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MEDICAL LABORATORIES REGULATIONS FOR INSPECTION, APPROVAL, MONITORING AND ACCREDITATION



ARRANGEMENT OF REGULATIONS

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S. I. No. 12 of 2015

MEDICAL LABORATORIES REGULATIONS FOR INSPECTION,
APPROVAL, MONITORING AND ACCREDITATION

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, No. 11, 2003, the Board hereby makes the following regulations.

[20th March, 2015]

Commence-
ment.

1. The Council shall have power to inspect, monitor, evaluate and accredit Medical Laboratories to ensure the maintenance of good standard of Medical Laboratory practice, international best practices, improving and strengthening the capacity and quality of services of the Medical Laboratories.

Powers to
Inspect,
Monitor,
Evaluate
and
Accredit.

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

Inspection,
Approval
and
Monitoring
of Medical
Laboratories.

(2) The Council shall also conduct periodic monitoring of registered Medical Laboratories' operations to ensure continuity in standard.

(3) There is hereby established for the council :

(a) An Inspection Team ;

(b) A monitoring team both of which shall consist of such number of persons as the Council may deem fit to appoint.

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

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

(6) No Medical Laboratory, its staff, the owner/proprietor (Practitioner or non-Practitioner) or person(s) acting through or for him shall prevent, deter or refuse the inspection and Monitoring Team of the Council from carrying out its exercise.

(7) Where any Medical Laboratory or the Practitioner/Owner permits, allows or authorizes directly or indirectly any staff or person(s) acting through or for him to act contrary to the provision in sub-section 6 above, such a Medical Laboratory or Practitioner/owner shall be held to have committed an offence under these Regulations

(8) Where an Inspection Team conducts an inspection of a Medical Laboratory and such Medical Laboratory fails to meet up to 40% (Forty *per cent*) of the requirements listed on the check list, it shall be closed and sealed by Council and the Medical Laboratory given at most 6 months period to regularise its status.

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

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

(11) Upon the expiration of the time stated in sub section (8) above, a 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 a Medical Laboratory or receives information that such a Medical Laboratory is operated by a person who is not a member of the profession but who holds himself out to the public as a member of the profession and/or is operated by a Medical Laboratory Scientist below Professional standard or against best practices, the Monitoring Team shall upon confirmation, close and seal the Medical Laboratory.

(13) The Council's Zonal Offices and State Offices shall conduct routine Monitoring visit before and after inspection visit on Medical Laboratories within their jurisdiction.

(14) Any Hospital that desires to set up a Medical Laboratory or a 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/
Accredita-
tion
Approach.

3.—(1) Every Medical Laboratory that applies for certification or accreditation shall be subjected to a baseline assessment of laboratory operating procedure and practices.

(2) The national accreditation check list shall be used for the base line assessment.

(3) Where a Medical Laboratory's performance is abysmal, or achieves less than the passing score on any one of the applicable criteria, it will be subject to mentoring by Council's Continual Quality Improvement to—

(a) Identify areas where improvement is needed ;

(b) Develop and implement a work plan ;

(c) Monitor Medical Laboratory progress ;

(d) Provide for inter-laboratory comparison and/or re-testing where CLSI is unavailable ;

(e) Continue steps to achieve full accreditation.

(4) A Medical Laboratory that has regularized its status after mentoring can apply to the Council for accreditation.

(5) The number of stars awarded to a Medical Laboratory from the laboratory audit check list in the 5 star tiered certification approach will be in the following manner—

No Stars	1Star	2Stars	3Stars	4Stars	5Stars
(0-142pts)	(143-165pts)	(166-191pts)	(192-217pts)	(218-243pts)	(244-258pts)
<55%	55-64%	65-74%	75-84%	85-94%	>95%

(6) A Medical Laboratory that has achieved the 5star status, can proceed to apply for national accreditation if it so desires.

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

(8) A Laboratory that scores below 5-star status shall be placed in a mentorship programme by Council for at least 6(six) months after which it shall invite Council to conduct another assessment. This mentorship process should continue until such Laboratory remedies the deficiencies to attaining the 5-star status and qualifies for accreditation.

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

Continuing
Quality
Improvement/
Mentorship
programme.

(2) The CQI is mandatory for accreditation. Registered Medical Laboratories that do not wish to be accredited should enroll for the purpose of improving the quality of services offered to the public.

5.—(1) There will be a base line assessment.

Criteria For
Continuing
Quality
Improvement/
Mentorship
programme.

(2) The Medical Laboratory will undergo corrective action based on observed non-conformances and conduct competency improvement trainings for personnel.

(3) The Medical Laboratory is to obtain appropriate application forms and relevant checklists.

(4) The appropriate fees as prescribed by Council will be paid by the consigned laboratory.

6.—(1) The Accreditation shall be conducted in conformity with the National Standard for accreditation of Medical Laboratories.

Standard
For
accreditation.

(2) The National Accreditation Check list will be based on International Organization for Standardization ISO . 15189 : 2012 (E) and to a lesser extent, CLSI guidelines GP26-A3.

Criteria for accreditation.

7.—(1) Any Medical Laboratory that is desirous of accreditation is expected to fulfill the following requirements :—

- (a) The Head/Director of the Medical Laboratory and all staff/personnel in the Medical Laboratory involved in the processing of samples for diagnostic purposes must be appropriately qualified Medical Laboratory personnel with qualifications registerable with the Council ;
- (b) The Medical Laboratory shall have appropriate ratio of support staff to Medical Laboratory Scientist ;
- (c) All components of the Quality Assurance must be current and operational ;
- (d) The Laboratory must be registered and participate in an External Quality Assurance Program within the last 6 months ;
- (e) Documentation (SOPs, Manuals, policies, guidelines, Records etc) of the Medical Laboratory facility must be in place ;
- (f) The Medical Laboratory must have its safety policies (staff, environment, sample collection, waste management etc) in place ;
- (g) The Medical Laboratory must provide documentary evidence of fulfillment of the above guideline prior to inspection and accreditation ;
- (h) Obtain appropriate application forms upon the payment of a fee ;
- (i) Pay the Prescribed Laboratory Assessment fee as may be fixed by Council ;
- (j) Provide proof of annual retention fee as may be fixed by Council ;
- (k) The Medical Laboratory personnel shall have their current license/ identification tag to practice ;
- (l) The Medical Laboratory should have obtained the 5-star tiered national certification in its previous site assessment ;
- (m) The Medical Laboratory specimen should meet at least 80% of turn around time (TAT) ;
- (n) Internal quality control should be practiced for all testing methods used in the laboratory ;
- (o) The medical laboratory must score 80% or more on the most two recent proficiency testing ;
- (p) The Medical Laboratory must have a well-defined operational organogram ;
- (q) All basic and assay specific Laboratory equipment must be appropriately and satisfactorily housed in the facility ;

(r) All equipment must be appropriately calibrated and standardized for the performance of appropriate laboratory investigation that it was installed to carry out ;

(s) Schedule of equipment preventive maintenance must be in place and maintained as at when due and must be documented.

8. The human resource competencies, technical knowledge and expertise needed for effective Laboratory service delivery in the health sector is specified as follows :

Human
Resources
Requirement
for
Approval,
Monitoring
and
Accreditation
of Medical
Laboratory.

(1) At each level of health care, the laboratory shall be staffed by adequate number of properly trained personnel to deliver adequate and quality Laboratory Services—

(2) In depth practical instruction in approved medical laboratory institutions or establishments shall be an integral part of training of all cadres of medical laboratory staff.

(3) All medical laboratory staff shall be certified by the Medical Laboratory Science Council of Nigeria.

(4) The Medical Laboratory Science Council of Nigeria shall maintain a database of all categories of certified laboratory staff.

(5) The laboratory human resources capacity needs to be standardized by aligning the numbers of trained laboratory personnel with clinicians and other health staff to ensure comprehensive, quality health service delivery.

(6) Continuing professional education with support in the work place (competence based task oriented) is required to retain the competence and motivation of laboratory staff personal development.

9. Any Medical Laboratory that is desirous of accreditation shall apply to the Council by forwarding a completed application form upon the payment of a fee as may be prescribed by Council..

Application
for
accreditation.

10.—(1) Council accreditation is a validation process established to ensure medical laboratories deliver high quality services that meets the needs and requirements of their clients. It demonstrates competence, impartiality, and performance capability, national and international recognition.

Accreditation
of Medical
Laboratories.

(2) Any Medical Laboratory that is registered with the Council may, if it so desires, apply to the Council for its accreditation.

3) Upon successful completion of the inspection, monitoring and certification process, the Medical laboratory is awarded Council's accreditation and becomes part of an exclusive group of laboratories nationally that have met the highest standards of excellence.

Life span for accreditation.

11. The life time of accreditation after partnering with Council for quarterly improvement is three (3) years from date of approval by the Independent Advisory Committee of Council.

Penalty.

12.—(1) Where a Medical Laboratory or a practitioner or person(s) acting through or for him contravenes any provisions of these regulations ; deliberately breaks the seal of Council placed on a sealed Medical Laboratory for purposes of commencing routine business without fulfilling the recommendations of the Monitoring Team, he is guilty of an offence and is liable on conviction to a fine of Two Hundred Thousand Naira (₦200,000.00) only or one year imprisonment or both.

(2) In addition, if the Person who commits the offence in subsection (1) is a Medical Laboratory Scientist, the Council may withdraw his license for a period of six (6) months or pending such time that the offender meets with the recommendations of the Monitoring Team and satisfies requirement by Council.

Interpretation.

13. For the purpose of these Regulations, unless the context otherwise requires—

“*Council*”—Medical Laboratory Science Council of Nigeria or the Governing Board of the Medical Laboratory Science Council of Nigeria ;

“*Practitioner*”—Registered Medical Laboratory Scientist ; Medical Laboratory Technician ; Medical Laboratory Assistant.

“*CQI*”—Continuing Quality Improvement ;

“*SOP*” - Standard Operating Procedure ;

“*WHO-AFRO*” - World Health Organization African Regional Office.

“*ISO*” - International Standardization for Organization ;

“*POCT*” - Point of Care Testing ;

“*TAT*” - Turn Around Time ;

“*CLSP*” - Clinical Laboratory Standards Institute.

Citation.

14. These Regulations may be cited as Medical Laboratories (Inspection, Approval, Monitoring and Accreditation) Regulations.