

GLI TB Implementation Plan and the WHO-AFRO SLIPTA

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National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention
Division of Tuberculosis Elimination



Accreditation Schemes

- Accreditation to international standards
 - WHO-AFRO SLIPTA
 - GLI TB plan
- ‘Specialty’ accreditation
 - WHO HIV drug resistance testing labs
 - WHO Polio Lab Network
 - etc.

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

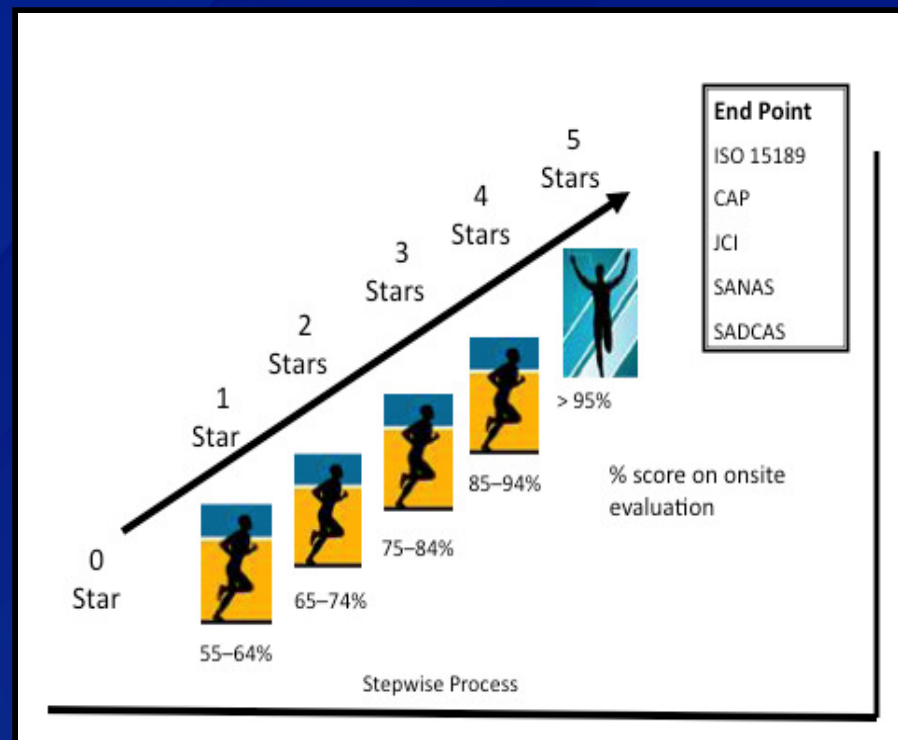


Criteria for Eligibility for SLIPTA

- **Criteria before 7/1/2011**
 - Results are reported on at least 80% of specimens within recommended TATs
 - Sufficient tests are performed to maintain competency
 - Internal quality control procedures are used for all testing
 - Scores on the two most recent proficiency tests is $\geq 80\%$
- **After 7/1/2011: To be determined by MOH**

Progress Towards Accreditation

Based on an onsite audit of procedures and practices using a checklist



Assessment Sections	Score
1: Documents and Records	25
2: Management Reviews	12
3: Organization & Personnel	20
4: Client Management & Customer Service	8
5: Equipment	30
6: Internal Audit	10
7: Purchasing & Inventory	30
8: Information Management	14
9: Process Control and Internal & External QA	43
10: Corrective Action	8
11: Occurrence Management /Process Imprvmnt	10
12: Facilities and Safety	40
TOTAL SCORE	250

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”.

Score

1. DOCUMENTS & RECORDS

1.1 Is there a system or procedure for document & record control and retention?

Y	P	N	2
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Standard: ISO 15189: 4.3.1

1.2. Are documents & records properly maintained and easily accessible?

Y	P	N	2
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Standard: ISO 15189:4.3.1, 4.3.2



Pts: 0-137	138-160	161-185	186-211	212-236	237-250
<55%	55-64%	65-74%	75-84%	85-94%	>95%

SLIPTA

- **Emphasis on improvement in laboratory quality management**
- **Less emphasis on proficiency or competency in laboratory testing**
- **Stars are awarded based on percentage completion of elements**
- **Stars are not associated with specific quality or competence requirements**

GLI Implementation Plan for TB Labs

- **Specifies quality and competency requirements**
 - methods, SOPs, equipment, facilities,
 - biosafety, process control, EQA
- **Supplemented with**
 - templates, resources
 - checklist questions
- **Provides step-by-step guidance**
- **Electronic format with links to resources and modifiable templates**

GLI Checklist Questions

- Aid for implementing plan and assessing progress towards accomplishing phases
- Based on ISO15189 standards
- **Started with WHO-AFRO checklist**
 - each WHO-AFRO question is in TB list
 - added TB-specific questions
- Questions matched with activities and phases

ISO **WHO-
AFRO**

1

5.8.3

A-8.3

Are test results recorded in a logbook or electronic record in a timely fashion?

1

5.1.12

Are results recorded in accordance with NTP and WHO/IUATLD recommendations?

2

5.6.4-7

A-9.18

Does the laboratory participate in an EQA scheme, proficiency testing, or inter-laboratory comparison for determining the acceptability of procedures?

2

5.6.4-7

For AFB-smear microscopy, does the lab participate in blinded rechecking; on-site evaluations; panel testing; or exchange slides with another laboratory?

					5 Stars
				4 Stars	
			3 Stars		
		2 Stars			
	1 Star				
0 Stars					
Pts: 0-137 <55%	138-160 55-64%	161-185 65-74%	186-211 75-84%	212-236 85-94%	237-250 >95%
Phase 1 62 pts	Phase 2 131 pts		Phase 3 183 pts		Phase 4 247 pts

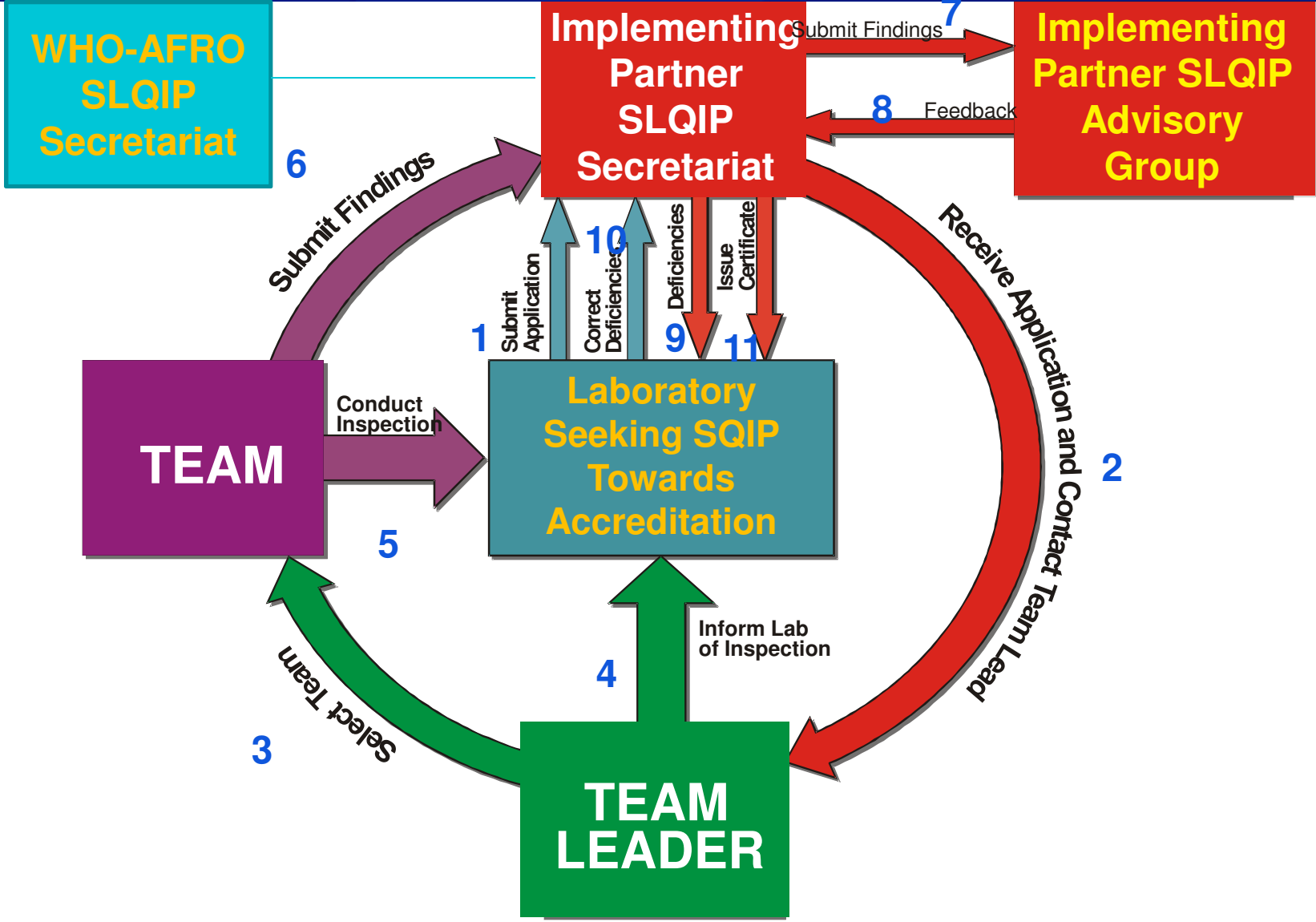
TB Specific Questions

- **Quality Checks**
- **Internal Quality Controls**
- **Performance Indicators**
- **Proficiency criteria**
- **Interpreting, recording, reporting**

TB Testing Quality Controls

- **AFB-smear microscopy**
 - AFB+ slides are re-read by a second person
 - quality of each batch of stain is checked
- **Culture and identification**
 - media supports the growth of *Mtb*
 - media passes sterility check
- **Drug susceptibility testing**
 - drug stocks are of the correct potency
 - drug-containing media are discriminatory

Feature	GLI	SLIPTA
Based on ISO15189	Y	Y
Phased approach	Y	Y
Comprehensive checklist	Y	Y
Quality & competency requirements	Y	N
Provides step-by-step guidance	Y	N
Electronic format with links	Y	N
Includes templates and resources	Y	N
Business plan	N	Y



Next Steps

- **Revise links between GLI and SLIPTA checklists**
- **WHO-AFRO is considering adding to SLIPTA quality and competency requirements similar to the GLI plan**

Thank You

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