TERMS OF REFERENCE (TOR)

REASSESSMENT AND STRENGTHENING OF BIOSAFETY LEVEL 3 FACILITY AT RCDC

Post Title	: Re-assessment and Strengthening of Biosafety Level 3 facility at RCDC
Organization	: RCDC, MoH, Thimphu (Bhutan)
Duty Station	: RCDC, MoH, Thimphu (Bhutan)
Duration	: 5-10 days work period. Time of completion before mid of June, 2025
Type of Contract	: Non-extendable

1. Background

The Biosafety Level-III facility at RCDC was built in 2016 and certified in 2018. The facility has not been reassessed since its initial certification, which raises concerns about compliance with current biosafety guidelines. Given the increasing complexity of biological research and the emergence of new infectious diseases, it is essential that this facility remains at the forefront of biosafety practices. This therefore necessitates a comprehensive reassessment to ensure that the facility adheres to the most current guidelines and effectively mitigates any risks associated with its operations.

Key areas that need evaluation includes review of architectural & mechanical layouts, schematics and design; & identifying gaps in bio-risk management system in accordance to ISO 35001. There is also a need to verify the functionality of essential equipment like biosafety cabinets and autoclaves, as well as to review staff training and competency.

Therefore, it is imperative that qualified contract experts are engaged to perform the re-assessment and re-certification of the BSL-III laboratory at RCDC.

2. Objective

The main objective of the activity is to reassess and re-certify the Biosafety Level-III facility at RCDC to ensure it complies with the latest biosafety guidelines, effectively manages risks, and remains prepared for advancements in biological research and emerging infectious diseases.

3. Scope of Work

The scope (Terms of Reference) includes the following elements:

1. Study and review architectural and mechanical layout and design of BSL-III lab.
2. Comprehensive gap analysis in the bio-risk management system in accordance with ISO 35001.
3. Review documents related to primary containment equipment.
4. Evaluate primary containment equipment, including waste treatment systems, HEPA filter units, security systems, emergency power systems, and containment seals.
5. Perform pre-certification engineering testing for the facility's air system, including compliance testing with required pressure relations and failure scenario analysis.
6. Perform a Biosafety SOP check to ensure all necessary components are available.
7. Identify critical single points of failure.
8. Inspect facility finishes.
9. Identify sustainability issues.
10. Evaluate the training programs for lab personnel to ensure they are up-to-date with biosafety and biosecurity protocols.
11. Prepare a comprehensive report on findings.
12. Propose preparation works and corrective actions.
13. Submit a gap analysis report.
14. Revise the report to address comments from the client.

4. Expected Outcome

The expected outcomes from this activity include:

1. Improved Compliance: Ensuring the facility meets the latest biosafety and biosecurity guidelines and standards.
2. Risk Mitigation: Identification and rectification of gaps in the bio-risk management system to better manage and mitigate risks associated with biological research.
3. Equipment Validation: Verification that all primary containment equipment and critical systems, such as waste treatment and HEPA filters, are functioning correctly and efficiently.
4. Enhanced Safety Protocols: Updated and validated Standard Operating Procedures (SOPs) and staff training programs to ensure personnel are well-prepared and knowledgeable about current biosafety practices.
5. Infrastructure Integrity: Confirmation that the architectural and mechanical designs, as well as facility finishes, are up to standard and do not pose any biosafety risks.
6. Operational Resilience: Identification of critical single points of failure and recommendations for corrective actions to ensure continuity and reliability of the facility's operations.
7. Sustainability Improvements: Addressing sustainability issues to ensure the facility operates in an environmentally responsible manner.
8. Comprehensive Documentation: Preparation of detailed reports, including gap analysis and corrective action plans, to provide a clear roadmap for maintaining and improving biosafety practices.

5. Duration of the Work

Expected duration of work is 5-10 days while, the timeline of work completion is before mid of June, 2025. The dates for in-country visit, if any will be mutually agreed.

6. Duty Station

a. The contract expert is expected to undertake in-country mode of working (Thimphu, Bhutan).
b. The expert is expected to use his/her additionally required equipment for the task.
c. A working space shall be provided by the Employer.

7. Required expertise & qualifications of Contract expert

The Contract expert needs to meet the following requirements:

1. Extensive experience at international level in biosafety and biosecurity, particularly in the certification and consultation of high-containment laboratories (BSL-3).
2. In-depth knowledge of ISO standards relevant to biosafety, such as ISO 35001 (Bio-risk management for laboratories and other related organizations).
3. Proven experience in guiding laboratories through the ISO certification process.
4. Ability to conduct internal audits to assess compliance with ISO standards, and prepare facilities for external audits and certification assessments.
5. Proven track record of working with governments, NGOs, pharmaceuticals, healthcare, or bio-research industries.
6. Should be approved certifiers by relevant health authorities.

8. Payments

Lump-sum: Payment shall be made on lump-sum basis upon the following payment milestones:

Sl. No.	Payment milestone	Percent
1	Upon completion of preparatory work	20%
2	Upon completion of on-site assessment	40%
3	Upon submission of final gap analysis report	40%

Note: The quoted rate should be inclusive of technical consultation, in-country travel and stay, and no additional cost shall be beared by the employer.

The Expression of Interest must be delivered to the address below on or before **10:00 hours (BST) on 20 March 2025**. After the evaluation, the highest-ranked consultant shall be asked to submit a Financial Proposal through email with the password encrypted, which shall be subject to negotiation. Late submissions shall be rejected. For further information please refer ToR available on the MoH website (www.moh.gov.bt).

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