WORKING TOWARDS ACCREDITATION

The Global Health Network

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OBJECTIVES

• Licensure? Certification? Accreditation?

• Accreditation Process

• SLIPTA/SLMTA

• Benefits of accreditation
• The Minister of Health has asked you as the chief laboratory specialist how to improve recognition/acceptance of laboratory results throughout the country and internationally. How would you go about doing that?

• What is a laboratory licensing?

• What is certification?

• What do we mean by accreditation?
LABORATORY QUALITY MANAGEMENT SYSTEM

- Assessment or evaluation
- Quality management system can
  - Accurate
  - Reproduceable results
- Qualified organisation
- Compliance with international norms and standards
**LICENSE**

- **Licensure** — the granting of ability to practise, usually provided by a local governmental agency.

- License to practice

- Example: Health Professions Council South Africa.
• Certification — the procedure by which an independent body gives written assurance that a product, process or service conforms to specific requirements.
ACCREDITATION

• **Accreditation** — the procedure by which an authoritative body gives formal recognition that a lab or person is **competent** to carry out specific tasks.

• Accreditation provides a higher level of assurance to those using the laboratory that its testing is reliable and accurate because it includes an evaluation of competency.
ELEMENTS OF ACCREDITATION

– Accreditation body

– Standards

– Assessors

– Laboratory
world's largest developer and publisher of international standards

standards are applicable to many kinds of organizations including clinical and public health laboratories
WHO guidelines **Stepwise Laboratory Improvement Process Towards Accreditation in African region.**

- Provides framework to **strengthen laboratory quality**
SLIPTA PHASE I

Phase 1: Create commitment (1)

Phase 2: Ensure adequate and competent personnel (2)

Phase 3: Make procedures for all tests (3), Make procedures for all equipment (4), Start organizing an inventory system (5), Start organizing the biosafety (6)

Phase 4:

THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge
Organisation Activities Phase I

- Quality Management team
- Make action plan with SMART
- Organise staff meetings (Weekly)
- Appoint Biosafety officer
- Appointment Equipment officer
- Stock management officer
- Make organogram
PHASE II PERSONNEL ACTIVITIES

- Competency Assessments
- Induction programme
- Performance appraisals
- Staff files
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SLIPTA PHASE III

Phase 1:
- Optimize personnel management (21)
- Optimize facilities and safety (23)
- Optimize support systems (24)
- Lay the foundation for the management cycle (28)
- Validate methods (34)

Phase 2:
- Optimize customer service (22)
- Optimize purchasing and inventory (25)
- Optimize document control (26)
- Optimize information management (27)
- Develop the quality manual (32)
- Establish the audit system (33)

Phase 3:
- Set up the management cycle (29)
- Monitor action plan implementation (30)
- Develop the quality year plan for next year (31)

Phase 4:
PHASE III PROCESS MANAGEMENT
ACTIVITIES

- Determine TAT
- Monitor adherence to TAT
- Validation SOP
- Validate all processes
• ISO 15189 and 17025 emphasise internal audits
  – Must have audit programme
  – Auditors independent of activity
  – Document audits
  – Retain audit reports
  – Report audits to management
  – Promptly address findings

• Audit training for QM/auditors
  • 12 months audit programme
  • Conduct audits
  • Formulate action plan
  • Write an internal audit SOP
SLIPTA PHASE IV

**Phase 1**
- Optimize human resource management (35)
- Optimize continuity of work (36)
- Optimize equipment management (37)
- Optimize management review process (38)

**Phase 2**

**Phase 3**
- Monitor the total testing process (40)
- Develop nonconformity management system (39)

**Phase 4**
- Prepare for accreditation (41)
PHASE IV PERSONNEL ACTIVITIES

- Staff complement
- Procedure for new staff
- Education needs
- Continuous professional development
- Failure mode effect analysis (FMEA)
ACCREDITATION PROCESS

- Formal recognition that a testing or calibration laboratory is competent to carry out specific tests or calibrations

**Competent”**

**Specific tests or calibrations**

- Accreditation is having a Management System and demonstrating competency

- Laboratories are accredited for specific tests or calibrations and particular products and test or calibration specifications
COMMON STANDARDS

• CERTIFICATION
  – ISO 9001:2015
  – ISO 14000

• ACCREDITATION
  – ISO 17025
  – ISO 15189:2012

• REGULATIONS
  – USA CLIA
  – French GBEA
  – UN Transport of Dangerous Goods
ISO/IEC 17025

- Enables laboratories to demonstrate they:
  - Operate competently
  - Generate valid results
  - Testing and calibration
  - Does not cover safety operations
ISO 15189:2012

- Specify requirements for:
  - Medical Laboratories
  - Quality Management processes
  - Technical processes
  - Administrative systems
ACCREDITATION STEPS

• Application

• On-site assessment

• Deficiencies

• Proficiency testing

• Accreditation decisions

• Annual review

• Re-assessment/Renewal of accreditation
BENEFITS OF ACCREDITATION

1. National and international recognition
2. Reduced costs of re-testing
3. Better control over laboratory operations
4. Increased confidence in testing/calibrations
5. Increased profits
6. Validity of test methods and provision of reliable data
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