

*Extraordinary*



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S. I. No. 13 of 2018

**MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA  
ACT (CAP. M25 LFN) 2004**

**REGULATIONS FOR INSPECTION, APPROVAL, MONITORING  
AND CERTIFICATION OF MEDICAL LABORATORIES, 2018**

[8th Day of June, 2018]

Commence-  
ment.

In exercise of the powers conferred on the Governing Board by Sections 4,7 and 19 of the Medical Laboratory Science Council of Nigeria Act (Cap. M25 LFN 2004), the Board of the Council hereby makes the following Regulations—

1. The Medical Laboratory Science Council of Nigeria (hereinafter referred to as “the Council”), shall have power to inspect, monitor, evaluate and certify medical laboratories to ensure that standard and best practices in medical laboratory profession is adhered to, with a view to improving and strengthening the capacity of practitioners and quality of medical laboratory services rendered.

Powers to  
inspect,  
monitor,  
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medical  
laboratory.

2.—(1) The Council shall conduct periodic inspection and approval for registration of medical laboratory.

Inspection,  
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of medical  
laboratory.

(2) The Council shall carry out periodic monitoring of registered Medical Laboratory’s operations, to ensure continuity and sustainability of standard in the profession.

(3) The Inspection and Monitoring Team of the Council, shall consist of such number of practitioners as may be appointed by the Council.

(4) The Inspection Team shall carry out periodic inspection activities on Medical Laboratory.

(5) The Monitoring Team shall conduct regular monitoring and evaluation of Medical Laboratory.

(6) No Medical Laboratory, its staff, the owner (Practitioner or non-Practitioner) or person acting through or for, shall prevent, deter or refuse the Inspection and Monitoring Team of the Council from carrying out its duties under these Regulations.

(7) Where any Medical Laboratory or Practitioner or Owner of a laboratory permits, or authorises directly or indirectly any staff or person acting through or for, act contrary to the provision of Regulation (2) sub-regulation (6) of these Regulations, such Medical Laboratory or Practitioner or Owner shall be liable to have committed an offence under these Regulations.

(8) Where the Inspection Team on inspection discovers that a Medical Laboratory fails to meet up to 40% of the requirements listed on the checklist of the Council, such laboratory shall be closed down and sealed by the Inspection Team of the Council and the Laboratory shall be given up to 12 weeks within which to regularise its status.

(9) The Inspection Team upon conclusion of its inspection visit shall submit a report of its findings inclusive of recommendations to the Council.

(10) Where a Medical Laboratory that is sealed by the Council is ready to regularise its status, it shall forward an application to the Registrar of the Council requesting for temporary access to the Medical Laboratory to enable it carry out the recommendations of the Inspection Team.

(11) At the expiration of the time stated in regulation 2, sub-regulation (8) of these Regulations, the Monitoring Team shall be sent by the Council in the appropriate jurisdiction to ensure compliance with the recommendations made by the Inspection Team to the Medical Laboratory.

(12) Where the Monitoring Team conducts a visit on any Medical Laboratory facilities or receives information that such a Medical Laboratory is operated by a person who is not a member of the profession but holds himself out to the public as a member of the profession or is operated by a Medical Laboratory Scientist below professional standard set by the Council, the Monitoring Team shall upon confirmation of such practices, close down and seal the Medical Laboratory facilities.

(13) Any of the Council's Zonal Office or State Office, may be authorised by the Council to conduct routine monitoring visits before and after inspection visits on any Medical Laboratory facilities within their jurisdiction.

(14) Any hospital that desires to set up a medical laboratory or any side laboratory for point of care testing (POCT), shall observe Council's guidelines as may be in force.

Procedure for achieving the 5-star tiered national certification.

3.—(1) Every medical laboratory that applies for certification shall be subjected to a baseline assessment.

(2) The National Certification checklist shall be used for the baseline assessment.

(3) Where a Medical Laboratory's performance is less than the passing score required of any of the applicable criteria, the laboratory shall be subjected to mentoring by the Council's Continual Quality Improvement Unit to—

- (a) identify areas where improvement is required ;
- (b) develop and implement a work plan ;
- (c) monitor the progress of such medical laboratory ;
- (d) provide for inter-laboratory collaboration testing and re-testing, where Clinical Laboratory Standards Institute is unavailable ; and

(e) take necessary step that may be required to achieve full certification.

(4) Any Medical Laboratory that has regularised its status after being mentored by the Council, may re- apply to the Council for inspection and certification.

(5) The number of stars that may be awarded to a Medical Laboratory facility from the laboratory audit checklist in the 5 star tiered certification approach, shall be as follows—

No STAR (0-142pts) <55%	1 STAR (143-165pts) 55-64%	2 STAR (166-191pts) 65-74%	3 STAR (192-217pts) 75-84%	4 STAR (218-243pts) 85-94%	5 STAR (244-258pts) >95%
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(6) Any medical laboratory that achieved 5 star tiered status, may proceed to apply for National Certification, if it so desires.

(7) Where a Laboratory scores below 5-star status, it shall be certified with the appropriate status commensurate to its scores.

(8) Any Laboratory that scores below 5-star status, shall be placed on the mentorship programme of the Council for not less than 6 months after which it shall invite the Council to conduct another round of assessment and where the medical laboratory did not still pass the assessment test, this mentorship process shall continue until such laboratory remedied the deficiencies to attaining 5- tiered star status.

4.—(1) The Council shall conduct continuing quality improvement/ mentorship programme for Medical Laboratory practitioners.

Continuing quality improvement/ mentorship programme.

(2) The Continuing quality improvement programme is mandatory for a registered Medical Laboratory that do not wish to be certified, but wish to enroll for the purpose of improving the quality of services offered to the public.

5.—(1) The Council shall formulate baseline assessment requirements.

Criteria for continuing quality improvement/ mentorship programme.

(2) The Medical Laboratory shall undergo corrective action, based on observed non-conformity with conduct competency improvement training for personnel.

(3) The Medical Laboratory shall obtain appropriate application form and comply with relevant checklists requirements set by the Council.

(4) Such Medical Laboratory shall pay required fees as may be set by the Council.

6.—(1) Certification shall be conducted in conformity with the National Standard for certification of Medical Laboratory.

Certification standard.

(2) The National Certification Checklist will be based on International Organisation for Standardisation ISO 15189:E) and to a lesser extent, Clinical Laboratory Standards Institute guidelines GP26 – A3.

