REPUBLIC OF KENYA
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS & TECHNOLOGIST BOARD
Make Testing a Safe Reality

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

BIOSAFETY, BIOSECURITY AND BIOMEDICAL WASTE MANAGEMENT STANDARD FOR MEDICAL LABORATORIES

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

KMLTTB QUALITY ASSURANCE SERVICES

	BIOSAFETY, BIOSECURITY AND BIOMEDICAL WASTE MANAGEMENT STANDARD FOR MEDICAL LABORATORIES		DOCUMENT CONTROL Serial: KMLTTB/BSBS/ML/WASTE/POL/01 Version 001 Date: 11TH,NOVEMBER, 2026
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BIOSAFETY, BIOSECURITY AND BIOMEDICAL WASTE MANAGEMENT STANDARD FOR MEDICAL LABORATORIES.

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.

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This Standard is based on MLTTB Act Cap 253A Sec 17, Health Act 2017, Biosafety Act 2009, EMCA Waste Regulations 2006, OSHA Act 2007, WHO Medical Laboratory Biosafety Manual 4th Ed 2020

Applicable to: All Classes - Class B, Class C, Class D, Class E, Class F, Class G , Point Of Care Testing Sites(POCT) and phlebotomy medical laboratory sites.

1. CLASSIFICATION OF MEDICAL LABORATORY WASTE - 7 CATEGORIES

All Medical Laboratories must segregate at point of generation into:

A. Infectious Waste - RED
   Blood, sera, cultures, stocks of infectious agents, swabs, PPE contaminated, pipette tips contaminated. Lab waste code: KMLTTB-W1

B. Sharps - YELLOW puncture-proof
   Needles, lancets, broken glass, scalpel blades. Container: UN3291 yellow sharps box. KMLTTB-W2

C. Pathological Waste - RED with BIOHAZARD
   Tissues, organs, placenta. KMLTTB-W3

D. Chemical Waste - BROWN
   Reagents, expired kits, disinfectants, stains, formalin. MSDS required. KMLTTB-W4

E. Pharmaceutical Waste - BLACK
   Expired drugs in Medical laboratory store.

F. Radioactive Waste, **LABELLED** with Radiation Symbol
   If using RIA. Requires Radiation Protection Board license.

G. General Non-infectious - BLACK BIN
   Office waste, uncontaminated paper. KMLTTB-W7

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2. SEGREGATION AND PACKAGING STANDARD - AT BENCH

Mandatory for all classes:

A. 3-bin system plus sharps at each workstation: Red bag holder with biohazard liner, Yellow sharps box, Black bin for general. No mixing.
B. Bags: Red bags 70 microns, biohazard symbol, labeled: Facility Name, Department, Date, and Weight. Max fill 3/4.
C. Sharps: Do NOT recap, bend, and break. Dispose immediately after use. Close box at 3/4 line. No sharps in red bags - Critical Nonconformity.
D. Liquid infectious waste: e.g., blood, serum - Pre-treat with 1% sodium hypochlorite for 30 min or autoclave before drain - per WHO. For Class D, use chemical disinfection if no autoclave.
E. Culture and stocks: All microbiology cultures, ATCC strains, isolates MUST be autoclaved at 121C, 15psi, 60min in lab BEFORE leaving lab. No movement of live cultures to waste area.

KMLTTB Inspection check: Random bin audit, any sharps in red bag = FAIL.

3. INTERNAL TRANSPORT AND STORAGE

3.1 Trolley: Dedicated closed, leak-proof, labeled, cleaned daily with 0.5% hypochlorite. Not used for reagents.
3.2 Waste store: Central holding area:

A. Locked, ventilated, roofed, impermeable floor, bund for chemical
B. Separate zones for infectious vs chemical
C. Signage: Biohazard, No Entry, PPE Required
D. Max holding time:
   Class B/C/D/E/F: 48 hours
E. Temperature control if holding >48h

3.3 Cold chain for infectious agents storage [if biobanking]:
Not waste, but culture collection requires separate standard BSL-2 freezer with access log, inventory, and double lock.

4. BIOSECURITY - SAFE KEEPING OF INFECTIOUS AGENTS

All Medical Laboratories storing infectious agents must implement:

4.1 Inventory: Full inventory of Risk Group 2, 3, 4 organisms - Form KMLTTB/BIO/INV/01 - Agent, quantity, location, freezer ID, responsible officer. Update monthly.

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4.2 Access control: Freezer/refrigerator with infectious agents locked, key log, only authorized personnel with KMLTTB license, 2-person rule for RG3.
4.3 No RG4 handling in medical Laboratories - Refer to KEMRI P3 lab.
4.4 Decontamination: before maintenance, equipment decontaminated and certificate issued - Form QAF-007A
4.5 BIOSAFETY CABINET (BSC) Certification: Class II BIOSAFETY CABINET (BSC) is mandatory for Microbiology culture in Class B and above - Certified annually, Certificate displayed. Check airflow, HEPA.
4.6 PPE Standard:

A. Lab coat - buttoned, long-sleeve, not worn outside
B. Gloves - nitrile - change between patients
C. Eye protection when splashing
D. N95 for TB culture processing
E. Closed shoes mandatory

5. TREATMENT AND DISPOSAL - APPROVED TECHNOLOGIES

KMLTTB recognizes only licensed waste handlers per NEMA.

A. Option A: Autoclave plus Shred plus Landfill [Preferred for Medical Laboratories]
    i. Infectious waste autoclaved 121C 60min with biological indicator - Geobacillus stearothermophilus - Weekly indicator log.
    ii. After autoclave, shredded, then general landfill as non-infectious.

Option B: Incineration

i. For pathological plus anatomical plus non-autoclavable
ii. Must be high-temperature incinerator >850C double chamber, NEMA licensed - e.g., at County Referral. No open burning - Prohibited.
iii. Ash: dispose in ash pit.

Option C: Chemical Disinfection

A. Only for liquid waste Class D where no autoclave - 1% hypochlorite.

Prohibited: Open burning, dumping in latrine, mixing chemical plus infectious [forms toxic gas], reuse of sharps boxes.

6. CHEMICAL WASTE MANAGEMENT

6.1 Inventory of chemicals with MSDS file.
6.2 Segregation: Acids separate from bases, flammables in flame cabinet, oxidizers separate.

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6.3 Expired reagents - Do not pour down sink if toxic - Return to supplier or NEMA handler - Waste manifest KMLTTB/CHEM/001
6.4 Formalin, xylene: Collect in brown jerry can, label, store in bunded area.

7. SPILL MANAGEMENT AND EMERGENCY

7.1 Blood/Body Fluid Spill:

A. PPE on, cordon area
B. Cover with absorbent paper, pour 1% hypochlorite around then over, leave 30 min, clean, dispose as infectious, handwash.
C. Kit must be available: Gloves, goggles, apron, absorbent, scoop, 1% hypo, red bag.

7.2 Culture Spill in BIOSAFETY CABINET (BIOSAFETY CABINET (BSC)):

A. Do NOT switch off BIOSAFETY CABINET (BIOSAFETY CABINET (BSC)), keep running, spray hypo, leave 30 min, wipe.

7.3 Needle Stick Injury:

A. Wash with soap and water, no squeezing, report immediately to supervisor, fill incident Form, PEP issued within 2 hours. Conduct HIV test at source, start PEP per National guideline, follow up 6 weeks, 3 months.

8. TRAINING AND VACCINATION

8.1 All Medical laboratory staff trained on biosafety and waste management at induction plus annual refresher
8.2 Competency assessed: segregation, spill, donning/doffing PPE.
8.3 Vaccination: Hepatitis B 3 doses mandatory 100% - record in personnel file. Annual flu recommended.
8.4 Medical surveillance: Baseline Medical Laboratories investigations/tests.

9. DOCUMENTATION AND RECORDS

Medical Laboratories must have and show during inspection:

A. Waste Management SOP
B. Waste Management Plan approved by County Medical Laboratory Coordinator (CMLC)
C. Waste register daily -weight per category .This is a Key Performance indicator (KPI)
D. NEMA license for waste transporter plus incinerator which should be a valid copy
E. Manifests: Consignment notes for each collection - signed transporter plus facility and their retention for 5 years
F. Autoclave log: Daily temp/pressure plus biological indicator weekly

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G. Biosafety cabinet certification, annual plus daily check logs.
H. Training records plus Hepatitis B vaccination register
I. Incident log - Needle sticks, spills - reviewed in management review

KPI Dashboard for Waste:

A. Segregation compliance >95%
B. Sharps injuries <2 per year per 10 staff
C. Waste collected within 48h = 100%
D. Autoclave biological indicator pass 100%

10. ENFORCEMENT AND SCORING - KMLTTB

Inspector scoring per QSE 3 Facility and Safety:

A. Mixing sharps in red bag: Critical = Immediate closure notice 14 days to correct
B. No NEMA licensed handler: Major - fine plus license conditional
C. No PPE, no waste register: Minor - CAPA 30 days
D. Repeated open burning: Refer to NEMA plus KMLTTB disciplinary - License revocation

Additional: Dedicated waste officer per shift, hourly waste collection from Point of Care testing (POCT)to main store, pre-positioned spill kits at each testing station, daily NEMA accredited handler pickup.

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

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