Government of St Vincent & the Grenadines
OECS Regional Health Project
Ministry of Finance, Economic Planning and Information Technology
Terms of Reference
Consultancy Accreditation Process of the National Laboratories and Laboratory Quality Management System
SVGRHP-C-IC-13

1. Introduction

The Government of St Vincent and the Grenadines (GoSVG) is implementing the OECS Regional Health Project (OECSRHP) with funding from the World Bank (WB). The objectives of the Project are to improve the resilience of the health system and to improve the responsiveness of health service delivery during public health emergencies. The Project consists of four components as follows:

Component 1: Improved Health Facilities and Laboratory Capacity
Component 2: Strengthening Public Health Surveillance and Emergency Management
Component 3: Institutional Capacity Building, Project Management and Coordination
Component 4: Contingency Emergency Response Component (CERC)

Details of the OECSRHP can be found on the WB website for the Project.

Regional laboratory services in general, and more specifically, in St Vincent and the Grenadines are critical to both components one and two of the Regional Health Project (as stated above). Funding is available to the Government of St Vincent and the Grenadines for strengthening the resilience and responsiveness of St Vincent and the Grenadines Public Health Preparedness Response to manage the challenges from new, emerging, and re-emerging diseases by financing activities to enhance the laboratory infrastructure and build capacity of staff, through accreditation.

The Laboratory Service Industry, like many other industries, has changed significantly throughout the past centuries. In the 21st century, there has been an increasing reliance on laboratory services globally, to provide information that is critical to the protection of the public's health and wellbeing. This has become increasingly challenging with the onset of climate change and a rapid increase in the frequency of new and re-emerging diseases of significant public health importance and impact on national economies worldwide. The COVID-19 pandemic illustrates the public health damage that these diseases can create.

Regional Governments are tasked with meeting a number of international mandates that have implications for how laboratories operate. Today's international and regional mandates and commitments, for example, include, inter alia, the International Health Regulations (IHR), the Sustainable Development Goals (SDG), The Caribbean Cooperation in Health (CCH) and the Port of Spain Declaration on NCDs. The WHO Maputo Declaration focused on the Strengthening of Laboratory systems and the recent WHO focus on the development of an Essential Diagnostics List (EDL) for Medical Laboratories that addresses reliable & affordable **community access** to diagnostic testing, should also be noted.

Laboratory strengthening in St Vincent and the Grenadines is thus essential if the Government is to comply with the international mandates to which it has committed and to fulfil its responsibility to protect the public's health. For example, the Government of St Vincent and the Grenadines has committed to the International Health Regulations (IHR, 2005) with a mandate to address the mobility, emergence and re-emergence of diseases of public health importance. The IHR as a legally binding instrument that aims "to prevent, protect against, control, and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."

Medical and public health laboratories, especially those in the public sector, are thus being urged to transform, to think beyond their current capacities, to develop more effective and relevant policies, strategies, structures and systems, to redefine functions, roles and responsibilities that align more closely with global, regional and national health goals and population needs in the 21st Century. In laboratory sector assessments conducted in St Vincent and the Grenadines in 2021-2022 by the Caribbean Med Labs Foundation, on behalf of the OECS Regional Health Project, among the existing gaps and priority actions recorded, stakeholders accorded the highest priority to the need for reorganisation of the National Laboratory Service, with focus on the decentralisation and expansion of the current facilities; strengthening of the National Laboratory Network; regulation of laboratories, and the quality improvement (accreditation and certification) of medical and public health laboratory facilities.

The Ministry of Health, Wellness and the Environment (MOHWE) in St Vincent and the Grenadines have committed to focusing on the transformation of their national medical and public health laboratory sector, with initial emphasis on operational reform of the public sector laboratory programme. Key to this has been the approval of a national laboratory policy, the recent passage of the Medical Laboratories Act and Regulations, and a national consultation to sensitise stakeholders, as well as a significant investment in training and strengthening systems. This consultation on **national laboratory transformation** is an important step towards a **strategic repositioning of the national laboratory service** to ensure the delivery of a more regulated and quality-assured laboratory service in St Vincent & the Grenadines.

Laboratory accreditation, an indicator of a functioning quality management system, is an essential step in the transformative process and serves as a basis for the continuous improvement of laboratory services to support the efficient and effective delivery of the national health service. Efforts to prevent and control the HIV epidemic and the more recent experience of national efforts to contain the COVID-19 pandemic have highlighted the importance of a sustainable, reliable and response laboratory infrastructure, capable of responding to public health emergencies, able to support the national healthcare system efficiently and effectively and able to deliver a range of diagnostic services and results that are readily accepted nationally and internationally.

The MCMH Laboratory embarked on preparation for accreditation to the ISO15189 with support from the OECS Global Fund HIV/TB Elimination Project (HTEP) 2016-2019, 2019-2022 and 2022-2024, and supported by a Caribbean Med Labs Foundation (CMLF) consultancy to support implementation. The Laboratory is poised to achieve that goal in 2025. The OECS Regional Health Project offers the opportunity to allocate the necessary resources to invest and to maintain progress towards the full implementation of a Laboratory Quality

Management System, and achievement of accreditation of the MCMH laboratory and certification of related testing sites. This investment in laboratory quality systems improvement and accreditation will significantly benefit and support the strengthening of core capacities for IHR in St Vincent and the Grenadines, particularly in the areas of surveillance, workforce development, and emergency management. Furthermore, project investments will contribute to sustainable, effective, and efficient regional collaboration for mitigating and/or preventing public health risks and the economic consequences associated with infectious diseases while also improving continuity of care following a disaster.

MOHWE now seeks to engage a consultant to deliver technical support services towards the achievement of laboratory accreditation of the MCMH Laboratory, based on the ISO 15189:2022 international standard, and the current national legislation Licensing and Certification programme, being mindful of the National Laboratory Act, progress already made, opportunities for Continuous Quality Improvement (CQI), regional collaborations, and compliance to the IHR.

2. Conceptual Framework

The Government of St Vincent & The Grenadines has developed plans for the expansion and strengthening of the Laboratory Services Programme. This initiative, in addition to IHR mandates, and emergency response capacities, requires the implementation of Quality Management Systems (QMS) in the medical laboratory sector to meet the needs of the citizens and residents of St Vincent & The Grenadines and to deliver acceptable standards of quality across the healthcare service.

The government as the primary provider of healthcare in St Vincent & the Grenadines, understands the importance of reliable service delivery, and more so the delivery of reliable diagnostic services. The government has recently approved both a National Laboratory Policy and a National Laboratory Act that establishes licencing standards for the operations of medical laboratories in St Vincent & the Grenadines. The effort to pursue the accreditation of the MCMH Laboratory and the certification of related testing sites that are currently operating is in alignment with the national laboratory policy and laboratory legislation and regulation.

The MCMH Laboratory must be accredited and related test sites that are currently operational must be certified, to improve the delivery of accurate and rapid diagnostic services, efficiency of treatment and reduction of errors in the laboratory process. Accreditation and certification ensure standards in service delivery which aim to improve the quality and safety and strengthen patient-centred care. Accreditation of the MCMH Laboratory will address several challenges identified in the prior evaluations while conveying many benefits including client confidence in services, recognition of technical competencies, strengthening of national response capacity, enhanced efficiency, and operating costs.

The MCMH Laboratory commenced work towards full accreditation by initiating the establishment of a Quality Management System based on the international standard - *ISO 15189:2012 Medical laboratories — Requirements for quality and competence* & guided by the phased Caribbean Guidance process entitled ‘the Laboratory Quality Management Systems – Stepwise Improvement Assay (LQMS-SIP). Significant progress has been made towards the achievement of LQMS-SIP Tiers 1-3 certification over the past 3-5 years with support provided

by the Caribbean Med Labs Foundation (CMLF) through the OECS HIV Global Fund Project. The laboratory is now poised to address the goal of accreditation to the updated ISO 15189:2022 Standard for the full laboratory operation, with appropriate technical guidance.

The Consultant selected to execute this consultancy will ensure that the Accreditation Body identified as the issuer of the Accreditation Certificate, is a signatory of the Mutual Recognition Arrangement (MRA) with the International Laboratory Accreditation Cooperation (ILAC).

3. Duration

The duration of the consultancy is expected to be approximately eight (8) months.

4. Objective

The main objective of the consultancy is as follows:

a. **General**
The MCMH Laboratory achieves full accreditation in accordance with requirements outlined in the ISO 15189:2022 international standard and ensures, that existing operational testing sites within the Ministry of Health's Laboratory Services Programme meet requisite certification requirements.

b. **Specific**

i. Develop a plan for the MCMH to address the achievement of full compliance with the requirements of the selected accreditation body that also ensures that the MCMH meets its unique service delivery requirements to improve and maintain the quality, safety, and efficiency of operations.

ii. Provide ongoing technical support, training and continuous assessments, to ensure that the professionals in practice at the MCMH and existing operational testing sites within the Laboratory Services Programme are working in compliance with the relevant ISO 15189:2022 international standard or the national standard for medical laboratory certification in St Vincent & the Grenadines, as indicated.

iii. Ensure that other key MOHWE laboratory stakeholders, external to the MCMH, such as relevant clinical staff, procurement, maintenance, human resource, information technology, biosafety and administrative staff, are engaged and educated about the requirements of the ISO 15189:2022 Standard.

iv. Provide quarterly progress reports to the Director of Economic Planning through the Project Coordinator, OECS Regional Health Project and the MOHWE, outlining the progress being made by the MCMH towards accreditation, according to the planned timetable, and confirming that the MCMH is competent to carry out the calibrations, tests, or types of tests

required for the quality, safety, and efficiency of operations, in compliance with the relevant ISO 15189:2022 Standard.

5. Scope of Work:

The consultant will be expected to work with the MCMH Laboratory and existing operational testing sites within the Laboratory Services Programme, to provide direct technical assistance to guide the strengthening of the laboratory's quality management system towards achieving accreditation or certification as applicable and as defined by the selected accreditation body and/or national regulations. The tasks and activities required for execution of the consultancy are as follows:

i. To review the existing broad structure and coordination of MCMH laboratory services and existing operational testing sites within the Laboratory Services Programme, to include, but not be limited to, activities such as, for example, management reviews, audits, equipment and test validations, internal & external quality assessments, external quality assessments and staff competency measures.

ii. Perform an accreditation readiness assessment or gap analysis, against the requirements of the ISO 15189:2022 Standard and a certification gap analysis for existing operational testing sites within the Laboratory Services Programme and provide a report detailing the Gaps to be addressed towards full compliance with the Standard. This analysis should include a review of all relevant laboratory documents and observation of and interviews with laboratory staff about current practices.

iii. Develop a stepwise action plan for the achievement of laboratory accreditation by the MCMH and certification by existing operational testing sites within the Laboratory Services Programme, using input from the gap analyses conducted. The plan should include all non-conformances and corrective actions needed, as well as clear timelines and milestones for addressing the gaps identified and a strategy for managing the engagement of both internal and external stakeholders to obtain their support and compliance with the changes required for laboratory accreditation.

iv. Develop a monitoring strategy & plan, to ensure effective tracking of progress towards QMS implementation and readiness for accreditation.

v. The consultant will be expected to address the following within the MCMH Laboratory and existing operational testing sites within the Laboratory Services Programme:
    a. Oversee the performance of the necessary corrective actions (gaps identified) by laboratory staff and monitor their compliance with the agreed timelines to ensure completion within the given time.
    b. Review the Document Control System and ensure that it is implemented for all documents in the Quality Management System (internal and external).

c. Work with the staff of the MCMH Laboratory and existing operational testing sites within the Laboratory Services Programme, to review, update, develop, and implement all documentation including, but not limited to, the technical and administrative standard operating procedures (SOPs), quality manual, safety manual, testing methods, forms, records, etc., as required by the ISO 15189:2022 international standard.
d. Ensure that all Laboratory Manuals are written in compliance with the ISO 15189:2022 standard requirements.
e. Assess the laboratory information system's relevance and capacity to support compliance with the ISO Standard
f. Develop & implement a system for performing staff competency assessments.
g. Identify technical & quality management systems training needs for laboratory staff and provide recommendations on possible approaches to addressing these technical gaps to include training in safety, auditing and various technical disciplines.
h. Provide virtual and/or face-to-face quality systems training for laboratory staff as needed and/or recommend appropriate providers, for example, training in internal auditing, root cause analysis, risk assessment, quality control and other key components of the QMS.
i. Monitor the laboratory's proficiency testing performance and support the development and execution of corrective action plans.
j. Assess the MCMH Laboratory's readiness for accreditation and the readiness of existing operational testing sites within the Laboratory Services Programme for certification.
k. Work with the laboratories to review the accreditation assessment report and perform corrective actions.

6. Deliverables

The client will respond with approval of deliverables in a timely manner.

Deliverable	Deliverable Description	Duration (From effective start of the contract)
1.	**Inception Report** Upon commencement of the consultancy, as advised by the Director of Economic Planning, the consultant shall prepare and submit an inception report to the Director of Economic Planning for approval. Prior to the submission of the report, the consultant is to participate in an inception meeting with the project coordinator for the OECS Regional Health Project, the staff of the MOHWE and the Economic Planning Division and other stakeholders to discuss the assignment. At a minimum, the Inception Report shall contain the following:	Three (3) weeks

Deliverable	Deliverable Description	Duration (From effective start of the contract)
	• The methodology and work plan for completion of the assignment • A logical framework providing guidance and support to the QMS implementation effort within the Laboratory Services Programme towards Accreditation and/or Certification. This logical framework should be supported by a plan identifying the activities milestone for completing the assignment. • The Inception report is to be presented via a PowerPoint presentation to the stakeholders and should also incorporate an electronic document (soft copy) version containing the Assessment tool for the Readiness Assessment of the Public Health Laboratories.	
2.	**Draft Initial Gap Analysis Report** The draft report should contain the findings of the Accreditation Readiness Assessment conducted by the consultant. Using the findings, the consultant is to provide a detailed Action Plan for achieving Laboratory Services Programme accreditation (MCMH) and/or certification. Additionally, the Plan should outline the following: a. Timelines, milestones, responsible staff, indicators for success and a Monitoring and Evaluation framework. The report should also be submitted electronically and also presented to the stakeholders via a PowerPoint presentation.	Eleven (11) Weeks
3.	**Final Initial Gap Analysis Report** The final Accreditation Readiness Assessment (Gap Analysis) Report should be submitted in the same format as the approved draft report taking into account the comments received on the submission. One (1) hard copy and one electronic copy of the report should be submitted.	Thirteen (13) Weeks
4.	**Interim Summary Progress Report** Submission of interim progress report at four (4) months post the start of the contract, to include achievement of project milestones as mandated by the implementation schedule. Reports can include electronic copies of updated Laboratory Quality documents such as the quality manual, policies and standard operating procedures, test methods, forms, equipment instructions, and records as required by the ISO 15189:2022, in keeping with the agreed timeline stipulated in the Laboratory work plans. Monitoring reports may also include non-conformance reports and corrective action plans with timelines and project success indicators, internal audit reports, corrective action reports, training records and staff competency reports, among other relevant materials. Monitoring reports can also document challenges encountered that impacted progress.	**Four (4) months**
5.	Monthly reports on the status and progress on; (i), the QMS implementation in the MCMH Laboratory movement towards accreditation by a reputable Accreditation Body that is a signatory of the Mutual Recognition Arrangement (MRA) with the International Laboratory Accreditation Cooperation, and (ii) the status and progress of QMS Systems implementation in the existing operational testing sites	

Deliverable	Deliverable Description	Duration (From effective start of the contract)
	within the Laboratory Services Programme, towards the Tier 1 certification requirements.	
6.	**Final Accreditation Readiness Assessment Report** The final Accreditation Readiness Assessment (Gap Analysis) Report should be submitted in the same format as the Initial Assessment Report and should include the next steps and or actions to be undertaken by the MOHWE for the attainment of accreditation of the MCMH clinical laboratory. **Two (2) hard copies and one electronic copy of the report should be submitted.**	Due eight (8) months from the commencement of the start of the contract

7. Payment Schedule

Items	Deliverables	Payment (%)
1	Inception Report	15%
2	Draft Initial Accreditation Readiness Assessment (Gap Analysis) Report	25%
3	Final Initial Accreditation Readiness Assessment (Gap Analysis) Report	15%
4	Interim Progress Report	15%
5	Final Readiness Assessment Report	30%

8. Project Management & Assignment Logistics

The Consultant will report to the Director of Economic Planning, Ministry of Finance, Economic Planning and Information Technology, through the Project Coordinator, OECS Regional Health Project. The consultant will also work in close collaboration with the Chief Laboratory Technologist, staff in the Laboratory Service Programme and other stakeholders.

The consultancy requires periodic in-country visits but will also include virtual sessions. The consultant will be required to be physically present in St Vincent & the Grenadines at critical periods, including presentation of the Draft Readiness Assessment (Gap Analysis) report, periodic QMS implementation interventions, audits and monitoring interventions. The consultant will participate in internal travel as site visits are likely required to assess the operations of health facilities in addition to the main public health laboratory. Internal travel in St Vincent & the Grenadines will require inter-island travel over water or single-engine aircraft to outlying islands.

9. Client Responsibility

The Client in collaboration with the MOHWE will evaluate the quality of work delivered by the Consultant, based on this TOR, to ensure the quality and relevance of work being conducted, and based on this, shall issue a written project acceptance/approval, retention, or discontinuance.

The Quality Management Team (MOHWE) will provide oversight for all activities undertaken, including monitoring of the progress of the various tasks, and provide the necessary guidance in respect to policy and regulatory requirements mandated for the execution of project activities.

For any request for change or cancellation of schedule, at least a one (1) week notice shall be given, and the said change/adjustment shall be made based on mutual agreement by both parties.

10. Consultant's Responsibility

The Consultant undertakes to perform the scope of work for the consultancy with the highest standards of professional and ethical competence and integrity and will be expected to:

1. Commit to treat with utmost confidentiality, **all** information and materials gathered and used relating to this engagement or the Client's business or operations.
2. Prepare the Work/Implementation Plan with a schedule of activities for the duration of the engagement.
3. Adhere to the Implementation schedules/appointments and any changes or adjustments of schedules as may be agreed upon. For any request for change or cancellation of schedule, however, at least a one (1) week notice shall be given, and the said change/adjustment shall be made based on mutual agreement by all parties;

vi. Minimum Qualifications, Skills and Experience

The consultancy is to be undertaken by a suitably qualified individual. The selected consultant is required to possess the minimum competency requirements listed hereunder:

General Areas of Expertise/Experience of the Consultant

1. MSc. In Medical Laboratory Science, Laboratory Science or other related technical fields.
2. A minimum of ten (10) years' experience in providing assistance to medical laboratories in developing countries, to prepare for certification, licensing and accreditation against the ISO 15189 Standard.
3. Demonstrated understanding of the requirements of the updated ISO15189:2022 Standard.
4. Minimum of seven (7) years specific experience in Medical Laboratory Quality Systems implementation.
5. Minimum of five (5) years of experience in conducting ISO Quality Management System audits in preparation for certification.
6. Minimum of five (5) years' experience in Continuous Quality Improvement Systems design and implementation in developing country laboratory environments, including in the Caribbean Region.
7. Proven record of at least three (3) assignments related to the Laboratory Accreditation process or similar accreditation processes associated with ISO 15189 Standard.
8. Demonstrated ability to provide the following expertise (assessing and updating policies, procedures, and guidelines) for the components of the accreditation process.
9. Proven ability to engage (coordination and working) with national counterparts including laboratory management and staff, senior government officials at national and state level, regional partners and other key laboratory stakeholders.

10. Be fluent (speaking and writing) in the English Language. Demonstrate excellent written and oral communication skills as stakeholder engagement and training is critical to the execution of this consultancy.
11. Be able to effectively engage with government agencies and health sector stakeholders as consultation is expected with a variety of stakeholders throughout the entire project cycle, from inception through closing.