




REPUBLIC OF KENYA
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

Standard operating procedure (SOP) on inspection of Medical Laboratory facilities
Business premises (public and private).

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

	SOP on inspection of Medical Laboratory facilities Business premises (public and private).		DOCUMENT CONTROL Serial: KMLTTB/SOP/LAB/01 Version 001 Date: 2 ND JANUARY ,2025
	OWNER OF THE FORM	REGISTRAR	

1. A person or entity seeking to establish a medical laboratory shall apply to the Board for registration in the Form KMLTTB/ LAB/ set out in the First Schedule.
2. An application under sub-regulation (1) shall be accompanied by the following—
 - (i). (a). a registration certificate in respect of a company or business name;
 - (b). a copy of the KRA pin;
 - (c). the list of medical equipment;
 - (d). prescribed fee;
 - (e). evidence of physical facilities, Validated medical laboratory equipment, reagents other chemicals and any other required resources;
 - (f). memorandum of understanding with a referral Medical laboratory recognized as such by KMLTTB.
 - (g). waste management certificate or contract for waste disposal.
 - (h). any other requirement as may be determined by the Board.
 - (ii). Requirements for the superintendent include
(KMLTTB valid superintendent License issued in accordance with the provisions of medical Laboratory regulations.
NB: SUPERINTENDENT LICENSE IS ISSUED FOR ONLY ONE MEDICAL LABORATORY PER PROFESSIONAL.
 - (a). current practice license.
 - (b). Evidence of five years of active practice post registration.
Updated curriculum vitae
 - (c) appointment and acceptance letters for those employed to superintend.
 - (d) Copies of National Identity card, KRA Tax compliance certificate and certificate of good conduct.
 - (e). certificate of good conduct from the Directorate of criminal investigations.
3. The Board shall review the application within seven days of receipt and notify the applicant of the status of the application.

4. Where the application under sub-regulation (1) meets the minimum requirements, the Board shall notify the applicant of the date for inspection of the proposed medical laboratory upon payment of the prescribed fee.
5. The Board shall cause the inspection of the medical laboratories for applicants who have paid the inspection fee.
6. Where the information submitted under sub-regulation (2) is incomplete, the Board shall notify the applicant to avail additional information within fourteen days.
7. Where an applicant, without good cause, fails to provide the additional information required by the Board under sub-regulation (6), within the fourteen days, the Board shall reject the application.
8. An applicant whose application has been rejected in accordance with sub-regulation (6), may reapply in accordance with sub-regulation (1).
9. There shall be Inspectors appointed by the Board after competitive recruitment process.
10. The Inspectors shall hold office on such terms and conditions as the Board shall determine from time to time.
11. The Inspectors shall conduct inspection of medical laboratories as the Board shall determine from time to time.
12. Medical laboratories shall be classified in accordance with the Checklist set out in the Schedule.
13. The Inspectors shall conduct the inspection and share with the medical laboratory a preliminary report with recommendations within thirty days.
14. The Inspectors shall submit a final report with recommendations to the Board, within seven days.
15. The recommendations referred to in sub-regulation (3) may either be for—
 - (a). the issuance of a medical laboratory registration certificate; or
 - (b). the rejection of the application.

16. Where the Board approves the recommendation of the Inspectors report, it shall issue the registration certificate within seven days of receipt of the Inspectors' final report.

17. Where the Board rejects the application in accordance with sub-regulation 15(b), it shall notify the medical laboratory of the rejection within seven days of receipt of the Inspectors' final report.

18. An applicant whose application has been rejected in accordance with sub-regulation (16b), may appeal to the Board within ninety days for review or re-inspection, as the case maybe, upon payment of the specified fees.

19. The Board may issue an immediate closure notice to a medical laboratory that has not complied with the provisions of the Act, any Regulations or standard set by the board.

20. A medical laboratory professional who operates a medical laboratory without the medical laboratory registration certificate and annual license shall be guilty of an offence and shall, on conviction, be liable to the penalties provided under section 18(2) of the Act.

21. All Medical laboratories shall engage a registered and licensed medical laboratory professional to be the Director/ superintendent/ manager, qualified to practice on their own in accordance with the provisions of mltt act, CAP 253A Laws of Kenya. He/She shall be the in charge of all professional operations of the medical Laboratory. The said medical Laboratory professional shall be responsible for all actions, omissions and commissions of professional undertakings of the medical laboratory and hence shall ensure only registered professional are engaged to practice, only Validated and verified reagents, equipment and chemicals are use in the Medical laboratory.

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