

# Federal Republic of Nigeria Official Gazette

No. 99

Lagos - 10th October, 2014

Vol. 101

Government Notice No. 137

The following is published as supplement to this Gazette:

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Annual Subscription from 1st January, 2015 is Local: N25,000.00 Overseas: N37,500.00 [Surface Mail] N49,500.00 [Second Class Air Mail]. Present issue N2,000.00 per copy. Subscribers who wish to obtain *Gazette* after 1st January should apply to the Federal Government Printer, Lagos for amended Subscriptions.

## REGULATIONS FOR MINIMUM PRACTICE STANDARD 2014



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## REGULATIONS FOR MINIMUM PRACTICE STANDARD 2014

In exercise of the authority conferred by Sections 4, 7(a) and 19 of the Medical Laboratory Science Council of Nigeria Act No. 11 of 2003, the Governing Board of Council hereby makes the following rules:

[26th September, 2014]

Commencement.

Preamble.

## A - MEDICAL LABORATORY SCIENCE PRACTICE

- 1. The provision of Medical Laboratory Services is core in healthcare delivery. On account of this vital role, substandard medical laboratories and unethical practice cannot be entertained in disease diagnosis, forcasting and management of patients' ailments as well as public health surveillance. Thus this Regulations for Minimum Practice Standards and Regulation defines international practice standards required of a practitioner in the discharge of his duties and for the advancement of the profession.
- 2. The objectives of the Regulations for Minimum Practice Standard Objectives. and Regulation are:
  - (a) To enable practitioners in Nigeria to maintain correct attitude universally expected of them.
  - (b) To meet with the prescriptions of the Medical Laboratory Science Council of Nigeria with regards to ethics and the quality of professional practice.
  - (c) To ensure that all practitioners carry on their professional duties in a manner that earns the trust of the patient and the respect of the society for the profession.
    - (d) To let the public know what they can expect from practitioners.

This Regulation shall be used by the Disciplinary Organs of Council to determine professional misconduct.

3.—(1) A practitioner to the exclusion of a Medical Laboratory Technician/ Assistant upon induction is 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) This registration lapses as soon as the practitioner presents his original logbook duly endorsed by the Consultant, Specialist or Senior Medical Laboratory Scientist under whose supervision he did his internship as proof of completion of his internship.

(3) While it subsists, it does not entitle the practitioner to set up and run an independent practice on his own.

Interns.

- 4.—(1) Every practitioner excluding the Medical Laboratory Technician and Medical Laboratory Assistant is expected to partake in the mandatory internship.
- (2) A practitioner who completes his internship successfully and satisfactorily, presents his original logbook and before proceeding on the mandatory National Youth Service Corps (or presents an exemption letter from NYSC) shall be given full registration and a license issued thereof.
- (3) Any Medical Laboratory Technician and Medical Laboratory Assistant who completes his laboratory posting and training, successfully sits for Council's professional examinations and passes satisfactorily shall be issued a Technician Registration Letter or a Medical Laboratory Assistant Registration Letter as the case maybe.
- (4) At the commencement of the internship programme, all training institutions (hospitals) shall forward the list of prospective or shortlisted interns to the Council for proper verification to prevent fake or multiple internship.
- (5) Only the Council's accredited public and private institutions shall be allowed to train interns.
- (6) A practitioner eligible for internship excluding the Medical Laboratory Technician and Medical Laboratory Assistant shall within two (2) months of securing a placement, forward his appointment letter through the Medical Laboratory Scientist supervising the internship with a photocopy of his provisional license to the Council for proper documentation and updating of database.
- (7) All accredited training institutions (private or public) must keep record of attendance of interns under their employ and same produced on demand.
- (8) The Council or its authorised agent shall conduct regular visits to these training facilities and such information obtained shall be the basis for verification of the logbooks submitted for clearance prior to induction and licensing.
- (9) Logbooks for commencement of internship shall be issued once at Induction. Any subsequent request by a practitioner on grounds of loss must be accompanied by:
  - (i) a letter endorsed by the most senior Medical Laboratory Scientist designated to sign off interns
    - (ii) an endorsement by the Chief Executive Officer of the Institution
    - (iii) a sworn affidavit.
    - (iv) a police report

- (10) Photocopies of logbooks are not acceptable.
- (11) Each intern is required in the course of training to present at least two (2) seminars and an endorsed power point presentation along with the logbook at the institution he was assigned to.
- (12) Each intern shall upon completion of his training be issued a letter of completion signed by the authorised officer.
- (13) Any practitioner who engages in the internship training more than once after satisfactorily completing the statutory one (1) year internship required after induction shall be guilty of professional misconduct.
- (14) Every practitioner is required to complete his internship within two (2) years of his graduation or he may, unless he gives a reason satisfactory to the Council, be subjected to an assessment examination by the Council.
- (15) However, notwithstanding the provisions of sub-regulation (14) above, a practitioner who fails to complete his internship satisfactorily as stipulated by the Council or scores less than 60 per cent of the total evaluation score shall repeat the internship without pay and shall not be signed off until a satisfactory evaluation is obtained.
- (16) Any practitioner who studied abroad shall before he is allowed to register and practice in Nigeria:
  - (i) Successfully sit and pass Council's professional examinations;
- (ii) Undertake Medical Laboratory posting in any of Council's approved Medical Laboratory under the supervision of a qualified and licensed Medical Laboratory Scientist for at least a period of six (6) months; and
- (iii) Undergo the mandatory one (1) year internship (for fresh graduates) and one (1) year National Youth Service Corps if not completed or exempted.
- (17) A practitioner undergoing internship training is not entitled to participate in strike or withdrawal of services.
- A practitioner shall upon satisfactory completion of his internship be conferred with full registration and a legal right to practice.

Full Registration.

6. Every Practitioner who has acquired specialist or any additional qualification after undergoing the requisite training or any other training deemed to be the equivalent is required by law to be registered with the Council as a specialist or in furtherance of his new qualification before he can practice and be recognized as such. A practitioner who is not so registered with the Council cannot validly sign off interns and the Council upon enquiry will not back up his opinion as a specialist.

Registration as a specialist.

## B 740

Foreign Practitioners. 7. Practitioners who graduate in colleges in foreign countries will be required to successfully pass the Assessment (Proficiency) Examination set by Council and if they are successful will receive full registration to practice in Nigeria. This is however subject to the provisions of Section 17 of the Medical Laboratory Science Council of Nigeria Act.

Annual Practicing Certificate.

- 8.—(1) Not later than a date in every year to be specified by it, the Council shall:
  - (a) Publish a list of practitioners who have complied with the requirements of the Continuing Professional Development Programme and have paid their practicing fees, accredited or undergoing accreditation of their laboratories and are entitled to practice in that year (hereinafter referred to as the Annual Practicing List);
  - (b) Issue a practicing certificate to a practitioner whose name is on the Annual Practicing List, certifying that he has paid his practice fee for the specified year and that he has also fulfilled the requirement of the Continuing Professional Development Programme for the year under the rules made for the purpose by the Council.
- (2) A practitioner unless he holds an Annual Practicing Certificate issued by the Council under this regulation shall not:
  - (a) Conduct tests, collect samples or take part in the preparation of any reagents, media;
    - (b) Sign documents, vet or validate laboratory results/reports.

Annual Renewal/ Retention Certificate

- 9. A practitioner must ensure that:
- (1) His Laboratory renews its registration status yearly by the payment of an annual renewal/retention fee.
  - (2) He obtains the Certificate of Registration issued upon the renewal;
- (3) The Certificate of Registration is displayed conspicuously on the walls within the Laboratory.

Approval of a Medical Laboratory.

- 10.—(1) All premises or laboratories set up for the practice of Medical Laboratory Science shall operate with the knowledge and backing of the Council and be fully approved by the Council for such purpose.
- (2) All laboratories for the practice of Medical Laboratory Science shall upon receipt of Council's approval observe the following:
  - (a) Be headed by a Medical Laboratory Scientist whether it is a government owned, faith based or private laboratory;
  - (b) Show evidence of registration with the Corporate Affairs Commission, Abuja, Nigeria or in the case of public/tertiary institutions, the law establishing it;

- (c) Display in a conspicuous area in the business premises a copy of the current license to practice;
- (d) Display conspicuously in front of the facilities the Council seal and a perspex sign embossed with the Council's logo;
- (e) Such other terms and conditions, the Council may deem fit to make.
- 11. A practitioner or Laboratory must display its Perspex or Neon sign conspicuously on the walls of its official premises only where it is:

Perspex or Neon sign.

- (a) Registered;
- (b) Has passed all inspection requirements upon inspection; and
- (c) Has paid the prescribed fees as fixed by Council.
- 12. Registration with the Corporate Affairs Commission could either be by Incorporation of limited liability Company or Business Name registration.
- (1)Where the Proprietor/Practitioner intends to register the Laboratory as a company limited by shares, he shall furnish to the Corporate Affairs Commission in addition to the requisite incorporation forms, the following documents:

Requirements for Registration at the Corporate Affairs Commission.

- (a) Where the Laboratory is owned by a Non-practitioner, there shall be a partnership agreement between the Proprietor and the practitioner acceptable to the Council;
- (b) The current practicing license of the Medical Laboratory Scientist in charge;
- (c) A Medical Laboratory Scientist must be a member of the Board of Directors.
- (2) Where the Proprietor/Practitioner intends to register the Laboratory as a Business name, he 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 there shall be a partnership agreement between the Proprietor and the Medical Laboratory Scientist duly endorsed by Council;
  - (b) The current practicing license of the Medical Laboratory Scientist in charge;
  - (c) A Medical Laboratory Scientist must be registered as a part-owner of the Medical Laboratory Enterprise.

## B 742

Inspection, Approval and Monitoring of Medical Laboratories.

- 13.—(1) Every Laboratory and practitioner shall adhere to the regulations of the Council on periodic inspection, approval for registration and monitoring of Laboratories operations to ensure continuity in standard.
- (2) No Laboratory or practitioner shall prevent, avoid or subvert the entry of the Inspection and Monitoring Team of Council into its official premises for purposes of carrying out statutory periodic inspection activities and regular monitoring and evaluation respectively.
- (3) Any Practitioner or his staff or person(s) acting on his behalf who acts contrary to the provision of sub-regulation (2) above shall be guilty of professional misconduct.
- (4) Any Laboratory which fails to adhere strictly to the provisions of subregulation (1) shall:
  - (a) Be sealed by the Inspection Team;
  - (b) Be issued a warning letter mandating it to regularize its status within 14 days after 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 the Laboratory is jointly owned by a Practitioner and a Non practitioner, a licensed practitioner to the exclusion of a Medical Laboratory Technical Assistant shall head the laboratory and shall be so stated in the agreement.
- (2) The terms of the partnership agreement shall be worked out between the two and presented to the Council.
- (3) Upon termination of the partnership agreement, Council shall be duly informed.
- (4) Practitioners who intend to set up private Laboratories are encouraged to practise joint ownership amongst themselves for purposes of ensuring quality management system and services.
- (5)Practitioners of less than 5 years post induction experience may not set up their private Laboratory but will undergo pupillage under a Senior Medical Laboratory Scientist.

Heads of Medical Laboratory. 15. The most senior practitioner to the exclusion of a Medical Laboratory Technician/Assistant in a Medical Laboratory in private and public health institutions/hospitals/clinics shall head the Laboratory notwithstanding if there is an administrator on ground or if the Laboratory is owned by a non-practitioner.

Accreditation of a Medical Laboratory

- 16.—(1) Every Practitioner must ensure that his laboratory enrols in continuing quality improvement for accreditation by the Council.
- (2) The practitioner requiring the accreditation of his laboratory shall observe the following:
  - (a) Pay the prescribed fees;
  - (b) The Head/Director of the Laboratory and all staff/personnel in the Laboratory involved in the processing of samples for diagnostic purposes must be appropriately qualified Medical Laboratory personnel with qualifications registerable with the Council and possessing their current license/annual registration letter to practice;
  - (c) The Laboratory shall have appropriate ratio of support staff to Medical laboratory staff;
    - (d) All components of the Quality Assurance are current and operational;
    - (e) Regular participation in an External Quality Assurance Program.
  - (f) Documentation (SOPs, Manuals) of the Laboratory facility must be in place;
  - (g) The Laboratory's safety policies (staff, environment, sample collection) must be in place;
    - (h) Provide proof of annual retention fee as may be fixed by Council;
    - (j) Have a well-defined operational organogram in the laboratory;
  - (k) All basic and assay specific Laboratory equipment must be appropriately and satisfactorily housed in the facility;
  - (1) All equipment must be appropriately calibrated and standardized for the performance of appropriate Laboratory investigation that it was installed to carry out.
  - (m) Schedule of equipment preventive maintenance must be in place and maintained as at when due and must be documented.
- 17.—(1) Where a Medical Laboratory upon periodic statutory inspection by Council fails to meet the minimum requirements for operation as a Medical Laboratory, such Medical Laboratory shall be sealed pending such time that it is able to meet those requirements and satisfy Council of same.
- (2) Any Medical Laboratory so sealed by the Council shall not be reopened by any individual or the owner (whether a non-practitioner or a practitioner) unless he has obtained from Council a written authority authorising him to have the Laboratory reopened. Any practitioner or non-practitioner who undertakes to break the seal of Council without obtaining the said written authority shall be liable upon conviction and guilty of professional misconduct.

Breaking of Council's Seal.

## B-MALPRACTICE

Malpractice in a general respect.

- 18.—(1) The practice of Medical Laboratory Science shall be conducted in accordance with standards, decorum and by methods that are adjudged acceptable and appropriate by the generality of practitioners. Such acceptable standards, decorum and methods are in accordance with the knowledge, skill and practice as imparted in institutions that are recognized and have been accredited by the Council.
- (2) Where a registered practitioner's conduct in his area of professional practice is called to question and such petition is brought to the information or attention of the Investigating Panel of the Council, by an aggrieved person or a colleague, or by any other means whatsoever, that aspect or area of the practice or professional relationship and any other relevant matters connected therewith shall be examined within the context of the provisions of the Medical Laboratory Science Council of Nigeria Act and other relevant regulations.
- (3) Upon proper examination and investigation, a practitioner shall be held guilty of malpractice where—
  - (a) He is found by statutory procedure to have failed to meet the professionally accepted standards, methods or decorum;
  - (b) He acts outside his limitations in terms of skills and facilities, or takes on cases which he cannot effectively handle.
- (4) It shall be the duty of all practitioners to report every case to the appropriate authorities including the Council. Failure to report any such case may render the practitioner in charge of such Laboratory service primarily liable for an infamous conduct in a professional respect.

### C—Self Advertisement and Related Offences

Notepapers, Envelopes and visiting cards.

- 19. A practitioner may cause to be printed on his notepapers, envelopes and visiting cards:
  - (a) His name and address;
  - (b) His academic and professional qualifications and title;
  - (c) Any National Honours.

Signs and notices.

- **20.**—(a) A practitioner or Laboratory may display at the entrance of, or outside any building or office in which he or it carries on practice, a sign or notice bearing the name of the Laboratory.
  - (b) The sign or notice shall be of reasonable size and may be placed on the wall of the appropriate part of the premises.
  - (c) In obscure neighbourhoods, directional signboards bearing only the inscription "Medical Laboratory" may be installed by a practitioner who has his practice there.

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

Books and articles.

22. On a change of address, telephone number or other circumstances relating to his practice, a practitioner may send to his clients, notice of the change and may insert an advertisement of such change in a newspaper, journal or electronic media.

Change of address.

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

Interviews by registered practitioners in administrative charge.

#### D-MISCELLANEOUS

24.—(1) A practitioner that 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 is adjudged to be fit to practice.

Fitness to practice.

- (2) A practitioner is unfit to practice where:
- (a) He is suffering from senile dementia;
- (b) He is suffering from physical or mental conditions which can imperil his patient, embarrass his professional colleagues and indeed jeopardise his own career and professional position;
- (c) He has become addicted to drugs and might or indeed does commit offences against the Dangerous Drugs Act and Regulation; and
- (d) He is addicted to drugs and may not be or is not in the right frame of mind to attend to his clients.
- 25. To determine a practitioner's fitness to practice, the following procedure shall be adopted:
- Procedure to determine fitness to practice.
- (1) The Council shall set up an Ad hoc Committee on Practitioners Health consisting of three (3) reputable members;
- (2) The Committee on Practitioners Health shall receive petitions and complaints, consider them and if satisfied that a question arises whether a practitioner is fit to practice, shall give the practitioner three (3) weeks to submit to examination in a medical institution as prescribed by the Committee.
- (3) The Committee on Practitioners Health shall consider reports from the medical institution and make recommendations to the Council as appropriate. The Registrar/CEO of the Council shall advice the practitioner accordingly as the Committee may direct. Where treatment is applicable, the practitioner shall be advised to submit to treatment.

(4) Where the practitioner refuses to submit to examination or to treatment, the Committee on Practitioners Health shall lay a complaint before the Investigating Panel which shall attend to the matters as appropriate.

Other General Requirements.

- **26.** In addition to all other requirements in this Regulation, the following general requirements shall be met by the Laboratory seeking to be approved by the Council:
  - (1) All Laboratories shall have verifiable information management system.
- (2) Appropriate Laboratory Equipment for the tests to be provided and planned preventive maintenance contract.
  - (3) Adequate Glassware and relevant consumables supplies lines.
- (4) Adequate source of electricity other than PHCN (generating set) shall be available.
  - (5) There shall be adequate water supply.
  - (6) An effective waste disposal system shall be provided (incinerator).
- (7) Appropriate fire extinguishers shall be provided for different locations in the laboratory.
  - (8) A wash up room shall be made available.
- (9) A separate fully air conditioned media room for microbiology shall be provided.
- (10) Adequate illumination and ventilation shall be made available in the laboratory.
  - (11) The Medical Laboratory shall ensure that there is adequate security.
- (12) Tertiary, Specialist and Health Research Institutions shall have relevant assay specific equipment and accessories.
- (13) The Laboratories' Quality Manual shall include staff health/vaccination and training policies amongst other requirements.

Enforcement of rules.

- 27.—(1) It is the duty of every practitioner to report any breach of any of these Regulations that comes to his knowledge to the appropriate authorities for necessary disciplinary action.
- (2) If a practitioner acts in contravention of any of these Regulations or fails to perform any of the duties imposed by the Regulations and having been adjudged by the Disciplinary Committee as being guilty of a professional misconduct, then the following steps will be taken:
  - (a) the name of the practitioner and the sentence pronounced shall be published in two national dailies. Notification of the publication shall be duly

deposited with the National Secretariat of the Association of Medical Laboratory Scientists of Nigeria.

- (b) where the name of the registered practitioner is suspended from the Register for a period of time, the Registrar/CEO will in addition to (a) above direct that the practitioner maintains compliance with the sentence until the period of suspension expires.
- (c) upon the expiration of the suspension and where the Disciplinary Committee is satisfied that a practitioner has satisfactorily completed same, it may direct the Registrar to re-enter the name of the practitioner into the Register of Members.
  - 28. In these Regulations unless the context otherwise admits—

Interpretation.

- "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.
- "Registrar" refers to the Chief Executive and Secretary to the Governing Board of Council.
  - "Laboratory" refers to Medical Laboratories
- 29. These Regulations shall be cited as the Regulation for Minimum Citation. Practice Standard and Regulations, 2014.