

MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA

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MINIMUM PRACTICE STANDARDS & REGULATIONS 2011

FOREWORD

In every profession, certain standards are set which act as indices for regulating service delivery within the framework of that profession. These standards in relation to practice regulation are important as it sets the boundaries and limits for the practitioner in the exercise of the profession.

The Medical Laboratory Science profession has been in existence in the country with the promulgation of the Institute of Medical Laboratory Technology Act of 1968 and due to the absence of appropriate regulations/rules regulating the standard of practice, practitioners have upon qualification provided essential services in healthcare delivery in accordance with their whims and caprices while impersonators domineered the system.

Thus, due to dire need, exigencies and the pivotal role the Medical Laboratory Science profession holds in the healthcare delivery system, the Minimum Practice Standard and Regulation was created to address this lacuna.

Strict adherence to these Rules by practitioners as enshrined in this document will lead to a reduction in mortality and morbidity rate due to poor laboratory tests and results, enhanced healthcare delivery, improve quality of life, eradicate impersonators, raise the standard of practice and an improvement in the health indicators of the people.

The Council is fully committed to its mission to be a renowned regulatory agency in the strengthening of health laboratory systems and professional practice for quality services through strategic regulations, international and best practices.

The Rules also will serve as a parameter to measure and guide the professional practice of all Medical Laboratory practitioners. It is my firm belief that the quality of professional service rendered to the public by all practitioners will improve dramatically as they observe and adhere faithfully to these Minimum Practice Standard and Regulation. I am certain that the Minimum Practice Standard and Regulation shall be subject to periodic revision to keep up with modern developments in the profession.

The Council has ensured that these Rules are written in clear and simple terms so that all practitioners and prospective practitioners can easily find out what is expected of them.

Prof. Anthony Emeribe
Registrar/CEO
Medical Laboratory Science Council of Nigeria

INTRODUCTION

The Medical Laboratory Science Council of Nigeria Act M25, LFN 2004 broadened the scope, functions and powers of the Governing Board of Council by empowering it amongst others in **Section 4 (b)** to:

“regulate the Practice of Medical Laboratory Science in Nigeria”

In ensuring the implementation/advancement of this function, Professionals and Experts in the field of Medical Laboratory Science in conjunction with the Council’s current reformation process on Medical Laboratory service delivery in the country are *ad idem* that to reduce the worsening decay in healthcare delivery in the health sector, dearth of standard skills and expertise, there was the need to set a standard for practice regulations in line with international and best practices. This resolution informed the Council’s decision to formulate this text - **Minimum Practice Standard and Regulation**.

These Rules have succinctly stated that registration as a practitioner is the bedrock of recognition and one’s passport to practise as a professional. It encourages practitioners to explore joint ownership of medical laboratories, be their brother’s keepers and hold the public (the final recipient of their services) in high regard while ensuring strict adherence to professionalism and standards.

Furthermore, to eradicate the worrisome growth of impersonators in the profession, provisions have been made governing the registration of Practitioners and Medical Laboratories in the Country; sanctions to be placed on Medical Laboratories that fall short of standards as may be prescribed by the Council and the punishments where these sanctions are broken.

The Rules also provide for the degree of care expected of a Practitioner in the exercise of his professional duties; conducts amounting to professional misconduct and malpractice and sanctions where a Practitioner is found to be in default.

It is the belief and desire of Council that with the promulgation of these practice regulations, the incidence of ethical violations will be reduced to the barest minimum while the confidence of the public in the Practitioner and the profession as a whole will be enhanced.

Finally, it is recommended that these Minimum Practice Standard and Regulation shall serve as information booklet to Medical Laboratory Scientists, Medical Laboratory Technicians and Medical Laboratory Assistants (practitioners and students alike), operators of Medical Laboratories, Lecturers of Medical Laboratory Science, Legal Practitioners interested in Medical Laboratory Science, lay persons and patients who may wish to seek information or further their knowledge on Medical Laboratory Science in Nigeria.

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[3rd November, 2011]

Commencement

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

PART A - MEDICAL LABORATORY SCIENCE PRACTICE

Preamble

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, forecasting and management of patients' ailments as well as public health surveillance. Thus this Minimum Practice Standard and Regulation defines international practice standards required of a practitioner in the discharge of his duties and for the advancement of the profession.

Objectives

2. The objectives of the Minimum Practice Standard 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.

Provisional
Registration

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.

(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.

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 Identity Card and Certificate or a Medical Laboratory Assistant Identity Card and Certificate as the case maybe.

(4) 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) an 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 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 own 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 subrule (14) above, a practitioner who fails to complete his internship satisfactorily as stipulated by the Council or scores less than 60% 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 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 exempted.

(17). A practitioner undergoing internship training is not entitled to participate in strike or withdrawal of services.

*Full
Registration*

5. A practitioner shall upon satisfactory completion of his internship be conferred with full registration and a legal right to practice however subject to Rule 13(5).

*Registration
as a specialist*

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.

*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, registered and accredited 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 rule shall not:

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

b) Sign documents, vet or validate laboratory results/reports.

*Annual
Renewal/Reten-
tion
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

*Registration 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 registered with the Council for such purpose.

(2) All laboratories for the practice of Medical Laboratory Science shall upon registration 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 all registered 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.

*Perspex or
Neon sign*

11. A practitioner or Laboratory must display its Perspex or Neon sign conspicuously on the walls of its official premises only where it is:

- (a) Registered;
- (b) Has passed all inspection requirements upon inspection; and
- (c) Has paid the prescribed fees as fixed by Council.

*Requirements
for
Registration
at the
Corporate
Affairs
Commission*

12. Registration with the Corporate Affairs Commission could either be by Incorporation of Companies 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:

- (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.

*Inspection,
Approval &
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 registered Laboratories operations to ensure continuity in standard.

- (2) No Laboratories or practitioners 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 subrule (2) above shall be guilty of professional misconduct.
- (4) Any Laboratory which fails to adhere strictly to the provisions of subrule (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 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.

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.

16. (1) Every Practitioner must ensure that his laboratory enrolls 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

*Heads of
Medical
Laboratory*

*Accreditation
of a Medical
Laboratory*

- (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/identification tag 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, etc) of the Laboratory facility must be in place.
- (g) The Laboratory's safety policies (staff, environment, sample collection, etc) 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.
- (l) 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.

*Breaking of
Council's Seal*

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.

PART 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 judged 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.

PART C - SELF ADVERTISEMENT AND RELATED OFFENCES

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.

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.

*Notepapers,
Envelopes
and visiting
cards*

*Signs and
notices*

(c) In obscure neighbourhoods, directional signboards bearing only the inscription “MEDICAL LABORATORY” may be installed by a practitioner who has his practice there.

Books and articles

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.

Change of address

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.

Interviews by registered practitioners in administrative charge

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.

PART D - MISCELLANEOUS

Fitness to practice

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.

(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.

Procedure to determine fitness to practice

25. To determine a practitioner’s fitness to practice, the following procedure shall be adopted:

- 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 advise the practitioner accordingly as the Council 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
Requirement*

26. In addition to all other requirements in this Regulation, the following general requirements shall be met by the Laboratory seeking to be registered 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 rules that comes to his knowledge to the appropriate authorities for necessary disciplinary action.

(2) If a practitioner acts in contravention of any of these Rules or fails to perform any of the duties imposed by the Rules 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 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.

Interpretation

28. In these Rules unless the context otherwise admits -

“**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

Citation **29.** These Rules shall be cited as the Minimum Practice Standard and Regulations, 2011.