



Royal Tropical Institute

TB laboratory performance indicators to measure the effect of ISO 15189 QMS implementation

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Does a laboratory really improve?

Establishing a QMS costs a lot of resources in terms of **time, efforts and money**

(quality costs money, but no quality costs a fortune!)

The question is:

- **What are the effects of establishment of a QMS on performance of laboratories?**





Why measure the effect of QMS implementation?

- Effectiveness of the GLI tool in improving quality in laboratories (“the performance”)
- Advocacy purposes
 - Internally (staff motivation, physicians, etc.)
 - Externally (government, sponsors, etc.)
- Research purposes



Methodology

- Two days workshop January 2012 at KIT in Amsterdam, The Netherlands (funded by TB Care)
- The workshop was attended by 12 participants representing SRL (Belgium), NTRL (Benin), CLSI, WHO, GLI, ACILT, CDC, CAREC, KNCV & KIT



Definition of laboratory performance

Laboratory performance is defined by what stakeholders of the laboratory perceive as important.

- Identification of all types of stakeholders of a laboratory.
- Determine for each stakeholder the most important element in laboratory performance.

Examples:

- For **sponsor**: **cost-efficiency** is most important aspect in laboratory performance.
- For **patient**: **timeliness** and **correctness of results** is most important aspect in laboratory performance.
- For **staff**: **pleasant** and **safe working environment** may be most important aspect in laboratory performance.



Stakeholders identified

Internal: Technical staff
 Management
 Support staff

External: Health care workers
 Patients
 Institutes/owners
 Other laboratories
 Authorities
 Accreditation bodies
 Payers & sponsors
 Research & education
 Industry as supplier

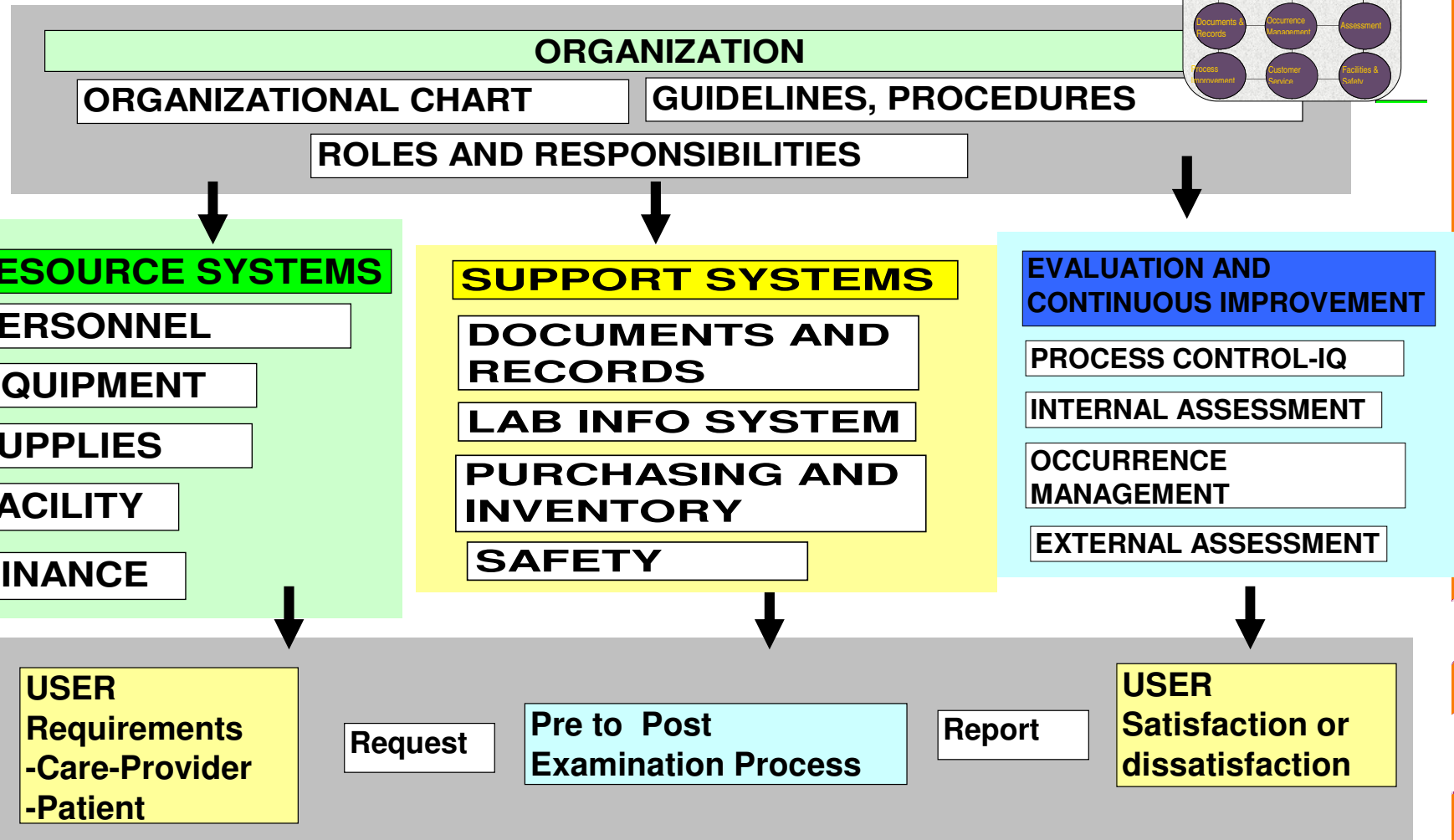
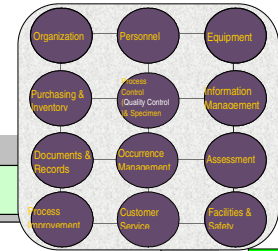


Topics

- Extent of implementing ISO 15189
- Access to adequate and safe facilities
- Ability to comply to regulations
- The analytical performance of the laboratory
- Staff competency
- Error reporting
- Work efficiency
- Guidance and education provided by the laboratory
- Timely and accurate results and reports
- Interruption of service
- Customer satisfaction



Output and outcome indicators





Topic	Indicator
Extent of implementing ISO 15189	<ul style="list-style-type: none">• Number of GLI tool activities completed versus the number of activities that still need to be completed.



Topic	Indicator
Access to adequate and safe facilities Ability to comply to regulations	<ul style="list-style-type: none">• The number of deficiencies found during the WHO Biosafety audit (based on checklist in the WHO Laboratory Biosafety Manual, 3rd edition).
The analytical performance of the laboratory Staff competency Error reporting	<ul style="list-style-type: none">• Percentage of correct results in proficiency testing (PT)/external quality assessment (EQA), or, if these are not available: inter laboratory testing rounds.• Percentage of tests covered by PT/EQA/inter laboratory testing.• Percentage of nonconformities in a specific process of the laboratory that have been solved/corrected.



Topic	Indicator
Work efficiency	<ul style="list-style-type: none">• Cultures contaminated vs. total no. of culture samples tested.• Stratified nr. of tests done per patient.• Nr. of tests done per technical FTEs.• Nr. of tests done per staff member (of total staff).
Guidance and education provided by the laboratory	<ul style="list-style-type: none">• Percentage of rejected sputum samples.• Percentage of requests for new samples.• The percentage of incompletely filled-out request forms.



Topic	Indicator
Timely and accurate results and reports Interruption of service	<ul style="list-style-type: none">• Accurateness: laboratory demonstrates constant or increased performance in PT (already included in subject 3).• Timeliness: relative proportion of results reported within established turnaround time (TAT).• Percentage of external reports submitted on, or before the deadline.
Customer satisfaction	<ul style="list-style-type: none">• Satisfaction measured with questionnaire (or, when budget is available, by focus group discussions and interviews in certain customer categories).



Next steps

- Validate indicators for feasibility of measurement
- Adapt indicators if necessary
- Integrate with the GLI tool for use by laboratories themselves
- Measure the effect of introducing a QMS on laboratory performance
- Advocacy

Validation will start Friday in Benin