National Health Directorate

National Laboratory Network

Terms of Reference

Recruitment of an International Multidisciplinary Consulting Team for the Standardization of Standard Operating Procedures (SOPs) and Definition of Laboratory Roles and Responsibilities for the Diagnosis of Epidemic-Prone Diseases in Cabo Verde

Table of Contents

1. Introductory Note

In the current global context of increasing emergence and re-emergence of diseases with epidemic potential, it is imperative to strengthen national laboratory diagnostic capacities, in line with the International Health Regulations (IHR 2005) and the One Health approach.

The WHO Joint External Evaluation (JEE) of Cabo Verde highlighted the need to strengthen the National Laboratory System, particularly in relation to diagnostic capacity, quality management systems, biosafety & biosecurity, and coordination across laboratory tiers. These dimensions correspond directly to internationally recognized performance indicators under the JEE National Laboratory System technical area, which assesses countries' capacity to detect priority pathogens, ensure laboratory quality, and support surveillance and emergency response. Currently, there is heterogeneity in laboratory procedures and in the functions assigned to each laboratory level (local, regional, and national), which can compromise the response to outbreaks and epidemics.

To ensure a rapid, efficient, and coordinated response, it is necessary to harmonize and describe in detail the Standard Operating Procedures (SOPs) for the laboratory diagnosis of priority diseases, ensuring uniformity of practices, quality, and biosafety at all levels of the Laboratory System for the Diagnosis of Diseases with Epidemic Potential in Cabo Verde.

The rapid detection and proper management of these diseases depend on structured and standardized laboratory capacity at all levels of the National Health System, including clear referral pathways, quality-assured testing, and effective intersectoral coordination under a One Health framework.

In this regard, and in alignment with the JEE recommendations, the National Action Plan for Health Security (NAPHS), and the HeSP results and monitoring framework, the Ministry of Health of Cabo Verde intends to implement this project to recruit an international multidisciplinary consulting team for the Standardization of Standard Operating Procedures (SOPs) and Definition of Laboratory Responsibilities for the Diagnosis of Diseases with Epidemic Potential in Cabo Verde.

This intervention is part of the HeSP – Health Security Program for West and Central Africa, a regional initiative funded by the World Bank and international partners, which aims to strengthen the capacity of participating countries to prevent, detect, and respond to public health emergencies, including outbreaks of epidemic-prone diseases and cross-border health threats, under the leadership and coordination of the Special Project Management Unit (UGPE) of the Cabo Verde Ministry of Finance

1.1 Justification

Cabo Verde faces a continuous risk of introducing diseases with epidemic potential due to its geographical location and population mobility. An effective response to outbreaks depends on well-structured laboratories with standardized procedures and clearly defined roles at all levels.
Currently, there are significant differences in laboratory procedures and responsibilities between laboratories, which undermines rapid detection and response to outbreaks.

The NRL, in particular, faces significant challenges that hinder the quality, reliability, and integration of its activities in the laboratory diagnosis of diseases with epidemic potential. The following issues were identified:

- **Lack of harmonized Standard Operating Procedures (SOPs)**:
  each laboratory currently adopts its own methodologies, often based on local experience or non-standardized recommendations, leading to inconsistencies in practice and variability in diagnostic results.

- It is acknowledged that effective harmonization of SOPs requires minimum biosafety and infrastructure conditions across laboratory levels. A national laboratory capacity and biosafety assessment is being conducted in parallel through WAHO/OOAS, and its findings will inform the development and adaptation of SOPs. The harmonized SOPs produced under this consulting team will therefore be tiered and adapted to the functional capacity and biosafety level of laboratories at local, regional, and national levels, ensuring feasibility, safety, and compliance with international standards. SOPs will include minimum biosafety requirements and risk mitigation measures for each laboratory tier.

- **High rate of discrepancy in results** between laboratories at different levels, undermining the confidence of clinicians, health programs, and epidemiological surveillance itself.

- **Lack of systematization of processes** throughout the network, with unclear sample flows, absence of formal referral protocols, and limitations in communication between different laboratory levels.

- **Insufficient intersectoral integration**, particularly regarding the animal and environmental components, hindering the effective application of the **One Health** approach.

Therefore, it is a priority to hire an international multidisciplinary consulting team with complementary expertise in laboratory systems, microbiology, biosafety and

biosecurity, veterinary health and environmental health, ensuring a comprehensive One Health approach, with proven experience in organizing and implementing laboratory networks and developing standardized SOPs. This support will enable to:

1. Harmonize laboratory procedures in accordance with international standards (WHO, ISO 15189 and IHR 2005), adapting them to the national context, and ensuring their formal institutionalization through approval by the Ministry of Health and integration into INSP technical norms and operational guidelines.

2. Reduce discrepancies in diagnostic results between laboratories by implementing standardized SOPs, quality assurance mechanisms (including internal quality control and external quality assessment schemes), and clearly defined referral pathways, supported by a system of continuous supervision, periodic SOP review and ongoing capacity building.

3. Systematize laboratory workflows, sample referral systems, and communication processes across all levels of the network, strengthening functional integration from peripheral laboratories to national reference level and ensuring timely reporting into epidemiological surveillance systems.

4. Operationalize the One Health approach by establishing practical intersectoral coordination mechanisms, including: (i) a national multisectoral laboratory coordination platform led by the Ministry of Health and INSP; (ii) joint standard operating procedures and referral pathways across human, veterinary and environmental laboratories; (iii) formal data-sharing and reporting channels between sectors; and (iv) regular technical coordination meetings and joint training activities to ensure sustained collaboration and information exchange.

5. Consolidate the national laboratory network as a core pillar of epidemiological surveillance and public health emergency response, aligned with the JEE National Laboratory System indicators, the National Action Plan for Health Security (NAPHS), and the HeSP monitoring and evaluation framework, through the establishment of measurable performance indicators, including but not limited to:
   - Number of SOPs harmonized, validated and formally adopted
   - Number and proportion of laboratories with defined roles and referral pathways
   - Percentage of laboratories implementing standardized SOPs
   - Number of laboratory personnel trained and certified in SOP implementation
   - Reduction in inter-laboratory diagnostic discrepancies (baseline vs post-intervention)
   - Functionality of intersectoral coordination mechanisms (e.g., number of coordination meetings held annually, data sharing events, joint investigations)

The recruitment of an international multidisciplinary consulting team is therefore strategic and essential to ensure that Cabo Verde has a resilient, integrated and sustainable laboratory network capable of responding effectively to current and future epidemic threats, with the strengthened biosafety and biosecurity measures and fully operational One Health coordination.

2. General Objective

Hire international consulting teams to standardize laboratory SOPs and define laboratory responsibilities for diagnosing diseases with epidemic potential, ensuring the harmonization of procedures at all levels of the health system in Cabo Verde.

3. Specific Objectives

a. Evaluate and review existing SOPs at different laboratory levels across the country, building on the results of the national laboratory capacity and biosafety assessment currently being conducted through WAHO/OOAS, and complementing it, where necessary, with targeted field verification of infrastructure, equipment, biosafety, human resources, and workflow practices to ensure that SOP harmonization is technically feasible and adapted to the operational realities of each laboratory tier;
b. Develop harmonized SOPs for priority epidemic-prone diseases, aligned with international standards including procedures for sampling, transport, storage, processing, and communication of results;
c. Define laboratory roles, responsibilities, and workflows at each level of the laboratory network (local, regional and national), and across sectors (human, veterinary and environmental), including clear referral pathways, communication channels, and data-sharing mechanisms within a One Health framework;
d. Produce a consolidated manual of SOPs and laboratory guidelines, integrating harmonized procedures, biosafety and biosecurity standards, and operational instructions applicable across the network
e. Conduct training for key laboratory staff on standardized SOPs and responsibilities.
f. Facilitate knowledge transfer and capacity building to ensure long-term sustainability of laboratory operations and intersectoral collaboration

4. Scope of Work

The consulting team will be composed of experts in clinical laboratory sciences, veterinary laboratory systems, environmental health, biosafety and quality management, working in an integrated One Health framework.

The consulting team will perform a comprehensive review, develop harmonized SOPs, define laboratory responsibilities, and deliver training and validation workshops. Coordination will be ensured with the National Health Directorate, and the National Institute of Public Health (INSP).

5. Expected Deliverables

Deliverables shall reflect contributions from all technical domains (human, animal and environmental health).

- Review and integration of the national laboratory capacity and biosafety assessment conducted through WAHO/OOAS, complemented by targeted validation of SOP-related processes and workflows to inform the harmonization of SOPs and definition of laboratory roles.
- Standardized SOPs for diagnosing diseases with epidemic potential.
- Document on laboratory assignments and responsibilities by level.
- Reference manual for laboratories.
- Final report and presentation to *stakeholders* in the health sector.
- Conduct of one national workshop.
- Training of key team members.

Deliverable	Description	Format	Deadline	Payment (%)
D1. Preliminary Diagnostic Report	Review of SOPs and integration of WAHO/OOAS laboratory assessment findings	Digital (PDF)	Week 1-2	20%
D2. Draft Harmonized SOPs	Development of standardized SOPs for epidemic-prone diseases	Digital (Word/PDF)	Weeks 3-5	15%
D3. Laboratory Roles Document	Definition of responsibilities per laboratory level	Digital (Word)	Week 6	15%
D4. Validation Workshop	Conduct national workshop and training for lab managers	Presentation & Report	Week 7-8	10%
D5. Consolidated Manual	Finalized SOPs and implementation guidelines	Digital & Printed	Week 9-10	20%
D6. Final Report	Summary of activities, recommendations, and follow-up plan	Digital (PDF)	Week 11-12	20%

6. Consulting team profile

The assignment will be carried out by a multidisciplinary consulting team composed of experts in:

- Laboratory systems and network organization
- Clinical and public health laboratory sciences
- Veterinary laboratory systems
- Environmental, water and food laboratories
- Biosafety and laboratory quality management (including ISO 15189)

The Team Leader shall have at least 10 years of relevant professional experience in laboratory systems strengthening and coordination of similar international assignments.

The consulting team shall meet the following minimum qualifications:

- Advanced academic degree (Master's or PhD) in Microbiology, Public Health, Clinical Laboratory Sciences or a related field
- At least 10 years of professional experience in clinical, public health or reference laboratories
- Demonstrated international experience in SOP development, laboratory systems strengthening, and implementation of ISO 15189 or equivalent quality management systems
- Proven experience working in health systems in developing countries, preferably in Africa or Small Island Developing States (SIDS)
- Strong experience in capacity building, training and knowledge transfer
- Working proficiency in English and fluency in Portuguese for at least one key expert (preferably the Team Leader).

Consultant typology

<u>Expert 1: Team Leader & One Health Network Specialist</u>

Focus: Organization of systems, intersectoral integration (Human, Animal and Environmental) and strategic leadership.

Key Experience:

- 5 or more years of relevant professional experience in laboratory systems strengthening and coordination of similar international assignments.
- Experience participating in "One Health" projects
- Ability to engage in political dialogue to institutionalize the organization of the network with the Ministry of Health and partners.
- Macro vision on the International Health Regulations (IHR).

Main Function:

- Laboratory systems and network organization: Responsible for the design of the national network, definition of referral flows between islands and laboratory levels.
- Veterinary laboratory systems: Integration of animal diagnostic protocols into the national surveillance network.
- Environmental, water and food laboratories: Harmonization of environmental and food safety laboratories with public health needs.
- Technical Drafting of SOPs related to the items above

Expert 2: Technical Specialist in Laboratory Sciences and Quality

Focus: Technical implementation, standardization of procedures (SOPs), biosafety and ISO standards.

Key Experience:

- 5 or more years of experience in Technical implementation, standardization of procedures (SOPs), biosafety and ISO standards.
- Practical experience in laboratory work and drafting of technical SOPs.
- Specialization in auditoriums or implementation of ISO 15189.
- Ability to train local technicians in biosafety and sample transport.

Main Function:

- Clinical and public health laboratory sciences: Technical expertise in human diagnostic assays, molecular biology and microbiology.
- Biosafety and laboratory quality management: Practical implementation of biosafety standards and structuring of the Quality Management System towards accreditation.
- Drafting of technical SOPs related to the items above

Expert 3: Veterinary Laboratory Expert

Focus: supporting the development, strengthening, and quality assurance of laboratory services in the field of animal health, with a special focus on the surveillance, diagnosis, and control of diseases, within the context of the One Health approach.

Key Experience:

- Bachelor's/Master's degree in Veterinary Medicine, Biology, Veterinary Sciences or related field

- 5 or more years of experience in technical implementation, standardization of procedures (SOPs), biosafety and ISO standards.
- Practical experience in laboratory work and drafting of technical SOPs.
- Relevant professional experience in a veterinary laboratory.
- Experience in public health projects or international cooperation (valued).

Main Function:

- Ensure laboratory quality, including the implementation of standards, biosafety, and bioprotection.
- Support the implementation and standardization of laboratory techniques for the diagnosis of animal diseases, including zoonoses.
- Support antimicrobial resistance (AMR) programs, including sensitivity testing and monitoring.
- Develop and deliver technical training to laboratory professionals.
- Participate in the development of protocols, manuals, and standard operating procedures (SOPs).

Expert 4: Environmental, Water and Food Laboratories Expert

Focus: support the strengthening of laboratory capabilities in environmental, water, and food quality control.

Key Experience:

- Solid knowledge in environmental microbiology, analytical chemistry, and food safety;
- Experience in laboratory techniques (physicochemical, microbiological, and contaminant analyses);
- Proficiency in laboratory quality standards (ISO/IEC 17025);
- Knowledge of water quality monitoring systems (drinking, wastewater, recreational) and food;
- Familiarity with international legislation and standards (e.g., Codex Alimentarius, WHO).
- Bachelor's/Master's degree in Environmental Sciences, Chemistry, Sanitary Engineering, Food Safety or related fields;
- Proven experience in environmental, water or food analysis laboratories;

Main Function:

- Support the implementation and standardization of laboratory methods for the analysis of water, food, and environmental samples.
- Strengthen water quality and food safety surveillance systems, including the detection of microbiological and chemical contaminants.

- Support the implementation of laboratory quality management systems (e.g., ISO 17025).
- Develop and review standard operating procedures (SOPs) and technical protocols.
- Train laboratory technicians through practical and theoretical training;
- Collaborate in environmental risk assessment and food safety.

Expert 5: Biosafety and Laboratory Quality Management Expert – including ISO 15189

Focus: Support the development, implementation, and monitoring of biosafety, bioprotection, and quality management systems in human, animal, and environmental health laboratories, within the framework of the One Health approach.

Key Experience:

- Experience in laboratory quality management and internal/external quality control.
- In-depth knowledge of the ISO 15189 standard and laboratory accreditation principles.
- Knowledge of biosafety and bioprotection (containment levels, risk assessment, waste management).
- Experience in audits and accreditation processes.
- Familiarity with international legislation and standards (e.g., Codex Alimentarius, WHO).

Main Function:

- Support the implementation of quality management systems in laboratories, aligned with ISO 15189 (clinical laboratories) and other relevant standards (e.g., ISO/IEC 17025).
- Develop, review, and harmonize standard operating procedures (SOPs) and quality manuals.
- Strengthen sample management, traceability, and quality control systems.
- Develop and deliver training in biosafety, quality, and good laboratory practices.
- Support the implementation of document management and continuous improvement systems.

7. Place of Execution

The consulting team will take place in Cabo Verde, with visits to national, regional, and local laboratories across the islands, coordinated by the National Health Directorate and the INSP.

8. Execution Deadline

The estimated duration of the consulting team is 90 calendar days from the date of contract signature.

9. Methodology and Work Strategy

The consulting team will work through coordinated field missions and parallel technical workstreams, combining joint site visits with domain-specific expertise in human, animal and environmental laboratory systems, in line with the One Health approach.

The methodology will be structured, participatory and results-oriented, ensuring alignment with international standards (WHO, IHR 2005, ISO 15189) while adapted to the operational realities of Cabo Verde.

The approach will emphasize standardization, quality assurance, biosafety compliance, and operational feasibility, and will include document review, stakeholder consultations, technical analysis, SOP drafting and revision, validation with end-users, and formal approval processes.

The consulting team will be implemented through six sequential and interlinked phases, as outlined below:

Phase 1 – Desk Review and Inception Planning

The consulting team will conduct a comprehensive review of all relevant documentation, including:

1. Existing SOPs and laboratory guidelines at national, regional and local levels across human, veterinary and environmental laboratories
2. National laboratory policies, technical guidelines and regulatory frameworks (Ministry of Health, INSP and relevant sectoral institutions)
3. Results of the national laboratory capacity and biosafety assessment conducted through WAHO/OOAS, as well as other laboratory assessment reports and surveillance system documentation
4. Sample referral protocols, laboratory information systems, and reporting mechanisms used within the national surveillance system
5. Previous evaluations, audit reports and laboratory quality management documentation (including ISO 15189-related materials, where applicable)
6. International standards and technical guidance, including WHO, FAO, WOAH, IHR (2005) and ISO 15189

7. Relevant national and regional frameworks such as the JEE National Laboratory System indicators, the National Action Plan for Health Security (NAPHS), and the HeSP monitoring and evaluation framework.

Based on this review, the consulting team will prepare an Inception Report and detailed Work Plan, including:

1. Refined methodological approach and implementation strategy
2. Detailed work schedule and field mission plan (including indicative timelines and locations)
3. Stakeholder mapping and coordination framework across human, animal and environmental sectors
4. Data collection tools and assessment templates (aligned with SOP review and laboratory tiering approach)
5. Risk management and quality assurance approach for the assignment.

Phase 2 – Field Assessment and Situational Analysis

Field missions will be conducted across selected laboratories (human, animal, and environmental sectors) to assess:

- Current laboratory practices and SOPs
- Diagnostic capacity and biosafety&biosecurity practices
- Sample collection, transport, and referral systems
- Data management and reporting systems
- Human resource capacity and training needs

Methods will include:

- On-site observations
- Structured interviews with laboratory staff and managers
- Review of laboratory records and workflows

This phase will result in a comprehensive situational diagnostic report, including gaps, strengths, and priority areas for harmonization.

Phase 3 – Development of Harmonized SOPs and Laboratory Framework

Based on the situational analysis, the consulting team will:

- Develop standardized SOPs for priority epidemic-prone diseases
- Define laboratory roles and responsibilities at each level (local, regional, national) and across sectors (human, veterinary and environmental)
- Establish referral pathways and sample flow systems
- Define and implement quality assurance and biosafety standards, including compliance with ISO 15189 and national guidelines
- Ensure alignment with One Health integration principles

Draft SOPs will follow a **standardized format** including:

- Scope and purpose
- Responsibilities
- Materials and equipment
- Step-by-step procedures
- Quality control measures
- Biosafety and biosecurity requirements
- Reporting and documentation

Phase 4 – Stakeholder Validation and Consensus Building

Draft documents will be presented through:

- Technical working group meetings
- Intersectoral consultations, engaging stakeholders from human, animal and environmental health sectors
- National validation workshop, convening MoH, INSP, and relevant partners to formally endorse and approve harmonized SOPs and laboratory guidelines.

This process will ensure:

- National ownership
- Technical validation
- Operational feasibility
- Alignment with national policies

All feedback will be systematically incorporated into the final documents.

Phase 5 – Capacity Building and Training

The consulting team will design and deliver targeted training sessions for key laboratory personnel, including:

- Implementation of standardized SOPs
- Laboratory biosafety and quality management
- Sample referral and reporting systems
- Inter-laboratory coordination

Training will include:

- Practical demonstrations
- Case-based exercises
- Training materials and manuals

Phase 6 – Finalization, Implementation Guidance and Exit Strategy

The consulting team will conclude with:

- Final consolidated SOP manual and laboratory network framework
- Implementation roadmap with timelines and responsibilities
- Recommendations for institutionalization and sustainability
- Monitoring and evaluation indicators
- Final report and presentation to stakeholders

Each phase will generate deliverables aligned with D1–D6 and will be validated by the National Health Directorate and INSP.

10. Contract Conditions

A lump-sum contract will be signed. Payments will be linked to the approval of deliverables, and reimbursable expenses will be paid upon presentation of valid supporting documentation.

11. Method of Selection

The consulting firm/team will be selected in accordance with the World Bank Procurement Regulations for IPF Borrowers using the Consultant Qualification Selection (CQS) method.

Under the CQS method, firms will be evaluated based on their relevant experience, technical competence, and qualifications of key experts in relation to the assignment. The firm with the most appropriate qualifications and relevant experience will be invited to submit a combined technical and financial proposal and to negotiate the contract.

The evaluation will take into consideration:

- Demonstrated experience in laboratory systems strengthening and SOP standardization
- Experience with ISO 15189 and laboratory quality management systems
- Experience in One Health and multisectoral laboratory coordination
- Experience in similar assignments in Africa or Small Island Developing States (SIDS)
- Qualifications and experience of proposed key experts

12. Schedule of Field Missions

The consulting team will conduct visits organized by region and laboratory type, aiming to ensure comprehensive assessment, validation, and training coverage.

Table 1: Schedule of Field Missions and Laboratory Visits

Seq.	Island / Location	Laboratories to Visit	Category	Indicative Timing	Estimated Duration
1	Santiago (Praia, São Lourenço dos Órgãos, Santa Cruz, Santa Catarina)	National Reference Laboratory (HAN); Santa Rita Vieira Hospital Laboratory; 1 Peripheral Laboratory; Virology Laboratory (INSP); Animal Health Laboratory; Environmental Health Laboratory	Human / Animal / Environmental	Day 1–7	7 days
2	São Vicente (Mindelo)	Intermediate Laboratory (HBS); Delegacia de Saúde Laboratory of São Vicente; Virology Laboratory (INSP – Mindelo)	Human	Day 10–13	4 days
3	Fogo (São Filipe)	Regional Hospital Laboratory; Virology Laboratory (INSP – Fogo)	Human	Day 16–18	3 days
4	Santo Antão (Ribeira Grande, Porto Novo)	Clinical Analysis Laboratories (Ribeira Grande and Porto Novo)	Human	Day 20–22	3 days
5	Santiago (INIDA / Ministry of Agriculture)	Animal Health Laboratory (Achada São Filipe)	Animal	Day 25–26	2 days

6	Santiago (INSP)	Water and Food Laboratory; Medical Entomology Laboratory	Environmental / Vector	Day 28–29	2 days
7	Follow-up Mission 1	Targeted revisit to selected laboratories for validation of SOP implementation (based on initial findings; not all laboratories)	Human / Animal	Day 45–50	5 days
8	Follow-up Mission 2	Consolidation visits to key laboratories and coordination units for final validation and alignment	Human / Intersectoral	Day 65–68	4 days
9	Praia (Headquarters)	National Coordination Body / Intersectoral platform meetings	Intersectoral	Throughout assignment (key milestones: Day 1, Day 30, Day 75)	As required

The schedule is indicative and may be adjusted in coordination with national authorities.

13. Monitoring and Evaluation Framework

Monitoring will be aligned with JEE National Laboratory System indicators and HeSP results framework, and reported through national health security monitoring mechanisms.

The implementation of this consultancy will be monitored using the following key performance indicators (KPIs):

- Number of SOPs harmonized and officially approved
- Number of laboratories with defined roles and referral pathways
- Number of laboratory personnel trained
- Percentage of laboratories implementing standardized SOPs
- Reduction in inter-laboratory diagnostic discrepancies (baseline vs post-intervention)

14. Sustainability and Institutionalization

To ensure long-term impact, the output of this consultancy will be institutionalized through:

- Formal adoption of SOPs by the Ministry of Health
- Integration into INSP operational and technical guidelines
- Continuous in-service training programs for laboratory staff
- Establishment of a periodic SOP review and update mechanism
- Integration into national surveillance and emergency response systems

15. Risk Management

Potential risks and mitigation measures include:

Risk	Mitigation Measure
Limited availability of laboratory staff	Early scheduling and coordination with regional managers
Logistical constraints for inter-island travel	Phased mission planning and use of remote support tools
Resistance to procedural changes	Participatory validation process and on-site training
Resource limitations for SOP implementation	Alignment with national investment plans and partner support

16. Final considerations

This consultancy will significantly strengthen Cabo Verde's laboratory system by establishing standardized procedures, clarifying laboratory roles and responsibilities across all levels of the network, and enhancing coordination across human, animal, and environmental health sectors under the One Health framework. The expected results will contribute directly to improved epidemic preparedness, early detection, and rapid response, in alignment with international health regulations and global health security priorities.

The output of this consultancy will be formally institutionalized through Ministerial approval and integration into national laboratory policies and INSP technical standards.