REPUBLIC OF KENYA
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

KMLTTB QUALITY POLICY MANUAL

Pursuant to the Medical Laboratory Technicians and Technologists Act, CAP 253 A Laws of Kenya.

KMLTTB QUALITY ASSURANCE SERVICES

	KMLTTB QUALITY POLICY MANUAL		DOCUMENT CONTROL Serial: KMLTTB/QUALITY/MANUAL/01 Version 001 Date: 2ND JANUARY,2026
	OWNERSHIP	REGISTRAR	

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1.0 INTRODUCTION

1.1 Background

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is a body corporate with statutory mandate to exercise general supervision and control over the training, practice, business and employment of medical laboratory technicians and technologists under Cap 253A Laws of Kenya. The Board also advises the Government in relations to all aspects thereof including validation of invitro diagnostics through Legal Notice NO.113 of 2011.

The corporate KMLTTB is governed by a Board of Directors (Board Members) who make policies and is headed by a Chairman. KMLTTB is Secretariats is Headed by The Registrar/Chief Executive Officer assisted by the heads of departments to run the day to day Board activities.

Its Headquarters is located at upper hill, ACK Garden house fourth floor, Nairobi. It has offices in the six geo-political zones and some states. KMLTTB intends to put up a National External Quality Assessment Laboratory (NEQAL), Nairobi, county and an In-Vitro Diagnostics Control Public Health Laboratory.

To fulfil this mandate effectively, KMLTTB has established a Quality Management System (QMS) that provides a structured framework for planning, implementing, monitoring, evaluating, and continually improving all regulatory activities. The QMS promotes consistency, transparency, accountability, impartiality, and compliance with statutory and regulatory requirements.

This Management Quality Manual describes the Quality Management System adopted by KMLTTB and serves as the principal document guiding the implementation and maintenance of quality management across all departments and regulatory functions.

1.2 Purpose of the Quality Manual

The purpose of this Management Quality Manual is to:

a) Describe the Quality Management System implemented by KMLTTB.
b) Define the quality policies, objectives, principles, and commitments of the organization.
c) Establish a common framework for the implementation of quality management across all departments.
d) Ensure consistency in the execution of regulatory functions.
e) Demonstrate compliance with applicable legislation, regulations, and recognized quality management standards.

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f) Promote continual improvement of regulatory services.
g) Provide guidance to staff, management, governing committees, and external stakeholders regarding quality management requirements.

1.3 Scope of the Quality Management System

The Quality Management System applies to all activities undertaken by KMLTTB in fulfilling its statutory mandate.

The scope includes, but is not limited to:

a) Registration of Medical Laboratory Professionals.
b) Professional licensing and licence renewal.
c) Administration of registration examinations.
d) Development and review of registration examination policies and procedures.
e) Accreditation and approval of Medical Laboratory Sciences education and training institutions.
f) Inspection and monitoring of professional practice.
g) Continuing Professional Development (CPD) programmes.
h) Investigation of complaints against practitioners.
i) Professional conduct and disciplinary processes.
j) Maintenance of professional registers.
k) Customer service and stakeholder engagement.
l) Financial and administrative support services.
m) Human resource management.
n) Procurement and supply chain management.
o) Information and communication technology services.
p) Records and document management.
q) Internal quality assurance and continuous improvement activities.

This Quality Management System applies to all employees, board members (Directors), committee members, contracted personnel, examination personnel, consultants, and any individual acting on behalf of KMLTTB.

1.4 Objectives of the Quality Management System

The objectives of the Quality Management System are to:

a) Ensure effective implementation of KMLTTB statutory mandate.
b) Promote public confidence in the regulation of Medical Laboratory Sciences profession.
c) Ensure fairness, transparency, and impartiality in all regulatory decisions.
d) Maintain the integrity and credibility of professional registration examinations.
e) Ensure compliance with applicable legal, regulatory, and ethical requirements.
f) Improve operational efficiency and service delivery.
g) Strengthen accountability at all organizational levels.

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h) Promote evidence-based decision-making.
i) Encourage continual quality improvement through monitoring, evaluation, and management review.

1.5 Guiding Principles

The Quality Management System is founded on the following principles:

a) Public protection.
b) Professional integrity.
c) Transparency.
d) Accountability.
e) Fairness and equity.
f) Confidentiality.
g) Impartiality.
h) Competence.
i) Evidence-based decision-making.
j) Risk-based thinking.
k) Customer focus.
l) Continual improvement.
m) Compliance with applicable Kenyan laws and regulations.

1.6 Application of the Manual

Management and staff are committed and actively participate in this quality process. Quality policies, processes and procedures are documented in the Quality Manual to ensure that Board meets the needs of its stake holders and the requirements as established by National and International standards.

KMLTTB has adopted and maintains a Quality Management System which is based on the international standard ISO 15189 and ISO 17011.

This Management Quality Manual serves as the highest-level quality document within KMLTTB's Quality Management System.
The manual:

a) Establishes the quality management framework.
b) References the Standard Operating Procedures (SOPs) that describe operational processes.
c) Provides guidance for implementing quality policies and objectives.
d) Supports staff orientation and competency development.
e) Serves as a reference during internal and external quality audits.
f) Supports management review and organizational improvement.

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All employees and persons acting on behalf of KMLTTB shall comply with the policies and requirements contained in this Manual and the associated Standard Operating Procedures.

2.0 ORGANIZATION PROFILE

2.1 Legal establishment

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is a body corporate with statutory mandate to exercise general supervision and control over the training, practice, business and employment of medical laboratory technicians and technologists created by Section 3 of Act No. 10 of 1999 (Cap 253A Laws of Kenya).

2.2 Mandate

To exercise general supervision and control over the training, practice, business and employment of medical laboratory technicians and technologists. The Board also advises the Government in relations to all aspects thereof including validation of invitro diagnostics through Legal Notice No. 113 of 2011.

2.3 Vision

"That the Health of every Kenyan will be fully protected through effective Regulation of the practice of laboratory medicine."

2.4 Mission

"To exercise general control and supervision over training, business, employment and practice of Laboratory Medicine and advise the Government on all related matters."

2.5 Core values

Integrity; Selfless service; Innovation and open-mindedness; Sense of belonging; Pride in what we do.

a) Integrity and ethical conduct.
b) Prioritizing patient and public well-being (Selflessness).
c) Encouraging innovation and openness to new ideas.
d) Promoting inclusivity and a sense of complementary.

2.6 Functions of KMLTTB

a) Determine from time to time the standards of knowledge and skill to be attained by persons seeking to become Medical Laboratory Sciences professionals in Kenya (Medical Laboratory Technicians, Technologists, officers and specialists).
b) Regulates the practice of Medical Laboratory Sciences in Republic of Kenya

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c) Regulates the training of Medical Laboratory Sciences professionals in Kenya (Medical Laboratory Technicians, Technologists, officers and specialists) and give periodic approval/accreditation to training institutions
d) Regulates the production, importation, sales and stocking of diagnostic laboratory reagents and chemicals (Invitro Diagnostics).
e) Conducts examinations for Medical laboratory sciences professionals
f) Assess, evaluate and register foreign graduates of Medical Laboratory Sciences.

3.0 Legal and Regulatory Framework

The Legal and Regulatory Framework establishes the statutory and regulatory basis under which KMLTTB. It ensures that all regulatory activities are conducted lawfully, transparently, fairly, and consistently in accordance with applicable legislation, regulations, policies, and recognized standards.

This framework guides the development, implementation, monitoring, and continual improvement of the Quality Management System (QMS) and provides assurance that the regulatory body's decisions are legally defensible and aligned with its mandate to protect public health and safety.

3.1 Registration
3.2 Licensing
3.3 Accreditation (where applicable)
3.4 Professional conduct
3.5 Discipline
3.5 Continuing Professional Development (CPD)
3.6 Education and training standards

4. O Approval, Revision and Distribution of the Quality Manual

The Quality Manual is prepared by the KMLTTB Quality assurance officer (QAO) with input staff from all Departments/Units in consultation with the registrar and the KMLTTB legal officer.

The quality manual is approved by the Registrar/CEO. It will be reviewed bi-annually and revised as the need arises. The Registrar/CEO is responsible for maintaining the official master copy of the QM. General distribution of this manual is accomplished using a controlled document distribution list kept in the Registrar/CEO office.

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1.8 Quality Policy Statement: The manual includes a commitment to quality, ensuring operations meet national and international standards like ISO 15189 to provide accurate results for public health.

1.9 Key Functions of the Board: These include approving training institutions and courses, approving qualifications for registration, licensing professionals, regulating professional conduct, and overseeing the validation of reagents and equipment.

The **KMLTTB Quality Manual** is a foundational document that outlines the **Quality Management System (QMS)** for medical laboratories and professionals in Kenya, as regulated by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB). Its primary purpose is to ensure consistent, reliable, and high-quality medical laboratory services across the country, in compliance with national and international standards.

Purpose and Importance

2.0 Standardization: The manual ensures uniform procedures and practices are followed in all KMLTTB operations, from indexing as a student, application for registration, filing of CPD points, practice license, medical laboratory business premises registration , Invitro diagnostic validation and verification to registration of MLS training institutions.

2.1 Regulatory Compliance: It serves as a guide for adherence to the **Medical Laboratory Technicians and Technologists Act (CAP 253A)** and relevant international quality standards like **ISO 15189:2022**.

2.2 Public Safety and Trust: By setting forth stringent quality standards, the manual aims to protect public health and build confidence in the accuracy and reliability of medical diagnostics in Kenya.

2.3 Continuous Improvement: The manual facilitates ongoing monitoring and evaluation of medical laboratory regulatory practices through mechanisms like internal audits and corrective actions, fostering a culture of continuous quality enhancement.

2.4 Personnel Qualifications and Training: Outlines the required education, training, and continuous professional development (CPD) for all laboratory staff to ensure competence.

2.5 Equipment and Reagents: Details the procedures for the validation, verification, maintenance, and quality assurance of all in vitro diagnostic equipment and reagents used in the medical laboratories in the Republic of Kenya in both public and private sector.

2.6 Standard Operating Procedures (SOPs): Refers to detailed operational guidelines for various KMLTTB regulatory processes.

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2.7 Quality Assurance and Control: Establishes systems for internal quality assessment (IQA) and external quality assurance (EQA) programs.

2.8 Documentation and Records: Specifies requirements for document control and the maintenance of accurate records.

2.9 Safety Addresses biosafety and biosecurity measures within the KMLTTB environment.

3.0 Organizational Structure and Responsibilities: The manual defines the roles of key personnel and clarifies reporting lines within the quality management system.

3.1 Target Audience: The manual is a critical reference for all stakeholders in the Kenyan medical laboratory sector, including medical laboratory technicians and technologists, laboratory managers and leadership, training institutions, manufacturers and dealers of medical laboratory equipment and reagents, and government health bodies.

3.2 QUALITY POLICY: A formal statement from management outlining the authority's commitment to quality, its objectives, compliance with regulatory requirements, and continual improvement.

3.3 MANAGEMENT REQUIREMENTS: The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) quality manual outlines several key management requirements aimed at ensuring the quality, accuracy, and reliability of medical laboratory services. These requirements emphasize leadership, resource management, and a commitment to quality improvement, and include: Leadership and Responsibility

3.4 Overall Operation and Administration: The Head of department is responsible for the overall operation and administration of their respective departments.

3.5 Accountability to KMLTTB: The secretariat/Management is answerable to KMLTTB Head of departments on all aspects of regulatory practice and operations within the institution.

3.6 Policy Development: Management is required to define and document clear quality policies that state the KMLTTB commitment to quality.

3.7 Oversight and Resources: Management must provide leadership, necessary resources (human, fiscal, and facilities), and oversight to support the quality management system (QMS).

3.8.0 HUMAN RESOURCE MANAGEMENT

3.8.1 Competent and Qualified Personnel: Management must ensure the employment of competent, duly registered, and licensed personnel where applicable.

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3.8.2 Staff Competency and Training: Ensuring staff competency through continuous training and development programs is a key requirement.

3.8.3 **Adequate Staffing:** Management must have contingency plans in place in case of staffing challenges.

3.9.0 QUALITY MANAGEMENT SYSTEM (QMS) IMPLEMENTATION

3.9.1 **Establishment of a QMS:** The KMLTTB management must establish and demonstrate compliance with an accepted Quality Management System (e.g., ISO 15189).

3.9.2 **Documentation and SOPs**: Management is responsible for ensuring the application of standard operating procedures (SOPs) in all regulatory activities.

3.9.3 **Performance Evaluation and Audits**: Management must ensure regular internal audits and performance reviews are conducted to assess the effectiveness of the QMS.

3.9.4 **Corrective and Preventive Actions**: Implementing processes for addressing non-conformities and preventing their recurrence is required.

4.0.0. OPERATIONAL AND RESOURCE REQUIREMENTS

4.1.0 Data and Information Management: Maintaining accurate, secure records and having sufficient data-handling capacity is essential.

- **Organization:**
- **KMLTTB shall maintain** an organizational chart showing the structure and the relationship of key personnel involved in quality management.
- **KMLTTB shall maintain** Job descriptions outlining the responsibilities, authorities, and minimum qualifications for all personnel involved in the quality process.

4.1.1 **Document control:** KMLTTB shall maintain Procedures for creating, reviewing, approving, distributing, and revising all QMS documentation, including the manual, policies, and procedures. This ensures that only current versions are used.

4.1.2 **Review of requests and contracts:** Describes the process for handling applications for laboratory accreditation or licensing. This includes a review to ensure the authority has the competence and resources to conduct the assessment.

4.1.3 **Management review:** Procedures for regular, formal reviews of the QMS by top management. The reviews should address suitability, adequacy, effectiveness, and continual improvement.

4.1.4 **Confidentiality and impartiality:** Policies to ensure impartiality in the accreditation and regulatory process and to protect the confidentiality of information from

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students, professionals, laboratories, manufacturers, Vendors and other stake holders.

4.1.5 Resource requirements

- **PERSONNEL:**

a. Requirements for ensuring the competence of the authority's own staff and external assessors, including training, qualifications, and ongoing monitoring.

b) **Facilities and environmental conditions:** Policies to ensure KMLTTB premises are suitable for its operations and that factors like security and safety are controlled.

4.1.6 **Equipment and materials:** Procedures for ensuring equipment used for assessments (e.g., test kits, reference materials) is properly handled, maintained, and calibrate

4.1.7Process requirements

(I) **Methods and procedures**:

a) A list or reference to the documented procedures used for all regulatory activities, such as licensing, inspections, and monitoring.

b) Policies regarding the accreditation standards KMLTTB will use (e.g., ISO 15189, other national standards).

(ii). **Handling of complaints:** Procedures for receiving, evaluating, and making decisions on complaints from registered/accredited laboratories/ MLS Professionals and/ or the members of the public.

4.1.8 **Non-conforming work and corrective actions:** Procedures for managing and investigating non-conformities that arise during the regulatory process. This includes taking corrective action and verifying its effectiveness.

4.1.9 Internal audits: A plan for regular internal audits to verify that the KMLTTB's QMS is operating effectively and is in compliance with its policies and procedures.

4.2.0 Glossary Accreditation: Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Reference: ISO 15189.

4.2.1 Audit: Systematic, independent, and documented process for gathering evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

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4.2.2 Bio-safety: The active, assertive, evidence-based process that medical laboratorians use to prevent microbial contamination, infection, or toxic reaction as they actively manipulate live microorganisms or their products, thus protecting themselves, other laboratory staff, the public, and the environment.

4.2.3 Competence: Demonstrated ability to apply knowledge and skills.

4.2.4 Confidentiality: Pertains to the disclosure of personal information in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the original disclosure.

4.2.5 Continual/Continuous Improvement: The cornerstone of quality management systems, allows the medical laboratory to gain insights from setting objectives, monitoring through audit and management review, addressing complaints and nonconformities, and performing facility satisfaction surveys.

4.2.6 A recurring activity to increase the ability to fulfill requirements:
Plan, Do, Check, Act. Control Substances: That contain an established amount of the substance being tested – the analyte. Controls are tested at the same time and in the same way as patient samples.

4.2.7 Customer: Organization or person that receives a product or service from a supplier organization.

4.2.8 Customer Satisfaction: Customer's perception of the degree to which the customer's requirements have been fulfilled. It can vary from high satisfaction to low satisfaction. If customers believe that you have met their requirements, they experience high satisfaction. If they believe that you have not met their requirements, they experience low satisfaction.

4.2.9 Document: Information and its supporting medium; digital or physical.

ISO identifies five types of documents: specifications, quality manuals, quality plans, records, and procedure documents.

4.3.0 Documentation: Written material defining the process to be followed. Examination:

- Activities and steps related to performing laboratory examinations.
- A set of operations having the object of determining the value or characteristics of a property to describe these processes.
- One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing. **Also referred to as Analytical phase**.

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4.3.1 External Quality Assessment (EQA): A system for objectively checking the medical laboratory's performance using an external agency or facility.

4.3.2 Indicators: Established measures used to determine how well an organization is meeting its customers' needs as well as other operational and financial performance expectations.

4.3.3 Internal Audits: Internal quality audits are audits carried-out by the medical laboratory personnel who examine the elements of a quality management system in their medical laboratory in order to evaluate how well these elements comply with quality system requirements.

4.3.4 Management Review: Evaluation of the overall performance of an organization's quality management system and identification of improvement opportunities. These reviews are carried-out by the organization's top managers and are done on a regular basis.

4.3.5 Non-conformity: Failure to fulfill the requirements of a specified process, structure or service. May be categorized as major (complete) or minor (partial).

4.3.6 A: An event, accident or circumstance that happened without intent, volition, or plan.

4.3.7 Organization: Group of people and facilities with an arrangement of responsibilities, authorities and relationships.

4.3.8 Path of Workflow: (Medical laboratory) Sequential processes in pre-examination, examination, and post examination medical laboratory activities that transform a physician's order into medical laboratory information.

4.3.9 Policy: An overarching plan (direction) for achieving an organization's goals.

4.3.10 Post-examination (also Post-analytical Phase): Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples for the examinations. One phase of the three-phase framework for the total testing process to describe issues related to the quality of medical laboratory testing.

4.3.11 Pre-examination (also Pre-analytical Phase): Steps starting, in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the examination phase begins. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing.

4.3.12. Preventive Action: Planned steps that are taken to remove the causes of potential nonconformities or to achieve quality improvements. Preventive actions address potential problems, ones that have not yet occurred. In

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general, the preventive action process can be thought of as a risk analysis process.

4.3.12 Process: The use of resources to transform inputs into outputs. In every case, inputs are turned into outputs because some kind of work, activity, or function is carried out. Proficiency Testing: ISO guide:

4.3.13 **Proficiency testing schemes (PTS):** These are inter-laboratory comparisons that are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel.

4.3.14 **EQA:** "A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others".

4.3.15 **Quality: Degree to which a set of inherent characteristics fulfill requirements. Quality Assurance:** A planned and systematic set of quality activities focused on providing confidence that quality requirements will be fulfilled.

4.3.16 **Quality Control:** A set of activities or techniques whose purpose is to ensure that all quality requirements are being met. Simply put, it is examining "control" materials of known substances along with patient samples to monitor the accuracy and precision of the complete examination process.

4.3.17 **Quality Indicator:** Established measures used to determine how well an organization meets needs and operational and performance expectations. Quality Management: Coordinated activities that managers carry out in an effort to implement their quality policy. These activities include quality planning, quality control, quality assurance, and quality improvement.

4.3.18 **Quality Management Standards:** (such as GP26 A4: 2011, ISO 15189:2012, ISO 17011:2004) are a series of policy statements.

4.3.19 **Quality Management System (QMS):** Management system to direct and control an organization with regard to quality. Quality Manual: Document specifying the quality management system of an organization.

4.3.20 **Quality Policy:** Overall intentions and direction of an organization related to quality as formally expressed by top management.

4.3.21 **Quality Record:** Objective evidence, which shows how well a quality requirement is being met or how well a quality process is performing. It always documents what has happened in the past.

4.3.22 **Quality System:** The defined organizational structure, responsibilities, processes, procedures and resources for implementing and coordinating the Quality

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Assurance and Quality System Audit. A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are suitable and have been developed, documented, and effectively implemented in accordance with specified requirements.

4.3.23 **Quality System Essentials (QSE):** The necessary infrastructure or foundational building blocks in any organization that need to be in place and functioning effectively in order to support the organization's work operations so that they proceed smoothly. Equally, Board is working assiduously at advocacy in order to continuously engage its stakeholders despite gaining recognition as a leading Regulatory Authority both nationally and internationally. Its efforts have also led to positive collaborations with international agencies with a view to improving its services.

4.3.24 **KMLTTB OPERATIONS:** The corporate headquarters is located at Upper Hill area, ACK Guest House, Nairobi. As a regulatory agency Board strives to maintain a culture of quality and is committed to a systematic approach to provide effective and efficient services to stakeholders.

The Board has adopted and maintains a Quality Management System which is based on the international standards (ISO/ IEC 17024:2012, ISO 15189.and ISO 17011).

The Management and staff are committed and actively participate in this quality process. Quality policies, processes and procedures are documented in the Quality Manual to ensure that the Board meets the needs of its stakeholders and the requirements as established by National and International standards. This manual defines the quality management system addressing all departments and Units.

Responsibilities and assignments are clearly defined for all departments and units of the Board. It establishes the means for management and staff to improve the Board's performance.

4.3.25 KMLTTB Board of directors have established the following committees for effective management of their mandate:-

a) Disciplinary committee
b) Finance and Administration
c) Compliance committee
d) Education and CPD
e) Internal Audit committee

4.3.26 KMLTTB OPERATIONS: KMLTTB is managed under the leadership of the Registrar/CEO with the support of senior management team comprising of Heads of Departments, Units and other Principal Officers who oversee all activities of the Board.

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Each Department or Unit of the Board shall be under the supervision of Head of department/Unit respectively. KMLTTB has the following committees:-
Disciplinary committee

a) Department of quality assurance.
b) Department of Human resource management.
c) Department of Education, Examinations, CPD, Ethics and Professional Discipline.
d) Department Planning, Research, Data Management and Statistics.
e) Department Administration, Finance, & Accounts
f) Department of External Quality Assurance Panel & Reference Medical Laboratory Services.
g) Department of Equipment, Chemicals & Reagent (Invitro diagnostics) Validation and verification Services.
h) Registration Unit.
i) Examinations Unit.
j) Medical Laboratory registration and compliance Unit.
k) Procurement Unit.

    a. The KMLTTB maintains a high level of confidentiality in its operations. An undertaking is obtained from the employees, assessors, contracted personnel and other third parties, to the maintenance and disclosure of confidential information. Any breach of confidentiality is viewed and handled appropriately.

l) KMLTTB requires all personnel (employees, assessors, technical experts) who may have interest related to their activities, to ensure the highest integrity and public confidence in their activities.
m) KMLTTB requires that all personnel disclose any circumstances that could give rise to a potential conflict of interest related to the subject of the activity in which they will be involved. All assessors, including contracted personnel must disclose any circumstances that could represent a potential conflict of interest.
n) **Authority:** All members of staff are given authority by the Registrar/CEO to perform their activities, and on behalf of KMLTTB in areas which they have been deemed competent.
o) Authorizations are generally documented in their individual job descriptions and followed by competence assessment forms.
p) **Resources:** Adequate human and financial resources are provided by management to ensure that KMLTTB general operations are not compromised which would affect the quality of service delivery

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q) Confidentiality Board has put in place at all levels adequate arrangement to safeguard the information obtained in the process of its accreditation activities including committees and individuals acting on its behalf. Board will not disclose classified official information about a particular institution without written consent of the institution, except where the law requires such information to be disclosed without such consent.

r) Impartiality to ensure the credibility and validity of the accreditation process, KMLTTB has put in place measures to safeguard the objectivity and impartiality of its activities.

s) KMLTTB ensures balanced representation of KMLTTB Quality Manual qualified persons in constituting accreditation teams. KMLTTB ensures its accreditation services are accessible to all applicants whose requests for accreditation fall within the activities and the limitations as defined in the policies and rules. KMLTTB has an Independent Advisory Committee (IAC) whose responsibility is to consider and approve accreditation reports. Complaints on the accreditation process are referred to the Governing Board of the Board which has in its fold an Arbitration Panel.

4.3.27 Internal and External Pressure: KMLTTB encourages all members of staff to disclose any internal and external commercial, financial or other pressures and influences that may affect the quality of their work.

Members of staff are free to approach any managerial staff in confidence and share their personal pressures.

4.3.28 Communication: Communication is vital for the effective performance as well as continual improvement of a Quality Management System.

It is in this regard that KMLTTB management has established communication mechanisms that will ensure that stake holders requirements (both internal and external) are met.

All communications (outgoing and incoming) are logged or filed whichever is appropriate. Internal Communication to achieve collective ownership of the system by both Management and staff, KMLTTB management involves all staff in every aspect of the development and implementation of the QMS.

For effective communication within the Board, Management shall adopt channels of communication, which include but not limited to the following:

a) Memos, letters, notices
b) Meetings
c) Oral communication

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d) Verbal or written instructions (e.g. through Quality Manual, Lectures).
e) Periodicals (Bulletin)

4.3.29 External Communication: Communication with external stakeholder is in the form of but not limited to letters, newspaper publication, electronic mail, telephone and meetings.

KMLTTB staff are authorized to offer telephonic consultations on technical matters within their scope of their responsibilities to external facilities. Records of all communications shall be kept thereof.

4.3.30 Quality Management System: The KMLTTB has a documented Quality Management System which comprises of policies, procedures, instructions, forms, job descriptions, external reference and regulatory documents and records.

The KMLTTB management ensures that all members of staff have been trained on QMS and understood it upon employment and as when necessary.

All relevant QMS documents are made available at each Department/Unit for easy implementation.

The Quality Manual is the governing document that defines the quality system policies and statements of intent by KMLTTB and is based on ISO 15189:2012 and ISO 17011 requirements.

KMLTTB's quality policies focus on ensuring high standards in medical laboratory services through professional conduct, continuous professional development, and strict adherence to regulations. Key policies include implementing a quality management system, such as the requirements of ISO 15189:2022, ensuring medical laboratory infrastructure is adequate, and that all medical laboratory personnel are competent and follow the code of ethics. The board also conducts regular inspections, enforces compliance through disciplinary actions like fines or license suspension, and mandates continuous professional development for all medical laboratory practitioners.

5.0 Medical laboratory Professional standards and ethics

a) **Code of ethics:** Medical laboratory professionals must adhere to a code of ethics that emphasizes accountability, professional judgment, and maintaining patient confidentiality.

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b) **Professionalism:** Medical laboratory Professionals are required to uphold the dignity of the profession, maintain honesty and integrity, and continuously improve their skills and knowledge.

Quality management and compliance

a) **Quality management system:** All medical laboratories must implement a Quality Management System, such as one based on ISO 15189 standards, to ensure quality service.

b) **Inspections and audits:** KMLTTB conducts regular inspections and audits to ensure medical laboratories comply with established best practices and standards.

c) **Regulatory compliance:** The board has the authority to take disciplinary actions against medical laboratory institutions and practitioners who fail to comply with standards.

d) Personnel and training

e) **Competency:** Medical Laboratories must have a sufficient number of adequately trained and competent personnel.

f) **Continuing Professional Development (CPD):** Medical Laboratory Practitioners are required to meet minimum CPD points to ensure their skills and knowledge remain up-to-date.

g) **CPD effectiveness:** Medical Laboratory Practitioners must reflect on how their CPD activities have improved the quality of their practice and benefited users.

h) Facilities and equipment

i) **Infrastructure:** Medical Laboratories must have adequate and functional facilities, including sufficient space, proper storage for reagents, and cleanable work areas.

j) **Equipment and reagents:** There must be a system for inspecting and managing Medical Laboratory reagents and equipment. New equipment and reagents must be validated for local conditions.

k) Licensing and accreditation

l) **Licensing:** KMLTTB processes licenses and renewals for Medical Laboratory professionals based on submitted documents and compliance with regulations.

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m) **Accreditation:** The board ensures that training institutions offering medical laboratory courses meet quality standards through annual assessments and accreditation

5. Ensuring quality of medical laboratory services in the KMLTTB context

a) **Conformity Assessment:** The KMLTTB requires Medical laboratories to undergo conformity assessment to ensure that they are safe and performing as intended.

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c) **Compliance with Standards:** Adhering to established national and international standards, such as ISO 15189:2022 for medical laboratories, is crucial for a functioning QMS.

6. Key quality management system (QMS) processes requirements by KMLTTB.

a) **Quality Policy and Objectives:** The Medical Laboratory's quality policy guides the yearly planning and sets the strategy for achieving long-term goals.

b) **Documentation and Record Keeping:** Implementing a QMS requires a structured approach to document all processes, procedures, and results.

c) **Method Validation and Verification:** Ensuring that all technical methods used in the Medical Laboratory are appropriate and provide accurate results.

d) **Internal Quality Control (IQC):** Ongoing monitoring of test results to ensure accuracy and reliability.

e) **External Quality Assessment (EQA):** Participation in proficiency testing schemes to compare the Medical Laboratory's performance with other Medical Laboratory laboratories.

f) **Equipment Management:** Maintenance, calibration, and validation of all Medical Laboratory equipment.

g) **Personnel Management:** Ensuring that all Medical Laboratory staff are adequately trained, competent, and understand the quality system.

h) **Corrective and Preventive Actions (CAPA):** A system for addressing any issues that arise and implementing measures to prevent their recurrence.

i) **Management Review:** Regular reviews by Medical Laboratory management to evaluate the effectiveness of the quality system.

j) **Continuous Improvement:** A commitment to continually improve all Medical Laboratory processes and services.

6.1 How KMLTTB make it happen: The Quality Procedures (SOPs) and Instructions describe who, what, when, where and how quality management system and processes are performed.

Quality Forms related to quality procedures are used for data collection. Quality Records are retained as objective evidence of compliance to the international requirements and KMLTTB processes and procedures.

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7. THE GOVERNING BOARD

The management Board of the KMLTTB is headed by a Chairman and other members drawn from:

a) Ministry of Health (5)
b) Association of Kenya Medical Laboratory Scientific officers (AKMLSO) (6)
c) Republic of Kenyan Universities offering Medical Laboratory Science as a course (2).
d) A representative from Ministry of Education
e) The Registrar/CEO (Secretary).

7.1 Responsibility of the Board is to make policies for the activities of the Board.

- The Registrar/CEO is the Chief Accounting Officer of the Board and is responsible for:

a) Keeping the records and conducting all correspondences of the Board
b) Preparing and maintaining in accordance with the rules made by Board a register of names, address, qualifications and other particulars of persons entitled for registration.
c) Issuance of licenses and tags to qualified Technologists, Technicians and other officers (Medical laboratory professionals)
d) Issuance of examination transcripts (compliance certificates) and evaluation of certificates
e) Conducting of examinations for Technicians, Technologist and other officers (Medical laboratory professionals) as well as foreign trained graduates
f) Conducting Approval/accreditation exercises for training institutions and Medical Laboratories
g) Inspecting and monitoring of Medical Laboratories
h) Publishing and updating the names of practitioners as well as those in default of payment of annual subscriptions and CPD points.
i) Publishing of the Medical laboratory sciences news bulletin.
j) Striking off the names of deceased members from the register

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8. THE QUALITY ASSURANCE OFFICER (QAO) SHALL BE RESPONSIBLE FOR:

a)
b) Coordinating the establishment of the quality management system based on ISO/IEC 17024:2012, ISO 15189:2022 and ISO 17011 supporting its implementation and coordinating activities pertaining to quality.
c) Supervising and directing the work at departmental/department levels.
d) Coordinating and supervising staff orientation, training and competence assessment.
e) Monitoring quality management system (QMS) implementation.
f) Ensuring the safety requirements of the KMLTTB are being followed.

9. THE HEADS OF DEPARTMENTS (HODs) SHALL BE RESPONSIBLE FOR:

a) Assisting the Quality assurance officer in providing advice to Registrar and the organisation Chief executive officer (CEO) information about Boards activities
b) Assisting the Quality assurance officer in supervising and overseeing the technical functions of the Board.
c) Assisting the Quality assurance officer in advising the Registrar/CEO in technical matters pertaining to the Board
d) Serving as an active member of the management team.
e) Assisting the Quality assurance officer in monitoring all works performed in the Board to determine that reliable data are being generated in the Board.
f) Assisting the Quality Assurance Officer in providing effective and efficient administration of the Board including budget planning and control with responsible financial management, in accordance with the National Government financial regulations
g) Assisting the Quality Assurance Officer in providing continuous professional development programs for the staff
h) Assisting the Quality Assurance Officer in planning and performing research appropriate to the Board.
i) Assisting the Quality Assurance Officer in selecting and monitoring all medical laboratories for the quality of service in conjunction with the quality officer in the facilities
j) Assisting the Quality Assurance Officer in Identifying and addressing complaints and corrective actions to satisfy stake holders' needs.
k) Assisting the Quality Assurance Officer in advising on various developments and review of policies and programs of the KMLTTB
l) Assisting the Quality Assurance Officer in Planning, issuing orders or instructions, providing leadership, enforcing discipline, handling grievances, controlling outputs, maintaining work conditions and preserving records.

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m) Assisting the Quality Assurance Officer in implementing a safe working environment in compliance with good practice and applicable regulations.
n) Assisting the Heads of Department in accountability for the implementation of the quality management system.
o) Assisting the Heads of Department in coordinating the planning and implementation of training workshops and seminars.
p) Assisting the Heads of Department in scheduling and organizing of management review meetings in consultation with the Registrar/CEO.
q) Assisting the Quality Assurance Officer in compilation and distribution of performance reports for Management review
r) To perform any other duties as assigned by the Registrar/ CEO from time to time.

10. DOCUMENTS AND RECORDS

Policy: The Kenya Medical Laboratory Technicians and Technologists Board of establishes and maintains as part of its quality management system these documents:

a) Quality Manual
b) Standard Operating Procedures
c) Forms, fees and logs
d) Guidelines, standards or regulations
e) Check-lists, licenses, tags, transcripts etc.

Purpose: This policy ensures that the documents and records are managed in a consistent manner and only current and approved documents are used by staff. All documents are managed according to ISO 15189 and ISO 17011 standards and also national laws or regulations.

Responsibility: Management and staff of KMLTTB all have a responsibility for the management and control of documents and records

11. DOCUMENTS AND RECORDS:

a) KMLTTB shall control all documents in its QMS from the creation, distribution, printing, reviewing, revision and destruction.
b) Handwritten amendments to documents are permitted only by those personnel authorized to do so through a documented Procedure for making changes to documents or records.
c) All records shall be stored in a safe environment to avoid deterioration and confidentiality.

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d) All documents shall be uniquely identified according to title, revision, number of pages, and authority for use and source identification.
e) KMLTTB shall retain or archive documents according to the document retention time in this manual.
f) All documents are reviewed and revised if necessary on an annual basis and if need arises by the Registrar/CEO or designee.
g) All documents deemed obsolete are destroyed and documented. (Added to retired Master Log)

Archiving: The Registrar/CEO is responsible for proper archiving of documents and records according to the documented procedure.

KMLTTB respects national laws concerning the retention time of all records.

Document Control: The Registrar/CEO or designees have ultimate responsibility for establishing and maintaining the document control system.

Document Review and Revising: There shall be a bi-annual review for every document.

Review of Contract: All contracts are reviewed to ensure availability of competence and resources to provide services .All records are maintained by KMLTTB. There is a contract review process Supporting Documents:

- Procedure for the creation, review and approval of new documents
- Procedure for making changes to documents or records
- Procedure for periodic review of documents
- Procedure for archival, storage and retention of documents and records
- Procedure for Contract review process Procedure for creating, identifying, revising, reviewing and approving new documents
- Procedure for Document Control
- Form for Master Index for identifying documents
- Procedure Manual Minor Correction
- Master Documents file form
- Master index Number Document
- Retention Schedule
- Document change request form
- Manual Minor Correction form
- Standard Operating
- Procedure template
- Retired Master Log

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12. PURCHASING AND INVENTORY:

Policy: The KMLTTB shall follow procurement policies and processes in purchasing office equipment, consumables and supplies. The mechanism for purchases is established by the procurement regulations according to the Public Procurement and disposal act

Responsibility: The procurement department in conjunction with the tender's board establishes selection of qualifying suppliers, approved vendor listing, and contract reviews.

Identification of Needs: The Head of department, with input from staff, identify and document needs prior to purchase.

Acquisition: The Registrar/CEO and Heads of department shall participate in the capital office equipment purchasing process.

Purchasing: The KMLTTB shall follow the established purchasing process for the selection and use of external services, equipment, consumables and supplies that affect the quality of service where National regulations are followed.

Receipt of Supplies: The KMLTTB receiver shall perform an inspection of all received supplies. Those that shall meet the inspection criteria are placed in the storage areas, while those that failed are rejected and returned to the supplier.

Storage: All items are stored according to the manufacturer's recommendations and all storage facilities are monitored for temperature to ensure that temperature will not affect the stored items.

Inventory Management: The KMLTTB has procurement officers who shall act as a liaison between the Board and the suppliers/vendors to ensure efficient delivery of office equipment and supplies.

Advisory Service: The tenders' board shall evaluates suppliers of office equipment and consumables, and maintains records of these evaluations and list of those approved. Supporting documents shall include:

- Procedure for External services and supplies.
- Procedure for Inventory Control.
- Procedure Form for Supplies.
- Quality Control form.
- Inventory Control form.
- Receiving and Inspection checklist.
- Reagent Daily Monitoring Log.

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- List of providers.
- List of referral laboratories.
- Stock log Inventory log.
- QSE: Non-conforming.
- Event Management

13. POLICY OF NON-CONFORMING EVENT MANAGEMENT

The policy of non-conforming event management includes nonconforming cases detection, identification, classification, documentation, investigation (analysis), solving the problem and reporting.

The occurrences at KMLTTB are classified as either internal or external and appropriate corrective actions are planned and implemented for removing the root cause of the problem.

KMLTTB shall have procedures for documentation and reporting of any problem emerging in and outside the Board, or issues that may interfere with the delivery of quality service in its registered and licensed/certified Medical laboratories. Such problems can be identified through any of the following means:

- Practitioner complaints
- Stake holder's complaints
- Non-conforming external quality assessment results
- Nonconforming reagents, equipment or consumables
- Staff comments
- Findings from internal or external audits
- Management reviews all event records are collected and analyzed during Management Reviews.

All events are addressed within a period not exceeding 30 days.

Responsibilities.

All KMLTTB staff are responsible for recognizing and reporting non-conforming events which could have adverse implications for stake holders and employees.

The KMLTTB departments and units are responsible for investigating occurrences, identifying and implementing appropriate corrective action.

The departmental/unit heads are responsible to fill out forms and enter occurrence information into the database.

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It is emphasized that all incidents are documented. KMLTTB staff reports the incident to their heads of department and units.

The Head of Departments review reports developed by department heads and conducts an investigation of the non-conforming event, implements corrective action if required and develops a final report.

The Quality assurance officer in conjunction with the Registrar/CEO is responsible for periodic review of the Quality Management System, compiling statistics, and trending to monitor the effectiveness of corrective action and the Quality Management System.

Identification of Non-conformities: KMLTTB shall establish a standardized mechanism for the Board's internal and external non-conforming event management processes which includes the following activities:

- Nonconforming events detection and notification
- Documentation of each episode of nonconformity
- Recall of nonconforming correspondences
- Immediate remedial action
- Definition of further corrective actions to be taken
- Designation of personnel responsible for resolving the problem.

Corrective Action: The KMLTTB management allows quick and regular identification of non-conformities and facilitates the implementation of Corrective Actions by using prescribed forms and corrective Action procedure when non conformities are noted.

Root cause analysis shall be conducted for every non-conformance noted before corrective action is implemented.

Corrective action (s) selected to eliminate the root cause of the nonconformance shall be appropriate to the magnitude of the problem and commensurate with possible risks. Whenever changes are to be made as a result of corrective actions, the changes are documented and communicated to the affected members of staff.

The results of corrective action taken shall be monitored, in order to ensure that they have been effective in overcoming the identified problem(s). The result of corrective actions shall be forwarded to management review meeting.

Preventive Action: KMLTTB shall take action to prevent non-conformance which shall be identified from potential sources, whether technical or affecting quality management

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system. When a potential non-conformance is identified, the organization shall follow the Preventive action procedure to come up with the preventive action plan.

The preventive action implementation shall be monitored to verify that the needed improvements have been realized and effective in reducing the likelihood of the occurrence of nonconformance.

The Board shall utilize information derived from Quality Indicator data, surveys and any other source to take action to prevent nonconformance.

The organization shall also utilize information about identified non-conformances by external assessment and quality audits to effect preventive action.

Preventive action shall include the use of data from external assessments, internal audit results, quality records and complaints to detect, analyze and eliminate potential causes of nonconformities.

All operational and technical procedures are reviewed annually. The quality system shall be reviewed for redundancies and inherent weaknesses especially in areas that have frequent nonconformance's or facility complaints, closer scrutiny or tighter control will be applied.

Each department implements quality indicators for the activities they perform.

Other means that contribute to the continual improvement of the QMS include but not limited to:

- Review of the preventive actions once every quarter.
- Systematic monitoring of quality indicators once every quarter including;
- Customer Satisfaction Survey –
- KMLTTB turnaround times –
- Percentage of sealed medical laboratories –
- Percentage of institutions failing accreditation –
- Percentage of students failing KMLTTB conducted examination –
- Number of complaints received –
- EQA results/performance by participating medical laboratories

When opportunities for improvement are identified, KMLTTB management shall address them accordingly regardless of where they occur.

All members of staff are provided with an opportunity to attend planned educational and training courses to ensure the continuous improvement of the system.

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KMLTTB management conducts review of the Boards QMS and all the activities annually.

The frequency of the reviews shall be increased depending on recommendations by the management review committee.

The management review committee shall include and not limited to the Registrar/CEO, Heads of Departments and Quality Assurance Officer.

It is up to the Registrar/CEO discretion to invite relevant stakeholders for the management review meetings.

The agenda for the management review is detailed in the management review procedure.

The ability of the QMS to meet the KMLTTB objectives is evaluated and any changes or improvements that may be essential implemented.

The quality and appropriateness of the Board contribution to public and stake holders needs shall be monitored and evaluated objectively.

The results of the review shall be captured and incorporated into a plan that includes goals, objectives and action plans.

Action plans shall be executed within an appropriate and agreed upon time.

Results of the management review are communicated to all members of staff at least 2 weeks after the management review meeting.

The Board shall have sufficient number of competent personnel with requisite education, training, technical knowledge, skills and experience to effectively manage the type, volume and scope of activities offered.

KMLTTB shall have access and maintain a pool of assessors, including lead assessors, technical experts, through Board stakeholders, internal technically qualified staff and contracted personnel that are conversant with current standards, for its accreditation activities.

14. ASSESSMENT PERSONNEL

Responsibilities and procedures for the selection and contracting of assessment personnel will be as defined

Prospective assessors shall be selected on the basis of Board's need for assessors, qualifications, experience and competence in the relevant field of expertise.

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KMLTTB Quality Manual Where feasible, Board shall certify/designate Lead Assessor(s) for accreditation programmes.

The Board may also use external KMLTTB registered Lead Assessors.

Due to the nature of assessment, technical assessors and experts need to maintain competence within a given field, the Board may therefore not employ full time technical assessors/experts but may use Board registered, contracted external Technical Assessors / experts on a need-be basis.

Responsibilities and procedures for the training and qualifying of assessors will be as defined in regulations.

15. REQUIREMENTS FOR KMLTTB ASSESSORS / EXPERTS. RESPONSIBILITIES OF THE ASSESSMENT TEAM:

KMLTTB shall ensure that assessors are aware of their duties, responsibilities and authorities.

Types of assessor and their function, specific responsibilities and methods of conducting assessments shall be defined in standard operating procedures and regulations as follows:-

- Leader of the assessment team.
- Technical Assessor.
- Team member,

Personnel Records:

KMLTTB shall maintain personal records of relevant qualifications, training, experience and competence for all staff, contracted personnel and committee members associated with the Board.

Records of training, experience and monitoring of each person involved in Board activities are kept up to date.

The KMLTTB shall keep up-to-date records on assessors, experts, committees, and other contracted personnel.

The file shall contain the following;

- Name and address, position held and for external assessor and experts, the position held in their own organization, educational qualification and professional status, work experience, training in management systems, assessment and conformity assessment activities, competence for specific assessment tasks and experience in assessment and results of their regular monitoring.

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- Staff competency Staff competencies cover technical, practical skills and general knowledge. Process for competency assessment after initial training and periodically thereafter, is established.

Employees must successfully demonstrate competence in the skills and working knowledge for which they were trained. Competency assessment applies to all employees including probationary and confirmed employees. Employees are encouraged to seek for opportunities to improve assigned tasks where appropriate.

Competency assessment:

Competency assessment of each person to perform assigned duties occurs initially following training (within the probationary period of the employee) and annually thereafter at the time of annual performance review.

List of core competencies have been defined for each job description.

The competency assessment carried out as detailed in procedure competency assessment.

16. PERSONNEL PERFORMANCE APPRAISAL:

- The KMLTTB management shall establish and maintains a process of periodically and objectively assessing individual performance.
- Each staff has an annual performance assessment with the approved Annual Performance Evaluation Report (APER) form rated by their immediate supervisors and counter signed by the heads of departments.
- Propositions are made for staff's promotions taking into account objective criteria and indicating an order of priority if several staff are qualified.
- Trainings or continuous education are discussed with staff for performance and personnel promotion.
- The head of department shall document interviews to support each staff.

TRAINING:

Training and assessment of competence for all staff members take place at several levels including the following areas:

- Quality management system
- Safety
- Computer system and job tasks.
- Competency assessment process.
- Continuing education process.
- Personnel record maintenance process.

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- Orientation-
- Training
- Performance procedure.
- Competency assessment form.
- Procedures for the selection and contracting of assessment personnel.
- Requirements for KMLTTB Assessors

17. PERSONEL MANAGEMENT

- The KMLTTB management shall ensure that there is adequate space to perform its work efficiently to ensure quality service delivery and safety of personnel.
- The Registrar/CEO shall provide enough resources to support quality service delivery and that the Board maintains a functional and conducive work climate. Access to the Board is controlled and limited to authorized personnel only through the use of identifications tags.
- All visitors require clearance from the security personnel to access the offices.
- All hazardous/biomedical waste is discarded into appropriate biohazard waste containers that are handled and disposed of in accordance with standard operating procedures and regulations.
- All work surfaces shall be maintained in clean condition and records of daily cleaning KMLTTB shall indulge in quality improvement activities that contribute positively to outcomes for Board and laboratory services.
- It reviews periodically and maintains guidelines, validated processes and procedures to ensure quality services.
- Opportunities for improvement are an ongoing process that is fundamental to the Quality Management System.
- Information is reviewed and appropriate action is taken to implement necessary action to improve processes and procedures.

18. CONTINUAL IMPROVEMENT

- Everyone is responsible for continual improvement.
- Management is responsible to take an active role to advocate appropriate action to improve all practices in the Board.
- The Registrar/CEO and top management team take a lead role in reviewing and preparing reports from vital information collected that monitors activities for improvement.
- The staff has the responsibility to document or make suggestions for improvements without fear of retribution.

19. SOURCES OF INFORMATION FOR CONTINUOUS IMPROVEMENT:

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A systematic review of QMS processes and respective documents is performed periodically to keep abreast of technologic changes.

Systemic review of **REGULATORY** processes to identify the process to be improved by applying a set of criteria derived from Quality Indicators.

Evaluation of Effectiveness of Actions taken. Appropriate action following the review of any non-conformance is submitted to Board management for review and implementation of any needed changes to the quality management system.

Corrective action is documented and evaluated for effectiveness with follow-up audits and reviews.

Process for continual improvement Procedure to identify opportunities for improvement Quality indicator selection opportunities for improvement.

KMLTTB management ensures that the Board and its committees are committed to the selection, acquisition, validation, maintenance, replacement and disposal of obsolete equipment to provide quality service delivery.

The policy provides guidance for the purchase of office equipment, installation and use according to the department's policies and procedures

Management ensures that the technical staff and other essential support service providers within the organization including purchasing, receiving, maintenance and staff are all given consideration in the selection and acquisition of equipment

Equipment Qualification:

a) A program is established that defines the installation and use of new equipment that includes the vendor in the set-up which assures that its performance meets the specifications.
b) There shall be a procedure for selection, acquisition, purchasing of equipment, Procedure for installation, operational and performance qualification Process and for routine maintenance.
c) There shall be procedure for decommission of equipment, procedure for troubleshooting, repair, service, equipment decontamination, selection and validation of new equipment.
d) There shall be a procedure for the development and use of Master Index for identifying equipment.

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e) There shall be a Procedure for repair or service of equipment, equipment master file, Preventative maintenance forms, temperature charts and master Documents file.

20.SAFE WORKING ENVIRONMENT

KMLTTB is committed to provide and maintain a safe working environment which provides a safe, adequate and comfortable physical environment to ensure that the safety and health of employees and visitors are not compromised.

The foundation of this policy is based on applicable laws, regulations and international laboratory safety standards.

RESPONSIBILITY:-

KMLTTB Management is responsible for:

a) Creating and maintaining a safe working environment
b) Providing a clean and well lighted work space
c) Providing sufficient space in configurations conducive to efficient handling of the workload
d) Establishing a comprehensive Safety program
e) Providing staff with the necessary Personal Protective Equipment (PPE)
f) Ensuring all Board staff receive appropriate safety training.

KMLTTB shall designate a Safety Officer who shall be responsible for assessment of safety requirements, develop procedures, identify needs and assist in implementation.

THE MEDICAL LABORATORIES

All medical laboratories in Kenya shall have a designated safety representative who is responsible to ensure that safety procedures and protocols are adhered to.

Policies and Procedures: The Board shall document policies and procedures to ensure the personnel safety as well as environmental safety in all medical laboratory facilities

Health and Safety Policy and Safety Manual: The Board shall establish procedures and guidelines in a Safety Manual which describes the policies and procedures relating to safety. These procedures and guidelines are documented in the Board Safety Manual which is available and accessible in all the laboratories and departments.

The Board Safety Manual is part of the controlled documents and is reviewed annually by all medical laboratories

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Universal Precautions: Universal safety precaution posters shall be posted in the Board website and all medical laboratories to remind staff of the basic personnel safety requirements.

Safety and First Aid Officers: The medical laboratories shall appoint a safety representative. All staff members, through their safety representatives are involved in discussion concerning safety at work.

Safety committee(s): A safety committee shall be nominated by the medical laboratory director/in charge or the medical laboratory superintendent and the individuals shall be officially appointed.

The members of the committee shall be responsible to oversee safety issues and attend scheduled Safety meetings.

Specific SOPs : Apart from the Safety Manual, various safety SOPs shall be made available in each medical laboratory to describe decontamination of workbenches, staff hygiene, emergency response, handling of highly infectious and dangerous material, handling of safety equipment, etc.

Staff Health requirements: An accident / incident register shall be kept in each medical laboratory. All accidents / incidents must be recorded in this register, and appropriate documentation must be forwarded to the Safety Officer.

Medical laboratory Quality Manual: Safety risk assessments shall be conducted at least twice annually according to a plan developed and implemented by the Safety Officer. **Documentation Specific staff**: Safety issues shall be described in the Safety Policy, and the Safety Manual. The following records are kept by the -Safety Officer.

a) Records of Service of Safety Equipment
b) Safety training record
c) Incident / Accident reports
d) Risk assessment reports
e) Safety Inspection reports
f) Analysis of accidents and preventive actions
g) Fire emergency drill
h) Minutes of safety meetings.

Environment and Premises: KMLTTB shall prescribe and document the minimum requirements for testing laboratories. The lay-out and use of different areas shall be shown

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in the floor plan. Each medical laboratory shall monitor environmental conditions to assure that test performance and equipment shall not be negatively influenced.

Access Control: KMLTTB shall prescribe for implementation, documents and controls and access to the medical laboratories.

Cleaning of the offices and medical laboratories; the offices and medical laboratories shall be cleaned by cleaning personnel according to documented procedures.

Waste Disposal: A procedure shall be in place for waste disposal

Medical laboratory Quality Manual: Documentation General Procedures and specific safety issues relating to infection control and hygiene of the environment shall be documented in the "Safety Manual" and relevant SOPs in the various departments and laboratories. Supporting Documents:

Facility Maintenance: Each medical laboratory shall have a Waste Disposal Procedure, Safety Incident Reporting Procedure, Unsafe condition Follow-up Procedure, Safety Manual, Post Exposure Prophylaxis, Safety Training Plan Logs/Forms , Safety Training Record Evacuation/Fire Drill Record , the Physical Facilities general Outline, Safety incident Reporting Form ,Safety Audit Checklist ,Floor plans

ACCREDITATION Purpose and Scope:

The purpose of this document is to provide the necessary information on the KMLTTB accreditation and assessment process to enable applicants to apply for approval. This document should be read in conjunction with the self-assessment

KMLTTB accreditation/ registration/approval is the official recognition that an institution/ facility is competent to perform specifically defined functions and also has a documented Management System in place to facilitate this process.

An accredited institution/facility will have demonstrated through formal assessment that it is competent to perform the defined functions and that it satisfies.

The requirements that have to be complied with for the various institutions/facilities are given in the KMLTTB documents relevant to the field of accreditation.

Compliance monitoring is a regular inspection of training institutions/medical laboratory facilities by a KMLTTB in order to evaluate the degree of conformity with training standards, testing standards and/or ISO 15189 standards for Medical Laboratories to determine the integrity of data, and assure that resulting data are of adequate quality for assessment and decision making by the body.

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If any problem is experienced the applicant should contact the KMLTTB office for further guidance. No institution/ facility is permitted to use the KMLTTB approval/accreditation certificate or symbol until they have received written confirmation from KMLTTB that they have been registered/accredited. An approved institution/facility or organisation should consult KMLTTB document on "Conditions for use of the Accreditation certificate/Symbol,

All applications are processed internally in accordance with KMLTTB procedures. Enquiries for application handled by the relevant officer, who shall provide the potential applicant with the following documents:-

a) Programme specific application form;
b) General Information on the approval/registration/Accreditation Process;
c) Programme specific procedures, and standard of approval/registration/ accreditation;
d) Any additional Requirements, Technical or Technical Guidance applicable. KMLTTB Documentation and Policy Manual are available on the KMLTTB website www.KMLTTB.org).

The institution/ facility submits the relevant application form, and read the relevant KMLTTB documents for their scope of application prior to completing and submitting the KMLTTB application form.

Note: Failure to complete and submit the required supporting documentation may result in a delay in processing the application.

An approval/registration/Accreditation invoice shall be given to the applicant, which must be signed and submitted back to KMLTTB.

KMLTTB quotes and invoices the facility for the application fee as per KMLTTB Fees schedule.

A Pre-assessment/Counselling visit is available at the request of the facility or may be required after review of the documents.

KMLTTB requires that a complete internal audit and management review be conducted prior to the assessment / inspection visit. Note: An application that has not proceeded to the initial assessment stage within three months from the date of application will lapse.

KMLTTB lead assessor and other inspectors shall be appointed, and on acceptance of the Lead Assessor by the facility, is given ample time (from the date of receipt of the completed application) to evaluate the self-assessment checklist and, upon receipt of payment and the

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signed invitation conducts the assessment/inspection and then submits a report to the KMLTTB office of the registrar/ chief executive (CEO).

The instituting/facility corrects any deficiencies noted in the document review report and the programme specific checklists and submits these to KMLTTB.

The institution/facility must ensure that there are sufficient records to confirm the system is implemented after the assessment / inspection visit.

Unless otherwise agreed with KMLTTB, this may result in the laboratory having to re-apply for approval/accreditation.

All application fees schedule shall be applied for the re-application.

The pre-assessment is an advisory /mentorship site visit by the lead assessor and /or other inspectors whereas the initial assessment /inspection is a site visit by the lead and technical assessor(s) / inspector(s) to conduct a full scale inspection.

KMLTTB Application Form and Requirements: The application form requires very comprehensive information on the applicant's organisation. This information is necessary to allow KMLTTB to judge the extent that the organisation's documented Quality System satisfies the KMLTTB approval/accreditation requirements.

The applicant is required to complete all sections of the application form. An organisation may submit to KMLTTB a completed application form for the sole purpose of obtaining a detailed quotation.

However, the application will not be processed further than the quotation stage without the submission of the organisation's quality manual and application fee.

KMLTTB will keep the applicant informed of any delays to any stage of the application process

The following documents are required together with the application form:

a) Copy of the Quality Manual (policies) and completed KMLTTB forms and indicating where in the quality manual the requirements have been met;
b) Appropriate application fee;
c) Completed all relevant parts of application form;

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21. APPLICATION FOR EXTENSION

Application for Extension of approval/accreditation applies to facilities which:

a) Have already been accredited, where the institution/facility wishes to extend the approval accredited scope of certifications within the existing approval /accredited field.
b) Where an already approved/accredited facility wishes to apply for accreditation in a new field altogether, but under the same management system.
c) The facility completes the relevant application form and submits to the relevant officer at least 6 weeks before the next scheduled assessment.
d) Where possible, assessment or witnessing of extensions for accreditation will be carried out at the next surveillance or reassessment visit, but when requested by the facility, additional visits will be arranged. Annual fees may need to be revised.
e) A quote is done and the facility is invoiced for the surveillance or re assessment, including the extension where necessary. On receipt of payment, an assessment date is arranged.
f) The facility must ensure that there are sufficient records for the extension to confirm the system is implemented prior to the assessment visit.
g) The assessment is conducted on site visit by the lead and other technical assessor/s.
h) Once all non-conformances recorded at the assessment are cleared, the Registrar may grant approval/accreditation, based on recommendations given in the report by the assessment Team.

22. CONFIDENTIALITY

All information submitted to KMLTTB in support of the application form shall be treated in confidence. All assessors used by KMLTTB are required to sign the KMLTTB Assessor Contract, as well as confidentiality agreements at each assessment performed.

Any breach of confidentiality is treated extremely seriously.

KMLTTB shall request written permission from all accredited facilities or applicants prior to releasing any information to a third party unless by a court order as may be required to release confidential information in compliance with the law.

23. TIME-SCALE FOR THE APPROVAL/REGISTRATION/ ACCREDITATION PROCESS

KMLTTB makes every effort to ensure that all applications are processed as efficiently as possible. The time taken to process an application depends on a number of factors, some of which are outside the control of KMLTTB.

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The timing is dependent on:-

a) The quality of the applicant's documentation and the extent to which it complies with KMLTTB and accreditation requirements. A delay can occur due to insufficient documented procedures and submission of inadequate Quality Manuals;
b) The availability of suitable assessors;
c) How efficiently the applicant organisation clears the non-conformances after the initial assessment;
d) The availability of the resources within KMLTTB. Generally, accreditation takes place between 1 - 2 months from receipt of the application form with a good Quality Manual supplied, to the initial assessment.

24. SUBCONTRACTING THE ASSESSMENT:-

AKMLTTB as matter of policy shall not subcontract any of its approval/registration/accreditation activities because of issues of confidentiality and conflict of interest. The Board will retain its full responsibility for granting, maintaining, extending, reducing, suspending or withdrawal of approval/registration/accreditation.

KMLTTB shall develop, design, review and validate all of its processes to assure that they fulfill regulatory standards, customer requirements and organizational needs. The Board shall ensure that all developed processes in the implementation of its mandate are monitored for efficiency and effectiveness. This also includes internal and external quality assurance programs and approval/registration/accreditation process to review KMLTTB activities and regulatory performances, detect non conformities and take corrective actions.

25. INFORMATION MANAGEMENT:-

Information Management: KMLTTB addresses the managing of information generated between Board and its stakeholders professionally. Security of accessing data information and the integrity of data transferred is managed in compliance with data protection ACT, 2019, freedom of information ACT and digital Health ACT, 2023.

Purpose: This policy addresses processes and procedures for the management of KMLTTB information to assure that confidentiality of the information is not breached.

Focus of Information Management System: KMLTTB information system is electronic and paper based and information can be disseminated verbally, e-mail or mail.

External Communication: Communication with external institutions/ facilities is in the form of but not limited to electronic mail, telephones and meetings.

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KMLTTB staff are authorized to offer telephone consultations on technical matters within the scope of their responsibilities to external facilities.

Records of all communications are documented.

Computer Access and Security KMLTTB establishes and documents processes and procedures for:

a) Identifying appropriate levels of computer access
b) Assigning passwords and changing them at regular intervals
c) Changing data and updating information
d) Maintaining confidentiality

Data Integrity: The KMLTTB verifies the accuracy of information before its release.

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.....THE END.....

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