Caribbean Guidance on the Stepwise Improvement Process for Strengthening Laboratory Quality Management Systems towards Accreditation

2nd Edition (January 2016)
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<tr>
<th>ORGANIZATION TYPE</th>
<th>ORGANIZATION NAME</th>
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<tbody>
<tr>
<td>International Health Quality</td>
<td><strong>PAHO/ WHO</strong> - Pan American Health Organization/ World Health Organization</td>
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<tr>
<td></td>
<td><strong>CDC</strong> - United States Centres for Disease Control</td>
</tr>
<tr>
<td></td>
<td><strong>AFENET</strong> – African Field Epidemiology Network</td>
</tr>
<tr>
<td>Regional Quality Infrastructure</td>
<td><strong>CROSQ</strong> – CARICOM Regional Organization for Standards and Quality</td>
</tr>
<tr>
<td></td>
<td><strong>CROSQ CCA Committee</strong>- CROSQ Caribbean Cooperation for Accreditation Committee</td>
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<tr>
<td>Regional Intergovernmental Health</td>
<td><strong>CARPHA</strong> – Caribbean Public Health Agency</td>
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<tr>
<td></td>
<td><strong>PANCAP</strong> – Pan Caribbean Partnership Against HIV and AIDS</td>
</tr>
<tr>
<td>Regional Non-Governmental Health</td>
<td><strong>CMLF</strong> – Caribbean MedLabs Foundation</td>
</tr>
<tr>
<td></td>
<td><strong>CASMET</strong> – Caribbean Association of Medical Technologists</td>
</tr>
<tr>
<td></td>
<td><strong>CCAS</strong> – Caribbean Cytometry and Analytical Society</td>
</tr>
<tr>
<td>International Health</td>
<td><strong>UNAIDS</strong> – Joint United Nations Program on HIV and AIDS</td>
</tr>
<tr>
<td>Regional Accreditation Bodies</td>
<td><strong>TTlabs</strong>- Trinidad and Tobago Laboratory Accreditation Service</td>
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<tr>
<td></td>
<td><strong>JANAAC</strong> – Jamaica National Accreditation Agency</td>
</tr>
</tbody>
</table>
LIST OF LQMS-SIP STAKEHOLDERS

1. **AFENET** – African Field Epidemiology Network
2. **CARICOM** Bureaus of Standards
3. **CARICOM** Ministries of Health
4. **Caribbean Cooperation for Accreditation Scheme** – CCA Scheme
5. **CARPHA** – Caribbean Public Health Agency
6. **CASMET** – Caribbean Association of Medical Technologists
7. **CCAS** – Caribbean Cytometry and Analytical Society
8. **CDC** - United States Centres for Disease Control
9. **CMLF** – Caribbean MedLabs Foundation
10. **CROSQ** – CARICOM Regional Organization for Standards and Quality
11. **CROSQ CCA Committee** - CROSQ Caribbean Cooperation for Accreditation Committee
12. **JANAAC** – Jamaica National Accreditation Agency
13. **PAHO/WHO** - Pan American Health Organization/ World Health Organization
14. **PANCAP** – Pan Caribbean Partnership Against HIV and AIDS
15. Regional Hospital Laboratories
16. Regional Private Laboratories
17. Regional Public Health Laboratories
18. **TTlabs** - Trinidad and Tobago Laboratory Accreditation Service
19. **UNAIDS** – Joint United Nations Program on HIV and AIDS
20. Universities and Training Institutions
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CLSI</td>
<td>Clinical and Laboratory Standards Institute</td>
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<tr>
<td>IEC</td>
<td>International Electrochemical Commission</td>
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<td>IHR</td>
<td>International Health Regulations, 2005</td>
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<tr>
<td>ILAC</td>
<td>International Laboratory Accreditation Corporation</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
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<tr>
<td>LQMS</td>
<td>Laboratory Quality Management System</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>QMS</td>
<td>Quality Management System</td>
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<tr>
<td>QSE</td>
<td>Quality System Essentials</td>
</tr>
<tr>
<td>SLMTA</td>
<td>Strengthening Laboratory Management towards Accreditation</td>
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<tr>
<td>VIM</td>
<td>International Vocabulary of Basic and General Terms in Metrology</td>
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PREFACE TO THE SECOND EDITION

Following the production of the LQMS-SIP Guidance document in 2012 there have been several key developments following a series of stakeholder meetings held to advance the process and determine the way forward. From 2010 until 2013, a series of stakeholder meetings were held to advance the LQMS-SIP and determine the way forward as well as gather information and prepare implementation documents. From 2014 until the 2015, the LQMS-SIP had progressed significantly by updating the LQMS-SIP Checklist from the 2007 to 2012 version of the International standard ISO 15189- Medical Laboratories: Requirements for Quality and Competence, obtaining copyright permission from the ISO for the updated Checklist, creation of an electronic version of the Checklist, creation of a Laboratory Non-conformance Report and Laboratory Action Plan, execution of the LQMS-SIP Pilot Study, convening several Stakeholders’ Meetings, constitution and mobilization of the LQMS-SIP Project Steering Committee\(^1\), further laboratory assessments and preparation for the initial award of Certificates of Recognition of Tier Achievement to laboratories.

An LQMS-SIP Strategic Plan 2015-2018 (Including Marketing and Communications Agenda) was developed; the document was approved by the CROSQ Council at its 27\(^{th}\) Council Meeting in October 2015. The strategic agenda, vision and mission of the LQMS-SIP respectively are: “To encourage each CARICOM Member State to have all Medical Laboratories accredited to ISO 15189” and “To advance patient care in CARICOM through improved laboratory systems and services, stakeholder consultation and policy advocacy”

This 2nd edition documents the developments that have occurred since the publication of the 1\(^{st}\) edition in 2012.

\(^{1}\) The LQMS-SIP Project Steering Committee (PSC) was constituted in March 2015 and functions as the policy setting and technical advisory body for the LQMS-SIP. The PSC provides oversight to the LQMS-SIP, guides the project and provide inputs on behalf of the sectors that Committee Members represent.
BACKGROUND

At the Joint WHO-CDC Conference on Laboratory Quality Systems in Lyon, France, April 2008, the following statement supporting a stepwise, standards-based process towards internationally-recognized accreditation was issued - "It is recommended that countries with limited resources consider taking a staged approach, where principal requirements for all are stated in the national laboratory standards as a minimum requirement, while more advanced and national reference laboratories are encouraged to aim at meeting internationally accepted standards such as ISO 15189." In order to fulfill this mandate it was agreed to develop a stepwise process for implementing laboratory quality management systems in the Caribbean.

The President’s Emergency Plan for AIDS Relief (PEPFAR) programme for the Caribbean Region was established in 2008 to address health system challenges, including fragile laboratory services and systems. The laboratory component of this programme consisted of several phases: assessment of laboratory needs of all 12 countries engaged in the programme; addressing gaps identified during the assessment; and monitoring and evaluation of the progress achieved. After one year of PEPFAR collaboration with national governments and other partners, laboratory services and systems greatly improved. Some of the milestones include: (1) the accreditation of a public laboratory; (2) improved access to HIV diagnosis with faster turnaround time; (3) establishment of capacity for platforms for DNA PCR, viral load and HIV drug resistance; (4) development of the laboratory workforce; and (5) establishment of a framework for implementation of sustainable quality management systems for laboratory accreditation. The progress recorded in strengthening laboratory health systems after one year of initiating this collaboration showed that with a rigorous initial assessment, programme design and intervention and strategic partnership, national laboratory health systems can be greatly enhanced to support programme implementation. Continued collaboration and country leadership is critical to create an integrated and sustainable laboratory network in the Caribbean (Alemnji et al 2012 pp 1-13 Global Public Health: An International Journal for Research, Policy and Practice).

Over the years, many Caribbean laboratory staff have been provided with information on QMS and accreditation in various forms, including training, conferences, meetings and printed material. However, using this knowledge collectively and developing a comprehensive plan in order to address quality gaps and begin the journey toward accreditation have been challenging. During a preliminary laboratory needs assessment survey conducted in 2009, laboratory managers and other stakeholders discussed the problems of an undertrained laboratory workforce, the lack of motivation and, most importantly, the perception that the quality improvement process was cumbersome. The need to put strategies in place to eliminate these hindrances as soon as possible was emphasised. The recommendation was that a more user-friendly, stepwise approach to quality systems implementation, in combination with task-based training tools to improve staff knowledge,
could lead to more substantial improvement in quality systems (Guevera et al 2014 3 (2)pp 199, African Journal of Laboratory Medicine).

The Laboratory Quality Management System–Stepwise Improvement Process (LQMS-SIP) Towards Accreditation is a comprehensive approach to strengthen medical and public health laboratory services and systems throughout CARICOM, and implemented by CROSQ. The LQMS-SIP is supported by the United States Government Centers for Disease Control and Prevention (CDC)/PEPFAR funding. It is designed to recognize laboratories in the process of quality improvement, assess their progress and recognize milestones towards meeting Quality management system requirements of the ISO 15189 standard. This Stepwise Improvement Process provides for recognition of the implementation of Quality Management systems in CARICOM laboratories and acknowledges achievement of such in a three-tiered approach.

This process is intended to encourage, support and recognize the implementation of Quality Management Systems in medical laboratories in the Caribbean region to provide accurate, timely and reliable results for patient care and public health purposes in a safe environment. The implementation of LQMS-SIP is a comprehensive approach to strengthen national health laboratory services in a staged and sustainable manner by providing graduated levels of performance recognition towards achievement of the ISO 15189 standard. LQMS-SIP recognizes laboratories in the process of quality improvement, supports them through assessments, monitors and rewards progress towards meeting internationally accepted standards.

The approach consists of a three (3) tiered system with the first Tier representing the minimum requirements which should correspond to the mandatory ones required for the granting of a medical laboratory license based on legislation enacted by the Ministries of Health. The following two Tiers are Quality Improvement Levels representing achievement in meeting specific requirements of a quality management system.

This guidance document provides information on LQMS-SIP. It describes key elements of the laboratory quality improvement process and details how countries and partners will implement this laboratory systems strengthening initiative. This document covers the following key items:

1. Implementation structure
2. Stakeholder roles and responsibilities
3. LQMS-SIP Process and Procedures
4. Requirements for recognition
1. PURPOSE
The purpose of this document is to provide information and guidance for the Implementation of a Laboratory Quality Management System through the Stepwise Improvement Process towards Accreditation (LQMS-SIP) in the Caribbean. It describes key elements of the laboratory quality improvement process and details how countries and partners will implement this laboratory systems strengthening initiative. It is anticipated that this document will assist key stakeholders - CROSQ, CARPHA, MOH, Bureaus of Standards, Accreditation bodies, scientific and professional associations, to improve the quality of national health laboratory services.

1.2 DEFINITIONS
For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC Guide 2, ISO/IEC 17000, VIM and the following apply.

1.2.1 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. Laboratory accreditation is a process that employs independent external assessment to determine conformity with recognized standards for quality management systems (QMS) and competent laboratory practice. Accreditation is a validation process established to ensure that laboratories deliver high quality services that meet the needs and requirements of their clients.

1.2.2 ACCREDITATION BODY
An authoritative body that performs accreditation\(^2\); Accreditation bodies usually implement a QMS based on ISO/IEC 17011:2004 "Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies."

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\(^2\) The authority of an accreditation body is generally derived from government.
1.2.3 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 are 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.

1.2.4 LABORATORY MANAGEMENT
Person(s) who manage(s) the activities of a laboratory headed by a laboratory director

1.2.5 LICENSURE
The granting of ability to practice, usually provided by a governmental agency. Licensure is usually based on demonstrated knowledge, training and skills. Generally, when laboratory licensure is used, it is a legal requirement for operation.

Licensure:
- Exists to ensure that an organization meets minimum standards to protect public health and safety
- Is usually granted after some form of examination or proof of competence
- Must be renewed periodically through payment of a fee and/or proof of competence
- 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. Maintenance of licensure is an on-going requirement for the health care organization to continue to operate and care for patients

1.2.6 MEDICAL LABORATORY
Laboratory for the biological, microbiological, immunological, chemical, immune-hematological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

Note: These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or microorganisms. Facilities which only
collect or prepare specimens, or act as a mailing or distribution centre, are not considered to be medical or clinical laboratories, although they may be part of a larger laboratory network or system.

1.2.7 QUALITY MANAGEMENT SYSTEM
Management system to direct and control an organization with regard to quality

1.2.8 REGISTRATION
Procedure by which a body indicates relevant characteristics of a product, process or service, or particulars of a body or person, in an appropriate publicly available list

1.2.9 STANDARDS
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.

The most widely accepted international standards are issued by the International Organization for Standardization (ISO), a federation of national standardization bodies from more than 140 countries.

ISO 9001 specifies the basic requirements for a quality management system (QMS) that an organization must fulfill to demonstrate its ability to consistently provide products (which include services) that enhance customer satisfaction and meet applicable statutory and regulatory requirements. It belongs to a family of standards (ISO 9000) that is designed to help organizations ensure that they meet the needs of customers and other stakeholders.

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories; is the main ISO standard used by testing and calibration laboratories. Originally known as ISO/IEC Guide 25, ISO/IEC 17025 was initially issued by the International Organization for Standardization in 1999. There are many commonalities with the ISO 9000 standard, but ISO/IEC 17025 includes aspects for verifying the competence of persons. It applies directly to those organizations that produce testing and calibration results.

ISO 15184 Medical laboratories — Requirements for quality and competence; specifies the quality management system requirements particular to medical laboratories. While the standard is based

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3 For the purposes of ISO 15189, the "quality" referred to in this definition relates to matters of both management and technical competence
on ISO/IEC 17025 and ISO 9001, it is a unique document that takes into consideration the specific requirements of the medical environment and the importance of the medical laboratory to patient care as it includes requirements for: provision of advice to users of the laboratory service, the collection of patient samples, the interpretation of test results, acceptable turnaround times, how testing is to be provided in a medical emergency and the lab’s role in the education and training of health care staff.

Standardization bodies have the authority to develop standards. ISO is composed of national standardization bodies as members. National standardization bodies can either develop their own national standards or adopt international standards (an international standard may adapted to be a locally used standard).

4 The third edition (ISO 15189:2012) cancels and replaces the second edition (ISO 15189:2007), which has been technically revised. The current standard ISO 15189: 2012 may be updated in 2017
2. BENEFITS & CHALLENGES OF QMS, LABORATORY LICENSURE AND ACCREDITATION

There are many benefits and challenges to implementing a QMS and pursuing accreditation. Some of these are summarized in the table below. Accreditation and licensure work synergistically; accreditation is usually a voluntary process and sometimes is a mandatory requirement for licensure by governments or health insurance systems. Ensuring that all laboratories in a country comply with basic quality requirements through a robust licensure system will benefit public health by ensuring that laboratory results are accurate.

**Table 3: Benefits and Challenges of Quality Management Systems**

<table>
<thead>
<tr>
<th>BENEFITS</th>
<th>CHALLENGES</th>
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<tbody>
<tr>
<td>Decrease costs by effectively improving both its management systems and its technical service</td>
<td>Lack of adequate resources (human and financial) for implementing and maintaining a QMS</td>
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<tr>
<td>Minimize errors, “waste” and complaints</td>
<td>Lack of co-operation by both management and general staff</td>
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<td>Improve efficiency, safety and morale</td>
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<td>Achieve customer satisfaction by meeting customer’s expectations and preventing non-conformity at all stages of the process from sample receipt to result reporting</td>
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<tr>
<td>Enhance the performance of the organization through internal and external audits</td>
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</tr>
<tr>
<td>BENEFITS</td>
<td>CHALLENGES</td>
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<tr>
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<tr>
<td>• Ensures that minimum requirements to protect public health and safety are met</td>
<td>• Cost, sustainability, no financial incentives for a public health laboratory</td>
</tr>
<tr>
<td>• Provides proof of a laboratory's commitment to quality. This can be useful when lobbying for government, donor funding or research funding</td>
<td>• Achieving and maintaining the standards necessary for accreditation can be expensive for institutions</td>
</tr>
<tr>
<td>• Can be used as a marketing tool for laboratories; Laboratories that are accredited can be positioned as Centres of Excellence in the provision of key services thereby bringing significant value added both politically and strategically at the national and regional levels</td>
<td>• Lack of commitment by management to go through the process when there are no national regulations to drive the procedure</td>
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<tr>
<td>• Effective management of the quality system enhances staff discipline and development and helps to boost staff morale</td>
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<tr>
<td>• Users of laboratory services (clinicians, patients and public health units) are more likely to use and have confidence in the results coming from an accredited laboratory</td>
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<tr>
<td>• Facilitates the recognition of the laboratory's technical competency to perform its duties</td>
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<td>• Meeting international standards facilitates the compliance with national legal requirements and international standards</td>
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<tr>
<td>• It supports policies to keep abreast of new technological developments</td>
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<td>• It promotes continuous improvement of the services offered</td>
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<tr>
<td>• Accreditation increases confidence in the data that are generated and publicized by the laboratories and reduces uncertainties associated with decisions that affect the protection of human health and the environment</td>
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</table>
3. INTRODUCTION TO LQMS -SIP

The Caribbean is the world’s largest collection of small states, rich in culture and diversity. Despite the variable growth rates, per capita income, national literacy levels, and poverty levels, the region’s states share an increasing dependence on the tourism industry as the primary economic driver\(^5\). Given the fragility of the economies, a disease outbreak or wide-spread public health issue would have severe ramifications on not only the progress of social and economic development, but also create global isolation. Ensuring medical laboratories provide reliable information is critical to the regional economic thrust and the long-term vitality of the Caribbean, and must remain a priority for regional governments.

Establishing the supportive environment for high quality laboratory operations has been a major Caribbean focus since the early 1990s especially with the advent of the HIV/AIDS epidemic. In 2002-2007 CAREC implemented a European Union-funded Project entitled “Strengthening of Medical Laboratories in the Caribbean (SMLS).” Significant achievements of this project included the decision by regional Governments and laboratory management that the ISO 15189 be adopted as the Standard for medical laboratories in the region, development of draft model legislation for regulation of medical laboratories, collaboration with CROSQ, JANAAC and TTLABS for establishment of a regional accreditation mechanism for medical laboratories, initial training of National Accreditation Focal Points and assessors to support the regional accreditation mechanism, building laboratory and quality management capacity among senior laboratory professionals, providing QMS training for more than 1000 medical laboratory technologists (MLTs) across the region and transforming the MLT curricula used by Caribbean training institutions.

Since 2008, Laboratory Strengthening activities have continued in the Caribbean with numerous inputs from several NGOs including the Caribbean Med Labs Foundation (CMLF) (CARICOM PANCAP Global Fund Round 9 implementing partner), the African Field Epidemiology Network (AFENET) (PEPFAR Laboratory Implementing partner) and Clinton Health Access Initiative (CHAI). These collaborative efforts continue in conjunction with national governments, CARPHA, CROSQ, CARICOM (PANCAP), PAHO/WHO and CDC, all with the same goal of building Laboratory capacity, improving quality management, supporting accreditation process and reducing error rates.

The Strategic Plan for the Caribbean Community (2015-2018) outlines the strategic repositioning of the Community, and captures a development agenda going forward that encompasses: i) a review of development needs; ii) a Resilience Model for socio-economic progress; iii) strategies to renew the commitment to and strengthen actions for enhancing regional unity; and, iv) an agenda for the reform of governance mechanisms to achieve these two major forward thrusts. The specific strategic areas that are related to the LQMS-SIP are as follows:

\(^5\) World Travel and Tourism Council Economic Impact Caribbean Report 2015
1. **Priority: Social Resilience** – Equitable Human and Social Development

2. **Goal**: To ensure sustainable human and social development in the Region with reduced levels of poverty and equitable access by vulnerable groups and significant improvement of citizen security by facilitating a safe and just and free Community

3. **Strategy 3**: Advance Initiatives for Health and Wellness

**Strategic objective:**

- **To reduce mortality and morbidity related to NCDs and HIV with a focus on:**
  - Health education and prevention initiatives re NCDs and HIV/AIDS
  - Regional management of pandemics
  - Creating an enabling environment and facilitation of inter-sectoral actions for improved health and wellness across the Community

Strengthening Caribbean medical and HIV laboratory testing services will support the achievement of UNAIDS 90-90-90 Targets. In 2014, UNAIDS launched new targets for the scale up of antiretroviral treatment. The aim is that by 2020, 90% of all people living with HIV will know their status, 90% of all people living with HIV will receive sustained HIV antiretroviral therapy and 90% of all people receiving HIV antiretroviral therapy will have durable viral suppression. The medical diagnostic laboratory services which are required to support the HIV treatment cascade are: HIV serology, 6P24, 7DNA PCR, 8NAAT testing, 9CD4 counts, chemistry, hematology and opportunistic infections testing, viral load and HIV virus drug resistance testing. Medical laboratories are essential for HIV drug resistance testing and surveillance providing valid, relevant and timely information to support HIV/AIDS treatment and care programmes.

Health and social care seeks to provide a competent service to doctors, patients, families, the public and regulators. The primary purpose of health and social care accreditation is to ensure that users of the service receive a consistent high level of care. CARICOM countries are being encouraged to develop a national laboratory policy which will govern the operation of the public and private medical laboratories, public health and hospital laboratories. In addition to the development of the

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6. P24 antigen testing is performed as part of a medical test that detects both P24 antigen and HIV antibody in the blood of patients. This test is used to screen for and diagnose HIV
7. DNA PCR is deoxyribonucleic acid polymerase chain reaction molecular test used to identify HIV
8. A NAAT is a nucleic acid amplification test is a molecular technique used to detect the HIV virus
9. A CD4 count is a lab test that measures the number of CD4 lymphocytes in a sample of blood. In people with HIV, it is the most important laboratory indicator of how well the immune system is working and the strongest predictor of HIV progression
national laboratory policy, instituting medical laboratory licensing is also important in establishing minimum requirements for operation. The LQMS-SIP Tier 1 requirements have been proposed as possible guidelines for medical laboratory licensing

The development of a national laboratory policy involves a detailed situational analysis involving a wide range of stakeholders, in-country policy makers and the public and private sector. A national laboratory policy includes a Laboratory Governance and Network Structure, Quality Management Systems, Laboratory Support Systems and Information and Data Management Systems.

Though the importance of public health reforms has been recognized, medical laboratories in the region continue to face barriers in the areas of legislation, accreditation, human resource development, laboratory management, and regional coordination. (Refer to Annex 1 - Summary of Country Legislation Regarding Laboratory Quality Standards in Caribbean Territories).
4. KEY DECLARATIONS

1. The International Health Regulations (2005): The IHR, which went into effect on 15 June 2007, requires countries to report certain disease outbreaks and public health events to WHO. This is an international legal instrument that is binding on 194 countries across the globe, including all the Member States of WHO. Their aim is to help the international community prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide. The IHR also require countries to strengthen their existing capacities for public health surveillance and response. Quality laboratory services are critical for IHR implementation.

2. Joint WHO-CDC Conference on Laboratory Quality Systems, Lyon, France (April 2008): “It is recommended that countries with limited resources consider taking a staged approach, where principal requirements for all are stated in the national laboratory standards as a minimum requirement, while more advanced and national reference laboratories are encouraged to aim at meeting internationally accepted standards such as ISO 15189.”

3. Meeting on implementation of CDC/WHO/PAHO Stepwise process to prepare laboratories for accreditation in the Caribbean Region, Port of Spain, Trinidad and Tobago (March 2010): In line with the WHO Lyon meeting in April 2008, PAHO/WHO—with the participation of other partners, including the United States CDC and CHAI, will provide guidance to develop a joint strategy to implement a stepwise approach to sustainable quality management systems and facilitate the process of accreditation of laboratories in the Caribbean region. PAHO/WHO and partners will advocate at all levels for a stepwise approach to strengthening, evaluating and recognizing progress in the improvement of laboratory quality management systems towards accreditation.

5. OVERVIEW OF THE LQMS-SIP INITIATIVE

The Caribbean Guidance for the LQMS-SIP provides a framework to support countries in their efforts to strengthen national laboratory services through the stepwise quality improvement process towards fulfillment of the ISO 15189 requirements. This process is intended to encourage, support and recognize the implementation of Quality Management Systems in medical laboratories in the Caribbean region to provide accurate, timely and reliable results for patient care and public health purposes in a safe environment.
Laboratories working through the programme will progressively develop compliance towards this ISO standard, and will ultimately be able to apply for accreditation from a recognized body.

The implementation of LQMS-SIP is a comprehensive approach to strengthen national health laboratory services in a staged and sustainable manner by providing graduated levels of performance recognition towards achievement of the ISO 15189 standard. Laboratories will be assessed against the requirements outlined in the LQMS-SIP using a 3 tiered system approach. LQMS-SIP recognizes laboratories in the process of quality improvement, supports them through assessments, provides technical assistance, monitors and rewards progress towards meeting internationally accepted standards. The process is expected to have a catalytic effect by:

- Encouraging quality improvement in individual laboratories
- Incorporating quality improvement into national and regional strategic and operational plans
- Sensitizing policy makers and laboratory staff to the benefits of sustainable Quality Management Systems

The first Tier will represent the minimum requirements which should correspond to the mandatory one required for the granting of a license based on legislation enacted by the Ministries of Health. Ministries of Health are expected to establish their own regulatory systems and build capacity for licensing. It is recognized that there will be countries with and those without national licensing requirements therefore the following will apply:

**Countries with licensing**

- These countries will be encouraged to upgrade (where applicable) their requirements to meet those of Tier 1.

**Countries without licensing**

- These countries will be encouraged to establish their own regulations to meet Tier 1 requirements and simultaneously can enroll their labs in LQMS-SIP and establish legal mechanisms for recognizing Tier 1 as national licensure.

The LQMS-SIP Secretariat provides assessments leading to recognition of enrolled laboratories that countries have prioritized for improvement. Following the assessment, laboratories that meet the QMS requirements will be recognized according to a three Tier system.

- One basic national mandatory level (Licensing and/or Quality Improvement: Tier 1)
- Caribbean Quality Improvement Milestones (Quality Improvement: Tier 2 and 3)

The second and third tiers correspond to quality improvement milestones based on the agreed criteria for QMS implementation. Once assessed, laboratories are expected to maintain their Tier
rating and work towards the next level, which would be evaluated during the reassessment process. Laboratories that have reached Tier 3 will be encouraged to enroll in an established ISO 15189 accreditation process. Figure 1 indicates the tiers of recognition employed in the LQMS-SIP.

Alternatively Ministries of Health could appoint the National Bureau of Standards/National Accreditation Focal Point (NAFP) or the NAFP within the Ministry of Health (if there is no National Bureau of Standards) to act on their behalf to determine whether the applying laboratory meets the minimum requirements before a formal application is sent to the LQMS-SIP Secretariat.

5.2 CARIBBEAN COOPERATION FOR ACCREDITATION SCHEME (CCA)

The Caribbean Cooperation for Accreditation (CCA) Scheme facilitates the harmonization of the Regional Quality Infrastructure (RQI) and supports the development of the National Quality Infrastructure (NQI) of Member States to enable intra and extra-regional trade by supporting Conformity Assessment Bodies (CABs) through coaching, training and other development assistance. The NAFP’s in each CARICOM country are working in a systematic way to improve their development and the work of the CCA is being enacted through the NAFP’s. A Developmental Rubric setting out three developmental stages – Beginning (Level 1), Emerging (Level 2) and Proficient (Level 3) based on the obligations of the NAFP as defined in the CCA MOU was prepared and is currently being implemented.

Figure 2: LQMS-SIP Quality Improvement Levels (PAHO-CDC Joint Initiative)
5.3 LQMS-SIP IMPLEMENTATION STRUCTURE

The LQMS-SIP Implementation structure is comprised of the following stakeholders:

1. CROSQ
2. LQMS-SIP Secretariat
3. LQMS-SIP Assessors
4. CARPHA
5. Ministries of Health
6. National Bureau of Standards
7. Accreditation bodies
8. Professional associations
9. PAHO
10. CDC
11. Additional Partners
12. Universities
13. Training institutions
6. STAKEHOLDER ROLES AND RESPONSIBILITIES

The stakeholders listed will play a role in implementing the process.

6.2 CROSQ

CROSQ is the CARICOM regional centre for promoting efficiency and competitive production in goods and services, through the process of standardization and the verification of quality. It is mandated to represent the interest of the region in international hemispheric standards work, to promote the harmonization of metrology systems and standards, and to increase the pace of development of regional standards for the sustainable production of goods and services in the CARICOM Single Market and Economy (CSME), and the enhancement of social and economic development.

The management of the LQMS –SIP will be based on the principles of mutual cooperation and collaboration amongst the recognized National Accreditation Bodies (NABs), National Accreditation Focal Points (NAFPs) and CROSQ Secretariat with coordination of support services by CROSQ Secretariat.

CROSQ’s Mandated objectives:

- Promote the development and harmonization of standards, metrology, technical regulations and the mutual recognition of conformity assessment procedures covering services provided in the Region
- Encourage the mutual recognition of accreditation and certification systems which are based on internationally accepted criteria
- Support standards infrastructure development at the national level
- Provide guidance to regional organizations and bodies regarding matters within its competence, including dispute settlement
- Promote awareness of standards and standards-related matters in governments, industry and commerce
- Promote and protect the interests of States Parties and Associate Members in regional and international standardising fora, including external negotiations
- Contribute to the preservation of the environment and conservation of the natural resources of the Community through its operations
o Promote consumer welfare and safety

o Facilitate the achievement of international competitiveness of regional goods and services by fostering a culture of quality in regional enterprises

**CROSQ’s Roles and Responsibilities as LQMS-SIP Secretariat**

1. Assist in strengthening of capacities of NAFPs and enrolled laboratories

2. Develop a marketing and communication strategy and mechanism to support laboratory system development, information sharing and communication

3. Coordinate periodic reviews of the LQMS-SIP with CARPHA and other stakeholders

4. Coordinate evaluations/assessments (impartiality will be insured) of enrolled laboratories and take decisions regarding the “tier” recognition to be given to assessed laboratories

5. Establish arrangements with NABs and Ministries of Health for conducting evaluations/assessments and issuing “joint” certificates

6. Monitor use of the LQMS-SIP recognition certificate

7. Promote technical guidelines i.e. for tiers of quality management systems implementation, for adoption by countries to facilitate the operation of the system

8. Convene a technical advisory committee to provide guidance on LQMS-SIP and establish criteria for classification of major and minor non-conformances

9. Develop and maintain a pool of qualified and competent assessors based on established criteria

**6.3 NATIONAL ACCREDITATION FOCAL POINTS/ NATIONAL ACCREDITATION BODIES**

**NAFPs’ Roles and responsibilities as part of the LQMS-SIP Secretariat**

o Promote the use and benefits of the LQMS-SIP within their country and serve as an information and resource centre for recognition under LQMS- SIP

o Monitor the use and report misuse of the LQMS –SIP Certificate to CROSQ Secretariat

o Provide mechanisms for capacity building in their respective countries for Laboratories seeking recognition under LQMS- SIP

o Promote LQMS-SIP process by serving as a liaison between CROSQ, Laboratories and MOH
- Incorporate activities supporting the implementation of the LQMS-SIP in NAFP annual work plans
- Participate in improvement activities sponsored by LQMS-SIP Secretariat

**NABs’ Roles and Responsibilities as part of the LQMS-SIP Secretariat**

1. Promote the LQMS-SIP
2. Conduct assessor training
3. Provide assessment services taking appropriate measures to ensure that chosen assessors are free from conflict of interest
4. Participate in evaluation activities as requested by the LQMS-SIP Secretariat

### 6.4 CARPHA

The Caribbean Public Health Agency (CARPHA) was legally established on 2nd July 2011 by an Inter-Governmental Agreement signed by Caribbean Community Member States. The creation of CARPHA signals a rationalization of public health arrangements in the Region, combining the functions of five Caribbean Regional Health Institutes into a single agency. The new arrangements are designed to maximize the benefit and effectiveness of existing public health work, boost collaborative initiatives, enhance evidence-based public health policy and achieve efficiencies. CARPHA is expected to provide leadership in public health, working with global, regional and national stakeholders to deliver better public health outcomes for the Caribbean residents and visitors.

**CARPHA will:**

- Enhance national capacities to deliver public health goods and services to address new and emerging public health priorities in the Caribbean through on-going skill building and collaboration
- Build strategic alliances with regional and international partners
- Mobilize resources for priority public health issues
- Support and coordinate the development of regional standards and networks related to laboratory practice
- Promote strategic alliances with Caribbean regional and international co-operation agencies for the benefit of quality management systems implementation
**CARPHA’s specific role in LQMS SIP will be to:**

1. Promote and advocate for the implementation of LQMS-SIP within the Region
2. Coordinate and promote quality assurance programmes for national health laboratories through consultation; training and oversight of implementation
3. Assist countries in accessing external quality assessment (EQA) schemes.
4. Participate in developing standards and regulation guidelines for all health-related laboratories
5. Collaborate with the review and updates of LQMS-SIP Checklist to keep it aligned with appropriate internationally recognized standards

**6.5 MINISTRIES OF HEALTH**

**MOH specific role in LQMS-SIP will be to:**

1. Designate an LQMS-SIP focal point responsible for coordination, information-sharing, and implementation
2. Develop and implement a country strategic plan for laboratory quality improvement and training with prioritization of potential applicant laboratories. Care should be given to the selection, orientation and performance evaluation of prioritized laboratories
3. Allocate financial and human resources
4. Oversee the implementation of corrective actions outlined in the assessment/audit reports
5. Grant licenses to laboratories (for countries with licensure requirements)

**6.6 BUREAU OF STANDARDS**

**Bureau of Standards roles and responsibilities in LQMS-SIP will be to:**

- Promote standardization in industry and commerce
- Prepare standards relating to products, measurements, materials, processes, etc. and their promotion at national, regional and international levels
- Provide certification of industrial products
o Assist in the production of quality goods

o Perform quality inspection of imports at ports of entry

o Improvement of measurement accuracies and dissemination of information relating to standards

o Provide for the testing, of locally manufactured and imported commodities with the view of determining whether such commodities comply with the provision of the Standards Act or any other law dealing with standards and quality

Bureaus of Standards specific role in LQMS SIP will be to:

1. Advocate for the use of the Tier approach (LQMS-SIP as a tool for assessment)

2. Support countries to establish its own set of standards according to country-specific needs and resource constraints, and based on regionally agreed requirements and internationally agreed standards

3. Provide technical assistance to national laboratories for implementation of quality management systems

4. Provide a pool of multi-disciplinary technical experts to serve as assessors

5. Provide laboratories with traceability of measurements

6.7 Professional Associations and Non-Governmental Organizations

Professional Associations and Non-Governmental Organizations specific role in LQMS SIP will be to:

1. Advocate and lobby for the enactment of national legislation for regulating laboratory operations based on LQMS-SIP requirements

2. Promote the implementation of QMS using LQMS-SIP

3. Contribute to the development of competencies required for effective and sustainable implementation of LQMS-SIP

4. Mobilize resources specifically for laboratory strengthening efforts in the region

5. Provide technical assistance and mentoring to regional laboratories for implementation of quality management systems
6. Provide training for improvement of laboratory services for laboratory staff and related support services

7. Facilitate linkages between the public and private sector

8. Provide a pool of multi-disciplinary technical experts to become advisors, mentors or assessors (taking appropriate measures to avoid any conflict of interest)

6.8 PAHO/WHO

WHO has a normative role in providing guidance on the appropriate selection, use of quality standards, promoting and monitoring implementation of quality management systems. In 2009 WHO, in collaboration with CDC and CLSI, published a training toolkit on laboratory quality management systems (LQMS) that has been used for training Laboratory Staff and Quality managers on the implementation of LQMS.

The Pan American Health Organization (PAHO) is an international public health agency with 110 years of experience in working to improve health and living standards of the countries of the Americas. It serves as the specialized organization for health of the Inter-American System. It also serves as the Regional Office for the Americas of the World Health Organization and enjoys international recognition as part of the United Nations system.

The Public Health Laboratory Services of the International Health Regulations, Alert and Response and Epidemic Disease, Area of Health surveillance, Disease Prevention and Control and Communicable Disease; (HSD/IR/LAB) and CARPHA will work in the Caribbean region to:

1. Improve and optimize public health laboratory services focusing on their essential functions

2. Support national and regional laboratory networks for the implementation of sustainable Quality Systems Management including biorisk management and good laboratory practice concepts, in accordance with International Standards such as ISO

3. Promote and monitor public health laboratory networking in the Region

4. Strengthen and expand existing infectious disease surveillance networks already operating in the Region, including reference laboratories for specific pathogens and disease

5. Support the development of an implementation component for laboratory quality improvement as part of the country’s strategic plan

6. Provide guidance on content and implementation as outlined in the LQMS-SIP Policy and Procedures (initial review and annual review), technical annexes and related documents

7. Develop a communication strategy that advocates and disseminates information with all countries on the Caribbean guidance on LQMS-SIP
6.9 PAHO (CPC)
Country Programme Coordinators (CPC) Representatives provide political support and strategic direction at sub-regional level while CPC Advisors provide technical support. PAHO Country Offices Country Representatives provide political support and strategic direction at country level. Health Services Advisors provide technical support to national staff for implementation of laboratory QMS plans.

6.10 CDC
Centers for Disease Control and Prevention (CDC) is one of the United States Government PEPFAR Implementing Agencies that utilizes its technical expertise in public health science and long-standing relationships with Ministries of Health across the globe to work side-by-side with countries to build strong national programs and sustainable public health systems that can respond effectively to the global HIV/AIDS epidemic and to other diseases that threaten the health and prosperity of the global community at large.

The Caribbean Regional Office (CRO) of the CDC was established in 2002 to improve the public health of the Caribbean region by supporting national governments and their partners – non-governmental, regional and international organizations – to characterize and effectively respond to the HIV/AIDS epidemic. CDC will provide further support to strengthen the CROSQ Secretariat that will coordinate the current quality systems strengthening and accreditation efforts.

CDC’s overall support for quality management systems and laboratory accreditation in the Caribbean region using the stepwise approach will be focused on the following priority areas:

- Developing National Laboratories’ Policies and Strategic Plans
- Strengthening a regional referral laboratory and sub-regional hubs, including infrastructure and equipment upgrades
- Increasing access to point-of-care laboratory services, including expanded HIV rapid testing and Prevention of Mother To Child Transmission (PMTCT) programs
- Enhancing Laboratory Quality Management System (LQMS) and the accreditation process to include Gap analysis, documentation, and training using the SLMTA package, and embedding laboratory mentors to drive through the accreditation process
- Supporting training, procurement, supply chain management systems, and Laboratory Management Information System (LMIS)
- Supporting the expansion of the Digital Proficiency Testing (PT) EQA panels and the Dry Tube Specimen (DTS) HIV EQA technology to testing sites
6.11 PANCAP
Pan Caribbean Partnership against HIV/AIDS (PANCAP) is a Caribbean regional partnership of governments, regional civil society organizations, regional institutions and organizations, bilateral and multilateral agencies and contributing donor partners which was established in 2001. PANCAP provides a structured and unified approach to the Caribbean's response to the HIV epidemic, coordinates the response through the Caribbean Regional Strategic Framework on HIV and AIDS to maximize efficient use of resources and increase impact, mobilizes resources and build capacity of partners.

PANCAP’s specific role in LQMS SIP will be to:

1. Promote and advocate for the implementation of LQMS-SIP within the Region
2. Facilitate linkages between the public health sector and private medical services sector
3. Promote public health laboratory networking in the Region
4. Contribute to the developmental processes required for effective and sustainable implementation of LQMS-SIP
7. STEPWISE LABORATORY IMPROVEMENT PROCESS

7.2 ELIGIBILITY AND APPLICATION FOR LQMS-SIP ENROLMENT

All registered public and private sector laboratories in the Caribbean are eligible for inclusion into the LQMS-SIP.

Countries without national laboratory regulations are encouraged to build their own regulatory systems and enact appropriate laws. During this period, the MOH can request support of the LQMS-SIP Secretariat to conduct an assessment for registered laboratories and advise on measures that need to be implemented in order to meet the minimum requirements defined by LQMS-SIP in Tier 1.

In order to start this process the MOH must have a strategic plan or policy that includes an action plan for implementation of laboratory quality improvement. The application request should aim at listing the laboratories to be enrolled for the year in order to facilitate the assessment process. All applications received will be reviewed by the LQMS-SIP Secretariat before laboratories are officially enrolled and scheduled for assessment.

In countries without licensing for Medical Laboratories, MOHs will submit applications from public laboratories that they have prioritized for quality improvement and private laboratories which have expressed an interest in the process.

In countries with licensing for Medical Laboratories, MOHs will submit applications from public laboratories. Registered or Licensed private laboratories can apply directly to the LQMS-SIP Secretariat. The Secretariat will inform the MOH about the application.

Unless there are special instructions from the MOH, enrolment will encompass the entire laboratory (all sections providing services for patients and/or public health). All services directly managed by the laboratory must also be declared on the application (Refer to Figure 3: Flow Chart of LQMS-SIP Process).

7.3 ENROLMENT

Upon approval of the laboratory's application by LQMS-SIP Secretariat an enrolment letter will be sent indicating the date of the enrolment, its enrolment number and suggested timeframes within which an assessment might be scheduled. Once an enrolment date has been issued, the laboratory will be considered an “ENROLLED LAB.”
Table 3: Laboratory Status Designations for LQMS-SIP

<table>
<thead>
<tr>
<th>Applicant Lab</th>
<th>Enrolled Lab</th>
<th>Assessed Tier 1</th>
<th>Assessed Tier 2</th>
<th>Assessed Tier 3</th>
<th>Graduate of LQMS-SIP Programme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application documents received</td>
<td>Application approved; ready to schedule assessment</td>
<td>Recognition meeting Tier 1 Requirements</td>
<td>Recognition meeting Tier 2 Requirements</td>
<td>Recognition meeting Tier 3 Requirements</td>
<td>Completed LQMS-SIP</td>
</tr>
</tbody>
</table>

Once the LQMS-SIP Secretariat has reviewed and approved the application, suitable assessors will be selected for the type of Laboratory. A team of assessors will be sent to conduct the laboratory assessments. Team size and composition may vary based on the size and scope of the laboratory, and the team will operate under the direction of a designated Lead Assessor. The Lead Assessor is the primary contact person for the team during the on-site assessment. The LQMS-SIP Secretariat has defined the Terms of Reference (TORs) for the assessors, who are bound by confidentiality and are free of conflicts-of-interest. Findings that indicate an LQMS-SIP assessor has breached confidentiality or participated in an assessment in which they had a conflict-of-interest will be acted upon by the Secretariat.

The LQMS-SIP Secretariat will facilitate the monitoring and evaluation of the performance of its laboratory assessors to ensure that standards of competence and professionalism are observed. This will be reviewed every two years through a combination of document review, field observation, competency exercises and solicitation of MOH and laboratory feedback. The LQMS-SIP Secretariat will coordinate logistics for the assessment team and communicate with the MOH/Laboratory to find suitable dates for the assessment.

Given the geographic range of this programme, if a MOH has successfully enrolled more than one laboratory, every effort will be made to schedule assessment visits that are of sufficient length to assess multiple laboratories. The length of assessment visits will vary based upon four main factors:

1. Number of laboratories to be assessed
2. The scope of the laboratories to be assessed
3. The number of assessors on the team
4. Logistics and transportation considerations.
8. LQMS-SIP CRITERIA AND CHECKLIST

8.2 CRITERIA
There are twelve areas (representing the twelve Quality System Essentials - QSE - of a Quality Management System as given in the LQMS Training Toolkit developed by WHO, CDC and CLSI). These areas will be assessed using the LQMS-SIP checklist that is based on the ISO 15189. The LQMS-SIP Process that laboratories will be evaluated on included these QSE's which are listed below:

QSE 1 - Organization
QSE 2 - Personnel
QSE 3 - Equipment
QSE 4 - Purchasing and Inventory
QSE 5 - Process Control (Pre-Analytical, Analytical, Post-Analytical)
QSE 6 - Documents and Records
QSE 7 - Information Management
QSE 8 - Occurrence Management
QSE 9 - Assessment
QSE 10 - Process Improvement
QSE 11 - Customer Service and Satisfaction
QSE 12 - Facilities and Environment

8.3 CHECKLIST
The LQMS-SIP checklist has one hundred and four requirements (104) that have to be met. The checklist follows the structure of the ISO 15189 and is organized into two main sections - Management Requirements and Technical Requirements. These are further subdivided into fifteen (15) and ten (10) sections, respectively. The same ISO 15189 standard clause numbering system has been used in the LQMS-SIP checklist categories (Table 4). Some clauses in the checklist have multiple requirements that require the satisfactory presence of all the sub-items listed below the main heading to receive full credit. The LQMS-SIP Checklist is available on the CROSQ website.
## Table 4: LQMS-SIP Checklist Sections and Tier Requirements

<table>
<thead>
<tr>
<th>Section</th>
<th>Requirements</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Number of Requirements at each Tier level</td>
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<tr>
<td></td>
<td>Tier 1</td>
<td>Tier 2</td>
<td>Tier 3</td>
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<tr>
<td><strong>Management Requirements</strong></td>
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<td>4.1</td>
<td>Organisation and Management Responsibility</td>
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<td>Document Control</td>
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<td>Resolution of Complaints</td>
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<td>Identification and Control of Nonconformities</td>
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<td>Personnel</td>
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<td>5.2</td>
<td>Accommodation and Environmental Conditions</td>
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<td>5.3</td>
<td>Laboratory Equipment, Reagents and Consumables</td>
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<td>Pre-Examination Processes</td>
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<td>5.5</td>
<td>Examination Processes</td>
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<td>5.6</td>
<td>Ensuring Quality of Examination Results</td>
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<td>Post-Examination Processes</td>
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<td>Reporting of Results</td>
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<td>Release of Results</td>
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<tr>
<td></td>
<td>42</td>
<td>81</td>
<td>104</td>
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</table>
DECISION-MAKING AND AWARDING OF RECOGNITION

After completing the assessment, the lead assessor will discuss the findings with the laboratory and will submit their assessment report to the LQMS-SIP Secretariat. The LQMS-SIP Secretariat will review and finalize the assessment report which will then be submitted to the laboratory along with a Laboratory Corrective Action Plan which is generated from the LQMS-SIP Checklist.

The laboratory will respond with a corrective action plan within 30 days and will then have a maximum of 90 days to provide evidence of satisfactory resolution of nonconformities before the LQMS-SIP Secretariat makes the final determination regarding the Certificate of Recognition of Tier Achievement the laboratory will be awarded.

FOLLOW UP ASSESSMENT FOR CONTINUED IMPROVEMENT PROCESS

Following assessment, successful laboratories will receive a Certificate of Recognition of Tier Achievement that is valid for two years from the date of issue. Applications for renewal should be submitted six months before the expiration of the certificate.

After obtaining Tier 3 recognition, laboratories are encouraged to request accreditation from a full member of ILAC, that is signatory to the ILAC Mutual Recognition Arrangement. Participating laboratories that obtain accreditation will be transitioned from the LQMS-SIP register and their achievement will be recognized on the CROSQ website. It is intended that this information will also be accessible from the CARPHA website through a link to the CROSQ site.

APPROPRIATE USE OF RECOGNITION CERTIFICATES

The LQMS-SIP Certificate of Recognition will clearly state that the laboratory has achieved a tier ranking on the LQMS-SIP Certificate of Recognition of Tier Achievement (Figure 1). This is not a certificate of laboratory accreditation. Laboratories displaying a LQMS-SIP recognition certificate must comply with the following provisions:

1. Display of certificate does not imply that the LQMS-SIP Secretariat, PAHO/WHO or CDC accept responsibility for activities carried out under the scope of the tier of recognition

2. A certificate may only be displayed at the laboratory to which it was issued. It cannot be transferred to another laboratory or displayed at another facility

3. Certificates cannot be amended or altered in any way

4. Certificates must be removed promptly following expiration

______________________________

10 The Jamaica National Agency for Accreditation JANAAC, signed an ILAC mutual recognition agreement on September 18th 2015 for testing ISO 15189 and for ISO/IEC 17025 31st August 2013
5. Certificates cannot be used in any way that might mislead the reader about the status of the laboratory.

Laboratories displaying the LQMS-SIP recognition certificate must notify the LQMS-SIP Secretariat in the event of a substantial change (e.g., change in key personnel, change of equipment, change of location) that affects the service provided by the laboratory. The LQMS-SIP Secretariat will determine the appropriate action to be taken. Failure to notify the LQMS-SIP Secretariat regarding major changes could result in suspension or withdrawal of recognition.

9. LQMS-SIP PROCEDURES

9.2 SUBMISSION OF INITIAL APPLICATION TO MOH - COUNTRIES WITH LICENSING

The local MOH will consider licensed public sector laboratories as candidates. Licensed private laboratories can apply directly to the Secretariat for enrolment. The initial application is to be sent by the candidate laboratory to their Ministry of Health LQMS-SIP Focal Point. All applications must meet the criteria outlined in the country strategic implementation plan or alternatively if the country does not have such a plan, the criteria in the LQMS-SIP enrolment process.

Continual cyclic mentoring and self-assessment activities may be needed to ensure that the laboratory candidate meets criteria outlined in the MOH country strategic implementation plan and the LQMS-SIP.

9.3 SUBMISSION OF INITIAL APPLICATION TO MOH - COUNTRIES WITHOUT LICENSING

The local MOH will consider registered laboratories (both private and public sector) as candidates. The initial application is to be sent by the candidate laboratory to their Ministry of Health LQMS-SIP Focal Point. All applications must meet the criteria outlined in the country strategic implementation plan or alternatively if the country does not have such a plan, the criteria in the LQMS-SIP enrolment process.

11 Countries without licensing will be encouraged to implement a licensing structure using LQMS-SIP Checklist Tier 1 requirements as the criteria for the minimum mandatory requirements within their licensure process.
9.3.1 DOCUMENTATION FOR LQMS-SIP ENROLMENT

Documentation required for Enrolment is as follows:

1. Completed Application form for LQMS-SIP
2. Company Registration (If available)
3. Certificate of Licensure (if applicable)
4. Laboratory Quality Manual (if available)
5. Laboratory Organisational Chart

- Once criteria are met, the candidate laboratory will send their completed application to the MOH LQMS-SIP Focal Point for consideration of LQMS-SIP enrolment.
- MOH LQMS-SIP Focal Point will send the completed application to LQMS-SIP Secretariat.
- LQMS-SIP Secretariat will confirm the receipt of application within two weeks.
- If a laboratory's application meets the LQMS-SIP criteria, the LQMS-SIP Secretariat will issue an enrolment letter and the laboratory will be considered an “Enrolled Lab.”

9.3.2 SELECTION OF ASSESSMENT TEAM AND ASSESSMENT

- Assessment team leader and team members will be contacted by LQMS-SIP Secretariat
- Assessors will be selected from the pool of trained assessors.
- LQMS-SIP Secretariat will communicate with the enrolled laboratory, while keeping MOH Focal Point informed, to find suitable dates for the assessment visit and coordinate logistics for the assessment team. The assessment of the laboratory must be conducted within a year of the enrolment date.
- Assessment team conducts assessment utilizing LQMS-SIP checklist
- Assessment team submits initial findings to LQMS-SIP secretariat and the enrolled laboratory
After completing the assessment, the assessment team will discuss the non-conformances cited with the Laboratory and will submit their report to LQMS-SIP Secretariat. The LQMS-SIP Secretariat will review the report and then submit it to the Laboratory and the country policy makers e.g. Ministry of Health, Chief Medical Officer.

9.3.3 ENROLLED LABORATORY TAKES CORRECTIVE ACTIONS
The laboratory will be encouraged to share the assessment report with the MOH and other in-country policy makers to rectify nonconformances. Corrective actions should be done within 3 months.

9.3.4 ASSESSMENT TEAM REVIEWS CORRECTIVE ACTIONS
**Major non-conformances:** The assessment team will conduct another site visit to re-assess the laboratory and submit final report to LQMS-SIP Secretariat which will in turn submit it to the enrolled Laboratory.

**Minor non-conformances:** The laboratory will submit documentation of corrective actions to the LQMS-SIP Secretariat which will in turn send them to the Assessment Team for review. After this documentation has been reviewed, the Assessment Team will submit a final report to the LQMS-SIP Secretariat.

The LQMS-SIP Secretariat will then make final determination regarding the level of recognition the enrolled laboratory will be awarded and issues Certificate of Recognition of Tier Achievement.

9.3.5 LQMS-SIP SECRETARIAT SENDS CERTIFICATE TO NAFP/LABORATORY
Successful laboratories will receive a certificate valid for 2 years from the date of issue. Applications for renewal should be submitted six months before the expiration of the certificate.

9.3.6 COMPLAINT RESOLUTION
During these processes circumstances may arise that warrant complaints from laboratories or MOHs. The LQMS-SIP Secretariat is responsible for ensuring that all complaints are dealt with impartially and objectively. Complaints must be submitted in writing to the LQMS-SIP Secretariat and will be handled in accordance with established procedures.
Figure 2: Flow Chart of LQMS-SIP Process

**Responsibilities**
- Laboratory/MOH
- LQMS-SIP Secretariat
- Assessment Team
- Lead Assessor
- Laboratory
- LQMS-SIP Secretariat
- LQMS-SIP Advisory Committee
- LQMS-SIP Secretariat

**Documents generated**
- Application form
- Assessor contract
- Assessor contracts
- Checklist
- Initial Assessment report
- Corrective Action report
- Final Assessment report
- Meeting minutes
CRITERIA FOR THE AWARD OF CERTIFICATES OF RECOGNITION OF TIER ACHIEVEMENT

Taking into consideration the technical and scientific data on the LQMS-SIP implementation, pilot study laboratory assessments and the current research findings on the stepwise process in the Caribbean, the following criteria have been developed.

TIER 1 CERTIFICATE

- Laboratory Achievement of 75% of LQMS-SIP Checklist Requirements for Tier 1
- Laboratory is provided with:
  - Completed LQMS-SIP Checklist generated during their laboratory assessment
  - LQMS-SIP Laboratory Report
  - Laboratory Corrective Action Plan
- Laboratory is given a time period of 3 months to address the non-conformances
- Laboratory is notified that after the 3 month period, a second laboratory assessment will be conducted using the LQMS-SIP Checklist to determine the progress
- Laboratory submits a Corrective Actions Report to the LQMS-SIP Secretariat which is reviewed by LQMS-SIP Technical and Management Assessors
- Laboratory is re-assessed and Certificate of Recognition of Tier Achievement is officially awarded to the laboratory; local policy makers and NAFP participate in ceremony

TIER 2 CERTIFICATE

- Laboratory Achievement of 100% of LQMS-SIP Checklist Requirements for Tier 1
- Laboratory Achievement of 85% of LQMS-SIP Checklist Requirements for Tier 2
- Laboratory is provided with:
  - Completed LQMS-SIP Checklist generated during their laboratory assessment
  - LQMS-SIP Laboratory Report
  - Laboratory Corrective Action Plan
- Laboratory is given a time period of 3 months to address the non-conformances
- Laboratory is notified that after the 3 month period, a second laboratory assessment will be conducted using the LQMS-SIP Checklist to determine the progress
- Laboratory submits a Corrective Actions Report to the LQMS-SIP Secretariat which is reviewed by LQMS-SIP Technical and Management Assessors
- Laboratory is re-assessed and Certificate of Recognition of Tier Achievement is officially awarded to the laboratory; local policy makers and NAFP participate in ceremony

TIER 3 CERTIFICATE

- Laboratory Achievement of 100% of LQMS-SIP Checklist Requirements for Tier 1
- Laboratory Achievement of 100% of LQMS-SIP Checklist Requirements for Tier 2
• Laboratory Achievement of 95% of LQMS-SIP Checklist Requirements for Tier 3
• Laboratory is provided with:
  o Completed LQMS-SIP Checklist generated during their laboratory assessment
  o LQMS-SIP Laboratory Report
  o Laboratory Corrective Action Plan
• Laboratory is given a time period of 3 months to address the non-conformances
• Laboratory is notified that after the 3 month period, a second laboratory assessment will be conducted using the LQMS-SIP Checklist to determine the progress
• Laboratory submits a Corrective Actions Report to the LQMS-SIP Secretariat which is reviewed by LQMS-SIP Technical and Management Assessors
• Laboratory is re-assessed and Certificate of Recognition of Tier Achievement is officially awarded to the laboratory; local policy makers and NAFP participate in ceremony
• **Laboratory is encouraged to seek medical laboratory accreditation to ISO 15189 with JANAAC**

**RESOURCE REQUIREMENTS**

Available and sustainable resources in each country will be a major determinant on the number of laboratories that can be enrolled. MOH should provide human and financial resources as part of their Country Strategic Implementation Plan to facilitate the participation of public laboratories since their participation is contingent upon the availability of resources. Private sector laboratories will be expected to pay for their participation in LQMS-SIP; the quantum of the fee has not been determined. Resources will be required for the LQMS-SIP implementation in the areas of:

  o Technical assistance/mentoring
  o Process improvement
  o Infrastructural upgrades
  o Equipment service and maintenance
  o Assessments

The LQMS-SIP Strategic Plan (2016 -2018) was developed with a LQMS-SIP Strategic Agenda (2016 – 2018). Critical Success Factors were identified via an Environmental and Organizational Scan and

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12 The Jamaica National Agency for Accreditation JANAAC, signed an ILAC mutual recognition agreement on September 18th 2015 for testing ISO 15189

13 It is expected that a uniform scale for payment of experts in the required fields will be used
from these analyses Strategic Themes, Results and Objectives were developed. The Strategic Themes constitute the four main development pillars of a long term LQMS-SIP Program and the Strategic Objectives represent the building blocks of these pillars. Financial sustainability is one of the major strategic themes of the LQMS-SIP.

**Strategic Theme: Financial Sustainability**

**Result: Constant financial support for QMS development**

- Increase International Donor Funding - Cash/Kind
- Encourage Regional (CARICOM) Government Funding - Cash/ Kind
- Develop User Fees for Services
10 REFERENCES


8. Laboratory Quality Standards and their implementation. World Health Organization Regional Office for South-East Asia and Regional Office for the Western Pacific. 2011.


Annex 1: Summary of Country Legislation Regarding Laboratory Quality Standards in Selected Caribbean Territories
<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LEGISLATION (Up to an including the year 2010)</th>
<th>COMMENTS</th>
</tr>
</thead>
</table>
| Anguilla                | *Public Health Act(1969)  
*Health Authority Act  
*Bill for National Health Fund Act                                                                                       | No legislation in Anguilla governing laboratory standards and regulation of medical and public health laboratories is described as minimal. |
| Aruba                   | *Public Health Act (1989 )  
*Law on Medical Practice (1996)  
*Law on Dental Practice (1989)  
*Law on the Authorization of Pharmacists and Pharmacy Assistants (1960)                                                                 | Currently there is no legislation in the country which governs laboratory quality standards. Also the national quality standards employed are administered on a voluntary basis, similar to the international standards. Furthermore, while there is no specific agency or service responsible for overseeing the application of standards, health care legislation in Aruba usually falls under the scope of general laws - also referred to as organizational regulations – or as specific or individual laws. The Public Health Act outlines the scope for the general regulations that set the institutional framework for the health system. |
| *Antigua and Barbuda    | *Public Health Act, Cap 353  
*Health Professionals Act                                                                                               | Regulates systems of licensing and registration for medical laboratories, technologists and technicians. |
| Barbados                | *Health Services Act, Cap 44  
(Pathological Laboratories) Regulations (1976)                                                                         | Sets out requirements for registration and licensing of health professionals who are regulated |
| *Belize                 | *Standards Act (1992)  
Revised Edition of 2000  
Chapter 295 - Accreditation of Laboratories and Testing Facilities                                                            | These standards are administered by the Belize Bureau of Standards and currently govern laboratory standards |
| Bermuda                 | *Public Health Act (1949)  
*Public Health (Hospitals) Regulations (2002)  
*Public Health (Clinical Laboratories) Regulations (2002)  
*Public Health (accreditation bodies) Notice (2008)  
*Public Health (Diagnostic Facilities (Mammography) Regulations (2002)  
*Professions Supplementary to Medicine Amendment Act (2006)  
*Medical Practitioners Act (1950)                                                                                           | Public Health (Clinical Laboratories) Regulations 2002, 1949:24 – which outlines the Registration of clinical laboratories, Qualifications for registration, Registration, and Conditions. According to the latter, one of the main qualifications for registration is that the laboratory must be accredited by an accreditation body. |
| *British Virgin Islands | *Public Health Act (1976)  
*Medical Act (2000)  
*Nursing Act (1976)  
*BVI Health Services Act (2005)                                                                                           | No legislation governing laboratory standards |
| Cayman Islands          |                                                                                                                              |                                                                                              |
Curacao

The Ministry of Health also observes the Advisory Report of December 2009 by laboratories of the Netherland Antilles.

*Dominica

Dominica Medical Act 39:02

*Grenada

Hospital Act 1953
Medical Officers Act 1903
Medical Practitioners, Dentists and Veterinary Surgeons Registration Act 1982
Public Health Act 1925
Medical Products Act
Hospital Authority Act

*Guyana

Public Health Act 1925
Medical Products Act
Hospital Authority Act

*Haiti

Health Facilities Licensing Act 2007

*Jamaica

Insufficient information for Health and Healthcare Legislation

Public health services are currently administered by the Health Services Authority. As a government authority, it is the primary provider of healthcare services in the Cayman Islands, covering such areas as patient surgeries, critically ill patients, emergency medical services, general medical conditions, community health, dental and eye health, mental health, *paediatrics and pre-natal care. Also, effective July 1, 2008, the Department of Health Regulatory Services was established following a merger of the Health Insurance Commission with the Health Practice Commission. The department is responsible for the general regulatory framework for the delivery of health services including the:

- Regulation of health insurers;
- Regulation and licensing of healthcare facilities; and
- Supervision of councils regulating healthcare professionals

While this report addresses laboratory quality standards, such standards are not enforced and inspection of these facilities is often absent. Also, while laboratories in Curacao are also subject to international quality standards of ISO: 15189, regulation is described as minimal.

The Act was enacted to make provision for the registration of medical practitioners, dentists, opticians, and druggists, and to regulate the practice of medicine, surgery, dentistry, sight-testing, and the sale of drugs, however it does not regulate laboratory quality standards.

None of these address medical laboratories or Laboratory quality standards.

Laboratories which are attached to healthcare facilities are to be inspected and licensed (certified)

No legislation governing laboratory standards

Laboratory quality standards are not directly governed by health legislation; however under the Standards Act the Bureau of Standards Jamaica was
<table>
<thead>
<tr>
<th>Country</th>
<th>Legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Montserrat</td>
<td><em>Public Health Act</em></td>
</tr>
<tr>
<td></td>
<td><em>Medical Act</em></td>
</tr>
<tr>
<td>St. Christopher and Nevis</td>
<td><em>The Public Health Act</em>, No.22/1969</td>
</tr>
<tr>
<td></td>
<td><em>The Medical Act</em>, Cap 220</td>
</tr>
<tr>
<td>St. Lucia</td>
<td><em>No Legislation</em></td>
</tr>
<tr>
<td>St. Vincent and the Grenadines</td>
<td><em>No Legislation</em></td>
</tr>
<tr>
<td>Suriname</td>
<td><em>No Legislation</em></td>
</tr>
<tr>
<td>Trinidad and Tobago</td>
<td><em>Public Health Ordinance Chapter 12 No 4</em></td>
</tr>
<tr>
<td></td>
<td><em>Standards Act No.18 1997</em></td>
</tr>
<tr>
<td></td>
<td><em>Health Practitioners Ordinance (1978)</em></td>
</tr>
<tr>
<td></td>
<td><em>Public and Environmental Health Ordinance (1992)</em></td>
</tr>
<tr>
<td></td>
<td><em>National Insurance Ordinance (1991)</em></td>
</tr>
<tr>
<td></td>
<td><em>National Standards (2007)</em></td>
</tr>
<tr>
<td>Turks and Caicos</td>
<td><em>Established the Central Board of Health and inter alia makes provisions with respect to public health and infectious diseases.</em></td>
</tr>
<tr>
<td></td>
<td><em>Established the Trinidad and Tobago Bureau of Standards, which is the national standard-setting body upon which the Trinidad and Tobago Laboratory Accreditation Service (TTLABS) was developed.</em></td>
</tr>
<tr>
<td></td>
<td><em>TTLABS operates as the sole national laboratory accrediting body for testing and calibration laboratories. However the country currently does not have any legislation in place governing laboratory quality standards.</em></td>
</tr>
<tr>
<td></td>
<td><em>The Health Practice Commission is responsible for overseeing the application of standards as stated in the National Standards (2007).</em></td>
</tr>
<tr>
<td></td>
<td><em>Furthermore, results of the survey of health personnel and stakeholders in the Turks and Caicos revealed that there is legislation governing laboratory quality standards in the territory; however this legislation does not include the accreditation of laboratories. At the national level, quality standards are mandatory but at international standards are administered on a voluntary basis.</em></td>
</tr>
</tbody>
</table>

* Summary of legislation for CARICOM countries sourced from CROSQ Report on Legislation Developed/Implemented to Support Laboratory Accreditation to Provide Technical assistance, 2010
12 ANNEX 2: REQUIREMENTS FOR LICENSURE- TIER 1

The text of the LQMS-SIP Checklist Tier 1 (Requirements for Licensure) is taken from the ISO 15189:2012, *Medical Laboratories - Requirements for quality and competence*, is reproduced with the permission of the International Organization for Standardization, ISO. This standard can be obtained from any ISO member and from the website of the ISO Central Secretariat at the following address: www.iso.org. Copyright remains with ISO. In each of the main sections of the LQMS-SIP Checklist, the requirements are separated into 3 distinct tiers, based upon relative importance/complexity.

- The text noted in black represents the requirements for Tier 1
- The text noted in blue represents the requirements for Tier 2
- The text noted in green represents the requirements for Tier 3

The requirements for Tier 1 listed below are summarized from the LQMS-SIP Checklist. Every health facility licensed as a medical laboratory shall ensure that the requirements listed below are met.

**MANAGEMENT REQUIREMENTS**

**Organization and Management Responsibility (Clause 4.1)**

1. The laboratory or the organization of which the laboratory is a part, can be held legally responsible for its activities (Clause 4.1.1.2)

**Ethical Conduct (Clause 4.1.1.3)**

2. The laboratory has arrangements to ensure (Clause 4.1.1.3):

   a. No involvement in activities which would diminish confidence in the laboratory's confidence, impartiality, judgment or operational integrity.

   b. Management and personnel are free from undue commercial, financial or other pressures

   c. Potential conflicts of interest are openly and appropriately declared

   d. Procedures are in place to ensure that human samples, tissues or remains are treated according to relevant legal requirements

   e. Confidentiality of information is maintained

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3. A competent person(s) with medical, scientific and technical background directs the laboratory (Clause 4.1.1.4)

Management Responsibility (Clause 4.1.2)

4. Management provides evidence of commitment to the development and implementation of the QMS and its continual improvement (Clause 4.1.2.1)

5. An appropriate quality policy defining the intent of the quality management system been established and documented (Clause 4.1.2.3)

6. The quality policy includes (Clause 4.1.2.3):
   a. A commitment to good professional practice, to conducting examinations fit for intended use, compliance with the requirements of the International Standard and continual improvement of the quality of laboratory services
   b. A framework for establishing and reviewing the quality objectives
   c. The policy is communicated and understood within the organization

7. Management has established quality objectives which address the needs of the users, are consistent with the quality policy and are measurable (Clause 4.1.2.4)

8. Management has defined, documented and communicated the responsibilities, authority and interrelationships within the organization (Clause 4.1.2.5)
   a. Deputies for all key functions have been appointed (Clause 4.1.2.5)

9. A quality manager has been appointed with delegated responsibility and authority for development, implementation and compliance with the QMS (Clause 4.1.2.7)

Quality Manual (Clause 4.2.2.2)

10. The laboratory has an established a quality manual that is accessible to and used by staff (Clause 4.2.2.2)

11. The Quality Manual includes all the requirements of ISO 15189:2012 Clause 4.2.2.2

Document Control (Clause 4.3)

12. The laboratory has established and maintained procedures to control all documents that form part of its quality system (Clause 4.3)
13. The laboratory document control procedure includes all the requirements of ISO 15189:2012 Clause 4.3

Provision of Examination Results (Clause 4.5.2)

14. The referring laboratory is responsible for ensuring that the examination results from the referral laboratory is made available to the person making the request, unless otherwise specified (Clause 4.5.2)

15. The reports prepared by referring laboratories include all essential elements of the results reported, without alterations that could affect clinical interpretation (Clause 4.5.2)

16. Reports indicate which examinations were performed by the referral laboratory or consultant (Clause 4.5.2)

17. The author of any additional information (provided in the report) is identified (Clause 4.5.2)

18. The laboratory adopts the most appropriate means of reporting referral lab results (Clause 4.5.2)

19. There are mechanisms in place to ensure that collaboration between referring and referral laboratories are not hindered by commercial or financial considerations (Clause 4.5.2)

Control of Records (Clause 4.13)

20. The laboratory has a documented procedure for control of quality and technical records (Clause 4.13)

21. The laboratory facility has suitable record storage areas (Clause 4.13)

Evaluation and Audits (Clause 4.14)

22. The laboratory plans and implements the evaluation and internal audit processes needed to ensure conformity to the QMS, improve its effectiveness and meet user needs (Clause 4.14.1)

Internal Audits (Clause 4.14.5)

23. The laboratory conducts internal audits at planned intervals to ascertain whether the QMS (Clause 4.14.5):
a. Conforms to the requirements of the ISO 15189:2012 and the laboratory requirements
b. Is implemented, effective, and maintained

24. Personnel are trained to conduct audits which assess the performance of managerial and technical processes of the QMS (Clause 4.14.5)

25. Audit criteria, scope, frequency and methods are defined and documented (Clause 4.14.5)

26. Auditors are selected and audits conducted to ensure objectivity and impartiality of the audit process (Clause 4.14.5)

27. The laboratory has a documented procedure for conducting internal audits (Clause 4.14.5)

28. The laboratory undertakes corrective actions promptly (Clause 4.14.5)

TECHNICAL REQUIREMENTS

Personnel (Clause 5.1)

29. The laboratory (Clause 5.1):
   a. Has a documented procedure for personnel management
   b. Maintains records for all personnel to indicate compliance with requirements

Personnel Qualifications (Clause 5.1.2)

30. The laboratory management has documented the personnel qualifications for each position as appropriate for the tasks to be performed (Clause 5.1.2)

Job Descriptions (Clause 5.1.3)

31. The laboratory has job descriptions for all personnel (Clause 5.1.3)

Personnel introduction to the organizational environment (Clause 5.1.4)

32. The laboratory has an orientation programme for new staff (Clause 5.1.4)
Accommodation and Environmental Conditions (Clause 5.2)

33. The laboratory has work space that is designed to ensure the quality and efficacy of the service and the health and safety of laboratory personnel, patients and visitors (Clause 5.2.1)

34. The laboratory has evaluated the adequacy of the space allocated for its work (Clause 5.2.1)

35. The laboratory and office facilities provide a suitable environment that ensures the requirements of ISO 15189:2012 Clause 5.2.2

36. The laboratory has adequate storage spaces and conditions provided (Clause 5.2.3)

37. Clinical samples and materials stored appropriately to prevent cross contamination (Clause 5.2.3)

38. Laboratory storage and disposal facilities for dangerous materials appropriate to the hazards of the materials (Clause 5.2.3)

39. Laboratory staff have adequate access to washrooms, drinking water, storage facilities for personal protective equipment and clothing (Clause 5.2.4)

40. The laboratory has considerations made for accommodating patient comfort, needs and privacy when primary sample collection facilities are provided (Clause 5.2.5)

41. Appropriate first aid materials for both patient and staff needs are available at collection facilities (Clause 5.2.5)

42. The laboratory premises are maintained in a functional and reliable condition (Clause 5.2.6)

43. Laboratory work areas are clean and well maintained (Clause 5.2.6)

44. The laboratory monitors, controls and records environmental conditions (Clause 5.2.6)

45. The laboratory has effective separation between neighboring areas where incompatible activities are performed (Clause 5.2.6)

46. The laboratory has appropriate measures taken to prevent cross-contamination (Clause 5.2.6)

47. The laboratory provides a quiet uninterrupted work environment (Clause 5.2.6)
Laboratory Equipment, Reagents and Consumables (Clause 5.3)

Equipment (Clause 5.3.1)

48. The laboratory has a documented procedure for the selection, purchasing and management of equipment (Clause 5.3.1.1)

49. The laboratory is furnished with all the items of equipment required for its services (Clause 5.3.1.1)

Equipment Instructions for Use (Clause 5.3.1.3)

50. Only trained and authorized personnel operate laboratory equipment (Clause 5.3.1.3)

51. The laboratory has procedures for safe handling, transport, storage and use of equipment to prevent its contamination/deterioration (Clause 5.3.1.3)

52. The laboratory has up-to-date instructions on the use and maintenance of equipment readily available to laboratory personnel (Clause 5.3.1.3)

Laboratory Equipment, Reagents and Consumables (Clause 5.3)

Reagents and Consumables (Clause 5.3.2)

53. Instructions for use of reagents and consumables readily available (Clause 5.3.2.5)

Pre-Examination Processes (Clause 5.4)

54. The laboratory has documented procedures and information for pre-examination activities that ensure the validity of the results of examinations (Clause 5.4.1)

Information for Patients and Users (Clause 5.4.2)

55. The laboratory provides appropriate information for patients and users of the laboratory services (Clause 5.4.2)

56. The laboratory provides information for patients and users that include an explanation of the clinical procedures to be performed to facilitate informed consent (Clause 5.4.2)

Request Form Information (Clause 5.4.3)

57. The laboratory has request forms
Primary Sample Collection and Handling (Clause 5.4.4)

58. The laboratory has documented procedures for the collection and handling of primary samples that are available to sample collectors within and outside of the laboratory (Clause 5.4.4.1)

59. The laboratory has instructions for pre-collection activities (Clause 5.4.4.2)

60. The laboratory has instructions for collection activities (Clause 5.4.4.3)

Sample Transportation (Clause 5.4.5)

61. The laboratory has instructions for post-collection activities that address requirements for packaging of samples for transportation (Clause 5.4.5)

Documentation of Examination Procedures (Clause 5.5.3)

62. The laboratory documents all examination procedures in a language commonly understood by staff and available in an appropriate location (Clause 5.5.3)

63. Laboratory condensed documents correspond to the documented procedure (Clause 5.5.3)

64. All laboratory documents associated with the performance of examinations are subject to document control (Clause 5.5.3)

65. Laboratory procedure documents contain document identifiers and required information (Clause 5.5.3)

66. The laboratory explains the implications of changes to existing examination procedures to users, where the results of their interpretations could be significantly different after the laboratory has validated the procedure (Clause 5.5.3)

Ensuring the Quality of Examination Results (Clause 5.6)

67. The laboratory ensures the quality of examinations by performing them under defined conditions (Clause 5.6.1)
68. The laboratory ensures appropriate pre- and post-examination processes are implemented (Clause 5.6.1)

69. The laboratory ensures that no results are fabricated (Clause 5.6.1)

Quality Control Materials (Clause 5.6.2.2)

70. The laboratory uses appropriate quality control materials (Clause 5.6.2.2)

71. The laboratory periodically examines quality control materials to prevent erroneous results and to ensure continued suitability (Clause 5.6.2.2)

Post-Examination Procedures (Clause 5.7)

Review of Results (Clause 5.7.1)

72. The laboratory has procedures to ensure authorized personnel review examination results before release, against internal quality control, clinical information and previous examination results (Clause 5.7.1)

Storage, Retention and Disposal of Clinical Samples (Clause 5.7.2)

73. The laboratory has a documented procedure for identification, collection, indexing, access, retention, storage, maintenance and safe disposal of samples (Clause 5.7.2)

74. The laboratory has defined sample retention times with criteria which are based on the nature of the sample, the examination and specified requirements (Clause 5.7.2)

75. Laboratory samples disposed safely and in accordance with regulations or recommendations for waste management (Clause 5.7.2)

Reporting of Results (Clause 5.8)

Report Content (Clause 5.8)

76. The laboratory has a standardized reporting format (Clause 5.8.3)
13 ANNEX 3: REQUIREMENTS FOR TIER 2

- The text noted in black represents the requirements for Tier 1
- The text noted in blue represents the requirements for Tier 2

The requirements for Tier 2 listed below are summarized from the LQMS-SIP Checklist. Every health facility licensed as a medical laboratory shall ensure that the requirements listed below are met.

MANAGEMENT REQUIREMENTS

Organization and Management Responsibility (Clause 4.1)

1. The laboratory or the organization of which the laboratory is a part, can be held legally responsible for its activities (Clause 4.1.1.2)

Ethical Conduct (Clause 4.1.1.3)

2. The laboratory has arrangements to ensure (Clause 4.1.1.3):
   a. No involvement in activities which would diminish confidence in the laboratory’s confidence, impartiality, judgment or operational integrity.
   b. Management and personnel are free from undue commercial, financial or other pressures
   c. Potential conflicts of interest are openly and appropriately declared
   d. Procedures are in place to ensure that human samples, tissues or remains are treated according to relevant legal requirements
   e. Confidentiality of information is maintained

3. A competent person(s) with medical, scientific and technical background directs the laboratory (Clause 4.1.1.4)

Management Responsibility (Clause 4.1.2)

4. Management provides evidence of commitment to the development and implementation of the QMS and its continual improvement (Clause 4.1.2.1)
5. An appropriate quality policy defining the intent of the quality management system been established and documented (Clause 4.1.2.3)

6. The quality policy includes (Clause 4.1.2.3):
   a. A commitment to good professional practice, to conducting examinations fit for intended use, compliance with the requirements of the International Standard and continual improvement of the quality of laboratory services
   b. A framework for establishing and reviewing the quality objectives
   c. The policy is communicated and understood within the organization

7. Management has established quality objectives which address the needs of the users, are consistent with the quality policy and are measureable (Clause 4.1.2.4)

8. Management has defined, documented and communicated the responsibilities, authority and interrelationships within the organization (Clause 4.1.2.5)
   a. Deputies for all key functions have been appointed (Clause 4.1.2.5)

9. A quality manager has been appointed with delegated responsibility and authority for development, implementation and compliance with the QMS (Clause 4.1.2.7)

Quality Management System (Clause 4.2)

Documentation Requirements (Clause 4.2.2)

10. The QMS documentation includes procedures and records required by the International Standard ISO 15189
    a. The documentation includes copies of applicable regulations, standards and other normative documents

Quality Manual (Clause 4.2.2.2)

11. The laboratory has established a quality manual that is accessible to and used by staff (Clause 4.2.2.2)

12. The Quality Manual includes all the requirements of ISO 15189:2012 Clause 4.2.2.2

Document Control (Clause 4.3)

13. The laboratory has established and maintained procedures to control all documents that form part of its quality system (Clause 4.3)

14. The laboratory document control procedure includes all the requirements of ISO 15189:2012 Clause 4.3
Service Agreements (Clause 4.4)

15. The laboratory has documented procedures for the establishment and review of agreements to provide services (Clause 4.4.1)
   a. These agreements take into account the request, the examination and the report including any information needed to ensure appropriate examination and result interpretation
   b. The service agreements that the laboratory enters into meet all the requirements of ISO 15189:2012 Clause 4.4.1
   c. Records of these service agreements reviewed and any significant changes maintained (Clause 4.4.2)
   d. The same review process repeated if the service agreement needs to be amended after the work commences; Amendments are communicated to all parties affected (Clause 4.4.2)

Examination by Referral Laboratories (Clause 4.5)

Selecting and Evaluating Referral Laboratories and Consultants (Clause 4.5.1)

16. The laboratory has a documented procedure for selecting and evaluating referral laboratories and consultants (Clause 4.5.1)
   a. The procedure ensures that the laboratory meets the requirements of ISO 15189:2012 Clause 4.5.1

Provision of Examination Results (Clause 4.5.2)

17. The referring laboratory is responsible for ensuring that the examination results from the referral laboratory is made available to the person making the request, unless otherwise specified (Clause 4.5.2)

18. The reports prepared by referring laboratories include all essential elements of the results reported, without alterations that could affect clinical interpretation (Clause 4.5.2)

19. Reports indicate which examinations were performed by the referral laboratory or consultant (Clause 4.5.2)

20. The author of any additional information (provided in the report) is identified (Clause 4.5.2)

21. The laboratory adopts the most appropriate means of reporting referral lab results (Clause 4.5.2)
22. There are mechanisms in place to ensure that collaboration between referring and referral laboratories are not hindered by commercial or financial considerations (Clause 4.5.2)

Resolution of Complaints (Clause 4.8)

23. There is a procedure for the management of complaints or other feedback from patients, clinicians, laboratory staff and other parties (Clause 4.8)

24. There are records of complaints, investigations and corrective actions

Control of Records (Clause 4.13)

25. The laboratory has a documented procedure for control of quality and technical records (Clause 4.13)

26. The laboratory facility has suitable record storage areas (Clause 4.13)

Evaluation and Audits (Clause 4.14)

27. The laboratory plans and implements the evaluation and internal audit processes needed to ensure conformity to the QMS, improve its effectiveness and meet user needs (Clause 4.14.1)

Periodic review of requests, and suitability of procedures and sample requirements (Clause 4.14.2)

28. Authorized personnel periodically review the laboratory’s examinations to ensure they are clinically relevant (Clause 4.14.2)

29. The laboratory periodically reviews its sample collection requirements to ensure the sample is properly collected to preserve the measurand

Assessment of User Feedback (Clause 4.14.3)

30. The laboratory seeks information from users on whether the service has met user needs (Clause 4.14.3)

31. The methods for obtaining and using this information include cooperation with users or their representatives (Clause 4.14.3)

32. The information is obtained in a manner that ensures user confidentiality (Clause 4.14.3)

33. Records of information collected and actions taken are kept (Clause 4.14.3)

Staff Suggestions (Clause 4.14.4)

34. The Laboratory management encourages staff to make suggestions for the improvement of the laboratory service (Clause 4.14.4)
35. Suggestions are evaluated, implemented as appropriate and feedback provided to the staff (Clause 4.14.4)

36. Records of suggestions and action taken by the management are maintained (Clause 4.14.4)

**Internal Audits (Clause 4.14.5)**

37. The laboratory conducts internal audits at planned intervals to ascertain whether the QMS (Clause 4.14.5):
   a. Conforms to the requirements of the ISO 15189:2012 and the laboratory requirements
   b. Is implemented, effective, and maintained

38. Personnel are trained to conduct audits which assess the performance of managerial and technical processes of the QMS (Clause 4.14.5)

39. Audit criteria, scope, frequency and methods are defined and documented (Clause 4.14.5)

40. Auditors are selected and audits conducted to ensure objectivity and impartiality of the audit process (Clause 4.14.5)

41. The laboratory has a documented procedure for conducting internal audits (Clause 4.14.5)

42. The laboratory undertakes corrective actions promptly (Clause 4.14.5)

**Quality Indicators (Clause 4.14.7)**

43. The laboratory has established quality indicators to monitor and evaluate performance (Clause 4.14.7)

44. The laboratory has a planned process of monitoring quality indicators (Clause 4.14.7)

45. The laboratory periodically reviews their indicators, to ensure their continued appropriateness (Clause 4.14.7)
TECHNICAL REQUIREMENTS

Personnel (Clause 5.1)

46. The laboratory (Clause 5.1):
   a. Has a documented procedure for personnel management
   b. Maintains records for all personnel to indicate compliance with requirements

Personnel Qualifications (Clause 5.1.2)

47. The laboratory management has documented the personnel qualifications for each position as appropriate for the tasks to be performed (Clause 5.1.2)

Job Descriptions (Clause 5.1.3)

48. The laboratory has job descriptions for all personnel (Clause 5.1.3)

Personnel introduction to the organizational environment (Clause 5.1.4)

49. The laboratory has an orientation programme for new staff (Clause 5.1.4)

Training (Clause 5.1.5)

50. The laboratory provides training for all personnel inclusive of the areas listed in ISO 15189:2012 Clause 5.1.5

51. Trainees are supervised at all times (Clause 5.1.5)

52. The training programme is periodically reviewed for effectiveness (Clause 5.1.5)

Competence Assessment (Clause 5.1.6)

53. The laboratory assesses the competence of each person to perform assigned managerial or technical tasks (Clause 5.1.6)

54. The laboratory periodically reassesses competence and retrains when necessary (Clause 5.1.6)
Reviews of Staff Performance (Clause 5.1.7)

55. Staff performance reviews consider the needs of the laboratory and the individual in order to maintain or improve the quality of service provided (Clause 5.1.7)

Continuing Education and Professional Development (Clause 5.1.8)

56. The laboratory has a continuing education programme available to managerial and technical personnel (Clause 5.1.8)

   a. The programme is periodically reviewed for effectiveness (Clause 5.1.8)

57. Personnel regularly participate in professional development or other professional liaison activities (Clause 5.1.8)

Personnel Records (Clause 5.1.9)

58. Personnel records maintained and accessible for all personnel (Clause 5.1.9)

Accommodation and Environmental Conditions (Clause 5.2)

59. The laboratory has work space that is designed to ensure the quality and efficacy of the service and the health and safety of laboratory personnel, patients and visitors (Clause 5.2.1)

60. The laboratory has evaluated the adequacy of the space allocated for its work (Clause 5.2.1)

61. The laboratory and office facilities provide a suitable environment that ensures the requirements of ISO 15189:2012 Clause 5.2.2

62. The laboratory has adequate storage spaces and conditions provided (Clause 5.2.3)

63. Clinical samples and materials stored appropriately to prevent cross contamination (Clause 5.2.3)

64. Laboratory storage and disposal facilities for dangerous materials appropriate to the hazards of the materials (Clause 5.2.3)

65. Laboratory staff have adequate access to washrooms, drinking water, storage facilities for personal protective equipment and clothing (Clause 5.2.4)

66. The laboratory has considerations made for accommodating patient comfort, needs and privacy when primary sample collection facilities are provided (Clause 5.2.5)

67. Appropriate first aid materials for both patient and staff needs are available at collection facilities (Clause 5.2.5)
68. The laboratory premises are maintained in a functional and reliable condition (Clause 5.2.6)

69. Laboratory work areas are clean and well maintained (Clause 5.2.6)

70. The laboratory monitors, controls and records environmental conditions (Clause 5.2.6)

71. The laboratory has effective separation between neighboring areas where incompatible activities are performed (Clause 5.2.6)

72. The laboratory has appropriate measures taken to prevent cross-contamination (Clause 5.2.6)

73. The laboratory provides a quiet uninterrupted work environment (Clause 5.2.6)

Laboratory Equipment, Reagents and Consumables (Clause 5.3)

Equipment (Clause 5.3.1)

74. The laboratory has a documented procedure for the selection, purchasing and management of equipment (Clause 5.3.1.1)

75. The laboratory is furnished with all the items of equipment required for its services (Clause 5.3.1.1)

Equipment Acceptance Testing (Clause 5.3.1.2)

76. Equipment shown to be capable of achieving the performance required and complies with specifications relevant to the examinations concerned (Clause 5.3.1.2)

77. Each piece of equipment is uniquely labeled, marked or otherwise identified (Clause 5.3.1.2)

Equipment Instructions for Use (Clause 5.3.1.3)

78. Only trained and authorized personnel operate laboratory equipment (Clause 5.3.1.3)

79. The laboratory has procedures for safe handling, transport, storage and use of equipment to prevent its contamination/ deterioration (Clause 5.3.1.3)

80. The laboratory has up-to-date instructions on the use and maintenance of equipment readily available to laboratory personnel (Clause 5.3.1.3)

Equipment Maintenance and Repair (Clause 5.3.1.5)

81. The laboratory has a documented programme of preventive maintenance (Clause 5.3.1.5)
82. Equipment maintained in a safe working condition and in working order (Clause 5.3.1.5)
83. Defective equipment is taken out of service and clearly labeled (Clause 5.3.1.5)
84. Repaired equipment is shown by verification to meet specified acceptance criteria before being placed back in operation (Clause 5.3.1.5)
85. The laboratory examines the effect of defects on the previous examinations (Clause 5.3.1.5)
86. Reasonable measures are taken to decontaminate equipment prior to service, repair or decommissioning (Clause 5.3.1.5)
87. The laboratory provides suitable space for repairs and appropriate personal protective equipment (Clause 5.3.1.5)
88. When equipment goes outside the direct control of the laboratory, its performance verified before resumption of use (Clause 5.3.1.5)

Laboratory Equipment, Reagents and Consumables (Clause 5.3)

Equipment Records (Clause 5.3.1.7)
89. Records are maintained for each item of equipment that contributes to the performance of examinations

Reagents and Consumables (Clause 5.3.2)
90. The laboratory has a documented procedure for management and inventory of reagents and consumables (Clause 5.3.2.1)
91. The laboratory verifies that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration (Clause 5.3.2.2)
92. Received reagents and consumables stored according to manufacturer’s specifications (Clause 5.3.2.2)
93. The laboratory has an inventory control system for reagents and consumables (Clause 5.3.2.4)
94. The inventory control system segregates uninspected and unacceptable reagents and consumables from those that have been accepted for use (Clause 5.3.2.4)
95. Instructions for use of reagents and consumables readily available (Clause 5.3.2.5)

Reagents and Consumables (Clause 5.3.2)
96. The laboratory maintains records for each reagent and consumable that contributes to the performance of examinations (Clause 5.3.2.7)

97. The laboratory maintains records for each reagent that is prepared or completed in-house (Clause 5.3.2.7)

Pre-Examination Processes (Clause 5.4)

98. The laboratory has documented procedures and information for pre-examination activities that ensure the validity of the results of examinations (Clause 5.4.1)

Information for Patients and Users (Clause 5.4.2)

99. The laboratory provides appropriate information for patients and users of the laboratory services (Clause 5.4.2)

100. The laboratory provides information for patients and users that include an explanation of the clinical procedures to be performed to facilitate informed consent (Clause 5.4.2)

Request Form Information (Clause 5.4.3)

101. The laboratory has request forms (Clause 5.4.3)

102. The laboratory has a documented procedure regarding verbal requests for examinations (Clause 5.4.3)

Primary Sample Collection and Handling (Clause 5.4.4)

103. The laboratory has documented procedures for the collection and handling of primary samples that are available to sample collectors within and outside of the laboratory (Clause 5.4.4.1)

104. The laboratory has instructions for pre-collection activities (Clause 5.4.4.2)

105. The laboratory has instructions for collection activities (Clause 5.4.4.3)

Sample Transportation (Clause 5.4.5)

106. The laboratory has instructions for post-collection activities that address requirements for packaging of samples for transportation (Clause 5.4.5)
107. The laboratory has a documented procedure for monitoring the transportation of samples (Clause 5.4.5)

Sample Reception (Clause 5.4.6)

108. The laboratory has a sample reception procedure (Clause 5.4.6)

109. The lab have procedures for pre-examination handling, preparation and storage (Clause 5.4.7)

Examination Processes (Examination Processes)

Selection, verification and validation of examination procedures (Clause 5.5.1)

110. The laboratory uses validated examination procedures (Clause 5.5.1.1)

111. The identity of persons performing activities in the examination processes is recorded (Clause 5.5.1.1)

Documentation of Examination Procedures (Clause 5.5.3)

112. The laboratory documents all examination procedures in a language commonly understood by staff and available in an appropriate location (Clause 5.5.3)

113. Laboratory condensed documents correspond to the documented procedure (Clause 5.5.3)

114. All laboratory documents associated with the performance of examinations are subject to document control (Clause 5.5.3)

115. Laboratory procedure documents contain document identifiers and required information (Clause 5.5.3)

116. The laboratory explains the implications of changes to existing examination procedures to users, where the results of their interpretations could be significantly different after the laboratory has validated the procedure (Clause 5.5.3)

Ensuring the Quality of Examination Results (Clause 5.6)

117. The laboratory ensures the quality of examinations by performing them under defined conditions (Clause 5.6.1)

118. The laboratory ensures appropriate pre- and post-examination processes are implemented (Clause 5.6.1)
119. The laboratory ensures that no results are fabricated (Clause 5.6.1)

Quality Control (Clause 5.6.2)

120. The laboratory designs quality control procedures that verify the attainment of the intended quality of results (Clause 5.6.2.1)

Quality Control Materials (Clause 5.6.2.2)

121. The laboratory uses appropriate quality control materials (Clause 5.6.2.2)

122. The laboratory periodically examines quality control materials to prevent erroneous results and to ensure continued suitability (Clause 5.6.2.2)

Quality Control Data (Clause 5.6.2.3)

123. The laboratory has a procedure to prevent the release of patient results in the event of quality control failure (Clause 5.6.2.3)

124. The laboratory rejects results and re-examines patient samples when a quality control performance error is detected that indicates that examination results are likely to contain clinically significant errors (Clause 5.6.2.3)

125. The laboratory evaluates the results from patient samples examined after the last successful quality control event (Clause 5.6.2.3)

126. The laboratory reviews quality control data at regular intervals to detect trends and take preventive action as necessary (Clause 5.6.2.3)

Inter-Laboratory Comparisons (Clause 5.6.3)

Participation (Clause 5.6.3.1)

127. The laboratory participates in inter-laboratory comparisons appropriate to the examination and interpretations of results (Clause 5.6.3.1)

128. The laboratory monitors the results of inter-laboratory comparisons and participate in the implementation of corrective actions when performance criteria are not fulfilled (Clause 5.6.3.1)
129. The laboratory has a procedure for inter-laboratory comparison participation (Clause 5.6.3.1)

130. The programme provides clinically relevant challenges that mimic patient samples and check the entire examination process, where possible (Clause 5.6.3.1)

**Alternative Approaches (Clause 5.6.3.2)**

131. When inter-laboratory comparison programmes are not available, the laboratory develops approaches for determining the acceptability of examination results (Clause 5.6.3.2)

**Analysis of Inter-Laboratory Comparison Samples (Clause 5.6.3.3)**

132. The laboratory has integrated inter-laboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples (Clause 5.6.3.3)

  a. These performed by personnel who routinely examine patient samples using routine methods (Clause 5.6.3.3)

133. The laboratory avoids collaboration with other participants about sample data before the deadline for submission of the data (Clause 5.6.3.3)

134. The laboratory avoids referring inter-laboratory comparison samples before submission of results (Clause 5.6.3.3)

**Evaluation of Laboratory Performance (Clause 5.6.3.4)**

135. The performance in inter-laboratory comparisons is reviewed and discussed with relevant staff (Clause 5.6.3.4)

136. When pre-determined performance criteria are not fulfilled, staff participate in the effective implementation and recording of corrective action (Clause 5.6.3.4)

137. Preventive action is taken where trends in returned results indicate potential nonconformities (Clause 5.6.3.4)

**Post-Examination Procedures (Clause 5.7)**

**Review of Results (Clause 5.7.1)**
138. The laboratory has procedures to ensure authorized personnel review examination results before release, against internal quality control, clinical information and previous examination results (Clause 5.7.1)

Storage, Retention and Disposal of Clinical Samples (Clause 5.7.2)

139. The laboratory has a documented procedure for identification, collection, indexing, access, retention, storage, maintenance and safe disposal of samples (Clause 5.7.2)

140. The laboratory has defined sample retention times with criteria which are based on the nature of the sample, the examination and specified requirements (Clause 5.7.2)

141. Laboratory samples disposed safely and in accordance with regulations or recommendations for waste management (Clause 5.7.2)

Reporting of Results (Clause 5.8)

142. Results of each examination are reported accurately, clearly, unambiguously in accordance with specific instructions in a defined format and medium (Clause 5.8.1)

143. The laboratory has a procedure to ensure the correctness of result transcription (Clause 5.8.1)

144. There is a process for notifying requester when an examination which could compromise patient care is delayed (Clause 5.8.1)

Report Attributes (Clause 5.8.2)

145. Laboratory reports effectively communicate laboratory results and meet users’ needs in accordance with ISO 15189:2012 Clause 5.8.2

Report Content (Clause 5.8)

146. The laboratory has a standardized reporting format (Clause 5.8.3)

Release of Results (Clause 5.9)
147. The lab has documented procedures for the release of examination results, including who may release results and to whom (Clause 5.9.1)

Revised Reports (Clause 5.9.3)

148. The Laboratory has written instructions regarding the revision of reports ensuring the original report is referenced, the user is notified and the action is recorded (Clause 5.9.3)

149. The Laboratory keeps records of revisions when the reporting system cannot capture amendments, changes or alterations (Clause 5.9.3)

Laboratory Information Management (Clause 5.10)

150. The Laboratory has a documented procedure to ensure the confidentiality of patient information is maintained at all times (Clause 5.10.1)

Authorities and Responsibilities (Clause 5.10.2)

151. The laboratory has defined the authorities and responsibilities for the management of the information system, including maintenance and modification affecting patient care (Clause 5.10.2)

152. The laboratory has defined the authorities and responsibilities of the personnel who use the Information Management System (Clause 5.10.2)
14 ANNEX 4: REQUIREMENTS FOR TIER 3

- The text noted in black represents the requirements for Tier 1
- The text noted in blue represents the requirements for Tier 2
- The text noted in green represents the requirements for Tier 3

The requirements for Tier 2 listed below are summarized from the LQMS-SIP Checklist. Every health facility licensed as a medical laboratory shall ensure that the requirements listed below are met.

MANAGEMENT REQUIREMENTS

Organization and Management Responsibility (Clause 4.1)

1. The laboratory or the organization of which the laboratory is a part, can be held legally responsible for its activities (Clause 4.1.1.2)

Ethical Conduct (Clause 4.1.1.3)

2. The laboratory has arrangements to ensure (Clause 4.1.1.3):
   a. No involvement in activities which would diminish confidence in the laboratory’s confidence, impartiality, judgment or operational integrity.
   b. Management and personnel are free from undue commercial, financial or other pressures
   c. Potential conflicts of interest are openly and appropriately declared
   d. Procedures are in place to ensure that human samples, tissues or remains are treated according to relevant legal requirements
   e. Confidentiality of information is maintained

3. A competent person(s) with medical, scientific and technical background directs the laboratory (Clause 4.1.1.4)
**Management Responsibility (Clause 4.1.2)**

4. Management provides evidence of commitment to the development and implementation of the QMS and its continual improvement (Clause 4.1.2.1)

5. An appropriate quality policy defining the intent of the quality management system been established and documented (Clause 4.1.2.3)

6. The quality policy includes (Clause 4.1.2.3):
   
   a. A commitment to good professional practice, to conducting examinations fit for intended use, compliance with the requirements of the International Standard and continual improvement of the quality of laboratory services
   
   b. A framework for establishing and reviewing the quality objectives
   
   c. The policy is communicated and understood within the organization

7. Management has established quality objectives which address the needs of the users, are consistent with the quality policy and are measureable (Clause 4.1.2.4)

8. Management has defined, documented and communicated the responsibilities, authority and interrelationships within the organization (Clause 4.1.2.5)
   
   a. Deputies for all key functions have been appointed (Clause 4.1.2.5)

9. A quality manager has been appointed with delegated responsibility and authority for development, implementation and compliance with the QMS (Clause 4.1.2.7)

**Quality Management System (Clause 4.2)**

10. Laboratory Management has established, documented, implemented and maintained a QMS and continually improved its effectiveness in accordance with the International Standard ISO 15189 (Clause 4.2.1)

**Documentation Requirements (Clause 4.2.2)**

11. The QMS documentation includes procedures and records required by the International Standard ISO 15189

   a. The documentation includes copies of applicable regulations, standards and other normative documents

**Quality Manual (Clause 4.2.2.2)**

12. The laboratory has an established a quality manual that is accessible to and used by staff (Clause 4.2.2.2)
13. The Quality Manual includes all the requirements of ISO 15189:2012 Clause 4.2.2.2

**Document Control (Clause 4.3)**

14. The laboratory has established and maintained procedures to control all documents that form part of its quality system (Clause 4.3)

15. The laboratory document control procedure includes all the requirements of ISO 15189:2012 Clause 4.3

**Service Agreements (Clause 4.4)**

16. The laboratory has documented procedures for the establishment and review of agreements to provide services (Clause 4.4.1)

   a. These agreements take into account the request, the examination and the report including any information needed to ensure appropriate examination and result interpretation

   b. The service agreements that the laboratory enters into meet all the requirements of ISO 15189:2012 Clause 4.4.1

   c. Records of these service agreements reviewed and any significant changes maintained (Clause 4.4.2)

   d. The same review process repeated if the service agreement needs to be amended after the work commences; Amendments are communicated to all parties affected (Clause 4.4.2)

**Examination by Referral Laboratories (Clause 4.5)**

**Selecting and Evaluating Referral Laboratories and Consultants (Clause 4.5.1)**

17. The laboratory has a documented procedure for selecting and evaluating referral laboratories and consultants (Clause 4.5.1)

   a. The procedure ensures that the laboratory meets the requirements of ISO 15189:2012 Clause 4.5.1

**Provision of Examination Results (Clause 4.5.2)**

18. The referring laboratory is responsible for ensuring that the examination results from the referral laboratory is made available to the person making the request, unless otherwise specified (Clause 4.5.2)
19. The reports prepared by referring laboratories include all essential elements of the results reported, without alterations that could affect clinical interpretation (Clause 4.5.2)

20. Reports indicate which examinations were performed by the referral laboratory or consultant (Clause 4.5.2)

21. The author of any additional information (provided in the report) is identified (Clause 4.5.2)

22. The laboratory adopts the most appropriate means of reporting referral lab results (Clause 4.5.2)

23. There are mechanisms in place to ensure that collaboration between referring and referral laboratories are not hindered by commercial or financial considerations (Clause 4.5.2)

External Services and Supplies (Clause 4.6)

24. Does the laboratory has a procedure(s) for selection, purchasing of services, equipment, reagents and consumable supplies (Clause 4.6)
   
   a. Criteria established for the selection and approval of suppliers (Clause 4.6)
   
   b. The criteria are established in collaboration with other organizational departments, where relevant (Clause 4.6)
   
   c. There a current list of approved suppliers of equipment, reagents and consumable supplies (Clause 4.6)
   
   d. The purchasing information describes the requirements for the product and / or service (Clause 4.6)
   
   e. The supplier’s performance is monitored to ensure that purchased services and items consistently meet the stated criteria (Clause 4.6)

Advisory Services (Clause 4.7)

25. The laboratory has established arrangements for communicating with users according to the requirements of ISO 15189:2012 Clause 4.7

Resolution of Complaints (Clause 4.8)

26. There is a procedure for the management of complaints or other feedback from patients, clinicians, laboratory staff and other parties (Clause 4.8)

27. There are records of complaints, investigations and corrective actions
Identification and Control of Non-Conformities (Clause 4.9)

28. Does the laboratory have a documented procedure to identify and manage non-conformities (Clause 4.9.1)

29. These procedures ensure that the laboratory meets the requirements of ISO 15189 Clause 4.9.1

Corrective Action (Clause 4.10)

30. The laboratory takes appropriate corrective actions to eliminate the causes of nonconformities (Clause 4.10)

31. The laboratory has a documented procedure for corrective actions which include all the requirements of ISO 15189:2012 Clause 4.10

Preventive Action (Clause 4.11)

32. The laboratory has a documented procedure for preventive action (Clause 4.11)

Continual Improvement (Clause 4.12)

33. The laboratory has a programme for continual improvement of its quality management system (Clause 4.12)

34. The laboratory conducts risk assessments for the procedures that it is undertaking? (see clause 4.14.6)

35. The laboratory has documented action plans for improvement (Clause 4.12)

36. The laboratory communicates improvement plans and goals to the staff (Clause 4.12)

Control of Records (Clause 4.13)

37. The laboratory has a documented procedure for control of quality and technical records (Clause 4.13)

38. The laboratory facility has suitable record storage areas (Clause 4.13)

Evaluation and Audits (Clause 4.14)

39. The laboratory plans and implements the evaluation and internal audit processes needed to ensure conformity to the QMS, improve its effectiveness and meet user needs (Clause 4.14.1)
Periodic review of requests, and suitability of procedures and sample requirements (Clause 4.14.2)

40. Authorized personnel periodically review the laboratory's examinations to ensure they are clinically relevant (Clause 4.14.2)

41. The laboratory periodically reviews its sample collection requirements to ensure the sample is properly collected to preserve the measurand

Assessment of User Feedback (Clause 4.14.3)

42. The laboratory seeks information from users on whether the service has met user needs (Clause 4.14.3)

43. The methods for obtaining and using this information include cooperation with users or their representatives (Clause 4.14.3)

44. The information is obtained in a manner that ensures user confidentiality (Clause 4.14.3)

45. Records of information collected and actions taken are kept (Clause 4.14.3)

Staff Suggestions (Clause 4.14.4)

46. The Laboratory management encourages staff to make suggestions for the improvement of the laboratory service (Clause 4.14.4)

47. Suggestions are evaluated, implemented as appropriate and feedback provided to the staff (Clause 4.14.4)

48. Records of suggestions and action taken by the management are maintained (Clause 4.14.4)

Internal Audits (Clause 4.14.5)

49. The laboratory conducts internal audits at planned intervals to ascertain whether the QMS (Clause 4.14.5):

   a. Conforms to the requirements of the ISO 15189:2012 and the laboratory requirements

   b. Is implemented, effective, and maintained

50. Personnel are trained to conduct audits which assess the performance of managerial and technical processes of the QMS (Clause 4.14.5)

51. Audit criteria, scope, frequency and methods are defined and documented (Clause 4.14.5)

52. Auditors are selected and audits conducted to ensure objectivity and impartiality of the audit process (Clause 4.14.5)
53. The laboratory has a documented procedure for conducting internal audits (Clause 4.14.5)

54. The laboratory undertakes corrective actions promptly (Clause 4.14.5)

Risk Management (Clause 4.14.6)

55. The laboratory evaluates the impact of work processes and potential failures on examination results as they affect patient safety (Clause 4.14.16)

56. The laboratory makes modifications to processes to reduce or eliminate identified risks and document decisions and actions taken (Clause 4.14.16)

Quality Indicators (Clause 4.14.7)

57. The laboratory has established quality indicators to monitor and evaluate performance (Clause 4.14.7)

58. The laboratory has a planned process of monitoring quality indicators (Clause 4.14.7)

59. The laboratory periodically reviews their indicators, to ensure their continued appropriateness (Clause 4.14.7)

Reviews by External Organizations (Clause 4.14.8)

60. The laboratory takes appropriate corrective action or preventive action when reviews by external organizations indicate current or potential nonconformities (Clause 4.14.8)

61. Records of reviews and corrective and preventive action are maintained (Clause 4.14.8)

Management Review (Clause 4.15.1)

62. The laboratory management conducts a review of the quality management system at planned intervals (Clause 4.15.1)

63. The input to laboratory's management review includes information from the results of evaluations of the requirements of ISO 15189:2012 Clause 4.15.2

64. The laboratory’s Management reviews analyses the input information (Clause 4.15.3)

   a. This review includes assessment of opportunities for improvement and need for changes to the QMS, and where possible, objective evaluations of appropriateness of the lab’s contribution to patient care (Clause 4.15.3)

65. The output from the management review incorporated into a record that documents any decisions made and actions taken related to (Clause 4.15.4)

   a. Improvement of the effectiveness of the QMS its processes
b. Improvement of services to users

c. Resource needs

66. The findings and actions arising from management reviews recorded and reported to laboratory and other relevant staff (Clause 4.15.4)

TECHNICAL REQUIREMENTS

Personnel (Clause 5.1)

67. The laboratory (Clause 5.1):

a. Has a documented procedure for personnel management

b. Maintains records for all personnel to indicate compliance with requirements

Personnel Qualifications (Clause 5.1.2)

68. The laboratory management has documented the personnel qualifications for each position as appropriate for the tasks to be performed (Clause 5.1.2)

Job Descriptions (Clause 5.1.3)

69. The laboratory has job descriptions for all personnel (Clause 5.1.3)

Personnel introduction to the organizational environment (Clause 5.1.4)

70. The laboratory has an orientation programme for new staff (Clause 5.1.4)

Training (Clause 5.1.5)

71. The laboratory provides training for all personnel inclusive of the areas listed in ISO 15189:2012 Clause 5.1.5

72. Trainees are supervised at all times (Clause 5.1.5)
73. The training programme is periodically reviewed for effectiveness (Clause 5.1.5)

**Competence Assessment (Clause 5.1.6)**

74. The laboratory assesses the competence of each person to perform assigned managerial or technical tasks (Clause 5.1.6)

75. The laboratory periodically reassesses competence and retrains when necessary (Clause 5.1.6)

**Reviews of Staff Performance (Clause 5.1.7)**

76. Staff performance reviews consider the needs of the laboratory and the individual in order to maintain or improve the quality of service provided (Clause 5.1.7)

**Continuing Education and Professional Development (Clause 5.1.8)**

77. The laboratory has a continuing education programme available to managerial and technical personnel (Clause 5.1.8)
   
   a. The programme is periodically reviewed for effectiveness (Clause 5.1.8)

78. Personnel regularly participate in professional development or other professional liaison activities (Clause 5.1.8)

**Personnel Records (Clause 5.1.9)**

79. Personnel records maintained and accessible for all personnel (Clause 5.1.9)

**Accommodation and Environmental Conditions (Clause 5.2)**

80. The laboratory has work space that is designed to ensure the quality and efficacy of the service and the health and safety of laboratory personnel, patients and visitors (Clause 5.2.1)

81. The laboratory has evaluated the adequacy of the space allocated for its work (Clause 5.2.1)

82. The laboratory and office facilities provide a suitable environment that ensures the requirements of ISO 15189:2012 Clause 5.2.2

83. The laboratory has adequate storage spaces and conditions provided (Clause 5.2.3)

84. Clinical samples and materials stored appropriately to prevent cross contamination (Clause 5.2.3)
85. Laboratory storage and disposal facilities for dangerous materials appropriate to the hazards of the materials (Clause 5.2.3)

86. Laboratory staff have adequate access to washrooms, drinking water, storage facilities for personal protective equipment and clothing (Clause 5.2.4)

87. The laboratory has considerations made for accommodating patient comfort, needs and privacy when primary sample collection facilities are provided (Clause 5.2.5)

88. Appropriate first aid materials for both patient and staff needs are available at collection facilities (Clause 5.2.5)

89. The laboratory premises are maintained in a functional and reliable condition (Clause 5.2.6)

90. Laboratory work areas are clean and well maintained (Clause 5.2.6)

91. The laboratory monitors, controls and records environmental conditions (Clause 5.2.6)

92. The laboratory has effective separation between neighboring areas where incompatible activities are performed (Clause 5.2.6)

93. The laboratory has appropriate measures taken to prevent cross-contamination (Clause 5.2.6)

94. The laboratory provides a quiet uninterrupted work environment (Clause 5.2.6)

**Laboratory Equipment, Reagents and Consumables (Clause 5.3)**

**Equipment (Clause 5.3.1)**

95. The laboratory has a documented procedure for the selection, purchasing and management of equipment (Clause 5.3.1.1)

96. The laboratory is furnished with all the items of equipment required for its services (Clause 5.3.1.1)

**Equipment Acceptance Testing (Clause 5.3.1.2)**

97. Equipment shown to be capable of achieving the performance required and complies with specifications relevant to the examinations concerned (Clause 5.3.1.2)

98. Each piece of equipment is uniquely labeled, marked or otherwise identified (Clause 5.3.1.2)

**Equipment Instructions for Use (Clause 5.3.1.3)**

99. Only trained and authorized personnel operate laboratory equipment (Clause 5.3.1.3)
100. The laboratory has procedures for safe handling, transport, storage and use of equipment to prevent its contamination/deterioration (Clause 5.3.1.3)

101. The laboratory has up-to-date instructions on the use and maintenance of equipment readily available to laboratory personnel (Clause 5.3.1.3)

**Equipment calibration and metrological traceability (Clause 5.3.1.4)**

102. The laboratory has a documented procedure for the calibration of equipment that directly or indirectly affects examination results (Clause 5.3.1.4)

   a. The procedure ensures that the laboratory meets the requirements of ISO 15189:2012 Clause 5.3.1.4

103. The metrological traceability to a reference material or reference procedure of the higher metrological order (Clause 5.3.1.4)

   a. Where not practical, the laboratory utilizes other methods

**Equipment Maintenance and Repair (Clause 5.3.1.5)**

104. The laboratory has a documented programme of preventive maintenance (Clause 5.3.1.5)

105. Equipment maintained in a safe working condition and in working order (Clause 5.3.1.5)

106. Defective equipment is taken out of service and clearly labeled (Clause 5.3.1.5)

107. Repaired equipment is shown by verification to meet specified acceptance criteria before being placed back in operation (Clause 5.3.1.5)

108. The laboratory examines the effect of defects on the previous examinations (Clause 5.3.1.5)

109. Reasonable measures are taken to decontaminate equipment prior to service, repair or decommissioning (Clause 5.3.1.5)

110. The laboratory provides suitable space for repairs and appropriate personal protective equipment (Clause 5.3.1.5)

111. When equipment goes outside the direct control of the laboratory, its performance verified before resumption of use (Clause 5.3.1.5)

**Equipment Adverse Incident Reporting (Clause 5.3.1.6)**

112. The laboratory investigates adverse incidents and accidents that can be attributed directly to specific equipment and report this to the equipment manufacturer and appropriate authorities (Clause 5.3.1.6)
Laboratory Equipment, Reagents and Consumables (Clause 5.3)

Equipment Records (Clause 5.3.1.7)

113. Records are maintained for each item of equipment that contributes to the performance of examinations

Reagents and Consumables (Clause 5.3.2)

114. The laboratory has a documented procedure for management and inventory of reagents and consumables (Clause 5.3.2.1)

115. The laboratory verifies that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration (Clause 5.3.2.2)

116. Received reagents and consumables stored according to manufacturer's specifications (Clause 5.3.2.2)

117. The laboratory verifies the performance of examination kits before use (Clause 5.3.2.3)

118. The laboratory has an inventory control system for reagents and consumables (Clause 5.3.2.4)

119. The inventory control system segregates uninspected and unacceptable reagents and consumables from those that have been accepted for use (Clause 5.3.2.4)

120. Instructions for use of reagents and consumables readily available (Clause 5.3.2.5)

121. The laboratory investigates adverse incidents and accidents that can be attributed directly to specific reagents and consumables and report this to the manufacturer and appropriate authorities (Clause 5.3.2.6)

Reagents and Consumables (Clause 5.3.2)

122. The laboratory maintains records for each reagent and consumable that contributes to the performance of examinations (Clause 5.3.2.7)

123. The laboratory maintains records for each reagent that is prepared or completed in-house (Clause 5.3.2.7)

Pre-Examination Processes (Clause 5.4)

124. The laboratory has documented procedures and information for pre-examination activities that ensure the validity of the results of examinations (Clause 5.4.1)
Information for Patients and Users (Clause 5.4.2)

125. The laboratory provides appropriate information for patients and users of the laboratory services (Clause 5.4.2)

126. The laboratory provides information for patients and users that include an explanation of the clinical procedures to be performed to facilitate informed consent (Clause 5.4.2)

Request Form Information (Clause 5.4.3)

127. The laboratory has request forms (Clause 5.4.3)

128. The laboratory has a documented procedure regarding verbal requests for examinations (Clause 5.4.3)

Primary Sample Collection and Handling (Clause 5.4.4)

129. The laboratory has documented procedures for the collection and handling of primary samples that are available to sample collectors within and outside of the laboratory (Clause 5.4.4.1)

130. The laboratory has instructions for pre-collection activities (Clause 5.4.4.2)

131. The laboratory has instructions for collection activities (Clause 5.4.4.3)

Sample Transportation (Clause 5.4.5)

132. The laboratory has instructions for post-collection activities that address requirements for packaging of samples for transportation (Clause 5.4.5)

133. The laboratory has a documented procedure for monitoring the transportation of samples (Clause 5.4.5)

Sample Reception (Clause 5.4.6)

134. The laboratory has a sample reception procedure (Clause 5.4.6)

135. The laboratory has procedures for pre-examination handling, preparation and storage (Clause 5.4.7)
Examination Processes (Examination Processes)

Selection, verification and validation of examination procedures (Clause 5.5.1)

136. The laboratory uses validated examination procedures (Clause 5.5.1.1)

137. The identity of persons performing activities in the examination processes is recorded (Clause 5.5.1.1)

138. Validated examination procedures are independently verified by the laboratory before being introduced into routine use (Clause 5.5.1.2)

139. The laboratory has obtained from the manufacturer/method developer information for confirming the performance characteristics (Clause 5.5.1.2)

140. The laboratory has confirmed through objective evidence that the performance claims for the examination procedure have been met (Clause 5.5.1.2)

141. Results obtained and the procedure used for verification are recorded (Clause 5.5.1.2)

142. Staff with the appropriate authority review the verification results and record the review (Clause 5.5.1.2)

Examination Processes (Clause 5.5)

143. The laboratory validates examination procedures derived from (Clause 5.5.1.3):
   a. Non-standard methods
   b. Lab-designed or developed methods
   c. Standard methods used outside their intended scope
   d. Validated methods subsequently modified

144. The laboratory has confirmed through objective evidence that the performance claims for the examination procedure have been met (Clause 5.5.1.3)

145. Results obtained and the procedure used for validation are recorded (Clause 5.5.1.3)

146. Staff with the appropriate authority review the validation results and record the review (Clause 5.5.1.3)

147. Changes to validated examination procedures are documented and are new validations performed (Clause 5.5.1.3)
Measurement uncertainty of measured quantity values (Clause 5.5.1.4)

148. The laboratory has determined measurement uncertainty for each measurement procedure in the examination phase which reports measured quantity values on patients’ samples (Clause 5.5.1.4)

149. Performance requirements for measurement uncertainty are defined and regularly reviewed (Clause 5.5.1.4)

150. Measurement uncertainty is considered when interpreting measured quantity values and are these made available to users (Clause 5.5.1.4)

151. Where there is no measured quantity value, the laboratory calculates the uncertainty of the measurement step in assessing reliability of the examination procedure on the reported result (Clause 5.5.1.4)

Biological Reference Intervals of Clinical Decision Values (Clause 5.5.2)

152. The biological reference intervals or clinical decision values are (Clause 5.5.2):

   a. Defined by the laboratory
   b. Documented along with the basis for them
   c. Communicated to users

153. The laboratory makes appropriate changes if a particular reference interval is no longer appropriate for the population served (Clause 5.5.2)

   a. Such changes in biological reference intervals communicated to users

154. Biological reference intervals reviewed, if appropriate, when the laboratory changes an examination procedure or pre-examination procedure (Clause 5.5.2)

Documentation of Examination Procedures (Clause 5.5.3)

155. The laboratory documents all examination procedures in a language commonly understood by staff and available in an appropriate location (Clause 5.5.3)

156. Laboratory condensed documents correspond to the documented procedure (Clause 5.5.3)

157. All laboratory documents associated with the performance of examinations are subject to document control (Clause 5.5.3)

158. Laboratory procedure documents contain document identifiers and required information (Clause 5.5.3)
159. The laboratory explains the implications of changes to existing examination procedures to users, where the results of their interpretations could be significantly different after the laboratory has validated the procedure (Clause 5.5.3)

**Ensuring the Quality of Examination Results (Clause 5.6)**

160. The laboratory ensures the quality of examinations by performing them under defined conditions (Clause 5.6.1)

161. The laboratory ensures appropriate pre- and post-examination processes are implemented (Clause 5.6.1)

162. The laboratory ensures that no results are fabricated (Clause 5.6.1)

**Quality Control (Clause 5.6.2)**

163. The laboratory designs quality control procedures that verify the attainment of the intended quality of results (Clause 5.6.2.1)

**Quality Control Materials (Clause 5.6.2.2)**

164. The laboratory uses appropriate quality control materials (Clause 5.6.2.2)

165. The laboratory periodically examines quality control materials to prevent erroneous results and to ensure continued suitability (Clause 5.6.2.2)

**Quality Control Data (Clause 5.6.2.3)**

166. The laboratory has a procedure to prevent the release of patient results in the event of quality control failure (Clause 5.6.2.3)

167. The laboratory rejects results and re-examines patient samples when a quality control performance error is detected that indicates that examination results are likely to contain clinically significant errors (Clause 5.6.2.3)

168. The laboratory evaluates the results from patient samples examined after the last successful quality control event (Clause 5.6.2.3)

169. The laboratory reviews quality control data at regular intervals to detect trends and take preventive action as necessary (Clause 5.6.2.3)
Inter-Laboratory Comparisons (Clause 5.6.3)

Participation (Clause 5.6.3.1)

170. The laboratory participates in inter-laboratory comparisons appropriate to the examination and interpretations of results (Clause 5.6.3.1)

171. The laboratory monitors the results of inter-laboratory comparisons and participate in the implementation of corrective actions when performance criteria are not fulfilled (Clause 5.6.3.1)

172. The laboratory has a procedure for inter-laboratory comparison participation (Clause 5.6.3.1)

173. The programme provides clinically relevant challenges that mimic patient samples and check the entire examination process, where possible (Clause 5.6.3.1)

Alternative Approaches (Clause 5.6.3.2)

174. When inter-laboratory comparison programmes are not available, the laboratory develops approaches for determining the acceptability of examination results (Clause 5.6.3.2)

Analysis of Inter-Laboratory Comparison Samples (Clause 5.6.3.3)

175. The laboratory has integrated inter-laboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples (Clause 5.6.3.3)

   a. These performed by personnel who routinely examine patient samples using routine methods (Clause 5.6.3.3)

176. The laboratory avoids collaboration with other participants about sample data before the deadline for submission of the data (Clause 5.6.3.3)

177. The laboratory avoids referring inter laboratory comparison samples before submission of results (Clause 5.6.3.3)

Evaluation of Laboratory Performance (Clause 5.6.3.4)

178. The performance in inter-laboratory comparisons is reviewed and discussed with relevant staff (Clause 5.6.3.4)
179. When pre-determined performance criteria are not fulfilled, staff participate in the effective implementation and recording of corrective action (Clause 5.6.3.4)

180. Preventive action is taken where trends in returned results indicate potential nonconformities (Clause 5.6.3.4)

Comparability of Examination Results (Clause 5.6.4)

181. For examinations performed using same or different procedures, equipment, and/or different sites the laboratory (Clause 5.6.4)
   a. Has a defined means for comparing procedures, equipment and methods and establishing the comparability of results throughout the clinically appropriate intervals (Clause 5.6.4)
   b. The laboratory notifies users of any differences in comparability of results and discuss implications for clinical practice (Clause 5.6.4)
   c. The laboratory documents and records the results of the comparisons performed and the actions taken (Clause 5.6.4)

Post-Examination Procedures (Clause 5.7)

Review of Results (Clause 5.7.1)

182. The laboratory has procedures to ensure authorized personnel review examination results before release, against internal quality control, clinical information and previous examination results (Clause 5.7.1)

Storage, Retention and Disposal of Clinical Samples (Clause 5.7.2)

183. The laboratory has a documented procedure for identification, collection, indexing, access, retention, storage, maintenance and safe disposal of samples (Clause 5.7.2)

184. The laboratory has defined sample retention times with criteria which are based on the nature of the sample, the examination and specified requirements (Clause 5.7.2)

185. Laboratory samples disposed safely and in accordance with regulations or recommendations for waste management (Clause 5.7.2)

Reporting of Results (Clause 5.8)

186. Results of each examination are reported accurately, clearly, unambiguously in accordance with specific instructions in a defined format and medium (Clause 5.8.1)
187. The laboratory has a procedure to ensure the correctness of result transcription (Clause 5.8.1)

188. There is a process for notifying requester when an examination which could compromise patient care is delayed (Clause 5.8.1)

Report Attributes (Clause 5.8.2)

189. Laboratory reports effectively communicate laboratory results and meet users’ needs in accordance with ISO 15189:2012 Clause 5.8.2

Report Content (Clause 5.8)

190. The laboratory has a standardized reporting format (Clause 5.8.3)

Release of Results (Clause 5.9)

191. The lab has documented procedures for the release of examination results, including who may release results and to whom (Clause 5.9.1)

Automated Selection and Reporting of Results (Clause 5.9.2)

192. The laboratory has a documented procedure for automated selection and reporting of results (Clause 5.9.2)

Revised Reports (Clause 5.9.3)

193. The Laboratory has written instructions regarding the revision of reports ensuring the original report is referenced, the user is notified and the action is recorded (Clause 5.9.3)

194. The Laboratory keeps records of revisions when the reporting system cannot capture amendments, changes or alterations (Clause 5.9.3)

Laboratory Information Management (Clause 5.10)

195. The Laboratory has a documented procedure to ensure the confidentiality of patient information is maintained at all times (Clause 5.10.1)

Authorities and Responsibilities (Clause 5.10.2)

196. The laboratory has defined the authorities and responsibilities for the management of the information system, including maintenance and modification affecting patient care (Clause 5.10.2)
197. The laboratory has defined the authorities and responsibilities of the personnel who use the Information Management System (Clause 5.10.2)

Information Systems Management (Clause 5.10.3)

198. There is evidence that the Laboratory information system meets the requirements of ISO 15189 Clause 5.10.3 (Clause 5.10.3)

199. The laboratory has a documented contingency plan for maintenance of services in the event of an information system failure or downtime which affects the laboratory’s ability to provide service (Clause 5.10.3)
15 ANNEX 5: LABORATORY SAFETY CHECKLIST

The text of the LQMS-SIP Laboratory Safety Checklist is taken from the ISO 15190:2003, Medical Laboratories - Requirements for Safety. This Safety Checklist is an addendum to the LQMS-SIP Checklist and it is labeled as Section 6. This standard can be obtained from any ISO member and from the website of the ISO Central Secretariat at the following address: www.iso.org. Copyright remains with ISO.

This International Standard specifies requirements to establish and maintain a safe working environment in a medical laboratory. There are requirements to ensure that there is a named person ultimately responsible and that all employees take personal responsibility for:

- Their own safety at work and;
- The safety of others who may be affected by it.

Every task requires risk assessment with the aim that hazards be eliminated wherever possible. Where this cannot be done, the risk from each hazard is reduced to as low a level as practicable using the following order of priority:

- By substitution;
- By containment; or
- By the use of personal protective measures and equipment

The ISO 15190 states that “Safety is the primary consideration and cost is of secondary importance”. Every health facility licensed as a medical laboratory shall ensure that the requirements listed below are met.

Section 6
Safety Officer, Safety Manual, Safety Programme Audit, Inspection & Records

1. The Laboratory has an appointed Biosafety Officer (BSO) (Section 6.1)
2. The Laboratory BSO has been trained to perform their duties (Section 6.2)
3. The Laboratory safety manual that is specific for the laboratory's needs is readily available to all employees (Section 6.3)(ISO 15190 Clause 7.2, 7.4, 8.0)
   a. The laboratory has evidence that employees have read the manual (Section 6.3)(ISO 15190 Clause 7.2, 7.4, 8.0)
4. The laboratory has instructions regarding job hazards that describe how to carry out tasks safely and what to do if an incident occurs (Section 6.4) (ISO 15190 Clause 7.2, 7.4, 8.0, 17.1)

5. The laboratory has other essential safety-related documents (separate from the safety manual) available (Section 6.5) (ISO 15190 Clause 7.2, 7.4)

6. The laboratory safety program is reviewed annually (Section 6.6) (ISO 15190 Clause 7.3.1, 7.5.3)

7. There is evidence that laboratory work areas are inspected annually for safety (Section 6.7) (ISO 15190 Clause 7.3.2)

8. The laboratory has identified hazardous areas and the presence of certain hazards (e.g., flammable) (Section 6.8) (ISO 15190 Clause 8.0)

9. The laboratory makes visitors, non-permanent staff and other workers made aware of hazards (Section 6.9) (ISO 15190 Clause 8.0)

10. Laboratory management has performed a risk assessment to determine which procedures require the use of a biological safety cabinet (Section 6.10)

Reporting of Incidents, Accidents and Occupational Illness

11. The laboratory has a program for reporting safety-related accidents/incidents (Section 6.11) (ISO 15190 Clause 7.5.2, 9.0)

12. The laboratory files reports for all incidents that include a detailed description of the accident/incident (persons involved, circumstances, time and place, identification of the cause, and recommendations for prevention and actions (Section 6.12) (ISO 15190 Clause 7.5.2, 9.0)

13. The laboratory accident/incident reports are reviewed by laboratory management to ensure that remedial action(s) is taken to avoid recurrence (Section 6.13) (ISO Clause 9.0)

14. The laboratory has a procedure and process (e.g., vaccination where applicable) regarding occupational exposure to Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus and tuberculosis (Section 6.14) (ISO 15190 Clause 7.5.2)

Training

15. The laboratory has evidence that a safety training program is in place (Section 6.15) (ISO 15190 Clause 5.2, 7.52, 9.0)

16. The laboratory has evidence that all staff have been trained in the safe handling, use and disposal of sharp instruments and devices (Section 6.16) (ISO 15190 Clause 9.0, 14.1)

17. The laboratory has evidence that staff are trained to be aware of the hazards associated with the handling of body fluids (Section 6.17) (ISO Clause 15190 Clause 9.0, 14.1 and 15.0)

18. Laboratory employees are trained to ensure that all applicable regulations are followed when transporting or offering for transport biological material and dangerous goods (Section 6.18)
Personnel Responsibilities and Safe Work Practices

19. Laboratory staff consistently practice standard precautions to ensure the protection of themselves, co-workers, patients, the public from exposure to sources of danger (Section 6.19) (ISO 15190 Clause 5.2, 14.1, 14.2, 15.0)

20. All laboratory samples, control materials, biologically sourced calibrators, cultures and waste assumed to contain viable pathogens are handled in a safe manner (Section 6.20)

21. The laboratory prohibits food and drink in the laboratory where specimens are stored and handled (Section 6.21) (ISO 15190 Clause 11.1)

22. The laboratory prohibits the use of cell phones prohibited in the lab (unless authorized) (Section 6.21)

23. The laboratory has evidence that the storage of food and drink is prohibited in refrigerators that contain potentially infectious materials? (Refrigerators should be appropriately labeled to indicate their use) (Section 6.23) (ISO 15190 Clause 11.1)

24. The laboratory prohibits smoking (Section 6.24) (ISO 15190 Clause 11.1)

25. The laboratory has evidence that the application of cosmetics and the handling of contact lenses are prohibited (Section 6.25) (ISO 15190 Clause 11.1)

26. The laboratory stipulates that staff members with long hair keep it tied back or disposable hair covers used, to keep it out of if there is a danger of it being caught in equipment or substances or chemicals contaminated by infectious substances (Section 6.26) (ISO 15190 Clause 11.1)

27. The laboratory stipulates that staff members refrain from wearing loose clothing or jewelry that may get caught in equipment or become contaminated (Section 6.27) (ISO 15190 Clause 11.1)

28. The laboratory stipulates that personal property be stored where it cannot become contaminated (Section 6.28) (ISO 15190 Clause 11.4)

29. The laboratory stipulates that all workers and visitors wash their hands immediately after contact with blood, body fluids or other contaminated materials, after removing gloves, before and after using the toilet, before leaving the laboratory, before eating or smoking, and before and after contact with each patient (Section 6.29) (ISO 15190 Clause 6.2, 12.7, 14.2)

30. The laboratory makes available dedicated hand-washing sinks closely located in areas where biological materials are handled and close to exits (Section 6.30) (ISO 15190 Clause 6.2, 12.9e)

31. The laboratory has evidence that mouth pipetting is prohibited (Section 6.31) (ISO 15190 Clause 14.1)

32. The laboratory management has determined and implemented a policy or process or procedure for handling sharps (Section 6.32) (ISO 15190 Clause 14.1)

33. The laboratory places sharps for disposal in a puncture-resistant container (Section 6.33) (ISO Clause 14.1, 23.0)

34. The laboratory centrifuges samples safely (Section 6.34) (ISO Clause 15.0)
Protective Clothing and Equipment
35. The laboratory provides PPE to staff, visitors, and patients as required (Section 6.35) (ISO 15190 Clause 12.1, 12.3, 14.2, 17.1)
36. The laboratory changes PPE when necessary (Section 6.36) (ISO 15190 Clause 12.1)
37. The laboratory management has determined and implemented the criteria for the transport and washing of contaminated clothing (Section 6.37) (ISO 15190 Clause 12.1)
38. Laboratory staff remove PPE when leaving the laboratory (Section 6.38) (ISO 15190 Clause 12.1)
39. The laboratory management has provided appropriate gloves for those staff that suffer from allergies or reactions (Section 6.39) (ISO 15190 Clause 12.4)
40. The laboratory has evidence that shoes with open toes are prohibited in the laboratory (Section 6.40) (ISO 15190 Clause 12.5)

First Aid and Emergency Practices
41. The laboratory has appropriately trained personnel and appropriate equipment available to provide first aid, if required (Section 6.41) (ISO 15190 Clause 12.9f)
42. The laboratory has a plan for emergency evacuation (Section 6.42) (ISO Clause 20.0)

Good Housekeeping
43. The laboratory has evidence that someone from the lab has been designated to oversee good housekeeping practices (Section 6.43) (ISO 15190 Clause 13.0)
44. Laboratory work areas are tidy and uncluttered (Section 6.44) (ISO 15190 Clause 13.0)
45. Laboratory exits, aisles and corridors unobstructed (Section 6.55) (ISO 15190 Clause 13.0)
46. The laboratory has exit signs and adequate lighting at the point of exit (Section 6.46) (ISO 15190 Clause 6.31, 6.37)
47. The laboratory has documented evidence that work surfaces and equipment are cleaned and disinfected when required (whenever spills or contaminations occur) and laboratory benches disinfected at the end of each shift (Section 6.47) (ISO 15190 Clause 13.0)
48. The laboratory restricts housekeeping activities by non-laboratory staff to the removal of non-hazardous waste, or appropriately labeled and packaged hazardous waste, and periodic cleaning of the floors, walls and ceilings (Section 6.48) (ISO 15190 Clause 13.0, 23.0)

Biological Hazard Containment
49. The laboratory biological safety cabinets (Class I and II) have been certified by a qualified person before being placed into service, when HEPA filters are changed, when moved or after maintenance, and at least annually to ensure that they function as designed (Section 6.49) (ISO 15190 Clause 16.0)
50. The laboratory employs an appropriate containment level for their operational practice (Section 6.50)
51. The laboratory staff are familiar with biosafety guidelines for their classified containment level (Section 6.51)
Chemical Safety (Including Gases and Liquid Nitrogen)

52. The Laboratory stores hazardous liquids and gas cylinders appropriately (Section 6.52) (ISO 15190 Clause 17.1)
53. The laboratory has eye wash stations (Section 6.53) (ISO 15190 Clause 12.1, 17.2)
54. The laboratory has emergency showers available where needed, and they are tested periodically and is documentation kept (Section 6.54) (ISO 15190 Clause 12.11, 17.2)
55. The laboratory has available chemical spill kits (Section 6.55) (ISO 15190 Clause 13.0, 17.2, 19.4)
56. The laboratory has a process defined for the disposal of chemicals (Section 6.56) (ISO 15190 Clause 13.0, 17.3)

Electrical Safety

57. The laboratory has that evidence that power cords and plugs are regularly inspected for damage and fraying (Section 6.57) (ISO 15190 Clause 21.0)

Fire Safety

58. The laboratory has a complete fire safety plan (Section 6.58) (ISO 15190 Clause 19.7)
59. The laboratory has portable fire extinguishers which are visible and accessible (Section 6.59) (ISO 15190 Clause 19.7)
60. The laboratory portable fire extinguishers have the correct rating for the hazards present? (e.g. Class A, B, C or D fires) (Section 6.60) (ISO 15190 Clause 19.7)
61. The laboratory has evidence that all personnel participate in an annual fire drill or other emergency evacuation training (Section 6.61) (ISO 15190 Clause 19.6. 19.7, 20.0)
62. The laboratory uses containers for flammable liquids which are as small as possible and closed when not in use (Section 6.62) (ISO 15190 Clause 19.5)
63. The laboratory stores flammable liquids appropriately (Section 6.63) (ISO 15190 Clause 19.5)
64. The laboratory areas where flammable gases and liquids are used are well ventilated (Section 6.64) (ISO 15190 Clause 19.4)
65. The laboratory keeps flammable gases and liquids away from sources of heat or ignition including electric motors and direct sunlight (Section 6.65) (ISO 15190 Clause 19.4)
66. The laboratory uses portable safety containers for flammable liquids (Section 6.66) (ISO 15190 Clause 19.5)

Waste Disposal

67. Laboratory staff are familiar with the requirements for the handling and disposal of hazardous waste (Section 6.67) (ISO 15190 Clause 18.23, 23.0)
68. Laboratory waste is disposed of on a regular basis and not allowed to accumulate (Section 6.68) (ISO 15190 Clause 23.0)