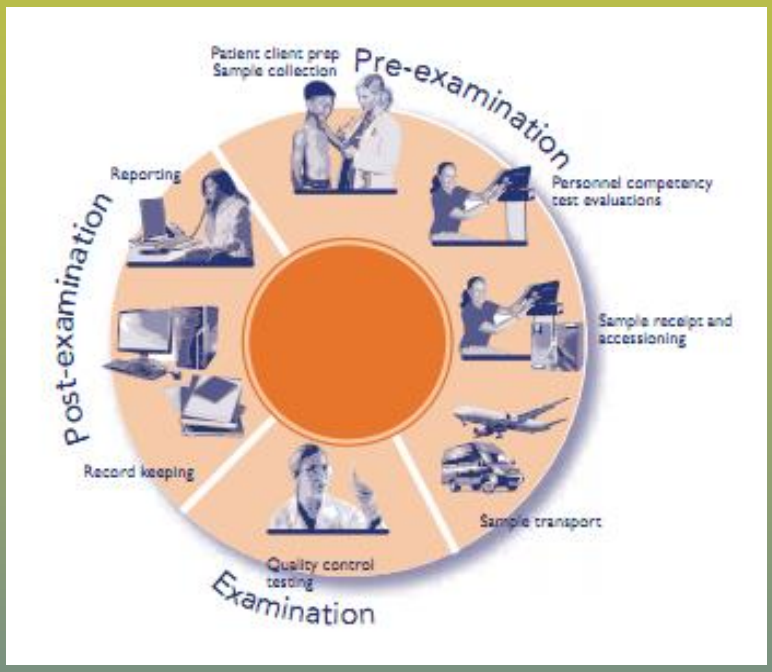
GUIDELINES FOR THE IMPLEMENTATION OF HEALTH LABORATORY QUALITY MANAGEMENT SYSTEM IN ETHIOPIA



Ethiopian Public Health Institute

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Foreword

Health laboratory services are an essential component and the backbone of a strong, functional, and resilient national health system. They are indubitably crucial in providing quality healthcare services by accurately diagnosing diseases and assisting clinicians in developing evidence-based care and treatment plans, monitoring treatment effects, and making timely prognoses of potential outcomes. Health laboratories play a vital role in epidemiological surveillance, prevention, control, and eradication of infectious diseases. An informed and effective response to disease outbreaks of epidemic or pandemic proportions is impossible without the support of health laboratories. Furthermore, undertaking basic biomedical and public health researches would be incomplete if not impossible without the support and involvement of health laboratories.

Successful implementation of Laboratory Quality Management System (LQMS) and achievement of accreditation to international quality standards is crucial to provide high quality laboratory testing services. Understanding and recognizing the critical importance of this fundamental fact, Ethiopia started with a modest, planned, and organized implementation of LQMS in 2006. It adopted the WHO-Afro Strengthening Laboratory Management Towards Accreditation (SLMTA) training and mentoring initiative in 2009 for the stepwise implementation of LQMS towards accreditation. Over these years, the country has significantly improved the quality of laboratory testing services provided at different levels. While few laboratories were able to achieve and maintain ISO 15189 or 17025 accreditation, the most notable achievements over these years have been the increased awareness, enthusiasm, and passion of the laboratory workforce for LQMS implementation and the provision of quality testing services, as well as the recognition of the health laboratory system at the highest national level as the backbone and vital component of a resilient health system.

The introduction of the SLMTA initiative into Ethiopia's health laboratory system has greatly influenced the implementation of LQMS and ISO accreditation efforts in the country. However, the comprehensive implementation of the initiative across all tiers of the national health laboratory system at the desired scale was not achieved due to many challenges and limitations associated with inadequate infrastructure including instrumentations, financial and human resource constraints and inconsistent supply chain of laboratory commodities, among others.

Against this background and taking the existing capacities and capabilities of health laboratories operating at different tiers of the national network into account, EPHI has decided to introduce three closely interrelated, tier-based approaches, namely, Basic Laboratory Quality Management System (BLQMS), SLMTA program and ISO accreditation to facilitate the implementation of LQMS and enhance accreditation efforts in a stepwise manner. The institute, in collaboration with all stakeholders and partners, has therefore developed this document to guide and provide details on requirements and conditions for laboratories to adopt and follow any one of the nationally recommended approaches. In addition to providing clear guidance for the adoption of a suitable approach for the effective and standardized implementation of LQMS across the different tiers of the national health laboratory network, the document also explicitly defines the roles and responsibilities of all key institutions involved in the implementation of laboratory programs at the different levels of the national health system. Furthermore, the document describes the necessary methods and tools required for the systematic monitoring of performance and effective use of evaluation results for the continual improvement in the quality of laboratory testing services provided at all tier levels.

This document is thus believed to serve as an invaluable resource material for laboratory program managers at all levels of the laboratory system, health facility managers, laboratory directors, technical laboratory professionals, and laboratory mentors alike in their concerted efforts towards comprehensive implementation of LQMS for the provision of quality service with reliable competence. It is also hoped that it will be instrumental in guiding other stakeholders, donors and partners engaged in or supporting the implementation of LQMS in Ethiopia.

On its part, the EPHI is as highly committed as ever to leading, coordinating, supporting, and facilitating the implementation of LQMS across all tiers of the national health laboratory system following the guidelines laid out in this document. The institute firmly believes that successfully implementing the guidelines will greatly enhance the provision of quality health laboratory services that will elevate the country's capacity and capability for pandemic preparedness and response, public health research and delivery of improved healthcare services in general.

Finally, I wish to thank all organizations and experts who were involved in and have contributed to the development of this guidance document and call upon all stakeholders and partners to contribute their due shares for the successful implementation of the guidelines towards achieving our shared goal of ensuring the provision of quality health laboratory services to all Ethiopian citizens wherever and whenever they need.

Saro Abdella (Ph.D.)
Deputy Director General for Health Laboratory Services,
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Message from National Laboratories Capacity Building Directorate

It has been several years now since the implementation of LQMS initiative was launched in Ethiopia. Even though marked improvements were observed over the years in the implementation of LQMS across all tiers of the national health laboratory system, many challenges still remain that need to be systematically addressed to facilitate and enhance interventions and practical activities towards achieving the ultimate goal, namely, ensuring the provision of quality testing services at national level in support of clinical care services, public health emergency management system and public health researches.

Repeated assessments and evaluations of LQMS implementation in the country have clearly revealed that the lack of a suitable operational guidance document that would detail workable approaches and prioritized interventions for the seamless adaptation and practical implementation of LQMS in the context of the Ethiopian health laboratory system. In this regard, it is of paramount importance that the development of such document particularly considers the existing organizational structure, leadership and management system, national quality infrastructure and financial resources, among other key factors. It is against this background that the Laboratory Quality Management system division of the National Laboratory Capacity Building Directorate has initiated the development of this guidance document which was enriched and finalized through a series of consultative workshops attended by laboratory program experts drawn from all stakeholder organizations, partner institutions and professional associations.

This guidance document is another forward step following the recent development and publication of the Strategic Plan for Health Laboratory System in Ethiopia (2023-2027). I am confident that these two important documents will serve as invaluable guiding tools for all stakeholders and partners committed to and engaged in building a resilient and sustainable quality health laboratory system in Ethiopia. As envisioned at their inceptions and developments, it is hoped that the documents will present objective opportunities for maximized collaborations and productive partnerships among all government, non-governmental and partner institutions having stakes and involved in the implementation of Ethiopian health laboratory programs through proper alignment of their actions and available resources.

Finally, I would like to express my deepest appreciation and thanks to all individual experts and their parent organizations for their valuable contributions to the drafting and finalization of this important document. I would also like to recognize and highly appreciate all members of the Laboratory Quality Management System Division for leading and coordinating the development of the guidance document and who will also be responsible for spearheading its implementation across all tiers of the national health laboratory network with the full and unreserved support of the Directorate.

Daniel Melese
Director, National Laboratories Capacity Building Directorate,
Ethiopian Public Health Institute.

Acknowledgements

The Ethiopian Public Health Institute would like to appreciate and acknowledge the contributions of professionals from its own institution, Regional Public Health Institutes/ Laboratories, stakeholders and partners that have made professional contributions to the successful development of these guidelines.

Abbreviations/Acronyms

BLQMS	Basic Laboratory Quality Management System
EAS	Ethiopian Accreditation Service
EMI	Ethiopian Metrology Institute
EPHI	Ethiopian Public Health Institute
EQA	External Quality Assessment
KPI	Key Performance Indicator
IQC	Internal Quality Control
ISO	International Organization for Standardization
LQMS	Laboratory Quality Management System
LQIA	Laboratory Quality Improvement and Accreditation
M&E	Monitoring and Evaluation
MOH	Ministry of Health
NLCBD	National Laboratories Capacity Building Directorate
PT	Proficiency Testing
QMS	Quality Management System
RHB	Regional Health Bureau
RRL	Regional Reference Laboratory
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
WHO	World Health Organization

Chapter 1: Introduction

Background

The healthcare service delivery system heavily relies on the essential pillar of health laboratory services, which stand as the backbone for effective, accurate, and reliable diagnostic outcomes within a national health system. These services are instrumental in providing precise disease diagnoses, supporting clinicians in formulating evidence-based care strategies, and enabling timely prognoses for potential health outcomes. Over the years, there has been an undeniable surge in the reliance on laboratory results for clinical decision-making. This increased dependence originates from the rapid development and dissemination of innovative diagnostic methodologies and technologies, the integration of automated testing instruments, the widespread implementation of data connectivity solutions, and the advancement of evidence-based medical practices.

Undoubtedly, health laboratories play an indispensable role not only in individual patient care but also in broader public health initiatives. They are pivotal in epidemiological surveillance, disease prevention, control, and eradication. The ability to mount an informed and effective response to disease outbreaks of epidemic or pandemic proportions relies significantly on the support provided by health laboratories. Their timely detection, characterization, and confirmation of causative biological agents form the foundation for designing and implementing appropriate strategies for swift containment, contact tracing, isolation, and provision of care and treatment services to affected individuals.

Moreover, health laboratories serve as critical information hubs for basic biomedical and public health researches. They facilitate survey and surveillance activities by generating essential qualitative and quantitative data from biological specimens collected from study populations. These invaluable laboratory insights help determine disease incidence and prevalence, enabling authorities to devise preventive strategies and action plans while also monitoring the effectiveness of public health interventions.

Recognizing the pivotal role of a robust health laboratory system, Ethiopia has embarked on a planned and coordinated implementation of LQMS in 2006. This strategic move supported and propelled by the concerted efforts of the laboratory community and partners has yielded commendable progress in enhancing the quality of laboratory testing services across various tiers

of the national health laboratory system. While a few laboratories achieved and maintained accreditation to ISO 15189 or 17025 standards, one of the most significant and fundamental breakthroughs has been the heightened awareness, enthusiasm and aspirations for quality laboratory services among healthcare service providers, public health emergency managers, laboratory professionals and scientists creating unprecedented quest and commitment the comprehensive implementation of LQMS. This paradigm shift in understanding the crucial role and importance of quality laboratory services for the provision of improved healthcare of international standards has further solidified the recognition of health laboratories at the national as the backbone of a resilient and sustainable health system.

However, as is generally the case in resource-constrained countries, the practical implementation of comprehensive LQMS at full scale across all levels of the Ethiopian health laboratory system also been found associated with immense challenges. Financial and human resource limitations have been major hurdles, limiting the number of laboratories that could be enrolled into and benefit from initiatives like the SLMTA. Efforts made to expand participation through regional stakeholders could not fully address the vast number of laboratories, especially those in health centers and smaller hospitals which are consistently suffering from infrastructure deficiencies, resource constraints, and unreliable supply chain of essential laboratory commodities among many other basic problems.

In order to systematically and sustainably address these challenges, the Ethiopian Public Health Institute, in collaboration with all stakeholders and partners, has recently developed a comprehensive Third Edition of Strategic Plan for the Health Laboratory System (2023-2027). This strategic blueprint aims to provide focused strategic directions, initiatives and major activities that need to be diligently implemented during the stated plan period to effectively address all impediments that have over the years been hindering the systematic implementation of LQMS at the desired pace towards achieving accreditation to international health laboratory quality standards. s. The Strategic Plan embodies the collective wisdom gleaned from the past years of experience based on which is envisioned to build a resilient, sustainable, and accessible quality laboratory system and services.

Building upon the SLMTA approach adopted in 2009, which significantly influenced LQMS implementation in the country, Ethiopia has embraced innovative strategies to tailor the

implementation of LQMS to diverse levels of existing laboratory capacities, capabilities and resources. The nation's vision and commitment to enhancing the advancement of quality and accessible laboratory services is evident in the designing and development of strategic roadmaps, mobilization of resources, meticulous planning for stepwise implementation, creating suitable platforms for the coordination and involvement of all stakeholders and partners, and crafting structured guidance documents for the concerted execution of activities in a standardized and harmonized manner. This document highlights three principal approaches for the tailored implementation of LQMS in the Ethiopian context: the Basic Laboratory Quality Management System (BLQMS), SLMTA, and direct engagement with ISO 15189 or 17025 accreditation efforts. Each approach is carefully tailored to suit laboratories at different levels of readiness and capacity within the national laboratory system.

The vast differences in capacities, available resources and overall readiness between the different tiers of the Ethiopian health laboratory network necessitate stratified approaches for the implementation of LQMS. As such, laboratories at different tiers ranging from Level I laboratories in rural settings to Level IV National Reference Laboratories are expected to pursue distinct pathways based on their capacities, capabilities, and readiness. This guidance document explicitly details general and specific requirements, implementation activities, and systems for monitoring and evaluation of performance for each approach, offering tailored roadmaps for the implementation of LQMS across the different tiers of the national health laboratory system. In line with the national definition and for the purpose of this document, a health laboratory is understood as a laboratory organization that performs various tests on specimens collected from humans, animals or the environment to generate and provide useful information for health care services, public health and health-related researches and multifaceted responses to public health emergency events**.**

In essence, this comprehensive guidance document stands as a beacon of knowledge and a roadmap for steering Ethiopia's health laboratory system and services towards greater heights. It doesn't only delineate realistic approaches for the seamless implementation of LQMS in this country, but also clearly outlines roles and responsibilities of stakeholders and partners involved in the implementation process at various levels while also providing mechanisms for systematic monitoring and evaluation of performance for continuous improvement. Therefore, the document is believed to serve as an invaluable resource material for guiding the development of SMART

operational plans with objective performance metrics, mobilization and allocation of resources and for fostering collaborations and alignment of efforts among stakeholders, donors, and partners engaged in strengthening Ethiopia's health laboratory system with the ultimate goal of elevating the system's overall capacity and capability to reliably and effectively contribute to the advancement of healthcare service delivery, public health emergency management and response system, and public health researches including survey and surveillance undertakings.

1.2. Purpose

The purpose of this document is to:

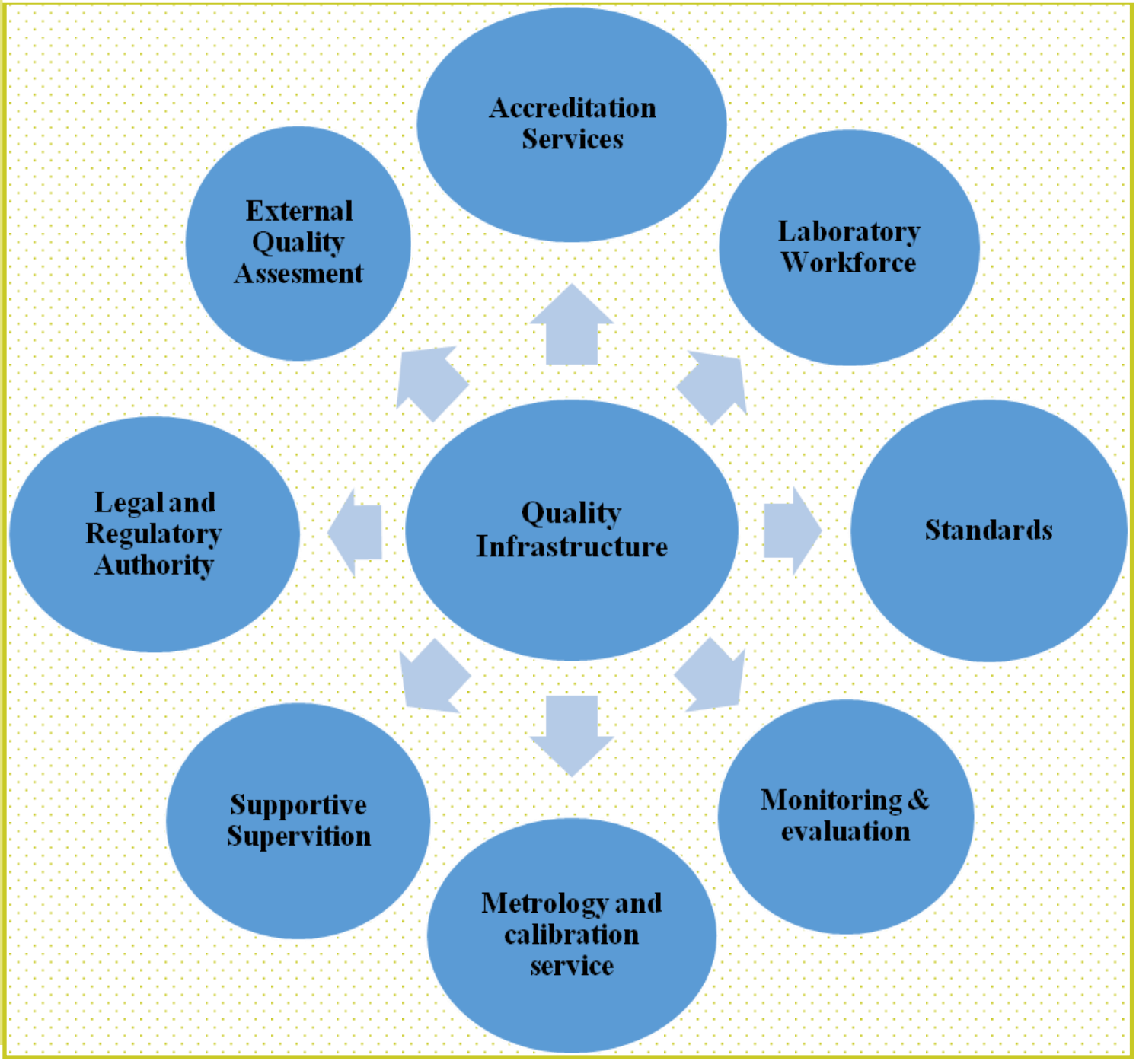
- Standardize approaches for tailored implementation of LQMS at different levels of the Ethiopian Health Laboratory System.
- Define the roles and responsibilities of all key players in the implementation of LQMS across the Ethiopian Health Laboratory System.
- Guide the standardization of systems and tools for continuous monitoring and evaluation of performance in the implementation of LQMS.

1.3. Scope

This document is developed to guide and facilitate the implementation and maintenance of LQMS across all tiers of the Ethiopian health laboratory system.

CHAPTER TWO

THE NATIONAL LABORATORY QUALITY FRAMEWORK



Chapter 2: The National Laboratory Quality Framework

2.1. Overview of Laboratory Quality Framework

Ethiopia has a five-year (2023-2027) National Health Laboratory Strategic Plan (NHLSP) endorsed by the MOH to be implemented across the country's health laboratory system. The Strategic Plan describes key strategic objectives, strategic directions, and major and detailed activities with indicators and anticipated targets. The overall objective of the NHLSP is to guide and facilitate the development of the national health laboratory system in all aspects to effectively and efficiently support the healthcare service delivery and public health emergency management systems as well as public health research undertakings through the provision of accurate, reliable and timely testing services. As such, it focuses on building the national quality infrastructure and overall capacity of the health laboratory system to advance the seamless implementation of LQMS at all laboratories towards achieving accreditation to international quality standards as the ultimate goal. The availability of laboratory quality infrastructure is crucial to enhance the implementation and maintenance of LQMS and achieving the envisaged goal of the Strategic Plan within the specified timeframe using available resources for the provision of sustainable quality laboratory services.

2.2. Quality Infrastructure

The National Laboratory Quality Infrastructure consists of several key components required for successful implementation and maintenance of LQMS. Some components of Laboratory Quality Infrastructure are discussed below.

2.2.1. Accreditation Services

At national level, the government is currently promoting LQMS implementation mainly through a phase-based or stepwise approach and the development of this guidance document helps to reinforce and strengthen the ongoing efforts. The Ethiopian Accreditation Service (EAS) is a

nationally authorized accreditation body for medical, calibration, and testing laboratories. It is a full member of the International Laboratory Accreditation Cooperation (ILAC) and the African Accreditation Cooperation (AFRAC).

2.2.2. Standards

Developing national standards or adapting/adopting international standards is fundamental for the LQMS implementation and pursuing accreditation for quality service and competence. Institute of Ethiopian Standards (IES) is nationally responsible for developing regulatory and quality standards. The IES has adopted the ISO 15189 and ISO 17025 international laboratory quality standards for assessing and confirming compliance with LQMS requirements and reliable competence for sustainable provision of quality testing services to all customers. In light of this, all health laboratories in Ethiopia are expected to implement LQMS requirements and fully comply with these standards to attain international accreditation.

2.2.3. Metrology and Calibration Services

For the calibration of measuring equipment and other laboratory-based equipment, Ethiopia has an internationally traceable calibration body, the Ethiopian Metrology Institute (EMI). Laboratories that implement LQMS get their major and ancillary/ auxiliary equipment periodically calibrated by EMI in accordance with manufacturers' recommendations and/or methods used or other national standard requirements. There are also functional programs in place for regular preventive maintenance, and certification of Biosafety Cabinet (BSC), Negative Pressure Systems, and other equipment by entities that are traceable.

2.2.4. Legal and Regulatory Authority

Regulatory bodies provide professional license to laboratory workforce, licensing and inspection of health facilities for conformity with pre-defined standards. All laboratory professionals practicing in health facilities should have professional licenses that should be renewed as per the requirement of the National Regulatory Authority.

2.2.5. Laboratory Workforce

Ensuring the availability of qualified, competent, adequate and multidisciplinary laboratory workforce is essential for strong and efficient health laboratory system at all levels through proper human resources planning, development, and management (training, capacity building, recruitment, deployment, performance management, and motivation). Continuous professional

development (CPD) centers regularly provide accredited courses to laboratory professionals to maintain their competency.

In order to effectively and efficiently run laboratory activities, responsibilities should be defined for key positions.

- **Laboratory Manager/Director/Head:** Competent and dedicated Laboratory Manager /Director/Head should be formally assigned to coordinate and manage the overall laboratory activities.
- **Quality Manager/Officer:** All laboratories should assign competent and dedicated Quality Manager/Officer to oversee and routinely monitor the overall LQMS implementation in the laboratory.
- **Biosafety and Biosecurity Officer**: All laboratories should assign a competent Biosafety and Biosecurity Officer to oversee the proper implementation of biosafety and biosecurity requirements and ensure maximum safety in the laboratory environment.

2.2.6. Monitoring and Evaluation

Implementing a monitoring and evaluation system is very important for an effective and efficient implementation of LQMS across all tiers of the health laboratory system and sustained improvement in the quality of services. Monitoring and evaluation should be in place while implementing the three LQMS implementation approaches. In addition, health Laboratories should identify quality indicators to monitor the day-to-day quality performances of the laboratory services. The quality indicators should be, measurable, attainable, and fit for purpose with defined targets as per indicated in the M&E section.

2.2.7. External Quality Assessment

Nationally, there is an integrated National External Quality Assessment (NEQA) program for laboratory tests to ensure the quality of results and compliance with LQMS and accreditation requirements. A coordinated management of EQA schemes using Proficiency Testing (PT), Random-Blinded-Rechecking/Re-testing (RBR), and On-site Evaluation (OSE) methods are required at each laboratory level as per their test scope and pertinent national guidelines. Laboratories enrolled in PT EQA schemes are expected to receive samples, conduct testing,

submit results in accordance with timelines established by the EQA providers, and develop improvement action plans to address the identified gaps.

Currently, the national PT EQA program is not strong enough as only limited PT panels are produced and distributed to assess, evaluate and continually improve laboratory testing services. Consequently, EPHI is striving to build capacity for PT production and distribution in conformance with ISO 17043 requirements.

2.2.8. Supportive Supervision

Supportive supervision is a system of tiered supervision where by laboratories in higher tiers of the laboratory network conduct audits, support LQMS implementation and monitor the quality and performance of laboratories in lower tiers of the network. It helps to make things work, rather than checking to see what is wrong.

2.2.9. Additional Quality Infrastructure Elements

Laboratory Infrastructure: The National Reference Laboratories at EPHI and most of the Regional Reference Laboratories have reasonably adequate infrastructure. In addition, twenty-eight Regional Reference Laboratories are under construction in various parts of the country and preparations are underway to start with the construction of state-of-the-art National Reference Laboratory Complex with BSL-3 laboratory facility at the Headquarters of EPHI. However, significant number of laboratories in the lower laboratory tiers need renovation and improvement in terms of the suitability of space for LQMS implementation.

The laboratory layout should be designed to facilitate the efficient flow of samples and personnel. It should include separate areas for sample processing, analysis, and storage, as well as dedicated spaces for equipment and administrative tasks. Workstations should be ergonomically designed to ensure comfort and efficiency for laboratory staff. They should be equipped with adequate lighting, ventilation, and space for equipment and supplies. The laboratory should be equipped with appropriate safety equipment, including fire extinguishers, emergency eyewash stations, and safety showers. The laboratory should comply with regulatory requirements and standards relevant to its operations.

Resources: According to the roles and responsibilities defined in chapter three of this document, adequate resources should be allocated for the implementation of LQMS related activities; procurement of quality control and PT materials, fees for calibration, accreditation and maintenance services including expenses for mentoring and supportive supervision, training, etc.

Internal Quality Control: All laboratories should have adequate stock of appropriately stored in-date internal quality control materials (commercial or in-house) for all tests and perform them regularly. In-house quality control materials are known test samples prepared in the laboratory following established protocols/procedures to monitor the quality of assay results. Health facilities managements are responsible for supporting the facilities on regular basis to make sure that in-house quality control materials are always prepared by meticulously following pertinent protocols/procedures and are of the highest quality.

Record Archival System: Retention time for records should be established and they should be maintained according to the requirements of regulatory body and legal authorities. Other factors like storage availability, clinical importance, and future research needs should be considered to define the retention period of records in all health laboratories.

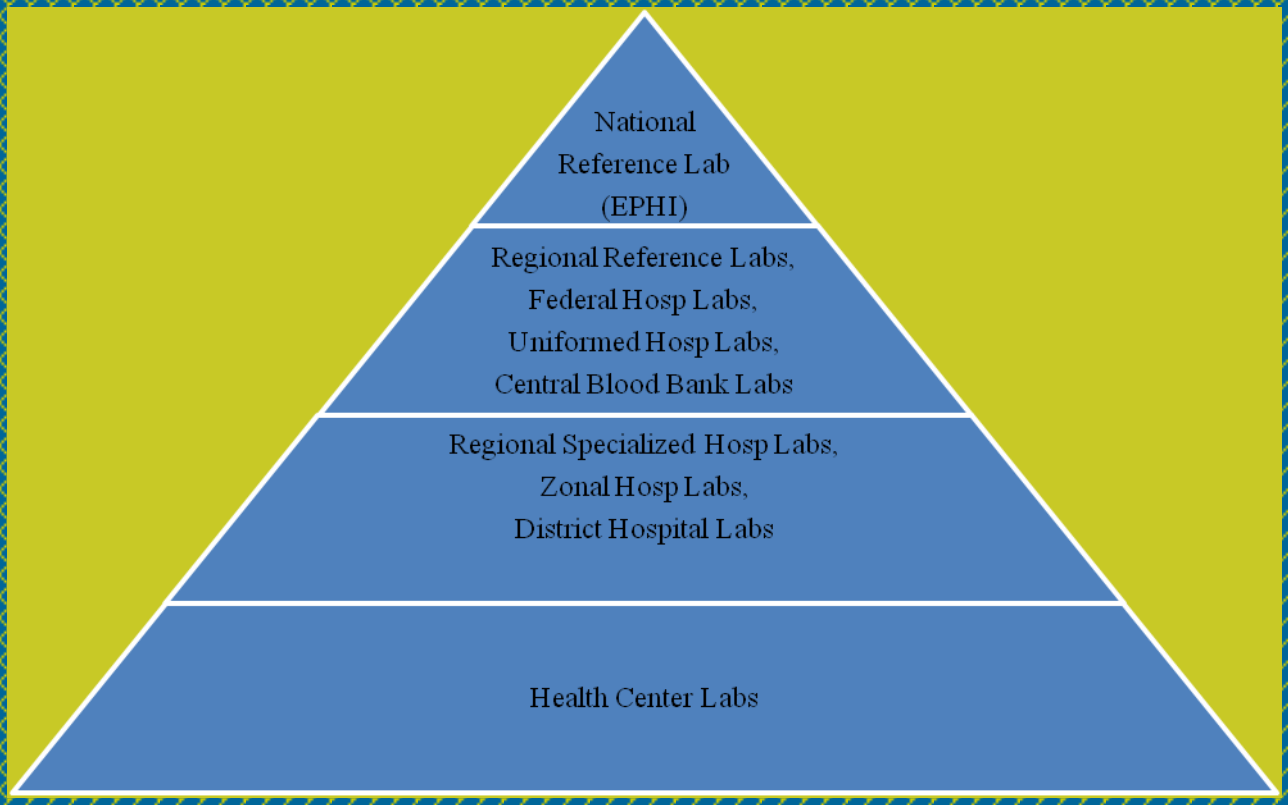
Selecting and Monitoring Quality Indicators

Quality indicators are important for the purpose of monitoring performance. Laboratories should have a plan with defined objectives to select and monitor quality indicators. Laboratories may use a combination of quality indicators especially those that indicate critical gaps in the pre-examination, examination and post examination processes in the laboratory.

Examples of Quality Indicators include, but not limited to: Turn-around-time, Sample rejection rate, Equipment down time, Stock out of reagents and supplies, Customer satisfaction, Performance in Internal Quality Control (IQC), etc.

CHAPTER THREE

LABORATORY QUALITY MANAGEMENT SYSTEM IMPLEMENTATION



SLMTA

ISO

Chapter 3: Laboratory Quality Management System Implementation

3.1. General Requirements for LQMS Implementation

The primary goal of implementing QMS in laboratories is to ensure continuous improvement so that they provide uninterrupted, accurate, reliable, and timely services. LQMS is a systematic approach that describes, documents, implements, measures, and monitors the effectiveness of laboratory work operations in meeting the national, international and other applicable requirements and promotes the efficient use of resources.

The QMS works on seven fundamental principles: customer focus, leadership, engagement of people, process approach, continuous improvement, evidence-based decision making, and relationship management (ISO 9001:2015). This helps to consistently provide products and services that meet customer and regulatory requirements. LQMS can be described as a set of 12 quality system essentials that need to be meticulously implemented to streamline a laboratory's work operations to fulfill laboratory quality requirements.

Table 1: The 12 quality system essentials as categorized into resources, process and continuous improvement

<table>
<tr><td colspan="3">1. Organization and leadership</td></tr>
<tr><th>Resources</th><th>Process</th><th>Continuous Improvement</th></tr>
<tr><td>2. Personnel Management</td><td>6. Process Management</td><td>9. Assessments</td></tr>
<tr><td>3. Equipment Management</td><td rowspan="2">7. Documents and Records Management</td><td rowspan="2">10.Nonconforming Event Management</td></tr>
<tr><td>4. Supplier and Inventory management</td></tr>
<tr><td>5. Facilities and Safety Management</td><td>8. Information Management</td><td>11. Continual Improvement</td></tr>
<tr><td colspan="3">12. Customer focus</td></tr>
</table>

Implementing LQMS entails establishing and maintaining continuous improvement in compliance with international and national requirements. Laboratories should:

a. Identify the processes needed for the LQMS implementation and their application throughout the organization.
b. Determine the sequence and interaction of these processes.
c. Determine the criteria and methods needed to ensure that the execution of these processes and their management is effective.
d. Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
e. Monitor the process, measure and analyze their performance.
f. Implement actions necessary to achieve planned results and continual improvement of these processes.

3.2. Implementation Approaches

There are three phase-based or stepwise approaches to implement LQMS in Ethiopia. The first approach is implementing a basic laboratory quality management system (BLQMS) in health laboratories with no prior experience in implementing LQMS. The second approach is enrolling the health laboratories in the strengthening laboratory management towards accreditation (SLMTA) program that have implemented the basic LQMS and graded as level 3 and above based on the basic LQMS checklist. The SLMTA provides a stepwise approach to the implementation of LQMS and measuring progress towards accreditation. The third approach is ISO 15189 and or 17025 accreditation for laboratories that have satisfactorily fulfilled the basic requirements of LQMS and the SLMTA program. However; a laboratory from any given tier can implement SLMTA or ISO 15189/17025 standards and engage in accreditation processes if it fulfills the respective mandatory requirements.

3.2.1. Implementation of Basic LQMS

The requirements for the implementation of Basic LQMS at Level I laboratories in Ethiopia were developed by EPHI in consultation with RRLs and other stakeholders. The program is designed to help laboratories implement the BLQMS on their own and conduct self-assessments using the BLQMS checklist. Implementation of BLQMS is a minimum quality criterion for all laboratories. All Level I laboratories implementing BLQMS should establish, document, implement and maintain BLMQS and monitor quality assurance activities throughout the laboratory workflow for continual service improvements in accordance with the requirements stipulated in this guidance document and other appropriate standards or guidelines to comply with national and international recommendations. The self-assessment result will determine whether the laboratories can join the SLMTA intuitive or engage in the ISO accreditation processes. The purpose of implementing BLQMS is to strengthen the laboratory's capacity to satisfactorily fulfill basic regulatory and quality requirements.

3.2.1.1. Target Health Facilities

Health laboratories that are not eligible for SLMTA or ISO accreditation programs are the target facilities that are anticipated to implement basic LQMS.

3.2.1.2. Mandatory Requirements and Tools

- All BLQMS implementing health laboratories should address the components of the basic LQMS checklist, and other local regulatory requirements.
- The laboratory shall have adequate working space and appropriate conditions to ensure the quality of its services.
- The laboratory staff should get basic LQMS training and undergo continual professional development.
- The laboratories should perform internal quality control and participate in regional EQA schemes.

3.2.1.3. Implementation Activities

Training: The Regional Public Health Institutes/Regional Reference Laboratories should provide in-service training to laboratory professionals to update their knowledge and skills of laboratory quality management requirements. Laboratory personnel at all BLQMS implementing facilities should get appropriate or tailored training on LQMS, laboratory biosafety and biosecurity and selected or prioritized laboratory subject areas.

Supportive Supervision and Mentorship: Each laboratory should get supportive supervision or mentorship on BLQMS implementation from the respective regional laboratories or selected facility laboratories at least twice per year. Onsite mentorship is a valuable means for the successful implementation of QMS.

Evaluation: Laboratories should conduct internal audit at least once annually and report the assessment results to their respective RPHIs/RRLs. The RPHI/RRL should perform random check of the evaluation results of 3-5 % of the laboratories. The evaluation should be conducted using the BLQMS checklist. The checklist has Level 0 up to Level V scoring system and laboratories that have achieved/scored more than Level III are encouraged to be enrolled into the SLMTA program.

Table 2: Scoring for BLQMS implementing laboratories

Level 0	Level I	Level II	Level III	Level IV	Level V
(0-56 pts.)	(57-67 pts.)	(68-78 pts.)	(79-89 pts.)	(90-100 pts.)	(101-111 pts.)
<50%	51-60%	61-70%	71-80%	81-90%	≥ 91%

3.2.1.4. Recognition

The authority to provide recognition is that of the facility management in close collaboration with the RPHIs/RRLs.

3.2.2. Implementation of the SLMTA Program

The SLMTA training and mentoring program is one of the LQMS implementation initiatives that aims to strengthen laboratory management, achieve immediate laboratory improvement, and accelerate preparedness towards accreditation. It emphasizes on actions and tangible

improvements. The content is a task-based training and mentoring curriculum and is closely linked to the WHO AFRO SLIPTA Checklist, which was developed based on ISO 15189 requirements.

SLIPTA is a framework for improving the quality of health laboratories and it is a comprehensive approach to strengthen national health laboratory services in a stepwise manner by providing graduated levels of performance recognition towards long-term fulfillment of the ISO 15189 standards. Moreover, SLIPTA recognizes laboratories where they are in the implementation of LQMS and the process of quality improvement; supports them through audits and technical assistance and rewards progress towards obtaining accreditation to the standards. While SLMTA provides laboratories with the "how to practically implement LQMS" through training and mentoring support, SLIPTA assesses their strengths, weaknesses and progresses made to measure the level of compliance with ISO15189 requirements. The two programs complement each other and together they provide the tools and processes needed to enhance the efforts of laboratories towards accreditation.

Each laboratory participating in SLMTA is audited at the beginning (baseline) and at the end (exit) using the SLIPTA checklist. The difference between baseline and exit scores, and their respective star ratings, is calculated to appreciate the effect of the program on laboratory functions and quality.

3.2.2.1. Eligibility Criteria

This program is intended to be implemented by tier level II health laboratories (comprehensive specialized and general hospitals, regional blood banks, standalone diagnostic laboratories, etc.), and Level I health laboratories that have achieved/scored more than Level III in BLQMS and that are not enrolled in the ISO accreditation program.

3.2.2.2. Mandatory Requirements

In order to be eligible for enrollment in the SLMTA program, laboratories should fulfill the following mandatory requirements:

- Fulfill the minimum requirements set for medical laboratories by regulatory bodies.
- Have evidence of EQA participation for the majority of tests they perform.
- Have a well-established quality control program and evidence of regularly performing IQC for all testing services.
- Have Laboratory Head, Quality officer, and Biosafety and Biosecurity Officers assigned to oversee and coordinate the implementation of quality and safety activities, respectively.

3.2.2.3. Implementation Activities

Training: Laboratory professionals working in SLMTA enrolled facilities should be trained on comprehensive SLMTA, LQMS, Biosafety/Biosecurity, internal audit and basic laboratory subject areas.

Baseline Assessment: Baseline assessment should be conducted using the SLIPTA checklist to determine the status of LQMS implementation and areas that need improvement.

Mentorship and Supportive Supervision: Mentorship and supportive supervision activities should be conducted at least twice a year.

Exit Assessment: Exit assessment should be undertaken using SLIPTA checklist and the outcome should be utilized for continual improvement.

3.2.2.4. Evaluation and Recognition

Recognition is provided using a five star-tiered approach, based on an on-site audit of laboratory operating procedures, practices, and performance. An independent evaluation team from RRLs/RPHIs and/or higher tier levels conducts audits using the SLIPTA assessment checklist. The audit checklist score will correspond to the number of Stars awarded to a laboratory in the following manner.

Table 3: SLMTA implementing laboratories SLIPTA score.

No Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
(0-205 pts)	(206-240 pts)	(241-277 pts)	(278-314 pts)	(315-352 pts)	(353-367 pts)
< 55%	55-64%	65-74%	75-84%	85-94%	≥95%

Laboratories that fail to achieve at least 55% (<205 pts) will not be awarded a star ranking. Once audited, laboratories are expected to maintain their star status and work towards the higher stars which will be evaluated during the next audit process. Laboratories that achieve at least 3 Stars are strongly encouraged to be enrolled in an established ISO 15189/17025 accreditation scheme.

Recognition of laboratories for their performance in SLMTA implementation is granted by the RHBs/RPHIs in close collaboration with EPHI and other stakeholders.

3.2.3. Implementation of ISO Accreditation

Accreditation to ISO 15189/17025 demonstrates that medical laboratories comply with comprehensive management and technical requirements that ensure their competence to provide timely, accurate and reliable results.

3.2.3.1. Target Health Facilities and Enrollment Criteria

As a standard, health laboratories that have succeeded in the implementation of BLQMS and SLMTA programs and have achieved the minimum performance of 3 Stars in SLIPTA will be enrolled in the ISO accreditation program. Tier III and IV laboratories are the main targets for ISO 15189/17025 accreditation program. However, a laboratory from any given tier level that fulfills basic LQMS and SLMTA requirements can be directly enrolled in accreditation processes and engage in the implementation of ISO 15189/17025 standards without necessarily going through the two stepwise consecutive pathways.

3.2.3.2. Mandatory Requirements

In order to be enrolled in the ISO 15189/17025 program, laboratories must conform to the following mandatory requirements. The laboratory shall have:

- Committed leadership and management that is ready and capable of allocating adequate budgets for the procurement of equipment, reagents and supplies, maintenance and calibration services, quality control and PT materials, IT systems and communication services, hiring qualified human resource, costs related to accreditation processes, etc.
- Adequate space for sample collection, storage, laboratory testing and staff facilities
- Adequate, qualified and competent staff.
- Access to PT from registered providers.
- Access to traceable calibration systems for all measuring instruments.

The laboratory must follow all applicable bio-safety and bio-security requirements stipulated in ISO 15189, and local regulations.

3.2.3.3. Implementation activities

Training: All laboratory professionals working at ISO accreditation enrolled sites should be trained at least LQMS, assigned working processes, Biosafety and Bio-security principles and requirements, Laboratory Information System (LIS), and laboratory ethics and confidentiality.

Mentorship and Supportive Supervision: Mentorship and supportive supervision shall be conducted at least per quarter in accordance with the national laboratory mentorship guidelines,

3.2.3.4. Evaluation and Recognition

Laboratories that have fully implemented ISO 15189/17025 standards are audited, recognized and conferred accreditation status by EAS. EPHI and RPHIs/RRLs should regularly monitor, evaluate and support these laboratories to maintain their accreditation status and scope expansion.

3.3. Measuring Operations

Laboratory quality management requires planning and measuring the results of operations to provide quality services that benefit all customers. This process involves the following key steps:

1. Deciding on what measurable objectives to achieve
2. Identifying specific measures to track and evaluate progress
3. Implement the selected measures
4. Collecting and analyzing data, using findings to improve performance and
5. Constantly improving the process

3.4. Roles and responsibilities

3.4.1. Ministry of Health

- Establish a national health laboratory policy.
- Allocate resources for laboratory services, LQMS implementation and efforts towards accreditation.
- Provide overall guidance and oversee the implementation of health laboratory programs.

3.4.2. Ethiopian Public Health Institute

- Develop national health laboratory roadmaps and strategic plans
- Conduct Star level determination, recognition and certification for health facilities enrolled in the SLMTA program.
- Provide technical support, mentorship and training to tier III and IV laboratories.
- Provide technical support to RPHIs/RRLs to effectively coordinate and manage the implementation of LQMS in their respective regions.
- Mobilize and avail resources for LQMS implementation,
- Install, maintain and certify BSC and negative pressure systems.
- Coordinate and facilitate equipment maintenance and calibration services. Procure or prepare and distribute traceable verification materials or certified reference materials.
- Procure and distribute PT samples from registered PT providers.
- Prepare and distribute traceable PT panels to improve access of laboratories to EQA schemes.
- Develop LQMS implementation guidelines and evaluation tools.
- Sensitize institutions and stakeholders for the implementation of quality initiatives.
- Lead and coordinate the implementation of LQMS and efforts towards accreditation nationwide.
- Provide TOT trainings.

3.4.3. Regional Health Bureaus

- Establish regional guidelines for the advancement of health laboratory services.
- Allocate resources for laboratory services, LQMS implementation and efforts towards accreditation in their respective regions.
- Provide overall guidance and oversee the implementation of health laboratory programs in their respective regions.

3.4.4. Regional Public Health Institutes/Regional Reference Laboratories

- Develop regional health laboratory strategic plans
- Mobilize resources for LQMS implementation and accreditation efforts.
- Adopt the national LQMS implementation guidelines
- Provide technical support including mentorship, training and audits for health laboratories enrolled in basic LQMS, SLMTA and ISO accreditation programs.
- Participate in the development of national health laboratory roadmaps and strategic plan.
- Facilitate equipment calibration and maintenance services for laboratory facilities.
- Establish and maintain efficient and effective communications systems with EPHI, regional health facilities and other stakeholders as related to the implementation of LQMS and efforts towards accreditation.
- Submit reports to RHB and EPHI on the performance of health laboratory programs
- Lead and coordinate regional rollout of laboratory training programs.

3.4.5. Health Facility

- Customize quality related documents.
- Provide effective leadership, management and planning to achieve LQMS quality objectives.
- Allocate adequate budget and resources (sufficient to procure the necessary reagents and supplies, equipment, IQC and calibration materials, maintenance services, etc.) for the proper functioning of laboratory testing services as well as for covering costs related to the implementation of LQMS and accreditation efforts.
- Implement, monitor and evaluate the implementation of LQMS requirements.

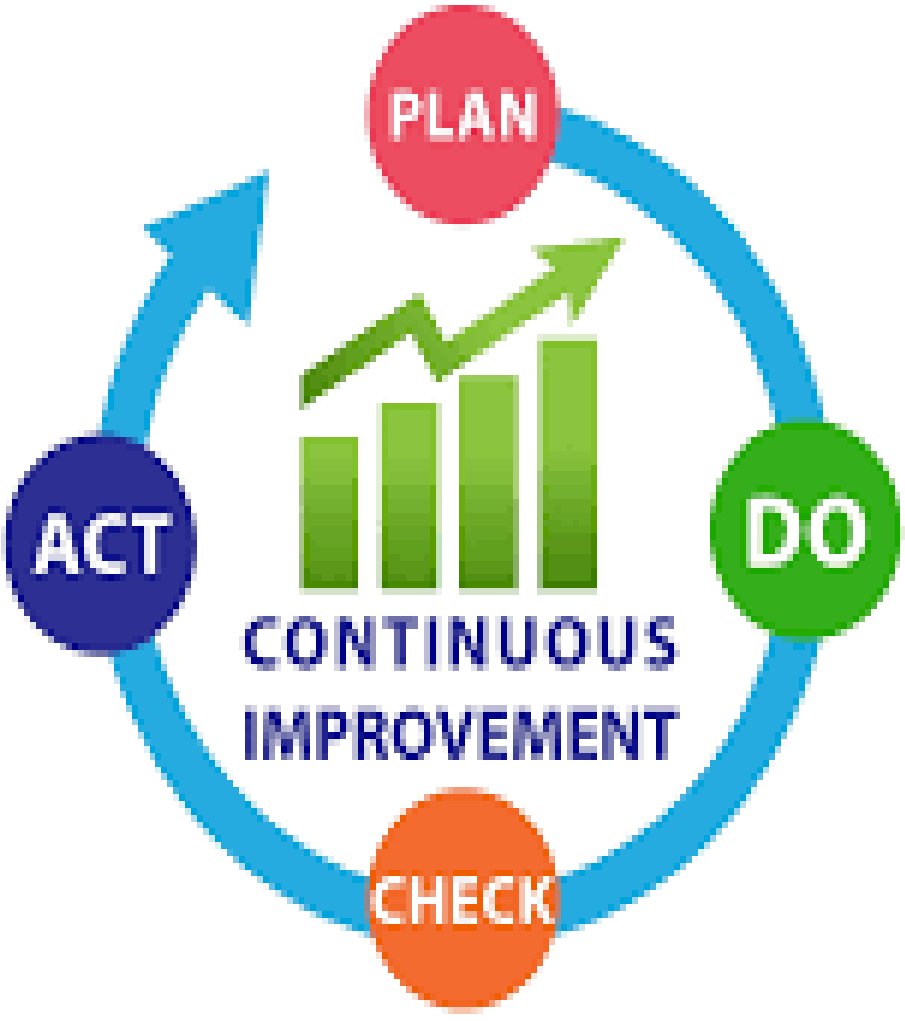
- Appoint competent, qualified and dedicated personnel for key positions of the laboratory which include Laboratory Director/Head, Quality Officer, Biosafety and Biosecurity Officer, and other positions as found necessary.
- Ensure all laboratory staff are engaged in the implementation of LQMS activities and accreditation efforts.
- Implement systems and mechanisms to build the capacity of laboratory personnel and motivate them for better achievement (training, recognition and rewards, etc.).

3.4.6. Partners and Non-governmental Stakeholders

- Provide advice and technical assistance for the implementation of LQMS across the national health laboratory network.
- Assist in mentorship, supportive supervision, laboratory audits and training activities.
- Provide financial and logistic assistance as found necessary.
- Assist in the development and implementation of national health laboratory roadmaps, strategic plans, guidelines, manuals and other related documents.

CHAPTER FOUR

MONITORING AND EVALUATION



Chapter 4: Monitoring and Evaluation

This chapter outlines the systematic approach for assessing and improving the quality of laboratory services at all levels of the healthcare system. Monitoring and evaluation defines key performance indicators for implementation at facility, regional and national levels, data sources, analysis and reporting, corrective actions and continuous improvement, documentation and recording to ensure that laboratories keep on improving to meet and maintain established quality standards. It also establishes a feedback loop for continuous quality improvement, allowing stakeholders to track progress, identify areas for enhancement, and make data-driven decisions to enhance and maintain the quality of laboratory services across the national healthcare service delivery system.

The objective of M&E for laboratories in QMS is to:

- Measure progress towards national targets for the implementation of LQMS and accreditation.
- Assess the enrollment status in QMS programs.
- Assess the performance of laboratories on key quality indicators over time.
- Identify barriers and weaknesses impacting the quality of laboratory services.
- Provide evidence to guide resource mobilization allocation, and technical assistance.
- Promote learning and knowledge exchange on effective QMS practices.
- Recognize the best performance in the implementation of LQMS and accreditation.
- Ensure the continuity of quality improvement following the scientific Plan, Do, Check and Act (PDCA) method or the Deming cycle.

Table 4: **Summary of KPIs, Data sources, Analysis and documentation**

Implementation Level	KPI	Data Sources	Analysis and Reporting	Corrective Action and Improvement	Documentation and Reporting
National Level	• Number of health facilities with functional laboratories • Proportion of laboratories enrolled in Basic LQMS program • Proportion of laboratories implementing basic quality management system • Proportion of laboratories with SLIPTA Star level recognition • Number of accredited laboratories (disaggregated into limited and full scopes) • Proportion of laboratories participating in EQA Program • Number of TOT/Basic trainings provided	• National and regional records • SLIPTA assessment reports • EAS database • National EQA database national and regional personnel training database	• Analyze KPIs presented in either number or percentage to identify trends and areas for improvement. • Assess training records to ensure staff competency. • Assess EQA performance records to ensure facilities' competency.	• Develop action plans to address the identified findings. • Implement appropriate corrective and preventive measures. • Continually update and improve policies, procedures and practices. • Adjust training programs based on training needs.	• Update and maintain all KPI performance records. • Maintain records of all corrective and preventive actions taken • Report the progress and outcomes to stakeholders regularly and as needed. • Document changes to policies, procedures and practices. • Keep records of changes made to training programs

Implementation Level	KPI	Data Sources	Analysis and Reporting	Corrective Action and Improvement	Documentation and Reporting
Regional Level	• Proportion of laboratories enrolled in Basic LQMS program • Proportion of laboratories implementing basic quality management system • Proportion of laboratories with SLIPTA Star level recognitions • Number of accredited laboratories (disaggregated into limited and full scopes) • Number of laboratory tests with limited scope accreditation • Proportions of laboratories participating in the EQA Program • Number of health facilities with functional laboratories • Proportion of laboratories performing the minimum standard test menu • Proportion of laboratories participating in EQA schemes with scores>80% on average • Number of basic trainings provided	• National and regional records • SLIPTA Assessment Report • EAS database • National EQA database • National and regional personnel training database • Regional EQA database • Regional personnel training database	• Analyze KPIs presented in either number or percentage to identify trends and areas for improvement. • Assess training records to ensure staff competency. • Assess EQA performance records to ensure facilities competency	• Develop action plans to address the identified findings. • Implement appropriate corrective and preventive measures. • Continually update and improve policies, procedures and practices. • Adjust training programs based on training needs.	• Update and maintain all KPI performance records. • Maintain records of all corrective and preventive actions taken • Report the progress and outcomes to stakeholders regularly and as needed. • Document changes to policies, procedures and practices. • Keep record of changes made to training programs.

Implementation Level	KPI	Data Sources	Analysis and Reporting	Corrective Action and Improvement	Documentation and Reporting
Facility Level	• Level of customer satisfaction • Equipment downtime • Turnaround times for test results • EQA/PT performance • Specimens rejection rate • Supplies stock outs rate • Test statistics • IQC Coverage • Proportion of tests performed against minimum standard Test Menu	• Laboratory records • Quality indicators summary report • Internal and external audit reports	• Analyze KPIs presented in either number or percentage to identify trends and areas for improvement. • Assess EQA performance records to ensure facilities competency.	• Develop action plans to address the identified findings. Implement appropriate corrective and preventive measures	• Update and maintain all KPI performance records. • Maintain records of all corrective and preventive actions taken

Table 5: Summary of KPIs and expected outputs at National, Regional and Facility Levels

Level of implementation	Indicators	Type of indicator	Unit of Measurement	Formula	Means of verification
National Level	Proportion of laboratories enrolled in basic quality management system	Input	%	$= \frac{\text{Number of laboratories enrolled in basic quality management system x 100}}{\text{Total number of functional laboratories}}$	Annual assessment report,
	Proportion of laboratories implementing basic quality management system	Process	%	$= \frac{\text{Number of laboratories with basic quality management systems Level 1 and above}}{\text{Total number of functional laboratories enrolled in BLQMS in the region}}$	Annual assessment report
	Proportion of laboratories with SLIPTA Star level recognition	Output	%	$= \frac{\text{Number of laboratories with SLIPTA Star 1 and above x 100}}{\text{Total number of laboratories enrolled in SLIPTA program}}$	Annual assessment report
	Number of accredited laboratories (disaggregated into limited and full scopes)	Output	Number	Number	Annual assessment report

	Indicators	Type of indicator	Unit of Measurement	Formula	Means of verification
	Proportion of laboratories participating in EQA Program	Process	%	$= \frac{\text{Number of laboratories participating in at least one of the EQA Schemes x 100}}{\text{Total number of functional laboratories}}$	EQA data base, Annual assessment report
	Number of laboratory tests with limited scope accreditation	Output	Number	Number	EAS certification
	Number of basic trainings provided	Input	Number	Number of QMS training given	Training certificate
Region level	Proportion of laboratories enrolled in BQMS program	Input	%	$= \frac{\text{Number of labs enrolled in the basic quality management systems programs x 100}}{\text{Total number of functional laboratories in the region}}$	Annual Report
	Proportion of laboratories implementing basic quality management system	Process	%	$= \frac{\text{Number of laboratories with basic quality management systems Level 1 and above}}{\text{Total number of functional laboratories enrolled in BQMS in the region}}$	Annual assessment report

	Indicators	Type of indicator	Unit of Measurement	Formula	Means of verification
Region level	Proportion of laboratories with SLIPTA Star level recognitions	Output	%	$= \frac{\text{Number of laboratories with SLIPTA Star 1 and above recognition x 100}}{\text{Total number of laboratories in the region enrolled in SLIPTA program}}$	Annual assessment report
	Number of accredited laboratories (disaggregated into limited and full scopes)	Output	Number	Number	Annual assessment report
	Proportion of laboratories participating in EQA Program	Process	%	$= \frac{\text{Number of laboratories participating in at least one of the EQA Schemes x 100}}{\text{Total number of functional laboratories in the region}}$	Annual Report and assessment report
	Proportion of functional laboratories in the region	Input	%	$= \frac{\text{Number of functionallaboratories x 100}}{\text{Total number of laboratories in the region}}$	Annual report, assessment report
	Proportion of laboratories participating in EQA schemes with scores $\geq$80% on average	Process	%	$= \frac{\text{Number of labs participating in EQA Schemes scored 80\% \& aboveonaveragex 100}}{\text{Total number of laboratories participating in EQA Program in the region}}$	Annual assessment report

	Indicators	Type of indicator	Unit of Measurement	Formula	Means of verification
	Number of laboratory tests with limited scope accreditation	Output	Number	Number	EAS Certification
	Proportion of laboratories performing minimum standard test menu	Output	%	$\frac{\text{Number of laboratories which have minimum standard test menu}}{\text{Total number of functional laboratories in the region}}$	Admin Report
	Number of basic trainings provided	Process	Number	Number	Training certificate
Facility level	Level of customer satisfaction (≥85%)	Output	%	$= \frac{\text{Number of survyed customers satisified with the laboratory services x 100}}{\text{Total number of customers particpated in the survey}}$	Assessment
	Equipment downtime (<5%)	Process	%	$= \frac{\text{Number of equipment working days x 100}}{\text{Total number of equipment functional days}}$	Assessment

	Indicators	Type of indicator	Unit of Measurement	Formula	Means of verification
Facility level	Turnaround times for test results (≥80%)	Output	%	$= \frac{\text{Number of results reported within defined TAT x 100}}{\text{Total number of results released from the laboratory}}$	Assessment
	EQA/PT performance (≥80%)	Process	%	$= \frac{\text{Number of EQA/PT test Performance Scored 80\% \& above on averagex 100}}{\text{Total number of tests covered by EQA schemes}}$	EQA/PT report
	Specimens' rejection rate (< 2%)	Process	%	$= \frac{\text{Number of specimens rejected x 100}}{\text{Totl number of specimences collected/received}}$	Record/report
	Supplies Stock outs rate(<5%)	Process	%	$= \frac{\text{Number of working days with stockouts of x 100}}{\text{Total number of working days}}$	Record/report
	Test Statistics	process	%	$= \frac{\text{Number of tests performed x 100}}{\text{Number of tests agrgated}}$	Record/report
	IQC coverage	process	%	$= \frac{\text{Number of test runs performed with IQC x 100}}{\text{Total number of test runs performed}}$	Record/report
	Number of laboratory tests with limited scope accreditation	Output	Number	Number of accredited scope of tests	EAS Certification
	Proportion of laboratory tests performed against minimum standard test menu	Output	%	$\frac{\text{Number of tests from the standard test menu performed in the laboratories x 100}}{\text{Total number of tests capured in the regional minimum standard test menu}}$	Admin Report

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Annex 1. Reporting templates for all tiers

A. Reporting template for Performance of KPIs and expected outputs at **National Level**

S.No.	Name of the Region	Performance on KPI	Year (2016)					Remark
			Q1	Q2	Q3	Q4	Total	
		Number of health facilities with functional laboratories						
		Proportion of laboratories enrolled in Basic QMS programs						
		Proportion of laboratories implementing basic quality management system						
		Proportion of laboratories with SLIPTA Star level recognitions						
		Number of accredited laboratories.						
		Proportion of laboratories participating in EQA Program						
		Number of basic trainings provided						
		Number of laboratory tests with limited scope accreditation						

B**.** Reporting template for Performance of KPIs and expected outputs at **Regional Level**

S.No	Region	Zone	Name of Facilities	Performance on KPI	Year (2016)					Remark
					Q1	Q2	Q3	Q4	Total	
				Proportion of laboratories enrolled in Basic QMS programs						
				Proportion of laboratories implementing basic quality management system						
				Proportion of laboratories with SLIPTA Star level recognitions						
				Number of accredited laboratories.						
				Number of laboratory tests with limited scope accreditation						
				Proportions of laboratories participating in EQA Program						
				Number of health facilities with functional laboratories						
				Proportion of laboratories performing minimum standard test menu						
				Proportion of laboratories participating in EQA schemes scored >80% on average						
				Number of basic trainings provided						

C. Reporting template for Performance of KPIs and expected outputs **at Facility Level**

S.No	Region	Zone	Woreda	Health facility	Performance on KPI	Year (2016)					Remark
						Q1	Q2	Q3	Q4	Total	
					Customer satisfaction rate						
					Equipment down time						
					Turnaround times for test results						
					EQA/PT performance						
					Specimens rejection rate						
					Supplies stock outs rate						
					Test statistics						
					IQC Coverage						
					Proportion of tests performed against minimum standard Test Menu						

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