I. Introduction

The Government of Saint Lucia (GOSL) has obtained financing under the World Bank (WB) OECS Regional Health Project (RHP) whose objective is to strengthen national and regional disease surveillance and public health emergency preparedness and response efforts in the four (4) member states of Dominica, Saint Lucia, Saint Vincent and the Grenadines, and Grenada. The Project is structured around three main pillars - Surveillance and information systems; Laboratory services; and Preparedness/response, with an additional component on institutional capacity building. The financing supports the GOSL in strengthening the resilience of Saint Lucia’s Public Health Preparedness and Response to manage the challenges from new, emerging, and re-emerging diseases.

In 2005, in response to an increase in global mobility, emergence and re-emergence diseases, nearly 200 countries across the world signed on to implement the International Health Regulations (2005) (IHR). The objective of this legally binding instrument is “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.” Following the Zika outbreak, a Rapid Needs Assessments was carried out by the World Bank (WB) in collaboration with Pan American Health Organisation (PAHO) in all four project-participating countries. This Rapid Assessment revealed the following shortcomings in infectious disease surveillance, epidemic preparedness, and response: (i) lack of an adequately trained health workforce for disease surveillance, preparedness, and response across the different levels of health services; (ii) non-existent or insufficient facility level surveillance and response structures; (iii) limited laboratory infrastructure for timely and quality diagnosis of epidemic-prone diseases; (iv) lack of interoperability of information systems hampers analysis and
utilization of information for decision-making and disease mitigation measures; (v) inadequate infection, prevention and control standards, infrastructure, and practices; (vi) significant gaps in regional level surge capacity for emergency response, stockpiling of essential goods, information sharing, and collaboration. As well, at the same time, there needs to be adequately trained public health specialists (e.g. epidemiologist, entomologist, etc.) and expertise across countries.¹

Under the OECS Regional Health Project, investments in health systems strengthening will have a direct impact on improving these IHR core capacities in the participating countries, particularly in the areas of surveillance, laboratories, 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.

The Government of Saint Lucia has recognised that some significant changes have to be made to strengthen the areas of surveillance, laboratories, workforce development, and emergency management. This includes a need to balance the provision of adequate and appropriate services to the population while ensuring quality and that there are sufficient resources to do so. Laboratory accreditation is recognized as an efficient tool for putting in place a quality system for achieving continuous improvement in laboratory services in a sustainable fashion. The laboratory accreditation system is important for the acceptance of test results nationally and internationally; accreditation is immensely beneficial in supporting an achievable and efficient health care system.

The Department of Health and Wellness (DoHW) now seeks a firm for technical services for supplying laboratory accreditation for the Public Health Laboratories based on the international standards, and the Licensing and Certification program – keeping in mind accomplishments and opportunities for Continuous Quality Improvement, and Regional collaborations.

II. Conceptual Framework

1. The Department of Health and Wellness is currently implementing a National Quality Management System (NQMS) for the health sector. The activities of the NQMS aims to respond to the needs of the residents of Saint Lucia, to access safe care and services that meets the acceptable standards of quality, irrespective of the facility visited. All health organisations will be required to have a quality management system in place that at a minimum can meet mandatory licensing standards in order to operate. This includes laboratory services, both public and private. The secondary tool, accreditation, while optional for the private sector is compulsory for government public and primary health care services.

¹ OECS Regional Health Project (P168539)
2. To date the Department of Health has commenced the implementation of its National Health Care Quality Policy which was approved by Cabinet of Ministers on April 23, 2019, for implementation across the national health sector. This Healthcare Quality Policy advocates for the use of a common and collective approach to the resolution of the many concerns at the national level regarding current issues of Quality Infrastructure pertinent to health, safety, and environment and consumer protection. It guides the health sector to achieve continuous improvement and client satisfaction for improved health outcomes; and the Sustainable Development Goals (SDGs) to “Ensure healthy lives and promote wellbeing for all at all ages” while promoting to “Reduce inequality within and among countries. Included within the National Quality Policy are the following four (4) priority areas designed to address the diagnosed health issues within Saint Lucia:

I. Enhancing Client-Centred – Care in the Health System  
II. Ensuring Supportive Health Care Environments  
III. Strengthening Leadership in Governance and Management for Improved Clinical Outcomes  
IV. Enabling a Culture of Continuous Quality Improvement in Health Care Delivery

3. As a part of the quality strategies for healthcare service improvement, the St. Lucia National Laboratory Policy, March 2015 is included within the National Quality Policy for implementation. It highlights the decrease of laboratory errors by promoting Quality Assurance and an accreditation scheme in Medical Laboratories. For Saint Lucia a standalone law for the Medical Laboratory, separate from those of all clinical services is not recommended, and it is therefore proposed that these documents be incorporated into Saint Lucia’s soon to be developed Laws addressing standards for licensing of all health and social clinics/practices.

4. The model proposed for the development and implementation of the Quality System in Saint Lucia must follow the logic of the quality ladder as depicted below in figure No. 1. According to most experts there are three (3) processes which are part of the continuous quality improvement of the care continuum: The Licensing processes, The Certification processes and the Accreditation processes. These processes can also be considered as steps in the quality of care ladder, due to the different purposes of each one. Achieving an effective Laboratory Quality System leading to Accreditation will provide Saint Lucia laboratories the ability to overcome various issues with the such benefits as the following:

- Facilitates the implementation and maintenance of an effective quality system.  
- Gives confidence to users in availing the services.  
- Gives confidence to clients of the laboratory in the results generated.  
- Provides national/international recognition of technical competence.
− Helps in defending laboratories while dealing with legal disputes pertaining to laboratory results.
− Reduces the operating costs of the laboratories by getting results right the first time and every time.
− Helps in national and international acceptance of results.
− Meets purchase or regulatory specifications.

**Figure 1. Quality of Care Ladder**

5. The Public Health Laboratories (Ezra Long Laboratory and the St Jude Hospital Laboratory) in recent years have made progress towards full accreditation by establishing a Quality Management System based on the international standard - *ISO 15189:2012 Medical laboratories — Requirements for quality and competence*; and using the three-tiered Caribbean Guidance for the Stepwise Improvement Process Towards Accreditation Checklist (LQMS-SIP), to guide the implementation process. During the period of 2018 through to 2020, the Public Health laboratories have been working hard towards developing and completing the requirements for Tier I and Tier II certification. Despite having most of the Tier I and many of the Tier II requirements, there were some unavoidable nonconformities. These nonconformities were such as not having all standard operating procedures in place, the laboratory layout needed for a safe and confidential environment, there were needs for safety devices such as eye wash stations and a safety shower in the current facility. The staff facilities (wash rooms) are inadequate for the number of staff. The layout in specimen collection and accessioning is a bit small but adequate. With the move to the newer facility at the Owen King EU Hospital and technical
support these nonconformities have since had corrective actions. Therefore, the Public Health Laboratories can have tremendous momentum towards the ultimate goal of full accreditation.

III. Objectives
The main objective of the consultancy is as follows:

a. General
Achieve Accreditation of the two (2) medical Public Health Laboratories in accordance to international criteria, the ISO 15189 (most recent version) international standard, and requirements for mutual recognition arrangements.

b. Specific

1. Provides the medical Public Health Laboratories with an Accreditation programme that meets their unique services to improve and maintain the quality, safety, and efficiency of their services.

2. Provide by means of assessment, the assurance that the professionals in practice at the Public Health Laboratories are working in accordance to international standards, ISO 15189.

3. A formal recognition that the medical Public Health Laboratories are competent to carry out specific calibrations, tests, or types of tests.

4. Complete Accreditation of the two (2) medical Public Health Laboratories in preparation for the implementation of the first and second phase of the Essential Health Care Services Package by the Department of Health and Wellness and the envisioned National Health Insurance.

IV. Scope of Work:
The consultant will be expected to work with the selected two (2) Public Health Laboratories to provide direct technical assistance to strengthen their quality management system to achieve Accreditation. There are activities which will require further stakeholder consultations, therefore the protocols for COVID-19 must be taken into account in the preparation of the work plan. The task and activities are as follows:

i. Review the planning, design, and coordination of the Public Health Laboratories services, including the Laboratory Quality Management System such as the management reviews, internal quality control, audits, validations, internal quality assessments, and external quality assessment schemes. The result of this review should be documented in the Inception Report.
ii. Perform an Accreditation Readiness Assessment against the requirements of the ISO 15189 (most recently version) and provide a report detailing the Non-conformances.

iii. Design a step-by-step process to achieve the requirements of accreditation of the laboratories. This includes the Road-map, the criteria for the Laboratory Accreditation Committee, and the Communication Plan to guide the Accreditation of the Public Health Laboratories.

iv. Perform a document review, and identify areas for improvement. This activity includes the following:

   a. Ensure that all Laboratory Manuals are written to meet the ISO 15189 (most recently version) standard requirements.
   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 two (2) Laboratories to develop, review, update, and implement Laboratory quality documents including the Quality Manual, Safety manual, Administrative Standard Operating Procedures, Test methods, forms, records, etc., as required by the ISO 15189 international standard.

v. Develop an Action plan, listing all Non-conformances, Corrective actions, and timelines for resolve.

vi. Assist with performing necessary Corrective actions and review the Action Plan at set time intervals and assist the Laboratories to eliminate each Non-conformance identified.

vii. Develop a system for performing Competency Assessments of the Laboratories staff.

viii. Implement capacity building initiatives to improve the competence of the Laboratory staff. This activity should include the following task:

   - Assist with the development of Safety training and Safety audits.
   - Perform training for the Laboratory staff on Standard Operating Procedures development, Internal audit, Safety Management, Root cause analysis, Risk assessment, Quality control and other relevant Quality Management System topics.
- Provide expertise and guidance in Quality Management Systems through onsite training and coaching to enhance good laboratory practice.

ix. Assist with the development of Standard Operating Procedures for identifying Non-conformities, conducting root-cause analysis, and performing corrective actions.

x. Conduct internal audits to strengthen the Laboratories accreditation capacity. This activity should include the following:

- Develop an internal audit schedule.
- Review general Non-conformance reports and assist Laboratories to develop strategies to eliminate any outstanding non-conformities.
- Assist the laboratories to conduct their Internal audits, including the review of the Audit reports and develop Action Plans based on the Audit results.

xi. Assist with the design of improvement projects and monitor attainment of indicators in the projects.

xii. Monitor execution of proficiency testing programmes and assist with corrective action plans based on results received.

xiii. Assess the readiness for accreditation and assist with the completion of the application and submission.

xiv. Work with the laboratories to review the accreditation assessment report and perform corrective actions.


xvi. Through assessment and consultation with the Health Information Unit, provide strategies for strengthening Laboratory Information Technology system to meet the requirements for the Accreditation Programme.

V. Deliverables
a. Initial assessment and documented Inception Report as a result of the review of the planning, design, and coordination of the Public Health Laboratories services and the Laboratory Quality Management System.
b. Roadmap for achieving Saint Lucia’s Laboratory Accreditation, the work/implementation plan, as well as a presentation to stakeholders on the work/implementation plan and chronogram (or time line chart with the representation of the activities and milestones), which should integrate feedback and criteria from the Quality Managers and officials of the Department of Health, as well as other relevant stakeholders. Formal meetings and presentations will be scheduled for the Consultant to discuss the results of this assignment.


d. Document and presentation containing Initial report on Accreditation Readiness with a detailed Action Plan for the Public Health Laboratories Accreditation programme outlining timelines and indicators of success. Formal meetings and presentations will be scheduled for the Consultant to discuss the results this report with officials of the Department of Health, as well as other relevant stakeholders. Consideration must be given to the COVID-19 situation and protocols.

e. Document containing the criteria for establishing a Laboratory Accreditation Committee.

f. Document containing the Accreditation programme Communication Plan, including budget.

g. Document containing 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 in keeping with the agreed timeline stipulated in the Laboratories work plans.

h. Document containing Non-conformance reports, and Corrective Actions Plans with timelines and indicators of success.

i. Document containing Internal audit schedules.

j. Reports on results of Internal audits and effectiveness of Corrective actions taken to address non-conformance.

k. Competency records for all staff completed.

l. Document with Training Plan with relevant Quality Management System topics.

m. Document containing reports on Laboratory training and the results and evidences of the training sessions to introduce the Laboratory Accreditation.
n. Document containing the evidences of the expertise and knowledge transfer to the Ministerial Quality Management Unit and Laboratory Quality Managers.

o. Document containing the Monitoring and Evaluation framework including all the indicators for success and reporting.

p. Documents containing monthly and summary reports submitted with clear updates and information on the outcome of Non-conformances, recommendations for future laboratory training, equipment upgrade, safety concerns; and any other issues to be addressed in order to implement the ISO 15189 Quality Management System and application for Accreditation.

q. Completed application for Accreditation, with the testing scope outlined.

r. The consultant will support the client in the identification of a recognized Accreditation body, which will be the issuer of the ISO 15189 Certificate Quality Management System (QMS) upon satisfactory compliance to the Standard and Certification requirements.

s. Document containing the design strategies for strengthening Laboratory Information Technology system to meet the requirements for the Accreditation.

VI. Minimum Qualifications, Skills and Experience

The assignment is to be undertaken by a suitably qualified Consulting Firm. The selected Consultant is required to possess the minimum competency requirements listed hereunder. Given the global public health situation with COVID-19 and the limitation of travel, the selected consultant may sub-contract at the local level any portion of the assignment with the written consent of the Department of Health and Wellness, but the consultant will remain being ultimately responsible for all required/specifed deliverables to the Department of Health and Wellness, as well as assume responsibility for all activities geared towards achieving the objectives of these terms of reference.

General Areas of Expertise/Experience of the Consulting Firm

1. Minimum of ten (10) years’ experience in the role of licensing and accreditation of health care in developing countries;
2. Minimum of seven (7) years specific experience in Laboratory Quality Systems design and implementation;
3. Minimum of five (5) years of experience in conducting ISO Quality Management System audits and certification;
4. Minimum of five (5) years experiences in Continuous Quality Improvement Systems design and implementation in development countries including Latin America and the Caribbean Region (LAC);
5. Proven record of at least three (3) assignment related to the Laboratory Accreditation process or similar accreditation processes associated with ISO 15189 or similar;
6. Demonstrated ability to provide the following expertise (assessing and updating policies, procedures, and guidelines) for the components of the accreditation process.
7. Proven ability to engage (coordination and working) with national counterparts (including senior government officials at national and state level), partners, stakeholders of Public Health;
8. The Firm will ensure that the accreditation body identified as the issuer of the Accreditation Certificate, must be a signatory of the Mutual Recognition Arrangement (MRA) with the International Laboratory Accreditation Cooperation (ILAC).
9. The Firm shall field a team (1 team leader and at least 4 team members with the following qualifications:

**For the Team**

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<th>Criteria for Technical Evaluation</th>
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| **Team Leader**                  | • University graduate with a Bachelor degree in Medical Laboratory, or a Master degree in Laboratory Sciences with not less than 7 years of experience in the field of laboratory quality management assessment.  
• At least five (5) similar assessments to similar Laboratories using ISO QMS Certification in health care or ISO 15189 or equivalent |
| **Team Member (2)**              | • University Graduate with a bachelor degree on Medical technology, Laboratory sciences or equivalent, with not less than five (5) years of experience in the field of Laboratory assessments or accreditation.  
• At least three (3) similar assessments using ISO Quality Management System Certification in health care or ISO 15189 or equivalent |
| **Team Member (2)**              | • University graduate with a Bachelor degree in Medicine, Medical Laboratory Science or equivalent with a Master degree in Public Health, with not less than five (5) years of experience in the field of Laboratory assessments or accreditation.  
• At least three (3) similar assessments using ISO Quality Management System Certification in health care or ISO 15189 or equivalent |
• No less than five (5) years of experience with certification in Quality Management in Health, Medical Laboratory or equivalent.
• At least three (3) experiences in laboratory certification and accreditation processes and proven experience in design, adaptation and implementation of standards, protocols and guidelines for Certification and accreditation of Laboratories.

VII. Duration and Characteristics of the Consultancy

• Type of consultancy: Firm
• Duration: This assignment is expected to be completed over a 12-month period from contract effective date.
• Assignment Location: The assignment requires field work on island in Saint Lucia and therefore the Consultants are required to ensure presence in Saint Lucia especially at critical periods, including implementation of the Readiness Assessment, and audits. Therefore, consideration should be given to the COVID-19 situation and the proposal of strategies towards achieving the scope of works of the terms of reference (TOR).

Execution of this Terms of Reference requires the following:

• Excellent communication skills and excellent knowledge of the English language (both spoken and written); it is important to note that Stakeholder engagement is critical to this consultancy.
• The consultant is expected to engage the Health Sector Stakeholders throughout the entire process from inception.
• Ability to interface with government officials, and other stakeholders;
• Ability to travel and conduct site visits to the laboratories and various testing sites (and possibly other health facilities) across Saint Lucia as necessary.

Client’s Responsibility

On behalf of the Department of Health and Wellness, the Quality Management Representative(s) or a duly designated representative(s), shall evaluate the quality of work delivered by the Consultants 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 following comprise the general expectations from Department of Health and Wellness, as client:

1. Prior to any execution of activities related to this Terms of Reference, the Department of Health Quality Management Structure shall convene a meeting between the representatives of the Firm and the Laboratory Focal point persons to be assigned to handle this project. A close anchoring and monitoring of all the
activities as indicated herein shall be undertaken by the Quality Management Representative(s);

2. The Quality Management Representative(s) and the Health System Strengthening Project Implementation Unit (HSSP-IU) shall be responsible for providing technical assistance for the project. They shall closely coordinate with the representatives of the Consultant in the conduct of the Audits and other related accreditation activities, including monitoring of the progress of the various tasks; and

3. The Quality Management Representative(s), Laboratory staff and the Department of Health shall cooperate in the conduct of audit activities, ensuring that the process owners and concerned officials and staff are available on the scheduled dates of audits. 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 both parties.

Consultant’s Responsibility
The Consultant shall provide information that indicates experience, educational/ training qualifications and capacity to undertake the work outlined herein. As part of this, the Consultant is expected to provide an indication of public quality management system-related engagements, as well as quality management system certification audit engagements that are currently committed, ongoing or completed. This will be considered in the assessment of the Firm QMS-related qualification.

The Consultant undertakes to perform the audit with the highest standards of professional and ethical competence and integrity.

The following are the general expectations from the Consultant:

1. Commitment to treat with utmost confidentiality, all information and materials gathered and used relating to this engagement or the Client’s business or operations;

2. Preparation of the Accreditation or Audit Plan, as the case may be, with schedule of activities for the entire duration of the engagement. The representatives from the Firm shall coordinate with the Quality Management Representative(s) through the HSSP-PIU regarding any changes on the dates of audit schedules or any delay in the activities related to Accreditation program;

3. Adherence to Audit 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;

VIII. Reporting/Coordination
The Consultant will report to the Project Manager of the Project Implementation Unit (PIU) for the Health System Strengthening Project (HSSP) and The OECS Regional Health Project, and will coordinate their work with the Chief Medical Officer, the Public Health Laboratories Directors and the Corporate Planning Unit of the Department of Health and Wellness, in close collaboration with the Monitoring and Evaluation Specialist of the PIU, and the Quality Assurance Managers within the health system. Formal meetings and presentations will be scheduled for the Consultant to discuss the progress of key assignments as necessary.