WHO

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

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World Health Organization

REGIONAL OFFICE FOR Africa

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

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Contents

Abbreviations

AFENET	African Field Epidemiology Network
AIDS	Acquired Immunodeficiency Syndrome
AMREF	African Medical and Research Foundation
APLAC	Asia Pacific Laboratory Accreditation Cooperation
ASCP	American Society for Clinical Pathology
ASLM	African Society for Laboratory Medicine
CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention (United States)
CEN	European Committee for Standardization
CGH	Center for Global Health (of CDC)
CHAI	Clinton Health Access Initiative
CLSI	Clinical and Laboratory Standards Institute
CMLF	Caribbean Med Labs Foundation (Trinidad)
EQC	External Quality Control
FEFO	First-Expiry-First-Out
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IAAC	InterAmerican Accreditation Cooperation
IAG	Independent Advisory Group
IEC	International Electrotechnical Commission
IEG	Independent Evaluating Group
ILAC	International Laboratory Accreditation Cooperation
IQC	Internal Quality Control
ISO	International Organization for Standardization
IST	Intercountry Support Team
IT	Information Technology
KENAS	Kenya Accreditation Service
KIT	Royal Tropical Institute (The Netherlands)

KMTTB	Kenya Medical Laboratory Technicians and Technologists Board
LoA	Letter of Agreement
LQMS	Laboratory Quality Management System
MoH	Ministry of Health
MoPH	Ministry of Public Health
MoU	Memorandum of Understanding
NCCLS	National Committee for Clinical Laboratory Standards (former name of CLSI)
NIH	National Institutes of Health (United States)
PCR	Polymerase Chain Reaction
PPD	Pharmaceutical Product Development
PPE	Personal Protective Equipment
PT	Proficiency Testing
QC	Quality Control
QMS	Quality Management System
QSE	Quality System Essential
RC	Regional Committee
SADCAS	Southern African Development Community Accreditation Service
SANAS	South African National Accreditation System
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
SOP	Standard Operating Procedure
TAT	Turnaround Time
TB	Tuberculosis
ToR	Terms of Reference
UPS	Uninterrupted Power Source
USAID	United States Agency for International Development
WHO	World Health Organization
WHO-AFRO	World Health Organization Regional Office for Africa
WHO-SEARO	World Health Organization Regional Office for South-East Asia
ZINQAP	Zimbabwe National Quality Assurance Programme

Foreword

Laboratory services form an essential component of health services and require necessary strengthening for improved testing, epidemiological surveillance, research and other related activities. Laboratories within the African Region need to expand in order to support the expansion of disease prevention and control services. However, most laboratories in the Region are not only poorly resourced but also operate with limited capacity.

There have been considerable efforts to improve laboratory services, most of them disease-specific for poliomyelitis, measles and influenza, but the result has been fragmented laboratory infrastructure and services. Most governments give very low priority to laboratory service delivery, financing and planning; hence, there are few national laboratory policies and plans in place to ensure delivery of comprehensive and integrated quality laboratory services.

Recognizing this, the WHO Regional Office for Africa prepared the 2010-2015 strategic direction priorities to focus on strengthening laboratories and providing quality assurance through partnerships and harmonization of support to countries as well as accelerated actions on HIV/AIDS, malaria and tuberculosis. Over the past four years, a number of key resolutions, declarations and initiatives have brought laboratory systems to the forefront of health systems strengthening to improve disease prevention and control. In 2008, WHO Regional Committee for Africa issued Resolution AFR/RC58/R2 (at Yaounde, Cameroon) calling for strengthened public health laboratories in the African Region. In the same year, the Maputo Declaration called for integrated laboratory support for major diseases as well as government development and implementation of national laboratory policies and strategic plans. In 2009, the WHO Regional Committee launched the stepwise laboratory accreditation preparedness scheme in Kigali. Empowered by these key initiatives, countries began to actively invest in strengthening their laboratories and adopted quality assurance and management tools to prepare for enrolment in the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) in the WHO African Region.

In July 2011, the Regional Office brought together key stakeholders for SLIPTA at a meeting in Nairobi, Kenya; the objective was to reach consensus on the WHO SLIPTA policy guidance and checklist documents. SLIPTA is a framework for improving the quality of public health laboratories in the African Region to achieve ISO 15189 standards. Based on the principles of affordability, scalability, measurability and accessibility, SLIPTA promotes country ownership of the process and sustainability of improved quality laboratories.

It is enlightening to see that a significant number of laboratories are now enroled in the process and have started implementing SLIPTA. These empowered laboratories are making marked improvements in accurate and timely diagnosis of disease and patient care, transforming the landscape of health systems, one laboratory at a time. The WHO Regional Office for Africa looks forward to working with partners including the African Society for Laboratory Medicine (ASLM), Clinton Health Access Initiative, and the US Centers for Disease Control and Prevention (CDC) to continue to promote the Stepwise Laboratory Improvement Process Towards Accrecitation throughout the Region and turn the tide on health laboratory management systems in Africa.

Dr Matshidiso Moeti
WHO Regional Director for Africa

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1. Background

1.1 Introduction

Public health systems in sub-Saharan Africa have long remained fragile due to fundamental limitations and lack of prioritization of human, financial and training resources; laboratory infrastructure; and resource and management capacity. Of the 340 accredited laboratories in Africa, only 28 (8.2%) are in sub-Saharan Africa; the other 312 primarily private laboratories are located in South Africa. Sub-Saharan Africa has a population of more than 800 million, the majority of whom rely on government services for health care. The increasing burden of priority diseases such as HIV, tuberculosis and malaria in the Region continues to challenge the weak existing systems. Public health programmes have encountered challenges linked to the lack of reliable laboratory support, disease diagnosis, and management of patient care.

1.2 Purpose, target and structure

The purpose of this document is to provide guidance for using the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA). 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.

The document is intended for use by policymakers; ministries of health; government and management officials; public health and medical professionals; laboratory technicians; clinicians; technical experts; laboratory and programme managers; and international, regional and local partners.

The World Health Organization Regional Office for Africa (WHO AFRO) will follow the policy and guidelines outlined in this document. The Regional Office will work with the Independent Evaluating Group (IEG) Secretariat, ministries of health (MoH), and other key partners to oversee the management of SLIPTA to strengthen national health laboratory services.

The guidelines contain seven parts. Part 1 includes the background, purpose and scope. It describes the background of public health systems in Africa; defines and clarifies technical terms; and discusses the role of WHO in laboratory quality management strengthening and accreditation. Part 2 describes the origins of the SLIPTA initiative; presents background in the form of WHO key declarations and Regional Committee resolutions on strengthening

laboratory quality management systems; and discusses SLIPTA governance and stakeholder roles and responsibilities. Part 3 gives an overview of the SLIPTA audit as well as the SLIPTA tiers of recognition of laboratory quality management. Part 4 describes eligibility and consideration for SLIPTA enrolment and the application process. Part 5 describes the audit visit, evaluation criteria categories and SLIPTA checklist. Part 6 details the decision-making and awarding of recognition; follow-up audit for continued improvement; and the appropriate use of recognition certificates. Part 7 presents SLIPTA operational issues including costs; issues management; monitoring of auditor performance; and release of audit reports.

Bibliographic references that were used to support the preparation of the guidelines are provided in Reference.

The SLIPTA checklist, to be used as the audit tool is posted in a separate document on the WHO/AFRO website, along with the current guide.

1.3 Definitions

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

Standard. A standard is 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), a federation of national standards bodies from more than 140 countries. ISO standards are formulated by technical committees.

In the case of medical laboratories, the most applicable standard is ISO 15189:2007, "Medical Laboratories—Particular requirements for quality and competence," for use by medical laboratories in developing their quality management systems (QMSs) and assessing their own competence, and for use by accreditation bodies in confirming or recognizing the competence of medical laboratories. Accreditation audit based on ISO 15189 evaluates a laboratory's QMS; technical competence; and ability to provide reliable and accurate test results.

Standardization bodies. Standardization bodies have the authority to develop standards. They can be national or international. The ISO is the world's largest developer of international standards, including the most common standard used by medical laboratories (i.e. ISO 15189), as well as ISO 17025 widely used by food safety or environmental laboratories. ISO is used to compose national standardization bodies. National standardization bodies can develop national standards or adopt international standards with or without modifications. The European Committee for Standardization (CEN) is an example of a regional standardization body with a technical cooperation agreement with ISO.

Licensure. Licensure is the granting of ability to practise. It is most often provided by a governmental agency, and is usually based on demonstrated knowledge, training and skills. Generally when laboratory licensure is used, it is a legal requirement for operation. Licensure criteria often include quality requirements. Licensure is normally a mandatory process described in national laboratory regulations.

Certification. Certification is a 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 also often a voluntary process. SLIPTA will certify progress in quality improvement of laboratories.

Certification bodies. Certification bodies are organizations or agencies with the authority to inspect a facility and provide written evidence of its compliance with regards to a standard. In the context of SLIPTA, this is an independent advisory body that will issue certificates recognizing the level of improvement based on audits using the WHO SLIPTA checklist for the African Region aligned with ISO 15189/17025.

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

Laboratory accreditation is a process that employs independent external assessment to determine conformity with recognized standards for quality management systems (QMSs) and competent laboratory practice. Accreditation is a validation process established to ensure that medical laboratories deliver high quality services that meet the needs and requirements of their clients. The intent of the SLIPTA is to improve performance and reliability of laboratories to eventually meet the standards required for application towards accreditation.

The difference between accreditation and certification may be illustrated by a clinical laboratory having a management system that is **certified** as conforming to ISO 9001 while being **accredited** to conduct testing of patient samples by meeting the requirements of ISO 15189.

Accreditation bodies. Accreditation bodies are organizations or agencies with the authority to inspect a facility and provide written evidence of its competence with regards to a standard. Many of them accredit medical laboratories using ISO 15189/17025 standard with or without national adaptation. Accreditation bodies usually require their own accreditation status to ISO 17011:2004 "Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies". This International Standard specifies the general requirements for accreditation bodies.

1.4 WHO Role

WHO has a normative role; provides guidance on the appropriate selection and use of standards; and promotes and monitors implementation of standards. WHO has developed standards to accredit specific tests performed by laboratories selected to undertake surveillance of disease-specific activities. In this capacity, WHO acts both as the standardization and accreditation body. However, these WHO standards are very technical and very limited in scope; they do not cover the entire quality management system of the laboratory as described by ISO 15189/17025.

The publication and implementation of ISO 15189/17025 as the gold standard to accredit medical laboratories has dramatically changed the accreditation landscape in the past decade. As a result, many accreditation systems coexist at national level, with a wide range of models and systems.

International organizations like ISO share the same mandate for setting standards or monitoring compliance, and national accreditation bodies often form regional or international bodies such as the Asia Pacific Laboratory Accreditation Cooperation (APLAC), the InterAmerican Accreditation Cooperation (IAAC) or the International Laboratory Accreditation Cooperation (ILAC). These organizations have a significant role in the international recognition of the accreditation of laboratories according to ISO 15189/17025.

In this context, many partners, donors and countries expect WHO to provide some guidance with regards to both accreditation and strengthening quality management. Thus, in 2007, 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.

2. Origin and Governance

The WHO Guidelines for the Stepwise Laboratory Improvement Process Towards Accreditation in the Africa Region (SLIPTA) provides a framework for countries in their efforts to strengthen national laboratory services through fulfilment of the requirements in the ISO 15189 standard. The SLIPTA guidelines are in accordance with WHO core functions to set standards and norms and to support countries to implement them. This process is intended to encourage, support and recognize the implementation of quality management systems (QMSs) in medical laboratories in the African Region so that laboratories provide safe, timely and accurate results for patient care and public health purposes.

Laboratories working through the programme will progressively develop compliance towards this standard and ultimately be able to apply for accreditation from a nationally, regionally or internationally recognized body.

SLIPTA is a comprehensive approach to strengthen national health laboratory services in a stepwise manner by providing graduated levels of performance recognition towards long-term fulfilment of the ISO 15189 standard. SLIPTA provides a pathway that recognizes conformity over time by breaking down the process into a series of specific implementation-friendly stages. SLIPTA recognizes laboratories where they are in the process of quality improvement; supports them through audits and technical assistance from an independent evaluating group (IEG); and tracks and rewards progress towards obtaining these accreditation standards.

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 in the African Region.

Laboratories will be audited against laboratory standards outlined in the WHO SLIPTA Checklist for the African Region and will be recognized as operating at one of the levels of performance demonstrated by a star rating. When a laboratory applies for accreditation, the WHO Regional Office and partners will send auditors to inspect that laboratory and advise on any technical measures that need to be implemented in order to improve quality management standards.

2.1 Key Declarations and Resolutions

The joint conference on laboratory quality management systems (LQMSs) was convened in Lyon, France in April 2008 by WHO and the US Centers for Disease Control and Prevention (CDC). the following statement was issued in support of 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 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 SLIPTA in the presence of government health officials from 13 African countries. The Strengthening Laboratory Management Towards Accreditation (SLMTA) training programme was also introduced in Kigali as a preparatory initiative to ready laboratories for SLIPTA. From late 2009 through 2010 SLMTA has been active in nine countries in sub-Saharan Africa.

At the fifty-eighth session of the WHO Regional Committee for Africa (held in Yaounde, Cameroon, September 2008) and the fifty-ninth session (held in Kigali, Rwanda, September 2009) Member States adopted Resolutions AFR/RC58/R2 and AFR/RC59/R4, respectively, calling for capacity strengthening of public health laboratories and centres of excellence to improve disease prevention and control.

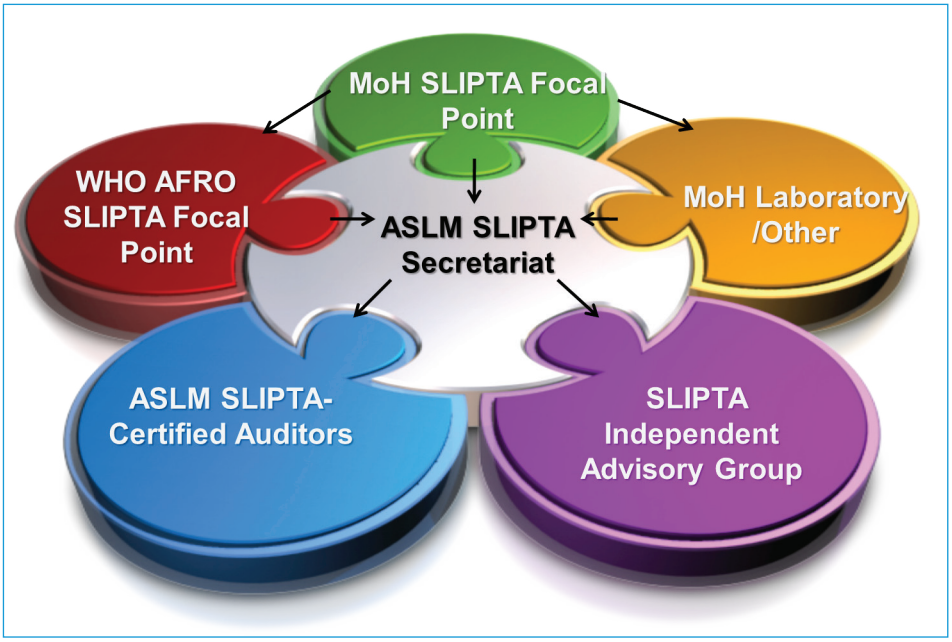
2.2 Governance

Recognizing that WHO is not an accrediting or implementing body, partner(s) will be identified to implement the Guidelines for SLIPTA. A memorandum of understanding (MOU) will be established between the WHO Regional Office for Africa and the IEG that will allow the IEG to implement the SLIPTA. The IEG will identify a Secretariat and establish a SLIPTA independent advisory group (IAG) comprised of regional and international experts in laboratory quality management systems and accreditation who will oversee the coordination and implementation of the process.

The SLIPTA implementation structure is comprised of the following stakeholders: the WHO Regional Office for Africa, ministries of health and applicant labortories, SLIPTA IEG Secretariat, SLIPTA IEG auditors, SLIPTA IEG IAG, and additional partners (see Figure 1).

Since 1971, when the notion of human blood transfusion was transformed into social policy and community responsibility,[14] it has been recognized that voluntary repeating non-remunerated blood donors are the best source to ensure maximum safety as well as an adequate and sustainable blood supply for the community.[5] Member countries therefore ought to phase out family and other types of donors to further minimize the risk of disease transmission through contaminated blood and also ensure blood supplies in a sustainable way.

Figure 1: Stakeholder governance structure



2.3 Stakeholder Roles and Responsibilities

In order for SLIPTA to be effective, various responsibilities have been assigned as appear in the following lists.

SLIPTA Point of Contact in the WHO Regional Office for Africa:

- Provides guidance on content and implementation as outlined in the SLIPTA Policy and Procedures (initial review and annual review), technical annexes and related documents;
- Reviews and updates the WHO SLIPTA Checklist for the African Region and keeps it closely aligned with appropriate internationally recognized standards;
- Convenes meetings and workshops with stakeholders;
- Oversees the identification of IEG members and coordinates the signing of MoUs between the Regional Office and IEGs;
- Monitors the stepwise process and identifies areas for improvement;
- Contributes to the training of auditors;
- Supports the development of an implementation component for laboratory quality improvement as part of the country's strategic plan;
- Develops and implements a communication strategy that advocates and disseminates information to all countries about the WHO Guidelines for SLIPTA in the African Region.

Ministries of Health:

- Designates a focal point responsible for coordination, information-sharing and implementation;
- Develops an implementation plan for SLIPTA with prioritization of potential applicant laboratories, using care in the selection, orientation and evaluation of the performance of prioritized laboratories;
- Allocates financial and human resources;
- Oversees the implementation of corrective actions outlined in audit reports.

The SLIPTA Independent Evaluating Group Secretariat should be regional or subregional in composition. The IEG Secretariat:

- Oversees the establishment of the SLIPTA IAG utilizing a vetted nomination process;
- Establishes a letter of agreement (LoA) with the MoH;
- Works with professional societies and other stakeholders to i) mobilize resources to support the laboratories for quality improvement; and ii) identify suitable experts to comprise a pool of auditors and sign LoAs with these partners when needed;
- Provides training of auditors to conduct laboratory audits using the WHO SLIPTA Checklist;
- Provides certificates of recognition issued by the SLIPTA IAG;
- Serves as primary point of contact for MoHs seeking further information on SLIPTA as well as MoHs assisting laboratories with applications for enrolment, technical support or monitoring;
- Receives and processes application requests from MoHs;
- Maintains a register of auditors with full contact details, institutional or professional affiliation, and record of past experiences;
- Organizes audit visits;
- Maintains documentation, records and information, and shares them in a timely manner with the Regional Office and MoHs.

SLIPTA auditors comprise a group of experienced laboratory auditors. They must attest that they have no conflict-of-interest in conducting the work for a particular audit and must maintain confidentiality. Their responsibilities are to:

- Conduct laboratory audits using the WHO SLIPTA Checklist for the African Region;
- Provide technical assistance and on-site mentoring to the enroled laboratories;
- Develop audit reports with recommendations.

The Independent Advisory Group (IAG) will be established by the SLIPTA IEG Secretariat. Membership will consist of technical experts from professional bodies such as laboratory associations via a vetted nomination process. Members will be trained by the IEG Secretariat and will serve as a standing board whose individuals are anonymous. IAG will be regional with eventual transition to independent national advisory committees as countries develop national capacity. The IAG:

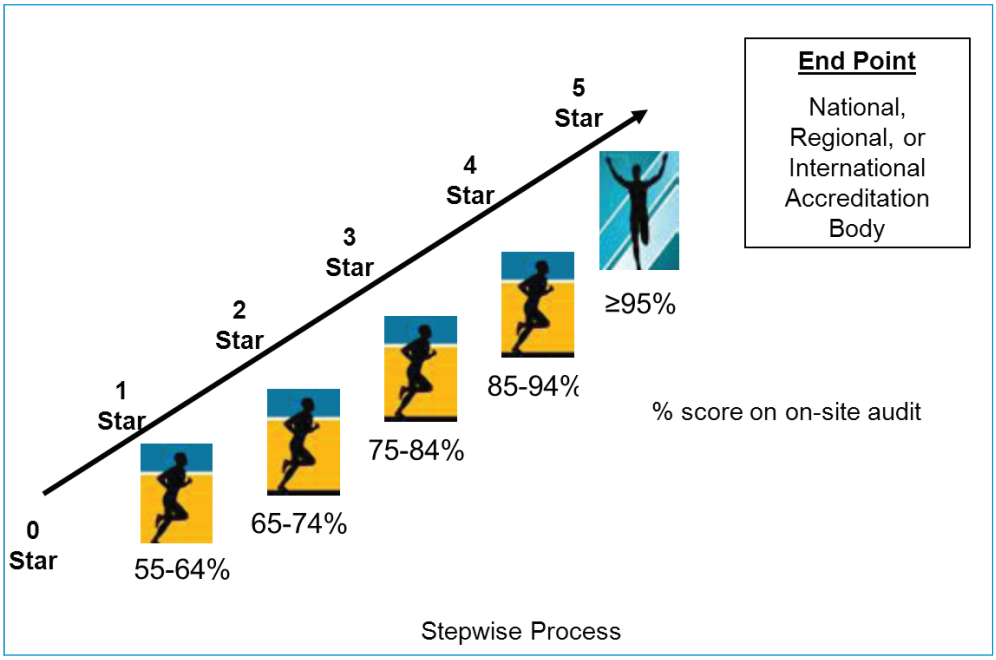
- Ensures specific standards are applied across the board;
- Advises on the resolution of conflicts or complaints from laboratories or other stakeholders;
- Issues Certificates of Recognition to laboratories.

3. The Audit

The Independent Evaluating Group (IEG) provides audits for laboratories that ministries of health (MoHs) in Member States have prioritized for improvement; the IEG also provides stepwise recognition in fulfilment of the ISO 15189/17025 standard. Following an audit, laboratories will be recognized on a zero to five star ascending scale. Laboratories that fail to achieve at least 55% compliance upon audit will not be awarded a star ranking. Laboratories that achieve > 95% upon audit will receive a five star rating.

Once audited, laboratories are expected to maintain their star status and work towards the next star which would be evaluated during the re-audit process. Laboratories that achieve five stars will be strongly encouraged to enrol in an established ISO 15189/17025 accreditation scheme. Figure 2 indicates the tiers of recognition employed in the WHO SLIPTA for the African Region.

Figure 2: SLIPTA tiers of recognition of laboratory quality management



4. Eligibility and Application for Enrolment

4.1 Eligibility and Consideration

All medical, clinical and public health laboratories in Member countries of the WHO African Region are eligible for consideration for accreditation. This presupposes that the Ministry of Health has a strategic plan for implementating laboratory quality improvement. However, the SLIPTA IEG Secretariat only accepts applications submitted by the MoH SLIPTA focal point. MoHs are encouraged to invest in this process in order to support the development of public sector laboratories. All applications received will be reviewed by the SLIPTA IEG Secretariat before laboratories are officially enroled in the SLIPTA and scheduled for audit.

Unless there are special circumstances or instructions from the MoH (see above), enrolment will be done on the basis of the entire laboratory (all sections providing services for patients and/or public health). Therefore, applicant laboratories must declare their full repertoire of tests in the application. All satellite services directly managed by the laboratory must also be declared. Inaccuracies identified during audit may delay the audit process. Only sections of the laboratory that specifically request the audit will be recognized as part of the SLIPTA and on the certificate.

The SLIPTA IEG Secretariat will only accept audit applications from the MoH. Individual laboratories should not apply directly to the SLIPTA IEG Secretariat. MoHs are invited to submit applications for laboratories they have prioritized for accreditation. All communications should be conducted between Ministry of Health laboratory leadership or designated contact person and the SLIPTA IEG Secretariat.

Eligibility is not conditioned by the size of the laboratory. 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 take into account the tiered laboratory network. For example, laboratories that have successfully completed a laboratory quality improvement training course, such as the Strengthening Laboratory Management Towards Accreditation (SLMTA) training programme or structured laboratory mentoring, are likely to be better prepared for SLIPTA enrolment. The current procedure recommends basing the number of proposed laboratories on available resources per country. The request should aim at listing all laboratories to be enroled for the year in order to facilitate the audit mission.

4.2 Enrolment

If a laboratory's application meets the SLIPTA enrolment criteria, the SLIPTA IEG Secretariat will send an enrolment letter. The enrolment letter will indicate the date of the laboratory's enrolment, its enrolment number, and suggested timeframes within which an audit might be scheduled. Once an enrolment date has been issued, the laboratory will be considered an "Enroled Laboratory".

The audit of the laboratory must be conducted within a year of the enrolment date. If the laboratory has not been audited within that time period the laboratory will be considered inactive. Table 1 shows the stepwise approach to application.

Table 1 : Laboratory status designations for SLIPTA

Applicant Laboratory	Enroled Laboratory	Audited 0 Star	Audited 0 Star	Audited 0 Star	Audited 0 Star	Audited 0 Star	Audited 0 Star	Graduated
Applicant documents received	Application approved; ready to schedule audit							Enroled in ISO 15189 scheme

5. Evaluation and Criteria

5.1 The Audit Visit

A team of 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. Audit teams operate under the direction of the designated lead auditor. During an audit visit the lead auditor is the primary contact person for the team. The SLIPTA IEG Secretariat will define the terms of reference (ToR) in collaboration with the WHO Regional Office SLIPTA focal point.

Once a laboratory is enroled, the SLIPTA IEG Secretariat will communicate with the applicant MoH to find suitable dates for the audit visit and coordinate logistics for the audit team. Due to the coordination challenges, any changes in audit dates may result in long rescheduling delays.

If a ministry has successfully enroled 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.

The length of audit visits will vary based upon four main factors: (i) number of laboratories to be audited, (ii) size of the laboratories to be audited, (iii) number of auditors on the audit team and (iv) logistics and transportation considerations.

The travel logistics for audit visits will be arranged through consultations between the IEG SLIPTA Secretariat and the applicant MoH. Schedules will be confirmed in advance, including whether MoH laboratory leadership will be available for an opening meeting and closing briefing at the beginning and end of the audit visit.

5.2 CRITERIA AND CHECKLIST

There are five audit criteria for evaluation in the SLIPTA. They include:

- Laboratory test results;
- Number of tests annually: defined as total annual volume of tests performed by laboratory;
- Internal quality control procedures implemented for all testing methods used;
- Two most recent proficiency test results for each test performed;
- WHO SLIPTA Checklist for the African Region.

The WHO SLIPTA Checklist is compliant with ISO 15189/17025. The Checklist has 334 questions and a possible 258 points. The questions are organized in 12 sections. While the checklist has been constructed to prepare laboratories for international accreditation, the headings are derived from the quality system essentials (QSEs) contained in the quality management system (QMS) of the renowned Clinical and Laboratory Standards Institute (CLSI). Table 2 provides a breakdown of the checklist categories and points.

Table 2: Sections and points in the SLIPTA checklist		
Section 1	Documents and Records	**28**
Section 2	Management Reviews	**14**
Section 3	Organization and Personnel	**22**
Section 4	Client Management and Customer Service	**10**
Section 5	Equipment	**35**
Section 6	Internal Audit	**15**
Section 7	Purchasing and Inventory	**24**
Section 8	Process Control and Internal and External Quality Assessment	**32**
Section 9	Information Management	**21**
Section 10	Corrective Action	**19**
Section 11	Occurrence Management and Process Improvement	**12**
Section 12	Facilities and Safety	**43**
Total Score		**275**

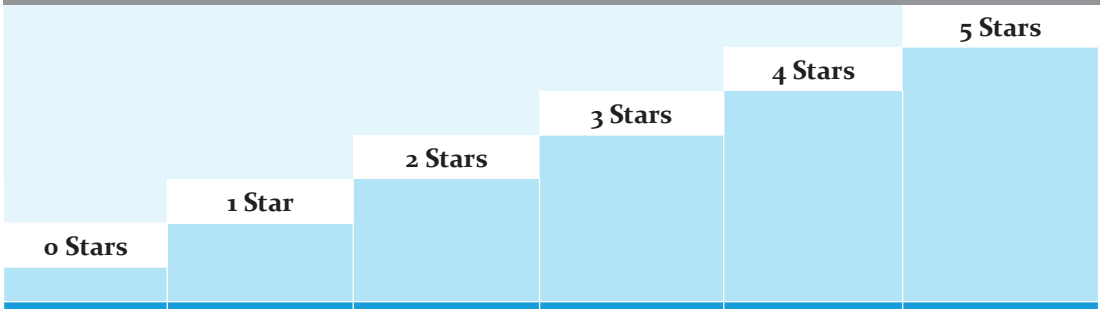
The WHO SLIPTA Checklist for the African Region is available on the Regional Office website which will be updated whenever the Checklist is revised.

6. Recognition and Certification

6.1 Decision-Making and Awarding of Recognition

Within two weeks of completing the audit, the SLIPTA audit team will submit a list of nonconformities to the laboratory and the IEG Secretariat. The laboratory will have six weeks to submit documentation of corrective actions of nonconformities to the audit team for reconsideration. At this stage, the audit team may provide technical assistance and guidance for the laboratory. Corrective action of major nonconformities may require a follow-up audit by the audit team, and this should be conducted within three to six months. The SLIPTA audit team will submit their final report to the IAG via the IEG Secretariat within one week of reconsideration. Within two weeks of receiving the final report, the SLIPTA IAG will make the final determination regarding what level of recognition the laboratory will be awarded. Table 3 indicates the possible recognition tiers to be awarded.

Table 3: SLIPTA tiers of recognition of laboratory quality management



0-150 pts	151-177 pts	178-205 pts	206-232 pts	233-260 pts	261-275 pts
<55%	55-64%	65-74%	75-84%	85-94%	≥95%

The current recognition status of enroled medical laboratories will be made available on the IEG website (www.aslm.org).

6.2 Follow-Up Audit for Continued Improvement

Following audit, successful laboratories will receive a certificate valid for two years from the date of issue. Applications for renewal should be submitted six months before the expiration of the certificate.

Since progression to full internationally-recognized accreditation is a key programme goal, laboratories are strongly encouraged to graduate to International Laboratory Accreditation Cooperation (ILAC) recognition level within six years (initial application and up to two renewal applications). This will require that the MoH allocate funding in the country strategic implementation plan for accreditation services in future budgets. In addition, the MoH will need to negotiate with accreditation providers based on the volume of laboratories to be serviced.

Participating laboratories that go on to receive an ILAC-recognized accreditation will be transitioned from the SLIPTA register and their achievement will be recognized on the IEG website.

6.3 Appropriate use of Recognition Certificates

Laboratories are encouraged to display the recognition certificates received from the SLIPTA IEG Secretariat as evidence of their enrolment in the process 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 of laboratory quality management (Figure 3). ***The Certificate of Recognition is not a certificate of laboratory accreditation.***

Laboratories displaying a SLIPTA recognition certificate should comply with the following provisions:

- Display of certificate does not imply that the IEG or the WHO Regional Office for Africa accepts responsibility for activities carried out under the scope of the level of recognition.
- 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.
- Certificates cannot be amended or altered in any way.
- Certificates must be removed promptly following expiration.
- Certificates cannot be used in any way that might mislead the reader about the status of the laboratory.
- Laboratories displaying the SLIPTA recognition certificate should notify the SLIPTA Secretariat 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 judgment. Failure to notify the SLIPTA IAG regarding major changes could result in suspension or withdrawal of recognition.

7. Operating Procedures

7.1 Cost

The cost will be covered by the MoH and its partners. MoH should mobilize these resources as part of an MoH national strategic implementation plan.

7.2 Issues Management

During these processes, circumstances may arise that warrant complaints from laboratories or MoHs. The head officer of the SLIPTA IEG Secretariat and the Chair of the SLIPTA IAG are responsible for ensuring that all complaints are dealt with impartially and objectively.

Complaints must be submitted in writing to the SLIPTA IEG Secretariat. Complaints might refer to inappropriate or unprofessional conduct by staff or auditors; conflicts of interest; or poor quality of services.

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

7.3 Monitoring of Auditor Performance

SLIPTA IEG Secretariat annually monitors and evaluates the performance of its laboratory auditors to ensure that standards of competence and professionalism are observed. Auditors are bound by confidentiality and must be free of conflicts-of-interest. Findings indicating that a SLIPTA IEG auditor has breached confidentiality or participated in an audit in which there was a conflict-of-interest will be acted upon.

7.4 Release of Audit Reports

The name of the enroled laboratory can be made public. Results of the internal audit will be disclosed by the director of each laboratory to the Ministry of Health and IEG Secretariat. The MoH is encouraged to mobilize appropriate resources to help the laboratory rectify any nonconformities found duing the audit.

Results of the external audit should be disclosed by the SLIPTA IEG Secretariat to the director of the laboratory and the Ministry of Health only. The SLIPTA IAG members will access results after signing a confidentiality agreement stating that data cannot be disclosed.

SLIPTA is a process that supports laboratories in the implementation of quality management systems and the development of technical competence. The WHO, the SLIPTA IEG Secretariat, IAG and auditors cannot accept liability for any laboratory testing conducted in facilities enroled in SLIPTA.

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