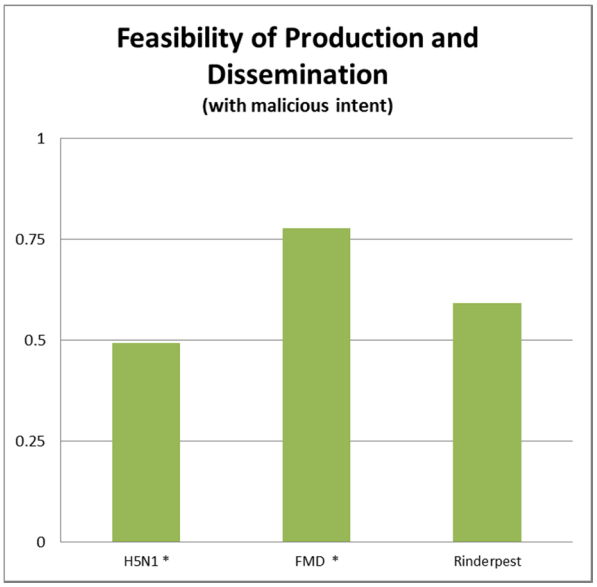

Figure 2: Feasibility of production and dissemination of agricultural agents

The consequences of misuse are defined based upon two primary attributes: the impact of the disease (species specific), and the socioeconomic impacts. These two objectives are considered preferentially independent and therefore are combined using a weighted additive function: $v(x,y) = k_x v_x(x) + k_y v_y(y)$, where x is the impact of the disease on a species and y is the socioeconomic impact. The impact of the disease is defined by a series of sub-attributes which include the morbidity rates, the host range, the ability for the disease to spread, the potential for herd immunity, and the ability to control or manage

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the disease following an occurrence. The socioeconomic impacts are further defined by the economic impact and level of public panic caused by the disease. Both of these attributes (and sub-attributes) are scored based upon the impact of an occurrence of the disease in the industrialized world.

The morbidity rates and the communicability of rinderpest disease are high, but less than of FMD. Also, control measures, while difficult, would be more easily implemented. The socioeconomic impact of FMD would be far greater (in the industrialized world) than that of an occurrence of rinderpest primarily due to public perception. The overall consequences of rinderpest would be high, FMD, in comparison, would be considered very high.

Overall, the risk of a malicious release of rinderpest would be high, sitting directly been FMD (very high risk) and the risk of malicious use of the H1N5 influenza virus in an agricultural terrorism event.

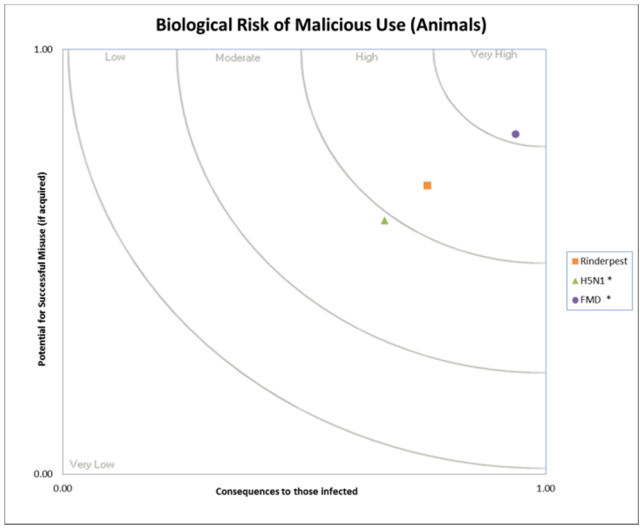

Figure 3: Risk of malicious use of biological agents

The biochemical properties of rinderpest which were used to define the values used in the technical risk assessment are outlined below.

The rinderpest virus is a medium sized ssRNA enveloped virus from the Paramyxoviridaefamily[5]; it impacts ruminants and swine via inhalation or ingestion. The virus is present in saliva, feces, urine, milk, and other bodily fluids. The virus, being enveloped, is not very stable in the environment and does not survive more a few days outside of a host[6]; UV light denatures the virus within 24 hours.

The disease in cattle is usually fatal and has an incubation period of less than one week.

[5] Geering, et al. Manual on Procedures for Disease Eradication by Stamping Out, FAO Corporate Document, Italy, 2001

[6] Hyslop, N. Observations on the Survival and Infectivity of Airborne Rinderpest Virus, International Journal of Biometeorology. 1979

Growth of rinderpest requires bovine cell lines. The virus must be inoculated in specific tissue cell lines, such as bovine lymphoblast or fetal calf serum, and be allowed to incubate for a specific length of time. Antibiotics are required to suppress growth of bacteria that otherwise would contaminate the media in which the cells are grown. At the end of the incubation period, the amount of virus depends on the inoculum.[7] [8] [9]

In the event of an outbreak, the primary method for control is restricting of movement of animals. Following this, destruction of infected animals and those in contact with infected animals must occur. Disposal of the caucuses, soil, feed, and other potentially contaminated items can be buried or incinerated. [10]

Based upon the biochemical properties of rinderpest and the potential risks regarding malicious release of the agent, the following biosecurity management recommendations should be considered for laboratories retaining stocks.

[7] Rossiter, et al, The Growth of Cell Culture-Attenuated Rinderpest Virus in Bovine Lymphoblasts with B Cells. Journal of General Virology, 1993
[8] Plowright, et al, Studies with Rinderpest Virus in Tissue Culture, Kenya 1961
[9] Baron, et al, Rescue of Rinderpest Virus from Cloned cDNA, Journal of Virology, 1997
[10] OIE Terrestrial Animal Health Code

Biosecurity Management Recommendations for Rinderpest Facilities (Based on requirements of CWA 15793:2011)

Entry	Section	Section Title	Requirement	Requirement Title	Requirement Text Body	Recommended Biosecurity Measures for Rinderpest
1	4.1	General Requirements	4.1.1	Biorisk management system	The organization shall establish, document, implement and maintain a biorisk management system in accordance with the requirements of this laboratory biorisk management agreement.	**Through risk assessment, mitigation, and periodic review, ensures that the biorisk management system is appropriate to address biosecurity risks associated with Rinderpest virus.**
2			4.1.2	Continual improvement	The organization shall continually improve the effectiveness of the biorisk management system through the use of the policy, objectives, self-audit programme, audit results, analysis of data, risk assessment, corrective and preventive actions and the management review.	**Self-audits of biorisk management program for Rinderpest stocks performed annually** **Audit findings should be translated into actions to improve the management of Rinderpest stocks.**
3	4.2	Policy	4.2.1	Biorisk management policy	The organization's top management shall develop, authorize and sign a policy concerning the management of laboratory biorisk (laboratory biosafety and laboratory biosecurity). It shall clearly state the overall biorisk management objectives and a commitment to improving biorisk management performance.	**Institutional policy should be established and documented that is at minimum consistent with FAO/OIE biorisk management requirements for the management of Rinderpest stocks, as well as any relevant national regulations or legal requirements.**

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					The policy shall be appropriate to the nature and scale of the risk associated with the facility and associated activities and commit to: a) protecting staff, contractors, visitors, community and environment from biological agents and toxins that are stored or handled within the facility; b) reducing the risk of unintentional release of, or exposure to biological agents and toxins; c) reducing the risk to an acceptable level of unauthorized intentional release of hazardous biological materials, including the need to conduct risk assessments and implement the required control measures; d) complying with all legal requirements applicable to the biological agents and toxins that will be handled or possessed, and with the requirements of this agreement; e) ensuring that the need for effective biorisk management shall take precedence over all non "health and safety" operational requirements; f) effectively informing all employees and relevant third parties and communicating individual obligations with regard to biorisk to those groups; g) continually improving biorisk management performance.	**The policy should clearly document the ongoing need(s) for the retention of Rinderpest virus at the facility.** **The policy should specifically address the institution's commitment to reducing biosafety and biosecurity risks to the facility associated with Rinderpest stocks.**
4	4.3	Planning	4.3.1.1	Planning and resources	The organization shall ensure that a risk assessment system is established, implemented and maintained in accordance with this agreement and that the performance of the risk management system is reported to senior management for review and as a basis for improvement. The organization shall identify resource requirements and provide adequate resources, including the assignment of trained personnel for management, performance of work, and verification activities, including internal review.	**The facility should identify and document all international, national, provincial and local requirements that are relevant for the storage, handling, production, disposal or transport of Rinderpest virus.** **Top management should commit sufficient resources to conduct a thorough biosecurity risk assessment at regular intervals and manage all identified biosecurity risks associated with Rinderpest stocks.** **The facility should establish and document a plan to routinely review the status of the risk management system for Rinderpest stocks. The results of the review should be reported to top management.** **The facility should identify all personnel who may be involved and/or affected by the risk management system for Rinderpest stocks.**

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						Top management should ensure that biorisk management-related roles and responsibilities are assigned to personnel who are or may be involved in work relating to Rinderpest virus.
5			4.3.1.2	Risk assessment timing and scope	The organization shall ensure the approach to risk assessment is defined with respect to its scope, nature and timing so that it is proactive rather than reactive.	**The institution should ensure that a biosecurity risk assessment has been performed and documented before determining whether or not to retain Rinderpest stocks.**
						The facility should identify and assign a team comprised of appropriate personnel to lead the biosecurity risk assessment.
						The organization should ensure that a biosecurity risk assessment is performed and documented whenever a significant change occurs that may affect the work involving Rinderpest virus.
						The organization should ensure that a biosecurity risk assessment is performed and documented following any biosecurity-related incident or "near-miss."
						The biosecurity risk assessment should be reviewed and updated regularly, as part of a regular review of the biorisk management system.
6			4.3.1.3	Hazard identification	The hazards associated with proposed work shall be identified and documented.	**The institution should maintain detailed records of all Rinderpest stocks; including at a minimum: Strain information, storage location, units and quantities, individual(s) responsible for the material, date received, date(s) used, purpose of use, and date destroyed.**

						The impact of Rinderpest strain characteristics on the potential consequences of accidental, negligent or deliberate release of the Rinderpest virus stocks from the facility should be characterized and documented.
						Hazard-related information should be treated as sensitive information and protected according to institutional information protection policies and procedures.
7			4.3.1.4	Risk assessment	The organization shall ensure that suitable methodologies for assessing and recording risks are identified, implemented and maintained.	**The institution should ensure that a process is in place to identify all potential biosecurity risks, and screen the identified risks for subsequent analysis**
						The institution should adopt or develop and document a reliable, reproducible methodology for the characterization and evaluation of biosecurity-related risks involving Rinderpest stocks.
						The risk assessment should consider all relevant facility assets, potential adversaries, and site vulnerabilities that may affect the likelihoods and consequences of each identified risk.
						The facility should evaluate each assessed risk and determine if additional risk mitigation measures are required to manage the risk effectively.
						The biosecurity risk assessment should be documented and retained for later review.

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						The biosecurity risk assessment should be treated as sensitive information and protected according to institutional information protection policies and procedures.
8			4.3.1.5	Risk Management	The organization shall ensure suitable methodologies for the allocation of actions resulting from risk assessments, including time lines, responsible persons and associated reporting and approval mechanisms are identified, implemented and maintained.	**Facility top management should commit resources adequate to effectively mitigate the Rinderpest-related biosecurity risks identified during the risk assessment.**
						For each assessed risk for which current measures are not adequate, the facility should establish and document specific, attainable, measurable objectives to address biosecurity risks. A timeline for the accomplishment of each objective should be documented.
						Top management should review and approve each objective and ensure that adequate resources are devoted to achieve each identified objective.
						The facility should identify and communicate specific responsibilities to appropriate personnel to meet the objectives.
						The facility should develop mechanisms to monitor ongoing implementation of the objectives, and make corrective actions if needed.
9			4.3.2	Conformity and Compliance	The organization shall ensure that all relevant requirements are identified and fulfilled within the biorisk management system. Legal requirements include national / federal, regional / state, provincial, city and local regulatory requirements with which the organization shall comply.	**The facility should identify and document all international, national, provincial and local requirements that are relevant for the storage, handling, production, disposal or transport of Rinderpest virus.**

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						The facility should conduct and document an analysis of the legal requirements to determine all areas of compliance and potential non-compliance.
						The facility should have a documented process in place for addressing any potential non-compliance with legal requirements.
10			4.3.3.1	Biorisk control objectives and targets	The organization shall establish, implement and maintain documented biorisk control objectives and targets for an effective control of biorisk at relevant functions and levels in the organization.	**For each assessed risk for which current measures are not adequate, the facility should establish and document specific, attainable, measurable objectives to address biosecurity risks. A timeline for the accomplishment of each objective should be documented.**
						Top management should review and approve each objective and ensure that adequate resources are devoted to achieve each identified objective.
						Each objective should be effectively communicated to all relevant personnel within the facility.
11			4.3.3.2	Monitoring Controls	Management shall establish the controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in the risk assessment process.	**A program of routine inspection of Rinderpest-containing facilities should be established.**
						A program of periodic internal management system audits should be established.
						Records of past inspections, audits, incident reports, review, etc. should be retained in a secure location.
						Incidents and accidents should be promptly investigated, and a written report filed with management, with recommendations for corrective actions.
						A process to report findings and corrective actions taken should be established.

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12	4.4	Implementation and operation	4.4.1.1	Top management	Top management shall take ultimate responsibility for the organization's biorisk management system. Top management shall ensure that roles, responsibilities and authorities related to biorisk management are defined, documented and communicated to those who manage, perform and verify work associated with the control of biological agents and toxins. Top management shall demonstrate its commitment by ensuring the availability of resources to establish, implement, maintain and improve the biorisk management system.	**Top management should clearly commit to the biorisk management system by ensuring the system is appropriately resourced, staffed, and maintained.** **Top management should ensure that roles and responsibilities related to the management of Rinderpest stocks are established and communicated.** **Top management should be aware of the overall status of the system; for example by participating in periodic reviews of the performance of the biorisk management system.**
13			4.4.1.2	Senior management	A responsible official shall be designated with operational responsibility for overseeing the system for management of biorisk. Functions of the system for the management of biorisk shall include: a) providing appropriate resources to ensure adequate provision of personnel, facilities and other resources deemed necessary for the safe and secure operation of the facility; b) reporting to top management on the performance of the biorisk management system and any need for improvement; c) ensuring promotion of the biorisk management system throughout the organization; d) instituting review, audit and reporting measures to provide assurance that the requirements of this agreement are being implemented and maintained effectively.	**Top management should assign a senior responsible official to directly oversee the Rinderpest biorisk management program, including resource allocation. The senior responsible official should have the authority to make decisions with respect to the program.** **The senior responsible official should regularly report to top management on the status of the Rinderpest biorisk management program.** **The senior responsible official should ensure that the Rinderpest biorisk management program undergoes monitoring and review on schedule and as warranted.**
14			4.4.1.3	Biorisk management committee	A biorisk management committee shall be constituted to act as an independent review group for biorisk issues. Reporting to senior management,	**The facility's biorisk management committee should review and approve all proposals to work with Rinderpest stocks.**

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					the committee shall: a) have documented terms of reference; b) include a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken; c) ensure issues addressed are formally recorded, actions allocated, tracked and closed out effectively; d) be chaired by a senior individual; e) meet at a defined and appropriate frequency, and when otherwise required.	**The committee should review all risk assessments, protocols, existing risk mitigation measures, and SOPs related to work with Rinderpest.**
						The committee should meet regularly to address any issues related to the management of Rinderpest stocks.
						The committee should be empowered to conduct independent reviews of any incidents or accidents involving Rinderpest.
						The committee should communicate its findings and recommendations regarding the Rinderpest biorisk management program to appropriate levels within the facility (top management, senior management, staff) via well-defined, documented communication mechanisms.
15			4.4.1.4	Biorisk management advisor	A competent individual(s) shall be designated to provide advice and guidance on biorisk management issues. This individual shall report directly to the responsible senior manager and have delegated authority to stop work in the event that it is considered necessary to do so. This role shall be independent of those responsible for implementing the programme of work.	**A competent individual should be designated to advise on biorisk management issues related to Rinderpest virus.**
						The biorisk management advisor should actively contribute to the development of facility policies, plans and procedures related to biosecurity of Rinderpest stocks.
						The biorisk management advisor should develop and execute means to ensure that biorisk management measures related to Rinderpest virus are being conducted properly in accordance with documented policies, plans and procedures.
						The biorisk management advisor should develop and/or conduct training of facility staff, as needed, on biosecurity measures related to Rinderpest virus stocks. This training should include (but is not limited to) issues related to controlling access to stocks, inventory recordkeeping, and incident reporting.
16			4.4.1.5	Scientific management	An individual(s) with responsibility for the scientific programme within the facility shall be designated with responsibilities relevant to biorisk management. Functions shall include: a) ensuring that all work is conducted in accordance with established policies and guidelines described in this agreement;	**Scientific management should ensure that all personnel working under his or her authority comply with all related policies, plans and procedures related to the biosecurity of Rinderpest stocks.**

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					b) supervising workers, including ensuring only competent and authorized personnel can enter and work in the facility; c) planning and conducting work activities, and ensuring adequate staffing levels, time, space and equipment are available; d) ensuring required authorizations for work are in place; e) ensuring laboratory biosafety and laboratory biosecurity risk assessments have been performed, reviewed and approved, and that the required control measures are in place; f) ensuring that all at-risk employees have been informed of risk assessments and/or provisions for any recommended precautionary medical practices (e.g. vaccinations or serum collections).	**Scientific management should ensure that all required work authorizations and approvals are secured prior to conducting work with Rinderpest virus.** **Scientific management should ensure that a biosecurity risk assessment has been performed, that the results are understood, and that appropriate risk mitigation measures are in place and functional prior to performing work with Rinderpest virus.**
17			4.4.1.6	Occupational Health	The organization shall have access to appropriate occupational health expertise and establish an occupational health programme commensurate with the activities and risks of the facility.	**None applicable from Rinderpest biosecurity perspective**
18			4.4.1.7	Facility management	Facilities manager(s) shall be appointed with responsibilities relevant to facilities and equipment determined in accordance with requirements set out in this agreement.	**The facility should ensure that a facilities manager is designated with responsibility for overseeing the installation, maintenance, repair of engineering controls and equipment related to the biosecurity of Rinderpest stocks.** **The facilities manager should liaise with and oversee the work of contractors on engineering controls and equipment related to the biosecurity of Rinderpest stocks.** **The facilities manager should ensure that a maintenance program is established to help ensure the continual operation of engineering controls and equipment related to the biosecurity of Rinderpest stocks.**

						The facilities manager should promptly respond to any notification or indication that engineering controls and equipment related to the biosecurity of Rinderpest stocks is inoperative or malfunctioning.
19			4.4.1.8	Security management	A security manager shall be designated with responsibilities determined in accordance with requirements set out in this agreement.	**The security manager should be a competent, trusted individual with in-depth knowledge of laboratory operations related to Rinderpest virus, and biosecurity.**
						The security manager is responsible for day-to-day management of the facility's biosecurity program.
						The facility manager should participate actively in internal discussions related to the use of Rinderpest virus, for example by becoming a member of the facility's biorisk committee.
						The security manager should be assigned responsibility for the development and oversight of the facility's biosecurity plan, in cooperation with the biorisk management advisor, biorisk management committee, and other individuals as appropriate.
						The security manager should ensure that the facility's security program is fully functional and in accordance with policies, plans and procedures. This includes conducting equipment performance tests, exercises and drills, and regular program reviews.
						The security manager should liaise with external security organizations, such as local law enforcement, to better understand potential threats and vulnerabilities.
						The security manager should liaise with external security organizations, such as local law enforcement, to plan and exercise response to potential biosecurity-related events involving Rinderpest virus stocks.

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20			4.4.1.9	Animal handling	In laboratories where animals are maintained, an animal care manager shall be designated with responsibilities determined in accordance with requirements set out in this agreement.	**Animal care managers should be familiar with and follow institutional policies related to the handling of animals that potentially are infected with Rinderpest virus (for example in the course of experimental studies). This includes ensuring that animals potentially infected with the Rinderpest virus are secured from unauthorized access at a level equal to that of the corresponding Rinderpest virus strain.**
						Animal care managers should ensure that any waste generated by the care of animals potentially infected with the Rinderpest virus is adequately secured until the waste may be properly decontaminated and disposed.
21			4.4.2	Personnel training, awareness and competence	The organization shall ensure that personnel that have responsibilities and/or perform tasks that may impact biorisk management in the workplace are competent to do so. Competence levels shall be judged on appropriate education, training and experience. The organization shall define required competency levels and shall maintain records verifying that staff members have attained and demonstrated those levels of competency.	**The facility should define and document which personnel who require training on Rinderpest biosecurity, and what competencies these personnel should demonstrate related to Rinderpest biosecurity.**
						The facility should ensure that those personnel with a "need to know" receive regular training on biosecurity of Rinderpest stocks, to include (but not necessarily limited to) access control requirements, inventory recordkeeping, and incident reporting.

						The facility should retain training records, including results of competency assessments.
22			4.4.2.1	Recruitment	The organization shall ensure that qualifications, experience and aptitudes relating to biorisk are considered as part of the recruitment process.	**The facility should strive to hire personnel who are reliable and conscious of the importance of biosecurity.**
						As part of the recruitment process, the facility should consider the reliability of the person, and the person's willingness to comply with policies, plans and procedures.
						The facility should ensure that all prospective new personnel undergo relevant background checks before hiring, in accordance with local laws and regulations.
23			4.4.2.2	Competence	The organization shall ensure that personnel conduct activities within the facility under close supervision until competency has been demonstrated.	**The facility should consider invoking a "two-person rule" for all activities involving Rinderpest virus, especially in cases where personnel are inexperienced in the safe and secure handling of Rinderpest virus.**
						The facility should put in place a process to periodically re-assess the competence of individuals to work safely and securely with Rinderpest virus.
						The facility should ensure that staff is able to maintain competence to work safely and securely through periodic training.
24			4.4.2.3	Continuity and succession training	The organization shall ensure that adequate back-up and contingency measures are in place to address the need for continuity and succession planning.	**The facility should ensure through appropriate advance planning that the security of Rinderpest virus stocks may not be compromised in any way due to the departure or long-term absence of facility personnel.**
25			4.4.2.4	Training	The organization shall ensure that requirements and procedures for biorisk-related training of personnel are identified, established and maintained.	**The organization should define and document training requirements for all staff related to the safety and security risks associated with Rinderpest virus.**
						The organization should develop training programs for staff and any visitors, contractors, etc. who may visit the facility.
						The facility should ensure that adequate training records, to include attendance and content, are generated and maintained securely.
						With respect to training related to Rinderpest virus biosecurity, the facility should ensure that all trainees

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						have "a need to know" the content of the training.
26			4.4.3	Consultation and communication	The organization shall ensure that relevant biorisk information relating to its activities is communicated to and from employees and other relevant parties. Employee involvement and consultation arrangements shall be documented. Personnel shall have access to adequate and up-to-date information pertaining to the biorisks of the organization.	**Effective mechanisms for internal communication should be implemented, including training, signage, notifications, consultations, etc.** **The facility should encourage active participation of staff in internal communication by establishing appropriate forums, such as committees, regular meetings, electronic mechanisms, etc.** **The organization should implement mechanisms to communicate with other external stakeholders regarding its RInderpest virus-realted activities. The organization should ensure that appropriate information protection measures are followed in the course of external communication.**
27			4.4.4	Operational control	The organization shall identify those operations and activities that are associated with possible biological risk and where control measures shall be applied. The organization shall plan these activities, including maintenance, and ensure that they are carried out under specified conditions.	**The facility should ensure that a comprehensive set of operational controls, based on a documented risk assessment, are established to mitigate the biosecurity risks associated with Rinderpest virus. These include controls related to physical protection, information security, transportation security, personnel management, and material control and accountability.**
28			4.4.4.1	General Safety	The organization shall ensure that a formal process is in place to identify and manage risk associated with general safety.	**The organization should ensure that prior to implementing measures identified to manage general safety risks, the organization considers and accounts for the potential impact of such measures on Rinderpest virus biosecurity.**
29			4.4.4.2	Biological agents and toxin inventory and information	The organization shall ensure that an accurate and up-to-date biological agents and toxin inventory is established and maintained. It shall ensure that records relating to the inventory of biological agents and toxins are current, complete and stored securely with adequate backup provision. It shall ensure that transfers of biological agents and toxins between laboratories at the facility or into and out of the facility are recorded and controlled in line with the level of the risk.	**The organization should ensure that an accurate and up-to-date inventory of all Rinderpest virus stocks is maintained.** **All Rinderpest virus inventory records should be stored securely, with access to records authorized only for those with a demonstrated work-related need.** **The inventory records should be periodically (at least once every six months) be checked against actual holdings, to ensure the accuracy of the inventory records and detect any missing materials.** **Information recorded in the inventory should include: name of the agent, quantity, location, responsible individual (including contact details), unique identifier, date received, date used, purpose of use, and date destroyed.** **The facility should adopt a robust and reliable sample identification system to facilitate tracking of all Rinderpest-containing materials on-site.**

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						The facility should ensure adequate records are retained whenever Rinderpest-containing materials are used, consumed, transferred, shipped, or destroyed.
30			4.4.4.3	Work programme, planning and capacity	The organization shall ensure that the programme of work for the facility is defined, documented and reviewed. The organization shall establish criteria for work that requires prior approval. It shall ensure there is sufficient resource capacity and capability to manage workflow, whether planned or unplanned.	**The facility should ensure that all work involving Rinderpest virus has been documented, reviewed, approved, and authorized prior to conducting work with Rinderpest.**
						Any changes to the work program should be formally documented, reviewed and approved; and additional work authorizations secured if required.
31			4.4.4.4	Change management	The organization shall ensure that all changes associated with the design, operation and maintenance of the facility are subject to a defined and documented change management process.	**Any changes to the Rinderpest biosecurity program should undergo a formal review and approval process prior to implementation. The impact of the proposed change on biosecurity risk at the facility should be taken into account. This may include changes to physical protection systems, personnel security measures, information protection measures, transport security measures, material control and accountability measures.**
						The facility should ensure that any changes implemented that affects Rinderpest biosecurity is promptly communicated to all staff with "a need to know."
32			4.4.4.5.1	Good microbiological technique	The organization shall ensure that all personnel handling biological agents and toxins are competent in good microbiological techniques and that appropriate resources (including time and equipment) are available to ensure such practices can be adhered to effectively.	**The organization should take reasonable steps to ensure that all personnel handling Rinderpest virus follow established procedures for the handling of the material, in order to avoid inadvertently creating potential security vulnerabilities.**
33			4.4.4.5.2	Inactivation of biological agents and toxins	The organization shall establish and maintain procedures to ensure that appropriate methods for disinfection and decontamination are chosen and implemented effectively. The organization shall ensure that all contaminated or potentially contaminated waste items have been identified and documented (including those that may result from an emergency), and that effective procedures are put in place to devise effective decontamination and other appropriate treatments.	**The organization should ensure that all materials potentially contaminated with Rinderpest virus are decontaminated using appropriate methods.**
						The facility should identify and document all waste streams that may be contaminated with Rinderpest virus.
						The facility should ensure that effective inactivation measures are in place to treat all waste streams potentially contaminated with Rinderpest virus.
						The facility should ensure that any waste that is potentially contaminated with Rinderpest virus is

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						stored in a secure location until it can be properly decontaminated.
						Autoclaves and/or other equipment used to inactivate Rinderpest virus should be located in the same secure area as where the contaminated material is generated. If this is not possible, administrative procedures should be established to ensure the contaminated materials are secured during transport to the area where inactivation will be performed.
						The facility should put in place procedures to verify that decontamination measures are effective.
34			4.4.4.5.3	Waste management	The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.	**The facility should seek to identify means to reduce the production of wastes that are potentially contaminated with Rinderpest virus.**
						The organization should ensure that its waste management policy is documented.
						Any wastes that are potentially contaminated with Rinderpest virus should be secured by appropriate measures, in line with a documented biosecurity risk assessment, until inactivation of the Rinderpest virus can be performed.
35			4.4.4.5.4	Clothing and Personal Protective Equipment (PPE)	The organization shall ensure that PPE needs are identified and suitable equipment is specified, made available, used and maintained appropriately within the facility.	**The facility should ensure that any biosecurity measures put in place to secure Rinderpest virus do not interfere with the proper use of PPE (for example, by forcing the removal of PPE).**
						PPE that is potentially contaminated with Rinderpest virus should be segregated from other contaminated materials and stored in a secure location until it can be treated appropriately.
36			4.4.4.6	Worker health programme	The organization shall ensure that risk to worker health, and that of other personnel whose health could be directly impacted by exposure to biological agents and toxins, is managed effectively including prevention and protection measures. The requirements of the health surveillance programme shall be determined by a defined health hazard identification and risk assessment process involving all relevant personnel.	**None applicable from Rinderpest biosecurity perspective**

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37			4.4.4.6.1	Vaccination of personnel	Based on risk, the need for vaccination shall be identified and shall cover groups identified as being potentially exposed to biological agents or toxins. The organization shall ensure that a vaccination policy be defined and implemented, and that access to laboratories or work is controlled for individuals until they comply with the policy.	**None applicable from Rinderpest biosecurity perspective**
38			4.4.4.7	Behavioural factors and control of workers	The organization shall establish and maintain a programme to address risk associated with human behavior, including the management of how workers interact with the facility and its equipment.	**The organization should put measures in place to ensure that staff and visitors comply with biosecurity-related requirements, procedures, posted signs, etc.**
						The organization should seek to encourage reporting of any security-related incidents, without fear of reprisals. Mechanisms for anonymous reporting of incidents may be considered.
						The organization should consider establishing employee assistance services, to help promote a positive working environment and address changes in behavior which may be prompted by changes in an individual's circumstances.
						The organization should establish mechanisms for staff to provide feedback and suggestions to management regarding biosecurity policies, plans and procedures that may impact their work, so that any concerns may be addressed constructively.
						In cases where corrective actions are required, corrective actions should be based on documented organizational policies and procedures, and corrective actions should be documented.
39			4.4.4.7.1	Personnel reliability	The organization shall ensure that a personnel reliability policy is defined and implemented, and that access to facilities or work is controlled for individuals according to the policy.	**Prospective and current employees should be subject to lawful and appropriate background screening, based on a documented risk assessment, before being granted access to Rinderpest virus stocks. Due to the biosecurity risk associated with Rinderpest virus, personnel whose functions require access to Rinderpest virus should, where lawful and appropriate, be subject to a higher degree of personnel reliability screening than personnel who occupy positions of lower biosecurity risk.**
						Periodic reviews of staff should be performed, to include current responsibilities, job performance, and any necessary changes in access to Rinderpest stocks taken accordingly.

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						Personnel records, including results of personnel background screenings and performance reviews, should be treated as sensitive information and protected from unauthorized disclosure.
						Personnel should be issued photographic identification badges that identify personnel and access authorization level, as well as an expiration date.
						Personnel should be required to display photographic identification badges at all times while on the organization's premises, unless displaying identification badge is precluded by safety considerations.
						Procedures for addressing lost or stolen badges, including deactivation of associated access permissions, should be implemented. Staff should be regularly trained on these procedures.
40			4.4.4.7.2	Contractors, visitors and suppliers	The organization shall ensure that suppliers, contractors, visitors and sub-contractors adhere to the requirements of established management systems and do not compromise biorisk management of the facility.	**Visitors should not be allowed unescorted access to any areas where Rinderpest virus-containing materials are stored or used.**
						The organization should identify staff who are authorized to escort visitors into restricted areas. These staff should be provided training on the organization's escort policies, and their associated responsibilities.
						An escort policy should be established, documented and strictly followed when allowing visitors access to any areas where Rinderpest virus-containing materials are stored or used.
						The organization should maintain a visitor log, including daily sign-in and sign-out of all visitors.
						A visitor badge policy and associated procedures should be implemented and enforced. Visitors should display visitor badges at all times while on the organization's premises. Lost or stolen badges should be reported immediately.
41			4.4.4.7.3	Exclusion	The organization shall ensure that measures are set in place for the removal and exclusion of personnel (both temporary and, if appropriate, permanent) from the facility where deemed necessary through risk assessment.	**SOPs for the removal and exclusion of personnel who are not authorized to access the facility premises should be developed.**
						The facility should ensure that personnel who no longer should have access to the facility, or restricted areas in the facility, no longer retain keys, credentials, passwords, PIN codes, or other means of access to the facility or restricted areas.
						The facility should ensure that personnel who no longer should have access to the facility or restricted areas in the facility may no longer access information pertaining to the facility or restricted areas. This may include

						ensuring the return of documentation, changing computer or network access passwords, and returning electronic equipment.
42			4.4.4.8	Infrastructure and operational management	The organization shall ensure that facilities, equipment and processes are designed and run in a safe and secure way with respect to biorisk management.	**The design of physical infrastructure (buildings, equipment) should be guided by a comprehensive biorisk assessment.**
						The operation of the facility, during normal and abnormal conditions, should be guided by a biosecurity risk assessment.
						Consideration of any proposed changes in the physical infrastructure of the facility should include an analysis of the potential impact on the biosecurity of Rinderpest virus stocks.
43			4.4.4.8.1	Planning, design and verification	The organization shall ensure that a formal planning, design and redesign process is adopted for the facility, based upon an assessment of risk associated with the materials to be used and activities undertaken. The design process shall identify and incorporate all relevant legislative requirements, together with information from recognized standards, guidelines, industry good practices and facility-specific risk assessments. The design process shall identify and consult all relevant parties associated with the facility and its operation. All design features, construction techniques, materials and equipment selected shall be documented in line with the need to provide sufficiently specific and detailed instruction and information on the design specification. The organization shall ensure that new construction and physical facility modifications are carried out according to an approved plan.	**A project committee should be established to consider facility needs and design requirements.**
						The facility should identify any external parties who may be consulted in the course of planning and design of facilities.
						All relevant legislation, legal requirements, standards, codes, etc. at the international, national and local levels should be identified.
						The design process should be guided by a facility-specific risk assessment. Design and engineering decisions in the planning phase should be based on the risk posed by materials and their intended use within the facility.
						Consideration of any proposed changes in the physical infrastructure of the facility should include an analysis of the potential impact on the biosecurity of Rinderpest virus stocks.
						The methods and standards that will be used to assure the facility performs as designed should be identified and clearly documented during the planning phase.
44			4.4.4.8.2	Commissioning and decommissioning	The organization shall ensure that there is a formal process for initial commissioning of new facilities and the final decommissioning of existing ones.	**The facility should ensure that the commissioning process includes consideration of the performance of the facility as it relates to Rinderpest biosecurity. This should include testing of systems, equipment and components related to the function of the biosecurity system.**
						The decommissioning process should include documented procedures for maintaining the security of any Rinderpest virus-containing materials, or materials or equipment potentially contaminated with Rinderpest virus, until such materials may be removed or properly inactivated.

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45			4.4.4.8.3	Maintenance, control, calibration, certification and validation	The organization shall establish and maintain documented procedures to ensure equipment and elements of the physical plant that may impact on biorisk be identified, purchased, maintained, calibrated, certified or validated in a manner consistent with the intent and requirements of the biorisk management programme.	**The facility should establish an equipment maintenance program to ensure regular preventative maintenance of all equipment and components of the physical protection system.**
						The facility should establish an inventory of all equipment and components of the security system, and record maintenance performed.
						The facility should ensure that any maintenance of the security system is performed by competent, trustworthy individuals and/or external companies.
						The facility should ensure the timely availability of spare parts for the physical protection system.
						The facility should ensure that all security equipment and components are properly calibrated by a competent individual. Calibration of equipment should be documented, and if necessary a schedule for checking and re-calibration should be established as part of the maintenance program.
						The performance of equipment and components of the physical protection system should be regularly validated through periodic testing. SOPs should be developed for use during testing.
						The results of performance testing should be documented. Records should be retained.
46			4.4.4.8.4	Physical security	The organization shall ensure that the controls for the physical security of cultures, specimens, samples and potentially contaminated materials or waste determined as part of the risk assessment process are implemented and maintained.	***General***
						The goal of the physical security system is to reduce the risk that Rinderpest virus-containing materials will be intentionally and maliciously removed from the premises, by reducing the likelihood that an adversary can access the materials. The physical security system is comprised of four elements: detection, delay, access control, and response.
						The facility should define the areas where Rinderpest virus is stored and handled as exclusion areas subject to specific physical security and access control requirements. The facility should seek to reduce the number of areas within the facility where Rinderpest virus is stored and handled to the minimum necessary to carry out operations safely and securely.
						The design of the physical protection system should be based on a facility-specific biosecurity risk assessment and include consideration of the biosecurity risks associated with different areas within the facility. The physical protection system should be based on the principle of "graded protection" and aligned with the biosecurity risks associated with each area.

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						The physical protection system should be regularly tested to ensure proper performance, and equipment and components maintained on a regular schedule as documented in the facility's maintenance plan.
						Information pertaining to the physical protection system should be protected as sensitive information, and secured to prevent unauthorized disclosure.
						Detection
						The facility should employ redundant electronic intrusion detection systems in areas where Rinderpest virus is stored and handled. For example, these areas should be equipped with boundary intrusion detection sensors and interior motion sensors.
						The facility may elect to supplement electronic intrusion detection with a guard force tasked with monitoring certain areas of access control points.
						The facility should consider all potential routes of entry for an adversary in designing the intrusion detection system, including doors, windows, pass-through autoclaves, air-handling systems, etc.
						The facility should have a central alarm monitoring station located in a secure area, which is monitored at all times by trained, authorized personnel who are capable of performing alarm assessment.
						Intrusion detection alarms should be immediately communicated to the central alarm monitoring station, for subsequent alarm assessment. The facility may decide based on risk assessment to communicate intrusion alarms directly to a response force.
						Alarm assessment may be aided by the use of remote video assessment. CCTV systems should be capable of facilitating alarm assessment through proper equipment selection and positioning. Video should be displayed at the central alarm monitoring station, and recorded for subsequent incident investigation.
						The remote video assessment system should be configured to record video before, during and after an alarm event.
						Records of each alarm event, including nuisance alarms, should be retained – records should include date, time, cause (or probable cause) for each alarm.
						Wires, cables and junction boxes should be protected from tampering, for example through the use of locks, conduit and tamper indicating measures.
						Delay

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						A perimeter boundary such as a wall or fence should be established to delineate public space from the facility's property. The perimeter should include personnel and vehicle entrances that can be controlled, and if necessary closed in case of an emergency situation.
						Restricted areas where Rinderpest virus is stored or handled should be located towards the interior of the facility, away from high-traffic areas and areas where the public or other visitors may have access.
						Walls surrounding the restricted area(s) where Rinderpest virus is stored or handled should be robust and in good condition, with no significant damage or other vulnerabilities that could be easily exploited by an adversary.
						Doors leading to restricted areas should be robust and secured with a strong security grade locks. Hinges and locking mechanisms should not be exposed to tampering (mounted on the secure side of the door). Keys, cards or other credentials should be issued only to authorized personnel.
						Consistent with local building safety codes, windows leading to restricted areas may be protected with security grade glass, window bars, or other delay mechanisms.
						Access Control
						Access to areas where Rinderpest virus is stored and handled should be restricted to authorized personnel to conduct authorized work only.
						Two-factor (minimum) electronic access controls should be employed at all entrances to restricted areas where Rinderpest virus is stored and handled.
						Access authorizations should be removed as soon as an individual no longer requires access to restricted areas to perform his/her duties. Keys and credentials should be immediately returned, revoked or modified accordingly.
						Response
						The facility should consider maintaining an on-site guard force that is equipped and trained to respond to intrusion alarms.
						The facility should establish MOUs with local law enforcement agencies to support response to intrusion alarms
						Communication between the central alarm monitoring station should be highly secure and reliable.
47			4.4.4.8.5	Information security	The organization shall have a policy and procedure in place to identify sensitive information; a review	**The institution should establish policies and procedures to identify, mark, store, and transmit sensitive**

					and approval process shall be used to control access to such information.	**information internally and externally.**
						The institution should treat all information pertaining to the security system of the facility as sensitive information and protect it accordingly.
						The facility should establish a process to review and approve information before it is released to audiences outside the facility.
						The institution should ensure that access to sensitive information is controlled at a level commensurate with risk; in general access to sensitive information should be restricted to those persons with "a need to know" in order to carry out their responsibilities.
						Sensitive information should be clearly marked, so that individuals may know to apply appropriate handling methods.
						Sensitive information (in hard copy and electronic forms) should be protected from unauthorized disclosure by storing the information in the facility's secure areas. Hard copy information should be further secured by storing in locked receptacles. Electronic information should be further secured through electronic means – for example, by using password protection, encryption, etc.
						The transmission of sensitive information internally and externally should occur through secure means; for example, by using reputable courier services, encrypted email, or fax.
						The institution's computer workstations, servers, networks, and other elements of the facility's information systems should be protected from unauthorized access through the use of appropriate network and computer security measures, such as passwords, anti-virus software, firewalls, email spam filters, etc.. The facility may need to consult external network security specialists to determine appropriate security measures.
						Individuals who are granted access to the facility's information networks should receive appropriate training on the handling of sensitive information stored on the network, and be subject to lawful and appropriate screening prior to being granted access to facility-specific sensitive information.
						The institution should ensure that sensitive information that is no longer required is disposed of in a secure manner.

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48			4.4.4.8.6	Control of supplies	The organization shall ensure that purchases (including services) conform to specified requirements. Controls shall be applied depending on potential impact on the biorisk involved. The organization shall ensure suppliers are evaluated and selected based on their ability to provide products / services that meet the requirements of this agreement. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.	**The organization should ensure that security-related equipment and supplies are purchased from reputable vendors, based on documented criteria for selection and evaluation.**
49			4.4.4.9	Transport of biological agents and toxins	The organization shall ensure that procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials are established and maintained in accordance with legal requirements for the transport of dangerous goods.	**Internal transport of Rinderpest virus-containing materials should occur using a "two-person rule." Only personnel who have completed appropriate background screening and training should have access to the materials while being transferred (i.e., transport personnel should be subject to the same requirements as personnel handling materials in the laboratory).**
						A standard operating procedure for the internal transfer of Rinderpest virus-containing materials should be established.
						Rinderpest virus-containing materials should not be left unattended at any point during the internal transfer process.
						All internal transfers of Rinderpest virus-containing materials should be carefully documented, such that a chain of custody is clearly recorded. Records should be retained in a secure location.
						The facility's inventory of Rinderpest virus containing materials should be promptly updated following an internal or external transfer of materials.
						External shipments of Rinderpest virus-containing materials should be approved by a designated authority prior to shipment.
						The facility should take steps to verify that the receiving facility is authorized and competent to receive Rinderpest-containing materials.
						The facility should utilize a reputable carrier to perform the transfer from one facility to another. If possible, a carrier with a transportation security plan should be selected.

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						Shipment by air is encouraged, as it typically reduces the amount of time the materials are outside a controlled laboratory environment.
						The shipping facility should communicate with the receiving facility to ensure the receiving facility is prepared to receive the shipment, and that the details of the shipment are shared. This will increase the probability that an unexpected delay, or a missing package, is detected quickly.
						When receiving a shipment of Rinderpest virus-containing materials, the facility should ensure that only authorized individuals have access to the package, and that the materials are transferred to a restricted area in the facility as soon as possible. Internal transfer to a restricted area should be conducted using a "two person rule."
50			4.4.4.10	Personal security	The organization shall have a policy in place to provide personal security support services to staff members that include, where appropriate, personal security awareness training.	**The facility should provide training to all staff on potential security-related scenarios and appropriate actions. These may include: unauthorized intruder, active shooter, anonymous threats, suspicious packages, cyber threats, contraband on site.**
						It is recommended that the facility communicate appropriate steps for staff to take to respond to these scenarios, through training, bulletins, discussions during meetings, signage, and other communication mechanisms.
51			4.4.5	Emergency response and contingency plans	The organization shall establish and maintain plans and procedures to identify the potential for incidents and emergency situations involving biological agents, toxins and materials, to prevent their occurrence, to respond to emergency situations and to limit the likely illness or other damage that may be associated with them. Emergency planning shall cover all aspects of biorisk and include general safety, security and medical issues.	**As part of the biosecurity risk assessment process, the facility should identify and document potential credible security scenarios which could occur that involve the theft or misuse of Rinderpest virus materials.**
						Based on the biosecurity risk assessment, the facility should ensure that emergency response plans are developed to address credible scenarios.
52			4.4.5.1	Emergency scenarios	The organization shall ensure that all credible and foreseeable emergency scenarios that may impact the organization's biorisks have been identified.	**In considering potential biosecurity-related scenarios, the organization should consider: theft, vandalism, sabotage of critical systems, acts of terrorism, explosion.**
						The facility should consider how other emergency scenarios, for example natural disasters, may impact the probability of occurrence of security-related incidents.

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53			4.4.5.2	Emergency plans	The organization shall ensure that biorisks are taken into account when preparing and implementing emergency plans. The organization shall ensure a system is established to effectively manage medical and/or environmental emergencies, including, but not limited to, the identification of potentially infected workers and provision of immediate medical care to exposed, ill or injured workers. The organization shall also ensure that control measures in place can be demonstrated as being reasonable and proportionate to the scale and nature of the emergency. Emergency plans shall be effectively communicated to all employees and relevant third parties, and tested, with the intention that everyone is aware of their obligations.	**The organization should develop incident response procedures for all credible security scenarios involving Rinderpest virus materials. Development of the plans and procedures should be based on biosecurity risk assessment information, lessons learned from previous incidents and exercises, and consultation with other stakeholders such as first responders and law enforcement officials.**
						The incident response plans should clearly identify roles and responsibilities for response to the incident, including lines of authority (chain of command).
						The plans should also clearly identify and document roles and responsibility for external responders, including response forces, law enforcement, and first aid. This should include documentation of how facility representatives will coordinate with external responders before, during and after an incident occurs. The incident response plans should be consistent with, refer to, and cite any relevant MOUs with external agencies.
						The facility should ensure that communication plans and procedures are prepared and implemented, to communicate the actions staff should take in response to various security scenarios. Communication may take the form of training, briefings, notices, signs, or other forms of communication.
						The incident response plans should include evacuation procedures, including appropriate evacuation routes, if necessary. The evacuation of personnel through high risk areas of the facility should be avoided. Evacuation procedures should be clearly communicated to staff.
						The facility should ensure that external agencies understand their roles and responsibilities under the incident response plans, and understand any potential risks they may be exposed to during a response.
54			4.4.5.3	Emergency exercises and simulations	The organization shall ensure that structured and realistic emergency exercises and simulations, including security drills are conducted at regular intervals, based on risk, to test the plans, prepare personnel, and learn from any good practices or deficiencies identified.	**The organization should regularly test emergency plans developed to respond to security scenarios involving Rinderpest virus-containing materials. These exercises may take several forms, including tabletop exercises, drills, or exercises conducted under controlled conditions.**

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						Observations made during the conduct of the exercises and simulations should be documented carefully.
						The organization should devote resources to the evaluation of the results of the exercises to identify relevant lessons learned.
						Based on the evaluation of the exercise, the organization should document actions to be taken to improve incident response procedures, as well as responsibilities for carrying out the actions.
55			4.4.5.4	Contingency plans	The organization shall ensure that in the event of an emergency, adequate contingency measures shall be in place to ensure the safety and security of continued operations.	**The organization should ensure that contingency plans are in place to ensure the security of Rinderpest virus-containing materials during and after unforeseen events, such as power loss, natural disasters, prolonged work stoppages, etc.**
						The organization should ensure that back-up provision has been made for the facility's security systems, including physical security and information security, in case of power failure or other disruptions. For example all doors may have the ability to be mechanically locked in the event of a long-term power outage.
56	4.5	Checking and corrective action	4.5.1	Performance measurement and analysis of data	The organization shall ensure that appropriate data are determined, collected and analysed to assess the suitability and effectiveness of the biorisk management system and to evaluate where continual improvement of the system can be made.	**The organization should establish and document performance measures to help assess the effectiveness of the facility's security system.**
						The organization should identify and document all sources of performance-related information, for example: inspections, audits, defined performance indicators, staff surveys, interviews, external inspections or audits, exercise outcomes, and incident reports.
						Examples of performance indicators, may include: number of security incidents, number of nuisance alarms, number of rules violations, staff training attendance, number of inventory discrepancies, etc.
						The organization should regularly review and analyze performance data in order to identify opportunities for continual improvement of the biosecurity system.
57			4.5.2	Records, document and data control	The organization shall ensure that records, documents and data are established, controlled and maintained to provide evidence of conformity to the requirements of this agreement and that they remain legible, readily identifiable and retrievable.	**A document control program should be established to demonstrate that the organization's Rinderpest biosecurity program conforms with legal and other requirements defined by the organization.**
						The organization should ensure that roles and responsibilities for document control are defined and communicated.
						The organization should ensure that controlled documents are secured in accordance with biosecurity risk.

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						The organization should establish a process to manage version control of documents.
58			4.5.3	Inventory monitoring and control	The organization shall ensure that a review of the inventory is conducted at predetermined intervals based on risk and at a level and frequency whereby materials can be accounted for in an appropriate manner. The organization shall ensure that the measures are put in place to minimize the quantities of biological agents and toxins that make up the inventory.	**The facility should conduct a thorough review of the Rinderpest virus inventory at least once every six months, or as needed depending on the biosecurity risk assessment and established biosecurity policies.**
						At defined intervals, all Rinderpest virus-containing materials should be accounted for during inventory checks (as opposed to selective sampling of a subset of the materials).
						The organization should ensure that roles and responsibilities for inventory monitoring are assigned, documented and communicated.
						Any discrepancies between the actual inventory and inventory records should be promptly investigated and reconciled.
						Rinderpest virus stocks that are no longer required should be securely and safely destroyed. The disposal of any Rinderpest virus-containing material should be documented.
59			4.5.4.1	Accident/incident investigation	The organization shall establish and maintain documented procedures to define, record, analyse and learn from accidents and incidents involving biological agents and toxins.	**The organization should ensure that a procedure is in place for recording and reporting any security-related incident involving Rinderpest virus-containing materials.**
						The organization should identify and document who is responsible for overseeing the incident response procedures, and that roles and responsibilities are clearly communicated.
						The organization should establish clear SOPs for investigating security incidents, including developing standard forms and reports.
60			4.5.4.2	Control of nonconformities	The organization shall ensure that situations that do not conform to the requirements of this agreement are identified and controlled to prevent undesirable consequences. Records of the nature of the non-conformity and any subsequent action taken shall be maintained.	**The organization should ensure that any identified non-conformities related to the biosecurity program are investigated, and controlled.**
						Results of investigations should be communicated to relevant stakeholders.
61			4.5.4.3	Corrective action	The organization shall ensure action is taken to eliminate the causes of non-conformities with the requirements of this agreement in order to prevent	**Based on the investigation of non-conformities in the biosecurity system, the organization should determine and implement actions to address the non-conformity.**

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					recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	**Any corrective actions taken should be documented and reviewed as part of the management review of the biosecurity system.**
62			4.5.4.4	Preventive action	The organization shall ensure action is taken to identify and eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential nonconformities.	**The organization should pro-actively seek to identify root causes of potential non-conformities with the biosecurity system, before such non-conformities occur.**
						Any preventive actions taken should be documented and reviewed as part of the management review of the biosecurity system.
63			4.5.5	Inspection and audit	The organization shall ensure that a programme of inspection and audit is conducted which is appropriate to the risk associated with the facility. Inspections and audits shall be conducted at planned intervals to determine if the biorisk management system conforms to the documented plans and to the requirements of this agreement, and that it is effectively implemented and maintained. Management responsible for the area being inspected / audited shall ensure that any actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities arising shall include the verification of the actions taken and the reporting of verification results.	**Internal audits should include evaluation of all aspects of the Rinderpest biosecurity program, including physical protection, personnel security, information security, material control and accountability, and transport security.**
						Internal audits should be performed by personnel who are independent of the activity being audited, but who have competence to perform the audit.
						Inspections of areas where Rinderpest virus is stored and handled should be conducted frequently and routinely, to ensure that the biosecurity system is functioning as intended and that staff is complying with all applicable policies, plans and procedures.
						The results of inspections and audits should be carefully documented and securely stored. Data collected during inspections and audits should be treated as sensitive proprietary information and protected from unauthorized disclosure.
						Reports of inspections and audits should be reviewed, and corrective actions, if needed, should be implemented promptly to address nonconformities.
64	4.6	Review	4.6.1	Biorisk management review	Top management shall review the organization's biorisk management system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the system, procedures, policies and objectives. Records from the management review shall be maintained.	**Top management should review the facility's biorisk management program for Rinderpest at least once every year, and after any reported incident.**
						Based on this review, management should determine what steps the facility should take to improve its biosecurity posture and further reduce the biosecurity risk associated with Rinderpest virus materials. These decisions should be clearly documented and communicated to appropriate individuals for subsequent action.

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