

**GUIDE FOR THE STEPWISE LABORATORY
QUALITY IMPROVEMENT PROCESS
TOWARDS ACCREDITATION (SLIPTA) IN
THE WHO AFRICAN REGION**



REGIONAL OFFICE FOR

**World Health
Organization**

Africa

**GUIDE FOR THE STEPWISE LABORATORY
QUALITY IMPROVEMENT PROCESS TOWARDS
ACCREDITATION (SLIPTA) IN THE WHO
AFRICAN REGION**

Guide for the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) in the WHO African Region — Revision 2

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ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
AMR	Antimicrobial resistance
ASCP	American Society for Clinical Pathology
ASLM	African Society for Laboratory Medicine
CDC	Centers for Disease Control and Prevention (United States)
CEN	European Committee for Standardization
CHAI	Clinton Health Access Initiative
CLSI	Clinical and Laboratory Standards Institute
HIV	Human Immunodeficiency Virus
IAG	Independent Advisory Group
IDSR	Integrated Disease Surveillance and Response
IEC	International Electrotechnical Commission
IEG	Independent Evaluating Group
IHR	International Health Regulations (2005)
ISO	International Organization for Standardization
LoA	Letter of Agreement
LQMS	Laboratory Quality Management System
MOH	Ministry of Health
MoU	Memorandum of Understanding
QMS	Quality Management System
QSE	Quality System Essential
SLIPTA	Stepwise Laboratory Quality Improvement Process towards Accreditation
WHO	World Health Organization
WHO/AFRO	World Health Organization Regional Office for Africa
WHO/SEARO	World Health Organization Regional Office for South-East Asia

DEFINITIONS

For the purpose of this guide, the following definitions are used to clarify terms used herein.

Accreditation bodies: Organizations or agencies with the authority to assess a facility and provide written evidence of its competence with regards to an International or National standard.

Accreditation: Procedure by which an authoritative body gives formal recognition that an organisation or person is competent to carry out specific tasks. *Reference: ISO 15189.*

Note: The authority of an accreditation body is generally derived from a country's government.

Certification: Procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements. *Reference: ISO/IEC 17000:2004.* Certification is often a voluntary process.

CLSI laboratory quality system essentials (QSEs): The necessary infrastructure or foundational building blocks in an organization that need to be in place and functioning effectively in order to support the organization's work operations so that they proceed smoothly.

Independent Advisory Group (IAG): An independent committee established by ASLM (and agreed on with WHO) and that comprises of regional and international experts in laboratory quality management systems that is responsible for overseeing the SLIPTA Audit Programme.

Independent Evaluating Group (IEG): An independent body that is responsible for coordinating and leading the implementation of the SLIPTA Programme through training of auditors, laboratory audits and technical assistance for ongoing improvements. ASLM is the identified body as the IEG by WHO/AFRO.

MOHSLIPTA Focal Point: The SLIPTA Focal Point may be a unit or a person that is responsible for coordination, leading and raising budget to support the implementation and expansion of SLIPTA in the country.

One Health: Concept/Approach that aims to improve health and well-being through the prevention of risks and the mitigation of effects of crises that originate at the interface between humans, animals, and their various environments including agricultural and food (www.onehealthglobal.net). It involves applying a coordinated, collaborative, multidisciplinary and cross-sectoral approach to address potential or existing risks.

Organization for Standardization (ISO): Federation of national standards bodies from various countries and the world's largest developer of international standards.

Quality Management System (QMS): System that comprises organizational structure, resource and processes needed to direct, plan and control quality activities.

SLIPTA auditors: Laboratory professionals trained and certified by the IEG (ASLM) to audit laboratories using SLIPTA Checklist and provide technical advice and guidance to improve the quality management system of the audited laboratory.

Standard: An authoritative “document” setting forth criteria for performance and characteristics (RHUD1.7CD/CLSI). Standards may be issued by national, regional, or international standards bodies. The most widely accepted international standards are issued by the International Organization for Standardization (ISO). ISO standards are formulated by technical committees.

In the case of medical laboratories, the most applicable standard is ***ISO 15189 Medical laboratories.***

Standardization bodies: Bodies that have the authority to develop standards and adopt International Standards with or without modifications. They can be national or international. The European Committee for Standardization (CEN) is an example of a regional standardization body with a technical cooperation agreement with ISO.

Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA): A Programme that aims to enhance the efficiency and effectiveness of the medical laboratories, and is used to audit medical and public health laboratories in recognition of their progress in defining and implementing quality improvement.

The Clinical & Laboratory Standards Institute (CLSI): A volunteer-driven, membership-supported, not-for-profit, standards development organization that provides standards and guidelines for medical professionals through a consensus process.

FOREWORD

Laboratory services form an essential component of health services and require adequate capacity for the purposes of care, epidemiological surveillance, disease prevention and control, research and other public health-related activities. The available data demonstrate that in most countries in the WHO African Region, laboratory services do not meet basic needs, mostly at intermediate and peripheral levels, largely due to the lack, or inadequacy, of existing laboratory systems. Lessons learnt from the deadly Ebola Virus Disease (EVD) outbreak in West Africa in 2014-2015 and other major public health events, as well as the findings from Joint External Evaluations (JEE) under the International Health Regulations (IHR) revealed the urgent need to reform the laboratory sector in the Region.

The WHO Regional Office for Africa has over the past years worked to promote better laboratory services. A number of key resolutions, declarations and initiatives have brought laboratory systems to the forefront of health systems strengthening. The Resolution AFR/RC58/R2 adopted by the WHO AFRO Regional Committee 58th session in Yaoundé, Cameroon, in 2008 called for strengthened public health laboratories in the African Region, including with respect to the development and implementation of national laboratory policies and strategic plans. The Maputo Declaration on Strengthening of Laboratory Systems (Maputo, January 2008) further called for integrated laboratory support for major diseases.

As a result of these calls, WHO AFRO launched the Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA) programme in July 2011. SLIPTA was conceived as a framework to improve the quality of medical testing laboratories in the African Region towards the achievement of ISO 15189 standards. It is based on the principles of affordability, scalability, measurability and accessibility, and it promotes country ownership of the process and sustainability of the quality improvement of laboratories.

Empowered by these key initiatives, countries in the African Region began to actively invest in strengthening their laboratories and adopted quality assurance and management tools to prepare for enrolment in the SLIPTA. Those laboratories that have enrolled are making improvements in providing accurate, safe and timely diagnosis of diseases, thereby transforming the landscape of health systems, one laboratory at a time.

This guide has been revised with the inputs from users and with a view to expanding its use beyond the scope of national laboratories. It is also expected that the SLIPTA programme will raise the performance of laboratories to enable them to make a significant contribution to Universal Health Coverage (UHC), the health targets in the Sustainable Development Goals (SDGs), as well as global health security.

The WHO Regional Office for Africa looks forward to working with all partners, including the African Society for Laboratory Medicine (ASLM), the Africa Centres for Disease Control and Prevention (Africa CDC), the Clinical and Laboratory Standards Institute (CLSI), the Clinton Health Access Initiative, and the US Centres for Disease Control and Prevention (CDC) in the promotion of the SLIPTA throughout the Region.



Dr Matshidiso Moeti
WHO Regional Director for Africa

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Participants included:

Experts:

Mr Donewell Bangure	Africa Centres for Disease Control and Prevention, African Union, Ethiopia
Dr Glen Fine	Clinical and Laboratory Standards Institute, USA
Dr Jacqueline Halatoko	Institut National d'Hygiène du Togo, Togo
Dr Linda Oskam	DATOS B.V, Amsterdam, the Netherlands
Mr Patrick Mateta	Clinical and Laboratory Standards Institute, USA
Mrs Patrina Chongo	National Institute of Health of Mozambique, Mozambique
Mr Habtamu Asrat	Ethiopian Public Health Institute, Ethiopia
Mr Julius Tome	African Medical and research Foundation, Health Africa, Kenya,
Mr Teferi Mekonen	African Society for Laboratory Medicine, Ethiopia
Mrs Vijay Padayachee	Vijay Consulting cc, South Africa
Prof Tiahou Georges	Centre Régional d'évaluation en Education, Environnement, Santé Et d'Accréditation en Afrique, Côte d'Ivoire

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WHO Secretariat

Dr Sheick Oumar Coulibaly	WHO/AFRO
Dr Laetitia Gahimbaré	WHO/AFRO
Dr Hughes Lago	WHO/AFRO
Dr Ali Ahmed Yahaya	WHO/AFRO

1. BACKGROUND

1. INTRODUCTION

Sub-Saharan Africa has a population of more than a billion, the majority of whom rely on government services for health care. The increasing burden of priority diseases (such as HIV, tuberculosis, malaria), outbreaks (meningitis, cholera, haemorrhagic viral fevers) and non-communicable diseases in the Region continues to challenge the existing systems. Public health systems in sub-Saharan Africa, including laboratory systems have long remained fragile due to fundamental limitations and lack of prioritization of human, infrastructure, financial and training resources. The lack of reliable laboratory support for disease diagnosis in particular, is one of the main factors limiting the confirmation of diagnoses including for epidemics and other public health events. The laboratory sector has been one of the weakest components of the health systems. This situation reveals the lack of capacity for the majority of African countries that are signatory to the International Health Regulations (2005) agreement that commits to provide quality laboratory results to identify any agents and substances likely to cause public health emergencies of concern to the international community.

Diagnosis of infectious diseases and public health events, including pathogens' susceptibility to antimicrobials is essential for their prevention and treatment. The common element in all infectious diseases is that all can and should be diagnosed and their treatment monitored by laboratory tests. The diagnosis of infectious diseases starts with an accurate laboratory test. There are many examples to support this. But one of them is sufficiently illustrative. In 2014, the Ebola Virus Disease (EVD) epidemic that would later become global and register as the worst outbreak of EVD in history took over three months to be identified as an Ebola virus infection. This delay in diagnosis gave room to the disease to reproduce and spread locally in one country, then to neighbouring countries. This occurrence was explained or at least strongly linked to the lack of quality laboratory capacity including adequate referral system, and a failed surveillance system in an already weak health system. Early detection of the disease would certainly have limited the disease to a district or at most to a region within the country.

Basing diagnoses on clinical symptoms only leads to misdiagnosis and consequently to inadequate treatment, over-treatment, increased morbidity and mortality, and inability to determine the true prevalence of diseases. This prevails also when the laboratory tests are not quality tests, unreliable, hence the need that in addition to having laboratories, they must meet the quality standards to generate reliable results. Quality laboratory tests will contribute to drastic reduction of unnecessary huge expenditures, misery in human lives and suffering, and the perception that the laboratory services are unhelpful.

Laboratory services are essential in all aspects of health. They require that high quality services are developed and maintained using a quality systems approach.

The Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA) program has been developed by WHO and its partners to improve the quality of laboratory services in order to better contribute to the care, prevention and public health services including disease control programmes, to IDSR, IHR (2005), AMR and many others.

1.2 WHO ROLE

WHO has a normative role, it provides guidance on the appropriate selection and use of guidelines, manuals and promotes and monitors implementation of standards. WHO has developed guidelines to technically audit the competency of selected laboratories to perform specific tests as part of surveillance of disease-specific activities.

Many partners, donors and countries expect WHO to provide guidance with regard to both accreditation and strengthening quality management systems within medical testing laboratories. Thus, in 2007, World Health Organization, South-East Asia Regional Office WHO-SEARO published Guidelines on Establishment of Accreditation of Health Laboratories. Also, in 2009, WHO, in cooperation with CDC and CLSI, published a training package on laboratory quality management systems (LQMSs) that has been used by countries for training laboratory managers and other staff in the implementation of quality systems. In 2014, WHO published the Laboratory Quality Stepwise Implementation Tool (LQSI tool), an online tool that supports laboratories wishing to implement an LQMS according to ISO 15189 (<https://extranet.who.int/lqsi/>)

1.3 PURPOSE, SCOPE AND STRUCTURE

1.3.1 Purpose

The purpose of this document is to provide guidance for using SLIPTA Programme. It describes key elements of the laboratory quality improvement process and details how Member States and partners can implement this initiative for strengthening laboratory systems.

1.3.2 Scope

This document is intended for use by persons or organizations aiming to improve the quality of medical testing laboratories using SLIPTA Programme. The ministries of health of countries in the region are particularly targeted to use the SLIPTA programme in order to take up the challenge of improving laboratory systems for more effective and efficient contribution to disease surveillance, prevention and control.

1.3.3 Structure

The document consists of 6 main sections

SECTION	CONTENT
Background	Introduces Public Health Systems in Sub-Saharan Africa. Addresses the role of WHO in strengthening the quality management systems of laboratories and defines the purpose, scope and structure of this Guide.
Origin and Governance	Describes the Origins and Governance of the WHO/AFRO SLIPTA initiative in the form of WHO key declarations and Regional Committee resolutions on strengthening laboratory quality management systems, and defines the SLIPTA Programme governance and stakeholder roles and responsibilities
Eligibility and Application for Enrolment	Describes eligibility and consideration criteria for enrolment of laboratories in the SLIPTA Programme and the application process thereof.
Audit Process	Overview of the SLIPTA audit process which describes the audit visit, evaluation criteria categories and the SLIPTA checklist.
Recognition and Certification	Defines the decision-making and awarding of recognition and the use of recognition certificates.
Operational Procedures	Describes the SLIPTA Programme operational issues including costs, complaints management, monitoring of auditor performance, and audit reports.

Bibliographic references that were used to support the preparation of this guide are provided in the Reference section.

The SLIPTA Programme checklist is available as a separate document on the WHO/AFRO website.

2. ORIGIN AND GOVERNANCE

The SLIPTA Guide provides a framework for countries in their efforts to strengthen laboratory services through the fulfilment of the requirements of the current version of ISO15189 or ISO/IEC17025 Standard. The SLIPTA guide is in accordance with WHO/AFRO core functions to set standards and norms and to support countries with implementation and expansion. This process is intended to encourage, support and recognize the implementation of quality management systems (QMSs) in medical testing laboratories so that laboratories can provide safe, timely and accurate test results for patient care and public health purposes.

Laboratories that are enrolled in the SLIPTA Programme will progressively conform to the requirements of ISO15189 or ISO/IEC17025 and may ultimately be able to apply for accreditation from a nationally, regionally or internationally recognized Accreditation Body.

The SLIPTA Programme is a comprehensive approach to strengthen laboratory services in a stepwise manner by recognising graduated levels of performance towards long-term fulfilment of the requirements of ISO15189 or ISO/IEC17025 standard. The SLIPTA Programme provides a pathway that recognizes conformity over time by allowing the laboratory to break down the process into a series of specific implementation-friendly

sections. WHO/AFRO recognizes laboratories using the SLIPTA Programme and supports them with the technical assistance from ASLM, through audits.

The process is expected to have a catalytic effect by encouraging quality improvement in individual laboratories, incorporating these goals into national strategic and operational plans, sensitizing policy-makers and laboratory staff on accreditation, and nurturing development of laboratories.

2.1 KEY DECLARATIONS AND RESOLUTIONS

A joint WHO - CDC conference on Health Laboratory Quality Systems held in Lyon, France in April 2008 made several recommendations for the establishment of national laboratory quality standards, and the implementation of major laboratory quality system programmes. Agreement was made for a stepwise, standards-based process towards internationally-recognized accreditation: *“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 2008, WHO/AFRO Member States adopted Resolutions AFR/RC58/R2 and AFR/RC59/R4, calling for capacity strengthening of public health laboratories and centres of excellence to improve disease prevention and control, respectively.

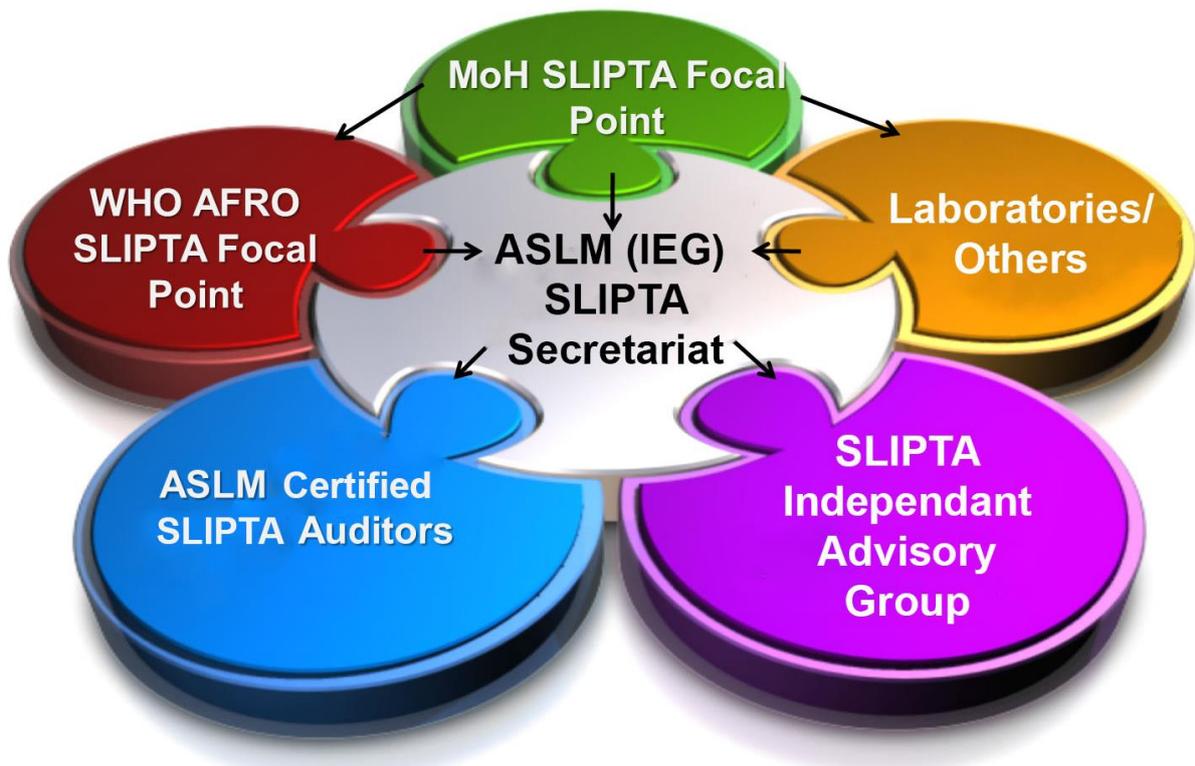
In Kigali, Rwanda, July 2009, the WHO Regional Office for Africa, in collaboration with CDC, the Clinton Health Access Initiative (CHAI), the American Society for Clinical Pathology (ASCP) and other partners, launched the strengthening laboratory management towards accreditation (SLMTA) Programme in the presence of government health officials from 13 African countries. In July 2011, the Regional Office brought together key stakeholders in Nairobi, Kenya, to reach a consensus on the WHO SLMTA policy guidance and checklist documents; the newly developed framework was termed SLIPTA.

In 2016, Member States of the WHO African Region adopted resolution on health security and emergencies which highlights the importance of a functional national laboratory system and network including the implementation of recommendations from the IHR JEE on laboratory components.

2.2 GOVERNANCE

The SLIPTA implementation structure comprises of the following stakeholders: ASLM (IEG)SLIPTA Secretariat, the WHO/AFRO SLIPTA Focal Point, MOH SLIPTA Focal Point, Laboratories and Others, SLIPTA Independent Advisory Group and ASLM Certified SLIPTA auditors, (see Figure 1).

Figure 1: Governance structure



2.3 STAKEHOLDER ROLES AND RESPONSIBILITIES

For SLIPTA to be effective, various responsibilities have been assigned as defined in the following lists.

2.3.1 WHO/AFRO SLIPTA FOCAL POINT

- (a) Mobilizes the required resources to support the implementation of the SLIPTA Programme.
- (b) Provides guidance on content and implementation as outlined in this guide, technical annexes and related documents.
- (c) Reviews and updates the SLIPTA Checklist and ensures it is aligned to the current version of ISO15189.
- (d) Convenes meetings and workshops with stakeholders.
- (e) Select and appoints SLIPTA IEG and coordinates the signing of MoUs between the Regional Office and delegated IEG.
- (f) Monitors the SLIPTA implementation and expansion process and identifies areas for improvement.
- (g) Contributes and oversees the training and management of SLIPTA auditors.
- (h) Supports the development of an implementation component for laboratory quality improvement as part of the country's policy, strategic or operational plan.

- (i) Develops and implements a communication strategy that advocates and disseminates information to all countries in the African Region about the SLIPTA Programme, including this guide.
- (j) Documents best practices on the SLIPTA implementation for decision making and improvement.

2.3.2 Ministry of health

- (a) Designates a focal point which can be either a unit or a person.
- (b) Develops an implementation plan for the SLIPTA Programme with prioritization of potential applicant laboratories, using care in the selection, orientation and evaluation of the performance of prioritized laboratories.
- (c) Allocates sufficient financial and human resources for implementation of the SLIPTA Programme.
- (d) Facilitates logistical arrangements for trainings and audits in the country.
- (e) Provides financial and technical support and oversees the implementation of corrective actions outlined in audit reports.
- (f) Selects and proposes candidates for auditor training.

2.3.3 MoH SLIPTA focal point

- (a) Coordinates the implementation of the SLIPTA Programme in the country.
- (b) Actively promotes laboratory improvements through implementation of QMS and scheduled SLIPTA audits for medical testing laboratories in a phased approach or following the tiered laboratory network system.
- (c) Prioritizes potential applicant medical testing laboratories.
- (d) Coordinates auditors and implement the SLIPTA Programme and support the laboratories.
- (e) Is the point of contact for all communication between the laboratory, ASLM and MoH.
- (f) Submits the laboratories' progress reports to the MoH.
- (g) Distributes certificates and reports received from ASLM.
- (h) Oversees the implementation of corrective actions outlined in audit reports.
- (i) Informs ASLM in advance in writing of any changes which may affect a laboratory's compliance with the SLIPTA Programme or which may potentially affect the laboratory's capability to achieve SLIPTA certification.
- (j) Monitors the removal of expired certificates from public display.

2.3.4 Independent evaluation group (IEG) secretariat

The appointed IEG Secretariat is ASLM.

- (a) Establishes the SLIPTA IAG using vetted nomination process.
- (b) Establishes a letter of agreement (LoA) with the MOHs and Partners.
- (c) Trains, evaluates and deploys auditors as required and should regularly checks their audit competency.

- (d) Provides MOHs with information and assistance on SLIPTA Programme.
- (e) Receives, reviews and processes application requests to enrol laboratories into the SLIPTA Programme.
- (f) Organizes SLIPTA audit visits.
- (g) Issues certificates of recognition as per the decision made by the SLIPTA IAG.
- (h) Provides biannual reports to WHO Regional Office and MOHs.
- (i) Maintains a register of certified SLIPTA auditors and their relevant details.

2.3.5 SLIPTA auditors

- (a) Conduct laboratory audits using the SLIPTA Checklist.
- (b) May provide advice to the auditees during the audit process.
- (c) Prepare and submit audit reports with recommendations.
- (d) Perform at least three SLIPTA Audits per year to maintain their certification.
- (e) Maintain an audit performance log which must be forwarded to ASLM at the end of the calendar year.
- (f) Declare any conflict of interest when selected to perform an audit.
- (g) Maintain confidentiality of the SLIPTA Programme.

2.3.6 THE INDEPENDENT ADVISORY GROUP (IAG)

- (a) Members of the IAG are anonymous to the public and particularly to the SLIPTA users to ensure confidentiality is maintained.
- (b) Reviews the audit report and makes a decision on the star level.
- (c) Ensures that the SLIPTA process was followed.
- (d) Advises on the resolution of conflicts and complaints from laboratories or other stakeholders.

WHO/AFRO designated ASLM as the implementing body for the SLIPTA Programme. ASLM established a SLIPTA Independent Advisory Group (IAG) which oversees the audit process and makes the final star level decision based on audit report and recommendation of the audit team.

3. ELIGIBILITY AND APPLICATION FOR ENROLMENT

3.1 ELIGIBILITY AND CONSIDERATION

All laboratories that fall under the One Health approach in Member States of the WHO/AFRO are eligible for consideration in the SLIPTA Programme. This presupposes that the MOH of the Member state has a strategic plan for implementing laboratory quality improvement.

However, the SLIPTA Programme is open for use within the limits of its objectives by any other country, organization or laboratory that wishes.

Eligibility is not determined by the size of the laboratory. However, given the capacity challenges entailed in responding to requests from across the entire Region, applicant MOHs are encouraged to select laboratories in phases. Prioritization should consider the tiered laboratory network or give precedence to laboratories that have successfully completed a laboratory quality improvement training or course. The consolidated country enrolment request should aim at listing all laboratories to be enrolled for the year in order to facilitate the audit mission.

The eligibility criteria for the enrolment of laboratories are listed below in no particular order:

- (a) Self-evaluation utilizing SLIPTA Checklist - Minimal score 55% is required.
- (b) Participation in proficiency testing (PT) schemes or External Quality Assessment (EQA) for at least one PT cycle in the past six months. In the event that PT is not available, an alternative method may be used, the laboratory must inform ASLM in writing when an alternate method is being used.
- (c) Routine running of daily quality controls for all test methods.
- (d) Evidence of internal audits conducted by the laboratory within the past 12 months.
- (e) Evidence of management review meeting within the past 12 months.
- (f) Evidence of documented Quality Management System.

3.2 ENROLMENT

If a laboratory's application meets the SLIPTA enrolment criteria, ASLM will send an enrolment letter to the Focal Point. The enrolment letter will indicate the date of the laboratory's enrolment, its enrolment number, and suggested timeframes within which an audit should be scheduled. Once an enrolment date has been issued, the laboratory will be considered an "Enrolled SLIPTA Laboratory".

The audit of the laboratory should be conducted within 3 months of the enrolment date.

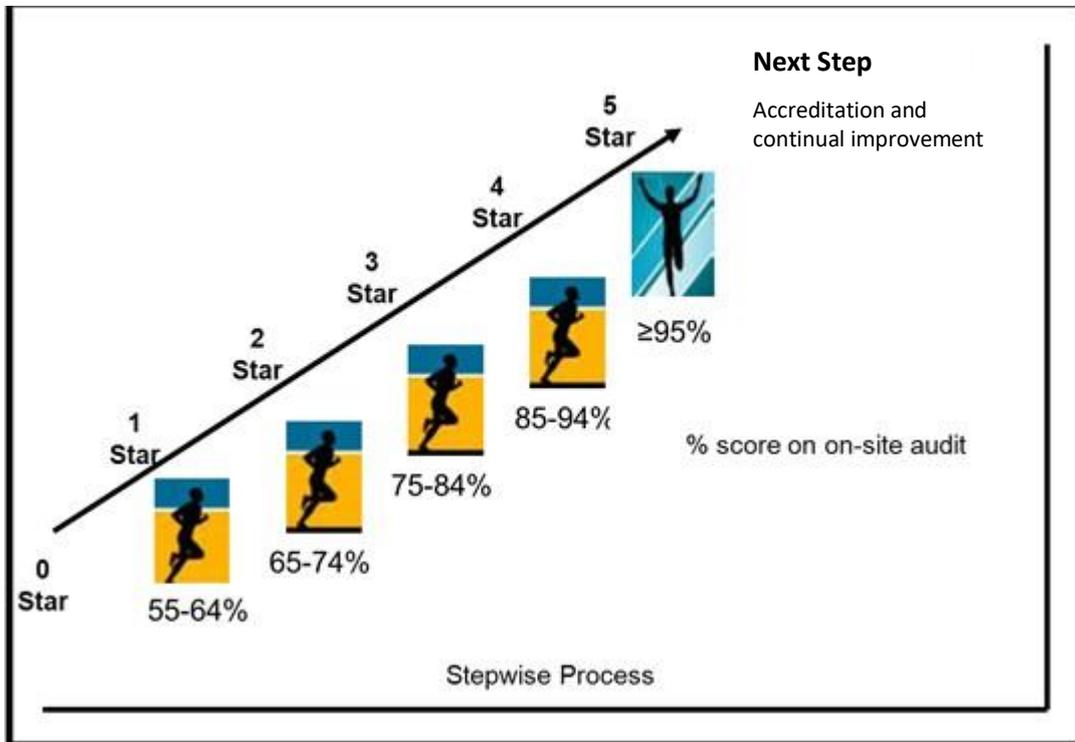
4. AUDIT PROCESS

ASLM audits laboratories that the Member States have prioritized for improvement using the SLIPTA Checklist. Following an audit, laboratories will be recognized on a zero to five-star ascending scale. Laboratories that fail to achieve at least 55% compliance will not be awarded a star ranking. Laboratories that achieve $\geq 95\%$ will receive a five-star rating. All star ratings are valid for a period of two years.

Once audited, laboratories are expected to maintain their star status and should work towards the next star which should be evaluated during the next audit visit. Laboratories that achieve five stars will be encouraged to apply to an accreditation body. Figure 2 indicates the tiers of recognition employed in the SLIPTA Programme for the African Region.

When a laboratory applies for ISO accreditation, ASLM and partners may send mentors to assist the laboratory and advise on any technical issues that need to be implemented in order to meet the requirements of the ISO Standard.

Figure 2: SLIPTA tiers of recognition of laboratory quality management



4.1 AUDIT VISIT

Once a laboratory is enrolled, ASLM will communicate with the MOH SLIPTA Focal Point to find suitable dates for the audit visit and coordinate logistics for the audit team. Due to coordination challenges, any changes in audit dates may result in long rescheduling delays.

If a country has successfully enrolled more than one laboratory, every effort will be made to schedule audit visits that are of sufficient length to audit multiple laboratories in close proximity of one another.

A team of SLIPTA auditors will be sent out to conduct laboratory audits. The composition and size of an audit team is based on the size of the laboratory or laboratory system to be audited and the amount of time required. The audit team may include trainees or monitors who may merely be observers. Audit teams function under the direction of the designated lead auditor. During an audit visit the lead auditor is the primary contact person for the audit team.

The length of audit visits will vary based upon five main factors:

- number of laboratories to be audited,
- size of the laboratories to be audited,
- scope of the audit,

- (d) number of auditors on the audit team and
- (e) logistics and transportation considerations.

The travel logistics for audit visits will be arranged through consultations between ASLM and the applicant MOH. ASLM will communicate the audit plan to MOH Focal Point. The lead auditor should communicate the audit plan at least one week prior to the scheduled audit to the laboratory management and the audit team.

4.2 CHECKLIST

The SLIPTA Checklist is based on ISO 15189 standard. It has been developed as a tool to audit the status of the quality management system in preparedness for international accreditation. The checklist comprises of three Parts: Part I Laboratory Profile, Part II Laboratory Audit and Part III Summary of Audit Findings. The questions are organized in 12 sections. The headings are derived from the quality system essentials (QSEs) contained in the quality management system (QMS) structure as defined by the Clinical and Laboratory Standards Institute (CLSI).

Table 2 provides a breakdown of the checklist sections. Refer to the current SLIPTA Checklist for the allocations of points per section.

Table 2: Sections in the SLIPTA checklist

SLIPTA Checklist Sections
Section 1: Documents and Records Management
Section 2: Organization and Leadership
Section 3: Personnel Management
Section 4: Customer Focus
Section 5: Equipment Management
Section 6: Assessments
Section 7: Supplier and Inventory Management
Section 8: Process Management
Section 9: Information Management
Section 10: Nonconforming Event Management
Section 11: Continual Improvement
Section 12: Facilities and Safety Management

The latest version of the SLIPTA checklist is available on the WHO/AFRO website.

5. RECOGNITION AND CERTIFICATION

5.1 DECISION-MAKING AND AWARDING OF RECOGNITION

Within two weeks of completing the audit, the SLIPTA audit team will submit an audit report to the laboratory and to ASLM. The laboratory should submit a Corrective Action Plan within six weeks to the audit team for review. Within two weeks of receiving the final report, the SLIPTA IAG will make the final decision regarding the level of recognition the laboratory will be awarded. Table 3 indicates the possible recognition tiers that can be awarded. The commensurate certificate will be signed by the sitting ASM CEO.

Table 3: SLIPTA tiers of recognition of improvement of the laboratory quality management system

					5 Stars
				4 Stars	
			3 Stars		
		2 Stars			
	1 Star				
0 Stars					
<55%	55-64%	65-74%	75-84%	85-94%	≥95%

The current recognition status of enrolled medical laboratories is available on the ASLM website (www.aslm.org).

5.2 USE OF RECOGNITION CERTIFICATES

Laboratories are encouraged to display the recognition certificates received from ASLM as evidence of their quality improvement and achievement as a laboratory.

The Certificate of Recognition will clearly state that the laboratory has achieved a star ranking according to the SLIPTA level of recognition improvement of laboratory quality management system (Figure 3).

Note: *The Certificate of Recognition is not a certificate of laboratory accreditation.*

Laboratories displaying a SLIPTA recognition certificate must take note of the following provisions:

- (a) Display of certificate does not imply that ASLM or the WHO/AFRO accepts responsibility for activities carried out under the scope of the level of recognition.
- (b) A certificate may only be displayed at the laboratory to which it was issued. Certificates cannot be transferred to another laboratory or displayed at another facility.
- (c) Certificates cannot be amended or altered in any way.
- (d) Certificates must be removed promptly following expiration.
- (e) Certificates cannot be used in any way that might mislead the reader about the status of the laboratory.
- (f) Laboratories displaying the SLIPTA recognition certificate must notify ASLM in the event of a substantial change in staffing, test menu, workload, discontinuation of proficiency testing or inter-laboratory comparisons, or two consecutive incidents of poor proficiency testing performance. An onsite visit may be required. The SLIPTA IAG will make this decision. Failure to notify ASLM in case of major changes could result in suspension or withdrawal of recognition.

ASLM will remove expired certificates, and certificates of laboratories that are suspended or withdrawn from the ASLM website.

WHO/AFRO, ASLM, IAG and auditors cannot accept liability for any laboratory testing conducted in facilities enrolled in SLIPTA.

6. OPERATIONAL PROCEDURES

6.1 COST

The SLIPTA Programme implementation cost for public sector laboratories will be covered by the MOH and its partners. MOH should mobilize these resources as part of an MOH national strategic or operational plan.

6.2 COMPLAINTS MANAGEMENT

During the process, circumstances may arise that warrant complaints from laboratories, MOHs or auditors. The head officer of ASLM and the Chair of the SLIPTA IAG are responsible for ensuring that all complaints are dealt with impartiality and objectivity.

Complaints must be submitted in writing to ASLM by the laboratory, MOH or the audit team.

Complaints will be logged with acknowledgement of receipt within two weeks. Complaints will be forwarded to the Chair of the SLIPTA IAG for discussion through email communication. Complaints should be investigated and addressed within four weeks. Corrective action will be taken as necessary.

All decisions made by the IAG are final.

6.3 MONITORING OF AUDITOR PERFORMANCE

ASLM should monitor and evaluate the performance of its certified SLIPTA auditors annually to ensure that standards of competence and professionalism are maintained.

6.4 AUDIT REPORTS

ASLM will communicate the results of the SLIPTA audit to the director of the laboratory and the MOH only. The SLIPTA IAG members may access results after signing a confidentiality agreement stating that data cannot be disclosed.

7. SUMMARY OF CHANGES

All additions to this document are highlighted in yellow.

Changes	
1.	Reformatted the structure of the document
2.	Inserted the title, effective date and Revision 02 in the header
3.	Corrected the title of the document by inserting “Quality”
4.	Inserted a table of contents
5.	Removed abbreviations and definitions that does not exist in the document
6.	“Definitions” was moved to section 2
7.	Deleted definitions that were not applicable to this document
8.	Updated Foreword
9.	Updated Acknowledgments
10.	Updated Figure 2 to include “Next Step”
11.	Deleted the points and applicable %
12.	The title Issues management was changed to Complaints Management

ANNEX

Comparison Table of SLIPTA Checklist Section Revision 2 and Applicable QSE as per CLSI

SLIPTA Checklist Section	Applicable QSE as per CLSI
Section 1: Documents and Records	Documents and Records Management
Section 2: Management Reviews	Organization and Leadership
Section 3: Organization and Personnel	Personnel Management
Section 4: Client Management and Customer Service	Customer Focus
Section 5: Equipment	Equipment Management
Section 6: Evaluations and Audits	Assessments
Section 7: Purchasing and Inventory	Supplier and Inventory Management
Section 8: Process Control	Process Management
Section 9: Information Management	Information Management
Section 10: Identification of Non-Conformities, Corrective and Preventive Action	Nonconforming Event Management
Section 11: Occurrence/ Incident Management and Process Improvement	Continual Improvement
Section 12: Facilities and Biosafety	Facilities and Safety Management

REFERENCES

1. CAP. Laboratory general and chemistry and toxicology checklists. Waukegen, IL: College of American Pathologists, 2010.
2. CLSI/NCCLS. Application of a quality management system model for laboratory services: approved guideline. Third edition (GP26-A3). Wayne, PA: NCCLS, 2004. www.clsi.org
3. CLSI/NCCLS. A quality management system model for health care: approved guideline. Second edition (HS01-A2). Wayne, PA: NCCLS, 2004. www.clsi.org
4. CLSI. Quality management system: a model for laboratory services. Fourth edition (GP26-A4). Englewood, Colorado: Clinical and Laboratory Standards Institute, 2010.
5. Gershy-Damet GM et al. The World Health Organization African Region laboratory accreditation process: improving the quality of laboratory systems in the African Region; Am J Clin Pathol 134:393-400, 2010.
6. ISO. Field application document AS 4633 (ISO 15189). Geneva: International Organization for Standardization, 2009.
7. ISO. Medical laboratories—ISO 15189:2012 Medical laboratories — Requirements for quality and competence. Geneva: International Organization for Standardization, 2012.
8. MoPH. Thailand Medical Technology Council quality system checklist. Bangkok: Ministry of Public Health, 2008.
9. National Institutes of Health, (2007, Feb 5). Chemical, laboratory: Quality assurance and quality improvement monitors. Checklist for site SOP required elements. Retrieved July 8, 2008, from: <http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Laboratories.htm>
10. National Institutes of Health, (2007, Feb 5). DAIDS laboratory assessment visit report. Retrieved July 8, 2008, from: <http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Laboratories.htm>
11. National Institutes of Health, (2007, Feb 5). Laboratory: chemical, biohazard and occupational safety, containment and disposal. Checklist for site SOP required elements. Retrieved July 8, 2008, from: <http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Laboratories.htm>
12. PPD. Laboratory report. Wilmington, NC: Pharmaceutical Product Development, 2007.
13. USAID. The logistics handbook (Task order 1). Washington, DC: USAID Deliver Project, 2007.
14. WHO. Achieving sustainable health development in the African Region: strategic directions for WHO 2010–2015. Brazzaville, Republic of Congo: World Health Organization Regional Office for Africa, 2010.
15. WHO. Asia Pacific strategy for strengthening health laboratory services (2010–2015). New Delhi, World Health Organization Regional Office for South-East Asia and Manila, Regional Office for the Western Pacific. 2010.

16. WHO. Best practice for developing standards for infectious disease laboratories in Europe. Copenhagen: WHO Regional Office for Europe, 2010. Available at: http://www.euro.who.int/data/assets/pdf_file/0005/133457/e94772.pdf
17. WHO. Guidelines on establishment of accreditation of health laboratories. New Delhi, World Health Organization Regional Office for South-East Asia (SEA-HLM-394), 2007.
18. WHO. Joint WHO – CDC Conference on Health Laboratory Quality Systems, Lyon, April 2008, WHO/HSE/IHR/LYO/2008.3 , <https://www.who.int/ihr/lyon/report20080409.pdf>
19. WHO. Laboratory quality standards and their implementation. New Delhi, World Health Organization Regional Office for South-East Asia and Manila, Regional Office for the Western Pacific. 2011.
20. WHO. Ouagadougou Declaration: primary health care and health systems in Africa. Brazzaville, Republic of Congo: World Health Organization Regional Office for Africa, 2008.
21. WHO. Resolution AFR/RC58/R2: Strengthening public health laboratories in the WHO African Region: a critical need for disease control. In: Fifty-eighth session of the WHO Regional Committee for Africa: final report. Brazzaville, Republic of Congo: World Health Organization Regional Office for Africa, 2008, pp. 11–13.
22. WHO. Resolution AFR/RC59/R2: Drug resistance related to AIDS, tuberculosis and malaria issues: challenges and the way forward. In: Fifty-ninth session of the WHO Regional Committee for Africa: final report. Brazzaville, Republic of Congo: World Health Organization Regional Office for Africa. 2009, pp. 7–9.
23. WHO. Resolution AFR/RC66/6: Regional strategy for health security and emergencies 2016–2020. Sixty-sixth session of the WHO Regional Committee for Africa. 2016
24. WHO. WHO stepwise laboratory quality improvement process towards accreditation in the African Region: checklist for clinical and public health laboratories. Brazzaville, Republic of Congo: World Health Organization Regional Office for Africa, 2015.
25. WHO. WHO/CDC/CLSI Laboratory quality management system training toolkit. Geneva: World Health Organization (WHO/HSE/IHR/LYO/2009.1), 2009.
26. Yao, K. Guidance for laboratory quality management system in the Caribbean—a stepwise improvement process. Atlanta, GA: Centers for Disease Control Global AIDS Programme, 2012.
27. Yao K. Laboratory management framework and guidelines. Atlanta, GA: Centers for Disease Control Global AIDS Programme, 2008.