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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

[8*th Day of June*, 2018]

Commencement.

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—

Powers to inspect, monitor, evaluate and certify medical laboratory.

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.

Inspection, approval and monitoring of medical laboratory.

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

(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.

Continuing quality improvement/ mentorship programme.

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

(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.

Criteria for continuing quality improvement/ mentorship programme.

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

(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.

Certification standard.

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

(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.

Criteria for certification.

7. Any Medical Laboratory that is desirous of certification shall fulfill the following requirements—

(*a*) personnel involved in the processing of samples for diagnostic purposes shall be a qualified Medical Laboratory Scientist with requisite qualifications registerable by the Council ;

(*b*) the Medical Laboratory shall have reasonable ratio of support staff to assist in the laboratory ;

(*c*) all components of the Quality Assurance must be up-to-date and operational ;

(*d*) the Medical Laboratory is registered and participates regularly in External Quality Assurance Program within the last 6 months ;

(*e*) documentation, Standard Operating Procedures, manuals, policies, guidelines, records and others, which shall be in place within the Medical Laboratory facility ;

(*f*) the Medical Laboratory facility shall have its safety policy for staff, environment, sample collection and waste management in place ;

(*g*) the Medical Laboratory shall provide documentary evidence of having complied with the requirements set by the Council for inspection and certification ;

(*h*) have obtained and processed appropriate application form upon payment of any fee prescribed by the Council ;

(*i*) pay the prescribed laboratory assessment fee as prescribed by the Council ;

(*j*) provide evidence of payment of the annual retention fee prescribed by the Council ;

(*k*) shall ensure that all medical laboratory professional staffs have paid and obtain their current Licence and identification tag to practice ;

(*l*) the Medical Laboratory specimen meets not less than 80% of turnaround time (TAT) required ;

(*m*) internal quality control is observed and practiced on all testing methods used in the laboratory ;

(*n*) the Medical Laboratory scored not less than 80% or more on the most two recent proficiency testing carried out by the Council ;

(*o*) the Medical Laboratory have a well-defined operational organogram ;

(*p*) all basic and assay specific Laboratory equipment are appropriately and satisfactorily housed in the facility ;

(*q*) all equipment are appropriately calibrated and standardised for the performance of appropriate Laboratory investigation that it was installed to carry out ; and

(*r*) schedule of equipment preventive maintenance must be in place and maintained as at and when due and properly documented.

Human resources requirement for approval, monitoring and certification of Medical Laboratory.

8. The technical know-how and expertise needed in terms of human resources to provide effective laboratory service delivery in the health sector shall be as follows—

(*a*) at each level of healthcare, every laboratory shall be staffed with adequate number of trained personnel that is competent to deliver quality laboratory services ;

(*b*) in-depth practical instruction in approved Medical Laboratory institutions or establishments, which shall be an integral part of training for all cadres of medical laboratory staff ;

(*c*) all medical laboratory staff shall be certified by the Council ;

(*d*) the Council shall maintain the database of all categories of certified laboratory staff ;

(*e*) the capacity of the human resources of every laboratory shall be standardised by aligning the numbers of trained laboratory personnel with clinicians and other health staff to ensure comprehensive, quality health service delivery ; and

(*e*) motivation of laboratory staffs, support for continuing professional education and create conducive environment in the work place to encourage staffs.

Application for certification of practitioners.

9. Any Medical Laboratory Scientist that is desirous of certification shall apply to the Council by forwarding a completed application form and payment of a fee as prescribed by the Council.

Certification of a Medical Laboratory.

10.—(1) The Council shall certify a medical laboratory facility after it has duly completed an application form and payment of a prescribed fees by the applicant.

(2) Any Medical Laboratory registered by the Council may, if it so desires, apply to the Council for certification.

(3) Having successfully completed the certification process, the Medical Laboratory may be awarded Council's certification and become part of an exclusive group of laboratories that have met the required standard of excellence.

Life span of certification.

11. The life time of any certification after partnering with Council for quarterly improvement is two (2) years, taking effect from the date of approval by the Independent Advisory Committee of the Council.

Penalty.

12.—(1) Where a Medical Laboratory or a practitioner or person acting through or for him contravenes any provisions of these Regulations or deliberately breaks the seal of the Council placed on a Laboratory for the purpose of commencing routine business without satisfying the recommendations of the Monitoring Team, shall be guilty of an offence and liable on conviction to a fine of ₦200,000.00 or 1 year imprisonment or to both.

(2) Where the person who commits the offence under sub-regulation (1) of this regulation is a Medical Laboratory Scientist, the Council may withdraw his license for a period of 6 months or pending such time the offender meets with the recommendations of the Council.

Interpretation.

13. In these Regulations unless the context otherwise so admits—

"*the Council*" means Medical Laboratory Science Council of Nigeria or the Governing Board of the Medical Laboratory Science Council of Nigeria ;

"*the Act*" refers to Medical Laboratory Science Council of Nigeria Act (Cap. M25 LFN) 2004 ;

"*Practitioner*" means Medical Laboratory Scientist; Medical Laboratory Technician, Medical Laboratory Assistant ;

"*CQI*" means Continuing Quality Improvement ;

"*SOP*" means Standard Operating Procedure ;

"*WHO-AFRO*" means World Health Organization African Regional Office ;

"*ISO*" means International Standardisation for Organization ;

"*POCT*" means Point of Care Testing ;

"*TAT*" means Turn Around Time ;

"*CLSI*" means Clinical Laboratory Standards Institute.

Citation.

14. These Regulations shall be cited as Medical Laboratories Inspection, Approval, Monitoring and Certification Regulations, 2018.

MADE at Abuja this 8th day of June, 2018.

ERHABOR, TOSAN
Registrar/Chief Executive Officer
Medical laboratory Science Council of Nigeria

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ARRANGEMENT OF REGULATIONS

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