

II. LEGAL NOTICE NO.

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

**THE MEDICAL LABORATORY TECHNICIANS AND
TECHNOLOGISTS (PRIVATE PRACTICE) 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 – PRIVATE PRACTICE

- 5- Application for practising certificate.
- 6- Application with incomplete or insufficient information.
- 7- Grant of practising certificate.
- 8- Refusal to issue a practising certificate.
- 9- Renewal of practising certificate.
- 10- Conditions of a practising certificate.
- 11- Notice of refusal to grant a practising certificate.
- 12- Locum in private practice.

PART III – PRIVATE MEDICAL LABORATORIES

- 13- Approval of private practice premises.
- 14- Conditions for licensed premises.
- 15- Scope of licence of private practice.

PART IV– CONDITIONS OF PRIVATE PRACTICE

- 16- Terms and conditions of private practice.
- 17- Operation of a private medical laboratory.
- 18- Duties of owners or operators of health institutions.
- 19- Requirements for private medical laboratories.
- 20- Duties in operating a private medical laboratory.
- 21- Display of practising certificate.
- 22- Notification of change of particulars.
- 23- Employment of a medical laboratory professional.
- 24- Fees.

PART V – SAVINGS

- 25- Savings.

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

IN EXERCISE of the powers conferred by section 25 (1) 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 (PRIVATE PRACTICE) REGULATIONS, 2024**

PART I—PRELIMINARY

Citation. 1. These Regulations may be cited as the Medical Laboratory Technicians and Technologists (Private Practice) 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;

 “hospital laboratory” means a facility in a health institution in which medical laboratory analysis and investigations are carried out;

 “immediate supervision” means being available to give help and guidance when required;

 “locum” means a registered medical laboratory technician or medical laboratory technologist substituting and providing services for another registered medical laboratory technician or medical laboratory technologist engaged in private practice;

 “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 certificate” means a practising certificate issued under section 21 of the Act;

“private medical laboratory” means a medical laboratory where a private practice is carried out;

“private practice” means providing medical laboratory services for a fee for own financial benefit in the manner set out in section 20(2) of the Act;

“private practitioner” means a medical laboratory technician or medical laboratory technologist licensed to engage in private practice; 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) terms and conditions of the business and practice of medical laboratory technicians and medical laboratory technologists engaged in private practice;
- (b) services to be rendered by medical laboratory technicians and medical laboratory technologists in private practice; and
- (c) employment of medical laboratory technicians and medical laboratory technologists in private medical laboratories.

PART II – PRIVATE PRACTICE

Application for practising certificate.

5. (1) A person who wishes to engage in private practice as a medical laboratory technician or medical laboratory technologist shall apply to the Board for a practising certificate in accordance with section 22(1) of the Act.

(2) An application for a practising certificate shall be made in KMLTTB/PP/01 set out in the Schedule.

(3) An application for a practising certificate under subregulation (2) shall be accompanied by a—

- (a) non-refundable application fee as set out in the Medical Laboratory Technicians and Technologists (Fees) Regulations, 2024;
- (b) certificate of good conduct; and
- (c) detailed inspection report of where the applicant intends to carry out the practice containing information including the—
 - (i) description of the premises;
 - (ii) physical address of the private medical laboratory; and
 - (iii) contact information including a telephone number and an e-mail address of the private medical laboratory.

(4) Where a medical laboratory technician or medical laboratory technologist intends to practice under a business name or a limited liability company, the application under this regulation shall be accompanied by—

- (a) a certified copy of the search of the business name;
- (b) a certified copy of the certificate of incorporation; and
- (c) documents clearly specifying the controlling interest which the applicant has in the company.

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 Form KMLTTB/PP/02 set out in the 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.

Grant of practising certificate.

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 practising certificate to the applicant in accordance with section 21 of the Act within thirty days from the date of the receipt of the application.

(2) A practising certificate issued under these Regulations shall be in Form KMLTTB/PP/03 set out in the Schedule and shall contain information including—

- (a) the commencement date of the practising certificate;
- (b) the expiry date of the practising certificate;
- (c) consequences of removal from the registers; and
- (d) the name of private medical laboratory for which the practicing certificate has been granted.

(3) A practising certificate issued under subregulation (1) shall expire on the 31st December of the year in which it was issued, and may thereafter be renewed annually on payment of the renewal fee set out in the Medical Laboratory Technicians and Technologists (Fees) Regulations, 2024.

(4) A practising certificate issued under the Act and these Regulations shall not be transferable.

Refusal to issue a practising certificate.

8. (1) Where an applicant in regulation 5 does not comply with these Regulations, the Board shall refuse to grant a practising certificate to the applicant.

(2) Where the Board refuses to grant a practising certificate, the Board shall inform the applicant, in writing, of the refusal and the reasons for the refusal using Form KMLTTB/PP/02 set out in the Schedule within fourteen days from the date of receipt of the application.

Renewal of practising certificate.

9. (1) An application for renewal of a practising certificate shall be made in Form KMLTTB/PP/04 set out in the Schedule, and shall be accompanied by the proof of payment of the renewal of practising certificate fee set out in the Medical Laboratory Technicians and Technologists (Fees) Regulations, 2024.

(2) The application in subregulation (1) shall be made thirty days before the date of expiry of the practising certificate.

(3) The Board may charge a late application fee of fifty percent of the application for practising certificate 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 subregulation (1) using Form KMLTTB/PP/05 set out in the Schedule.

Conditions of a practising certificate.

10. (1) The Board may impose any conditions on a private practitioner under these Regulations and in particular may impose a condition that the private practice of the private practitioner shall not conflict with the terms and conditions of his or her employment.

(2) A practising certificate shall be issued in respect only of the premises named therein and may not apply to any other premises unless the authority of the Board for it to do so has been obtained.

(3) A private practitioner shall display a practising certificate in a conspicuous position at the premises to which it relates and any private practitioner who fails to do so shall be guilty of an offence.

(4) The Board may cancel a practising certificate if any of the conditions imposed under the practising certificate are contravened.

(5) Where a private practitioner ceases his or her private practice he or she shall surrender his or her practising certificate to the Board within thirty days of the cessation.

Notice of refusal to grant a practising certificate.

11. (1) The Board shall, before—

- (a) refusing to grant or renew a practising certificate;
- (b) refusing to allow a change of premises to which the practising certificate relates; or
- (c) cancelling or withdrawing the practising certificate,

give to the applicant or private practitioner not less than fourteen days notice in writing stating its intention; and such notice shall inform the applicant or private practitioner that he or she may within fourteen days of receipt of the notice inform

the Board in writing whether he or she wishes to be heard on the intended refusal, cancellation or withdrawal.

(2) Where the applicant or private practitioner informs the Board in writing under subregulation (1) that he or she wishes to be heard the Board shall not effect such refusal, cancellation or withdrawal before it has given the applicant or private practitioner an opportunity to show cause why the application or practising certificate should not be refused, cancelled or withdrawn.

(3) Where the Board, after complying with this regulation, refuses to grant or renew a practising certificate, or cancels a practising certificate, it shall inform the applicant or private practitioner of its decision within fourteen days or, where the applicant or private practitioner has been heard, within fourteen days of the hearing; and the Board shall inform the applicant or private practitioner the reason for its decision.

(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.

Locum in private practice.

12. (1) A medical laboratory technician or medical laboratory technologist who wishes to work as a locum for another private practitioner shall be required to satisfy requirements for eligibility for a practising certificate to engage in private practice specified in section 20(1) of the Act and these Regulations.

(2) A prospective locum shall make an application in Form KMLTTB/PP/01B set out in the Schedule stating the period during which he or she requires to be a locum:

Provided that in the case of an emergency a medical laboratory technician or medical laboratory technologist may act as a locum for a period not exceeding fourteen days during which time he or she shall inform the Board of his or her action and make a formal application under this regulation.

(3) Where the duration of a locum practice does not exceed six weeks the Registrar may give written consent to the applicant to practice as a locum in Form KMLTTB/PP/06 set out in the Schedule and no fee shall be payable by the applicant.

(4) Where an applicant wishes to work as a locum for a period exceeding six weeks the applicant shall obtain a licence to engage in private practice in Form KMLTTB/PP/07 set out in the Schedule and pay the locum practice fees set out in the

Medical Laboratory Technicians and Technologists (Fees) Regulations, 2024.

PART III – PRIVATE MEDICAL LABORATORIES

Approval of private practice premises.

13. (1) A private practitioner shall operate a private medical laboratory in a premise approved by the Board.

(2) A private practitioner who wishes to operate a private medical laboratory shall apply to the Board in writing for approval of the premises intended for use as a private medical laboratory:

Provided that the application for approval of the private medical laboratory shall be made prior to making an application for a practising certificate to engage in private practice.

(3) The application under subregulation (2) shall be made in Form KMLTTBB/PP/07 set out in the Schedule and shall be accompanied by—

- (a) proof of payment of the fees set out in the Medical Laboratory Technicians and Technologists (Fees) Regulations, 2024.; and
- (b) an inspection report on the premises.

(4) The Board shall consider the application made under subregulation (2) within thirty days from the date of the application and shall—

- (a) grant the licence; or
- (b) refuse to grant a licence.

(5) A licence to operate a private medical laboratory shall be in Form KMLTTB/PP/08 set out in the Schedule.

(6) An application for permission to change the premises to which the licence relates may be made at any time.

(7) The Board may, on application for change of premises under subregulation (6), request relevant information from an applicant as it thinks fit.

(8) Any person who includes, or causes to be included, in any application relating to change of premises, or in response to a request for information from the Board, any information which he or she knows or has cause to believe is incorrect shall

be guilty of an offence and on conviction shall be liable to the penalty specified in section 20(3).

Conditions for
licensed premises.

14. (1) A licence under regulation 13 shall be issued where the licensed premise —

- (a) is kept in good order and a good state of repair;
- (b) is kept reasonably secure from unauthorized entry;
- (c) conforms to the minimum requirements set by the Board and any other written law, and in particular the Public Health Act;
- (d) is not in a residential building;
- (e) meets the description, infrastructure and personnel criteria for the respective classification of the medical laboratory as determined by the Board;
- (f) provides the quality of care that meets the minimum standards acceptable by the Board;
- (g) uses reagents and equipment validated by the Board for medical laboratory investigations and analysis;
- (h) has a designated medical laboratory technician or medical laboratory technologist with a valid practising certificate and practising license as the incharge of the licensed premises; and
- (i) is run or operated by licensed medical laboratory technicians or medical laboratory technologists.

(2) A private medical laboratory licensed under these Regulations shall be open for inspection at any reasonable time by an authorized officer of the Board and any person who willfully obstructs such an officer acting in the course of his or her duty shall be guilty of an offence and shall be liable on conviction to the fine specified in section 25(3) of the Act.

Scope of licence of
private practice.

15. (1) A private practitioner shall not be licensed to operate more than one private medical laboratory.

(2) Despite subregulation (1), the Board may permit a private practitioner to operate a branch of the licensed private medical laboratory.

(3) Where a branch of a private medical laboratory is permitted under subregulation (2), a separate licence shall be issued and a separate fee paid in respect of each branch.

PART IV – CONDITIONS OF PRIVATE PRACTICE

Terms and conditions
of private practice.

16. (1) A medical laboratory technician or medical laboratory technologist issued with a practising certificate under the Act and these Regulations shall—

- (a) only engage in the practice for the class of the medical laboratory for which the practising certificate of the private practitioner has been issued;
- (b) employ qualified, registered and licensed medical laboratory technicians and medical laboratory technologists;
- (c) display the practising certificate and licence in a conspicuous place at the premises to which it relates;
- (d) at all times observe the standards of ethics set out in the Code of Ethics issued by the Board;
- (e) write and display his or her name and qualifications outside the private medical laboratory in an unostentatious manner and in accordance with the Code of Ethics issued by the Board;
- (f) keep in the private medical laboratory adequate stock of essential reagents and equipment;
- (g) use the medical laboratory reagents and equipment that are duly validated and verified scientifically by the Board using certified medical laboratories in their practice in accordance with their laboratory classification;
- (h) maintain an accurate record of all reagents and equipment;
- (i) immediately, through the relevant reporting channels, notify the Director-General for Health in his or her area of practice any notifiable disease which has been tested at the private medical laboratory;
- (j) ensure that all staff comply with standards on medical laboratory analysis and investigations;
- (k) ensure that all staff and the public are protected from any hazards; and
- (l) whilst on duty, at all times be dressed and groomed in a manner that portrays a respectable image to the public.

Operation of a private medical laboratory.

17. A person shall not operate a private medical laboratory unless —

- (a) the person is qualified in medical laboratory sciences and holds a valid practising certificate; or
- (b) employs a registered and licensed medical laboratory technician or medical laboratory technologist with a valid practising certificate

to undertake medical laboratory analysis and investigations in that private medical laboratory.

Duties of owners or operators of health institutions.

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

Requirements for private medical laboratories.

19. (1)A private medical laboratory shall—

- (a) conform to the terms, conditions and standards issued by the Board;
- (b) be approved by the Board before starting to function;
- (c) be at all times managed by a registered and licensed medical laboratory technician or technologist designated as the head of the private medical laboratory; and

- (d) keep an accurate record of all medical laboratory analysis and investigations undertaken by private medical laboratory.

Duties in operating a private medical laboratory.

20. A medical laboratory technician or medical laboratory technologist operating, managing or supervising a private medical laboratory—

- (a) shall provide diagnostic services to the community by meeting the needs of health institutions 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 for all members of the medical laboratory staff and other healthcare professionals;
- (d) may collaborate in the development, study and laboratory control of new methods of analysis and investigations whilst adhering to the laid down medical ethics;
- (e) may provide laboratory facilities for and advice on approved research projects undertaken by healthcare professionals; and
- (f) may undertake medical laboratory analysis and investigations as may from time to time be specified by the Board.

Display of practising certificate.

21. (1) A practising certificate shall be issued in respect of the premises named in the practising certificate and shall not be displayed in any other premises without the written permission of the Board.

(2) A private practitioner who fails to display the practising certificate in accordance with subregulation (1) commits professional malpractice and on conviction shall be liable to the penalty specified in section 20(3).

Notification of change of particulars.

22. A medical laboratory technician or medical laboratory technologist issued with a practising certificate under these Regulations shall notify and seek the approval of the Board for any proposed change —

- (a) of the name, contact address or other particulars filed with the Board at least thirty days before effecting such change; and
- (b) in ownership, control or proportion of shareholding of the firm or company at least thirty days before the change is effected.

Employment of a medical laboratory professional.

23. (1) A private practitioner may, subject to these Regulations, employ the services of a medical laboratory professional who has—

- (a) undergone an approved course of instruction for laboratory technicians or laboratory technologists at an approved training institution; and
- (b) been registered as a medical laboratory technician or medical laboratory technologist by the Board

to undertake defined duties under the immediate supervision of the private practitioner.

(2) Where any medical laboratory professional employed under subregulation (1) undertakes or offers to undertake any form of medical laboratory analysis and investigations independently without the immediate supervision of the private practitioner, that medical laboratory professional shall be guilty of an offence and shall be liable on conviction to the fine specified in section 20(3) of the Act.

(3) Where a private practitioner to whom a practising certificate has been issued employs a medical laboratory professional who does not have any medical laboratory sciences training, the private practitioner shall ensure that the medical laboratory professional does not undertake any form of medical laboratory analysis and investigations.

Fees.

24. (1) The owner or operator of a health institution managed by a medical laboratory technician or medical laboratory technologist to whom a practising certificate has been issued under these Regulations shall charge a fee for medical laboratory analysis and investigations in a private medical laboratory as determined by the Board by notice in the Gazette.

(2) A receipt shall be issued for any fee charged for any medical laboratory services rendered.

(3) The Board shall investigate and determine complaints relating to fees charged in private medical laboratories by medical laboratory technicians or medical laboratory technologists.

PART V – SAVINGS

Savings.

25. (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 was operating a licensed private medical laboratory shall continue to operate that licensed private medical laboratory.

(2) A medical laboratory technician or medical laboratory technologist referred to in sub regulation (1) shall make an application in Form KMLTTB/PP/01 set out in the Schedule within three months of the coming into force of these Regulations for a licence under regulation 5.

(3) Where the Board refuses a licence applied for under this regulation, the medical laboratory technician or medical laboratory technologist shall cease to operate the private medical laboratory from the date of the refusal.

Made on the, 2024.

DR. TITUS MUTWIRI,
*Chairperson of the Kenya Medical Laboratory
Technicians and Technologists Board.*

