GLI approach to TB Lab Accreditation

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Need for recognized quality assured services

There is a need to develop a laboratory systems approach, with a focus on quality systems and standards to achieve the common goals of quality patient care and public health programs.

Programs gain through a shared system approach

Picture: PP Lyon April 7th 2008;
Essential factors in quality management systems according to ISO15189
## Comparison of 11 international QM standards

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Amsterdam, The Netherlands    www.kit.nl
Goal of a QM System

For the laboratory:

- To operate efficiently and effectively, meeting regulatory requirements (e.g. ISO15189)
- To be managed with the interests of the patients
- To ensure that everyone understands who is responsible for doing what, when, why, where and how
- To continually strive for improvement
Stated simply

- Say what you do (document)
- Do what you say
- State of the art (professionally)
- Standardize, standardize, standardize
- Measure and monitor those things that are important to your customer
- Focus on the process
- Assess
Quality standards

Standards:

- Lists requirements, no guidance on implementation

- “The laboratory shall be designed for the efficiency of its operation, to optimize the comfort of its occupants and to minimize the risk of injury and occupational illness. Patients, employees and visitors shall be protected from recognized hazards”

- Useful for oversight
Many documents and tools available

- Roadmaps, guidelines, SOPs formats, training tool kits, roadmaps, checklists, etc.
Guidelines

- More explanation on “content” of requirements, but no guidance on best sequence of implementation

- Useful for deeper understanding of a QMS and the meaning of requirements in a standard.

Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition
Implementation guidelines often not useful

“All staff must be properly trained for the work they are expected to perform, and provided with the authority and resources to carry out their responsibilities.”

Cited from one of the many Implementation Guides available

- Which activities to be undertaken not clear
- System approach lost
Checklists

- Requirements formulated as question, can have more guidance by including sub-questions asking for details related to specific requirements
- Especially useful for assessors and for measuring achievements

\[1.6\] Is there a current laboratory quality manual, understood and implemented by all staff, that contains the quality management system’s policies & procedures?
(Level II: 6.1, 6.2, 10.1)

Does the quality manual include the following elements?

- Quality policy statement, including scope of service, standard of service, objectives of the quality management system, and management commitment to compliance.
- Description of the quality management system and the structure of its documentation.
- Reference to supporting procedures, including technical procedures.
- Description of the roles and responsibilities of the laboratory manager, quality manager, and other personnel related to ensuring compliance.
- Evidence of at least annual management review and approval.

(WHO-AFRO Laboratory Accreditation Checklist)
Many documents and tools available

- Roadmaps, guidelines, SOPs formats, training tool kits, roadmaps, checklists, etc.

BUT:

- Operational translation of guidelines is missing: where to start and how to proceed?
- Little attention to management aspects.
- Shortage of harmonization/standardization.
- Not always addressing TB specific needs.
Recommendations:

Include:

- **A directive** telling the manager which question should be complied to first, second, and so on.
- **A guideline** telling the manager with each question who should do what by when and how.
- **Templates** (example SOP, example quality manual, example equipment register, example request form, example result report, example laboratory register, etc.)
- **References** to standard articles with each question.
Development of the guide

• Work group meetings in August 2010 and March 2011 at KIT in Amsterdam
  • Brainstorm led to formulation of goals and contents of different levels and total outline of the guide.
  • Formulating requirements for different levels based on ISO 15189 articles

• Start drafting of the guide by KIT

• Sending of drafts to work group members and processing remarks and corrections

• Current meeting
This list breaks out the QSEs according the 12 CLSI elements with the corresponding ISO15189 element and assigns a tentative 'step" for each.

Steps: 1=minimum for reliable testing; 2='1'+minimal mgmt; 3="2"+good mgmt, 4=Full ISO15189

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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>5.2.8 The lab is locked outside of working hours or resources are otherwise safeguarded.</td>
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<td>5.2.9 There is a way to communicate efficiently with staff in the laboratory</td>
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<td>Adequate storage space and conditions for samples, documents, records, equipment, consumables, etc are available.</td>
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Outline of the guide

The GLI Implementation Guide will contain the following sections:

- Introduction
Outline of the guide

The GLI Implementation Guide will contain the following sections:

- Introduction
- Quality management in TB laboratories
  - *What is QM, what does it mean for TB laboratories and what does it take?*
Outline of the guide

The GLI Implementation Guide will contain the following sections:

- Introduction
- Quality management in TB laboratories
- Directive on using the tool
  - How should the tool be used?
  - Defines order of steps that should be implemented first, second, and so on... (Structuring of activities according to CLSI QSEs is not the optimal order for the user, only for the developers of the guide)
Outline of the guide

The GLI Implementation Guide will contain the following sections:

- Introduction
- Quality management in TB laboratories
- Directive on using the tool
- Implementation guide level 1
- Implementation guide level 2
- Implementation guide level 3
- Implementation guide level 4
- Roadmap
- Checklist level 1
- Checklist level 2
- Checklist level 3
- Checklist level 4