REPUBLIC OF KENYA
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

KMLTTB REGULATORY CPD NON COMPLIANCE PENALTY, REMEDIAL ACTION, AND FACILITY SANCTIONS POLICY

Technologists Act CAP 253 A Laws of Kenya

KMLTTB QUALITY ASSURANCE SERVICES

	KMLTTB REGULATORY CPD NON COMPLIANCE PENALTY, REMEDIAL ACTION, AND FACILITY SANCTIONS POLICY		DOCUMENT CONTROL Serial: KMLTTB/CPD/NON.COMPLINCE/REMED/PENAL/POL/01 Version 001 Date: 2ND, JUNE, 2026
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Make Testing a Safe Reality

INTRODUCTION

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

Pursuant to the **Medical Laboratory Technicians and Technologists Act, CAP 253A of the Laws of Kenya**, the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) establishes TRAINING STANDARDS which are a comprehensive regulatory framework. This standard governs medical laboratory operations for the diagnosis, treatment, clinical management, treatment monitoring, and prevention of all diseases, within the Republic of Kenya.

The main goal of the MLS services is to ensure provision of safe, professional, competent and ethical Medical Laboratory Services in accordance to Cap 253A of the Laws of Kenya.

The **Standards for Medical Laboratory Services in Food and Nutrition Diseases** is one of the guidelines prepared by the KMLTTB prescribing mandatory clinical practice and competencies professionals shall practice in the course of their duty.

Our Vision

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

Our Mission

"To Exercise General Control and Supervision over training, business, employment and practice of Laboratory Medicine and Advise the Government on all related matters."

Our Core Values

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

KMLTTB Regulatory Penalty, Remedial Action, and Facility Sanctions Policy
Strictly Tailored under the Medical Laboratory Technicians and Technologists Act (Cap 253A)

1. Chronological Compliance Phases & Licensure Status

This framework governs the enforcement of annual CPD thresholds for Medical Laboratory Technicians and Technologists in Kenya. Practitioners are mandated to accumulate **50 CPD points annually** (where 1 point equates to 2 contact hours of interactive learning or 1 hour of intense bench training).

Phase I: Beginning of the Practice Year (Days 1–90)

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A. **Target Group:** Practitioners entering the practice year with an unresolved points deficit from the previous cycle.

B. **Licensure Status:** Denial of standard renewal. Progression to a *Conditional Provisional Practicing Certificate* valid for a non-extendable maximum of 90 days.

C. **Surcharges:** Administrative late-compliance fee of KES 15,000 for Technicians and KES 25,000 for Technologists.

D. **Remedial Pathway (RAP):** Execution of a binding 90-day Rectification Agreement to clear the deficit via the online Integrated CPD Management System (iCPD).

Phase II: Middle of the Practice Year (Months 4–8)

A. **Target Group:** Practitioners failing to fulfill Phase I agreements or falling under the pro-rata mid-year milestone (< 25 points by June 30th).

B. **Licensure Status:** Transition to a *Restricted License*. Immediate bench ban from high-consequence diagnostic domains (e.g., Blood Transfusion, Molecular PCR, Microbiology) and restriction to supervised duty.

C. **Individual Penalty:** Escalated individual non-compliance fine of KES 50,000.

D. **Remedial Pathway (RAP):** Compulsory enrollment in a 14-day accelerated practical hands-on training module at an approved tertiary institution personal expense.

Phase III: End of the Practice Year (Months 9–12)

a. **Target Group:** Chronic, unmitigated non-compliance persisting past October 31st.
b. **Licensure Status:** Immediate suspension of the practicing license and automated deletion from the active KMLTTB Roll.
c. **Individual Penalty:** Maximum Board disciplinary fine of KES 150,000. Operating without a license constitutes a criminal offense under Cap 253A, carrying court fines up to KES 1,000,000 or up to 5 years imprisonment.
d. **Remedial Pathway (RAP):** Formal reinstatement requires passing a Peer-Review Panel Evaluation, clearing all historical deficits, completing a 15-hour penalty overhead course, and paying a KES 50,000 reinstatement fee.

2. Tiered Facility Fine Structure (KEPH Alignment)

To ensure accountability among employers, vicarious corporate fines are levied against laboratories deploying non-compliant personnel. Fines are systematically tiered based on the Kenya Essential Package for Health (KEPH) facility categories:

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Institution Classification	Example Facility Level	Mid-Year Fine (Phase II Deficit)	End-of-Year Corporate Fine (Phase III Deficit)
Tier 1: Low-Volume / Primary Care	Levels 2 & 3 (Dispensaries, Health Centres, Private Clinics)	KES 5,000	KES 10,000 + 14-day compliance notice
Tier 2: Medium-Volume / Secondary Care	Level 4 (Sub-County Hospitals, Medium Private Laboratories)	KES 7500	KES 12,500 + Temporary closure warning
Tier 3: High-Volume / Tertiary Care	Levels 5 & 6 (County Referral Hospitals,	KES 20,000	KES 25,000 + Sanction on Facility Board License

3. Appeals Procedure & Statutory Exemptions

The 30-Day Appeals Window: Any practitioner or facility manager aggrieved by a Board sanction has a statutory right to appeal under Cap 253A. A written appeal must be filed with the KMLTTB Registrar within exactly **thirty (30) calendar days** of notification, accompanied by Form KMLTTB-CPD-APL and a
Non-refundable KES 5,000 filing fee. An Independent Appeals Tribunal will issue a binding determination within 21 days. Filing an appeal does not stay bench restrictions.

Statutory Exemptions Framework: Applications must be submitted via the KMLTTB portal before October 31st:

A. **Long-Term Medical Leave:** Prolonged illness (> 3 months) verified by a registered medical practitioner under the KMPDC triggers pro-rata point reductions or a zero-penalty extension up to 6 months.

B. **Foreign Postgraduate Study:** Full-time enrollment in relevant MSc/PhD or advanced clinical fellowships outside Kenya converts automatically to CPD credits. Full 50 points are awarded upon submission of official transcripts.

C. **Retrospective Filing:** Exemptions sought post-penalty generation incur a KES 2,500 late processing fee and forensic verification.

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4. Curriculum Criteria: 15-Hour Penalty QMS Overhead Course

Suspended professionals must complete a mandatory 15-contact-hour remedial curriculum focusing heavily on ISO 15189:2022 standards and laboratory safety protocols:

Module 1: Pre-Analytical Error Management & Sample Integrity (3 Hours)

Traceability frameworks; tracking of mislabeled samples, haemolysed specimens, and inappropriate anticoagulants; chain-of-custody protocols for emergency cross-matching and high-consequence clinical specimens.

Module 2: Analytical Quality Control & Equipment Troubleshooting (4 Hours)

Statistical quality control; plotting Levey-Jennings (L-J) charts and executing corrective actions based on Westgard Rules; calibration cycles and decontamination for automated diagnostic systems.

Module 3: Post-Analytical Validation & Critical Value Reporting (3 Hours)

Turn-around-time (TAT) data metrics; verification of critical thresholds; technical protocols for immediate verbal and electronic escalation of alert values (e.g., positive blood cultures) to clinical teams.

Module 4: Biosafety, Biosecurity, and Waste Disposal (3 Hours)

Compliance with national environmental laws (NEMA); hazardous biomedical waste segregation matrices; emergency drills for chemical and bio-hazardous infectious spills on the diagnostic bench.

Module 5: CAPA Logs & Auditing Readiness (2 Hours)

Drafting, implementing, and closing formal non-conformance reports; root-cause analysis documentation; structuring laboratory workflows for impromptu spot-audits by KMLTTB Quality Assurance inspectors.

5. Peer-Review Panel Evaluation Structure

Reinstatement requires a minimum score of **70%** across an oral and portfolio-based forensic audit executed by a 5-member panel (comprising a Board Chair, Academic Representative, Clinical Laboratory Consultant, practicing Peer Representative, and Legal Secretariat).

Scoring Breakdown: Portfolio & Deficit Audit (30 Points) | Diagnostic Case Defense (40 Points)

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| Regulatory Compliance, Ethics & QMS (30 Points).

Determinations: 70% results in Unconditional Reinstatement; 50%-69% grants Conditional Reinstatement under direct peer supervision for 90 days; < 50% maintains suspension for a 6-month cooling-off period.

APPENDICES

Appendix A: Standardized Phase II Diagnostic Case Studies

Case Study 1: Blood Transfusion (Immunohematology)

Scenario: A 34-year-old maternity patient requires packed red blood cells for emergency postpartum hemorrhage. Immediate spin cross-matching indicates compatibility, but the anti-human globulin (AHG) phase reveals macroscopic agglutination (Grade 2+) accompanied by a weakly positive Direct Antiglobulin Test (DAT) on the patient's pre-transfusion sample.

Competency Expectations: Candidate must immediately halt blood release; demonstrate knowledge of antibody screening using a 3-cell panel and auto-control testing; outline risks of acute hemolytic transfusion reactions; communicate sample constraints to clinicians.

Case Study 2: Molecular Diagnostics & Virology (PCR)

Scenario: During a high-throughput real-time PCR run for HIV Viral Load testing, the automated liquid handler suffers a sudden micro-clogging event. Final curves show all patient samples in Row D returned flat (negative) results, the Positive Control amplified late (Ct 39, target <32), and the Negative Control showed weak amplification at Ct 38.

Competency Expectations: Candidate must invalidate the entire run; isolate mechanical pipetting head contamination vs. reagent degradation; detail an institutional standard operating procedure (SOP) for decontamination using RNA/DNA destroying agents and sample re-extraction.

Case Study 3: Clinical Microbiology & Antimicrobial Resistance (AMR)

Scenario: An ICU blood culture flags positive for Gram-negative rods, growing mucoid, lactose-fermenting colonies on MacConkey agar. Preliminary disk diffusion shows resistance to all 3rd generation cephalosporins (Ceftriaxone, Ceftazidime) and Aztreonam, but susceptibility to Imipenem and Meropenem.

Competency Expectations: Candidate must identify potential ESBL-producing organisms (*Klebsiella pneumoniae / E. coli*); outline phenotypic confirmatory steps (double-disk synergy testing); execute urgent reporting to the ICU clinical team and Infection Prevention and Control (IPC) officers.

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Appendix B: Verbatim Certificate of Reinstatement Layout

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD (KMLTTB) THE MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS ACT (CAP 253A)

CERTIFICATE OF REINSTATEMENT TO THE BOARD REGISTER

This is to certify that:
Practitioner Name: _____
Registration No: _____Designation: _____

Having successfully satisfied the continuous professional development requirements, completed the prescribed remediation pathways, and passed the formal Peer-Review Evaluation administered under the authority of the Education and Quality Assurance Committee on this _____day of _____, 20___.

The suspension of the practicing license of the aforementioned practitioner is hereby LIFTED. The practitioner's name has been fully reinstated into the Active Roll of the Board Register with effect from the date of this certificate.

The practitioner is authorized to resume medical laboratory practice in the Republic of Kenya, subject to holding a valid, current Annual Practicing License (APL) and maintaining strict adherence to the Code of Professional Conduct and statutory frameworks under Cap 253A of the Laws of Kenya.

Given under the common seal of the Board this _____day of _____, 20___.

_____ _____

REGISTRAR / SECRETARY CHAIRPERSON OF THE
BOARD KMLTTB

[OFFICIAL KMLTTB SEAL]

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Appendix C: Form KMLTTB-CPD-RA90 (90-Day Rectification Agreement)

This binding legal document must be executed in triplicate during Phase I by non-compliant practitioners wishing to obtain a Conditional Provisional License.

PART I: PRACTITIONER DECLARATION & COVENANT

I, _____, Registration Number _____, holding the designation of Medical Laboratory [Technician / Technologist], do hereby acknowledge that as of Day 1 of this practice year, my verified CPD account reflects a deficit of _____CPD points from the mandatory statutory threshold.

In consideration of the Board granting me a non-extendable 90-Day Conditional Provisional Practicing Certificate, I solemnly covenant and agree to:

1. Liquidate the entire outstanding deficit of _____points within exactly ninety (90) calendar days from the execution date below.
2. Complete a minimum of 60% of these deficit points via the accredited KMLTTB online iCPD portal.
3. Remit the mandatory late-compliance administrative surcharge of KES [15,000 / 25,000] simultaneously with this filing.

PART II: CONDITIONALITY AND CONSEST TO SANCTION

I explicitly understand and accept that failure to verify full resolution of this deficit on or before the close of business on Day 90 will result in automatic,
Non-notified escalation to Phase II sanctions. This includes an immediate bench ban from high-consequence diagnostics, mandatory placement under direct supervision, and a personal penalty fine of KES 50,000.

Practitioner Signature: _____Date: _____

PART III: INSTITUTIONAL ACKNOWLEDGMENT

I, _____, acting as the Laboratory Director / Facility Manager for _____(KMLTTB Facility License No: _____), certify that I am aware of the practitioner's deficit. I guarantee that the practitioner will be given reasonable accommodation to complete their remediation, and I acknowledge our facility's vicarious liability to tiered fines should this agreement fail.

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Manager Signature: _____Date: _____

PART IV: FOR BOARD USE ONLY

Approved / Deferred by the Office of the Registrar:

Signature: _____Effective Date: _____

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

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