INTERNATIONAL INSTITUTE FOR PATHOLOGY AND FORENSIC SCIENCE RESEARCH

COLLEGE of AMERICAN PATHOLOGISTS FOUNDATION

DAVID UMAHI FEDERAL UNIVERSITY OF HEALTH SCIENCES UBURU, EBONYI STATE.

Leadership, Governance & Documentation for Effective Laboratory QMS.

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Advancing Laboratory Quality Management Systems for Better Patient Outcomes

Outline

- Preamble
- Terms and Definitions
- Strengthening Laboratory Leadership & governance
- Documentation of Quality Management System
- Strategies for Document control to ensure adherence to quality standards
- Laboratory documentation required for Effective QMS.
- Conclusion

Poll Question #1

Laboratory leadership should be based on the following except :

a. Specified Qualifications

b. Demonstrated competence

c. Political / religious affiliation

d. Delegated authority

e. Documented responsibilities

Poll Question #2

The following are elements of QMS Document control features except

a. Documents are maintained as hard copy only.

b. documents are uniquely identified

c. documents are approved by authorized personnel

d. documents are periodically reviewed and updated as necessary

e. Obsolete documents are removed from circulation and labeled properly

Poll Question #3

The following records are required for accreditation assessment (select all correct options):

a. Proficiency Testing

b. Equipment verification

c. staff Payslips

d. Internal audit record

e. Copies of voters' registration card

Poll Question #4

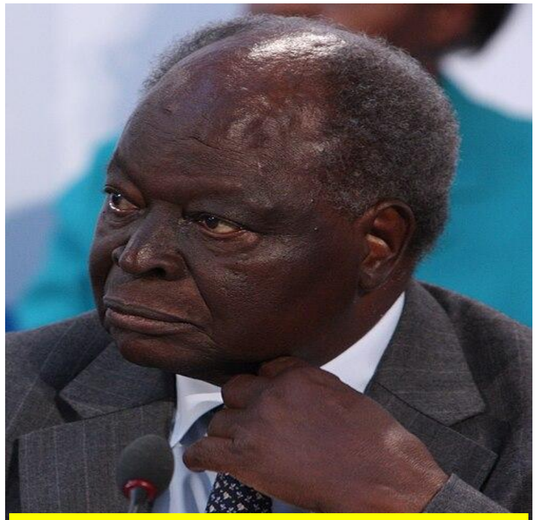
The Clause “Management Systems Documentation” is identified in ISO 15189:2022 under :

a. Clause 8.1
b. Clause 8.2
c. Clause 8.3
d. Clause 8.4
e. Clause 8.5

Preamble

Nnamdi Azikiwe

"Leadership is not about the position one holds, but about the positive impact one has on others."



Mwai Kibaki

"Leadership is a privilege to better the lives of others. It is not an opportunity to satisfy personal greed."

John Maxwell

"Leadership is taking responsibility while others are making excuses."

Terms and Definitions

- Leadership in the laboratory requires interaction with other front-line health care providers towards the management, maintenance, and development of clinical laboratory services to meet needs.
- Laboratory leadership requires effective interactions with individuals within the laboratory, suppliers, and manufacturers, higher administration, and those relying on the services provided.

https://pmc.ncbi.nlm.nih.gov/articles/PMC6995455/

Leadership

1. Creates and adapts an organization
2. Establishes direction and defines the future
3. Aligns and inspires
4. Can be learned
5. Is crucial to success

APHL FOUNDATIONS OF LABORATORY LEADERSHIP AND MANAGEMENT: CORE CURRICULUM FLLM 1.2 :: 5

Terms and Definitions

- National Laboratory Directorates (NLDs) refers to the entity in charge of laboratory networks at the national level, typically but not exclusively related to laboratory services for diagnostics.
- Leadership refers to the cadre and skills of those heading National Laboratory Directorate (NLDs)
- Governance entails the contextual elements outside the NLDs themselves, such as the institutional hierarchy above a given NLD within a Ministry of Health and the technical working groups that help guide and govern laboratory decisions in country.

Status Report on Laboratory Leadership in Africa published by ASLM

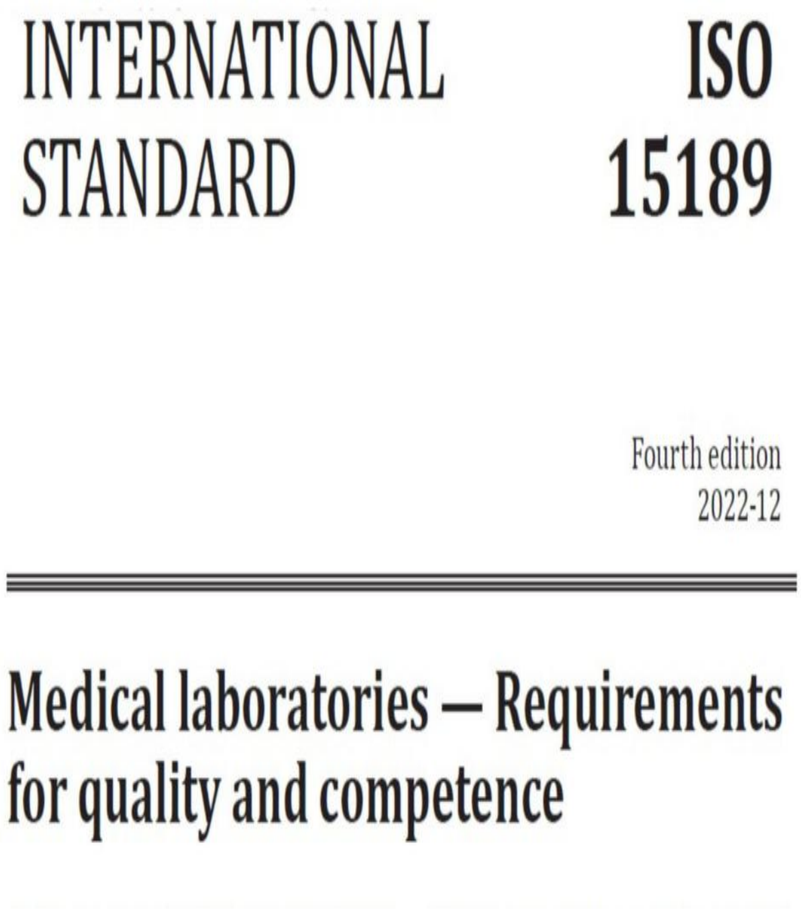
- In Nigeria NLD is Medical Laboratory Services Division (MLSD) of FMoH

Terms and Definitions

- Governance is the act or process of overseeing the control and direction of something (such as an organization)
- Laboratory governance is a framework that helps medical laboratories become accountable for continuously improving the quality of their services[i]
- Quality initiatives to facilitate clinical governance in the laboratory include accreditation to an external standard such as ISO 15189, and benchmarking[ii].

i https://healthgovernanceunit.com/get_sub_page.php?ID=11&sub_id=67

ii https://clinicalpub.com/governance-risk-and-quality-management-in-the-medical-laboratory/



Laboratory Governance in ISO 15189:2022

5 Structural and governance requirements

5.1 Legal entity

The laboratory or the organization of which the laboratory is a part shall be an entity that can be held legally responsible for its activities.

NOTE For the purposes of this document, a government laboratory is deemed to be a legal entity on the basis of its government status.

5. Structural and governance requirements

- 5.1 – Legal Entity
- 5.2 – Laboratory Director
- 5.3 – Laboratory activities
- 5.4 – Structure and Authority
- 5.5 – Objectives and Policies
- 5.6 – Risk Management

Laboratory Leadership and Governance in Nigeria

- A **functional** organizational structure provide stewardship, coordination and management of laboratory services at all level
- One of the major constraints against the effective contribution of the laboratory sector to health care delivery is weak governance structure due to absence of a clear organizational structure and management roles within the FMOH and SMOH.
- The management, coordination and supervisory responsibilities of laboratories are undertaken by different units of the FMoH.
- The current Division of Medical Laboratory Services is the technical focal point of laboratory services in the Federal Ministry of Health
- The national laboratory regulatory framework is provided by MLSCN and the MDCN. These regulatory councils exercise oversight over the activities of their members based on the provisions of the respective Acts that established them

Source : NNMLSP 2023

Strengthening Laboratory Leadership and Governance

- Laboratories often struggle with creating a strong governance structure that ensures sustainability for their stewardship program – ADLM
- In a study of 47 survey respondents who rated the success of their stewardship programs, several who rated their program as “somewhat successful” or “very successful” highlighted the importance of multidisciplinary teams being a contributor to their program success.

https://myadlm.org/cln/articles/2023/janfeb/good-governance-in-laboratory-stewardship-a-roadmap-for-success

To meet their objectives around appropriate test ordering, financial coverage, and improving patient care, laboratory stewardship programs should have four key elements:

- Governance
- Interventions
- Data extraction and monitoring,
- Review of data coupled with strategies and tactics for improvement.

Strengthening Laboratory Leadership and Governance

The space and Voice of Laboratory in MoH

- Suboptimal positioning of Laboratory services within the MoH causes challenges in many areas: top-down budgeting and policy formulation which inhibit autonomy to shape its own organizational culture.
- The most salient concern is how National Laboratory Directorates positions restrict communication with top decision-makers.
- Hierarchy and # of levels observed between the laboratory directorate and Minister of Health or Permanent Secretary, clearly showing the challenge of accessing top MoH leadership to ensure available financing, clear mandate, and prompt decision-making

chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://aslm.org/wp-content/uploads/2025/03/ASLM-Status-Report.pdf

Strengthening Laboratory Leadership and Governance

5.2 Laboratory director

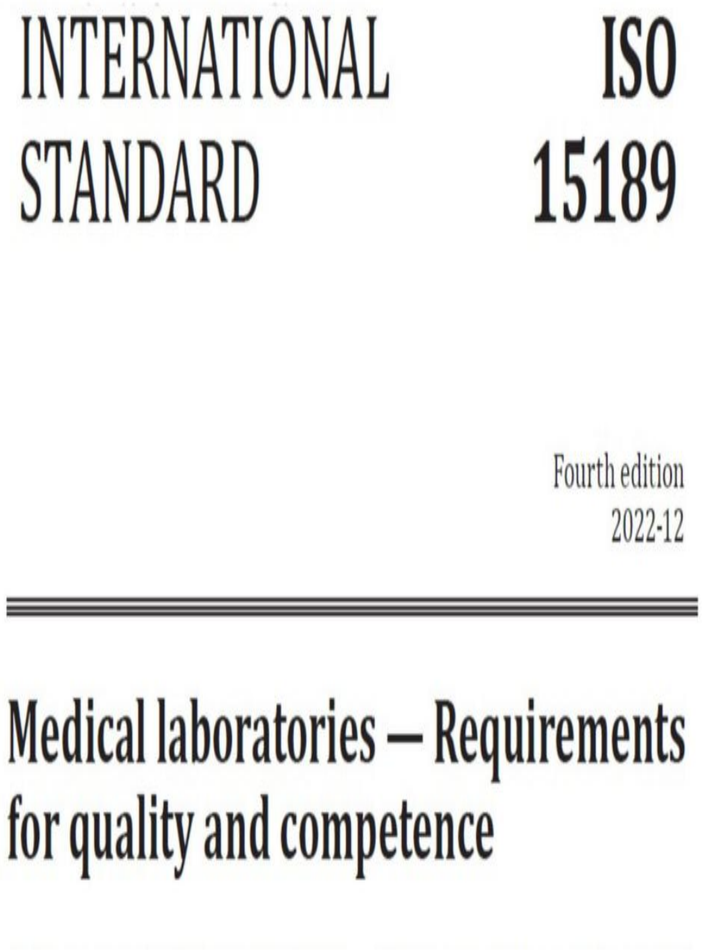
5.2.1 Laboratory director competence

The laboratory shall be directed by a person, or persons however named, with the specified qualifications, competence, delegated authority, responsibility, and resources to fulfil the requirements of this document.

5.2.2 Laboratory director responsibilities

The laboratory director is responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed.

The duties and responsibilities of the laboratory director shall be documented.



Strengthening Leadership and Governance – The Medical Laboratory focus

One of the major constraints against the effective contribution of the laboratory sector to health care delivery is weak governance structure due to absence of a clear organizational structure and management roles within the FMOH and SMOH.

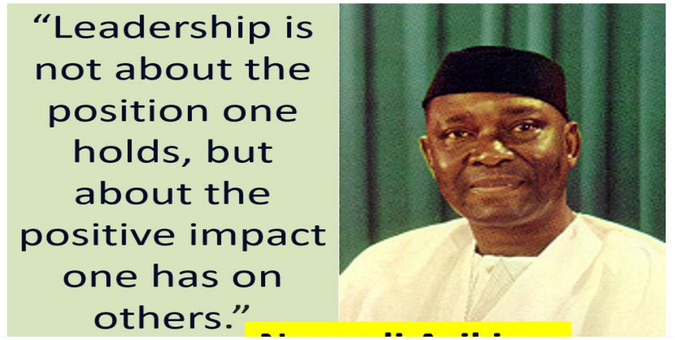
So, how do we address this and change the narrative in a typical Laboratory setting

Some Key considerations

- The medical Laboratory workforce comprises of highly skilled and educated laboratory professionals
- Inter professional harmony among these professionals is key in ensuring the Laboratory deliver on the #1 goal – improved patient outcome

The Essentials

- A well formulated policy on Human resources
- Organogram showing interrelationship of staff
- Job description for each staff with details on key responsibilities
- **Appropriate capacity building program for each cadre of staff will improve productivity starting with Lab Directors / Lab managers**



global health

Building International Laboratory Management Skills with Training: The Foundations of Laboratory Leadership and Management Course

by APHL member consultants *Sally Liska*, PhD, and *Paul Kimsey*, PhD, with contributions from *Esther Gathinji*, APHL global health specialist, and in-country consultant *Maada-Sesi Gombu*

As nations gear up to meet the demand for increased AIDS screening, diagnosis and treatment it is critical to build a strong foundation for laboratory practice. In many countries, there was a gap in management and leadership training among senior laboratorians. To bridge that gap, APHL developed a five-day workshop with modules covering communication, team building, organizational structure, conflict resolution, leadership, human resources, problem solving, financial management and strategic planning.

The course, which is supported by PEPFAR (President's Emergency Program for AIDS Relief), is the brainchild of Ralph Timperi, APHL's senior advisor for laboratory practice and management; Brad Hill, an independent laboratory consultant, developed the course content while working closely with several APHL members. The laboratory management course debuted in 2004 in Zimbabwe. With a class of 40 senior laboratory scientists from several African countries, PEPFAR partners such as the American Society for Clinical Pathology and the Clinton Foundation, were invited to participate in a follow-up training in Kenya in 2006. Results from the course evaluation and verbal comments were overwhelmingly favorable; better yet, requests came in from many of the African countries to host a workshop in their own country.

The FLLM core curriculum has been translated into Portuguese and, more recently, into French. FLLM has since been presented in Haiti, and can now be shared with more French-speaking countries.

Over time, the course has been revised and renamed "Foundations of Laboratory Leadership and Management" (FLLM). Now a complete training package, it includes in-class exercises, student document tools and an instructor's manual. To date, FLLM has been offered in more than a dozen African countries with consistent positive feedback. Students are highly motivated and appreciative of the expertise offered by APHL faculty, who are able to answer questions with real world experience.

This past year has seen an increased interest in the course. In keeping with CDC's efforts toward sustainability, several PEPFAR countries have requested the train-the-trainer (ToT) version of FLLM. The ToT is an extended two-week course, composed of the core curriculum plus extra sessions on training. Class participants are given an opportunity to present some of the material to their colleagues, with subsequent verbal and written evaluations. To date, Ethiopia, Nigeria and Mozambique have adopted the curriculum and are using their own facilitators for the training.

The FLLM core curriculum has been translated into Portuguese and, more recently, into French. FLLM has since been presented in Haiti, and can now be shared with more French-speaking countries.

Recent events in Nigeria show that the FLLM course is valued highly. ToT graduates taught the FLLM core curriculum in both Lagos and Enugu, fully supported by Nigeria, and more trainings are planned in 2014. The Medical Laboratory Science Council of Nigeria (MLSCN) recently approved the FLLM course as one of its continuing professional development (CPD) courses. The MLSCN assigned 10 credit points to FLLM, the requisite number for laboratory license renewal. In addition, the Ambrose Ali University in Edo, a southern state in Nigeria, offered the course to its university professors, and hopes to include FLLM course essentials in the curriculum for medical laboratory science technology.

APHL is proud to be a partner in shaping the future of laboratory leadership and management in the ever-changing, international laboratory field. With a constant focus on sustainability, APHL continues its commitment to building laboratory capacity and strengthening health systems through workforce development and other key initiatives.

Some Key considerations

5.2 Laboratory director

ISO 15189:2022

5.2.1 Laboratory director competence

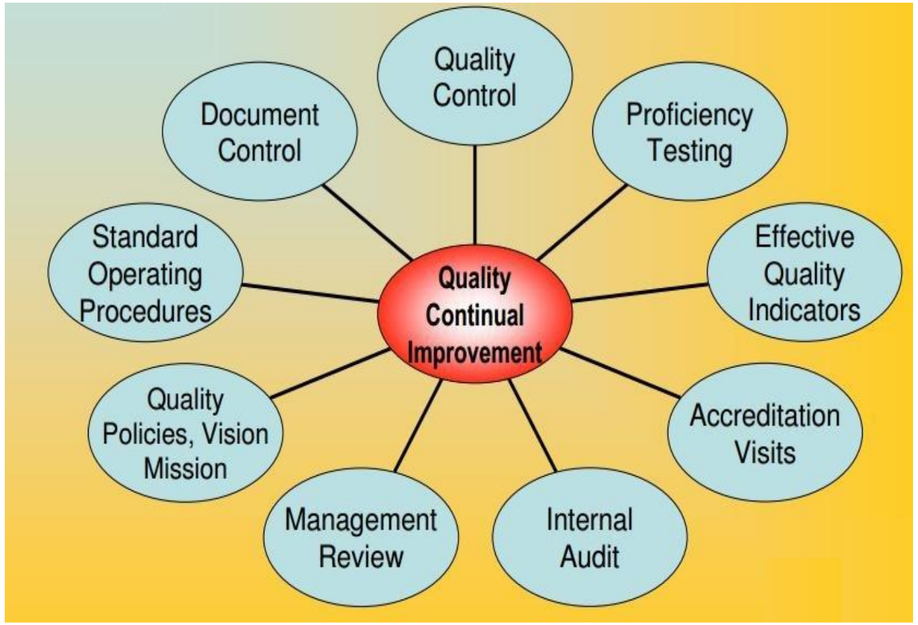
The laboratory shall be directed by a person, or persons however named, with the specified qualifications, competence, delegated authority, responsibility, and resources to fulfil the requirements of this document.

- Leadership should be based on specified **Qualifications, demonstrated competence,** delegated authority, documented responsibilities and availability of resources.
- The ability of the Leadership **to manage all the teams playing the different roles** is necessary for an effective governance in the Laboratory.
- To effectively meet the need of clients, the leadership and governance structure is key.

Suggested Positions for effective governance

- Quality Assurance (QA) Team
- Client / Stakeholders management
- Equipment management
- Logistics and Inventory management
- Sample management / Pre-Examination
- Result management / Post Examination
- Biosafety / Bio risk management
- Documentation / Administrative functions
- Research and Innovation

QA Team monitor activities such as : PT, IQC, MRM, Audit, QI, Accreditation Prep, QMS Doc development / review



https://www.researchgate.net/figure/Continuous-Laboratory-Quality-Management_fig1_308785557

Laboratory Documentation for compliance and productivity

Documentation ????

Baby Eniola, LUTH and Law!

- material that provides official information or evidence or that serves as a record.
- material that provides official information or evidence or that serves as a record.

If it's not written, it never happened. If it is written, it doesn't matter what happened.
--Sercan Leylek

In the Laboratory, we say it was never done if it's not documented!

Documentation of QMS is an ISO 15189 requirement

8.2 Management system documentation

8.2.1 General

- Laboratory management shall establish, **document**, and maintain objectives and policies for the fulfilment of the purposes of this document and shall ensure that the objectives and policies are acknowledged and implemented at all levels of the laboratory organization.

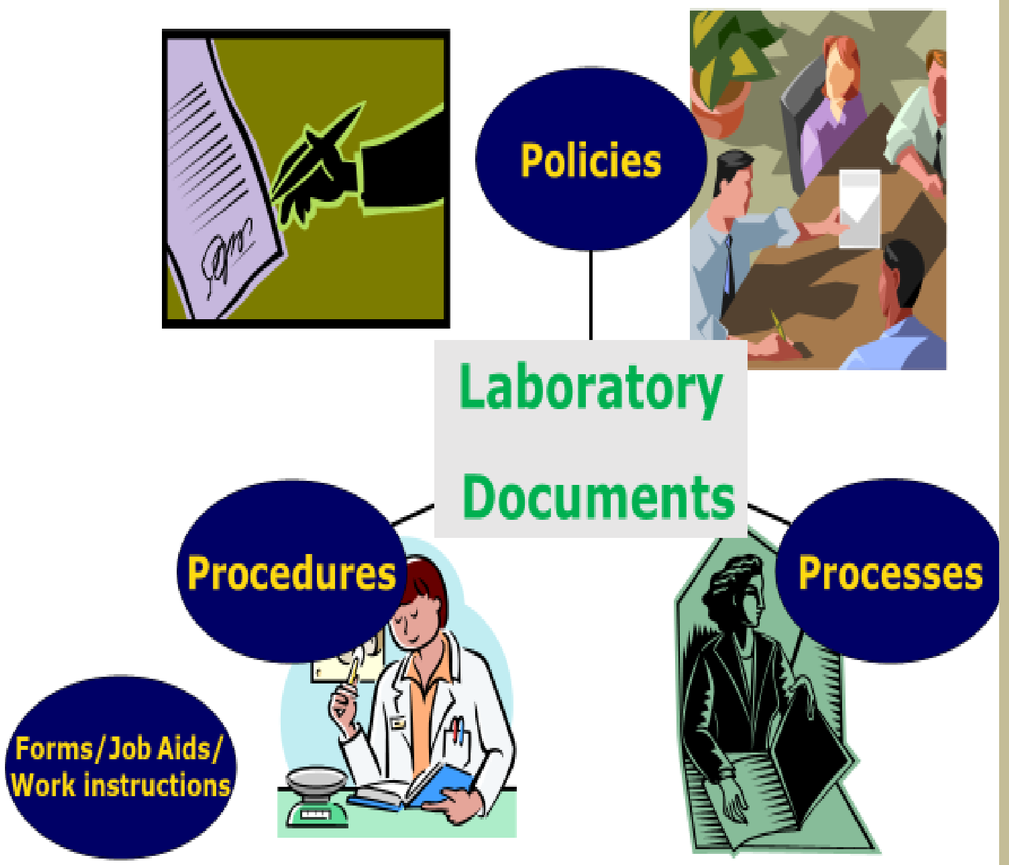
***NOTE**: The management system documents can, but are not required to, be contained in a quality manual*

8.2.5 Personnel access

- All personnel involved in laboratory activities shall have **access** to the parts of the **management system documentation** and related information that are applicable to their responsibilities.

Documentation of QMS is ISO 15189 requirement

Basic QMS Documents (what should the Laboratory document ?)



POLICIES – THE WHAT TO DO

A written statement of overall intentions and directions defined by those in the organization and endorsed by management." (CLSI HS1-A2)

PROCESSES – THE HOW IT HAPPENS

A "set of interrelated or interacting activities that transform inputs into outputs." (ISO 9000 4.3.1)

SOPs – THE HOW TO DO IT

step-by-step instructions for performing a single activity

Job Aids

Shortened version of SOPs for quick reference, also called Bench Top reference

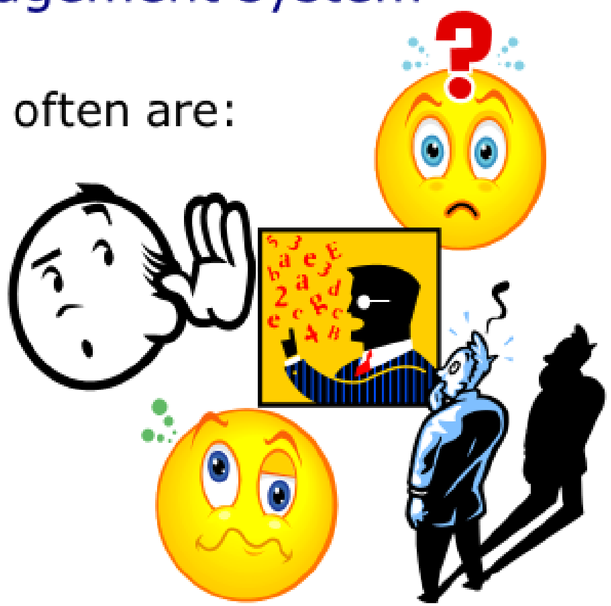
Documentation of Quality Management System

What are QMS Documents

Documents are the **communicators** of the quality management system

Verbal instructions often are:

- not heard
- misunderstood
- quickly forgotten
- difficult to follow



Documents and Records - Module 16 14

Documents are a reflection of the laboratory's organization and its quality management.

A good rule to follow is:
"Do what you wrote and write what you are doing."

Good Documents must be:

- clear
- concise
- user-friendly
- explicit
- accurate
- up-to-date

Credit: WHO/CLSI LQMS Training modules

QMS Documents and Records

Documents and Records—How do they differ?

Documents

- communicate information via policies, processes, and procedures
- need updating

Records

- capture information on worksheets, forms, labels, and charts
- permanent, do not change

Records are documentation (evidences) of all activities performed by the laboratory

Credit : WHO/CLSI LQMS Training modules

From Document to Records

- Records are created as evidence of the implementation of quality or technical (testing) activities in the Lab
- When data is captured on a document, it turns into a record
- Records are created concurrently with the implementation of tasks in the Laboratory

Strategies for Document control to ensure adherence to quality standards

The goal of Document control is to ensure that only the current version of the document is always available for use.

Document Control prevents the unintended use of any obsolete document.

Document control is a requirement of quality standards

Clause 8.3 – Control of management system documents

26

- Clause 8.3.1 - General requirements
- Clause 8.3.2 - Control of documents

Document control is a requirement of quality standards

8.3.1 General

The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.

•NOTE In this context, "document" can be policy statements, procedures and related job aids, flow charts, instructions for use, specifications, manufacturer's instructions, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software documentation, drawings, plans, agreements, and documents of external origin such as laws, regulations, standards and textbooks from which examination methods are taken, documents describing personnel qualifications (such as job descriptions), etc. These can be in any form or type of medium, such as hard copy or digital.

ISO 15189:2022 Clause 8.3 – Control of management system documents

Clause 8.3 – Control of management system documents

8.3.2 Control of documents

The laboratory shall ensure that:

- documents are uniquely identified;
- documents are approved for adequacy before issue by authorized personnel who have the expertise and competence to determine adequacy;
- documents are periodically reviewed and updated as necessary;
- relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
- changes and the current revision status of documents are identified;

Clause 8.3 – Control of management system documents

8.3.2 Control of documents

- documents are protected from unauthorized changes and any deletion or removal;
- documents are protected from unauthorized access;
- the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose;
- at least one paper or electronic copy of each obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements.

Use of Document master list is critical

Clause 8.3 – Control of management system documents

Title : Laboratory Quality Manual	Document ID: MA/QM/V4	Version: 4
Section: Quality Management	Effective Date: 01/08/2018	Supersedes: 3

	Written by	Reviewed by	Approved by
Name			
Signature			
Date:			

Clause 8.3 – Control of management system documents

QMS DOCUMENT REVIEW/CHANGES LOG:

Version no.	Review/ Revision Date	Next Review Date	Details of amendment/Comments	Signature/ Date
4	01/08/2018	30/07/2019	Document template changed, content of manual reviewed to conform with ISO 15189 :2012 requirements.	

Clause 8.3 – Control of management system documents

Medical Laboratory Science Council of Nigeria

Guideline on Documents and Records Retention

Laboratory Documentation for compliance and productivity

Why worry about Documentation ????

- To ensure compliance with Quality standards
- To ensure consistency and uniformity – variation is the #1 enemy of Quality
- Evidence of QMS implementation – Audit evidence

Laboratory Documentation for compliance and productivity

Common Documentation / Records for Accreditation Assessment

- Complete and current version of QMS Documents
- Personnel folders
- Proficiency Testing & IQC
- Meetings – Management review, staff meetings
- Nonconformities and Corrective Actions
- Internal audit
- Equipment maintenance
- Method verification
- Customer survey, complaints, other Quality indicators

Laboratory Documentation for compliance and productivity

QMS Documentation required for effective QMS **ISO 15189:2012**

4.2.2 Documentation requirements

4.2.2.1 General

The quality management system documentation shall include:

a) statements of a quality policy (see 4.1.2.3) and quality objectives (see 4.1.2.4);

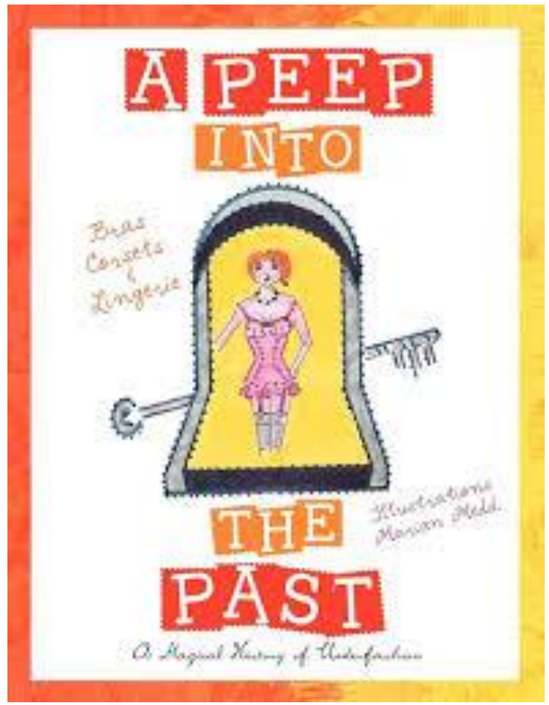
b**) a quality manual (see 4.2.2.2);**

c) procedures and records required by this International Standard;

d) documents, and records (see 4.13), determined by the laboratory to ensure the effective planning, operation and control of its processes;

e) copies of applicable regulations, standards and other normative documents.

NOTE The documentation can be in any form or type of medium, providing it is readily accessible and protected from unauthorized changes and undue deterioration.



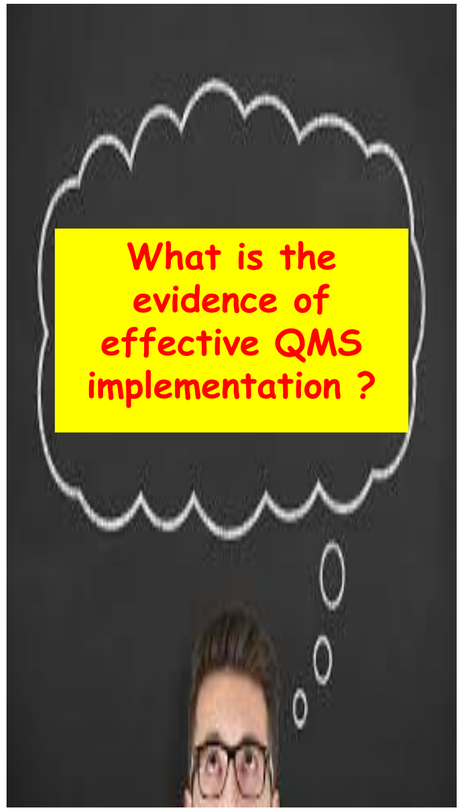
Clause 5.5 of ISO 15189:2022 – Review of QMS Objectives

a) Laboratory management shall establish and maintain objectives and policies (see 8.2) to:
   1) meet the needs and requirements of its patients and users;
   2) commit to good professional practice;
   3) provide examinations that fulfil their intended use;
   4) conform to this document.

b) Objectives shall be measurable, and consistent with policies. The laboratory shall ensure that the objectives and policies are implemented at all levels of the laboratory organization.

c) Laboratory management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

d) The laboratory shall establish quality indicators to evaluate performance throughout key aspects of pre-examination, examination, and post-examination processes and monitor performance in relation to objectives (see 8.8.2).

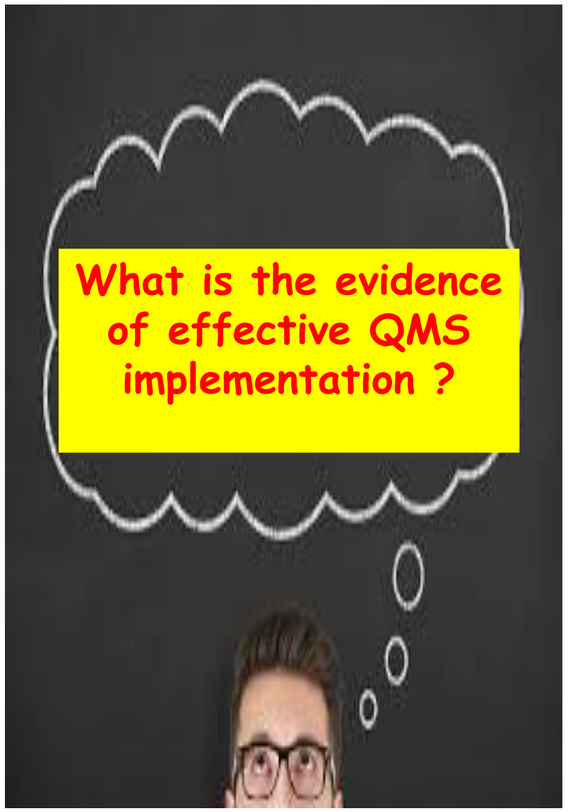


NOTE Types of quality indicators include the number of unacceptable samples relative to the number received, the number of errors at either registration or sample receipt, or both, the number of corrected reports, the rate of achievement of specified turnaround times.

Clause 5.5 of ISO 15189:2022 – Review of QMS Objectives

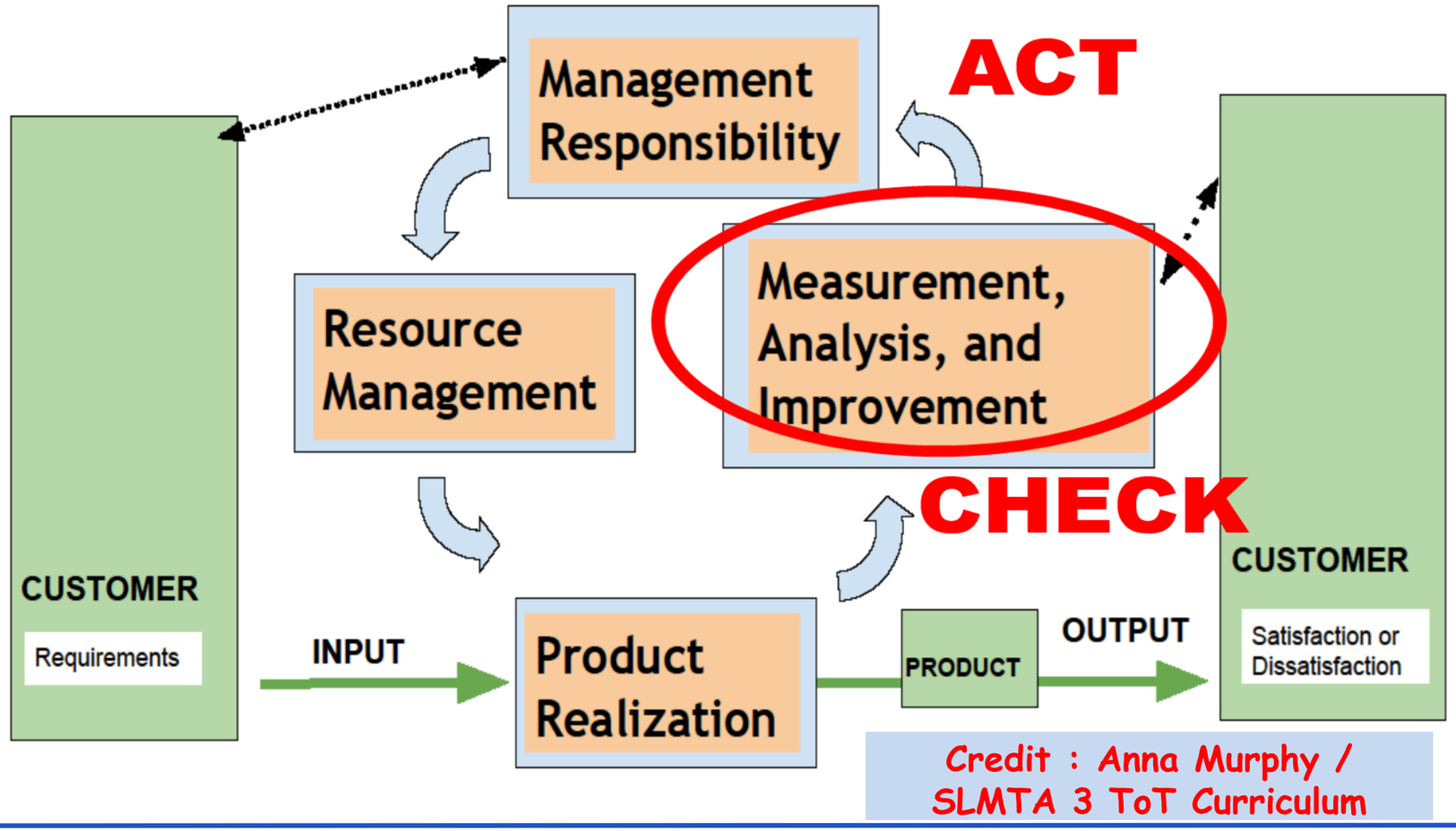
Quality objectives and planning for Dr Adewale Ojo Laboratory – 2025.

1. To provide quality laboratory services that will meet customer satisfaction of greater than75% annually
2. To produce greater than 85% of all Laboratory results within the Laboratory turnaround time.
3. To achieve minimum of 80% score in all EQA – PT exercise as a measure of Accuracy of test results.
4. To reduce service interruption to less than 5% per year by providing adequate supplies, reagents and equipment for carrying out tests.
5. To achieve ISO 15189 accreditation through MLSCN / SANAS by December, 2026.



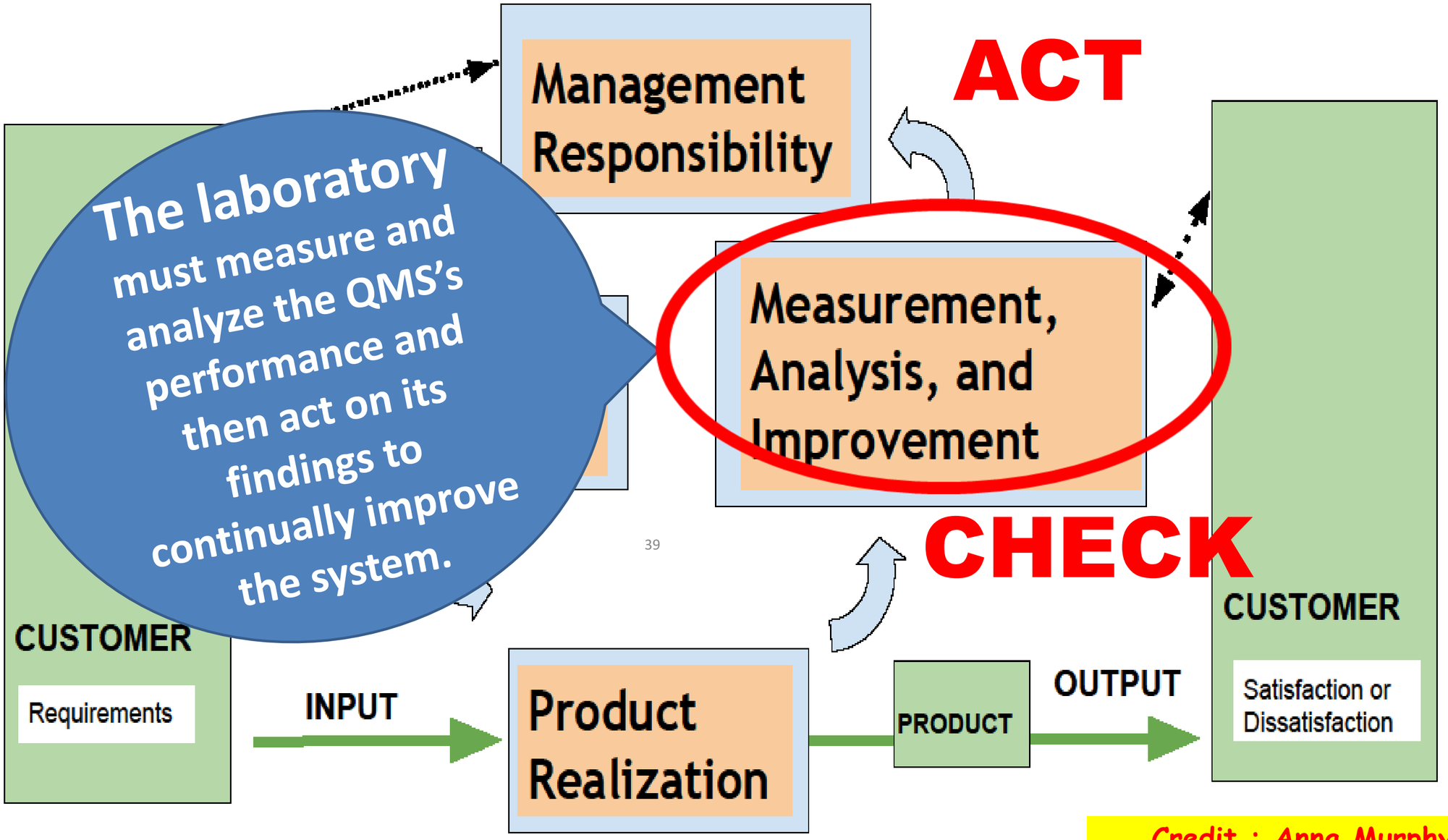
Laboratory Documentation for compliance and productivity

Overall QMS – the system level



Credit : Anna Murphy / SLMTA 3 ToT Curriculum

Overall QMS – the system level

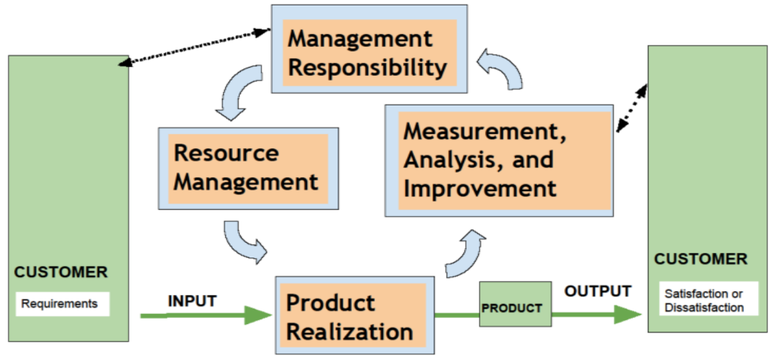


Credit : Anna Murphy / SLMTA 3 ToT Curriculum

ISO 15189 Continual Improvement Tools

ISO 15189 Continual Improvement Tools

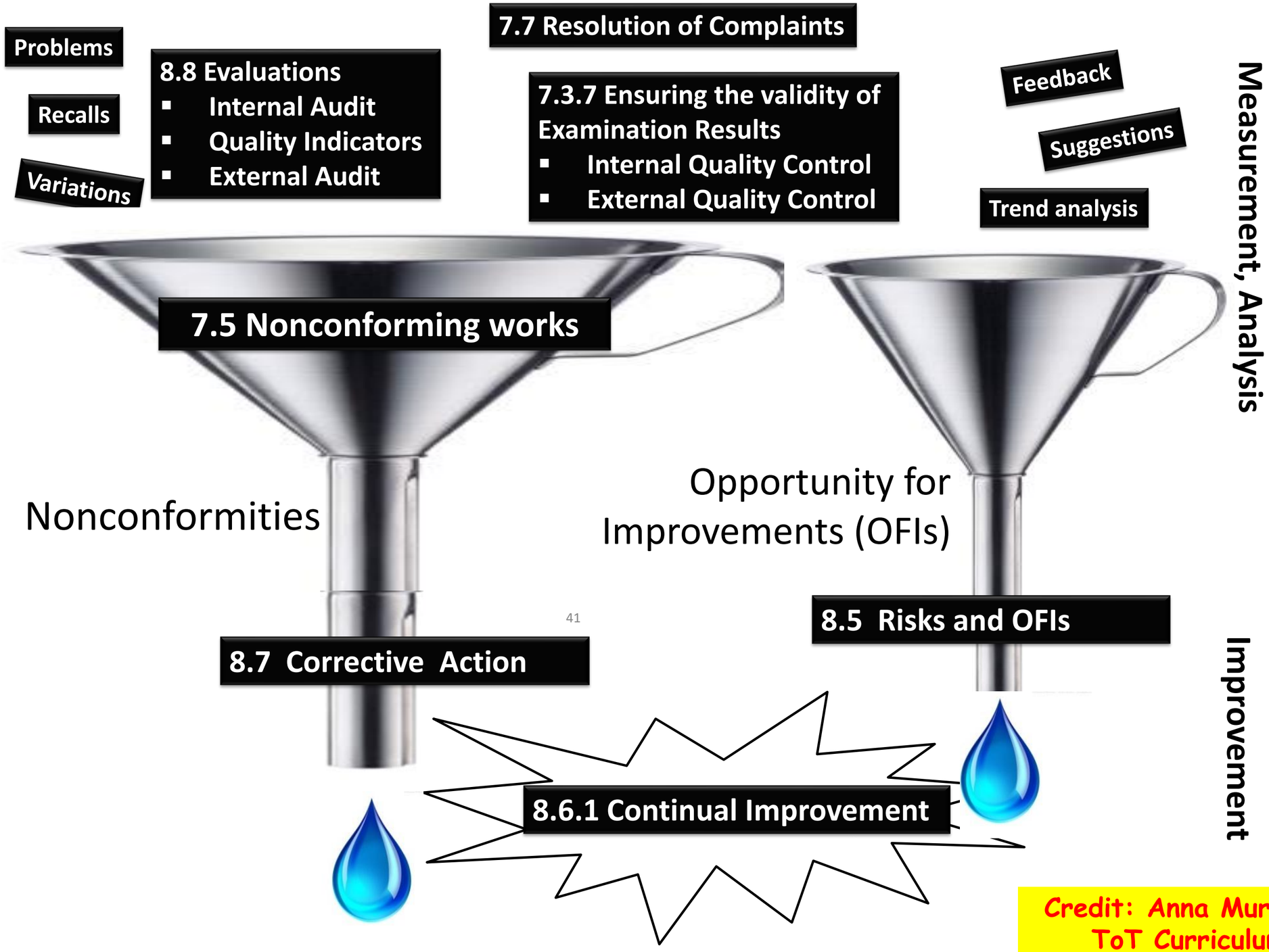
- ✓ Using Quality Indicator (QI) information
- Managing nonconformities (Occurrence Management System)
- Performing internal and external audits
- Conducting regular management reviews



Credit : Anna Murphy / SLMTA 3 ToT Curriculum

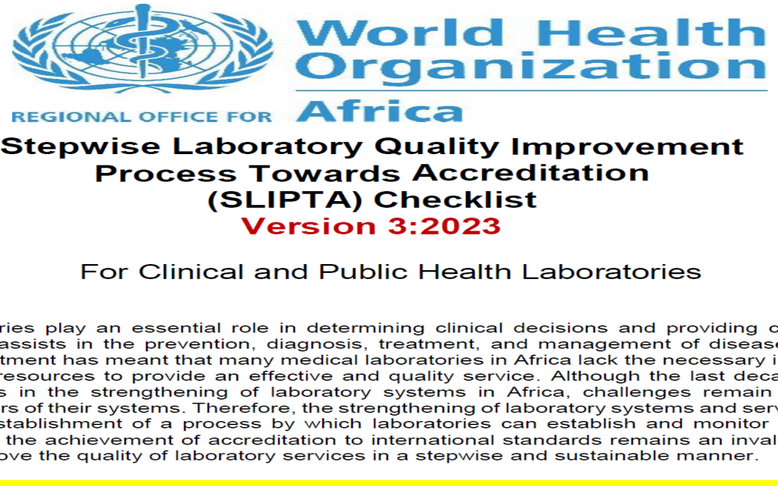
CHECK - Gather and analyze information to make a decision

ACT – Take appropriate action based on the decision made



Credit: Anna Murphy / SLMTA 3 ToT Curriculum (modified)

Review of Quality Records for Effective QMS



World Health Organization
REGIONAL OFFICE FOR Africa

Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist
Version 3:2023

For Clinical and Public Health Laboratories

Introduction

Medical laboratories play an essential role in determining clinical decisions and providing clinicians with information that assists in the prevention, diagnosis, treatment, and management of diseases. However, inadequate investment has meant that many medical laboratories in Africa lack the necessary infrastructure, equipment, and resources to provide an effective and quality service. Although the last decade has seen significant strides in the strengthening of laboratory systems in Africa, challenges remain across most countries at all tiers of their systems. Therefore, the strengthening of laboratory systems and services remains a priority. The establishment of a process by which laboratories can establish and monitor management systems towards the achievement of accreditation to international standards remains an invaluable tool for countries to improve the quality of laboratory services in a stepwise and sustainable manner.

SECTION 02: ORGANISATION AND LEADERSHIP

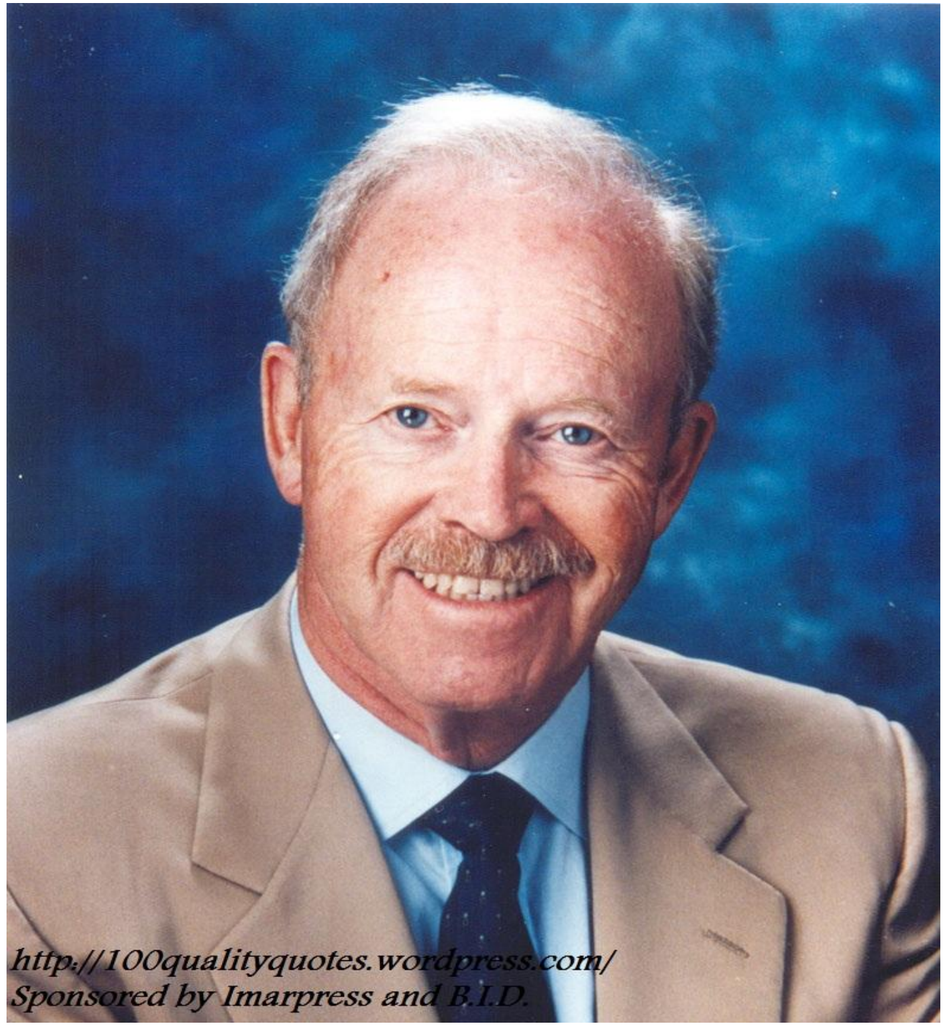
2.5 Routine Review of Quality and Technical Records

Does the laboratory routinely perform a documented review of all quality and technical records?

Note: There must be documentation that quality records are regularly reviewed and monitored by authorised person(s). This routine review (the laboratory must define their frequency of review, e.g., daily, weekly, monthly) must ensure that recurrent problems have been addressed and new or redesigned activities have been evaluated.

a. Follow-up of action items from previous reviews;
b. Status of corrective actions taken and required risk mitigation actions;
c. Reports from personnel;
d. Environmental monitoring logs;
e. Sample rejection records;
f. Equipment calibration and maintenance records;
g. IQC records across all test areas;
h. Outcomes of PTs and other forms of inter-laboratory comparisons;
i. Quality indicators;
j. Customer complaints and feedback;
K .Results of improvement projects;
l. Documentation of this routine review and action planning with personnel for resolution and follow-up review.

Quality improvement is “acting on findings”



It isn't what you find, it's **what you do about what you find**.

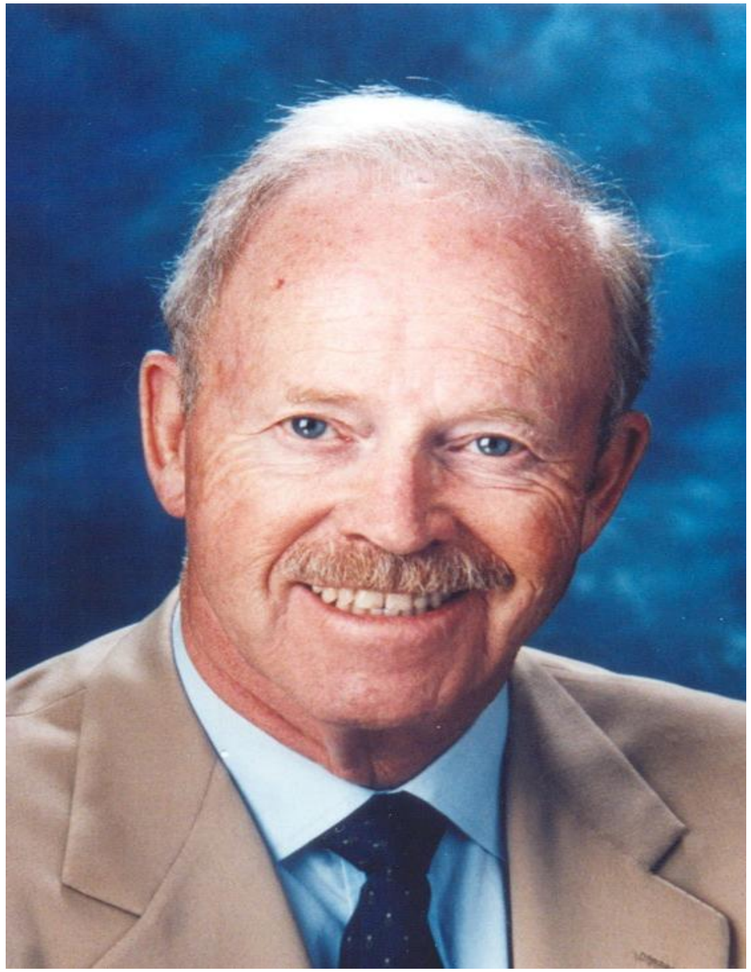
Philip Crosby.

Quality improvement is "Acting on findings."

To achieve improvement across all the areas of Lab operation:

- **Set appropriate indicators**
- **Monitor and track the Quality indicators over time**
- **Review data from the indicators**
- **Act on the findings /gaps**

Quality improvement is “acting on findings”



It isn't what you find, it's **what you do about what you find**.

Philip Crosby.

~~CHECK ACT~~

Analysis without action is

meaningless.

~~CHECK ACT~~

Action without analysis is

dangerous.

Credit: Anna Murphy / SLMTA 3 ToT Curriculum

Key messages

- To effectively meet clients' needs, the leadership and governance structure is key.
- Documents are essential for assuring accuracy and consistency in the laboratory.
- Document Control prevents the unintended use of any obsolete document.

Conclusion

"Leadership is, not occupying a seat, It is accomplishing a feat. It is not occupying a position; it is making outstanding contributions. It is not an appointment, but an attainment.."

Dr David Oyedepo
Chancellor Covenant University

Conclusion

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If it's not written, it never happened. If it is written, it doesn't matter what happened.
--Sercan Leylek

In the Laboratory we say: if its not written it was never done!

Thank You

NEXT WEEK:

Ensuring Compliance Through Laboratory Assessments & Audits

- Conducting internal audits for quality improvement and accreditation readiness
- Key elements of ISO 15189 compliance and regulatory expectations
- Digital audit tools for enhancing accuracy and efficiency in assessments

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