Meeting on Consultation on the Global Laboratory Initiative (GLI) Standards and Stepwise Process towards TB Laboratory Accreditation Meeting

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WHO-AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA)
Introduction

• Global movement to strengthen the quality of Public Health Laboratories (PHLs) in developing countries

• WHO-AFRO SLIPTA emerged as a result of critical country political commitments to strengthen the capacity of PHLs and other Centers of Excellence in the African Region to improve disease prevention and control.

➢ Resolution AFR/RC58/R2 on Public Health Laboratory Strengthening
58th WHO African Regional Committee Meeting, Yaoundé, Cameroon, September 2008
Strong commitment by governments of Member States to PHLs

➢ Resolution AFR/RC59/R4 on the establishment of Centers of Excellence and PHLs
59th session, Regional Committee, Kigali, Rwanda, September 2009
SLIPTA – WHO-AFRO, CDC, and ASLM Initiative

• Supports laboratories in a stepwise quality improvement process towards obtaining nationally, regionally or internationally recognized accreditation standards compliant with the ISO 15189 standard.
• Serves as pathway that recognizes conformity over time marked by graduated recognition of quality improvement of laboratory performance.
• Intended to encourage, support and recognize implementation of QMS in medical laboratories so that African laboratories can provide safe, timely and accurate results for patient care and public health purposes.
• Technical support and mentoring by Independent Evaluation Group (IEG) to help countries meet their accreditation goals.
• Cost: MoH to mobilize resources - Country Strategic Implementation Plan
• SLIPTA 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,
  ➢ nurturing development of laboratories in the African region.
Stakeholders

- Ministries of Health
- WHO-AFRO
- SLIPTA Independent Evaluation Group (IEG) Secretariat
- SLIPTA Auditors
- Independent Advisory Group (IAG)
Stakeholders
Roles and Responsibilities

Ministries of Health

- Designate SLIPTA focal point responsible for coordination, information-sharing, and implementation.
- Develop and implement a country strategic plan for laboratory quality improvement & training and prioritization of potential applicant laboratories.
- Allocate financial and human resources.
- Oversee implementation of corrective actions outlined in audit reports.

WHO-AFRO SLIPTA

- Provides guidance on SLIPTA Policy & Procedures, technical documents, and Checklist; monitors SLI process.
- Convenes meetings and workshops with stakeholders.
- Supports the development of implementation component for laboratory quality improvement as part of country’s strategic plan.
- Develop communication strategy that advocates and disseminates information with all countries on SLIPTA.
SLIPTA IEG Secretariat – Regional or Sub-regional

- Oversees establishment of SLIPTA IAG (vetted nomination process)
- Establishes Letter of Agreement with respective MoH
- Works with professional societies and stakeholders to:
  1) mobilize resources to support laboratories
  2) identify suitable experts to comprise pool of auditors and sign Letters of Agreement with these partners when needed
- Provides auditor training to conduct audits using SLIPTA Checklist
- Provides certificates of recognition issued by SLIPTA IAG
- Serves as primary POC for MoHs and processes application requests
- Maintains register of auditor pool and organizes audit visits
- Maintains documentation & records and shares information with WHO-AFRO and MoH in a timely manner
Stakeholders
Roles and Responsibilities

**SLIPTA Auditors**
- Comprised of experienced laboratory audit professionals.
- Conduct laboratory audits using the SLIPTA Checklist
- Provide technical assistance and mentoring to enrolled laboratories
- Must attest that they have no conflict-of-interest in conducting the work for a particular audit and must maintain confidentiality.
- Develop audit reports with recommendations

**Independent Advisory Group (IAG)**
- Composed of technical experts from professional bodies (i.e. laboratory associations) trained by IEG Secretariat
- Ensure specific standards are applied across the board
- Advise on conflict resolution from laboratories or other stakeholders
- Issue Certificates of Recognition to laboratories
- Initially IAG will be regional with eventual transition to independent national advisory committees as countries develop their national capacity.
Eligibility for SLIPTA Enrollment

- All medical, clinical, and public health laboratories in WHO-AFRO member countries
- Presupposes that MoH has country strategic plan for implementation of laboratory quality improvement
  - MoH and local implementing partners prepare labs to meet minimal requirements outlined in strategic plan
- SLIPTA IEG Secretariat will only accept applications submitted by MoH SLIPTA Focal Point
- MoHS are encouraged to invest in SLIPTA to support development of public sector laboratories.
- All applications received will be reviewed by the SLIPTA before official enrollment.
WHO-AFRO SLIPTA guidance

- Describes key elements of the laboratory quality improvement process and details how Partners and Member states implement this initiative
- Provides a framework for countries to support them in their efforts to strengthen their national laboratory services through the stepwise quality improvement process towards fulfillment of the ISO 15189 standard.

WHO-AFRO SLIPTA checklist
Checklist: ISO 15189 + CLSI Standards
### WHO-AFRO Accreditation Checklist Sections

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<td>Facilities &amp; Safety</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>250</strong></td>
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</table>
- Documents and Records
- Organization
- Personnel
- Equipment
- Purchasing and Inventory
- Process Control
- Information Management
- Occurrence Management
- Assessments: Internal and External
- Process Improvement
- Customer Satisfaction
- Facilities and Safety
### 4 Management requirements (15)

- 4.1 Organisation and management
- 4.2 Quality management system
- 4.3 Document control
- 4.4 Review of contracts
- 4.5 Examination by referral laboratories
- 4.6 External services and supplies
- 4.7 Advisory services
- 4.8 Resolution of complaints
- 4.9 Identification and control of nonconformities
- 4.10 Corrective action
- 4.11 Preventive action
- 4.12 Continual improvement
- 4.13 Quality and technical records
- 4.14 Internal audits
- 4.15 Management review

### 5 Technical requirements (8)

- 5.1 Personnel
- 5.2 Accommodation and environmental conditions
- 5.3 Laboratory equipment
- 5.4 Pre-examination procedures
- 5.5 Examination procedures
- 5.6 Assuring the quality of examination procedures
- 5.7 Post-examination process
- 5.8 Reporting results
| For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the item must be satisfactorily present to indicate “yes”. Provide explanation or further comments for each “partial” or “no” response. |
|---|---|---|---|---|
| 1. DOCUMENTS & RECORDS | Y | P | N | Comments |
| 1.1 Is there a system or procedure for document & record control and retention? | Y | P | N |
| **(Level II: 6.1, 10.1, 10.2, 10.3)** | 2 |
| **Standard:** A document control system should be in place to ensure that records and all copies of policies/procedures are current, read by personnel, authorized by proper authorities, reviewed annually, and immediately prior versions filed separately as per national policy. Laboratories should maintain a document control log listing all current policies and procedures and their locations. |
| 1.2 Are documents & records properly maintained, easily accessible and indicated on an up-to-date Master List? | Y | P | N |
| **(Level II: 6.1, 10.1, 10.2 10.3)** | 2 |
| **Standard:** An up-to-date Master List that comprehensively details all laboratory documents, policies, and procedures should be readily accessible in either hard copy or electronic form. These should be retrievable within a timely manner. If documents and records are maintained in electronic form they should be backed up on CD or other media. |
| 1.4 Are policies and SOPs easily accessible / available to all staff? | Y | P | N |
| **(Level II: 1.1, 2.6, 6.10, 6.11, 8.1, 10.1)** | 2 |
| **Standard:** SOPs should be available in the laboratory (hard or soft copy) and easily accessible to all staff. Testing SOPs should be available in hard copy at each bench. |
SLIPTA technical tools – Next Steps

- A small group of experts will work on the prioritization of elements in the checklist related to technical performance of laboratory testing.

- Guidelines on how to use the checklist to conduct lab self-assessment will be developed.
Laboratories will be audited against laboratory standards outlined in the SLIPTA Checklist and will be recognized as operating at one of the levels of accreditation:

- **1 Star**: 55-64% Score on-site checklist
- **2 Star**: 65-74% Score on-site checklist
- **3 Star**: 75-84% Score on-site checklist
- **4 Star**: 85-94% Score on-site checklist
- **5 Star**: > 95% Score on-site checklist

The end point is either International, Regional, or National Accreditation Body.
Thank you
Merci
Obrigada