Royal Tropical Institute

GLI approach to TB Lab Accreditation

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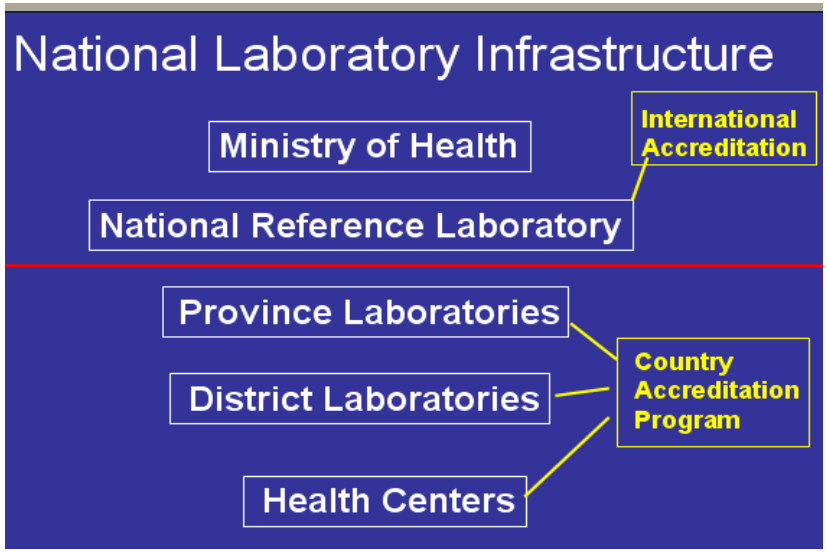
Need for recognized quality assured services

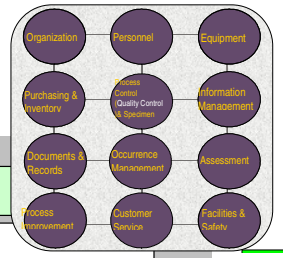
There is a need to develop a laboratory systems approach, with a focus on quality systems and standards to achieve the common goals of quality patient care and public health programs.

Programs gain through a shared system approach



Picture: PP Lyon April 7th 2008;

Essential factors in quality management systems according to ISO15189



ORGANIZATION

- ORGANIZATIONAL CHART
- GUIDELINES, PROCEDURES
- ROLES AND RESPONSIBILITIES

RESOURCE SYSTEMS

- PERSONNEL
- EQUIPMENT
- SUPPLIES
- FACILITY
- FINANCE

SUPPORT SYSTEMS

- DOCUMENTS AND RECORDS
- LAB INFO SYSTEM
- PURCHASING AND INVENTORY
- SAFETY

EVALUATION AND CONTINUOUS IMPROVEMENT

- PROCESS CONTROL-IQ
- INTERNAL ASSESSMENT
- OCCURRENCE MANAGEMENT
- EXTERNAL ASSESSMENT

USER Requirements -Care-Provider -Patient

Request

Pre to Post Examination Process

Report

USER Satisfaction or dissatisfaction

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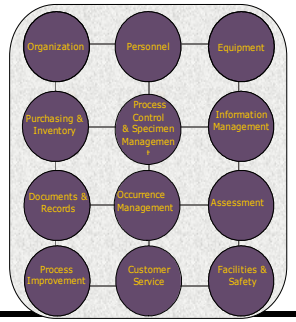
Comparison of 11 international QM standards



	GLP [FDA]	GLP [OECD]	GCLP [BARQA]	CLIA[a]	ISO9001[b]	ISO 15189:2003[b]	ISO 15189:2007	CLSI HSI[b]	CLSI GP26[b]	JCI clinical laboratory standard	WHO-AFRO system	WHO-SEARO system
Organization	+	+	+	+	+	+	+	+	+	+	+	+
Personnel	+	+	+	+	+	+	+	+	+	+	+	+
Equipment	+	+	+	+	+	+	+	+	+	+	+	+
Purchasing & inventory	-	+	-	+	+	+	+	+	+	+	+	+
Process control QC & specimen management	+	+	+	+	+	+	+	+	+	+	+	+
Information management	+	+	+	+	-	+	+	+	+	+	+	+
Documents & records	+	+	+	+	+	+	+	+	+	+	+	+
Occurrence management	-	-	-	+	+	+	+	+	+	-	+	+
Assessment	+	+	+	+	+	+	+	+	+	+	+	+
Process improvement	+	+	-	+	+	+	+	+	+	+	+	+
Customer service	-	-	-	+	+	+	+	+	+	-	+	+
Facilities & safety	+	+	+	+	+	+	+	+	+	+	+	+

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

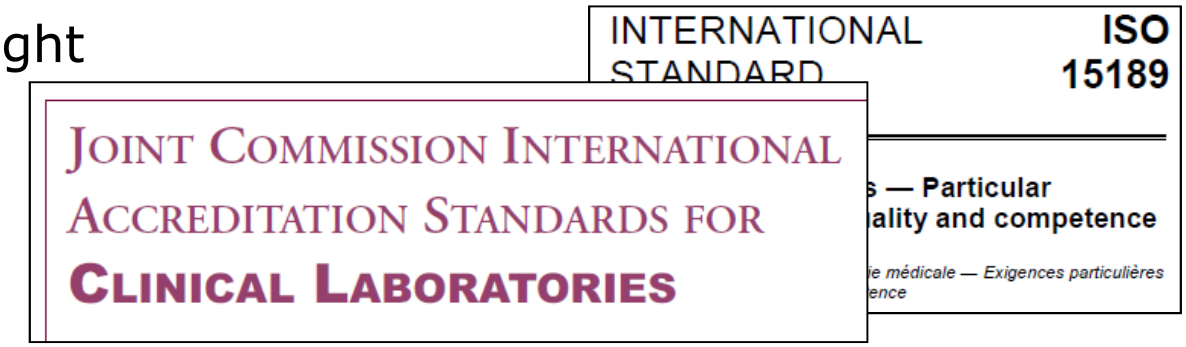
Stated simply

- 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"* *ISO 15189:2007*
- Useful for oversight



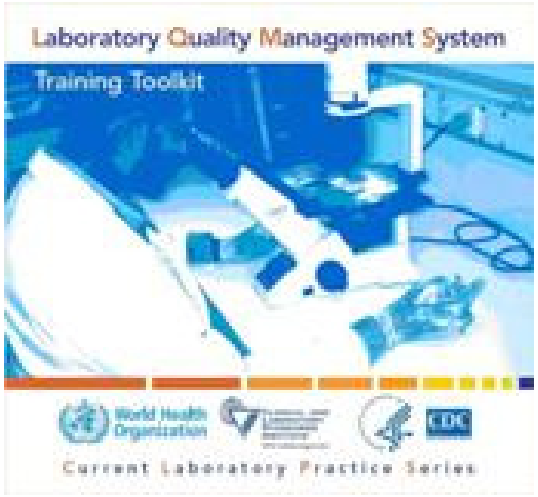
Many documents and tools available

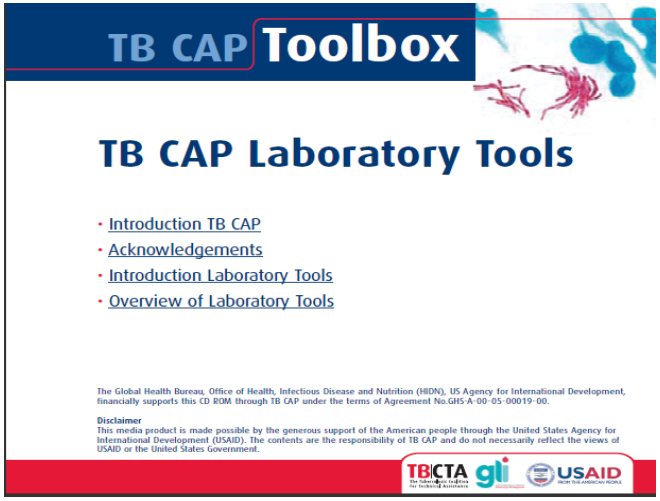
- Roadmaps, guidelines, SOPs formats, training tool kits, roadmaps, checklists, etc.

World Health Organization

CDC

CLINICAL AND LABORATORY STANDARDS INSTITUTE
WHO Collaborating Center

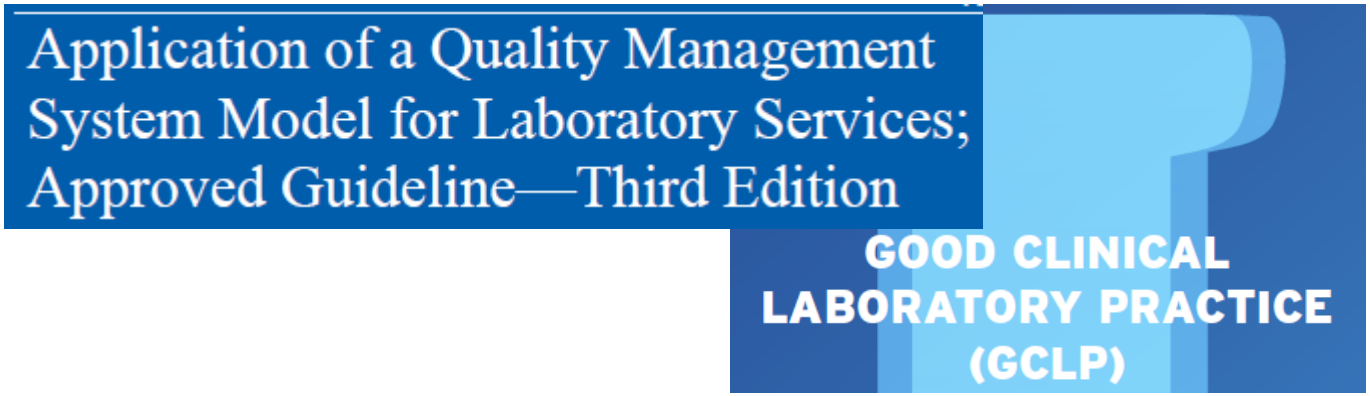




Guidelines

- 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.



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.

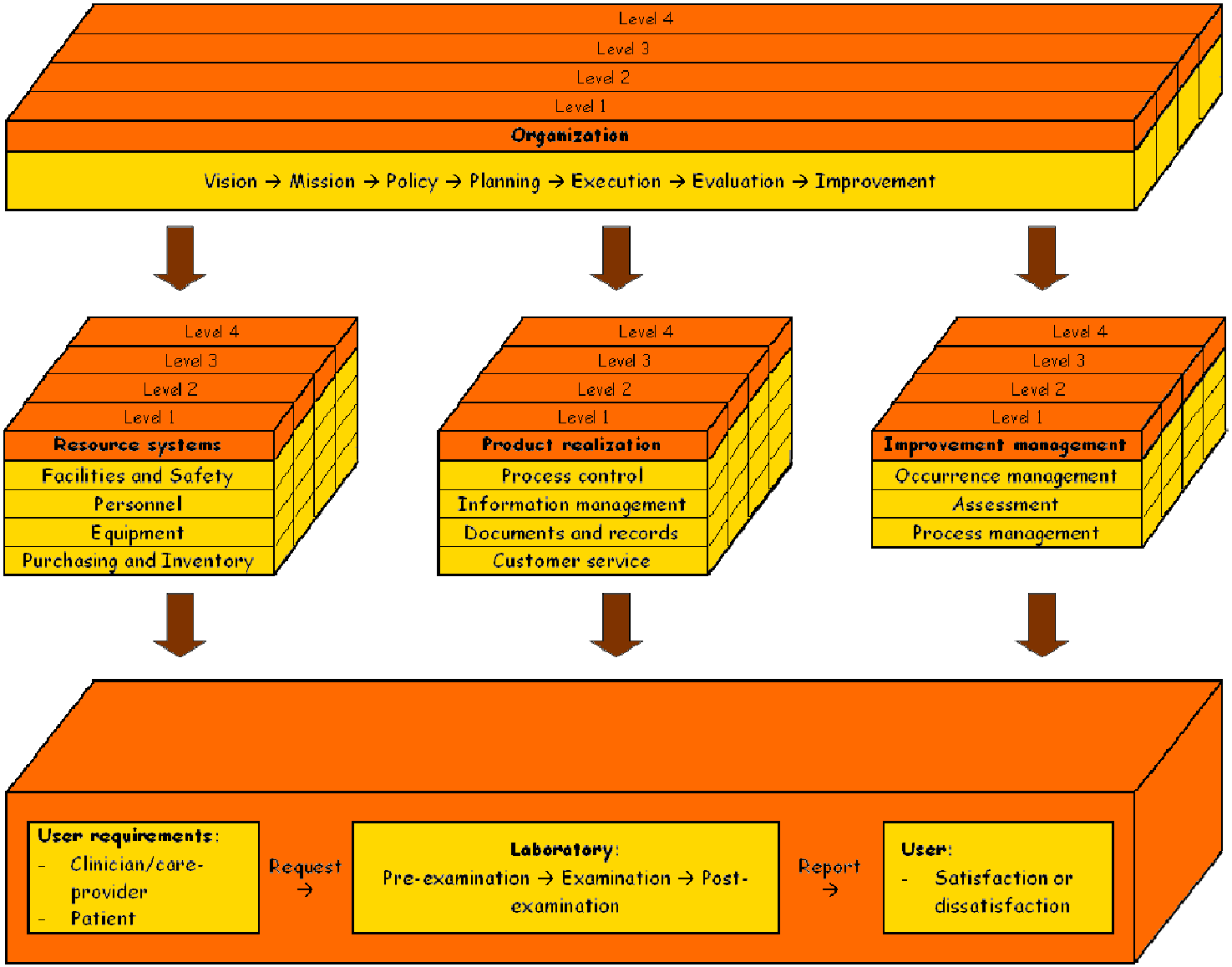
Recommendations:

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


Level 4
Level 3
Level 2
Level 1
Organization
Vision → Mission → Policy → Planning → Execution → Evaluation → Improvement
Level 4
Level 3
Level 2
Level 1
Resource systems
Facilities and Safety
Personnel
Equipment
Purchasing and Inventory
Level 4
Level 3
Level 2
Level 1
Product realization
Process control
Information management
Documents and records
Customer service
Level 4
Level 3
Level 2
Level 1
Improvement management
Occurrence management
Assessment
Process management
User requirements:
- Clinician/care-provider
- Patient
Request →
Laboratory:
Pre-examination → Examination → Post-examination
Report →
User:
- Satisfaction or dissatisfaction

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

Step				ISO	QSE
					Facilities and safety: The laboratory is designed and maintained to be efficient, comfortable, provide a safe working environment, and minimize risk of injury and occupational illness.
1	2	3	4	5.2.1	Adequate space is allocated for staff, instruments, storage, bench work, etc.
		3	4	5.2.2	The laboratory space and workflow are designed as suggested in relevant manuals.
1	2	3	4	5.2.3	Sample collection facilities meet the needs of the patients and laboratory staff.
1	2	3	4	5.2.4	There is adequate electricity, lighting, ventilation, water, temperature control, and waste disposable facilities.
	2	3	4	5.2.5	Environmental conditions, such as temperature or electrical supply, that might affect the quality of the results are monitored, controlled, and recorded.
	2	3	4	5.2.6	There is effective separation between adjacent laboratory sections to reduce hazards and prevent cross contamination.
	2	3	4	5.2.7	Access to laboratory areas is restricted during working hours.
	2	3	4	5.2.7	The lab is locked outside of working hours or resources are otherwise safeguarded.
		3	4	5.2.8	There is a way to communicate efficiently with staff in the laboratory
		3	4	5.2.9	Adequate storage space and conditions for samples, documents, records, equipment, consumables, etc are available.

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