THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagonostics for a TB-Free Africa

Laboratory Quality Management System

Module 14: Accreditation

Venue:

Presenter:

Date:

Introduction Laboratory Accreditation

Laboratory Assessment – WHY?

- recognition as delivering accurate and reproducible results
- recognition of compliance with the quality standards and norms used fo the assessment

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Learning Objectives

At the end of this module, participants will be able to:

- Compare and contrast accreditation, certification and licensure;
- Describe the process involved in the development of standards;
- Discuss the need for laboratory norms and standards.

Module Outline

- Laboratory Accreditation
- Responsibilities
- Definitions
- Self-developed standards
- Standard bodies
- National Standards and Technical Guidelines
- Specific and National Norms, Standards and Regulations
- Elements of Accreditation process
- Process of Accreditation
- Accreditation outcomes

Activity 14-1:

Preparations Needed for a Laboratory Accreditation

Purpose:

To provide an opportunity for participants to discuss preparations needed for a laboratory accreditation.

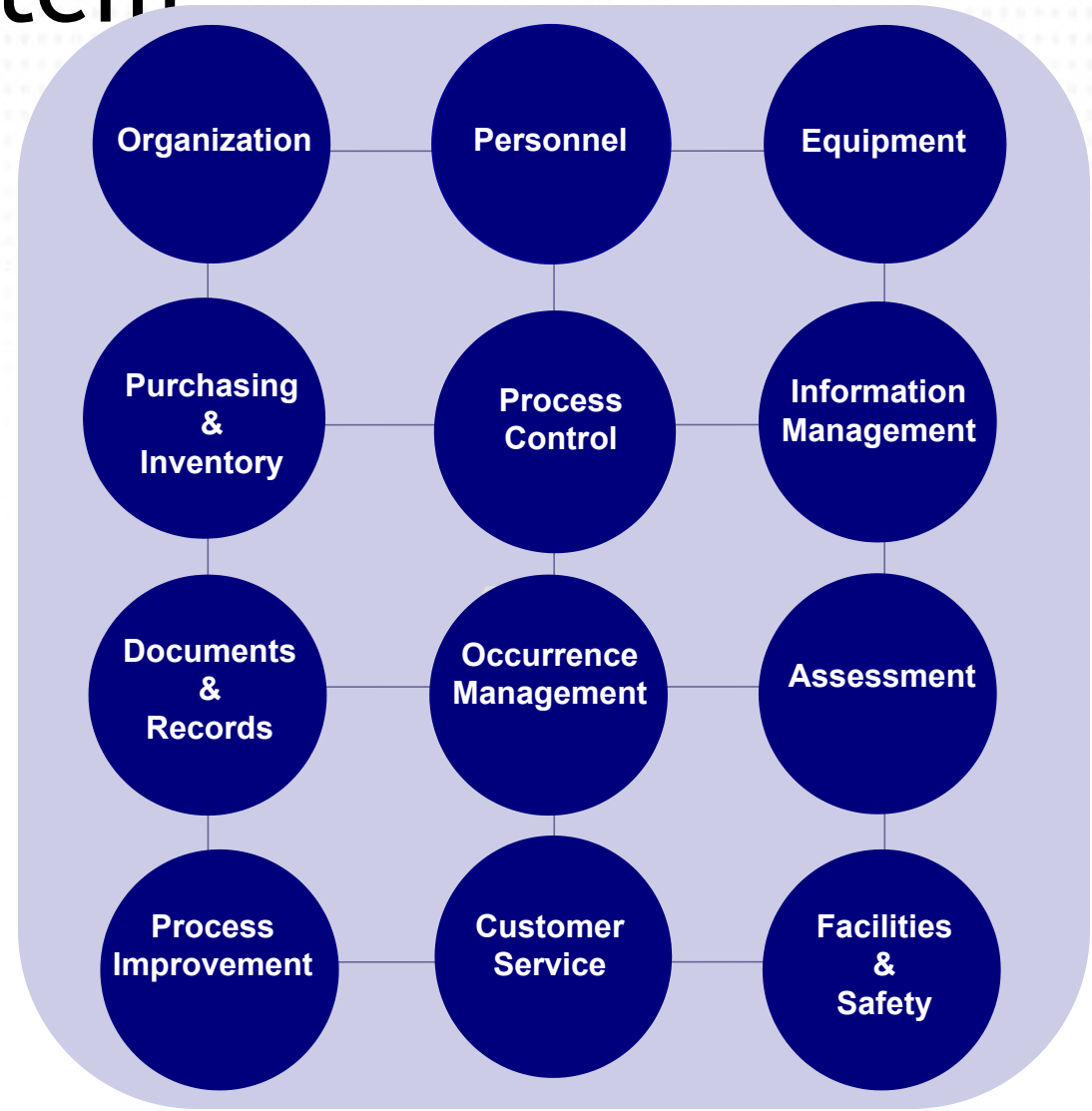
Suggested time: 10 minutes

Scenario

Your hospital administrator has asked you, the laboratory manager, to examine the possibility of having the laboratory accredited.

- **What does it mean to be accredited?**
- **Where can you get information?**
- **How would you get started?**

The Quality Management System



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1. Responsibilities

Laboratory Director

implements international or national standards

seeks information about appropriate norms and standards

seeks information about accreditation and certification processes

uses outcomes to provide better service

Responsibilities

Laboratorian

aware of requirements

contributes to meeting standards

aware of assessment processes

helps prepare for assessment

Quality Manager

explains the process for meeting standards to staff

organizes the laboratory in preparation for assessments

2. Definitions

- **Normative document—** provides rules, guidelines or characteristics for activities or their results
- **Standard document—**established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context
- **Regulation—**any standard that is mandated by a governmental agency or authoritative body

3. Self-developed Standards

Many agencies, organizations, or regions develop their own accreditation requirements rather than using internationally recognized standards.

- **Advantages:**
  - optimized for local use, recognized local strengths and weaknesses
  - can be developed in progressive steps
  - can lead to full international recognition
- **Weaknesses:**
  - may be narrow or biased
  - may not be recognized by other organizations

4. Standardization Bodies

International organizations include:

- ISO
- CLSI
- CEN
- WHO

International Organization for Standardization

- world's largest developer and publisher of international standards
- standards are applicable to many kinds of organizations including clinical and public health laboratories

Clinical and Laboratory Standards Institute

- global, nonprofit, standards-developing organization
- promotes the development and use of voluntary consensus standards and guidelines within the health care community
- documents are developed by experts working on subcommittees or working groups

European Committee for Standardization

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

- national standards bodies in the European Economic Community and associated countries
- general terms include openness and transparency, consensus, and integration

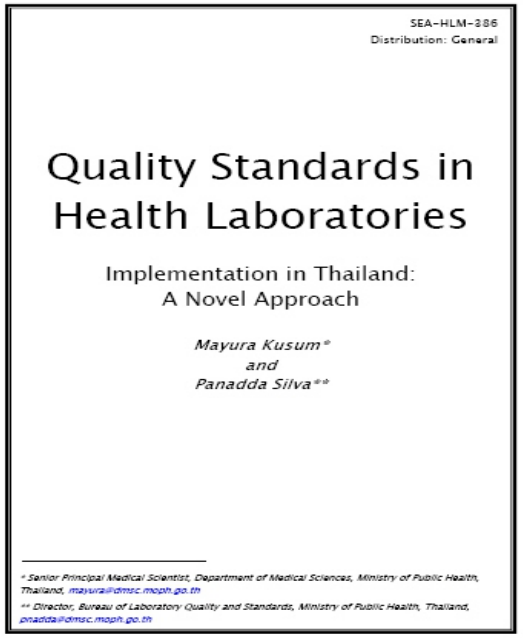
World Health Organization

- has developed several standards for disease-specific diagnostic laboratories, such as polio, tuberculosis, influenza, measles

5. National Standards and Technical Guidelines

- **Country-specific standards**
  - based on international standards
  - adapted to the culture and general condition of the country
- **Guidelines**
  - supplement ISO standards with technical guidance for use in laboratories
  - can address a specific kind of testing

6. Specific and National Norms, Standards, Regulations


SEA-HLM-386
Distribution: General

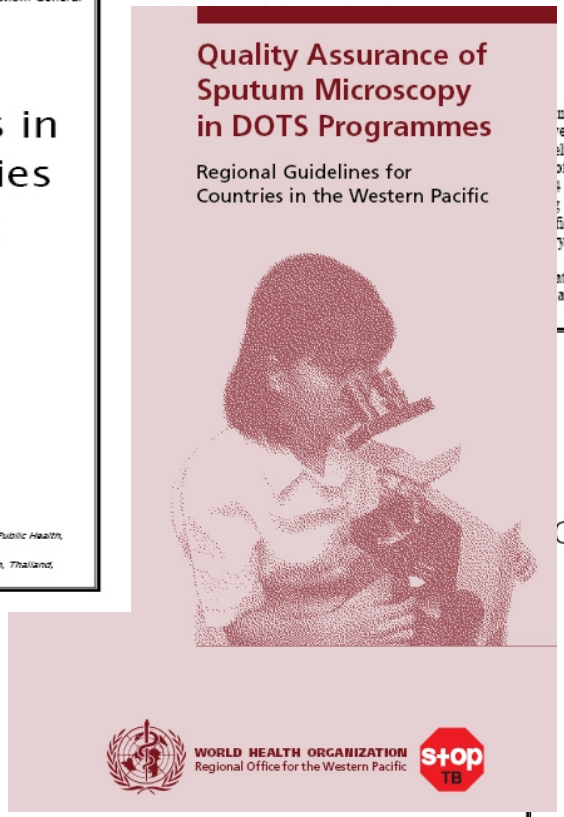
Quality Standards in Health Laboratories

Implementation in Thailand: A Novel Approach

Mayura Kusum and Panadda Silva***

* Senior Principal Medical Scientist, Department of Medical Sciences, Ministry of Public Health, Thailand, mayura@dmsc.moph.go.th

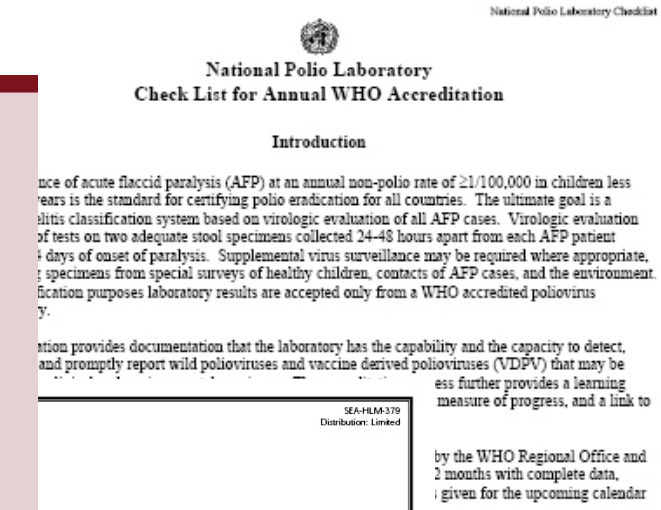
** Director, Bureau of Laboratory Quality and Standards, Ministry of Public Health, Thailand, pnadda@dmsc.moph.go.th


Quality Assurance of Sputum Microscopy in DOTS Programmes

Regional Guidelines for Countries in the Western Pacific

WORLD HEALTH ORGANIZATION
Regional Office for the Western Pacific

STOP TB


National Polio Laboratory Checklist

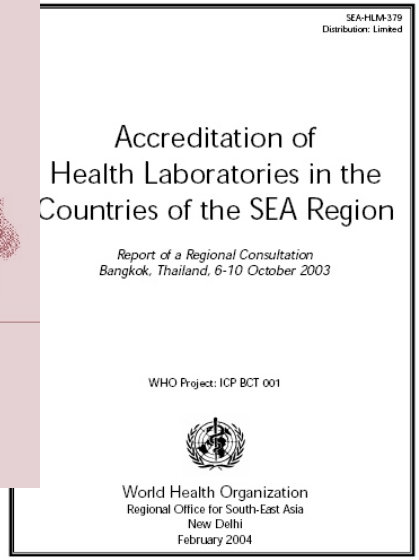
National Polio Laboratory
Check List for Annual WHO Accreditation

Introduction

nce of acute flaccid paralysis (AFP) at an annual non-polio rate of ≥1/100,000 in children less
ears is the standard for certifying polio eradication for all countries. The ultimate goal is a
elitis classification system based on virologic evaluation of all AFP cases. Virologic evaluation
of tests on two adequate stool specimens collected 24-48 hours apart from each AFP patient
days of onset of paralysis. Supplemental virus surveillance may be required where appropriate,
specimens from special surveys of healthy children, contacts of AFP cases, and the environment.
fication purposes laboratory results are accepted only from a WHO accredited poliovirus
y.

tion provides documentation that the laboratory has the capability and the capacity to detect,
and promptly report wild polioviruses and vaccine derived polioviruses (VDPV) that may be
ess further provides a learning
measure of progress, and a link to

by the WHO Regional Office and
2 months with complete data,
given for the upcoming calendar


SEA-HLM-379
Distribution: Limited

Accreditation of Health Laboratories in the Countries of the SEA Region

Report of a Regional Consultation
Bangkok, Thailand, 6-10 October 2003

WHO Project: ICP BCT 001

World Health Organization
Regional Office for South-East Asia
New Delhi
February 2004

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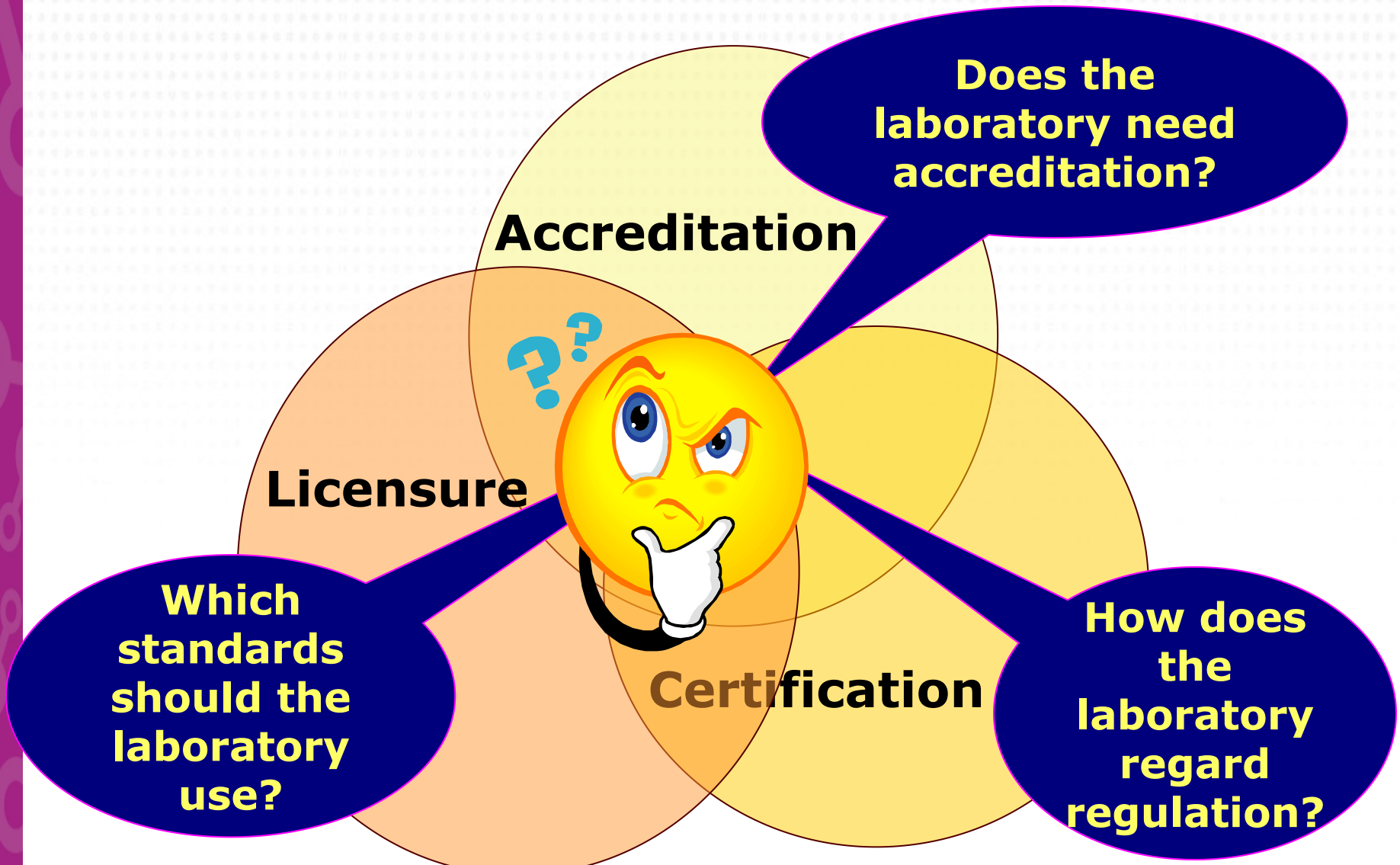
Definitions

- Certification (ISO/IEC 17000)
  - Procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements.

- Accreditation (ISO 15189)
  - Procedure by which an authoritative body gives formal recognition that a body or person is competent to care out specific tasks.

- Licensure (Wikipedia 2007)
  - Granting of ability to practice provided most often by a local governmental agency, usually based on demonstrated knowledge, training and skills.



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7. 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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Examples: commonly used standards

- **Certification standards**
  - ISO 9001:2000
  - ISO 14000
- **Accreditation standards**
  - ISO 17025
  - ISO 15189
  - WHO polio standards
- **Regulations**
  - US CLIA Regulations
  - French GBEA
  - UN Transport of Dangerous Goods Regulations

Scope of ISO 17025

to confirm or recognize competence

General requirements for competence

tests
calibrations
sampling

testing / calibration laboratories

quality administrative technical systems

Does not cover compliance with regulatory and safety requirements for laboratory operations

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Scope of ISO 15189

Based on ISO 17025:1999 & 9001:2000

Medical Laboratory
Particular requirements for quality & competence

to confirm or recognize competence

laboratory QM technical processes

quality administrative technical systems

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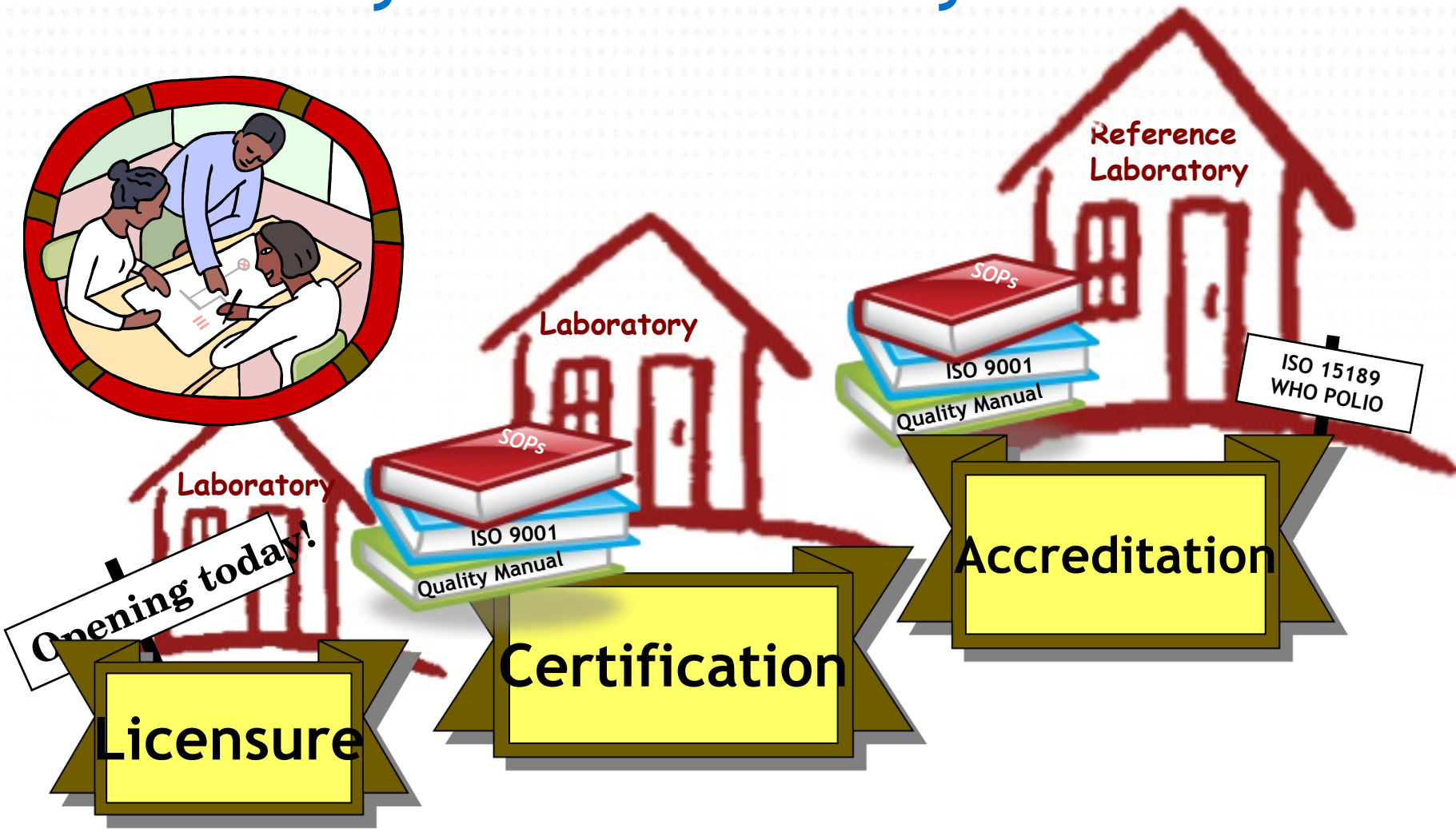
Where is your Laboratory?



Process for Accreditation

not one to be taken lightly
or without forethought

commitment — planning

Requirements

knowledge — resources

Accreditation Terms

Consensus

- represents general agreement in the absence of strong and compelling objection

Normative Statement

- required and essential part of the standard
- includes the word “shall”

Informative Statement

- information (often a ‘note’) that may be explanatory, or cautionary, or provide an example

Accreditation Terms

Compliance

- meets both the text and the spirit of a requirement

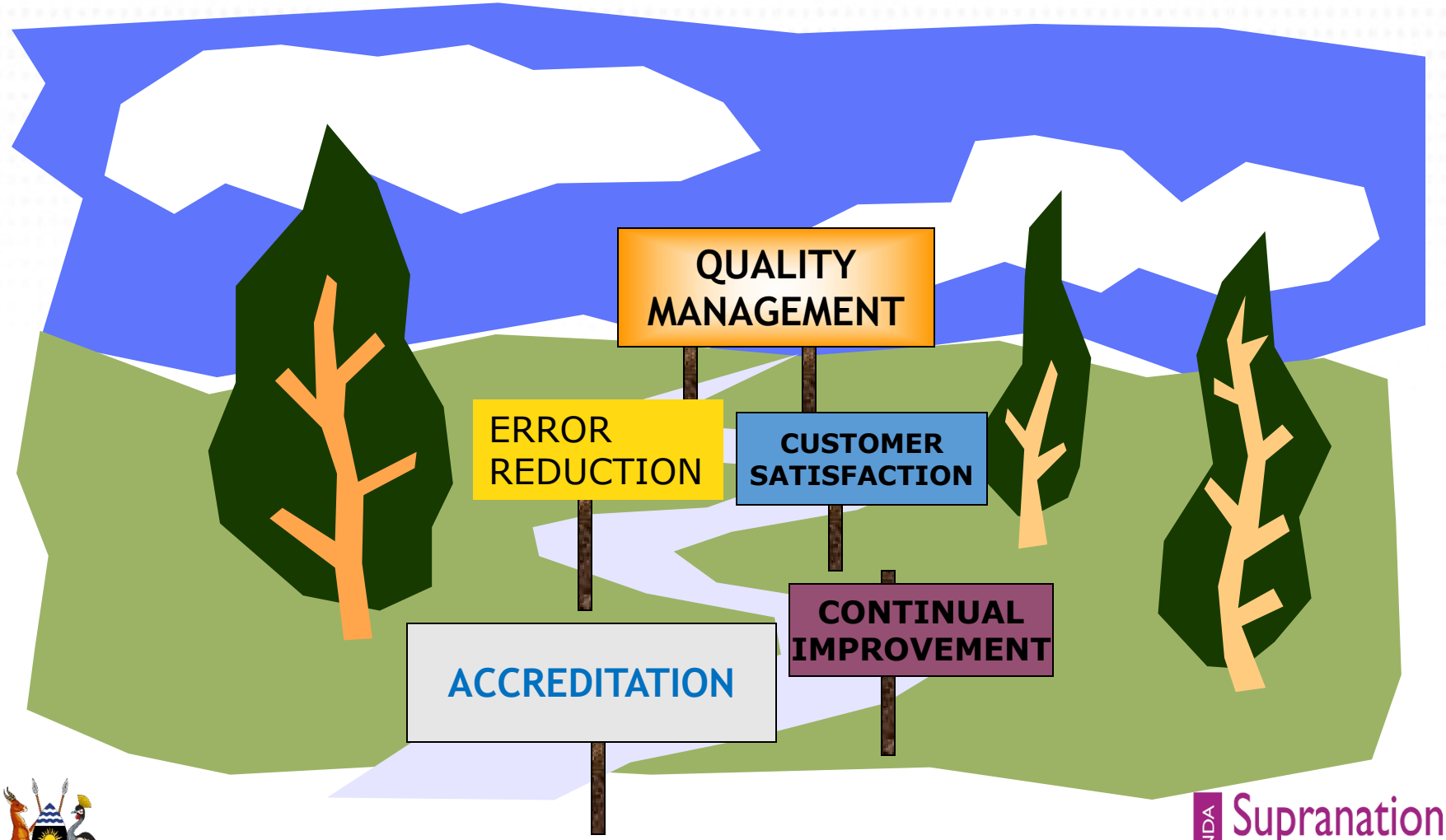
Non-conformity

- failure to fulfill the requirements of a specified process, structure or service
- may be categorized as major (complete) or minor (partial)

Verification of conformity

- confirmation by examination of evidence

Accreditation does not *guarantee* success, it is only **one step** along the quality journey



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9. Accreditation outcomes

- strength and integrity of the quality system are measured
- continual monitoring of the quality system
- recognition for efforts

Accredited laboratories tend to:

- perform better on proficiency testing
- are more likely to have a working quality management system

It is an **accomplishment** to receive accreditation

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It is an **ACHIEVEMENT** to maintain accreditation

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Test Questions

Microsoft Word
7 - 2003 Documer

Assessment

1. compare and contrast accreditation, certification and licensure;

2. What are the process involved in development of standards;

3. discuss the need for laboratory norms and standards.

Summary

- Standards provide guidelines that form the basis for quality practices. They are developed by organizations.
- Accreditation and certification are processes that recognize that a laboratory is meeting the designated standards.
- An active quality management program can assure the laboratory is in a constant state of “accreditation-readiness”.

Key Messages

- Accreditation is an important step in the continual improvement of the quality management system.

- It is an accomplishment to be accredited; it is an achievement to maintain accreditation.

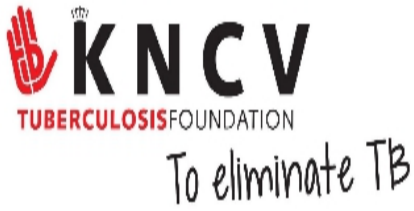
References

- **ISO 15189:2012 Medical Laboratories – Requirements for Quality and Competence**

« Clause 4.14»

- CLSI
- ASLM

Acknowledgement



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