July 2017

ISO/IEC17020 Stepwise Improvement Programme (SIP)

VERSION 1 JULY 2017

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LIST OF ACRONYMS

AB	Accreditation Body (within CARIFORUM)
ACP	African, Caribbean and Pacific
AFRAC	The African Accreditation Cooperation
APLAC	Asia Pacific Laboratory Accreditation Cooperation for chemical metrology
CAB	Conformity Assessment Body
CARICOM	The Caribbean Community
CCA	Caribbean Cooperation for Accreditation
CRIP	Caribbean Regional Indicative Programme
CROSQ	CARICOM Regional Organisation for Standards and Quality
EA	European Accreditation
EDF	European Development Fund
EPA	Economic Partnership Agreement
IAAC	Inter-American Accreditation Cooperation
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
JANAAC	Jamaica National Agency for Accreditation
NAFP	National Accreditation Focal Points
NQI	National Quality Infrastructure
NSB	National Standards Body
PTB	Physikalisch-Technische Bundesanstalt
QA	Quality Assurance
QMS	Quality Management System
RQI	Regional Quality Infrastructure
SADCA	Southern African Development Community Cooperation in Accreditation
SIP	Stepwise Improvement Programme

SLIPTA	Stepwise Laboratory Improvement Process towards Accreditation
SLMTA	Strengthening Laboratory Management Toward Accreditation
TBT	Technical Barriers to Trade
TTLABS	Trinidad and Tobago Laboratory Accreditation Service
VIM	International Vocabulary of Metrology

PREFACE

This Stepwise Improvement Programme (SIP) will form part of the overall toolkit which is intended for National Accreditation Focal Point (NAFP) Officers tasked with assisting, guiding and assessing labs on their path towards accreditation. Other persons who are involved in the accreditation process and who are specifically engaged in the use of, or assessment against the *ISO/IEC 17020:2012 Conformity Assessment - Requirements for the operation of various types of bodies performing inspection,* standard can also benefit from using this document.

This SIP has been developed from the ISO/IEC 17020:2012 that contains requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities.

The contents are the result of collaboration between the members of the Caribbean Cooperation for Accreditation (CCA) community. This specifically includes members of CARICOM Regional Organisation for Standards and Quality (CROSQ), Mr. Pasquale Paladino, (PTB Consultant) with reviews by the Accreditation Bodies (ABs) and the National Accreditation Focal Points (NAFPs) in the CARICOM region. We would like to thank all the who provided technical guidance and contributed to the design, creation and testing of the contents of this Guide.

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INTRODUCTION

The Caribbean Cooperation for Accreditation (CCA) was designed to increase the demand for accreditation by facilitating the outreach and management of accreditation services. This is particularly relevant for the small and developing nations of CARICOM. Based on discussions with the National Standards Bodies (NSBs), it became quite evident that it is important for CROSQ to help to build and expand the competency, expertise and/or capacities of the Conformity Assessment Bodies (CABs), National Accreditation Focal Points (NAFPs), and Accreditation Bodies (ABs) if the primary goal outlined is to be achieved in each Member State. This program therefore, facilitates the development of the Regional Quality Infrastructure (RQI) and advance the harmonisation of the National Quality Infrastructure (NQI) of Member States.

One response to this need is a Stepwise Improvement Programme (SIP) for the accreditation of Inspection Bodies to ISO/IEC 17020. This is the third SIP in the series, complementing the first two developed for medical and testing labs.

This SIP will enable inspection bodies to interpret and follow a simplified tiered approach to achieve accreditation. With the support of the NAFPs in the Member State, the SIP is designed to simplify the requirements in such a way as to engage the inspection bodies in meeting the requirements at a pace that is more easily handled by to the inspection body.

The programme will be primarily delivered through the assistance of the NAFPs. The NAFPs are the primary national institutions established in or through the NSBs to actively participate in the CCA. The responsibilities of the NAFPs are to strengthen the promotion of standards and quality and provide assistance to CABs, including inspection bodies. The NAFPs also facilitates the national quality infrastructure through guided interventions and capacity building of the CABs and QA service providers. This assistance is normally in the form of in-plant consultancy, mentorship, coaching and special training of CABs.

PURPOSE

The purpose of this document is to provide information and guidance for the implementation of ISO/IEC 17020 using the Stepwise Improvement Programme outlined below. It gives the key elements of the accreditation process and with the assistance of the NAFPs will guide the inspection bodies in the implementation of the requirements to achieve accreditation. The Stepwise Improvement Programme, assists in the preparation towards accreditation, will improve the quality of inspection services and consequently, trade relations at the regional and international levels. This guide however does not obviate the need for training and third party assistance; instead, it is intended to compliment and strengthen these activities.

DEFINITIONS

For the purposes of this document, the terms in the following table apply as well as terms and definitions given in:

1. ISO 9000 Quality management systems —Fundamentals and vocabulary
2. ISO/IEC Guide 2 Standardization and related activities -- General vocabulary,
3. ISO/IEC 17000 Conformity assessment -- Vocabulary and general principles
4. International Vocabulary of Metrology (VIM).
5. ILAC P15:07/2016 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies.

Accreditation	Accreditation is a procedure by which an authoritative body (Accreditation body) gives formal recognition that an organization or person is competent to carry out specific tasks. Inspection body accreditation is a process that employs independent external assessment to determine conformity with recognized standards for quality management systems (QMS) and competence in inspection practices. Accreditation is a validation process established to ensure that conformity assessment bodies (such as the inspection bodies) meet the needs and requirements of their clients.
Accreditation Body[1]	An authoritative body that performs accreditation
Certification	Procedure by which a third party (Certification body) gives written assurance that the capacity of a person, organization, or other entity to perform a function or service conforms to specified requirements
Certification bodies	Organizations or agencies with the authority to carry out third party certification activities (audits) following stipulated criteria and conditions in order to confirm that an organization has met the requirements of a standard.
Competence	The ability to apply knowledge and skills to achieve intended results
Inspection	Examination of a product, process, service, or installation or their design and determination of its conformity with specific requirements or on the basis of professional judgment, with general requirements
Inspection Body	Body that performs inspection
Licensure[2]	The granting of written permission to practice or operate a business. It is usually provided by a governmental agency.
Non-Conformity	The non-fulfilment of a requirement
Process	Set of interrelated or interacting activities which transforms inputs into outputs
Product	Result of a process
Quality Management System	Management system established to direct and control an organization with regards to quality
Registration	Procedure by which a body indicates that it is a legal entity
Service	Result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible

[1] The authority of an accreditation body is generally derived from government.

[2] Licensure is usually a legal requirement for operation. It ensures that an organization meets minimum standards to protect public health and safety. It must be renewed periodically through payment of a fee and/or proof of competence and is usually granted to an organization following an on-site inspection to determine if minimum service quality and health and safety standards have been met."

Standard	A document established by consensus and approved by a recognized body that contains technical specifications or other precise criteria to be consistently used as rules, guidelines, or definition of characteristics, to ensure that materials, products and services are fit for that purpose.

PROGRAMME OVERVIEW

Core Concepts

The ISO/IEC 17020 Stepwise Improvement Programme is designed to assist inspection bodies on their journey towards accreditation. It recognises the technical nature of the process required, the capacity challenges and the discipline needed to see the inspection body through the process of accreditation. This programme therefore seeks to lend assistance to the inspection body through the use of an incremental stepwise approach aided by the NAFPs. The programme is based on the fundamental concepts outlined in Figure 1 below that underpin the ISO/IEC 17020 Standard itself.

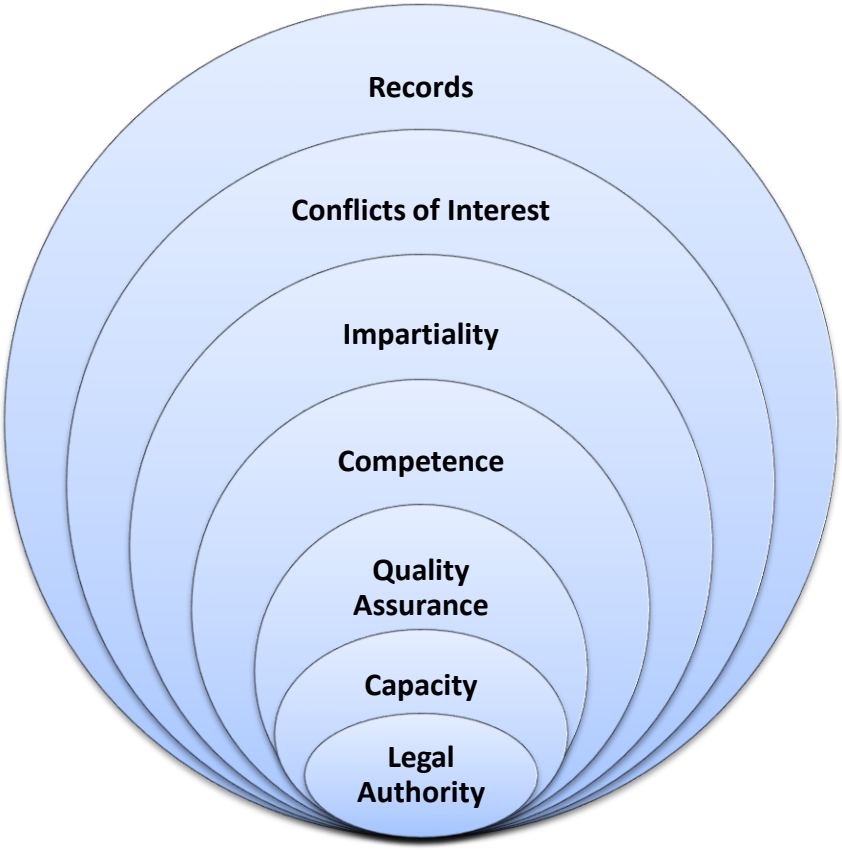


Figure 1: ISO/IEC 17020 Concept Diagram

The figure demonstrates the key requirements listed in the ISO/IEC 17020 starting with the requirement for ensuring the legality and authority of the inspection body. The capacity of the inspection body and the quality assurance in the execution of its duties are also principal features that

must be demonstrated in the operations. Competence must be complimented by impartiality, and the removal of any conflicts of interest. These are the features that inspire confidence and assure the inspection bodies' clients of the abilities of the inspection body to carry out the inspections.

The overarching proof of all the components is the records. Record keeping has always been the major challenge for many organisations. It normally requires a culture shift, dedication and commitment by all. It however is a measure of all the other inputs since it is the single most demonstrative proof of conformance and integrity. If what is not done is recorded as done, or what is done is not recorded, it will be discovered during the assessment and could result in additional scrutiny during the assessment and the issuance of nonconformities.

The figure's conical appearance is not intended to show hierarchy but rather the layered inclusive relationship of the measures. Stakeholders are therefore encouraged to buttress the information provided in this guide with hands-on understanding of ISO/IEC 17020 and related standards and tour the accreditation websites such as:

- Jamaica National Agency for Accreditation (JANAAC)
- Trinidad & Tobago Laboratory Accreditation Service (TTLABS)
- Inter-American Accreditation Cooperation (IAAC)
- International Laboratory Accreditation Cooperation (ILAC).
- International Accreditation Forum (IAF):
- Southern African Development Community Cooperation in Accreditation (SADCA)
- The African Accreditation Cooperation (AFRAC)
- Asia Pacific Laboratory Accreditation Cooperation for chemical metrology (APLAC)
- European Accreditation (EA)

Design Principles of the Tier Programme

The Stepwise Improvement Programme Checklist was designed and developed on the basis of ideas generated from a literature review and experiences with the practices cited in the Reference Section of this manual. As a stepping stone or tiered methodology to help a wide array of inspection bodies at various levels of maturity in respect of their quality management systems, it is structured along a linear approach to evolution in preparation for accreditation, but with full acceptance of the inherent multifaceted and multitasking nature of the job at hand.

The elements of the Checklist are drawn from an interpreted view of the more common achievements that can be used to demonstrate implementation of the respective clauses of the ISO /IEC 17020 Standard. This was done to make the requirements of the standard a little more tangible, understandable, intuitive, directional and motivational. Whilst comprehensiveness was a key design principle, there may be other illustrations of achievements that may be particularly useful to the specific inspection body or based on a Quality Manager's or Assessors own initiative and the Checklist can so accommodate.

Tier 1 seeks to highlight the minimum entry requirements of what it might take just to be in the business of inspection and is thus called Organizational Readiness. Tier 2 then focuses attention on developing the organization's human, plant and equipment resources and is therefore termed Personnel Excellence and Equipment Functionality. Tier 3 seeks to capture and codify for repeatability, the hallmarks of operational quality and hence the thematic title of Quality System Documentation and Realization. Tier 4, the Verification and Implementation of the Standard is of course then used to objectively assess the System's reliability and encourage learning and growth.

Participants in the Programme will be independently and objectively assessed against the respective Tier Checklists and will receive a Certificate of Recognition (Bronze, Silver or Gold) to the highest Tier achieved, except for Tier 1 which is an essential entry level requirement. Tier achievement will be judged by surpassing a minimum hurdle limit of accomplishment of elements in that tier; each element of which, for the purpose of this Improvement instrument, carries equal weight (though, depending on the nature of the inspection body and the inspections under consideration, this may not be so on a risk acceptance basis). The hurdle limits were initialized from literature reviews and experiences with comparative programmes within the context of what this SIP is trying to achieve via the CCA Scheme.

It is assumed that this tool will be used developmentally by someone with an understanding of the inspection environment, the ISO/IEC 17020 standard and a working knowledge of a quality management system; one does not have to be an expert to apply or assess against it.

Completing all the Tiers is of course not a guarantee for accreditation by any internationally recognized Accrediting Body (AB). It is however a logical aid to the process and facilitates an understanding of the principles of accreditation.

Criteria for the award of recognition Certificates for Tier Achievement

<table>
<tr><th>% Completion</th><th>Award</th><th>Comments</th></tr>
<tr><td>≥ 90% Tier 1</td><td>N/A</td><td>Eligible to enter the Tier Recognition part of the Programme</td></tr>
<tr><td>100% Tier 1
≥ 75% Tier 2
≥ 10% Tier 3</td><td>Bronze Certificate of Achievement</td><td rowspan="3">See below for additional criteria</td></tr>
<tr><td>100% Tier 1
≥ 90% Tier 2
≥ 75% Tier 3
≥ 25% Tier 4</td><td>Silver Certificate of Achievement</td></tr>
<tr><td>100% Tier 1
100% Tier 2
≥ 90% Tier 3
≥75% Tier 4</td><td>Gold Certificate of Achievement</td></tr>
<tr><td colspan="3">Note: Prior to submitting application to the Accreditation Body, there should be a well thought out and documented action plan and corrective measures to fill the gaps that are identified under this programme.</td></tr>
</table>

The Process of the Tier Recognition Programme

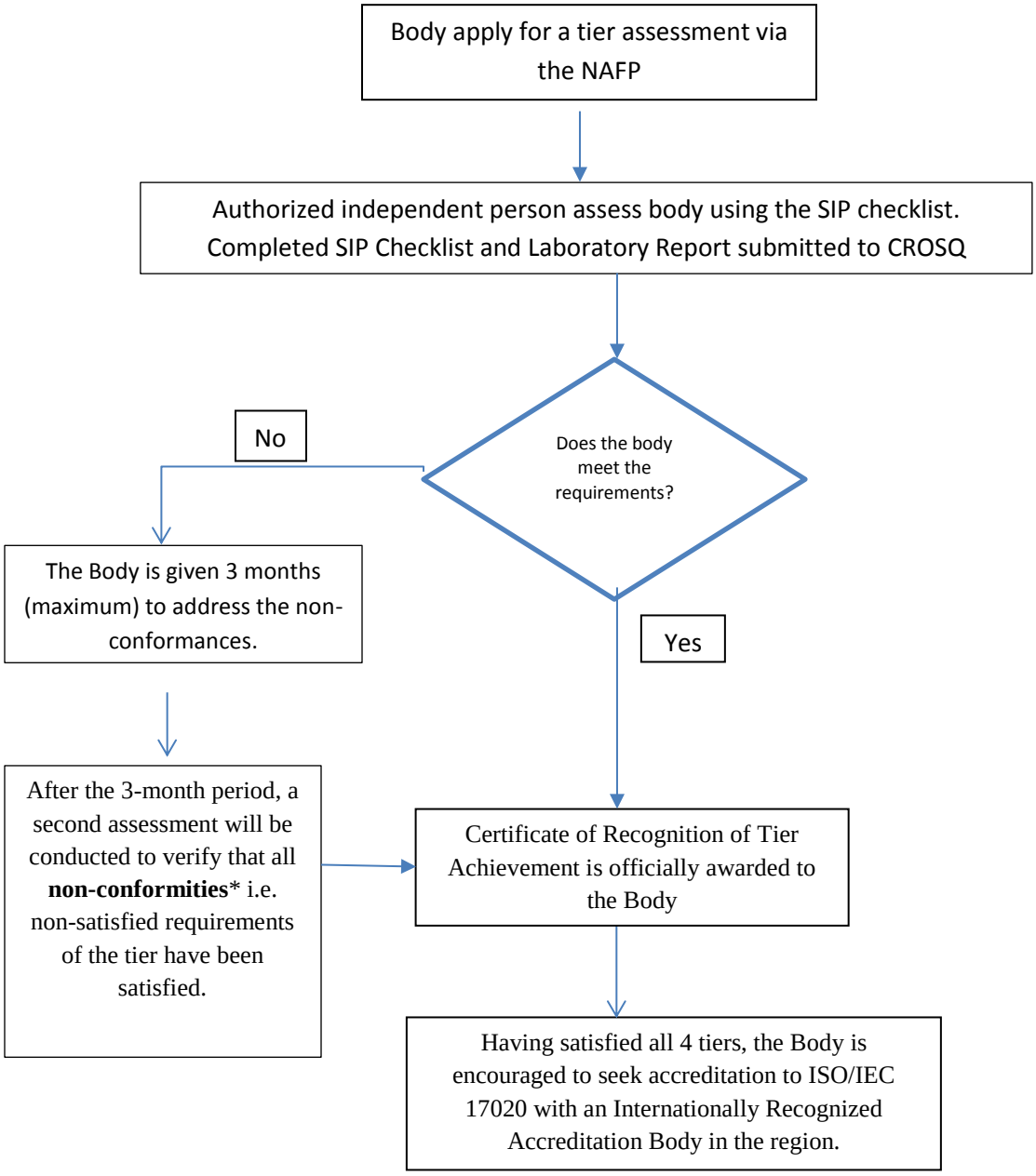
An independent assessment and gap analyses must be conducted in the inspection body at the end of each Tier from level 2 upwards in order to qualify for the Certificate of Achievement. Where the results show that the inspection body has achieved the stipulated minimum proportion of the requirements in each of Tier 1, 2, 3 and 4, of the SIP Checklist, the inspection body will receive an award. By the demonstration of commitment and achievement, this award programme is expected to:

- ✓ Boost the morale of the management and staff of the inspection body.
- ✓ Assist the inspection body in gaining the possible recognition needed to attract possible funding and resource mobilization.
- ✓ Provide feedback to stakeholders on the progress being made by the inspection body.
- ✓ Enable the inspection body to know and understand their level of readiness for accreditation
- ✓ Provide a platform for improved communication on the QMS.

This awards programme is not expected to:

- ✓ Replace functional and meaningful programmes that may be already in use but rather complement them.
- ✓ Negate the need or use of consultants but may be applied without one.
- ✓ Solve all issues or challenges in the undertakings towards accreditation but to simplify and facilitate easier understanding.
- ✓ Reduce the scope of the accreditation but enhance the process of achieving accreditation to the scope.

For the successful completion of any tier and the award of a Certificate of Tier Achievement as outlined in the table above, the following process shall apply:


Body apply for a tier assessment via the NAFP
Authorized independent person assess body using the SIP checklist. Completed SIP Checklist and Laboratory Report submitted to CROSQ
Does the body meet the requirements?
No
Yes
The Body is given 3 months (maximum) to address the non-conformances.
After the 3-month period, a second assessment will be conducted to verify that all **non-conformities*** i.e. non-satisfied requirements of the tier have been satisfied.
Certificate of Recognition of Tier Achievement is officially awarded to the Body
Having satisfied all 4 tiers, the Body is encouraged to seek accreditation to ISO/IEC 17020 with an Internationally Recognized Accreditation Body in the region.

PROGRAMME CONTENT

- ✓ **Tier 1 – Entry Level - Organizational Readiness**
  - Organization and Management
  - Impartiality and Confidentiality

- ✓ **Tier 2 – Bronze Level - Personnel Excellence, Facilities and Equipment Functionality**
  - Technical Competence
  - Facilities and Equipment
  - Subcontracting

- ✓ **Tier 3 – Silver Level – Process Requirements and Quality System Documentation and Realization**
  - Inspection methods and procedures
  - Handling of inspection items and samples
  - Inspection reports and certificates
  - Management system
  - Document control
  - Review of requests, tender and contracts
  - Subcontracting
  - Complaints and appeals
  - Corrective action
  - Preventive action
  - Control of records
  - Internal audits
  - Management reviews
  - Inspection method validation
  - Control of records
  - Inspection Equipment
  - Sampling
  - Handling of test and calibration items

- ✓ **Tier 4 – Gold Level - Verification of Implementation of the Standard**
  - Preventive action
  - Internal audits
  - Management reviews

Tier 1 – Entry Level				
Organizational Readiness	**Clause in ISO/IEC 17020**	**Expected Achievements**	**Achieved (Y/N)**	**Date**
Administrative Organization and Management	5.1 5.2	A Certificate of Registration showing inspection body as a Legal Entity or documentation to identify the inspection body's position within government		
		Evidence to demonstrate that the size, structure, composition and management of the inspection body is suitable for the performance of the activities.		
		Documentation which describes the activities for which the organization is competent.		
		Adequate insurance or reserves to cover liabilities.		
		Documentation describing the contractual conditions that it provides the inspections.		
		Management structure that safeguards impartiality.		
		An up-to-date organization chart inclusive of technical managers and person responsible for a. Ensuring that processes and procedures needed for the management system are established, implemented and maintained. b. Reporting to top management on the performance of the management system and any need for improvement.		
		A job description or definition of the responsibilities, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the inspections. These positions identified are those that could have an effect on the management, performance, recording or reporting of inspections.		
		Assignment of the technical manager(s)[3] and deputy(ies) and evidence of both parties' technical competencies.		
		Names of deputies for the technical manager.		
Impartiality, Independence and Confidentiality	4.1 4.2	Identified risks to impartiality of the inspection body. i.e are risk assessment done for all events and appropriate response(s) considered.		
		Related body analysis. All relationships analysed that can affect impartiality.		
		Conflict of Interest and Confidentiality Policies and forms signed by all Inspection body staff and contracted personnel		
		Able to demonstrate independence with respect to the entities/organizations for which inspection is provided		
Congratulations on the Successful Completion of Tier 1 – Entry Level **Continue to Tier 2 – Bronze Level**				

[3] Having responsibility for the technical operations and the provision of the resources to ensure the required quality of the inspections carried out.

Tier 2 – Bronze Level				
Personnel Excellence and Equipment Functionality	**Clause in ISO/IEC 17020**	**Expected Achievements**	**Achieved (Y/N)**	**Date**
Technical Competence	6.1	An evaluation of competence is completed for all personnel (employed or contracted) involved in inspection activities. This includes requirements for education, training, technical knowledge, skills and experience.		
		On-site observation of inspectors must show: a. The risks and complexities of the inspections. b. Results of previous monitoring activities c. Technical, procedural or legislative developments relevant to the inspections.		
		Competence requirement for each inspection activity must be identified		
		Monitoring and supervision of personnel and processes and equipment is being done.		
		A sufficient number of qualified personnel are performing specific tasks. Qualified personnel should be substantiated by a combination of information such as: a. satisfactory performance of examinations and determinations, b. positive outcome of report reviews, interviews, simulated inspections and other performance assessments (see note to clause 6.1.8), c. positive outcome of separate evaluations to confirm the outcome of the inspections (this may be possible and appropriate in the case of e.g. the inspection of construction documentation), d. positive outcome of mentoring and training, - absence of legitimate appeals or complaints, and e. satisfactory results of witnessing by a competent body, e.g. a certification body for persons.		
		Requirements for selecting, training, formally authorizing and monitoring inspectors and other personnel in inspection activities. Formal records of these activities are kept and should include: a. An induction period. b. A "mentored working period" [4] with experienced inspectors. c. Continued training to keep pace with developing technology and inspection methods.		
		Formal authorization must include: a. Area of authorised inspection activity b. Date of authorization c. Person performing authorization. d. Termination of authorization (where appropriate).		
		Management gave the requisite authorization of personnel to perform assigned task		

[4] with respect to the entities/organizations for which inspection is provided

		There are current job descriptions for managerial, technical and key support personnel involved in inspections		
		Management ensure all personnel act impartially and are not remunerated in a way that could influence the results of inspections.		
Facilities and Equipment	**6.2**	The inspection body has suitable facilities and equipment for carrying out inspections in a competent and safe manner.		
		Rules for access and use of facilities and equipment.		
		Each equipment and its related software used for inspection is uniquely identified and logged.		
		Procedures for maintenance of all equipment having an influence on the inspection results.		
		Policy or procedure to ensure that Reference Standard of measurement are used for calibration only providing traceability to a national or international standard of measurement. Where traceability to national or international standards of measurement is not applicable, evidence of correlation or accuracy of inspection results are kept.		
		Procedure for taking out of service, any equipment that has been subjected to overloading or mishandling (inclusive of falling),, gives suspect results, or has been shown to be defective or outside specified limits.		
		Procedure to ensure that all equipment under the control of the inspection body and requiring calibration are labelled, coded or otherwise identified to indicate the status of calibration. This should include the date showing when it was last calibrated, the date or expiration criteria and when recalibration is due. See section 6.2 ILAC P15 document.		
		Procedure is in place to carry out selection and approving of suppliers, verifications of incoming goods and ensuring suitable storage facilities.		
		Computers and automated equipment used for carrying out inspections are suitable for use and maintained and a procedure in place to ensure the integrity and security of data.		
Subcontracting	**6.3**	Records demonstrating that all subcontractors are competent and meet the requirement in ISO/IEC 17020.		
		Register of all qualified subcontractors.		
		Procedure to ensure clients are informed of any activity to be subcontracted.		

Congratulations on the Successful Completion of Tier 2 – Bronze Level
Proceed to Tier 3 – Silver Level

Tier 3 – Silver Level				
Process Requirements and Quality System Documentation and Realization	**Clause in ISO/IEC 17020**	**Expected Achievements**	**Achieved (Y/N)**	**Date**
Inspection Methods and Procedures	**7.1**	Procedure to ensure that appropriate methods or procedures are used when inspections are performed.		
		Any non-standard procedures or methods used are appropriate and documented.		
		Instructions, procedures, worksheets, checklists and reference data relevant to inspections that are maintained up-to-date and are readily available to personnel.		
		Procedure for inspection planning and sampling, as required.		
		Documented instructions for carrying out inspections.		
		Procedure for ensuring calculations and data transfer are appropriately checked.		
		Procedure for verifying information supplied by other parties.		
		Procedure for ensuring appropriate checks are carried out for calculations and data transfers.		
		Contract or work order control system.		
Handling Inspection Items and Samples	**7.2**	A system for uniquely identifying items and samples to be inspected.		
		A system for examining items before inspection, recording any abnormalities and informing client of status.		
		Have procedures and appropriate facilities for avoiding deterioration, loss or damage to inspected items during storage, handling and preparation.		
Inspection Records	**7.3**	A record system to demonstrate effective fulfilment of the inspection procedures and enable the evaluation of the inspection conducted.		
Inspection Reports and Certificates	**7.4**	Inspection reports/certificates for the inspections carried out. Reports/certificates must bear the name or identification of the inspector.		
		Procedure for making corrections or additions to inspection reports/certificates.		
Complaints and Appeals	**7.5** **7.6**	Have a policy and procedure for the resolution of complaints received from customers or other parties and for appeals of any decisions.		
		Have and maintain records of all complaints and of the investigations and corrective actions taken by the inspection body.		
Management system (Option A)	**8.1.2** **8.2**	Have a developed and implemented management system appropriate to the scope of the inspection activities.		
		A developed and approved quality manual, policy and objectives are in place. The quality policy statement is issued under the authority of the top management.		

		Top management commitment to the management system and communication to the organization of the importance of meeting customer requirements as well as the management system.		
		The roles and responsibilities of the quality manager, however named, are identified.		
		All documentation, processes, systems, records, etc. related to the requirements of ISO/IEC 17020 are included or referenced in the management system.		
Management system (Option B)	**8.1.3**	Management system that is demonstrated to comply with ISO 9001.		
Document control (Option A)	**8.4**	Procedures to control all documents that form part of its management system have been developed and are maintained.		
		All documents issued to personnel in the inspection body as part of the management system have been reviewed and approved for use by authorized personnel prior to issue.		
		Procedure to ensure that relevant versions of documents are available at points of use.		
		A procedure to prevent unintended use of obsolete documents.		
		A procedure to describe how changes in documents are maintained in computerized systems are made and controlled.		
Corrective action (Option A)	**8.7**	A procedure is in place for identifying and management of nonconformities and implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified.		
Preventive action (Option A)	**8.8**	A procedure for taking preventive actions to identify needed improvements and potential sources of nonconformities, either technical or concerning the quality system		
Control of records (Option A)	**8.4**	Have procedures for identification, collection, indexing, access, filing, storage, protection, maintenance and disposal of quality and technical records, including reports from internal audits and management reviews as well as records of corrective and preventive actions.		
Internal audits	**8.6**	Have a predetermined schedule and procedure for the conduct of internal audits of the inspection body's activities to verify that its operations continue to comply with the requirements of the quality system and ISO/IEC 17020.		
Management reviews	**8.5**	Have in place a predetermined schedule and procedure for the inspection body's top management to periodically conduct a review of the inspection body's management system and inspection activities to ensure their continued suitability and effectiveness, and to introduce necessary changes or improvements.		

Congratulations on the Successful Completion of Tier 3 – Silver Level
Proceed to Tier 4 - Gold Level

Tier 4 – Gold Level				
Verification of Implementation	**Clause in ISO/IEC 17020**	**Expected Achievements**	**Achieved (Y/N)**	**Date**
Preventive action (Option A)	**8.8**	Implemented preventive action procedure to identify needed improvements and potential sources of nonconformities, either technical or concerning the quality system.		
		Action plans developed, implemented and monitored to reduce the likelihood of the occurrence of identified potential nonconformities and to take advantage of the opportunities for improvement.		
Internal Audits (Option A)	**8.6**	Internal Audit conducted and audit report issued identifying areas of conformance and non-conformance issued.		
		Root cause analysis recorded for all nonconformities.		
		Corrective action plans are executed and maintained		
		Evidence of follow-up audit activities to verify and record the implementation and effectiveness of the corrective action taken.		
Management reviews (Option A)	**8.5**	Management Review conducted and findings documented.		
		Documentation of the findings and the actions taken to address the findings are available.		
Congratulations on the Successful Completion of Tier 4 **Proceed to Apply for Accreditation**				

REFERENCES

1. Quality Management Standards

    a) ISO/IEC 17020:2012 Conformity Assessment - Requirements for the operation of various types of bodies performing inspection
    b) ISO 9000 Quality management systems —Fundamentals and vocabulary
    c) ISO/IEC Guide 2 Standardization and related activities -- General vocabulary,
    d) ISO/IEC 17000 Conformity assessment -- Vocabulary and general principles
    e) International Vocabulary of Metrology (VIM).

2. Guidance Documents

    a) ISO/IEC17025 Stepwise Improvement Programme (SIP)
    b) WHO-AFRO Guidance for the Stepwise Laboratory Improvement Process towards Accreditation (SLIPTA). Draft Document
    c) The 20 Milestones Roadmap for ISO 15189 Accreditations
    d) Guidance on Quality Management Systems for Laboratories – Testing and Calibration (2010) G. Guevara and Ing. Manfred Kindler
    e) Guidance on Internal Auditing of Laboratories – Testing and Calibration (2010) G. Guevara and Ing. Manfred Kindler
    f) The Caribbean Cooperation for Accreditation Scheme Overview
    g) Caribbean Guidance on the Stepwise Improvement Process for Strengthening Laboratory Quality Management Systems towards Accreditation
    h) Checklist for The Stepwise Improvement Process for Strengthening Laboratory Quality Management Systems (LQMS-SIP) Towards Accreditation
    i) The impact of SLMTA in improving laboratory quality systems in the Caribbean Region. Guevara G, Gordon F, Irving Y, et al.

3. Websites

    a) Inter-American Accreditation Cooperation (IAAC)
    b) International Laboratory Accreditation Cooperation (ILAC).
    c) International Accreditation Forum (IAF):
    d) Southern African Development Community Cooperation in Accreditation (SADCA)
    e) The African Accreditation Cooperation (AFRAC)
    f) Asia Pacific Laboratory Accreditation Cooperation for chemical metrology (APLAC)
    g) European Accreditation (EA)