THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagnostics for a TB Free Africa

Training on Proficiency Testing Scheme (GeneXpert DTS)

Module 17: ISO 17043:2010 Requirements

Venue

Facilitator's name

Date

Module outline

- Objectives of EQA schemes for laboratories
- Elements of an accreditation process
- Key elements from the ISO 17043 standard
- The Ugandan context of implementation

Objectives of EQA schemes for laboratories

- Evaluation of Lab testing competence
- Assessment of individual testing performance of the lab staff
- Evaluation of reliability of a test procedure
- Production of relevant information to participating labs when necessary

Objectives of EQA schemes for laboratories

- Providing the basis for the comparability of results during epidemiological surveillance and disease control
- Collecting information on laboratory measurements (intra- and inter-laboratory)
- Collecting information for the purpose of licensing or accreditation of laboratories

Elements of an Accreditation Process

- Accreditation Body
- Standards
- Assessors
- User laboratory

Approved

Knowledgeable

Certification and Accreditation Bodies

Standards-based

Competent staff

Objective

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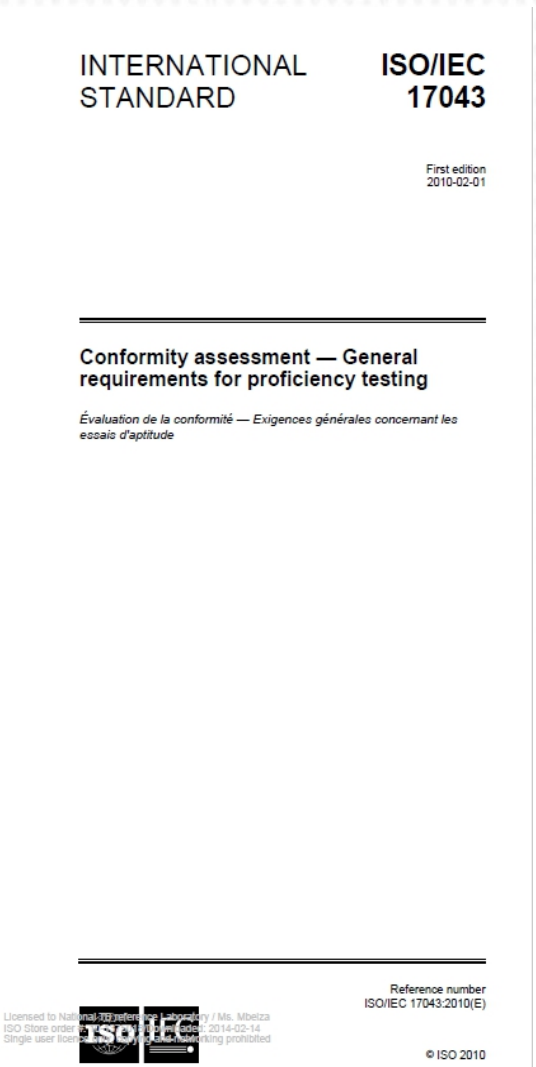
Group activity

- What is the difference between accreditation and certification? (5 minutes)

What is ISO 17043:2010

- ISO/IEC 17043 was prepared by the ISO Committee on conformity assessment (CASCO).

- This first edition of ISO/IEC 17043 cancels and replaces ISO/IEC Guide 43-1:1997 and ISO/IEC Guide 43-2:1997
- **Scope:**
  - specifies general requirements for the competence of providers of proficiency testing schemes and
  - for the development and operation of proficiency testing schemes.



INTERNATIONAL STANDARD **ISO/IEC 17043**

First edition
2010-02-01

Conformity assessment — General requirements for proficiency testing

Évaluation de la conformité — Exigences générales concernant les essais d'aptitude

Reference number
ISO/IEC 17043:2010(E)

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ISO 17043 accreditation requirements

- **Technical requirements**
  - Personnel, accommodation and environment
  - Design of PT schemes
  - Choice of method or procedure
  - Operation of PT schemes
  - Data analysis and evaluation
  - Reports
  - Communication with participants
  - confidentiality

ISO 17043 accreditation requirements

- **Management requirements**
  - Organization
  - Management system
  - Document control
  - Review of requests, tenders and contracts
  - Sub contracting services
  - Purchasing services and supplies
  - Complaints and appeals
  - Corrective actions
  - Preventive actions
  - Control of records
  - Internal audits
  - Management reviews

Getting Started: Issues to Consider

- Capacity of NRL
  - HR
  - Training and expertise
- Type and Composition of PT panels
- Internal QC procedures to ensure
  - Homogeneity
  - Stability
- System for sending PT panels
- Frequency of testing
- Forms to record and report results
- Time allowed for technicians to complete PT
- Availability of microscopes
- Performance criteria
- Feedback and corrective action if needed
- Mechanism to resolve discrepant results

Getting Started: Issues to Consider

Dispatch of PT panels

- Delivery system based on services, regulations, resources available:
  - mail/post
  - courier
  - supervisory visit

- Turnaround time; consideration of
  - total no. of days from dispatch of panels to closing dates,
  - preparation of individual and summary reports,
  - presentations to PT team,
  - dispatch of the individual and summary reports

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Getting Started: Issues to Consider

- Safe package to prevent breakage/damage of PT materials:
  - strong plastic slide holders
- A standardized PT reporting form / an accompanying letter to provide instructions
- No incentives or punitive actions as a result of the PT exercise
- Time allowed to complete the PT exercise

Getting Started: Issues to Consider

Analysis of PT Results

- A scoring system is to be developed prior to test
- Distinguish major and minor errors
- Determine successful score
- Determine plan of action for poor performances
- Database for analysis

Getting Started: Issues to Consider

Feedback to Laboratories on PT results

- Timely and confidential
- Individual and aggregate test results
- Criteria for acceptable performance
- Reports to TB program coordinator should provide appropriate background information and recommendations and not simply scores
- Poor performance often requires a visit to laboratory

NTRL/SRL UGANDA JOURNEY

- Policy guidelines for C&DST developed in 2008
- Training at ITM Antwerp (C&DST PT) in 2010
- C&DST PT initiated in 2010 with 4 labs
- Microscopy PT scheme initiated in 2013
- GeneXpert PT scheme initiated in 2015
- Rigorous SOP development: 2016
- Application for ISO 17043:2010 in 2017
- ISO 17043:2010 Assessment in June 2018
- Training at CDC-Atlanta in 2017
- Procurement of other major equipment

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- HR at inception of PTS vs Now
- SM PT labs at inception of PTS vs Now
- Xpert sites at inception of PTS vs Now
- DST sites at inception of PTS vs Now
- LPA sites at inception of PTS vs Now

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Assessment

1. What are the Issues to consider when establishing an EQA scheme?

2. What are the objectives of EQA schemes to the laboratory network?

Summary

- Proper consideration should be done to see the issues to consider when establishing an EQA scheme
- EQA schemes play a key role in establishing to the laboratory network?

References

- External Quality for AFB Smear microscopy by IUATLD
- ISO 13528:2005, *Statistical methods for use in proficiency testing by interlaboratory comparisons*
- ISO 15189, *Medical laboratories — Particular requirements for quality and competence*
- ISO Guide 34, *General requirements for the competence of reference material producers*
- ISO Guide 35, *Reference materials — General and statistical principles for certification*
- *ISO/IEC 17043 First edition 2010-02-01*
- Guide 34, ISO Guide 35 and ISO 13528 (homogeneity and stability)
- ISO/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement* (GUM:1995)
- ISO/IEC 17011:2004, *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*
- ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

Acknowledgments

KOFIH
Korea Foundation for International Healthcare
한국국제보건의료재단