I. LEGAL NOTICE NO.

THE MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS ACT (Cap. 253A)

THE MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS (REGISTRATION AND LICENSING) REGULATIONS, 2024

Arrangement of Regulations

Regulation	PART I- PRELIMINARY
1-	Citation.
2-	Interpretation.
3-	Object of the Regulations.
4-	Application of the Regulations.
	PART II – REGISTRATION
5-	Application for registration.
6-	Application with incomplete or insufficient information.
7-	Certificate of registration.
8-	Refusal to issue a certificate of registration.
9-	Notice of refusal of certification.
	PART III –REGISTER OF MEDICAL LABORATORY TECHNICIANS AND REGISTER OF MEDICAL TECHNOLOGISTS
10-	Content of the registers.
11-	Changes in the registers.
12-	Inspection of registers.
13-	Correction of errors in the registers.
14-	Removal from registers.
	PART IV- LICENSING
15-	Licensing.
16-	Application for a licence to practice.
17-	Renewal of a licence to practice.
18-	Licensing conditions.
19-	Standards of practice.
20-	Nature of practice.
21-	Duties of owners or operators of a health institution.
22-	Lifting of suspension to practice.

PART V – CONTINUING PROFESSIONAL DEVELOPMENT

23-	Continuing professional development programmes.	
24-	Accreditation of continuing professional development providers.	
25-	Continuing professional development requirements.	
26-	Proof of compliance with the continuing professional development	
27-	Award of points and certificates.	
28-	Compliance with continuing professional development requirements.	
29-	Non-compliance by an accredited continuing professional development provider.	
	PART VI-SAVINGS	
30-	Savings.	

THE MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS ACT

(Cap. 253A)

IN EXERCISE of the powers conferred by section 15(1) (a)(b)(c) 2,3 (a)(b) ,4, 5 of the Medical Laboratory Technicians and Technologists Act, Cap. 253A, the Chairperson of the Kenya Medical Laboratory Technicians and Technologists Board makes the following Regulations—

THE MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS (REGISTRATION AND LICENSING) REGULATIONS, 2024

PART I —PRELIMINARY

Citation.

1. These Regulations may be cited as the Medical Laboratory Technicians and Technologists (Registration and Licensing) Regulations, 2024.

Interpretation.

2. In these Regulations, unless the context otherwise requires—

Cap. 253A.

"Act" means the Medical Laboratory Technicians and Technologists Act;

"Board" means the Kenya Medical Laboratory Technicians and Technologists Board established under section 3 of the Act;

"health institution" means a hospital, nursing home, convalescent home, maternity home, health centre, dispensary or other institution where health or medical services are rendered;

"medical laboratory" includes any facility where medical laboratory analysis and investigations are carried out and includes a hospital laboratory;

"medical laboratory technician" means a person holding a certificate in medical laboratory technology issued by the Kenya Medical Training College or other similar institution recognized by the Board;

"medical laboratory technologist" means a person holding a diploma, higher diploma or degree in medical laboratory technology issued by the Kenya Medical Training College or other similar institution approved by the Board;

"practising licence" means a practising licence issued under section 21 of the Act; and

"Registers" means the register of medical laboratory technicians and the register of medical laboratory technologists maintained pursuant to section 16(1) of the Act.

Object of the Regulations.

3. The object of these Regulations is to give effect to the provisions of the Act by facilitating access to the highest attainable standard of health care.

Application of the Regulations.

- **4.** These Regulations shall apply to the—
 - (a) registration and licensing of medical laboratory technicians and medical laboratory technologists; and
 - (b) Maintenance of the register of medical laboratory technicians and the register of medical laboratory technologists.

PART II – REGISTRATION

Application for registration.

- **5.** (1)An application for registration as a medical laboratory technician or medical laboratory technologist shall be submitted to the Registrar in **KMLTTB/APL/01** set out in the First Schedule and shall be accompanied by—
 - (a) proof of payment of the prescribed fee;
 - (b) legible certified copies of the applicant's academic certificates, academic transcripts, professional certificates and testimonials;
 - (c) proof of passing the registration examination conducted by the Board under these Regulations;
 - (d) a certificate of good conduct; and
 - (e) a curriculum vitae.
- (2) An application by a person registered outside Kenya shall, in addition to the documents specified in sub regulation (1), be accompanied by—

- (a) a certificate of good standing from the relevant authority responsible for registration in the country of origin;
- (b) a certificate of registration or its equivalent containing evidence of registration from the relevant authority responsible for registration in the country of origin;
- (c) a copy of the course outline of the institution from where the qualification in medical laboratory science was obtained certified by that institution;
- (d) proof of completion of the probation period under these Regulations; and
- (e) a letter of equation of the certificate issued by a relevant authority in Kenya.
- (3) A person who has qualified outside Kenya shall, for purposes of sub regulation (2)(d), be required to engage in probation for a period of at least one year where the person shall—
 - (a) be attached to a health institution, organization or project of a health institution or organization as part of the workforce of the health institution or organization;
 - (b) be assigned duties at the health institution, organization or project of a health institution or organization;
 - (c) perform the assignments given to him or her to the expected standards;
 - (d) be supervised by the senior staff of the health institution or organization, designated as the cooperating officer and who shall be responsible for—
 - (i) assigning duties to the person under probation; and
 - (ii) determining the level of performance desired for the duties assigned; and
 - (e) Adhere to the requirements and directives issued by the Board in relation to probation regarding matters of reporting on the probation including on the assignments undertaken.

Application with incomplete or insufficient information.

- **6.** (1)Where an applicant fails to submit all documents or information required under these Regulations, the Board shall reject the application and inform the applicant, in writing, of the rejection and the reasons for the rejection using **KMLTTB/PP/02** set out in the First Schedule within twenty one days from the date of receipt of the application
- (2) Where the Board rejects an application due to incomplete or insufficient information, the rejection shall not bar the applicant from re-submitting the application.
- (3)The Board shall treat the re-submitted application as a new application.

Certificate of registration.

- 7. (1) The Board shall, if it is satisfied that the applicant has complied with the requirements under the Act and these Regulations and is in good standing, issue a certificate of registration to the applicant in accordance with section 15 of the Act within thirty days from the date of the receipt of the application.
- (2) The certificate of registration issued under these Regulations shall be in **KMLTTB/PP/01A**

set out in the First Schedule.

Refusal to issue a certificate of registration.

- **8.** (1) Where an applicant in regulation 5 does not comply with these Regulations, the Board may refuse to grant a certificate of registration to the applicant.
- (2) Where the Board refuses to grant a certificate of registration, the Board shall inform the applicant, in writing, of the refusal and the reasons for the refusal using **KMLTTB/PP/02** set out in the First Schedule within twenty-one days from the date of receipt of the application.

Notice of refusal of certification.

- **9.** (1) The Board shall, before refusing to issue a certificate of registration, give the applicant not less than fourteen days' notice in writing stating its intention; and such notice shall in form the applicant that he or she may within seven days of receipt of the notice inform the Board in writing whether he or she wishes to be heard on the intended refusal.
- (2) Where the applicant informs the Board in writing under regulation (1) that he or she wishes to be heard the Board shall not effect such refusal before it has given the applicant an

opportunity to show cause why the application for registration should not be refused.

- (3) Where the Board, after complying with this regulation, refuses to issue a certificate of registration, it shall inform the applicant of its decision and the reasons for the decision within fourteen days.
- (4) A person dissatisfied with decision of the Board under this regulation may lodge an appeal to the High Court within thirty days from the date of the decision.

PART III-REGISTER OF MEDICAL LABORATORY TECHNICIANS AND REGISTER OF MEDICAL TECHNOLOGISTS

Content of the registers.

- **10.** (1) The Registrar, shall enter the name of registered medical laboratory technicians and registered medical laboratory technologists into the—
 - (a) register of medical laboratory technicians; or
 - (b) register of medical laboratory technologists;

maintained in accordance with section 16(1) of the Act.

- (2) The register of medical laboratory technicians shall be in Form MLTTB/REG/01 Set out in the Second Schedule.
- (3) The register of medical laboratory technologists shall be in Form **KMLTTB/REG/02** set out in the Third Schedule.
- (4) The registers in sub regulation (1) shall contain information on the registered medical laboratory technicians or registered medical laboratory technologists including their—
 - (a) full name;
 - (b) nationality;
 - (c) postal address;
 - (d) registration number;

- (e) national identity card number;
- (f) contact information including email address and telephone number;
- (g) date of registration and entry in the register;
- (h) basic academic qualifications;
- (i) highest professional qualifications;
- (j) additional professional qualifications; and
- (k) work station of practice or employment.
- (5)The Board shall ensure that the registers in sub regulation (1) and other records are—
 - (a) kept in safe custody by storing their
 - (i) hard copies in burglar and fireproof safes; and
 - (ii) soft copies in a secure electronic system with appropriate backup; and

Cap. 411C. No. 15 of 2023. (b) maintained and secured in accordance with the provisions of the Data Protection Act and the Digital Health Act, 2023.

Changes in the registers.

11. A person whose name is entered in the registers under regulation 10(1) shall inform the Registrar of any changes in the particulars set out under regulation 10(4).

Inspection of registers.

- **12.** A person may, during normal office hours and on payment of the prescribed fee,
 - (a) inspect the registers and any document relating to an entry in the registers; and
 - (b) obtain from the Registrar a copy or extract of a document from the registers.

Correction of errors in the registers.

- 13. (1) Where the Registrar establishes that an entry has been erroneously or incorrectly entered in the register, the Registrar may correct the error and notify the affected person of such corrections.
- (2) A person whose name is entered in the registers under regulation 10(1) shall, in writing to the Registrar, make a request using **KMLTTB/PP/04** for the correction or erasure of

inaccurate, outdated, incomplete or misleading information in the registers.

- (3) The request in sub regulation (2) shall specify the
 - (a) information that is to be corrected indicating how such information is out of date, inaccurate, incomplete or misleading; and
 - (b) remedy sought by the person.
- (4) The Registrar shall, within seventy-two hours from the date of the receipt of the request under sub regulation (2), correct or erase the information of the person who requested the correction or erasure.

Removal from registers.

- **14.** (1)Where the name of a person is removed from the registers in accordance with section 17 of the Act, the Registrar shall give written notice of fourteen days to that person, or if the person is dead, to that person's legal personal representative, requiring surrender of the certificate of registration to the Registrar.
- (2) A person removed from the registers under sub regulation (1) may appeal against the removal by
 - (a) submitting a letter to the Board citing the grounds of appeal; and
 - (b) Filing an appeal form which shall be in **KMLTTB/DC/011** set out in the First Schedule.
- (3) The Board shall consider the appeal and communicate its decision to the appellant within twenty one days from the date of the receipt of the appeal.
- (4) The Board shall, in making its decision under sub regulation (3) where the appellant was removed from the registers on the account of a disciplinary matter pursuant to section 30(1) of the Act, consider whether the appellant has
 - (a) completed the period prescribed in section 32(1) of the Act;
 - (b) complied with the recommendations of the Board on disciplinary including probation, fines or retraining; and
 - (c) paid the restoration fee as determined by the Board.

- (5) The Board shall determine the fee payable for the restoration of the name of an appellant in the registers which shall in any case not less than one hundred thousand shillings and the determination shall be guided by—
 - (a) the merits of the appeal; and
 - (b) whether the appellant has complied with the recommendations of the Board.
- (6) Where the appeal is successful, the Board shall direct the Registrar to restore the name of the appellant in the appropriate register within seven days from the date of the decision of the Board.

PART IV-LICENSING

Licensing.

15. A person who intends to practice as a medical laboratory technician or medical laboratory technologist shall be licensed by the Board in accordance with requirements in these Regulations.

Application for a licence to practice.

- . (1) A person who intends to practice as a medical laboratory technician or medical laboratory technologist shall make an application to the Board in **KMLTTB/APL/01** set out in the First Schedule for a licence to practice and the application shall be accompanied by documents including the
 - (a) the registration number in the certificate of registration;
 - (b) statement on the work station of the person; and
 - (c) Proof of payment of the application for licence to practice fee set out in the Medical Laboratory Technicians and Technologists (Fees) Regulations, 2024.
- (2) Where the Board is satisfied that the person meets the requirements for licensing, the Registrar shall issue a licence to practice to the medical laboratory technician or medical laboratory technologist.
- (3) The Board shall consider the application made under sub regulation (1) within thirty days from the date of the application and shall—
 - (a) issue a licence to practice; or

- (b) refuse to grant a licence to practice.
- (4) A licence to practice issued under these Regulations shall be in **KMLTTB/PP/01A** set out in the First Schedule.
- (5) Any person who includes, or causes to be included, in any application relating to a licence to practice, or in response to a request for information from the Board, any information which he or she knows or has cause to believe is in correct commits an offence and shall, on conviction, be liable to the penalty specified under section 19(4) of the Act.

Renewal of a licence to practice.

- 17. (1) An application for renewal of a licence to practice shall be made in KMLTTB/PP/06 set out in the First Schedule, and shall be accompanied by the proof of payment of the renewal of licence to practice fee set out in the Medical Laboratory Technicians and Technologists (Fees) Regulations, 2024.
- (2) The application in sub regulation (1) shall be made thirty days before the date of expiry of the licence to practice.
- (3) The Board may charge a late application fee of fifty percent of the application for licence to practice fee set out in the Medical Laboratory Technicians and Technologists (Fees) Regulations, 2024.
- (4) The Board shall communicate its decision on the application made in sub regulation (1) using **KMLTTB/PP/07** set out in the First Schedule.

Licensing conditions.

- **18.** A registered medical laboratory technician or medical laboratory technologist issued with a licence to practice under the Act and these Regulations shall—
 - (a) adhere to the code of ethics issued by the Board that provides for the duty to the—
 - (i) medical laboratory science profession;
 - (ii) global society or mankind;
 - (iii) patient or client;
 - (iv) colleagues in the medical laboratory science profession; and
 - (v) other healthcare professionals or healthcare providers.

- (b) in case of breach of the code of ethics issued by the Board and the standards of practice provided in these regulations, be referred for disciplinary processes which may lead to suspension of the licence to practice or removal from the registers;
- (c) only engage in the practice for which the medical laboratory technician or medical laboratory technologist is qualified as specified in the licence to practice;
- (d) Whilst on duty, at all times be dressed and groomed in such a manner as to portray a respectable image to the public.

Standards of practice.

- 19. A registered medical laboratory technician or medical laboratory technologist issued with a license to practice under the Act and these Regulations shall adhere to the standards of practice issued by the Board and shall, in particular,
 - (a) be responsible for their individual laboratory professional practice and conduct;
 - (b) adhere to the scope of practice and code of ethics issued by the Board;
 - (c) be competent and demonstrate sound judgment in accordance with the competency profile issued by the Board;
 - (d) demonstrate appropriate professional conduct at all times:
 - (e) be responsible and accountable for continued individual competence;
 - (f) practice within the legal and ethical framework of the medical laboratory science profession;
 - (g) adhere to globally accepted standards within the medical laboratory science profession;
 - (h) prioritize patient welfare and care for improved health outcomes;
 - (i) maintain confidentiality at all times in the course of their work;
 - (j) promote interdisciplinary collaboration with other healthcare providers and healthcare professionals;
 - (k) use medical laboratory reagents and equipment's validated by the Board;
 - (l) prepare reagents for medical laboratory diagnosis and testing using approved methods in accordance with laboratory standards and

- requirements for medical laboratory reagents and equipment issued by the Board; and
- (m) Demonstrate sound professional judgment when procuring and handling specimens.

Nature of practice.

- **20.** A registered medical laboratory technician or medical laboratory technologist issued with a licence to practice under the Act and these Regulations
 - (a) shall provide diagnostic services to the community by meeting the needs of hospitals and the healthcare professionals;
 - (b) shall provide consultant advisory services in all aspects of medical laboratory investigations, including the interpretation of results and advice on any further appropriate investigations;
 - (c) shall collaborate in systematic education and training members for all members of the medical laboratory staff;
 - (d) may collaborate in the development, study and laboratory control of new methods of medical laboratory investigations and analysis, whilst adhering to the laid down medical ethics;
 - (e) may provide advice on approved research projects undertaken by healthcare professionals; and
 - (f) may undertake medical laboratory science operations as may from time to time be specified by the Board.

Duties of owners or operators of a health institution.

- **21.** The owner or operator of a health institution shall—
 - (a) submit to the Board once in every six months a list of all medical laboratory technicians and medical laboratory technologists
 - (i) in their employment; and
 - (ii) who are authorized to use their premises, indicating in each case the authorized place for use as a private medical laboratory;
 - (b) designate a medical laboratory technician or medical laboratory technologist with a valid practising certificate and practising licence to be

- in charge of medical laboratory services at the health institution;
- (c) acquaint themselves fully with the qualifications and professional conduct of all medical laboratory technicians and medical laboratory technologists working at the health institution;
- (d) be responsible for any instance of professional misconduct occurring within the premises about which they know or ought reasonably to have known; and
- (e) ensure that no medical laboratory technician and medical laboratory technologist working in their premises engages in private practice outside the areas of specialization and competency for which they have been licensed.

Lifting of suspension to practice.

- 22. (1) The Registrar shall give a written notice of fourteen days to a medical laboratory technician or a medical laboratory technologist whose practising licence has been suspended in accordance with section 30 of the Act.
- (2) A person suspended under sub regulation (1) may appeal against the suspension by filling the appeal against suspension form which shall be in Form **KMLTTB/DC/09** set out in the First Schedule.
- (3) The Board shall consider the appeal and communicate its decision to the appellant within twenty one days from the date of the receipt of the appeal.
- (4) The Board shall, in making its decision under sub regulation (3), consider whether the appellant has
 - (a) complied with the recommendations of the Board on the suspension including probation, fines or re-training; and
 - (b) paid the lifting of suspension fee.
- (5) The Board shall determine the fee payable for the lifting of a suspension of an appellant which shall in any case not be less than one hundred thousand shillings and the determination shall be guided by—
 - (a) the merits of the appeal; and
 - (b) whether the appellant has complied with the recommendations of the Board.

(6) Where the appeal is successful, the Board shall direct the Registrar to lift the suspension by issuing a certificate of lifting suspension which shall be in **KMLTTB/DC/010** set out in the First Schedule within seven days from the date of the decision of the Board.

PART V CONTINUING PROFESSIONAL DEVELOPMENT

Continuing professional development programme.

23. (1) The Board shall—

- (a) continuously review continuing professional development guidelines for medical laboratory technicians and medical laboratory technologists;
- (b) accredit eligible continuing professional development providers in line with the continuing professional development guidelines issued by the Board;
- (c) accredit any continuing professional development programme conducted by any institution, body or other organization where that institution, body or organization has filed a return with the Board;
- (d) keep a record of all accredited continuing professional development programmes showing the description of such programmes; and
- (e) keep a register of all accredited continuing professional development providers offering training in areas of medical laboratory science; and
- (f) keep track of points earned by the registered medical laboratory technicians and medical laboratory technologists from various continuing professional development activities every year.
- (2) Where the Board offers continuing professional development programmes, the Board shall—
 - (a) conduct relevant continuing professional development programmes from time to time; and
 - (b) keep a record of the participants taking part in any continuing professional development programme offered by the Board indicating

whether each participant completed the programme or not.

Accreditation of continuing professional development providers.

- **24.** (1) A person seeking accreditation as a continuing professional development provider under these Regulations shall
 - (a) make an application to the Board in the Form **KMLTTB/TRN/03/03A/03B** set out in the First Schedule:
 - (b) provide proof of payment of the accreditation fees set out in the Medical Laboratory Technicians and Technologists (Fees) Regulations, 2024.
- (2) The Board shall consider the application for accreditation in sub regulation (1) and shall approve or reject the application guided by the—
 - (a) intended learning outcomes to the target audience:
 - (b) alignment with needs assessment identified by the Board:
 - (c) teaching and learning methodologies used by the provider;
 - (d) adequacy of teaching and learning resources;
 - (e) expertise of the course facilitators;
 - (f) conformity to the standardized evaluation tool provided by the Board; and
 - (g) provision for consistent assessment of the effectiveness and impact of the continuing professional development activities.

Continuing professional development requirements.

- **25.** Every continuing professional development activity for medical laboratory technicians and medical laboratory technologists shall focus on ethical, practical and professional aspects of medical laboratory science including
 - (a) work-based learning including—
 - (i) experiential learning;
 - (ii) in-service training;
 - (iii) secondment; and
 - (iv) supervision;
 - (b) professional activities including—

- (i) involvement in a professional body;
- (ii) making presentations in conferences;
- (iii)research and publications; and
- (c) educational activities including—
 - (i) writing articles or papers;
 - (ii) attending training courses and scientific meetings;
 - (iii)acquiring additional academic qualifications; and
 - (iv)publishing professional books in medical laboratory sciences.

Proof of compliance with the continuing professional development.

- **26.** (1) An application by a registered medical laboratory technician or medical laboratory technologist for a practising licence or a practising certificate shall be accompanied by proof that the medical laboratory technician or medical laboratory technologist has secured fifty points upon attending and participating in a continuing professional development activity offered or accredited by the Board in the preceding year.
- (2) A registered medical laboratory technician or medical laboratory technologist shall obtain ten percent of the fifty points secured under sub regulation (1) from undertaking a continuing professional development activity on medical laboratory quality assurance.

Award of points and certificates.

27. The Board shall—

- (a) assign continuing professional development points for each continuing professional development activity;
- (b) assign a unit or units to each continuing professional development activity to be used in awarding credits to the registered medical laboratory technicians and medical laboratory technologists; and
- (c) issue certificates of participation to participants who have successfully completed a continuing professional development activity.

Compliance with continuing professional

28. (1) A registered medical laboratory technician or medical laboratory technologist shall comply with the

development requirements.

continuing professional development guidelines issued by the Board.

- (2) Where a registered medical laboratory technician or medical laboratory technologist fails to comply with the continuing professional development guidelines, the Board may—
 - (a) revoke or suspend the practising licence of the medical laboratory technician or medical laboratory technologist; or
 - (b) temporarily remove the suspended medical laboratory technician or medical laboratory technologist from the registers.
- (3) A registered medical laboratory technician or medical laboratory technologist shall, subject to the approval of the Board, be exempt from the penalties under subregulation (2) where the registered medical laboratory technician or medical laboratory technologist proves that the non-compliance was occasioned by factors including—
 - (a) illness lasting for more than six months;
 - (b) disciplinary process including suspension lasting for more than six months; or
 - (c) enrolment in full-time training or course work.
- (4) A registered medical laboratory technician or medical laboratory technologist may appeal against the decision of the Board in subregulation (2) within thirty days from the date of the communication of the decision of the Board.

Non-compliance by an accredited continuing professional development provider.

- **29.** (1)Where an accredited continuing professional development provider fails to comply with the continuing professional development guidelines issued by the Board, the Board shall issue a letter of non-compliance to the accredited continuing professional development provider indicating the period upon which the provider shall redress the non-compliance.
- (2) Where at the end of the period specified in sub regulation (1), the accredited continuing professional development provider has not redressed the non-compliance to the satisfaction of the Board, the Board shall issue a letter—
 - (a) suspending the accredited continuing professional development provider for a period

- of not less than one year but not exceeding two years; or
- (b) revoking the accreditation of the continuing professional development provider.

PART VI- SAVINGS

Savings.

- **30.** (1) A registered medical laboratory technician or medical laboratory technologist who, subject to sub regulation (2) and (3), immediately before the commencement of these regulations had a practising licence shall practice with that licence.
- (2) A medical laboratory technician or medical laboratory technologist referred to in sub regulation (1) shall make an application in Form **KMLTTB/APL/01** set out in the First Schedule within three months of the coming into force of these Regulations for a practising license under regulation 16.
- (3) Where the Board refuses a licence applied for under this regulation, the medical laboratory technician or medical laboratory technologist shall cease to use the practising licence from the date of the refusal.

Made on the	, 2024.
-------------	---------

DR. TITUS MUTWIRI,