

Formalization of a Framework for a Risk Management Program for the RRL FMD BSL-3



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Background

- FMD is highly contagious virus for cloven hoof animals that is spread through respiratory and droplet contact
- Picornaviridae, Aphovirus, Non-enveloped virus with single strain RNA, 7 serotypes: O, A, Asia1, SAT1, SAT2, SAT3, and C
- Morbidity can reach 100%, and Mortality is generally low in adult animals (1-5%)
- Impact to endemic regions worldwide estimated to be US 6.5 billion in production loss and 21 billion vaccination
- Studies have estimated \$50 billion in economic losses over 10 years if a medium to large FMD outbreak to occur

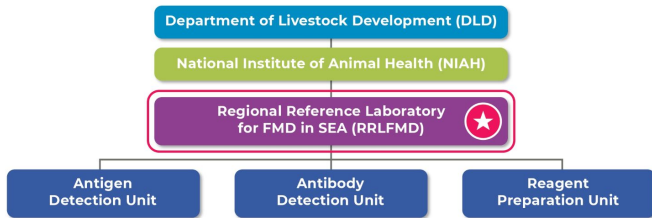
The RRLFMD laboratory is a regional reference diagnostic center for Foot-and-Mouth Disease (FMD) in Southeast Asia.

It processes different samples from domestic and exotic specimens. Exotic samples are from outside or not currently circulating in the region. The potential for release of these exotic strains increases the risk of this laboratory.

The laboratory is divided into three sections: Antigen, Antibody, and Reagent preparation units. Each section has specific risks for handling the FMD virus, reagents, and waste.

The laboratory also collaborates on research and development of diagnostic methods both national and international partners.

A new RRL FMD BSL-3 laboratory is currently being constructed and expected to be completed May 2025.



Goals, Objectives & Methodology

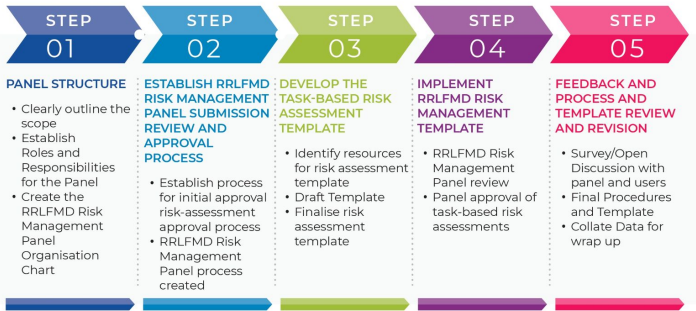
The project's **primary goal** is to formalize and optimize a **risk management framework** tailored to the unique challenges of handling FMDV and to facilitate transition into the new BSL-3 laboratory.

This will enhance biosafety and biosecurity through:

- Enhanced Risk Management
- Standardization of Practices
- Support for Outbreak Preparedness and Response
- Capacity Building and Professional Development
- Compliance with International Standards
- Facilitation of Collaborative Research and Diagnostics



Process



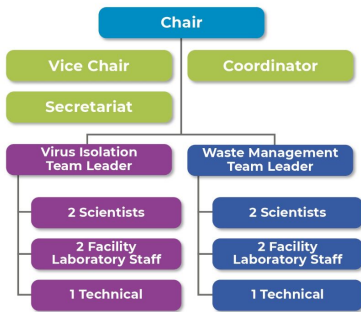
To Develop the Task-Based Template we first identified resources for risk management, such as WHO and WOAAH.



Results

- A Risk Management Panel was created along with terms of reference clearly defining the scope of the panel and roles and responsibilities of panel members.
- A Risk Management Template was created, piloted and finalized.
- Training was held for 100% of the laboratory staff.
- A process for continuous improvement and feedback was developed.

RRLFMD RISK MANAGEMENT PANEL ORGANIZATIONAL CHART



To establish the panel, the scope of the panel, and roles and responsibilities of panel members, a terms of reference document was created. Panel members were assigned per the RRLFMD Risk Management Panel and Organization Chart.

Almost 50% of the staff were involved in this panel.

The next step was to establish the process for submission, review and approval. To test the process, we have two important tasks that have different risks and considerations.

These are Waste Management and Viral Isolation. The working group assigned to virus isolation focused on risk management of propagating live viruses that could be released in the BSL-3 facility.

The working group assigned to waste management considered the mitigation of the risks associated with the virus's ability to persist in the environment and the potential vector spread of the virus.

Training

PANEL MEETING AND FEEDBACK COLLECTION



FINAL RISK MANAGEMENT TEMPLATE

Activity	Hours	Type	Who completed	Who used	Risk factor
Panel meeting	3	L	Panel members	Panel members	High risk of infection spread
Panel meeting	3	L	Panel members	Panel members	High risk of infection spread
Panel meeting	3	L	Panel members	Panel members	High risk of infection spread
Panel meeting	3	L	Panel members	Panel members	High risk of infection spread
Panel meeting	3	L	Panel members	Panel members	High risk of infection spread
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Conclusions

- This risk management system developed will ensure a consistent approach to managing biosafety risks, protecting personnel, and maintaining high standards of laboratory safety and security.
- It includes document control measures, identifies potential new hazards, and creates training and awareness opportunities for staff.



Lessons Learned



Next step and Moving Forward

- Monthly panel meetings
- Conduct task-based risk assessment on all activities in the BSL-3
- Establish a bank of procedures that are reviewed and approved for use when the BSL-3 laboratory becomes operational next year

Acknowledgements

