



Accreditation of TB diagnostic laboratories and services: the way forward

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Quality of labs is essential in health laboratories and health care systems

- Reliable results by laboratories improve the decision making capacity of the clinicians/health workers as well as public health authorities.
- The consequences of poor quality are serious: inappropriate treatment, investigation and responses.
- Quality can only be assured by a well-defined QS, as part of an overall quality management aimed at ensuring consistency, reproducibility, traceability and efficacy of the products and services.

Seventy percent of clinical medicine decision making is predicated upon, or confirmed by, or documented by medical laboratory test results (Dighe AS et al. Semin Diagn Pathol. 2007 May;24(2):98-107).



**World Health
Organization**

REGIONAL OFFICE FOR **Africa**

The Maputo Declaration



The Maputo Declaration on Strengthening of Laboratory Systems

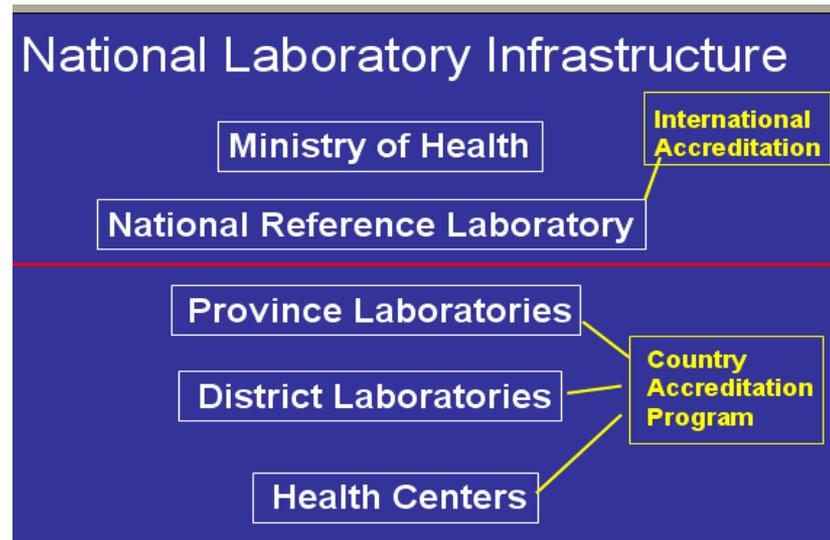
We, representatives of governments, multilateral agencies, development partners, professional associations, and academic institutions, participated in a Consensus Meeting on Clinical Laboratory Testing Harmonization and Standardization in Maputo, Mozambique, on 22nd - 24th January 2008. The meeting sought to address laboratory challenges that limit the scale-up of services for tuberculosis, malaria and HIV diagnosis and care.



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;



GLI Strategic Priorities

- Establish GLI partnership projects
- Develop templates for country-specific roadmaps for laboratory strengthening
- Develop human resource strategies
- Develop appropriate and adequate laboratory biosafety standards
- **Develop a process for the accreditation of labs or sections of labs that do TB testing**
- Move new diagnostics into countries



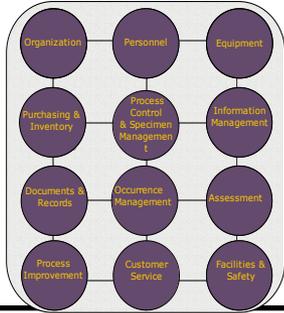
GLI approach to TB Lab Accreditation

IUATLD workgroup led by GLI tasked with:

- ✓ reviewing existing documents on TB lab accreditation
- developing consensus on a quality system element (QSE) framework
 - defining QSEs for TB labs performing microscopy, culture/DST, and molecular tests
 - defining QSEs for TB lab networks
- developing roadmaps, checklists, and resources for accrediting/certifying TB labs/networks



Comparison of 11 international QM standards



	GLP [FDA]	GLP [OECD]	GCLP [BARQA]	CLIA ^a GCLP	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	+	+	+	+	+	+	+	+	+	+	+	+



The laboratory	The work	Measurement
<i>Pre-analytical</i>	<i>Analytical</i>	<i>Post-Analytical</i>
<i>AFRO and CLSI - similar headings</i>		
Organization Facilities and Safety Personnel Equipment Purchasing and Inventory	Process Control Documents and Records Information Management	Occurrence Management Customer Service Process Improvement
<i>CLSI</i>		
Assessments		
<i>AFRO</i>		
<i>- Organization and Personnel - Process Control & Internal and External Quality Assessment -Occurrence/Incidence Management & Process Improvement</i>		Management Reviews Internal audit Internal & External Quality assessment Corrective action



WHO AFRO tiered QM system

Category	WHO-AFRO Category	Max. points	Points (%)
Inputs	3. Organization & Personnel	20	120 (48)
	5. Equipment	30	
	7. Purchasing & inventory	30	
	12. Facilities & safety	40	
Process	1. Documents & records	25	82 (33)
	8. Information management	14	
	9. Process control & IQA/EQA	43	
Assessment	2. Management reviews	12	48 (19)
	4. Client management & customer service	8	
	6. Internal audit	10	
	10. Corrective action	8	
	11. Occurrence management & process improvement	10	

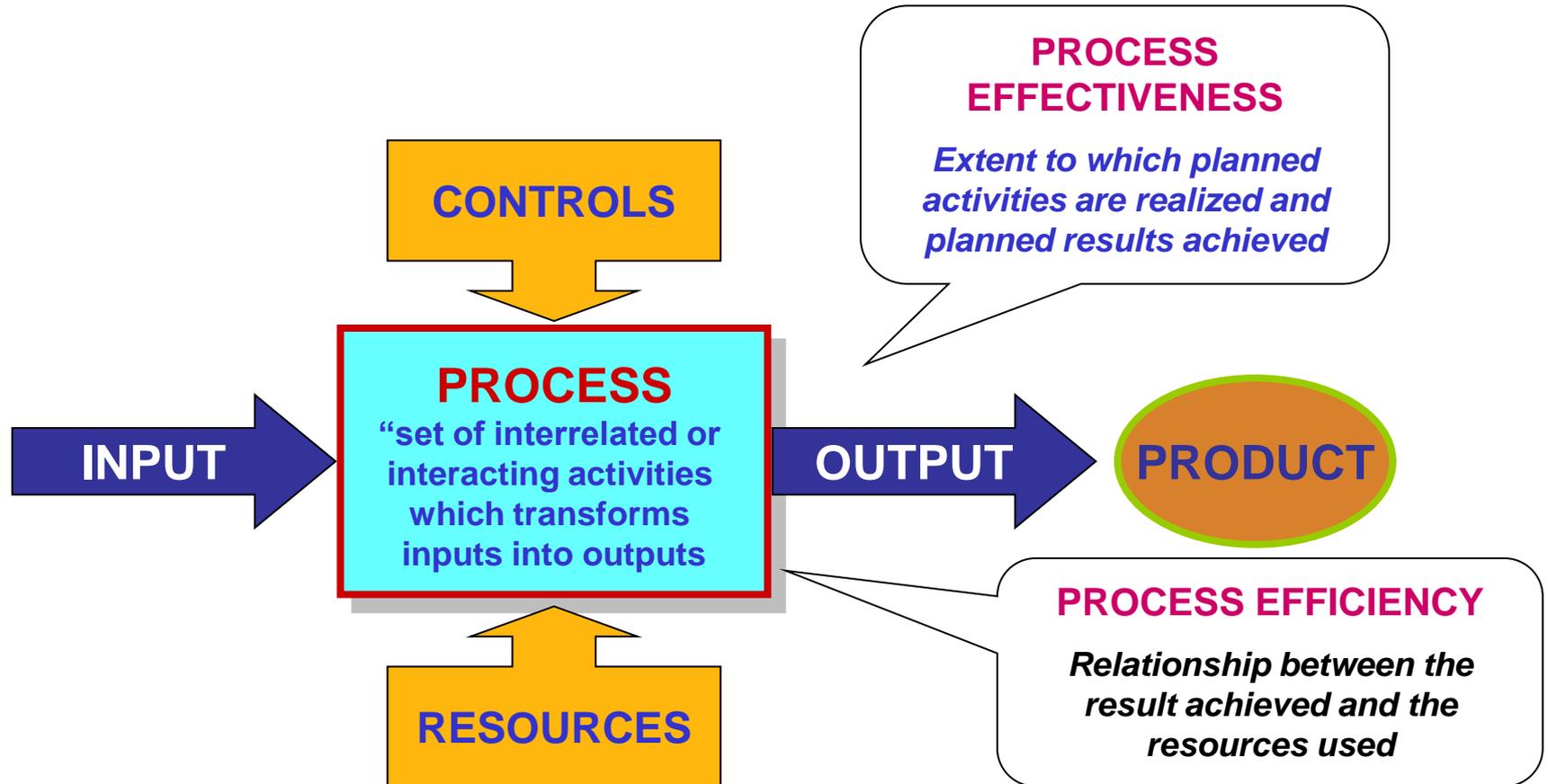


We all are most comfortable with own habits





ISO 9001:2000 Process Approach

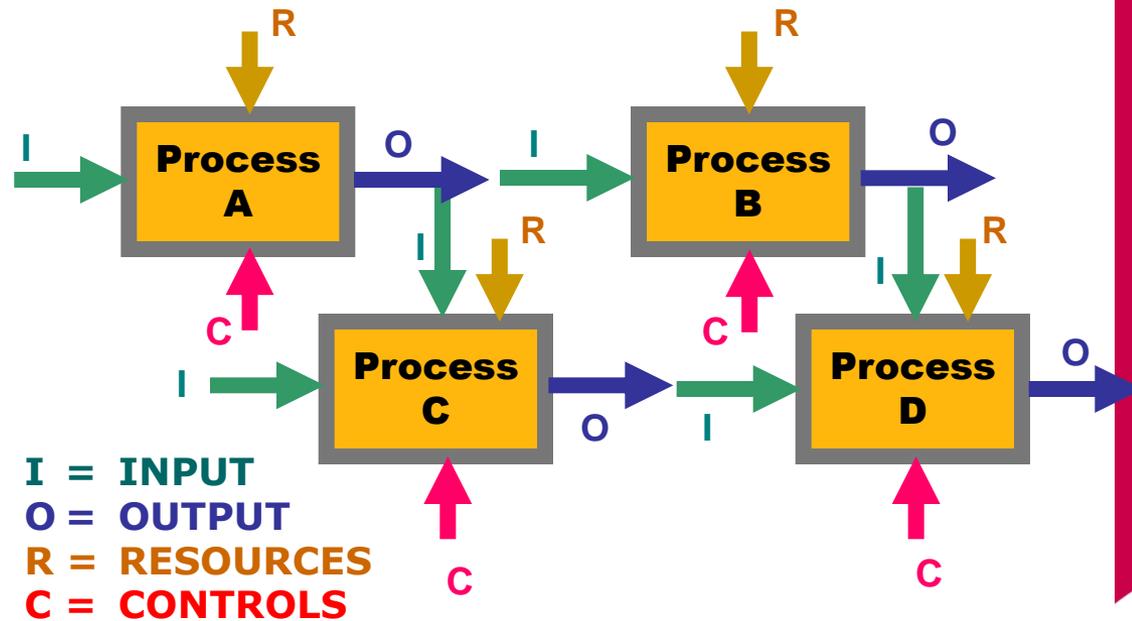


**A desired result is achieved more efficiently
when activities and related resources are
managed as a process**



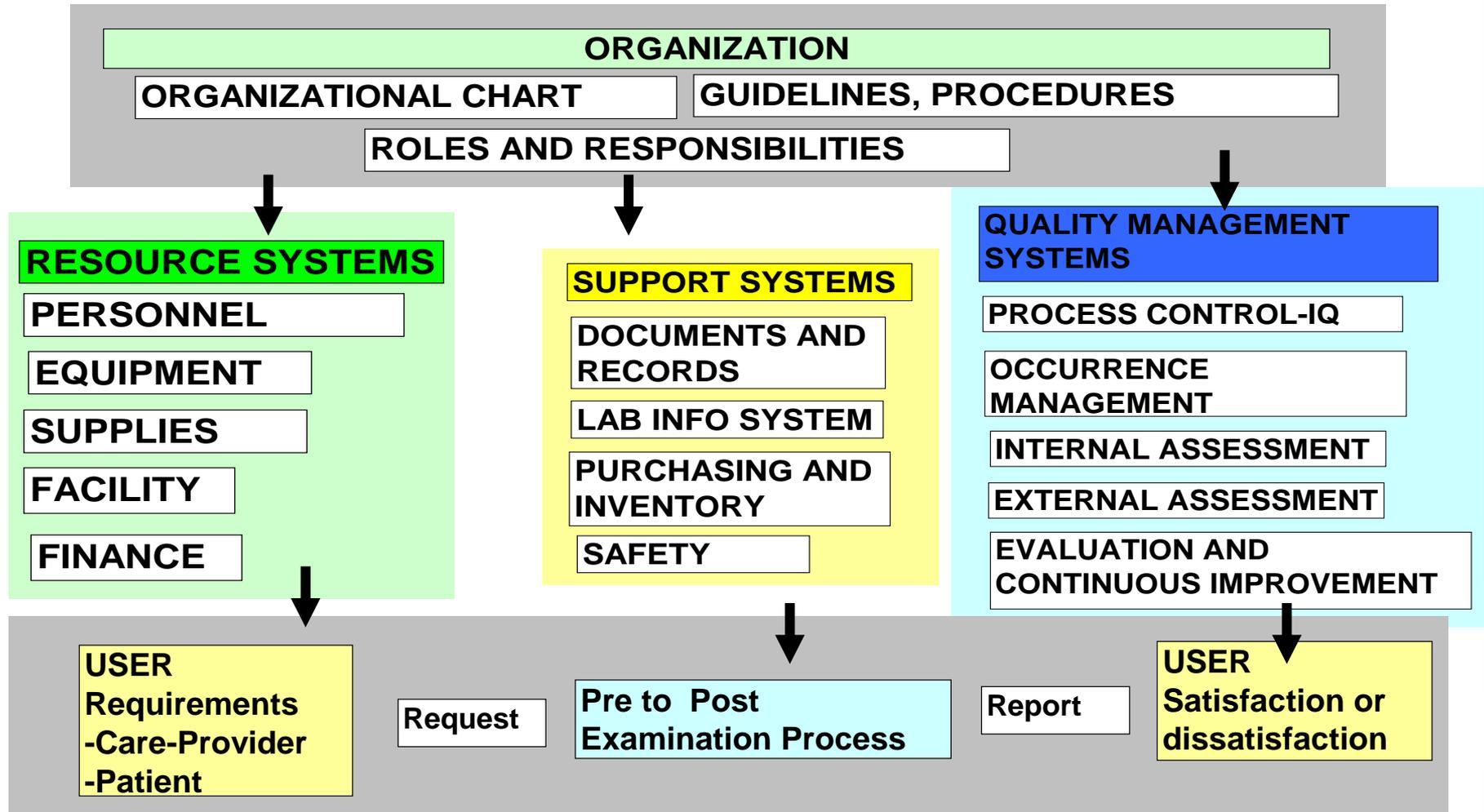
ISO 9001:2000 System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives





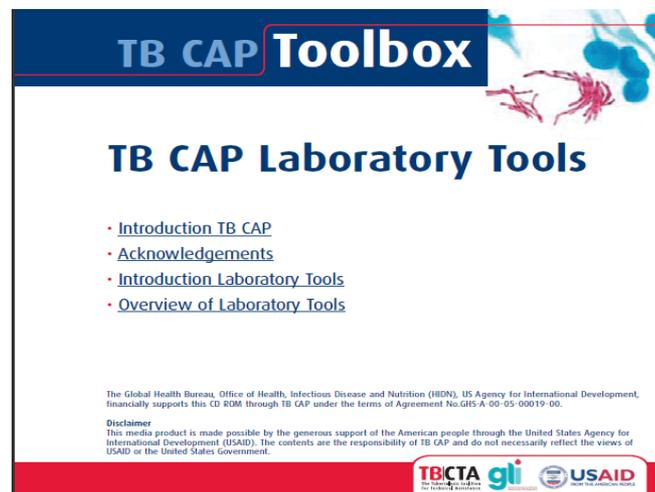
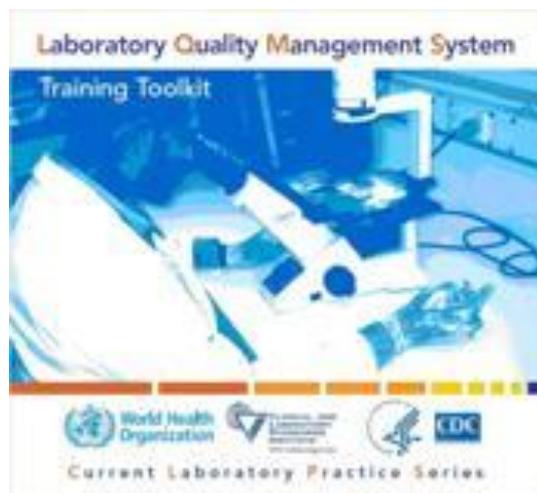
Essential factors in quality management systems according to ISO15189





Many documents and tools available

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



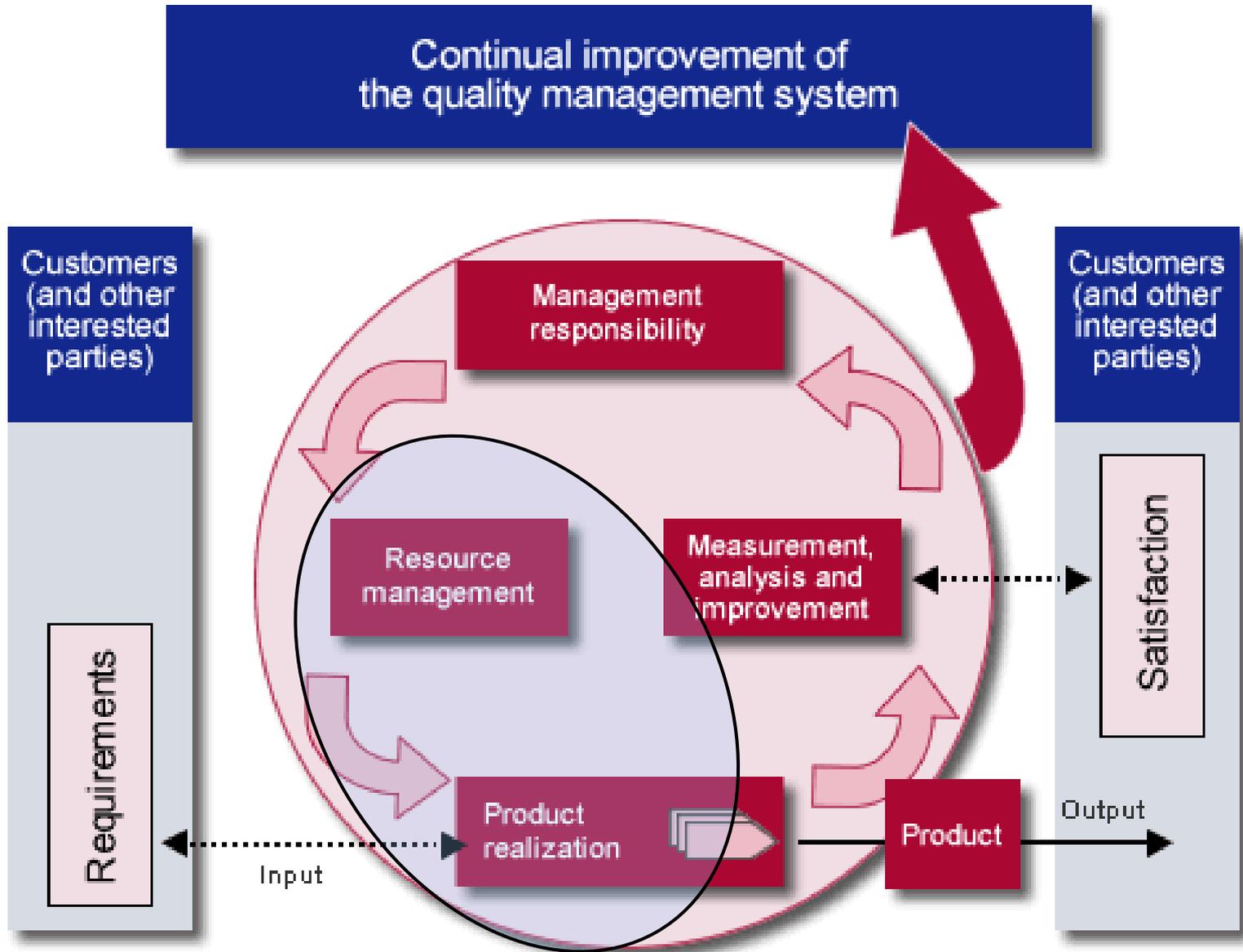


Many documents and tools available

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

BUT:

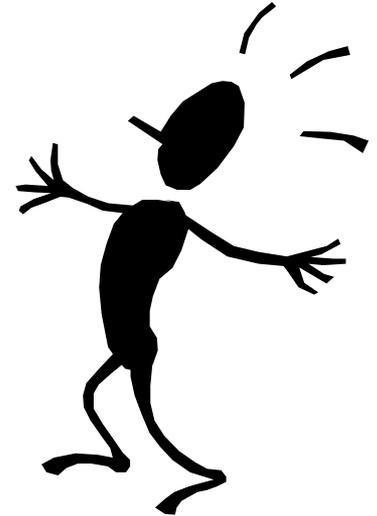
- Operational translation of guidelines: where to start and how to proceed?
- Little attention to management aspects.
- Shortage of harmonization/standardization.
- Not always addressing TB specific needs.





The Eight (8) Quality Management Principles

1. A Customer Focused Organization
- 2. Leadership**
3. Involvement of People
4. Process Approach
- 5. System Approach to Management**
6. Continual Improvement
- 7. Factual Approach to Decision-Making**
8. Mutually Beneficial Supplier Relationships



ISO 9001-2000



What is still needed for accreditation of national reference laboratories?

- Coordination / harmonization with existing initiatives
- Defining the quality system elements/framework on basis of existing QS (ISO/CLSI/AFRO/CPA/Other)
- Specific TB guidelines for all elements
 - Translating standards into technical requirements for each category of TB diagnostic tests/service (ZN/FM, culture, DST, new molecular tests ...): most are available.
 - Translating standards into requirements for pre- and post-analytical processes: not all available; need adaptation to local situation.
 - Translating standards into requirements into TB-specific performance indicators and measures for continuous improvement.



What is still needed for accreditation of national reference laboratories? (2)

- Implementation guidelines with templates, formats, etc.
- Complement existing trainings especially with management and leadership training programmes.

In conclusion: making the toolbox complete!

- Define national notifying body endorsed by the MOH or use existing accreditation bodies (SANAS, CAP, etc.).
- Develop and offer a teaching module on laboratory quality for adaptation and implementation in country vocational curricula.

Quality Standards

- The available quality standards (like ISO 15189 or AFRO) are very resource/time demanding and not suited/needed for every level of laboratories in developing countries.



- Developing countries (through WHO/GLI?) should therefore develop minimal quality standards for their health laboratories adapted to their situation.



Certification needed for laboratories in TB laboratory networks: ensuring quality

Requirements specifically targeting the operation of microscopy labs

Pre-analytical

Analytical

Post-analytical

Policy, organization and management

- Establish requirements for Organization and Management, and for each path of workflow described in detail in a quality manual;
- Format provided, details filled in at local level;
- District lab responsible for providing certification for the three main steps of the workflow (assessments by peer-review/quality circles).
- New test introductions only beneficial if basic Q requirements are met.



Franchising as a means of contracting diagnostic services

- Quality diagnostic services can be defined by objectively verifiable outputs and outcomes, but...
 - ...quality systems should be adapted to reality of DC and take into account the role of private labs
- Franchising could offer:
 - Implementation of quality systems
 - Central purchase of (cheap) Dx tests and supplies (and thus prevent entrance of bad quality tests)
 - Central maintenance services
 - Connecting to insurance schemes (opening up new markets for the branded labs)



THANK YOU for your attention