



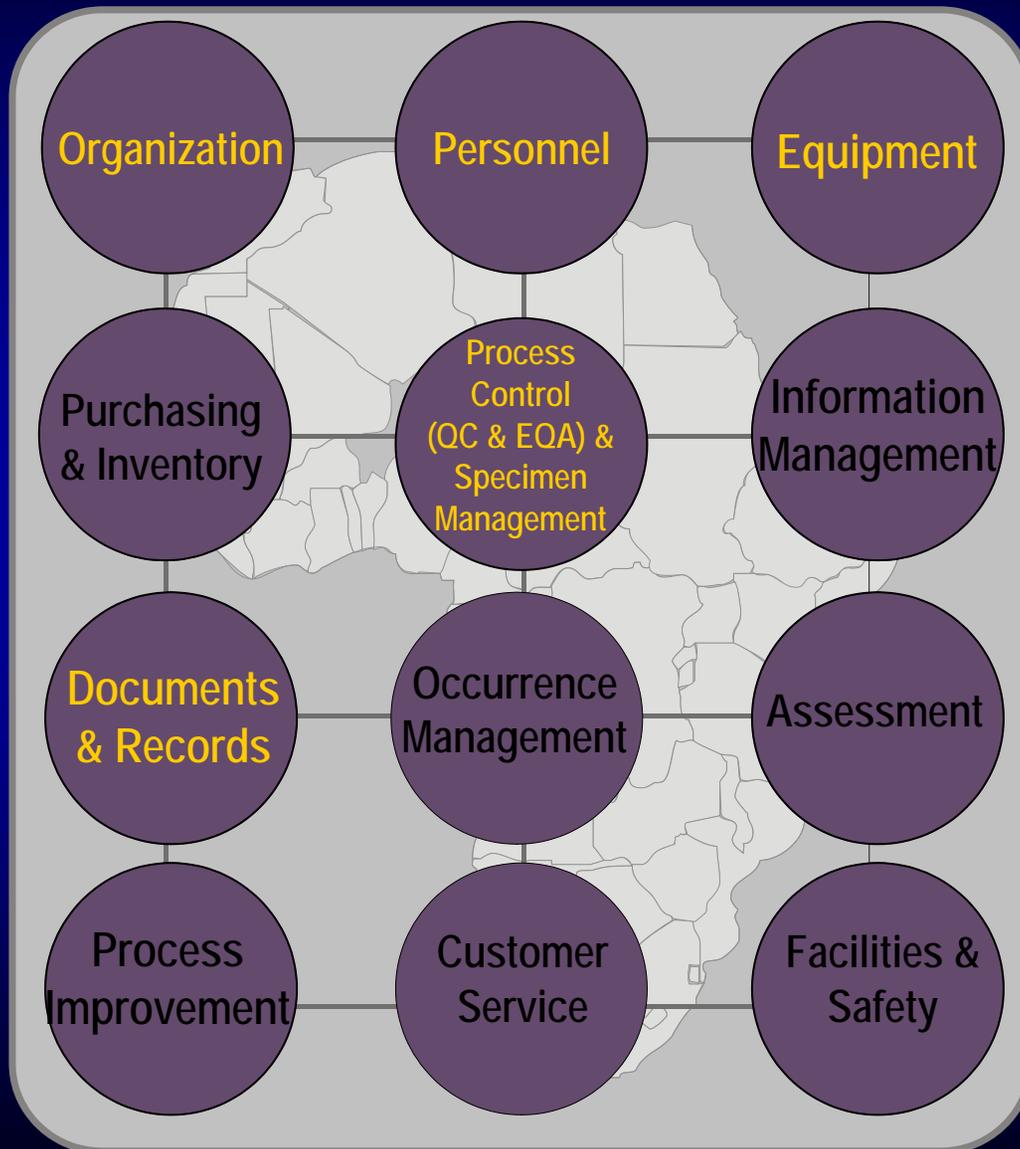
DEPARTMENT OF HEALTH AND HUMAN SERVICES

External Quality Assessment (EQA)



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The Quality System



The Problem

- A newly appointed supervisor of the laboratory has begun reviewing past EQA performance reports. The reports indicated a trend in poor performance on interpreting gram stains.
 - How should the laboratory investigate this problem?
 - What are the implications for patient test results performed and reported during the same time period?
 - What corrective actions might be taken?

EQA

- Definitions
- Responsibilities
- EQA benefits
- EQA methods
- Documentation
- ZINQAP's experience

External Quality Assessment

A system of objectively checking the laboratory's results by means of an external agency

EQA Methods

- Proficiency Testing
- Split Sample Comparison
- Blinded Rechecking
- On-site Evaluation

Proficiency Testing

“A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory’s results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others.” (NCCLS)

Split Sample Comparison

Aliquots of specimens distributed to another laboratory for testing using the same method

Blinded Rechecking

Random statistical sampling of specimens or slides for rechecking by a reference laboratory

- Rechecking is blinded

Onsite Evaluation and Review

- Periodic visits to the laboratory to assess laboratory practices

- **Why?**

Obtain a realistic picture of laboratory practices

Provide assistance with problem areas

Laboratory Responsibilities

- Should participate in organized interlaboratory comparisons, e.g., EQA schemes
- Participation in EQA should encompass the extent and complexity of examination procedures used by the laboratory

ISO Standard – prEN ISO/DIS 15189.2

Management Responsibilities

- Develop policy
- Assign responsibility
- Monitor the results of external quality assessments
- Participate in the implementation of corrective actions

ISO Standard – prEN ISO/DIS 15189.2

EQA Benefits

- Allows comparison of performance and results
- Serves as an early warning-system for problems
 - Identifies systematic kit problems
- Provides objective evidence of laboratory quality
- Serves as an indicator of where to direct improvement efforts
- Identifies training needs

Proficiency Testing Process

- Central organization sends out challenge specimens for testing
- Laboratories analyze specimens, return results to central organization
- Results evaluated, laboratories sent scores, performance report
- Laboratories take appropriate corrective actions and document

PT Analysis / Reporting Protocols

- Handle in the same manner as patient/client samples
 - Follow your testing strategy
 - Use same method
 - Analysis by the tech who routinely performs testing
 - Conduct testing within required timeframe
- Communicate problems to supervisors, PT organizers
- Inter-laboratory discussion of PT specimens or results are not permitted

Blind Rechecking

- Most commonly used for smears, e.g., TB
- Must consider:
 - Sample size
 - Proper specimen handling
 - Procedures to ensure blinding
 - Procedures to resolve discrepancies
- *Details outlined in: EQA for AFB Microscopy*

Split Sample Comparison

- Evaluates imprecision and testing errors
- Must consider:
 - Procedures for tracking results
 - Procedures for maintaining sample integrity
 - Procedures for tracking sample data
 - Procedures to resolve discrepancies

On-Site Evaluation

- Conducted by:
 - PT organization
 - Laboratory leaders, e.g., provincial, district supervisors
- Consider:
 - Frequency, e.g., monthly, quarterly
 - Use of checklists
 - Follow-up to visits
 - Monitoring corrective actions
 - Training

On-site Evaluation Results - Uganda

	BEFORE	AFTER
No sand bucket	96%	27%
No decontamination of sputum cups	60	23
No disinfectant	31	4
No biohazard waste bin (covered)	48	8
No lab coats	48	46
Technicians do not wash hands	17	4
Shortage of lab reagents	75	27
Improper sputum collection	60	31
Improper filling of lab register	29	4
Improper labeling slides/containers	32	13

Aziz, M. and G. Bretzel, Int J Tuberc Lung Dis
2002:6(4):340-349

Evaluation of EQA Reports

Where are the problems?

- Pre-analytic
 - Specimen compromised during preparation, transport, or after receipt by improper storage or handling
- Analytic
 - Reagents, instruments, methods, calibration, QC - Analytical error
 - Calculation
 - Competency of Staff*
- Post-analytic
 - Report format
 - Interpretation
- Data
 - Clerical/transcription error

Investigating Unacceptable EQA Performance

- Clerical error
- Methodological problem
- Technical problem
- Problem with PT materials
- Problem with evaluation of results
- No explanation

EQA Documentation

- Establish written procedures for:
 - Handling of samples
 - Analysis of sample
 - Recording of results on report forms
 - Verification of clerical accuracy
 - Use of statistical tools
 - Handling corrective actions