



**LABORATORY QUALITY
MANAGEMENT SYSTEM (LQMS)
TRAINING AND CAPACITY BUILDING
FRAMEWORK**

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ABBREVIATIONS

AFRO	African Region
ASLM	African Society for Laboratory Medicine
ECSA-HC	East Central and Southern Africa Health Community
EQA	External quality assessment
CDC	Centers for Disease Control and Prevention
CPD	Continued Professional Development
IEC	International Electrochemical Committee
ISO	International Organisation for Standardisation
LABCOP	Laboratory Community of Practice
LQMS	Laboratory Quality Management Systems
M&E	Monitoring & Evaluation
PEPFAR	US President's Emergency Program for AIDS Relief
PT	Proficiency Testing
QSSR	Quality Systems Standards and Regulation
QMS	Quality Management System
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
SOPs	Standard Operating Procedures
SME	Subject Matter Experts
ToT	Training of Trainers
TWG	Technical Working Group
WAHO	West Africa Health Organization
WHO	World Health Organization

INTRODUCTION

High-quality laboratory services are fundamental to accurate diagnosis, disease surveillance, and effective public health interventions. Many laboratories in Africa face challenges in implementing and sustaining Laboratory Quality Management Systems (LQMS) in line with national and international standards such as ISO 15189:2022 and ISO/IEC 17043:2023.

The African Society for Laboratory Medicine (ASLM) has successfully implemented initiatives such as the WHO AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) and provided technical support for recognition and ISO accreditation. This framework outlines ASLM's structured approach to LQMS training and capacity building, designed to develop a competent workforce, institutionalize quality systems, and ensure sustainability.

To ensure smooth implementation of this strategy, it is vital to develop a Training and Capacity Building Framework in LQMS, which guides development of training content for the LQMS strategy. This framework provides a structured, harmonized, and sustainable approach to developing laboratory human resources at all levels of the health system. It defines priority competency areas, training pathways, and capacity-building strategies aligned with national laboratory policies, regional priorities, and internationally recognized standards. The framework is designed to support continuous professional development, promote quality and foster leadership and innovation within laboratory medicine.

The framework serves as a guiding reference for training institutions, laboratory professionals, national health authorities, implementing partners, and development stakeholders involved in laboratory workforce development. It emphasizes competency-based training, mentorship, and systems strengthening to ensure that laboratory services are accurate, reliable, safe, and responsive to Africa's evolving health needs, including emerging and re-emerging diseases.

Through this framework, ASLM aims to enhance workforce capacity, harmonize training standards across countries, and support sustainable laboratory systems that contribute to improved patient outcomes, strengthened public health surveillance, and increased preparedness for epidemics and pandemics across the African continent.

BACKGROUND OF THE FRAMEWORK



2.1 Scope

The ASLM training framework is a pan-African, multi-level, and quality-driven document, designed to build a competent laboratory workforce, strengthen laboratory systems, and ensure sustainable, world class diagnostic services across Africa.



2.2 Goal

To guide the development and implementation of a standardized, competency-based LQMS training and certification framework that strengthens the capacity of laboratory personnel and institutions in Africa to implement, monitor, and sustain quality systems aligned with international standards.



2.3 Objectives





2.4 Alignment of this framework with ASLM mission, vision and strategic objectives

ASLM is dedicated to the development, strengthening, and improvement of laboratory medicine across Africa. ASLM works to ensure that laboratories across the continent provide high-quality services that meet international standards, ultimately contributing to better healthcare outcomes.

This framework aligns with the ASLM mission, vision and strategic objectives as follows:

2.4.1 Enhancing Professional Competence

Training programs are designed to empower laboratory professionals across Africa by providing them with the knowledge, skills, and certification needed to excel in their roles.

2.4.2 Improving Laboratory Systems and Quality Assurance

ASLM works to improve laboratory quality, ensuring labs meet international standards. Training is a cornerstone of achieving this.

2.4.3 Strengthening Laboratory Networks and Collaboration

ASLM works to enhance collaboration between laboratory professionals across Africa and internationally. Training is not just about individual competence, but also about creating a robust network of well-trained laboratory personnel.

2.4.4 Developing Leadership and Management Skills

As part of its efforts to develop laboratory professionals, ASLM focuses on building the leadership and management skills necessary for running efficient laboratory services.



2.5 What are the current gaps that the framework is trying to address?

The ASLM Training and Capacity Building framework has been developed to provide a structured, systematic approach for developing the skills, knowledge, and competencies of laboratory personnel, improving laboratory processes, and ensuring that laboratories operate at optimal quality standards. Such a framework is essential to the growth and sustainability of laboratory services, particularly in settings where diagnostic capabilities are critical for public health, research, and clinical outcomes.

2.6 Key Purposes of a Laboratory Training and Capacity-Building Framework



Improve the Skills and Competencies of Laboratory Personnel

To enhance the technical abilities, knowledge, and professional performance of laboratory staff, from technicians to managers, in a way that aligns with both national and international standards.

**Standardize Laboratory Practices**

To ensure that laboratories follow consistent protocols and practices that meet established standards, ensuring quality control, reproducibility, and reliability of laboratory results.

**Strengthen Laboratory Systems and Infrastructure**

To improve the overall functioning of laboratory services, ensuring that laboratories are equipped to handle both routine and emergency testing.

**Build Sustainable Professional Development**

To create a culture of continuous learning and professional growth among laboratory staff, encouraging lifelong learning and adaptability.

**Address Laboratory Workforce Gaps**

To address the shortage of qualified laboratory professionals, particularly in underserved or low-resource settings.

**Improve Laboratory Leadership and Management**

To enhance the management and leadership skills of laboratory managers, ensuring the laboratory is efficiently run and can adapt to changing needs.

**Ensure Compliance with National and International Regulations**

To ensure that laboratories comply with local regulations, global standards, and ethical guidelines.

**Foster Research and Innovation in Laboratory Medicine**

Goal: To encourage laboratory professionals to engage in research and innovation that advances the field of laboratory medicine.

**Support Public Health and Disease Surveillance**

To ensure that laboratories are prepared to detect and monitor diseases, contributing to public health initiatives and epidemiological surveillance.

**Enhance Laboratory Networks and Collaboration**

To create strong, collaborative laboratory networks that improve knowledge sharing and collective problem-solving across different laboratories, institutions, and regions.

SWOT ANALYSIS OF LABORATORY TRAINING AND CAPACITY BUILDING FRAMEWORK

3.1 Strengths



Increased Focus on Professional Development:

Many countries and organizations are emphasizing continuous training for laboratory professionals, helping to maintain up-to-date knowledge and skills.



Certification and Accreditation Programs:

International standards such as ISO 15189 and ISO 17025 are helping to shape quality and ensure laboratories meet international benchmarks. Many laboratories have been able to achieve these certifications due to training initiatives.



Growing Number of Training Initiatives:

Regular workshops, online courses, and international conferences are promoting laboratory training, ensuring professionals can continually update their skills in emerging fields like molecular diagnostics, microbiology, and biochemistry.

3.2 Weaknesses (Current Gaps and Challenges)

Inadequate Resources for Training:

Many laboratories, especially in low-resource settings (e.g., rural areas, small clinics), lack access to training materials, modern equipment, or internet connectivity to benefit from online learning platforms.

Limited Availability of Advanced Training:

While basic laboratory skills and quality assurance training are common, there is often a lack of specialized training in advanced diagnostics, research methodologies, and innovative laboratory techniques (e.g., molecular testing, genetic analysis).

Fragmented Training Programs:

Training programs are often disjointed and not systematically integrated into the laboratory ecosystem. There's no national framework or standardized curriculum, meaning the quality and type of training can vary widely from region to region.

Shortage of Trained Trainers:

There is a shortage of qualified trainers to deliver training programs. This limits the effectiveness and scalability of capacity-building efforts.

Weak Focus on Leadership and Management:

Many training programs focus mainly on technical skills and fail to address leadership and management skills necessary to lead laboratory teams effectively. There is often a lack of training in lab management, financial oversight, and team leadership.

Insufficient Emphasis on Practical, Hands-On Learning

Some training programs rely too heavily on theoretical knowledge, with little emphasis on practical, hands-on experience in real-world lab settings. This leads to gaps in applying knowledge to actual laboratory challenges.

**3.3 Opportunities (Areas for Improvement)****Digital and Remote Learning:**

With advances in online education and e-learning platforms, there is a huge opportunity to make training accessible to laboratory professionals worldwide, including those in remote or underserved regions. Development of interactive online platforms for virtual labs, simulations, and video tutorials can overcome geographical limitations.

Collaboration and Partnerships:

There is an opportunity to foster greater collaboration between international organizations, local governments, and educational institutions to create standardized curricula, training certifications, and laboratory exchange programs. Public-private partnerships could support the delivery of advanced training on the latest technologies and diagnostic techniques.

Integration of Soft Skills:

There's an emerging opportunity to integrate soft skills training (e.g., communication skills, ethical decision-making, team collaboration, and conflict resolution) into laboratory training programs to create well-rounded professionals who can thrive in diverse working environments.

Incorporation of Research and Innovation:

Training programs can be designed to foster innovation and research skills, particularly in areas like molecular biology, bioinformatics, and laboratory automation, where there is growing demand for expertise.



3.4 Threats (Challenges and Risks)

Limited Funding:

Many training programs are underfunded, particularly in low-resource settings, which limits their reach and effectiveness. Lack of financial support can hinder the development of new training initiatives and the purchase of necessary training materials or equipment.

Cultural Barriers:

In some regions, there may be resistance to new ideas or reluctance to adopt modern training methods, especially when they challenge traditional practices or require new technology.

Inconsistent Quality of Training:

There is no uniformity in the quality of training programs, which can lead to disparities in laboratory performance and competencies. Some programs may not meet the standards required by global accrediting bodies.

High Turnover of Laboratory Staff:

High turnover rates among laboratory staff, particularly in rural or underserved areas, can make it difficult to retain the trained professionals. This leads to loss of investment in training and a cycle of skill gaps.

Regulatory and Legal Barriers:

In some countries, complex regulations and legal barriers may slow down the implementation of certain training programs or create bureaucratic hurdles in accreditation and certification.

Technological Challenges:

The rapid pace of technological change can create challenges in ensuring that laboratory staff are always trained on the latest technologies. There's also the risk of technology overload, where laboratories are introduced to too many new tools at once, making it hard for staff to keep up.



3.5 Addressing the Gaps in a Laboratory Training and Capacity-Building Framework

Based on the SWOT analysis, a well-designed laboratory training and capacity-building framework can address the following gaps:

Develop a Comprehensive, Standardized Curriculum:

To address the fragmented nature of training, creating a national or regional standardized curriculum will ensure consistency in training content and quality across laboratories.

Focus on Hands-On Training and Real-World Scenarios:

Incorporating more practical training in real lab settings, possibly through internships or hands-on workshops, will help bridge the gap between theory and practice.

Leverage Technology:

Expanding access to e-learning platforms, virtual labs, and online certifications can overcome resource constraints and geographical barriers.

Increase Funding and Support for Training Initiatives:

Governments, international organizations, and private sector partners should collaborate to secure funding for training programs and support research-based innovations in laboratory science.

Improve Soft Skills and Leadership Development:

Integrating training for leadership, communication, and management will help build a more competent workforce capable of handling both technical and interpersonal challenges.

**3.6 Thematic Areas to be addressed in this framework**

The following thematic areas are addressed by this framework

Introduction to QMS

ISO 15189

Understanding 17025

Process control and internal quality control (IQC)
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Root Cause Analysis, Corrective (RCA)

Internal Audits

Management Reviews

Biosafety and Biosecurity

INTRODUCTION TO QMS TRAINING

A Laboratory Quality Management System (LQMS) training is designed to provide laboratory professionals with the necessary skills and knowledge to implement, maintain, and improve quality management systems in laboratory settings. The goal is to ensure that laboratories operate efficiently, maintain high standards of accuracy, reliability, and safety, and comply with international standards like ISO 15189 (for medical laboratories) or ISO/IEC 17025 (for testing and calibration laboratories).



4.1 Competencies Built by the Framework

The Introduction to QMS training will aim to build competencies in the following areas:

- Quality Assurance (QA) and Quality Control
- Understand the difference between QA and QC
- Implement quality control measures in laboratory testing
- Identify and correct errors to maintain accuracy and reliability
- Development of Standard Operating Procedures
- Document Control and management
- Internal Audits
- Corrective and Preventive Actions
- Risk Management



4.2 Training Content/Modules

The training will cover a comprehensive set of modules to address the various components of an effective Laboratory Quality Management System (LQMS).

Some key modules may include:

Module 1:	Introduction to Quality Management in Laboratories
Module 2:	Laboratory Quality Assurance and Control
Module 3:	Standard Operating Procedures (SOPs)
Module 4:	Laboratory Documentation and Record Keeping
Module 5:	Internal Auditing and External Audits
Module 6:	Risk Management in Laboratories
Module 7:	Laboratory Accreditation and Certification



4.3 Certifications/Certification Levels Available

The LQMS training framework will offer different levels of certification, depending on the individual's role and expertise.

These levels may include:

1

Level 1: Basic Quality Management Training

For entry-level lab technicians, this certification provides foundational knowledge in laboratory quality management.

Focuses on key concepts like SOPs, quality control, and record keeping.

2

Level 2: Intermediate Laboratory Quality Management Certification

For mid-level laboratory staff (e.g., lab supervisors, senior technicians). Builds on the basic certification and includes modules on internal audits, CAPA, and risk management.

This level prepares staff for managerial roles or as quality assurance coordinators.

3

Level 3: Advanced Laboratory Quality Management Certification

For senior laboratory managers or those responsible for overall laboratory quality and accreditation. Includes in-depth training on accreditation procedures, external audits, and leading quality improvement initiatives in large laboratories.

4

ISO 15189 or ISO/IEC 17025 Specialized Certification:

This can be offered as an advanced certification for those involved in laboratories seeking international accreditation. Focuses on the specific requirements of ISO 15189 (medical laboratories) or ISO 17025 (testing and calibration laboratories), including detailed steps in achieving accreditation.



4.4 How the Training Will Be Done

The training can be delivered through various methods to ensure maximum accessibility and effectiveness:

- In-person Workshops
- Hands-on training and interactive learning in a physical classroom setting
- Case studies, role-playing, and group discussions to reinforce concepts

- Online Courses and Webinars
- Flexible, self-paced learning with online materials, video tutorials, and quizzes
- Blended Learning



4.5 Who Qualifies for the Training?

The LQMS training framework is designed for all levels of laboratory staff, from entry-level technicians to senior laboratory managers.

Specific qualifications may include:

1

Level 1: (Basic):

Entry-level laboratory technicians and junior staff who are new to laboratory work or need a foundational understanding of quality management.

2

Level 2: (Intermediate):

Laboratory supervisors, senior technicians, or quality control personnel with some experience in laboratory operations, and those looking to deepen their quality management expertise.

3

Level 3: (Advanced):

Laboratory managers, quality managers, and senior staff responsible for managing laboratory quality and pursuing laboratory accreditation.

4

Specialized Certification (ISO 15189/17025):

Laboratory professionals involved in accreditation processes or who are responsible for ensuring that their lab meets ISO standards.

UNDERSTANDING ISO 15189: 2022 TRAINING

ISO 15189:2022 is the latest version of the international standard that specifies the requirements for quality and competence in medical laboratories. It provides a framework for laboratories to ensure they deliver accurate, reliable, and timely results that meet the needs of healthcare providers, patients, and regulatory bodies. ISO 15189:2022 training focuses on providing laboratory professionals with the skills and knowledge required to meet the updated requirements of the standard. The goal is to help laboratories achieve ISO 15189:2022 accreditation and continuously improve their quality management systems (QMS).



5.1 Purpose of ISO 15189:2022 Training

The purpose of ISO 15189:2022 training is to:

- Equip laboratory professionals with a thorough understanding of the updated requirements in ISO 15189:2022.
- Help laboratories build a comprehensive Quality Management System (QMS) that aligns with the latest standard.
- Enable laboratory staff to maintain accreditation, improve laboratory operations, and ensure consistent quality in laboratory testing.
- Provide laboratory leaders with tools to manage quality, ensure regulatory compliance, and foster continuous improvement.



5.2 Competencies Built Through ISO 15189:2022 Training

ISO 15189:2022 training helps to develop a wide range of competencies across multiple areas of laboratory operations, including:

a. Quality Management System (QMS)

Develop and implement a QMS that meets the updated ISO 15189:2022 requirements, including areas like document control, quality control procedures, and resource management.

b. Risk Management

Understand how to conduct risk assessments and manage potential risks to laboratory services and patient safety.

c. Competence of Personnel

Develop and maintain personnel competence and training programs to ensure that laboratory staff are adequately qualified and up-to-date with their skills.

d. Internal Auditing and External Audits

Learn how to conduct internal audits to assess compliance with ISO 15189:2022 and prepare for external accreditation audits by regulatory bodies.

e. Document and Record Management

Implement best practices for document control, including maintaining SOPs, records, and ensuring traceability of laboratory results.

f. Corrective and Preventive Actions (CAPA)

Learn how to identify problems, conduct root cause analysis, and implement corrective and preventive actions to improve laboratory processes.

g. Continuous Improvement

Apply principles of continuous improvement to laboratory operations, ensuring ongoing adaptation to evolving healthcare needs and standards.

h. Leadership and Management

Develop the leadership skills required to manage a laboratory's QMS, including strategic planning, resource management, and team leadership.



5.3 Training Content/Modules

ISO 15189:2022 training typically includes a series of modules covering various aspects of the standard. Here's an outline of the core training content/modules:

Module 1:	Introduction to ISO 15189:2022
Module 2:	Structure of ISO 15189:2022
Module 3:	Developing and Implementing a Quality Management System (QMS)
Module 4:	Risk Management and Contingency Planning
Module 5:	Competence and Training of Personnel
Module 6:	Internal Auditing and External Audits
Module 7:	Corrective and Preventive Actions (CAPA)
Module 8:	Continuous Improvement and Innovation
Module 9:	Preparing for Accreditation and Certification



5.4 Certifications/Certification Levels Available

ISO 15189:2022 training offers various levels of certification to match the different roles and responsibilities in the laboratory. The main certification levels are:

<p>Level 1: Introductory Certification (Basic Understanding)</p>	<p>Target Audience: Laboratory technicians, junior staff, and those new to ISO 15189.</p> <p>Content: A basic understanding of ISO 15189:2022, including the structure and general requirements of the standard.</p> <p>Certification: Completion of introductory modules and a final assessment (multiple-choice quiz or short assignment).</p>
<p>Level 2: Intermediate Certification (Implementation and Management)</p>	<p>Target Audience: Laboratory supervisors, managers, quality control coordinators, and lead technicians.</p> <p>Content: Focus on implementing and maintaining a QMS, performing internal audits, and handling risk management processes.</p> <p>Certification: Completion of intermediate-level modules, a final written exam, and practical assessments of applying the standard in the laboratory.</p>
<p>Level 3: Advanced Certification (Auditing and Leadership)</p>	<p>Target Audience: Senior laboratory managers, quality managers, lead auditors, and laboratory directors.</p> <p>Content: In-depth focus on leadership, audit processes, and maintaining ISO 15189:2022 compliance in large laboratory operations.</p> <p>Certification: A comprehensive examination that includes written assessments, practical application, and possibly a lead auditor certification for conducting ISO 15189 audits.</p>
<p>ISO 15189 Auditor/ Lead Auditor Certification</p>	<p>Target Audience: Professionals interested in becoming ISO 15189 auditors.</p> <p>Content: Specific training on how to conduct audits of medical laboratories to evaluate compliance with ISO 15189:2022, including audit techniques, report writing, and corrective actions.</p> <p>Certification: Successful completion of a detailed auditor training program, practical audit experience, and a final audit exam.</p>



5.5 How the Training Will Be Done

ISO 15189:2022 training can be delivered through various formats to accommodate the needs of different learning environments:

a. In-person Workshops

Intensive, hands-on sessions led by certified instructors.

Includes case studies, role-playing, group discussions, and real-life examples of how to implement ISO 15189:2022.

b. Online Courses

Flexible, self-paced online training with access to learning modules, video lectures, and quizzes.

Virtual workshops and webinars with instructors to address specific queries or challenges.

c. Blended Learning

A combination of online modules for theoretical knowledge and in-person workshops or practical assessments to reinforce learning and gain real-world experience.

d. On-the-job Training

Practical, hands-on experience in laboratories, where trainees can apply ISO 15189 principles to actual lab operations under the supervision of experienced mentors.

e. Webinars and Online Seminars

Live online training sessions led by experts in ISO 15189:2022, with opportunities to interact, ask questions, and participate in discussions.



5.6. How Certification Will Be Done

Certification for ISO 15189:2022 training is typically awarded after the successful completion of the following:

Completion of Training Modules:

Participants must complete the required modules for their certification level.

The training may involve online quizzes, assignments, and participation in interactive workshops.

Final Assessment:

A final exam that assesses theoretical knowledge and practical application of ISO 15189:2022 principles.

The assessment may include multiple-choice questions, short-answer questions, and scenario-based questions.

Practical Evaluation (if applicable):

For advanced certifications or auditor training, participants may need to demonstrate practical knowledge by conducting audits or developing QMS in a laboratory setting.



PROCESS CONTROL AND INTERNAL QUALITY CONTROL (IQC) TRAINING

This training is designed to provide laboratory professionals with essential skills and knowledge in process control and internal quality control (IQC) systems. The goal is to ensure that laboratory operations maintain high standards of accuracy, precision, and consistency in test results. By understanding and implementing effective IQC systems, lab personnel can identify errors early, troubleshoot issues, and maintain the reliability of laboratory testing.



6.1 Competencies Built by the Framework

The Process Control and IQC training framework will help build the following competencies:

- a. Process Control
- b. Internal Quality Control (IQC)
- c. Data Interpretation and Decision Making
- d. Documentation and Compliance



6.2 Training Content/Modules

The training will be divided into modules that focus on different aspects of process control and IQC:

Module 1:	Introduction to Process Control and Internal Quality Control (IQC)
Module 2:	Principles of Process Control
Module 3:	Designing and Implementing an IQC System
Module 4:	Monitoring and Evaluating IQC
Module 5:	Corrective and Preventive Actions (CAPA) in IQC
Module 6:	Compliance and Record-Keeping for IQC
Module 7:	Troubleshooting and Continuous Improvement



6.3 Certifications/Certification Levels Available

The Process Control and IQC training will offer certifications at multiple levels based on the depth of knowledge and responsibility:

<p>Level 1: Introductory Certification (Basic Understanding)</p>	<p>Target Audience: Laboratory technicians, junior staff, and those new to quality control and process management.</p> <p>Focus: Basic understanding of process control principles, introduction to IQC, and the role of quality assurance in laboratory operations.</p> <p>Certification Requirements: Completion of the introductory modules and successful performance on a basic-level exam or assessment.</p>
<p>Level 2: Intermediate Certification (Implementation and Monitoring)</p>	<p>Target Audience: Laboratory supervisors, managers, and quality control coordinators.</p> <p>Focus: Designing, implementing, and monitoring IQC systems, troubleshooting, and data analysis using control charts.</p> <p>Certification Requirements: Completion of intermediate modules, successful performance in practical exercises, and a written exam.</p>
<p>Level 3: Advanced Certification (System Optimization and Leadership)</p>	<p>Target Audience: Senior laboratory staff, quality assurance leads, and laboratory managers.</p> <p>Focus: Advanced techniques for process optimization, leading IQC programs, implementing corrective and preventive actions (CAPA), and managing compliance with international standards.</p> <p>Certification Requirements: Completion of advanced modules, practical application exercises, and a comprehensive exam.</p>



6.4 How the Training Will Be Done

The Process Control and IQC training can be delivered in several formats to ensure flexibility and practical engagement:

a. In-person Workshops

Hands-on, interactive sessions where participants design and implement process control systems and IQC programs.

Group discussions, case studies, and real-world problem-solving exercises focused on process control and quality management in the laboratory.

b. Online Courses

Flexible self-paced learning with video lectures, reading materials, quizzes, and interactive activities.

Opportunities for live webinars and Q&A sessions with experts in quality management.

c. Blended Learning

A combination of online modules (for theoretical knowledge) and in-person workshops (for hands-on application of IQC principles).

Includes practical assignments, quizzes, and group projects.

d. On-the-job Training

Practical, real-world experience in the laboratory setting where participants apply IQC principles under the supervision of a mentor or experienced staff member.

Continuous support and feedback from trainers and peers.



6.5 How the Certification Will Be Done

Certification will be awarded upon successful completion of the training program and assessment:

Module Completion: Participants must complete the required training modules for their certification level.

Assessments:

Written Exam: Participants will complete a final exam to assess their theoretical knowledge of process control and IQC principles.

Practical Evaluation: In some cases, participants may need to demonstrate their ability to apply IQC concepts through practical assessments or case studies.

Certification Award: Upon passing the assessments, participants will receive an official certification corresponding to their level of training (Level 1, 2, or 3).

Continuing Education: To maintain certification, laboratory professionals may be required to engage in ongoing learning and professional development activities related to process control and quality management.



6.6 Who Qualifies for the Training

The Process Control and IQC Training is suitable for laboratory professionals at different stages of their career, from junior staff to senior managers:

Level 1: Introductory	Target Audience: Entry-level laboratory technicians, laboratory assistants, and individuals new to quality management in laboratory settings.
Level 2: Intermediate	Target Audience: Laboratory supervisors, quality control staff, senior technicians, and anyone responsible for implementing or overseeing IQC systems.
Level 3: Advanced	Target Audience: Laboratory managers, quality assurance leads, senior staff responsible for managing laboratory operations, and individuals in leadership roles who oversee quality control and process optimization in the laboratory.



INTERNAL AUDITING TRAINING



7.1 Competencies Built by the Framework

The Internal Auditing Training framework will help participants develop key competencies essential for conducting effective audits in a laboratory setting:

- a. Understanding Auditing Principles
- b. Audit Planning and Preparation
- c. Conducting Audits
- d. Reporting and Documentation
- e. Corrective Actions and Follow-up
- f. Continuous Improvement and Audit Effectiveness



7.2 Training Content/Modules

The training will be divided into structured modules that address all aspects of internal auditing, from the fundamentals to advanced auditing techniques:

Module 1:	Introduction to Internal Auditing
Module 2:	Auditing Principles and Standards
Module 3:	Audit Planning and Preparation
Module 4:	Conducting the Internal Audit
Module 5:	Reporting Audit Findings
Module 6:	Corrective and Preventive Actions (CAPA)
Module 7:	Follow-up Audits and Verification
Module 8:	Auditing for Continuous Improvement
Module 9:	Advanced Auditing Techniques (Optional)



7.3 Certifications/Certification Levels Available

The Internal Auditing Training program will offer certification levels based on the participant's experience and their role within the laboratory. Each level will focus on different aspects of internal auditing, from foundational knowledge to advanced auditing skills.

<p>Level 1: Introductory Certification (Basic Understanding)</p>	<p>Target Audience: Laboratory staff, junior technicians, and individuals with little to no auditing experience.</p> <p>Focus: Introduction to the auditing process, the role of internal audits in laboratories, and basic auditing principles.</p> <p>Certification Requirements: Completion of foundational modules, participation in quizzes and activities, and successful completion of a basic-level exam.</p>
<p>Level 2: Intermediate Certification (Audit Execution and Reporting)</p>	<p>Target Audience: Laboratory supervisors, quality control personnel, or staff who actively participate in internal audits.</p> <p>Focus: Developing practical skills in planning and conducting internal audits, creating checklists, reporting findings, and understanding the CAPA process.</p> <p>Certification Requirements: Completion of intermediate-level modules, participation in practical exercises, and a written exam or audit project.</p>
<p>Level 2: Advanced Certification (Lead Auditor)</p>	<p>Target Audience: Senior laboratory staff, managers, or those aiming to lead audits across multiple laboratories or departments.</p> <p>Focus: Advanced auditing techniques, leading audits, managing large-scale audits, and presenting results to upper management. Also includes training for ISO 15189 Lead Auditors or ISO/IEC 17025 Lead Auditors.</p> <p>Certification Requirements: Completion of advanced modules, participation in practical audits, and passing a comprehensive final exam that includes a case study and practical application of auditing skills.</p>



7.4 How the Training Will Be Done

The Internal Auditing Training will be delivered through multiple formats to cater to different learning preferences:

a. In-person Workshops

Hands-on experience in audit execution, mock audits, and group exercises.

Role-playing exercises where participants simulate audits in laboratory settings, analyze findings, and present audit reports.

Facilitated discussions on audit techniques, challenges, and real-world applications.

b. Online Courses

Self-paced, interactive online modules with video lectures, quizzes, and assignments.

Virtual case studies, where participants analyze audit scenarios and apply auditing techniques.

Scheduled webinars and Q&A sessions with expert auditors for real-time interaction.

c. Blended Learning

Combination of online theoretical modules and in-person workshops or practical auditing exercises to reinforce learning.

Mentorship and guided feedback through practical audits or case studies.

d. On-the-job Training

Real-world experience: Internally conducted audits in a laboratory setting, guided by trained auditors. Continuous feedback and coaching by mentors during actual audits.



7.5 How the Certification Will Be Done

Certification will be awarded upon successful completion of the following steps:

Completion of Training Modules:

Participants must complete all required modules for the certification level they are pursuing.

Assessment: Written Exam: Theoretical assessment on the key auditing principles, standards, and laboratory processes.

Practical Evaluation: A mock audit, where participants apply their knowledge by auditing laboratory processes and preparing a report with findings and recommendations.

Audit Report Submission: A report that documents audit findings, non-conformities, and proposed corrective actions.



7.6 Certification Issuance:

Successful participants will receive a certification indicating their level of proficiency in internal auditing (Level 1, 2, or 3).

Ongoing Professional Development:

To maintain certification, participants may need to engage in continuing education or periodic audits to keep their skills and knowledge up-to-date.



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LABORATORY MANAGEMENT REVIEW TRAINING

The Management Review Training program focuses on educating laboratory managers and quality assurance professionals on how to effectively conduct management reviews. These reviews are crucial in evaluating the overall effectiveness of the laboratory's quality management system (QMS) and ensuring that it meets the required regulatory standards and laboratory goals. The training aims to enhance decision-making, prioritize improvements, and drive continuous improvement in laboratory practices.



8.1 Competencies Built by the Framework

- a. Understanding Management Reviews and Their Role
- b. Planning and Preparation for Management Reviews
- c. Conducting Management Reviews
- d. Reporting and Documenting Management Reviews
- e. Driving Continuous Improvement



8.2 Training Content/Modules

The Management Review Training will cover the following content and modules to ensure comprehensive knowledge and skills:

Module 1:	Introduction to Management Reviews
Module 2:	Preparing for Management Reviews
Module 3:	Conducting Effective Management Reviews
Module 4:	Reporting and Documenting Management Review Outcomes
Module 5:	Management Review Follow-Up
Module 6:	Continuous Improvement and Management Reviews



8.3 Certifications/Certification Levels Available

The Management Review Training program will offer certifications at different levels based on the participant's experience and role within the laboratory.

Level 1:

Introductory
Certification
(Basic
Understanding)

Target Audience: Laboratory assistants, junior managers, and laboratory technicians who are new to management reviews or have minimal experience.

Focus: Basic concepts of management reviews, their purpose, and understanding how data informs decision-making.

Certification Requirements: Completion of foundational modules and a basic-level exam or assessment.

Level 2:

Intermediate
Certification
(Conducting
and Facilitating
Reviews)

Target Audience: Laboratory supervisors, quality control staff, or middle management responsible for facilitating or participating in management reviews.

Focus: Developing the ability to conduct management reviews, analyze data, and track follow-up actions.

Certification Requirements: Successful completion of intermediate-level modules, participation in practical exercises, and a written exam. This level may include a mock management review session to test facilitation skills.

Level 3:

Advanced
Certification
(Leading
Management
Reviews)

Target Audience: Senior laboratory managers, quality assurance leads, and personnel responsible for leading and overseeing laboratory management reviews at a high level.

Focus: Leading strategic management reviews, making high-level decisions, and ensuring the laboratory meets continuous improvement goals.

Certification Requirements: Completion of advanced modules, a comprehensive case study, and a final exam. This may include participation in a live management review session where participants lead discussions and make decisions based on data.



8.4 How the Training Will Be Done

The Management Review Training will be conducted using various formats to ensure flexibility and engagement for all learners:

- a. In-person Workshops
- b. Online Courses
- c. Blended Learning
- d. On-the-job Training



8.5 How the Certification Will Be Done

Certification for Management Review Training will be granted after successful completion of the following steps:

Completion of Training Modules:

Participants must complete the required modules for their certification level (Introductory, Intermediate, or Advanced).

Assessments:

Written Exam: Theoretical questions on the core concepts of management reviews, including their role, the preparation process, and how to analyze data.

Practical Evaluation: A case study or mock management review where participants demonstrate their ability to analyze laboratory performance, identify trends, and propose actionable decisions.

Certification Award:

Upon successful completion of training and assessments, participants will receive a certificate indicating their Management Review Certification level (Level 1, 2, or 3).

Follow-up and Continuing Education:

For those who wish to maintain certification, there may be a requirement for ongoing professional development or periodic refresher courses.



8.6 Who Qualifies for the Training

The Management Review Training is designed for laboratory professionals at various levels, depending on their role in the laboratory's quality management system.

Level 1: (Introductory):	Target Audience: Laboratory assistants, technicians, or junior staff with little or no prior experience in management reviews. Prerequisites: No prior management review experience required, but a basic understanding of laboratory quality systems would be helpful.
Level 2: (Intermediate):	Target Audience: Laboratory supervisors, middle management, quality control staff, or personnel directly involved in conducting or participating in management reviews. Prerequisites: Some familiarity with laboratory quality management systems or prior experience in supporting management reviews.
Level 3: (Advanced):	Target Audience: Senior laboratory managers, quality assurance leaders, and those responsible for leading and overseeing management reviews across the laboratory. Prerequisites: Experience in conducting management reviews and leading laboratory teams, as well as in-depth knowledge of the laboratory's quality management system and performance metrics.

BIO SAFETY AND BIOSECURITY TRAINING PROGRAM

The Africa Center for Disease and Prevention (ACD) working with African Union (AU) member states developed a Regional Training and Certification Program for Biosafety and Biosecurity Experts. The four areas of specialty identified and developed are (i) Selection, Installation, Maintenance, and Certification of Biological Safety Cabinets (ii) Risk Management (iii) Design and Maintenance of Facilities Handling High Risk Pathogens (Biocontainment Engineering), and (iv) Biological Waste Management. Graduates of the training program will receive recognition and certification recognized by the African Union Members States under the Africa CDC Biosafety and Biosecurity Initiative. Qualified personnel would be incorporated into the African Union Register of Biosafety and Biosecurity Professionals and available for deployment across the region when required. [The Regional Training And Certification Program For Biosafety And Biosecurity Professionals - Africa CDC](#)

COMPETENCY LEVELS

A competency level approach will be implemented, as it provides a structured way to assess and understand an individual's skills and abilities by categorizing them into different proficiency levels. The competencies are broken down into levels, with the specific expected knowledge, skills and behaviours.

1 Level 1: Basic (Foundational Level)

To attain this level, participants must complete online modules and attain a 60% score. An online component is included to ensure participants are familiar with the Level 1 content before the didactic sessions and to serve as a measure of their commitment to the training. Participants who successfully pass their online courses are enrolled in a 10-day face-to-face training, Workshop 1, which consists of didactic training and a qualifying examination. Participants are expected to demonstrate basic understanding of the LQMS principles and modules and should be able to conduct basic management tasks within the context of the modules covered in Workshop 1. The didactic portion of Level 1 will cover all the course content proposed above.

2 Level 2: Intermediate:

This level is attained when participants successfully complete Workshop 1 and conduct an improvement/research project under the guidance of an experienced laboratory leader or mentor. The improvement/research project is conducted within a six months period. For Level 2 certification, participants will submit a portfolio of evidence to the ASLM Academy that includes:

- i. marks for the online research courses;
- ii. a technical report on the improvement/research project; and
- iii. a manuscript accepted by a peer-reviewed journal.

3 Level 3: Expert in Laboratory Management (Subject Matter Expert [SME])

This level should demonstrate experience working as an LQMS leader for at least one year after Level 2 qualification. For Level 3 (SME) certification, participants should submit a portfolio of evidence to ASLM Academy that includes documentation of:

- Working experience as an LQMS leader (e.g., holding An LQMS position for at least 2 years)
- Continuous professional development via other LQMS courses, knowledge exchange programmes
- Mentorship or training of other emerging LQMS leaders in the laboratory fraternity

4

Expected Outcomes

- Increased number of laboratories implementing LQMS in line with ISO 15189.
- Strengthened LQMS practices in laboratory operations.
- Established cadre of national and regional LQMS trainers and mentors.
- Improved diagnostic accuracy, reliability, and turnaround times.
- Greater resilience of laboratory systems during public health emergencies.
- Institutionalization of LQMS leading to sustainability

Table 1 : Competency level of each thematic area

Thematic Area	Level 1	Level 2	Level 3
Introduction to QMS ISO 15189	Understanding the requirements of ISO 15189. Passing examination by attaining 70% mark	Implementing improvement projects based on ISO 15189 standard	Conducting training on laboratory to attain ISO 15189 accreditation
Understanding 17025	Being trained and Understanding the requirements of ISO 17025. Passing examination by attaining 70% mark	Successfully Implementing improvement projects based on ISO 17025 standard	Mentoring laboratory to attain ISO 15189 accreditation
Process control and internal quality control (IQC)	Understanding the principles of IQC. Passing examination by attaining 70% mark	Implementing improvement projects based on setting an IQC system	Mentoring laboratory to establish and implement an IQC system
Root Cause Analysis, Corrective (RCA)	Understanding the principles of Root Cause Analysis	Setting up a RCA system	Mentoring other laboratory professionals in RCA
Internal Audits	Understanding the principles of Internal Auditing and attaining at least 70% in the examination	Setting up an Internal Audit system as an improvement project	Training other laboratory professionals in Internal Auditing
Management Reviews	Understanding the principles of conducting a Management Review and attaining at least 70% in the examination	Leading a Management review as an improvement project	Working with a laboratory to attain accreditation

Biosafety and Biosecurity	Understanding the principles of Biosafety and Biosecurity and attaining at least 70% in the examination	Training other laboratory professionals in Biosafety and Biosecurity	Mentoring a laboratory to set up a Biosafety and Biosecurity program
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Implementation Timeline

Phase	Activities	Duration
Phase 1	Needs assessment and curriculum development	3 months
Phase 2	Training-of-trainers and pilot sessions	4 months
Phase 3	Country cascade trainings and mentoring	6-12 months
Phase 4	Monitoring, evaluation, and sustainability planning	Ongoing

Potential Partners and Stakeholders

- Africa CDC - Policy alignment and regional coordination
- WHO AFRO - Technical guidance
- National Public Health Institutes - Local implementation
- Donor agencies - Funding support (PEPFAR, Global Fund, Fleming Fund, Gates Foundation, WAHO/PROALAB)
- Academic institutions - Curriculum integration

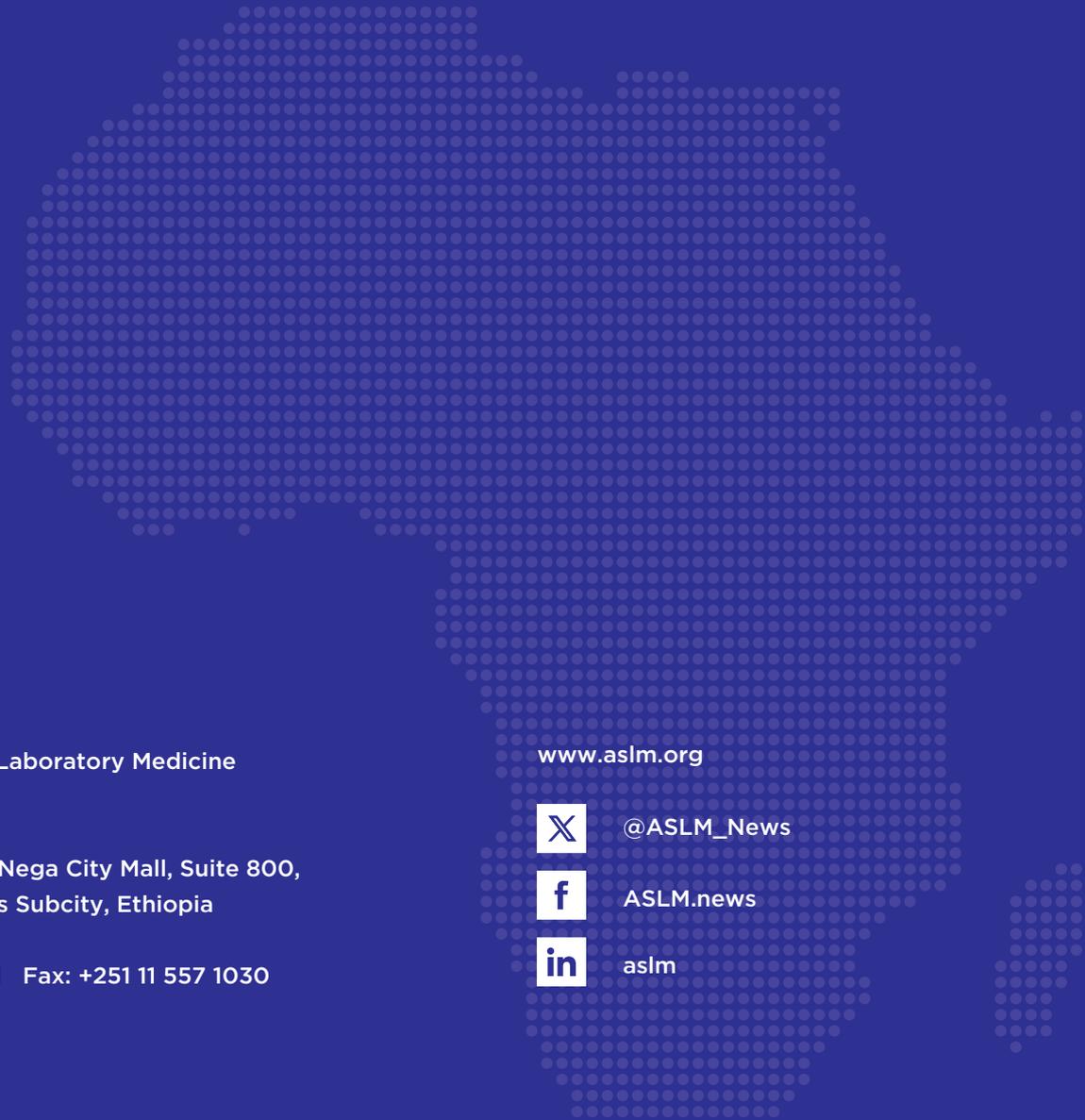
Annex 1: Proposed Roadmap for Laboratory Leadership Training

Level	Minimum requirements	Model of Training	Duration	Competencies gained
Entry	Complete online screening training and score of at least 60%	Online modules	15 days	Principles of LQMS Laboratory systems strengthening modules
1	Complete Level 1 online modules and attain a score of at least 60% Successful candidates are enrolled in a face-to-face training and qualifying examination	Pre-workshop online training Didactic Level 1 training	15 days (online training) 10 days (face-to-face training)	Basic understanding of LQMS principles Ability to conduct LQMS and management tasks within context of Workshop 1
2	Completion of Workshop 1 training Improvement/research project Pass online modules on research writing Submit a portfolio to ASLM	Mentorship Online modules Improvement / research project Publication in peer-reviewed journal	6 months	Implementation of improvement/research projects Research implementation Research writing skills
3	Participants will submit a portfolio of evidence to the ASLM Academy that includes: (i) marks for the online research courses; (ii) a technical report on the improvement/research project Experience working as a laboratory leader for at least three years post Level 2 qualification Continuous professional development.	Continuous professional development	6 months	LQMS implementation Mentoring other LQMS personnel Continuing to publish in peer-reviewed journals



ASLM

AFRICAN SOCIETY FOR LABORATORY MEDICINE



African Society for Laboratory Medicine
(ASLM)

Joseph Tito Street, Nega City Mall, Suite 800,
P.O Box 5487 Kirkos Subcity, Ethiopia

Tel: +251 11 557 1021 Fax: +251 11 557 1030

www.aslm.org



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