REPUBLIC OF KENYA

MINISTRY OF HEALTH

Kenya Medical Laboratory Continuous Quality Improvement (LCQI) Guideline 2022

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FOREWORD

Provision of accurate and reliable laboratory diagnosis is key to patient treatment, management and surveillance of diseases and adverse effects. The country has long been implementing laboratory Quality Management Systems (QMS) leading to ISO 15189 accreditation of more than 100 laboratories. Accredited laboratories provide additional competency for laboratory staff and timely testing services that address current and emerging health threats.

It is however widely acknowledged that accreditation is not a one-off activity but a continuous process improvement that seeks to improve and sustain laboratory services. This calls for self-driven strategies at the laboratory level to implement continuous quality improvement (CQI) across 12 quality system essentials (QSEs) to achieve and sustain external accreditation. One of these strategies is the Laboratory Continuous Quality Improvement (LCQI) that may be used as part of continuous improvements for routine surveillance and annual assessments to ensure adherence to the requirements of the ISO 15189.

As the cost of obtaining accreditation may limit the number of laboratories achieving the ISO 15189 standard, other laboratories can also routinely implement LCQI across the testing cycle as a way of ensuring timely, accurate, reliable and reproducible results for patient care.

To improve and sustain QMS, laboratories need to implement CQI coupled with monitoring and evaluation of the outcome. In the context of laboratory QMS, monitoring and evaluation will be conducted using standardized CQI tools such as Stepwise Laboratory Implementation Process towards Accreditation (SLIPTA) Checklist, Stepwise Process of Improvement in HIV Rapid Testing (SPI-RT) checklist, and Site Improvement Monitoring Systems (SIMS).

The Laboratory African Regional Collaborative (LARC) has also developed additional standardized Continuous Quality Improvement (CQI) approaches that can be used to monitor and evaluate LCQI implementation. When implemented using these tools and approaches, LCQI will both identify and resolve deficiencies across all the three examination phases.

This LCQI guideline will give guidance to laboratories to improve services by identifying opportunities for improvement, implementing corrective action and preventive action and monitoring effectiveness and to ensure that laboratories use a structured and standardized process for LCQI. Implementation of the guideline will ensure quality services across all laboratories and testing points in Kenya.

Dr. Patrick Amoth | Ag. Director General for Health

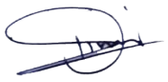
EXECUTIVE SUMMARY

This Laboratory Continuous Quality Improvement guideline aims at providing guidance to the laboratories to improve services by identifying opportunities for improvement, implementing corrective action, preventive action and monitoring effectiveness and ensure that laboratories use a structured and standardized process for LCQI implementation.

The guideline is designed for use by both ISO 15189 accredited laboratories in order to sustain their accreditation status and those that are not accredited to routinely implement LCQI across the three testing phases (pre-examination, examination and post-examination) as a way of ensuring timely, accurate, reliable and reproducible results for patient care

The guideline targets Medical Laboratory Managers, Laboratory quality Assurance (QA) officers, laboratory mentors and other stakeholders in implementing CQI and assisting laboratories to receive and maintain accreditation standards.

The guideline aims at ensuring standardized processes for implementing laboratory quality systems improvement are followed while using CQI tools to implement monitoring and corrective actions and sustaining gains. The main objectives are to: guide laboratory supervisors, technical advisors (TAs), mentors, facility staff and other stakeholders in LCQI implementation; guide implementation of LCQI in a standard and structured approach across all the laboratory networks; promote CQI culture for sustenance of efficient laboratory services; and set minimum QMS standards for laboratories and Point of Care (POCs).



Dr. Francis Kuria | Head, Directorate of Public Health

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I would like to thank personnel from the Department of Laboratory Services in the Ministry of Health (MOH), President's Emergency Plan for AIDS Relief (PEPFAR) Kenya, Center for Disease Control (CDC) Kenya, and African Medical Research Foundation (AMREF) Health Africa who developed, reviewed and finalized the Kenya Laboratory continuous Quality Improvement (LCQI) guidelines.

In particular, I would like to appreciate and acknowledge the Quality Assurance Manager at the Department of Laboratory Services, whose leadership ensured that the document was completed.

I am grateful to CDC Kenya and AMREF Health Africa for their technical and financial inputs. We also register special appreciation to the CDC - DGHT Kenya - Laboratory and Health Systems Pillar and AMREF Africa Laboratory teams for their professionalism, dedication and commitment in putting this technical document together.

The launch of these guideline is timely and marks the beginning of a deliberate process to encourage the use of continuous quality improvement across all medical laboratories to ensure provision of timely, accurate, reliable and reproducible results for patient care in Kenya. This document is a valuable resource for all medical laboratory stakeholders in Kenya. We encourage its wide usage.

Dr. John Kiiru | Head, Department of Laboratory Services

ABBREVIATION AND ACRONYMS

AMREF	Africa Medical Research Foundation
CAPA	Corrective Action Preventive Action
CDC	Centres for Disease Control and Prevention
CLSI	Clinical and Laboratory Standards Institute
CMEs	Continuous Medical Education
CQI	Continuous Quality Improvement
EMR	Electronic Medical Records
EQA	External Quality Assessment
IHI	Institute of Healthcare Improvement
IP	Implementing Partners
IPC	Infection Prevention and Control
IQC	Internal Quality Control
ISO	International Organization for Standardization
KMLTTB	Kenya Medical Laboratory Technician and Technologist Board
LARC	Laboratory African Regional Collaboration
LCQI	Laboratory Continuous Quality Improvement
LIMS	Laboratory Information Management System
LIS	Laboratory Information System
M & E	Monitoring and Evaluation
MOH	Ministry of Health
PEP	Post Exposure Prophylaxis
PEPFAR	Presidential Emergency Plan for AIDS Relief
POCs	Point of Care
PPE	Personal Protective Equipment
PQ	Process Qualification
QA	Quality Assurance

QI	Quality Improvement
QMS	Quality Management System
QSE	Quality Standard Essentials
RT-CQI	Rapid Testing Continuous Quality Improvement
SHW	Sustainable Health Workforce
SIMS	Site Improvement Monitoring Systems
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
SOPs	Standard Operating Procedures
SPI-RT	Stepwise Process Improvement in HIV Rapid Testing
TA	Technical Advisor
TAT	Turnaround Time
TB	Tuberculosis

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1.0: INTRODUCTION

1.1: Background

Accurate laboratory diagnosis is critical in providing quality and effective treatment, monitoring and surveillance of diseases. To this effort, Kenya has implemented Laboratory Quality Management Systems (QMS) leading to ISO 15189 accreditation of more than 100 laboratories by October 2022. Accredited laboratories provide additional quality systems and up-to-date competency for laboratory staff.

It is widely acknowledged that accreditation is not a one-off activity but a continuous process improvement that seeks to improve and sustain laboratory services towards efficiency, access and cost- effectiveness. According to the Clinical and Laboratory Standard Institute (CLSI) model, laboratories need to implement continuous quality improvement (CQI) across 12 quality system essentials (QSEs) to achieve and sustain external accreditation. Accredited laboratories will implement LCQI as part of continuous improvements for routine surveillance and annual assessments to ensure adherence to the requirements of the ISO 15189. As the cost of obtaining accreditation may limit the number of laboratories achieving accreditation, other laboratories can routinely implement LCQI across the three testing phases (pre-examination, examination and post-examination) as a way of ensuring timely, accurate, reliable and reproducible results for patient care.

To improve and sustain QMS, the laboratory needs to implement CQI coupled with monitoring and evaluation of the outcome. In the context of laboratory QMS, monitoring and evaluation is conducted using standardized CQI tools such as Stepwise Laboratory Implementation Process towards Accreditation (SLIPTA) Checklist, Stepwise Process of Improvement in HIV Rapid Testing (SPI-RT) checklist and Site Improvement Monitoring Systems (SIMS).

The Laboratory African Regional Collaborative (LARC) has also developed additional standardized Continuous Quality Improvement (CQI) approaches that can be used to monitor and evaluate LCQI implementation. When implemented using these tools and approaches, LCQI will both identify and resolve deficiencies across all the three examination phases. This guideline will serve as an implementation tool to ensure quality services across all laboratories and testing points in Kenya.

1.2: Purpose of this Guideline

To provide guidance to laboratories to improve services by identifying opportunities for improvement, implementing corrective action and preventive action and monitoring effectiveness and to ensure that laboratories use a structured and standardized process for LCQI implementation.

1. CLSI. A Quality Management System Model for Laboratory Services. 5th ed. CLSI guidelines QMS01. Wayne, PA: Clinical and Laboratory Standard Institute, 2019.

1.3: Target Audience

This guideline targets Medical Laboratory Managers, Laboratory Quality Assurance (QA) officers, laboratory mentors and other stakeholders in implementing CQI and assisting laboratories to receive and maintain accreditation standards.

1.4: Goal

The goal of the Kenya Medical Laboratory Continuous Quality Improvement Implementation Guideline is to ensure standardized processes for implementing laboratory level quality systems improvement while using CQI tools to implement monitoring and corrective actions and sustaining gains

1.5: Objectives

- ***To guide laboratory supervisors, technical advisors (TAs), mentors, facility staff and other stakeholders in LCQI implementation.***
- ***To guide implementation of LCQI in a standard and structured approach across all the laboratory networks***
- ***To promote CQI culture for sustenance of efficient laboratory quality services***
- ***To set minimum QMS standards for laboratories and Point of Care (POCs).***

2.0 LABORATORY CONTINUOUS QUALITY IMPROVEMENT

LCQI is a never-ending cycle used to measure, improve and sustain quality across the three testing phases: pre analytical, analytical and post-testing. Laboratories need to think about value instead of volume, which translates into a need to have leaner processes, work more efficiently, eliminate redundant testing, and work cooperatively with the rest of the clinical patient management team.

A comprehensive LCQI can help a laboratory ensure that all activities are monitored and evaluated, and results are accurate and reliable.

The "L" is added to the "CQI" to reflect this focus on the laboratory indicators that may need to be monitored using appropriate tools. Besides measures of indicators, LCQI, like all CQI approaches, shall also run on inter-cadre collaboration and good communication.

2.1: LCQI Implementation Model

There are various models of implementing CQI. For the laboratory QMS however, the selected CQI model must addresses the overall activities in the different testing phases, from the pre-analytic to the post-analytic testing phase. The DMAIC approach is the recommended for quality improvement (QI) approach for healthcare worldwide by the Institute for Health Care Improvement (IHI). This model is simple, standardized, data-driven and focuses on setting aims while developing measures to indicate if change has resulted in improvement. As shown in Figure 1, this approach has five steps to be implemented, namely Define, Measure, Analyze, Improve and Control.

In this model, D=Define (this involves creating problem statement, defining goals and aim and developing timelines and scope)

M=Measure (involves selecting metric/measure and collecting data)

A=Analyze (identifying Root Cause using 5 WHYS, Fishbone, Pareto Diagram)

I= Improve (involves Testing and selecting Changes using brainstorming, Affinity diagrams, Impact-Effort Grids, 5S, Before and After Pictures) and

C=Control (involves monitoring process, communicating and reporting).

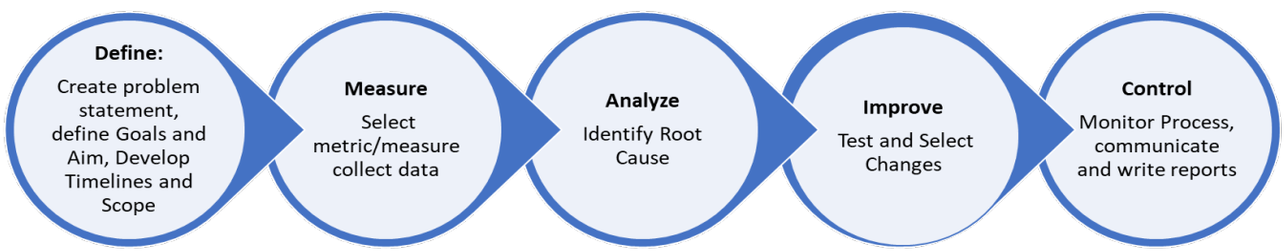

Figure 1: The DMAIC model of implementing CQI | Reference. http://www.ihi.org/resources/Pages/HowtoImprove/default.aspx

3.0: COMPONENTS OF LCQI GUIDELINE.

3.1: *Section1*: Identifying Laboratory Management and Policy Stakeholders

3.1.1: The Purpose

This section seeks to link the laboratory department to the upper management and how routinely, the laboratory communicates with the upper management on laboratory operations, financial, training and human resource needs.

3.1.2: Policy Guidance

Laboratory management shall provide evidence of its commitment to the development and implementation of LCQI and continually improve its effectiveness. The laboratory's design and functioning must be recognized legally and by the relevant regulatory authorities (Kenya Medical Laboratory Technicians Technologist Board (KMLTTB) Cap 253A and public health act 2012.

3.1.3: Implementation requirements

The laboratory management shall

1. Establish a communication and feedback mechanism among key stakeholders on the lab needs and users' requirements: management review meeting, regular facility level meeting.
2. Address issues in implementing laboratory quality needs.
3. Define responsibilities, authorities, and interrelationships of all personnel.
4. Appoint a quality manager.
5. Train and conduct personnel competency assessment.
6. Develop costed work plan that ensure availability of adequate resources to enable the proper conduct of pre-examination, examination and post-examination activities.

Key Stakeholders

The key stakeholders whose inputs and participation may be required for LCQI include:

1. Health facility management team
2. Biomedical Engineer
3. Sub- County Health Management team
4. County Health Management team
5. Relevant Hospital Committee(s)
6. Implementing Partners (IP)
7. And any other relevant stakeholder(s)
8. Suppliers and vendors Key documents

Key documents

Key documents (National and /or customized) that the laboratory shall include are;

1. Laboratory Policy Guidelines
2. Biosafety Manual
3. Quality Manual
4. Equipment Manual
5. Laboratory test menu
6. Laboratory Annual Work Plan
7. Approved laboratory Budget
8. Clinician Handbook

Key Standard Operating Procedures

The laboratory shall have SOPs that are current and approved for use. The SOPs shall include but not limited to:

- *Testing procedure as per the testing menu.*
- *Equipment management procedure*
- *Reporting and release of results procedure*
- *Inventory management procedure*
- *Internal quality control procedure*
- *Sample collection procedures for all tests*
- *Safety Procedures*
- *Procedures for handling EQA/ proficiency panel testing.*
- *Communication to both internal and external customers.*

The laboratory staff shall be trained on how to develop, review and update SOPs

3.1.4: Laboratory Clinician Interface

Communication between laboratory staff and clinicians with a view to improving efficiencies around specimen collection, handling, testing and result reporting for timely clinical intervention is key. The areas of convergence between laboratory staff and clinicians are spread from health facility, region/county and national levels.

3.1.5: Section Indicators

1. Number of scheduled laboratory meetings conducted
2. Number of laboratory documents available (Laboratory Policy Guidelines, Biosafety Manual, Quality Manual, Equipment Manuals, Laboratory test menu, approved costed Work Plan, Clinician Handbook)
3. Number of updated Standard Operation Procedures (SOPs) available in the laboratory
4. Number of Laboratory staffs trained or refreshed on current updates

3.2: Section 2: Personnel

3.2.1: The Purpose

To provide a link between the quality of laboratory services and adequate, skilled and competent work force with specific job descriptions and clear professional growth opportunities. As competent laboratory staff are the most single important asset to the laboratory, training, motivation and engagement are critical parts of achieving quality laboratory services.

3.2.2: Policy guidance

Medical laboratories shall be staffed with adequate, qualified and competent personnel certified and licensed by the established regulatory agency or equivalent.

Individual personnel competency will be ascertained by their ability to perform relevant laboratory tasks and active participation in continuous professional development.

3.2.3: Implementation requirements

The laboratory shall conduct the following;

- *Develop a standard operating procedure on personnel management*
- *Establish a laboratory training program and coordinate equitable continuous professional development for all the personnel*
- *Appoint relevant laboratory authorities with defined roles and responsibilities to include on a minimum the laboratory manager, quality manager, safety officer and their respective deputies where applicable*
- *Develop, maintain, and update individual laboratory personnel file(s) comprising of the key documents.*
- *Perform induction and orientation to laboratory staff in all relevant workstations*
- *Depending on the tasks performed, facilitate vaccination against potential nosocomial infections such as hepatitis B, influenza, measles, mumps, rubella, and varicella*
- *Develop a duty roster and assign tasks*
- *Perform competency assessment to all the personnel at least annually*
- *Facilitate participation of personnel in annual staff appraisal*

3.2.4: Laboratory Clinician Interface

Competent laboratory personnel shall ensure correct, reliable and reproducible results which will inform timely clinical interventions. The laboratory personnel shall create awareness of the testing scope/menu to its customers hence increase utilization of laboratory services. The laboratory department shall continuously interact with the clinical teams to promote productive working relationships and to support capacity building activities leading to enhanced quality services. To achieve patient- centered approaches to services, the laboratory and the clinical teams shall review reference intervals and clinical decision values and communicate to its users. Delays in provision of services, critical findings, amended reports and service interruptions shall be communicated to the requesting clinicians/customers, while expeditiously acting upon the deficiencies or problems whenever necessary. In collaboration with the clinical staff, the laboratory shall resolve complaints and address gaps identified during routine service provision, periodic customer satisfactory survey, or scheduled supervision.

3.2.5: Section Indicators

1. Proportion of staff with current/updated personnel files
2. Number of laboratory personnel trained in line with the current requirements
3. Number of laboratory staff with documented and current competency assessment reports
4. Proportion of laboratory staff with documented and current annual appraisals.

3.3: Section 3: Sample management

3.3.1: The Purpose

To provide a link between the quality of results and the sample collection, processing and the results reported. The results reported are only as good as the sample collected for testing.

3.3.2: Policy guidance

The medical laboratory shall have written procedures for specimen collection, identification, transportation, receipt and rejection, testing, storage and disposal of specimens.

3.3.3: Implementation Requirements.

The laboratory shall ensure the following;

- *Availability of clinician handbook*
- *Personnel training on sample collection and management*
- *Availability of sample collection commodities*
- *Availability & correct use of Laboratory requisition/report form.*
- *Availability of Sample collection and identification procedures/SOPs/Job aids*
- *Availability & use of Sample acceptance and rejection criteria*
- *Effective Sample referral system*
- *Availability of sample shipment and transportation requirements /*
- *Availability Material transfer agreement*
- *Routine Storage Temperature monitoring*
- *Availability of Sample storage, archival and disposal criteria*

3.3.4: Laboratory clinical interface

Quality Sample collection & Handling

The laboratory shall facilitate proper handling of specimen and ensure clinicians understand sample management requirement as contained in Clinician handbook (3.1.2).

Understanding and implementation of sample management procedures will ensure that:

- **The right type of samples collected**
- **The appropriate type of container is used**
- **The sufficient of sample is collected**
- **The Sample is appropriately labelled.**
- **The Sample appropriately stored**

For samples that are to be shipped/transported to referral facilities, the following procedures shall be observed:

- **Appropriate Sample packaging is done (including triple packaging)**
- **Sample shipment conditions are observed**
- **Sample referral network is adhered to**

When sample rejection occurs, or a sample is not processed for any reason, the laboratory shall communicate appropriately to the requesting clinician providing reasons for rejection or delayed processing.

Observing the above requirements will lead to quality samples and ensure quality laboratory results that will inform appropriate patient management.

3.3.5: Key Indicators

1. Availability of updated clinician handbook
2. Availability and use of current and approved sample management SOPs.
3. Availability of specimen collection and labelling job aids.
4. Number of samples rejected.
5. Availability of sample referral networks.
6. Number of Health care workers trained on safe phlebotomy training.

3.4: Section 4: *Facility and Safety*

3.4.1: The Purpose

The purpose of this section is to ensure link between optimal biosafety and biosecurity practices and quality of work. Good biosafety and biosecurity process enhance efficient laboratory processes, staff retention, and cost-effective human resource management.

3.4.2: Policy guidance

The medical laboratory shall have documented evidence for facility design, safety structures and procedures.

3.4.3: Implementation requirements

- *Have a designated biosafety officer who shall form part of an integrated IPC committee.*
- *Have a designated and adequate laboratory space to accommodate the three testing phases (Pre-Analytical, Analytical and Post Analytical)*
- *Ensure a clean, free of leakage, free -of clutter, and controlled access lab infrastructure with dedicated storage facilities.*
- *Have appropriate safety measures in place including and not limited to signage, fire extinguishers and fire alarm.*
- *Ensure that all health care workers undergo an annual medical surveillance for common circulating exposure risk pathogens.*
- *Have hand hygiene station complaint with standard safety protocols.*
- *Ensure availability and use of standard safety equipment, personal protective equipment (PPEs) and post exposure prophylaxis (PEP)*
- *Ensure all laboratory personnel have received basic biosafety training, annual refresher trainings, safe phlebotomy, levels and operationalization of biosafety cabinets, Infection Prevention Control (IPC) and waste management.*
- *Provide relevant biosafety and biosecurity training to cleaners, drivers, couriers, riders and any other relevant persons*
- *Ensure availability and appropriate usage of safety Job aids.*
- *Ensure the facility has updated laboratory safety manual.*
- *Ensure that all the healthcare personnel have undertaken vaccinations profiles and abided by them.*

- *Ensure there is appropriate laboratory waste management practices entailing use of foot lid dust bins with black, yellow, black or purple liners.*
- *Ensure there is an emergency wash station to accommodate flush or spill that accidentally may contaminate health care workers and aliens.*
- *Ensure that the laboratories conduct and document an annual safety audits and assessments to monitor compliance with national standards.*

3.4.4: Laboratory Clinician Interface

Laboratory biosafety/biosecurity may be addressed through the coordination of administrative, regulatory and physical security procedures and practices implemented in a working environment that utilizes good biosafety practices, and where responsibilities and accountabilities are clearly defined.

Each laboratory should prepare and install basic safety practices such as hand washing stations, proper use and disposal of PPEs, waste management and periodic audit for biosafety process within the facility.

3.4.5: Section Indicators.

1. Availability of a designated and adequate laboratory space to accommodate the three testing phases.
2. Availability of a dedicated storage facilities.
3. Availability of appropriate safety measures (signage, fire extinguishers, fire alarm).
4. Availability of standard safety Equipment (Personal Protective Equipment (PPEs) and Post Exposure Prophylaxis (PEP).
5. Proportion of personnel with Basic Biosafety training
6. Availability of a designated biosafety/safety office.

3.5: Section 5: *Equipment management*

3.5.1: The Purpose

This section underscores the role of proper functioning equipment in the provision of reliable results that increase staff performance and confidence. In this context, equipment used in the laboratory, however acquired, needs to be properly selected installed, calibrated, validated, operated monitored, maintained and serviced according to manufacturers' recommendations and established national guidelines.

3.5.2: Policy guidance

The laboratory shall maintain processes and procedures that ensure that equipment used is selected, installed, validated, calibrated, maintained, serviced, stored and used according to manufacturers' recommendations.

3.5.3: LCQI Activities

The laboratory shall conduct the following:

- *Conduct needs assessment and user requirements*
- *Select and accept laboratory equipment based on user needs and in line with established procurement policies*
- *Review utilization of laboratory equipment based on emerging needs and technologies with possibility of multiplexing*
- *Review/explore potential for equipment upgrade and inter-operability/interphase with established information management systems*
- *Adopt manufacturer's manual for development and review of equipment management procedure*
- *Provide suitable environmental condition and facility for equipment installation and verify equipment performance.*
- *Train laboratory personnel on equipment operation, maintenance, and troubleshooting.*
- *Develop and update the equipment master list /equipment inventory that has all the vital information on equipment in the laboratory*
- *Establish an equipment maintenance schedule and maintain an up-to-date service records*
- *Establish equipment service contracts (SLA) with vendors/Suppliers.*
- *Facilitate routine and scheduled equipment service, calibration and maintenance provided by certified biomedical engineers according to manufacturer's minimum requirements.*
- *Monitor equipment performance to ensure their proper working condition, and document equipment down time/failure*

- *Identify obsolete equipment, label, retire and dispose of according to the Public Procurement and Disposal Act (regulations), and update equipment inventory*
- *Document equipment related adverse incidence*
- *Establish a contingency plan to prevent interruption of laboratory services*

3.5.4: Laboratory Clinician Interface

Timely serviced and calibrated Equipment will lead to quality result that support optimal patient management. Equipment downtime may lead to service interruptions resulting in delayed or missed clinical intervention .Effective communication and synergy between the laboratory and clinical teams on available laboratory tests/services will result to the optimization of equipment and diagnostic capacity.

3.5.5: Key Indicators

1. Number of equipment with complete documentation on installation qualification(IQ), Operational qualification (OQ) and performance qualification (PQ)
2. Number of equipment with evidence of routine preventive maintenance
3. Number of equipment serviced, calibrated and certified
4. Number of obsolete equipment retired and updated in the inventory
5. Number of days of equipment downtime
6. Equipment Error rates
7. Number of equipment related adverse incidence reported

3.6: Section 6: *Laboratory Commodity Management*

3.6.1: The Purpose

The purpose of this section is to providethe link between effective commodity management and provision of reliable, uninterrupted and cost-effective laboratory services. Proper purchasing and inventory will ensure that laboratory commodities are available when required, testing is efficient and cost effective.

3.6.2: Policy Guidance

The laboratory shall have a system that ensures uninterrupted availability of reagents, commodities and supplies to meet quality requirements of all laboratory procedures.

3.6.3: Implementation requirements tation requirements

- *Laboratory to provide timely commodity reports using standardized*
- *Develop/adopt and review a list of prequalified vendors/suppliers*
- *Conduct Forecasting, quantification of commodities and order with the right specifications*
- *Set minimum and maximum stock levels for all reagents and commodities in use*
- *Provide commodity management tools (annex tools)*
- *Appoint designated commodity focal person*
- *Monitor and document laboratory commodity related indicators*
- *Monitor the performance of the supplier to ensure the stated criteria are met*
- *Maintain records for each reagent/consumable.*
- *Perform physical stock counts monthly*
- *Provide adequate and appropriate storage facility for commodities*
- *Verify received commodities before reception*
- *Verify performance of reagents/consumables before use in the examination*
- *Report any adverse incident and accidents directly attributes to specific reagents/Consumables*

3.6.4: Laboratory Clinician Interface

The laboratory shall appropriately notify the clinician of any testing interruptions due to stock outs and other commodity related challenges. The laboratory shall appropriately advice on the resumption of services.

3.6.5: Key Indicators

1. Availability of recommended and updated commodity reporting tools
2. Quantity of commodities expiring in the next six months
3. Quantity of commodities expired in the last six months
4. Available commodity management focal person with clear TORs
5. Number of Days out of stock for lab commodities

3.7: Section 7: *Laboratory Quality Testing Monitoring*

3.7.1: The Purpose:

The purpose of this section is to guide on how each stage of laboratory processes and procedures across the testing cycle is controlled to ensure provision of quality, accurate, reliable and reproducible results.

3.7.2: Policy guidance:

The medical laboratory shall have a comprehensive Quality Assurance Program to cover pre-analytical, analytical and post-analytical cycle of the laboratory processes. Throughout the cycle, the laboratory shall have a well-defined metrics of quality Indicators to monitor quality laboratory services delivery.

3.7.3: Implementation Requirement.

- *Training and ongoing mentorship on Laboratory QA programs*
- *Participation in IQC and EQA programs across all tests*
- *Monitor the trend of IQC outcomes*
- *Monitor the trend of EQA outcomes*
- *Documentation of occurrence /incidences at workplace*
- *Identify, address and document nonconformities*
- *Perform method verification/validation*
- *Conduct and document CAPA where results are not satisfactory*
- *Develop, review and adherence to relevant testing SOPs*
- *Establish/adopt biological test reference ranges.*
- *Conduct and evaluate client satisfaction surveys.*
- *Review and documentation of laboratory results before release*
- *Amendment of released results/reports (data recal)*
- *Test results traceable to the equipment used*

3.7.4: Section Indicators

1. Proportion of laboratory tests enrolled in EQA programs
2. Proportion of laboratory tests with documented IQC reports.
3. Availability and documentation of occurrence /incidences in the laboratory.
4. Proportion of reported laboratory occurrences/Incidences investigated and closed.
5. Proportion of identified nonconformities with CAPA conducted and closed.
6. Number of client satisfaction surveys conducted and evaluated.

3.7.5: Laboratory Clinician Interface

Results interpretation and utilization:

Proper interpretation of the results is important in ensuring health care providers offer appropriate health services to clients. In addition to the clinicians' handbook, the laboratory shall establish a system to:

- **Flag off critical values results and communicate appropriately with clinicians**
- **Give feedback on quality and adequate sample collection to aid quality testing**
- **Provide timely communication to clinician on testing interruptions due to equipment down time, stock outs and other factors.**
- **Promptly communicate resumption of tests**
- **Alert on urgent laboratory test requests**

3.8: Section 8: Laboratory information system

3.8.1: The Purpose

The purpose of this section is to ensure data generated in the laboratory is managed appropriately. Laboratory. Laboratory generates various types of information/data including QC test results, maintenance reports and test results that need to be managed accurately, securely and with confidentiality and privacy of a patient. Manual or electronic devices can be used to manage this data.

3.8.2: Policy guidance

The laboratory shall record and manage laboratory test data properly and have a procedure for reporting, review, release, recall and archival of laboratory test data as appropriate. The laboratory shall ensure that information is accurate, secure and accessible only to individuals with the right of access privileges.

3.8.3: LCQI Activities

- *Establish a system (manual or electronic) to document, report and archive laboratory test data and associated information.*
- *Avail data management standard operating procedures in place (SOPs) on results reporting, review, release, recall, archiving and disposal.*
- *Use standardized test request and result forms*
- *Conduct routine review of laboratory records for completeness, legibility and accurate.*
- *Assign data access responsibilities*
- *Provide secure storage and archival facility for laboratory data.*
- *Provide Laboratory information system (LIS) backup.*
- *Select and verify Laboratory Information Management Systems (LIMS) before use*
- *Establish an effective and timely communication.*

3.8.4: Laboratory Clinician Interface

Results availability and access

Where LIMS exists it should be interfaced with EMR for remote login of client information and timely transmission of results. Results transmission in a timely manner to facilitate clinical decision making

The laboratory should use available data to inform on the emerging epidemiological trends.

The laboratory shall use available information to analyze workload and other quality indicators for decision making and better patient management and internal laboratory planning.

There should be collaborative research and scientific products drawn from the laboratory information between the clinicians and laboratory staff

3.8.5: Key Indicators

1. Number of laboratories with standard approved data collection and reporting MOH tools
2. Number of laboratories with registers whose test results are complete, legible and verified by an authorized person.
3. Proportion of laboratory request forms dully filled by clinicians
4. Proportion of laboratory results dispatched to clinicians within acceptable timelines (TA)

4.0: MONITORING AND EVALUATION

During implementation of the Laboratory Continuous Quality Improvement process, laboratories shall monitor and continuously improve on the selected key indicators (Annex 3)

Progress and achievements of the Implementation of the LCQI guideline will be monitored using selected indicators. Monitoring of the implementation of the guideline will be done at county and national levels using the following indicators:

1. Number of laboratories undergoing LCQI process (aggregated by County, facility Level, facility affiliation)
2. Number of accredited facilities implementing LCQI to sustain their accreditation status
3. Number of laboratories with Internal assessment conducted (aggregated by County, facility Level, facility affiliation)
4. Proportion of laboratories assessed achieving an overall score rating of: (0-50%; 51-70; 71-80%; 81-90%; over 90 %, (aggregated by County, facility Level, facility affiliation)
5. Proportion of assessed laboratories with improved performance score from previous assessment (aggregated by County, facility Level, facility affiliation)
6. Proportion of assessed laboratories with lower performance score from previous assessment (aggregated by County, facility Level, facility affiliation)
7. Proportion of labs implementing quality improvement projects. (e.g. TAT, rejection rates, EQA performance, CAPA, sample management, error rate)
8. Number of laboratory staff receiving complementary QMS refresher trainings
9. Proportion of facilities with Laboratory clinical interface (Inter-cadre collaboration through: joint review of lab quality indicators, joint CMEs, joint ward rounds, joint site.

5.0: REFERENCES

1. ISO 15189:2012- Requirements for quality and competence particular for medical laboratories
2. CLSI. A Quality Management System Model for Laboratory Services. 5th ed. CLSI guidelines QMS01. Wayne, PA: Clinical and Laboratory Standard Institute, 2019
3. https://aslm.org/resource/whos-stepwise-laboratory-quality-improvement-process-towards-accreditation-slipta-checklist/
4. Quality Policy for Medical laboratory Services in Kenya, Ministry of Health, 2012
5. Human Resource Development Procedure Guidelines, MOH, May 2016
6. Operational Manual and Guidelines for the Management of the Sustainable Health
7. Workforce (SHW)
8. Kenya Health Policy 2014-2030
9. National integrated sample referral guideline-2021.
10. Kenya Health Sector Referral Implementation Guideline 2014.
11. Kenya Biosafety and Biosecurity Training Manual
12. National Guidelines for Medical Laboratory Equipment Management

6.0 ANNEX

Annex 1: An Example of Equipment Master List

Laboratory Equipment inventory												
Name of equipment	Manufacturer	Model	Serial Number	Date Received	Laboratory Unique Identifier	Condition when received	Manual provided?	Vendor/ Supplier	Date of installation	Location	Date last serviced/ calibrated	Date retired/ disposed

Annex 2: Key Laboratory Quality Indicators

1. *Turnaround time (TAT) for Laboratory test*
2. *Sample rejection rate*
3. *Equipment down time.*
4. *Commodity stock outs*
5. *Staff turnover*
6. *Contamination/error/invalid rates*
7. *Corrected Laboratory reports*
8. *Critical values reporting*
9. *Proficiency testing performance*

Annex 3: Comprehensive List of LCQI Implementation Indicators

Section	Indicators
Section1: Identifying Laboratory Management and Policy Stakeholders	Number of scheduled laboratory meetings conducted
	Number of laboratory documents available (Laboratory Policy Guidelines, Biosafety Manual, Quality Manual, Equipment Manuals, Laboratory test menu, Approved costed Work Plan, , Clinician Handbook)
	Number of updated Standard Operation Procedures (SOPs) available in the laboratory
	Number of Laboratory staffs trained or refreshed on current updates
	Number of Laboratory staffs trained or refreshed on current updates
Section 2: Personnel management	Proportion of staff with personnel files containing educational, professional certificates, Curriculum Vitae and professional board registration
	Proportion of staff with personnel files containing Orientation records, Competency assessment records, Appraisal record and Job description records
	Number of laboratory staff with a valid professional practicing license
	Proportion of laboratory staff with satisfactory performance in competency assessments
	Proportion of laboratory staff attaining a satisfactory performance score (>80%) in annual appraisals.
Section 3: Sample management	Availability of updated clinician handbook
	Availability and use of current and approved sample management SOPs.
	Availability of specimen collection and labelling job aids.
	Number of samples rejected.
	Number of samples unlabeled
	Number of misidentified
	Number of insufficient samples
	Availability of sample referral networks.
	Number of Health care workers trained on safe phlebotomy training.
Section 4: Facility and Safety	Availability of a designated and adequate laboratory space to accommodate the three testing phases.
	Availability of a dedicated storage facilities.
	Availability of appropriate safety measures (signage, fire extinguishers, fire alarm).
	Availability of standard safety Equipment (Personal Protective Equipment (PPEs) and Post Exposure Prophylaxis (PEP).
	Proportion of personnel with Basic Biosafety training
	Availability of a designated biosafety/safety office.
Section 5: Equipment management	Number of equipment with complete documentation on installation qualification(IQ), Operational qualification(OP) and performance qualification (PQ)
	Number of equipment with evidence of routine preventive maintenance
	Number of equipment serviced, calibrated and certified
	Number of obsolete equipment retired and updated in the inventory
	Number of days of equipment downtime
	Equipment Error rates
	Number of equipment related adverse incidence reported

Section 6: Laboratory Commodity Management	Availability of recommended and updated commodity reporting tools
	Quantity of commodities expiring in the next six months
	Quantity of commodities expired in the last six months
	Available commodity management focal person with clear TORs
	Number of Days out of stock for lab commodities
Section 7: Laboratory Quality Testing Monitoring	Proportion of laboratory tests enrolled in EQA programs
	Proportion of laboratory tests with documented IQC reports.
	Availability and documentation of occurrence /incidences in the laboratory.
	Proportion of reported laboratory occurrences/Incidences investigated and closed.
	Proportion of identified nonconformities with CAPA conducted and closed.
	Number of client satisfaction surveys conducted and evaluated.
Section 8: Laboratory information system	Number of laboratories with standard approved data collection and reporting MOH tools
	Number of test results with wrong data entry
	Number of laboratories with registers whose test results are complete, legible and verified by an authorized person.
	Proportion of laboratory request forms dully filled by clinicians
	Proportion of laboratory results dispatched to clinicians within acceptable timelines (TAT)

Annex 4: LCQI Assessment Checklist

MINISTRY OF HEALTH

Kenya Medical Laboratory Continuous Quality Improvement (LCQI) Assessment Checklist

Facility Profile	Facility Name_____ MFL Code:_____ County_____ Sub-County_____ Geo-codes Latitude_____Longitude_____ Contacts: Name of Facility In-charge _____ Phone No._____e-mail:_____ Name of Laboratory In-charge_____ Phone No._____e-mail: Facility Level_____ Facility Affiliation: Public ( ) Private ( ) FBO ( ) Research ( ) Non-Hospital Out Patient Clinic ( ) Other ( ) (Specify)

Assessment Details	Date of Assessment: __ __/__ __/__ __ __ __ Name of Assessor (s) and Affiliation 1: 2: Assessment Type : Initial ( ) , Follow Up ( ) Previous Assessment Scores % ( )
Staffing Summary	Cert ( ) Dip ( ) , HND ( ) , Degree ( ) , Master and Above ( ) Total staff Number __ __
Scoring	Criteria (Points) NB: Yes (Y) requirement fully met, Partial (P) requirements not fully met , No – no evidence , N/A Yes (1) , Partial (0.5), No (0), Not Applicable (N/A) Total Scores (TS)

Assessment Scores Sheet

LCQI Section	Total Scores (TS)	
Section 1: Identifying Laboratory Management and Policy Stakeholders	8	
Section 2: Personnel management	6	
Section 3: Sample management	5	
Section 4: Facility and Safety	15	
Section 5: Equipment management	7	
Section 6: Laboratory Commodity Management	7	
Section 7: Laboratory Quality Testing Monitoring	8	
Section 8: Laboratory information system	4	
OVERALL SCORES		
NB:- If not applicable(N/A) the overall performance should be expressed as % less the relevant section(s)	60	

Section	Key requirements	Y	P	NO	N/A	TS	Comment

Section1: Identifying Laboratory Management and Policy Stakeholders	1) Are key Laboratory documents available • National Biosafety Manual, • National Quality Manual, • National Equipment Manual, • Laboratory test menu • Clinician Handbook • Approved and costed work plan • Does the laboratory has appointed Quality Manager • Is a distribution list of the Clinician handbook to all facility departments available • Are current laboratory review meeting available • Are All test SOPs accessible and reviewed as per lab quality manual • Are the staffs trained or refreshed on the current • update • Does the laboratory has communication and feedback mechanism • Has the laboratory developed and documented quality objectives in line with established policy						
Section score							
Section 2: Personnel management	• Is there a documented procedure on personnel management • Is the laboratory adequately staffed? • Are all laboratory personnel trained on the following : • Basic Biosafety and Biosecurity • Commodity management • IPC • Are appropriate personnel records (Education, professional, practicing license) available? • Are current competency records available for all staff? • Is annual staff training plan available? • Is the laboratory duty rosters well documented?						
Section Scores							

Section 3: Sample management	• Does the laboratory have SOPs or job aids on sample collection and handling? • Are all staffs trained on Safe Phlebotomy? (Training file) • Are samples shipment done under required temperature conditions and temperature monitored during shipment? (Check shipment records) • Does the laboratory have sample rejection register/log • Does the laboratory have defined sample referral mechanism in place (referral directory)						
Section Scores							
Section 4: Facility and Safety	• Is there adequate space for efficient workflow in the laboratory • Is each workstation maintained free of clutter? • Does the laboratory have safety signage posted in strategic places • Does the laboratory have access control • Is the work area clean and free of leakage and spills • Does the laboratory conduct routine disinfection • Does the laboratory have emergency exit • Does the laboratory have fire alarm and extinguishers installed and operational • Does the laboratory have hand hygiene facilities and in use (hand sanitizer and liquid soap • Does the laboratory have Personnel protective equipment at the work station • Is waste segregated and disposed off in appropriate color-coded bins • Are support staff cleaner, drivers, couriers, riders and other non-lab health-worker provided with relevant safety training • Are laboratory personnel offered appropriate vaccination and employee medical surveillance • Are hazardous chemicals properly utilized and disposed according to national guidelines • Are incidences and injuries recorded and managed according to the National guidelines						
Section Scores							

Section 5: Equipment management	• Are equipment properly installed and performance verified? • Is an up-to-date equipment Master List available? • Are equipment uniquely labeled? • Is the facility conducting routine equipment preventive maintenance? • Is there evidence of equipment servicing, calibration and certification? • Does the laboratory monitor equipment related quality indicators (Equipment downtime, error rates, etc.)? • Are equipment related occurrence/incidents documented and investigated?						
Section Scores							
Section 6: Laboratory Commodity Management	• Does the laboratory has a designated commodity focal person • Are basic commodity reporting and management tools available ,current and in use • S11 • Stock control cards • Expiry tracking charts • Temperature monitoring charts • MOH 643 • MOH 706 • Is a developed and implemented procedure on inventory management system available • Does the laboratory conduct forecasting , quantification and order commodities with the right specifications • Number of commodities that expired within the last six months • Does the laboratory verify commodities before receiving • Does the laboratory has dedicated storage area and lockable • Does the laboratory have a list of prequalified vendors/suppliers						
Section Scores							

Section 7: Laboratory Quality Testing Monitoring	• Is the laboratory conducting IQC procedures during testing? (Check IQC reports) • Are all the laboratory tests enrolled into EQA scheme (s) or inter-lab comparisons? (EQA reports) • Is the lab participating in EQA schedule as planned for all the laboratory tests? • Are EQA and/or inter-lab comparisons reports reviewed before filing? • Is the lab tracking nonconformities? • Is root cause analysis conducted for nonconformities • Is the laboratory conducting CAPA on nonconformities? (Check for CAPA conducted and closed) • Are client satisfaction surveys conducted and evaluated?						
Section Scores							
Section 8: Laboratory information system	• Is there an established LIS in use (manual or electronic)? • Does the laboratory use a standardized test request and result reporting form • Does the laboratory have SOP for managing laboratory data including backup? • Does the laboratory have adequate laboratory data management tools? • Are laboratory data properly stored and retrievable by authorized personnel						
Section Scores							
Overall Score							

Comments

Challenges

Work Plan Template

Follow-Up-Activity	Responsible Person	Resources Required	Timeline

Annex 5: List of Participants

Dr John Ndemi Kiiru	DLS, MOH
Lily Kirui	DLS, MOH
Charity Maina	DLS, MOH
Bernard Muture	NPHL, MOH
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Jedidah Kahura	NPHL, Ministry of Health
Nahashon Marebe	Ministry of Health, Nairobi County
Joseph Nzomo	Ministry of Health, Machakos County
Hellen Ogollah	Ministry of Health, Kisumu County
Dr Jane Mwangi	CDC Kenya
Dr Ernest Makokha	CDC Kenya
Dr Muthoni Junghae	CDC Kenya
Dr Daniel Kimani	CDC Kenya
Mercy Njeru	CDC Kenya
Catherine Bonde,	USAID, Tujenge Jamii
Dr Dennis Wanyama	Amref Health Africa, Kenya
Noel Odhiambo	Amref Health Africa, Kenya
Eric Opiyo	Amref Health Africa, Kenya
Erastus Cheti	Amref Health Africa, Kenya
Alex Makokha	Centre for Health Solutions Kenya (CHS)
Alex Nyatigo Morwabe	CRISSP, University of Nairobi
Paul Gathii	JHPIEGO
James Njogu	CHS
Jorum Ondigo	CIHEB Kenya
Lucas Oketch	LVCT

REPUBLIC OF KENYA

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