



REPUBLIC OF KENYA
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

SOP on Registration and licensure of Medical Laboratory sciences professionals.

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

	Standard operating procedure (SOP) on registration and licensure of medical Laboratory sciences professionals.		DOCUMENT CONTROL Serial: KMLTTB/SOP/DC/01 Version 001 Date: 2 ND JANUARY ,2024
	OWNER OF THE FORM	REGISTRAR	

**STANDARD OPERATING PROCEDURE (SOP) ON REGISTRATION AND LICENSURE OF
MEDICAL LABORATORY PROFESSIONALS.**

SOP Number	Process Name:	Review Cycle	Author
KMLTTB approved registration of professionals-SOP-001	REGISTRATION OF PROFESSIONALS	ONCE	Quality Assurance Department
Responsible Audience	Effective Date	Approved By	
KMLTTB Staff, MLS Students, MLS practitioners and prospective registration applicants	2 ND , JANUARY, 2024	Registrar KMLTTB	

1. 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.

2. Purpose

The purpose of registration of professionals SOP is to establish a standardized process for registration and recording registration of professionals at KMLTTB. This ensures that applicants obtain registration certificate in accordance with the KMLTTB Guidelines/ Standard 2024, based on their time spent in educational activities, and that the calculation is accurate, consistent, and transparent.

3. Scope of Applicability

A. Definitions

“Act” means the Medical Laboratory Technicians and Technologists Act;

“Board” means the Board of Management established by section 3 of the Act;

“Committee” means the Medical Laboratory Technicians and Technologists Compliance Committee.

“Contact Hours” The total number of hours a professionals spends in direct contact with the medical laboratory sciences course material, including instruction time, class participation, and engagement with assessments or activities.

“Instructor-Led Training (ILT)” Training that is conducted by a lecturer or an instructor in a classroom or virtual setting, where applicants engage in live sessions.

“Self-Paced Learning” Learning where the learner progresses at their own pace without direct instruction, typically delivered via online modules.

“Blended Learning” A learning format that combines both instructor-led and self-paced learning components.

“Learning Event” A structured educational activity or program

B. This sop applies to all application of registration including: -

1. Online applications.
2. Professionals trained in Kenya.
3. Professional trained outside Kenya.
4. Certificate in medical laboratory sciences holders
5. Diploma in medical laboratory sciences holders
6. BSc in medical laboratory sciences holders
7. MSc in medical laboratory sciences holders.

8. PhD in medical laboratory sciences holders

The Standard operating procedure (SOP) on registration and licensure of medical Laboratory professionals governs how applications for registration are processed based on their academic and professional qualifications and KMLTTB standards requirements

4. Responsibilities

A). Responsibilities

Ensuring accurate registration certificate issuing and recording which is crucial for maintaining compliance with registration standards and providing applicants with appropriate recognition for their educational and professional achievements. The following outlines the key responsibilities for each role in the registration process.

l). registration officer:

The registration officer plays a central role in ensuring that are calculated in compliance with KMLTTB Guidelines/ standards2024 and accurately awarded to applicants.

(a). Ensures Compliance with KMLTTB Standards:

The Registration officer ensures that the registration process adheres to KMLTTB Guidelines/ standards 2024, which specify the requirements for academic and professional documentation before a certificate of registration is issued. The registration officer in liaison with the Quality Assurance Department will regularly review course content to verify that all filed certificates and academic transcripts meets the contact hours, and pass mark threshold as per KMLTTB standards/requirements, for registration eligibility.

(b). Monitors the Registration process:

The Registration officer in liaison with the Quality Assurance Department shall monitor the registration process to ensure that all applications are accurately recorded and meet the necessary criteria for issuing registration certificates. This includes ensuring that all required documentation by the applicants meet the standards for registration as defined by KMLTTB Guidelines.

(c). Coordinates registration Recording in the KMLTTB registers for technicians, technologists, officers and specialists.

The registration officer shall ensure that registered professionals are properly recorded in the KMLTTB registers for each professional whose application is successfully processed. The Registration officer shall oversee the process of updating professionals' records, ensuring that registration certificates are correctly issued.

(II). Head /Chair of departments of medical laboratory sciences training institutions:

Head /Chair of departments of approved medical laboratory sciences training institutions shall be responsible for overseeing the indexing of medical laboratory sciences students thirty (30) days after admission for a KMLTTB approved course. They shall also be responsible of ensuring that content and all instructional hours, materials are available in their respective approved training institutions in accordance with the prescribed standards.

They shall be responsible for ensuring academic and professional certificates and/or academic transcripts content are in compliance with KMLTTB standards:

They shall ensure that the course content is developed in accordance with KMLTTB Guidelines/ standards 2024 and that the core KMLTTB core curriculum is always adhered to at all times. This includes reviewing course materials, scheduling, and confirming that all instructional hours are appropriately documented.

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They shall verify the students indexing process for the MLS courses they manage, ensuring that all professional (including direct instruction, group activities, assessments, and other learning activities) are included in the training. They will work with lecturers and instructors to confirm that learning activities are accurately taking place and documented in line with KMLTTB guidelines/ standards.

They shall oversee the verification that the total instructional hours in the courses meet the required **professional standards** for awarding Registration certificate. They shall confirm that any additional activities, such as homework, self-directed study, or laboratory work, are correctly accounted for in the academic transcripts and professional certificate.

(III). Prescribed minimum training period for medical laboratory sciences in Kenya

The period for basic training in Medical Laboratory sciences:

1. Diploma: Three (3) academic years on full time basis and shall not be allowed to exceed seven (6) academic years.
2. Degree: Four (4) academic years on full time basis and shall not be allowed to exceed seven (7) academic years.
3. One (1) year compulsory probation in an approved Medical laboratory Science facility of class D and above for foreign trained persons who meet the local /Kenya equivalent training standards in accordance with section 15(b) of the Act.

The Board has already developed a Diploma in Medical laboratory Curriculum **KMLTTB/IMLS/01** and Bachelor of Science in medical laboratory sciences **KMLTTB/IMLS/02** available to approved training institutions at the prescribed fee.

4. While in training, the trainees shall attend a MINIMUM of sixteen (16) weeks of attachment and rotate in all core areas of the Medical Laboratory sciences practice and fill in an official Board approved logbook as proof for training during attachment

A report from the completed practical logbook shall be submitted to the Board during the application for examination, registration and licensing in form of practical rotation completion report duly signed by the attaching medical Laboratory and the approved training institution.

5. Applicants trained outside Kenya shall be required to **undergo a one-year** probation period covering all core areas of Medical laboratory sciences class D and above and have details recorded in a log book for the foreign trained.

A report extracted from logbook shall be accompany application for examination, registration and licensing.

(v). Medical laboratory sciences students:

Medical laboratory sciences students shall be responsible for engaging fully in the courses to meet the necessary professional qualifications for Registration certificate eligibility and academic transcripts once the course is completed successfully.

Medical laboratory sciences students are responsible for participating in all required learning activities and completing the course requirements to ensure they meet the necessary professional registration eligibility. Medical laboratory sciences students must ensure that they meet the minimum participation requirements to be eligible for registration.

This shall include attending live sessions, completing assignments, and actively participating in discussions or group activities.

On successful completion of the medical laboratory sciences course and meet the required contact hours, they shall be able to apply for the KMLTTB registration examination which is a prerequisite to apply for professional registration.

No applicant shall be registered before sitting for registration examinations as per KMLTTB guidelines.

(VI). Qualifications for Practice:

KMLTTB has prescribed standards to all medical laboratory professionals who practice as medical laboratory technicians, medical laboratory technologists, medical laboratory officers, medical laboratory directors, medical laboratory specialists and medical laboratory superintendents, to ensure the professional accountability, accuracy and reliability of test performance and results.

KMLTTB has developed core curricula for Diploma and Degree (BSc) levels of medical laboratory sciences education and training at colleges and universities. These curricula forms the bases for basic training for one to join medical laboratory sciences profession in Kenya.

Further, KMLTTB regulations sets out the minimum standards of training in terms of physical facilities (Medical Laboratory Sciences Demonstration Laboratories, medical Library and lecture rooms. This standards also include academic profile where the requirement are:-

(A). Diploma medical laboratory sciences training : An individual must have completed secondary school education and obtained, in **one (1)** sitting, a minimum of mean grade of C plain at KCSE and cluster subject that consist of;

English/Kiswahili- C plain

Mathematic /Physics- C plain,

Biology- C plain

Chemistry- C plain

(B). BSc medical laboratory sciences training: An individual must have completed secondary school education and obtained, in **one (1)** sitting, a minimum of mean grade of :-

C+ (plus) at KCSE and cluster subject that consist of

English/Kiswahili- C+ plus

Mathematics/Physics- C+ plus,

Biology- C+ plus

Chemistry- C+ plus.

The KMLTTB Regulations makes it mandatory for institutions to present admitted students/trainees in medical laboratory sciences to the Board within thirty (30) days post admission for scrutiny of their qualification and they are thereby indexed for future reference in training and practical areas allocations.

KMLTTB regulations requires that approved medical laboratory sciences training institutions be equipped with human resource capacity that is composed of registered and licensed medical laboratory sciences professionals who are specialised in the areas that they teach. These areas are mainly the core units of medical laboratories sciences as indicated as the basic discipline.

Persons not qualified, registered and licensed by KMLTTB as medical laboratory sciences specialists in any of the subjects in the approved thematic areas are not allowed to be engaged in teaching the core areas of the profession.

(VII). Application for registration as a medical laboratory sciences professional.

1. An application for registration as a medical laboratory Sciences professional (Medical laboratory technician, medical laboratory technologist, Medical laboratory officer or Medical laboratory sciences specialist) shall be submitted to the Registrar in FORM KMLTTB/APL/01 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, practical rotation completion report form, professional certificates and testimonials;
- (c). proof of passing the registration examination conducted by the Board under these Procedure s (Compliance certificate/ result slip);
- (d). a certificate of good conduct; and
- (e). Detailed curriculum vitae.

2. For an application by a person **trained outside Kenya** shall, in addition to the documents specified in sub procedure (1), be accompanied by—

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- (a). a certificate of good standing from the relevant authority responsible for registration in the country of origin (training);
 - (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 or applicable curriculum of the institution from where the qualification in medical laboratory sciences was obtained certified by that institution;
 - (e). Letters of equation of the secondary school and professional certificates issued by a relevant ministry of education authorities in Kenya such as KNEC, KNQA , TVETA and/or commission of university education.
 - (f). Letters of recognition of the foreign training institutions by a relevant ministry of education authorities in Kenya such as TVETA for Diploma holders and commission of university education for degree holders.
- (3) A person who has qualified outside Kenya shall and has satisfied the Board that he/she meets the for registration in Kenya in accordance with provisions of section 15 (1) (b) of the ACT shall be required to fulfil the provisions of section 15 (c) and (d) through proceeding to a 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 with a medical laboratory facility registered as KMLTTB Class **D** and above as part of the training/internship of the health institution or organization;
 - (b). Undergoes the requisite practical rotation 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 responsible for the students’ practical rotation /internship/probation officer and who shall be responsible for:—
 - (i). Assigning duties to the person under probation.

(ii). Determining the level of performance desired for the duties assigned.

(iii). 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.

3. Where an applicant fails to submit all documents or information required under these Procedures, the Board shall reject the application and inform the applicant, in writing, of the rejection and the reasons for the rejection within twenty-one days from the date of receipt of the application

4. Where the Board rejects an application due to incomplete or insufficient information, the rejection shall not bar the applicant from re-submitting the application.

5. The Board shall treat the re-submitted application as a new application.

6. The Board shall, if it is satisfied that the applicant has complied with the requirements under the Act and these Procedures 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.

7. The certificate of registration issued under these Procedures shall be in the prescribed form.

8. Where an applicant in procedure 1(one) does not comply with these Procedures, the Board may refuse to grant a certificate of registration to the applicant.

9. 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 the prescribed form within twenty-one days from the date of receipt of the application.

10. 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 inform 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.

11. Where the applicant informs the Board in writing under procedure (10) that he or she wishes to be heard, the Board shall not effect such refusal before it has given the applicant an opportunity to file extra documentation or explain why the application for registration should not be refused.

12. Where the Board, after complying with this procedure, refuses to issue a certificate of registration, it shall inform the applicant of its decision and the reasons for the decision within fourteen days.

13. Where the applicant fails to meet professional standards but meets minimum entry criteria, the Board may recommend such a person to take necessary measures to meet the required training in the approved medical laboratory sciences training institutions.

13. A person dissatisfied with decision of the Board under this procedure may lodge an appeal to the High Court within thirty days from the date of the decision.

5. Procedure for Registration of medical laboratory professionals Record-Keeping and Retention

A).Objective:

To ensure the accurate and secure retention of registration records for audit and compliance purposes, guaranteeing that all registration-related data is properly documented, stored, and accessible as needed.

i). Process for registration Record Maintenance

a). Records Retention :(Retention Period)

- i. Registration records, including copies of certificates and professionals participation in CPD activities data, shall be retained for infinite period to ensure compliance with KMLTTB Guidelines/standards and meet archival legal requirements.

- ii. The infinite retention period allows KMLTTB to maintain a comprehensive and accessible record of all professional registration and CPD data, providing a robust audit trail for internal and external reviews.

b). Types of Records Retained:

- I. CPD Certificates: Official documentation showing the number of CPD points filed by professionals.
- II. Professional Participation Data: Records detailing the professional involvement in approved medical laboratory courses, including attendance, adherence with licensure requirements and any other relevant professional participation metrics.
- III. Course Data: Information on the course, such as the course syllabus, instructor information, and contact hours, which supports the registration of professional process.

c).Secure Storage:

All professional records will be stored in a secure records management system, either within KMLTTB's registration Management System (RMS) or a secure digital file storage platform. This ensures the confidentiality, integrity, and availability of records over the retention period.

d). Access to Records:

I). Professionals Access:

- a) Medical labor Professionals may have the ability to view and download their registration records through the KMLTTB registration Portal. This allows professionals to easily access their professional progress over time.
- b) Professionals may be able to see a complete history of the CPD Points they've earned, along with the associated course details (e.g., course name, completion date, and CPDs awarded).

II).Administrative Access:

The Registry staff shall be responsible for ensuring that all professional records are properly maintained and accessible for auditing. This includes:

- a) Routine audits to verify the accuracy and completeness of the records.
- b) Ensuring compliance with KMLTTB Guidelines/ standards for record-keeping and retention.
- c) Accessing historical records when needed for accreditation reviews, regulatory audits, or internal assessments.

IV. Audit and Compliance:

- a) Professional records shall be made available for internal and external audits as required. The registry Coordinator shall ensure that all records are properly organized, accessible, and compliant with regulatory standards for audit purposes.
- b) Audit-Ready Records: The system shall be designed to allow quick access to all relevant professional data to facilitate smooth audits and demonstrate compliance with KMLTTB and other accrediting bodies.

6. .References

a) Relevant Authorities

- i. KMLTTB Guidelines/ Standards 2024 for Continuing Education and Training.
- ii. KMLTTB core curriculums for Diploma in Medical laboratory sciences.
- iii. KMLTTB core curriculums for BSc in Medical laboratory sciences

b). Relevant Laws

1. The Medical laboratory Technicians and Technologists Act, CAP 253A Laws of Kenya.
2. Persons with Disability Act (PWD), NO. OF 4 OF 2025
3. Ensures that all professionals including those with disabilities, can participate in professional experiences and receive registration certificates.
4. The Data protection act 2019.
5. Governs the privacy of educational records, ensuring that professionals' records are kept confidential and Ensures that personal data used in professional registration records is handled in compliance with National data protection laws.
6. The Access to information act, 2016
7. The Digital Health Act, 2023
8. The health act, NO. 21 of 2017.
9. The KMLTTB Quality Management Manual.

7. Review schedule and History

(i). This standard operating procedure shall be reviewed periodically and when

Need arises. There shall be a review every five years

(ii). Last Review Date: [Not yet due]

(iii). Revision History: [NONE]

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