FEDERAL REPUBLIC OF NIGERIA
FEDERAL MINISTRY OF HEALTH AND SOCIAL WELFARE

DEPARTMENT OF HOSPITAL SERVICES
MEDICAL LABORATORY SERVICES DIVISION

# NATIONAL GUIDELINE FOR THE IMPLEMENTATION OF MEDICAL LABORATORY QUALITY MANAGEMENT SYSTEM

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FIRST EDITION

# FOREWORD

Ensuring the highest standards of quality in healthcare delivery remains a cornerstone of Nigeria's national health agenda. As we strive toward achieving Universal Health Coverage (UHC), the critical role of medical laboratories in the health system cannot be overstated. Reliable and timely diagnostic services are the backbone of effective clinical decision-making, disease surveillance, public health response, and overall healthcare efficiency.

The emergence of COVID-19 pandemic in recent time has highlighted the critical role of medical laboratories, particularly in the context of emerging health threats and pandemics. The accuracy, reliability, and credibility of laboratory results are essential not only for individual patient care but also for safeguarding the health of our communities. Therefore, establishing robust and sustainable quality management systems across all tiers of laboratory service delivery is not just desirable-it is imperative.

It is within this context that I am pleased to present the National Guideline for the Implementation of Medical Laboratory Quality Management System (NGLQMS). This comprehensive document provides a structured, practical framework to guide the implementation, standardization, and continual improvement of quality management systems in medical laboratories across Nigeria. Developed through a consultative and inclusive process involving stakeholders from government, academia, private sector, and development partners, this guideline is aligned with international best practices including ISO 15189:2022 standards while remaining grounded in our national priorities and realities.

The NGLQMS guideline is more than a technical resource; it is a bold step toward institutionalizing a culture of quality, accountability, and excellence in medical laboratory services. Its implementation will significantly contribute to strengthening Nigeria's health system, improving health outcomes, and enhancing public trust in healthcare delivery.

This milestone aligns fully with the vision of President Bola Ahmed Tinubu's Renewed Hope Agenda and the Nigeria Health Sector Blueprint anchored on four critical pillars:

1. Governance and Leadership-for stronger stewardship and institutional accountability.
2. Population Health Outcomes-through equitable, efficient, and high-quality service delivery.
3. Unlocking the Healthcare Value Chain-through local manufacturing, research, and innovation.
4. Health Security and Emergency Preparedness-ensuring resilient systems that can respond to present and future health threats.

Through mechanisms such as the Basic Health Care Provision Fund (BHCPF), Sector-Wide Approaches (SWAp), improved regulation, and strategic investments in public health infrastructure, we are committed to building a system where quality is the norm and not the exception.

I extend my sincere appreciation to all medical laboratory professionals, quality management system experts, policymakers, and development partners whose tireless contributions made this guideline possible. The Federal Ministry of Health and Social Welfare remains resolute in its leadership and coordination role to ensure successful implementation and continuous improvement.

Let this document be a catalyst for transformation-a national call to action to raise the bar in medical laboratory services and move us closer to a healthier, safer, and more prosperous Nigeria.

**Prof. Muhammad Ali Pate** *CON*
Coordinating Minister of Health and Social Welfare

# PREFACE

High-quality medical laboratory services are a cornerstone of effective healthcare systems. They play a pivotal role in ensuring accurate diagnoses, enabling timely and appropriate treatment, supporting disease surveillance, and guiding public health interventions. Without reliable laboratory data, healthcare delivery becomes fragmented and less effective, ultimately compromising patient outcomes and the overall resilience of the health system.

In recognition of the indispensable role medical laboratories play in safeguarding public health, the Federal Ministry of Health and Social Welfare through the Medical Laboratory Services Division and in collaboration with key stakeholders across the health sector has developed this National Guideline for the Implementation of Medical Laboratory Quality Management System. This document represents a strategic commitment to strengthening the quality of medical laboratory services nationwide.

This guideline provides a comprehensive framework for the implementation of robust Quality Management Systems (QMS) within medical laboratories at all levels of the healthcare system. It is aligned with globally recognized standards, including ISO 15189:2022, and leverages tools such as the World Health Organization's Laboratory Quality Stepwise Implementation (LQSI) tool. These international benchmarks ensure that the guidance provided is both credible and adaptable to the unique context of laboratory services in the country.

By outlining core quality principles, best practices, and actionable steps, this guideline serves as both a technical reference and a practical roadmap for establishing and maintaining high-performing laboratory operations. It emphasizes the need for standardization, integration, and continuous improvement, addressing long-standing challenges in laboratory service delivery such as variability in practices, lack of quality oversight, and insufficient capacity for consistent monitoring and evaluation.

The development and implementation of this guideline signal a firm commitment to upholding quality, safety, and technical competence in laboratory environments. More importantly, it aims to close the implementation gap between health policies and actual laboratory practices, thereby enhancing the reliability of diagnostic services and promoting better health outcomes. Moreover, this guideline supports the broader health sector goal of achieving Universal Health Coverage (UHC) by reinforcing evidence-based decision-making and bolstering the foundational systems upon which effective healthcare relies. By ensuring that laboratory services are dependable and standardized, the guideline helps healthcare providers deliver care that is timely, precise, and tailored to individual and population health needs.

This document is intended for a wide audience, including medical laboratory managers, quality officers, healthcare professionals, policymakers, development partners, and all other stakeholders engaged in laboratory service delivery. Whether in public or private settings, it serves as both a strategic guide and a hands-on resource for embedding a culture of quality within laboratory practices.

Ultimately, the National Guideline for the Implementation of Medical Laboratory Quality Management System promotes accountability, reduces diagnostic errors, and ensures that laboratory results are not only accurate and timely but also fully integrated into clinical and public health decision-making. It is a foundational tool in the journey toward a more resilient, equitable, and quality-driven healthcare system.

**Daju Kachollom S.** *mni*
Permanent Secretary

# ACKNOWLEDGEMENT

The development of this National Guideline for the Implementation of Medical Laboratory Quality Management System has been a collaborative and comprehensive effort, reflecting the commitment and expertise of various organizations and individuals dedicated to improving healthcare delivery.

We extend our deepest gratitude to the Resolve To Save Life (RTSL) through the Institute of Human Virology of Nigeria (IHVN), World Health Organization (WHO) and The Global Funds (GF) through National Agency for the Control of AIDS (NACA) for their support and partnership, which has been instrumental in the formulation of this guideline.

Finally, we acknowledge the efforts of all stakeholders, including government agencies, health professionals, and technical experts, whose collective input and dedication have been pivotal in the successful development of this guideline. Your hard work and collaboration are the foundation upon which this guideline stands.

Thank you for your invaluable contributions.

**Dr. Jimoh O. Salaudeen** *mni*
Director Department of Hospital Services
Federal Ministry of Health and Social Welfare

# EXECUTIVE SUMMARY

Quality Management System (QMS) is a vital tool in global business operations, serving as a foundational framework for establishing, institutionalising, and sustaining a culture of quality within organisations. It plays a crucial role in promoting quality-driven behaviour and aligning organisational processes with the overarching goal of meeting client requirements and ensuring client satisfaction particularly in service-oriented sectors such as healthcare.

While the concept of "quality" has long been integral to organisational excellence, the structured approach known as the Quality Management System and its acronym QMS were first formally introduced in 1991 by Ken Croucher, a British management consultant. QMS is defined as a formalised system that documents processes, procedures, and responsibilities necessary to achieve quality policies and objectives. In essence, it provides a systematic framework that guides the delivery of consistent, high-quality services and supports continuous improvement.

In the context of medical laboratories, both public and private, the application of QMS has proven invaluable. It has driven significant improvements in the accuracy and reliability of laboratory results, operational efficiency, and overall client satisfaction. The implementation of QMS not only supports regulatory compliance but also fosters trust and accountability in laboratory practices.

This document is developed with the primary objective of supporting the institutionalisation of QMS in medical laboratory practice in Nigeria. It aims to provide a comprehensive roadmap for QMS implementation across the country, focusing on:

- Bridging existing gaps in Laboratory Quality Management System (LQMS) implementation and maintenance.
- Providing a nationally standardised approach aligned with international best practices.
- Strengthening the existing quality infrastructure in laboratory services.
- Ensuring long-term sustainability and scalability of QMS implementation across different levels of healthcare delivery.

To ensure alignment with global best practices and national requirements, the following standards have been adopted for the establishment of a robust National Medical Laboratory Quality Management System:

- ISO 15189:2022 - Medical laboratories Requirements for quality and competence
- NIS ISO 15189:2019 - Nigerian Standard equivalent of ISO 15189

- ISO 15190:2020 - Medical laboratories Requirements for safety

These standards provide the regulatory, technical, and safety frameworks necessary for ensuring excellence in laboratory services.

The document is structured into 16 chapters, each addressing key aspects of QMS implementation in medical laboratories.

Chapter 1:

Introduces the fourteen (14) Quality System Requirements (QSRs), which serve as the foundational building blocks for QMS. It outlines the guiding principles behind each QSR and identifies four major barriers to QMS implementation, providing practical solutions to overcome them.

Chapters 2 to 15:

Provides detail, practical and ethical framework on what to implement (standard requirement), how to implement (strategies) and documents/records as evidence (output) of implementation. These chapters, respectively, cover Organization and Management, Personnel (Human Resource), Laboratory Equipment, Reagents and Consumables, Purchasing and Inventory, Process Management, Documents and Records, Information Management, Management of Non-Conforming Events, Assessments, Client Focus, Continuous improvement, Facility and safety, Infectious disease outbreak alert and Laboratory ethics.

Chapter 16:

Provides practical guidelines for the utilisation of this document at the national, state, and facility levels including tertiary, secondary, and primary healthcare facilities. It outlines:

- Key activities and QMS components to be implemented.
- Implementation strategies and timelines.
- Monitoring and evaluation mechanisms.
- Required documentation and performance indicators.

This document concludes with a list of references and recommended resources to support further reading, research, and capacity development. These references offer additional insights into international standards, national policies, and implementation tools necessary for a sustainable and effective Quality Management System in the medical laboratory sector.

By adopting this comprehensive QMS guideline, Nigeria is poised to significantly enhance the quality, reliability, and credibility of its medical laboratory services, ultimately contributing to better patient outcomes, improved public health response, and strengthened health systems.

**Elom Emeka U.**
Director/Head Medical Laboratory Services Division

# LIST OF ABBREVIATIONS

| | |
|---|---|
| APER | Annual Performance Evaluation Report |
| CLSI | Clinical and Laboratory Standards Institute |
| DSNOs | Disease Surveillance and Notification Officers |
| EQA | External Quality Assessment |
| ISO | International Organization for Standardization |
| IQC | Internal Quality Control |
| KPI | Key performance Indicator |
| LIMS | Laboratory Information Management System |
| LQMS | Laboratory Quality Management System |
| MLSCN | Medical Laboratory Science Council of Nigeria |
| NMLQMS | National Medical Laboratory Quality Management System |
| NGLQMS | National Guideline for the Implementation of Medical Laboratory Quality Management System |
| NIS | Nigeria Industrial Standard |
| SLMTA | Strengthening Laboratory Management Toward Accreditation |
| SLIPTA | Stepwise Laboratory (Quality) Improvement Process Towards Accreditation |
| SOP | Standard Operating Procedure |
| SMOH | State Ministry of Health |
| QSEs | Quality System Essentials |
| UHC | Universal Health Coverage |
| WHO | World Health Organization |
| POC | Point of Care |
| FMOH&SW | Federal Ministry of Health and Social Welfare |
| NLTWG | National Laboratory Technical Working Group |
| NMLSP | National Medical Laboratory Service Policy |
| NMLStP | National Medical Laboratory Strategic Plan |
| GoN | Government of Nigeria |
| FCT | Federal Capital Territory |
| PoW | Path of Workflow |
| NCE | Non-Conforming Event |

| | |
|---|---|
| MLSD | Medical Laboratory Service Division |
| IHVN | Institute of Human Virology Nigeria |
| RTSL | Resolve to Save Lives |
| GF | Global Fund |
| NACA | National Agency for Control of AIDS |
| PPE | Personal Protective Equipment |
| IDSR | Integrated Disease Surveillance and Response |

# DEFINITION OF TERMS

**Validation**: Extensive process of providing objective evidence that particular requirement for a specific intended use can be fulfilled. Equipment, reagents or methods validation process will include testing for precision, accuracy, linearity, stability, sensitivity and specificity for quantitative and/or qualitative test methods. This is usually done by the manufacturer. A laboratory conducts validation only when it;

a) designs its own methods

b) modifies a method outside the manufacturers' scope.

**Verification**: A process to determine if information generated by a method is in conformance with specified requirements. This is done by the user of an instrument or method to verify accuracy and precision in a local set-up. Verification is done in the following scenarios;

a) after movement of laboratory equipment.

b) when an equipment is newly introduced in the laboratory or an existing one is upgraded.

c) a reagent upgrade has been implemented.

**Vendors**: Any individual or organisation who provides materials, products or services for the laboratory e. g. Suppliers of reagents, consumables, equipment and infrastructure.

**SOP**: Standard Operating Procedure. A detailed step by step instructions that state how an activity must be carried out.

**EQA:** External Quality Assessment. A system that allows the laboratory to compare its performance with other laboratories. EQA process may include proficiency testing, rechecking or retesting and evaluation done by independent persons or organisations.

**LIMS**: Laboratory Information Management System. A system used for managing laboratory data including patient registration, results generation, and other processes. This could either be paper-based or electronic.

**IQC**: Internal Quality Control is the System specific control materials of known values that are run concurrently with test specimens to determine if a procedure is valid and consistently generate expected results.

**Client:** Any individual/organisation who employs the services of the laboratory

**Clinical and Laboratory Standards Institute (CLSI):** Is a not-for-profit organisation that develops laboratory standards worldwide. Their standards are recognized by laboratories, accreditors, and government agencies as the best way to improve medical laboratory testing.

**Quality Policy:** The overall quality intentions and direction of the laboratory with regard to quality, determined by top management.

**Quality Objectives**: Objectives or goals, related to quality.

**Quality Management System (QMS):** is a formalised system that documents the structure, responsibilities and procedures required to achieve effective quality management.

**Quality Management:** is the application of a quality management system in managing a process to achieve maximum client satisfaction at the lowest overall cost to the organisation while continuing to improve the process.

**Quality procedures:** Written instructions for implementing various components of the QMS.

**Quality Plan:** The typical form of the main document used in developing and implementing QMS. The Quality Plan should contain the Quality Policy, objectives, and written procedures.

**Quality Programme:** The coordinated execution of applicable Quality Plans and activities for a project.

**Quality Control (QC):** Techniques that are used to assure that a product or service meets requirements and that the work meets the product or service goals. Generally, QC refers to the act of taking measurements, testing, and inspecting a process or product to assure that it meets specification.

**Quality Assurance (QA):** Involves all those planned and systematic actions necessary to provide adequate confidence to the management that a product or service will satisfy given requirements for quality.

**Quality Oversight**: this can be defined as watchful care or general supervision. Quality oversight can range from an informal process of keeping in touch with the QA organisation to a second layer of QA activities, depending upon the circumstances. Quality oversight verifies the execution of the Quality Program.

**Quality Audit:** A documented activity conducted to access the performance/implementation of QMS by evaluating conformance to applicable standards.

**Quality System Essentials (QSEs):** The quality system essentials (QSE) are the building blocks of QMS and are 12 in number. All 12 QSEs must be included in the QMS to assure accurate, reliable, and timely laboratory results.

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# CHAPTER 1: INTRODUCTION

## 1.1 Background

The term "Quality Management System" and the acronym "QMS" was first introduced as far back as 1991 by Ken Croucher, a British management consultant. Since then, it has been recognized and implemented widely as a business requirement and compliance parameter to ensure quality. According to the International Standard Organization (ISO), Quality Management System is a formalised system that documents processes, procedures and responsibilities for achieving quality policies and objectives. It helps to drive impressive gains in quality, client satisfaction and meeting requirements.

Medical laboratories are essential components of quality health care service delivery. It provides timely and accurate information about people's health through risk assessment, screening, diagnosis, treatment selection, monitoring of treatment response, disease surveillance programmes and clinical research in a country. The framework that would promote this, must ensure quality in all aspects of the laboratory operation. While the significance of Medical laboratory services in evidence-based medicine cannot be overemphasised, especially with the emergence and re-emergence of infections believed to have been effectively controlled, quality service is the goal.

The implementation of a Laboratory Quality Management System (LQMS), a key intervention to strengthen laboratories, was marked as a priority by the World Health Organization ((WHO) Maputo, 2008). This led to the development of the WHO AFRO Strengthening Laboratory Management Toward Accreditation (SLMTA) and Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) programmes. Nigeria commenced training and implementation in 2009.

Implementing a QMS helps to prevent mistakes from occurring, or at most, limits the risk of errors occurring. This system provides the framework to ensure consistency in the delivery of laboratory services. QMS implementation in Nigeria started in 2004 a year after the coming of PEPFAR in Nigeria, however implementation was not properly coordinated.

Records available to the Federal Ministry of Health indicate that 4,000 medical laboratories are registered as of June 30th, 2023 out of which about 20% are implementing QMS and 0.35% (14) has achieved accreditation to ISO 15189:2012.

Medical Laboratory services in Nigeria are grouped into three levels of service which are primary, secondary and tertiary. There are also reference and research laboratories that provide specialised services. Laboratory could either be a stand-alone or within Hospitals/Institutions.

Quality laboratory services are key to quality healthcare services and achieving Universal Health Coverage (UHC). Currently, there is no national guideline to provide guidance and uniformity in QMS implementation in Nigeria.

This document is to support laboratories in implementing QMS and meet the requirements of the national, regional and international standards.

Following the gap identified by the National Laboratory Technical Working Group (NLTWG) during the assessment on implementation of the Nigerian National Medical Laboratory Service policy (NNMLSP) and National Medical Laboratory Strategic Plan (NMLStP). The Government of Nigeria (GoN) realize the need for the development of the National Medical Laboratory Quality Management System (NMLQMS).

With support from Resolve to Save Lives (RTSL) through Institute of Human Virology Nigeria (IHVN), the MLSD organised series of document development workshops that involved engagement of subject matter experts and other stakeholders for the development, review, finalization and production of the NMLQMS Guideline.

## 1.2 Scope

This document applies to all medical laboratories at all levels of health care service delivery in Nigeria. It provides guidance for implementing quality management systems based on ISO 15189:2022.

## 1.3 Objective

The primary objective of these guidelines is to institutionalise and strengthen QMS in laboratory practice.

The specific objectives are as follows:

I. To create a roadmap for the implementation of a Medical Laboratory quality management system across the country.

II. To strengthen, improve and sustain QMS practice in Laboratories already implementing QMS

III. To address critical gaps in LQMS implementation

IV. To provide working tool for laboratories toward achievement of ISO 15189 accreditation

## 1.4 Applicable Standards Relevant to Laboratory QMS in Nigeria

There are a number of international and national standards that have been developed for medical laboratory QMS implementation. Depending on the type of laboratory, one or more standards may apply. A laboratory is expected to understand the scope of its operations and apply the necessary

standard(s). The table below describes some of the applicable standards for QMS implementation in laboratories and has been given as a guide.

| **Standard** | **Brief** |
|---|---|
| ISO 15189:2022 | Medical laboratory requirements for quality and competence. This standard specifies requirements for quality and competence in medical laboratories. |
| NIS ISO 15189: 2019 | Medical laboratories - This standard includes all the requirements that medical laboratories in charge of human biological sample analysis must comply to guarantee that they:<br>i. have a quality management system.<br>ii. are technically competent.<br>iii. have the capacity to produce technically valid results. |
| ISO/IEC 17025:2017 | This was developed for laboratories that perform calibration or testing. It enables the calibration performing laboratory to prove accuracy in results. This helps to increase client trust around the world and harmony among all laboratories. |
| ISO 17043: 2023 | Conformity assessment- General Principles for proficiency testing |

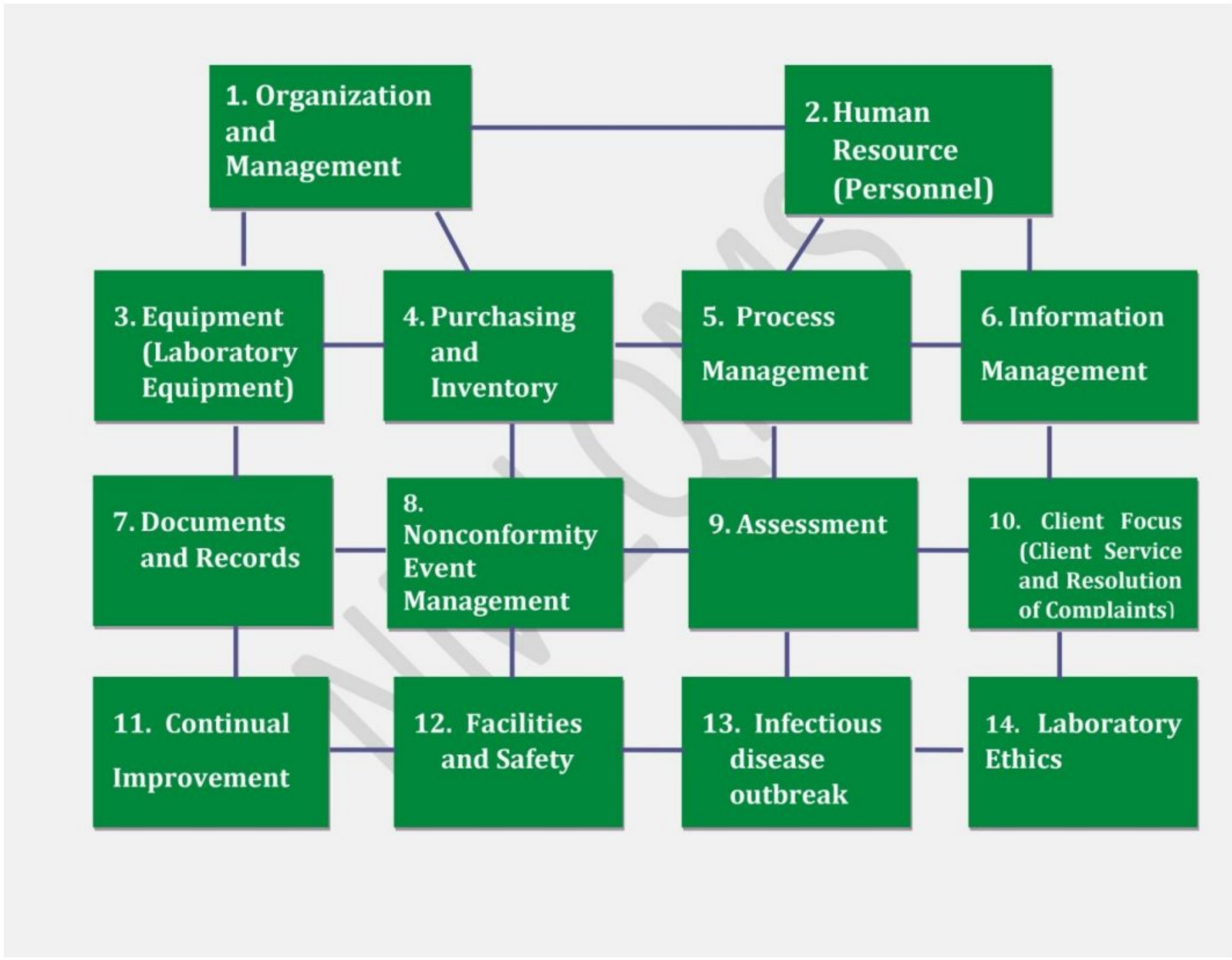
| | |
|---|---|
| ISO 35001:2019 | Biorisk management for laboratories and other related organisations. This document defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials. |
| ISO 15190:2020 | Medical laboratories requirements for safety. This standard specifies requirement for safe practices in medical laboratories. |
| ISO 13528: 2015 | Statistical methods for use in proficiency testing by inter-laboratory comparison. |
| ISO 19011:2018 | Guidelines for quality and/or environmental management system auditing |
| NIS ISO 9001: 2015 | Quality Management Systems - requirements |
| ISO 9000:2015 | Quality Management System - fundamentals and vocabulary |

This NMLQMS Guidelines is based on ISO 15189:2022 standard.

## 1.5 The Quality Management System Requirements

Establishing an effective QMS in a laboratory involves meeting requirements defined in ISO 15189 standards. For the purpose of national implementation, Nigeria has adopted Quality System Requirements (QSRs) derived from ISO 15189 standard, CLSI 12 QSEs and ISO 15190. This will provide organisational basics that guide all operations in the delivery of quality laboratory services. These requirements is developed as a framework of fourteen (14) QSRs as illustrated in **Figure 1** and outlined below**.**

**Figure 1: NMLQMS** framework of fourteen (14) QSRs




1. Organization (Organization and Management)
2. Human Resource (Personnel)
3. Equipment (Laboratory Equipment)
4. Purchasing and Inventory
5. Process Management (Managing Laboratory Specimens)
6. Information Management
7. Documents and Records
8. Nonconformity Event Management (Occurrence Management)
9. Assessment

10. Client Focus (Client Service and Resolution of Complaints)

11. Continual Improvement

12. Facilities and Safety

13. Infectious disease outbreak

14. Laboratory Ethics

The Medical Laboratory as an organisation performs activities that are categorized into pre-analytical, analytical, and post analytical phase. Each of these captures various activities as part of the laboratory's operations to provide services.

- The **Pre-analytical phase** involves crucial first step activities that lead to a biological sample being collected for testing. A laboratory result is as good as the sample collected. This underscore the need to strengthen pre-analytical steps to ensure that the *right* patient is attended to, the *right* sample is collected at the *right*t time into the *right* container, appropriately handled by a trained and competent personnel according to Standard Operating Procedure (SOP). If there is an error occurring in the pre-analytical phase then this can compromise the quality of the result.

- The **Analytical phase** involves the actual performance of the laboratory test, i.e. the measurement of the analyte and the validation of the result.

- **The Post-analytical phase** involves review, report and release of laboratory test results.

## 1.6 Principles of QMS

QMS implementation is a work culture that is not separated from the day-to-day activities in a laboratory. Principles of QMS include the following:

- **Leadership** - Strong leadership from all levels of the workforce in the laboratory is essential to implementing a QMS. Leadership is not limited to those in positions of authority, but it should be instilled that everyone in the laboratory has a responsibility to provide leadership.

- **Strategic Quality Planning** - QMS involves establishing a vision for what the laboratory should look like and mission on how it should operate. Strategic quality planning is an essential aspect of QMS because it is the foundation on which all the visioning, planning and execution is laid.

- **Focus on client satisfaction** - QMS involves clearly identifying internal and external clients as well as their needs and requirements, and making decisions that support the laboratory's commitment to meet those requirements.

- **Teamwork and employee participation** – Implementing QMS requires teamwork and participation of all employees to ensure that the laboratory meets all its quality requirements.

- **Training and Development** – Training and continuous professional development of laboratory staff is crucial to QMS implementation. All staff should receive basic and advanced training to enable them to fulfil their managerial and technical responsibilities in the laboratory.

- **Clear communication**- Clear line of communication within the laboratory is essential to QMS implementation.

## 1.7 Possible Barriers to QMS Implementation and Suggested solutions

The barriers to implementation of QMS and suggested solutions to overcome them include the following:

1. **Lack of commitment by the top Management** - Management support and leadership is critical to the implementation of QMS in a laboratory. The Management sets the direction for the laboratory, provides resources and inspires the attitudes that drive their individual teams. This commitment should be visible in the laboratory.

**Suggested solutions**

a. Advocacy and stakeholder engagement to ensure key individuals in management positions understand the concept of quality and its benefits when implemented in laboratory settings.

b. Training and re-training for managers should be available and they should be educated on the benefits of focusing on quality and the need to keep encouraging staff to embrace it.

c. Providing information materials that break down the complex QMS processes so that they are better understood by all.

2. **Cost of Quality** - Implementing QMS can be expensive and time consuming.

**Suggested solutions**

a. Life cycle costing should be used to evaluate cost of activities, rather than simply using activity costs. This ensures that the laboratory is able to consider the total cost to implement activities over a particular life cycle (e.g annually) to ensure activity continuity.

b. Staff should be educated on QMS activities as part of the routine expectations for their roles. Quality should be a way of life for all laboratory staff.

3. **Resistance to change** - many people and organisations are apprehensive to change, and consequently are slow to adapt to or accept new systems. In some severe cases, staff may be so averse to change that they thwart every effort to implement new systems. It is the responsibility of management to ensure they carry all staff in the laboratory along so much so that change is welcome and championed by everyone.

**Suggested solutions**

i. Decide to implement QMS

ii. Work with recognized laboratory and facility leadership.

iii. Treat people with respect and dignity.

iv. Carry every staff of the laboratory along in all QMS implementation activities, from the most junior to the most senior member of the team.

v. Start with quick wins that can be used to easily and effectively communicate the gains of implementing QMS in the laboratory.

vi. Avoid (as much as possible) surprises that can negatively affect QMS outcomes.

vii. Deal directly and timely with any and all resistance from staff as they occur.

4. **Lack of training** – an effective QMS involves all laboratory staff at all levels receiving basic to advanced training in different aspects of QMS. Every staff of the laboratory should be trained periodically so that they have a full understanding of what their roles are in implementing QMS in the laboratory:

**Suggested solutions**

a. Include costs of QMS training in the life cycle cost analysis (e.g annual budgets) of the laboratory operations.

b. Maintain a pool of resource persons and plan periodic training in such a way that training resource persons are given enough time to provide services.

c. Create opportunities for staff to engage in QMS training and for them to be able to leverage these training for personal and career development.

d. Advocate and encourage training institutions and regulatory agencies to include QMS training as part of the teaching/training curriculum.

## 1.8 Implementation Guide

This guideline has been prepared for all medical laboratories in Nigeria as a means to support the nationwide implementation of quality management systems, not just a series of isolated events or activities.

Medical Laboratories should use these guidelines to develop their Quality Plans. To develop and implement an effective QMS the laboratory staff should:

1. Read these guidelines in order to understand what a QMS entails.
2. Seek advice and mentorship from trained QMS mentors.
3. Get acquainted with national and relevant ISO standards for the laboratory operations.
4. Collect resource materials that may be useful and applicable.
5. Review the examples provided in the appendix to this document.
6. Start QMS implementation in the laboratory following the direction of these guidelines and the applicable elements.

# CHAPTER 2: ORGANISATION AND MANAGEMENT

## 2.1 Preamble

Organisation and management describe organisation's structure, roles and responsibilities in laboratory management.

## 2.2 Requirements:

### 2.2.1 Legal Entity:

All laboratories including those attached to an organisation (Hospitals, schools, research centres, companies, etc) must be legally registered with the appropriate national and state regulatory authorities in Nigeria.

*Reference: Explanatory note clause: 5.1 Legal entity*

### 2.2.2 Organisational Structure:

There should be a clearly defined laboratory structure that describes the leadership/managerial roles and responsibilities, communication and information flow as well as internal and external reporting relationships. This structure should be described in an organogram.

*Reference: Explanatory note clause: 5.2 Laboratory Director*
*Reference: Explanatory note clause: 5.4 Structure and authority*

### 2.2.3 Management Responsibilities

Laboratory management should provide the policy and strategic direction for the design, implementation, maintenance, and improvement of the quality management system. This should include maintaining up-to-date laboratory quality manual, quality objectives, developing relevant policies, processes and procedures for the laboratory. The laboratory should have an established Laboratory QMS committee and provide required resources for the committee to perform its responsibilities.

*Reference: Explanatory note clause: 5.0 Structure and Governance requirements*

### 2.2.4 Communication: Internal and External Communication

Management should develop an effective means of communicating with staff, users and relevant stakeholders and maintain relevant records.

*Reference: Explanatory note clause: 5.4 Structure and authority*

# CHAPTER 3: PERSONNEL (HUMAN RESOURCES)

## 3.1 Preamble

Personnel are the most important resources, as every other resource is driven by personnel. There should be an adequate number of personnel with respect to the scope and volume of work performed. All staff members should possess requisite qualifications, skills and required licensure for assigned tasks.

## 3.2 Requirement:

### 3.2.1 Job Description:

Clearly assign documented job description to every staff which should be read, understood, accepted and signed by individual staff.

### 3.2.2 Personnel Orientation:

Conduct staff orientation for all new employees within the period stipulated in the laboratory Policy. The orientation should include comprehensive training on QMS, policies, procedures and assigned responsibilities that apply to their job description and assignments.

### 3.2.3 Training:

The Laboratory should develop a training programme/plan which includes training and retraining for all personnel on assigned work processes and procedures, QMS, laboratory information system, health and safety, ethics, confidentiality, etc.

### 3.2.4 Competence Assessment:

Assess staff competency as specified in the laboratory policy.

### 3.2.5 Review/Evaluation of staff performance:

Conduct staff performance evaluation periodically or at least annually based on the laboratory policy. The Management should decide the tool that best fits its requirements which should cover efficiency, adherence to policies, communication skills, client service, punctuality, and professional behaviour.

### 3.2.6 Continuing Education and Professional Development:

Develop and implement a continuing educational and professional development programme for staff. Encourage staff to participate in personal development programmes that can impact positively on their job descriptions.

### 3.2.7 Personnel records:

Maintain records of all relevant educational and professional qualifications, training, experience, and assessment of competence of all personnel.

### 3.2.8 Occupational Health and Safety/Medical Surveillance:

Provide pre-employment medical, mental and physical assessment of all laboratory personnel as required. Adequate vaccination for at-risk diseases should be enforced and staff records updated accordingly.

### 3.2.9 Staff Motivation/Retention:

The laboratory should provide a programme for staff motivation and retention.

*Reference: Explanatory note clause: 4.2.3 Personnel responsibility*
*Reference: Explanatory note clause: 6.2 personnel*

# CHAPTER 4: LABORATORY EQUIPMENT, REAGENT AND CONSUMABLES

## 4.1 Preamble

Laboratory equipment, reagent and consumables must be adequately managed to ensure non-interruption of services in the laboratory.

## 4.2 Requirements:

### 4.2.1 Equipment

The Laboratory should develop and implement a good equipment management program that is necessary to ensure uninterrupted, accurate, reliable and timely testing.

*Reference: Explanatory note clause: 6.4 Equipment*
*Reference: Explanatory note clause: 6.5 Equipment calibration and metrological traceability*

### 4.2.2 Reagents and Consumables

The laboratory should develop and implement a program for management of reagents and consumables.

*Reference: Explanatory note clause: 6.6 Reagents and Consumables*

# CHAPTER 5: PURCHASING AND INVENTORY

## 5.1 Preamble

Efficient and cost-effective medical laboratory operations depend on uninterrupted availability of reagents, supplies and services. Laboratories should maintain a list of approved suppliers and set requirements for managing reagents and consumables to function efficiently and maintain continued quality of services provided.

## 5.2 Requirement:

Develop and implement purchasing and inventory management procedure for evaluation and selection of suppliers, competitive bidding and purchase of reagents and consumables, acceptance and rejection criteria for consumables, managing related complaints, store management, management of expired items/disposal and maintenance of appropriated records.

Note: Purchasing of all laboratory equipment, reagents and consumables in public laboratories should be in line with the provisions of the Procurement Act 2007

*Reference: Explanatory note clause: 6.4 Equipment*
*Reference: Explanatory note clause: 6.6.4 Reagents and consumables; Inventory management*
*Reference: Explanatory note clause: 6.8; 6.8.1 Externally provided products and services*

# CHAPTER 6: PROCESS MANAGEMENT

## 6.1 Preamble

Medical laboratory processes are broadly categorised to pre-analytical, analytical and post-analytical which is otherwise known as Path of Workflow (PoW). These processes should be designed to ensure optimal workflow of laboratory operations. The operational processes should be developed and regularly assessed to identify risks to patient care and relevant actions taken to redesign and ensure the process meets expectations.

## 6.2 Requirements:

### Pre-Analytical Phase:

Develop and implement procedures for managing pre-analytical phase to include Information for Patients and Users, laboratory request form, sample collection and handling, sample transportation, sample storage and sample rejection and acceptance criteria

### Analytical Phase

The laboratory should develop and implement procedures for all analytical processes which include the actual performance of the laboratory test, i.e. the measurement of the analyte and the validation of the result.

### Post-Analytical Phase

Develop and implement procedures for all post-analytical processes to include review of examination results, content of patient examination reports, specimen retention and archiving and specimen disposal.

*Reference: Explanatory note clause: 7.0 Process requirements*

# CHAPTER 7: DOCUMENTS AND RECORDS

## 7.1 Preamble

Documents are written, printed or electronic materials that provide information on policies, processes and procedures in the laboratory.

Records are information generated by the laboratory in the process of performing and reporting activities such as test results/reports, quality control records, audit reports.

## 7.2 Requirements:

### 7.2.1 Documents:

Develop documents required for all activities by skilled and competent personnel which should be authorised, reviewed when appropriate, retrieved and archived when obsolete and disposed after expiration of an established retention period.

*Reference: Explanatory note clause: 8.2 Management system documentation*
*Reference: Explanatory note clause: 8.3 Control of management system documents*

### 7.2.2 Records:

Records of all activities performed in the laboratory should be collected using appropriate tools such as registers, forms, logs, checklists etc, stored in a secured location, maintained and protected from damage and unauthorised access

*Reference: Explanatory note clause: 6.6.7 Reagents and consumables-Records*
*Reference: Explanatory note clause: 8.4 Control of records*

# CHAPTER 8: INFORMATION MANAGEMENT

## 8.1 Preamble

Information management is the system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data. Information in the laboratory can either be paper or electronic-based and are managed using appropriate tools as established by the laboratory.

## 8.2 Requirements:

The laboratory should develop and implement a procedure for managing laboratory information which include selection of appropriate tools for collection and storage, assigning authorities and responsibilities, maintaining the tools, developing a backup system and ensuring confidentiality.

*Reference: Explanatory note clause*: *7.6 Control of data and information management*

# CHAPTER 9: MANAGEMENT OF NON-CONFORMING EVENTS

## 9.1 Preamble

Non-conformity is defined as a non-fulfilment of a requirement. A non-conforming event (NCE) occurs when there is a deviation from established policies, processes and procedures, ISO standard or when a product or service does not meet the client's expectations.

The purpose of NCE management is to capture and analyse information from non-conforming events, to identify systemic problems and gain management's commitment to removing the cause of the non-conformity.

## 9.2 Requirements

Develop and implement a procedure for management of nonconforming events which should include, identification and documentation of NCEs, analysis of NCEs, investigation of NCEs, correction of NCEs, prevention of potential NCEs and monitoring the effectiveness of corrective or preventive actions.

*Reference: Explanatory note clause: 6.6.6 Reagents and consumables-Adverse incident reporting*
*Reference: Explanatory note clause: 7.5 Nonconforming work*
*Reference: Explanatory note clause: 8.7 Nonconformity and corrective actions*

# CHAPTER 10: ASSESSMENTS

## 10.1 Preamble

Assessment is evaluating what is being done, how it complies with written policies, procedures and standard requirements. Assessments are integral to achieving an effective QMS which can either be internal or external. Through these, laboratories can determine whether or not they are compliant with requirements. Assessment can be in the form of audit, inspection, management review and external quality assessment.

## 10.2 Requirements

### 10.2.1 Internal Assessment

Internal assessments are activities carried out by the laboratory to evaluate and improve QMS implementation. These include, internal audit, quality risk assessment etc.

Develop and implement an internal assessment program which should include the development of procedures for internal assessment, identification and training of assessors, development of assessment tools, development of assessment plan, conduct assessment, documentation of assessment report, review of assessment report, implementing corrective action, follow-up and closure of assessment.

### 10.2.2 Management Reviews:

The laboratory management should conduct a management review of the quality management system at planned intervals (minimum once a year) to ensure continuous suitability, adequacy, effectiveness and support for patient care.

### 10.2.3 External Assessment

External assessments are activities conducted by organizations and individual outside the laboratory, to evaluate the effectiveness of the laboratory's QMS. The assessment can be carried out by regulatory, supervisory, accreditation bodies and non-governmental organisations. Develop and implement programs for laboratory preparation and participation in external assessment activities. Report of external assessment activities should be reviewed and corrective action taken for identified nonconformity.

### 10.2.4 External Quality Assessment

The laboratory should develop and implement a programme for participation in EQA. This should include enrolment of test menu into recognized EQA programme participation, review of EQA reports and implementation of corrective action when necessary.

*Reference: Explanatory note clause: 7.3.7.3 External quality Assessment*
*Reference: Explanatory note clause: 8.8.3. Internal audits*
*Reference: Explanatory note clause: 8.9 Management reviews.*

# CHAPTER 11: CLIENT FOCUS (CLIENT SERVICE AND RESOLUTION OF COMPLAINTS)

## 11.1 Preamble:

This describes the medical laboratory's need to identify its clients, their expectations, and to design a framework that meets those expectations. It also describes methods to evaluate clients' satisfaction. Laboratory clients include healthcare providers, patients and the general community.

## 11.2 Requirements:

### 11.2.1 Identification of Client expectation and feedback

Develop and implement programme for identification of clients, identification of clients' needs and expectations, provide the relevant services based on needs and expectations, assessment of clients' satisfaction, analyse feedbacks and utilise feedbacks to improve clients' satisfaction.

### 11.2.2 Handling and resolution of complaints

Develop and implement programme for receiving clients' complaints, review and evaluate complaints, investigate complaints, address complaints, evaluate effectiveness and provide feedbacks to clients when necessary.

*Reference: Explanatory note clause: 8.6.2 Laboratory Patients, users, and personnel feedback*
*Reference: Explanatory note clause: 7.7 Complaints*

### 11.2.3 Advisory services to clients

Develop and implement procedure for assigning responsibilities for providing professional advice, documented information to clients (client handbook) and notifying clients on delays in services or service interruption.

*Reference: Explanatory note clause: 5.2.3 Delegation of duties*
*Reference: Explanatory note clause: 5.3.3 Advisory activities*

# CHAPTER 12: CONTINUAL IMPROVEMENT

## 12.1 Preamble

Continual improvement is an ongoing effort to improve the effectiveness of the quality management system in all aspects of the laboratory activities, including the pre-examination, examination and post-examination processes. Continual improvement ensures that laboratory processes are measured, monitored, and improved.

## 12.2 Requirements:

### 12.2.1 Steps for continual improvement

Develop a program for identification and selection of opportunities for improvement, implement improvement activities using appropriate tools and evaluate effectiveness of improvement activities

*Reference: Explanatory note clause: 8.6.1 Continual improvement*

### 12.2.2 Quality Indicators

Quality indicators are metrics selected to monitor performance of a system. It provides laboratory management with evidence on the degree to which laboratory is meeting quality goals. A laboratory should establish a program to identify/select quality indicators, monitor against set targets, review performance and develop action plan to address gaps.

*Reference: Explanatory note clause: 5.5 (d) Objectives and Policies*
*Reference: Explanatory note clause: 8.8.2 Quality indicators*

# CHAPTER 13: FACILITIES AND SAFETY

## 13.1 Preamble

The medical laboratory facility comprises space allocated for testing, offices, storage, patient waiting area, call room and meeting/common rooms. These spaces should be adequate based on the scope and volume of work performed in the laboratory. The laboratory facility should be designed to ensure optimal workflow, as well as the safety of staff, clients and the environment.

## 13.2 Requirements

### 13.2.1 Laboratory design:

Laboratories should develop and implement a procedure to assess the suitability of the laboratory space based on relevant regulatory guidelines and international standards.

### 13.2.2 Laboratory Safety programme

The laboratory should develop a safety programme that addresses chemical safety, bio safety, bio security, occupational health, waste management, electrical/fire safety, mechanical safety, and radiation safety.

*Reference: Explanatory note clause: 6.3 Facilities and environmental conditions*
*Reference: ISO 15190:2020 Medical Laboratory requirement for safety*

### 13.2.3 Emergency management:

The medical laboratory has both regulatory obligations and ethical responsibilities to its patients and its staff during an emergency. These responsibilities include preventive measures (when possible), and measures to facilitate quick recovery from such an event. With careful preparation, planning, and regular drill, a comprehensive laboratory emergency management plan can ensure that those responsibilities are fulfilled. Given the wide variety of possible emergencies that may occur in the laboratory, it may seem impossible to be prepared for every type of event that could occur. However, it is imperative that every laboratory should have an emergency response plan.

*Reference: Explanatory note: 7.8 Continuity and emergency preparedness planning*

# CHAPTER 14: INFECTIOUS DISEASE OUTBREAK ALERT

## 14.1 Preamble

Infectious disease outbreak is a sudden rise in the number of cases of a disease in excess of the normal expectancy of the disease. The number of cases varies according to the disease-causing agent, the size and type of previous and existing exposure to the etiological agent. Laboratories should be prepared at all times to detect an outbreak and alert the relevant authorities.

## 14.2 Requirements:

Develop a programme that detects and alerts disease outbreaks with special consideration to the following;

i. Awareness of pathogens of diseases of public health importance.

ii. Mechanisms for specimen collection and transfer need to be established for both national and international levels.

iii. Availability of the capacity/resources (facility, personnel, equipment, reagents and/or conventional or rapid tests) to address disease outbreaks.

iv. Appropriate levels of safety should be taken during sampling and testing. Personal Protective Equipment (PPE) should be selected and worn based on risk assessment of the infectious agent/disease.

v. Access the list of national and sub national laboratories that are part of the national surveillance and response system.

vi. Utilisation of the national standardised surveillance reporting system for priority diseases including reporting form and/or software for laboratory data created by FMoH.

vii. A system for reporting data in a timely manner should be put in place in case of disease outbreak.

viii. The contact of state Disease Surveillance and Notification Officers (DSNOs)/ State Epidemiologists should be available for the notification of laboratory results.

*Reference: Explanatory note clause: 7.8 Continuity and emergency preparedness planning*

*Reference: Integrated Disease Surveillance and Response (IDSR) Technical guideline*

# CHAPTER 15: LABORATORY ETHICS

## 15.1 Preamble

Laboratory ethics describes the codes of conduct or principles that guide the personnel in the course of their professional practice.

## 15.2 Requirements:

The laboratory should adopt the relevant ethical code of conduct that covers general operational ethics and professional practice such as**:**

i. confidentiality of information

ii. data protection

iii. operational integrity and judgement.

iv. undue commercial, financial or other pressures.

v. declaration of any potential conflict of interests in treatment of samples, tissue or remnant in accordance with relevant legal requirements.

The laboratory should ensure that staffs at all levels are trained on ethical code of conducts. Ethics should be included as part of orientation for new staff.

*Reference: Explanatory note clause: 4.1 Impartiality*
*Reference: Explanatory note clause: 4.2 Confidentiality*
*Reference: Rules of the Professional Conduct for Medical Laboratory Scientist, Laboratory Technicians and Laboratory Assistants, 2018.*

# CHAPTER 16: HOW TO USE THIS GUIDELINE.

## 16.1 Preamble:

The approved guideline will be disseminated at all levels and the Ministry will engage with relevant stakeholders to ensure appropriate implementation accordingly.

A stepwise approach should be employed in the implementation of this guideline. There should be supervision of LQMS implementation at facilities through annual oversight or supportive supervisory visit to facilities under the guidance of the Ministries of Health.

## 16.2 National level

### 16.2.1 Requirements:

The Medical Laboratory Services Division (MLSD) of the Federal Ministry of Health takes the driving seat and coordinates laboratory QMS activities in the country, making sure the guidelines and the strategic objectives are translated into actions. MLSD is responsible for the following:

i. Create a LQMS unit

ii. Collaborate with the relevant Regulatory Agency and other bodies to ensure the implementation of this guideline

iii. Designate and empower the following key officers with appropriate resources to carry out their responsibilities:

   a. National Medical Laboratory Quality Officer

   b. National Medical Laboratory Information Management System Officer

   c. National Medical Laboratory Bio safety Officer

## 16.3 State level

### 16.3.1 Requirements:

Guidelines and policies are processed through the national council of health adoption by states. The head of laboratory services of the State Ministry of Health takes the lead to coordinate the Laboratory QMS implementation in all laboratories in the State. Designates and empowers the key quality management and safety officers with appropriate resources to carry out their responsibilities.

## 16.4 Facility Level (Tertiary, Secondary, Primary)

### 16.4.1 Requirements

Based on the agreed plan for the implementation of quality standards as contained in this guideline, a stepwise approach is suggested but each facility must determine how to implement. For a laboratory to implement QMS, every person in the laboratory must participate. This includes members of senior management, technical and non-technical staff, consultants, contractors, vendors and suppliers.

## 16.5 QMS implementation process:

i. Top Management must commit to the process

ii. Laboratory quality objectives must be defined and followed

iii. Client expectations must be clearly defined and followed

iv. Data related to the laboratory's services and operations must be collected appropriately and periodically, analysed and used for process and service improvement

v. Mechanisms must be put in place for feedback to the responsible managerial, technical and non-technical staff, consultant, vendors, clients etc.

vi. The steps for QMS implementation are captured in appendix 1

## 16.6 Monitoring and Evaluation Plan

As QMS is implemented in the laboratories, relevant stakeholders should develop an M&E framework to monitor implementation at the facility level. The M&E framework should be part of the planning phase before implementing QMS. This framework will serve as the foundation for informed, data-driven decision-making; support a holistic and adaptive management strategy based on identified challenges; track progress toward defined goals across all tiers of laboratories; and establish an accountability system for relevant stakeholders.

### 16.6.1 Key Performance Indicators for LQMS

Below are some indicators used for monitoring the LQMS;

i. Number of medical laboratories with released operational budgets.

ii. Number of medical laboratories participating in an EQA programme

iii. Number of medical laboratories with an acceptable EQA score

iv. Number of medical laboratory personnel trained on LQMS based on training need identified.

v. Number of medical laboratories that have record of annual internal audit report

vi. Number of medical laboratories implementing QMS

vii. Number of medical laboratories Registered

viii. Number of medical laboratories accredited.

### 16.6.2 Scope of M&E Framework

| S/N | Entity | Roles & Responsibilities | Deliverables |
|---|---|---|---|
| 1 | FMOH-MLSD | Provide oversight, coordination, resource mobilization/allocation, and strategic guidance. | • Develop M&E tools and indicators<br>• Conduct national performance reviews<br>• Maintain QMS implementation database<br>• Validate reports from state level |
| 2 | SMOH | Coordinate laboratory QMS implementation across state facilities. | • Conduct state-level supportive supervision<br>• Collate data from facilities<br>• Submit quarterly M&E reports to FMoH |
| 3 | Facility (Tertiary, Secondary, Primary) | Implement QMS practices and track operational indicators. | • Conduct internal audits and self-assessments<br>• Submit monthly/quarterly reports to SMoH<br>• Track indicators using checklists and tools |

Learning and adaptation will leverage on the following:

i. Routine review meetings at national and state levels to interpret M&E data.

ii. Dissemination of lessons learned and best practices through QMS bulletins and workshops

iii. Adaptive revisions to the guideline and tools based on findings.

### 16.6.3 Data Collection Tools

The following tools will be deployed at facility and state level (as the case may be) to ensure that all dimensions of data quality (Validity, Integrity, Reliability, Timeliness, Confidentiality and Precision) are adhered to.

- LQMS Supportive Supervision Checklist
- Internal Audit Reporting Tool
- Training Tracker
- EQA Participation Monitoring Template
- Facility QMS Scorecard (based on SLIPTA)

### 16.6.4 Data Flow

i. Facilities compile M&E data monthly and submit to SMoH Lab Focal Persons.

ii. States aggregate and validate facility data, then forward quarterly reports to MLSD/FMoH.

iii. MLSD maintains a central database, conducts periodic analysis, and produces national reports.

### 16.6.5 Evaluation Strategy

| S/N | Evaluation Type | Timeline | Purpose |
|---|---|---|---|
| 1 | Baseline assessment | At the commencement of QMS implementation | To establish current capacity and gaps |
| 2 | Mid-term review | Halfway into implementation | Assess implementation progress, address bottlenecks |
| 3 | Endline evaluation | After implementation is concluded | Measure overall impact, inform scale-up and policy |

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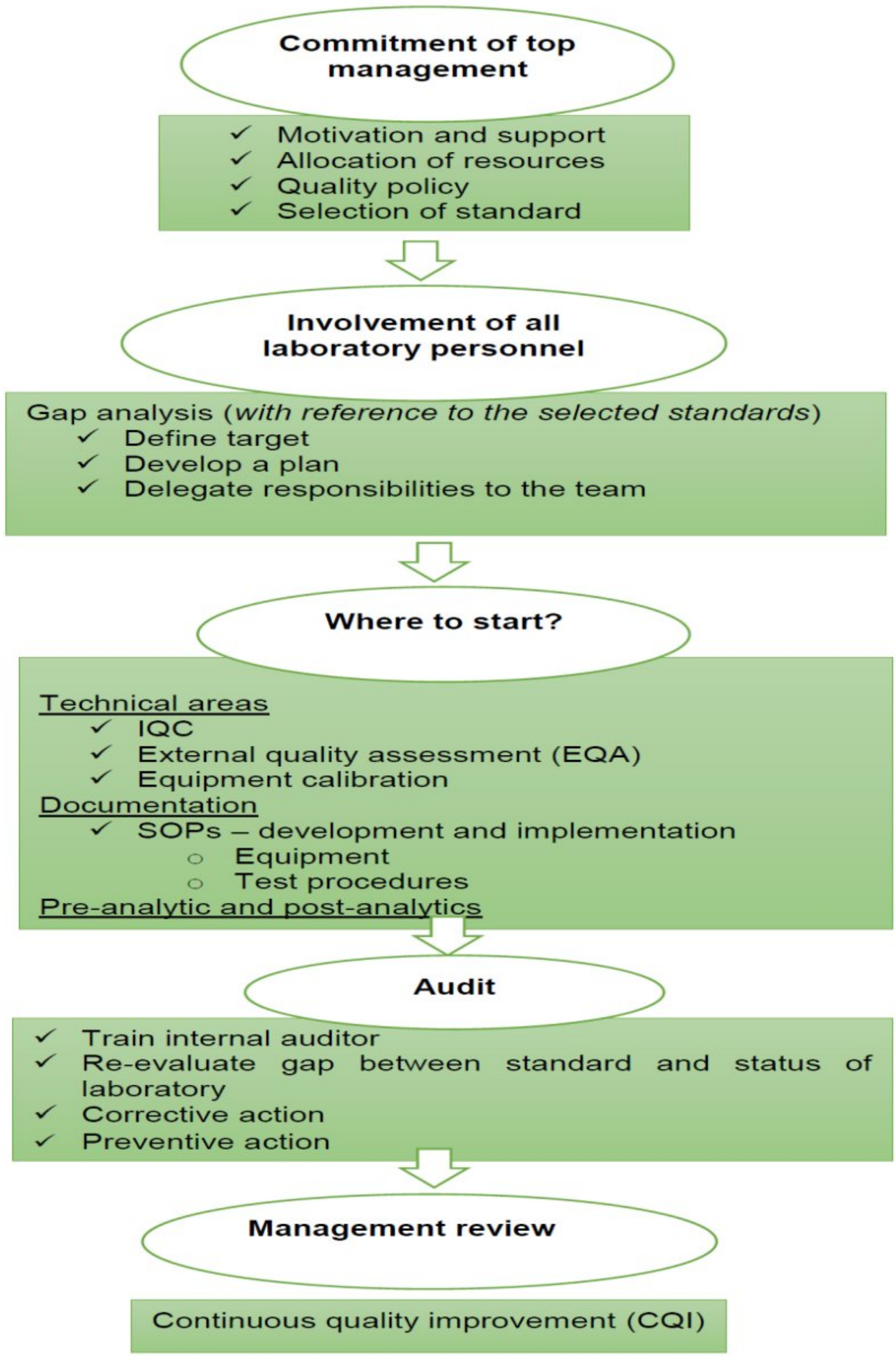


Appendix 1: Models of QMS (Flow chart)

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| 114 | Zubair Kabiru | FTH LOKOJA |

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|---|---|---|
| 115 | Kingston Omo-Emmanuel | USAID |