WHO/AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Implementation Roll Out

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Director Programs and Grants
African Society for Laboratory Medicine (ASLM)

GLI Conference
April 15-18, 2013
Annecy, France
Vision: Improve healthcare in Africa by strengthening laboratory services

Mission: Advance professional laboratory medicine practices, science and networks in Africa
Strengthened Laboratories Improve Healthcare

**Goal 1 – African Laboratory Workforce Development**
Train and certify 30,000 laboratory professionals and clinicians

**Goal 2 – Laboratory Accreditation**
Enroll 2,500 laboratories in the WHO/AFRO SLIPTA quality improvement program and enable 250 laboratories to achieve accreditation

**Goal 3 – African National and Regional Regulatory Environments**
Raise regulatory standards for diagnostic products to stringent international standards in 25 countries (50%) and promote harmonization in the 5 economic regions of Africa

**Goal 4 - African Network of National Public Health Reference Laboratories**
Develop national public health reference laboratories in 30 countries and an African Network of National Public Health Reference laboratories
By 2020: 2,500 laboratories enrolled in SLIPTA
Getting there in a stepwise manner

In the year 2012:

- SLMTA: 330 laboratories
- World Bank project:
  - Labs in Burundi, Rwanda, Kenya, Tanzania, Uganda
- Other projects and programs contributed
SLIPTA (Framework) & SLMTA (Tool)

SLIPTA: A framework to encourage, support and recognize the implementation of QMS in medical laboratories in a stepwise manner.

SLIPTA does not guarantee accreditation – it prepares labs to apply.
What is SLIPTA?

What SLIPTA is
- Framework for monitoring and checking
- Brings stepwise improvement
- Recognition of improvement
- Country owned program
- etc

What SLIPTA isn’t
- Tool for teaching/mentoring
- One time process
- Accreditation
- Accrediting body
- etc
WHO/AFRO SLIPTA Implementation

AFRO - MEMORANDUM

From: Dr Bokar TOURE  
HSS/AFRO  
Our ref.:  
Your ref.:  
Originator: CLT

To: Those listed below

Date: 08 October 2012

Attention:

Subject: REQUEST FOR DESIGNATION OF A NATIONAL FOcal POINT FOR THE WHO/AFRO STEPWISE LABORATORY QUALITY IMPROVEMENT PROCESS TOWARDS ACCREDITATION (SLIPTA)

In January 2008, the World Health Organization, Regional Office for Africa (WHO/AFRO) issued the Maputo Declaration to Strengthen Laboratory Systems and in September 2008, Resolution AFR/RC58/R2 on Public Health Laboratory Strengthening that was adopted by the Member States during the 58th session of the Regional Committee in Yaoundé, Cameroon.

In 2009 in Kigali, Rwanda, in accordance with WHO’s core functions of setting standards and building institutional capacity, WHO/AFRO launched the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) to guide countries in their efforts to strengthen national laboratory systems.

Key Message:

- ASLM and SLIPTA implementation
- Designation of SLIPTA Focal Point
- SLIPTA Technical Documents
WHO/AFRO SLIPTA: ASLM Implementation Framework

- Developed by SLIPTA Technical Coordination Group (STCG)
  - WHO/AFRO, ASLM, and US-CDC
- Defined Roles, Responsibilities, and Communications of stakeholders

- **ASLM SLIPTA Auditor Training**
  - Curriculum and course materials, logistics
  - Trainer and Participant selection
  - Post-training Requirements
  - Competency of auditors

- **ASLM SLIPTA Audits**
  - Procedures, Audit Report Review, Certificate of Recognition

- **ASLM SLIPTA Centralized Database**
Different Levels of ASLM SLIPTA Auditor Training

• ASLM SLIPTA Tier 1 Auditor: Country Level
  – Training: Basic Principles of Auditing and Accreditation
  – Post-training Audit Practicum Requirement
  – ASLM SLIPTA Auditor Tier I Training Certificate of Completion
  – Certificate validation and refresher training required
  – Rollout: Sept, 2011

• ASLM SLIPTA Tier II Auditor: Regional Level
  – Experienced Auditors
  – Nominated by ASLM SLIPTA IAC for training
  – Training: Advanced Principles of Auditing and Accreditation
  – Rollout: Sept, 2013
Standardized SLIPTA Auditor Training curriculum

- Developed in collaboration with **US-CDC, CLSI** and **Vijay Consulting**

**5-day Program**

- Content includes, but not limited to:
  - SLMTA and SLIPTA
  - Introduction to accreditation and ISO 15189:2007 Standards
  - Audit techniques
  - WHO/AFRO SLIPTA Checklist
  - Identification of Nonconformities (Major/Minor)
  - Professional Ethics
  - Reporting

- 3 days for lectures & 2 days on lab audit practicum
- Post training practicum of 3-5 shadowed audits
Tier I Auditor Training: Selection Criteria

- B. Sc. Degree/Advanced Diploma in Medical Laboratory Sciences or related field
- **Five years** of experience in medical laboratory testing for B.Sc. holders and **10 years** for Advanced Diploma holders
- Knowledge and experience in laboratory management & operations, and laboratory quality management systems
- High degree of communication skills, both oral and written. For Francophone and Portuguese-speakers, bilingual proficiency (English) is preferred but not required.
- Related professional activities, e.g.. Writing of technical papers in the testing and participation and/or coordinating proficiency testing programs
- Experience in providing feedback to laboratories
Database of Trained SLIPTA Auditors

Calculated with the following assumptions:

✓ Number of trainees per training: 20

✓ Percentage of participants who pass final exam and receive certificate of successful completion: 80% \( (n=16) \)

✓ Percentage of trained auditors who complete post-training requirement of 3-5 inter-laboratory audits with mentorship (shadowed): \( \sim 70\% \ (n=11) \)
Evaluation Criteria during post-training Practicum

- Understanding of the purpose and scope of the lab audit
- Understanding of the standard being audited against
- Performing the audit to collect evidence, to verify major and minor nonconformance
- Recording the results of the audit using the checklist
- Reporting findings to the lead auditor
- Cooperating with the lead auditor
- Providing input to the formal report if requested by the lead auditor
- Maintaining confidentiality of the audit information
- Preparing audit report
- Communicating with the auditee
- Practicing codes of ethics
ASLM SLIPTA Auditor Training Providers

Training Providers

- includes accreditation by the ILAC
- Experience and knowledge of ISO 15189/17025/17011 Standards
- Knowledge of SLIPTA Checklist
- Adoption of SLIPTA Standardized curriculum
- Reasonable cost

- **Consultants** may serve as trainers and must have similar qualifications
  - 10 years of quality management experience and as laboratory auditor
  - Certification or professional qualification by a recognized accreditation body
  - Technical expert in specified field of auditing
### Number of Auditors Trained: September 2011 to December 2012

<table>
<thead>
<tr>
<th>Country</th>
<th>Time</th>
<th>Number of Participants</th>
<th>Successfully Completed</th>
<th>Collaborative Organization</th>
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<tr>
<td>Tanzania</td>
<td>Sept/11</td>
<td>16</td>
<td>12</td>
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<tr>
<td>Cote d’Ivoire</td>
<td>July/12</td>
<td>16</td>
<td>16</td>
<td>CRESAC</td>
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<tr>
<td>Botswana</td>
<td>July/12</td>
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<td>17</td>
<td>AGHPF</td>
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<td>Kenya</td>
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<tr>
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<td>Oct/12</td>
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<td>16</td>
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<tr>
<td>Cameroon</td>
<td>Oct/12</td>
<td>11</td>
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<td>GHSS</td>
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<tr>
<td>Nigeria</td>
<td>Nov/12</td>
<td>23</td>
<td>21</td>
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<tr>
<td>South Africa</td>
<td>Dec/12</td>
<td>19</td>
<td>19</td>
<td>NHLS</td>
</tr>
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</table>

**Total ASLM Certified**: 123 (27*)

* Francophone
Number of Auditors  Projected for Training in 2013

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of Participants</th>
</tr>
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<tr>
<td>Cote d’Ivoire</td>
<td>22</td>
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<tr>
<td>Namibia</td>
<td>20</td>
</tr>
<tr>
<td>Tanzania</td>
<td>10</td>
</tr>
<tr>
<td>Angola</td>
<td>14</td>
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<tr>
<td>Swaziland</td>
<td>15</td>
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<tr>
<td>Nigeria</td>
<td>15</td>
</tr>
<tr>
<td>SLPTA HQ</td>
<td>80</td>
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<tr>
<td>Total</td>
<td>186</td>
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ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

Tanzania, 2011

Cote d’Ivoire, 2012
ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

Tanzania 2012

Nigeria 2012
Projected Number of Auditors: December 2012 to March 2013

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of Auditors</th>
</tr>
</thead>
<tbody>
<tr>
<td>DR Congo</td>
<td>20</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>20</td>
</tr>
<tr>
<td>Nigeria</td>
<td>20</td>
</tr>
<tr>
<td>Lesotho</td>
<td>20</td>
</tr>
<tr>
<td>Mozambique</td>
<td>20</td>
</tr>
<tr>
<td>South Africa</td>
<td>20</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>20</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>140</strong></td>
</tr>
</tbody>
</table>

Projected Number of Auditors: December 2012 to March 2013

- DR Congo: 20
- Ethiopia: 20
- Nigeria: 20
- Lesotho: 20
- Mozambique: 20
- South Africa: 20
- Zimbabwe: 20
- Total: 140

Map indicating countries: South Africa, Lesotho, Zimbabwe, and others with projected numbers of auditors.
Procedures for WHO/AFRO SLIPAT Implementation

- Application from MoHs
- Enrollment
- Auditing
- Report and Recommendations
- TA and guidance
- Final report
- Provision of Certificate of recognition
- Link with TA and Mentorship
Application for SLIPTA Enrollment

- Application should be filled and submitted to ASLM by SLIPTA MoH Focal Point
- Application Form can be found at ASLM website
  - in English, French and Portuguese

Eligibility Criteria for enrolment of laboratory for SLIPTA:
- Self-evaluation using SLIPTA Checklist - Minimal score: 143 points (55%)
- Participation in proficiency testing (PT) schemes or inter-laboratory comparisons for all tests for at least one PT cycle in past six months
- Routine use of quality controls for all test methods
- Evidence of internal audits conducted by laboratory
- Laboratory Quality Document/Manual
Enrollment of Laboratory for SLIPTA

- If the application meets the enrollment criteria, ASLM will send an enrollment letter.
- Enrollment letter indicates the date of laboratory’s enrollment, its enrollment number, and suggested timeframe for auditing.
- The laboratory will be considered as ENROLLED LABORATORY.
- Audit MUST be conducted within a year of enrollment date.
Audit Visit

- Auditor team will be deployed to conduct auditing.
- After completing the audit, the audit team will submit the Non-conformities to the laboratory and ASLM within two weeks.
- Laboratory will submit documentation of corrective actions of nonconformities to the audit team for reconsideration within six weeks.
- The laboratory may work with the auditor team for technical assistance and guidance.
- Corrective actions of major nonconformities may require a follow-up visit by the audit team within three to six months.
- Auditor team will submit their final report to ASLM within one week of reconsideration.
Determination of Level of Recognition

- ASLM will submit the report to the ASLM SLIPTA IAC
- The IAC will make the final determination regarding the level of recognition **within two weeks**
- ASLM will issue Certificate of Recognition
- The certificate will be valid for two years from the date of issue
<table>
<thead>
<tr>
<th>Country</th>
<th>Applied/Enrolled</th>
<th>Audited</th>
<th>Time</th>
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<tbody>
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<td>Tanzania</td>
<td>4</td>
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<tr>
<td>Cote d’Ivoire</td>
<td>4</td>
<td></td>
<td>2012</td>
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</tbody>
</table>

* Four laboratories have received SLIPTA Certificates
## Number of Laboratories Expected/Enroll and Audit 2013

<table>
<thead>
<tr>
<th>Country</th>
<th>Applied/Enrolled</th>
<th>Audited</th>
<th>Time</th>
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<tbody>
<tr>
<td>Tanzania</td>
<td>15</td>
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<tr>
<td>Burkina Faso</td>
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<td>Rwanda</td>
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<tr>
<td>SLPTA HQ</td>
<td>48</td>
<td>48</td>
<td>2013</td>
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</tbody>
</table>

**Total labs expected for auditing: 108**
WHO AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation

Certificate of Recognition issued to:
ARUSHA REGIONAL HOSPITAL LABORATORY

has been audited per the WHO AFRO SLIPTA Checklist and has met the requirements for the following star recognition level:


The African Society for Laboratory Medicine accepts no liability for the laboratory testing conducted in facilities enrolled in SLIPTA.

The laboratory has achieved a star ranking on the SLIPTA Tier of Recognition of Laboratory Quality Management and is not a certificate of accreditation.

Tsehaynes Messele, Ph.D.
Chief Executive Officer, ASLM

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ASLM
Thank You!

• Application for SLIPTA can be sent to: SLIPTA@aslm.org
• For More Information please visit us at: www.aslm.org
• Or contact me at: tmekonen@aslm.org