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Terms of Reference – Quality Assurance Consultant – Next Generation Medical Laboratory

Hiring organization
CROSQ

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1. BACKGROUND

1.01. The Caribbean Community Single Market and Economy (CSME) was established in 1989 to provide more and better opportunities to produce and sell goods and services, increase competitiveness, provide employment and improved standards of living for the people of the Caribbean Community (CARICOM). The CSME now boast some successes in the areas of functional cooperation, economic integration and foreign policy coordination. Within these categories the implementation of the common external tariff, free movement of skills and the establishment of regional quality and research institutions are of significance to trade.

1.02. Notwithstanding the achievements of the CSME, challenges in intra-regional trade still remain. Some of the key constraints (particularly for manufacturers, exporters and service providers) in CARICOM are related to challenges in overcoming Technical Barriers to Trade (TBTs) in order to increase market access and penetrate new markets. Most of these TBTs are related to a weak quality infrastructure and developing related institutions in the CARICOM region.

1.03. A Quality Infrastructure (QI) is “the institutional framework that contains mechanisms for developing standards, ensuring accuracy of measurements (metrology), verifying conformity to standards through inspection, testing and certification (conformity assessment), assuring competence in conformity processes (accreditation), and promoting awareness through information and education campaigns. Some of the specific challenges identified in relation to quality infrastructure in the CSME are as follows:

(a) Technical regulations, standards and conformity assessment regimes are not well known to all CARICOM manufacturers, exporters and service providers leading to limited compliance with national, regional and international requirements.

(b) Key standards, technical regulations and conformity assessment procedures are not harmonized regionally leading to imperfect regional and national quality infrastructure legislative & regulatory framework.

(c) Insufficient number of internationally recognised or accredited conformity assessment bodies such as testing/medical laboratories, inspection and certification bodies.

(d) Inadequate mutual recognition and acceptance of conformity assessment regimes in Member States.

(e) Limited awareness of quality issues resulting in weak culture of quality; especially amongst public sector policy makers, civil society and consumers.

1.04. The aforementioned challenges have not only impacted intra-regional trade but have also constrained access to international markets, especially those liberalized through the European Union (EU) CARIFORUM Economic Partnership

Agreement (EPA). For example; pepper sauces from the CARICOM region were denied entry into the European markets for the presence of a banned additive/and were returned based on non-compliance to standard and conformity assessment requirements of the importing country. The inability of the region to test for some of these banned additives resulted in the exporting CARICOM member countries having to perform the analytical test at accredited facilities located outside of the region at far higher costs.

1.05. Since its inception, The CARICOM Regional Organisation for Standards and Quality (CROSQ) has been actively engaged in establishing regional systems and mechanisms for the development of a Regional Quality Infrastructure (RQI) as well as providing support through its programmes to Member States for their national quality infrastructure development. It is responsible for the development and/or harmonisation of a regional quality infrastructure to facilitate trade both intra and extra regionally; to ensure consumer safety and to protect the environment.

1.06. The presence and use of internationally recognised conformity assessment bodies in the region reduces the costs associated with obtaining testing and inspection from outside the region. These regionally available internationally recognised conformity assessment bodies also reduce the risk of products being rejected at the border of the destination country by providing credible data before shipment.

1.07. During the period July 2025 to May 2027, CROSQ will be supporting conformity assessment bodies (CABs) to get accredited under the Technical Barriers to Trade (TBT) Phase III Project, which is part of the new European Union´s Neighbourhood, Development, and International Cooperation Instrument (NDICI), which constitutes the legal basis for programming EU cooperation in developing countries during the period 2021-2027. Consultants are being engaged to assist with this process and will facilitate the process in the identified and selected CAB.

2. OBJECTIVE

2.01. The objective of this assignment is to provide technical support to **Next Generation Medical Laboratory**, hereunder referred to as the CAB, towards the implementation of an internationally recognised Quality Management System (QMS); namely the **ISO 15189** so that they can provide accredited testing services to the medical institutions in accordance with their mandate.

3. SCOPE OF WORK

3.01 The Consultant will carry out the activities described hereunder and any other activities necessary to accomplish the stated objectives of the consultancy assignment, whether or not a specific activity is cited in these terms of reference. Throughout the assignment, the Consultant will liaise with the Project Team, which has been appointed to lead and monitor the Project. The Consultant is also required to provide monthly updates, including precise information on progress made based on activities outlined in the terms of reference. These updates should be submitted no later than three weeks after the end of each month. Note that these updates are separate from the payable deliverables outlined in Section 5 below.

3.02 The main tasks/activities to facilitate the readiness for internationally recognised accreditation of the CAB are described below:

(a) Carry out, during the process, a technical audit/gap analysis/internal audit of the CAB, comparing the current QMS to the requirements of **ISO 15189**.

(b) Review and as necessary, give recommendations as well as guide the

implementation of an appropriate governance structure that is aligned with the accreditation requirements of the **ISO 15189** with respect to impartiality.

(c) Prepare an internal audit report which will include an analytic gap analysis and recommendations for closing observed gaps and produce an implementation plan.

(d) Assess the training needs of staff in the CAB based on the gap analysis carried out and formulate an overall training programme.

(e) Ensure that trainings are competence-based and where possible – gender-balanced ensuring that the composition of teams are taken into account.

(f) Advise on the establishment of an audit team to carry out future internal audits and mentor this team to ensure its competence and continuity.

(g) Engage a Technical Expert, (based on demonstrated need and agreement by the Project Team) to facilitate the internal audit and evaluation of specific test(s) as deemed necessary.

(h) Design and deliver technical training for the technical staff of the CAB on the application of techniques/standards and on the conduct of internal audits/management reviews. The workshops should be carried out on a 'train-the-trainer' basis, and topics should include, but not limited to the following:

(i) Managing the accreditation/quality management (as applicable);

(ii) Internal auditing;

(iii) Introduction to the **ISO 15189** and other relevant standards as required for accreditation;

(iv) Writing Procedures/work Instructions for a QMS;

(v) Method verification and validation (in the case of laboratories);

(vi) Measurement Uncertainty (if applicable);

(vii) Internal quality control;

(viii) Proficiency Testing/Inter-laboratory Comparison/Trend analysis; and;

(ix) Managing of findings including route cause analysis;

(x) Other relevant areas based on training needs identified in the gap analysis.

(i) In consultation with the CAB technical and managerial staff, create templates and other forms that comply with the respective standard and are acceptable to the CAB.

(j) Review the preliminary and revised drafts of all documentation submitted by the Quality Manager (e.g. the quality manual, standard operating procedures, work instructions and personnel records), provide detailed feedback and approve final documentation.

(k) Review and provide feedback on each audit plan; assess the performance of a few audits and the performance of the internal auditors; review each audit report and provide comments to the audit team.

(l) Assist the CAB in preparing the application for the selected Accreditation Body.

(m) Review the results of the pre-assessment audit conducted by the Accreditation Body for the CAB and prepare an end-of-project report, which includes recommendations on the way forward for the CAB.

3.03 In conducting the assignment, the Consultant is required to facilitate the participation and engagement of relevant staff at the facility.

4. DURATION

4.01 This assignment is for a total of 40 person-days over the period of the accreditation of the CAB. The CAB must be accredited within a period not exceeding 24 months.

5. DELIVERABLES AND REPORTING REQUIREMENTS

5.01 The consultant will report to the Technical Officer –Accreditation and Conformity Assessment, CROSQ and will be required to submit/deliver the following:

(a) Within two weeks of commencing the assignment, an **Inception Report** containing a detailed work plan and schedule.

(b) Within 6 weeks of commencing the assignment, a**Gap Analysis/Internal audit Report and an Implementation Plan for the CAB**, including perspective and concept/plan for the governance structure.

(c) A Report containing detailed feedback on a Preliminary Draft of **the QMS Documentation**.

(d) A report containing detailed feedback on the **Final Draft of the QMS Documentation**.

(e) A **Training Report** that outlines all workshops conducted, participant post training survey, effectiveness of training analysis, a draft in-house training programme and related training materials along with details of the assignment, including activities performed, results obtained, recommendations and follow-up actions required.

(f) A report showing detailed feedback on the **final preparation and recommendation** leading up to the accreditation assessment.

(g) A **Final Report** containing summarised feedback on the overall accreditation support to the CAB towards its accreditation readiness.

6. QUALIFICATIONS AND EXPERIENCE

6.01 The consultant should possess the following qualifications and experience:

(a) At least a Bachelor of Science (BSc) in Natural Sciences, Applied Sciences, Engineering or any other related field.

(b) At least 10 years' work experience in implementing conformity assessment systems in a conformity assessment body(ies) of which at least 3 years' experience implementing and/or leading ISO 15189 type activities in a similar organisation.

(c) Competence to conduct an internal audit/gap analysis.

(d) Experience in providing a conformity assessment service in the CARICOM

Region or in a developing country will be an asset.

(e) Strong interpersonal and communication skills; ability to be tactful and flexible in dealing with personnel at all levels of an organisation.

(f) Excellent command of written and spoken English.

7. SUBMISSIONS

7.01 Proposals and Curriculum Vitae(s) are to be sent to Mr. Terry Hutchinson at terry.hutchinson@crosq.org and copied to Ms. Teyonna Delice-Mayers at teyonna.delicemayers@crosq.org by **1:00 pm AST on Monday, 21 July 2025**. The proposal will be evaluated on the following criteria: Education; Experience; Skills and Competences; Adequacy and Technical approach. The proposal must include a financial indication of man-day rates and consultancy charges. CROSQ reserves the right to negotiate rates with the most technically eligible respondent.