Easing Into Quality – A Successful International Model

Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA)

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Easing Into Quality – An Successful International Model SLIPTA

- Introduction
- Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA)
- Stakeholders
- SLIPTA Checklist
- ASLM Auditors and Audits
- Conclusions

Introduction

- Quality-assured laboratory services are essential to provide accurate patient diagnoses and timely detection of diseases.
- Presently, the laboratory infrastructure and test quality for all types of clinical laboratories remain in nascent stages in most countries of Africa.
- Consequently, there is an urgent need to strengthen laboratory systems and services.
- Of the 49 sub-Saharan African countries, there are no accredited laboratories in 37 countries and 380 accredited laboratories in 12 countries, with 345 of these in South Africa.

Introduction (continued)

- A number of key statements and resolutions emphasize this need by embedding the culture of quality into laboratory testing:
  - Resolution AFR/RC58/R2 on Public Health Laboratory Strengthening 58th WHO African Regional Committee Meeting, Yaoundé, Cameroon, September 2008, **Strong commitment by gov'ts of Member States to PHLs**
  - Resolution AFR/RC59/R4 on the establishment of Centers of Excellence and PHLs, Resolution 59th session, Regional Committee, Kigali, Rwanda, September 2009

SLIPTA

- Launched the WHO/AFRO stepwise accreditation process in Kigali in 2009
  - WHO Regional Office for Africa (WHO AFRO)
  - United States Centers for Disease Control and Prevention (CDC)
  - Clinton Health Access Initiative (CHAI)
  - American Society for Clinical Pathology (ASCP)
  - Other partners

SLIPTA

- Renamed and endorsed by WHO AFRO, CDC and partners as the WHO AFRO Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) in 2011

- Finalized the WHO AFRO Stepwise Laboratory Accreditation Process in Nairobi, Kenya in 2011

Stakeholders

- Ministries of Health
- WHO-AFRO
- SLIPTA Independent Evaluating Group (IEG)
- Secretariat of ASLM
- SLIPTA Auditors
- SLIPTA Independent Advisory Group (IAG)
- Independent Evaluating Group (IEG)

Stakeholders

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
- Allocate financial and human resources
- Oversee implementation of corrective actions outlined in audit reports

Stakeholders

WHO-AFRO SLIPTA

- Provides guidance on SLIPTA Policy & Procedures, technical documents, and Checklist
- Convenes meetings and workshops with stakeholders
- Develop communication strategy that advocates and disseminates information with all countries on SLIPTA

Stakeholders

SLIPTA IEG Secretariat

- Oversees establishment of SLIPTA IAG
- Works with professional societies and stakeholders to mobilize resource to support laboratories
- Provides auditor training to conduct audits using SLIPTA Checklist
- Maintains documentS & records and shares information with WHO-AFRO and MoH in a timely manner

Stakeholders

SLIPTA Auditors

- Comprised of experienced laboratory audit professionals
- Conduct laboratory audits using the SLIPTA Checklist
- Provide technical assistance and mentoring to enrolled laboratories
- Develop audit reports with recommendations

World Health Organization

REGIONAL OFFICE FOR Africa

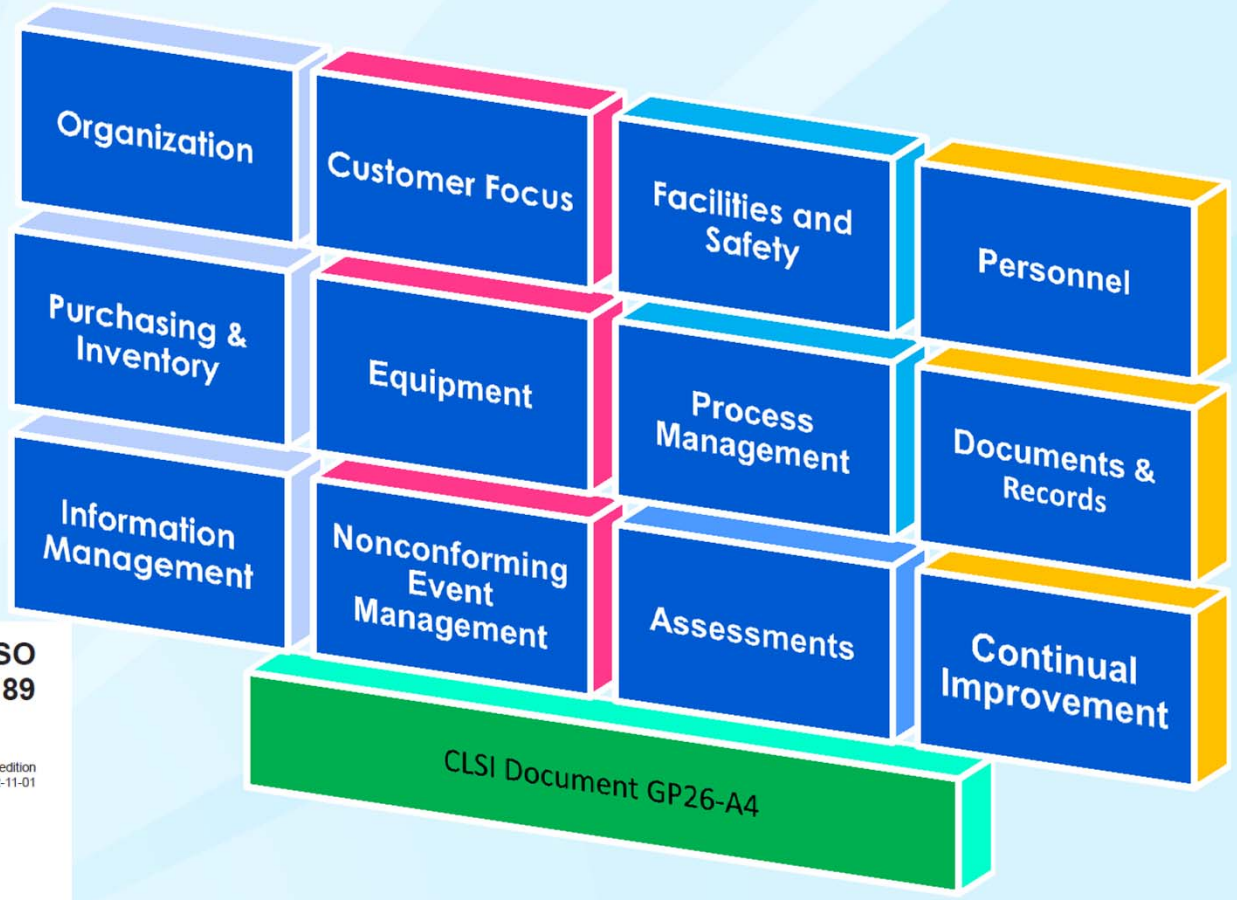
Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2:2015

For Clinical and Public Health Laboratories

SLIPTA

- A framework for improving quality of public health laboratories in developing countries to achieve ISO 15189 standards
- 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
- Serves as pathway that recognizes conformity over time marked by graduated recognition of quality improvement of laboratory performance

12 Quality System Essentials (QSE)



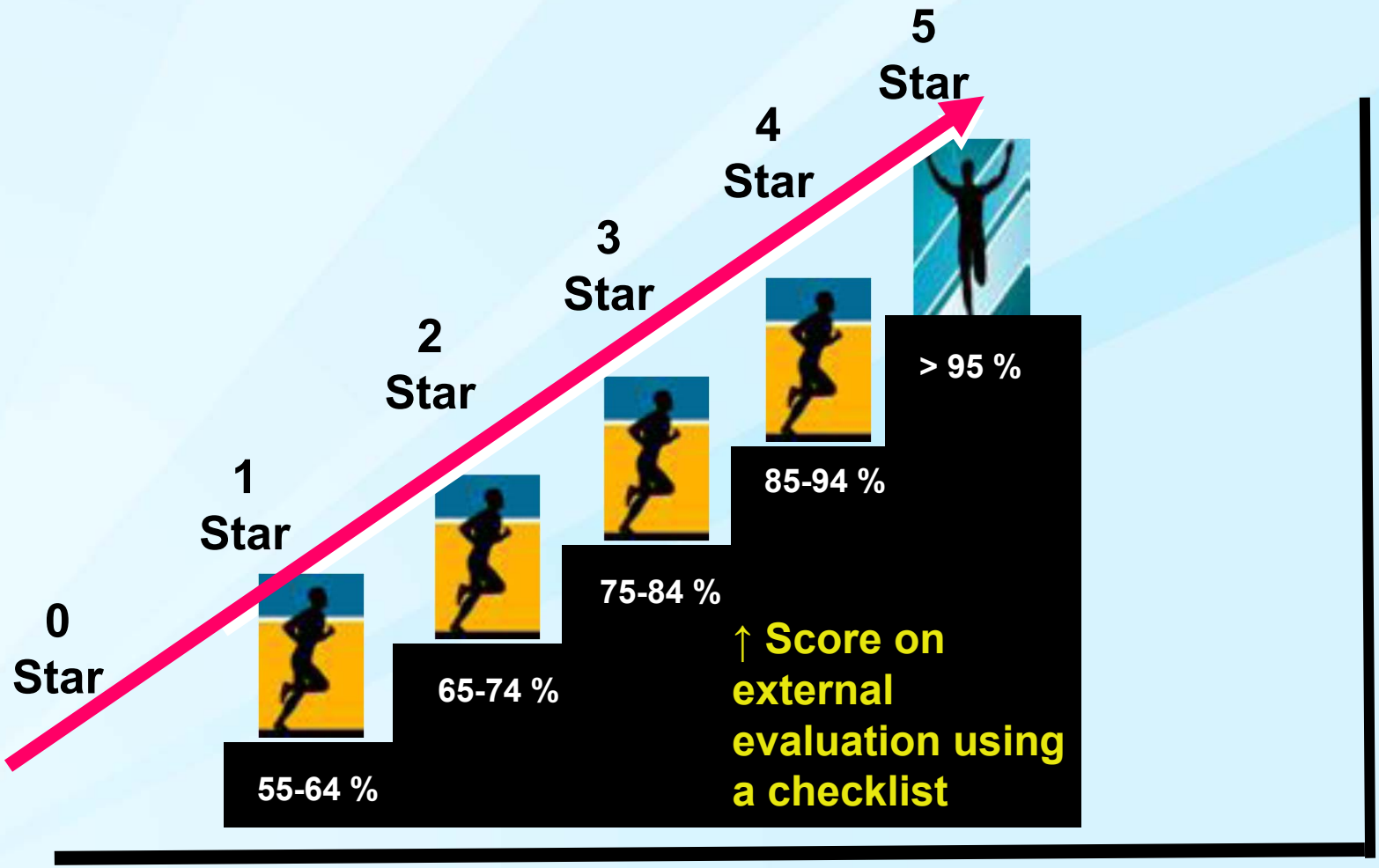
INTERNATIONAL STANDARD **ISO 15189**

Third edition
2012-11-01

Medical laboratories — Requirements for quality and competence

Laboratoires de biologie médicale — Exigences concernant la qualité et la compétence

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



SLIPTA

- The checklist includes 275 maximum points that a laboratory can score.
- The 275 points are divided into a five steps that correspond with a star.

SLIPTA Checklist

For each item, please circle as relevant Not Applicable (NA), 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.

Section 1 : DOCUMENT AND RECORDS

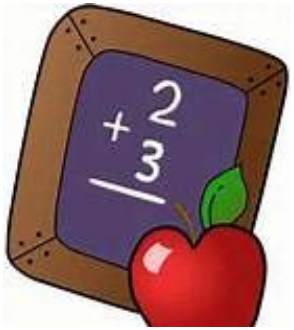
Requirement	Y	P	N	Comments	Score
1.1 Legal Entity Does the laboratory have documentation stating its legal identity?	**Y**	**P**	**N**		2
ISO15189:2012 Clause 4.1.1.2" *The laboratory or the organization of which the laboratory is a part shall be an entity that can be held legally responsible for its activities.* ***Note: Documentation could be in the form of a National Act, Company registration certificate, License number or Practice number.***					
1.2 Laboratory Quality Manual Is there a current laboratory quality manual, composed of the quality management system's policies and has the manual content been communicated to, understood and implemented by all staff?	**Y**	**P**	**N**		5
The quality manual includes the following elements:	**Tick for each item as Yes (Y), No (N) or Partial (P)** **Y**	**P**	**N**		

SLIPTA Checklist Sections

Section	Audit Element	Points
1	Documents & Records	28
2	Management Reviews	14
3	Organization and Personnel	22
4	Client Management & Customer Service	10
5	Equipment	35
6	Evaluation and Audits	15
7	Purchasing & Inventory	24
8	Process Control	32
9	Information Management	21
10	Identification of Non Conformities, Corrective and Preventive Actions	19
11	Occurrence/Incident Management & Process Improvement	12
12	Facilities and Biosafety	43
Total Score		**275**

SLIPTA Checklist

No Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
(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%



SLIPTA

- Identify areas where improvement is needed
- Develop and implement a work plan
- Continue steps to achieve full accreditation

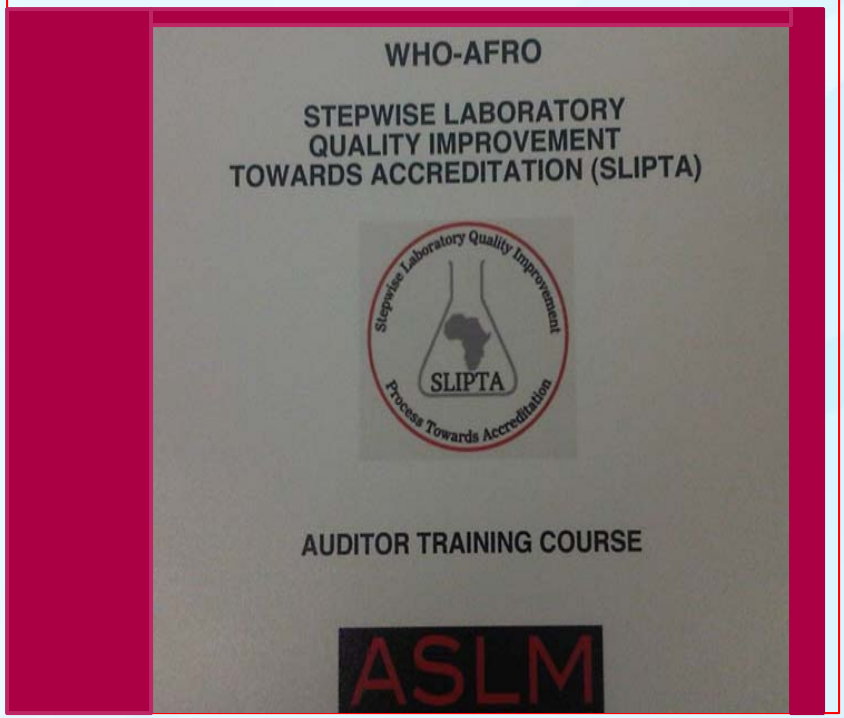
Collaboration with ASLM and Other Partners

To collaborate with the African Society for Laboratory Medicine (ASLM) and other partners to strengthen local capacity and promote country ownership and sustainability

Strengthening Laboratories in Developing Countries

Task

- To develop the Standardized Auditor Training Manual



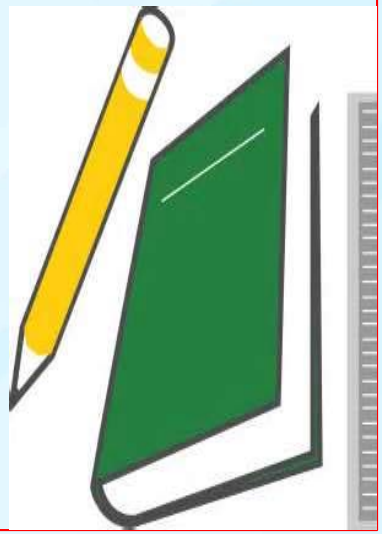
13 Training Modules

- Developed the training modules based on 12 QSEs
- Present an overview information on lab quality management
- Understand the relationship between the ISO 15189 standards and WHO-AFRO SLIPTA Checklist
- Explain the management and technical requirements of the ISO 15189 Standards

Strengthening Laboratories in Developing Countries

Task

- To train the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) auditors in Africa



13 Training Modules

- Introduction to QMS (Quality Management Systems) and Accreditation
- Assessment Methods
- Overview of SLIPTA and Audit Process
- Review of ISO 15189:2012
- Review of the WHO-AFRO SLIPTA Checklist and Professional Ethics for Auditors

Strengthening Laboratories in Developing Countries

Task

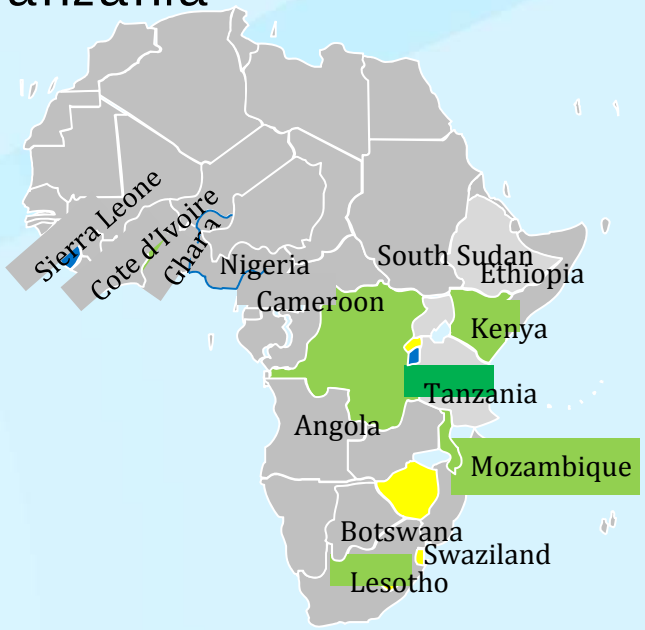
- To utilize in-country auditors to conduct the labs using the SLIPTA checklist

World Health Organization
REGIONAL OFFICE FOR Africa

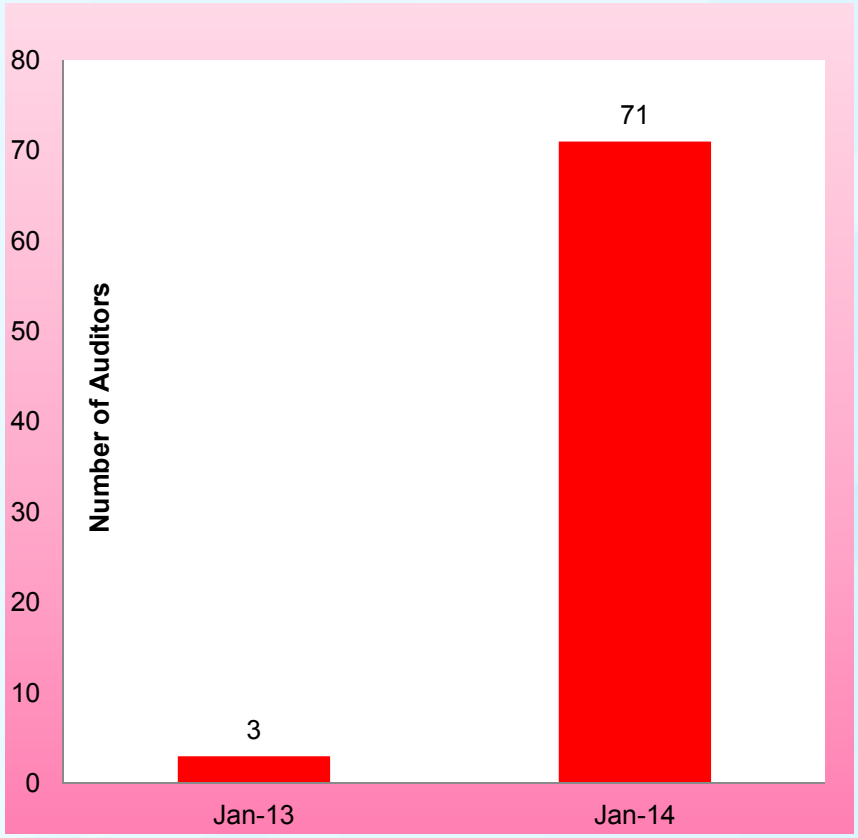
Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) Checklist

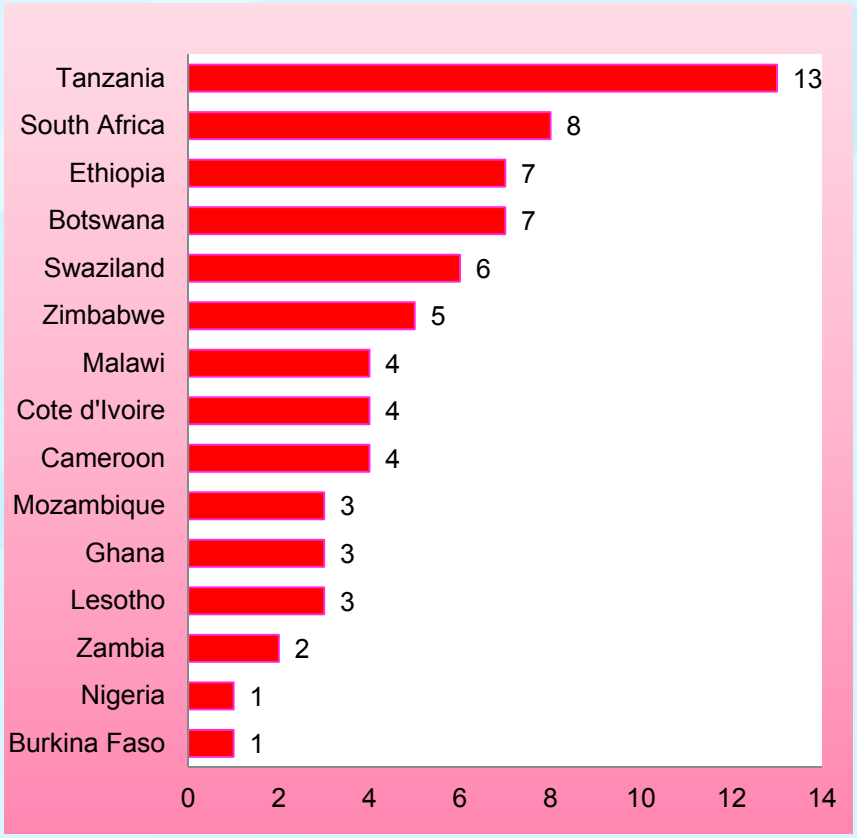
13 Training Modules

- In-country auditors utilized to conduct the lab audits in Mozambique, Kenya, and Tanzania



ASLM Certified Auditors





Laboratories Audited by ASLM Auditors in 2013 - 2014

Country	Number of Laboratories
Botswana	11
Cameroon	9
Coted'Ivoire	4
Ethiopia	9
Ghana	10
Kenya	4
Lesotho	3
Malawi	12
Mozambique	4
Namibia	4
Nigeria	23
Rwanda	2
South Africa	14
Swiziland	9
Tanzania	19
Uganda	8
Zambia	2
Zimbabwe	10
	157

SLIPTA Auditors

ASLM Trained Auditors in Benin

ASLM Auditors

Certificate of Recognition

[Name of Laboratory Here]

[Location here]

has been audited by the African Society for Laboratory Medicine on [date] using the WHO-AFRO Stepwise Laboratory Quality Improvement Process towards Accreditation Checklist and achieved [#] star Levels. This certificate is valid for two years from [date of issue].

Tsehaynesh Messele, Ph.D.

Zambia

Before

After

ISO 15189 Accreditation

- To be accredited, a laboratory has to implement all the requirement of ISO 15189
- The National HIV Reference Lab has achieved ISO 15189 accreditation (2013)
- Cheikh Anta Diop University (CADU), 2015

NHRL: Kenya


HARAMBEE
KENAS
Accreditation Certificate
National HIV Reference Laboratory
ISO 15189:2007

Kenya National HIV Reference Laboratory (NHRL)

SLIPTA Audit: Tanzania

NHRL: Kenya

SLIPTA

- **SLIPTA** is expected to have a catalytic effect by:
  - Encouraging quality improvement 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

References

- ISO 15189:2007, Medical Laboratories – Particular Requirements for Quality and Confidence.
- ISO 15189:2012, Medical Laboratories – Particular Requirements for Quality and Confidence.
- Meeting on Consultation on the Global Laboratory Initiative (GLI) Standards and Stepwise Process towards TB Laboratory Accreditation Meeting Geneva, *Switzerland 06-07 July 2011,* Dr Jean Bosco Ndihokubwayo, MD Lab Program Manager WHO-Regional Office for Africa-AFRO.
- SLIPTA Checklist Version 2:2015.