TRINIDAD AND TOBAGO BUREAU OF STANDARDS

ACCREDITATION PROGRAMME FOR PUBLIC LABORATORIES

CONSULTANCY SERVICES FOR THE DEVELOPMENT AND IMPLEMENTATION OF A QUALITY MANAGEMENT SYSTEM BASED ON ISO/IEC 17025 OR ISO 15189

REQUEST FOR EXPRESSIONS OF INTEREST

1.0 BACKGROUND

The Government of the Republic of Trinidad and Tobago approved the National Quality Policy of Trinidad and Tobago (NQP-TT) via a cabinet note for the period 2018 – 2030 on April 12th 2018. The Public Laboratories Accreditation Programme, described as "the Project" hereinafter, was launched on June 11th 2019. Two laboratories are currently in the process of preparing for the accreditation application and the second project call is to be conducted in the second half of fiscal 2021.

The Trinidad and Tobago Bureau of Standards (TTBS) as the executing agency is desirous of recruiting Consultant(s) for the 2021/2023 period. Two laboratories would be selected and therefore the Consultant(s) would be required to provide consultancy, mentoring and coaching in becoming accredited to ISO/ IEC 17025: 2017 - General requirements for the competence of testing and calibration laboratories and/or ISO 15189:2012- Medical laboratories — Requirements for quality and competence

2.0 GENERAL OBJECTIVES OF THE CONSULTANCY

The objectives of this consultancy are to:

1. build the capabilities of public laboratories to meet the requirements of either ISO/ IEC 17025 and/or ISO 15189; and
2. support the laboratories in submitting an application for accreditation to the aforementioned standards for at least one scope of accreditation.
3. prepare the laboratory for the accreditation assessment and provide support to the laboratory in closing out any identified non-conformances

TTBS now invites interested eligible individual Consultants to submit Expressions of Interest indicating qualifications and experience required to provide these consultancy services.

Further details can be found in the attached draft Terms of Reference.

3.0 SCOPE OF WORK

The Consultant will perform 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 a NQP Project Team, which will be appointed to lead and monitor the Project.

The main tasks/activities are described below:

1. Review the Pre Assessment reports submitted by the Laboratory Accreditation Body and prepare a technical audit/gap analysis report, with recommendations for closing observed gaps, with a proposed implementation plan.

2. Assist the laboratory in Quality Management System (QMS) documentation necessary to assure the compliance to either of the accreditation standards.

3. Assess the training needs of staff in the laboratory based on the gap analysis carried out and formulate an overall training programme.

4. Design and deliver technical, competence based training for the appropriate staff of the organization on the application of the respective standard. The workshops should be carried out on a 'train-the-trainer' basis and topics should cover the following:
   (a) Managing accreditation systems for laboratory technical staff and the Quality Manager (where applicable);

   (b) Internal Auditing and Conduct of Management Reviews for technical staff;

   (c) Introduction to the *ISO/IEC 17025:2017* or *ISO 15189:2012* standard

   (d) Documentation and Procedure Writing for QMS technical staff;

   (e) Method Validation for appropriate technical staff;

   (f) Measurement Uncertainty for appropriate technical staff;

   (g) Basic Metrology & Calibration for appropriate technical staff;

   (h) Control Measures for appropriate technical staff;

   (i) Proficiency Testing/Statistics for appropriate technical staff; and

   (j) Root Cause Analysis for appropriate technical staff.

5. In consultation with laboratory technical and managerial staff, advise and propose templates and other forms that comply with the respective standard and are acceptable to the laboratory.

6. Review the preliminary and revised drafts of all QMS documentation submitted by the Laboratory's Representative responsible for the implementation of the standard (e.g. the quality manual, standard operating procedures, work instructions and personnel records), provide detailed feedback and approve final documentation.

7. Advise on the establishment of an audit plan, audit team to carry out performance and internal systems audits. Review and provide feedback on each Audit Plan; assess the performance of a minimum of 3 and maximum of 6 audits and the performance of the internal auditors; review each Audit report and provide comments to the audit team, support the laboratories in developing their auditing skills, including conducting mock audits.

8. Assist the laboratory in developing a quality assurance plan such as a proficiency testing plan for the laboratory(s), schedule proficiency tests, review test results and provide comments on corrective action taken.

9. Provide input or feedback on Management Review to the Laboratory's Representative as well as the NQP Accreditation Project Steering Committee and the Project Coordinator as required.

10. Validate all monthly reports to be submitted by the laboratories to the Project Steering Committee.

11. Participate in meetings/engagements as organized by the Project Coordinator. This may include meetings with the National Quality Council or its sub Committees. This may also include project promotional activities.

12. Assist the laboratories in preparing the Application for Accreditation and approving same prior to submission to the Laboratory Accreditation Body.

13. Assist the laboratories prior to the accreditation assessment with assessment strategy, auditee preparation and organization and preparation of documented information.

14. Review the results of the assessment audits conducted for the laboratories by the Laboratory Accreditation Body and support/assist the laboratory in closing out any identified non-conformances.

15. Prepare a final end-of-project report (post accreditation assessment and close out of non-conformances), which includes recommendations on the way forward for the laboratories.

16. In conducting the assignment, the Consultant is required to facilitate the participation and engagement of the relevant staff of the Laboratories and TTBS.

4.0 DURATION

This assignment is for an estimated 120 person-days per laboratory over a maximum period of 24 calendar months starting within the third quarter of 2021, subject to satisfactory fulfilment of project deliverables.

5.0 DELIVERABLES AND REPORTING REQUIREMENTS

The Consultant will report to the Standards Officer III, Corporate Projects Function and the Executive Director, TTBS. Additionally, the incumbent will be required to work with the selected laboratories, the National Quality Council and other key stakeholders in executing this consultancy.The Consultant will be required to submit/deliver the following:

NO	DELIVERABLE	DELIVERY TIMEFRAMES (WORKING DAYS)	CLIENT REVIEW PERIOD (WORKING DAYS)	PAYMENT AMOUNT	REPORT DETAILS
1	Draft Inception Report which includes gap analysis report and detailed project implementation plan and schedule for the laboratories.	Within one month of commencing the assignment	14 Days	Twenty five percent (25%) of contract price payable upon approval of Deliverable 2.	Electronic MS Word and PDF PIP to be submitted in MS Excel
2	Final Inception Report	7 days after client's review	7 days		
3	Monthly reports to provide progress updates as per work schedule and implementation plan (The specific items indicated in item f above may be incorporated into monthly reports as a subheading). Ad hoc reports may also be requested on behalf of the Ministry of Trade and Industry, the	5 days after the end of the previous month		NA	Electronic MS Word and PDF MS Powerpoint – Status Update Meetings with Laboratories, National Quality Council

NO	DELIVERABLE	DELIVERY TIMEFRAMES (WORKING DAYS)	CLIENT REVIEW PERIOD (WORKING DAYS)	PAYMENT AMOUNT	REPORT DETAILS
	National Quality Council or TTBS Management.				
4.	Copies of templates and forms complying with respective standard and acceptable to the laboratory and TTBS. This may be incorporated into the regular monthly report as updates on progress.	Within six months of commencing the assignment	14 days	Ten percent (10%) of contract price payable upon approval of Deliverable 4.	Electronic MS Word and PDF
5	A Report containing detailed feedback on a preliminary draft of the QMS documentation. This may be incorporated into the regular monthly report as updates on progress	Within seven months of commencing the assignment	14 days	Ten percent (10%) of contract price payable upon approval of Deliverable 5.	Electronic MS Word and PDF
6	A Report containing detailed feedback on the first draft of the QMS documentation. This may be incorporated into the regular monthly as updates on progress	Within nine months of commencing the assignment	7 days	Ten percent (10%) of contract price payable upon approval of Deliverable 6.	Electronic MS Word and PDF
7.	A Report containing detailed feedback on the final draft of the QMS documentation.	Within twelve months of commencing the assignment	14 days	Ten percent (10%) of contract price payable upon approval of Deliverable 7.	Electronic MS Word and PDF

NO	DELIVERABLE	DELIVERY TIMEFRAMES (WORKING DAYS)	CLIENT REVIEW PERIOD (WORKING DAYS)	PAYMENT AMOUNT	REPORT DETAILS
8	A Report that outlines all training workshops conducted, a draft in-house training programme and related training materials. A report outlining the Laboratories' Audit Programme. This may be incorporated into the regular monthly report as updates on progress.	Within fifteen months of commencing the assignment	14 days	Ten percent (10%) of contract price payable upon approval of Deliverable 8.	Electronic MS Word and PDF
9.	A draft Final Report that provides details of the assignment, including activities performed, results obtained, recommendations and post project follow-up actions that may be required.	Within twenty four months of commencing the assignment days	14 days	Twenty five percent (25%) of contract price payable upon approval of Deliverable 10.	Electronic MS Word and PDF
10.	Final Report	7 days after client's review	7 days		

The Consultant must have the capability for the use of electronic signatures.

6.0 CHARACTERISTICS OF THE CONSULTANCY

The characteristics of this Consultancy are outlined as follows:

- Type of Consultant: Individual Consultant selection based on qualifications
- Start and Contract Duration:3rd Quarter of 2021 - One (1) calendar month after signing of contract.

Place(s) of work: Laboratories Offices (online/remote) and Consultant's work office. The Consultant will initially be required to work remotely. No in person engagements are

envisaged at this time, however site visit/s to the laboratory itself may be required. **This requirement will be reviewed given COVID-19 precautions in place at time of negotiations with shortlisted Consultant and maybe reviewed periodically.**

7.0 REQUIREMENTS, SKILLS AND CORE COMPETENCIES

The Consultant should possess the following qualifications and experience:

1. Specific technical expertise/competence pertinent to the public laboratories of Trinidad and Tobago. The specific technical expertise will be refined based on the laboratories selected to participate in the particular project call.

   In exceptional circumstances technical subject matter experts may be subcontracted to assist in the development of the management system but this must be explicitly stated and must not form an additional cost to the projected overall cost of the contract with the main Consultant.

2. Ten (10) years' work experience in implementing quality management systems in a laboratory. Experience in a laboratory assessment service in the CARICOM Region or in a developing country will be an asset.

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

4. Excellent command of written and spoken English. Knowledge of other regional language would be an asset.

5. Familiarity with the policies and procedures of accreditation bodies in general and the Trinidad and Tobago Laboratory Accreditation Service specifically

8.0 SELECTION CRITERIA

In order to be considered for evaluation, the Consultant must have at a minimum, a Degree preferably in a Natural Science and at least ten (10) years' work experience in implementing quality management systems in a laboratory. Experience with a laboratory accreditation body and/or laboratory assessment service in the CARICOM Region or in a developing country will be an asset.

CRITERIA	**WEIGHT**
Academic Qualifications	30
General Experience	20

CRITERIA	WEIGHT
Local & Regional Experience on similar Assignments/ Specific experience	30
Adequacy for the Assignment	10
Existing Commitments	10

In exceptional circumstances individual consultancies maybe considered based on the chosen laboratories i.e. one consultant for ISO/ IEC 17025 and one consultant for ISO 15189.

9.0 SUBMISSION REQUIREMENTS

All submissions must be in English Language, delivered via the form and media stated by the TTBS and delivered on the date requested and addressed to:

Procurement Officer

Trinidad and Tobago Bureau of Standards

Century Drive

Trincity Industrial Estate,

Macoya, Tunapuna

Trinidad, WI

Email: procurement.officer@ttbs.org.tt

Ph: 1(868)662-8827 Ext 2004

10.0 RESPONSIBILITY OF THE CLIENT

The TTBS, as the Executing Agency for the Project, shall support the implementation of this Consultancy.

Accordingly, the TTBS shall:

- Facilitate the arrangements for interviews and provision of access to project documents. Efforts will also be made to have the Consultant provided with relevant reports, information and contacts from other key stakeholders;
- Provide a Counterpart Team to guide the implementation of the Consultancy.
- Provide relevant and appropriate information as required by the Consultant.

11.0 RESPONSIBILITY OF THE CONSULTANT

The Consultant will:

- Absorb all other expenses including direct staff, office space and facilities, computer systems and software, telecommunication systems, travel expenses, and any other incidentals.
- Undertake the activities of the consultancy utilizing primarily its own resources.
- Respect and adhere to the proposed time-frames.
- Conduct meetings with stakeholders in a professional, responsible manner.
- Ensure the confidentiality of all aspects of the process/consultancy

12.0 WORKING LANGUAGE

The working language shall be English

13.0 CONFIDENTIALITY

The Consultant shall not, except as authorized by TTBS or required by the stipulated duties under the contract, use for the Consultant's own benefit or gain or divulge to any persons, firm, company or other organization whatsoever any confidential information belonging to the laboratories or relating to the affairs or dealing which may come to the provider's knowledge during the engagement. This restriction shall cease to apply to any information or knowledge which may subsequently come into the public domain other than in breach of this clause.