

ASLM

AFRICAN SOCIETY FOR LABORATORY MEDICINE



Lab
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Laboratory Quality Management System

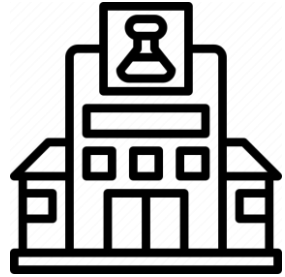
Key definitions

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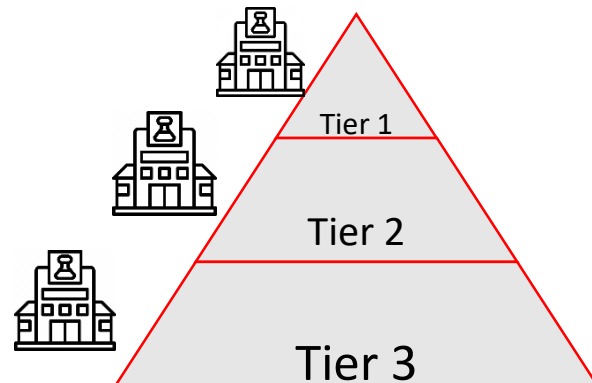
What is Quality Management System (QMS)?

- Laboratory quality in healthcare can be defined based on **accuracy, reliability and timeliness** of the test results generated.
- QMS was first implemented in various industries (Toyota, Ford,...) to improve their efficiency and effectiveness to produce quality products
- The concept of QMS was introduced into the medical laboratory in the 20th century to ensure the generation of quality test results
- **QMS can be defined as “coordinated activities to plan, direct and control an organization with regard to quality” (ISO, CLSI)**

- Laboratory QMS is implemented at facility level



- But it is the collective implementation of QMS within the national laboratory network that can durably impact clinical and public health outcomes



QMS in a laboratory: why?

Inaccurate test results cause

- unnecessary treatment
- treatment complications
- failure to provide the proper treatment
- delay in correct diagnosis
- additional and unnecessary diagnostic testing.

QMS Implementation

- Helps to maintain **consistency** throughout the laboratory (policy and procedures)
- Have a **well organized and coordinated** processes and procedures
- Clear definition and understanding of who is **responsible** for doing **what, when, how** and **why**
- Financial and other resources are used **effectively** and **efficiently**

QMS 'scope of work'

The entire Path of workflow



And the associated

- **People**
- **Processes**
- **Procedures**

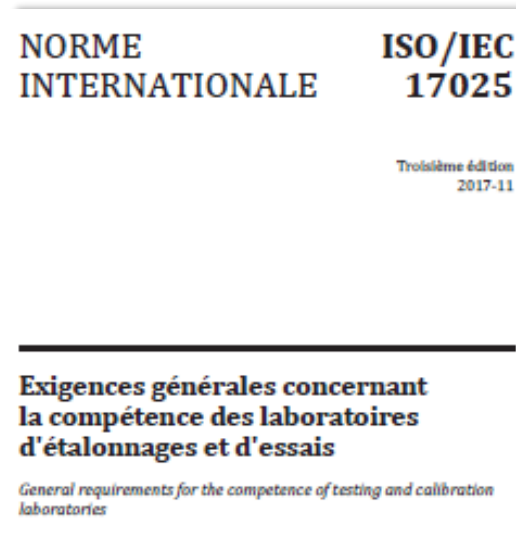
The 12 Quality System Essentials



Standards are the cornerstone of QMS

“Standard is essentially an internationally recognized way of doing something.” ISO

It is basically advising and guiding everyone to follow the same set of requirements no matter where they are based, and it ensures safer practice to produce more consistent end result.



The ISO 15189 standards is about being competent

The ultimate ISO 15189 recognition is an **accreditation**

ACCREDITATION
= CERTIFICATE OF COMPETENCE

i.e Procedure by which an **authoritative** body gives formal recognition that an organization **is competent to carry out specific tasks** (ISO 15189:2012)

International ISO LQMS Standard
Accrediting Body
For 2 - 5 tier
(according to AB)

This is different from a **certification !!!!**

CERTIFICATION
= CERTIFICATE OF COMPLIANCE

i.e Procedure by which an **independent** body provides a written assurance that a product, service or system in question **meets specific requirements**.
(www.iso.org/certification.html)

National LQMS/ISO Standard
Certification Body (e.g. 9001)
For 2 - 3 tier
(according to country)

Tools to implement QMS towards ISO15189 accreditation

HOW TO?

*Strengthening
Laboratory
Management
Towards
Accreditation*



Structured quality improvement programme design for LMIC

DO IT YOURSELF

*Laboratory Quality
Stepwise
Implementation*

LQSI

Online tool for the stepwise implementation of QMS with specifics for Clinic & Public health laboratories

HOW FAR?

*Stepwise Laboratory
Quality Improvement
Process Towards
Accreditation*



Benchmarks (checklist) the advancement of QMS in stepwise manner -> (temporary alternative to accreditation in LMIC)

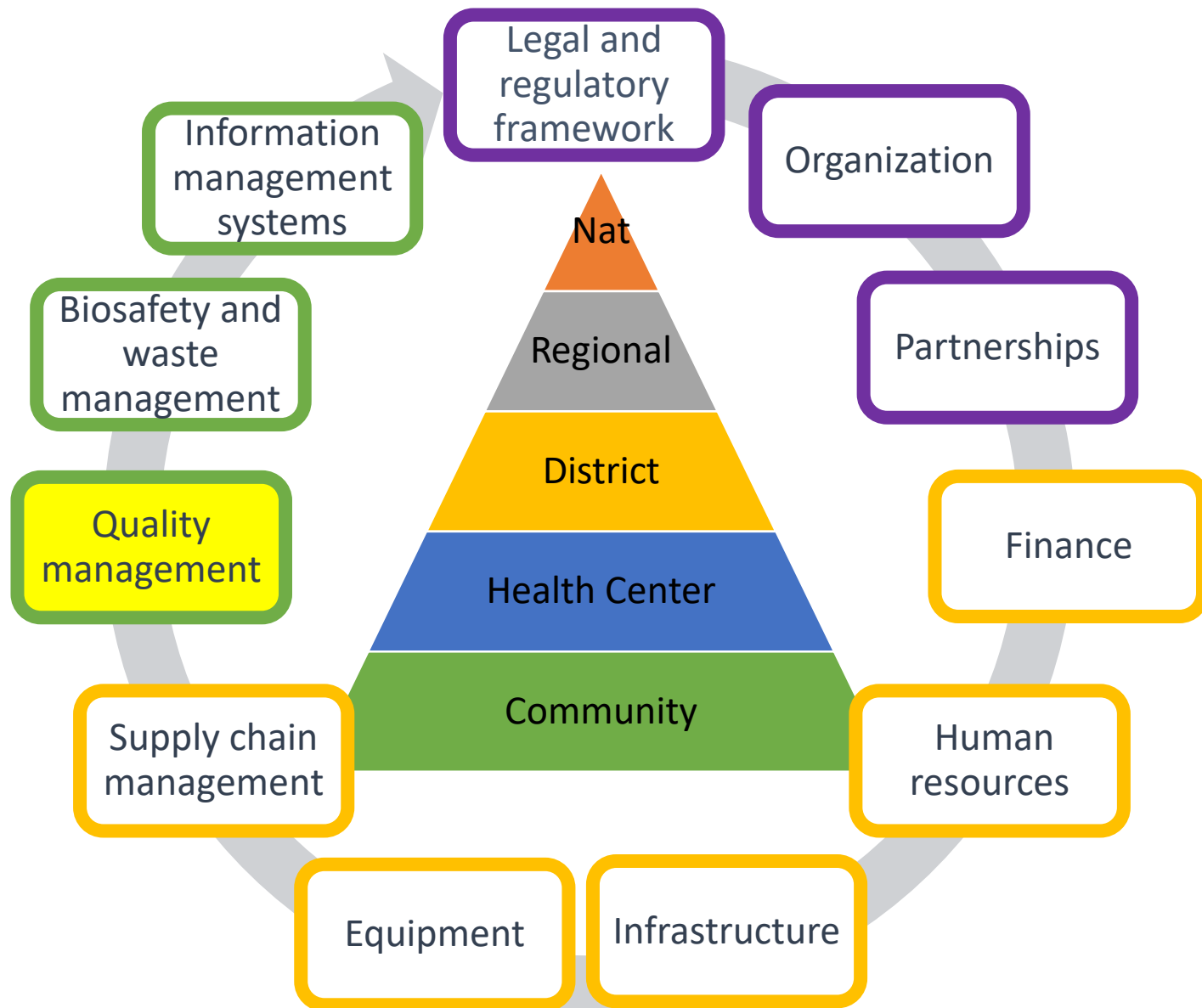
Examining 7 years of implementing quality management systems in medical laboratories in sub-Saharan Africa

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668 ISO15189 accredited laboratories on in SSA by December 2020 → not enough to ensure PH outcomes at country level

QMS has to advance further through entire Lab network

Key considerations to implement
Laboratory QMS at all levels of the
national tiered laboratory network

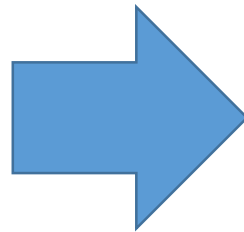


- Laboratories are part of the national tiered laboratory network
- **QMS is one of the systems that supports the laboratory network**
- **All laboratories need a QMS system** (not all need an accreditation)
- Deciding which lab shall move to accreditation depends on national regulation.
- Advancing accreditation in eligible laboratories requires roles and responsibilities at country level.

Establishing national LQMS (1)

1. Build a National Laboratory Quality Infrastructure (QI)

The QI enables a country, region or continent **to set and achieve quality objectives** to the level of customer satisfaction.



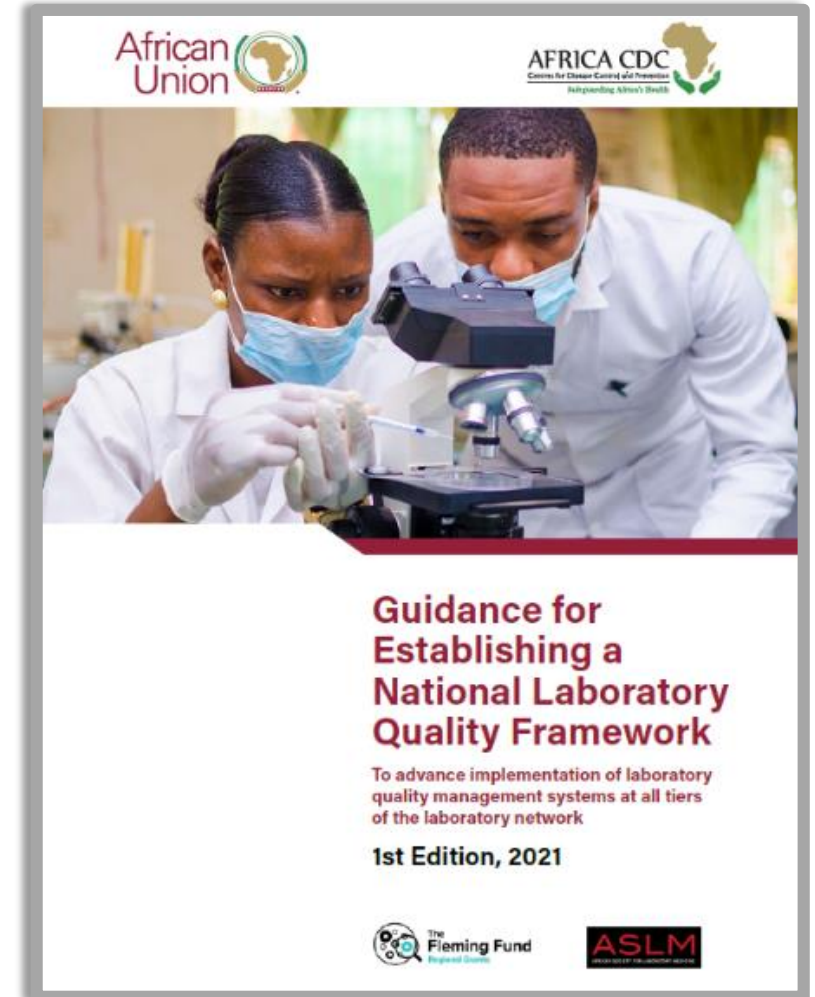
KEY COMPONENTS of QI

- National accreditation body
- **National laboratory quality standards (*role of ISO 15189?*)**
- National laboratory licensing system
- Skilled workforce
- National EQA programme
- Calibration of equipment
- M & E framework
- Tiered supervision

Establishing national LQMS (2)

2. Develop National Laboratory Strategic documents (NLQP & NLSP)

- To create a country-wide approach to advance QMS implementation at all levels of the health system
- Enables policy makers to solidify QMS efforts into National policy and planning.
- **Using the National Laboratory Quality Framework (NLQF) guidance**
- Continental initiative, **under the mandate of Africa CDC .**



What are the implications of the new ISO 15189:2022



What are the changes?

impact on LQMS implementation at facility and country level?

Transitioning process and timeline?

Impact on SLMTA & SLIPTA ?

impact on strategies of accreditation /certification bodies ?

Series of ECHO sessions from January to March 2023



Thank you for joining