Consultation

Global Laboratory Initiative Stepwise process towards TB Laboratory Accreditation

6-7th July 2011, WHO Headquarters, Geneva, Switzerland

World Health Organization

Background

The Global Laboratory Initiative (GLI) is accelerating and expanded access to quality assured laboratory services in response to the diagnostic challenges of TB. To reinforce the need for sustainability and quality assurance, a systematic process of laboratory strengthening is now needed to ensure proper utilization and sustainability of these laboratory resources. As National Reference Laboratories (NRLs) provide a range of sophisticated TB diagnostic services , a system for organizing and managing service quality at the national level must be established.

GLI partners including the International Union Against Tuberculosis and Lung Disease (IUATLD), Centre for Disease Control and Prevention (CDC), The Royal Tropical Institute, Netherlands (KIT) and the World Health Organization (WHO), have developed an implementation guide to assist in implementation of a quality management system (QMS) at the NRL level The basis for this guide is *ISO 15189:2007, Medical Laboratories – Requirements for quality and competence,* as developed and published by the International Organization of Standardization (ISO).

Implementation of ISO 15189:2007 quality requirements presents a challenge to novice organizations because they require significant financial and organizational commitment. To this end, ISO15189 standards have been further developed and organized into a comprehensive framework by the Clinical and Laboratory Standards Institute (CLSI) to ease understanding and application. Specifically, the standards have been organized into a framework of twelve Quality System Essentials[i] (QSE's):

1. Facilities & Safety
2. Organization
3. Personnel
4. Equipment
5. Purchasing & Inventory
6. Process Control
7. Information management
8. Documents & Records
9. Customer Service
10. Assessment
11. Occurrence management
12. Process Improvement

This guide includes several items, which will aide in implementation of a sequential framework or "step-wise" approach for achieving the ISO standard. The steps recommended within this guide are based upon the practical experience of those who have already implemented a quality system and take into consideration limitations created by inadequate financial and human resources that would be required for a more aggressive approach.

The defined phases are provided below, with each successive step building on its predecessor:

1. GLI Step1: Minimum requirements for performing laboratory tests;
2. GLI Step 2: Implements basic management requirements (predominantly resource management);
3. GLI Step 3: Good management practices implemented (predominantly process management);
4. GLI Step 4: Meets all the requirements of the ISO15189:2007 standards (predominantly improvement management).

The draft implementation guide to meet the requirements for laboratory accreditation will be available to meeting participants on CD with in-built hyperlinks to associated GLI tools and resources including relevant templates.

The overall goal of the consultation is to review and refine the implementation guide and establish plans for roll-out at country level.

Meeting Objectives

- **To review existing laboratory accreditation programmes and processes;**
- **To review and refine the draft GLI accreditation implementation guide;**
- **To develop a plan to support the roll-out and country uptake of the implementation guide**

Expected outcomes

Stakeholder support for the roll-out of the revised implementation guide.

Participants

The meeting will include representatives from leading international institutions and agencies supporting implementation of laboratory quality management systems into National Public Health Laboratories and National TB Reference Laboratories

Provisional Agenda
Venue: Salle A, World Health Organization, Geneva

Day 1 – 6th July 2011		
9:00-9:20	Welcome and meeting objectives	Chris Gilpin
9:20-9:40	Overview of International Standards for Laboratory Accreditation	Glen Fine
9:40-10:00	What is needed for different levels of TB Laboratory Accreditation?	John Ridderhof
10:00-10:30	Discussion	
10:30-11:00	Coffee break	
Objective 1	*To review existing laboratory accreditation programmes and processes*	
11:00-11:20	The WHO AFRO accreditation Process (SLIP-TA)	Chris Gilpin
11:20-11:40	SANAS accreditation	John Peart
11:40-12:00	Accreditation bodies in other WHO Regions	Jeanette Twell
12:00-12:30	WHO Lyon - Global Perspective	Sebastian Cognat
12:30-13:00	Discussion	
13:00-14:00	Lunch	
Objective 2	*To revise and refine the draft GLI accreditation implementation guide*	
14:00-14:30	How to align these accreditation schemes	Tom Shinnick
14:30-15:00	Overview of the GLI Accreditation Process	Paul Klatser
15:00-16:00	Demonstration: How does the tool work?	Tjeerd Datema
16:00-16:30	Coffee break	
16:30-17:30	Discussion	All

Provisional Agenda

Day 2 – 7th July 2011		
9:00-9:15	Review of outcomes from Day 1	Chris Gilpin
9:15-10:30	Facilitated discussion: • Classification of the requirements to meet different standards for different GLI levels? • Existing GLI tools available to support implementation? • What are the gaps and what needs to be further developed?	Tom Shinnick
10:30-11:00	Coffee break	
Objective 3	*To develop a plan to support the roll-out and country uptake of the implementation guide*	
11:00-11:30	Implementation Experience: The Ugandan National TB Reference Laboratory	Mirjam Engelberts / Paul Klatser
11:30-12:00	How to assess laboratory preparedness for accreditation?	Linda Oskam
12:00-13:00	The Role of partners to support roll-out ?	Discussion
13:00-14:00	Lunch	
14:00-16:00	Panel Discussion: Building partnerships with existing processes towards accreditation	Tom Shinnick, Paul Klatser, Glen Fine
16:00-16:30	Coffee break	
16:30-17:00	Summary an next steps	Chris Gilpin