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MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA
ACT (CAP. M25 LFN) 2004
REGULATIONS FOR MINIMUM PRACTICE STANDARDS, 2018



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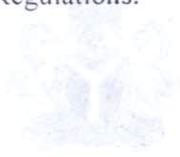
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S. I. No. 14 of 2018

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

REGULATIONS FOR MINIMUM PRACTICE STANDARDS, 2018

[8th Day of June, 2018]

Commence-
ment.

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

PART I—MEDICAL LABORATORY SCIENCE PRACTICE

1. Realising that medical laboratory services is fundamental to healthcare delivery, provision and management in Nigeria, the practitioners needs to inculcate standards and ethical practices in disease diagnosis, forecasting and management of patient's ailments as well as public health surveillance, thus these Regulations for Minimum Practice Standards defines best practice and standards required of a practitioner. Aim.

2. The objectives of these Regulations are to—

Objectives.

(a) provide legal and regulatory framework for minimum practice guideline for medical laboratory practitioners in Nigeria and to give effect to the provisions of the Act ;

(b) ensure compliance by medical laboratory practitioners with these Regulations with a view to sustaining best ethical practices capable of promoting quality health services ;

(c) regulate and ensure that all practitioners carry out their professional duties in a manner to earn the trust of patients and promote the image of the Council ;

(d) sensitise the public on what they need to know and expect from practitioners on medical laboratory practice ;

(e) prescribe penalties for medical laboratory practitioners for non-compliance with these Regulations ; and

(f) be used by the Disciplinary Organs of the Council to determine what constitute professional misconduct.

3.—(1) A practitioner to the exclusion of a Medical Laboratory Technician and Assistant, upon induction shall be given a provisional registration to undergo internship for a period of one year under the supervision of a Consultant or Specialist or Senior Medical Laboratory Scientist in a Medical Laboratory approved by the Council for internship training. Provisional
Registration.

(2) Provisional registration referred to under sub-regulation (1) of regulation 3 shall lapse as soon as the practitioner presents his original logbook duly endorsed by the Consultant, Specialist or Senior Medical Laboratory Scientist under whose supervision the internship training was carried out.

(3) Every Intern under training shall not run and operate an independent Medical Laboratory while his internship subsists.

Interns.

4.—(1) Every Medical Laboratory practitioner, with the exception of the Medical Laboratory Technician and Medical Laboratory Assistant shall partake in the mandatory internship.

(2) Any practitioner who after completing his internship training successfully and satisfactorily, shall submit to the Council his original logbook and such Practitioner shall be given full registration and issue a Licence by the Council before proceeding on the mandatory National Youth Service Corps or presented with NYSC Exemption Certificate.

(3) Every Medical Laboratory Technician and Medical Laboratory Assistant who completes his laboratory posting, training, sits and pass the Council's professional examinations, shall be issued a Technician Registration Certificate or a Medical Laboratory Assistant Registration Certificate.

(4) At the commencement of the internship programme, all training institutions, shall forward the list of prospective interns to the Council for verification and confirmation not later than thirty days from the date of commencement of training.

(5) Internship programme or training shall only be carried out in the Council's accredited public and private institutions.

(6) Any Medical Laboratory practitioner that is eligible for internship shall within two months of securing a placement, forward his appointment letter through the supervising institution of the interns with a copy of his Provisional Licence to the Council for proper documentation and updating the database of practitioners.

(7) Every accredited training institutions shall keep record of attendance of interns and produced same on demand.

(8) The Council or any of its authorised agent shall carryout regular visits to training institutions and any information obtained on such visits shall constitute basis for verification of logbooks submitted for clearance prior to licensing of interns.

(9) Internship Logbook shall be issued at the commencement of every internship training and any subsequent request by a practitioner on the ground of loss shall be accompanied with—

(a) a letter endorsed by the most Senior Medical Laboratory Scientist designated to sign off Interns ;

(b) an endorsement by the Chief Executive Officer of the Institution ;

(c) a sworn affidavit ; and

(d) a police report.

(10) Photocopy of logbook is not accepted by the Council.

(11) Every intern shall in the course of their training, present not less than two seminar papers and an endorsed power point presentation along with the logbook at the institution he was assigned to.

(12) Every intern shall upon completion of his training, be issued with a letter of completion and duly signed by any authorised officer of the institution where the training was carried out.

(13) Any practitioner who engages in internship training more than once after satisfactory completion of the one year mandatory internship training shall be guilty of professional misconduct.

(14) Every practitioner shall complete his internship programme within two years after graduation and failure to do so, unless satisfactory reason is given to the Council, may be subjected to an assessment examination of the Council.

(15) Notwithstanding the provisions of sub-regulation (14) of regulation 4 of these Regulations, any practitioner who fails to complete his internship programme as stipulated by the Council or scores less than 60 per cent of the total evaluation assessment score, shall repeat the internship programme and shall not be signed off until a satisfactory evaluation is obtained.

(16) Any practitioner who studied abroad shall before being registered and allowed to practice in Nigeria, shall—

(a) sit and pass the Council's professional examinations ;

(b) undertake Medical Laboratory posting to any of the Council's approved Medical Laboratory under the supervision of a qualified and licenced Medical Laboratory Scientist for not less than a period of six months ; and

(c) undergo the one year mandatory internship programme.

(17) Any interns undergoing training shall not be allowed to participate in strike or withdrawal of services, except such practitioner is directed by the Council to join in the strike.

5. A practitioner shall upon satisfactory completion of his internship programme be conferred with full registration and a legal right to practice in Nigeria.

Full
Registration.

Registration
as a
Specialist.

6.—(1) Any Practitioner who has acquired the title of a specialist or additional qualification after undergoing requisite training or any other training deemed to be recognised by the Council can practice and be recognised as a specialist.

(2) Any practitioner who refuses to register with the Council as a specialist cannot validly sign off interns and back up his opinion as a specialist.

Foreign
Practitioners.

7.—(1) Practitioners who graduated from foreign colleges outside Nigeria shall be required to sit and pass an Assessment (Proficiency) Examination of the Council.

(2) Any practitioner that passed the proficiency examination set by the Council in accordance with regulations 7 of these Regulations, such practitioner shall be accorded full registration and be allowed to practice in Nigeria, subject to section 17 of the Act.

Annual
Practicing
Certificate.

8.—(1) Not later than 30th of October of every year, the Council shall publish the—

(a) list of practitioners who have complied with the requirements of the Continuing Professional Development Programme of the Council ;

(b) names of practitioners who have paid their practicing fees up-to-date ;

(c) list of accredited laboratories or laboratories undergoing accreditation that are entitled to practice for the year (hereinafter referred to as the "Annual Practicing List").

(2) Issue a practicing Certificate to practitioners whose names are on the Annual Practicing List, certifying that they have paid their practicing fee for the specified year and fulfilled the requirement of the Council.

(3) Unless a practitioner holds an Annual Practicing Certificate issued by the Council under these Regulations, such practitioner shall not—

(a) conduct tests, collect samples or take part in the preparation of any reagents, media ; and

(b) sign documents, vet or validate laboratory results or reports.

Annual
Renewal and
Retention
Certificate.

9. The Council shall ensure that every practitioner—

(a) register and renew its Laboratory status every year through payment of an annual renewal or retention fee prescribed by the Council ;

(b) obtains Certificate of Registration renewal issued upon the renewal ; and

(c) displays Certificate of Registration in a conspicuous location within the Laboratory.

10.—(1) All premises used for the practice of Medical Laboratory Science shall be fully approved by the Council.

Approval of
a Medical
Laboratory.

(2) The Council shall ensure that Medical Laboratory observes the following—

(a) be headed by a qualified Medical Laboratory Scientist, whether it is government owned, faith based or private laboratory ;

(b) display evidence of registration with the Corporate Affairs Commission or in the case of public or tertiary institutions, the law establishing it ;

(c) display in a conspicuous area in the business premises, a copy of the current licence to practice ;

(d) display conspicuously in front of the facilities the Council's seal and a Perspex sign embossed with the Council's logo ; and

(e) such other terms and conditions, the Council may deem fit to make.

11. The Council shall ensure that every practitioner displays its Perspex or Neon sign conspicuously on the walls of its official premises where the laboratory is located.

Perspex or
Neon sign.

12.—(1) Where the Proprietor or Practitioner intends to register the Laboratory as a company limited by shares, he shall furnish to the Corporate Affairs Commission in addition to incorporation forms, the following documents—

Requirements
for
Registration.

(a) where the Laboratory is owned by a non-practitioner, there shall be a Partnership Agreement between the Proprietor and the Practitioner endorsed by the Council ;

(b) the current practicing Licence of the practitioner ; and

(c) inclusion of at least a Medical Laboratory Scientist in the composition of the Board of Directors.

(2) Where the Laboratory is registered with a Business name, it shall furnish to the Corporate Affairs Commission in addition to the requisite forms, the following documents—

(a) where the Laboratory is owned by a Non-Medical Laboratory Scientist, the Partnership Agreement between the Proprietor and the Medical Laboratory Scientist shall be endorsed by the Council ;

(b) the current practicing Licence of the Medical Laboratory Scientist in charge ; and

(c) the Medical Laboratory Scientist shall be registered as a part-owner of the Medical Laboratory Enterprise.

Inspection,
approval and
monitoring
of medical
laboratories.

13.—(1) Every Laboratory and Practitioners shall adhere to these Regulations and any other Regulations made by the Council on periodic inspection, approval, registration and monitoring of Laboratory operations to ensure continuity in standard.

(2) No practitioner shall prevent, avoid or subvert the entry into any Laboratory for Inspection/Monitoring Team of the Council, for purposes of carrying out its statutory periodic inspection, regular monitoring and evaluation.

(3) Any Practitioner or Staff of the practitioner or person acting on behalf of the practitioner, who acts contrary to the provision of sub-regulation (2) of this regulation, shall be guilty of professional misconduct.

(4) Any Laboratory that fails to adhere strictly to the provisions of regulation 13, sub-regulation (1) of these Regulations shall be—

(a) sealed off by the Inspection Team ; and

(b) issued a warning letter mandating the laboratory to regularise its status within 14 days from the date of receipt of the letter.

(5) The Laboratory in default shall only be unsealed, where it has fulfilled the conditions set out by the Inspection Team.

Joint
ownership
of a Medical
Laboratory.

14.—(1) Where a Laboratory is jointly owned by a Practitioner and a Non-Practitioner, a licenced practitioner, to the exclusion of a Medical Laboratory Technician Assistant, shall head the laboratory and shall be so stated in the Partnership Agreement.

(2) The Partnership Agreement shall be presented to the Council.

(3) Where the Partners terminate the Agreement between them, the Council shall be duly notified.

(4) Practitioners of less than 5 years post induction experience shall not set up its own private Laboratory but will undergo pupillage under a Senior Medical Laboratory Scientist before establishing his own.

Management
of Medical
Laboratory.

15. The most senior practitioner to the exclusion of a Medical Laboratory Technician and Assistant in a Medical Laboratory, either in private or public health institutions, shall be made the head of the Laboratory, notwithstanding whether there is an existing administrator, where the Laboratory is owned by a non-practitioner.

Certification
of Medical
Laboratory.

16.—(1) Every Practitioner shall register its laboratory and actively participate in quality improvement programme for certification by the Council.

(2) Any practitioner seeking certification of its laboratory with the Council shall observe the following—

(a) pay all the prescribed fees of the Council ;

(b) the Head and other staff of every Laboratory involved in the processing of samples for diagnostic purposes shall be a qualified Medical Laboratory scientist registered with the Council and possess current Licence or Annual Registration Letter to practice ;

(c) the Laboratory shall have appropriate ratio of support staff to assist in the laboratory ;

(d) every component of Quality Assurance shall be current and operational ;

(e) participate regularly in External Quality Assurance Program ;

(f) comply with Laboratory Standard Procedures and manual's facilities ;

(g) comply with Laboratory's safety policies as it relates to staff, environment, sample collection, which shall be in place ;

(h) provide proof of payment of annual retention fee as prescribed by the Council ;

(i) develop a well-defined operational organogram for the laboratory ;

(k) all basic and assay specific Laboratory equipment shall be appropriately and satisfactorily housed in the facility ;

(l) equipment shall be appropriately calibrated and standardised for the performance of appropriate Laboratory investigation it was designed to carry out ; and

(m) develop schedule of equipment preventive maintenance and carry out Certification of Medical Laboratory maintenance as at when due with requisite documentation.

17.—(1) Where a Laboratory is sealed up upon periodic statutory inspection by the Council for failure to meet the minimum requirements for operation as a Medical Laboratory, such Medical Laboratory shall remain sealed pending the time the owner shall be able to meet all requirements set out by the Council.

Breaking
of the
Council's
Seal.

(2) Any Medical Laboratory so sealed by the Council shall not be reopened by any person or the owner, whether a non-practitioner or a practitioner, unless a written authority is obtained from the Council, authorising him to open the Laboratory.

(3) Any practitioner or non-practitioner who breaks the seal of the Council without obtaining the authorisation of the Council shall be guilty of professional misconduct and liable on conviction.

PART II—MALPRACTICE

18.—(1) The practice of Medical Laboratory Science shall be carried out in accordance with standards, decorum and methods, adjudged by the Council to be appropriate and acceptable by the generality of the practitioners.

Malpractice
in a general
respect.

(2) Notwithstanding Regulation 18, sub-regulation (1) of these Regulations, acceptable standards, decorum and methods shall be in accordance with the knowledge, skill and practice imparted by recognised institutions that have been accredited by the Council.

(3) Where a registered practitioner's conduct in his area of professional practice is queried and such petition is brought to the attention of the Investigating Panel of the Council by an aggrieved person, the aspect complained thereof shall be investigated within the context of the provisions of the Act and other relevant Regulations of the Council.

(4) Where a proper investigation has been carried out on the alleged allegation, the practitioner shall be adjudged to be guilty of malpractice where he fails to—

(a) comply with statutory procedure to meet the professionally accepted standards, methods or decorum ; and

(b) act within his limitations in terms of skills and facilities or accepted cases, which he cannot effectively handle.

(5) It shall be the duty of Practitioners to report complex case to the appropriate authorities including the Council.

(6) Failure to report any of such complex case may render the practitioner in charge of such Laboratory service primarily liable for an infamous conduct in a professional respect.

PART III—SELF ADVERTISEMENT AND RELATED OFFENCES

Notepapers.
Envelopes
and visiting
cards.

19. A practitioner may cause to be printed on notepapers, envelopes and visiting cards—

(a) his name and address ;

(b) his title, academic and professional qualifications ; and

(c) any National Honours obtained.

Signs and
notices.

20. A practitioner may display—

(a) at the entrance of, or outside any building or office in which he practices, a sign or notice bearing the name of the Laboratory ;

(b) in an obscure neighbourhood, directional signboard bearing only the inscription "MEDICAL LABORATORY" is to be displayed ; and

(c) notwithstanding paragraphs (a) and (b) of this regulation, sign or notice to be displayed shall be of a reasonable size and may be placed on the wall of the office or any appropriate part of the premises.

21. Where a practitioner writes a book or an article for publication and gives information on Medical Laboratory Science or an aspect of it, may add his professional qualification after his name.

Books and articles.

22. Where there is a change in the address, telephone number or other circumstances relating to practice, the practitioner shall notify his Clients of such changes and may publish an advertisement of such changes in a newspaper, journal or electronic media.

Change of address.

23. Registered practitioners who are in administrative charge of Medical Laboratory in a public institutions may grant interviews without being liable of misconduct, except they specifically call attention to themselves or their professional competence.

Granting of interviews by registered practitioners in administrative charge.

PART IV—MISCELLANEOUS

24.—(1) Where a practitioner does not suffer any ailments or habits that may impair his productivity, judgement and alertness so as to make whatever results released from his Laboratory unreliable, he is adjudged to be fit to practice.

Fitness to practice.

(2) A practitioner is unfit to practice where he—

(a) suffers from senile dementia ;

(b) suffers physical or mental conditions, which can expose his patient, embarrass his professional colleagues, jeopardise his own career and professional position ;

(c) has become addicted to drugs and might or indeed does commit offences against the Dangerous Drugs Act and Regulations ; and

(d) is addicted to drugs and may not be or is not in the right frame of mind to attend to his clients.

25.—(1) The Council shall set up an *Ad-hoc* Committee on Practitioner's Health, consisting of three reputable members.

Procedure for determination of practitioner's fitness to practice.

(2) The Practitioner's Health Committee shall receive petition or complaints from aggrieved person, consider it and where questions arises as to practitioner's fitness to practice, the practitioner shall be given three weeks within which to make representation to a medical institution as may be prescribed by the Committee.

(3) The Practitioner's Health Committee shall consider reports from the medical institution and make recommendation to the Council as may be appropriate in the circumstance and the Registrar/Chief Executive Officer of the Council shall advice the practitioner accordingly; where treatment is required, the practitioner shall be advised to submit himself for treatment.

(4) Where the practitioner refused to submit to examination or treatment, the Registrar/Chief Executive Officer shall direct that the Licence of the Practitioner be suspended until compliance.

Other
general
requirements.

26. In addition to other requirements set out for running a laboratory under these Regulations, the Council shall ensure that the following requirements are complied with by practitioners seeking to establish a Laboratory before approval is granted—

(a) ensure that all Laboratories have verifiable information management system ;

(b) appropriate Laboratory equipment for conducting tests are procured and planned preventive maintenance contract on equipment is provided for ;

(c) there is adequate Glassware and relevant consumable supply lines ;

(d) there is an alternative source of electricity other than public electricity ;

(e) there is steady supply of water ;

(f) there is provision for effective and efficient waste disposal system or incinerator ;

(g) appropriate fire extinguishers are provided for at different locations in the laboratory ;

(h) there is clean-up room within the laboratory complex ;

(i) a separate fully air conditioned media room for microbiology is provided ;

(j) there is sufficient illumination and ventilation within the laboratory ;

(k) there is provision for adequate security measure put in place within the Laboratory complex ;

(l) tertiary, specialist and Health Research Institutions have relevant assay specific equipment and accessories ; and

(m) the Laboratories' Quality Manual shall be made to include staff health, vaccination and training amongst other requirements.

Enforcement
of these
Regulations.

27.—(1) It shall be the duty of the Council to ensure that these Regulations is complied with by practitioner and non-practitioners.

(2) Practitioner is obligated to report the breach of any of the provisions of these Regulations by any person to the appropriate authorities for necessary disciplinary action.

(3) Any practitioner that acts in contravention of these Regulations or fails to comply with any of the duties imposed by these Regulations and having been adjudged by the Disciplinary Committee to be guilty of professional misconduct, the following steps shall be taken—

(a) suspend and have the name of the practitioner deleted from the Register for a period of time, pending when the Registrar may recall him ;

(b) direct that the practitioner comply with whatever sanction imposed by the Council before the expiration of the period of suspension ;

(c) the decision of the Council may be published in any two of the national dailies and notification of such publication shall be duly deposited with the National Secretariat of the Association of Medical Laboratory Scientists of Nigeria ;

(d) where the name of any registered practitioner is removed from the Register for a period of time, the Registrar of the Council may in addition to sub-paragraph (a) of this regulation, direct that the practitioner complies with the decision of the Council ; and

(e) at the expiration of any Suspension Order imposed by the Council, where the Council is satisfied that the practitioner has satisfactorily complied with requirement of these Regulations, may direct the Registrar to re-enter the name of the practitioner into the Register of Members and lift the Suspension Order.

28. In these Regulations unless the context otherwise admits—

Interpretation.

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

“Practitioner” includes a registered Medical Laboratory Scientist, Medical Laboratory Technician and Medical Laboratory Assistant ;

“Board” refers to the Medical Laboratory Science Council of Nigeria Governing Board ;

“Council” refers to the Medical Laboratory Science Council of Nigeria ;

“Disciplinary Committee” refers to the Medical Laboratory Science Council of Nigeria Disciplinary Committee ;

“Institution” refers to hospital and other tertiary institution accredited by the Council ;

“Registrar” refers to the Chief Executive and Secretary to the Governing Board of Council ;

“Laboratory” refers to Medical Laboratories registered by the Council.

29. These Regulations shall be cited as the Regulations for Minimum Practice Standard, 2018. Citation.

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

ERHABOR, TOSAN

*Registrar/Chief Executive Officer
Medical laboratory Science Council of Nigeria*