

## CHAPTER 3.5.

# MANAGING BIORISK: EXAMPLES OF ALIGNING RISK MANAGEMENT STRATEGIES WITH ASSESSED BIORISKS

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### A. INTRODUCTION

*Chapter 1.1.4 Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities describes the use of biorisk analysis for effectively identifying and managing laboratory biosafety and biosecurity risks for individual veterinary laboratories and animal facilities based on their unique facility, infrastructure, and the surrounding environment in which the biological agent or toxin is to be handled, including relevant national policies and legislation. The process of biorisk analysis includes biohazard identification, biorisk assessment, biorisk management, and biorisk communication.*

*This Guideline provides, in a table format, two working **examples** of the risk assessment component of the process. The risk assessments include review of laboratory control measures that a fictional veterinary laboratory evaluated in order to protect laboratory workers from inadvertent exposures and infection, and also importantly to protect as appropriate the local and regional animal populations, human populations, and environment from accidental or intentional release and spread of a biological agent or toxin from their laboratory or animal facility. As such, the risk analysis includes consideration of the likelihood of an event occurring and the consequences of such an event.*

*The first example uses Bacillus anthracis, a zoonotic agent, as an example of a biosafety risk managed by veterinary laboratories that is also considered a biosecurity risk based on its potential as a biothreat agent. The second example uses foot and mouth disease (FMD) virus as an example of a veterinary pathogen of variable economic significance depending on the endemic disease status and the location of the laboratory in relation to geopolitical borders. The FMD example represents an assessment completed by a laboratory located in an FMD-endemic area, and importantly notes in the assessment where laboratory control measures will be re-evaluated and modified as FMDV is eradicated in the specific region. Disease control and eradication programmes increase the economic impact of the disease and associated biorisks of handling the agent in the laboratory.*

**NOTE:** *It must be stressed that the two examples provided here are just that – examples invented for the purpose of showing what an actual laboratory may need to evaluate or consider as part of its biorisk assessment. The text in bold in the tables indicates matters that should be included in any agent-specific risk assessment. The text not in bold is fictitious data included to help demonstrate the process. It is equally important to note that the examples are short, concise summaries of biorisk analyses. Dependent on the complexity of the specific-agent, the laboratory facility, the proposed laboratory procedures, and the regulatory environment, actual biorisk analyses may vary from a similar short summary to a multiple-page dossier.*

## Example Risk Analysis 1: Anthrax

**Hazard:** *Bacillus anthracis*

**Location:** Country where anthrax is not usually considered endemic but disease freedom not claimed – laboratory located in site where there are no domestic animals and no habitations (20 km around the facility).

**Pathogen and disease:** Anthrax is an acute bacterial disease primarily of herbivores and is transmissible to humans. It is caused by *B. anthracis*, a Gram-positive spore-forming rod-shaped bacterium.

Animals become infected by ingesting spores or possibly by being bitten by flies that have fed on an infected animal or carcass. Infected animals are usually found dead as death can occur within 24 hours. A careful post-mortem examination of recently dead animals may show any number of lesions, none of which is pathognomonic or entirely consistent. To avoid environmental contamination, post-mortem examinations conducted in the field (outside of laboratory containment) of carcasses of animals suspected to have died of anthrax is discouraged. Lesions most commonly seen are those of a generalised septicaemia often accompanied by an enlarged spleen having a 'blackberry jam' consistency and poorly clotted blood. Haemorrhage from the nose, mouth, vagina and/or anus at death is not a common sign.

More than 95% of human anthrax cases take the cutaneous form and result from handling infected carcasses or hides, hair, meat or bones from such carcasses. *Bacillus anthracis* is not invasive and requires a lesion to infect. Protection for veterinarians and other animal handlers involves wearing gloves, and other protective clothing when handling specimens from suspected anthrax carcasses and never rubbing the face or eyes. The risk of gastrointestinal anthrax may arise if individuals eat meat from animals infected with anthrax.

**NOTE:** The Table that follows is an example. The cells have been filled in in response to an imaginary scenario. The data are fictitious and included to help demonstrate the process. The requirements in the hypothetical examples are based on the country's standards and guidelines, as would be used for an actual biorisk analysis.

RISK ASSESSMENT (Likelihood and Severity)	RISK MANAGEMENT Administrative Controls	RISK MANAGEMENT Operational Controls	RISK MANAGEMENT Engineering Controls	RISK MANAGEMENT Personal Protective Equipment
<p><b>Health Risk</b></p> <p><b>Humans</b> – YES, treatment available.</p> <p><b>Animals</b> – YES, treatment not usually attempted or recommended, case fatality rate high, herd morbidity variable.</p> <p><b>Transmissible by</b> contact with body fluids of infected animals or carcasses, excretions of infected animals, or contaminated environment.</p>	<p><b>Requirements:</b></p> <ol style="list-style-type: none"> <li><b>1. Communication plan:</b> reportable disease list and reporting requirements for both animal and public health authorities.</li> <li><b>2. Qualified/suitable staff:</b> training and competency requirements for work with infectious diseases in place and current for all laboratory staff.</li> <li><b>3. Health and safety programme:</b> prophylaxis and treatment for anthrax exposures reviewed.</li> <li><b>4. Accident/incident reporting programme</b></li> <li><b>5. Emergency response plan:</b> actions including notification list for accidental exposure, spill/contamination in lab, release from lab, and theft of agent.</li> <li><b>6. Agent inventory management programme</b></li> <li><b>7. Waste management policy</b></li> <li><b>8. Security programme:</b> laboratory biosecurity for preventing unauthorised access to <i>B. anthracis</i>.</li> </ol>	<p><b>Requirements:</b></p> <ol style="list-style-type: none"> <li><b>1. Standard operating procedures (SOPs)</b> and training materials comprehensively covering <b>laboratory safety and laboratory biosecurity</b> comprehensively that address the biorisks posed by the handling and storage of suspect diagnostic case materials and <i>B. anthracis</i> cultures. Good Laboratory Practices included in all working SOPs.</li> <li><b>2. Disinfection/decontamination SOPs</b> are written for disinfecting/decontaminating necropsy and laboratory areas and equipment, for carcasses and tissues, for packaging and shipping materials, and for laboratory wastes.</li> <li><b>3. Transport SOPs</b>, regulatory approvals, and certifications for packaging and shipping to the reference laboratory are current. Sample (specimen) containment SOPs are in place for movement within the laboratory facility.</li> <li><b>4. Response plan</b> drill/exercise specific to <i>B. anthracis</i> identification from clinical materials and to associated laboratory responses, including incident response to spills and release from the laboratory.</li> <li><b>5. Accident/incident reporting</b> and response SOPs and forms, audit schedule for reviewing accident reporting.</li> <li><b>6. Audit and review schedule</b> for <i>B. anthracis</i> biorisk assessment and management</li> </ol>	<p><b>Requirements:</b></p> <ol style="list-style-type: none"> <li><b>1. Biocontainment</b> addresses prevention of accidental and/or deliberate release of infectious material.</li> <li><b>2. Separation of incompatible activities</b></li> <li><b>3. Equipment maintenance, calibration, certification</b> current</li> <li><b>4. Facility security</b></li> </ol>	<p><b>Requirements:</b></p> <p><b>Personal protective equipment (PPE):</b> respiratory protection and dedicated laboratory clothing.</p>
<p><b>In the Laboratory</b></p> <p><b>Necropsy:</b> body fluids released, environment contaminated, high risk of human exposure by contact with body fluids and by inhalation.</p>	<p><b>Assessment findings:</b></p> <ol style="list-style-type: none"> <li>1. Reporting plan for <i>Bacillus anthracis</i> and contact list (names and numbers) is current. Includes public health, animal health.</li> </ol>	<p><b>Assessment findings:</b></p> <ol style="list-style-type: none"> <li>1. Good microbiology practices followed by all lab staff; review included in annual audit of laboratory practices to insure compliance.</li> </ol>	<p><b>Assessment findings:</b></p> <ol style="list-style-type: none"> <li>1. Biosafety cabinets located in sample receiving area and microbiology area. Centrifuge equipped with closed carriers (aerosol containment).</li> </ol>	<p><b>Assessment findings:</b></p> <ol style="list-style-type: none"> <li>1. Respiratory protection available on-site for receiving, necropsy, microbiology staff.</li> </ol> <p>Dedicated coveralls and boots used in necropsy area.</p>

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<p><b>Handling of specimens:</b> unknowns via diagnostic submissions including tissues, carcasses. (High risk for exposure to spores), swabs of blood, other body fluids or swabs taken from incisions in tissues or organs can be source of exposure (low exposure risk)</p> <p><b>Volumes and concentrations:</b> Anticipate two diagnostic cases per year (moderate risk). Amplification with short and long-term storage on solid media, &lt;1 mg agent (moderate risk)</p> <p><b>Diagnostic test methods:</b> Identification and characterisation of the agent: Culture, immunological detection, characterisation and differentiation from vaccine strain by polymerase chain reaction (PCR).</p> <p><b>Research:</b> No experimental work to be conducted</p> <p><b>Bacterial isolate archives:</b> Short and long term storage of isolates. (High risk for intentional misuse – see Security risks.)</p>	<p>2. Training and competency in good microbiology practices current for all staff. Anthrax-specific training for clinical disease recognition and handling competency documented for pathology staff. Anthrax-specific training for handling of high risk specimens for receiving and testing lab staff.</p> <p>3 and 4. Employee health and safety programme in place.</p> <ul style="list-style-type: none"> <li>- All employees enrolled in the health and safety programme, trained in accident reporting policy and procedures.</li> <li>- Policy and procedure for providing health information and health surveillance related to Anthrax exposure for non-employee trainees and students present in the laboratory is in place.</li> <li>- Anthrax prophylaxis and treatment options reviewed with occupational health officer: decision made not to vaccinate lab staff.</li> </ul> <p>5. Response plan addresses accidental and intentional release of <i>Bacillus anthracis</i>. All employees trained on plan.</p> <p>6. Agent inventory management plan addresses access, secure storage, transfer, and destruction. Mandates annual audit and reconciliation of inventory records. Laboratory storage and archive system and procedures comply with relevant national regulations for <i>B. anthracis</i>.</p> <p>7. Waste management policy addresses carcasses, tissues, and all laboratory wastes containing potentially infectious material. All anthrax-suspect material to be diverted from laboratory rendering.</p>	<p>Current SOPs are in place for receiving, processing, testing, storage, and disposal of <i>B. anthracis</i> suspect case materials.</p> <p>Microbiology culture SOP includes steps to minimise potential for spore formation and subsequent exposure of staff to spores (reduction in anthrax inhalation biorisk)</p> <p>2. General disinfection and decontamination protocols in place for all laboratory areas. Gap: The general disinfection/decontamination plan for the laboratory does not include specific references for disinfectants, concentrations, and contact times for <i>B. anthracis</i>.</p> <p>SOPs and training materials for recognition, handling, and destruction of high risk <i>B. anthracis</i> specimens in place.</p> <p>3. Certification current for staff member responsible for packaging and shipping to reference laboratory. SOP for movement of <i>B. anthracis</i> within the laboratory includes requirement for transport in a secondary leak-proof non-breakable container marked with a biohazard label.</p> <p>4. Emergency response plan was exercised within the prior 12 months; exercise specific to anthrax identified a gap: <i>Actions needed: Restrict potential for inadvertent contamination from necropsy area by (1) restricting visitors, (2) developing a policy for visitors (no street clothing or shoes in necropsy area), (3) review SOP with staff on rendering of carcasses from necropsy area to address holding, decontaminating or destroying potentially contaminated hides/ carcasses, and (4) develop a laboratory labelling system to clearly identify high-risk and/or potential zoonotic agent containing carcasses or specimens during short and long-term storage.</i></p>	<p>Additional documents needed: Effluent treatment verification records, certifications for directional airflow.</p> <p>2. Clerical areas separate from testing areas. Dedicated secure freezer used for agent inventory.</p> <p>3. Biosafety cabinets in receiving and microbiology sections have certification of correct operation (air-flow) verified annually per pre-existing preventive maintenance schedule.</p> <p>4. Doors to testing areas can be locked. Entry to building controlled by key-card access and alarmed off-hours. Inventory storage location is secured by lock and key, with key access available only to authorised personnel. The necropsy area used for short term storage of the carcass prior to incineration and disposal is secure and signage is posted to prevent unauthorised access.</p>	<p>Laboratory coats, gloves used for all specimen handling. SOPs for putting on and removing PPE available and systematically followed, PPE regularly collected and laundered in appropriate facility</p> <p><i>Gap: Insecure availability of coveralls and boots on-site for authorised visitors (students/trainees) to necropsy area.</i></p>

<b>RISK ASSESSMENT</b> (Likelihood and Severity)	<b>RISK MANAGEMENT</b> <b>Administrative Controls</b>	<b>RISK MANAGEMENT</b> <b>Operational Controls</b>	<b>RISK MANAGEMENT</b> <b>Engineering Controls</b>	<b>RISK MANAGEMENT</b> <b>Personal Protective Equipment</b>
	<p>8. Laboratory biosecurity includes restricted access to testing areas. Biohazard signage available to post at entrance doors. Key-controlled access to incubator and freezer used for storage of <i>B. anthracis</i> cultures.</p> <p><i>Gap: Laboratory policy needed to define the boundaries regarding types of research to be allowed, and B. anthracis to be included in risk profiles of organisms with which research will not be conducted.</i></p>	<p>5. Accident/incident reporting protocols cover <i>B. anthracis</i>. Laboratory director and safety officer review of all accident reports. Accident/Incident reporting is a component of the laboratory quality system and continual improvement plan and is audited annually.</p> <p>6. Audit of <i>B. anthracis</i> control measures is scheduled for 30 days following first case presented. Review of risk assessment and management plan is scheduled to be completed annually and immediately after any significant change to the laboratory facility or management.</p>		
<b>ECONOMIC RISKS</b>				
<p><b>Endemic in region:</b></p> <p>1. Sporadic cases possible.</p>				
<p><b>Trade barrier:</b> A possibility to be managed. (High risk for restriction against movement of wool and hides.)</p>	<p><i>In progress: Veterinary Authority advised that B. anthracis may be worked with in the laboratory, currently reviewing economic risks to region, working with trade partners to assess impact on trade related to laboratory handling and storing B. anthracis.</i></p>			
<b>ENVIRONMENTAL RISKS</b>				
<p><b>Stable in environment:</b> YES. (High risk for soil contamination; spores stable for years.)</p>		<p>SOP on handling of anthrax suspect carcasses, includes movement from necropsy area to holding area, decontamination and destruction of potentially contaminated hides/carcasses to insure no release to landfill or rendering facilities.</p>	<p>Microbiology laboratory liquid waste and solid waste inactivated before release.</p>	
<b>SECURITY RISKS</b>				
<p>Short- and long-term storage of isolates. (High risk for intentional misuse.)</p>	<p>Security policy and procedures in place: laboratory security programme includes visitor restrictions.</p> <p>Biothreat: Authority/agency has</p>	<p>Access to inventory records restricted by password protection. Inventory reconciled with inventory records annually, and immediately if unauthorised access is suspected.</p>	<p>Inventory access controlled by lock on storage freezers, and alarm to inventory area.</p>	

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	reviewed laboratory security policy, chain of custody and investigative protocol required if laboratory becomes involved in diagnosis/investigation of intentional Anthrax exposure incident.			

## Risk communication

### Notification to appropriate public health authority and animal health authority

The laboratory is planning to begin diagnostic testing for *Bacillus anthracis* (anthrax) in order to support the detection and diagnosis of a naturally occurring or intentional introduction of the agent affecting local livestock species. The laboratory has completed a laboratory biorisk assessment and has in place appropriate control measures to prevent accidental exposures and release of the agent from the laboratory. The designated laboratory contact person is \_\_\_\_\_.

Actions to be completed:

1. In consultation with the national animal health authority, identify responsible person(s) and develop a message to be activated in the event of a positive anthrax diagnosis, including a press release, contact lists and a questions and answers document.
2. In consultation with the national animal health authority and/or public health authority as appropriate, identify responsible person(s) and develop a communication message to be activated in the event of a laboratory spill or accident, or accidental human infection with *B. anthracis*.
3. In consultation with the national animal health authority, public health authority and/or security agency as appropriate, identify responsible person(s) and develop a communication message to be activated in the event of a real or apparent deliberate release of the anthrax organism.

### Verification, corrective actions, and continuous improvement

Action to be completed: Schedule and conduct internal audits of policy and procedures relating to the handling of organisms that constitute risks such as posed by *B. anthracis*. Exercise (audit) the pathway of activities and actions that would be followed in the laboratory should a potential anthrax disease submission be received. Perform an additional review of the biorisk assessment and control measures should changes be made to the facilities, management practices, or technical procedures associated with the laboratory handling and storage of the anthrax organism.

## Example Risk Analysis 2: Foot and mouth disease

**Hazard:** Foot and mouth disease

**Location:** Country is FMD-endemic, disease control and eradication efforts are in initial phases. Laboratory located at a fenced site; no susceptible animals within 3 km of the facility.

**Pathogen and disease:** FMD is a highly contagious viral disease of cattle and swine. It also affects sheep, goats, deer, and other cloven-hooved ruminants. The disease is caused by a non-enveloped virus of the genus *Aphthovirus*, family *Picornaviridae*. There are seven serotypes of FMD virus (FMDV), namely O, A, C, SAT 1, SAT 2, SAT 3, and Asia 1 with various subtypes. Infection with any one serotype does not confer immunity against another. Within serotypes, many strains can be identified by biochemical and immunological tests.

The transmission of FMDV occurs either by direct contact between infected and susceptible animals, by direct contact of susceptible animals with contaminated material or objects (hands, clothing etc.) or by consumption of untreated contaminated meat products (primarily by pigs). Furthermore, inhalation of infectious aerosols is known. Humans can be carrier of FMDV in their respiratory tract for up to 48 hours.

FMD is characterised by fever and blister-like lesions followed by erosions on the tongue and lips, in the mouth, on the teats, and between the hooves. Most affected animals recover, but the disease leaves them debilitated. The severity of clinical signs varies with the strain of virus, exposure dose, age and breed of animal, host species, and degree of host immunity. Signs can range from mild or inapparent to severe. Morbidity may approach 100%. Mortality in general is low in adult animals (1–5%) but higher in young calves, lambs and piglets (20% or higher). Recovery in uncomplicated cases is usually about 2 weeks.

**NOTE:** The Table that follows is an example. The cells have been filled in in response to an imaginary scenario. The data are fictitious included to help demonstrate the process. The requirements in the hypothetical examples are based on the country's standards and guidelines, as would be used for an actual risk assessment.

RISK ASSESSMENT (Likelihood and Severity)	RISK MANAGEMENT Administrative Controls	RISK MANAGEMENT Operational Controls	RISK MANAGEMENT Engineering Controls	RISK MANAGEMENT Personal Protective Equipment
<p><b>Health risk:</b>  <b>Humans</b> – NO  <b>Animals</b> – YES (domestic and wild hoofstock)  <b>Transmissible by</b> direct contact with infected animals, their excretions, or contaminated environment; consumption of contaminated meat; aerosol transmission over distances is documented (references on file).</p>	<p><b>Requirements:</b>  <b>1. Communication plan:</b> reportable disease list and reporting requirements for animal health authority.  <b>2. Qualified/suitable staff:</b> training and competency requirements for work with infectious diseases in place and current for all laboratory staff.  <b>3. Health and safety programme</b>  <b>4. Accident/incident reporting programme</b>  <b>5. Emergency response plan:</b> actions including notification list spill/contamination in lab, release from lab, and theft of agent.  <b>6. Agent inventory management programme</b>  <b>7. Waste management policy</b>  <b>8. Security programme:</b> laboratory biosecurity for preventing unauthorised access to FMDV.</p>	<p><b>Requirements:</b>  <b>1. SOPs and training materials cover laboratory safety and laboratory biosecurity.</b>  Routine use of Good Microbiology Practices is required of all staff.  <b>2. Disinfection, decontamination, destruction SOPs</b> are available for all laboratory sections for both solid and liquid wastes.  <b>3. Transport:</b> the laboratory uses an externally trained and certified staff member for packaging and shipping specimens and infectious substances to the regional reference laboratory.  <b>4. The laboratory response plan</b> has been prepared and includes steps required for containment of an FMDV spill, and steps for notification and control following inadvertent movement of untreated waste materials from the laboratory.  <b>5. Accident/incident reporting:</b> the laboratory safety officer is responsible for reviewing accident reports submitted by staff. Each accident and immediate response is reviewed, changes made as necessary to prevent a repeat occurrence, staff are notified of the changes, and an audit is scheduled to document effectiveness of the correction.  <b>6. Audit</b></p>	<p><b>Requirements:</b>  <b>1. Biocontainment</b>  <b>2. Separation of incompatible activities</b>  <b>3. Equipment maintenance, calibration, certification</b> current  <b>4. Facility security.</b></p>	<p><b>Requirements:</b>  <b>PPE:</b> dedicated laboratory clothing is used at all times in the laboratory, is never removed from the laboratory and is laundered on site.</p>
<p><b>In the Laboratory</b>  <b>Necropsy:</b> environment contaminated with fluids, low risk of exposure to outside environment.  <b>Handling of specimens:</b> unknowns via diagnostic submissions including</p>	<p><b>Assessment findings:</b>  <b>1.</b> Reporting plan FMDV positive animals/herds and contact list (names and numbers of animal health authority) is current.  <b>2.</b> Training and competency in Good Microbiology Practices is current for all staff.</p>	<p><b>Assessment findings:</b>  <b>1.</b> Staff have been trained by the regional reference laboratory in the technical methods and safe handling requirements for FMDV. Proficiency tests have been successfully passed.  SOPs for the handling, testing, archive, and destruction of FMDV and</p>	<p><b>Assessment findings:</b>  <b>1.</b> All FMDV handling and diagnostic testing is conducted in a biosafety cabinet. When not in a cabinet, all FMDV specimens or assay materials are in a closed container.</p>	<p><b>Assessment findings:</b>  Laboratory coats and gloves are required to be worn when working in the receiving or technical areas of the laboratory.  Laboratory PPE is not worn outside of the technical areas of the lab.</p>

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<p>vesicular fluids, saliva (probing), vesicular epithelium containing potentially high virus load. (High risk for laboratory contamination.) Blood and serum (low risk)</p> <p><b>Volumes and concentrations:</b></p> <p>Anticipate 1200 diagnostic and disease control cases per year; archive 120 × 0.25 ml aliquots at ≥ 10<sup>5</sup> TCID<sub>50</sub>/vial. (Low risk while disease remains endemic. At later stages of eradication effort, risk will progress to high risk). Amplification in cell culture; short and long-term storage of viral isolates (Moderate Risk while disease remains endemic. At later stages of eradication effort, risk will progress to high risk justifying elimination of routine on-site amplification in cell culture and long-term archive of isolates).</p> <p><b>Diagnostic test methods:</b></p> <p>Identification and characterisation of the agent: Virus isolation, antigen detection (ELISA), nucleic acid detection (real-time PCR). Serology: ELISA, CF, virus neutralisation (VN). (Note: as eradication progresses the risk of amplifying virus and maintaining live FMDV for use in the VN assay will no longer be justified and will be discontinued).</p>	<p>Laboratory policy requires that staff agree to not come in direct contact with susceptible species for 96 hours after working with FMDV diagnostic cases and assays.</p> <p>3. Employee health and safety programme. FMDV is not a human pathogen.</p> <p>4. Accident/incident reporting programme in place; covers unintentional laboratory contamination associated with diagnostic specimens and derived materials (e.g. FMDV cultures).</p> <p>5. Response plan addresses accidental and intentional release of FMDV.</p> <p>6. Agent inventory management plan addresses access, secure storage, transfer, and destruction. Inventory management plan requires annual audit and reconciliation of inventory records.</p> <p>7. Waste management policy addresses carcasses, tissues, fluids, and all laboratory wastes containing potentially infectious material. All potentially infectious laboratory wastes are autoclaved or incinerated prior to removal from the site.</p> <p><i>Gap: cell culture flasks are accumulated in the un-restricted glass-washing/autoclave area prior to disinfection/destruction. Policy and procedure change is being implemented to insure inactivation of virus prior to transferring the flasks from the virology laboratory (e.g. bleach).</i></p> <p>8. Laboratory biosecurity includes signage noting authorised access only to testing and storage areas.</p>	<p>related case materials have been prepared, reviewed by the regional reference laboratory, and used in the training of staff.</p> <p>2. Decontamination, inactivation, and destruction protocols are in place for all laboratory areas.</p> <p>Specific pH and temperature requirements for inactivation of FMD virus are included.</p> <p>3. External training and certification was obtained for one staff member responsible for packaging and shipping to reference laboratory. A second individual is currently scheduled for international packaging and shipping training.</p> <p>4. A laboratory response plan has been prepared, including steps for containment of an FMDV spill, and steps for notification and recovery or destruction following inadvertent movement of untreated waste materials from the laboratory.</p> <p><i>Gap: the laboratory has not had an exercise to test the response plan. Additionally the plan does not address the potential for intentional misuse of FMDV: these issues will gain importance as the disease control effort nears completion, and so will be corrected.</i></p> <p>5. The Accident/Incident Reporting process is applicable to work with FMDV.</p> <p>6. Audit of FMDV biorisk control measures will be included with the laboratory quality system audits (2 per year).</p> <p>Review of the FMDV risk assessment and biorisk management plan will occur at 14 months following initiation of the FMDV testing or earlier should there be changes made to the facility or to any FMDV-related SOPs or laboratory procedures.</p>	<p>Note: the regional reference laboratory uses additional measures including FMDV-dedicated rooms with air-lock entry. As the laboratory does not have these facilities, the risk assessment will be reviewed with consideration given to transferring case materials and non-serology FMDV testing to the regional laboratory as the eradication effort progresses.</p> <p>2. Separation of incompatible activities: The virology testing area where FMDV specimens are handled is separated from other areas of the laboratory by closed doors posted with restricted access signage.</p> <p>A dedicated incubator is used for amplifying FMDV reference viruses and for virus neutralisation assays (e.g. sources of high concentration of FMDV). The incubator is cleaned and decontaminated at the end of each work week.</p> <p>Real-time PCR tubes are not opened following amplification steps.</p> <p>Note: as the eradication effort progresses toward completion, the amplification of reference virus for PCR controls and for VN assays will be discontinued. The risks associated with all testing requiring live virus will be assessed, with the option of transferring samples and testing to the regional reference laboratory being given a high priority.</p> <p>3. The laboratory has maintenance contracts for Biosafety cabinets and thermocyclers. Calibration is</p>	<p>Laboratory wear inadvertently contaminated with FMDV is autoclaved prior to being laundered.</p> <p>Note: additional measures including dedicated clothing and showering after work with the agent are used in the regional reference laboratory. This facility does not have shower facilities, so as the eradication effort progresses toward completion, the risk assessment will be reviewed with consideration given to transferring case materials and non-serology FMDV testing to the regional laboratory.</p>

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<p><b>Research:</b> No experimental work to be conducted on site. Isolates to be transferred to international reference laboratories only.</p> <p><b>Viral isolate archives:</b> Short- and long-term storage of isolates. (Low risk while disease is endemic, progressing to high risk for intentional misuse as eradication of disease nears completion - see Security risks.)</p>	<p>Visitors are allowed only with a laboratory escort and prior permission of the laboratory director or his designee. (Note: as eradication progresses, more stringent access control is justified, e.g. padlock or equivalent to be added to archive freezer).</p>		<p>performed by a commercial vendor for pipettors and CO<sub>2</sub> incubators.</p> <p>4. Facility Security: Staff and visitors enter the laboratory grounds via a locked gate in a perimeter fence. The laboratory external doors are locked after business hours. The gate and doors are posted with signage stating "authorised individuals only".</p>	
<b>ECONOMIC RISKS</b>				
<p><b>Endemic in region:</b> Cattle, sheep, and wildlife (hoofstock).</p>				
<p><b>Trade barrier:</b> Due to endemic status, there is no current trade. (Note: goal of eradication is to open markets for wool and hides. As eradication effort nears completion the risk of handling the agent in the laboratory will progressively increase, at that time the laboratory must re-evaluate on-site testing and options for transfer of samples to a regional reference laboratory.</p>	<p>Update for current risk assessment is scheduled for 14 months from initiation of control programme, assuming that the disease prevalence will significantly decrease and the severity of economic impact from a laboratory release of FMDV will amplify to high risk.</p>			
<b>ENVIRONMENTAL RISKS</b>				
<p><b>Stable in environment:</b> YES. Survives drying, may persist for days to weeks in organic matter under moist cool conditions; may persist in contaminated fodder and environment for</p>	<p>Policy regarding recycling/re-use of expendable supplies (e.g. plastic culture flasks) has been modified to state re-use is never allowed for laboratory supplies used in FMDV detection and diagnosis; FMDV related laboratory wastes are placed</p>	<p>SOP on incineration (destruction) of solid laboratory wastes is in place; SOP on autoclave and chemical inactivation of liquid wastes is in place. Temperature and pH requirements for inactivation of FMDV are included.</p>	<p>Autoclave and incinerator available on-site. Indicator strips used with each run of the autoclave to ensure proper inactivation was achieved.</p>	

RISK ASSESSMENT (Likelihood and Severity)	RISK MANAGEMENT Administrative Controls	RISK MANAGEMENT Operational Controls	RISK MANAGEMENT Engineering Controls	RISK MANAGEMENT Personal Protective Equipment
1 month (temperature, pH dependent).	in a biohazard bag and decontaminated at the end of each day to ensure they are never sent to landfill without prior treatment.			
<b>SECURITY RISKS</b>				
Short- and long-term storage of isolates. (Low risk while disease is endemic, progressing to high risk for intentional misuse as eradication of disease nears completion - see Security risks.)	Security policy requires visitors to sign a log, be escorted and not allowed in direct contact with diagnostic samples or tests.  Note: FMDV has been identified by the international community as a potential biothreat agent.	An inventory log has been created to identify each vial of virus archived, and matches the identification on each vial. The log is electronic and is password protected.  Gap: a pre-determined schedule for comparing the inventory to the inventory log has not been formally documented.	The virus inventory is stored on a designated shelf in a freezer with access restricted by signage to authorised staff.  <i>Gap: a padlock is needed to further secure the virus archive.</i>	

## **Risk communication**

### **Notification to appropriate animal health authority**

The laboratory is planning to begin diagnostic testing for Foot and Mouth Disease in order to support the national FMDV eradication effort. The laboratory has completed a laboratory biorisk assessment and has in place appropriate control measures to prevent release of the agent from the laboratory. The designated laboratory contact for further information is \_\_\_\_\_.

Actions to be completed:

1. In consultation with the national animal health authority identify responsible person(s) and develop a communication message to be activated in the event of a laboratory spill or accident resulting in the release of FMDV from the laboratory.
2. In consultation with the national animal health authority and security agency as appropriate, identify responsible person(s) and develop a communication message to be activated in the event of theft or apparent deliberate release of FMDV from the laboratory.

### **Verification, corrective actions, and continuous improvement**

Actions to be completed:

Training and exercises are to be scheduled in order to practice procedures for spill decontamination and for proper use of biosafety cabinets, autoclaves and incinerators; and for the proper response and notification procedures should a security breach be detected. Periodic self-assessment and review of standard operating procedures by the biorisk manager and laboratory staff are to be scheduled and completed at an approximate 6-month interval in coordination with the laboratory's quality system audit process. Reporting and documentation of biosafety or biosecurity incidents and breaches involving the FMD virus will automatically trigger a re-assessment of the FMD laboratory biorisks. All incidents will be reviewed by management, the biorisk manager, all impacted staff, and the applicable biosafety committee in order to correct the problem and to identify opportunities for improved laboratory practices and implementation of biorisk control measures.

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