Global Laboratory Initiative
Stepwise Implementation Tool towards Accreditation

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GOAL: To provide universal access to an appropriate, quality assured, laboratory diagnosis for TB

- Universal access to quality assured AFB microscopy with effective EQA
- Universal access to improved diagnosis of AFB smear negative TB suspects and especially among persons living with HIV
- Universal access to rapid laboratory diagnosis of drug resistant TB among persons at risk of M/XDR-TB
- Establish an integrated laboratory accreditation scheme
Accreditation recognised as a priority with the establishment of GLI working group in 2007

A Technical Working Group on Laboratory Accreditation established for the Bacteriology and Immunology sub-section of the Union in 2009

Taskforce of GLI partners established in 2010 to set objectives and priorities to guide TB laboratories towards accreditation

Recognition of three distinct types of TB laboratory accreditation needs:
- National TB Reference Laboratories
- Integrated laboratories services
- TB Laboratory Networks
GLI Laboratory Accreditation

- Principles of the technical working group were that:
  - WHO is not an accreditation authority
  - WHO role is normative and provides guidance to countries BUT cannot set standards for laboratory accreditation

- Given the hierarchy of TB laboratory networks priority was to be given to guide National TB Reference Laboratories towards international standards of laboratory accreditation

- Develop consensus on a quality system element (QSE) framework and standard for accreditation

- Defined specific QSE which have special requirements for TB laboratories performing culture, DST and molecular tests
GLI Laboratory Accreditation - Agreed Principles

- Base the accreditation process on an existing international standards - ISO15189
- Use an existing Quality System Elements framework to help define the specific requirements for National TB Reference Laboratories - CLSI
- Laboratory bio-safety is a critical component for TB laboratories
- The accreditation system should be developed as a stepwise approach with Phase 1 being easily achieved to Phase 4 which meets the requirements of the standard
- Establish an implementation plan which gives priorities to the order in which requirements in the standard should be implemented
### GLI Laboratory Accreditation

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<tr>
<th>Step</th>
<th>ISO</th>
<th>QSE</th>
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<tbody>
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<td></td>
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<td><strong>Facilities and safety:</strong> The laboratory is designed and maintained to be efficient, comfortable, provide a safe working environment, and minimize risk of injury and occupational illness.</td>
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<td>1</td>
<td>2</td>
<td>Adequate space is allocated for staff, instruments, storage, bench work, etc.</td>
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<td>2</td>
<td>3</td>
<td>The laboratory space and workflow are designed as suggested in relevant manuals.</td>
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<td>3</td>
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<td>Sample collection facilities meet the needs of the patients and laboratory staff.</td>
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<td>4</td>
<td>5.2.1</td>
<td>There is adequate electricity, lighting, ventilation, water, temperature control, and waste disposable facilities.</td>
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<td>5.2.2</td>
<td>Environmental conditions, such as temperature or electrical supply, that might affect the quality of the results are monitored, controlled, and recorded.</td>
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<td>5.2.3</td>
<td>There is effective separation between adjacent laboratory sections to reduce hazards and prevent cross contamination.</td>
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<td>5.2.4</td>
<td>Access to laboratory areas is restricted during working hours.</td>
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<td>5.2.5</td>
<td>The lab is locked outside of working hours or resources are otherwise safeguarded.</td>
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<td>5.2.6</td>
<td>There is a way to communicate efficiently with staff in the laboratory.</td>
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<td>5.2.7</td>
<td>Adequate storage space and conditions for samples, documents, records, equipment, consumables, etc are available.</td>
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<td>5.2.8</td>
<td>Hazardous materials are stored and disposed in compliance with all regulations.</td>
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<td>5.2.9</td>
<td>Work areas are clean, tidy, and free of clutter.</td>
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<td>5.2.10</td>
<td>The laboratory is cleaned and tidied at the end of each work day.</td>
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<td>5.2.10</td>
<td>Staff are supervised by an experienced scientist.</td>
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<td>5.2.10</td>
<td>A safety coordinator has been appointed to ensure that safety policies and documents are readily available, appropriate training is provided, safety requirements are continuously met, and personnel comply with the requirements.</td>
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<td>5.2.10</td>
<td>There is a manual that describes procedures for working safely in the laboratory including emergency preparedness, infection control, biosafety, hand washing.</td>
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Available guidance and tools

Links to additional materials to prevent each laboratory from reinventing the Wheel!

Guidelines on specific topics (e.g. EQA)
Course materials
Document templates (KIT, GLI)
Procurement software (GLI)
Requirements in establishing a QMS simplified

- Standards & guidelines don’t provide (daily) guidance on implementing requirements – The tool translates requirements in the standard requirements into activities
- Explanation on why and how to carry-out activities
- Examples of documents, background information on quality management aspects, etc.

No laboratory should have to reinvent the wheel.
GLI tool – 4 phases

**Activities divided over 4 phases**

- **Phase 1**: relatively easy to achieve; focusing on assuring technical competency of testing performed.
- **Phase 2**: implement quality control measures and create traceability.
- **Phase 3**: establish the policy cycle with proper management, leadership and planning.
- **Phase 4**: create continuous improvement, accumulate evidence.
Level 1

Goal

To ensure that the primary process operates correctly and safely.

Description

In this level the fundamentals of a quality management system (QMS) will be set up. A quality project team will be formed. Background knowledge will be updated (i.e. through courses on quality management for staff and management). SOPs will be written for the primary process only, i.e. for the core processes the lab is already carrying out. For the primary process equipment is essential, therefore SOPs for the proper and safe use of equipment and a maintenance schedule will also be prepared. This level will further focus on upgrading the laboratory safety with introduction of a safety manual and execution of a risk assessment.

NOTE: When certain steps in this implementation cannot be complied with yet due to external factors, but the rest of the actions of level 1 have been implemented, the laboratory may advance with implementing level 2 actions, keeping in mind that elements of level 1 still need to be implemented.
GLI accreditation guide – How it works

• In an interactive roadmap
  • Providing day-to-day guidance

• Structured according to the CLSI 12 quality system essentials framework
  • Providing oversight of activities on each aspect of the quality management system

• Checklist for each phase
The same activities as the implementation guide. However, in the implementation guide the activities are all grouped within 12 Quality System essentials (QSEs). This is good for getting an overview on all activities that need to be carried out for each element of the quality management system. In this roadmap the activities are put in a most optimal sequence for day-to-day implementation of activities.

Mind that it is not required to strictly adhere to this roadmap (it is just and indication of a proper sequence of implementing activities). When another sequence suits better the local situation in your laboratory, feel free to make our own optimal sequence for carrying out activities.
Create commitment for accreditation.
Provide staff with basic orientation on principles of a quality management system.
Appoint a quality project team. The chair of this team is appointed as a quality focal point.
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This should be done by the laboratory supervisor.

The quality project team will be the main coordinating body in setting up the quality management system. This team will support the management in carrying out the activities of this GLI implementation guide leading to establishment of the quality management system, so that the laboratory supervisor will not be burdened with coordinating the establishment of the quality management system all by himself/herself. The laboratory supervisor needs to decide for himself/herself how many persons will be included in the quality project team, depending on what is appropriate for the local situation.

The chair of the quality project team will be the quality focal person and coordinate the main activities of the team. He/she is responsible for the correct execution of activities of the GLI implementation guide by team members and decides who should focus on which activity and when.

This team will have meetings with the laboratory director and/or manager at least twice per month to discuss progress and find solutions to problems encountered. Minutes of these meetings are made by one member of the quality project team (not the quality focal person since he/she has to lead the meetings) and these minutes are given to all members of the project team, including the laboratory manager/director, and they are archived (i.e., they serve as proof that the meetings were held and they serve as tool to monitor progress).
The persistent gap in TB case detection (only 63% of new smear-positive TB cases are detected) amongst both new and previously treated cases underscores the need for a strengthened commitment. Quality assured laboratory services are an essential component of TB control programs and have been considered amongst the weakest components of TB treatment and control efforts. Lack of realization of the importance of laboratory services, limited funding, lack of specialized materials, and insufficient technical assistance. The need to strengthen laboratory services remains urgent and is a priority for the Global Laboratory Initiative (GLI), one of seven STOP Working Groups established to tackle diagnostic challenges of TB. To reinforce the need for quality laboratory services, the World Health Organization (WHO) has developed a GLI tool – display of activities.
Conclusion

- What GLI strives to achieve:
  - To speed up and expand the laboratory improvement process and make it more efficient
  - Making better use of already existing laboratory support material which can help to increase the number of ISO 15189 accredited laboratories (and thus the assurance of good quality lab services)

Final goal:
More patients correctly diagnosed.
Available online at: www.GLIdiquality.org

GHDonline discussion forum 2-16\textsuperscript{th} April 2012
www.ghdonline.org

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