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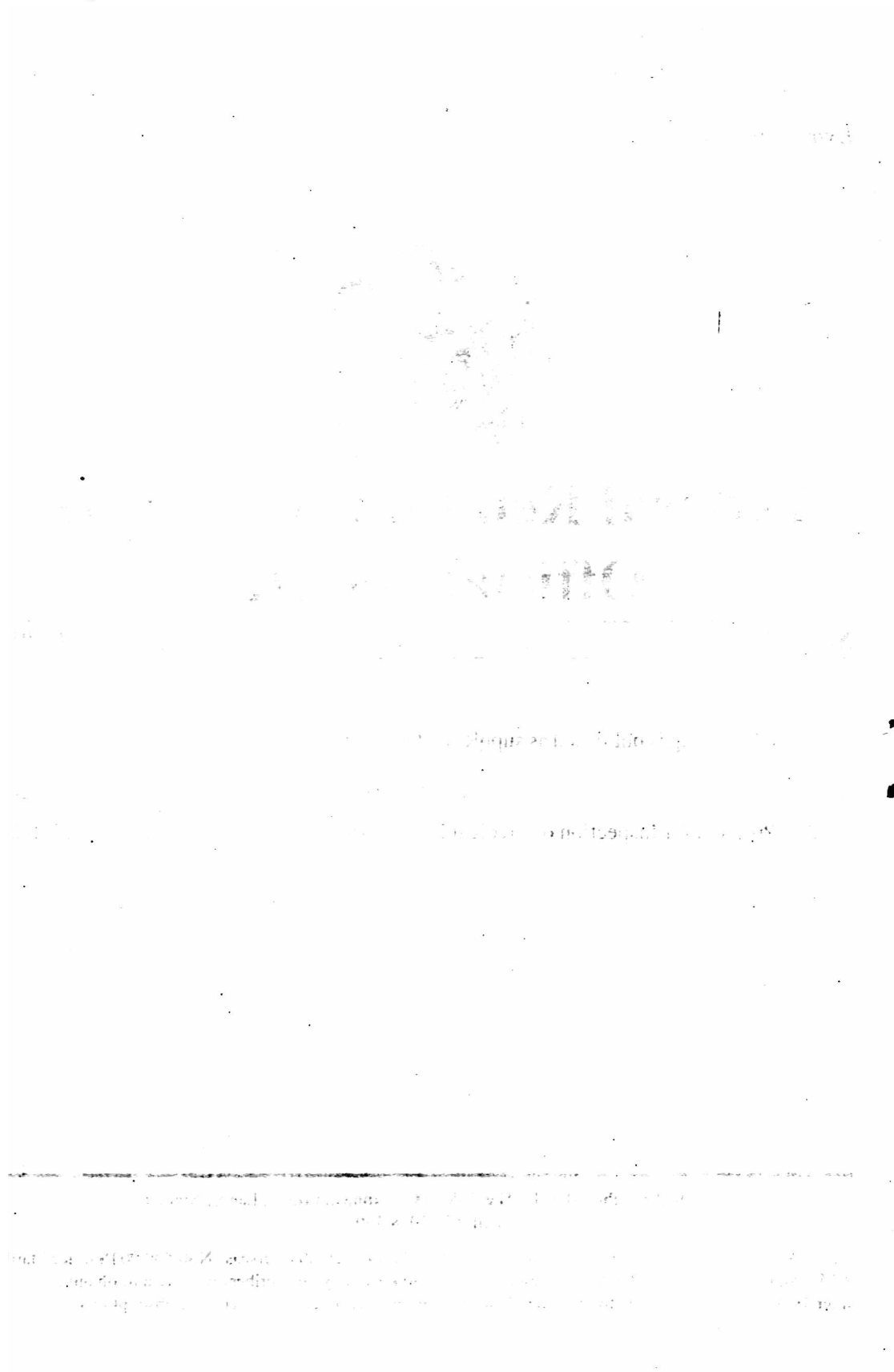
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**MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA
ACT (CAP. M25 LFN) 2004**

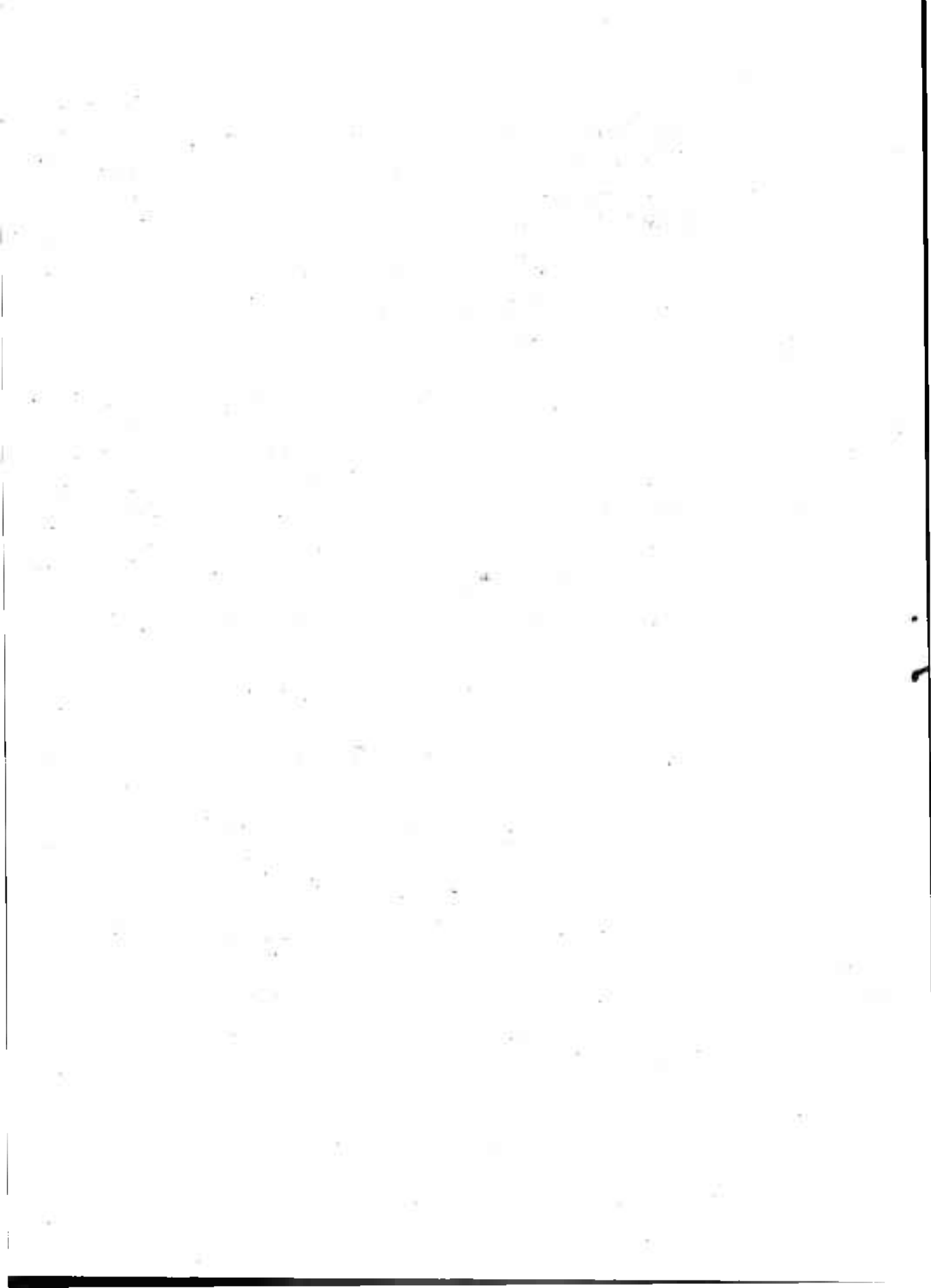
**PROTOCOL FOR INSPECTION OF MEDICAL
LABORATORIES IN NIGERIA, 2018**



ARRANGEMENT OF RULES

Rules :

1. Aim.
2. Objectives.
3. Pre-Inspection preparation.
4. Actual Inspection.
5. Citation.



S. I. No. 12 of 2018

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

**PROTOCOL FOR INSPECTION OF MEDICAL
LABORATORIES IN NIGERIA, 2018**

[8th Day of June, 2018]

Commence-
ment.

In exercise of the powers conferred by Sections 4, 7(a), 15(6) of the Medical Laboratory Science Council of Nigeria Act (Cap. M25 LFN, 2004), the Governing Board of the Council hereby makes the following Rules—

1. These Regulations seeks to provide legal and regulatory framework for the practice of Medical Laboratory Scientist, Medical Laboratory Technician and Medical Laboratory Assistant in Nigeria as it relates to inspection and monitoring of medical laboratory facilities in Nigeria.

Aim.

2. The objectives of these Regulations are to—

Objectives.

(a) ensure that Medical Laboratories generate accurate, reliable and timely results required for effective treatment and management of patients disease ;

(b) inspect, monitor, evaluate and accredit all Medical Laboratories in both public and private health sectors in Nigeria ; and

(c) ensure that good laboratory practice, ethical values and orientation are complied with by practitioners.

3.—(1) The Medical Laboratory Science Council of Nigeria (hereinafter referred to as "the Council"), shall ensure that pre-inspection activities includes—

Pre-
Inspection
preparation.

(a) sensitisation advocacy to create awareness amongst stakeholders in public and private medical facilities in not less than 3 months before embarking on any inspection visit via print and electronic media ;

(b) conduct pre-inspection workshop for stakeholders at least once in a year ;

(c) constitute Inspection Team in not less than 3 months prior to inspection visits ; and

(d) conduct orientation workshop for the Inspection Team at least a day before embarking on any inspection visits.

(2) The Inspection Team shall be led by the Council Certified Medical Laboratory Assessor of not less than 15 years with relevant experience in medical laboratory practice and assessment.

(3) the Team shall also include—

(a) not less than 2 Assessors of 10 years with relevant experience in medical laboratory practice, one of the Assessor shall be a representative of the Council ;

(b) 1 representative from the Ministry of Health at both the Federal and State level ;

(c) the State Chairman of Association of Medical Laboratory Scientists of Nigeria in the state where the inspection visits is to be carried out ;

(d) a representative of Guild of Medical Laboratory Directors ;

(e) a representative of the Association of General Private Medical Practitioners of Nigeria ; and

(f) a member representing public interest group or Civil Society Organisation.

(4) The Inspection Team shall be supported by—

(a) not less than 2 Police officers ; and

(b) not less than 1 operational aid.

**Procedure
for
Inspection.**

4.—(1) The Medical Laboratory Inspection Checklist of the Council shall be followed while carrying out inspection on any Medical Laboratory facility in Nigeria.

(2) On the arrival of Inspection Team to any medical laboratory facility, the Team—

(a) shall hold a brief meeting with the Laboratory management in order to explain the purpose of the exercise ;

(b) shall thereafter, carry out inspection as required ;

(c) may debrief the management of the Laboratory in relation to any of its findings during inspection and give timeline of maximum of 12 weeks depending on the complexity of the non-conformity observed to regularise all deficiencies occasioned ;

(d) any Medical Laboratory that scores 40% and above of the requirements listed on the checklist, in addition to evidence of registration of medical laboratory facility with the Council and participates in the Council's proficiency testing scheme or any other accredited proficiency testing provider, shall be regarded as having passed the inspection visit ; and

(e) shall, where any Registered Medical Laboratory scores less than 40% of the requirements listed on the checklist of the Council, such medical laboratory shall be required to remedy the deficiencies and be given time limit within which is to rectify the identified non-conformities ;

(3) Notwithstanding any score attained by a medical laboratory on inspection, any Medical Laboratory discovered not to have registered with the Council, the Inspection Team shall give such medical laboratory a maximum of 12 weeks within which to get registered.

(4) The approved sum by the Council for medical laboratory registration is as follows—

- (a) primary facility is ₦50,000.00 ;
- (b) secondary facility is ₦100,000.00 ; and
- (c) tertiary facility is ₦150,000.00.

(5) At the expiration of the time stipulated by the Inspection Team for the medical laboratory to comply with registration requirements, where it fails to comply, such laboratory facility shall be closed down and sealed by the Council.

(6) Where a medical laboratory is discovered not to have a registered Medical Laboratory Scientists as a staff and it is confirmed that the facility has been operating with an un-registered or unqualified person, the Medical Laboratory shall be closed down and be sealed off.

(7) At the conclusion of any inspection visits, the Inspection Team shall prepare and submit a report of its finding with recommendations to the Council within 2 weeks.

(8) The Council shall consider the reports of the Inspection Team and communicates its decision to the owner of the laboratory within 2 weeks of receipt of the reports.

(9) If by 12 weeks, the medical laboratory refused to comply with the direction of the Council, depending on the complexity of the non-conformity observed, the Council's Zonal Monitoring Team shall ensure that the laboratory comply with the recommendations made by the Inspection Team and report appropriately to the Council within 1 week of the monitoring visit.

(10) Where a Medical Laboratory that is previously sealed desires to regularise its status and be un-sealed, it shall—

(a) forward an application letter to the Registrar of the Council requesting temporary access to the facility to enable it carry out the recommendations of the inspection team ;

(b) attach to the application, an evidence of payment of a non-refundable fee of ₦100,000.00, paid into the Council's Treasury Single Account (TSA) with Central Bank of Nigeria of Nigeria ; and

(c) be the duty of the Council to respond to the request within 2 weeks of the receipt of evidence of payment.

(11) Where a Medical Laboratory previously sealed by the Council is unsealed without recourse to the Council, the Monitoring Team shall closedown and seal the Laboratory and make a report of the offender to the Nigerian Police Force for prosecution.

(12) The Council may grant temporary registration for a period of 3 months to a newly established medical laboratory awaiting pre-approval inspection provided all documents needed for registration have been reviewed and submitted.

Citation. **5. These Regulations** shall be cited as the Protocol for Inspection of Medical Laboratories in Nigeria, 2018.

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

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